How to Make the Right Decision

With Environmental Data

Advanced Systems Inc.

Presented: April 2008

P.O. Box 8032 ◆ Newark, Delaware 19714 ◆ (800) 598-9984 ◆ Internet: mmoore@advancedsys.com

HOW TO MAKE THE RIGHT DECISION WITH ENVIRONMENTAL DATA

OR

HOW TO AVOID PAYING A FINE OR PENALTY FOR MAKING THE WRONG DECISION

Prepared by:

Advanced Systems, Inc.
P.O. Box 8032
Newark, DE 19714
mmoore@advancedsys,com
(302) 368-1211
Marlene Moore
James J. McAteer, Jr.,
QA/QC Solutions LLC.

COURSE BACKGROUND

How do you know if you the decisions you have made using data are scientifically valid, meaningful, and legally defensible? Making the wrong environmental decision can be costly to everyone involved. Sometimes it takes months or years before you find out that you made the wrong decision. It is very costly, not only in dollars, but also in time and to the environment. Making the right decision using the right data save time and money in the long run. Proper planning and documentation is required in order to achieve this goal. **BUT** – We continue to hear, "We don't have enough money to plan or do it right the first time!" **THEN** why do we always have enough money to do the sampling and testing again and again?

This training presents how, what, and why data usability reports are necessary to ensure the proper use of environmental data. Practical examples will be presented during the class that provides the decision maker with information on the risk(s) of making the right (or wrong) decision(s). Data usability reports are more than just providing letters with numbers, such as the current data validation practices. For example, if a chemical of concern, such as PCBs, are reported as not detected by a laboratory, but a data reviewer identifies characteristic peaks in the laboratory data output, the data review may determine that highly weathered PCBs are present. This mean that the laboratory likely ran the method as prescribed, but did not observe or was not asked to report to the decision maker that aged PCB's are present, resulting in possible presence of contaminants that may be of concern. These and other critical data review, validation, and usability assessment information will be presented and addressed during this class.

OBJECTIVES OF COURSE

1. This course is intended to familiarize decision makers with the importance of receiving a data usability report. This Report will help the decision maker understand the risk associated with the decision and determine the defensibility or strength of making the right decision.

2. The course presents examples to demonstrate how this defensibility ensures that fines or penalties are not incurred in the future.

3. An overview of the processes needed to develop and complete a data usability report will be presented.

4. The course content includes state-of-the-art techniques for data gathering and decision-making by using quality assurance and other planned approaches for making the right decision the first time.

COURSE AGENDA

ONE DAY

1. Introduction

    - What is data usability?
    - Why is this important

2. Historical Perspective

    - Reasons for using sound science
    - Why does EPA and others make us do all that quality assurance and quality control

3. Data Usability: The Preliminary Steps

    - Systematic planning, implementation and oversight,
    - Data Quality Objectives (Not done by the lab)
    - Sampling and Analytical Considerations
    - Measurement Quality Objectives
    - Data Quality Indicators
    - Data Assessment
    - Documentation (Writing a Quality Assurance Project Plan)

4. Determination of Data Usability

    - Data verification
    - Data validation
    - Data quality assessment and usability evaluation
    - Data usability report
    - Assessing and interpreting data usability

5. The Decision Making Process

    - Case Study - examples showing when decision making goes wrong
    - Case Study – examples showing when decision making goes right and dollars are saved
    - Documentation of Decision Outcome

6. Summary and Warp-Up

    - Questions/Answers

INSTRUCTORS

Marlene Moore, Advanced Systems, Inc.

Marlene Moore is President of Advanced Systems, Inc. Advanced Systems conducts environmental management system reviews and evaluation of environmental programs; develops and designs quality systems, provides quality system training programs, analytical and sampling methods and SOP review; designs environmental surveys for chemical and biological contaminants; and performs data management, assessment, validation, and interpretation.

Ms. Moore has been providing training since 1992 to a variety of private, public and regulatory organizations. She has experience generating the data and working on projects to assist in the data review, usability, and interpretation

James J. Mc Ateer, Jr., QA/QC Solutions, LLC.

James J. Mc Ateer, Jr. is the managing member of QA/QC Solutions, LLC and has worked for more than 20 years in environmental consulting, analytical laboratory, and research settings. His areas of expertise, in part, include completing data quality assessment (DQA) and usability evaluations; interpreting chemical fingerprinting data; verifying, validating, and evaluating analytical data; and, managing the QA/QC aspects projects. He also develops QA/QC strategies, data quality objectives (DQOs), and sampling and analytical protocols to meet project-specific objectives and regulatory requirements.

How To Make The Right Decision With Environmental Data

How to Avoid Paying a Fine or Penalty for Making The Wrong Decision

Slide 1

Agenda

- Introduction
- Historical Perspective
- The Preliminary Steps
- Determination of Data Usability
- Decision Making Process
- Summary - Wrap-up

Slide 2

Objectives

- Familiarize decision makers with the importance of receiving a data usability report
  - The report to help the decision maker understand the risk associated with the decision and determine the defensibility or strength of making the right decision.
- Present examples to demonstrate how data defensibility ensures that fines or penalties are not incurred in the future
- Overview of the processes needed to develop and complete a data usability report
- Present state-of-the-art techniques for data gathering and decision-making for making the right decision the first time

Slide 3

Introduction

- What is Data Usability?
- Why is it Important?

Section 1

Slide 4

Data Usability

- The process of ensuring or determining whether the quality of the data produced meets the intended use of the data
- Each project should have a report on the data usability
  - The final outcome of the data review process for any project is the data usability report
- Allows the decision maker to understand the level of confidence in the decision based on the data

Slide 5

Data Review

- The process of examining and/or evaluating data to varying levels of detail and specificity by a variety of personnel who have different responsibilities within the data management process. It includes verification, validation, and usability assessment

http://www.epa.gov/fedfac/documents/qualityassurance.htm

UFP-QAPP Part 1
March 2005

Slide 6

Importance

- Proper planning assures data gathered is correct for the intended use
  - The right amount of data, quality of data and cost of the data are appropriately balanced for the job
- Understanding how the information will be used - drives the quality program
- Doing it right the first time always saves money
  - No need for additional dollars to do the work over again.

Slide 7

Data Usability Assesses

- *Measurement Performance Criteria*
  - *For test method*
  - *For sample collection method*
  - *As defined in QAPP*
- *Sample & analytical error*
- *Spatial variability*
- *Quantitation Limit/Detection Limit*
- *Data limitations determined and reported*
- *Data compared to Project Objectives*
- *Corrective action initiated* and effects evaluated
- *Data compared to historical data*

Slide 8

Historical Perspective

- Reasons for sound science
- Why does EPA and others make us do all that QA and QC?

www.epa.gov/quality

Section 2

Slide 9

Sound Science

- Scientific method used to provide legally and scientifically defensible decisions.
- Requires planning
- Requires implementation of Plan
  - Know when deviation from plan changes decision
- Requires data review
  - Peer review to provide defensibility
- Requires understanding of how the data supports the decision

Slide 10

In the Past

- Running the approved or the same method provides correct data
- Data validation assured the data was correct since it verified the method was performed as required by the contract
  - Not used to understand how the data supports the decision
- Data quality often defined in detail for the lab operations,
  - Not defined for sampling and decision making
- Data review is often a checkbox exercise and not a process to understand the data

Slide 11

Data Qualifiers

- Inconsistent across the country
- Applies only to laboratory not sample collection
- Relates to method or contract compliance
- Common letters
  - J = Estimate
  - U = Non detect
  - B = Blank contamination
  - R = Rejected

Slide 12

False Assumption

- The Contract Laboratory Program (CLP) or an approved laboratory provides sufficient quality assurance for environmental data by ensuring data of known and documented quality
- Isn't that enough?

No!

It does not address any of the data usability requirements and therefore does not provide assurance that collected data are appropriate for the intended use!

Slide 13

Why Do We Need QA/QC?

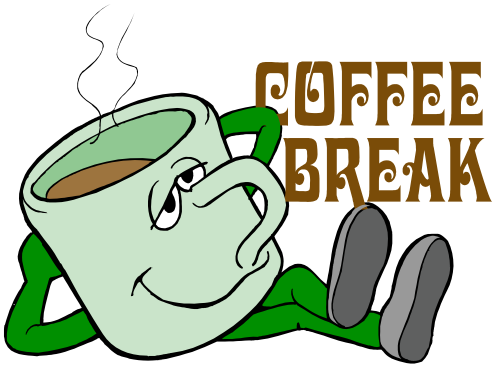
- Provides quantitative information about the data
  - Understanding the uncertainty of the data ensures the risk of making the right or wrong decision is known
- Allows source of data variability to be identified
  - Contaminant distribution
  - Process (e.g.; sampling, sample handling, etc.)
  - Other (e.g.; blunder in system)

Slide 14

BREAK

Course Resumes

in 10 Minutes



Slide 15

Preliminary Steps

- Systematic Planning Process
- Data Quality Objectives
- Sampling and Analytical Considerations
- Measurement Quality Objectives
- Data Quality Indicators
- Data Assessment
- Documentation

Section 3

Slide 16

Systematic Planning Process

- EPA 5360.1 - Quality systems
- Scientific method - logical
- Ensures
  - appropriate amount and type of data for decision
  - data collected addresses special physical, environmental and chemical characteristics of the site

Slide 17

Why Systematic Planning?

- Ensures that there is a clear understanding of the information needed to make the required decisions (ties data collection to decisions)
- Requires up-front investments. The rewards include increasing the likelihood of project success, reducing overall project costs, and shortening project life-cycles.
- Key for the implementation of a defensible approach and the generation of scientifically sound data.

Slide 18

SPP Elements

- Team based approach to planning
- Project goal, objectives, questions and issues
- Project schedule, resources, milestones and applicable requirements
- Data collection and analysis process matched to project objectives
- Collection and analysis requirements
- Process for generation, evaluation and assessment of collected data

Slide 19

DQO Process

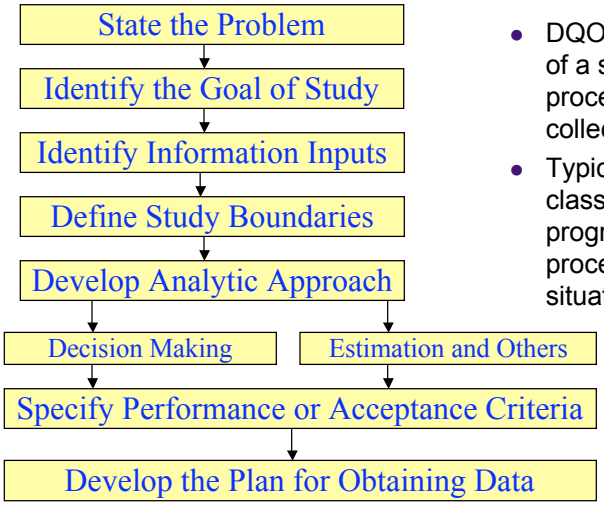
- Reference: EPA QA/G-4, 2006
- Systematic planning tool
- Applies to decision making
- 7-step structure

Other SPP includes:

- ✓ Triad
- ✓ Technical Planning

Slide 20

EPA DQO Process



- DQO process is an example of a systematic planning process applied to data collection design
- Typically associated with classical statistical sampling program design, but the process works for other situations as well

Slide 21

What Are DQOs?

- EPA Definition:
  - "Qualitative and quantitative statements derived from the output of each step of the DQO process that clarify study objectives, define the appropriate type of data, and specify the tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions" (USEPA QA/G-4, 2000)

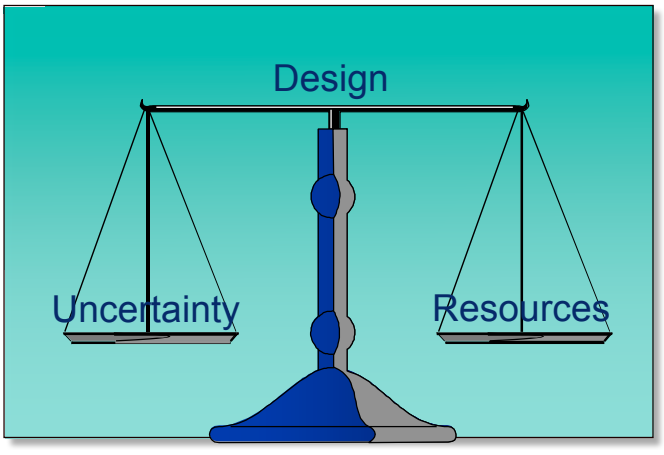
Slide 22

What Does The DQO Process Do?

- Encourages thoughtful consideration about why data are needed and how data will be used in decision making
- Structures the discussion of project personnel, regulators and stakeholders
  - facilitates the best use of everyone's time
  - addresses the hard questions up-front
- Leads to development of the QAPP and other project documents

Slide 23

DQO Process: A Balancing Tool



Slide 24

How Can the DQO Process Help With Success?

- By focusing data requirements and optimizing the design for data collection throughout all project phases
- By facilitating rapid review and approval by regulators and other stakeholders
  - reach consensus among project staff, regulators and other stakeholders on a logical decision-flow and associated technical assumptions (interpretation of regulations), rather than accepting conservative or prescriptive requirements

Slide 25

Data Quality Objectives Process

- Designed to answer:
  - What is needed?
  - Why is it needed?
  - How will it be used?
  - What is your tolerance for decision errors?

Slide 26

Selecting a Design Strategy

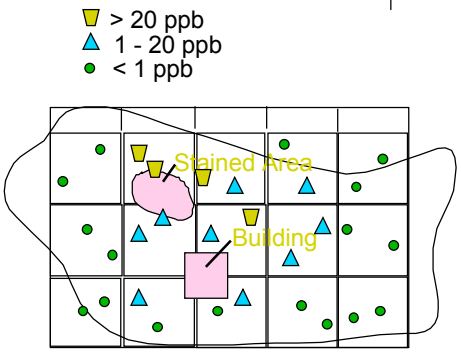
- Complete Steps 1-6 of DQO planning process
  - Understand why you need the data
    - Estimate a mean?
    - Estimate spatial pattern?
    - Look for hot spots?
    - Test for compliance with action level?
    - Look for trends over time?
    - Etc.
  - Determine the quality and quantity of data needed

http://vsp.pnl.gov

Slide 27

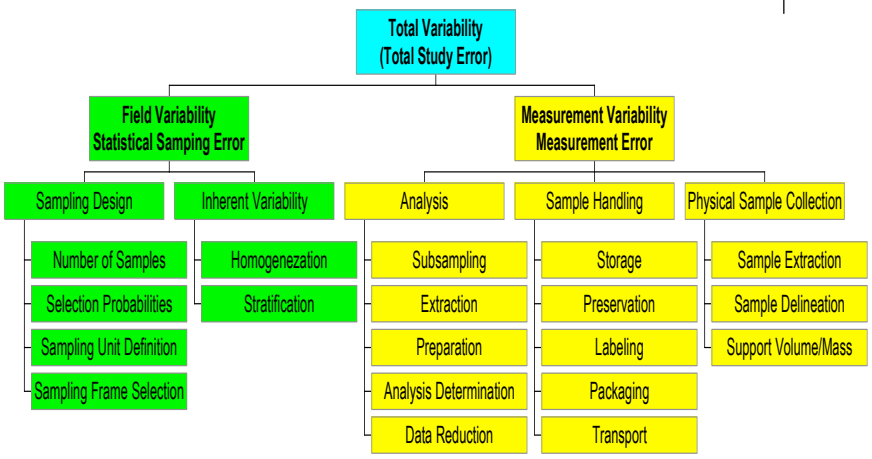
Document the Problem

- Analysis of existing data
- Conceptual Site Model (CSM)
- Site map noting sample locations and measured concentrations
- Historical process knowledge



Slide 28

Total Study Error



Slide 29

Selecting Sampling Locations

- Probability-Based Strategies
  - Simple random
  - Systematic (grid)
  - Stratified
  - Collaborative
  - Ranked Set
  - Adaptive cluster
  - Sequential
  - Perimeter
  - Transect

Slide 30

Physical Sample Collection

- Sampling Variability
  - Method of collection
    - Procedure
  - Support activities
    - Logistics
    - Handling
    - Storage

Slide 31

Field Operations & Implementation

- Sampling Equipment
- Field Procedures
- Sampling Procedure Content
- Handling of Samples
- Sample Identification
- Labels and Chain of Custody Forms
- Security and Custody Seals
- Containers

Slide 32

Field Operations & Implementation

- Preservation
- Special Procedures for VOCs
- Background or Reference Samples
- Shipping and Storage
- Field Documentation
- Photographs/Video
- Field Change Request Forms

Slide 33

Field and Testing Operations

- Equipment Preventative Maintenance
- Measurement Traceability and Calibration
- Materials, Supplies, Services, and Chemicals
- Field and Testing Change Request
- Data Verification and Retention
- Electronic Data Records
- Reports

Slide 34

Field and Testing Operations

- Standard Operating Procedures and Methods
- Audits
- Complaints
- Decontamination Procedures
- Temperature Control
- Holding Times
- Sample Delivery

Slide 35

Lab Operations & Implementation

- Laboratory Facilities
  - Testing equipment
  - Testing procedures
  - Testing procedures content
  - Sample identification
  - Laboratory documentation
  - Laboratory quality control

Slide 36

Data Quality Indicators

- Precision
- Bias
- Accuracy
- Representativeness
- Comparability
- Completeness
- Sensitivity
  - Selectivity used by some organizations

Sampling and Testing defined for project

Slide 37

Limits and Data Qualifiers

- Detection Limits or Minimum Activity Level
- Reporting Limits (Quantitation Limits)
- Action Limits
  - Risk based
  - Method based
  - Performance based
- Qualification of Data
  - Functional guidelines
  - Laboratory defined
  - Contractor defined

Slide 38

Source: UFP QAPP Manual, V1 March 2005

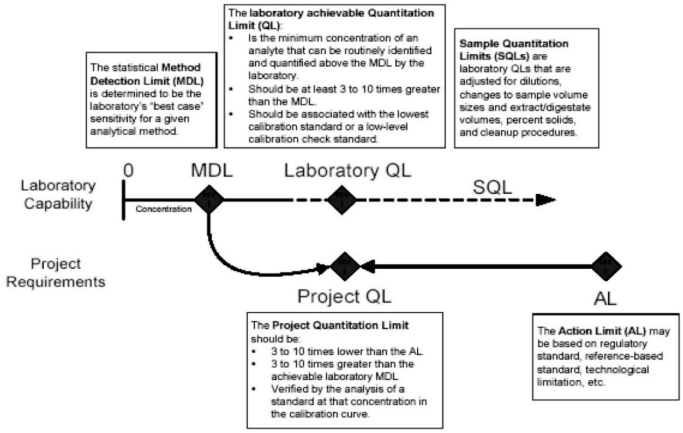


Figure 15. Relationships to Project Quantitation Limits

Slide 39

Data Review

- Verification
- Validation
- Assessment
- Usability

Slide 40

EPA QA/R-5

QAPP Requirements

- Project/Task Organization
- Problem Definition/Background
- Project/Task Description
- Quality Objectives & Criteria for Data
- Sampling Process Design
- Sampling/Analytical Method Requirements
- Quality Control Requirements

Slide 41

Document the Rationale for the Proposed Approach in the Plan

- What decision(s) will be made?
- What data are needed to support the decisions and why?
- What portion of the environment (and/or what time frame) must be represented by data?
- How will data be used to support the decision?
- What level of decision certainty hence data quality is desired?

These statements are the DQOs, translated for incorporation in the Plan

Slide 42

LUNCH

Course Resumes in 1 Hour

Slide 43

Determination

- Data Verification
- Data Validation
- Data Quality Assessment and Usability Evaluation
- Data Usability Report
- Assessing and Interpreting Data Usability

Section 4

Slide 44

Data Review

- Define at start of project
- Define terms validation, verification, etc.
- Identify who will perform each data review task, when it will be performed
- Document when project quality objective is met and not met
  - if not are there lessons learned
  - if not are corrective actions implemented

Slide 45

Data Review Specifications

- Assessment
  - Sample design
  - Sample collection process
  - Laboratory analytical data
- Expansion of elements
  - Project specific criteria review
  - Assessment of usability

Slide 46

Data Review Process

- Step I Data Verification
  - Review for completeness
- Step II Data Validation
  - Review for compliance
- Step III Data Usability Assessment
  - Assess results from above to determine usability of data for making decision

Slide 47

Data Review Process

- Data Review Inputs
  - Planning documents
  - Analytical data package
  - Sampling documents
  - External reports

Slide 48

Table 9. Example Inputs to Data Review Process

	Item	Step I Verification	Step IIa Compliance	Step IIb Comparison	Step III Usability
	Planning Documents				
1	Evidence of required approval of plan (QAPP)	X			Uses outputs from previous steps
2	Identification of personnel (those involved in the project and those conducting verification steps)	X			
3	Laboratory name	X			
4	Methods (sampling and analysis)	X	X		
5	Performance requirements (including QC criteria) for all inputs	X	X	X	
6	Project quality objectives	X		X	
7	Reporting forms	X	X		
8	Sampling plans, location, maps, grids, and sample ID numbers	X	X		
9	Site identification	X			
10	SOPs (sampling and analytical)	X	X		
11	Staff training and certification	X			
12	List of project-specific analytes	X	X		
	Analytical Data Package				
13	Case narrative	X	X	X	Uses outputs from previous steps
14	Internal laboratory chain of custody	X	X		
15	Sample condition upon receipt, and storage records	X	X		
16	Sample chronology (time of receipt, extraction, and analysis)	X	X		
17	Identification of QC samples (sampling or lab, temporal, and spatial)	X	X		
18	Associated (batch or periodic) PT sample results	X	X	X	
19	Communication logs	X	X		
20	Copies of laboratory notebook, records, prep sheets	X	X		
21	Corrective action reports	X	X		
22	Definitions of laboratory qualifiers	X	X	X	
23	Documentation of corrective action results	X	X	X	
24	Documentation of individual QC results (e.g., spike, duplicate, LCS)	X	X	X	
25	Documentation of laboratory method deviations	X	X	X	
26	Electronic data deliverables	X	X		
27	Instrument calibration reports	X	X	X	
28	Laboratory name	X	X		
29	Laboratory sample identification numbers	X	X		
30	QC sample raw data	X	X	X	
31	QC summary report	X	X	X	
32	Raw data	X	X	X	
33	Reporting forms, completed with actual results	X	X	X	
34	Signatures for laboratory sign-off (e.g., laboratory QA manager)	X	X		

Slide 49

Table 9. Example Inputs to Data Review Process (continued)

	Item	Step I Verification	Step IIa Compliance	Step IIb Comparison	Step III Usability
35	Standards traceability records (to trace standard source from NIST, for example)	X	X	X	
	Sampling Documents				
36	Chain of custody	X	X		
37	Communication logs	X	X		
38	Corrective action reports	X	X	X	
39	Documentation of corrective action results	X	X	X	
40	Documentation of deviation from methods	X	X	X	
41	Documentation of internal QA review	X	X	X	
42	Electronic data deliverables	X	X		
43	Identification of QC samples	X	X	X	
44	Meteorological data from field (e.g., wind, temperature)	X	X	X	
45	Sampling instrument decontamination records	X	X		
46	Sampling instrument calibration logs	X	X		
47	Sampling location and plan	X	X	X	
48	Sampling notes and drilling logs	X	X	X	
49	Sampling report (from field team leader to project manager describing sampling activities)	X	X	X	
	External Reports				
50	External audit report	X	X	X	Uses outputs from previous steps
51	External PT sample results	X	X		
52	Laboratory assessment	X	X		
53	Laboratory QA plan	X	X		
54	MDL study information	X	X	X	
55	NELAP accreditation	X	X		

The QAPP planning process must establish verification procedures, which should be documented in the QAPP to ensure that data are evaluated properly, completely, and consistently for use in meeting PQOs. The procedures should address the following:

The process that will be used to verify sample collection, handling, field analysis, and analytical laboratory project data.
The procedures and criteria that will be used to verify data information operations. These operations include, but are not limited to, the electronic and/or manual transfer, entry, use, and reporting of data for computer models, algorithms, and databases; correlation studies between variables; data plotting and so forth.

Figure 38 (QAPP Worksheet #34) provides an example Verification (Step I) Process table that can be used to present the process that will be followed to verify project data. Verification inputs include

Slide 50

Data Verification (Step I)

- Completeness
  - Are all the required records present?
  - Are the records filled out completely?
  - Are the required signatures present?

Slide 51

Worksheet #34

QAPP 5.2.1

Verification Input	Description	Internal/ External	Responsible for Verification (Name, Organization)

Verification Process (Step I)

Slide 52

Data Validation

- Assess and document performance of field and analytical process
- Determine compliance with method, procedure and contract requirements
- Compare with project quality criteria from the QAPP

Slide 53

Data Validation (Step IIa)

- Correctness - Sampling and Testing
- Compliance with procedures, methods and contracts
  - Is the information in the records correct?
  - Are the dates of sample collection, shipment, and receipt in the logical order?
  - Does the count of samples match the number of containers received?

Slide 54

Table 10. Step IIa Validation Activities
(Compliance with Methods, Procedures, and Contracts)

	Activity
Data Deliverables and QAPP	Ensure that all required information on sampling and analysis from step I was provided (including planning documents).
Analytes	Ensure that required lists of analytes were reported as specified in governing documents (i.e., method, procedure, or contract).
Chain-of-Custody	Examine the traceability of the data from time of sample collection until reporting of data. Examine chain-of-custody records against contract, method, or procedural requirements.
Holding Times	Identify holding time criteria, and either confirm that they were met or document any deviations. Ensure that samples were analyzed within holding times specified in method, procedure, or contract requirements. If holding times were not met, confirm that deviations were documented, that appropriate notifications were made (consistent with procedural requirements), and that approval to proceed was received prior to analysis.
Sample Handling	Ensure that required sample handling, receipt, and storage procedures were followed, and that any deviations were documented.
Sampling Methods and Procedures	Establish that required sampling methods were used and that any deviations were noted. Ensure that the sampling procedures and field measurements met performance criteria and that any deviations were documented.
Field Transcription	Authenticate transcription accuracy of sampling data (i.e., from field notebook to reports).
Analytical Methods and Procedures	Establish that required analytical methods (off-site laboratory and on-site analytical) were used and that any deviations were noted. Ensure that the QC samples met performance criteria and that any deviations were documented.
Data Qualifiers	Determine that the laboratory data qualifiers were defined and applied as specified in methods, procedures, or contracts.
Laboratory Transcription	Authenticate accuracy of the transcription of analytical data (i.e., laboratory notebook to reporting form, or instrument to LIMS).
Proficiency Testing	Confirm acceptance of PT sample results against performance requirements as specified in methods, procedures, or contracts.
Standards	Determine that standards are traceable and meet contract, method, or procedural requirements.
Communication	Establish that required communication procedures were followed by field or laboratory personnel.

Slide 55

Data Validation (Step IIb)

- Technical compliance sampling and testing
- Meeting measurement performance criteria
  - Are the analytical methods referenced on the Chain of Custody form or analysis request the same as those given in the planning documents?
  - Are samples properly preserved in accordance with the requested method?
  - Were samples received in a timely manner to allow holding times to be met?
  - Are samples, data and methods traceable from the field to laboratory and then to the project report?

Slide 56

Step IIb Validation Activities

Data Deliverables and QAPP	Ensure that the data report from step IIa was provided.
Deviations	Determine the impacts of any deviations from sampling or analytical methods and SOPs. For example, confirm that the methods given in the QAPP were used and, if they were not, determine if data still meet MPCs. Consider the effectiveness and appropriateness of any corrective action.
Sampling Plan	Determine whether the sampling plan was executed as specified (i.e., the number, location, and type of field samples were collected and analyzed as specified in the QAPP)
Sampling Procedures	Evaluate whether sampling procedures were followed with respect to equipment and proper sampling support (e.g., techniques, equipment, decontamination, volume, temperature, preservatives, etc.).
Co-located Field Duplicates	Compare results of collocated field duplicates with criteria established in the QAPP.
Project Quantitation Limits	Determine that quantitation limits were achieved, as outlined in the QAPP and that the laboratory successfully analyzed a standard at the QL.
Confirmatory	Evaluate agreement of laboratory results.
Performance Criteria	Evaluate QC data against project-specific performance criteria in the QAPP (i.e., evaluate quality parameters beyond those outlined in the methods).
Data Qualifiers	Determine that the data qualifiers applied in step IIa were those specified in the QAPP and that any deviations from specifications were justified.
Step IIb Validation Report	Summarize outcome of comparison of data to MPC in the QAPP. Include qualified data and explanation of all data qualifiers.

Slide 57

Data Validation (Step IIb)

- Compliance with QAPP
  - How well was the sample design implemented?
  - How well were project-specific sampling requirements met?
  - Does analytical data quality meet the project specific measurement performance criteria?

Slide 58

Worksheet #35

QAPP 5.2.2

Step IIa/IIb	Validation Input	Description	Responsible for Validation (Name, Organization)

Validation Process (Steps IIa and IIb)

Slide 59

Worksheet #36

Step IIa/IIb	Matrix	Analytical Group	Concentration Level	Validation Criteria	Validator (title and organizational affiliation)

Validation Summary (Steps IIa and IIb)

Slide 60

Final Project Reports

- Narrative and timeline of project activities
- Summary of PQO development
- Reconciliation of project data with PQOs
- Summary of major problems encountered and their resolution (lessons learned)
- Data summary, including tables, charts, and graphs with appropriate sample identification or station location numbers, concentration units, percent solids (if applicable), and data quality flags
- QA Section - Management Report
- Conclusions and recommendations

Slide 61

Data Usability (Step III)

- Plan how you will make your decision, once you have your data
- Things to consider:
  - Does the data tend to confirm or refute your CSM?
  - What do the quality system results tell you about how the project was implemented?
  - What affect do deviations have on data usability?

UFP - QAPP 5.2.3

Slide 62

Table 12. Considerations for Usability Assessment

Item	Assessment Activity
Data Deliverables and QAPP	Ensure that all necessary information was provided, including but not limited to validation results.
Deviations	Determine the impact of deviations on the usability of data.
Sampling Locations, Deviation	Determine if alterations to sample locations continue to satisfy the project objectives.
Chain-of-Custody, Deviation	Establish that any problems with documentation or custody procedures do not prevent the data from being used for the intended purpose.
Holding Times, Deviation	Determine the acceptability of data where holding times were exceeded.
Damaged Samples, Deviation	Determine whether the data from damaged samples are usable. If the data cannot be used, determine whether resampling is necessary.
PT Sample Results, Deviation	Determine the implications of any unacceptable analytes (as identified by the PT sample results) on the usability of the analytical results. Describe any limitations on the data.
SOPs and Methods, Deviation	Evaluate the impact of deviations from SOPs and specified methods on data quality.

Slide 63

Item	Assessment Activity
QC Samples	Evaluate the implications of unacceptable QC sample results on the data usability for the associated samples. For example, consider the effects of observed blank contamination.
Matrix	Evaluate matrix effects (interference or bias).
Meteorological Data and Site Conditions	Evaluate the possible effects of meteorological (e.g., wind, rain, temperature) and site conditions on sample results. Review field reports to identify whether any unusual conditions were present and how the sampling plan was executed.
Comparability	Ensure that results from different data collection activities achieve an acceptable level of agreement.
Completeness	Evaluate the impact of missing information. Ensure that enough information was obtained for the data to be usable (completeness as defined in PQOs documented in the QAPP).
Background	Determine if background levels have been adequately established (if appropriate).
Critical Samples	Establish that critical samples and critical target analytes/COCs, as defined in the QAPP, were collected and analyzed. Determine if the results meet criteria specified in the QAPP.
Data Restrictions	Describe the exact process for handling data that do not meet PQOs (i.e., when measurement performance criteria are not met). Depending on how those data will be used, specify the restrictions on use of those data for environmental decision-making.
Usability Decision	Determine if the data can be used to make a specific decision considering the implications of all deviations and corrective actions.
Usability Report	Discuss and compare overall precision, accuracy/bias, representativeness, comparability, completeness, and sensitivity for each matrix, analytical group, and concentration level. Describe limitations on the use of project data if criteria for data quality indicators are not met.

Slide 64

Data Assessment (Step III)

Five Steps of the data quality assessment (DQA) process, EPA QA/G-9

1. Review DQOs and the sampling design
2. Conduct a preliminary data review
3. Select the statistical test
4. Verify the assumptions of the statistical test
5. Draw conclusions from the data

Slide 65

Worksheet #37

- Summarize the usability assessment process
- Describe evaluative procedures to assess measurement error
- Identify responsible personnel
- Describe the documentation of the usability process

Don't forget to define the significant figures in deliverables!

Slide 66

Usability Report Contents

- The usability report should discuss and compare overall field duplicate precision data from multiple data sets collected for the project for each matrix, analytical group, and concentration level. Usability reports should describe the limitations on the use of project data when overall precision is poor or when poor precision is limited to a specific sampling or laboratory (analytical) group, data set or SDG, matrix, analytical group, or concentration level.

Slide 67

Usability Report Contents

- Discuss and compare overall contamination and accuracy/bias data from multiple data sets collected for the project for each matrix, analytical group, and concentration level.
- Describe the limitations on the use of project data if extensive contamination and/or inaccuracy or bias exist, or when inaccuracy is limited to a specific sampling or laboratory group, data set or SDG, matrix, analytical group, or concentration level.
- Identify qualitative and/or quantitative bias trends in multiple proficiency testing (PT) sample results for each matrix, analytical group, and concentration level.
- Discuss the impact of any qualitative and quantitative trends in bias on the sample data.

Slide 68

Usability Report Contents

- The usability report should discuss and compare overall sample representativeness for each matrix, analytical group, and concentration level. Usability reports should describe the limitations on the use of project data when overall nonrepresentative sampling has occurred, or when nonrepresentative sampling is limited to a specific sampling, group, data set or SDG, matrix, analytical group, or concentration level.

Slide 69

Usability Report Contents

- Discuss and compare overall comparability between multiple data sets collected for the project for each matrix, analytical group, and concentration level.
- Describe the limitations on the use of project data when project-required data comparability is not achieved for the overall project or when comparability is limited to a specific sampling or laboratory group, data set or SDG, matrix, analytical group, or concentration level.
- Document the failure to meet screening/confirmatory comparability criteria and discuss the impact on usability.

Slide 70

Usability Report Contents

- Document the failure to meet split sampling comparability criteria and discuss the impact on usability.
- If data are not usable to adequately address environmental questions or support project decision-making, address how this problem will be resolved and discuss the potential need for resampling.
- If long-term monitoring data are not comparable, address whether the data indicate a changing environment or are a result of sampling or analytical error.

Slide 71

Usability Report Contents

- Discuss and compare overall sensitivity and QLs from multiple data sets collected for the project for each matrix, analytical group, and concentration level.
- Discuss the impact of that lack of sensitivity or higher QLs on data usability, if validation reports indicate that sensitivity or QLs were not achieved
- Describe the limitations on the use of project data if project-required sensitivity and QLs are not achieved for all project data, or when sensitivity is limited to a specific sampling or laboratory group, data set or SDG, matrix, analytical group, or concentration level.

Slide 72

Usability Report Contents

- Discuss and compare overall completeness of multiple data sets collected for the project for each matrix, analytical group, and concentration level.
- Describe the limitations on the use of project data if project-required completeness is not achieved for the overall project, or when completeness is limited to a specific sampling or laboratory group, data set or SDG, matrix, analytical group, or concentration level.

Slide 73

Should Data be Rejected

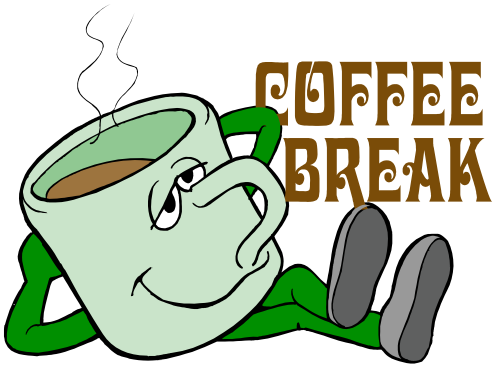
- Data tells you something
  - About site, sample collection or testing
  - All data means something
- Data is not rejected,
  - It may not be usable to solve the problem.

Slide 74

BREAK

Course Resumes

in 10 Minutes



Slide 75

Decision Making Process

- Case Studies
  - Examples of when decision making goes wrong
    - Incorrect conclusions and unnecessary actions taken
    - Likely not legally defensible/supported
    - Added costs (budget over limits) and poor use of resources
  - Examples of when decision making goes right
    - Conclusions based on sound science
    - Legally defensible/supported
    - Dollars and resources are saved
- Lessons Learned
- Documentation of Decision Outcome

Section 5

Slide 76

Case Example 1 – Ammonia Analyses and NPDES

- Ammonia analysis - to distill or not to distill for samples to meet NPDES requirements
  - Use correct method
  - Properly collect and preserve samples for specific form of nitrogen to ensure appropriate treatment at facility
- Accuracy of determination begins with sampling
  - Preserve with sulfuric acid to pH <2 to minimize biological or chemical degradation
- If sample is not analyzed within 28 days, then results are qualified for NPDES purposes

Slide 77

Case Example 1, cont.

- Accuracy of ammonia determination dependent on many factors:
  - Presence of interferences will bias results (e.g., residual chlorine, aromatic/aliphatic amines, cyanate, volatile alkaline compounds [ketones, aldehydes, and alcohols])
  - Quality of distillation process
- Must buffer sample to decrease hydrolysis of interferences before distillation

Slide 78

Case Example 1, cont.

- Ammonia in distillate can be determined by several methods:
  - Colorimetrically by nesslerization
  - Titrimetrically with standard H_2SO_4 and mixed indicator
  - Potentiometrically by use of the ammonia-selective electrode
- Each method has its own potential problems
- Must make sure results are reported using proper units (e.g., ammonia as NH_3 or ammonia as N)

Slide 79

40 CFR 136

Parameter	Methodology[16]	Reference (method number or page)					
		EPA[35, 52]	Standard methods (18th, 19th)	Standard methods (20th)	Standard methods online	ASTM	USGS/AOAC/other
1. Acidity, as $CaCO_3$, mg/L	Electrometric endpoint or phenolphthalein endpoint.		2310 B(4a)	2310 B(4a)	2310 B(4a)–97	D1067–92, 02	I–1020–85[2]
2. Alkalinity, as $CaCO_3$, mg/L	Electrometric or Colorimetric titration to pH 4.5, manual, or		2320 B	2320 B	2320 B–97	D1067–92, 02	973.43[3], I–1030–85[2]
	automatic	310.2 (Rev. 1974)[1].					I–2030–85[2]
3. Aluminum—Total,[4] mg/L	Digestion[4] followed by:						
	AA direct aspiration[36]		3111 D		3111 D–99		I–3051–85[2]
	AA furnace		3113 B		3113 B–99.		
	STGFAA	200.9, Rev. 2.2 (1994).					
	ICP/AES[36]	200.7, Rev. 4.4 (1994).	3120 B	3120 B	3120 B–99		I–4471–9750
	ICP/MS	200.8, Rev. 5.4 (1994).				D5673–03	993.14[3]
	Direct Current Plasma (DCP)[36]					D4190–94, 99	See footnote[34]
	Colorimetric (Eriochrome cyanine R)		3500–Al D	3500–Al B	3500–Al B–01.		
4. Ammonia (as N), mg/L	Manual, distillation (at pH 9.5)[6] followed by:	350.1, Rev. 2.0 (1993).	4500–NH B_3	4500–NH_3 B	4500–NH_3 B–97		973.49[3]
	Nesslerization		4500–NH_3 C (18th only),			D1426–98, 03 (A)	973.49[3], I–3520–85[2]
	Titration		4500–NH_3 C (19th) and 4500–NH_3 E (18th).	4500–NH_3 C	4500–NH_3 C–97.		
	Electrode		4500–NH_3 D or E (19th) and 4500–NH_3 F or G (18th).	4500–NH_3 D or E	4500–NH_3 D or E–97.	D1426–98, 03 (B).	
	Automated phenate, or	350.1[60], Rev. 2.0 (1993).	4500–NH_3 G (19th) and 4500–NH_3 H (18th).	4500–NH_3 G	4500–NH_3 G–97		I–4523–85[2]
	Automated electrode						See footnote 7
	Ion Chromatography					D6919–03.	

Slide 80

Preservation

Table IB—Inorganic Tests:			
1. Acidity	P, FP, G	Cool, ≤6 °C [18]	14 days
2. Alkalinity	P, FP, G	Cool, ≤6 °C [18]	14 days
4. Ammonia	P, FP, G	Cool, ≤6 °C [18], H_2SO_4 to pH<2.	28 days

18 Aqueous samples must be preserved at ≤ 6°C, and should not be frozen unless data demonstrating that sample freezing does not adversely impact sample integrity is maintained on file and accepted as valid by the regulatory authority. Also, for purposes of NPDES monitoring, the specification of "≤ ° C" is used in place of the "4°C" and "<4°C" sample temperature requirements listed in some methods. It is not necessary to measure the sample temperature to three significant figures (1/100th of 1 degree); rather, three significant figures are specified so that rounding down to 6 °C may not be used to meet the ≤ 6 °C requirement. The preservation temperature does not apply to samples that are analyzed immediately (less than 15 minutes).

Slide 81

Usability Report

- The records for the ammonia data are complete and available. The field records and laboratory records were reviewed. A listing of the records should be presented.

  (Verification - Step 1a)

Slide 82

Usability Report

- The field and laboratory records review found compliance with method and the NPDES permit except for the following:
  - The sample pH at the time of laboratory receipt was 3.5 units. The field records indicate a pH <2. The laboratory adjusted the sample upon receipt. (Validation Step 2a)
  - The laboratory records do not indicate a distillation was performed prior to performing the electrode method. (Validation Step 2a)
  - The sample results show non detect at 0.1 mg/L. The permit limit is 0.05 mg/L. The results are not reported at a limit below the permit limit. (Validation Step 2b)
- The NPDES program requires all data from effluent samples must be reported.

Slide 83

Usability Report

- A request to the state to remove this result from the data set for the month is recommended for the following reasons:
  - pH was not maintained below 2 as required by 40CFR Part 136. The initial pH was <2, but due to the nature of the sample, the pH was not maintained. The laboratory acidified the sample to pH < 2 within 12 hours of sample collection. A study of holding the sample without pH preservation, pH of 5 and pH of 2 was performed using the sample matrix. Results demonstrated a recovery of 85% to 110%. The pH preservation does not have an effect on the reported data.
  - Distillation records are on file to demonstrate that distillation is not necessary are required by 40CFR 136 footnote 6. Therefore no effect is found on the reported data.

Slide 84

Usability Report

- A request to the state to report this result as less than 0.05 is recommended for the following reasons:
  - The results were not reported to the requested reporting limit. This makes the results reported as not usable for purposes of NPDES reporting. A review of laboratory raw data determined that the laboratory performed a low level standard at 0.05 mg/L with a recovery of 70%. This is a low bias. A review of the sample result response found that the sample response is below the blank reading. Since a standard at 0.05 mg/L was measured to demonstrate that if the sample contained this amount it would have been measured.
  - The laboratory reports an LOQ of 0.1 mg/L (low standard in calibration curve) and an LOD of 0.05 mg/L. The calculated MDL is 0.03mg/L
- The permittee has taken corrective action to ensure that the reporting limit is below the permit limit. (Usability Step 3)

Slide 85

Lessons Learned

- How could we avoid this for the next project?
  - Ensure the laboratory has the correct reporting limit needed for the data.
  - Ensure the sample is received by the laboratory as quickly as possible.
  - Document the location of the distillation records and note this in the reported results.

Slide 86

Case Example 2 – Need to Select Correct Analytical Method!

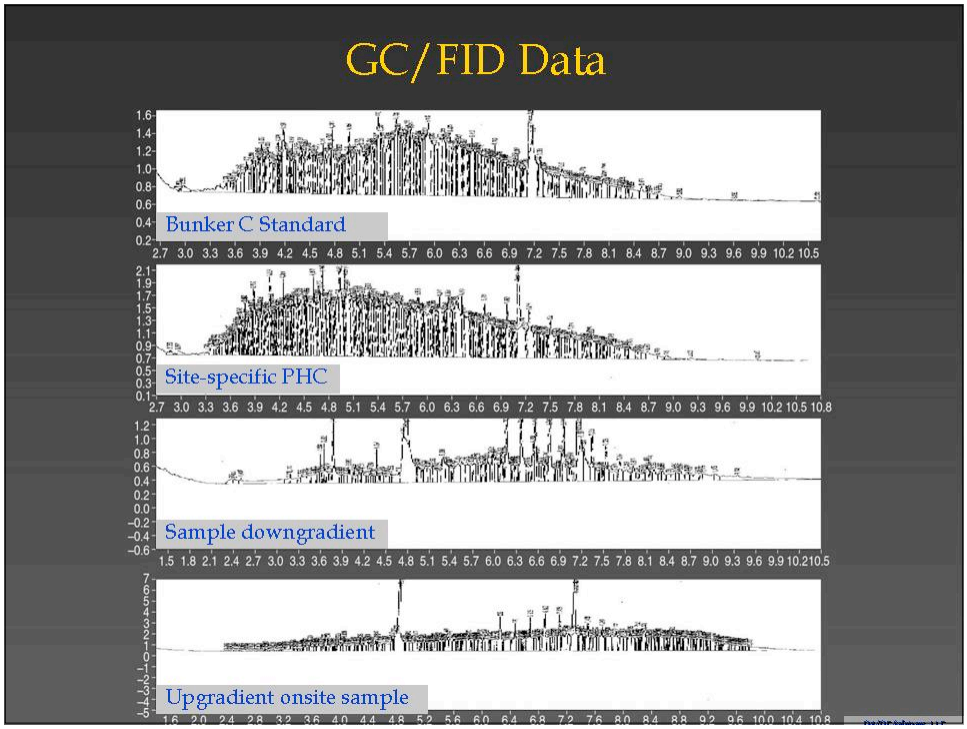
- Are site-specific PHCs migrating offsite?
- GW samples collected quarterly over several years
- Analyses for diesel-range (extended) PHCs by GC/FID
- Overall quality of data suspect:
  - Chromatography not best quality
  - Sample extracts not “cleaned up”; interferences
  - Improper quantification on non-target peaks

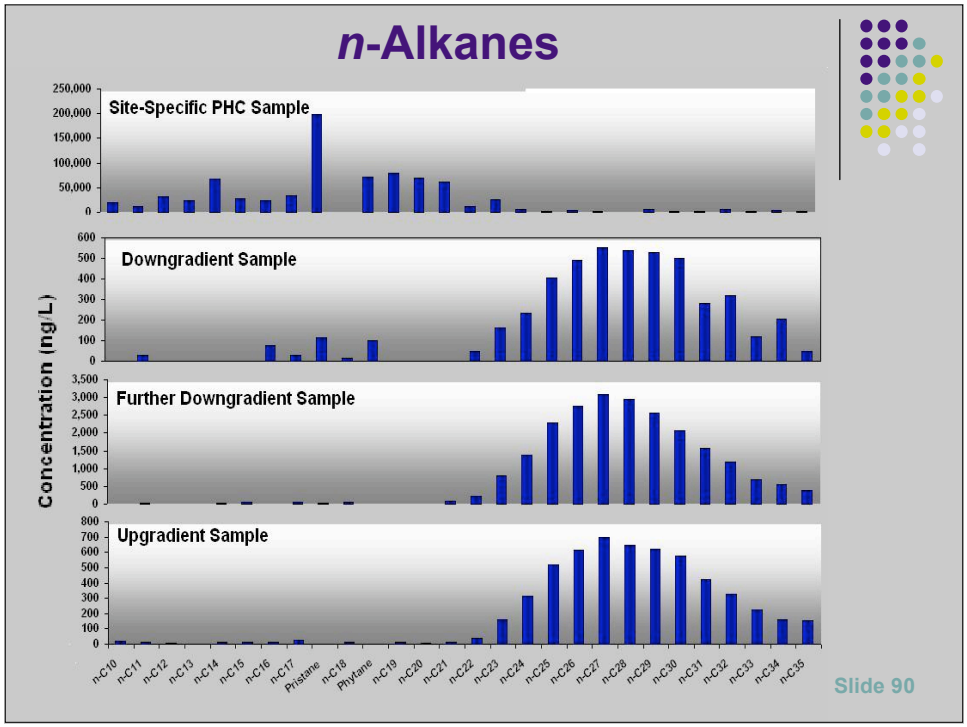
Slide 87

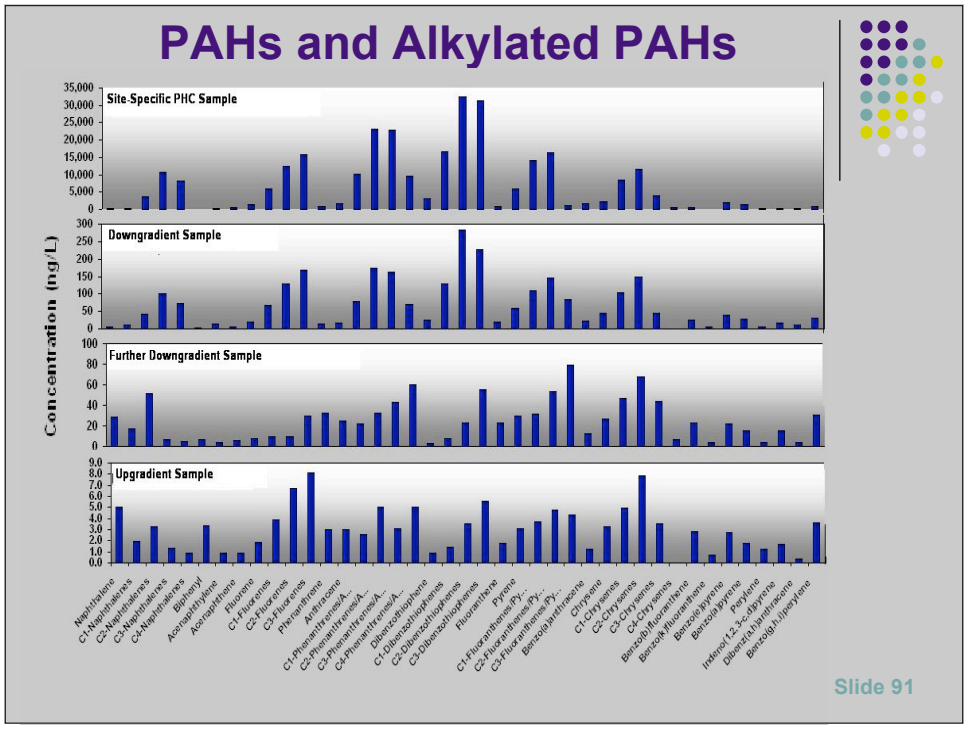
Case Example 2, cont.

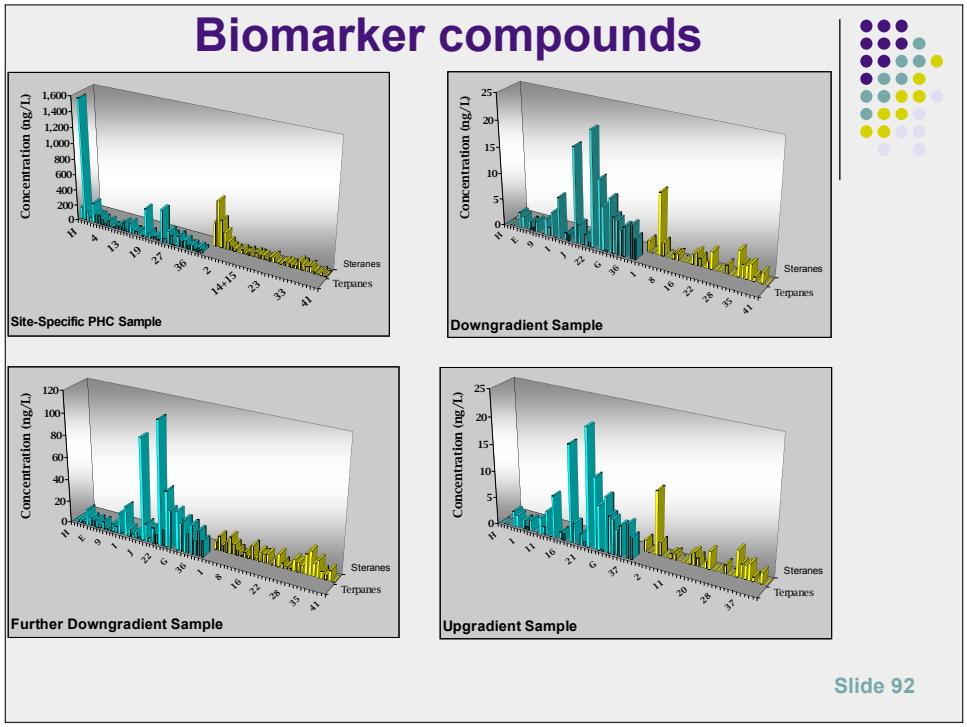
  - Laboratory inconsistent with flagging of data
  - Definitive chemical analyses never completed
- Alternative chemical analyses required to answer question
  - Saturated hydrocarbons (i.e., *n*-Alkanes)
  - PAHs/Alkylated PAHs
  - Biomarker compounds
- Complete analyses, review new data, and draw conclusions

Slide 88


GC/FID Data
Bunker C Standard
Site-specific PHC
Sample downgradient
Upgradient onsite sample


n-Alkanes
Site-Specific PHC Sample
Downgradient Sample
Further Downgradient Sample
Upgradient Sample
Concentration (ng/L)
n-C10 n-C11 n-C12 n-C13 n-C14 n-C15 n-C16 n-C17 Pristane n-C18 Phytane n-C19 n-C20 n-C21 n-C22 n-C23 n-C24 n-C25 n-C26 n-C27 n-C28 n-C29 n-C30 n-C31 n-C32 n-C33 n-C34 n-C35
Slide 90


PAHs and Alkylated PAHs
Site-Specific PHC Sample
Downgradient Sample
Further Downgradient Sample
Upgradient Sample
Concentration (ng/L)
Slide 91


Biomarker compounds
Concentration (ng/L)
Steranes
Terpanes
Site-Specific PHC Sample
Downgradient Sample
Further Downgradient Sample
Upgradient Sample
Slide 92

Conclusions

- Site-specific PHCs do not appear to be migrating offsite!
- Previous data should have be verified and validated while it was generated!
- Analytical method used was “approved” but was not appropriate for end-use!
- Unnecessary sampling and analyses completed over many years!
- Question resolved at significant cost savings

Slide 93

Usability Report

- The records for the diesel-range (extended) PHCs by GC/FID were complete. The field records and laboratory records were reviewed.
- Review of records determined there are issues with the overall quality (and usability) of the data reported:
  - Chromatography was not of the best quality
  - The sample extracts not subjected to silica gel column cleanup to remove biogenic interferences that are present
  - Non-target chromatographic peaks were improper used during quantification
  - The laboratory did not consistently “flag” the data
  - Definitive chemical analyses have not been completed

Slide 94

Usability Report

- It is concluded that the data as reported cannot be used for its intended purpose.
- Alternative chemical analyses must be completed to confidently make decision:
  - Saturated hydrocarbons (i.e., *n*-Alkanes)
  - PAHs/Alkylated PAHs
  - Biomarker compounds (e.g., steranes and terpanes)

Slide 95

Usability Report

- New samples were collected and analyzed for *n*-Alkanes, PAHs/Alkylated PAHs, and biomarkers.
- New data was subjected to thorough verification and validation. The following conclusions can be made:
  - Overall quality of the data reported and the methods used are acceptable
  - Data indicate a slightly weathered heavy fuel oil (i.e., No. 6 fuel oil or Bunker C) is present from the site
  - Distributions of the saturated hydrocarbons, PAHs, and chemical biomarkers in all but one of the groundwater samples (PAHs only) are not related to the site

Slide 96

Usability Report

- Site-specific PHCs do not appear to be migrating offsite and is not the source of the trace (or low levels) of a PHCs in the other groundwater samples
- This new data set more confidently indicates site-specific PHCs are not migrating offsite and impacting surrounding groundwater

Slide 97

Usability Report

- The following recommendations should be considered in the future:
  - All sample extracts should be subjected to silica gel column cleanup
  - Late eluting chromatographic peaks cannot be included in quantification
  - Results need to be consistently flagged and more completely noted in case narrative
  - Chemical fingerprinting analyses should be completed on critical samples yearly
  - Decisions to made should made based on chemical fingerprinting

Slide 98

Lessons Learned

- How could we avoid this for the next project?
  - Get QA/QC staff involved early in project planning
  - Carefully evaluate data early and determine if assumptions are correct
  - Work closely with analytical laboratory; seek advice as to best method(s) to use
  - Be sure the data make sense
  - Make sure interpretations are supported by data and not by speculation or assumptions
  - Have expert(s) develop usability report to identify method limitations and probability of correct compounds identified

Slide 99

Case Example 3 – Must Verify Data are Correct!

- If the data that are used are not correct, then conclusions drawn will be incorrect!
- Purported issue with offsite contamination
- Question is are PCDD/Fs from site getting into adjacent body of water?
- PCDD/F analyses for different matrices

Slide 100

Case Example 3, continued

- Review of data did not seem correct:
  - All PCDD/Fs reported as detected in many water samples
  - Distribution of PCDD/Fs detected and the concentrations reported did not make sense
- Steps taken included:
  - Get laboratory data and verify/validate
  - Found quality of laboratory data was quite good
  - Identified major issue with database – unit conversion errors and non-detects now detects!

Slide 101

Laboratory Data vs. Database

PCDD and PCDF Compound	Results reported by laboratory in units of pg/L	Results converted to units of mg/L	Results. in database in units of mg/L)
2,3,7,8-TCDD	0.857 U	8.57E-10 U	5.16E-07 =
1,2,3,7,8-PeCDD	0.988 U	9.88E-10 U	9.88E-07 =
1,2,3,6,7,8-HxCDD	0.921 U	9.21E-10 U	9.21E-07 =
1,2,3,7,8,9-HxCDD	0.985 U	9.85E-10 U	9.85E-07 =
1,2,3,4,7,8-HxCDD	0.921 U	9.21E-10 U	9.21E-07 =
1,2,3,4,6,7,8-HpCDD	1.02 U	1.02E-09 U	1.02E-06 =
OCDD	5 U	5.00E-09 U	5.00E-06 U
2,3,7,8-TCDF	0.943 U	9.43E-10 U	9.43E-07 =
1,2,3,7,8-PeCDF	1.43 U	1.43E-09 U	1.43E-06 =
2,3,4,7,8-PeCDF	1.24 U	1.24E-09 U	1.24E-06 =
1,2,3,4,7,8-HxCDF	2.5 U	2.50E-09 U	2.50E-06 U
1,2,3,6,7,8-HxCDF	0.616 U	6.16E-10 U	6.16E-07 =
1,2,3,7,8,9-HxCDF	0.914 U	9.14E-10 U	9.14E-07 =
2,3,4,6,7,8-HxCDF	0.679 U	6.79E-10 U	6.79E-07 =
1,2,3,4,7,8,9-HpCDF	0.831 U	8.31E-10 U	8.31E-07 =
1,2,3,4,6,7,8-HpCDF	2.5 U	2.50E-09 U	2.50E-06 U
OCDF	2.3 U	2.30E-09 U	2.30E-06 =

Notes: -- - not detected = - compound detected U - undetected

Slide 102

TEQs: Correct Values vs. RI

Sample	1A	2B	3B	4C	AWQC	PRG
RI TEQs	2,810	22	2,760	3,170	–	–
Laboratory (I-TEQs)	0	NR	4.26 x 10–2	0	–	–
TEQs (WHO)	0	0	4.26 x 10–3	0	5.0 x 10–3	0.45

Notes:

TEQ = Toxicity Equivalents
I-TEQ = Intonation Toxicity Equivalents
RI = Remedial Investigation
WHO = World Health Organization

Slide 103

Conclusions

- When corrected data were used, the issue of concern was not that bad!
- Should have done a reality check to make sure data made sense!
- Verify, verify, and verify!
- Validated, validate, and validate!
- With correct data, extensive sampling and analyses not required
- Major savings in costs and resources

Slide 104

Lessons Learned

- How could we avoid this for the next project?
  - Get QA/QC staff involved early in project planning
  - Ensure information technology staff are part of planning
  - Verify and validate data in hardcopy and electronic files before releasing final report
  - Be sure the data make sense
  - Carefully evaluate all assumptions and decisions made
  - Usability report needed that reviewed validation and verification information to identify the data changes made in the final reporting.

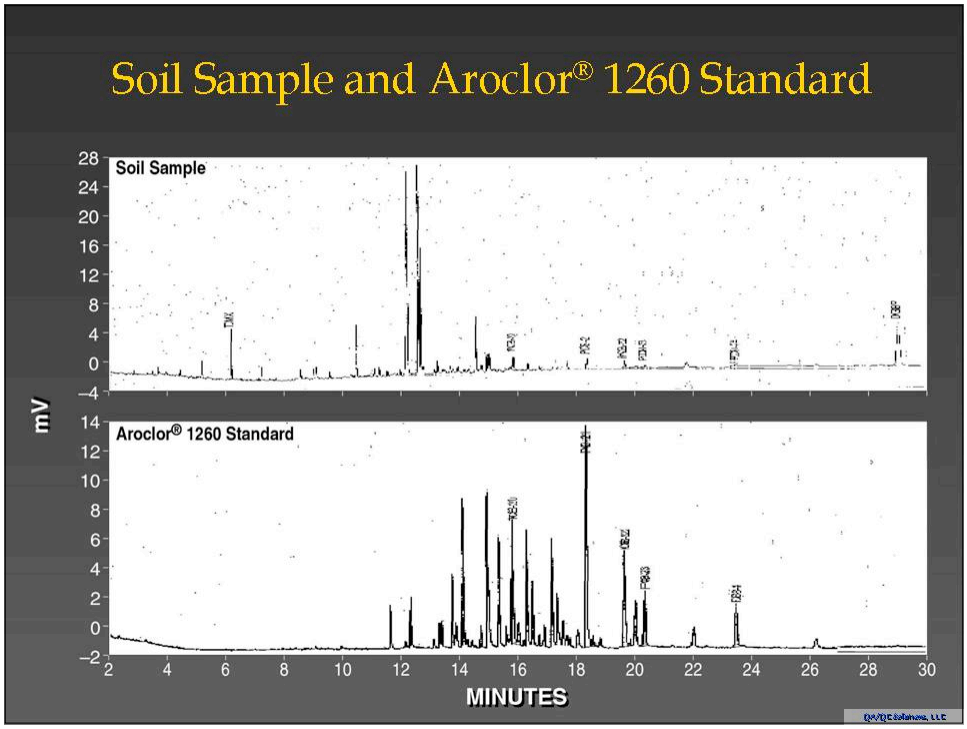
Slide 105

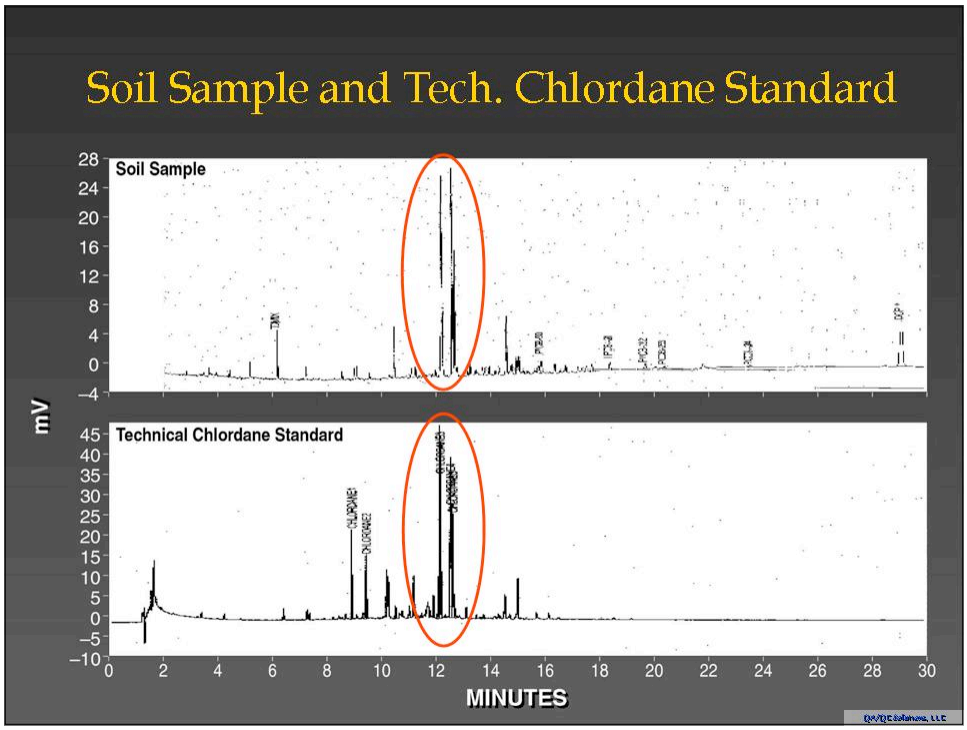
Case Example 4 – Data Must Support Your Conclusions!

- Incorrect conclusions will be made is do not use sound science!
- Question is to determine if PCBs in surface soil is source of PCBs in groundwater?
- According to expert witness, YES!
- Be careful what you say based on the data presented!

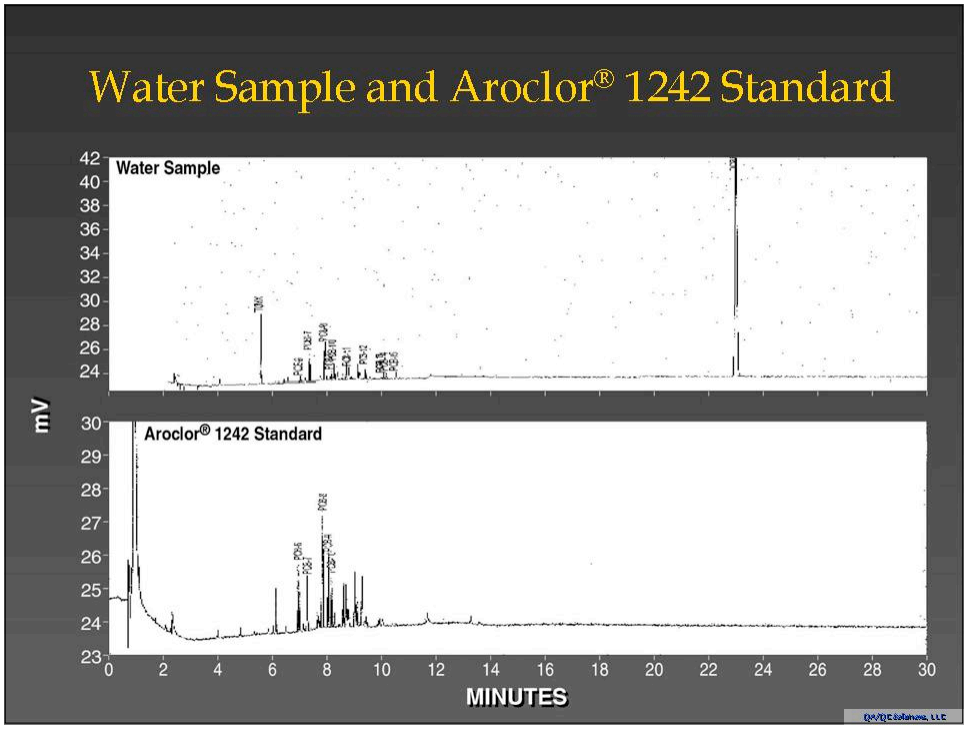
Slide 106

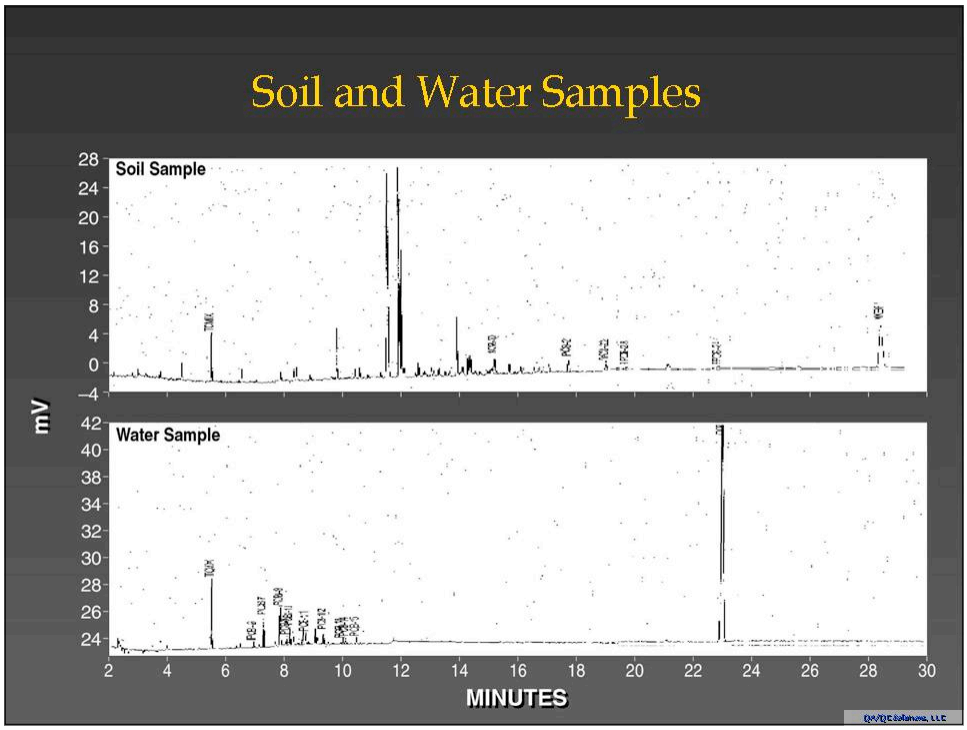
How to Make the Right Decision With Environmental Data





Advanced Systems, Inc. *April 2008*


Water Sample and Aroclor® 1242 Standard
Water Sample
Aroclor® 1242 Standard
mV
MINUTES


Soil and Water Samples
Soil Sample
Water Sample
mV
MINUTES

Conclusions

- Two different PCB mixtures from two different sources
- Concern with surface soil is technical grade chlordane, not Aroclor® 1260
- Expert witness statements not factually correct nor legally defensible!
- Data should have been verified and validated!
- Cannot make data say what you want!
- Cost Savings

Slide 111

Lessons Learned

- How could we avoid this for the next project?
  - Get QA/QC staff involved early in project planning
  - Verify and validate the data qualitatively (also termed selectivity)
  - Make sure interpretations and assumptions are supported
  - Work closely with analytical laboratory
  - Seek advice and have laboratory technical staff involved in final interpretations
  - Be sure the data make sense
  - Follow the scientific method
  - Data usability report reviews validation to ensure selectivity correct. Data usability report ensures final conclusions are supported by the data.

Slide 112

Summary

Proper planning and documentation is required to make the right decision using the right data for the right price!

Slide 113

Any Questions?

Slide 114

End Course

Thank you !!

Slide 115

Acronyms

- AWQC – Ambient water quality criteria
- DQA – Data quality assessment
- DQI – Data quality indicator
- DQO – Data quality objective
- EPA – Environmental Protection Agency
- GC/FID – Gas chromatography/flame ionization detection
- NPDES – National Pollutant Discharge Elimination System
- PAH – Polycyclic aromatic Hydrocarbon
- PCB – Polychlorinated biphenyl
- PCDD – Polychlorinated dibenzo-*p*-dioxin
- PCDF – Polychlorinated dibenzofuran
- PHC – Petroleum hydrocarbon

Slide 116

Acronyms, continued

- PQO – Project quality objective
- PRG – Preliminary remediation goals
- QA/QC – Quality assurance/quality control
- QAPP – Quality assurance project plan
- QL – Quantitation limit
- SDG – Sample delivery group
- RI – Remedial investigation
- TEF – Toxicity equivalency factor
- TEQ – Toxicity equivalent
- UFP – Uniform Federal Policy
- VOC – Volatile organic compound
- WHO – World Health Organization

Slide 117