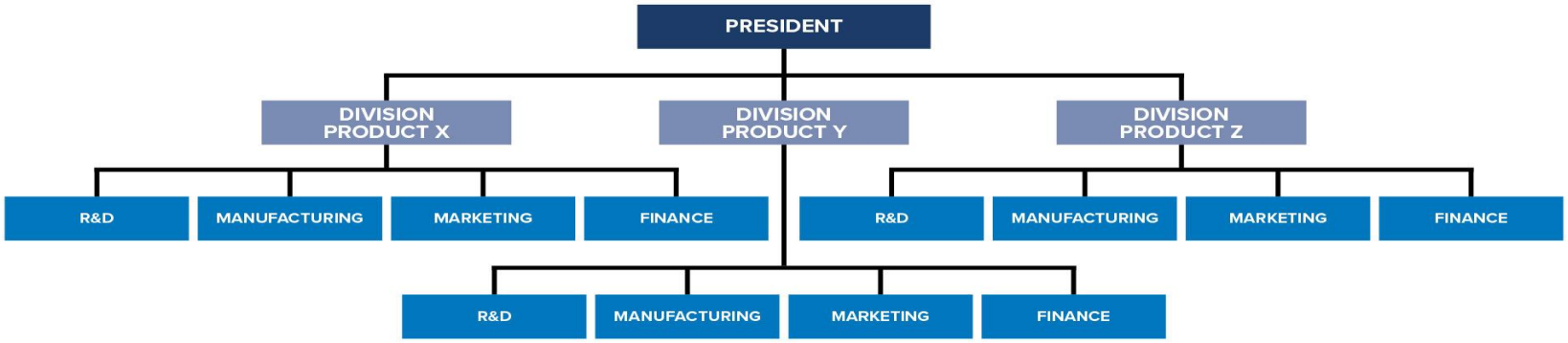
ISO/IEC 17025:2017: Section 5
“Structural Requirements”



Presenter: Michael Kramer
PJLA Calibration/Inspection Program Manager
30-December-2021

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ISO/IEC 17025:2017: Section 5 “Structural Requirements”

- This webinar is being recorded
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  - https://www.pjlabs.com/training/pjla-webinars
- All attendees are muted. However, feel free to utilize the questions tab and they will be answered at the end of the session.

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ISO/IEC 17025:2017: Section 5 “Structural Requirements”

This section details:

- The basic organizational components of a laboratory,
- Its range of activities,
- Its commitment to an effective management system.
- Accredited laboratory must be a legal entity or part of a legal entity
- Sets management’s responsibilities in an accredited laboratory and their responsibilities to customers, regulatory authorities, and organizations that provide recognition.
- Defines the basic requirements for personnel, the authority given to them, and the resources needed to carry out their duties.

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5.1 The laboratory shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities.

NOTE For the purposes of this document, a governmental laboratory is deemed to be a legal entity on the basis of its governmental status.

Definition: An association, corporation, partnership, proprietorship, trust, or individual that has legal standing in the eyes of the law. A legal entity has legal capacity to enter into agreements or contracts, assume obligations, incur and pay debts, sue and be sued in its own right, and to be held responsible for its actions.

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5.2 The laboratory shall identify management that has overall responsibility for the laboratory.

Functions are still specified for Quality or Technical Manager however ISO/IEC 17025:2017 does not require identifying them.

Management must be identified for having responsibility for the laboratory;

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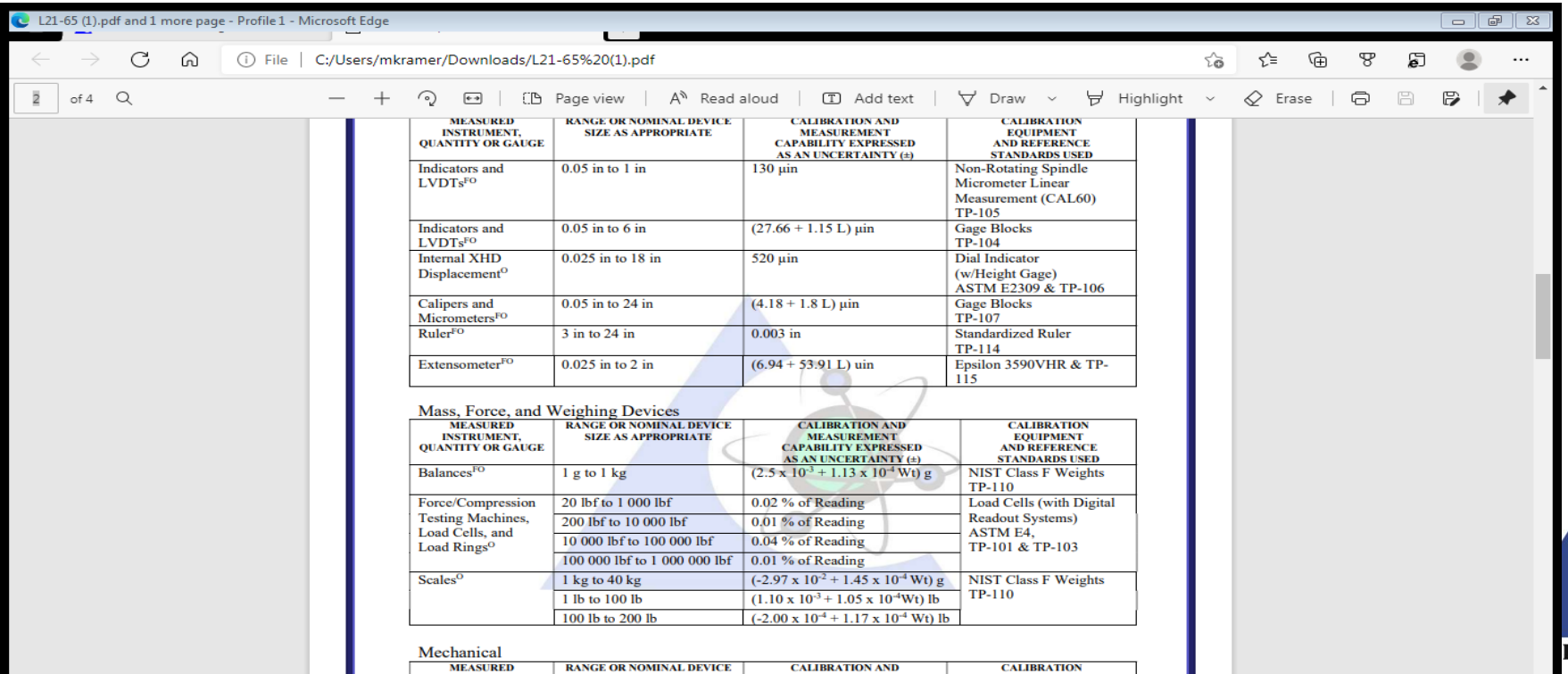
5.3 The laboratory shall define and document the range of laboratory activities for which it conforms with this document. The laboratory shall only claim conformity with this document for this range of laboratory activities, excludes externally provided laboratory activities on an ongoing basis.



MEASURED INSTRUMENT, QUANTITY OR GAUGE	RANGE OR NOMINAL DEVICE SIZE AS APPROPRIATE	CALIBRATION AND MEASUREMENT CAPABILITY EXPRESSED AS AN UNCERTAINTY (±)	CALIBRATION EQUIPMENT AND REFERENCE STANDARDS USED
Indicators and LVDTs[FO]	0.05 in to 1 in	130 µin	Non-Rotating Spindle Micrometer Linear Measurement (CAL60) TP-105
Indicators and LVDTs[FO]	0.05 in to 6 in	(27.66 + 1.15 L) µin	Gage Blocks TP-104
Internal XHD Displacement[O]	0.025 in to 18 in	520 µin	Dial Indicator (w/Height Gage) ASTM E2309 & TP-106
Calipers and Micrometers[FO]	0.05 in to 24 in	(4.18 + 1.8 L) µin	Gage Blocks TP-107
Ruler[FO]	3 in to 24 in	0.003 in	Standardized Ruler TP-114
Extensometer[FO]	0.025 in to 2 in	(6.94 + 53.91 L) uin	Epsilon 3590VHR & TP-115

Mass, Force, and Weighing Devices

MEASURED INSTRUMENT, QUANTITY OR GAUGE	RANGE OR NOMINAL DEVICE SIZE AS APPROPRIATE	CALIBRATION AND MEASUREMENT CAPABILITY EXPRESSED AS AN UNCERTAINTY (±)	CALIBRATION EQUIPMENT AND REFERENCE STANDARDS USED
Balances[FO]	1 g to 1 kg	(2.5 x 10^{-3} + 1.13 x 10^{-4} Wt) g	NIST Class F Weights TP-110
Force/Compression Testing Machines, Load Cells, and Load Rings[O]	20 lbf to 1 000 lbf	0.02 % of Reading	Load Cells (with Digital Readout Systems) ASTM E4, TP-101 & TP-103
	200 lbf to 10 000 lbf	0.01 % of Reading	
	10 000 lbf to 100 000 lbf	0.04 % of Reading	
	100 000 lbf to 1 000 000 lbf	0.01 % of Reading	
Scales[O]	1 kg to 40 kg	(-2.97 x 10^{-2} + 1.45 x 10^{-4} Wt) g	NIST Class F Weights TP-110
	1 lb to 100 lb	(1.10 x 10^{-3} + 1.05 x 10^{-4}Wt) lb	
	100 lb to 200 lb	(-2.00 x 10^{-4} + 1.17 x 10^{-4} Wt) lb	

Mechanical

MEASURED	RANGE OR NOMINAL DEVICE	CALIBRATION AND	CALIBRATION

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The scope of accreditation issued/developed could be sufficient documentation. The CAB should define additional ranges for any scope expansion prior to the claiming conformity and proceeding with the re-accreditation assessment.

It also may be important to communicate different levels of service for items identified on the scope. There should be evidence that provides confidence the customer is clearly aware of the options.

- ISO/IEC 17025 accredited calibration
- NIST Traceable Calibration
- Certificate of Accuracy

which excludes externally provided laboratory activities on an ongoing basis; = subcontracting

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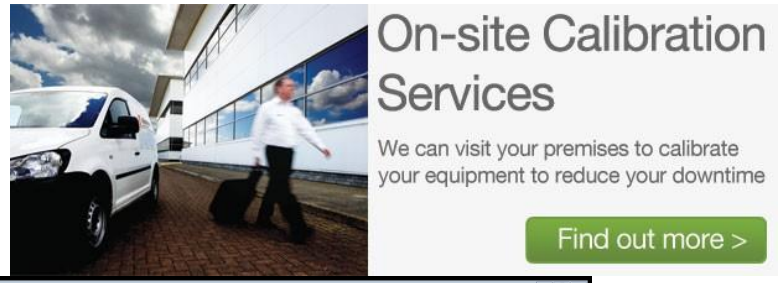
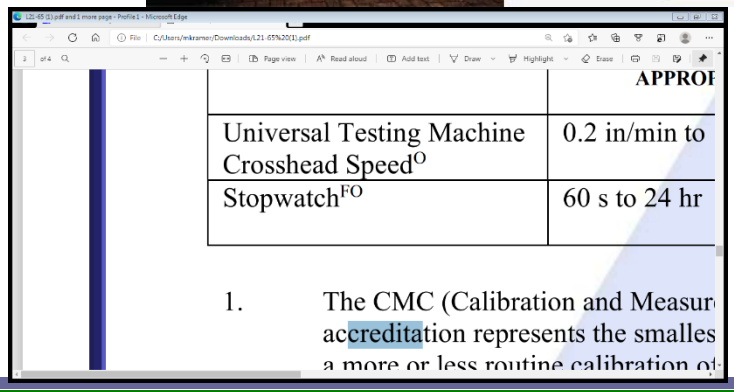
5.4 Laboratory activities shall be carried out in such a way as to meet the requirements of this document, the laboratory’s customers, regulatory authorities and organizations providing recognition. This shall include laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility

PERRY JOHNSON LABORATORY ACCREDITATION, INC. (PJLA)





Universal Testing Machine Crosshead Speed[O]	0.2 in/min to
Stopwatch[FO]	60 s to 24 hr

1. The CMC (Calibration and Measur
accreditation represents the smalles
a more or less routine calibration o

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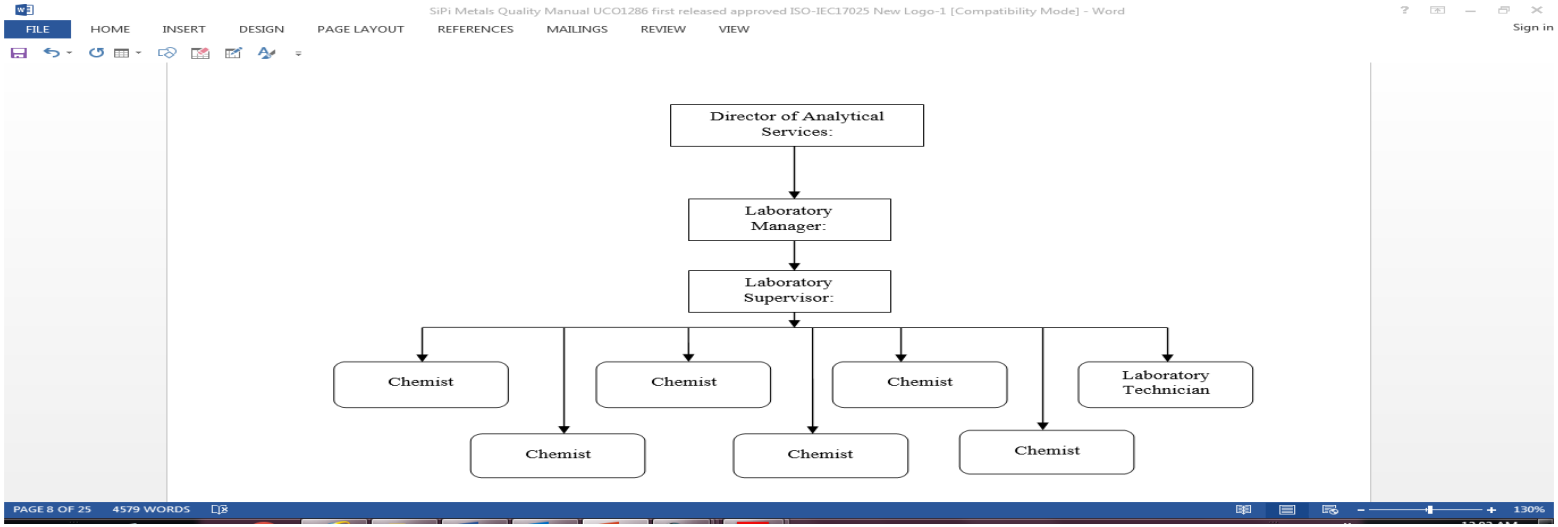
5.5 The laboratory shall

a) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services;



Organizational chart is not required however appear the objective evidence produced when looking for compliance to this clause.

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5.5 The laboratory shall:

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

- **Director of Analytical Services:**
- The Director of Analytical Services interacts with upper management and lab staff regarding lab shortcomings, direction, new instrumentation, technical issues and customer complaints.
- **Laboratory Manager:**
- Oversees the day to day lab operations for both the Brass and Precious Metals, monitors flow of samples in and out of the lab and oversees the Quality control system. Coordinates with the Technical Director, Director of Analytical Services, and the Customer Service Manager and informs them of any unexpected delays to ensure customers and notified. Attend meetings regularly and gives input if appropriate.
- **Laboratory Supervisor:**
- Monitors the proficiency of the Laboratory Chemists and Technicians, day-to-day operations to ensure samples are moving through the lab. The Laboratory Supervisor Monitors lab stats, along with the lab personnel, to track lab capacity at any given time. Along with the Laboratory Manager, the Laboratory Supervisor is responsible for the reporting of results.

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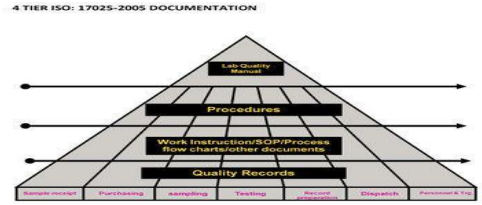
5.5 The laboratory shall:

c) document its procedures **to the extent necessary** to ensure the consistent application of its laboratory activities and the validity of the results.



Need access and need to be implemented with uniformity

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5.6 The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:

a) implementation, maintenance and improvement of the management system;

b) identification of deviations from the management system or from the procedures for performing laboratory activities

c) initiation of actions to prevent or minimize such deviations;

d) reporting to laboratory management on the performance of the management system and any need for improvement;

e) ensuring the effectiveness of laboratory activities;

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5.7 Laboratory management shall ensure that:

a) communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements;

This is an output requirement of the Management review

8.9.3 The outputs from the management review shall record all decisions and actions related to at least:

a) the effectiveness of the management system and its processes

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5.7 Laboratory management shall ensure that:

b) the integrity of the management system is maintained when changes to the management system are planned and implemented

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Thank You

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

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

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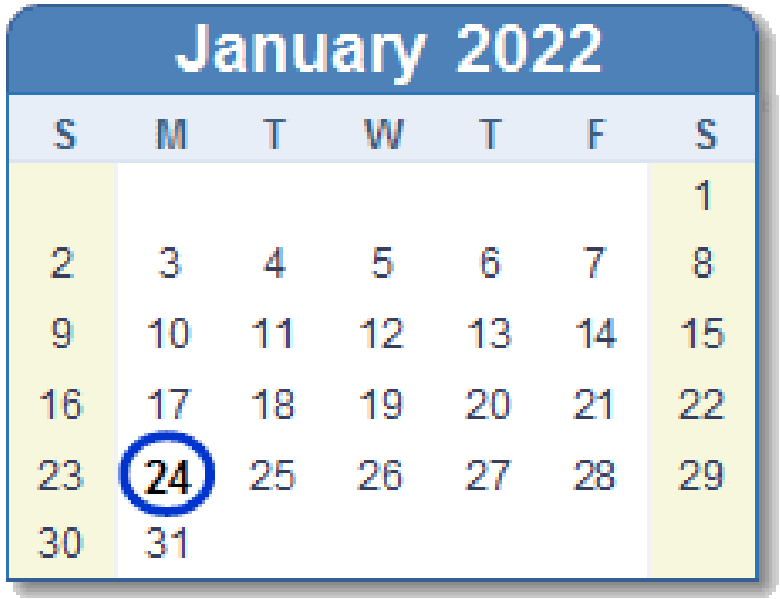
Save the Date

Top 10 List of Findings Written by PJLA During 2021



Monday, Jan 24th 2022

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