Accreditation Insider

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PJLA Is Now Approved By The FCC!

The Federal Communications Commission (FCC) and the Office of Engineering and Technology (OET) regulates all Radio Frequency devices and finalizes the approval of each type of device before it can be marketed or imported to the United States. PJLA has now been recognized by the FCC and added to the list of accreditation bodies that are acceptable for use by testing laboratories. Laboratories seeking recognition by the Commission to perform testing of telecommunication equipment subject to the FCC's rules can reach out to PJLA to receive ISO/IEC 17025 accreditation. ◆

PJLA Has Applied To APLAC For Our Medical Laboratory Accreditation Program

PJLA has applied to APLAC for ISO 15189 Recognition, the Accreditation for medical laboratories. This standard includes an assessment of the laboratories quality management system and technical practices. It aligns with good medical laboratory practices such as the importance of: appropriate technical qualifications, ethical practices, safe environmental conditions, rigorous traceable reporting requirements, the use of validated methods, sample storage, retention and disposal requirements and traceable equipment and reference standards. PJLA expects an evaluation this summer, with final approval at the end of 2018. If you are interested in this program, please contact us for a free quote. ◆

Laboratory Testing Of Medical Marijuana Edibles – FDA Now Involved

With cannabis legalization spreading across the United States and Canada, there are many issues to take into consideration, such as federal standards for food safety in regards to cannabis products. The FDA has been able to send warning letters to food and drug manufacturers that have violated food safety procedures and controls in regards to preparation, packaging, or holding conditions of the cannabis products. The FDA Food Safety Modernization Act (FSMA) has recently issued new regulations that influence the production and processing of cannabis. Food processors must be able to recognize any harmful chemical hazards within the product, as well as minimize or prevent these risks for consumers. However, since these products are still not legal under the federal law, regulations are not always accurately followed. It is extremely important that each state considers these food safety regulations when creating cannabis products, and establish regulated laws individually to produce quality product and minimize health risks. Laboratory testing of edibles is crucial in order to preserve the health and safety of its consumers. PJLA encourages all labs to closely review their state requirements when they apply for accreditation, to ensure that they meet the needs of their customers as well as following their state's guidelines. ◆

IN THIS ISSUE:

Perry Johnson Laboratory Accreditation, Inc.

World Headquarters
755 W. Big Beaver, Suite 1325
Troy, Michigan 48084

Phone:
1-877-369-5227 or
(248) 519-2603

Email:
pjlabs@pjlabs.com

Website:
www.pjlabs.com

Publisher:
Tracy Szerszen

Editor:
Tracy Szerszen • Tami Carr

Writer:
Lauren Masko

Layout & Design:
Jason Millbrand

PJLA Visits The Emerald Conference

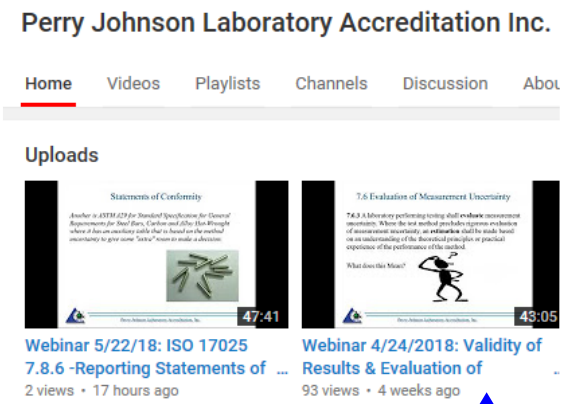
During the month of February, PJLA had the opportunity to exhibit and speak at the Emerald Conference, which took place in San Diego, California. PJLA's President Tracy Szerszen spoke on the panel session 'Regulatory and Consensus Method Developments', and shared the benefits of cannabis analytical testing. ◆

PJLA Visits The Pittcon Conference & Expo

PJLA attended, and exhibited at the Pittcon Conference & Expo in Orlando, Florida! PJLA's project managers Brett McMillen and Gary Steed had the opportunity to get a hands-on look at the latest developments in laboratory instrumentation, participate in live demos and seminars, and share their knowledge and services with hundreds of attendees. ◆

Subscribe To PJLA's YouTube Channel

Make sure to subscribe to PJLA's YouTube channel to view all our past webinars and any new information. ◆



Coordinate Measurement Machine (CMM) Calibration

Are you getting a true Calibration or just a Performance Verification?

Author: Henry L. Alexander CMfgE CQE

Many laboratories utilize Coordinate Measurement Machines (CMMs) to perform dimensional calibration (gages and similar items) or to perform dimensional inspection (parts, fixtures, tooling etc.), for which they issue endorsed certificates or reports.

Laboratories engaged in this type of work, need a calibration that addresses the ability of the machine to take incremental measurements within the working envelope of their CMM. The laboratory will in the course of its work measure features that range in magnitude from small to large. What constitutes an acceptable calibration of their CMM is one that compares their CMM's result to the known value of various dimensional standards small to large used in performing the calibration. These standards are typically step gages or a variety of gage blocks.

There are many “tests” described in the available standards. Most of them are intended as “acceptance” tests. The original ASME B89 standard, defined 5 different tests each intended to evaluate a particular error source of the CMM. This provided valid and useful information about the machine, but it does not constitute a calibration that reflects the manner in which these machines are typically used. These are performance tests that a manufacturer may perform to establish performance parameters for a class of machines. The customer may use these same tests hoping to reproduce the manufacturer's results as acceptance criteria. It might also be used as an Intermediate check as addressed in, ISO/IEC 17025:2005 5.5.10 and 5.6.3.3 and ISO/IEC 17025:2017 6.4.11 and 7.7.1 e).

Multiple measurements of a ball bar in various orientations or linear displacement accuracy of the machine along an axis measured by means of a laser may have value as indicators of machine performance or stability. However, they do not provide the same information that is obtained when the CMM is calibrated using a step gage utilizing7 different orientations (3 along the X, Y and Z axes and 4 along the body diagonals of the working volume of the CMM). This type of calibration accurately reflects the actual use of the machine.

The calibration certificate should report dimensional results and their uncertainty. Since such a calibration is performed by means of incremental measurements, the uncertainty should be reported as a relative uncertainty in terms of one variable with that variable being “L”, the length of the measurement. This permits the laboratory to develop and report relative uncertainty for the measurements taken when performing either calibration or dimensional inspection. The ball bar test, while popular as a performance indicator, produces an absolute uncertainty, which is not adequate for a laboratory performing incremental measurements.

Laboratories should specify in their request for quote. The type of calibration they require. It is recommended that they request a calibration using a step gage parallel to each of the three axes and along the 4 body diagonals of the machine. A performance test designed in this manner is described in ISO 10360-2 and its counterpart ASME B89.4.10360.2-2008. The laboratory may wish to have any of the remaining acceptance tests performed, but these tests cannot be the basis of a calibration to take incremental measurements. ◆

Reference Links:

- https://www.mitutoyo.com/news/resource-center/performance-of-cmms-testing-calibration-and-uncertainty/ “Performance of CMMs: Testing, Calibration, and Uncertainty”
- ISO 10360-2: Coordinate Metrology, Part 2: Performance Assessment of Coordinate Measuring Machines
- ASME B89.4.10360.2-2008: Acceptance Test and Reverification Test for Coordinate Measuring Machines (CMMs) Part 2: CMMs Used for Measuring Linear Dimensions (Technical Report)

ISO/IEC 17025:2005 & ISO/IEC 17025:2017 – What The New Transition Has To Offer

Author: Mike Kramer, Calibration Program Manager

The previous version of ISO/IEC 17025 was the second edition, published back in 2005. Since then, market conditions have changed. Furthermore, the shared aspects among ISO international standards has driven the need for further harmonization among other existing international documents.

In meeting these two progressions, the third edition of the standard, ISO/IEC 17025:2005, has undergone numerous changes. In meeting the current industry needs, the changes to ISO/IEC 17025:2017 include:

- A new chapter on risk-based thinking has been added
- Greater flexibility in the guidelines for processes, procedures, documented information, and organizational responsibilities
- Terminology has been updated
- The standard now recognizes and incorporates the use of computer systems, electronic records, and the production of electronic results and reports
- The scope has been revised to cover all laboratory activities. This includes testing, calibration, and the sampling associated with subsequent calibration and testing.

The new structure is closely aligned with all recent 17000-series standards. The 2005 edition was split into Management requirements and Technical requirements, appearing in that order, but the 2017 Standard has five sections.

Structure of ISO/IEC 17025:2017

1 Scope – 7.3 Sampling
2 Normative References – 7.4 Handling of Test or Calibration Items
3 Terms and Definitions – 7.5 Technical Records
4 General Requirements – 7.6 Evaluation of Measurement Uncertainty
4.1 Impartiality – 7.7 Assuring the Quality of Results.
4.2 Confidentiality – 7.8 Reporting of Results
5 Structural Requirements – 7.9 Complaints
6 Resource Requirements – 7.10 Management of Nonconforming Work
6.1 General – 7.11 Control of Data – Information Management
6.2 Personnel – 8 Management Requirements
6.3 Laboratory facilities and Environmental Conditions – 8.1 Options
6.4 Equipment – 8.2 Management System Documentation (Option A)
6.5 Metrological Traceability – 8.3 Control of Management System Documents (Option A)
6.6 Externally Provided Products and Services – 8.4 Control of Records (Option A)
7 Process Requirements – 8.5 Actions to Address Risks and Opportunities (Option A)
7.1 Review of Requests, Tenders and Contracts – 8.6 Improvement (Option A)
7.2 Selection, Verification and Validation of Methods – 8.7 Corrective Action (Option A)
8.8 Internal Audits – 8.9 Management Reviews (Option A) ◆

Client Spotlight: ACS/QCS Calibration Services

TRANSITIONING TO ISO/IEC 17025:2017

PJLA had the opportunity to speak with Mark Rudek, Owner of QCS Calibration Services S.R.L. and ACS American Calibration Services, E.I.R.L. about their experience partnering with PJLA to receive ISO/IEC 17025:2017 Accreditation, and their views on implementing the new standard.

Mark stated that the new ISO/IEC 17025:2017 standard does a better job of aligning itself with the other existing standards. It not just focuses on Risks, Confidentiality, Impartiality, and Antitrust rules which is carefully elaborated and defined throughout the whole accreditation process, but also ensures integrity and confidence of the final result reported to the client for the item calibrated.

ACS and QCS have a code of conduct that is followed which is also commonly followed within many other ISO registered companies, ACS and QCS Calibration Services has to take into consideration all of the international regulations and laws as well. There must be complete confidence, integrity and impartiality.

The main focus in accountability, confidentiality and impartiality in order to maintain quality performance for their clients that have an implemented ISO Registration related to Medical Device, Automotive and Aerospace industries.

Furthermore, he explains how the new standard has a more intricate process when determining the final result of calibration reported to the Client on a Calibration Certificate. Defining uncertainties and managing mitigated risks more in depth within the calibration process so when there is a decision rule of pass or fail is made, that decision does not result in a false accept or false reject of the item calibrated.

Mark believes the new standard is placing additional responsibility for both the accredited lab and the client in the quoting and calibration process so that clients have a better understanding for what they are asking and paying for. In the case of customer complaints, it emphasizes that these be documented, understood, communicated and objectively dealt with.

In regards to experience with PJLA, Mark states that working alongside PJLA has been a pleasure as PJLA has very experienced knowledgeable staff with a full understanding of the new requirements.

PJLA has seminars related to ISO/IEC 17025 that is available to any person in the calibration, testing and inspection industries. ”PJLA has been supportive to ensure a full understanding and implementation of the ISO/IEC 17025:2017 standard for the calibration industry.”

ACS American Calibration Services and QCS Calibration Services intends to provide Accredited Calibration services and be a leader of Calibration Services in the Dominican Republic. This accreditation is the first step, as we are the very first company accredited by PJLA to this standard. Please call Mark or Carlos at 1-809-246-7960/1-809-791-4116.

We service the entire Dominican Republic, other Caribbean islands and South American Countries. ◆

PJLA Would Love To See You At The Following Trade Shows:

Detroit CANNACON 2018
Cobo Center - Detroit, Michigan
June 1-2, 2018

PJLA will be exhibiting at the CANNACON conference, stop by our booth and visit!

CANNA WEST 2018
Crowne Plaza Redondo Beach & Marina Hotel
Redondo Beach, California
June 5-7, 2018

PJLA's Food Science Program Manager Larry Lagman is speaking from 9:00-9:30 on June 5th about Assessing Risks & Opportunities for Meeting the Requirement ISO/IEC 17025:2017.

2018 Midwest AOAC International Conference
Lincoln, Nebraska
June 5, 2018

PJLA's Food Science Program Manager Larry Lagman is speaking from 9:00-9:30 on June 5th about Assessing Risks & Opportunities for Meeting the Requirement ISO/IEC 17025:2017.

NELAC Conference 2018
New Orleans, Louisiana
August 6-9, 2018

PJLA will be exhibiting at the NELAC conference, stop by our booth and visit!

PJLA Sponsors A Transition Course In Conjunction With The SSAOAC Meeting

April 16th in Atlanta Georgia, PJLA sponsored a 17025 transition course at the SSAOAC Annual Meeting! Instructor Larry Lagman, Food Testing Program Manager & Lead Assessor presented the course "Transitioning to ISO/IEC 17025:2017" We also had the opportunity to exhibit during the meeting and network with industry experts. ◆

Advantages Of Partnering With PJLA

- Free Advertisement Opportunities
- Press Releases featured on all our Social Media channels
- International Recognition
- Dedicated Point of Contact
- Friendly knowledgeable assessors
- No application fees
- No travel mark-up
- No assessor transit-day billing
- No hidden costs
- PJLA clients have a voice in assessor selection
- PJLA is sensitive and responsive to needs of businesses of all sizes: small, medium or large ◆

PJLA Welcomes New Staff Member

Vanessa Abrou is PJLA's new Accreditation Program Assistant. She attended Rochester College and Oakland Community College where she received her certification as a medical assistant. Previously, she worked for Financial and Mortgage companies, as well as several hospitals. PJLA is very excited to have Vanessa as part of our team! ◆

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www.pjlabs.com

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

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Call: **1-877-369-5227** or Visit our website: **www.pjlabs.com**

Look Out For PJLA's FREE Online Webinars!

PJLA is now offering free webinars on various topics in relation to ISO/IEC 17025 for both testing and calibration laboratories. These are for all interested parties including: laboratories seeking accreditation, accredited laboratories, assessors, and consultants. To see our full schedule and register for upcoming webinars visit our website at www.pjlabs.com/training/pjla-webinars. ◆

Thursday, June 28, 2018:
ISO/IEC 17025:2017 A Look at Section 8.5 – Actions to Address Risks and Opportunities – Including Tools that can be Utilized by Organizations to Comply with this Section

Thursday, July 26, 2018:
A look at the ISO/IEC 17025:2017 Requirements Concerning Document Control and Control of Records