Data Quality, Management and Validation Through the Eyes of a LIMS

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A laboratory's task:

Produce quality data under proper management oversight with appropriate validation criteria in place…

while realistically…

operating under time constraints, understaffed, working for demanding clients/managers who want everything done perfectly no later than yesterday and see no reason a BOD cannot be run within 24 hours.

Mistakes Happen

"err is human" - *errāre hūmānum est*.

Simple typo

Temporary dyslexia

Right samples, wrong test assigned

Wrong column of data on the right line

Careless blunders on a tired day…

We all made mistakes – sometimes caught and corrected, sometimes not.

Data Quality, Management and
Validation from an IT perspective…

Data Quality

This list is taken from the online book "Data Quality: High-impact Strategies".

- Degree of excellence exhibited by the data in relation to the portrayal of the actual scenario.
- The state of completeness, validity, consistency, timeliness and accuracy that makes data appropriate for a specific use.
- The totality of features and characteristics of data that bears on its ability to satisfy a given purpose; the sum of the degrees of excellence for factors related to data.
- The processes and technologies involved in ensuring the conformance of data values to business requirements and acceptance criteria.
- **Complete, standards based, consistent, accurate and time stamped.**

In the ISO 9000:2015 definition of quality is applied, **data quality can be defined as the degree to which a set of characteristics of data fulfills requirements**. Examples of characteristics are: completeness, validity, accuracy, consistency, availability and timeliness. Requirements are defined as the need or expectation that is stated, generally implied or obligatory.

Incorrect data – which includes invalid and outdated information – can originate from different data sources – through data entry, or data migration and conversion projects.

Data management

"Data management is the development, execution and supervision of plans, policies, programs and practices that control, protect, deliver and enhance the value of data and information assets."

Data Validation

Data validation is intended to provide certain well-defined guarantees for fitness, accuracy, and consistency for any of various kinds of user input into an application or automated system. Data validation rules can be defined and designed using any of various methodologies, and be deployed in any of various contexts.

LIMS have the “computer advantage”

- LIMS do not require sleep
- LIMS do not suffer from bad moods
- LIMS do not make erroneous calculations unless programmed incorrectly
- LIMS do not call out sick
- Never has a LIMS suffered from a hangover on a Tuesday morning after a big Monday night game!

Insurance of Assurance: Data through LIMS

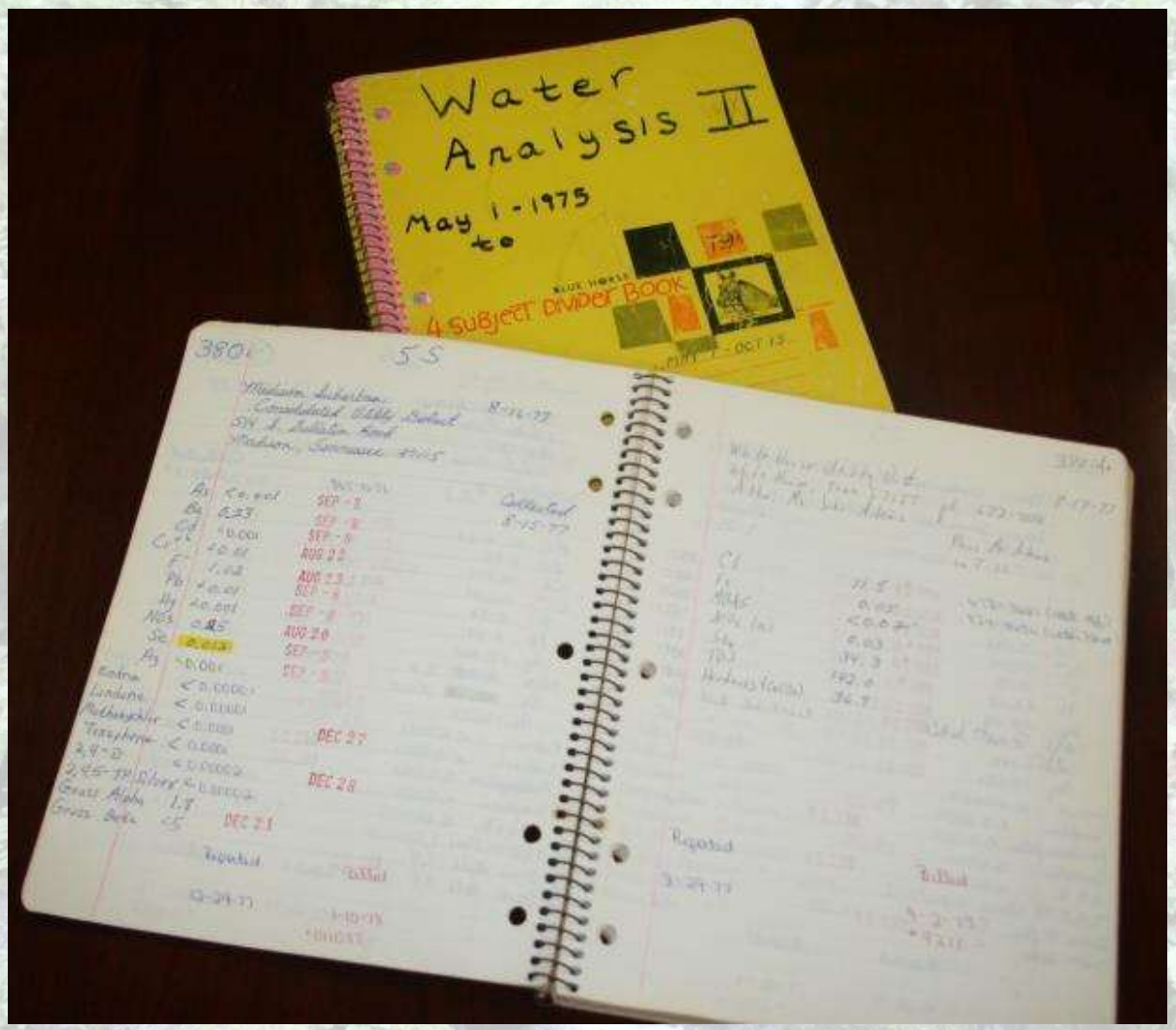
"Cradle through grave tracking"

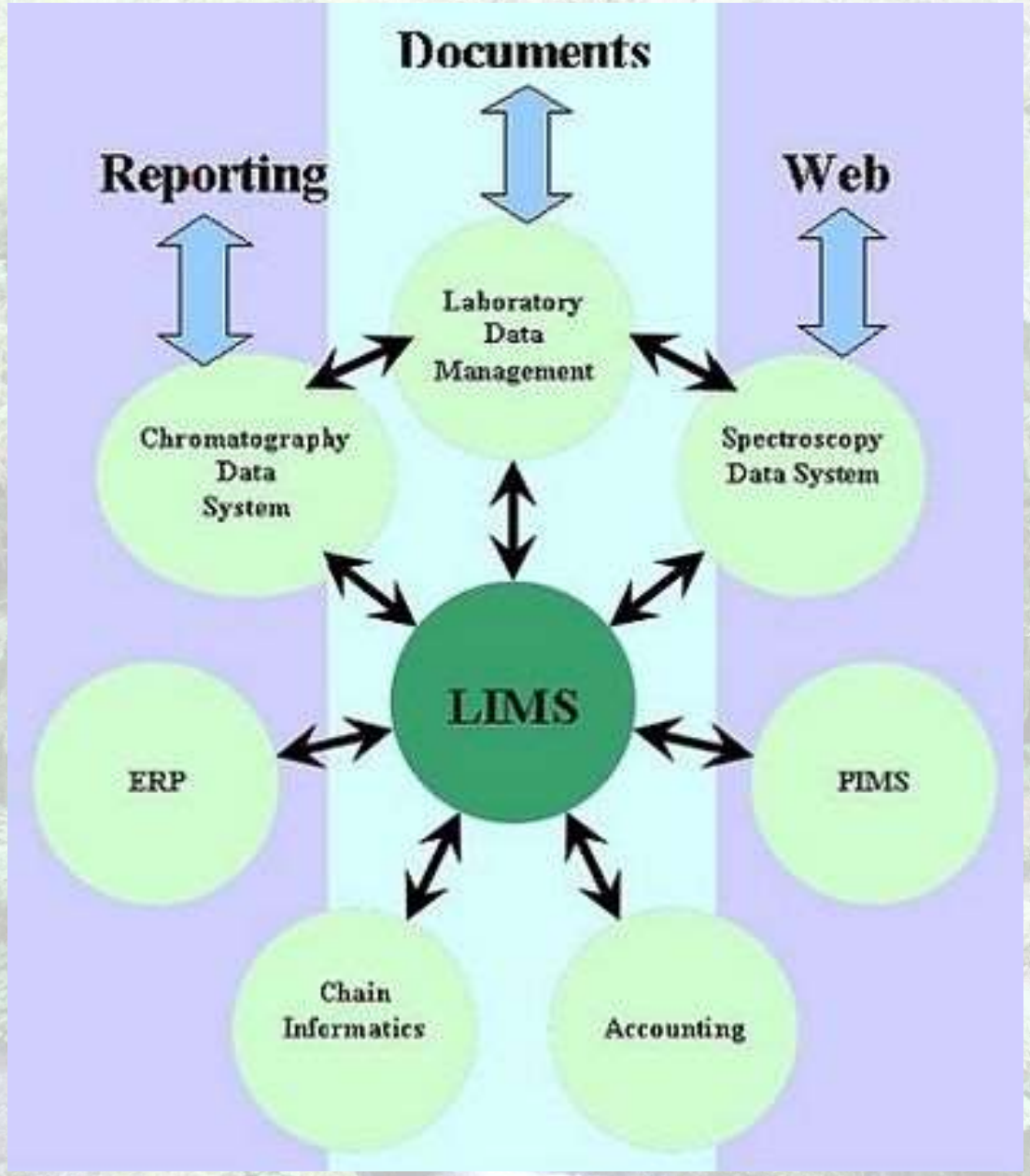
No gaps or black holes

Every step can/may be documented (i.e. internal CoCs)

Integrated QA/QC

“LIMS” - circa 1987




Documents
Reporting
Web
Laboratory Data Management
Chromatography Data System
Spectroscopy Data System
LIMS
ERP
PIMS
Chain Informatics
Accounting

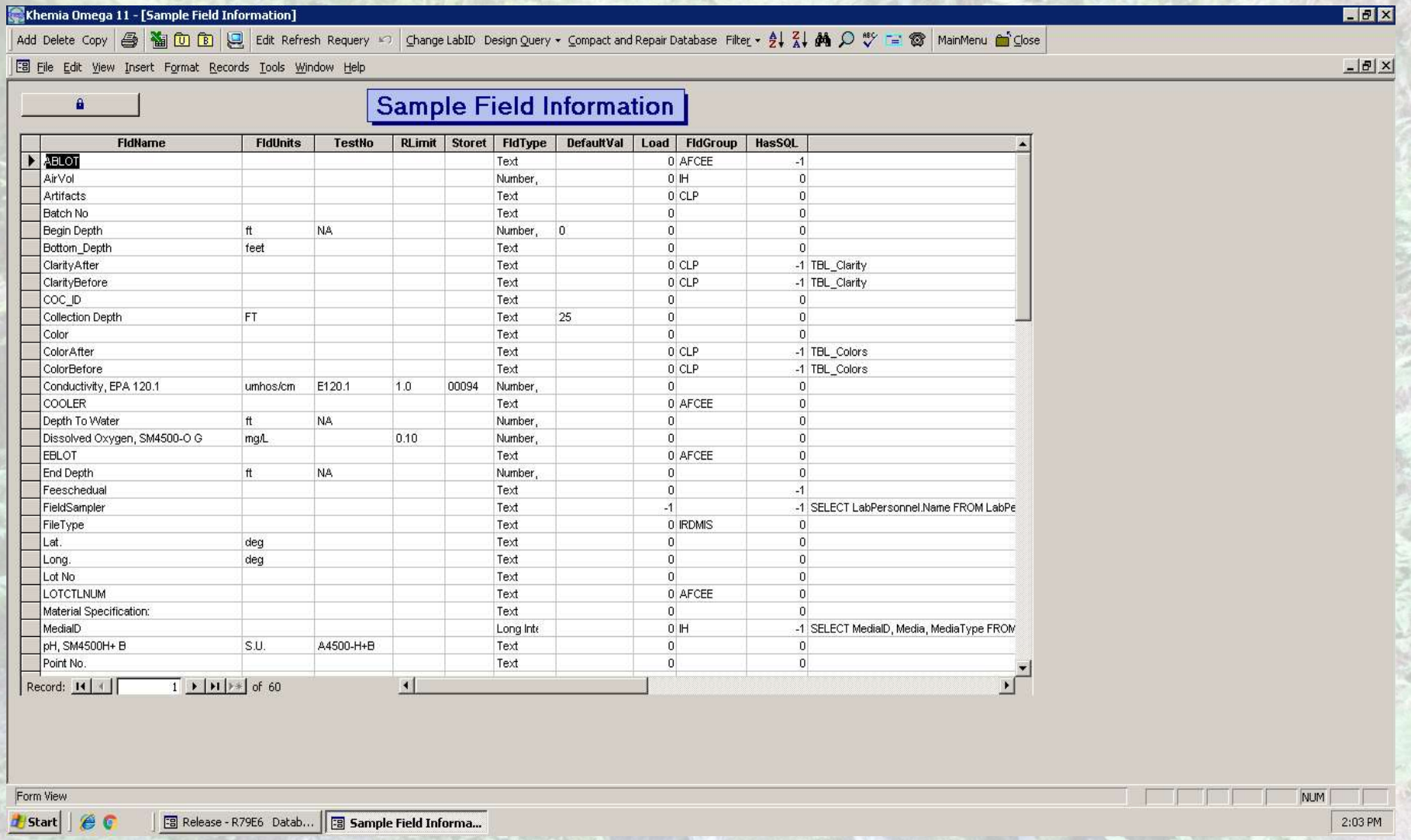
“Building” the LIMS

A LIMS is only as good as the information plugged in.

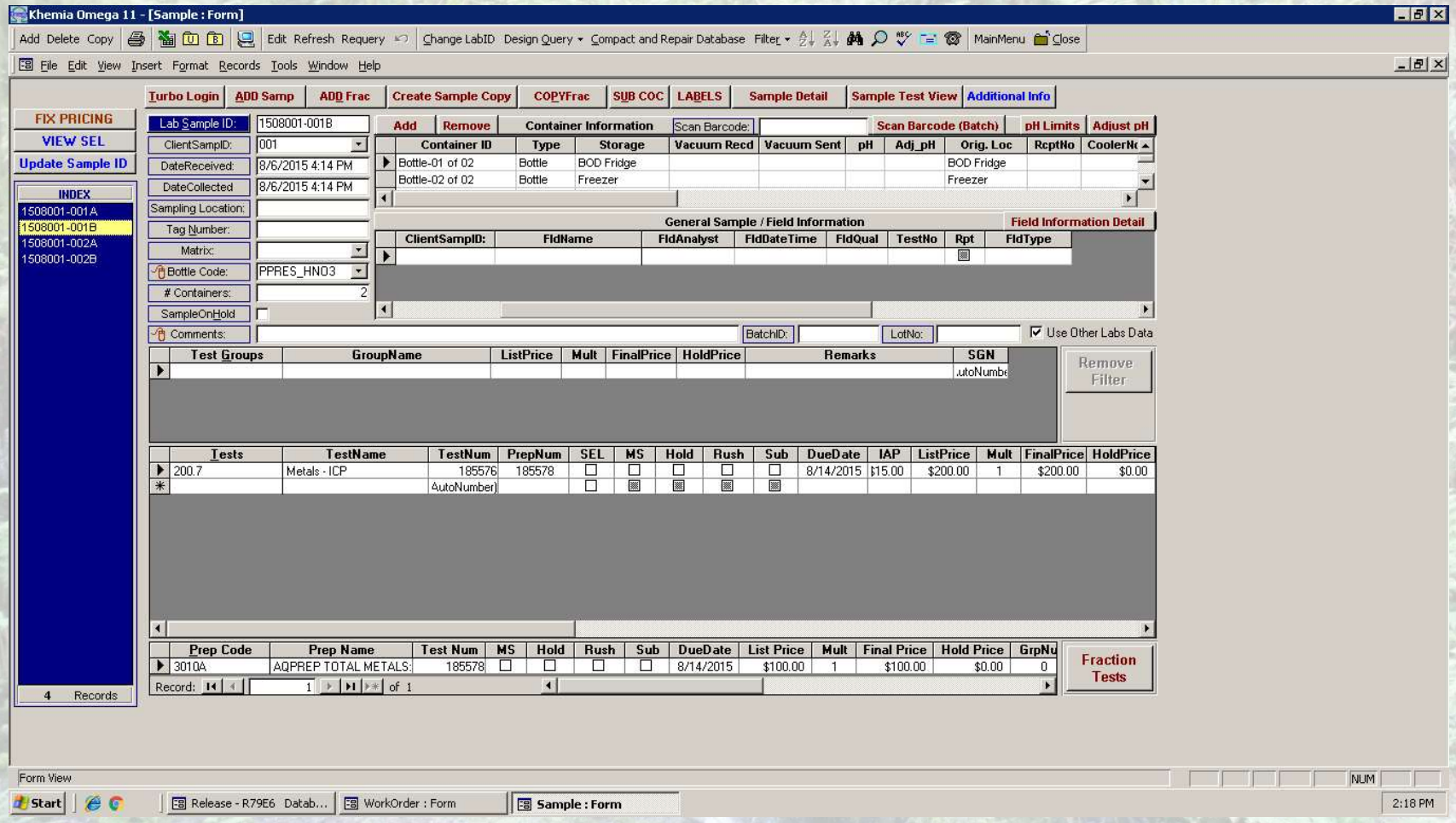
<u>ALL values need to be added or imported</u>

- ALL standards and reference materials need to be entered
- ALL regulatory criteria must be entered
- ALL clients, projects & methods must be entered, etc., etc.

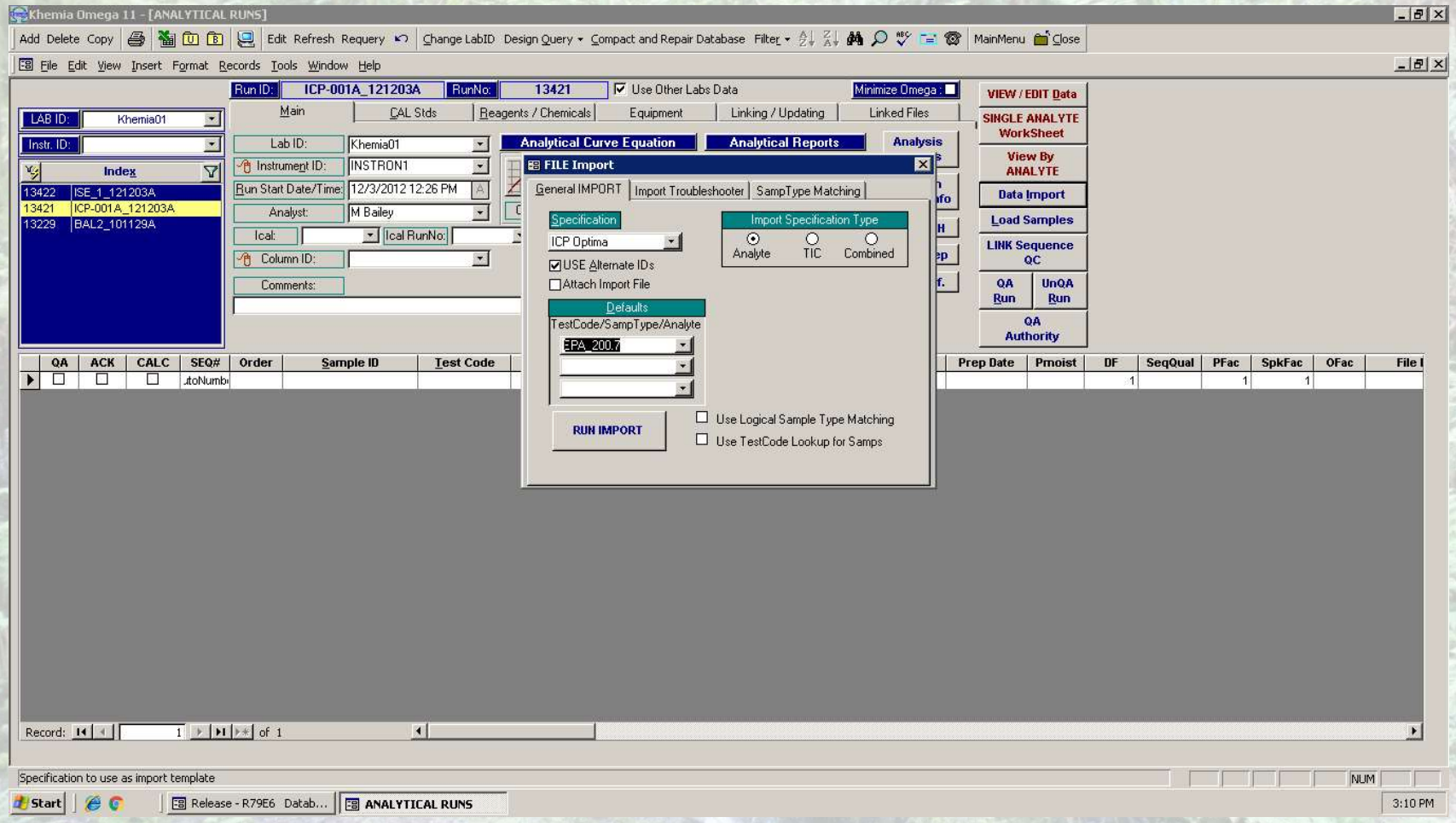
Defining the input



Recording of input



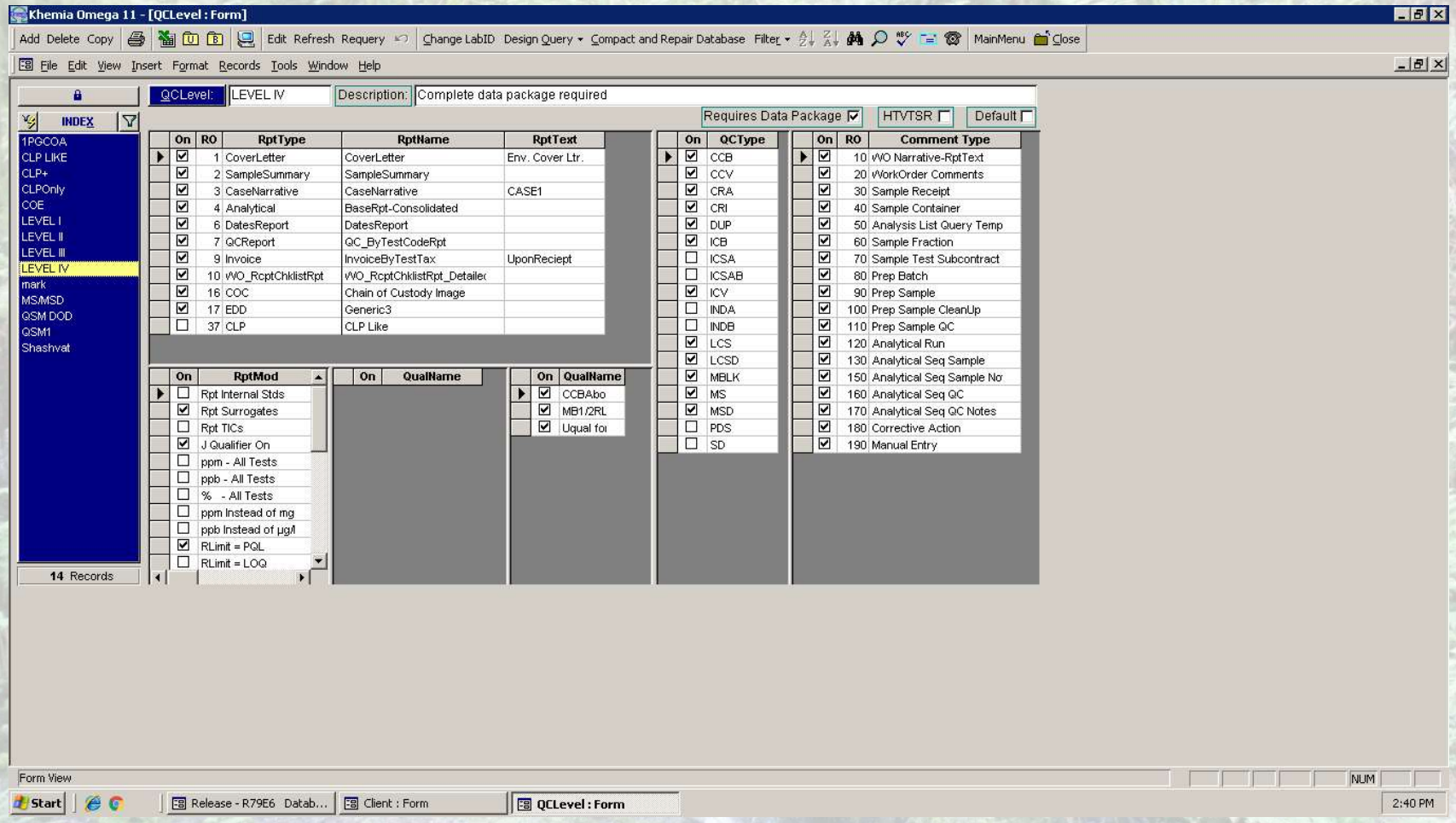
Instrument data import



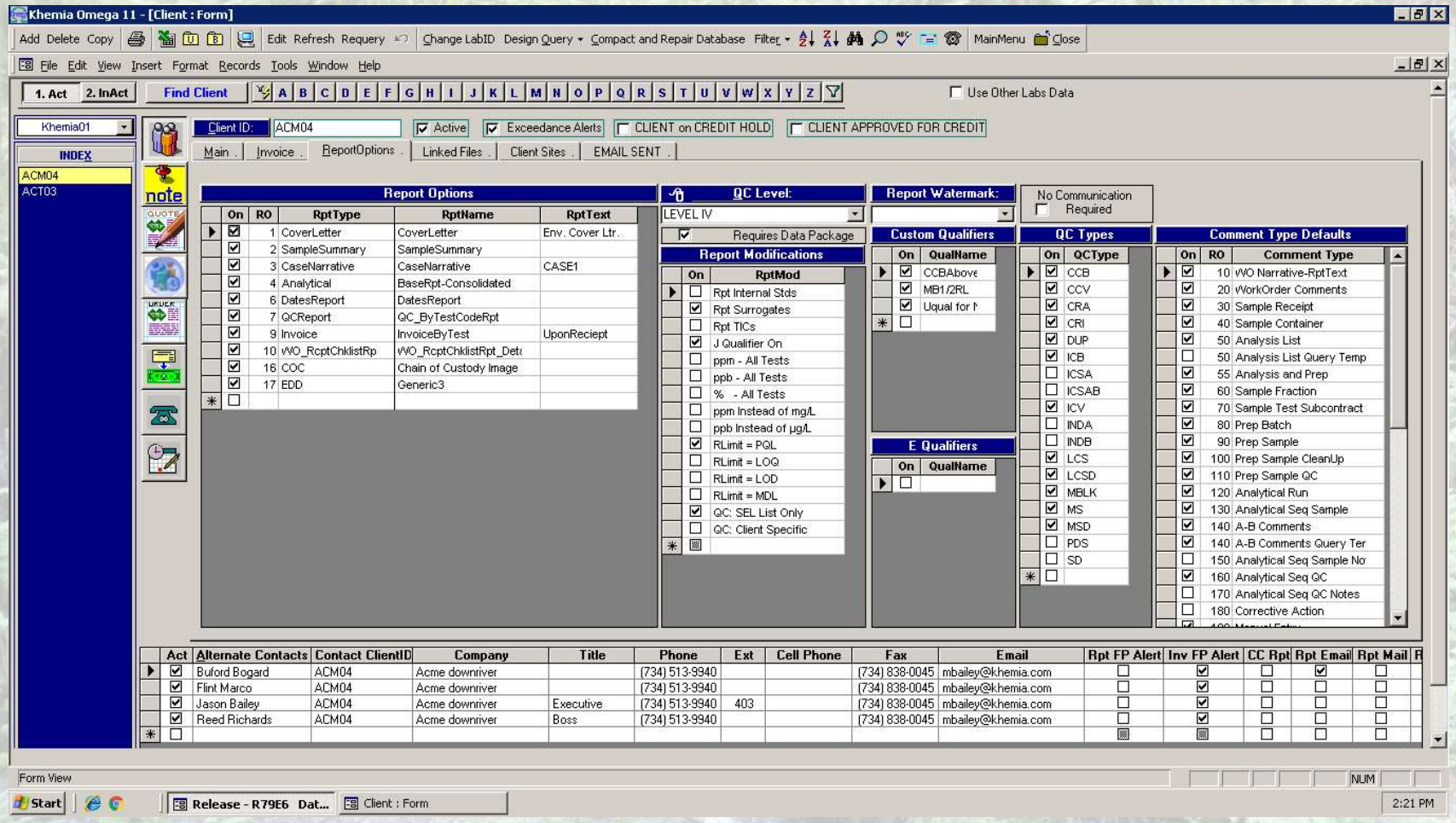
QA/QC data

Khemia Omega 11 - [Release - R79E6 Database - OmegaDev]
Add Delete Copy Edit Refresh Requery Change LabID Design Query Compact and Repair Database Filter MainMenu Close
File Edit View Insert Format Records Tools Window Help
Menu
System Administration
LIMS Configuration
Laboratory Management
Coordination
Analytical
Industrial Hygiene
Quality Assurance
Sales
Test Information
Operations
Reports
Documents and SOPs
Ad Hoc Management Reports
General Business Management
Accounting and Invoicing
Alerts
General Scheduler
Flashpoint Configuration
Custom Development
Khemia
Quality Assurance
Accreditation Bodies
Accreditation Programs
Accredited Analytes
Analytical Run RE Test Prep GALP Data
Analytical Run Seq GALP Data
Control Charting
Control Charting Types
Corrective Action Reports
Custom Qualifiers
Equals
Omega Qualifiers
QA Validation
QC Levels
QC Notes
QC Report
Training Primary Data
Training Sessions
Omega 11 LIMS
www.khemia.com
Local User Applications
Form View
NUM
Start
Release - R79E6 Datab...
Client : Form
2:42 PM

Where and how to apply QA/QC



Reporting of entered data



Weak Links

- Humans are human and still involved
- Every LIMS company has made a programming error
- Hardware/software upgrades (we all blame Microsoft sometimes!)
- Labs needs and LIMS are still evolving

THANK YOU
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