The Expanding Role of LIMS in Laboratory Quality Assurance

Charles O'Bryan
Director, Quality Management
RTI Laboratories, Inc.

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L.I.M.S.

Laboratory
Information
Management
System





Motivators for Quality Assurance

 Laboratory's Reputation, Goals and Company Philosophy

Accreditations and Certifications

Customer Expectations





Requirements are continually being placed on laboratories whether through advances in process understanding, evolving standards, user specifications or internal improvements.

Requirements are added but rarely subtracted resulting in laboratories having to implement systems for compliance.

Additional requirements necessitate changes in order to continue to operate a successful QA program.

RTI LABORATORIES

Successful QA programs will be able to

- Adequately assess and monitor the quality of laboratory data
- Efficiently review the analytical process
- Expedite the decision making process
- Maintain productivity
- Ensure adherence with all applicable standards
- Provide the end user with compliant reports





Importance needs to be placed on automating QA functions

Expanding the role of Laboratory Information Management System (LIMS) in the QA program provides

- Automation
- Central Storage
- Ability to Correctly Link the Necessary Information
- Documentation
- Traceability





Integrated Data Assessment in the LIMS

Automated System for Qualifying Data

- System Qualifiers-Built in QC evaluation functions
- Custom Qualifiers Configurable automated qualifiers
- Extended Qualifiers Extension and expansion of system qualifiers
- User Qualifiers Ability to assign additional data flags





Automated qualifiers assist in laboratory data review by allowing expedited assessment of the analytical event, providing necessary information for data acceptance/rejection and enhance the overall quality of laboratory data. Data qualifiers provide information to the user for interpretation and evaluation



of laboratory data.

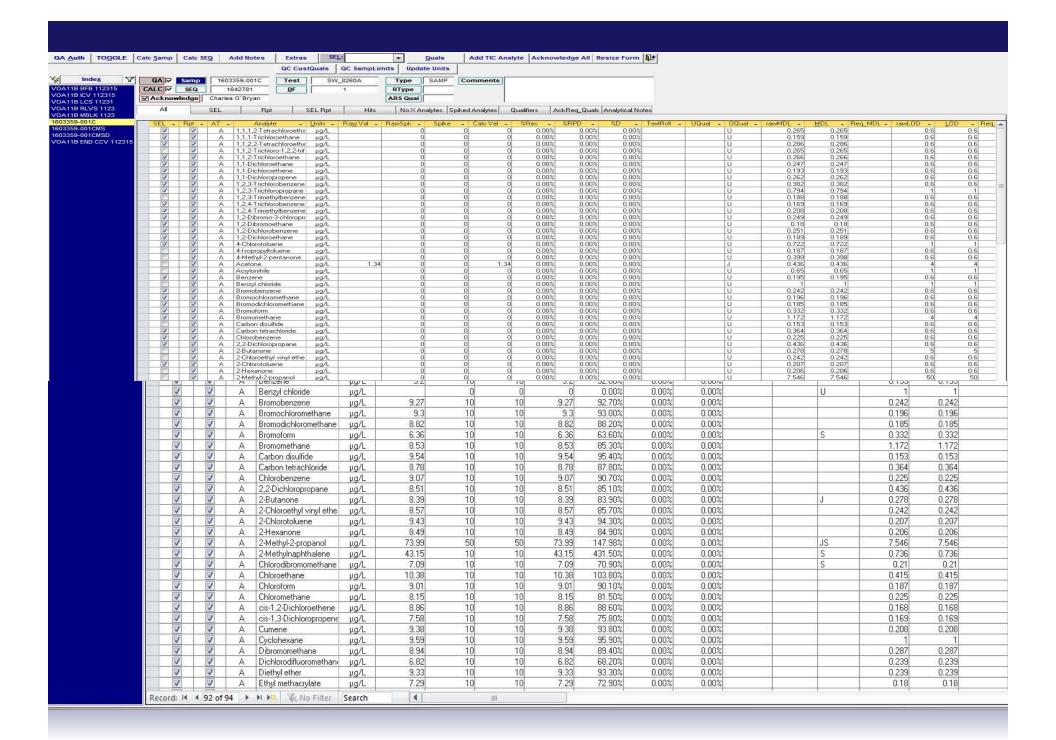


LIMS systems allow qualifier flags that can be translated into various program requirements that mandate specific flagging characters.

Qualifiers can indicate when sample results exceed a specified limit (regulatory, permit, client designated).







RTI Laboratories - Analytical Report

Original

WO#: 1603359

Client: Magisterial Environ Inc. Collection Date: 3/9/2016 7:00:00 AM

Project: Antepenult

Lab ID: 1603359-001 Matrix: Aqueous

Client Sample ID: OR6-0096

Analysis	Result	Qual	DL	LOD	LOQ	Units	DF	Date Analyzed
Molybdenum	5.0	U	1.3	5.0	10	μg/L	1	3/13/2016 1:51 PM
Nickel	20	U	16	20	100	µg/L	1	3/13/2016 1:51 PM
Potassium	200	U	100	200	400	μg/L	1	3/13/2016 1:51 PM
Selenium	30	U	23	30	40	μg/L	1	3/13/2016 1:51 PM
Silver	5.0	U	2.6	5.0	20	µg/L	1	3/13/2016 1:51 PM
Sodium	100	U	85	100	1,000	μg/L	1	3/13/2016 1:51 PM
Thallium	20	U	15	20	40	μg/L	1	3/13/2016 1:51 PM
Vanadium	20	U	9.8	20	50	μg/L	1	3/13/2016 1:51 PM
Zinc	10	U	6.8	10	100	μg/L	1	3/13/2016 1:51 PM
Volatile Organic Compounds		r	Method:	SW8260C				Analyst: AS1
1,1,1,2-Tetrachloroethane	0.60	U	0.26	0.60	1.0	μg/L	1	3/13/2016 9:37 PM
1,1,1-Trichloroethane	0.60	U	0.16	0.60	1.0	μg/L	1	3/13/2016 9:37 PM
1,1,2,2-Tetrachloroethane	0.60	U	0.29	0.60	1.0	μg/L	1	3/13/2016 9:37 PM
1,1,2-Trichloroethane	0.60	U	0.27	0.60	1.0	μg/L	1	3/13/2016 9:37 PM
1,1-Dichloroethane	0.60	U	0.25	0.60	1.0	μg/L	1	3/13/2016 9:37 PM
1,1-Dichloroethene	0.60	U	0.19	0.60	1.0	μg/L	1	3/13/2016 9:37 PM
1,1-Dichloropropene	0.60	U	0.26	0.60	1.0	μg/L	1	3/13/2016 9:37 PM
1,2,3-Trichlorobenzene	0.60	UQ	0.38	0.60	1.0	μg/L	1	3/13/2016 9:37 PM
1.2.3-Trichloropropane	1.0	IJ	0.79	1 0	5.0	ua/l	1	3/13/2016 9:37 PM

LIMS can be used to store and maintain information pertaining to the accessory information required for assessing the analytical process.

- Initial calibration data linked to the associated sample analysis
- Continuing calibration samples (ICV, CCV, CCB, Tune) included in the data set and referenced to the associated samples
- All batch QC samples associated and referenced to the samples





LIMS can be used to store and maintain information pertaining to the accessory information required for assessing the analytical process.

- Calibration and QC standards applicable to the analysis with direct access to the stock standards and certificates of analysis
- Equipment (balances, pipettes, etc.) used during the specific analytical process
- All raw data linked to the analytical results form and readily available for review







Automated systems that facilitate data evaluation are incorporated in the LIMS

Data Checker Programs

- Consolidate and display exceeding results
 - -Summarize QC data
 - -Focused assessment CCV, LCS
 - -Allow evaluation of impact on sample data





Automated systems that facilitate data evaluation are incorporated in the LIMS

Data Checker Programs

- Evaluate QC results (both Cal Data and Batch QC) against specific requirements
 - Method criteria
 - Program requirements (drinking water/wastewater)
 - Quality control specifications (DoD QSM/SW-846)
 - Project QA Plans (QAPP)





- Corrective action reports
 - Ability to associate situations requiring corrective actions to specific analytical runs, sample batches, instruments, analysts
 - Allow assessment of effectiveness
 - Identify reoccurrences
 - Create reports for submitting to requesting parties





- Traceability
 - -Chemicals, Standards and Reagents
 - -Instruments
 - -Equipment





- Control Charting
 - -Automatically generate control limits
 - -Assess method performance
 - -Trend analysis





- Automated Information Updating
 - -Readily update control limits
 - Automatically assign current
 detection limits (DL, LOD, LOQ)
 - -Easily add required QC sample types





- Analyst Training Status
 - -Maintain analyst method approval status
 - -Assign tests to approved analysts
 - Associate demonstration of capability records





- Accreditation Status Reporting
 - -Maintain multiple accreditations
 - Associate method/analyte accreditation status to the individual programs
 - Generate reports displaying accreditation status for each analyte





Thank you for your Attention to this Presentation!

Questions or Comments are Welcome!



