

Welcome to the CLU-IN Internet Seminar

QA in Electronic Environmental Data Management

Delivered: October 20, 2011, 10:30 AM - 4:00 PM, EDT (14:30-20:00 GMT)

Presenters:

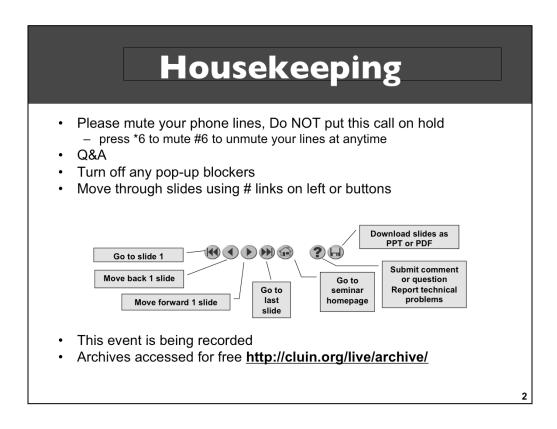
Roseanne Sakamoto, U.S. EPA, Quality Assurance Office (sakamoto.roseanne@epa.gov or 415-972-3813)

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George M. Brilis, U.S. EPA, Office of Research and Development, National Exposure Research Laboratory (brilis.george@epa.gov or 702-798-3128) Moderators:

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Visit the Clean Up Information Network online at www.cluin.org



Although I'm sure that some of you have these rules memorized from previous CLU-IN events, let's run through them quickly for our new participants.

Please mute your phone lines during the seminar to minimize disruption and background noise. If you do not have a mute button, press *6 to mute #6 to unmute your lines at anytime. Also, please do NOT put this call on hold as this may bring delightful, but unwanted background music over the lines and interupt the seminar.

You should note that throughout the seminar, we will ask for your feedback. You do not need to wait for Q&A breaks to ask questions or provide comments. To submit comments/ questions and report technical problems, please use the ? Icon at the top of your screen. You can move forward/backward in the slides by using the single arrow buttons (left moves back 1 slide, right moves advances 1 slide). The double arrowed buttons will take you to 1st and last slides respectively. You may also advance to any slide using the numbered links that appear on the left side of your screen. The button with a house icon will take you back to main seminar page which displays our agenda, speaker information, links to the slides and additional resources. Lastly, the button with a computer disc can be used to download and save today's presentation materials.

With that, please move to slide 3.

Quality Assurance in Electronic Environmental Data Management Intro

- Dawn Banks-Waller, Quality Staff, Office of Environmental Information, US EPA
- George Brilis, EPA/ORD National Exposure Research Laboratory (NERL)
- Roseanne Sakamoto, Quality Assurance Region 9 EPA

Intermission

You've joined EPA Region 6's webinar on Quality Assurance in Electronic Environmental Data Management

We will continue on this schedule shortly.

Eastern (EDT) 10:30 am	Intro	
	Part I:	Data Standards at EPA Dawn Banks Waller Quality Staff, Office of Environmental Information, US EPA
11:30 am	Part II:	Quality and Legal Considerations in the Development and Use of an Information Management System in EPA George Brilis US EPA Office of Research and Development National Exposure Research Laboratory
2:00 pm	Part III:	Method for Screening Data Quality in Electronic Data Systems Roseanne Sakamoto Region 9, US EPA

DISCLAIMER

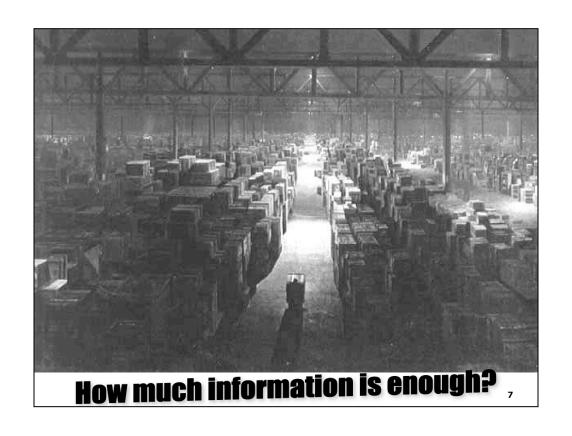
The opinions expressed in this technical presentation are those of the author and do not necessarily reflect the views of the US EPA, unless stated otherwise.

What are the products of the Agency that are *information*?

EVERYTHING!!!

information is ubiquitous

IT IS ALL **INFORMATION**



Purpose of Presentation

- SHARE AND OBTAIN FEEDBACK ON THE FOLLOWING:
- Part I. Data Standards at EPA for storing data and your role by Dawn Banks-Waller.
- Part II. Quality and Legal Considerations in the Development and Use of an Information Management System in EPA identifying important quality assurance features when developing data management systems for EPA (collection, distribution and content over lifecycle of media program retention requirements) by George Brilis
 - Note hard copies should be maintained even if stored electronically, until the integrity of the data is assured (i.e., not corrupted by outdated software or intrusion).
- Part III. Method for Screening Data Quality in Electronic Data Management Systems. Propose "core" QC field and laboratory elements for **screening** data quality in EDS like systems in a transparent, quantitative manner by Roseanne Sakamoto

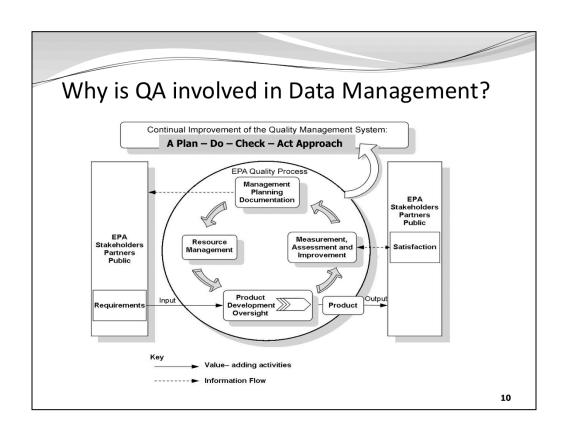
INFORMATION QUALITY ASSURANCE

• INFORMATION CONTENT

• The noun, the "what" of the information including the format it is in and the processes that led us to having good content.

• INFORMATION COLLECTION/ACCESS

• The verb, how information is collected, accessed and shared, secured, moved, updated, interacted with (to make new information) and the processes to ensure interaction can occur.



Isn't quality free!!!!!!

The cost of quality

QUALITY = features + freedom from defects

More features = cost more \$\$\$\$\$\$ More defects = will cost more \$\$\$\$\$



therefore, reducing defects can save \$\$\$\$\$\$\$\$

because it costs \$\$\$\$\$ to fix mistakes, rework, re-inspect



What are EPA Data Standards?

- Documented agreements on representations, formats, and definitions of common data
 - (http://www.epa.gov/datastandards) under the Find a Standard tab; EPA Approved Standards subtab
- Implemented per business rules that are maintained in separate guidance documentation
- Developed collaboratively and in consensus with Exchange Network partners and EPA Organizations
- Only developed when no similar international, national, or federal standard exists
 - NIEM is a national standard that should be used when appropriate

Why You Must Use Standards

- National Technology Transfer and Advancement Act of 1995 (NTTAA)
- OMB Circular A-119 Federal Participation in the Development and Use of Voluntary Standards
- OMB Circular A-130 Management of Federal Information Resources
- EPA Data Standards Policy
- EPA Enterprise Architecture Policy
- EPA Central Data Exchange (CDX)
- Exchange Network
- IT Contract Requirement

Benefits of EPA Data Standards

- Support business needs
 - Environmental business processes (Common fields and definitions for information related to permitting, sampling, etc.)
 - Environmental analysis (Enables data to be compared over time by location, toxic chemicals involved, facility, etc.)
 - Environmental data exchange (common structures and definitions to enable accurate and efficient transfer of data between organizations)
 - Environmental reporting (ability to aggregate or present data to decision makers that is based on common, well-understood meanings)
- Works within and across business areas

Benefits of EPA Data Standards

- Benefits as applicable to any standard
 - Developed by subject matter experts coming to common consensus on how to solve business problems so represents the "best" solution
 - Harder to develop, but **cheaper** in the long term because you can use the same code, the same presentation/publishing mechanisms to provide access to information
 - Enable transparency and understanding use of standards promotes common, **clear meanings** for data that is often reused
 - Enable access the same well understood terms, codes, and data structures can be used for data retrieval
 - Encourages and enables reuse of data and software for multiple purposes
 - Mappings to standards allow comparisons even when data isn't standardized – solves "environmental interest" problem
 - Consistent results during data retrieval

How EPA Data Standards are Developed

- Proposal
- Action Team Charter Developed/Approved
- Action Team Launched
- Draft Approved for Technical Review
- Resolution of Comments
- Draft Approved for Public Review
- Resolution of Comments
- Draft Adopted
- Periodic Review
- Revision as Needed

Implementation

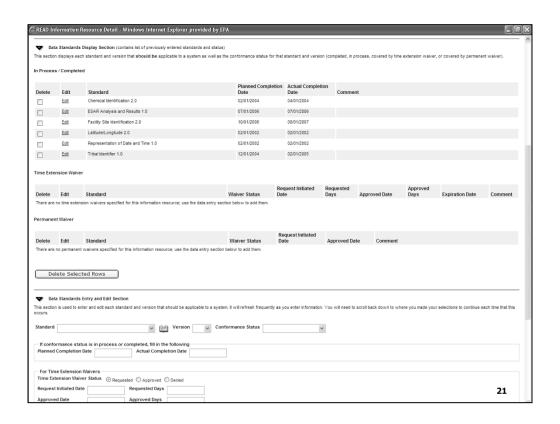
- Data Standards Web Site for EPA allows developers and individuals across federal and other standards communities to find information (and collaborate) about standards and related services
- Training course
 - On-line modules on Web site (http://www.epa.gov/datastandards) under the Training tab; On-line Training subtab

EPA Data Standard Implementation Rules

- Data Standards implementation depends on the context; frequently there is no "right" way.
- What is in a standard data elements, blocks and tags
 - Terms and meaning
 - Structure and Format
 - Possible code sets

Implementation Assessments

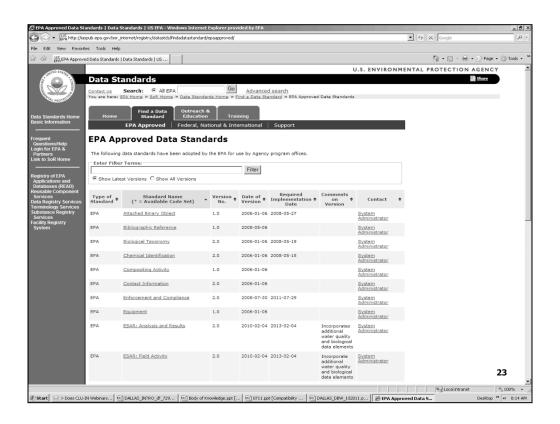
- Program Office self assessments
 - READ "Report Card" for each EPA system completed by system owners and approved by IMO or IRM branch chiefs (report available by office or by standard)
- DSB or contractor conformance reviews for individual systems (expensive and fairly rare)



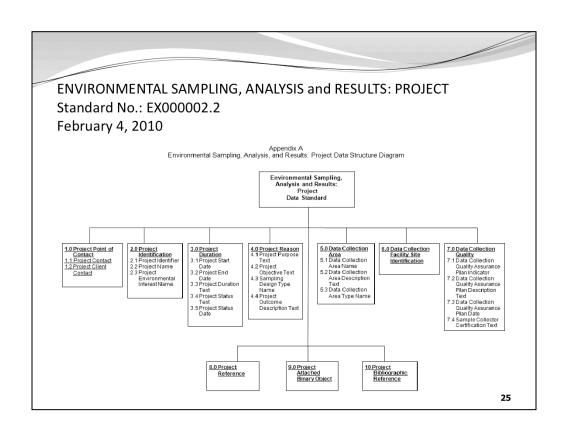
Current Approved EPA Standards

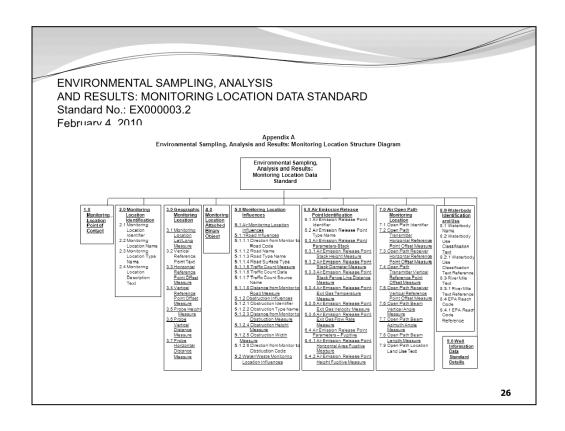
- Attached Binary Object
- · Facility Identification
- Institutional Control
- Latitude/Longitude
- Measure
- Method
- Permitting Information
- Quality Assurance and Quality Control ESAR: Monitoring Location
- · Representation of Date and Time
- Sample Handling
- SIC/NAICS
- Tribal Identifier
- Well Information

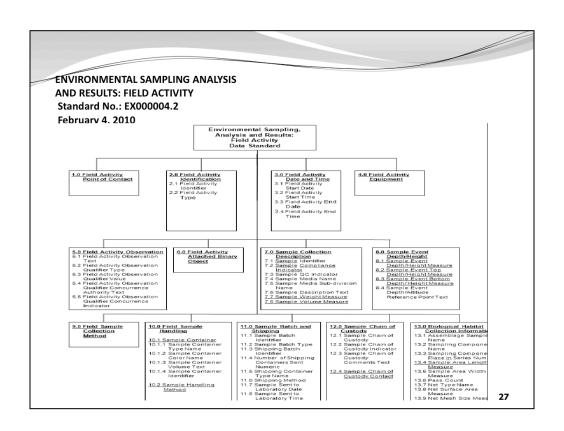
- Bibliographic Reference
- **Biological Taxonomy**
- **Chemical Identification**
- Compositing Activity
- Contact Information
- Enforcement and Compliance
- Equipment
- . ESAR: Analysis and Results
- ESAR: Field Activity
- ESAR: Overview
- ESAR: Project

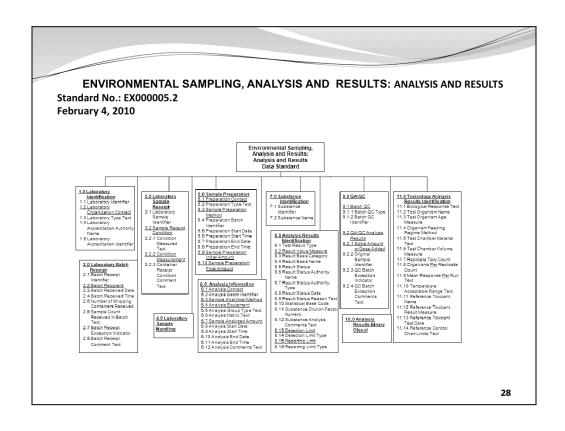


Lal	oratory QC					
EΡΑ	ESAR: Analysis and Results	2.0	2010-02-04 2	013-02-04	Incorporates additional water quality and biological data elements	<u>System</u> <u>Administrator</u>
ĒΡΑ	ESAR: Field Activity	2.0	2010-02-04 2	013-02-04	Incorporate additional water quality and biological data elements	<u>System</u> <u>Administrator</u>
ĒΡΑ	ESAR: Monitoring Location	2.0	2010-02-04 2	013-02-04	Incorporates additional water quality and biological data elements	<u>Svstem</u> <u>Administrator</u>
PA	ESAR: Overview	1.0	2006-01-06			<u>System</u> Administrator
EPA	ESAR: Project	2.0	2010-02-04 2	013-02-04	Incorporates additional water quality and biological data elements	System Administrator









Your Role in the Process

- Assistance needed from program managers to encourage documentation of system level business rules related to specific standards.
- Support to assure that "program office" standards have data standard stewards with subject matter and data management expertise over the long term
- Support to get accurate conformance and waiver reporting information into READ
- Overall promotion of EPA data standards and the data standards program

For Additional Information Contact

John Harman – Chief, Data Standard Branch Harman.John@epa.gov 202- 566 -0748

Lauren Gordon – Data Standards Branch Gordon.Lauren@epa.gov 202-566-0613

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Part II. Quality and Legal Considerations in the Development and use of an Information Management System in EPA.

George M. Brilis

QA Scientist

EPA/ORD/NERL/ESD

Presented to the

21st Annual Quality Assurance Conference
U.S. Environmental Protection Agency
Dallas, TX
October 20, 2011

Notice

- Although this work was reviewed by EPA and approved for publication it may not necessarily reflect official Agency policy.
- Mention of trade names or commercial products do not constitute endorsement or recommendation for use.
- The opinions expressed in this technical presentation are those of the author and do not necessarily reflect the views of the US EPA, unless stated otherwise.

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General Considerations

- In this section we move from manually documented logbooks and notebooks to electronic data management systems.
- It is a good practice to maintain hard copies of records even if stored electronically, until the integrity of its contents (data) is assured (i.e., not corrupted by outdated software or intrusion).

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Records include all books, papers, maps, photographs, machine-readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the United States Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value of the data in them (44 U.S.C. 3301).

Documentary materials is a collective term for records and nonrecord materials that refers to all media on which information is recorded, regardless of the nature of the medium or the method or circumstances of recording. http://www.archives.gov/midatlantic/agencies/records-mgmt/definitions.html

In ISO – a Document can be changed. A Records, once completed, can not be changed.

Primary Concerns of an Information Management System

- Confidentiality the element that limits information access and disclosure to authorized users.
- <u>Integrity</u> the element of trustworthiness, includes the concept that the validity of the data has not been compromised.
- <u>Availability</u> the element that represents the requirement that ensures accessibility.

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Six Principles for Quality Considerations

- Laboratory Management must provide a method of assuring the integrity of all data and records.
- 2. The formulas and decision algorithms employed by the Electronic Recordkeeping System (ERS) must be accurate and appropriate.

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- 1. Communication, transfer, manipulation, and the storage/recall processes all offer potential for data corruption. The demonstration of control necessitates the collection of evidence to prove that the system provides demonstrable protection against data corruption.
- 2. Users cannot assume that the test or decision criteria are correct; those formulas must be inspected and calculations verified.

Six Principles for Quality Considerations

- A critical control element is the capability to track data entry, modification, and recording to the individual doing the activities within the ERS or data system.
- Consistent and appropriate change controls, capable of tracking the ERS operations and software, are a vital element in the control process.

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- 3. This capability utilizes a password system or equivalent authentication techniques to identify the time, date, and person or persons entering, modifying, or recording data.
- 4. All changes must follow carefully planned procedures, be properly documented, and when appropriate include change control, acceptance testing, and validation processes.

Six Principles for Quality Considerations

5. Procedures must be established and documented for all users to follow.

Control of even the most carefully designed and implemented ERS will be thwarted if the user does not follow these procedures.

6. The risk of ERS failure requires that procedures be established and documented to minimize and manage their occurrence.

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- 5. This principle implies the development of clear directions and SOPs, the training of all users, and the availability of appropriate user support documentation. Ideally the technology system itself is designed to enforce the procedures and prevent any users from circumventing the Standard Operating Procedures.
- 6. Where appropriate, redundant systems must be installed and periodic archival quality recordkeeping system backups (not simply IT system backup copies) must be made at a frequency consistent with the consequences of the loss of information resulting from a failure. The principle of control must extend to planning for reasonable unusual events and system stresses, such as a vendor's failure to continue the product line and provide an errorless and lossless migration to replacement systems. Archival quality record collection backups are much more comprehensive and product-independent backups that allow the archival record collections to be reconstructed, accessed, and retrieved by record users in the future.

Legal Considerations

 Always contact the EPA Office of General Counsel if the review of items results in a strong cause for concern!

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Legal Protection of Databases

- Ensure that any contracts dealing with the creation or licensing of databases adequately cover the new rights where other intellectual property rights may have overlooked them.
- Ensure that you know what rights subsist (or will subsist) in your databases and those that are being created. Consider getting expert help to audit existing databases and contracts or agreements governing their creation and disposition.

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Legal Protection of Databases

- Avoid situations where the ownership of any copyright and database right is held by different people.
- Regularly update any new databases in order to maximize the term of protection available, but keep good records of the work which is undertaken, any financial or other investment in the database and the date(s) on which it is carried out.
- Use notices or disclaimers regarding the intended use and/or application of the database.

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Extramural Agreements

A database may be heterogeneous in nature.
 That is, it may contain data generated by the owner and data generated from another source – possible even by subscription. In these instances, one does not own the entire database. Therefore, one may not be able to freely distribute the entire database. The alternative may be to license the use of the database.

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Whether one is the licensee or the licensor, the following items should be considered

What is being licensed? To avoid later disputes, the parties must be as specific as possible.

Whether license rights, including the rights of production, distribution, manufacture and sale and the right to transfer license to a third party are permitted In what projects, products, or publications can one be permitted to use the licensed material?

What rights are being granted?

Is the license exclusive or non-exclusive?

Will the owner get credit, and if so, how will this be shown?

What intellectual property rights are retained by the licensor?

What is the license fee: a single one time fee, an annual fee, or royalty?

What is the duration of the license, and can it be renewed?

What warranties are being given for the use of the product by the licensor?

What are the liabilities of the licensor?

What remedies are available if the products and services are not warranted?

What obligations are there as to confidentiality of proprietary information?

 $Check\ if\ licensors\ have\ excluded\ liabilities\ for\ any\ indirect,\ incidental,\ special\ or\ consequential\ damages.$

Ensure that there is a statement as to whether the agreement is subject to export control laws, regulations and requirements – depending on jurisdiction.

Under miscellaneous provisions check if there are any provisions in the agreement that may be severable and whether the invalidity or enforceability of one of the provisions affects any other.

Ensure that the relationship between the parties in the license is that between independent contractors.

Check is all claims and disputes relating to the agreement are subject to final and binding arbitration, and under what jurisdiction.

The agreement should conclude by stating that it contains the entire agreement of the parties and that it supersedes all prior oral or written understandings or agreements between the parties with respect to the subject matter. Services of notices, contract offers, and postal address etc must be shown here as well.

Subcontracting

- A prime contractor may find another contractor to perform a part of the work. Ensuring that the subcontractor complies with EPA policies is a responsibility of the prime contractor.
- When most prime contracts are written, the right of the EPA QA Professional to directly communicate with the subcontractor may not be explicitly addressed in the contract. Consequently, EPA must rely on the prime contractor to check and report on the subcontractors' performance

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Subcontracting

 The author of this paper believes that it is in the best interest of the public if, in all prime contracts, the following phrase (or appropriate derivative) is included:

"The US EPA reserves the right to directly communicate with and perform assessments of any subcontractors that may be attached to this contract subsequent to award. In addition, the EPA may assess the performance of the subcontractor onsite; "at will" and without prior notification to the prime contractor or subcontractor."

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Legal Considerations

 Always contact the EPA Office of General Counsel if the review of items results in a strong cause for concern!

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References

- National Archives and Records Administration http://www.archives.gov/midatlantic/agencies/records-mgmt/definitions.html
- Documents and Records Management: Understanding the Differences and Embracing Integration, White Paper, Priscilla Emery, e-Nterprise Advisors, September 2003. http://www.docu-man.co.uk/ecm365files/documentandrecordsmanagement.pdf
- Good Automated Laboratory Practices (GALP), EPA 1995, Office of Information Resources Management, U.S. Environmental Protection Agency. Research Triangle Park, North Carolina: Scientific Systems Staff, 166 pgs [Out-of-Print]

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References

- Implementing and Auditing Electronic Recordkeeping Systems Used In Scientific Research and Development, Brilis G.M., Lyon, J.G., Worthington, J.C., Lysakowski, R Quality Assurance: Good Practice, Regulation, and Law, Vol. 11, No.1, 2004.
- Electronic Records: What to Look and Ask For (with Glossary),
 L.J. Marco, K. M. Connoly, The Practical Litigator, American Law Institute, American Bar Association, March 2004, pgs 39-46
- The Ethics of Electronic Discovery, S.C. Bennett, The Practical Litigator, American Law Institute, American Bar Association, March 2006, pgs 45-57
- Preservation of Electronic Records of Third-Party Contractors, M.J. Daley, The Practical Litigator, American Law Institute, American Bar Association, January 2007, pgs 29-36

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References

- Managing Electronic Data Transfer in Environmental Cleanups, G.M. Brilis, J.G. Lyon, R.S. Lunetta, J.W. Worthington, The Practical Litigator, American Law Institute, American Bar Association, September 2004, pgs 37-44.
- Document Retention and Electronic Discovery, B.E. Jameson, The Practical Litigator, American Law Institute, American Bar Association, September 2004, pgs 37-44.
- Discovery of Databases in Litigation, D.H. Junke, The Practical Litigator, American Law Institute, American Bar Association, November 2003, pgs 7-14

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We will continue on this schedule shortly

Eastern	(EDT)
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10:30 am

Intro

Part I: Data Standards at EPA

Dawn Banks Waller

Quality Staff, Office of Environmental Information, US EPA

11:30 am Part II: Quality

Quality and Legal Considerations in the Development and Use

of an Information Management System in EPA

George Brilis

US EPA Office of Research and Development National Exposure Research Laboratory

2:00 pm Part III: Method for Screening Data Quality in Electronic Data Systems

Roseanne Sakamoto Region 9, US EPA

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Part III

Method for Screening Data Quality in Electronic Data Systems



Roseanne Sakamoto, Quality Assurance Office, Region 9 October 2011

Purpose of Presentation

- Propose "core" field and laboratory QC elements electronic data management systems to screen for data quality in a transparent, quantitative manner
- Making sense of chemical analytical data and its quality using electronic data management systems and trend charts, whether collected for Superfund, RCRA, Water or Air
- Propose how one might review existing data collected by others

Using Electronic Data Systems to Transparently Summarize Data Quality Information

GROUNDWATER SAMPLING
VALIDATION OF LABORATORY RESULTS
ENVIRONMENTAL LABORATORY
LABORATORY REPORT # 07010104 - REPORT DATED JANUARY 11, 2007

LEVEL 4 – FULL QC DELIVERABLES EVALUATION FOR VOCs AND PERCHLORATE

INTRODUCTION

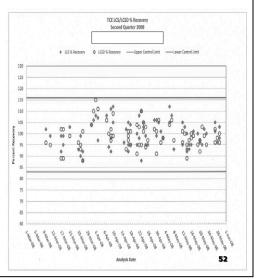
collected seven groundwater samples and one quality control sample on January 4, 2007. The samples were hand delivered to Environmental Laboratory located in on January 4, 2007. Analyses for perchlorate were subconstrated to Laboratory located in Seramento, California. The sample identifications and requested analyses are listed below.

ARCADIS Sample ID	Lab ID	Matrix	Analyses Requested / Comments			
COG-10-01042007	07010104-01 A,D	Groundwater	VOCs and Perchlorate			
33A-INF-01042007	07010104-02 A,D	Groundwater	VOCs and Perchlorate			
33A-EFF-01042007	07010104-03 D	Groundwater	VOCs			
33A-201-01042007	07010104-04 D	Groundwater	VOCs			
3A-202-01042007	07010104-05 D	Groundwater	VOCs			
33A-101-01042007	07010104-06 D	Groundwater	VOCs			
33A-102-01042007	07010104-07 D	Groundwater	VOCs			
TB001-01042007	07010104-08 D	Water Quality	VOCs / Trin Blank			

Samples were submitted for analysis of organic and inorganic compounds, as listed below:

- Volatile Organic Compounds (VOCs) EPA Method 8260B
- Perchlorate EPA 314.0 (Subcontracted to Sacramento)

Quality Control for the water sample is evaluated in the following checklist tables and comments. A summary of data quality for the samples analyzed is provided in the final page of this validation report.



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Environmental Data Standards (EDS) for Sampling, Analysis and Results

- □ Project, February 4, 2010
- Quality Assurance and Quality Control Data Standards, February 4, 2010
- Field Activity Data Standard, February 4, 2010
- Analysis and Results, February 4, 2010

Environmental Data Standards (EDS) Project

- □ Verify Quality Assurance Project Plan (QAPP) Implementation
- Evaluate
 - ■Field Sampling QC results and criteria
 - Laboratory Analytical QC results and criteria
 - -Performance Evaluation Samples

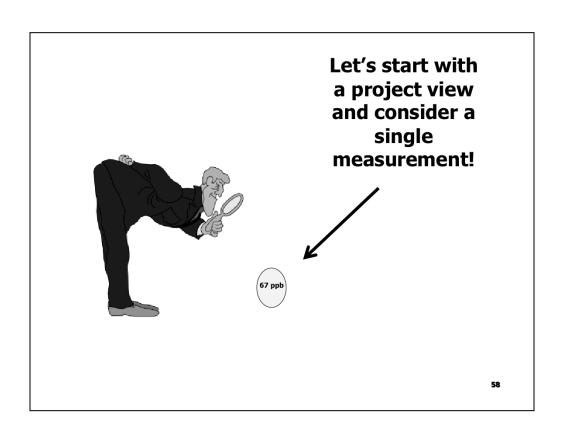
EDS Results

Project Name: X	Benzene				
Soil	8260	Detection Limit 10 ppb			
Date	Time Analyzed	Results (ppb)			
01/01/2011	12:01 pm	67			
02/01/2011	10:00 am	ND			
03/01/2011	09:00 am	85			
04/01/2011	01:00 pm	45			
05/01/2011	09:18 am	ND			
06/01/2011	09:00 am	65			
07/01/2011	01:15 pm	ND			
08/01/2011	03:37 pm	88			
09/01/2011	11:07 am	78			
10/01/2011	08:15 am	76			
11/01/2011	02:10 pm	66			
12/01/2011	10:29 am	60			

Environmental Data Standards



- Now that we have the information, what is the value of it to you?
- How do you know the quality of the information?

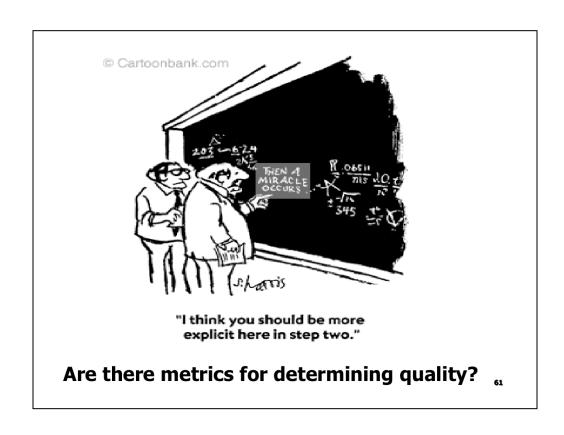


Original results Matrix, contaminant of concern (coc) 67 ppb Can you determine data quality based on information you might ordinarily get?

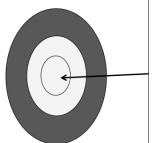
Where does the quality of the measurement come from?

The processes









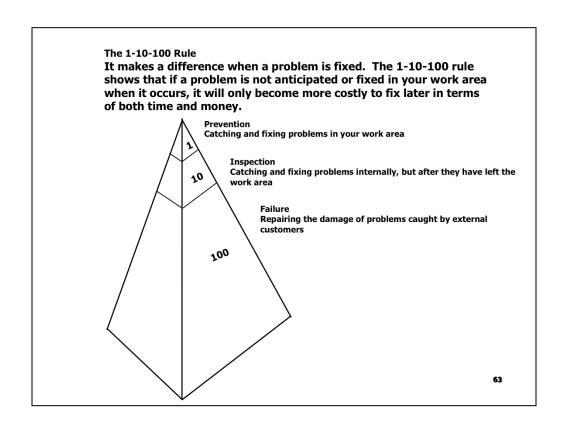
Core: original data, matrix and contaminant of concern

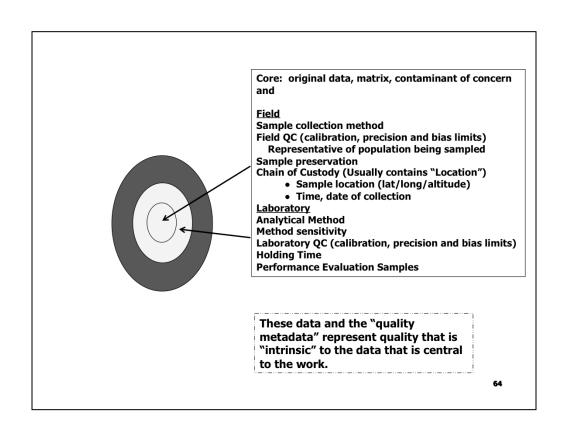
Sample collection method

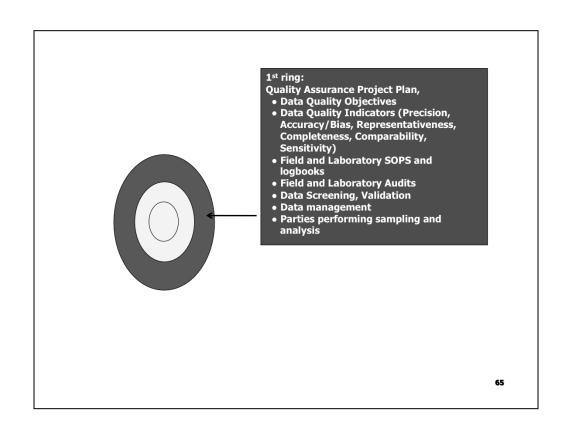
Field QC (calibration, precision and bias limits) Representative of population being sampled

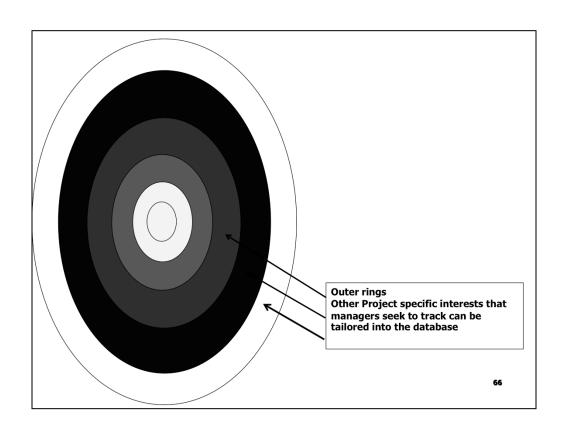
Sample preservation
Chain of Custody (Usually contains "Location")

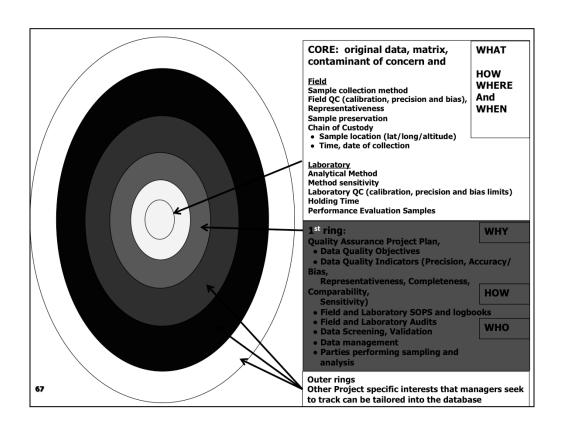
- Sample location (lat/long/altitude)
 Time, date of collection









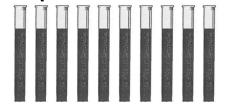


Proposed Core Laboratory QC Info

- Analytical results, matrix, contaminant of concern
 - Method
 - Sensitivity (ppm, ppb, ppt)
 - Laboratory QC (calibration, precision and bias limits)
 - Holding times met
 - Performance evaluation samples

What Happens at the Laboratory? **Batch of Samples**

Samples sent to the lab



OC Samples Lab Generates



LCS MS

- I/O Calibration bias/accuracy
- I/O Continuing Calibration precision
- I/O Lab Control Sample (LCS) bias/accuracy
- I/O Matrix Spike (MS) bias/accuracy and matrix effects/interference
- I/O Matrix Spike Duplicate (MSD) Precision
 O Surrogate Spike Method Bias/Accuracy and Extraction Efficiency
- I/O Blank contamination
- I/O Duplicates Precision

Legend I = inorganic; O = organic

Common QC Already Performed by Laboratories

	Laboratory	Method	Sensitivity (MDI/POL)	Lab Reagent Blank (LRB)	Lab Fortified hlank (LFR)	Matrix Snike/	ICV	CCV	QC Criteria	Trend Charts	Min Freauency	Batch Definition	Corrective Action	PE sample
WW	X	X	X	X	X	X	X	X	X	X	X	X	X	X
SW-846	Х	X	Х	X	Х	X	X	Х	Х		X			
CLP	X	X	Х	X		X	X	Х	Х	Х	X			X
DW	Х	Х	Х	X	Х	X	X	X	X		X			X
EDS	Х	Х	Х	X	Х	Х	X	Х	Х					X

WW wastewater SW846 -solid waste (RCRA) CLP contract laboratory program DW drinking water EDS Environmental Data Standards

Determining Data Quality

Types of Measurements on QC Samples

ACCURACY/BIAS

Percent Recovery = Amount Recovered (Results) x 100 Amount Spiked (True Value)

Measures how close you are to the "True Value;" the closer the number, the better.

PRECISION

Relative Percent Difference (RPD) = $| \frac{\text{Dup } 1^* - \text{Dup } 2^*}{[(\text{Dup } 1^* + \text{Dup } 2^*)/2]} | \times 100$

*Dup = results from lab duplicates Smaller RPDs the better, results reproducible Larger RPDs, the more unpredictable is the resulting data

Example Accuracy/Bias Calculations

$$\frac{20 \text{ ug/l}}{30 \text{ ug/l}}$$
 x 100 = 67%



 $\frac{31 \text{ ug/l}}{30 \text{ ug/l}}$ x 100 = 103%



ACCURACY/BIAS ASSOCIATED WITH SPIKED SAMPLES

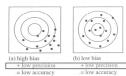
Measures how close you are to the "True Value." The closer the results to the true value, the better (i.e., recovery of 100%).

Results of Accuracy/Bias Calculations

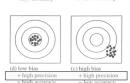
Project Name		
Date	Time Analyzed	Results (ppm)
01/01/2011	12:01 pm	67
02/01/2011	10:00 am	103
03/01/2011	09:00 am	85
04/01/2011	01:00 pm	45
05/01/2011	09:18 am	98
06/01/2011	09:00 am	65
07/01/2011	01:15 pm	109
08/01/2011	03:37 pm	88
09/01/2011	11:07 am	78
10/01/2011	08:15 am	76
11/01/2011	02:10 pm	66
12/01/2011	10:29 am	60

Example Precision Calculations

$$|20-50|$$
 x 100 = 86 RPD $[(20+50)/2]$

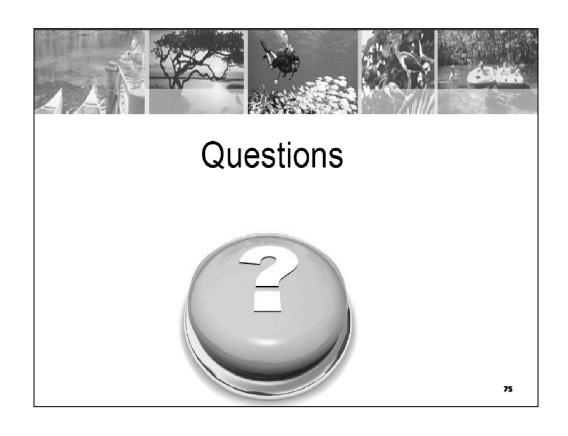


$$\frac{|49-50|}{[(49+50)/2]}$$
 x 100 = 2 RPD



PRECISION ASSOCIATED WITH DUPLICATES

Smaller RPDs the better, results reproducible. Larger RPDs, the more unpredictable is the resulting data



Intermission You've joined EPA Region 6's webinar on Quality Assurance in Electronic Environmental Data Management

We will continue on this schedule shortly.

Eastern (EDT)

10:30 am

Intro

Part I: Data Standards at EPA

Dawn Banks Waller

Quality Staff, Office of Environmental Information, US EPA

11:30 am Part II: Quality and Legal Considerations in the Development and

Use of an Information Management System in EPA

George Brilis

US EPA Office of Research and Development National Exposure Research Laboratory

2:00 pm Part III: Method for Screening Data Quality in Electronic Data Systems

Roseanne Sakamoto

Region 9, US EPA

Making Sense of Analytical Data Using Trend Charts

Traditional Validation Report (5-100 pages)

- GROUNDWATER SAMPLING VALIDATION OF LABORATORY RESULTS

ENVIRONMENTAL LABORATORY LABORATORY REPORT # 07010104 - REPORT DATED JANUARY 11, 2007

LEVEL 4 – FULL QC DELIVERABLES EVALUATION FOR VOCs AND PERCHLORATE

collected seven groundwater samples and one quality control sample on January 4, 2007. The samples were hand delivered to Laboratory located in on January 4, 2007. Analyses for perchlorate were subcontracted to Laboratory located in Sacramento, California. The sample identifications and requested analyses are listed below.

ARCADIS Sample ID	Lab ID	Matrix	Analyses Requested / Comments			
COG-10-01042007	07010104-01 A,D	Groundwater	VOCs and Perchlorate			
33A-INF-01042007	07010104-02 A,D	Groundwater	VOCs and Perchlorate			
33A-EFF-01042007	07010104-03 D	Groundwater	VOCs			
33A-201-01042007	07010104-04 D	Groundwater	VOCs			
3A-202-01042007	07010104-05 D	Groundwater	VOCs			
33A-101-01042007	07010104-06 D	Groundwater	VOCs			
33A-102-01042007	07010104-07 D	Groundwater	VOCs			
MM 001 0101000	00010101007	XXX	MOC- (T DII-			

Samples were submitted for analysis of organic and inorganic compounds, as listed below:

- Volatile Organic Compounds (VOCs) EPA Method 8260B
- Perchlorate EPA 314.0 (Subcontracted to

Quality Control for the water sample is evaluated in the following checklist tables and comments. A summary of data quality for the samples analyzed is provided in the final page of this validation report.

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33A-EFF-01042007	07010104-03 D	Groundwater	VOCs			
33A-201-01042007	07010104-04 D	Groundwater	VOCs			
3A-202-01042007	07010104-05 D	Groundwater	VOCs			
33A-101-01042007	07010104-06 D	Groundwater	VOCs			
33A-102-01042007	07010104-07 D	Groundwater	VOCs			
TB001-01042007	07010104-08 D	Water Quality	VOCs / Trip Blank			

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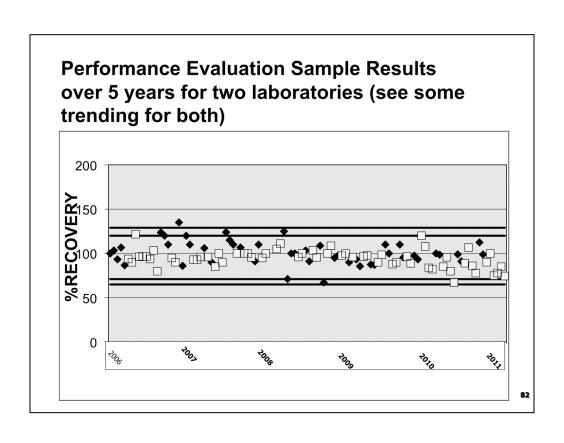


	loroet				CASREGIST				
case	sdg	LABID	CLIENTSA FRACTION MPLEID	MATRIXID	 RYNUMBE R	ANALYTEN AME Trichloroet	adate	PercentRSD	
		STLV	VOA_TRACE		79-01-6	hene Trichloroet	27-Jul-10	5.2	
		MITKEM	VOA_TRACE		79-01-6	hene Trichloroet	4-Aug-09	5	
		SHEALY	VOA_TRACE		79-01-6	hene Trichloroet	27-Dec-10		
		ENVSYS	VOA_TRACE		79-01-6	hene Trichloroet	20-Jun-08		
		LIBRTY	VOA_TRACE		79-01-6	hene Trichloroet	8-Nov-07		
		MITKEM	VOA_TRACE		79-01-6	hene Trichloroet	13-Oct-06		
		SHEALY	VOA_TRACE		79-01-6	hene Trichloroet	17-Nov-06		
		MITKEM	VOA_TRACE		79-01-6	hene Trichloroet	12-Jun-07		
		ENVSYS	VOA_TRACE		79-01-6	hene Trichloroet	28-Dec-06		
		SHEALY	VOA_TRACE		79-01-6	hene Trichloroet	25-Sep-06		
		MITKEM	VOA_TRACE		79-01-6 79-01-6	hene Trichloroet	21-Oct-06 20-Jun-06		
			VOA_TRACE			hene Trichloroet			
		DATAC	VOA_TRACE		79-01-6	hene Trichloroet	16-May-06		80
		KAP	VOA_TRACE		79-01-6	hene Trichloroet	5-Oct-06		80
		DATAC	VOA TRACE		79-01-6	hene	12-Jun-06	7.988618	

Trend Charts convey a thousand words . . .

What are they?

- Plots to present laboratory and other QC results for specific compounds of concern (COC) over time.
- They are a tool for monitoring and minimizing excursions from acceptance or control criteria either above (>) or below (<) a single line or resting within two lines.
- These lines are based on laboratory and field precision and accuracy/bias criteria established in a QAPP.



Example Accuracy/Bias Calculations

$$\frac{20 \text{ ug/l}}{30 \text{ ug/l}}$$
 x $100 = 67\%$



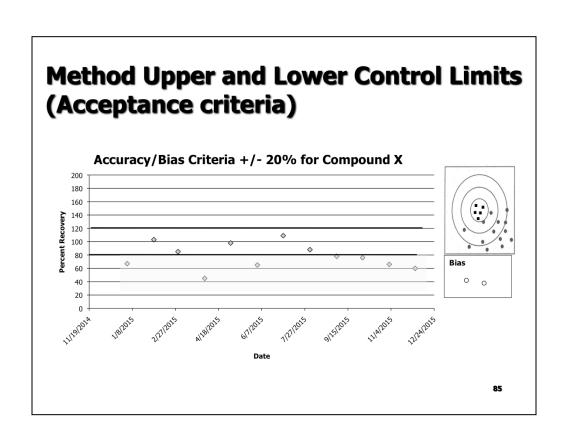
 $\frac{31 \text{ ug/l}}{30 \text{ ug/l}}$ x 100 = 103%

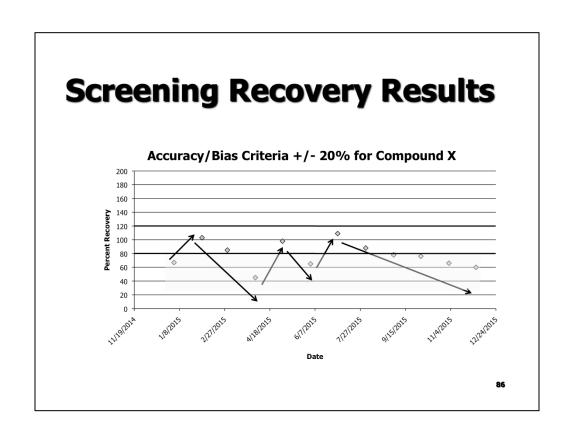


ACCURACY/BIAS ASSOCIATED WITH SPIKED SAMPLES

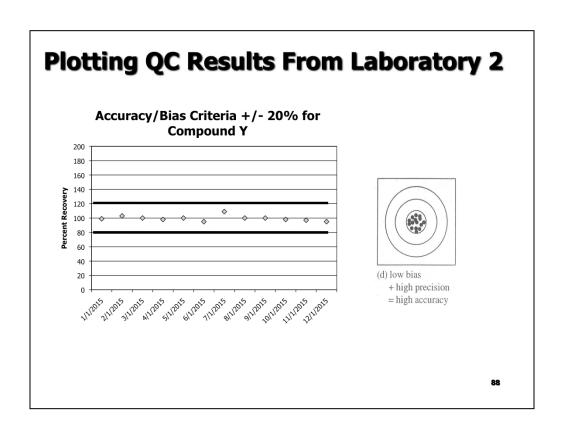
Measures how close you are to the "True Value." The closer the results to the true value, the better (i.e., recovery of 100%).

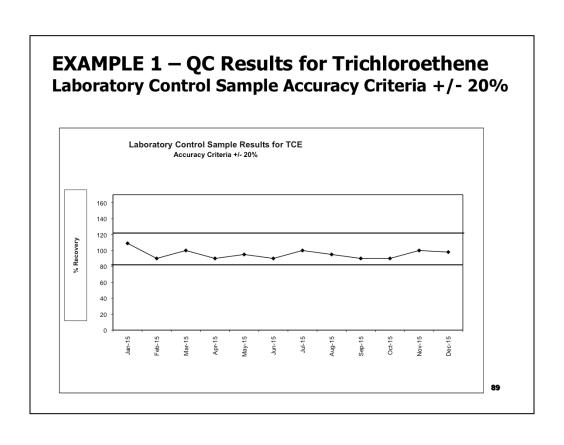
Plotting QC Results From Laboratory 1 8260 Soil % Recovery (Accuracy/Bias) Benzene **Results for Compound X** Date Results (ppm) 200 01/01/2011 67 180 02/01/2011 103 160 140 03/01/2011 120 04/01/2011 45 100 05/01/2011 80 98 60 06/01/2011 65 40 07/01/2011 109 20 08/01/2011 88 TIZTIZOLS 09/01/2011 78 10/01/2011 76 11/01/2011 66 12/01/2011 60

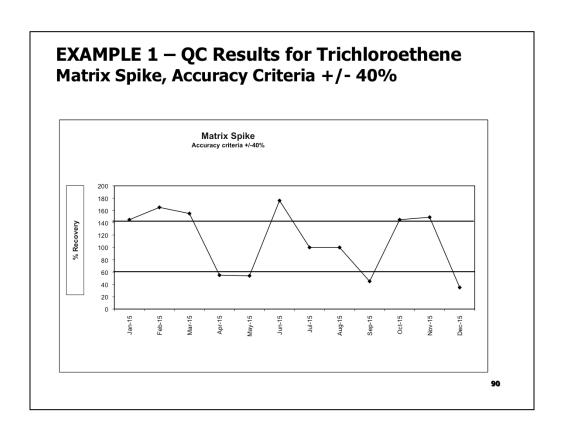


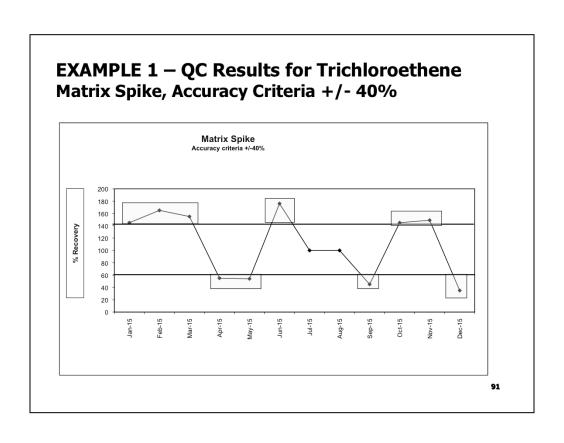


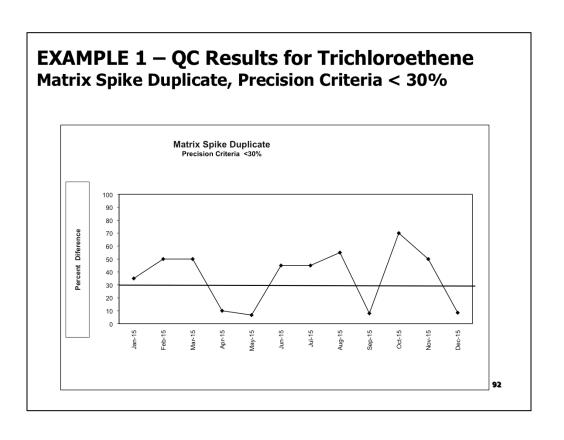
Laboratom	Duoingt Name	1
Laboratory	Project Name	
Soil	8260	
Benzene		Accuracy/Bias Results for
Date	Results (ppm)	Compound Y
01/01/2011	99	200
02/01/2011	103	180
03/01/2011	100	
04/01/2011	98	120
05/01/2011	100	140 ten 140 te
06/01/2011	95	
07/01/2011	109	40 20
08/01/2011	100	
09/01/2011	100	ings shars shars that shars that that the shars shart in the shart shart in the sha
10/01/2011	98	
11/01/2011	97	
12/01/2011	95	87

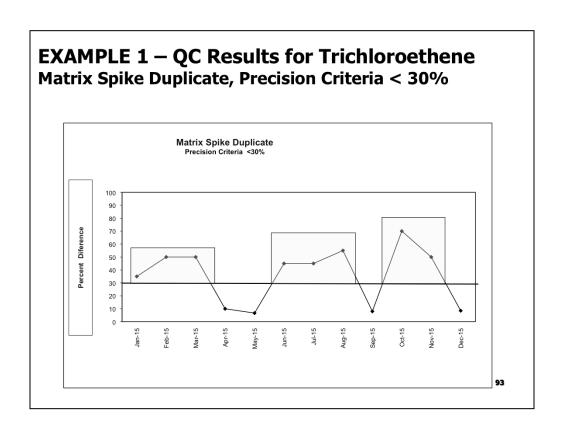


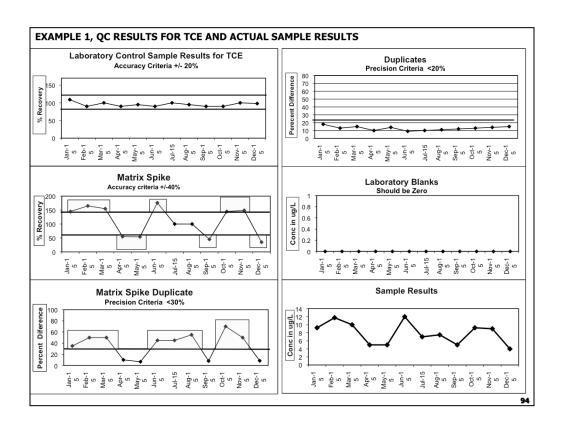


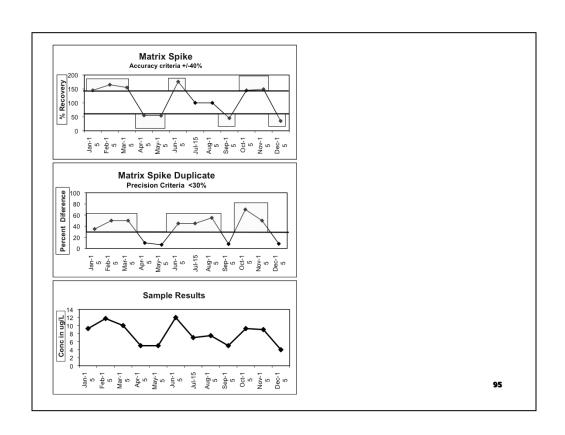


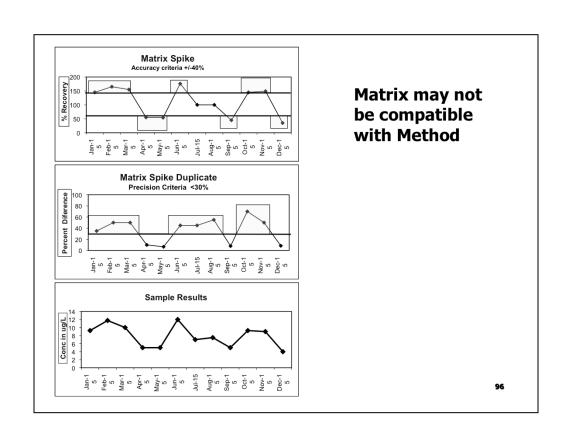


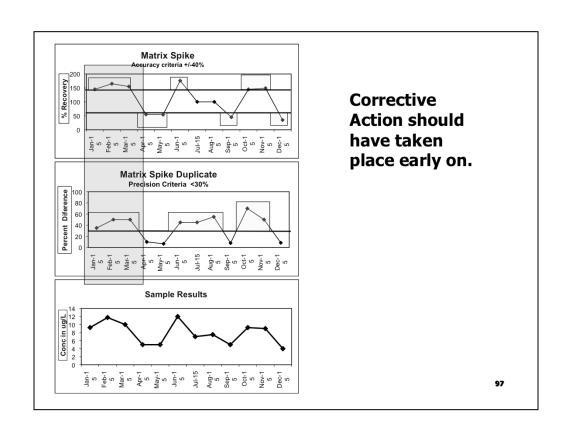




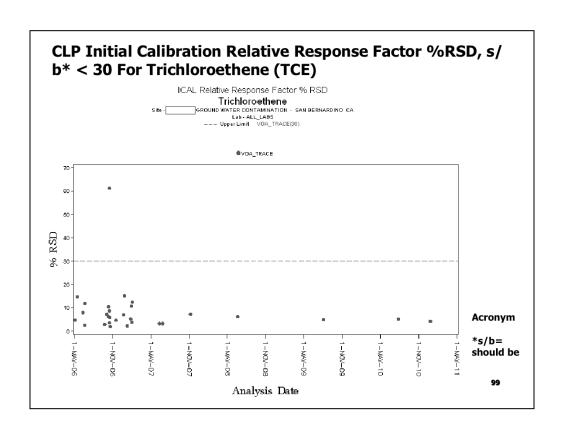


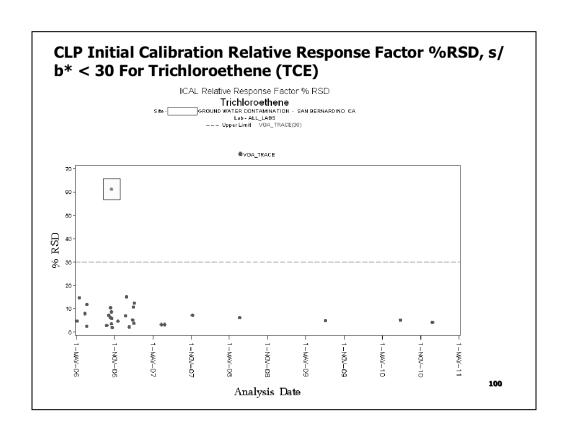


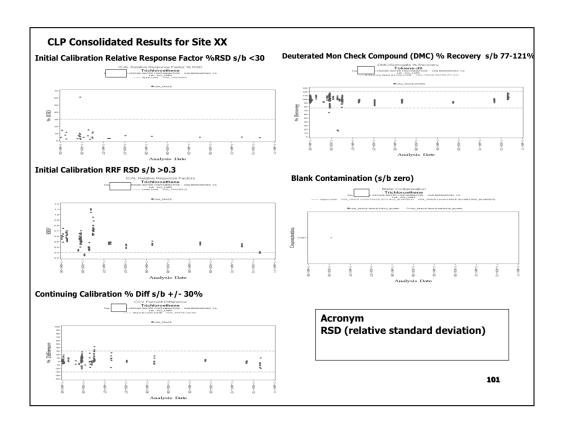


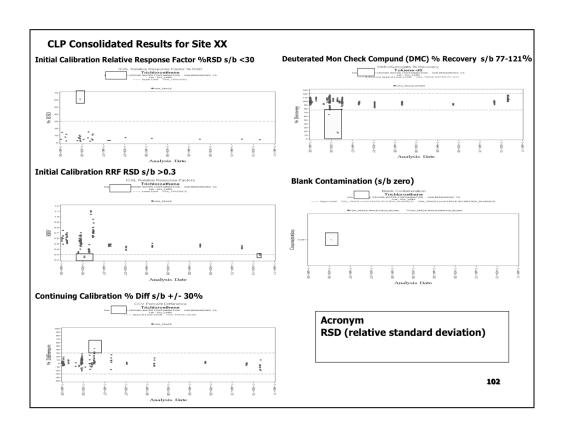


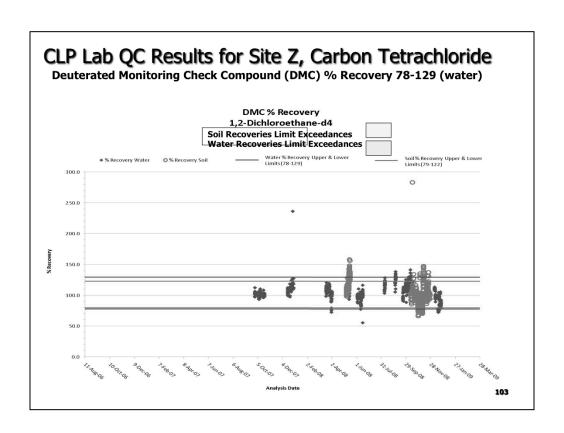
ICNI	oroet	nene .	Initial Calib	oration	Kela	CASREGIST	-	ise ra	ctor Da	ita
			CLIENTSA	C	IFNTAN		ANALYTEN			
ase	sdg	LABID	FRACTION MPLEID	MATRIXID A		R		adate	PercentRSD	
		STLV	VOA_TRACE			79-01-6	hene Trichloroet	27-Jul-10	5.2	
		MITKEM	VOA_TRACE			79-01-6	hene Trichloroet	4-Aug-09	5	
		SHEALY	VOA_TRACE			79-01-6	hene Trichloroet	27-Dec-10	4.3	
		ENVSYS	VOA_TRACE			79-01-6	hene Trichloroet	20-Jun-08	6.3	
		LIBRTY	VOA_TRACE			79-01-6	hene Trichloroet	8-Nov-07	7.3	
		MITKEM	VOA_TRACE			79-01-6	hene Trichloroet	13-Oct-06	10.5	
		SHEALY	VOA_TRACE			79-01-6	hene Trichloroet	17-Nov-06	4.7	
		MITKEM	VOA_TRACE			79-01-6	hene Trichloroet	12-Jun-07	3.3	
		ENVSYS	VOA_TRACE			79-01-6	hene Trichloroet	28-Dec-06	15.2	
		SHEALY	VOA_TRACE			79-01-6	hene Trichloroet	25-Sep-06	2.9	
		MITKEM	VOA_TRACE			79-01-6	hene Trichloroet	21-Oct-06	2.1	
		KAP	VOA_TRACE			79-01-6	hene Trichloroet	20-Jun-06	2.5	
		DATAC	VOA_TRACE			79-01-6	hene Trichloroet	16-May-06	14.69673	
		KAP	VOA_TRACE			79-01-6	hene	5-Oct-06	7.3	98

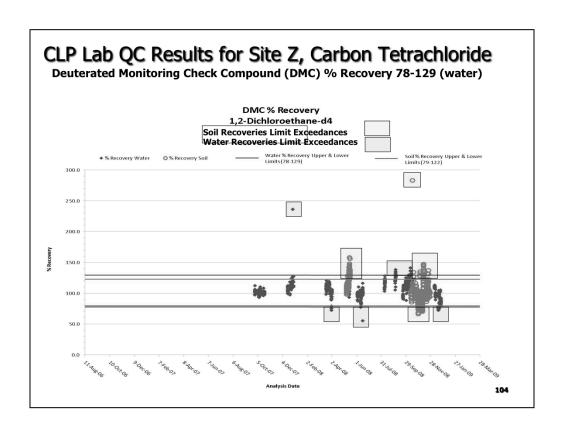


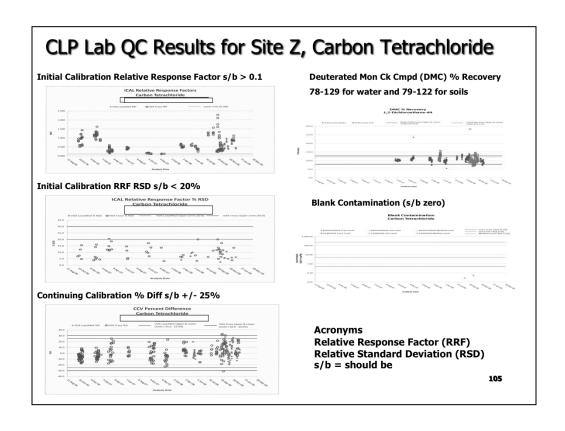


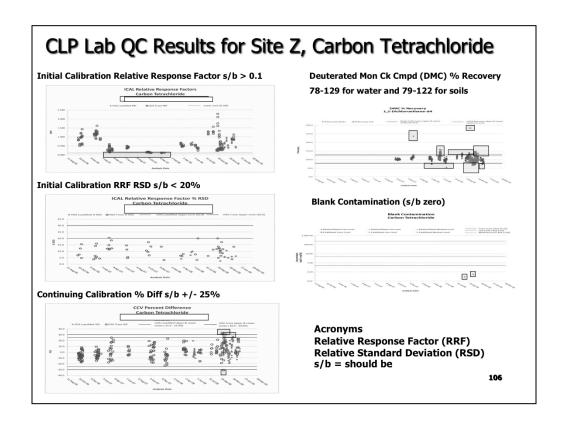


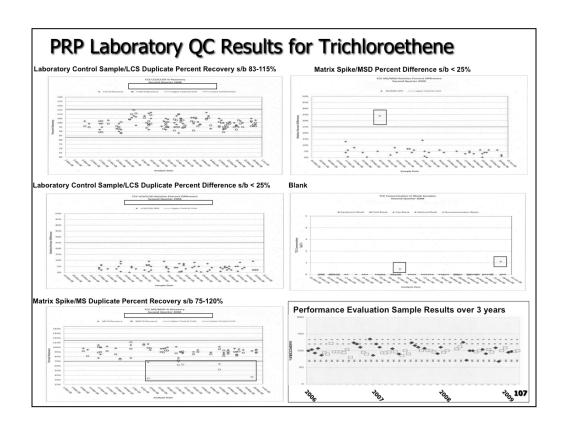












Core Laboratory QC Information that may be charted

- Sensitivity
- Initial calibration and continuing calibration
- Laboratory Control Sample (LCS) and LCS Duplicate Percent recovery
- □ LCS/LCSD Relative Percent Difference
- □ Matrix Spike (MS) Percent Recovery
- MS and Matrix Spike Duplicate (MSD) Relative Percent Difference
- Deuterated monitoring compound (DMC) (similar to surrogates and MS) - Percent recoveries
- Blanks
- Internal Standards
- Tunes and holding time

Proposed Core Field QC Information that also may be charted

Field QC checks

to monitor over time What they can Indicate:

$\ \square$ Field Duplicates

- ☐ Field Blanks
 - EquipmentField
 - Trip
- **☐ Split Samples**

Sampler precision Contamination

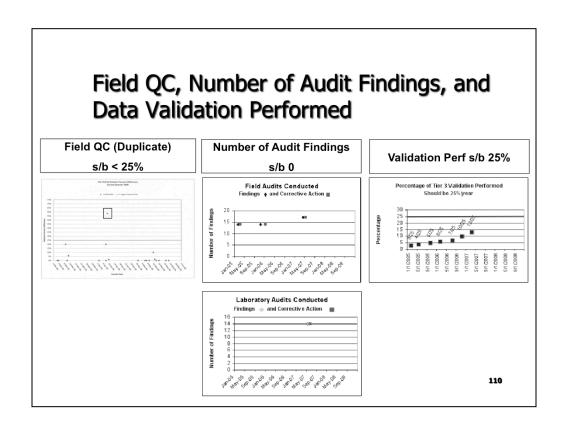
Equipment Field En Route

Laboratory precision

(compare results from two diff laboratories)

□ Other checks:

- Field Instrument Calibration, standard expiration date
- Chain of custody (presence/absence), sample preservation
- Site Physical/Chem measurement changes (for long term projects)
- Field Audits conducted and number of findings
- Laboratory Audits
- Percentage of data validated (screening and full validation)



Chemicals often reported but may not be in the sample (blank contamination)

Laboratory, common solvents used

<u>Chemical</u> <u>Possible Source of Contamination</u>

Methylene chloride Carbon Disulfide

Carbon Disulfide Acetone

Motor Exhaust

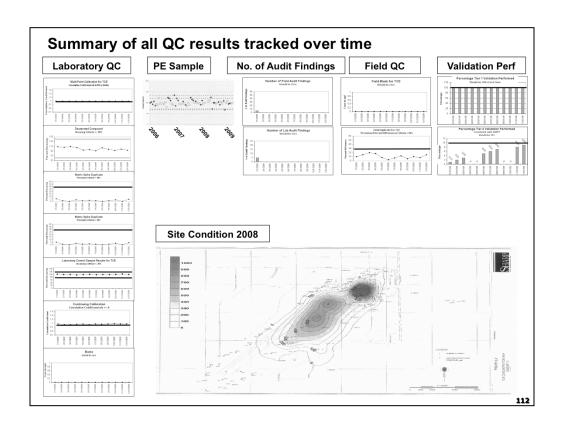
Benzene Toluene Ethyl Benzene Xylenes MTBE

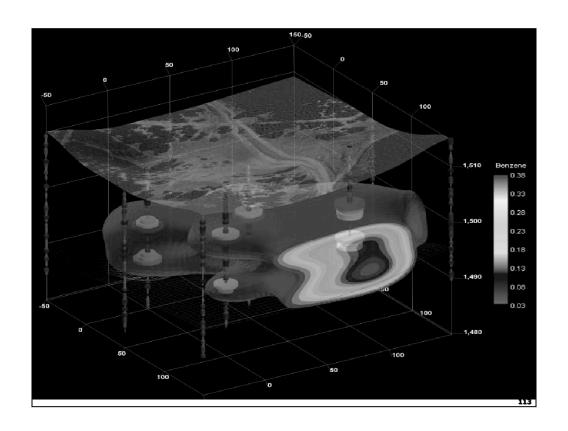
Trace Metals Nitric Acid Preservative

Para-Dichlorobenzene Restrooms

Freons Leaking refrigerators and air conditioners

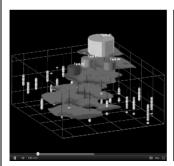
Phthalate esters Plastics (sampling devices, gloves, etc.)

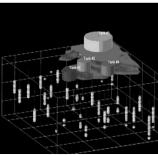


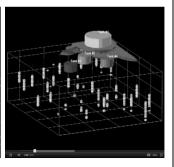


MONITOR CLEANUP PROGRESSION

2011 2012 2013







RockWorks 15 by RockWare

Value of Trend Charts

- Quantitative, transparent method for condensing data quality information in an easy to assimilate, visual method for QAPP implementation oversight;
- Improved use of time and money; focus validation on those instances where conditions do not meet acceptance criteria.
- Self monitoring and tracking performance (short and long term trends) of QA/
 QC conducted by laboratory and field staff, and whether there were excursions from QAPP criteria (e.g., +/- 15%); bias may also be determined.
- Sources of error, whether field or lab, can easily be determined by aligning charts by date.
- Implement corrective action in lab and field.
- □ Improved oversight and control of data quality. Allows QA Office to spot check
- sites offer assistance to Project Manager.
- Single out of control events fade into background of long term positive trend keeps things in perspective.

Other Advantages

- Improved language for contracting with laboratories and field personnel.
- Potentially Responsible Party vice-president sold by this feature; stated he never had time to read QTRLY reports or understand them.
- Potential usefulness at public meetings to show overall positive trend where there is concern over an anomalous result.
- Improved collaboration and increased trust between stakeholders via transparency, open government.
- Screen data obtained from other sources, if QC data available for charting.

LIMITATIONS

- An effective broad brush tool, fine tuned oversight still necessary to determine cause of deviations outside of acceptance criteria.
- Check with project chemist on the validity of your assumptions
 before using the data to make decisions.

Other Organizations Using Similar Tools



- EPA's Ambient Air Quality Monitoring Program
- Bay Area Air Quality Monitoring District

 Steve Randall
- California Air Resources Board

United States Environmental Pr Agency Office of Environmental Information Washington, DC 20460

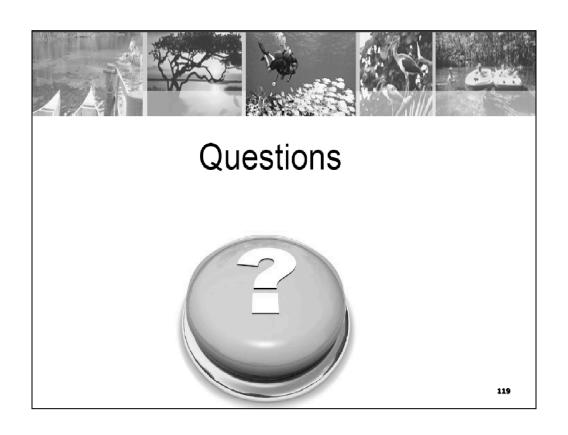
EPA/240/B-06/002 February 2006

\$EPA

Data Quality Assessment: A Reviewer's Guide

EPA QA/G-9R

http://www.epa.gov/quality/ qs-docs/g9r-final.pdf



Intermission You've joined EPA Region 6's webinar on Quality **Assurance in Electronic Environmental Data Management**

We will continue on this schedule shortly.

Eastern (EDT)

10:30 am Intro

> Part I: **Data Standards at EPA**

Dawn Banks Waller

Quality Staff, Office of Environmental Information, US EPA

Quality and Legal Considerations in the Development and Use of an Information Management System in EPA 11:30 am Part II:

George Brilis

US EPA Office of Research and Development National Exposure Research Laboratory

2:00 pm Part III: Method for Screening Data Quality in Electronic Data Systems

Roseanne Sakamoto

Region 9, US EPA

Reviewing Data from Other Sources

QMPs, QAPPS and SOPs



QMP - Organization Specific

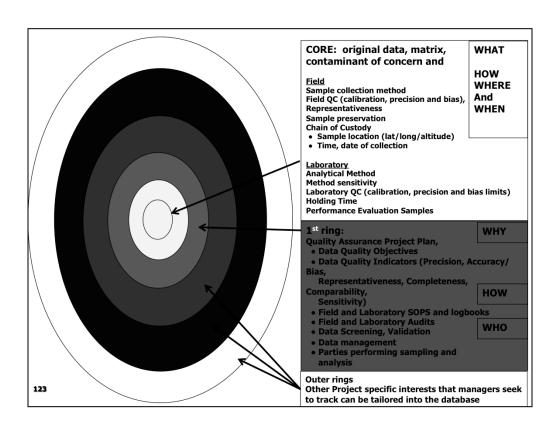
- •Describes organizations quality system
- Establishes capability

QAPP - Project Specific

- •Identifies the reasons for collecting data and for collecting it in a specific way
- •Documents how the data are collected and how quality is maintained

SOP - Instrument/Method Specific

- Ensures consistency
 - From day to day
 - From one person to the next

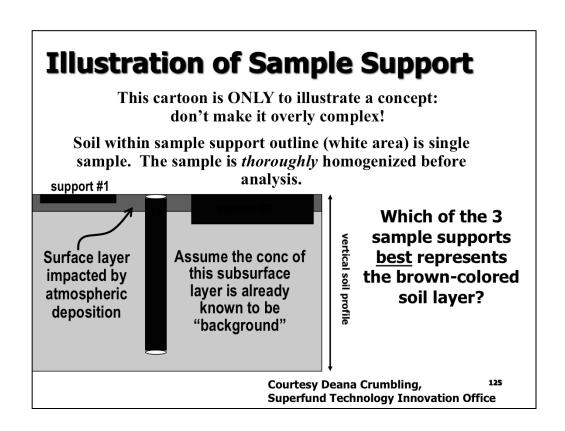


Comparability

Qualitative term that expresses the confidence that two data sets can contribute to common interpretation and analysis (e.g., compare sample collection methods, analytical procedures, holding times, stability issues, and QA/QC protocols).

Comparability should be carefully evaluated in order to establish whether two data sets can be considered equivalent in regard to the measurement of a specific variable or groups of variables.

Quantitative measures of comparability are also possible and involve statistical tests that measure the similarity or difference between two or more data sets.



Emphasize that this is cartoon whose only purpose is to illustrate the sample support concept.

Representativeness:

Central to representativeness is assurance that both the sampling and measurement processes are free from known biases and which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition.

RCRA (40 CFR 260.10): "Representative sample means a sample of a universe or whole (e.g., waste pile, lagoon, ground water) which can be expected to exhibit the average properties of the universe or the whole."

It implies that the decision maker can extrapolate results from an analytical subsample to a larger mass.

Completeness

A measure of the amount of valid data obtained from a measurement system vs those planned.

It may be calculated using the following formula:

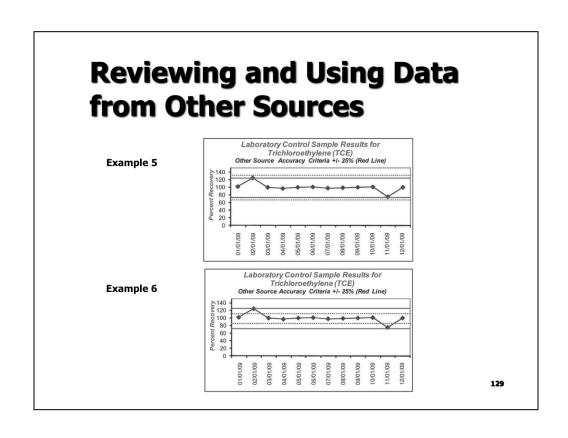
Percent completeness = <u>number of valid measurements</u> x 100

Total number of measurements planned

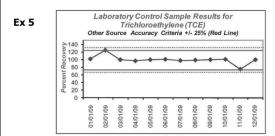
Generally like to see ≥ 90% completeness

Sensitivity

The capability of a method or instrument to discriminate between measurement responses representing different levels or amounts of the variable of interest.



Reviewing and Using Data from Other Sources

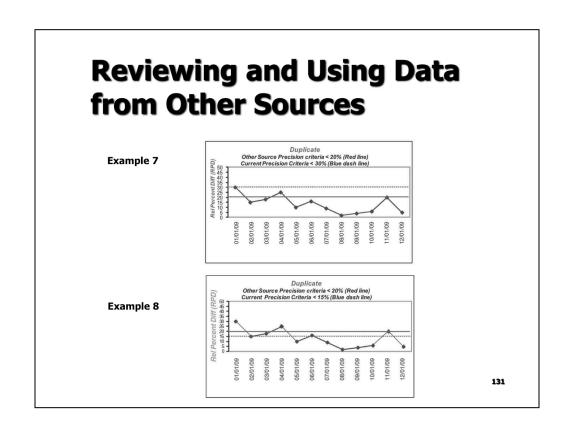


Current Criteria represented by blue dashed lines

In Example 5, current criteria are wider, broader (+/- 30%) than the criteria for data obtained from other sources (+/- 25%). One may use all data obtained from other sources.

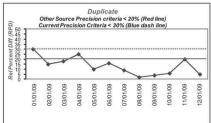
Current criteria are more stringent (+/- 15%) than the criteria for data obtained from other sources in the Example 6.

One may use only the data associated with QC results falling within current criteria (i.e., exclude February and November, 2009, unless you've consulted with a chemist on the data usability).

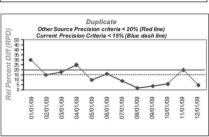


Reviewing and Using Data from Other Sources





Ex 8



Current Criteria represented by blue dashed lines

In Example 7, current criteria are wider (<30%) than the criteria for data obtained from other sources (<20%). With exception of January, 09, one may use all data obtained from other sources.

Current criteria are more stringent (< 15%) than the criteria for data obtained from other sources in the Example 8.

One may use only the data associated with QC results falling below/within current criteria (i.e., Feb and Jun 2009 data are marginally acceptable; exclude Jan, Mar, Apr, Nov, 2009, unless you've consulted with a chemist on the data usability).



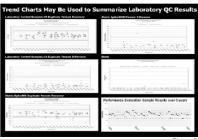
Data Quality Screening Using Trend Charts

Quality Assurance Office, Region 9 - July, 2011

INTRODUCTION

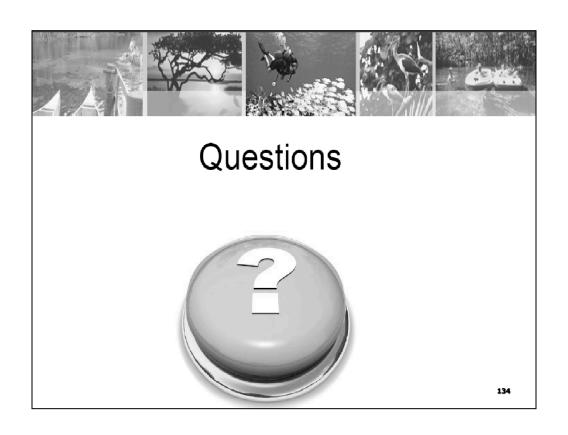
Frequently the quality of results from data collection activities are difficult to assess due to the number of reports one needs to review and digest to reach a conclusion (see Figure 1). These reviews may take place months after data collection is conducted.

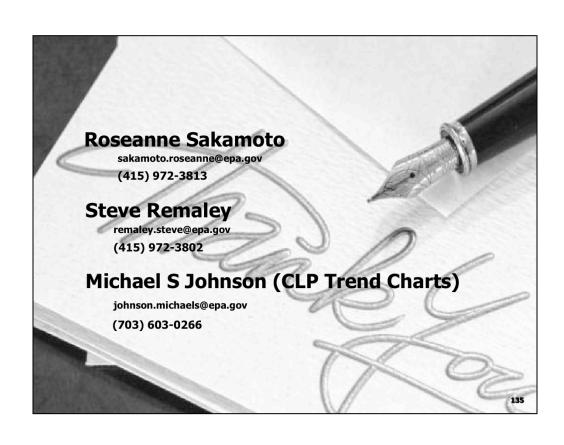


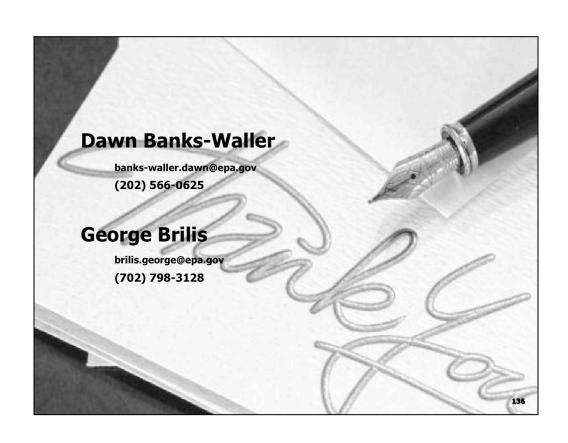


Trend charts are an effective, efficient oversight **screening** tool for Remedial Project Managers (RPMs), QA Officers (QAOs), field samplers and laboratory managers for monitoring data quality for specific contaminants of concern (COC). Figure 2 illustrates laboratory quality control (QC) results for a year or more. The visual display of data helps to identify patterns and trends that might go unnoticed using

www.epa.gov/region09/qa/dataval.html







Resources & Feedback

- To view a complete list of resources for this seminar, please visit the <u>Additional Resources</u>
- Please complete the <u>Feedback Form</u> to help ensure events like this are offered in the future

