



Managing Environmental Laboratories

With all the competing requirements how does a laboratory become profitable.



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Discussion Items

- Do you really want to do this?
- Can it be done?
- Basic Concepts used
- Important Processes

Why would I do this?



Open a savings and loan, I said. It's the perfect crime! But no, you had to go and open an environmental laboratory!

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Why would I do this?



Albert Einstein quotes

- "If you can't explain it simply, you don't understand it well enough."
- "We cannot solve our problems with the same thinking we used when we created them."
- "Logic will get you from A to B. Imagination will take you everywhere."
- "The true sign of intelligence is not knowledge but imagination."

Can it be done?

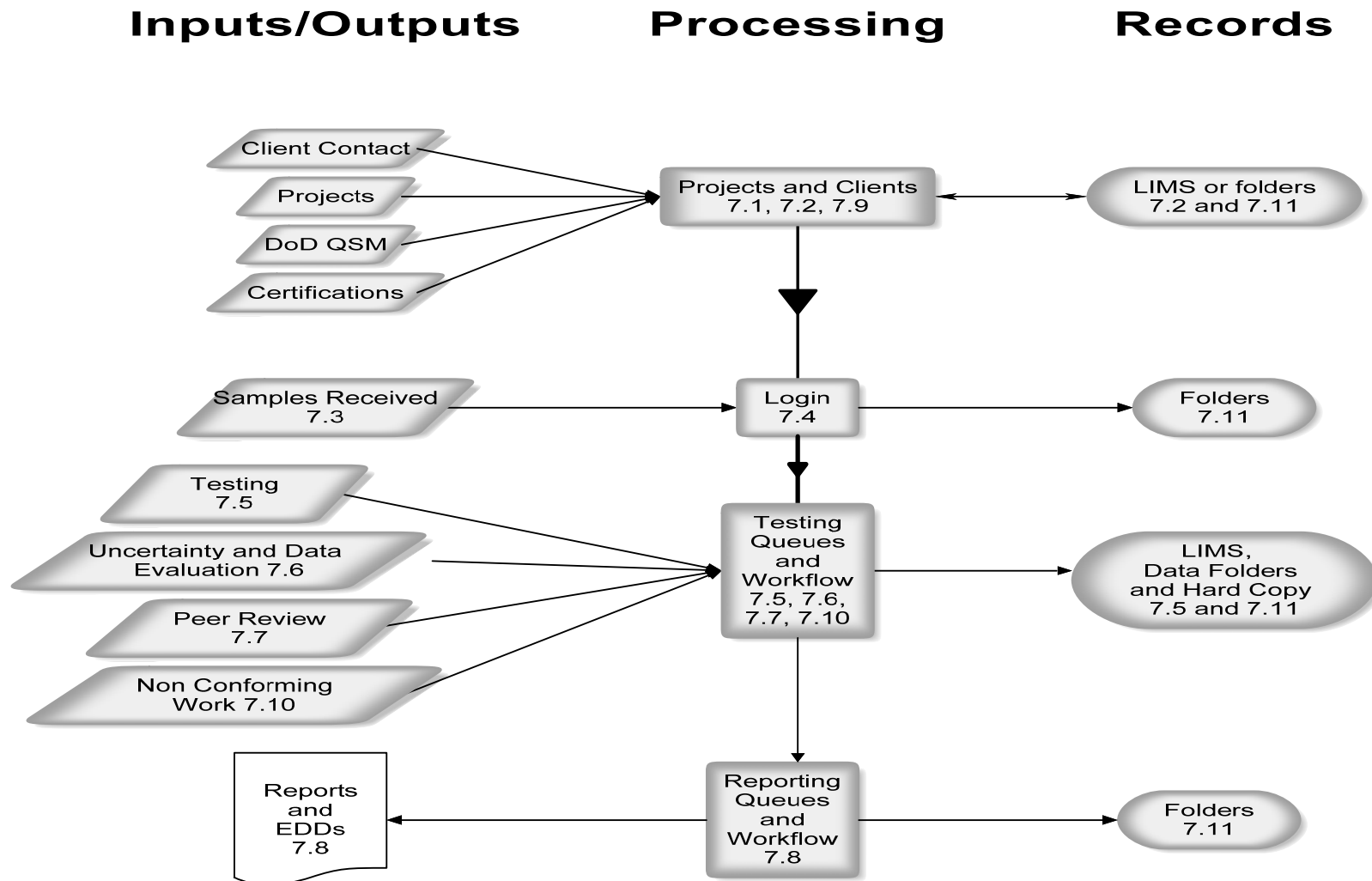


Fiscal Year	Revenue (\$000)	Revenue (\$000) per FTE
2013	8,652	143
2014	8,180	149
2015	9,872	142
2016	8,871	166
2017	9,405	160
2018	10,000	160
2019	10,780	167

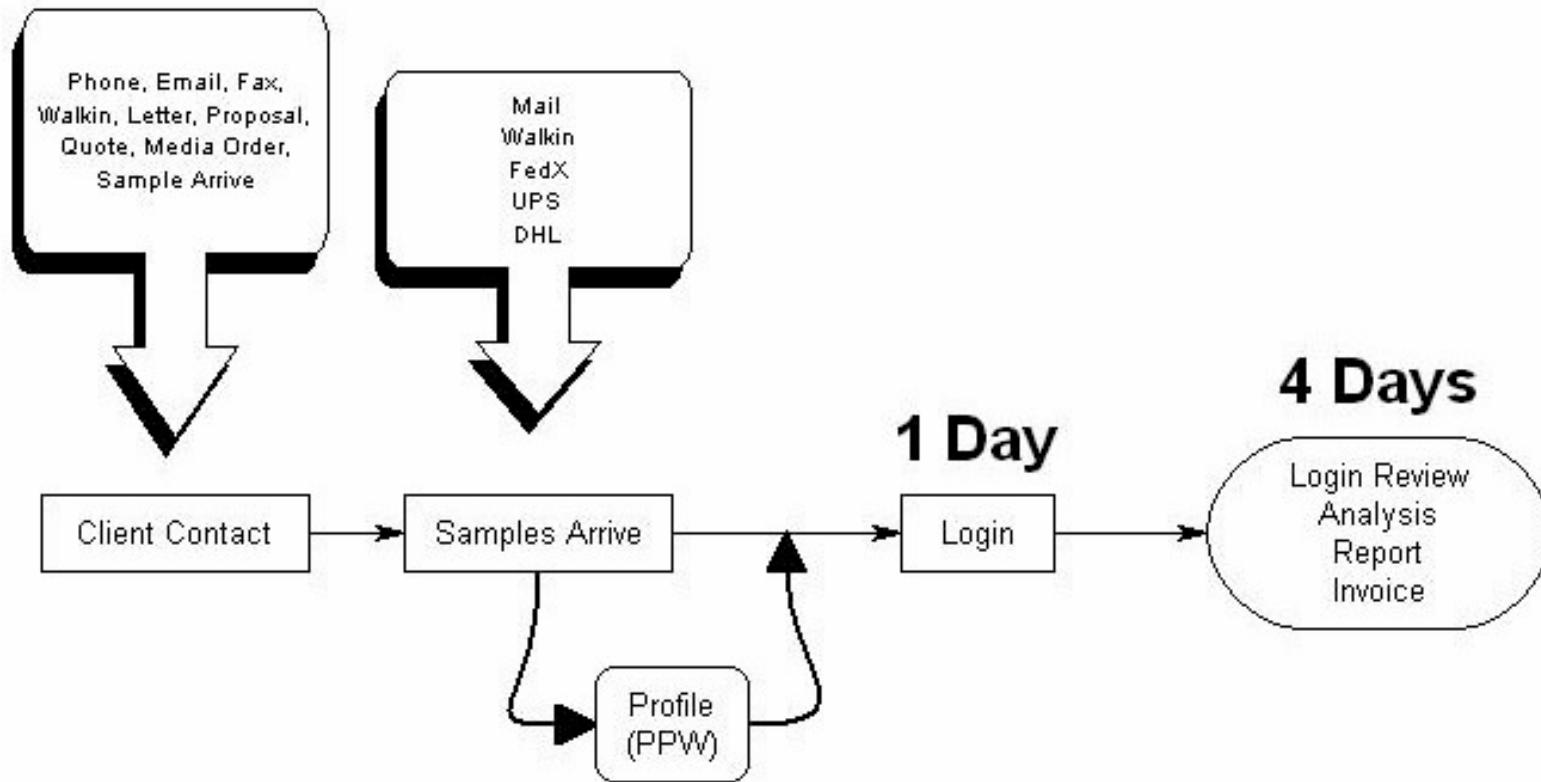


Basic Concepts

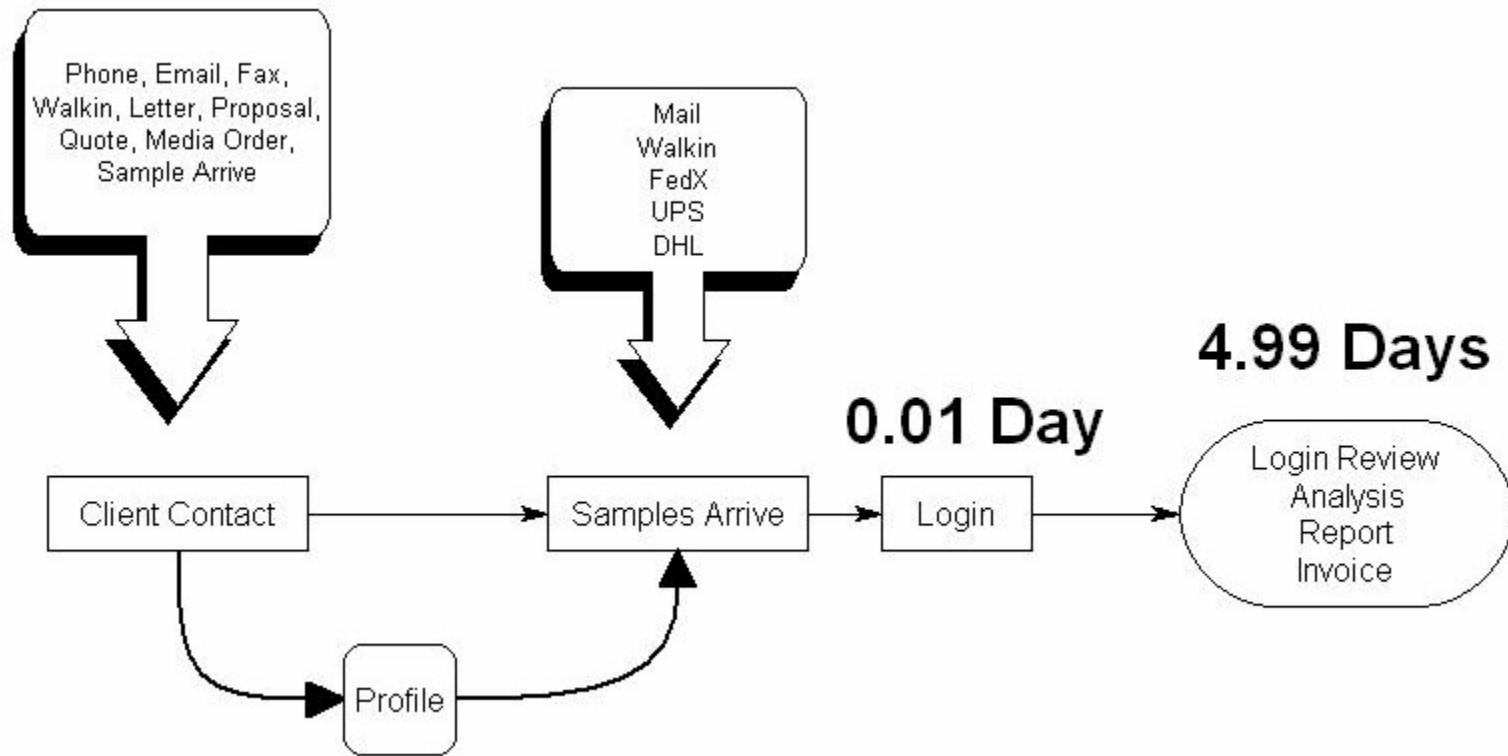
- Know your business
 - Flow diagram of process
 - Do it right the first time
 - Time = Waste = \$\$\$\$



Process Flow



Process Flow





Basic Concepts

- Enlist all employees
 - Managers
 - All in it together
 - Implementing Process Changes
 - Innovations and Changes
 - Staff
 - All in it together
 - Solutions not complaints
 - Making Improvements



- LIMS
 - Must support the processes you want and not dictate a way to do something
 - Work with electronic communications processes
 - Upload, download, email, notifications
 - Front loaded requirements for client satisfaction
 - Support electronic data storage and retrieval



Important Processes

- Quality Assurance Manual
 - Policy not procedure
 - Orientation Training for employees
 - KISS
 - Sharing Knowledge (intranet)



Important Processes

- Internal Audits
 - Say what you do and do what you say
 - Familiarity with ISO and Requirements
 - Corrective Actions with root cause and follow up for effectiveness
 - Opportunities for Improvement
 - Trending using Statistical Process Control (SPC)



Important Processes

- Nonconformance vs. corrective actions
 - Capturing random events (all)
 - Evaluation for systemic events
 - Corrective Actions with root cause and follow up for effectiveness



Important Processes

- Corrective Actions
 - Root Cause
 - Involve users in corrective actions
 - Follow up for effectiveness

PDCA, Plan, do, check, act



Important Processes

- Training Programs
 - Initial and Ongoing
 - Communication of outcomes
 - None of us are as smart as all of us



Thank You

Robert P. Di Rienzo, CQA (Bob)
ALS USA Quality Improvement Manager
Email: Bob.DiRienzo@ALSGlobal.com

Part 2

The Most Clueless



The laboratory is not validating Eppendorf pipettes with the solvent that they will be dispensing. This is a repeat finding. See section V1M2 5.5.13.1 in 2009 standard.

The Most Clueless



State rule required that refrigerator thermometers be immersed in 1:1 Ethylene Glycol/water mix. There was no documentation demonstrating the 1:1 preparation of the mixture or COA stating glycol was of sufficient purity to constitute a 1:1 ratio.

The Most Clueless



Preparation batch for EPA 625 did not contain an MS/MSD, as insufficient sample was provided. Assessor recommendation was we grab some water from the creek outside the building to fulfill the matrix spikes requirement.

The Most Clueless



We did not document that every position of a 90 place hot-block had been measured for consistent temperature. “Random placement” of thermometer was not adequate.

NELAC Ref: 5.4.12.2.4 **(b)** TNI V1M2, 4.13.3 **(f)** –

The laboratory does not maintain accurate, unequivocal records that document all laboratory activities. For example:

Boiling chips used in preparation of TKN do not have a unique ID recorded.



NELAC Ref: 5.4.12.2.5.3 **(i)** TNI V1M2, 4.13.3 **(f)(xi)**

Records of standard and reagent origin, receipt, preparation, and use are not uniformly available. Examples include:

Lot numbers or other unique identifiers for reagent test strips used for pH and chlorine checks are not recorded.

Why are you concerned?



Tasks of 15 seconds are costly

Example

$0.00417 \text{ hours/Day} * 50 \text{ person} * 250 \text{ Day/year}$

$= 51.25 \text{ hours per year of additional work}$



Thank You

Robert P. Di Rienzo, CQA (Bob)

ALS USA Quality Improvement Manager

Email: Bob.DiRienzo@ALSGlobal.com