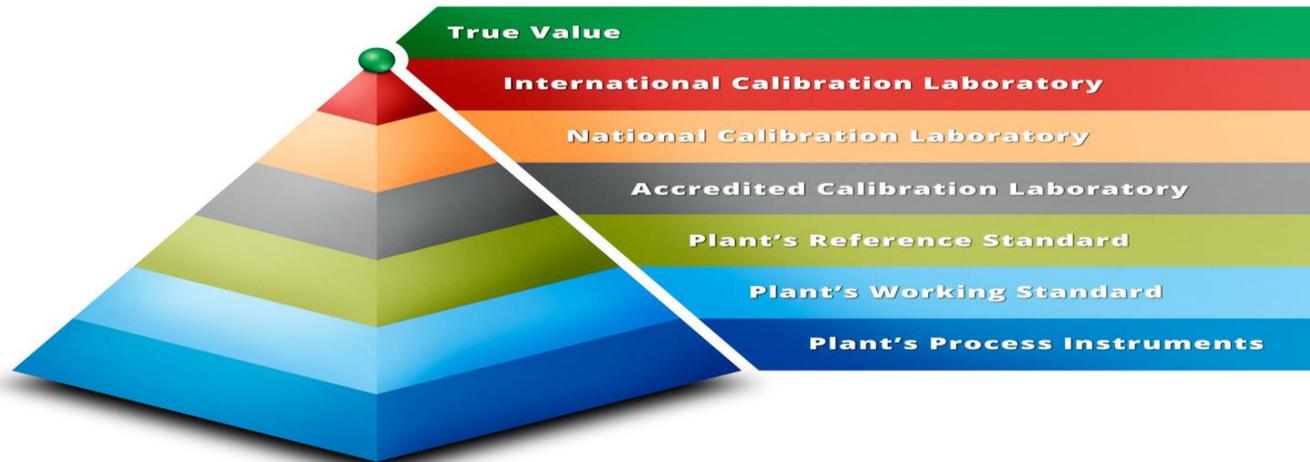


# Traceability Requirements of ISO/IEC 17025:2017 and PJLA Policy on Measurement Traceability PL-2

28-March-2019

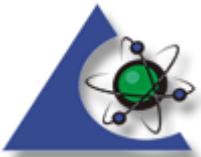


*Michael Kramer*

*Calibration/Inspection Program Manager*

*Perry Johnson Laboratory Accreditation, Inc.*

*[mkramer@pjlabs.com](mailto:mkramer@pjlabs.com)*



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*Perry Johnson Laboratory Accreditation, Inc.*

# **Traceability Requirements of ISO/IEC 17025:2017 and PJLA Policy on Measurement Traceability PL-2**

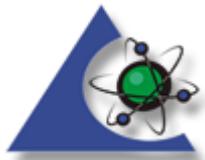
*This webinar is being recorded and will be available in it's entirely on the Perry Johnson Laboratory Accreditation Website.*

[www.pjlabs.com](http://www.pjlabs.com)

*Go to the link for recorded webinars.*

*Duration of webinar is set for one hour.*

*You can type any questions directly into your webinar box; We will review them at the conclusion of today's session;*



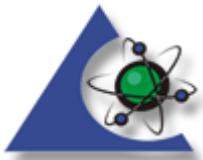
# Traceability Requirements of ISO/IEC 17025:2017

## 6.5 Metrological traceability → 5.6 Measurement traceability

### Identification of changes

Most of the notes have been erased, and a new Informative Annex on metrological traceability has been created. In Annex A, possibilities have been included on how to establish and demonstrate traceability:

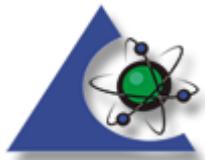
- through the use of a NMI
- accredited calibration laboratory
- reference material producers conforming to ISO 17034



# Traceability Requirements of ISO/IEC 17025:2017

## From Annex A

**A.3.2** The Joint BIPM (International Bureau of Weights and Measures) , OIML (International Organization of Legal Metrology), ILAC and ISO Declaration on Metrological Traceability provides specific guidance when there is a need to demonstrate inter-laboratory traceability chain.

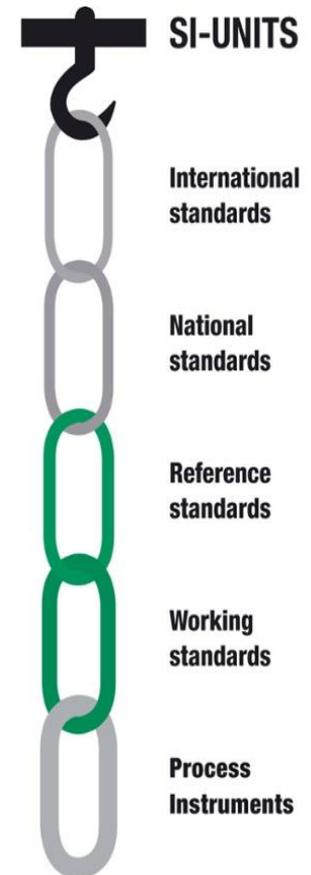


# Traceability Requirements of ISO/IEC 17025:2017

**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.

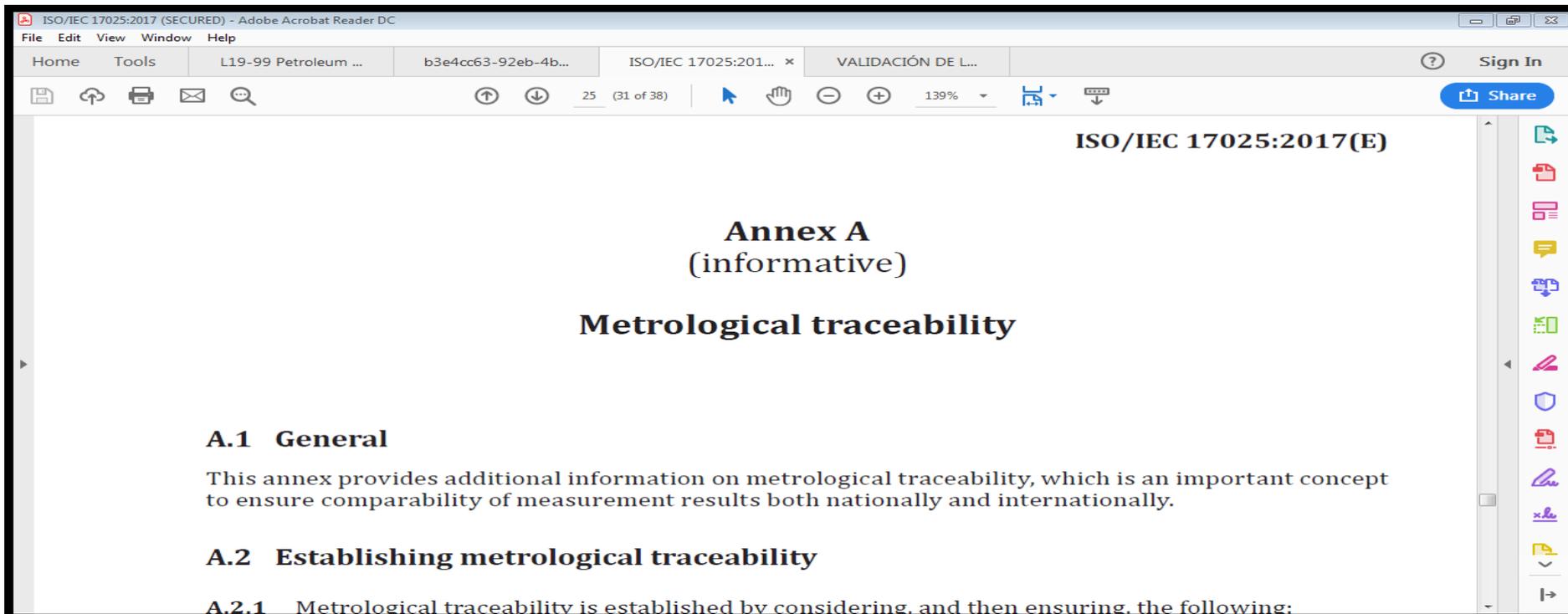
NOTE 1 In ISO/IEC Guide 99, metrological traceability is defined as the “property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the **measurement uncertainty**”.

ISO/IEC Guide 99 = International Vocabulary of Metrology (VIM)



# Traceability Requirements of ISO/IEC 17025:2017

NOTE 2 See Annex A for additional information on metrological traceability.



The screenshot displays the Adobe Acrobat Reader DC interface. The title bar indicates the document is 'ISO/IEC 17025:2017 (SECURED)'. The main content area shows the title page of Annex A (informative) titled 'Metrological traceability'. The page number is 25 out of 38, and the zoom level is 139%. The document is in Spanish, as indicated by the 'VALIDACIÓN DE L...' in the tab and the '(E)' in the title.

**ISO/IEC 17025:2017(E)**

**Annex A**  
**(informative)**

**Metrological traceability**

**A.1 General**

This annex provides additional information on metrological traceability, which is an important concept to ensure comparability of measurement results both nationally and internationally.

**A.2 Establishing metrological traceability**

**A.2.1** Metrological traceability is established by considering, and then ensuring, the following:



# Traceability Requirements of ISO/IEC 17025:2017

**6.5.2** The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through:

a) calibration provided by a competent laboratory; or

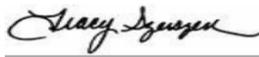
**NOTE 1** Laboratories fulfilling the requirements of this document are considered to be competent.

The screenshot shows a PDF document titled 'L17-162.pdf' in Adobe Acrobat Reader DC. The document content includes:

*(As detailed in the supplement)*

Accreditation claims for such testing and/or calibration services shall only be made from addresses referenced within this certificate. This Accreditation is granted subject to the system rules governing the Accreditation referred to above, and the Organization hereby covenants with the Accreditation body's duty to observe and comply with the said rules.

For PJLA:

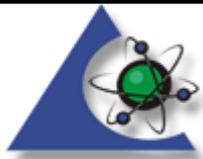
	<i>Initial Accreditation Date:</i> March 5, 2005	<i>Issue Date:</i> April 18, 2017	<i>Expiration Date:</i> June 30, 2019
	<i>Revision Date.:</i> October 4, 2018	<i>Accreditation No.:</i> 59316	<i>Certificate No.:</i> L17-162-R1

Tracy Szerszen  
President/Operations Manager

Perry Johnson Laboratory  
Accreditation, Inc. (PJLA)  
755 W. Big Beaver, Suite 1325  
Troy, Michigan 48084

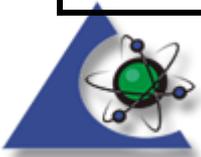
*The validity of this certificate is maintained through ongoing assessments based on a continuous accreditation cycle. The validity of this certificate should be confirmed through the PJLA website: [www.pjlabs.com](http://www.pjlabs.com)*

Page 1 of 3



# SI Base Units

<b>Base Quantity</b>	<b>Name</b>	<b>Symbol</b>
<b>Length</b>	<b>meter</b>	<b>m</b>
<b>Mass</b>	<b>kilogram</b>	<b>kg</b>
<b>Time</b>	<b>second</b>	<b>s</b>
<b>Electric Current</b>	<b>ampere</b>	<b>A</b>
<b>Thermodynamic Temperature</b>	<b>kelvin</b>	<b>K</b>
<b>Luminous Intensity</b>	<b>candela</b>	<b>Cd</b>
<b>Amount of Substance</b>	<b>mole</b>	<b>mol</b>

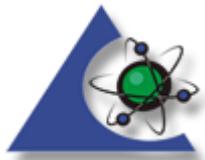
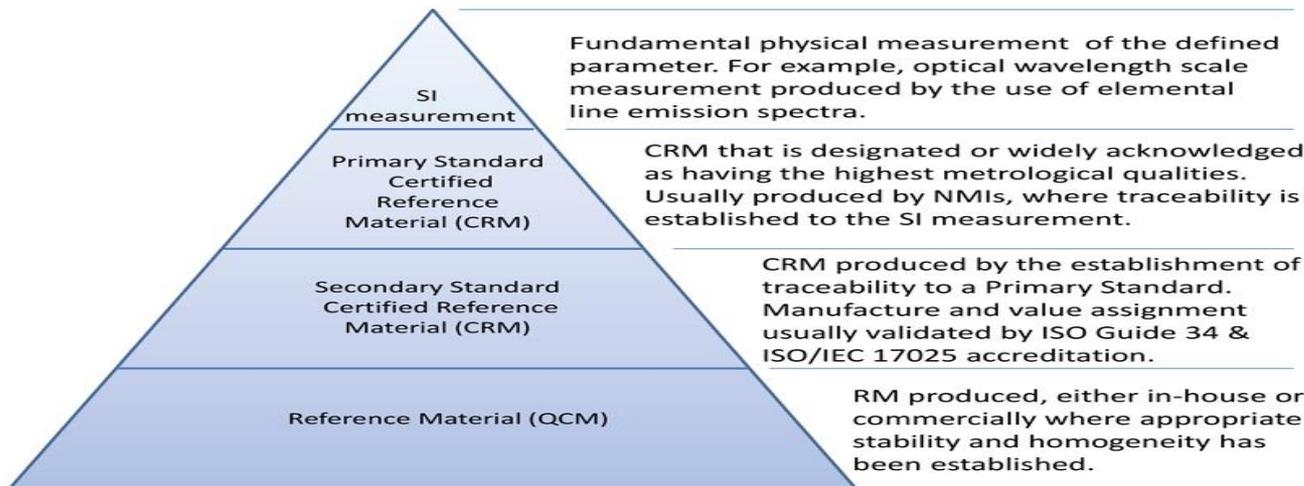


# Traceability Requirements of ISO/IEC 17025:2017

**6.5.2** The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through

b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; or

**NOTE 2** Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent.



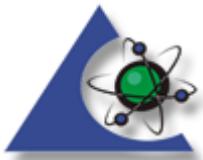
## Traceability Requirements of ISO/IEC 17025:2017

**6.5.2** The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through:

c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.



This traceability to a national measurement institute other than the National Institute of Standards and Technology is acceptable when a mutual recognition agreement, such as the Comité International des Poids et Mesures (CIPM) Mutual Recognition Arrangement (MRA), is in effect with the National Institute of Standards and Technology and sufficient equivalence of applicable calibration services exists.

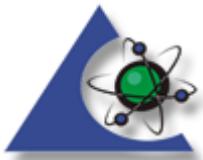


# Traceability Requirements of ISO/IEC 17025:2017

The CIPM Mutual Recognition Arrangement (CIPM MRA) is the framework through which National Metrology Institutes demonstrate the international equivalence of their measurement standards and the calibration and measurement certificates they issue

The Regional Metrology Organizations (RMOs) play an important role in the CIPM MRA. The RMOs are responsible for carrying out comparisons and other actions within their regions to support mutual confidence in the validity of the calibration and measurement certificates of their member NMIs.

For list of participants go to: <https://www.bipm.org/en/cipm-mra/>



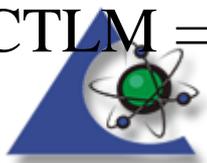
# Traceability Requirements of ISO/IEC 17025:2017

**6.5.3** When metrological traceability to the SI units is not technically possible, the laboratory shall demonstrate metrological traceability to an appropriate reference, e.g.:

- a) certified values of certified reference materials provided by a competent producer;
- b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

(for example, hardness scales, reference standards established by the World Health Organization, and measurement procedures accepted by the JCTLM).

JCTLM = *Joint Committee for Traceability in Laboratory Medicine*



# 6.5 Metrological Traceability

*Added Annex A “Metrological Traceability”  
Informative*

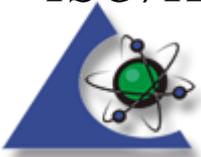
This closely correlates to the requirements already specified in PL-2 which recognizes the use of 17025 accredited sources or producing objective evidence in regards to 6 elements of traceability;

*To SI  
through NIST*



*Commercial  
Lab*

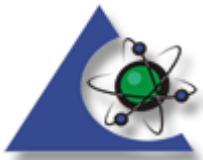
*If your organization complies with PL-2 “PJLA Policy on Traceability” you will meet the requirements of Section 6.5 of ISO/IEC 17025: 2017*



## *Annex A Key Points*

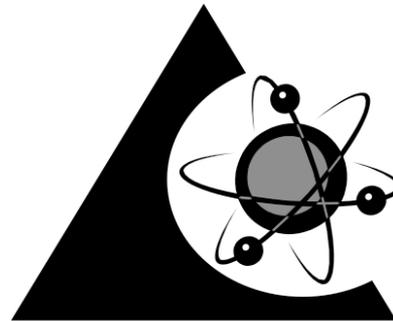
There are various ways to demonstrate conformity with this document, i.e. third party recognition (such as an accreditation body), external assessment by customers or self-assessment. Internationally accepted paths include, but are not limited to the following.

*a) Calibration and measurement capabilities provided by national metrology institutes and designated institutes that have been subject to suitable peer-review processes. Such peer-review is conducted under the CIPM MRA (International Committee for Weights and Measures Mutual Recognition Arrangement). Services covered by the CIPM MRA can be viewed in Appendix C of the BIPM KCDB (International Bureau of Weights and Measures Key Comparison Database) which details the range and measurement uncertainty for each listed service.*



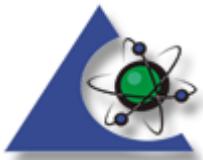
## *Annex A Key Points*

*b) Calibration and measurement capabilities that have been accredited by an accreditation body subject to the ILAC (International Laboratory Accreditation Cooperation) Arrangement or to Regional Arrangements recognized by ILAC have demonstrated metrological traceability. Scopes of accredited laboratories are publicly available from their respective accreditation bodies*



**PJLA**  
**Calibration**

**Accreditation# XXXXX**



# Traceability

*Results are traceable because that laboratory has been accessed and it's ability to produce traceable results has been established. This means that an investigation has taken place to determine that the chain of traceability is unbroken.*



# Traceability

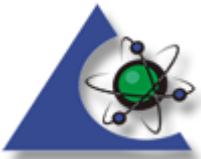
*Objective Evidence needed to confirm that traceability is obtained through the laboratories accreditation includes:*

*Actual calibration report provided.*

- Is it an accredited type report?*
- Does it contain the accreditation body logo?*

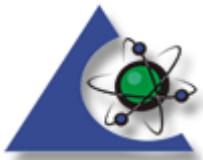
*Review of the laboratory “Scope of Accreditation”*

- Just because the lab is accredited, does not necessarily mean that the particular calibration performed is covered under that scope of accreditation.*

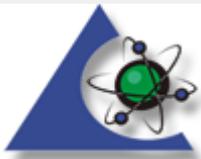


## PL-2 “PJLA Policy on Measurement Traceability

In addition to recognized national metrology institutes and accredited lab recognized under the ILAC PL-2 also recognizes State laboratories recognized by NIST through it Weights and Measures program. For the published scopes NIST, the NMI, assesses the laboratories based on ISO/IEC 17025: other criteria (National Conference on Weights and Measures (NCWM) and International Organization of Legal Metrology (OIML) and this is supplemented by an established inter-laboratory comparison proficiency program. Calibrations performed by the laboratories for items covered on their published scopes are accepted as being traceable. The Office of Weights and Measures within NIST maintains current Certificates of Metrological Traceability on their website.



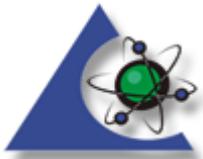
# PL-2 “PJLA Policy on Measurement Traceability



## PL-2 “PJLA Policy on Measurement Traceability

Use of non-accredited external calibration providers and NMI’s not recognized by the CIPM MRA will be approved on a case-by-case basis

Copies of all documents and records associated with the organizations verification shall be submitted to PJLA headquarters along with a completed copy of PJLA form LF-123 (available upon request from PJLA headquarters) summarizing the evidence that the non-accredited external calibration provider is capable of producing traceable results.



# *Traceability*

*The six common elements for all valid statements or claims of traceability (taken from NIST website)*

- 1) provide a clearly defined quantity that has been measured
- 2) provide a complete description of the measurement system or working standard used to perform the measurement
- 3) provide a stated measurement result or value, with a documented uncertainty
- 4) provide a complete specification of the stated reference at the time the measurement system or working standard that was compared to it (UUT)
- 5) provide an internal measurement assurance program for establishing the status of the measurement system or working standard at all times pertinent to the claim of traceability (IMAP)

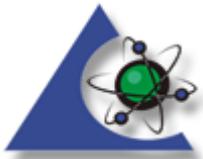


# Traceability PL-2

*Six common elements of traceability (LF 123)*

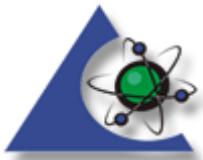
*6) provide an internal measurement assurance program for establishing the status of the stated reference at the time that the measurement system or working standard was compared to it. (organization seeking calibration)*

*In other words, the integrity of the calibration needs to be maintained. An IMAP should be established by the laboratory seeking traceable calibration services as a means of maintaining that traceability.*



# Traceability PL-2

**In-house Calibration:** A calibration performed by an organization of its own equipment for use in its accredited calibration or testing activities. By definition an in-house calibration is a calibration the organization is not accredited to perform. An organization must establish traceability for the results of in-house calibrations with the same degree of rigor required of accredited calibrations. The following requirements must be met for all in-house calibrations

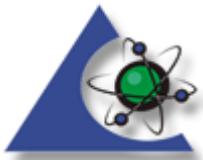


# Traceability PL-2

If the organization chooses to reference this traceability on test reports/certificates, it must reference traceability to the SI when possible and relevant.

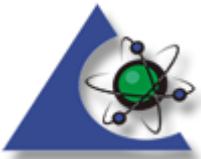
This can be accomplished through inclusion of a statement similar to the following on the certificate or report. “The test results published in this report were obtained using equipment capable of producing results that are traceable through NIST to the International System of Units (SI)”

Not appropriate to state to NIST



# Traceability and NIST Numbers

*Are submission of a NIST number by a laboratory or acceptance of a NIST number as evidence that calibration results are traceable; **NO**: Test report numbers issued by NIST are used solely for administrative purposes. Although they often uniquely identify documents that bear evidence of traceability, they are not to be accepted as evidence of traceability.*

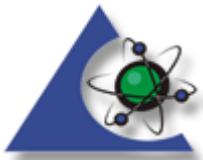


# Traceability Requirements of ISO/IEC 17025:2017 and PJLA Policy on Measurement Traceability PL-2



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

*Please keep questions related to the topic covered in this webinar;*



# Save the Date

*Next PJLA Webinar*

April 2019						
S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	<b>25</b>	26	27
28	29	30				

**Thursday, Apr 25th 2019**

ISO/IEC 17025:2017 Section 6.2 “Personnel”

