LIMS: The Backbone to Your Quality Management System (QMS)

Presented by:

Stephen Wesson, Senior Sales Account Executive

Accelerated Technology Laboratories

October 8, 2019
9 a.m. to 3 p.m.

cwea
Chesapeake Water Environment Association

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Agenda

- ATL
- What is ISO 17025:2017
- What is a LIMS
- Section 5: Structural Requirements
- Section 6: Resource Requirements
- Section 7: Process Requirements
- Section 8: Management Systems Requirements
- Review

Accelerated Technology Laboratories

- **25 Years** of Expertise in LIMS & Laboratory Automation
- Our LIMS solutions are installed in >**600 laboratories** globally
- **ISO 9001:2015** Certified
- Sample Master® and TITAN® LIMS solutions
  - Premise or Hosted (Cloud)
  - Architecture: Client-Server or web based

ISO/IEC 17025:2017 (International Organization for Standardization)

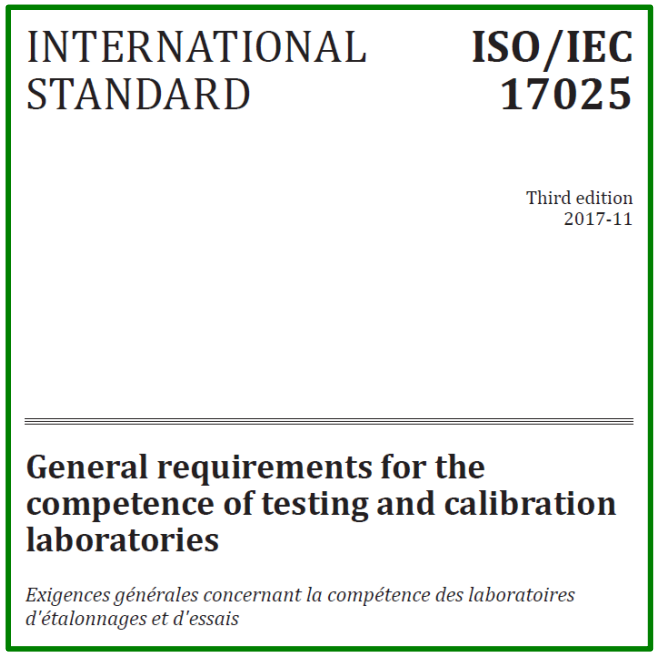
- This document specifies **the general requirements for the competence, impartiality and consistent operation of laboratories.**
- This document is **applicable to all organizations performing laboratory activities**, regardless of the number of personnel.
- Laboratory customers, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies, and others use this document in confirming or **recognizing the competence of laboratories**.

The Modern LIMS

- 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.

The 8 Sections of ISO 17025:2017

1) Scope
2) Normative References
3) Terms and Definitions
4) General Requirements
5) Structural requirements
6) Resource Requirements
7) Process Requirements
8) Management System Requirements


INTERNATIONAL STANDARD

ISO/IEC 17025

Third edition
2017-11

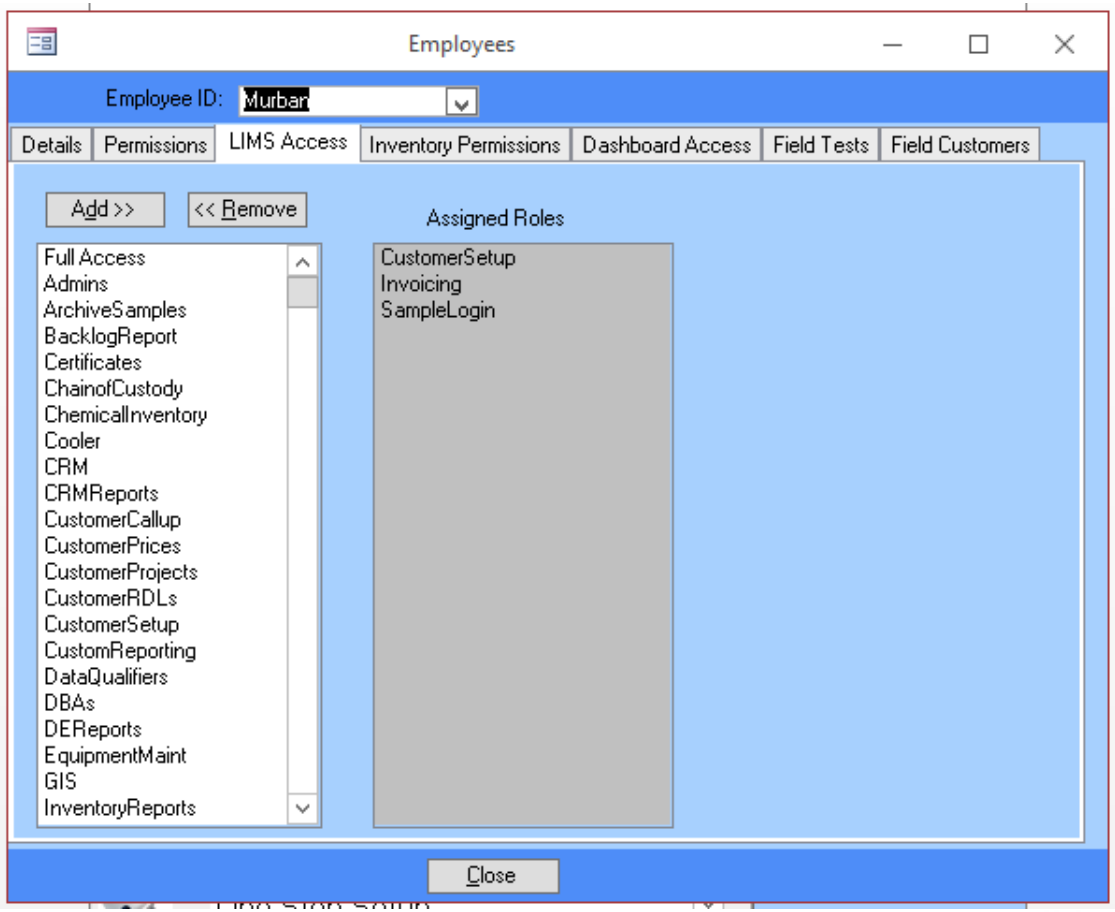
General requirements for the competence of testing and calibration laboratories

Exigences générales concernant la compétence des laboratoires d'étalonnages et d'essais

ISO 17025: Section 5 Structural Requirements

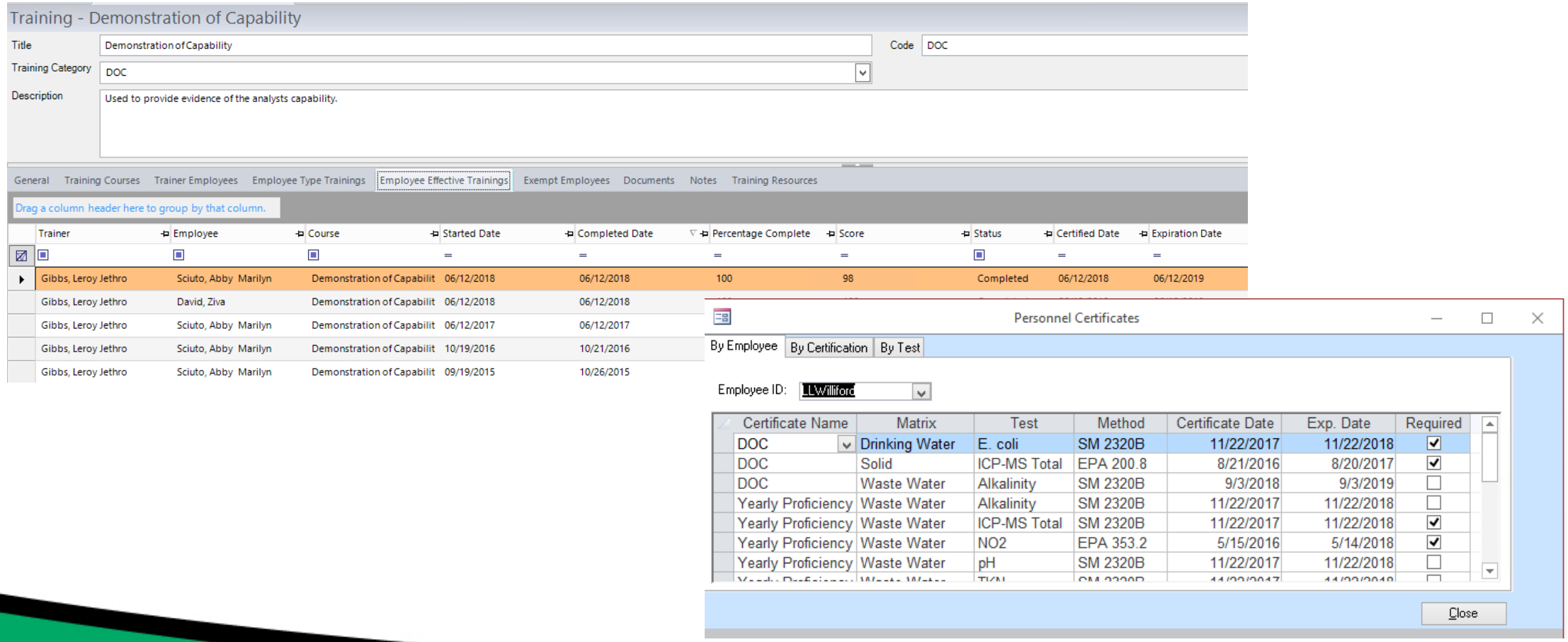
5.5.b (Organization Roles)

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



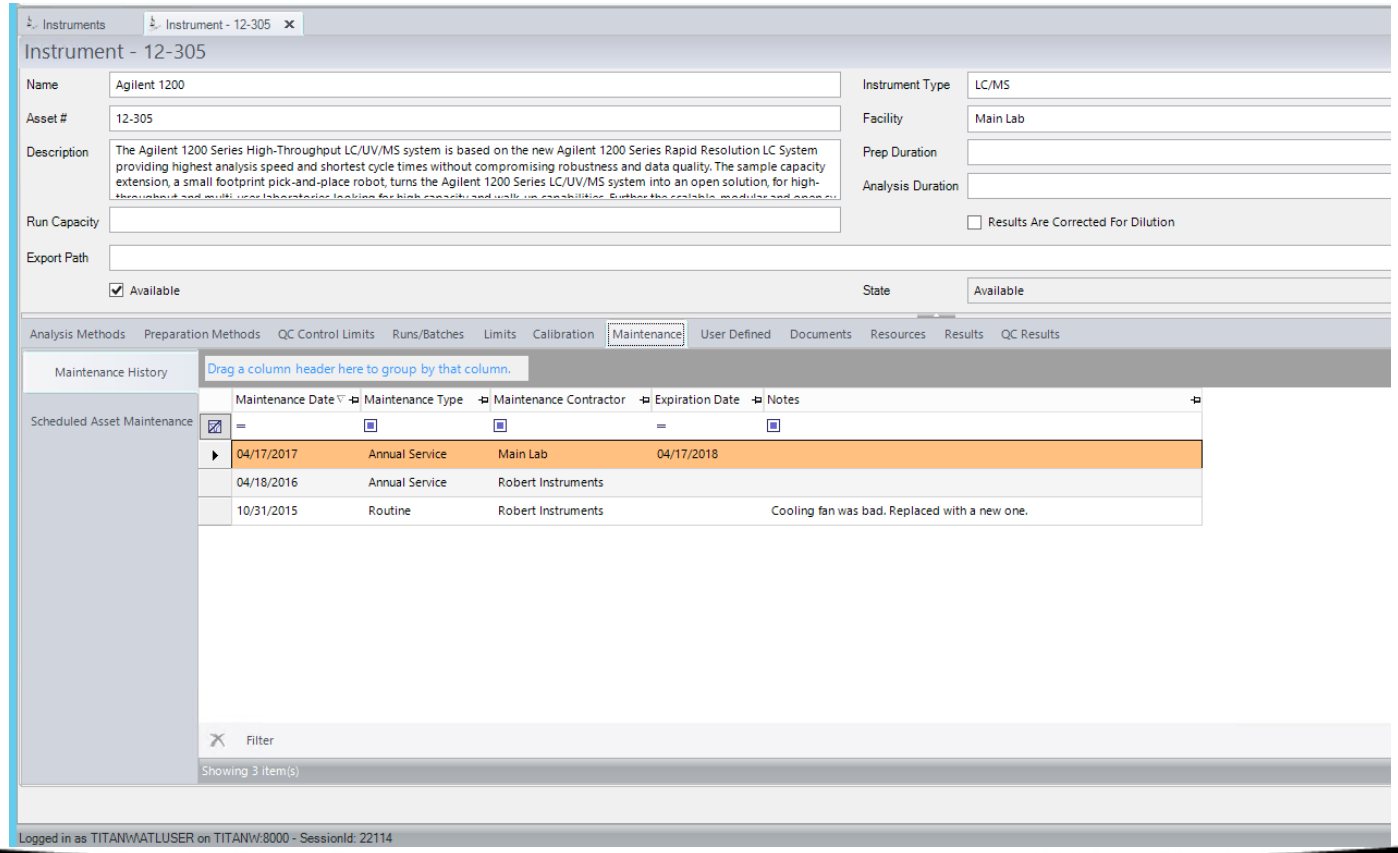
ISO 17025 Section 6 Resource Requirements

6.2 Personnel (Employee Training & Certificate Tracking)



ISO 17025 Section 6 Resource Requirements

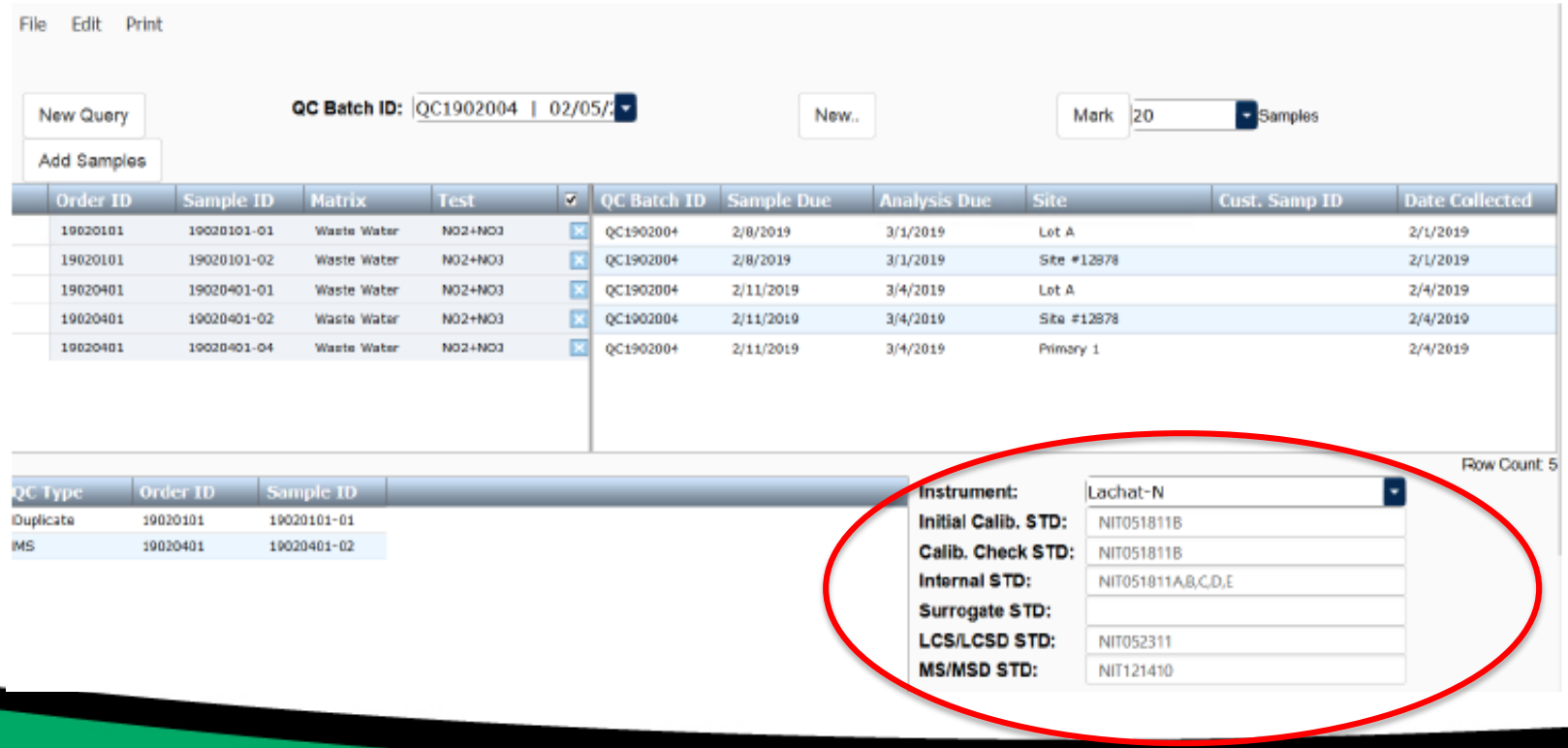
6.4 Equipment (Records shall be retained for equipment which can influence laboratory activities.)



ISO 17025 Section 6 Resource Requirements

6.5 Metrological Traceability (Standard Traceability)

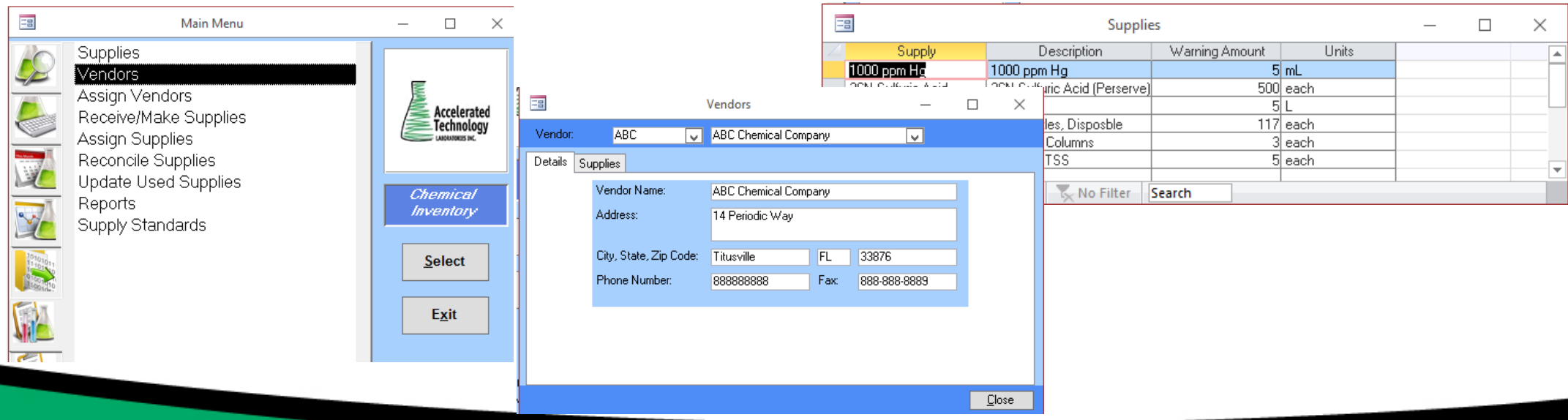
6.5.1 The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.



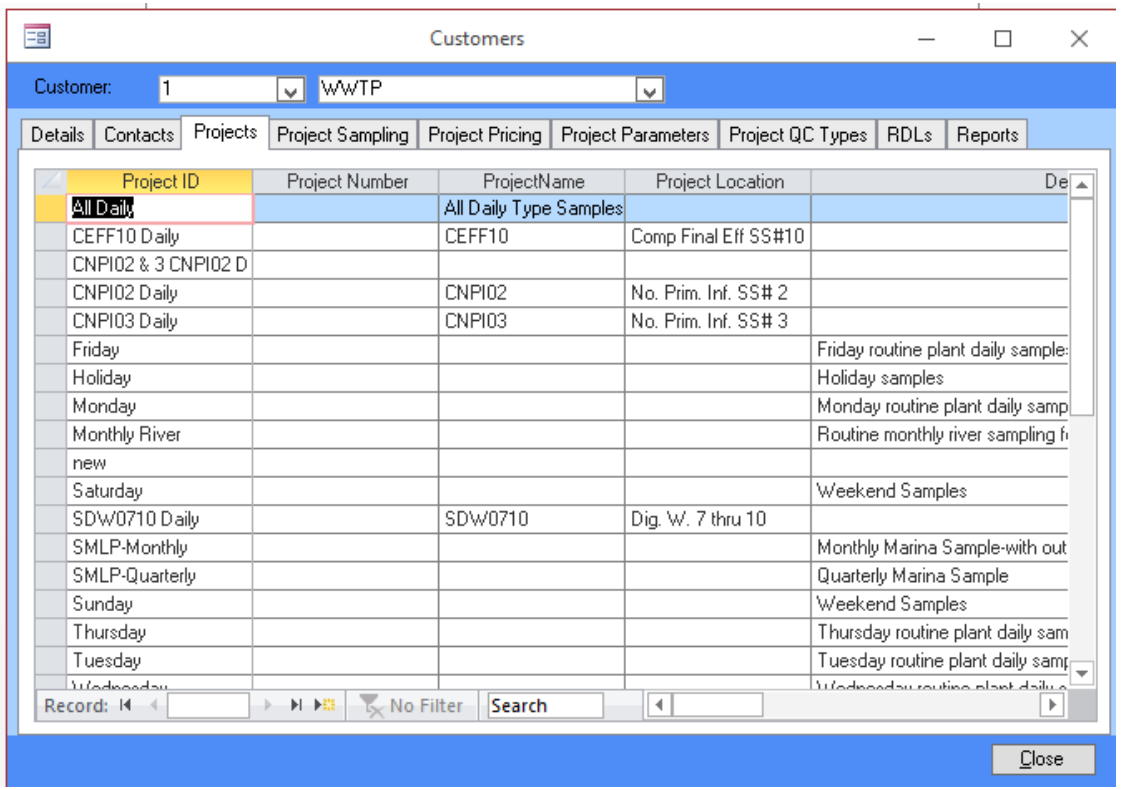
ISO 17025 Section 6 Resource Requirements

6.6 Externally provided products & services (Vendors: Purchasing Services and Supplies)

Ensure that services and supplies delivered by third parties do not adversely impact the quality and effectiveness of laboratory operations.



ISO 17025 Section 7 Process Requirements



7.1 - Review of Requests, Tenders, and Contracts

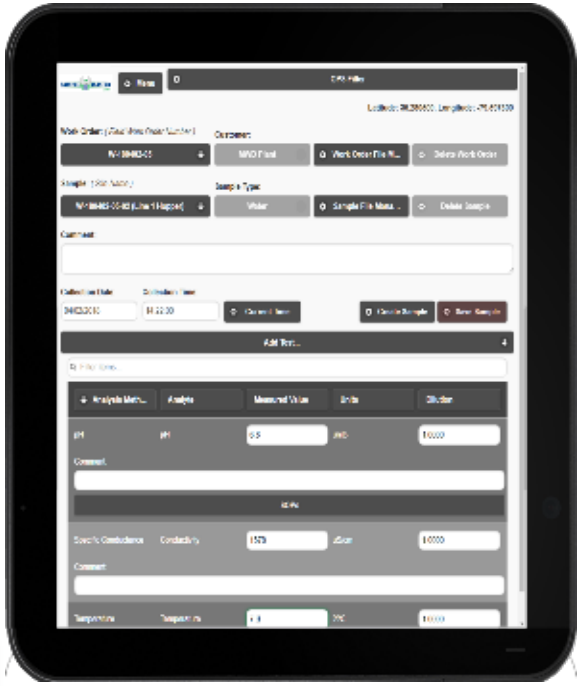
Ensure that requirements of requests, tenders and contracts are **adequately defined, documented and understood.**

ISO 17025 Section 7 Process Requirements

7.3 – Sampling

Retain Records including:

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

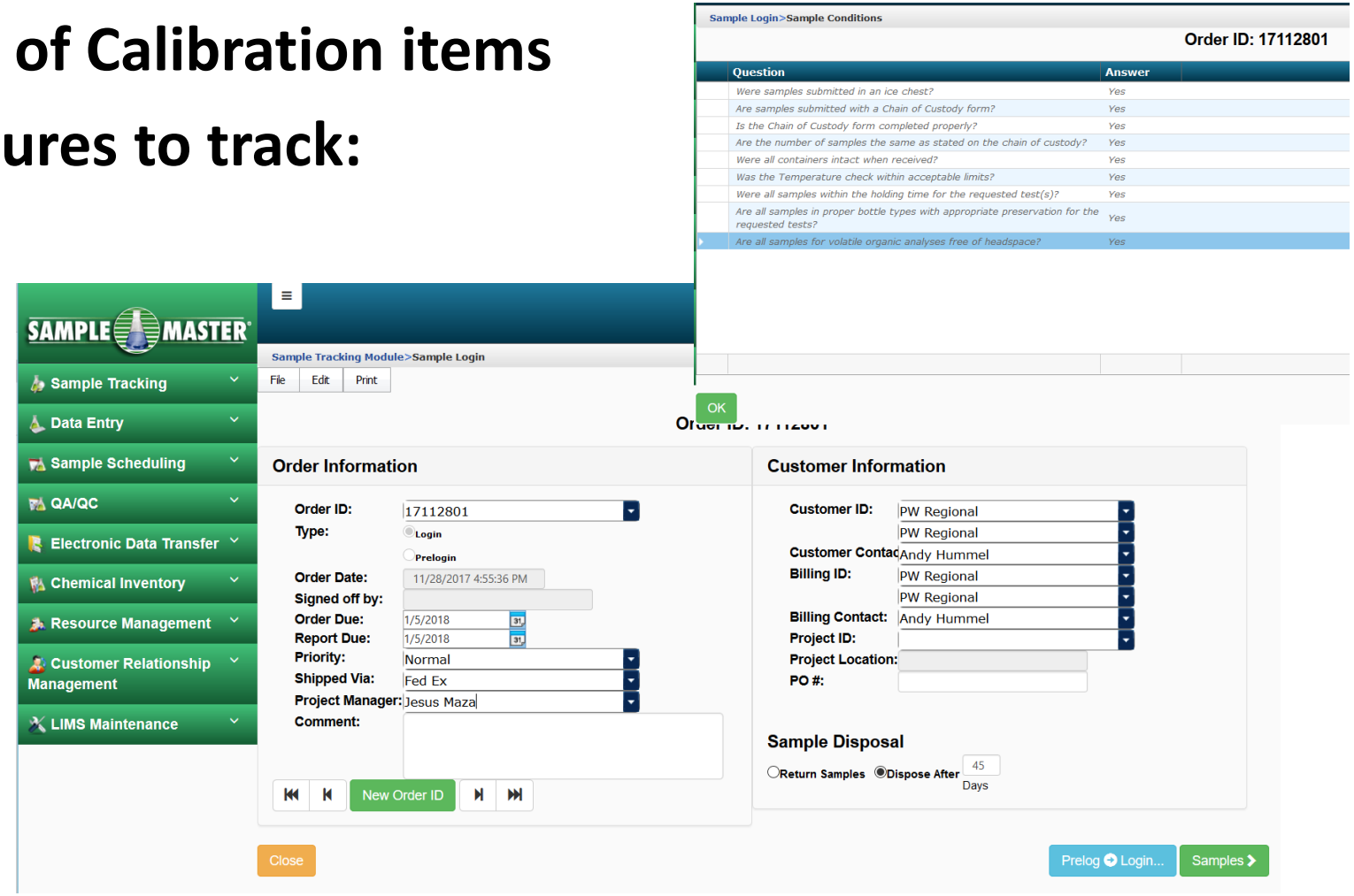


ISO 17025 Section 7 Process Requirements

7.4 – Handling of Test of Calibration items

Lab shall have Procedures to track:

- Transportation
- Receipt
- Storage
- Retention
- Disposal
- Comments



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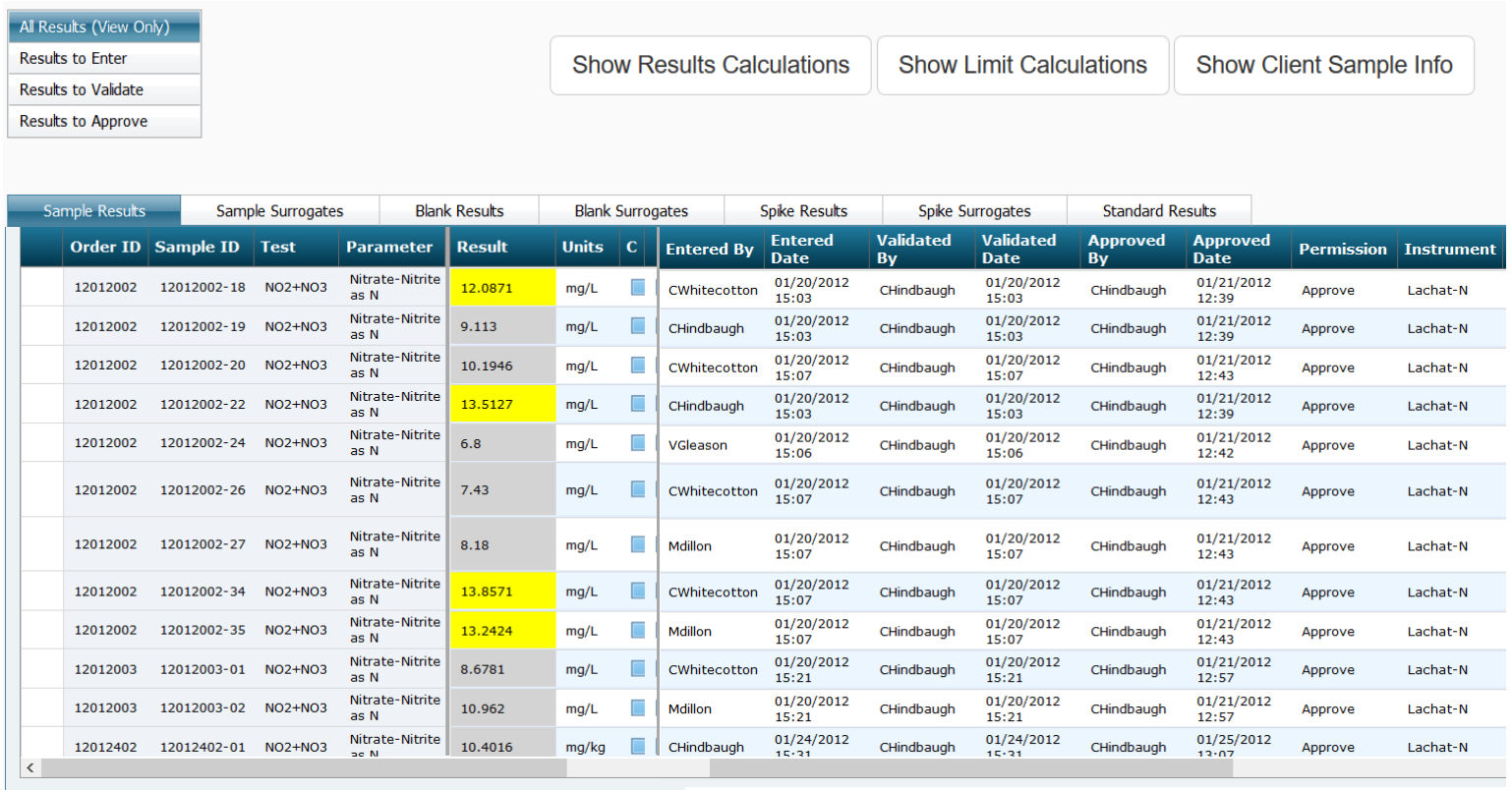
ISO 17025 Section 7 Process Requirements

7.5 – Technical records: Technical Records shall include:



All Results (View Only)
Results to Enter
Results to Validate
Results to Approve

Show Results Calculations | Show Limit Calculations | Show Client Sample Info

Sample Results | Sample Surrogates | Blank Results | Blank Surrogates | Spike Results | Spike Surrogates | Standard Results

Order ID	Sample ID	Test	Parameter	Result	Units	C	Entered By	Entered Date	Validated By	Validated Date	Approved By	Approved Date	Permission	Instrument
12012002	12012002-18	NO2+NO3	Nitrate-Nitrite as N	12.0871	mg/L		CWhitecotton	01/20/2012 15:03	CHindbaugh	01/20/2012 15:03	CHindbaugh	01/21/2012 12:39	Approve	Lachat-N
12012002	12012002-19	NO2+NO3	Nitrate-Nitrite as N	9.113	mg/L		CHindbaugh	01/20/2012 15:03	CHindbaugh	01/20/2012 15:03	CHindbaugh	01/21/2012 12:39	Approve	Lachat-N
12012002	12012002-20	NO2+NO3	Nitrate-Nitrite as N	10.1946	mg/L		CWhitecotton	01/20/2012 15:07	CHindbaugh	01/20/2012 15:07	CHindbaugh	01/21/2012 12:43	Approve	Lachat-N
12012002	12012002-22	NO2+NO3	Nitrate-Nitrite as N	13.5127	mg/L		CHindbaugh	01/20/2012 15:03	CHindbaugh	01/20/2012 15:03	CHindbaugh	01/21/2012 12:39	Approve	Lachat-N
12012002	12012002-24	NO2+NO3	Nitrate-Nitrite as N	6.8	mg/L		VGleason	01/20/2012 15:06	CHindbaugh	01/20/2012 15:06	CHindbaugh	01/21/2012 12:42	Approve	Lachat-N
12012002	12012002-26	NO2+NO3	Nitrate-Nitrite as N	7.43	mg/L		CWhitecotton	01/20/2012 15:07	CHindbaugh	01/20/2012 15:07	CHindbaugh	01/21/2012 12:43	Approve	Lachat-N
12012002	12012002-27	NO2+NO3	Nitrate-Nitrite as N	8.18	mg/L		Mdillon	01/20/2012 15:07	CHindbaugh	01/20/2012 15:07	CHindbaugh	01/21/2012 12:43	Approve	Lachat-N
12012002	12012002-34	NO2+NO3	Nitrate-Nitrite as N	13.8571	mg/L		CWhitecotton	01/20/2012 15:07	CHindbaugh	01/20/2012 15:07	CHindbaugh	01/21/2012 12:43	Approve	Lachat-N
12012002	12012002-35	NO2+NO3	Nitrate-Nitrite as N	13.2424	mg/L		Mdillon	01/20/2012 15:07	CHindbaugh	01/20/2012 15:07	CHindbaugh	01/21/2012 12:43	Approve	Lachat-N
12012003	12012003-01	NO2+NO3	Nitrate-Nitrite as N	8.6781	mg/L		CWhitecotton	01/20/2012 15:21	CHindbaugh	01/20/2012 15:21	CHindbaugh	01/21/2012 12:57	Approve	Lachat-N
12012003	12012003-02	NO2+NO3	Nitrate-Nitrite as N	10.962	mg/L		Mdillon	01/20/2012 15:21	CHindbaugh	01/20/2012 15:21	CHindbaugh	01/21/2012 12:57	Approve	Lachat-N
12012402	12012402-01	NO2+NO3	Nitrate-Nitrite as N	10.4016	mg/kg		CHindbaugh	01/24/2012 15:31	CHindbaugh	01/24/2012 15:31	CHindbaugh	01/25/2012 13:07	Approve	Lachat-N

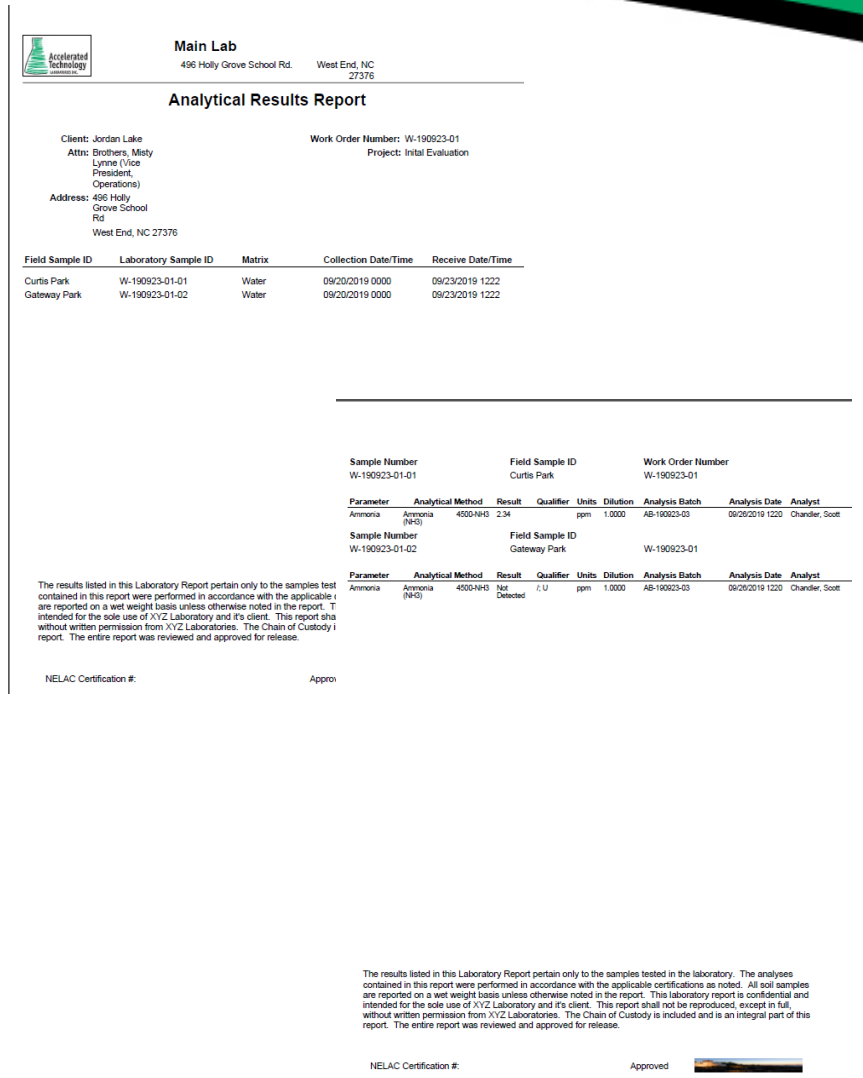
- Comments
- Results
- QA/QC
- Reports
- Person Responsible
- Date & Time of Activity

ISO 17025 Section 7 Process Requirements

7.8 – Reporting

Reports should include:

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



Main Lab
496 Holly Grove School Rd. West End, NC 27376

Analytical Results Report

Client: Jordan Lake
Attn: Brothers, Misty Lynne (Vice President, Operations)
Address: 496 Holly Grove School Rd
West End, NC 27376

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

Field Sample ID	Laboratory Sample ID	Matrix	Collection Date/Time	Receive Date/Time
Curtis Park	W-190923-01-01	Water	09/20/2019 0000	09/23/2019 1222
Gateway Park	W-190923-01-02	Water	09/20/2019 0000	09/23/2019 1222

Sample Number: W-190923-01-01 | Field Sample ID: Curtis Park | Work Order Number: W-190923-01

Parameter	Analytical Method	Result	Qualifier	Units	Dilution	Analysis Batch	Analysis Date	Analyst
Ammonia	Ammonia (NH3) 4500-NH3	2.34		ppm	1.0000	AB-190923-03	09/26/2019 1220	Chandler, Scott

Sample Number: W-190923-01-02 | Field Sample ID: Gateway Park | Work Order Number: W-190923-01

Parameter	Analytical Method	Result	Qualifier	Units	Dilution	Analysis Batch	Analysis Date	Analyst
Ammonia	Ammonia (NH3) 4500-NH3	Not Detected	I; U	ppm	1.0000	AB-190923-03	09/26/2019 1220	Chandler, Scott

The results listed in this Laboratory Report pertain only to the samples test
contained in this report were performed in accordance with the applicable
are reported on a wet weight basis unless otherwise noted in the report. T
intended for the sole use of XYZ Laboratory and it's client. This report sha
without written permission from XYZ Laboratories. The Chain of Custody i
report. The entire report was reviewed and approved for release.

NELAC Certification #: Appro

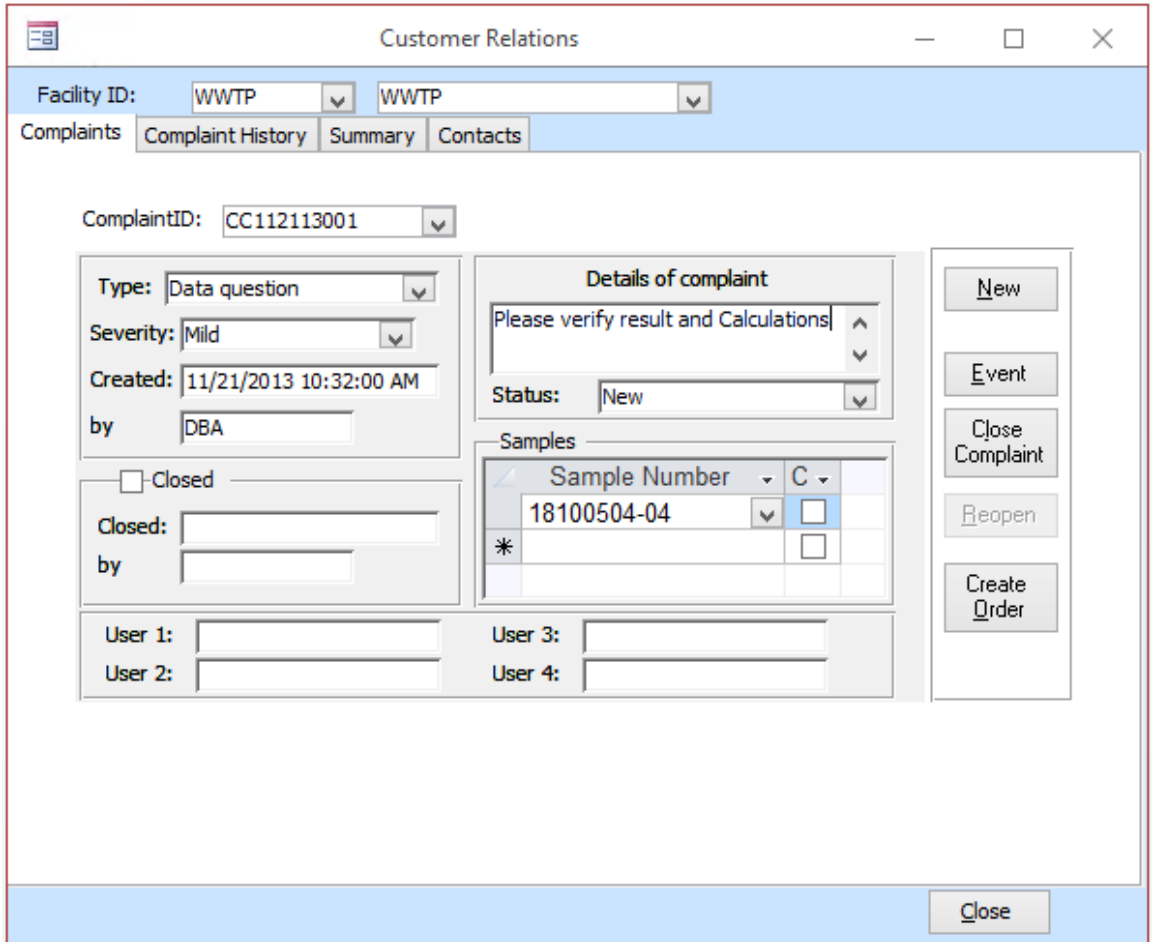
The results listed in this Laboratory Report pertain only to the samples tested in the laboratory. The analyses contained in this report were performed in accordance with the applicable certifications as noted. All soil samples are reported on a wet weight basis unless otherwise noted in the report. This laboratory report is confidential and intended for the sole use of XYZ Laboratory and it's client. This report shall not be reproduced, except in full, without written permission from XYZ 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

ISO 17025 Section 7 Process Requirements

7.9 - Complaints

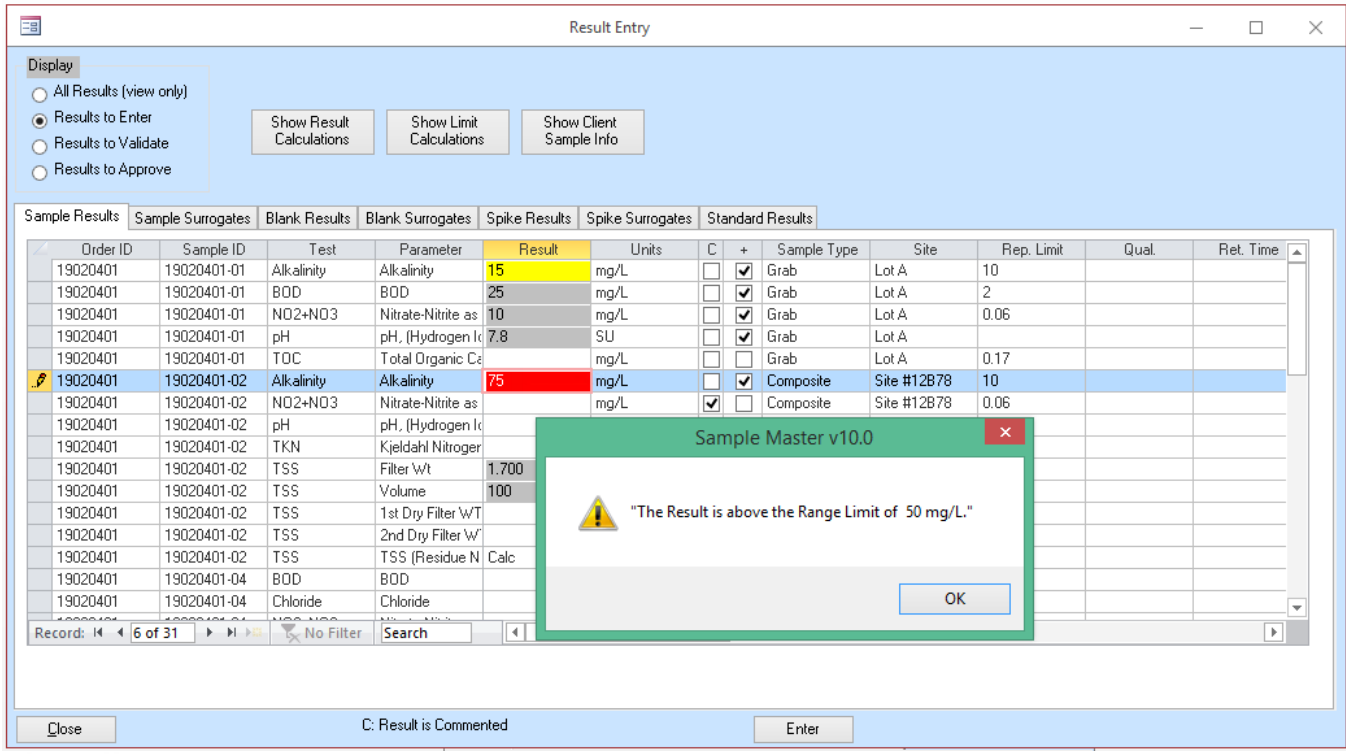
The laboratory shall have a documented process to receive, evaluate and make decisions on complaints.



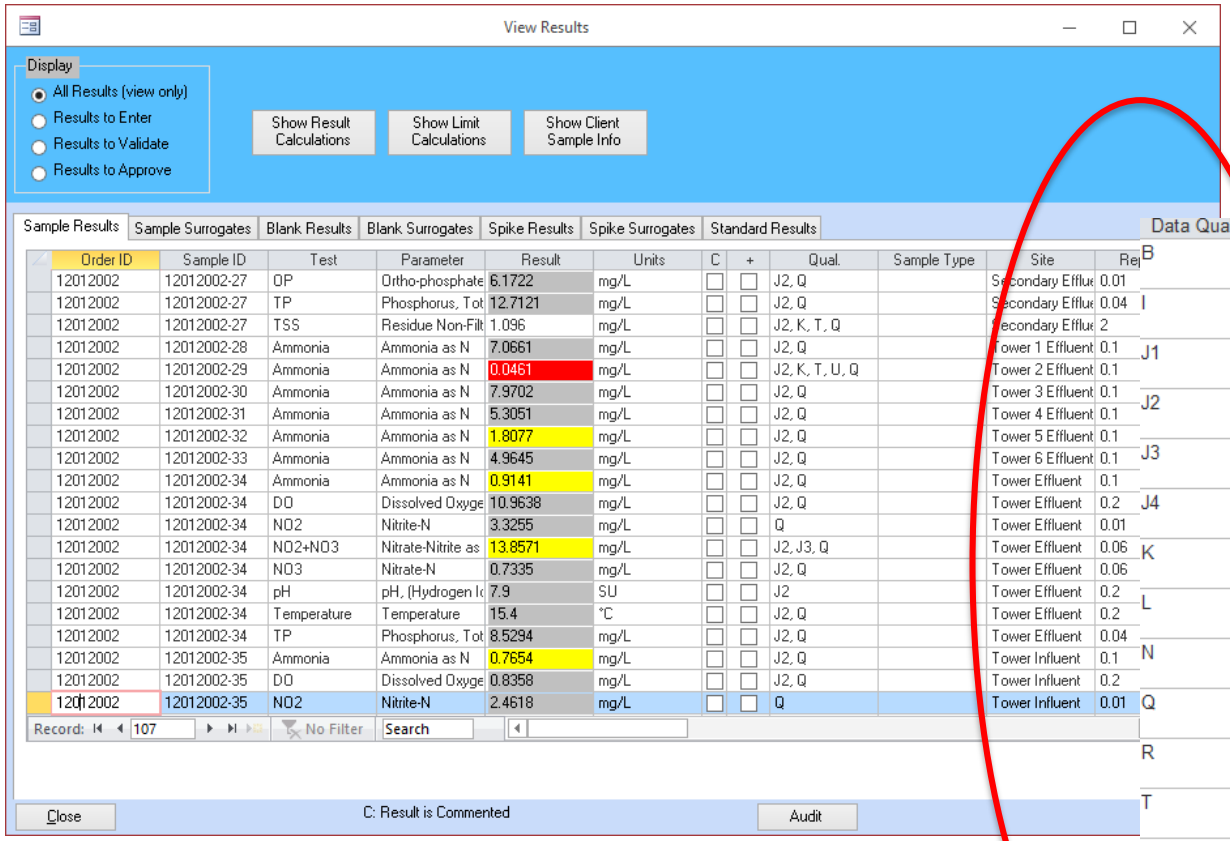
ISO 17025 Section 7 Process Requirements

7.10 - Nonconforming Work

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



Data Qualifiers



Data Qualifier	Translation
B	Blank contamination; Analyte detected above the method reporting limit (RepLimit) in an associated blank
I	The reported value is between the laboratory method detection limit (DetectionLimit) and the laboratory practical quantitation limit (PQL)
J1	Reported value is estimated; Surrogate recoveries limits were exceeded (Not between LCL and UCL for Surrogates)
J2	Reported value is estimated; No known QC criteria for this component.
J3	Reported value is estimated; The value failed to meet QC criteria for either precision or accuracy. (Result Not between LCL and UCL for Spikes, Duplicates and Standards)
J4	Reported value is estimated; The sample matrix interfered with the analysis (Percent Recovery Not between LCL and UCL for Spikes)
K	Off-scale low. Actual value is known to be less than the value given (below RepLimit)
L	Off-scale high. Actual value is known to be greater than value given (above RangeLimit), corrected for Prep
N	Non-target analyte; Tentatively identified compound (using mass spectroscopy). (TIC value is True)
Q	Sample held beyond the accepted holding time (AnalysisDueDate)
R	Rejected data; Not suitable for the projects intended use.
T	Value reported is less than the reporting detection limit (below RDL RepLimit)
U	Compound was analyzed for but not detected (below Detection Limit, corrected for Prep, or null)
V	Analyte was detected in both the sample and the associated method blank. (Blank result > Detection Limit or Blank result > 0)
Z	Too Numerous to count (Result = TNTC)

ISO 17025 Section 7 Process Requirements

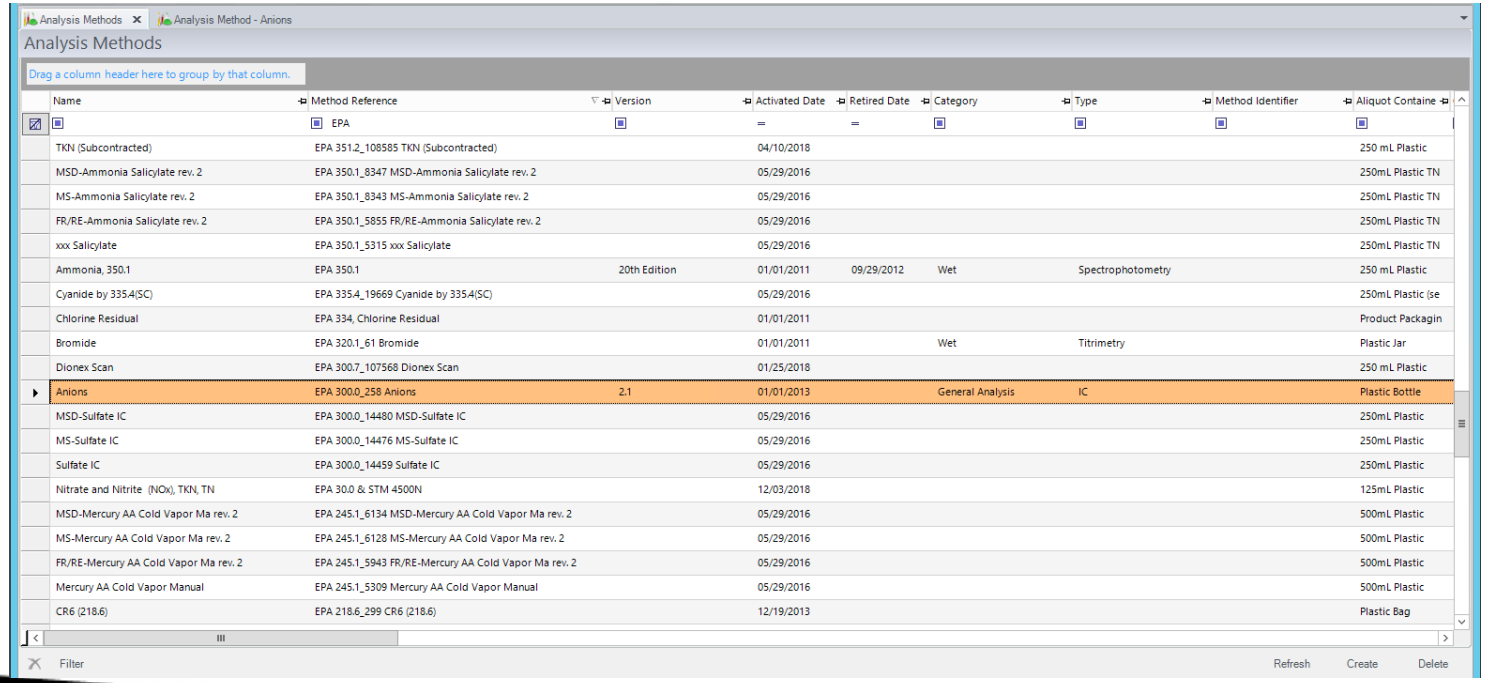
Section 7.11 Control of Data and Information Management

- This is the only section in ISO 17025 that speaks specifically to LIMS.
  - 7.11.3 – **Data Integrity, Security** and the ability to **record system failures**.
  - 7.11.4 - If a system is managed **off-site**, the **provider/operator must comply with ISO 17025**

ISO 17025 Section 8 Management System Requirements

8.3 – Control of management system documents

– Ensure that all documents are approved, reviewed, with current versions identified.



Name	Method Reference	Version	Activated Date	Retired Date	Category	Type	Method Identifier	Aliquot Containe
	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
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

ISO 17025 Section 8 Management System Requirements

8.6: Improvement (*Preventative Actions*)

8.7: Corrective Actions - (*CAPA)*

a) React to nonconformity (*Investigate Incident*)

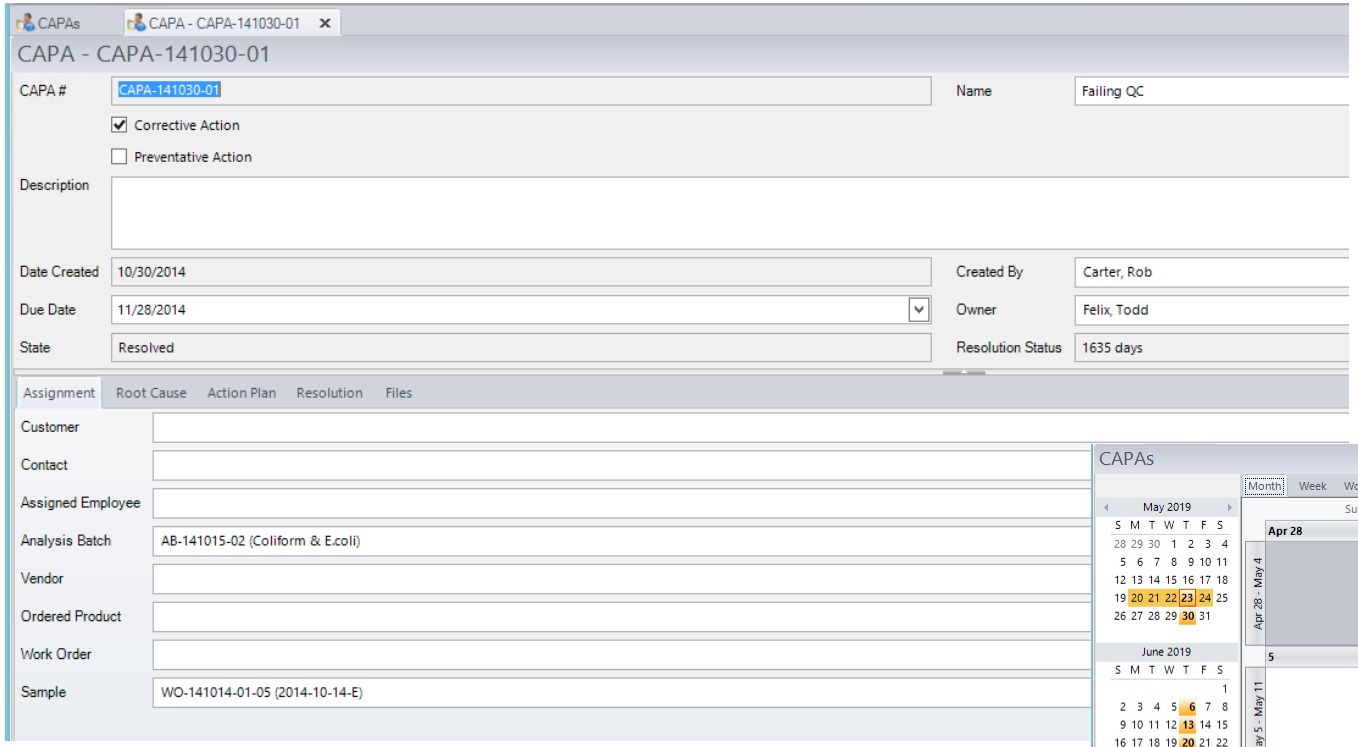
b) Evaluate the need for action (*Root Cause*)

c) Implement action (*Action Plan*)

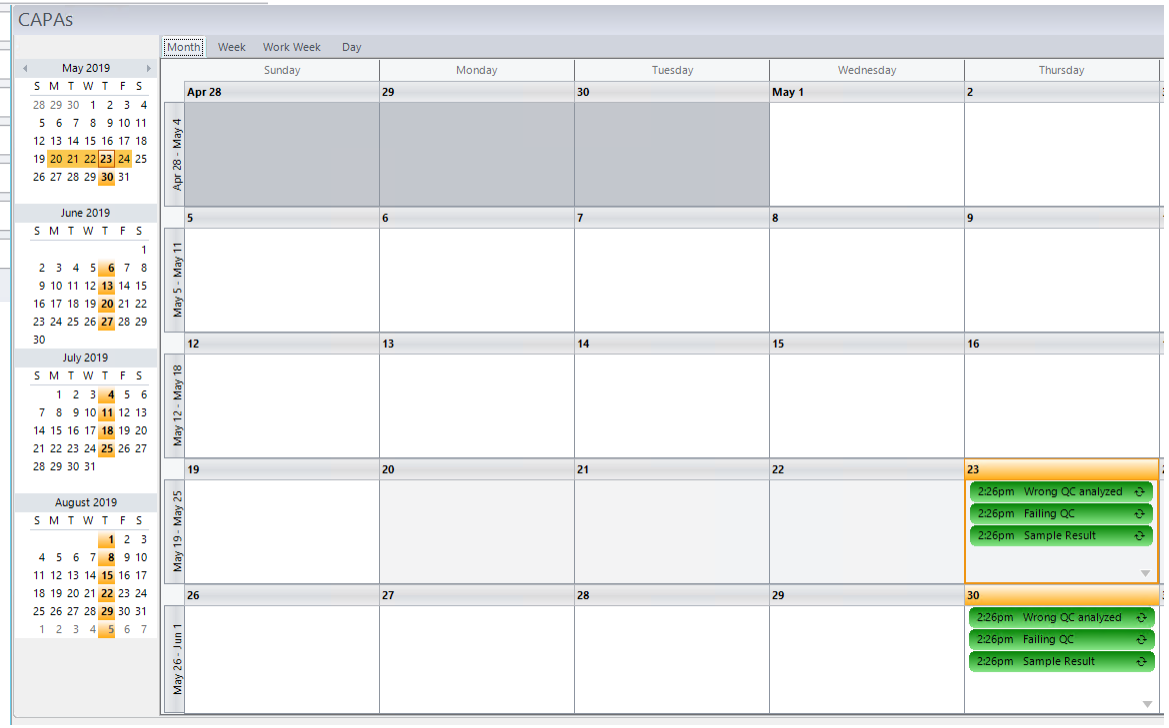
d) Review the effectiveness (*resolution*)

e) Make changes to management system

CAPA documentation



CAPA Calendar



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.

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Review

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Questions?

THANK YOU!

Stephen Wesson, Senior Sales Account Executive
Accelerated Technology Laboratories

- Email: swesson@atlab.com

October 8, 2019
9 a.m. to 3 p.m.

cwea
Chesapeake Water Environment Association