Preparing for an ISO/IEC 17025:2017 Accreditation Assessment

Presented By:

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&

Gordon Antonello

PJLA Assessor and Technical Advisor

Welcome

- This webinar will be recorded and made available on the PJLA website shortly after the conclusion.
- All attendees are in ‘Listen-Only’ mode.
- Please utilize the Question Tool Bar to type in questions to be answered at the end.
- Poll questions will be utilized throughout the webinar - we appreciate your participation!

Webinar Overview

- To educate attendees on the following:
  - The accreditation process
  - Expectations of becoming and maintaining accredited
  - The ISO/IEC 17025 standard requirements
  - Common challenges
  - Opportunity to ask questions

Poll Question 1

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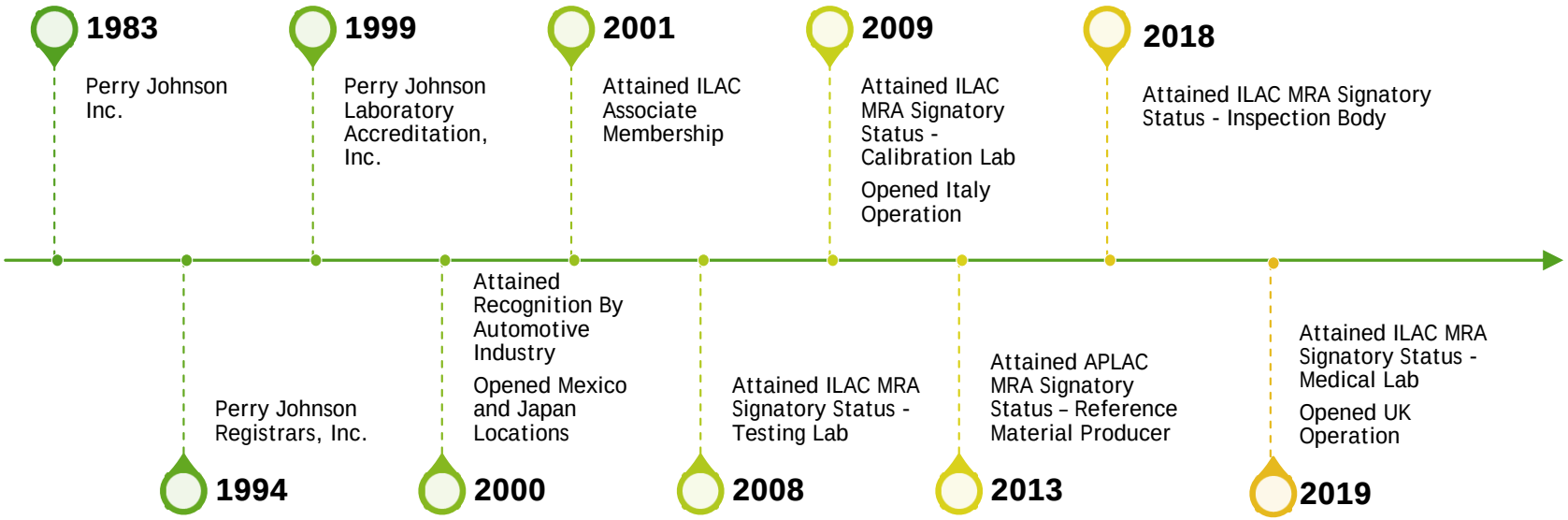
A Global Accreditation Body

- Headquartered in the United States
- Accreditation Services Offered Globally
  - Mexico
  - Japan
  - Italy
  - United Kingdom
  - Middle East
- ILAC MRA Signatory
  - Testing, Calibration, Inspection, Reference Material, Medical
- 1500+ Accredited Facilities

Perry Johnson Laboratory Accreditation, Inc.
Our History



PJLA Credentials and Recognitions

- PJLA, along with over 100 other accreditation bodies across the world, holds international recognition through ILAC
- ILAC - The International Laboratory Accreditation Cooperation
  - Recognizes Accreditation Bodies for multiple ISO standards: ISO/IEC 17025-Testing/Calibration, ISO/IEC 17020:2012-Inspection Bodies, ISO/IEC 15189:2012-Medical Labs, ISO/IEC 17043:2010-Proficency Testing Provider
  - ILAC along with their regional bodies (i.e. APAC, EA, IAAC evaluates accreditation bodies to ISO/IEC 17011:2017 -*Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies*

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Steps to Accreditation

Apply for Accreditation for a certain scope

- Includes type of products tested, types of tests, methods and equipment used

Commit to accreditation terms in order to start the process

- Receive a pending letter & get on the schedule

Pre-documentation Review Performed Prior to the Assessment

- 30 days prior to the scheduled on-site visit

On-site Assessment will cover all QMS activities and testing activities

- Equipment, staff, proficiency testing, measurement uncertainty - data, methods, records

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Steps to Accreditation

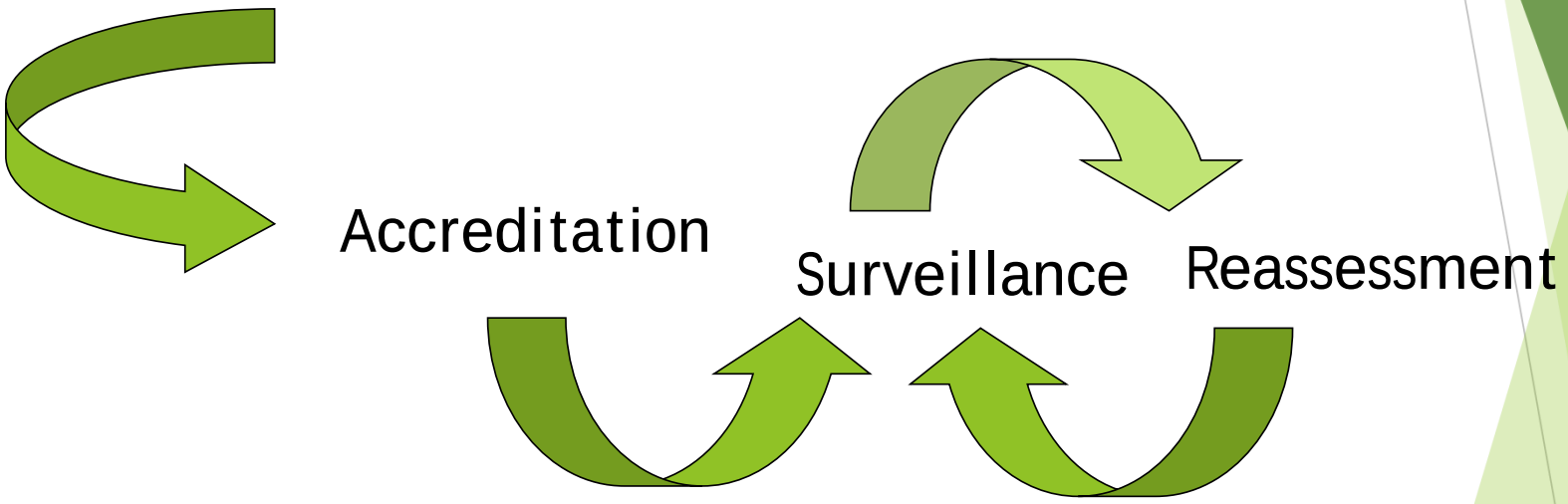
A final report with any nonconformities will be issued at the end of the assessment;

A 60-day corrective action timeline will be provided to answer nonconformities

Once accepted by the assessor an independent final review process will take place in order to accept or deny accreditation

A certificate is granted for a two-year period

Accreditation Cycle



Scope Expansions can occur anytime after accreditation is granted.

Poll Question 2

Welcome Gordon Antonello

Gordon has over 40 years of experience working in the product R&D, product manufacturing and product testing. He is an ISO/IEC 17025 technical assessor and industry consultant. Gordon currently works as an independent consultant and advisor to manufacturers and laboratories to ensure that they are following product specifications, product testing and certification protocols. Gordon is an NFC Forum auditor and has many years of experience auditing certification testing laboratories utilizing ISO/IEC 17025 requirements and SDO test methods.

Gordon formerly worked for InterDigital Communications, Inc., NFC Forum, and the Power Matters Alliance as the Certification Program Director. Gordon was instrumental in establishing the WiMAX Forum, and was on its Board of Directors from 2002 through 2007. He worked at AT4 Wireless as a Specialized Test Equipment Business Unit Manager and Validation Program Manager. He has experience with defining & deriving requirements, defining & developing Test Cases/Plans. Gordon holds a background from the Northern Alberta Institute of Technology in Electronics Engineering Technology and from the University of Calgary in General Management and Engineering Project Management.

Understanding What the Laboratory is Being Assessed To

Gordon Antonello, PJLA Assessor and Technical Advisor

Poll Question 3

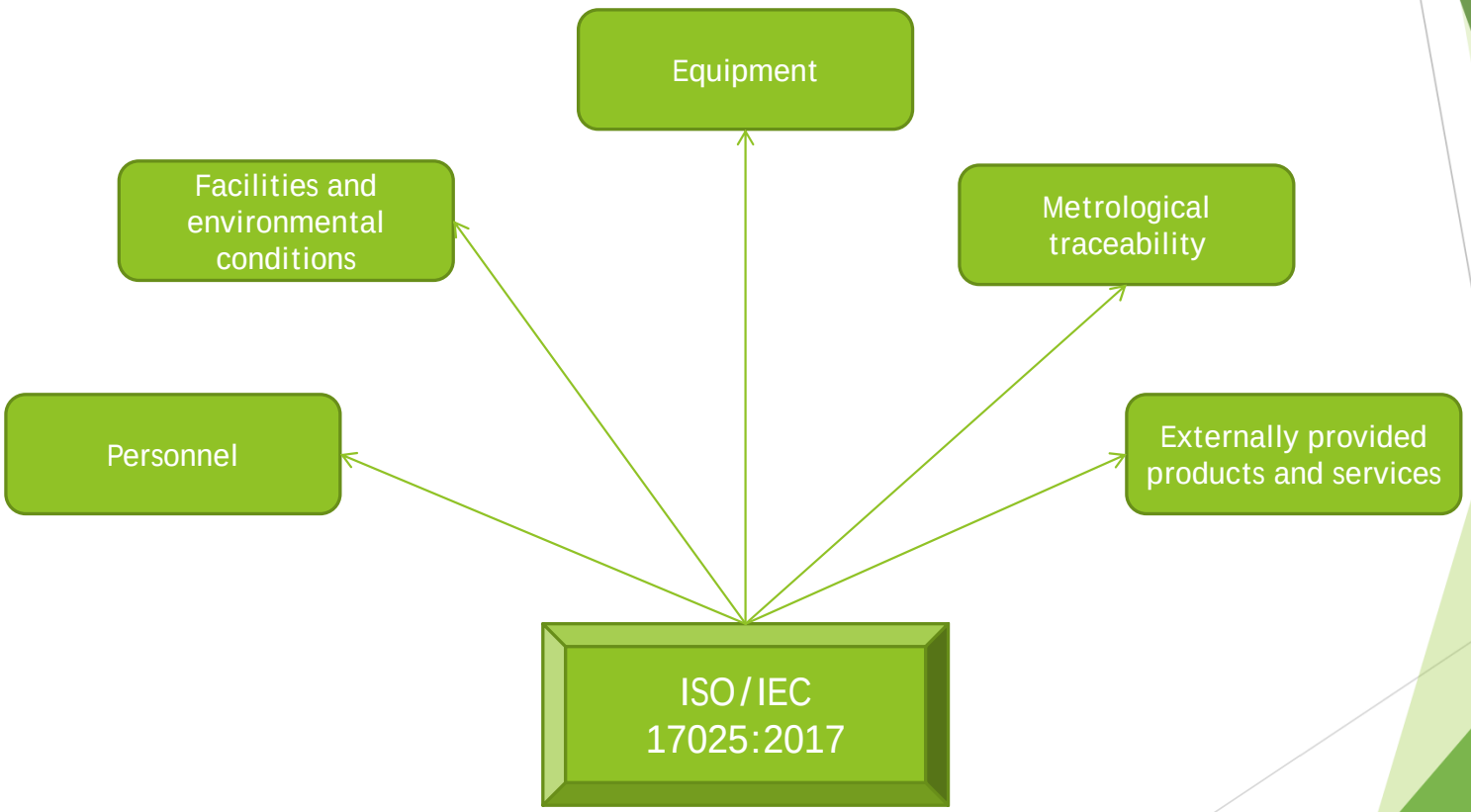
Understanding What the Laboratory is Being Assessed To

- Knowing and understanding the ISO/IEC 17025:2017 Standard
- Purpose of a Quality Management System (QMS)
- QMS supporting documentation; Standard Operating Procedures, Working Instructions
- Proficiency Testing
- Measurement Uncertainty

Knowing and Understanding the ISO/IEC 17025:2017 Standard

- ISO/IEC 17025:2017 (“17025”) states the requirements for the competence of testing and calibration laboratories. These requirements include but are not limited to:
  - Structural requirements
  - **Resource requirements**
  - **Process requirements**
  - Management system requirements
- Today, my presentation focuses on **resource** and **process** requirements

Resource Requirements



Resource Requirements cont'd

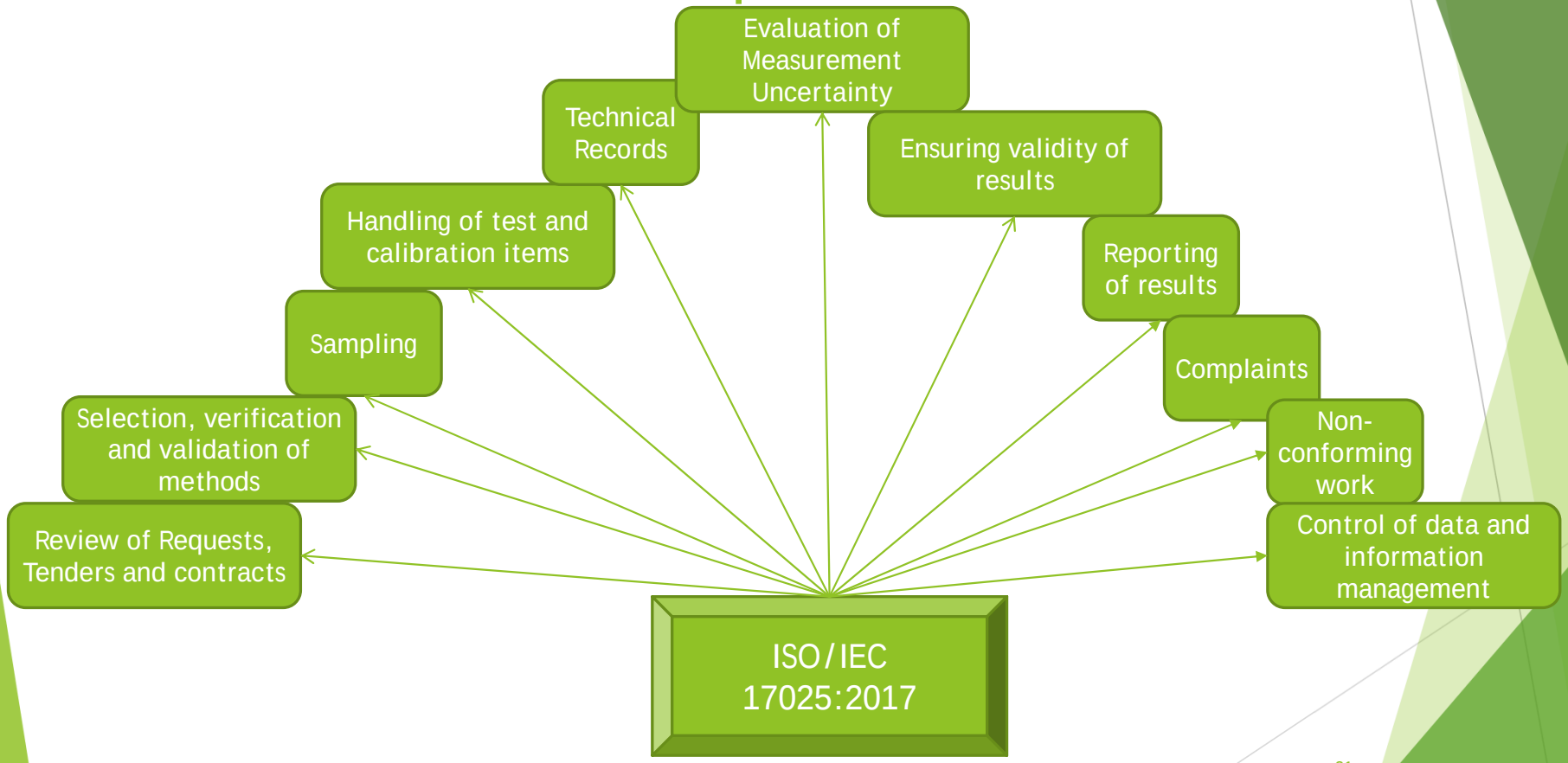
- Personnel
  - The key factor here is that all personnel that could impact the results of the laboratory activities must be impartial, must be competent and work according to the laboratory's management system. The QMS must document policies and procedures to ensure each of these factors.
- Facilities and Environmental Conditions
  - Laboratory facilities and environment must be suitable for all its activities and not affect the validity of results.
- Equipment
  - The laboratory must have access to equipment required to proper performance of its activities and that can influence the results.

Resource Requirements cont'd

- Metrological Traceability
  - 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*"
    This means that each measurement contributes to the final result and that each measurement has a level of uncertainty (e.g. +/- x%) associated with it, which must be taken into account when reporting the result.
- Externally Provided Products and Services
  - The laboratory must have policies, procedures and records of externally provided products and services that affect its testing or calibration activities.

Poll Question 2

Process Requirements



Process Requirements cont'd

- Review of requests, tenders and contracts

  Laboratories must have policies and procedures for the review of requests, tenders and contracts to ensure the requirements are adequately defined, documented and understood; that it has the capability and resources to meet the requirements; client notification procedures of externally provided products and services; selection of methods that are capable of meeting the clients' requirements.

- Selection, verification and validation of methods

  Method, in this context, can be considered the same as "measurement procedure". The laboratory must select methods it uses to conduct its testing or calibration activities meets the requirements of the client.

- Sampling

  Where a laboratory's activities require taking of samples, the laboratory must have a documented sampling plan. The sampling plan must address the impact of the plan on subsequent testing or calibration results.

Process Requirements cont'd

- Handling of Test or Calibration Items
  The laboratory must have a procedure for receiving, handling, protection, storage, recording and retention/disposal of test or calibration items.
- Technical records
  The laboratory must ensure that technical records for laboratory activities contain the results.
- Evaluation of Measurement Uncertainty
  The laboratory must identify all contributions to measurement uncertainty.
- Ensuring the Validity of Results
  The laboratory must have a procedure for monitoring the validity of results. The results must be recorded such that trends are detectable and that the results are reasonable.

Process Requirements cont'd

- Reporting of Results
  The laboratory must have a procedure to review and authorise the results before being released. The results must be unambiguous, clear and objectively reported in accordance to the client's requirements.
- Complaints
  The laboratory must have a document process to receive, evaluate and make decisions on complaints from clients. This process must be made available to any interested party upon request.
- Non-conforming Work
  The laboratory must a procedure that must be implemented when any of its' activities do not conform to its own procedures.
- Control of Data and Information Management
  The laboratory information management system must allow access to the data and information needed to perform laboratory activities for the collection, processing, recording, reporting storage and retrieval of data resulting from its activities.

QMS supporting documentation

- Standard Operating Procedures (SOPs)
  SOPs are step-by-step instructions to help workers carry out complex routine operations to achieve efficiency, quality output and uniform results. SOPs also help to reduce miscommunication and comply with industry regulations.
- Work Instructions (WIs)
  WIs are documents that precisely describe the correct way to perform specific tasks, including testing or calibration, that may result in erroneous results when not performed in a correct sequence and manner.

Proficiency Testing

Proficiency Testing (PT) demonstrates effectiveness of internal procedures in relation to reproducibility and accuracy. PT schemes are very effective for ensuring quality control and can be informal between laboratories or conducted in cooperation with third party organizations*. The data and information produced can be used to take remedial actions to bring laboratory performance to the required level.

Proficiency testing conducted by one or more laboratories must use the same sample (e.g. mobile phone h/w and s/w) and be subjected to the same environmental conditions (i.e. temperature, relative humidity, background RF, etc.) in each of the laboratories conducting the PT.

https://www.eptis.org/
or PJLA website
https://www.pjlabs.com/resources/proficiency-testing

Measurement Uncertainty

Every measurement is subject to some uncertainty or doubt about the result of the measurement. Even when precautions are taken, there is always a margin of error or doubt.

The concept of Measurement Uncertainty (MU) is a relatively new in the history of measurement and in the area of certification testing. MU is separate from errors due to tolerances or analysis of tolerances, which have been part of the practice of measurement science for quite some time. **Error** is the difference between the measured value and the true value while **uncertainty** is the **statement of doubt** about the measurement result.

Uncertainties can come from the measuring instrument, the item being measured, the process used to obtain the measurement, the lab environment, and operator skill level among others. MU is not operator mistakes, tolerances or specifications.

Measurement Uncertainty cont'd

The science of Measurement Uncertainty has developed rules on how to calculate the overall estimate of the uncertainty from pieces of data relevant to a measurement.

A simple example:
A stick may 'say' that it is 20 centimeters in length, plus or minus 1 centimeter, at the 95% confidence level; 10 cm +/- 1 cm, at a level of confidence of 95%.

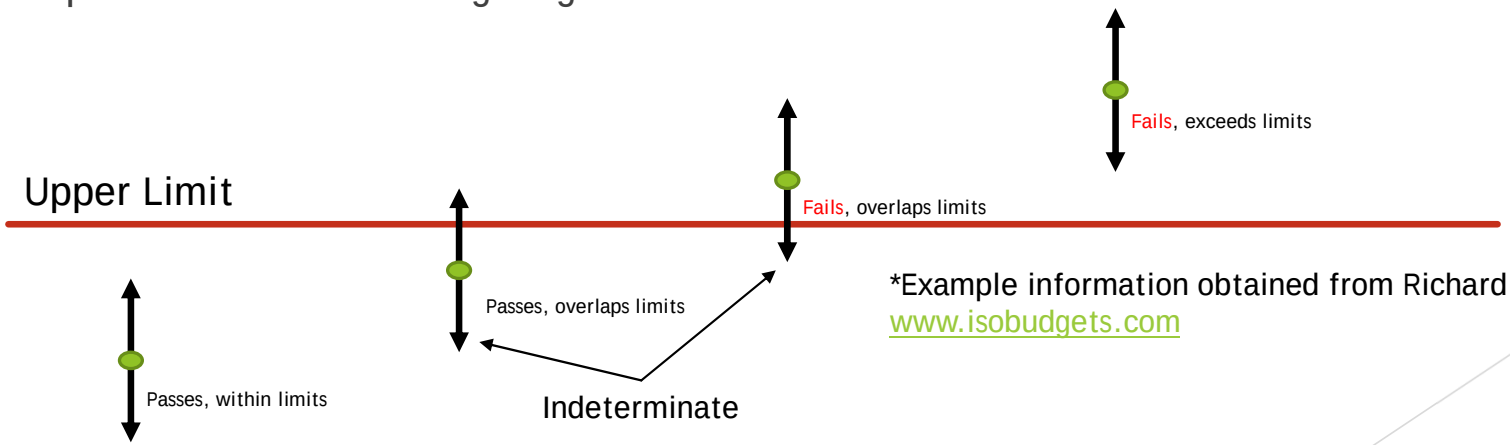
The statement says that we can be 95% confident that the stick is between 19 cm and 21 cm in length.

The actual process of determining Measurement Uncertainty is more complex, but the above example shows in a simple way what Measurement Uncertainty is.

*More information on Measurement Uncertainty is available on PJLA's Website
https://www.pjlabs.com/resources/calculators
Other References Available
www.isobudgets.com

Statements of Conformity and Decision Rules

Conformity can be defined as "*a statement of compliance or non-compliance to a specification, requirement or standard*". Conformity can be stated, for example, as *Pass / Fail* or *In Specification / Out of Specification.* Three common types of conformity are *Compliance*, *Non-compliance* or *Indeterminate*. These can be expressed in the following diagram.



*Example information obtained from Richard Hogan at www.isobudgets.com

Decision Rules

A decision rule can be derived based on the information provided in the previous slide. As an example the following decision rules can be defined:

- PASS – The results +/- the expanded uncertainty within the limits
- PASS* – The results are within the limits but overlap the limits when expanded uncertainty is taken into account
- FAIL** – The results exceed the limits but overlap the limits when expanded uncertainty is taken into account
- FAIL – The results +/- the expanded uncertainty exceed the limits

* The decision rule states PASS but could be stated INDETERMINATE

**The decision rule states FAIL but could be stated INDETERMINATE

Key Steps for Implementing ISO/IEC 17025:2017

- Appointment of a Quality Manager and a Laboratory Technical Manager
- Define a policy statement
- Engage a consultant to develop and carry out an implementation plan
- Review of current Management Systems; develop a gap analysis between the current QMS and ISO/IEC 17025:2017
- Devise a strategy and plan for implementing a QMS that meets the requirements of the ISO/IEC 17025:2017 standard; normally based on the gap analysis
- Training and/or education on ISO/IEC 17025:2017 including measurement uncertainty
- Determine the scope of tests to be accredited for
- Determine the appropriate test or calibration methods, their verification and validation procedures and parameters
- Engage in inter-lab proficiency testing

Time for Questions & Answers

Thank you for attending PJLA's Webinar on *"Preparing for an Accreditation Assessment"!*