Standardizing Electronic Data Deliverables:Public Health Laboratory Emergency Response

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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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Analysis, Answers, Action

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Information Access
National Laboratory System
Federal Laboratories
State & Local Public Health Labs
Hospital, Independent, Physician Office Labs

“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!

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Why is informatics relevant now?

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

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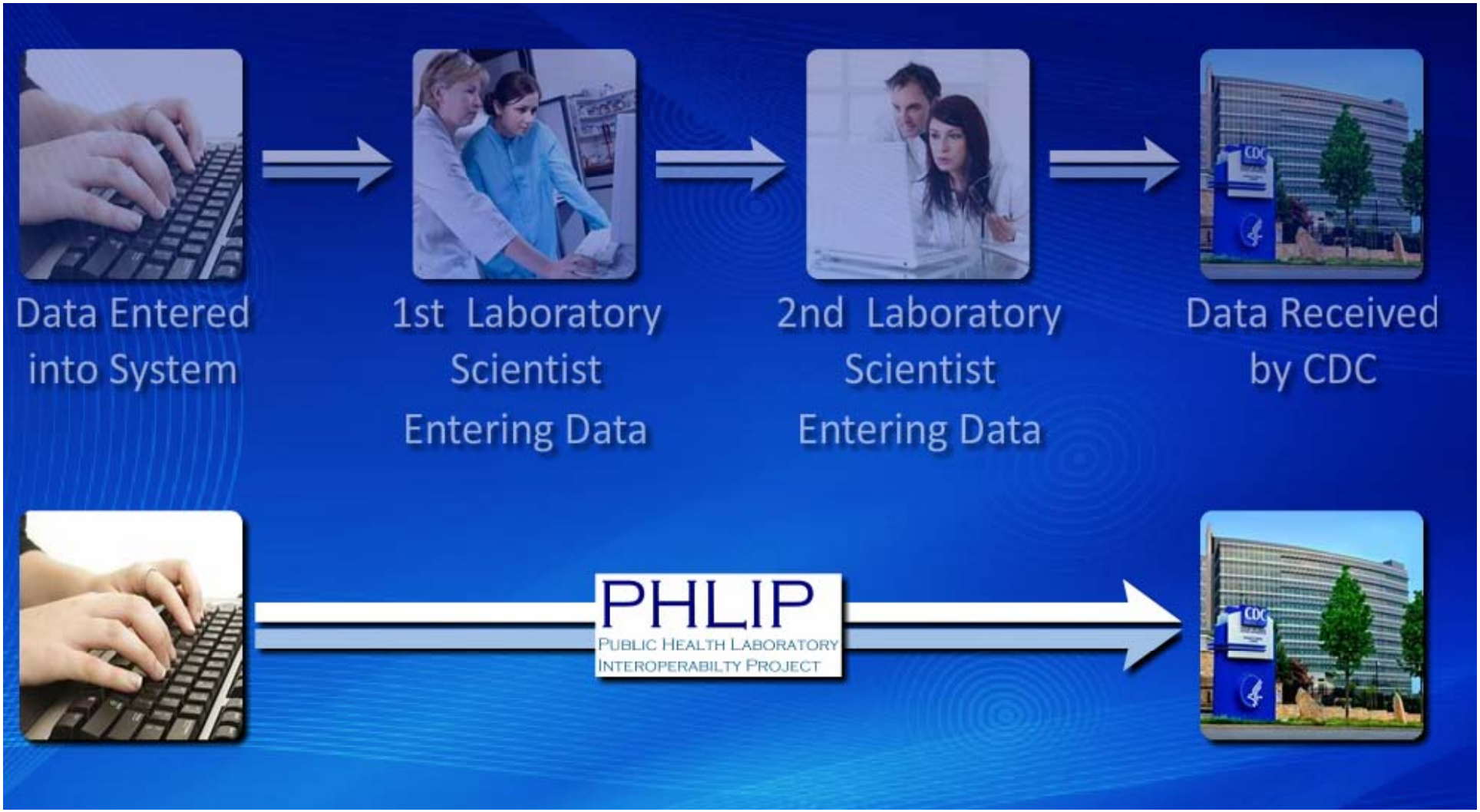
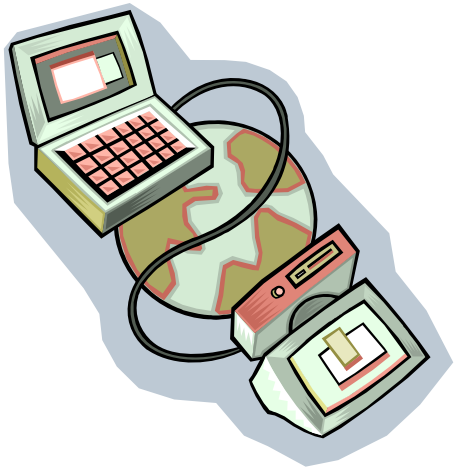
Public Health Laboratory Interoperability Project





Goal:

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

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

ENVIRONMENTAL LABORATORY
ELECTRONIC DATA MANAGEMENT

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

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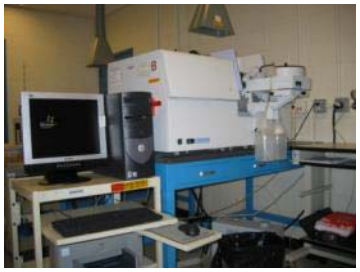
Successful LIMS "See" Down the Road

- 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

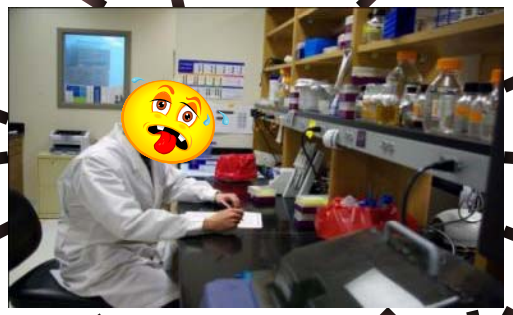

Patients


FDA


EPA


State PH Depts


City PH Depts


PH Labs


Practitioners


CDC

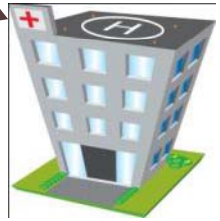

PH Field Teams


Emergency Ops Centers


First Responders


Commercial orgs


Other Labs


Hospitals

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

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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

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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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APHL recommends that interoperability be based upon the **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	Particpants
May 2011	2011 Region 3 CWA Throughput	1	(1) EPA
April 2011	2011 EPA Radiological PT Study	19	(4) State (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	8	(7) EPA (2) State

Contact Information

Thanks for your attention

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