

Standardizing Electronic Data Deliverables:Public Health Laboratory Emergency Response

Jack Krueger

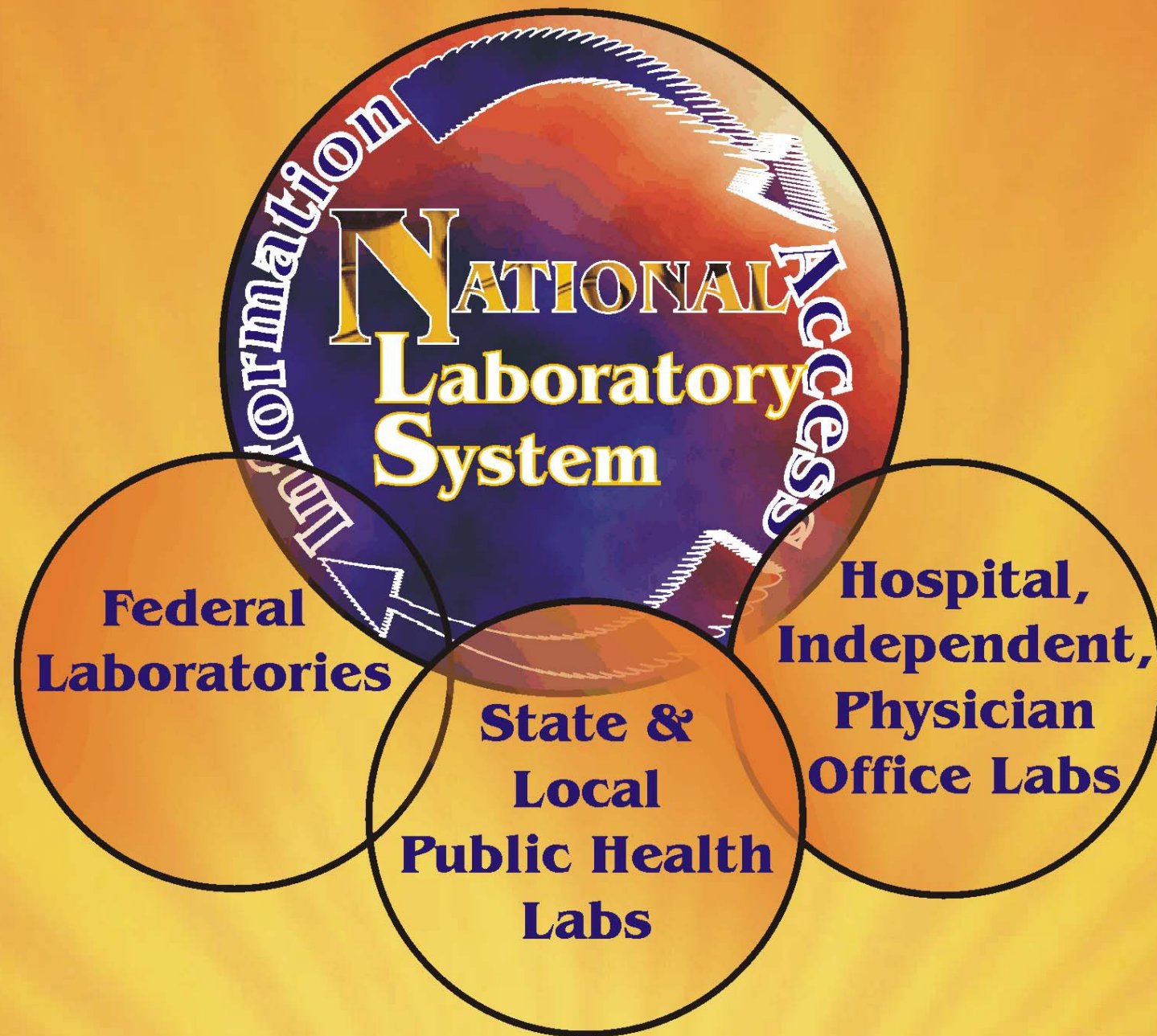
Informatics Consultant for APHL

Outline

- What do public environmental labs offer?
- What informatics issues plague them?
 - Environmental health LIMS
 - Environmental electronic data exchange
 - Quality control data
 - WebEDR as an approach to interoperability
- It is possible (a real-world example)!

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“The state PHL is the only lab with the culture & the mentality of emergency response.

We’re [the only] emergency responders from the lab perspective.”



Peter Shult, PhD

Director, Communicable Disease Division and Emergency Laboratory Response

Wisconsin State Laboratory of Hygiene

Public Environmental Health Laboratories

- Homeland security (clinical & non-clinical)
- Drinking water compliance
- Environmental assessment
- Waste water treatment
- Solid waste testing
- And much more!

Outline

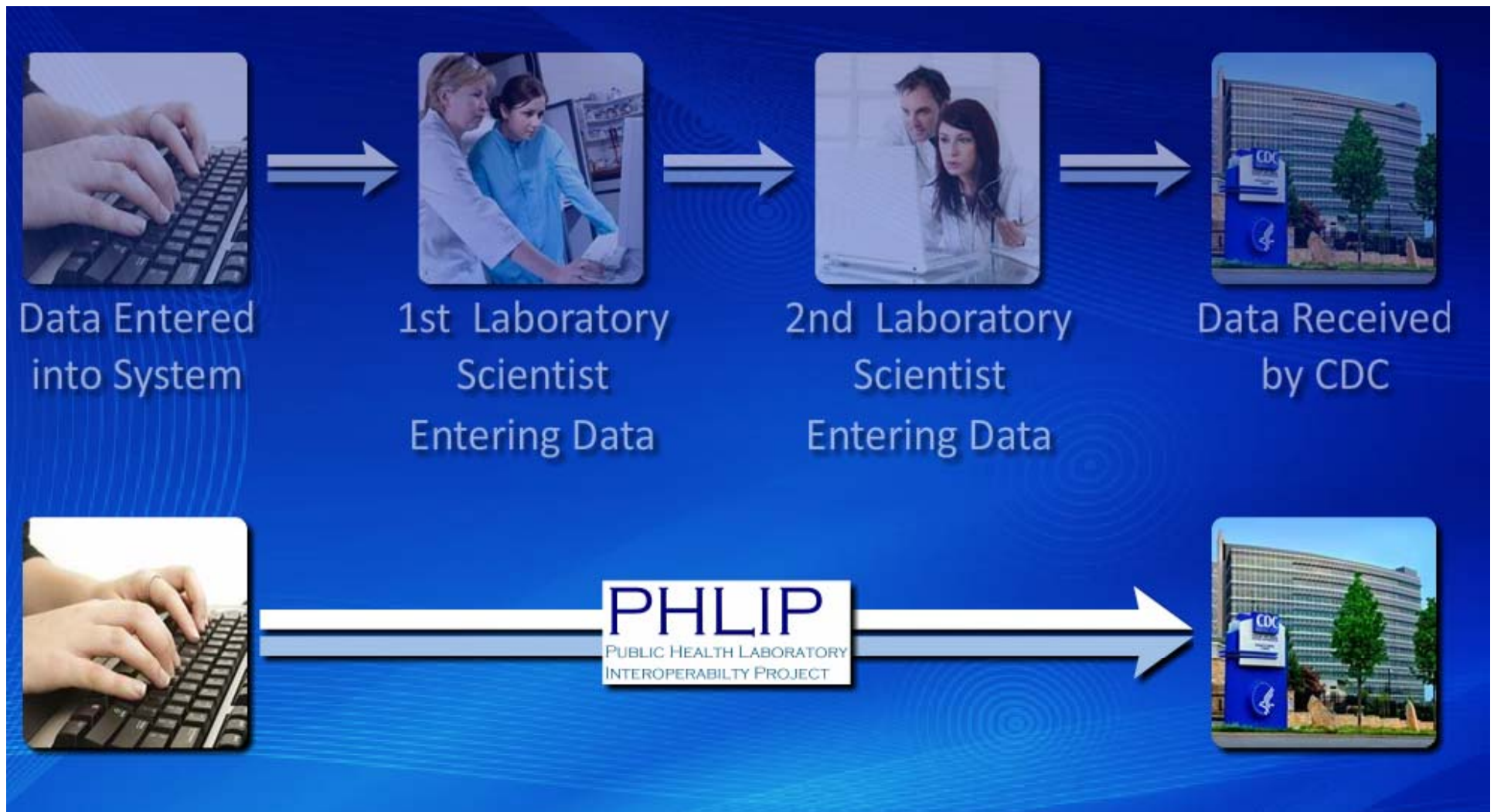
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Why is informatics relevant now?



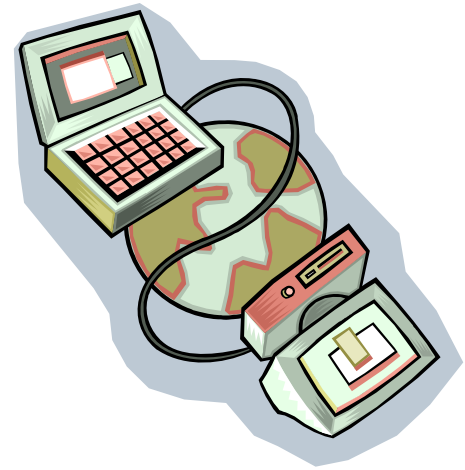
Hint: Buried in paper? ...and
Everyone wants your data.. Now!

Public Health Laboratory Interoperability Project



Goal:

Develop & implement an electronic data flow directly from environmental laboratories to multiple state and federal agencies



ENVIRONMENTAL LABORATORY

ELECTRONIC DATA MANAGEMENT



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Successful LIMS “See” Down the Road

- Support collection of pure measurements
- Measurements stem directly from instruments
- Data is based upon standards
- Are normalized
- Have machine-to-machine connectivity
- Include quality control data
- Are not matrix-dependent
- Look at how data is collected, not reported

Two Types of Business Cases for LIMS

1. Local needs to manage your laboratory
2. A national need for LIMS integration

Environmental Laboratory Testing



GFAAS



CVAF



ICP



ICP-MS



Samples In



Data Out



α , β , γ Detection Systems



GC



GC-MS

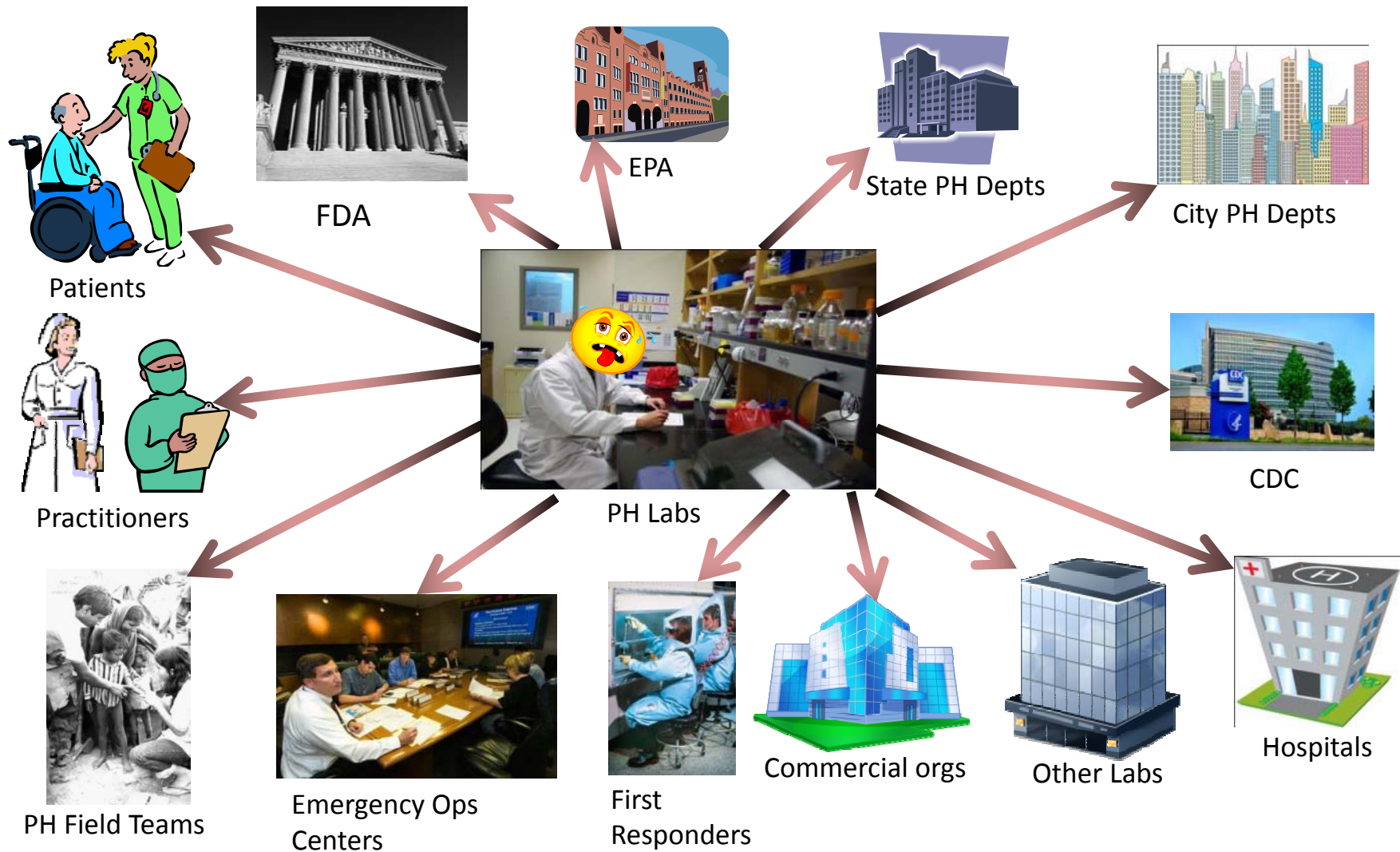


Automated Colorimetric

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Environmental Laboratory Reporting





Need a single, nationally-standardized lab reporting format.

Multiple data exchange templates compromise commercial production of tools to produce electronic messaging.

PHLs Putting their House in Order



Components of this Goal

- Tools to extract data from LIMS and export it to a laboratory network
- Connectivity of environmental laboratories, including private & public

Points of Confusion

- Minimum data sets vs. *comprehensive* minimum data element sets
- Intra-agency interoperability
- Inter-agency interoperability
- Laboratory generated data-results & measurement quality objectives
- Meta-data or auxiliary data

Interoperability Model 1: CDC LRN-C

- All laboratories use the SAME:
 - method, instruments, software, QC samples, analytical sequence, training, results spreadsheet, and secure messaging service
- Don't need a LIMS, as comprehensive LIMS capability rests at CDC

Interoperability Model 2: EPA ERLN

- A robust data exchange template:
 - Not matrix dependent
 - Not method dependent
 - Uses common analytical data
- Includes significant QC data
- Data is sent as an xml (accepts xls, SEDD, et al)

Pros and Cons for Each

- LIMS costs
- Data review
- Centralization of data collection
- Need for consistency across laboratory
- Surge capability
- APHL favors the EPA ERLN model.

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Assuring Accountability

- Certification assures capability
- Reporting raw data (including QC) assures accountability
- Measurement Quality Objectives include:
 - Completeness
 - Sequence
 - Frequency
 - Limits

Lab Certification Assures Capability

- Quality Assurance Plan
- Method Detection Limit (MDL) studies
- Initial Demonstration of Capability
- Standard Operating Procedures
- Annual Proficiency Testing
- Training documentation
- On-site assessments every 2-3 years

Certification Doesn't Assure Accountability

- Are sample testing Quality Controls met?
- Are test results and reports reviewed?
- Is compliance and monitoring data acceptable?
- Did the laboratory follow approved methods?

Quality Control Data

- Collected w/ each sample batch in an analytical run
- Examples include:
 - Blank
 - CCB-Continuing Cal. Blank
 - CCC-Continuing Cal. Check
 - LRB-Lab Reagent Blank
 - LFB-Lab Fortified Blank or Laboratory Control Sample (LCS)- a Key QC Sample
 - MS-Matrix Spike
 - MSD- Matrix Spike Dup
 - SD-Sample Duplicate
 - QCS-Quality Control Sample

Quality Control Data not Limited to EPA

- CDC's LRN-C will include (limited) QA/QC data
- Air Force Center for Environmental Excellence (Environmental Resources Program Information Management System)
- Human biomonitoring & environmental exposure assessment



Looking
forward to
our future..

What is the ERLN

Environmental Response Laboratory Network

APHL recommends
that EDDs be based
upon **EPA's ERLN Type
1t and Type 2** data
exchange template

What's in a Name?



A pig by any other name....

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ERLN WebEDR

What is WebEDR?

A free, web-based system that performs automated data evaluation on ERLN Electronic Data Deliverables

WebEDR

- Uses tests derived from the National Functional Guidelines (NFGs) for data evaluation and review.
- Uses a Data Exchange Template (DET) and XML Data Type Definitions (DTD) to exchange laboratory measurements
- Uses method-defined limits to measure data.
- Performs standardized evaluation of the overall quality of data.
- Provides reviewers with tools to measure data against different quality objectives.
- Capable of processing multiple EDDs

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Recent Uranium Exercise

- Data was:
 - Successfully collected from multiple laboratories
 - Evaluated at a central site for data quality, and
 - Processed as if all came from a single laboratory.

Laboratories Reporting

Laboratory Type	Number Participating	Used EXCEL EDD	Used XML EDD
State	4	3	1
DOE	4	3	1
Commercial	11	5	6

Parameter	Test Type	Data Quality Indicator
Method Blank	Frequency	Completeness
Duplicate Relative Percent Difference	Limit	Precision/Accuracy/Bias
Duplicate Frequency	Frequency	Completeness
Analyzed Time Limit	Limit	Representativeness/Completeness/Accuracy/Bias
Laboratory Control Sample (LCS)	Frequency	Completeness
LCS Spike Percent Recovery Limit	Limit	Accuracy/Bias/Precision
Sample Properly Received	Limit	Representativeness, Accuracy/Bias
Target Completeness	Completeness	Completeness

Other ERLN Exercises

Date	Exercise	# of Labs	Participants
May 2011	2011 Region 3 CWA Throughput	1	(1) EPA (4) State
April 2011	2011 EPA Radiological PT Study	19	(11) Commerical (4) DOE
March 2011	2011 PHILIS Deployment Sanford Gassification, FL	1	(1) EPA
November 2010	2010 Fall CWA Study	4	(2) EPA (2) State
August 2010	2010 Full-scale Exercise (Region 9,10)	16	(2) EPA (16) State/Local (4) Commercial
August 2010	Joint Confidence Building Exercise (Cyanide)	10	(8) EPA (2) State
July 2010	2010 Spring CWA Study NEMC 2011	8	(7) EPA (2) State

Contact Information



Thanks for your attention

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