

# Accreditation Insider

A Newsletter Published by Perry Johnson Laboratory Accreditation, Inc. (PJLA)

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## *ISO 15189 - The Accreditation of Medical Laboratories is Making Progress*



**O**n February 2017, PJLA performed its first accreditation to ISO 15189:2012, the international standard designed for the assessment of medical laboratories. Mr. Javed Khan and Ms. Rae Cote assessed Personal Genome Diagnostics in Baltimore, Maryland, a lab that performs genetic testing for cancer treatments.

ISO 15189:2012 is very similar to ISO 17025, but focuses specifically on the protocols and practices required within a clinical laboratory. This includes testing fields such as pathology, cytogenetics, chemistry, toxicology, urinalysis, hematology, and a range of others. An international standard utilized and mandated by many countries, ISO 15189 helps laboratories demonstrate to the healthcare community that extra steps have been taken to ensure quality.

Once PJLA finalizes accreditation, an application for recognition will be submitted to the APLAC MRA Council for approval and an evaluation will be scheduled. PJLA is targeting a final recognition to be granted by the end of 2017. ♦

## *Are Your Calibrations Really Traceable to NIST?*

Many calibration service providers in the United States and also in other countries advertise that their calibrations are traceable to NIST and quite often also make this statement on their certificates of calibration. For calibration service providers that want to ensure that all information contained in their calibration certificates are correct, it is beneficial to understand the requirements of ISO/IEC 17025 as well as the traceability path of their reference standards.

### **ISO/IEC 17025 Requirements for Metrological Traceability**

Section 5.6.2.1.1 states that "For calibration laboratories, the program for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI)."

(NIST CONTINUED ON PG 4)

## *Updates to PJLA Forms and Criteria*

Just a reminder the following Policies and Procedures have been updated and the new version should be made available. Please view PJLA's website at [www.pjllabs.com/resources/pjla-documents](http://www.pjllabs.com/resources/pjla-documents) to download your own copies.

- DoD QSM Version 5.1
- PL-1 Proficiency Testing Requirements
- LF-56ELAP Rev 1.4 Working Document/Checklist
- PJLA Policy Updates: PL-1, PL-2, PL-3, PL-4

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## 2016 PJLA Annual Assessor Conclave

PJLA had another successful assessor conclave this year. This included technical sessions for specific testing, field sampling, inspection, and calibration programs. A general session was also presented, focusing on a myriad of issues including review of common findings, case studies for assessors, documentation changes, recognition updates and an overview of the new ISO 17025 standard. This was accompanied by national and international assessors and program management. PJLA's technical committee also met to discuss changes to PJLA policies PL-1, PL-2, PL-3, and PL-4. This was a successful meeting with a majority of members in attendance. Some critical topics discussed were the changes in the new DoD ELAP QSM and its implementation date, changes to ISO 17034 for reference material producers, and specific training on Risk Analysis in ISO 17025. Thank you to all PJLA management and staff for organizing this event! ♦



## TNI Non-Governmental Accreditation Body Program (TNI-NGAB) Update

PJLA has now been recognized by The NELAC Institute as an approved TNI Non-Governmental Accreditation Body (NGAB). This recognition allows PJLA to assess laboratories to the TNI EL Volume 1, 2009 standard. Currently, we are working with various states to evaluate whether this accreditation will be recognized as primary or secondary accreditation within their state and will keep all laboratories posted as we confirm this acceptance level. If your laboratory does not have any particular requirements to use current TNI State AB(s), then PJLA is an option for you to obtain TNI EL Volume 1, 2009 accreditation. ♦



LEFT TO RIGHT:  
TRACY SZERSEN, PJLA PRESIDENT  
JUDY MORGAN, TNRC CHAIR

## *PJLA Attends the Emerald Conference in San Diego, CA*

PJLA attended the third annual Emerald Conference on February 2-3, 2017. The conference covered various topics relevant in the Medical Marijuana industry, from specific state regulatory requirements to overviews of testing and sampling. PJLA had the opportunity to meet with several of its accredited laboratories and networked with a range of up-and-coming labs throughout the country "This is such an exciting industry to be part of," said Tracy Szerszen, PJLA President. "Every time we attend one of these conferences we learn something new and build valuable relationships with other interested parties in the industry. I believe part of our success in this industry is that we work well with small startup labs and offer as much valuable feedback as possible. Accreditation is not easy for laboratories that have never been through the process before. Our goal is to see everyone succeed." ♦



LEFT TO RIGHT:  
BRETT McMILLEN, PJLA NATIONAL SALES MANAGER,  
GREG MAGDOFF, PHARMLABS,  
TRACY SZERSZEN, PJLA PRESIDENT,  
CHRIS HUDALLA, PROVERDE LABORATORIES, INC.

## *The Louisiana Department of Environmental Quality (LDEQ)/LELAP Program*

Perry Johnson Laboratory Accreditation, Inc. has now been selected as one of the contracted auditing firms to assess for the Louisiana Department of Environmental Quality (LELAP). This includes both the LA in-state program and to the TNI EL standard Volume 1. Laboratories under this program will now have the option to choose an Accreditation Body that can assist them with multiple standards above and beyond the LELAP program such as ISO/IEC 17025, DoD ELAP, and TNI NEFAP. At this time PJLA is in the process of quoting laboratories for first quarter assessments. If you are accredited to this program and would like a consolidated assessment, please feel free to reach out to us at any time. PJLA can work with the LDEQ to make this possible. ♦



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(NIST CONTINUED FROM PG 1)

The SI defines seven units of measure which serve as the basis for all other measurements. It is important to note that ISO/IEC 17025 does not require traceability to a National Metrology Institute (NMI), but the link to the SI may be established through calibrations that are traceable through an NMI. Nowhere in ISO/IEC 17025 does it require that calibrations must be traceable to NIST.

The International Vocabulary of Metrology (VIM) defines Metrological Traceability as “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.”



In order to meet requirement 5.6.2.1.1, the laboratory must have a documented chain of traceability from their reference standards downward in the laboratory. This is usually done by keeping quality records that contain information about standards that were used in the calibration. Of course, the uncertainty for each measurement must also be calculated and recorded as this is part of the definition of traceability.

It is also very important to review what the certificates of calibration for your laboratory reference standards state for traceability. As an example, certificates of calibration from Fluke

state that they are traceable to the SI through various NMI's. The reason for this is because Fluke is a multinational company where calibration standards are manufactured in both the U.S. and the United Kingdom (UK). The equipment that Fluke builds and calibrates are some of the world's most accurate reference standards. As such, Fluke must use NMI's that can produce the smallest measurement uncertainty. As a result, Fluke uses NMI's from countries such as the UK, the U.S., Germany and Canada. For the case of DC voltage, Fluke's traceability is to a Josephson Voltage System, which is an intrinsic standard maintained in the Primary Electrical Laboratory in Everett, WA and is routinely compared to other Josephson Voltage Systems in North America.



JEFF GUST  
CHIEF CORPORATE  
METROLOGIST FOR  
FLUKE CORPORATION

You should also review certificates of calibration for your reference standards to ensure that they have complete and unambiguous statements of measurement uncertainty.

As a result of the review of the certificates of calibration for your reference standards, it may be necessary to update your laboratory's calibration certificates and advertising materials to ensure that any statements of traceability are accurate.

Jeff Gust is the Chief Corporate Metrologist for Fluke Corporation. Mr. Gust serves on the Board of Directors of NCSL International and represents this organization on the Laboratory Committee of the International Laboratory Accreditation Cooperation. He is also on the ISO/CASCO working group for the revision of ISO/IEC 17025. ♦

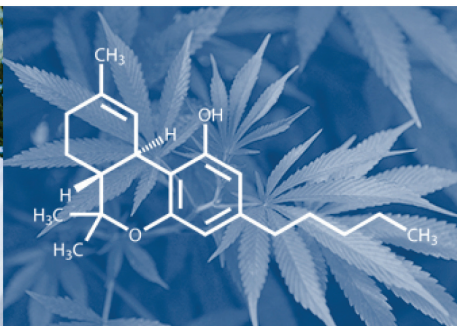


2<sup>ND</sup> ANNUAL

# CANNABIS

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July 19-21, 2017 | Los Angeles, CA



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### *Upcoming Tradeshows*

PJLA will be exhibiting at the 2nd Annual - Cannabis Compliance Summit 2017 on July 19-21.

Tracy Szerszen, PJLA President, will be presenting at the show on July 20th speaking on the ISO/IEC 17025 Laboratory Accreditation Process and Common Findings During an Assessment.





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## *PJLA Offers FREE Training!*

PJLA offers free webinars on various topics in relation to ISO/IEC 17025 for both testing and calibration laboratories. These are beneficial to laboratories seeking accreditation, accredited laboratories, assessors, and consultants. Register for upcoming webinars on our website at [www.pjlabs.com/training/pjla-webinars](http://www.pjlabs.com/training/pjla-webinars). ♦

**– 17025:2005 Common Findings on Initial and Routine Assessments - Friday, April 28th**

Japanese | Spanish

**PERRY JOHNSON LABORATORY ACCREDITATION, INC. (PJLA)**

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**PJLA Webinars** PJLA is now offering free webinars on various topics for both testing and calibration laboratories. These are for all interested parties including: laboratories seeking accreditation, accredited laboratories, assessors and consultants.

**Free Webinars**

PJLA is now offering free webinars on various topics in relation to ISO/IEC 17025:2005 for both testing and calibration laboratories. These are for all interested parties including: laboratories seeking accreditation, accredited laboratories, assessors and consultants.

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