

On Being a QA Officer Part 2!

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FSEA Fall Meeting

October 28, 2010

Palm Beach Gardens, FL

Agenda, 10/28/10

- Preparing and maintaining a Quality Manual
- Conducting internal audits
- External audits
- Performance assessments
- FDEP QA Rule
- Data verification and validation
- Data quality assessment
- Data qualifiers
- FDEP Quality Assurance Rule – Chapter 62-160, Florida Administrative Code
- Root cause analysis

Quality Manuals

- QAO is responsible for preparing and maintaining the currency of QM
 - TNI 4.2.8.3 and 4.2.8.4
 - NELAC (2003) 5.4.2.3
- QM - a document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users.

Preparing and Maintaining the QM

- Ensure all the elements are included
- Gather any existing materials (old QMs, SOPs, instrument and equipment instruction manuals, notes from analysts, etc.)
- Best to organize in a logical manner.
- Have a table of contents – detailed enough to cross-walk NELAC (TNI) requirements
- To keep up, through the year, maintain a file of changes and edits and update the manual periodically when there are major changes.

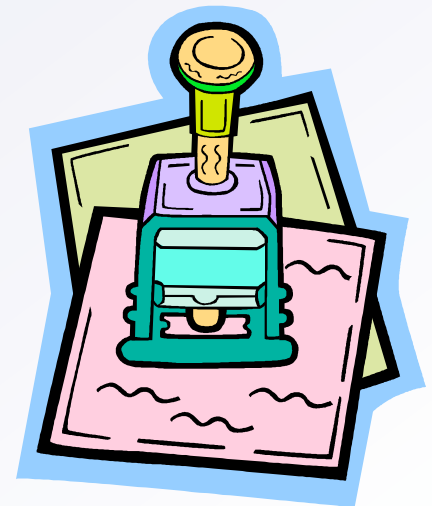
Document Version Control

- Develop and implement a system for version control.
- Keep a master list of all QS documents and versions, including effective dates.
- Ensure that all versions, including drafts, are labeled properly.



Document Version Control

- Amendments must be clearly marked, signed, dated, reviewed, and approved,
- Distribute and clearly communicate to staff on any changes
- Outdated (outside of effective period) must be removed from circulation.



Internal Audits

- QAO plans and schedules for annual internal audits to verify that its operations continue to comply with the requirements for the laboratory's quality system
- Audit must address all elements of the quality system, including the environmental testing activities
- Works with management and staff to ensure timely corrective action when the internal audit findings cast doubt on the correctness or validity of the laboratory's test results
- Documents all internal audit findings plus any corrective actions that arise from them.

Suggested checklist

[http://www.doh.state.fl.us/lab/EnvLabCert/
EnvChemChecklist.html](http://www.doh.state.fl.us/lab/EnvLabCert/EnvChemChecklist.html)

- ___ 5.4.12 Does the laboratory maintain a **record system** to suit its particular circumstances & to comply with any applicable regulations

- ___ 5.4.12 Does the record system produce **unequivocal, accurate records** which document **all laboratory activities**

QA Role in External Audits

- Coordinates schedule with the auditor and the laboratory.
- Prepares the laboratory to facilitate an efficient audit.
- Briefs staff and management before and after the audit.
- Coordinates meetings, staff interviews, and inspection of documents.
- Receives and reviews audit reports.
- Work with lab staff and management in developing a corrective action plan.
- Submits corrective action plan to auditor.
- Follow-up on implementation of corrective action plan.

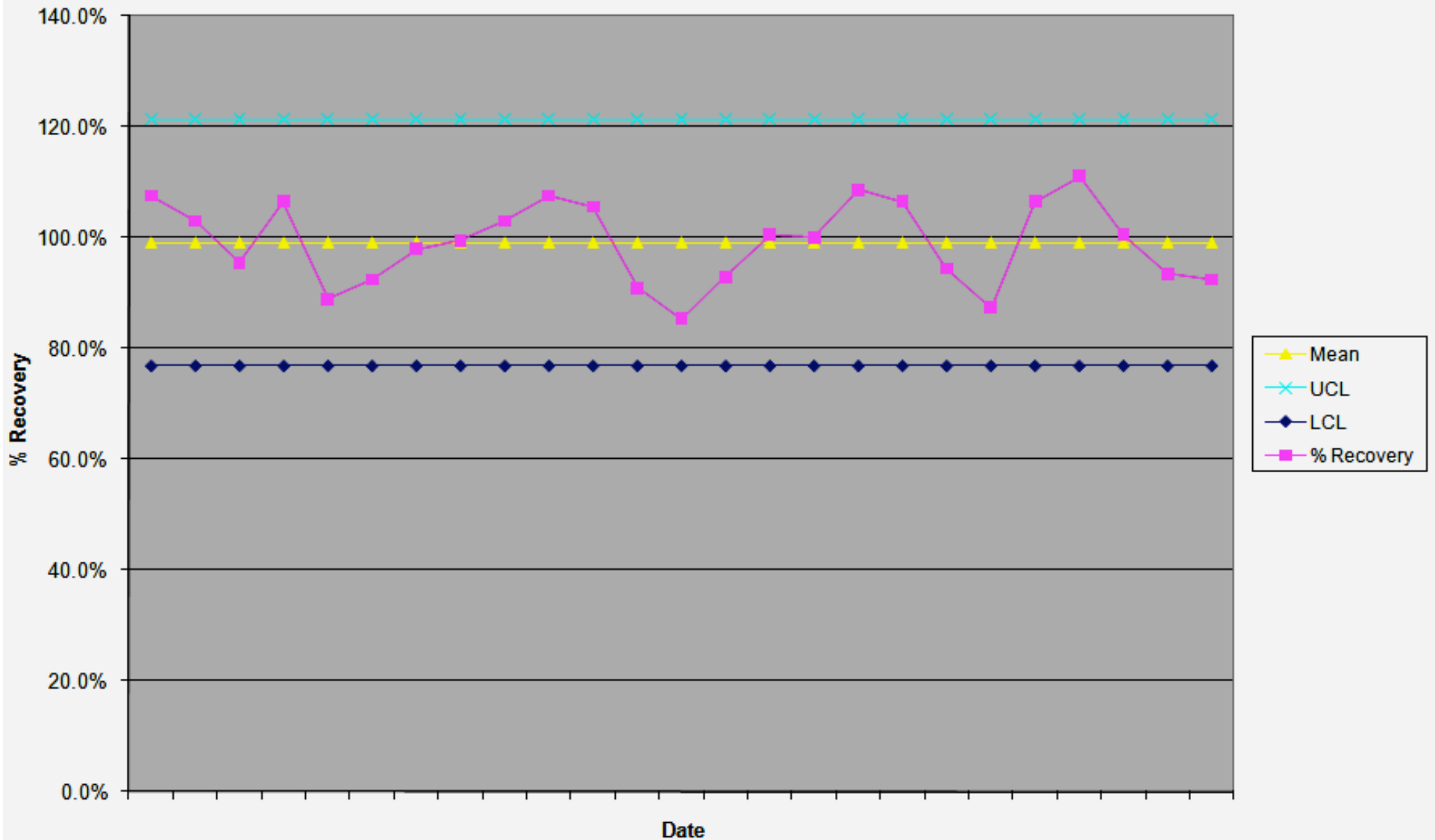
QAO's Responsibilities doesn't End There!

- Watch out for recurring deficiencies
- Communicate findings to staff and explain the proper corrective action.
- Find and work on solving the root cause(s)
- Look for areas of improvement

Performance Assessment

- PT studies
- Blinds
- Interlaboratory analyses
- QC tracking
 - Examine trends, recurring problems
 - Check QC recoveries, method blanks, turnaround times, holding times
- Audits
- Timeliness and accuracy of reports
- Feedback from customers

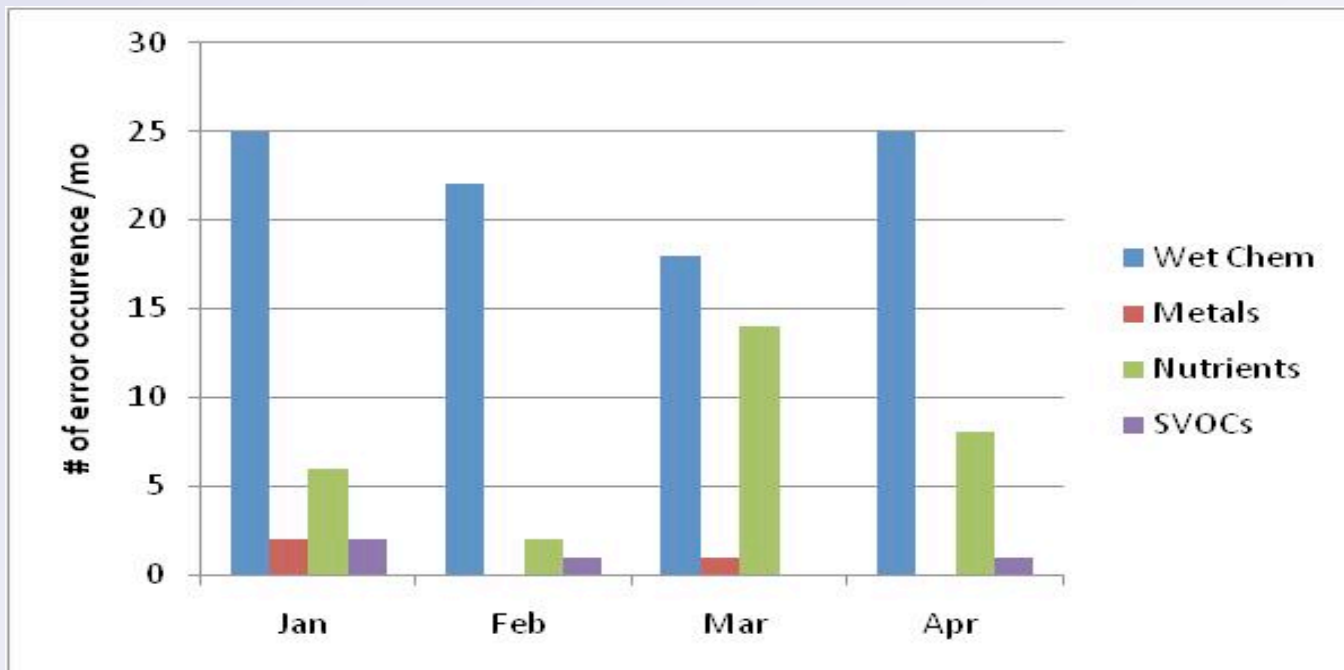
Quality Control Charts



Tracking Other Performance Indicators

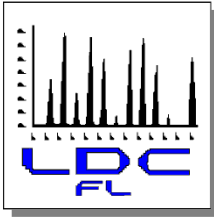
Ex. Monthly Data Entry Errors

	Jan	Feb	Mar	Apr
Wet Chem	25	22	18	25
Metals	2	0	1	0
Nutrients	6	2	14	8
SVOCs	2	1	0	1



QAO's Role and Responsibilities in the Data Review Process

- *NELAC/TNI*: A QAO shall serve as the focal point for QA/QC and be responsible for the oversight and/or review of quality control data.
- Data verification – performed by or overseen by QAOs.
- Data Validation – In some organizations, QAOs also perform this function.

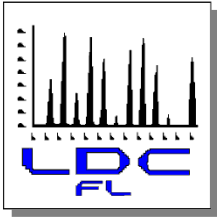


Data Validation and Data Verification

Data Verification - the process of evaluating the completeness, correctness, and conformance of a specific data set against the method, procedural, or contractual requirements.

Data Validation - an analyte- and sample-specific process that extends the evaluation of data beyond method, procedural, or contractual compliance (i.e., data verification) to determine the analytical quality of a specific data set.



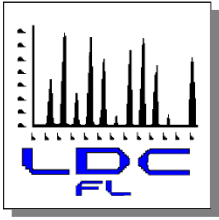


Typical Areas of Validation

- COC (Chain of Custody)
- Receipt Temperature
- Preservation
- Containers Used
- Holding Times
- Sample Integrity
- Field QC (Trip blanks, Equipment Blanks)
- Technical Holding Times
- Batch Requirements
- Method Blanks

ADaPT

- Lab Control Samples
- Matrix Spikes
- Surrogates
- Detection limits
- Method Compliance
- Internal Standards
- Calibration (Initial, Continuing)
- Specific Instrument/methods QC
- Compound Identification
- Compound Quantitation



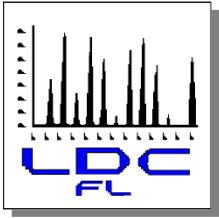
Data Qualifiers



Data qualification is an integral component of data reporting, review and validation.

- Laboratories data qualifiers indicate the quality of results being reported.
- During data validation, separate qualifiers maybe applied to signify the overall usability of individual data with regards to the project DQOs and measurement quality objectives.
 - alert the data end user to quality problems that may impact the usability of the data.



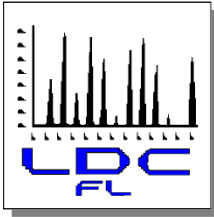


Lab Data Qualifiers

FDEP 62-160.700 - Table 1 DATA QUALIFIER CODES

The following codes **shall** be used by laboratories and/or field organizations when reporting data values that either meet the specified description outlined below or do not meet the quality control criteria of the laboratory:

Q	Sample held beyond the accepted holding time. This code shall be used if the value is derived from a sample that was prepared or analyzed after the approved holding time restrictions for sample preparation or analysis.
T	Value reported is less than the laboratory method detection limit. The value is reported for informational purposes only and shall not be used in statistical analysis.
U	Indicates that the compound was analyzed for but not detected. This symbol shall be used to indicate that the specified component was not detected. The value associated with the qualifier shall be the laboratory method detection limit. Unless requested by the client, less than the method detection limit values shall not be reported (see "T" above).

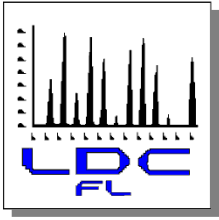


Lab Data Reporting and Review

NELAC 5.5.10.3 Supplemental Information for Test Reports

5.5.10.3.1 In addition to the requirements listed in 5.5.10.2, test reports shall, where necessary for the interpretation of the test results, include the following:

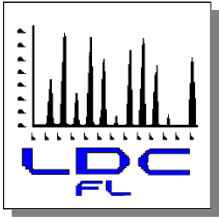
a) deviations from (such as failed quality control), additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions and any non-standard conditions that may have affected the quality of results, **including the use and definitions of data qualifiers**



Data Validation Qualifiers

FDEP 62-160.340 Record Keeping and Reporting Requirements for Laboratory Procedures.

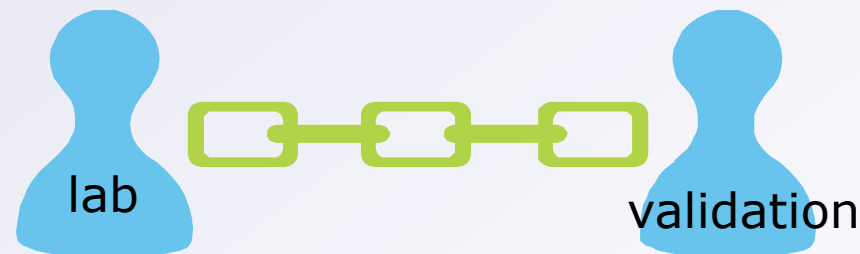
(7) When data qualifiers are added through a validation or review process that is independent of the laboratory reporting process, the reason for the addition, the date of the addition, and the person adding the qualifier(s) shall be included. These qualifiers shall be included in any documents that are summaries or re-published formats, as described in subsection (6) above.

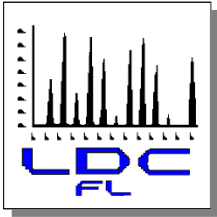


Data Validation Qualifiers

Data Validation Qualifiers differ from FDEP Qualifier codes or other lab-specific flags.

Separate qualifiers, when needed, are added to the data during validation process. The laboratory qualifiers are not removed from the data.



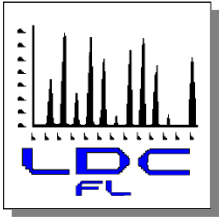


Data Validation Qualifiers



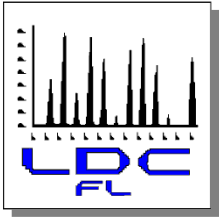
- J** Estimated
- J+** Estimated High (results are likely reported higher than the true value)
- J-** Estimated Low (results are likely reported lower than the true value)
- R** Rejected
- UJ** Undetected Estimated
- NJ** Tentatively Identified, Quantitation Estimated

J



Reasons for Qualifying Data

- Results between the MDL and PQL
- Instrument calibration does not meet criteria
- Samples exceed holding time
- Low or high MS/MSD or LCS spike recoveries
- Results associated with contaminated field blanks
- Improper preservation/containers
- Instrument QC check failures
- Internal Standard failure
- Results associated with contaminated method blank
- Duplicate failures
- Low or high surrogate recoveries
- Missing QC steps



Qualified Data Scenarios

LCSD,MS,MSD recovered within 80-120%

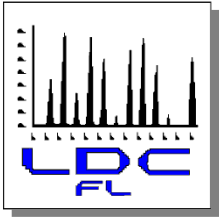
LCS Recovery below LCL at 72%

RPD within 20%

Non project sample spiked for MS/MSD

Lab} **Qualify all batch samples with J and
comment on %Recovery (Low bias)**

Third party }
Validation } **Qualify detected batch samples with J
and Non detect samples with UJ**



Qualified Data Scenarios

MS,MSD recovered within 90-110%

LCS Recovery below LCL at 9%

RPD within 20%

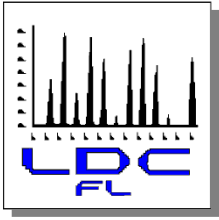
Non project sample spiked for MS/MSD



Lab} **Qualify all batch samples with J and
comment on %Recovery (Low bias)**

Third party }
Validation } **Qualify positive batch samples with J
and Non detect samples with R**

<10% TYPICALLY FOR ORGANICS <30% FOR METALS, <30-50% FOR WET CHEM



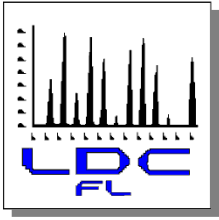
Lab Data Qualifiers

x4

Matrix Spike Failure reminders

Is the sample concentration > 4 times the spiked concentration?

If yes, add “J” discuss in comment that spike recoveries for analytes whose concentrations in samples are > 4 times the spike added.



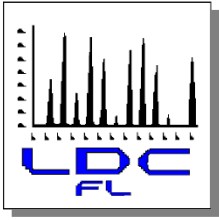
Lab Data Qualifiers

Reminder

Matrix interference verification

- To confirm Surrogate MI: rerun/re-extract
- To confirm Metals MI: Method of Standard Additions (MSA), post spikes, dilutions.





Qualified Data Scenarios

The sample result(s) are more than **10X** the concentration of the detected target analytes in the blanks.

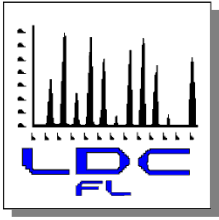
Lab}

No V Qualifier on samples results needed.

Third party }
Validation }

Sample results will not be qualified.





Qualified Data Scenarios

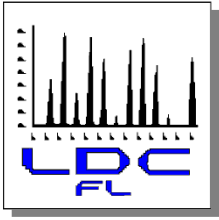
The sample result(s) are less than **10X** the concentration of the detected target analytes in the blank.

Lab}

Qualify samples with the **V** qualifier, (show blank value with results)

Third party }
Validation }

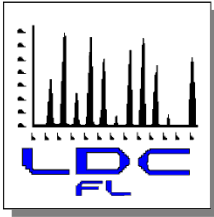
Sample results will be qualified as **“U”**, undetected.



Data Qualifiers



- Be careful when identifying dilutions in final reports.
- Do not place D (for dilution) in Qualifier column if reporting to FDEP
- FDEP's D qualifier code is for:
"Measurement was made in the field (i.e., in situ).
This code applies to....."



Technical Holding Time Qualifiers

Which analysis will have a qualifier for Technical Holding Time exceedance?

- SVOL extraction to analysis?

True

- Chlorophyll filtered to analysis?

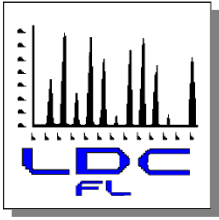
True (48-28 days rule)

- BOD set up to analysis?

False (analysis date time starts at first DO measure)

- TCLP extraction to SVOL extraction?

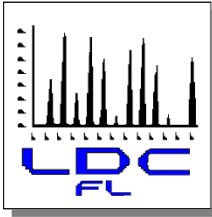
True



Data Qualifiers Summary



- ✓ Laboratory Qualifiers are not to be deleted or changed by validators or data end users.
- ✓ Electronic validation software such as ADaPT adds the validation qualifiers without removing the lab qualifiers from the data
- ✓ Data upload to databases will have both sets of qualifiers.
- ✓ Qualified data does not automatically mean not useable data
- ✓ The use of qualifiers are mandatory according to FDEP and NELAC
- ✓ Data usability guidance: FDEP's document DEP-EA 001/07, Process for Assessing Data Usability

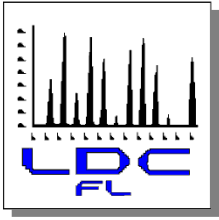


Role: Finding the Root Cause

■ Root Cause Analysis (RCA):

- A structured evaluation method that identifies the root causes for an undesired outcome and the actions adequate to prevent recurrence.
- A method that helps professionals determine:
 - What happened
 - How it happened
 - Why it happened
- Allows learning from past problems, failures, and accidents.





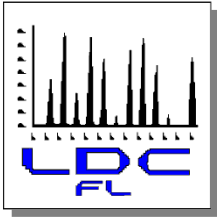
Root Cause Analysis (RCA)

■ Proximate Cause(s)

The event(s) that occurred, including any condition(s) that existed immediately before the undesired outcome, directly resulted in its occurrence and, if eliminated or modified, would have prevented the undesired outcome.

□ **Also known as the direct cause.**

- Examples of undesired outcomes: failure, anomaly, schedule delay, broken equipment, product defect, problem, close call, mishap, etc.



Root Cause – Definition

One of multiple factors (events, conditions or organizational factors) that contributed to or created the proximate cause and subsequent undesired outcome and, if eliminated, or modified would have prevented the undesired outcome.

Typically multiple root causes contribute to an undesired outcome.

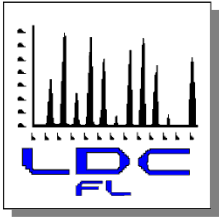


Organizational Root Causes

Any operational or management structural entity that exerts control over the system at any stage in its life cycle, including but not limited to the system's concept development, design, fabrication, test, maintenance, operation, and disposal.

Examples: Resource management (budget, staff, training); policy (content, implementation, verification); and management decisions.

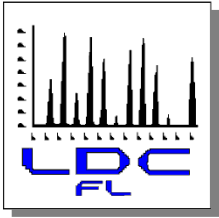




Why do RCA?



- Analysis pitfall: If RCA is not performed, and the analyst only identifies and fixes the proximate causes, then the underlying causes may continue to produce similar problems in the same or related areas.
- Root cause analysis seeks to identify the systemic problems, and correct these so that related problems or mishaps do not occur.



RCA Tools – 5 Whys



1. *Why did we get unacceptable PT result for this analyte?*

It's what the instrument gave us!

2. *Why did the instrument produce that result?*

It was improperly calibrated.

3. *Why was it not calibrated properly?*

Because the analyst did not do it correctly.

4. *Why didn't the analyst calibrate properly?*

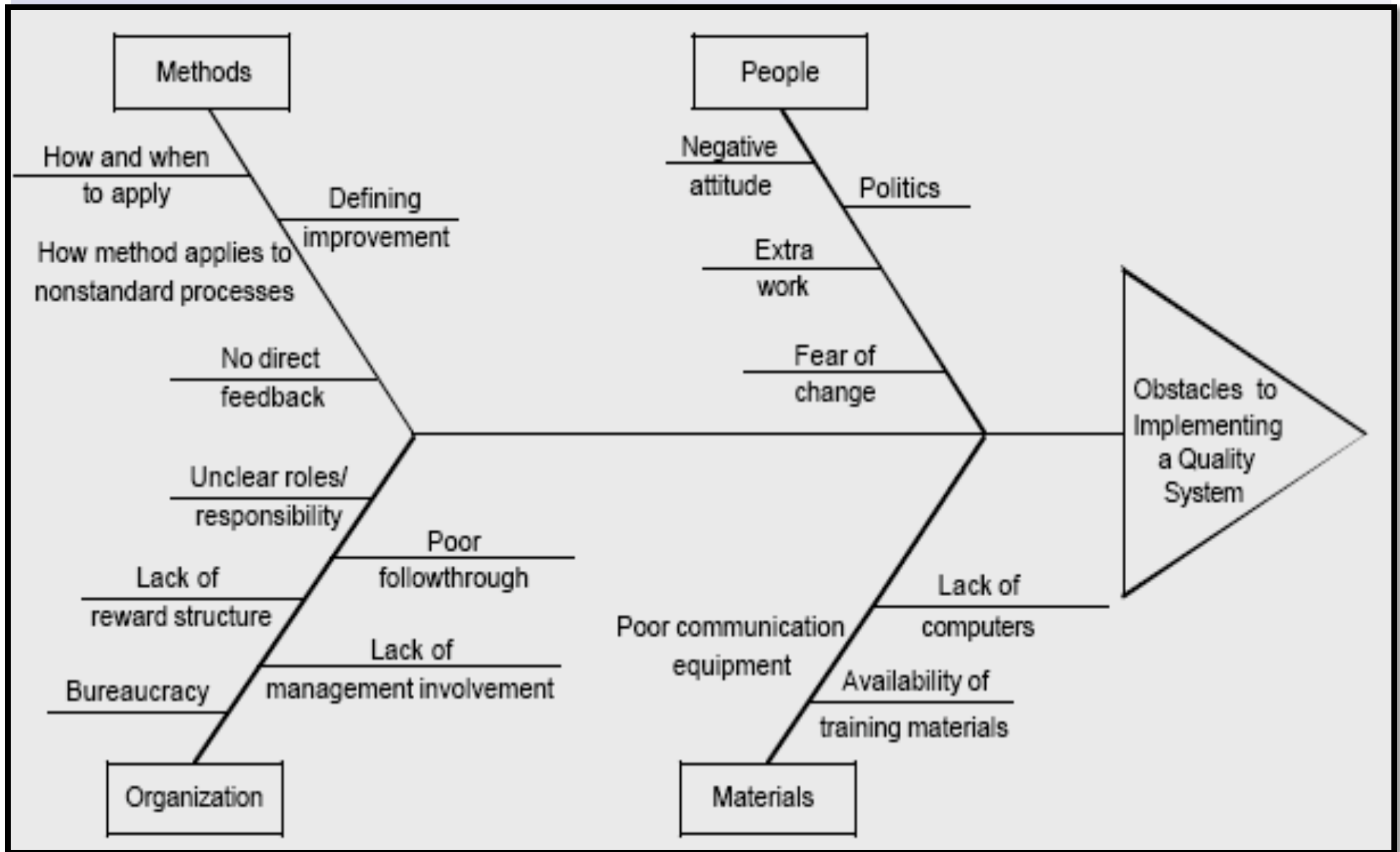
Because she has not been fully trained.

5. *Why was she not fully trained?*

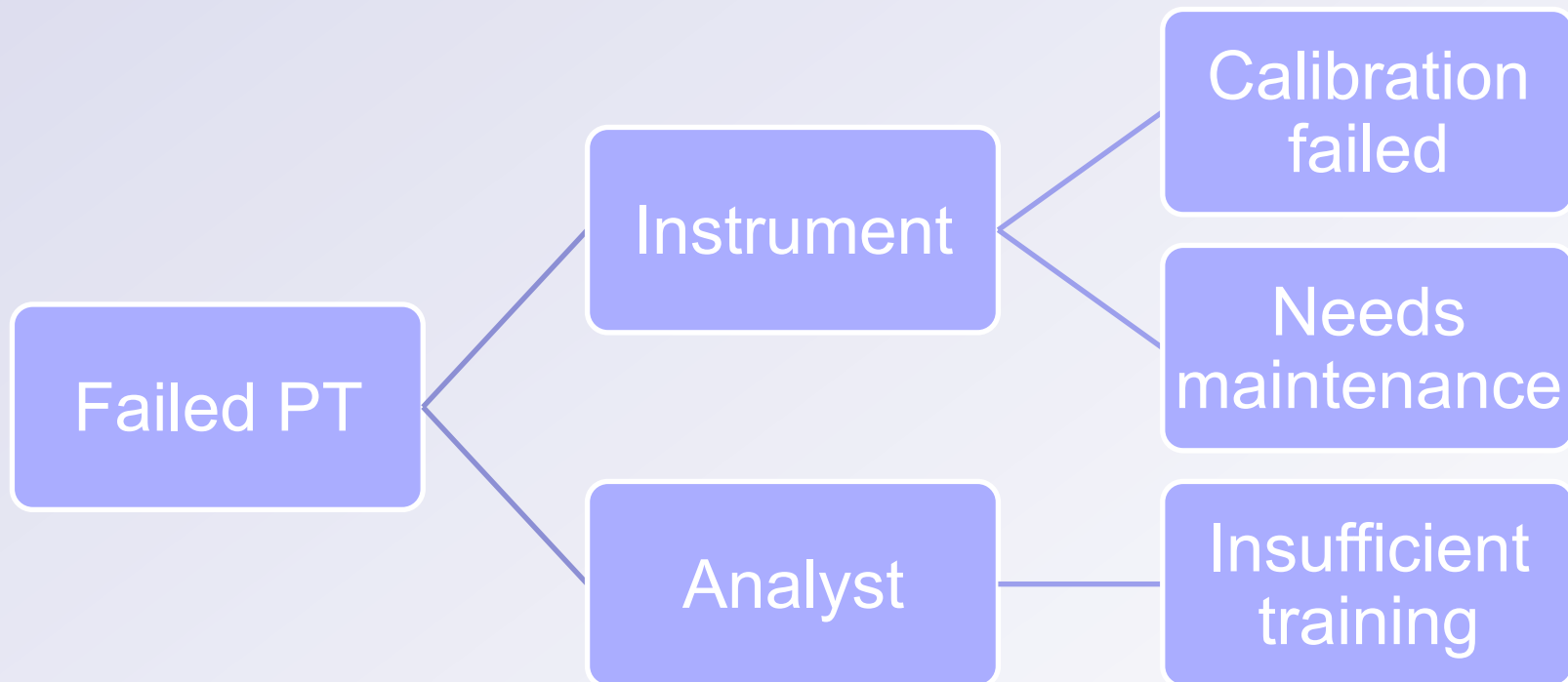
Because we're short-staffed and noone was available to train her.

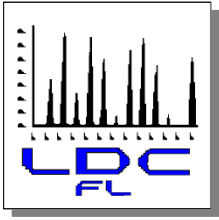


RCA Tools: Fishbone diagram



RCA Tools: Flow Charts

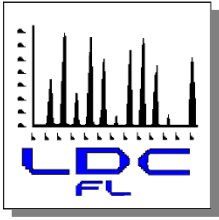




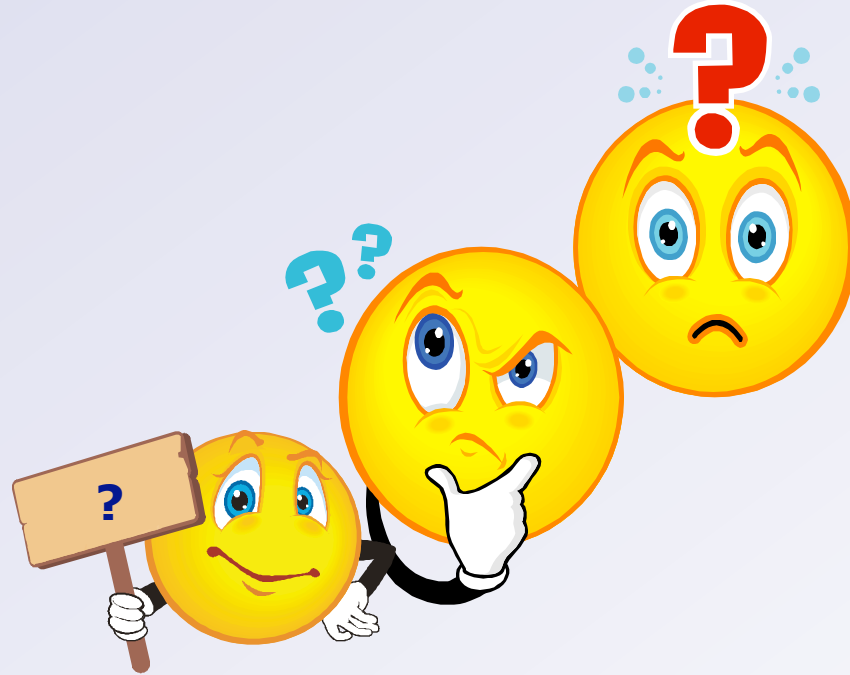
RCA Process Overview

- ✓ Clearly define the undesired outcome.
- ✓ Gather data, including a list of all potential causes.
- ✓ Create an event and causal factor tree.
- ✓ Continue asking “why” to identify root causes.
- ✓ Check your logic and eliminate items that are not causes.
- ✓ Generate solutions that address both proximate causes and root causes.
- ✓ Monitor to ensure successful **continuing** outcome





Questions



Thank you!