Section 5.0 “Structural Requirements” of ISO/IEC 17025:2017

Thursday, July 25 – 1:00pm EST

Presented by:

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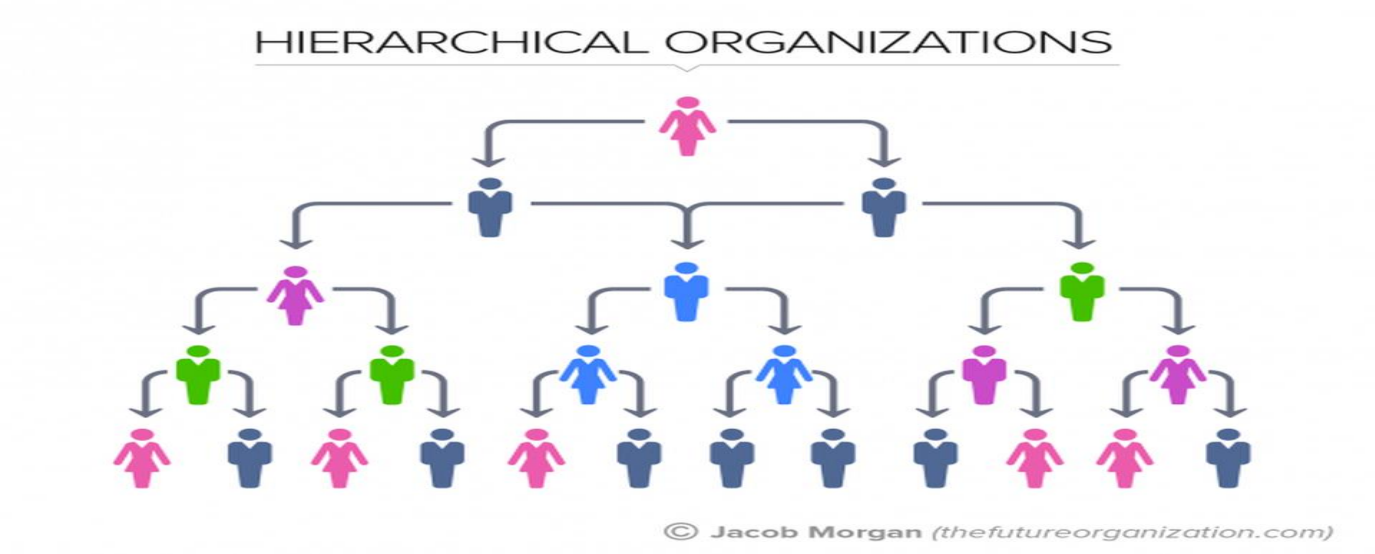

ISO/IEC 17025:2017 Section 7.10" Nonconforming Work" & Section 8.6 "Improvement"

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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; Please keep question presented related to the topic of today's webinar.

Section 5.0 “Structural Requirements

Identification of changes

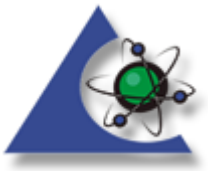
The requirements have been restructured. The most important changes are:

• The term “quality manager” is not mentioned, even though the functions are still included in the standard. (5.6)

• The term “technical manager” is not mentioned, even though the functions are still included in the standard. (5.2)

• It is no longer necessary to have deputies for key positions.

• The laboratory is obliged to write down the range of activities (5.3, 5.4). The range of activities does not include those activities that have been permanently subcontracted

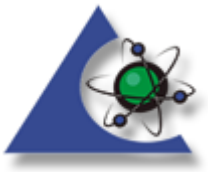


Section 5.0 “Structural Requirements

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 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.



Section 5.0 “Structural Requirements

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

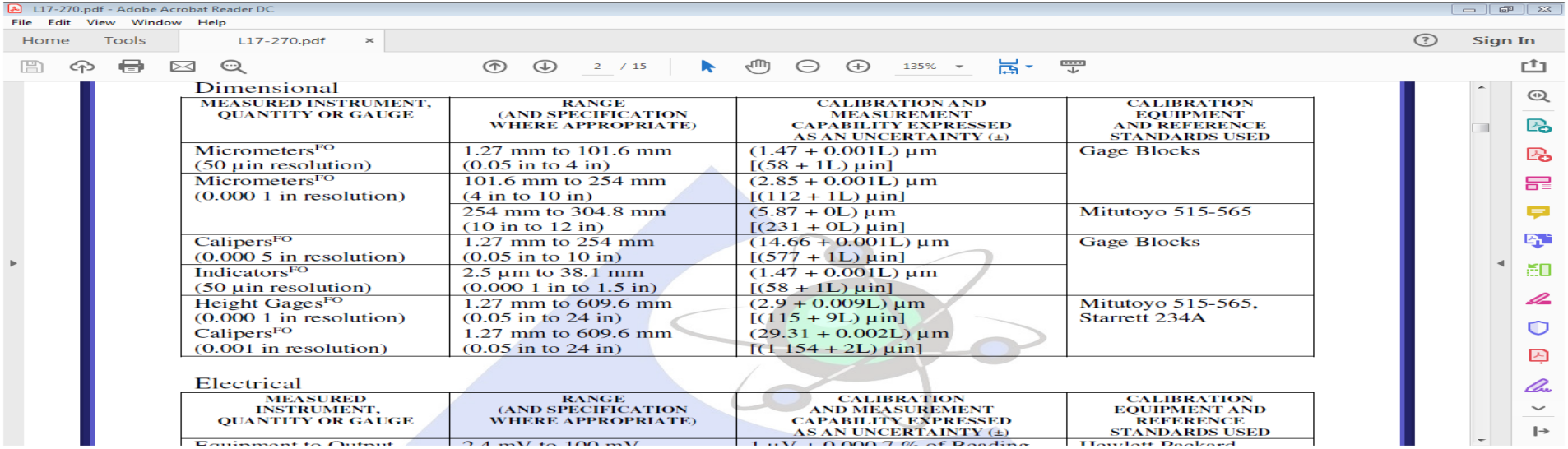
No longer specific about identifying a Quality or Technical Manager; even though the functions are still included in the standard

It is no longer necessary to have deputies for key positions.

Can be associated with Technical Manager

Section 5.0 “Structural Requirements”

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, which excludes externally provided laboratory activities on an ongoing basis.



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Dimensional

MEASURED INSTRUMENT, QUANTITY OR GAUGE	RANGE (AND SPECIFICATION WHERE APPROPRIATE)	CALIBRATION AND MEASUREMENT CAPABILITY EXPRESSED AS AN UNCERTAINTY (±)	CALIBRATION EQUIPMENT AND REFERENCE STANDARDS USED
Micrometers[FO] (50 µin resolution)	1.27 mm to 101.6 mm (0.05 in to 4 in)	(1.47 + 0.001L) µm [(58 + 1L) µin]	Gage Blocks
Micrometers[FO] (0.000 1 in resolution)	101.6 mm to 254 mm (4 in to 10 in)	(2.85 + 0.001L) µm [(112 + 1L) µin]	
	254 mm to 304.8 mm (10 in to 12 in)	(5.87 + 0L) µm [(231 + 0L) µin]	Mitutoyo 515-565
Calipers[FO] (0.000 5 in resolution)	1.27 mm to 254 mm (0.05 in to 10 in)	(14.66 + 0.001L) µm [(577 + 1L) µin]	Gage Blocks
Indicators[FO] (50 µin resolution)	2.5 µm to 38.1 mm (0.000 1 in to 1.5 in)	(1.47 + 0.001L) µm [(58 + 1L) µin]	
Height Gages[FO] (0.000 1 in resolution)	1.27 mm to 609.6 mm (0.05 in to 24 in)	(2.9 + 0.009L) µm [(115 + 9L) µin]	Mitutoyo 515-565, Starrett 234A
Calipers[FO] (0.001 in resolution)	1.27 mm to 609.6 mm (0.05 in to 24 in)	(29.31 + 0.002L) µm [(1 154 + 2L) µin]	

Electrical

MEASURED INSTRUMENT, QUANTITY OR GAUGE	RANGE (AND SPECIFICATION WHERE APPROPRIATE)	CALIBRATION AND MEASUREMENT CAPABILITY EXPRESSED AS AN UNCERTAINTY (±)	CALIBRATION EQUIPMENT AND REFERENCE STANDARDS USED
Equipment to Output	2.4 mV to 100 mV	1 µV + 0.000 7 % of Reading	Hewlett Packard

Section 5.0 “Structural Requirements”

The scope of accreditation issued/developed could be sufficient documentation

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

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Section 5.0 “Structural Requirements”

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.

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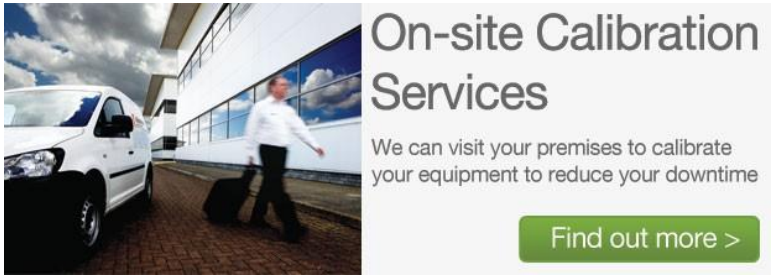
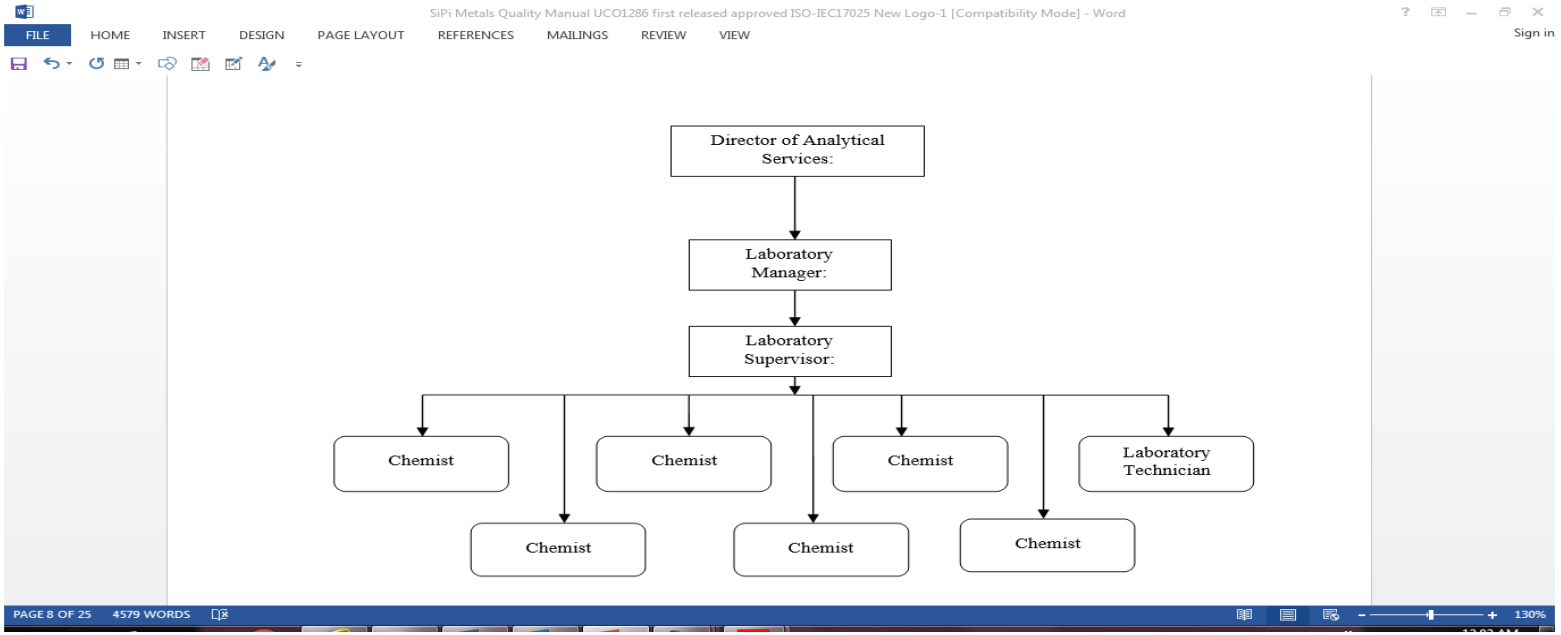


Section 5.0 "Structural Requirements"

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



Section 5.0 “Structural Requirements”

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.

Section 5.0 "Structural Requirements"

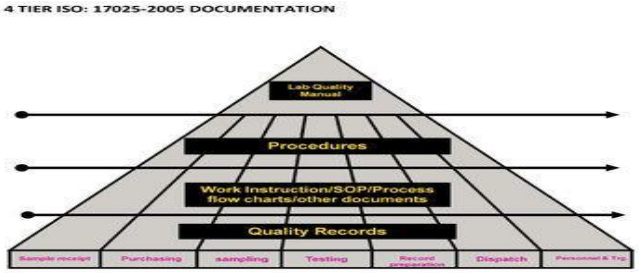
5.5 The laboratory shall:

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

Typically the laboratory processes are documented with a quality manual standard operating procedures and work instructions. "need access"

From ISO/IEC 17025:2005

4.2.5 The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the management system



Section 5.0 “Structural Requirements”

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;

Section 5.0 “Structural Requirements”

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

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

e) ensuring the effectiveness of laboratory activities.

Appears to be duties related to activities of a Quality Manager.

Can an individual or a team of individuals

Section 5.0 “Structural Requirements”

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

Section 5.0 “Structural Requirements”

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

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

Thursday, August 29 – 1:00pm EST

Common Findings in Assessments to the ISO/IEC 17025:2017 Standard