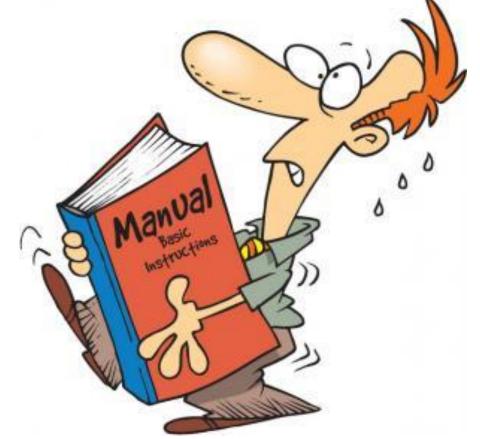
Using LIMS to Streamline Your Quality Management System (QMS)





Presented by:
Stephen Wesson, Director of Sales
Accelerated Technology Laboratories





Agenda



What is a Quality Assurance Manual?

What is a LIMS?

Outline of A Quality Assurance Manual

Sectional Review of Using LIMS as the backbone to your QAM

Laboratory Documents you can get directly from the LIMS

Review and Q & A





What is a Laboratory Quality Assurance Manual?

• A living document stating the Laboratories Policies and Procedures designed to manage quality in accordance with the requirements established by a governing Agency or Agencies.

"Say what you do! Do what you say! And Document the heck out of it!"







- Today's LIMS provide laboratories with functionality that extends well beyond – A Database for Sample Tracking, Data Entry and Reporting.
- A modern LIMS should be the backbone of the Lab's QMS, offering support for regulatory compliance like ISO 17025, NELAC and related regulations.





Sections of a Quality Assurance Manual



- 1) Title Page
- 2) Table of contents
- 3) Introduction and Scope
- 4) Organization
- 5) Management
- 6) Document control
- 7) Review of Requests
- 8) Subcontracting
- 9) Purchasing
- 10) Service to clients
- 11) Complaints
- 12) Control of Non-conformance
- 13) Improvement
- **14) Corrective Actions**

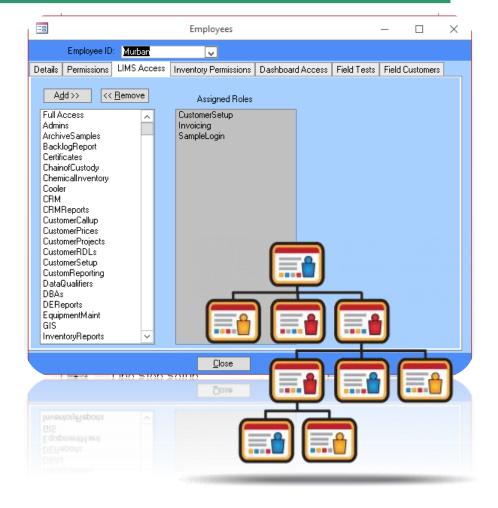
- **15) Preventive Action**
- **16) Control of Records**
- 17) Audits
- 18) Management Review
- 19) Data Integrity Investigations
- 20) Personnel
- 21) Accommodations and Environmental Conditions
- 22) Methods and Method validation
- 23) Calibration Requirements
- 24) Measurement Traceability
- 25) Collection of Samples
- 26) Handling Samples and Test Items
- 27) Quality Assurance for Testing
- 28) Reporting and Results



^{*} TNI 2016 Quality Manual Template

4 – Organization & 20 - Personnel

Specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities











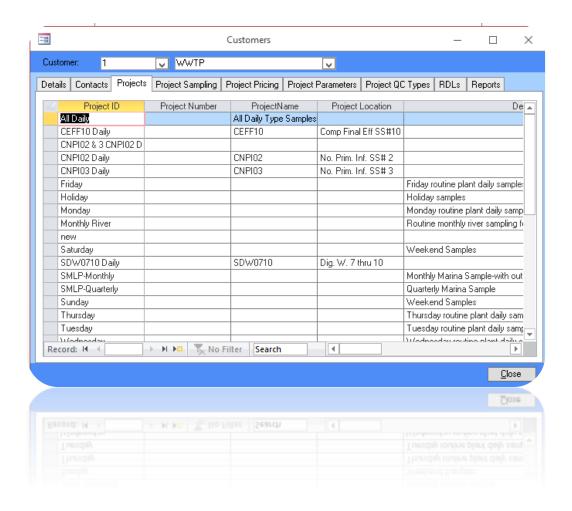
• Ensure that all documents are approved, reviewed, with current versions identified. "Controlled Documents"

Drag	g a column header here to group by that colum	n.							
	Name	- □ Method Reference	∇ → Version	→ Activated Date	- □ Retired Date	- □ Category	- □ Type	- Method Identifier	-Þ Aliquot Containe -Þ
M		■ EPA		=	=				
	TKN (Subcontracted)	EPA 351.2_108585 TKN (Subcontracted)		04/10/2018					250 mL Plastic
	MSD-Ammonia Salicylate rev. 2	EPA 350.1_8347 MSD-Ammonia Salicylate rev. 2		05/29/2016					250mL Plastic TN
	MS-Ammonia Salicylate rev. 2	EPA 350.1_8343 MS-Ammonia Salicylate rev. 2		05/29/2016					250mL Plastic TN
	FR/RE-Ammonia Salicylate rev. 2	EPA 350.1_5855 FR/RE-Ammonia Salicylate rev. 2		05/29/2016					250mL Plastic TN
	xxx Salicylate	EPA 350.1_5315 xxx Salicylate		05/29/2016					250mL Plastic TN
	Ammonia, 350.1	EPA 350.1	20th Edition	01/01/2011	09/29/2012	Wet	Spectrophotometry		250 mL Plastic
	Cyanide by 335.4(SC)	EPA 335.4_19669 Cyanide by 335.4(SC)		05/29/2016					250mL Plastic (se
	Chlorine Residual	EPA 334, Chlorine Residual		01/01/2011					Product Packagin
	Bromide	EPA 320.1_61 Bromide		01/01/2011		Wet	Titrimetry		Plastic Jar
	Dionex Scan	EPA 300.7_107568 Dionex Scan		01/25/2018					250 mL Plastic
٠	Anions	EPA 300.0_258 Anions	2.1	01/01/2013		General Analysis	IC		Plastic Bottle
	MSD-Sulfate IC	EPA 300.0_14480 MSD-Sulfate IC		05/29/2016					250mL Plastic
	MS-Sulfate IC	EPA 300.0_14476 MS-Sulfate IC		05/29/2016					250mL Plastic
	Sulfate IC	EPA 300.0_14459 Sulfate IC		05/29/2016					250mL Plastic
	Nitrate and Nitrite (NOx), TKN, TN	EPA 30.0 & STM 4500N		12/03/2018					125mL Plastic
	MSD-Mercury AA Cold Vapor Ma rev. 2	EPA 245.1_6134 MSD-Mercury AA Cold Vapor Ma rev. 2		05/29/2016					500mL Plastic
	MS-Mercury AA Cold Vapor Ma rev. 2	EPA 245.1_6128 MS-Mercury AA Cold Vapor Ma rev. 2		05/29/2016					500mL Plastic
	FR/RE-Mercury AA Cold Vapor Ma rev. 2	EPA 245.1_5943 FR/RE-Mercury AA Cold Vapor Ma rev. 2		05/29/2016					500mL Plastic
	Mercury AA Cold Vapor Manual	EPA 245.1_5309 Mercury AA Cold Vapor Manual		05/29/2016					500mL Plastic
	CR6 (218.6)	EPA 218.6_299 CR6 (218.6)		12/19/2013					Plastic Bag





7 - Review of Requests, Tenders & Contracts

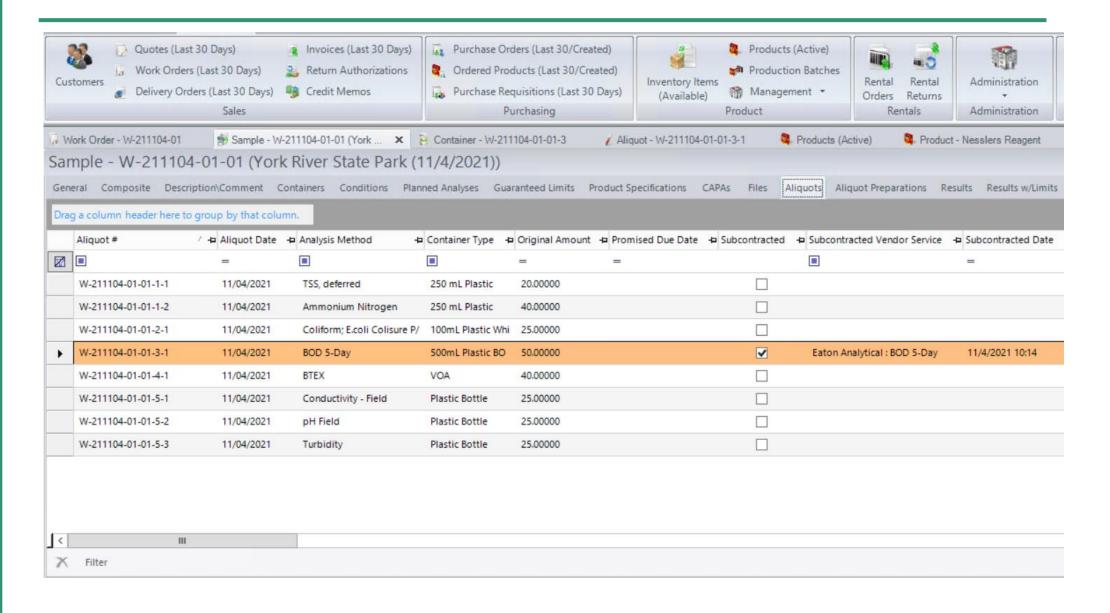


Ensure that requirements of requests, tenders and contracts are adequately defined, documented and understood.















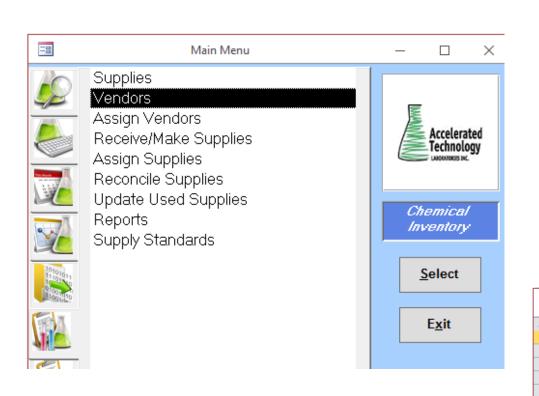
Delivery Orders (Last 30) Sales	ys) 2. Return Authorization Days) 9 Credit Memos		Inventory It	ems Production Batches	Rental Rental Orders Returns Rentals	Administration Administration	
& Vendor - Eaton Analytic	al X Vendor Service - Eato	on Analytical : BO 😺 Work (Orders (Last 30 Days)	Aliquots (Last 30 Days)	Work Order - W-21110	04-01 🙀 San	nple - V
- Eaton Analytical							
Eaton Analytical			Ac	count Number			
(626) 386-1100 ✓ Active ucts Vendor Services Vend	or Facilities Addresses Conta	ncts Purchase Orders Vendor Ser	We	eb			
nn header here to group by th	at column.						
nn header here to group by th		→ Description	ь				
		⊅ Description	40				
→ Service Co	ode - Price		-D				
→ Service Co	ode		40				
Analysis, EPA 200.8 ICP-01	ode → Price = 9.87		40				
	Eaton Analytical Eaton Analytical (626) 386-1100 Active	Eaton Analytical Eaton Analytical (626) 386-1100 Active	Eaton Analytical Eaton Analytical (626) 386-1100 ✓ Active	Eaton Analytical Ac (626) 386-1100 En We Active	Eaton Analytical Account Number (626) 386-1100 Email Web	Eaton Analytical Account Number (626) 386-1100 Email Web	Eaton Analytical Eaton Analytical (626) 386-1100 Email Web

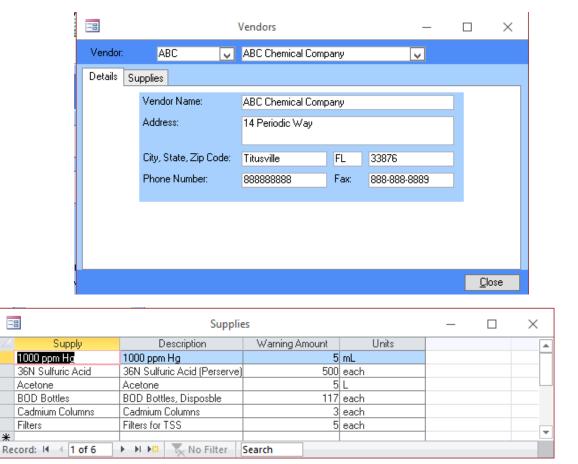




9 – Purchasing Services & Supplies

Approval of Suppliers and a documented procedure for tracking supplies and quality records.

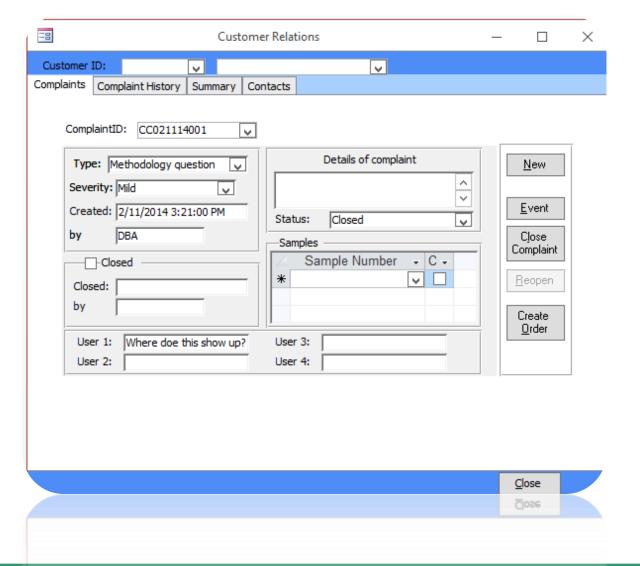








The laboratory shall have a documented process to receive, evaluate and make decisions on complaints.



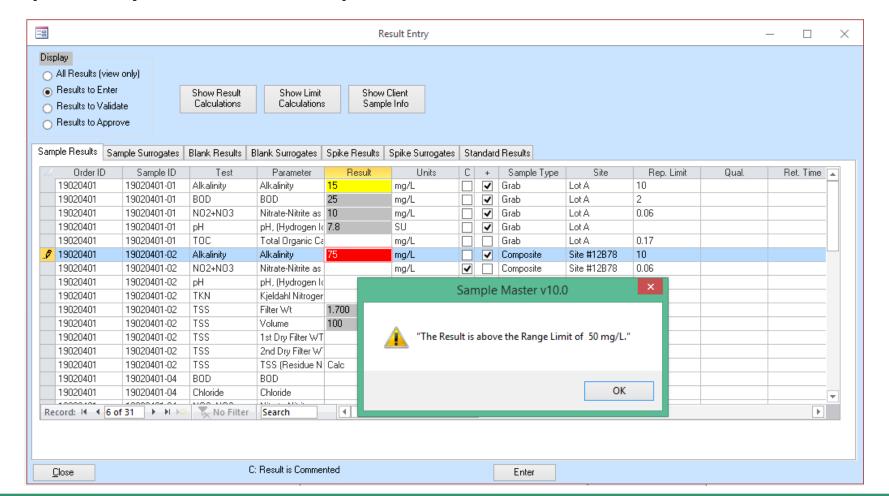






12 – Control of Non-conforming Work

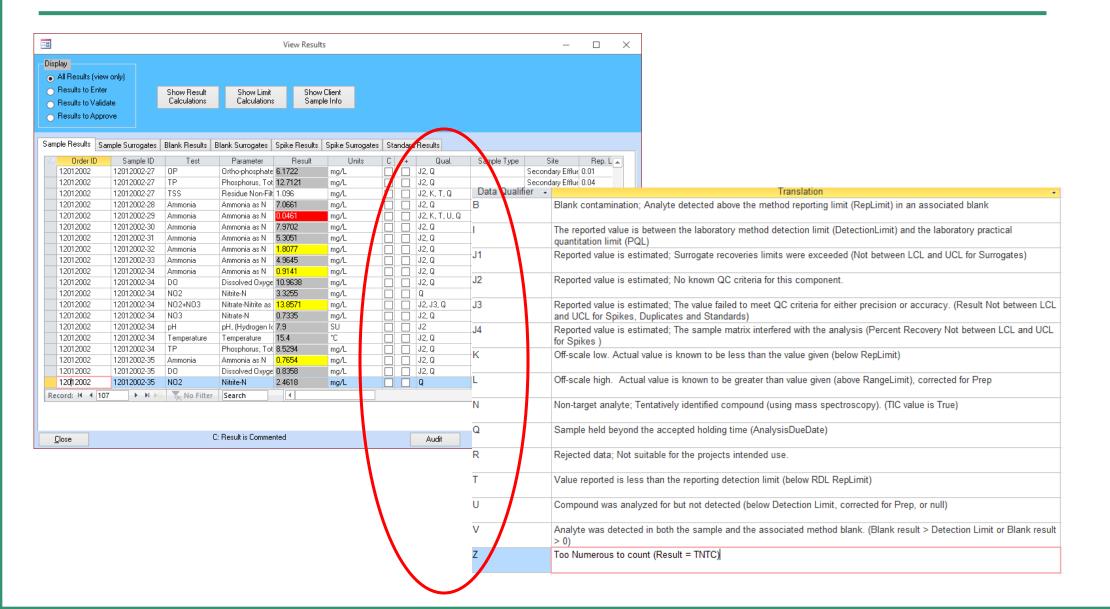
Ensure that nonconforming test and calibration results are adequately followed up, and that corrections are initiated.













13/14/15 – Improvement, Corrective & Preventative Actions



Corrective Actions - (CAPA)

a) React to nonconformity (*Investigate Incident*)



- c) Implement action (Action Plan)
- d) Review the effectiveness (resolution)
- e) Make changes to management system







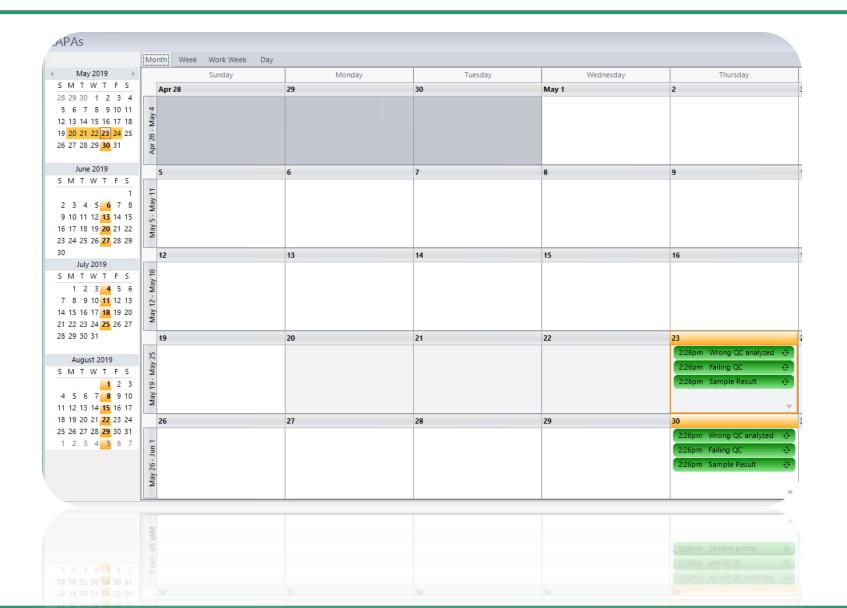
CAPA creation, evaluation, Action and Resolution

Corrective along with preventive actions can easily be managed, and automated alerts can be sent out to key individuals to ensure effective and timely management of any open issues.













16 - Control of Records

 Records allow for the historical reconstruction of laboratory activities related to sample-handling and analysis and may include:

Sample information
Sample Receipt conditions
Storage information
Internal Chain of Custody
Sample Prep. Information
Raw data
Hard copy data
Dates/times for all steps
Instrument ID
Instrument calibration
Analysts

Analyst training records
Standard traceability
Inventory traceability
Temperature Records
QC records
Method Specifications
Client specifications
Proficiency results
Records of DOCs
SOPS used
Review sign offs

Audit Trails
Audit records
CAPA Records
Data Calculations
Final results
Final reports





16 - Control of Records - Legal Chain of Custody

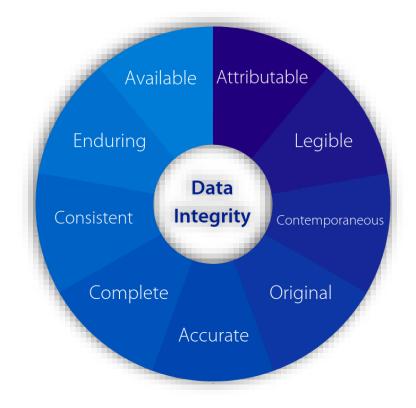
		С	HAIN OF	CUSTO	DY RI	ECC	ORE)								
CLIENT NAME / ADDRESS: McGrains College Drive West End NC 27376			Total # of sample containers Permit Number	Samplers Ini		II Sample omment	_	gerated?:	Y N _							
			U SA	I certify that these at this time.	e samples are rep	presentati	ive of the n	normal daily fo	w from this facility;	and that w	e are in normal operation					
I'we certify that the samples below have not been out of	our custo	dyuntil relin	nquished													
SAMPLER(S) SIGNATURE: Set Date End Date		ample		SIGNATURE	Container				Sample	Date:	Time: Blanks					
Set Time End Time Sample ID - Site ID	+	Wa	ste EPA 200.8 - ICP-	Method MS Total	Type 1/2 Gallon		to pH < 2			С	hain of Custo	dy Recor	d and Ana	ysis Request For	m	
1:23 PM 1/1/1900 1:23-52 PM		War	iter		Plastic (acid preserved)		$\overline{}$	40	ATL		ccelerated Technology Labora 496 Holly Grove School		Work Order	Lake Lure		
Relinquished by: (Signature)	Date:	Time:	Received by: (Signature)		Date:	Time:	Trip B	SEVONO L	ABORATORY INFORMATION MANAGET	MENT	West End, NC 27376		Requester: Project:	Weekly - Weekly Monitoring	Fax: Email:	
Relinquished by: (Signature)	Date:	Time:	Received by: (Signature)		Date:	Time:	Trip B	LIMS San	•		Sample #	Collection Date Time	on Information e Collector	Analysis Methods	Container	Recieved
Relinquished by: (Signature)	Date:	Time:	Received by: (Signature)		Date:	Time:	Trip B	W-211028	8-02-01		Sample Effluent (009) (10/28/2021)			zzother name pH Temperature - Field Alkalinity	W-211028-02-01-1 W-211028-02-01-1 W-211028-02-01-1 W-211028-02-01-1	
														Ammonia, 350.1 ICP Metals Anions	W-211028-02-01-1 W-211028-02-01-1 W-211028-02-01-1	
								W-211028	8-02-02		Sample Influent (008) (10/28/2021)			zzother name pH Temperature - Field	W-211028-02-02-1 W-211028-02-02-1 W-211028-02-02-1	
														Alkalinity Ammonia, 350.1 ICP Metals	W-211028-02-02-1 W-211028-02-02-1 W-211028-02-02-1	
														Anions	W-211028-02-02-1	
								[Relinquished By:	Customer	r to sign & date below Date/Time:	Accepte	ed By:	Date/Time:	T	
									Relinquished By:		Date/Time:	Accepte	ed By:	Date/Time:	Total Samples: 2 Priority	
									Relinquished By:		Date/Time:	Accepte	ad By:	Date/Time:	Normal 10.00 day	
									Relinquished By:		Date/Time:	Accepte	ed By:	Date/Time:	Date Results Requested	
									Seal/Locked By:		Date/Time:	Senied	Lock Opened By:	Date/Time:	1	



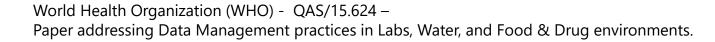


19 - Data Integrity

For data to be acceptable, it should meet certain fundamental elements of quality whether collected or recorded electronically or on paper (1999 FDA Guidance.)



 As companies move to more automated laboratories with computerized systems, most of the fundamental ALCOA+ principles are satisfied by an automatically generated audit trail providing the who, the when, accuracy, originality, and legibility, all on the system with the raw data.

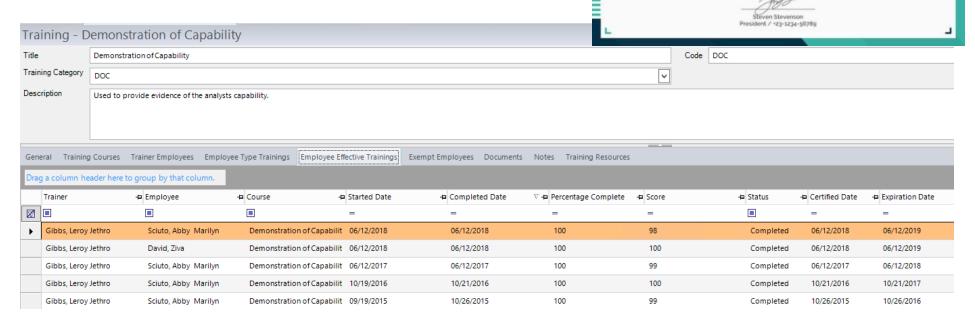






20 - Personnel (Employee Training)

- A. SOP Review
- B. Work with trained Analyst
- C. Demonstration of Capability
- D. Perform PE Sample



REYNOLDTRENDS 711-2880 Nulla St. Mankato Mississippi 98522

CERTIFICATE OF TRAINING
This certificate is hereby bestowed upon

CHARLES REYNOLDS

Has successfully completed the course and has achieved the required level of competence in IName of the Training!

Awarded this IMONTH DATE YEAR!





NEMC

- The laboratory has procedures for the use, maintenance, handling and storage of equipment and they are readily available to laboratory personnel.
- There is a lot of ground to cover here:

Laboratory Equipment Lists
Laboratory Instrument Lists
Support Equipment Calibration
Support Equipment Maintenance
Calibration Acceptance Criteria
Routine Maintenance Schedules

Routine Maintenance Records Vendor Maintenance Records Instrument Calibrations Temperature Monitoring





NEMC

The laboratory has procedures for the use, maintenance, handling and storage of equipment and they are readily available to laboratory

personnel



1 .	(L .											
Instruments	s 🤌 Instru ent - 12-30		- 12-305 ×									
)										
Name	Agilent 1200							Instrument Type	LC/MS			
Asset#	12-305							Facility	Main Lab			
Description	providing high	est an	alysis speed and shorte	est cycle times without	sed on the new Agilent 1200 S compromising robustness ar nt 1200 Series LC/UV/MS syste	sample capacity	Prep Duration Analysis Duration					
Run Capacity		l mult	ti ucar laboratorias loa	kina for high canacity	and walk un canabilities. Eurtl	dular and on on or	, maryone Dardmen	Results Are Corrected For Dilution				
Export Path												
	✓ Available							State	Available			
	hods Preparation	_	ethods QC Control Li		Limits Calibration Mai	intenance User D	efined Documen	ts Resources Res	ults QC Results			
			Maintenance Date ▽	Maintenance Type	→ Maintenance Contractor		. → Notes		-p			
Scheduled Ass	sset Maintenance		7]=			-					
		→	04/17/2017	Annual Service	Main Lab	04/17/2018						
			04/18/2016	Annual Service	Robert Instruments							
		10/31/2015 Routine Robert Instruments Cooling to					Cooling fan v	n was bad. Replaced with a new one.				
			Filter									
		Shov	ving 3 item(s)									
Logged in as TII	TANWATLUSER	on TI	TANW:8000 - SessionId	d: 22114								



23 – Calibration Requirements



Calibrations Expiring within 1 Month

Report Date: Thursday, November 4, 2021

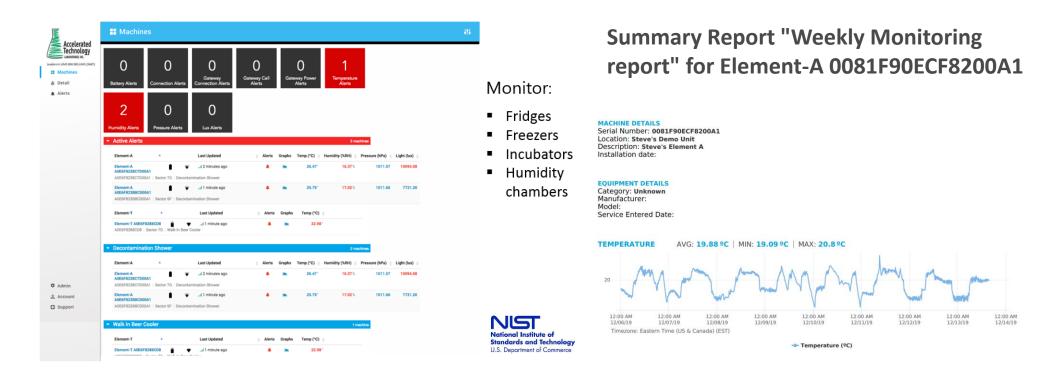
Expiration Date	Calibration Description	Instrument	Cert. A gency	Matrix	Test	Method
11/22/2020	Annual Sewice	ICP	In House	Waste Water	EC_7 metals	EPA 200.7
11/22/2020	Annual Sewice	ICP	In House	Waste Water	ICP-OES Dissolved	EPA 200.7
9/3/2020	Annual Sewice	ICP	In House	Waste Water	ICP-OES Total	EPA 200.7
9/3/2020	Annual Service	ICP	In House	Waste Water	Mg (sol)	EPA 200.7
11/22/2020	Annual Sewice	ICP	In House	Waste Water	Potassium	EPA 200.7
11/22/2020	Annual Service	ICP	In House	Waste Water	Reno Total Metals	EPA 200.7
11/22/2020	Annual Service	ICP	In House	Waste Water	Sodium	EPA 200.7
11/22/2020	Annual Service	ICP	In House	WW Sludge	ICP-OES Total	EPA 200.7
9/3/2020	Annual Sewice	ICP-MS	In House	Ground Water	ICP-MS Dissolved	EPA 200.8
9/3/2020	Annual Service	ICP-MS	In House	Ground Water	ICP-MS Total	EPA 200.8
11/22/2020	Annual Service	ICP-MS	In House	Waste Water	Antimony	EPA 200.8
11/22/2020	Annual Service	ICP-MS	In House	Waste Water	Arsenic	EPA 200.8
11/22/2020	Annual Service	ICP-MS	In House	Waste Water	Barlum	EPA 200.8
11/22/2020	Annual Service	ICP-MS	In House	Waste Water	Beryllum	EPA 200.8
11/22/2020	Annual Service	ICP-MS	In House	Waste Water	Cadmium	EPA 200.8
11/22/2020	Annual Service	ICP-MS	In House	Waste Water	Chromium	EPA 200.8
11/22/2020	Annual Sewice	ICP-MS	In House	Waste Water	Cobat	EPA 200.8







Monitor Plus – Remote Temperature Monitoring

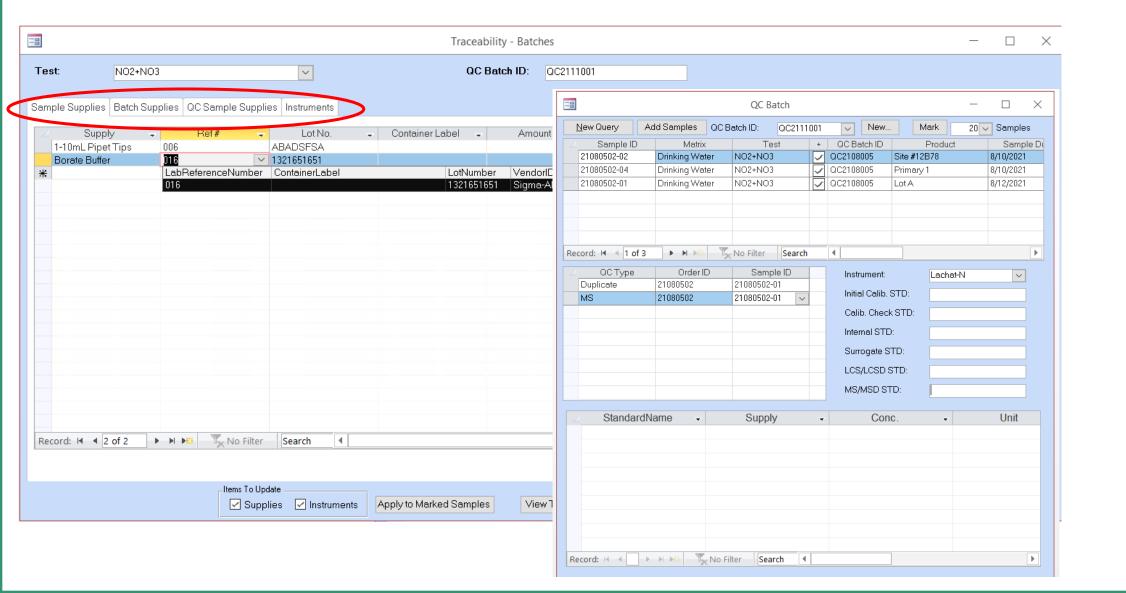


Replacement of mundane tasks – Temperature Monitoring daily recording of incubators, fridges and freezers





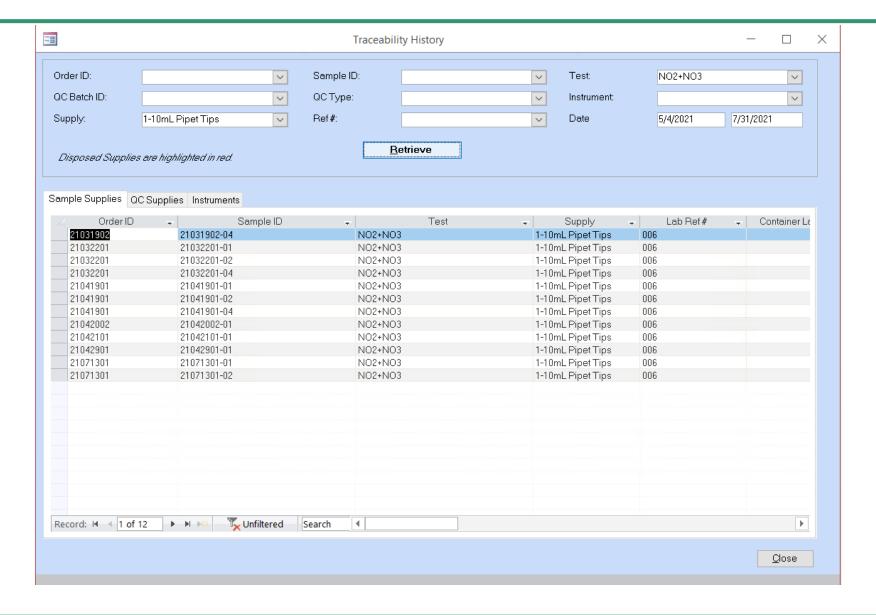
24 - Measurement Traceability







24 – Measurement Traceability



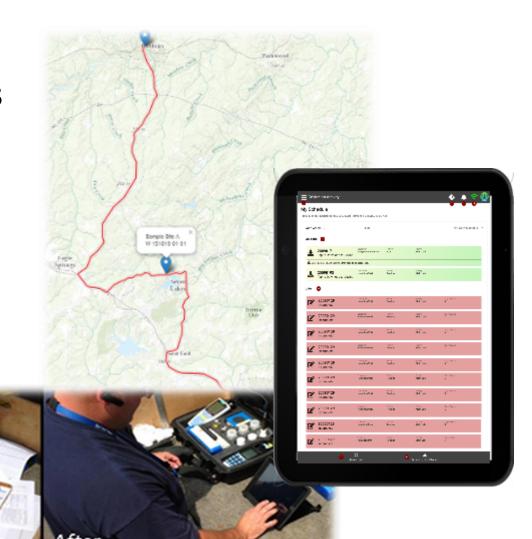




NEMC

Retain Records including:

- Reference to sampling methods
- Date, time and conditions of sampling
- Person collecting the samples
- Location information/site identification
- Field Results
- Comments







Order ID: 17112801

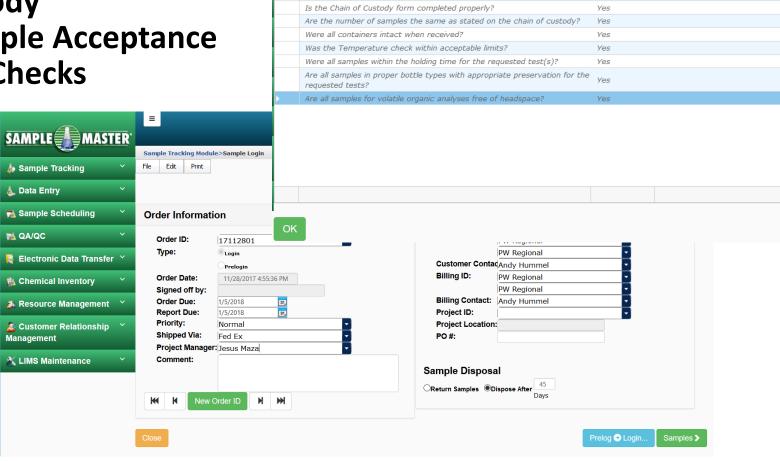
Answer

Yes

26 - Handling Samples and Test Items

Lab shall have Procedures to track:

- Transportation
- Chain of Custody
- Receipt Sample Acceptance
- Preservation Checks
- Subsampling
- Storage
- Retention
- Disposal
- Comments



Sample Login>Sample Conditions

Were samples submitted in an ice chest?

Are samples submitted with a Chain of Custody form?

Ouestion







		Log	in Report
Customer Name: McGrains		Order II): 21101901
Purchase Order:		Order Date	e: 10/19/2021
Project ID:			
Comment:			
Sample #: 21101901-01 Customer Sample #:	SI	b:	
Rec√d: ☑ Collector:	Date Collected:	10/19/21 8:56	AM
Quantity: 1 Matrix: Air	Date Received:	10/19/21 8:56	AM
Comment:			
Test Group	Method	Due Date	Priority
Asb PCM Air - 7400	NIOSH7400	11/2/2021	
Sample #: 21101901-02 Customer Sample #:	SI	b:	
Rec√d: ☑ Collector:	Date Collected:	10/19/21 8:56	AM
Quantity: 1 Matrix: Soll	Date Received:	10/19/21 8:56	AM
Comment:			
Test Group	Method	Due Date	Priority
Asb PLM Soll - CARB 435	CARB 435 - Asbestos In Aggregate	11/2/2021	
Asb PLM Soil - EPA Region	EPA Region 1 PLM Screening - Qual		
Asb PLM Soil - Visual Est	EPA 600/R-93/116	11/2/2021	
Asb TEM Soll - CARB 435	CARB 435 - Asbestos In Aggregate	11/2/2021	
Asb TEM Soll - Sleve	Sieve - TEM Confirm	11/2/2021	

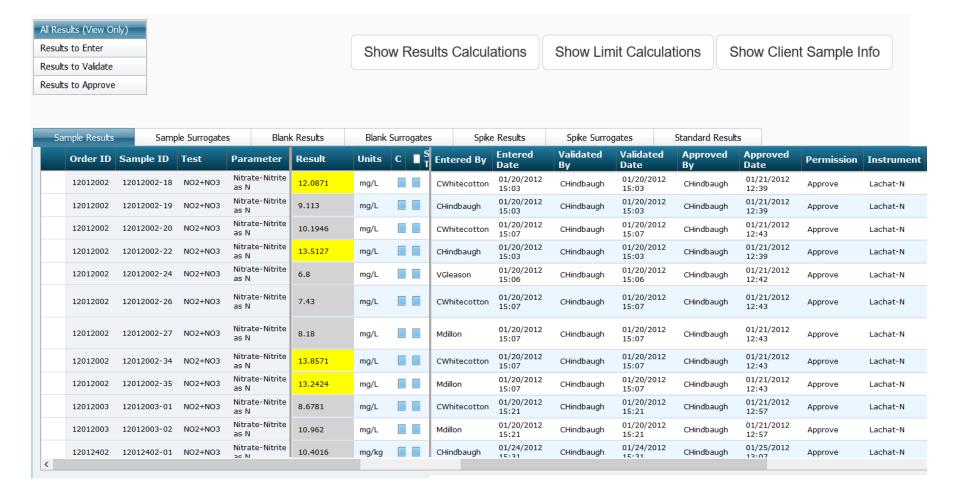
Customer Name: McGrains	Order ID:	21101901
Purchase Order:	Order Date:	10/19/2021
Project ID:		
Comment:		
SAMPLE CONDITION RECORD		
Were samples submitted in an ice chest?	Yes	
Are samples submitted with a Chain of Custody form?	Yes	
Is the Chain of Custody form completed properly?	Yes	
Are the number of samples the same as stated on the chain of custody?	Yes	
Were all containers intact when received?	Yes	
Was the Temperature check within acceptable limits?	Yes	
Were all samples within the holding time for the requested test(s)?	Yes	
Are all samples in proper bottle types with appropriate preservation for the requested	tests Yes	
Are all samples for volatile organic analyses free of headspace?	N/A	





NEMC

Data Review







27 – Quality Assurance for Testing

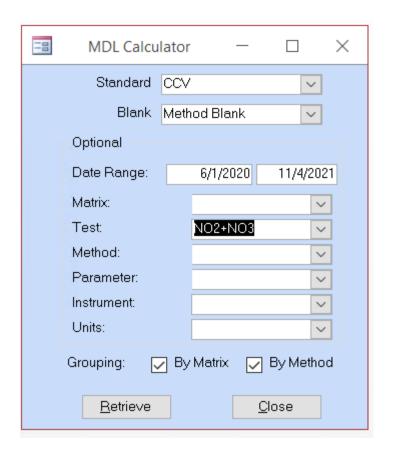


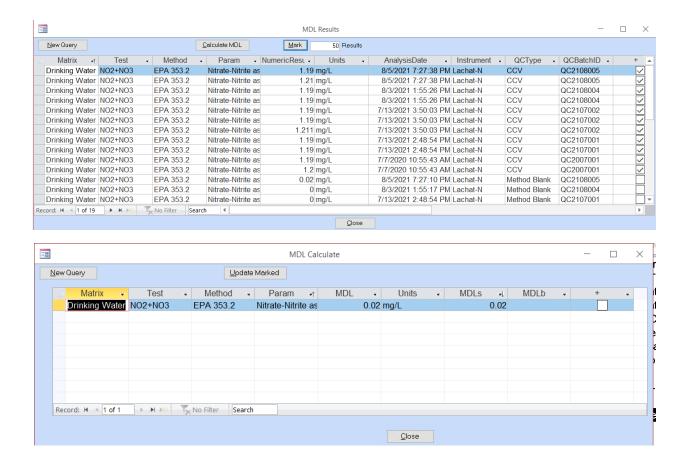




27 – Quality Assurance for Testing

MDL Calculator







28 – Reporting and Results



Reports should include:

- Title
- Names and Address
- Identification of method
- Date, time of activities
- Results with appropriate units of measure
- Specifications where appropriate
- Deviations & Exclusions (Qualifiers)
- Identification of Authorizing person

Accelerated E-technology

Main Lab

496 Holly Grove School Rd. West End, NO

Analytical Results Report

Client: Jordan Lake
Attn: Brothers, Misty
Lynne (Vice
President,
Operations)
Address: 496 Holly

Work Order Number: W-190923-01 Project: Inital Evaluation

Grove School Rd West End, NC 27376

Id Sample ID Laboratory Sample ID Matrix Collection Date/Time Receive Date/Til tis Park W-198923-01-01 Water 8/20/2019 0000 09/23/2019 1222

 Sample Number
 Field Sample ID
 Work Order Number

 W-190923-01-01
 Curtis Park
 W-190923-01

 Parameter
 Analytical Method
 Result
 Qualifier
 Units
 Dilution
 Analysis Batch
 Analysis Date
 Analysis Date

 Ammonia
 Ammonia
 450D-NHS
 2.34
 ppm
 1.0000
 AB-190923-03
 09/20/2019 1220
 Chandler, Scott (NHS)

 Sample Number
 Field Sample ID

 W-190923-01-02
 Gateway Park
 W-19

 Parameter
 Analytical Method
 Result
 Qualifier
 Units
 Dilution
 Analysis Batch
 Analysis Date
 Analyst

 Ammonia
 Ammonia
 4500-NH3
 Not
 I, U
 ppm
 1,0000
 AB-190923-03
 09/20/2019 1220
 Chandler, Soot

 (NH3)
 (NH3)
 Obeteded
 Not
 I, W
 Ppm
 1,0000
 AB-190923-03
 09/20/2019 1220
 Chandler, Soot

eport. The entire report was reviewed and

The results listed in this Laboratory Report pertain only contained in this report were performed in accordance are reported on a wet weight basis unless otherwise no intended for the sole use of XYZ Laboratory and it's cli-

NELAC Certification

EDDs – Electronic Data Deliverables

The results listed in this Laboratory Report pertain only to the samples tested in the laboratory. The analyses contained in this report were performed in accordance with the applicable certifications an order. All poil analyses are reported on a wet weight basis unless otherwise noted in the report. This laboratory report is confidential and intended for the selle used XVIZ Laboratority and its client. This report stails not be reproduced, except in full, without written permission from XVIZ Laboratories. The Chain of Custody is included and is an integral part of this report. The entire report was reviewed and approved for release.

NELAC Certification #:

Approved



Laboratory Documents that come from the LIMS

NEMC

- Quotes
- Bottle Orders
- Labels
- Chain of Custody
- Sample Log-in Report
- Backlogs
- Worklists
- Prep. Logbooks and/or Sheets
- QC Batch Summary
- Results reports
- Certificates of Analysis

- Invoices
- Production Reports
- Control Charts
- Sample Inventory
- Disposal reports
- Expiring Training records
- Expiring Maintenance
- Complaints Reports



Laboratory Documents that come from the LIMS

NEMC

- Analysis Due Today
- Auto Report Status
- Backlog
- Barcoded Label Report
- Bottle Order
- Calibrations Expiring
- Certificates Expiring
- Chain of Custody Internal
- Chain of Custody
- CRM Customer History
- CRM Summary by Type
- CRM Open Complaints by Severity
- CRM Executive Summary
- Disposal Report
- Invoice

- Invoice Sales Tax
- Orders
- Orders Summary
- PreLog Detail
- PreLog Order Details
- PreLog Summary
- Prep Batch
- Prep Due Today
- Production
- QC Batch
- QC Batch Bench Sheet
- QC Batch Run Sequence
- QC Control Chart



Laboratory Documents that come from the LIMS

NEMC

- QC Control Charts Data
- Quote
- Results Audit Trail
- Run Sequence Bench Sheet
- Sample Labels
- Sample Routing Sheet
- Sample Conditions
- Supply Below Warning Limit
- Supply Expiring
- Trend Analysis Chart
- Test Due Today
- Turn Around Time (TAT)
- Worklist
- Worklist Bench Sheet
- Reports Used from Result Reporting:
- COA Basic

- COA Basic QC
- COA Chemistry
- COA By Parameter
- COA By Parameter with QC
- COA By Parameter with Surrogate
- COA By Parameter with Surrogate and QC
- COA By Sample
- COA By Sample with QC
- COA By Sample with Surrogate
- COA By Sample with Surrogate and QC
- Results by Order ID
- Results By Order ID With QC
- Results By Order ID With Surrogates
- Results by Parameter
- Results by Sample Number
- Results by Test



Using LIMS to Streamline Your Quality Management System (QMS)





So, which is easier a LIMS as the backbone to your Quality Management System or all of those Logbooks, Spreadsheets, worksheets, and hand written records that you currently have?



THANK YOU!



Stephen Wesson, Director of Sales **Accelerated Technology Laboratories**

Email: <u>swesson@atlab.com</u>

Stop by Booth #17

