2020 NEMC/TNI CONFERENCE
Virtual Presentation

Understanding and Managing Proficiency Testing Requirements for Laboratory Accreditations

Presented by:

Cornelius Andy Valkenburg

PJLA Lead Assessor

Perry Johnson Laboratory Accreditation, Inc.

August 17, 2020 12:15 Eastern Time, Virtual Meeting

DISCLAIMER

The material given in this presentation is the professional opinion and interpretations of the presenter only.

DEFINITIONS

Interconnectivity: www.definition.net

…A concept summarized that all parts of a system interact with and rely on one another simply by the fact that they occupy the same system and that a system is difficult or sometimes impossible to analyze through its individual parts considered alone…

Proficiency Testing: ISO/IEC 17025: 2017 3.5

evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (3.3)

interlaboratory comparison: ISO/IEC 17025: 2017 3.3

organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

Proficiency Testing (PT): TNI V1M1-2016 3.4

A means to evaluate a laboratory's performance under controlled conditions relative to a given set of criteria, through analysis of unknown samples provided by an external source.

Prescriptive Hierarchy of References

ISO/IEC:17025:2017, 38 Pages

"Risk" mentioned 31X

ISO/IEC 17025:2005, 36 Pages

Risk mentioned 4X

TNI Standards EL-V1-2016, 180 Pages

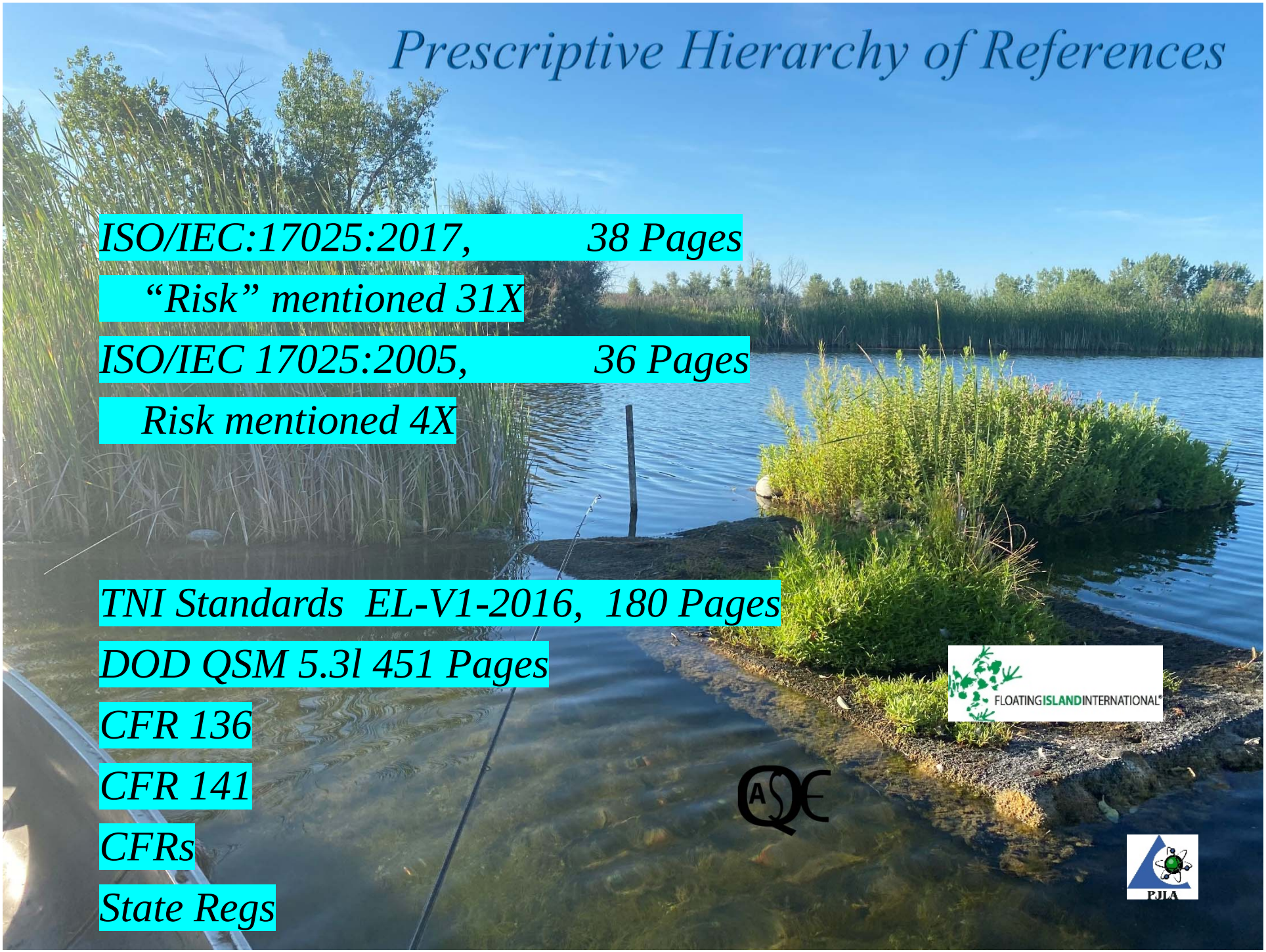
DOD QSM 5.3l 451 Pages

CFR 136

CFR 141

CFRs

State Regs



U.S. ENVIRONMENTAL LABORATORY ACCREDITORS

FEDERAL

- **EPA's SDWA, CWA, RCRA Regulations = State Primacy**
- **CERCLA, DOD ELAP, NLLAP, DMRQA**

STATE *(State Specific Regulations)*

Each State with Specific Reciprocity Accreditation Requirements

States with TNI Accrediting Programs:

https://nelac-institute.org/content/NELAP/accred-bodies.php

NGABs – *Non-Governmental Accrediting Bodies*

- **ISO/IEC 17025 (Testing and Calibration Laboratories)**
- **ISO/IEC 17034 (Reference Material Providers)**
- **ISO/IEC 17043 (Accreditations Proficiency Testing Providers)**
- **ISO/IEC 17020 (Inspection Bodies)**

TNI (The NELAC Institute)

"One of the ways that TNI fosters the generation of data of known and documented quality is through the National Laboratory Accreditation Program, or NELAP. The purpose of this program is to establish and implement a program for the accreditation of environmental laboratories." (EPA Supported and Approved)

Consensus Standards Development:

"The purpose of the program is to develop consensus standards for use by TNI's programs. This group has a support role in assisting other programs with activities such as guidance and standards interpretation."

- *Expert Committees on: Consensus Standards Executive, Lab Accreditation, Asbestos, Chemistry, Field Activities, Proficiency Testing, Lab Quality Systems, Microbiology, Radiochemistry, Station Source Audit Sample, and Whole Effluent Toxicity*

Note: TNI 2016 Standards are based on ISO17025:2005 Requirements

Proficiency Testing

ILAC Policy for Participation in Proficiency Testing Activities P-9

International Laboratory Accreditation Cooperation

ISO Approved AB's are Signatories of the International Laboratory Accreditation Cooperation for testing and calibration;

4.2 The minimum PT activity according to a laboratory's or inspection body's (where relevant) scope is:

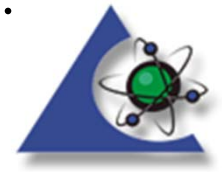
- evidence of satisfactory participation prior to gaining accreditation where PT is available and appropriate;
- further and ongoing activity that is appropriate to the scope of accreditation and consistent with the PT participation plan.

Proficiency Testing P-9

4.3 ILAC Approved Accrediting Bodies shall have a policy on the use of PT activities in the assessment and accreditation process. This policy shall include the following:

- a reference to the importance of PT as a tool to demonstrate laboratory and inspection body competence (where relevant) and to assist in maintaining the quality of the laboratory or inspection body performance;
- any requirements regarding the minimum level and frequency of participation in PT by accredited laboratories, including the need for a PT participation plan which has been formulated by the laboratory or inspection body (where relevant) and is regularly reviewed in response to changes in staffing, methodology, instrumentation etc.;

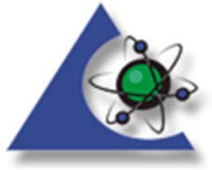
.



Proficiency Testing P-9

4.4 Accreditation bodies shall fully document their policies and procedures in relation to the use of PT. In particular, they must be able to evaluate, through the accreditation process, that the participation in PT activities of laboratories and (where relevant) inspection bodies accredited by them is effective, and that corrective actions are carried out when necessary.

4.6 It is recognized that there are areas of testing and calibration for which suitable PT does not exist or is not practical. In such cases, the accreditation body and the laboratory or where relevant the inspection body shall discuss and agree on suitable alternative means by which performance can be assessed and monitored. This would need to be considered as part of the planned PT and/or related activities.



Proficiency Testing

Hence, Perry Johnson Laboratory Accreditation has PL-1

"Perry Johnson Laboratory Accreditation, Inc. Proficiency Testing Requirements"

Available at www.pjlabs.com under the resource tab;

(33 Pages Long)

Proficiency Testing PL-1

2.1 …The results of this proficiency testing must be meaningful, in that the organization not only needs to perform the proficiency testing, the resulting data must demonstrate the organization's competence in performing the specified test or calibration.

ISO/IEC 17025: 2017, 7.7.2 (7.7 = "Ensuring the Validity of Results")

"The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:

a) participation in proficiency testing;

NOTE ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirements of ISO/IEC 17043 are considered to be competent.

b) participation in interlaboratory comparisons other than proficiency testing."

Proficiency Testing PL-1

Upon achieving accreditation laboratories are required to perform proficiency testing **per approved PT plan**. Alternate 3rd party PT providers can be used.

Calibration or Testing "Discipline": A category of calibrations or set of test intended to quantify or evaluate common or related parameters of a unit, device or substance submitted for calibration or test;

Proficiency Testing Plan

PJLA currently accredits organizations in the following disciplines

Calibration: *1)* Acoustic *2)* Chemical *3)* Dimensional *4)* Electrical *5)* Mass, Force, and Weighing Devices *6)* Mechanical *7)* Optical *8)* Thermodynamic *9)* Time and Frequency

Testing: *1)* Acoustical *2)* Biological *3)* Chemical *4)* Dimensional Inspection *5)* Electrical *6)* Environmental *7)* Mechanical *8)* Microbiological *9)* Non-Destructive *10)* Thermodynamic

See TNI FOPT Tables

Proficiency Testing Plan

Calibration or Testing "Sub Discipline": At a minimum a sub discipline is an element of an associated calibration or test discipline for which the magnitude of a stated parameter has been defined as a measurement objective and will be determined by a specified method using appropriate skills and equipment. A sub discipline may be composed of one or more such elements where the organization has determined that the measurement objective, the specified method and the appropriate equipment are either identical or similar to such a degree that they can be considered as mutually representative. In addition the organization shall have determined that the successful performance of either would be satisfactory objective evidence of the technical competence

Proficiency Testing Plan

Calibration: Discipline: Dimensional

Discipline: "Dimensional"; MEASURED INSTRUMENT, QUANTITY OR GAUGE includes the following

Micrometer, Dial Indicator, Caliper

Need Traceability Certificates

SI BASE UNITS = Ampere, Candela, Kelvin, Kilogram, Meter, Mole, Second

Testing: Discipline: Mechanical Testing

Discipline: Mechanical: ITEMS, MATERIALS OR PRODUCTS TESTED

"Threaded fasteners, Knoop hardness"; "Machined components Vickers hardness"; "Leaf springs Rockwell hardness";

For the mechanical testing discipline the organization has determined that the measurement objective, the specified method and the appropriate skills and equipment used to test hardness by the Knoop and Vickers method are either identical or similar to such a degree that they can be considered as mutually representative (=TNI for Matrix/Method/Analyte)

TNI PT PLAN

EL-V1M1-2016-Rev. 2.1 - Proficiency Testing

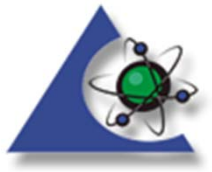
Table of Contents

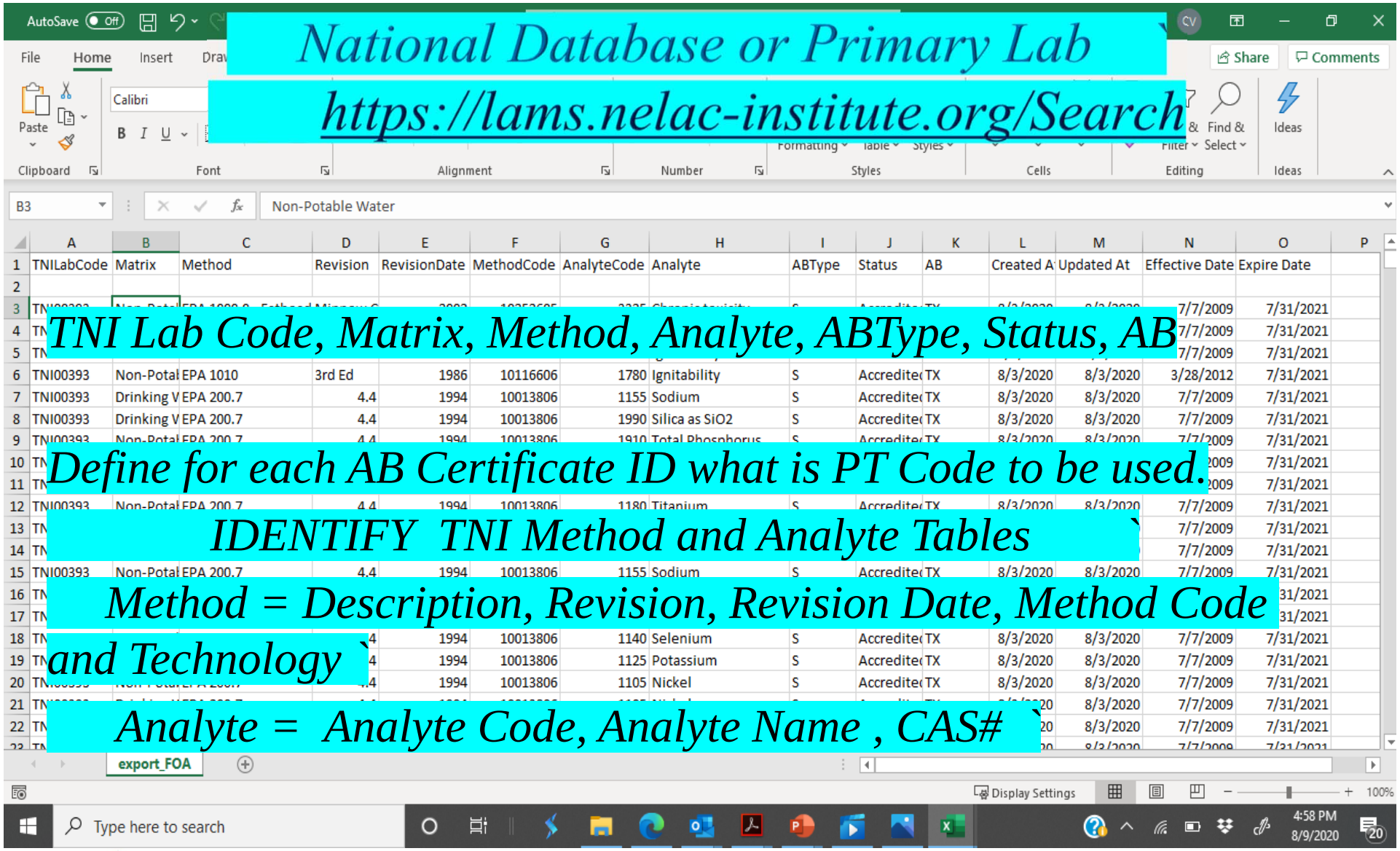
Managing Accreditations and PT Data

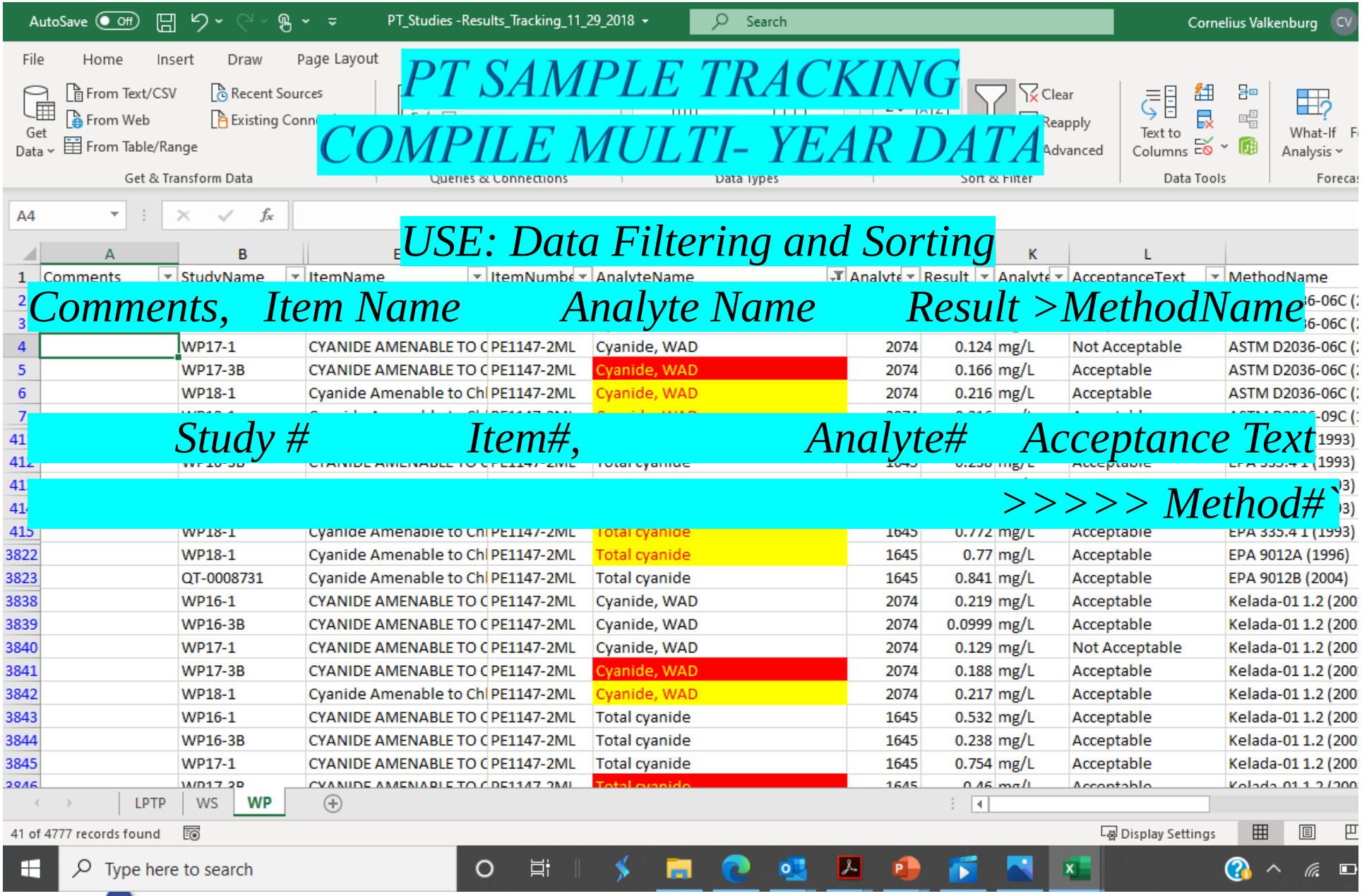
List of Matrix/Method/Analytes from Primary Certificate: (ABs XL file)

- **State/TNI/DOD/ISO Primary Certification Columns (Matrix/Method/Analyte)**
  - **Primary Certificate TNI Analyte Codes**
  - **Primary Certificate TNI Method Codes**
- **Current PT Analyte Codes**
- **Current PT Method Codes (Use Current Approved Methods)**
- **Laboratory Analyte Name**
- **TNI Analyte Name (VLOOKUP's)**
- **CAS# (VLOOKUP's)**
- **Method/Revision/Revision Date, Name, Technology, Method Source**

PT Data – Obtain XL file of PT data from providers and combine all recent studies (Line up different providers for key columns)




National Database or Primary Lab
https://lams.nelac-institute.org/Search
TNI Lab Code, Matrix, Method, Analyte, ABType, Status, AB
Define for each AB Certificate ID what is PT Code to be used.
IDENTIFY TNI Method and Analyte Tables
Method = Description, Revision, Revision Date, Method Code and Technology
Analyte = Analyte Code, Analyte Name , CAS#
export_FOA



Perry Johnson Laboratory Accreditation, Inc.

Proficiency Testing Plan

4-year PT plan using LF-81 form example, or equivalent form.

(Enter Organization Name Here)

#	Proficiency Test Discipline	Year	Year	Year	Year	Source or Type (3rd party/Inter laboratory)
Enter the calibration or test discipline						
1	Sub discipline to be tested					
2						
3						

This plan defines the specific calibration or test disciplines or sub disciplines for which PT will be performed during the four year period indicated. This plan includes representative sub disciplines from each calibration or test discipline for which the organization is accredited. Please refer to PL-1 regarding PJLA policy on PT. ***Where third party proficiency testing or Inter laboratory comparisons are not feasible, then the organization must include other means of evaluating such as intra laboratory or repeatability studies. When these are indicated, the organization must submit their reasoning for doing so and their procedure.***

PJLA Approval: _____

Signature/Date

Need Certified PT Plan Listed down to matrix/method/analyte level, and with current TNI method and analyte codes used for PT reporting.

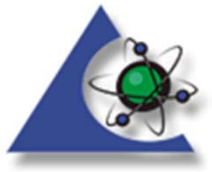
Need XL File of combined PT reports results

Need PT Corrective Actions

Proficiency Testing Plan

- ISO/IEC 17025:2017 requires review of policies and procedures as a mandatory activity during management review. Accredited organizations shall be able to provide objective evidence that their policies and procedures related to proficiency testing are reviewed for suitability.\

- ISO/IEC 1025:2017 requires that only suitable externally provided products and services that affect laboratory activities are used, and "defined criteria are established for evaluation, selection, monitoring of performance and re-evaluation of external providers".



Approved Means of Proficiency Testing

The following activities (listed in their order of preference and acceptability) for the purpose of demonstrating proficiency:

a) participation in proficiency testing programs sponsored by a third party accredited provider

b) participation in proficiency testing programs sponsored by a third party provider

c) inter-laboratory comparisons

NO PT's or Inter-laboratory Data Available ???

Approved Means of Proficiency Testing

(listed in their order of preference)

a) intra-laboratory comparisons
b) repeatability studies

Note: PT Plan subject to AB approval

Third Party Proficiency Programs

Preferred is 3 party PT programs.

Use of accredited PT providers gives advantages of:

a) assurance that the proficiency testing takes place at appropriate and regular intervals

b) complete objectivity on the part of the proficiency testing sponsor

c) statistical analysis and reporting of the resultant data by the provider

d) direct reporting of the results to AB by the provider on behalf of the organization upon availability

Third Party Programs

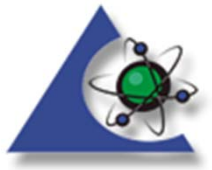
AB's may provide a list of approved proficiency testing providers.

It is the responsibility of the organization to confirm the proficiency testing provider's competence. Competence can be demonstrated in several ways one of which is through ISO/IEC 17043:2010 compliance or accreditation;

However, there are other bases for determining competency such as well recognized national or international programs or organizations mandated by regulatory authority.

Inter-laboratory Comparisons

An acceptable inter-laboratory comparison is one in which two or more organizations perform testing or calibration on the same or similar artifact, using compatible methods, under specified conditions. The resulting data from each organization should be in agreement with that of the other participants. Organizations should be accredited or in the applicant stages of accreditation whenever practicable. However, in cases where the participating laboratories are not accredited, contractor SI traceability records must be available.

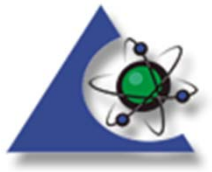


Analyzing PT Data

Agreement in results is generally determined through the use of the following equation:

$$E_n = \frac{Lab - Ref}{\sqrt{Unc_{95Lab}^2 + Unc_{95Ref}^2}}$$

Where Lab is the result obtained, Ref is the value obtained by the outside organization, to be used as reference, U95Lab is the expanded uncertainty of the organization at the 95% confidence level and U95Ref is the expanded uncertainty of the reference organization at the 95% confidence level. If the resulting value is between 1 and -1 the organization is considered to have an acceptable measurement and a “meaningful” result. Values beyond the range of 1 to -1 (higher or lower) are unacceptable and indicate that the results of the respective organizations are not in agreement



Alternate methods of PT analysis

Other sound, statistical or graphical analyses may be appropriate. Typically these involve other statistics (for example, "Z" scores), correlative analysis of "repeat" measurements, or other graphical techniques that can compare a laboratory's relative performance in relationship to others, in the study in terms of measured values and variation or uncertainty. This is not an all-inclusive list of statistical methods. (See ISO 13528 for further guidance)

Z-Score = (Participant's Reported Value – Mean Reference Value) / Standard Deviation

Intra-laboratory Comparisons

An intra-laboratory comparison is conducted when several analysts or technicians within an organization perform testing or calibrations on the same or similar artifact, using the same method, under specified, controlled conditions. The data resulting from this activity shall be analyzed for statistical validity;

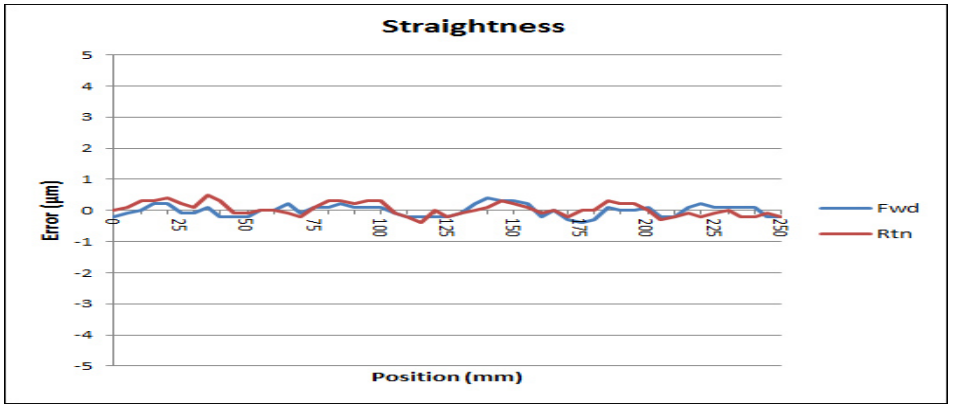
Proficiency Testing Repeatability

If none of the aforementioned proficiency testing activities are feasible, as in the case of a specialized organization employing a single technician, proficiency may be demonstrated through repeatability studies with the prior approval of PJLA.

Repeatability studies consist of a number of tests or measurements (generally at least 8) performed on the same or similar artifact, using the same method, under specified, controlled conditions. The results of these studies shall be analyzed for statistical validity by appropriate means;

Need to Evaluate as

a PT Study Sample ->

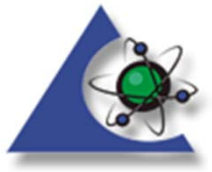


Accreditation Program Requirements

DoD ELAP program shall meet the requirements for proficiency testing as specified in the DoD ELAP QSM.

EPA NLLAP program shall meet the requirements for proficiency testing as specified in the EPA LQSR Version 3.0. All laboratories under the EPA NLLAP program shall participate in the American Industrial Hygiene Association (AIHA) Environmental Lead Proficiency Testing Program.

Each AB will have their specific criteria needing to be met.



DoD ELAP -SAMPLING

DOD QSM 5.3, 7.1, Note 2:GRAYBOX

Sample handling procedures shall address laboratory practices for recording the presence of extraneous materials (e.g., rocks, twigs, vegetation) present in samples in the case of heterogeneous materials. To avoid preparing non-representative samples, the laboratory shall not "target" within a relatively small mass range (e.g., 1.00 ± 0.01 g) because such targeting will produce non-representative subsamples if the sample has high heterogeneity. The laboratory shall not manipulate the sample material so the sample aliquot weighs exactly 1.00g ± 0.01g, as an example. The handling of multiphase samples shall be addressed in specific sampling procedures, as appropriate. The laboratory's sampling procedures shall comply with recognized consensus standards (for example, ASTM standards or EPA's *Guidance for Obtaining Representative Laboratory Analytical Subsamples from Particulate Laboratory Samples* (EPA/600/R-03/027)) where available.

TNI 2016 PT Highlights

V1M1-2016 4.2.2 *PT samples shall be analyzed in accordance with the laboratory's routine standard operating procedures (SOPs) using the same quality control (QC), acceptance criteria and staff as used for the analysis of routine environmental samples.*

V1M1 4.1.2 *The laboratory shall participate in PT studies for each field of accreditation where corresponding FoPTs exist in the TNI FoPT tables and for which the laboratory seeks to obtain or maintain accreditation.*

Drinking Water

Non-Potable Water

Solid and Chemical Materials

V1M1 4.1.7 *When a regulatory program has additional PT requirements for FoPTs not covered by this Standard (TNI) , then the laboratory shall follow those requirements.*

Is Critically Important with Reciprocity Accreditations

TNI PT for Accreditation

Fields of Proficiency Testing with PTRLs

Non-Potable Water (NPW)

Effective: October 1, 2020

TNI Non-Potable Water FOPT TABLE

Matrix/Codes, CAS#, ANALTE, CONC RANGE, CRITERIA, PTRL

Matrix	EPA Analyte Code	TNI Analyte Code	CAS Number	Analyte [1c]	Conc Range	Acceptance Criteria [6,7,8,9] a	b	c	d	TNI PTRL [7]
				Demands [10b]	mg/L					mg/L
NPW	0038	1530	NA	Biochemical oxygen demand [10c]	18 to 230	0.6237	0.7022	0.0928	0.6636	4.9
NPW	0102	1555	NA	Carbonaceous BOD (CBOD) [10c]	18 to 230	0.5648	0.6665	0.0965	0.8253	3.1
NPW	0036	1565	NA	Chemical Oxygen Demand (COD) [10d]	30 to 250	0.9843	-0.3171	0.0432	3.0191	16
NPW	0037	2040	NA	Total Organic Carbon (TOC) [10e]	6.0 to 100	0.9926	0.1680	0.0473	0.3536	4.2
				Minerals	mg/L					mg/L
NPW	0027	1505	NA	Alkalinity as $CaCO_3$	25 to 400	±20% at < 40; ±15% at ≥ 40 fixed acceptance limit				20
NPW		1540	24959-67-9	Bromide	1.0 to 10	1.0098	-0.0533	0.0400	0.0912	0.56
NPW	0023	1035	7440-70-2	Calcium	10 to 100	±15% fixed acceptance limit				8.5
NPW	0028	1575	16887-00-6	Chloride	35 to 275	1.0005	0.0490	0.0376	0.3716	30
NPW	0029	1730	16984-48-8	Fluoride	0.4 to 4	0.9748	0.0156	0.0487	0.0277	0.26
NPW		1550	NA	Calcium hardness as CaCO3	25 to 250	±15% fixed acceptance limit				21
NPW	0022	1755	NA	Total hardness as CaCO3	40 to 415	±15% fixed acceptance limit				34
NPW	0024	1085	7439-95-4	Magnesium	4.0 to 40	±15% fixed acceptance limit				3.4
NPW	0026	1125	7440-09-7	Potassium	4.0 to 40	±20% fixed acceptance limit				3.2
NPW	0025	1155	7440-23-5	Sodium	10 to 100	±20% fixed acceptance limit				8.0
NPW	0020	1610	NA	Conductivity	200 to 1200 umhos/cm	+10% fixed acceptance limit				180 umhos/cm

TNI PT for Accreditation
Fields of Proficiency Testing with PTRLs
Non-Potable Water (NPW)
Effective: October 1, 2020

TNI Non-Potable Water FOPT TAB

Matrix	EPA Analyte Code	TNI Analyte Code	CAS Number	Analyte [1,2]	Conc Range	Acceptance Criteria [3,4,5,6] a	b	c	d	TNI PTRL [7]

1) For volatiles, base/neutrals, acids, organochlorine pesticides, herbicides, and low level PAHs, providers must include a minimum number of analytes using the criteria described below:
PT samples that are to be scored for one to ten analytes must include all of these analytes.
PT samples that are to be scored for ten to twenty analytes must include at least ten of these analytes or 80% ot the total, whichever number is greater.
PT samples that are to be scored for more than twenty analytes must include at least sixteen of these analytes or 60% ot the total, whichever number is greater.
If the calculated percentage of the total number of analytes in the PT sample is a fraction, the fraction shall be rounded up to the next whole number.

2) One sample (minimum) in every study, containing one Aroclor, selected at random from among the Aroclors listed above.

3) Acceptance limits are set at the Mean ± 3 SD
Where the a, b, c and d factors are presented, Mean = a*T + b; SD = c*T + d where T is the assigned value.
Where only the c and d factors are presented, Mean = Robust Study Mean; SD = c*X + d where X is the Robust Study Mean.
Where no factors are presented (Study Mean ±3SD), Mean = Robust Study Mean, SD = Robust Study Standard Deviation.
Robust Study Mean and Standard Deviation are generated using statistical analysis of study data set. (ie. Bi-weight, Grubbs, Dixon, etc.)
Quantitative Microbiology acceptance criteria are based on the robust participant Mean and SD determined from each respective PT study

4) If the lower acceptance limit generated using the criteria contained in this table is less than (<) 10% of the assigned value, the lower acceptance limits are set at 10% of the assigned value with the exception of microbiology analytes.

5) If the lower acceptance limit generated using the criteria contained in this table is greater than 90% of the assigned value, the lower acceptance limits are set at 90% of the assigned value with the exception of microbiology analytes.

6) If the upper acceptance limit generated using the criteria contained in this table is less than 110% of the assigned value, the upper acceptance limits are set

7) TNI Proficiency Testing Reporting Limits (PTRLs) are provided as guidance to laboratories analyzing TNI PT samples. These levels are the lowest acceptable results that could be obtained from the lowest spike level for each analyte. The laboratory should report any positive result down to the PTRL. It is recognized that in some cases (especially for analytes that typically exhibit low recovery) the PTRL may be below the standard laboratory reporting limit. However, the laboratory should use a method that is sensitive enough to generate results at the PTRL shown…

SPECIAL TNI PT TOPICS

- *FREQUENCY – 2X per Year not more than 7 Months apart (closing date), Passing last 2 out of 3 PT studies, 7-day minimum separation between PT studies.*
- *NO NO's – Shall not subcontract, receive subcontract, discuss, or request results*
- *Corrective Action Required for ALL "Not-Acceptable"*
- *Accreditation Scopes offered by States will vary per State AB*

  May require a PT for each method (Always for Drinking Water Matrix)

  May require PREP Methods
- *If laboratory LOQ is < PTRL, may report either LOQ or PTRL*
- *If Laboratory LOQ is > PTRL may report numeric value between PTRL and LOQ without qualification.*
- *Acceptable is defined by AB, have 30 days to respond to AB request for CAR report.*

SPECIAL TNI PT TOPICS

V1M1 4.3.4 Except for drinking water analytes referenced in 40 CFR 141, a laboratory may choose to analyze and report a single method to represent a technology in a single PT study for a particular analyte. If the laboratory analyzes and reports PT studies by "technology," the score obtained for the reported method will be applied to all methods in that technology for which the laboratory seeks to obtain or maintain accreditation in that matrix.

- **NOTE: If a laboratory reports PT results for multiple methods using the same analytical technology, an evaluation of "not acceptable" for one method will be applied to all methods reported with that technology.**

PT-NOT ACCEPTABLES – ROOT CAUSES

Sample Preparation Error – (Review recorded PT prep details)

Dilution Errors (Dilutions allowed)

Method Design (Extraction/Digestion/Concentration Steps)

PT Reporting Errors (Method & Analyte Codes, Typos, EDD, Units, PTRL, missed closing date, no results generated, …)

Not Selecting Accreditor

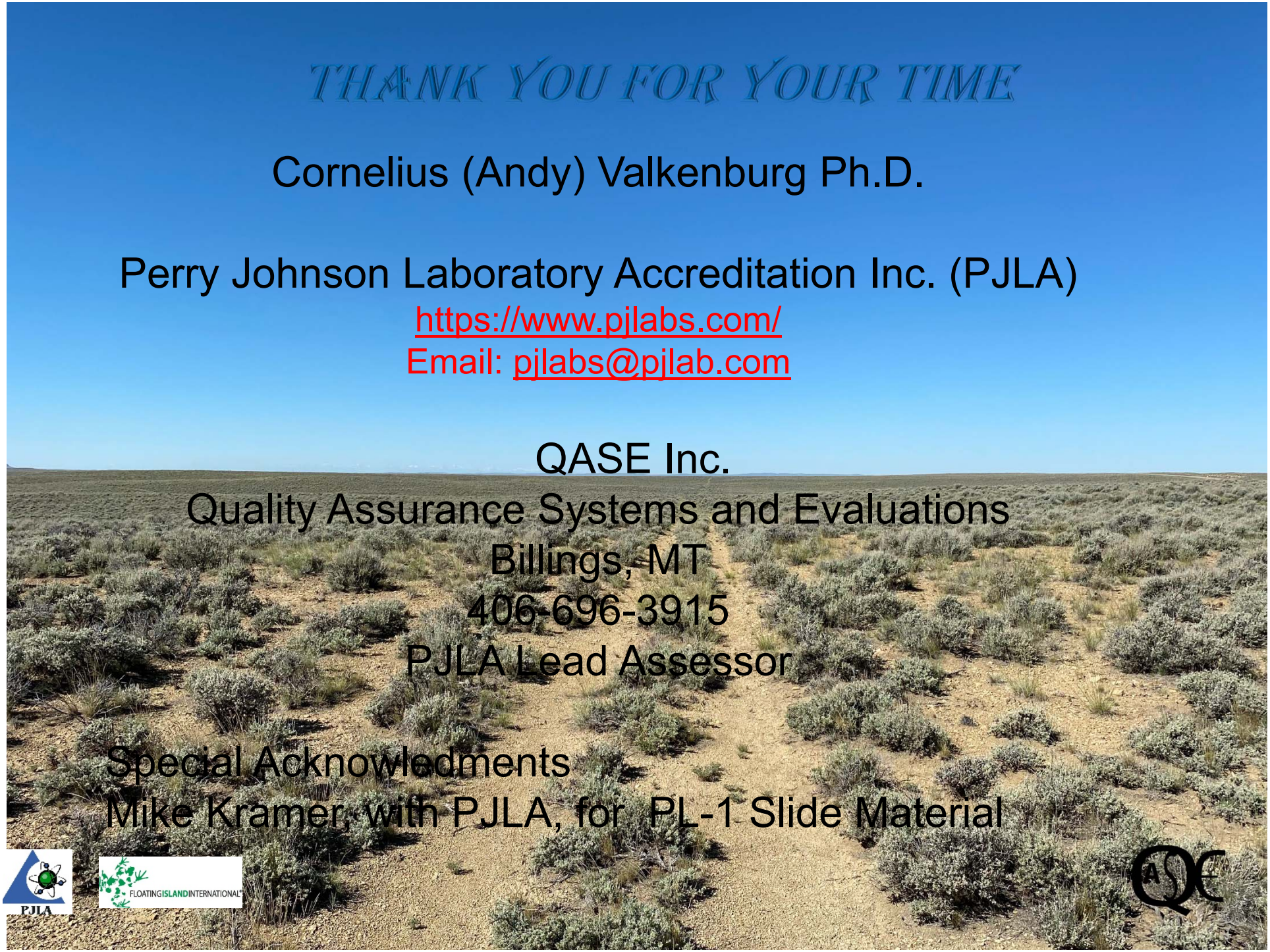
PT Selection/Design

PT Provider Scoring Error

No Root Cause – All QC in Control, result near assigned limit??

Evaluate Biases/Trends based on QC data

LCS, CCV, ICV, Surrogates, I.S., Calibration RE


THANK YOU FOR YOUR TIME
Cornelius (Andy) Valkenburg Ph.D.
Perry Johnson Laboratory Accreditation Inc. (PJLA)
https://www.pjlabs.com/
Email: pjlabs@pjlab.com
QASE Inc.
Quality Assurance Systems and Evaluations
Billings, MT
406-696-3915
PJLA Lead Assessor
Special Acknowledgments
Mike Kramer, with PJLA, for PL-1 Slide Material
PJLA
FLOATINGISLANDINTERNATIONAL
QASE


QUESTIONS???
PJIA
FLOATINGISLANDINTERNATIONAL®


Stay Safe, Be Well, Love Life, Enjoy the Sunrises
ASQE
FLOATINGISLANDINTERNATIONAL®