## Identify and Explore PT Resources

Presenter: Douglas Berg PJLA Testing Program Manager



## Webinar Overview

This webinar will include an overview on how to evaluate available proficiency testing resources to accommodate accreditation requirements. This will include various considerations such as:

- Review of relevant requirements documents
- Finding, selecting a competent provider-ISO/IEC 17043 Accredited, Approved by the AB, Nationally recognized
- Non-accredited third party programs, other Inter-laboratory Comparison (ILC) schemes or arrangements
- Evaluation of the PT scheme Does it align with your scope?
- Planning of PTs based upon a risk-based thinking approach, volume of work, etc.
- Alternative PTs -Intra-laboratory, Repeatability Studies why and when to resort to these options
- Opportunity for Questions



### Webinar Housekeeping

- This webinar is being recorded
- All PJLA webinar recordings and slides are available for download from the Past Webinars section of our website
  - <u>https://www.pjlabs.com/training/pjla-webinars</u>
- All attendees are muted. However, feel free to utilize the questions tab and they will be answered at the end of the session.



#### Welcome and Introductions



Presenter/MC PJLA – Tracy Szerszen President tszerszen@pjlabs.com

> Presenter: Doug Berg PJLA –Testing, RMP, PTP Program Manager dberg@pjlabs.com



**Douglas Berg** has 45+ years' experience in testing, calibration, laboratory operations, engineering, and management. He has worked for the US EPA and GM and, since retiring, has worked with accreditation organizations as an assessor and program manager. He's currently the Testing Program Manager for PJLA, an ILAC MRA signatory. As program manager, he is responsible for the programs for testing, environmental field sampling, reference materials, and proficiency testing. He is also a peer evaluator for other accreditation bodies in the Asia Pacific Accreditation Cooperation (APAC)



## Webinar Overview

This webinar will include an overview on how to evaluate available proficiency testing resources to accommodate accreditation requirements. This will include various considerations such as:

- Review of relevant requirement documents
- Finding, selecting a competent provider-ISO/IEC 17043 Accredited, Approved by the AB, Nationally recognized
- Non-accredited third party programs, other Inter-laboratory Comparison (ILC) schemes or arrangements
- Evaluation of the PT scheme Does it align with your scope?
- Planning of PTs based upon a risk-based thinking approach, volume of work, etc.
- Alternative PTs -Intra-laboratory, Repeatability Studies why and when to resort to these options
- Opportunity for Questions



#### **ILAC P9:2024 ILAC Policy for Participation in Proficiency Testing**

This document sets out the policy for accreditation bodies on the use of proficiency testing activities in the accreditation process

## E/A-4/18:2021 Guidance on the level and frequency of proficiency testing participation.

"This paper provides guidance to accreditation bodies with the aim to promote harmonization between accreditation bodies on how the level and frequency of participation in PT is evaluated and to assist laboratories in determining their own levels and frequency of participation." (discusses "risk" considerations)



#### ISO/IEC 17011:2017 Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies

This document specifies the requirements for accreditation bodies accrediting conformity assessment bodies.

Note: In the context of this document, activities covered by accreditation include. but are not limited to testing, calibration, inspection, certification of management systems, persons, products, processes and services, *provision of proficiency testing*, production of reference materials, validation and verification.

## **ISO/IEC 17000:2004 Conformity assessment — Vocabulary and General Principles**

This International Standard specifies general terms and definitions relating to conformity assessment, including the accreditation of conformity assessment bodies, and to the use of conformity assessment to facilitate trade



ISO/IEC 17011:2017 Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies (ISO/IEC 17000 references in "[]")

**3.1- accreditation:** third-party attestation related to a *conformity assessment body* (3.4) conveying formal demonstration of its competence to carry out specific conformity assessment tasks [5.6]

**3.2 accreditation body -** authoritative body that performs *accreditation* (3.1)[2.6]

**3.4 conformity assessment body -** body that performs conformity assessment activities and that can be the object of *accreditation* (3.1) [2.5]



ISO/IEC 17011:2017 Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies (ISO/IEC 17000 references in "[]")

**3.5 conformity assessment activity -** activity conducted by a *conformity assessment body* (3.4) when assessing conformity

Note 1 to entry: In the context of this document, activities covered by *accreditation* (3.1) include, but are not limited to, *testing, calibration, inspection,* certification of management systems, persons, products, processes and services, *provision of proficiency testing, production of reference materials*, validation and verification. For simplicity, these are referred to as conformity assessment activities being performed by conformity assessment bodies.

PILA

#### ISO 13528 Statistical methods for use in proficiency testing by interlaboratory comparison:2022 (was 2015/2016)

This document provides detailed descriptions of statistical methods for *proficiency testing providers* to use to *design proficiency testing schemes* and to *analyze the data obtained from those schemes*. This document provides *recommendations* on the *interpretation* of proficiency testing data by *participants* in such proficiency testing schemes and by *accreditation bodies*.

The procedures in this document *can be applied* to demonstrate that the measurement results obtained by laboratories, inspection bodies, and individuals meet specified criteria for acceptable performance ... (more)



#### ISO 13528 Statistical methods for use in proficiency testing by interlaboratory comparison:2022 (was 2015/2016)

NOTE The procedures in this document *can* also be applied for the assessment of expert opinion where the opinions or judgments are reported in a form which can be compared objectively with an independent reference value or a consensus statistic. For example, when classifying proficiency test items into known categories by inspection - or in determining by inspection whether proficiency test items arise, or do not arise, from the same original source - and the classification results are compared objectively, the provisions of this document that relate to nominal (qualitative) properties can be applied.



## **ISO/IEC 17025:2017** General requirements for the competence of testing and calibration laboratories

**7.7.2** 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 that meet the requirements of ISO/IEC 17043 are considered to be competent.

b) Participation in interlaboratory comparisons other than proficiency testing



## **ISO/IEC 17025:2017** General requirements for the competence of testing and calibration laboratories

**8.5.1** The laboratory shall consider **risks and opportunities** associated with the laboratory activities in order to:

- a) give assurance that the management system achieves its intended results
- b) enhance opportunities to achieve the purpose and objectives of the laboratory
- c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities
- d) achieve improvement
- **8.5.2** The laboratory shall plan:
  - a) actions to address these risks and opportunities
  - b) how to:
    - integrate and implement the actions into its management system
    - evaluate the effectiveness of these actions

## **ISO/IEC 17025:2017** General requirements for the competence of testing and calibration laboratories

Note: Although this document specifies that the organization plans actions to address risks, there is no requirement for formal methods of risk management of a documented risk management process. Laboratories can decide than is required by this whether or not develop a more extensive risk management methodology than is required by this document, e.g. *through the application of other guidance or standards* 

**8.5.3** Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.

Note 1: Options to address risks can include identifying and avoiding threats, taking a risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing risk, or retaining risk by informed decisions.

Note 2: Opportunities can lead to expanding the scope of the laboratory activates, addressing new customers, using new technology, and other possibilities to address customer needs.



# **ISO/IEC** Conformity assessment — General requirements for the competence of proficiency testing providers: ISO/IEC 17043:2023

#### **3.4 Interlaboratory Comparison**

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

Note 1 to entry: The term "laboratories" is used in this document to cover all organizations that provide information on items based on experimental observation, including measurement, testing, calibration, examination, sampling and inspection.

Note 2 to entry: The term "measurements or tests" is used throughout this document to apply to any activities undertaken by the proficiency testing *participants* (3.6) that are subject to the *proficiency testing* (3.7), whether quantitative, qualitative or interpretative, unless otherwise qualified.





# **ISO/IEC** Conformity assessment — General requirements for the competence of proficiency testing providers: ISO/IEC 17043:2023

#### **3.4 Interlaboratory Comparison**

Note 3 to entry: Interlaboratory comparisons that involve measurements convey more insight regarding performance when measurement uncertainty is considered.

[SOURCE: ISO 13528:2022, 3.1, modified — The word "organization" has been replaced with "design" and the Notes to entry have been added]



# **ISO/IEC** Conformity assessment — General requirements for the competence of proficiency testing providers: ISO/IEC 17043:2023

**3.11proficiency testing scheme PT scheme** 

*proficiency testing* (3.7) designed and operated in one or more *proficiency testing rounds* (3.10) for a specified area of measurement, testing, calibration, examination, sampling or inspection

Note1 to entry: A proficiency testing scheme can cover a particular type of activity or a number of activity types within the same area.

#### 3.3 customer client

organization or individual for which a *proficiency testing scheme* (3.11) is provided through a contractual arrangement

Note 1 to entry: The term "client" is an alternative term for "customer" used in parts of this document and these terms are regarded as having the same definition

PJLA

#### PJLA PL-1 – Discipline, Sub-discipline

#### 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.

#### **Sub-discipline (testing/calibration)**

- 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 necessary to successfully perform the other



## How does PJLA describe what conformity assessment bodies must/can do? .... PL-1

- Initial Accreditation Objective evidence for at least one item on the proposed scope ... within 12 months of the date of initial assessment – demonstrate the organization competence
- When accredited perform PT annually evidence of favorable performance for each discipline over a four year period. Changes can be made by PJLA if proposed by the CAB

#### But then ....

- For programs such as TNI, DoD/DOE, EPA NLAP, etc. follow the specifics regarding proficiency testing in the particular document.
- EPA NLAP 4 times per year, paint chips, dust and soil and **only from AIHA** scored and sent to accrediting body
- TNI, DoD/DoE twice per year scored sent to accrediting body specific PT providers listed (DoD)/DoE all analyte/matrix combinations 6+/- 2 months apart ISO/IEC 17043 accredited)

PJLA

#### PJLA LF-81 - FOUR-YEAR PT (Proficiency Test) SCHEDULE

- PJLA LF-81 is not a requirement, a "plan" is the requirement
- Other formats can be used to be the "plan" whole or in part (calendars, descriptive "schedule", etc etc.
- For programs like those on the previous slide (TNI, DOE, etc ) it could be a "document" that commits to the frequency and sources ...
- PJLA LF-81 is structured with a "blank" first page (table/spreadsheet) and examples on the 2<sup>nd</sup> page illustrating "Discipline", "Sub-discipline" with examples



#### PJLA LF-81 - FOUR-YEAR PT (Proficiency Test) SCHEDULE



#### FOUR-YEAR PT (Proficiency Test) SCHEDULE

(At a minimum this should include 4 years of PT activities. Additional sheets may be used for further years)

#### (Enter Organization Name Here)

This plan defines the specific calibration or test disciplines or sub disciplines for which PTs 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 Proficiency Testing for the P11A. PT policy.

		Year	Year	Year	Year	Source or Type
#	Proficiency Test Discipline					(ISO.IEC 17043 PT Provider, 3 <sup>rd</sup> party/Inter laboratory, Repeatability/Intra-lab)
Ente	r the calibration or test discipline					
1	Sub discipline to be tested					
2						
3						
4						
5						
6						
7						
8						
9						
10						

#### Intra-laboratory comparisons and repeatability studies

Where third party proficiency testing or inter-laboratory comparisons are not achievable in accordance with PJLA PL-1 Proficiency Testing, the organization must obtain PJLA headquarters approval for other means of evaluating performance (e.g., intra-laboratory and/or repeatability studies). The laboratory shall submit this LF-81 Four-Year PT (Proficiency Test) Schedule along with the reasoning for doings on adh procedure for administering/evaluating the PTs.

PJLA Headquarters Approval: (only required when third party proficiency testing or inter-laboratory comparisons are not achievable)

Signature

Date



Rev 1.2 Page 1 of 2



#### PJLA LF-81 - FOUR-YEAR PT (Proficiency Test) SCHEDULE



FOUR-YEAR PT (Proficiency Test) SCHEDULE (At a minimum this should include 4 years of PT activities. Additional sheets may be used for further years)

#### Examples

PJLA lists approved PT providers on the website (http://www.pjlabs.com/resources/proficiency-testing). Fictitious PT provider names were used for the examples below.

#### **Calibration Laboratory**

	Des Cales on Tast Diadalia	Year	Year	Year	Year	C
#	Proficiency Test Discipline	2014	2015	2016	2017	Source or Type
Dime	nsional					
1	Outside Micrometer	~				3 <sup>rd</sup> Party (Integrity PT)
Mech	anical					
2	Indirect Verification of Rockwell Hardness Tester		~			Inter laboratory comparison
Chen	nical					
3	pH Meters			~		3rd Party (American PT)
Elect	rical					
4	Electrical Simulation of thermocouple output				~	Inter laboratory comparison

**Testing Laboratory** 

#	Proficiency Test Discipline	Year	Year	Year	Year	Source or Type
"	Fronciency Test Discipline	2014	2015	2016	2017	source or Type
Envi	ronmental Testing					
1	EPA 3050B test for Lead (Pb) in Paint Chips.	$\mathbf{\mathbf{v}}$				3 <sup>rd</sup> Party (PJLA sponsored PT)
Mec	hanical Testing					
2	US Steel Retention Test (Four Gram Method)		×			Inter laboratory comparison
Cher	nical Testing					
3	ASTM D1121 test for Reserve Alkalinity of Oils and Greases			~		3 <sup>rd</sup> Party (Chemical PT, Inc.)
4	RSK-175 Dissolved Gases (Aqueous)			~		Internal PT (intra or repeatability) *
Biol	ogical Testing					
5	PCR test for Specified Microorganism (Salmonella)				~	Inter laboratory comparison

 PTs other than third party proficiency festing or inter-laboratory comparison require submittal of the reasoning for doing so and procedure for performing/evaluating the PTs with the LF-81 to obtain PJLA headquarters approval.

Issued: 6/07

Revised: 5/20

Rev 1.2

Page 2 of 2



#### Know Your Program ... TNI listed PT Sample Providers

A provider of PT satisfies that are accredited	amples must be accredited by a Proficiency Te to provide PT samples is available below.	_	- The NELAC Institute (TNI) nat meets the TNI requirement:	s. A listing of organizations
TNI PT Provider Code	PT Provider	Contact	City, State	Phone
TNIPTP16	Absolute Standards, Inc.	Stephen Arpie	Hamden, CT	800-368-1131
TNIPTP19	Advanced Analytical Solutions, LLC	Frederick Anderson	Parkersburg, WV	304-422-4274
TNIPTP21	ERA	Craig Huff	Golden, CO	303-431-8454
TNIPTP31	NYS DOH Wadsworth Center	Patrick Parsons	Albany, NY	518-474-7161
TNIPTP36	NSI Solutions, Inc.	Kenneth Grybowski	Raleigh, NC	800-234-7837
TNIPTP46	Phenova	PT Service	Golden, CO	303-940-0033

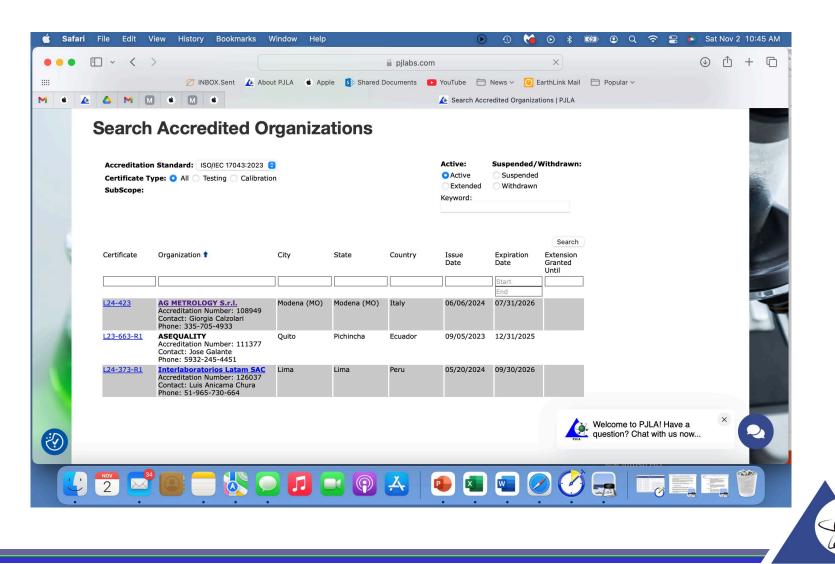
## Finding a Competent Provider ... ILAC/APAC recognized US PT providers – web sites

- Accredited to ISO/IEC 17043:2013 by an ILAC recognized (for PT) AB (etc. PJLA, A2LA, ANAB, IAS in US, others in the EA, etc.)
   All these have web sites with searchable features ...
- BAM (German "NIST") eptis data base (eptis.bam.de)
- European PT Information System (EPTIS online 2000)
  - Search by country, testing field, product groups, accreditation (y/n/other)
  - Be warned ... takes some practice and patience ... example
    - Country Italy
    - Testing Fields Electrotechnic/electronics
    - Product Groups Electrical/electronic devices
    - Accreditation yes
    - Screen shows 2 of several rows for AG Metrology (PJLA accredited to ISO/IEC 17043:2013)

#### Bundesanstalt für Materialforschuntund-prüfune (BAM) eptis data base

			Bookmarks	Window H	lelp				$\mathbf{igstar}$	$\odot$		$\odot$	* 🗳	• •	Q	<u></u>	8 🌔	Fri No
•						eptis.	.bam.de 🔒											
Search	n a Proficier	ncy Testin	ng (PT) s	cheme i	n the	databas	е											8
Turnella														0	SEAR	cu l		
	i one or more ke	<i></i>												4	SEAR	CH	RE	SEI
Your sea	rch filters: 🔇 It	aly 🛛 🕹 electro	otechnics / ele	ctronics	electrica	l / electronical	l devices	✓ accre	dited									
		•			FIELD	5-		🕴 PRO	DUCT GF	OUPS	•			✓ A(	CRED	ITATI	ON -	
				← Previo		Page <b>1</b> of <b>1</b>				t →								
ID	COUNTRY	PT PRO	VIDER	PT SCHEM	ИE										ţŗ	LAST	CHAN	GED
<b>ID</b> 708020	COUNTRY	PT PROV	trology	PT SCHEN	on of a dout Th									un		<b>LAST</b> -10-28		GED

#### Finding a Competent Provider ... PJLA web site



#### Finding a Competent Provider ... A2LA web site

	History Bookmarks	Willdow Help				e u ÷	🖻 😑 🌔 Sat N	ov 2 10:52 AM										
•••			🗎 customer.a2la.org		5		٩	1 + C										
	💋 INBOX.Sent 🔥 At	bout PJLA 🔹 Apple 🔹 Shari	ed Documents 🛛 🕒 YouTu	be 🗎 News 🗸	🧿 EarthLink Mail 🛛 🗎	Popular ~												
M 4 🚣 🛆 M 🖾 4		<ul> <li>Assessment Accredit</li> </ul>	ation Services   A2LA		Touchstone:Accreditati	on & Assessmen	nt Management System	- Customer Po										
		A Better	World Throu	gh Accre	ditation													
	Search A2L	A Directory of Ac																
			5	uspended, Withd	awn and Inactive Certif False Claims of Accredi	itation												
	Q Search Cr	riteria			reset criteria	~												
	Keyword:	electronics Enter scope, test method, ce	rtificate no., organizatio	n name, etc														
	Filter Program(s):	× • A2LA : ISO/IEC 17043	]															
	Accreditation:	Organization Name	*	Cert. No. 🔻	Commercial Status	•												
	Location:	Select one or more	State/Province Select one or more	City		Zi												
				Back to Home	age Search Direc	tory	Ś	Safari File Ed	lit View History B	Bookmar	rks Window Help		19	•••		) @ Q	ଚ 🔒 🍋 S	at Nov 2
								• • •				🔒 customer.a			c			) ①
										X.Sent	👍 About PJLA 🔹 Apple 🛐			🗀 News 🗸		🗎 Popular 🗸		
💽 🛃 📴 🚺	I 🥅 法 🤇	) 🗾 🗔 🖗	🙏 🚺	💶 💶	🧭 🕗 🚽		M	• 🚣 🛆 1	• 🛛 • 🖾 •		👀 Assessment Acc	creditation Services	A2LA		Touchstone:Accredi	itation & Assess	ment Management Sy	stem - Cu:
														ack to Homep	age Search Di			
										Searc	th Results - found 3 rec	ord(s)				×		
									i≣ Show		ch Results - <i>found 3 rec</i>	ord(s)						
									Show Ce	20 ert. ¢ No.	Rows	Location	Country	Comm. Code	Program			
									Show Ce 307	20 ert. (*) No. (*)	Rows  Organization  Signature Science, LLC	Location Austin, TX	Country United States	Comm. Code	Program ISO/IEC 17043			
									Show Ce 107 407	20 ert. No. 76.01 5 77.01 0	Rows  Organization  Signature Science, LLC  QLStandard	Location Austin, TX Ciudad de México	Country United States Mexico	Comm. Code	Program ISO/IEC 17043 ISO/IEC 17043			
									Show Ce 107 407	20 ert. No. 76.01 5 77.01 0	Rows  Organization  Signature Science, LLC	Location     Austin, TX     Ciudad de	Country United States	Comm. Code	Program ISO/IEC 17043			
									Show 6 8 307 407 309	rt. () (6.01 ) (7.01 ) (4.01 )	Rows  Organization  Signature Science, LLC  QLStandard	Location     Austin, TX     Ciudad de     México     Traverse	Country United States United	Comm. Code	Program ISO/IEC 17043 ISO/IEC 17043	• •		
									Show 6 8 307 407 309	rt. () (6.01 ) (7.01 ) (4.01 )	Rows      Organization      Qrganization      Quistandard  American Proficiency Institute      3 of 3 entries	Location     Austin, TX     Ciudad de     México     Traverse	Country United States Mexico United States Firm	Comm. Code	Program ISO/IEC 17043 ISO/IEC 17043	• •		
								2	Show 6 8 307 407 309	rt. •	Rows  Organization  Organization  Qustandard  American Proficiency Institute  3 of 3 entries  powe	<ul> <li>Location</li> <li>Austin, TX</li> <li>Giudad de México</li> <li>Traverse City, Mi</li> </ul>	Country United States United States Fin	Comm. Code C1 C1 C1 C1 C1 t Previou	Program ISO/IEC 17043 ISO/IEC 17043	Last		
									Show 6 8 307 407 309 Show	rt. •	Rows  Organization  Organization  Qustandard  American Proficiency Institute  3 of 3 entries  powe	Location     Location     Austin, TX     Ciudad de     México     Traverse     Traverse tred by Touchs	Country United States United States Fin	Comm. Code C1 C1 C1 C1 C1 t Previou	Program           ISO/IEC 17043           ISO/IEC 17043           ISO/IEC 17043           ISO/IEC 17043           ISO/IEC 17043	Last		
								2	Show 6 8 307 407 309 Show	rt. •	Rows  Organization  Organization  Qustandard  American Proficiency Institute  3 of 3 entries  powe	Location     Location     Austin, TX     Ciudad de     México     Traverse     Traverse tred by Touchs	Country United States United States Fin	Comm. Code C1 C1 C1 C1 C1 t Previou	Program           ISO/IEC 17043           ISO/IEC 17043           ISO/IEC 17043           ISO/IEC 17043           ISO/IEC 17043	Last		
								2	Show 6 8 307 407 309 Show	rt. •	Rows  Organization  Organization  Qustandard  American Proficiency Institute  3 of 3 entries  powe	Location     Location     Austin, TX     Ciudad de     México     Traverse     Traverse tred by Touchs	Country United States United States Fin	Comm. Code C1 C1 C1 C1 C1 t Previou	Program           ISO/IEC 17043           ISO/IEC 17043           ISO/IEC 17043           ISO/IEC 17043           ISO/IEC 17043	Last		

PJLA

#### Finding a Competent Provider ... ANAB web site

	Directory Of Accredited Organizations	🗯 Safari File Edit View	History Bookmarks Window Help	۰ و او او	ට 🖇 🛤 🛈 Q 🗢 🚼 🔸 Sat Nov 2
	General Keyword Company Certificate #	••• • • < >	🖉 INBOX.Sent 🏠 About PJLA 🔹 Apple 🚯 Shared D	search.anab.org	Č
	Company Certificate w		ReuX.sent Accreditation Se		EarthLink Wall     Coppuse      Popuse      Coppuse      Coppuse
	Status All ÷ Standard ISOREC 17043:2023 ÷		Scopes of Accreditation Calibration Labs None Dimensional Measurement	Testing Labs     None     Inspection Bodies/Agence	¢)
File Edit Vie	w History Bookmarks Window Help 💿 👀 🎲 👀 🐮	▶ ② Q 奈 〓 ● Sat Nov 2 11:06 AM こ ③ 作	None	None     Reference Material Prod	¢)
	NBOX.Sent      About PJLA      Apple      Shared Documents      YouTube      News      EarthLink     Counter      About PJLA      Apple      Shared Documents      YouTube      News      EarthLink     Counter      Assessment Accreditation Services (AZLA		None Forensic Testing None	None     Proficiency Testing Provi     Electrical	\$
(	Organizations Found: 3		Forensic Calibration None	Medical / Clinical Testing     None	
	National Association for Proficiency Testing 3470 Washington Dr., Suite 122 Eagan, MN 55122 USA Phone: 952-303-6126 Web: www.proficiency.org		Forensic Inspection None	Property and Evidence C	control Units
	Accreditation Status: Active		Programs/Schemes Calibration Programs	Reset the Form	
	Standard: ISO/IEC 17043-2023       Certificate: AP-1873       Effective Through: 07/14/2026       Field(s)       Proficiency Testing Providers       Acoustics, Calibration, Electrical, Mass, Other, Thermal		8 💳 🐇 🗩 🚺 🔤 🖗 🔺	1 🔹 🖬 🗶	) 🖉 🔒 🔲 🖷 🗮 🕻
	Certificate Scope				

PJLA

#### Finding a Competent Provider ... IAS web site





# **ISO/IEC** Conformity assessment — General requirements for the competence of proficiency testing providers: ISO/IEC 17043:2023 – What has changed?

- The main changes are as follows:
  - Harmonization with ISO/IEC 17025:2017, including technical requirements and structure;
  - Harmonization with ISO 13528:2022 in terms of terminology;
  - Incorporation of requirements from ISO/CASCO PROC 33;
  - Inclusion of the requirement that testing activities, calibration activities and PT item production conform to the relevant requirements of appropriate ISO conformity assessment standards;
  - Deletion of Annex C and revision of Annexes A and B



# **ISO/IEC** Conformity assessment — General requirements for the competence of proficiency tesg providers: ISO/IEC 17043:2023

- 1. Scope
- 2. Normative references
- 3. Terms and definitions
- 4. General requirements impartiality, confidentiality
- 5. Structural requirements
- 6. Resource requirements general, personnel, facilities and environmental conditions, externally provided products and services
- 7. Process requirements
- 8. Management system requirements

Annex A (informative) Types of PT schemes Annex B (informative) Statistical methods for PT



#### ILAC P9:2024 – Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing :01/2024 – ILAC POLICY ON Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing

- ABS seeking to maintain status as a signatory to the ILAC MRA shall demonstrate technical competence of their CABS
- One elements of this demonstration is the comparison with other CABs where available and appropriate, the ILAC policy on PT an and/or ILCs other than PT:

 Taking into consideration the outcome of the CAB's risk assessment, participation in PT and/or ILCs other than PT is considered, by ISO/IEC 17025:2017 as mandatory when available, appropriate and deemed necessary. For ISO 15189:2022, participation in PT is considered mandatory when available, appropriate and deemed necessary.

2) Participation is applicable not only to laboratories, but also to CABs accredited to other standards performing testing and/or calibration activities as part of their accredited conformity assessment activities.



#### ILAC P9:2024 – Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing :01/2024 – ILAC POLICY ON Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing

(continued)

3) The AB shall request their applicant and accredited CABs to develop a participation plan in PT and/or ILCs other than PT (PT participation plan).

- 4) The AB shall assess the PT participation plan to ensure that there is a representative and satisfactory participation in PT and/or ILCs other than PT activities regarding an applicant scope before granting accreditation.
- 5) The AB shall ensure that the PT participation plan foresees a representative participation in PT and/or ILCs other than PT activities regarding any accreditation scope.

6) Where satisfactory performance is not achieved, the AB shall assess the evidence of the implementation of prompt and appropriate corrective actions

7) The AB shall assess the justifications of the CAB's alternative approaches when there are no available and appropriate PT and/or ILC's other than PT to cover the applicant or accredited scope. The AB shall verify that the alternative approach implemented by the CAB ensures the validity of the results.



#### ILAC P9:2024 – Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing :01/2024 – ILAC POLICY ON Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing

(continued)

8) The AB shall define its process on the use of PT and/or ILCs other than PT. The process shall include, at least, the following:

a) how the AB takes into consideration PT and/or ILCs other than PT participation and performance (in particular when persistent poor performance is identified);

Note: This includes PT and/or ILCs other than PT that has been mandated, for example by a regulator, an industry or professional sector.

) how the AB deals with the situation where the CAB's PT participation plan is considered not suitable in relation to the scope of accreditation;

c) how the AB takes into account a CAB's PT and/or ILCs other than PT performance, to plan the assessments;

d) how the AB ensures that the CABs have appropriate evidence of the competence of the PT provider or the organization providing ILCs other than PT (see Appendix A).



**1.2** This document outlines PJLA's general requirements in regards to proficiency testing including: required frequencies, acceptable means of comparing and analyzing data, competency requirements and international program requirements. This document is designed based upon requirements of ISO/IEC 17025:2017, ISO 15189:2012, ISO 17034:2016, ISO/IEC 17011:2017, ISO/IEC 17043:2010 and ILAC P9:6/2014.

Some accreditation programs have more specific requirements regarding proficiency testing, established by legislation, regulation, or specification. These may involve increased frequency, specified sources for PT, acceptability criteria, and the like.



**1.2** (cont'd) In some instances, these requirements are more stringent and comprehensive than those mandated as referenced above and PJLA's own requirements as detailed in this document. In such cases PJLA will enforce such requirements by exercising its responsibility as a recognized accrediting body for these programs (i.e. DoD ELAP, EPA NLLAP, TNI EL Program).

• • • •

**1.2.1** *Note:* Specific PT criteria for PJLA's Medical Laboratory Program (ISO 15189:2012) are detailed in Appendix A of this policy. Appendix A and the body of the main policy shall be adhered to for medical laboratories.



## **3.0 PROFICIENCY TESTING REQUIREMENTS: APPLICANT ORGANIZATIONS**

- Prior to accreditation provide objective evidence of PT with at least one item from the desired scope
  - Results must be suitable for demonstrating competence in performing the test or calibration
  - The test data must be dated no more than 12 months from the initial assessment date

#### Accredited organization

- Perform PT annually
- Results monitored in subsequent surveillances or At minimum organizations must have evidence of favorable PT results for each discipline in their scope over the four year cycle (this may be shortened by PJLA due to changes in staff or scope)
- PT plans adjusted to reflect changes in personnel/scope



#### 6.0 APPROVED MEANS OF PROFICIENCY TESTING

6.1 The following activities (listed in their order of preference and acceptability) have been approved by PJLA for the purpose of demonstrating proficiency:

1.participation in proficiency testing programs sponsored by a third party accredited provider;

2.participation in proficiency testing programs sponsored by a third party provider,;3.inter-laboratory comparisons organized by industry groups (round robins, method validation studies, small group (including two party) comparisons etc

6.2 When use of the above approved methods is considered by the organization as being impractical as a means of demonstrating proficiency the following activities, listed in their order of preference, may be used pending prior approval by PJLA:

1.-intra-laboratory comparisons, and;

2.-repeatability studies.

*Note:* If an organization wishes to proceed with one of the above-mentioned means, they must state in writing why third party or inter laboratory comparisons are not feasible and how they plan to conduct the test and analyze the data. This document shall be submitted to PJLA headquarters for review and approval

#### 6.0 APPROVED MEANS OF PROFICIENCY TESTING (continued)

6.3 PJLA promotes 3<sup>rd</sup> party proficiency testing programs by an accredited or other whenever such programs exist. Advantages are:

- Testing at appropriate intervals
- Objectivity of the sponsoring organization
- Statistical analysis, expert review of the data by the provider
- Direct reporting to PJLA by the provider if required by program etc.

#### 6.4 Inter-laboratory Comparisons

- Two or more organizations perform testing/calibration on the same artifact, comparable methods, conditions etc. accredited or not.
- Results should be in agreement as determined by appropriate analyses, statistical analytical or graphical (various ref. see ISO 13528:2015)
- Participation in the characterization of a reference material by a competent reference material provider (ISO 17034:2016 or
- Standards development or maintenance to determine bias, precision, repeatability, reproducibility, uncertainty by a standards body

PJLA

#### 6.0 APPROVED MEANS OF PROFICIENCY TESTING (continued)

#### 6.5 Intra-laboratory Comparisons

- Two or more analysts/technicians perform testing/calibrations on the same artifact(s) using the same method on the same or similar artifact
- Results to be analyzed for statistical validity

#### 6.6 Repeatability Studies

- If none of the other methods are feasible (an organization with only one technician or special circumstances) proficiency may be demonstrated with prior review and approval by PJLA
- A number of tests or measurements (8 or more) on the same or similar item/artifact using the same method under similar conditions. Results analyzed for statistical validity by appropriate means.

Note: Use of 6.5 & 6.6 even partially requires PJLA review and approval, and reviewed at every assessment

## **ISO/IEC** Conformity assessment — General requirements for the competence of proficiency testing providers: ISO/IEC 17043:2023 – Transition Period

ILAC Resolution GA 26.09

As the revised version of ISO/IEC 17043 is scheduled for publication in 2022 or early 2023, the General Assembly endorses the recommendation of the AIC that a transition period of 3 years from the date of publication be adopted.

At the end of the transition period, accreditation of a proficiency testing provider to ISO/IEC 17043:2010 will not be recognized under the ILAC Arrangement.

In addition, as highlighted by the ILAC AMC Chair, Jennifer Evans, at the General Assembly meeting, the AMC will be responsible for monitoring this transition and the process used will be similar to that used during the implementation of ISO/IEC 17025:2017.



## **ISO/IEC** Conformity assessment — General requirements for the competence of proficiency testing providers: ISO/IEC 17043:2023 – Transition Period

**Dear ILAC members** 

I am pleased to advise that ISO/IEC 17043:2023 Conformity assessment — General requirements for the competence of proficiency testing providers has now been published.

I would like to take this opportunity to thank Erik Oehlenschlaeger, ILAC AIC Chair, the members of the AIC PT working group and our liaison officers to the ISO WG responsible for this standard that have contributed significantly to the revision of this important standard for ILAC, our accreditation body members and their accredited proficiency testing providers.

As you will also recall a resolution was endorsed at the General Assembly held in November 2022 to allow a 3-year implementation period from the date of publication of this revised standard (that will now be 31 May 2026) as shown below



### Thank You



This time is allocated for questions. You should have a space provided for submitting questions.

If a question is not answered, please submit directly to webinar@pjlabs.com



## PJLA Upcoming courses ...

ISO/IEC 17025:2017 2-DAY OVERVIEW COURSE Tuesday, November 19 – Wednesday, November 20, 2024 – 10:00-4:30pm ET \$500.00 Live Overview Course presented by Matthew Sica

#### DOCUMENTING & MAINTAINING A QUALITY MANAGEMENT SYSTEM Tuesday, December 17, 2024 – 1:00-3:00pm ET Free Live Workshop presented by Matthew Sica





## PJLA

#### Contact Information

- Perry Johnson Laboratory Accreditation, Inc.
- 755 West Big Beaver Road, Suite 1325
- Troy, MI 48084
- Tel: (248)-519-2603
- Website: <u>www.pjlabs.com</u>
- Email: <u>tszerszen@pjlabs.com</u>
- Email: <u>dberg@pjlabs.com</u>

