Accreditation Insider

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PJLA Continues to Strive in the Medical Cannabis Industry

PJLA continues to strive to be the leading accreditation body in the cannabis testing industry. As states continue to legalize medical marijuana dispensaries, testing requirements have been developed to support the health and safety of consumers. Many states have already specified ISO 17025 accreditation as a credential for the laboratories. In addition to this requirement, some of the states require accreditation by an accrediting body that is a non-profit and an ILAC signatory. Since this was announced by two states California and Maryland, PJLA moved very quickly to develop a non-profit affiliate organization. Perry Johnson Laboratory Accreditation NP, Inc. (PJLA NP, Inc.) is the named organization operating as the non-profit affiliate of PJLA, Inc. This was a minor structure change and PJLA along with PJLANP will be the accreditor of the organizations. We would like to thank our customer base for their continued support during this minor transition period.

(Strive Continued on PG 2)

PJLA Future Accreditation Programs on the Way...

ISO 17020: 2012 Accreditation of Inspection Organizations

PJLA has now accredited our first Inspection Organization to ISO 17020:2012. We would like to congratulate and express our gratitude to Damarc Quality Inspections Services, LLC on achieving their 17020 accreditation on May 8, 2016. Their achievement of this accreditation signifies their commitment to quality and inspection conformity. Damarc Quality Inspections is a third party inspection body performing inspections on pressure equipment in accordance to ASME and ANSI requirements and other nationally accepted criteria.

ISO 17020 is a standard built for inspection agencies or even for organizations that inspect parts or processes to confirm compliance with their product requirement. PJLA encourages our client base to evaluate all aspects of their organization and consider becoming accredited to this standard. PJLA has a simplified process to add this standard to organizations already holding other accreditations.

Now that PJLA has accredited our first inspection organization, an evaluation by the Asia Pacific Laboratory Accreditation, Inc. (APLAC) will be completed. Once the final approval is achieved, PJLA will gain international recognition through the International Laboratory Accreditation Cooperation, Inc. (ILAC) for Inspection. The expected completion date is June 2017.

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

PJLA has completed our full evaluation by the NELAC Institute in April 2016. This evaluation included an on-site evaluation at our facility and at a client facility to the TNI Standard EL- Volume 1 and Volume 2. PJLA would like to personally thank Eurofins Frontier Global Sciences, LLC located in Bothell, WA for participating in this evaluation. Additionally, we would like to thank the TNI Evaluators, Ms. Ilona Taunton and Mr. Carl Kircher for their invaluable feedback. PJLA received a minimal amount of nonconformities, concerns and comments and are in the process of submitting corrective action. The goal is to receive a final approval by September 2016. Once this is achieved, PJLA will be a recognized AB to assess to the TNI NELAC standards.

ISO 15189 Accreditation

PJLA will be offering ISO 15189 accreditation, which is an international standard for medical/clinical testing laboratories. Laboratories obtaining this accreditation have demonstrated competence to perform clinical tests resulting in repeatable and reliable results. PJLA is currently seeking applicant laboratories and additional technical experts for this program. Contact PJLA at pjlabs@pjlabs.com for additional information. ◆

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

Writers:
Tracy Szerszen • Natalie Cloutier
Doug Berg • Lindsay Boecki

Layout & Design:
Jason Millbrand

(Strive Continued from pg 1)

Laboratories are achieving accreditation for the testing of cannabinoid potency, containment levels and microbiological aspects within plant/leaf products, edibles and liquids. The trend now within the laboratories is to go where the market is growing in relation to expanding their main location by adding remote sites to their certificate of accreditation. We have simplified this process for each laboratory by avoiding duplicative assessment activities that have already been assessed at the main location. The new remote sites are checked primarily for technical aspects and their commitment to the main location's quality management system. PJLA encourages laboratories expanding new locations to contact us immediately to schedule an on-site assessment. ◆

Client Spotlight: PharmLabs LLC

PharmLabs™ provides the cannabis community and beyond with laboratory testing and analytic services to ensure consumers have access to safe medicine. Through laboratory testing, PharmLabs™ ensures safe medicine for the medical cannabis community and LLC arms patients in the medical cannabis community with the proper information to make an informed decision on proper dosing and type of medicines they require to best combat their specific medical condition. PharmLabs™ offers potency, terpene, residual solvent, heavy metals, microbiological contaminations and pesticide testing for the cannabis community and beyond!

PharmLabs LLC has seen a huge benefit that the ISO management system has brought to their company in regards to corporate structure, best laboratory practices, and ensured accuracy from validated and calibrated instruments that are carefully gauged for any deviation in accuracy. PharmLabs is growing fast but the accuracy and quality of service has not been sacrificed. Accuracy is of the up most importance to PharmLabs; a factor that sets them apart from the other cannabis labs.

PJLA ISO-17025 accreditation has become a huge competitive advantage for their business! According to Greg Magdoff, PharmLabs Founder and CEO, “PJLA makes the ISO accreditation process easy and affordable. They really take the time to understand your company's needs and ensure accuracy and precision are executed on every level. PJLA also understands the cannabis industry and the unique challenges the industry faces. I always see PJLA at every cannabis expo and conference gaining the latest knowledge in the industry so they can ensure the best possible service to my industry. Thanks for all you do PJLA!” ◆

Cannabis Laboratory Accreditation History

PJLA accredited the first cannabis testing laboratory in the United States and is continually growing our client base. We are attentive to the needs of the cannabis industry and provide value-added assessments to our laboratories.

Congratulations to the following Cannabis Testing Laboratories for Achieving 17025 Accreditation:

Act Laboratories-Lansing, MI

Advanced Herbal Analytics, LLC-Carbondale, IL

Canna Safe Analytics-Murrieta, CA

CW Analytical- Oakland, CA

Grace Analytical-Berkeley, IL

Iron Laboratories, LLC.-Walled Lake, MI

PharmLabs- LLC-San Diego, CA

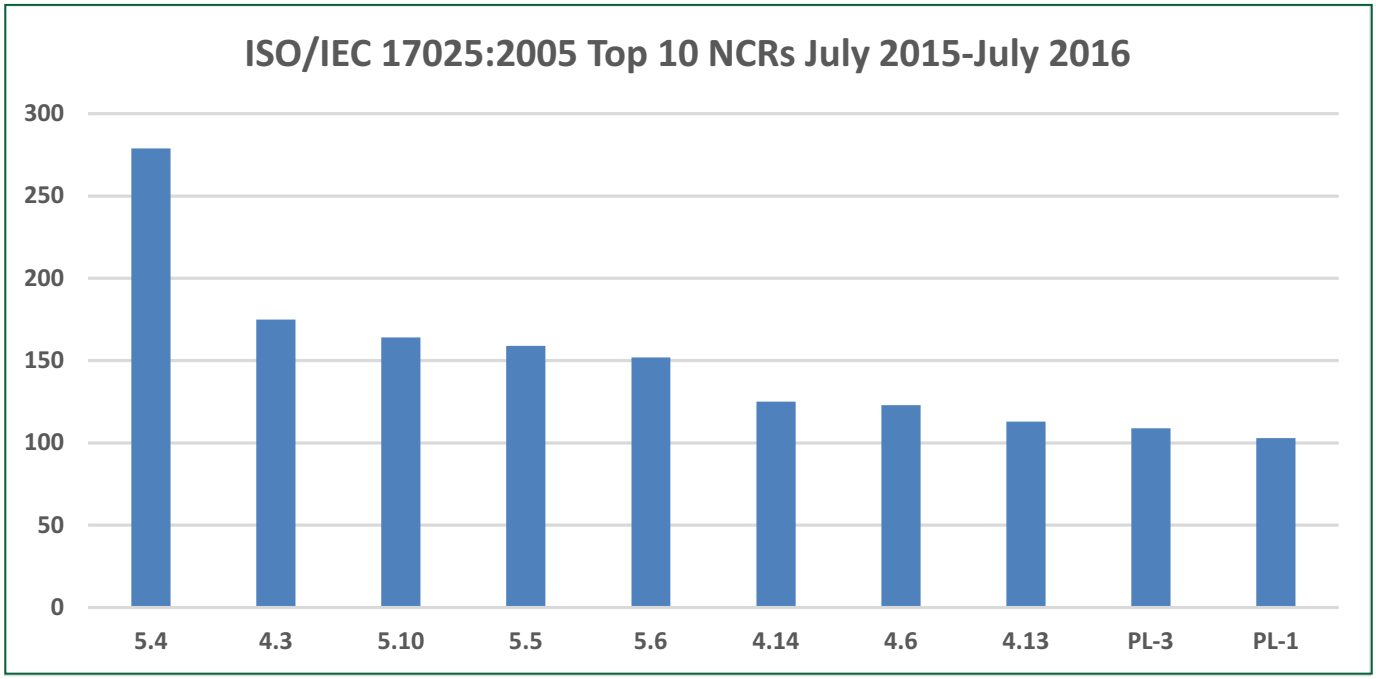
ProVerde Laboratories-Milford, MA

We look forward to adding additional laboratories to our listing. We foresee an additional 10 facilities to be added by the end of 2016.

We would like to recognize one of our lead assessors, Mr. Albert Ellis for spearheading this program. Albert has conducted a bulk of the cannabis laboratory assessments providing value-added assessments and promotes consistency among each laboratory. Albert has assisted with strengthening PJLA's accreditation program by providing technical advisement to assessors and clients. Albert has over 30 years of experience in the chemistry and biological fields. He has worked as a laboratory director and quality manager for several environmental and biological testing laboratories. He continues his knowledge in the industry by providing independent consulting and third party assessments. ◆

Report on the Top 10 Common Nonconformities Detected on an Assessment

PJLA finds it critical to inform and educate our customer base whenever possible on troublesome areas of ISO 17025. The top ten findings from the past 12 months have been provided below.



PJLA encourages laboratories to use this data to prepare for assessments and make the necessary improvements to decrease the number of findings on your assessment. This data includes all types of assessments performed across the globe. Below are some examples of the top 5 common nonconformities:

5.4 - No process or procedure for validating internal methods; Unable to apply a procedure for determining measurement uncertainty; Failure to have uncertainty budget, or inadequate uncertainty budgets.

4.3 - No Master list or equivalent; external documents not addressed; Document changes in computerized systems not addressed; Documents are not uniquely identified as specified in 4.3.2.3 (the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority; Revision status on document not matching master list.

5.10 - Line items of section 5.10 requirements not on reports such as the units of measure or title of person authorizing reports; Statements of compliance are made without taking uncertainty into account; No Evidence that measurements are traceable; The requirements for amended reports not being met.

5.5 - Records on equipment not maintained; Equipment not calibrated or checked appropriately prior to be put into service; Equipment not capable of achieving required accuracy (example: resolution or readability);No procedure in place for safe handling, transport, storage, use and planned maintenance (off site work).

5.6 - Standards or Equipment not calibrated by an accredited source; Calibration Reports for Equipment and Standards lacks evidence supporting traceability. ◆

ISO/IEC Guide 34: 2006 Transition to ISO 17034

Update on ISO 17034 "General requirements for the competence of reference material producers"

PJLA has been recognized under the APLAC MRA as an accreditor of reference material producers to ISO Guide 34:2009 since 2013. This Guide has evolved into ISO 17034 "General requirements for the competence of reference material producers". This document is now being circulated as a Final Draft International Standard (FDIS) with balloting ending in September 2016.

ISO 17034 will cancel and replace ISO Guide 34:2009. However, there will be a transition period agreed to by the recognition bodies that have reference material programs.

The major changes from ISO Guide 34:2009 are:

- Inclusion of requirements for production of all types of reference material, and additional specified requirements for certified reference materials;
- Harmonization with the revisions to ISO Guide 31 (in 2015) and Guide 35 (currently in process not yet formally released);
- Inclusion of more details on required reference material documentation;
- Inclusion of risks and opportunities;
- Restructuring based on the common structure adopted by other International Standards on conformity assessment developed by CASCO;
- Incorporation of modifications based on ISO/CASCO PROC 33.

Structurally, there are differences in ordering and numbering of elements. There is a provision for the demonstration of the fulfillment of the ISO 17034 standard with two options, A and B. Option A is a full assessment of the scope of the reference material production activities which covers the type, range and scope of the reference materials it undertakes. This would require the RMP to define and document its scope of activities addressing: quality policy, general management system documentation, control of management system documents, control of records, management review, internal audit, actions to address risks and opportunities, corrective actions, improvement, and feedback from customers.

Option B would be a demonstration with evidence that the RMP has established and maintains a management system in accordance with the requirements of ISO 9001. It would also have to be capable of supporting and demonstrating the fulfillment of the technical clauses (4 through 7) of ISO 17034 and fulfill the management system clauses (8.2 through 8.11). The accreditation body would have to ensure that the management system comprehends all aspects of the reference material production and the specific requirements for the management system in ISO 17034 are being met.

An APLAC AB workshop is scheduled later this Fall to work on implementation issues such as revisions to APLAC TC 008, "Requirements and Guidance on the Accreditation of a Reference Material Producer". This document is a requirement for the RMPs and ABs under the APLAC MRA.

Upcoming Tradeshows

PJLA will be exhibiting and presenting at the **AOAC Annual Meeting** held on **September 18-21, 2016 in Dallas, TX**. On Tuesday September 20th from 5:30-6:00p.m., we will be giving a presentation on Internal Method Validation with a guest speaker Pathogen Dx who will be presenting on a new microbiological rapid detection technology in support of the food, dietary supplement and cannabis industries.

PJLA is planning some educational opportunities regarding ISO 17034 and its implementation for laboratories (users), reference materials producers and its assessors. These will be announced shortly. ◆

FAQs on the Importance of Repeat Measurement in Surface Plate Calibration

What does 'repeat measurement' mean? Is it the same as flatness?

- Repeat measurement is a measure of localized flatness variation. The repeat measurement specification states that a measurement taken anywhere on the surface of a plate (with equipment intended to measure local flatness variation) will repeat within the stated tolerance. (Controlling local area flatness tighter than overall flatness guarantees a gradual change in surface flatness profile thereby minimizing local errors).

What flatness tolerances do most brands adhere to?

- Most manufacturers, including imported brands, adhere to the overall flatness tolerances of Federal Specification GGG-P-463c and the new ASME B89.3.7-2013 Granite Surface Plate standard, but many overlook the repeat measurement requirements.
- Many of the "budget plates" available in the market today are not guaranteed to meet the repeat measurement requirements. A manufacturer who does not guarantee that both overall flatness and repeat measurement requirements are met is not producing plates that comply with either Federal Specification GGG-P-463c or ASME B89.3.7-2013.

Which is more important: flatness or repeat measurement?

Both are critical to insure a precision surface for accurate measurements. Flatness specification alone is not sufficient to guarantee measurement accuracy. Repeat measurement error is less than the overall flatness regardless of where the measurement is taken on the plate.

- EXAMPLE: A 36 X 48 Inspection Grade A surface plate, which meets only the flatness specification of 0.000300 in. If an item being inspected bridges several peaks on the plate surface, and the gage being used to inspect it is in a low spot (localized error) between the peaks, the measurement error could be the full tolerance in one area, 0.000300 in. Actually, it can be much higher if the gage is resting on the slope of an incline on the surface. Errors of 0.000600in - 0.000800 in are possible, depending upon the severity of the slope, and the arm length of the gage being used. If this plate had a Repeat Measurement specification of 0.000050 in Total Indicator Reading, then the measurement error would be less than the overall flatness tolerance (0.000300 in) regardless of where the measurement is taken on the plate.

The instruments which are used to verify repeatability are not designed to check overall flatness. When set to zero on a perfectly curved surface they will continue to read zero, whether that surface is perfectly flat, or perfectly spherical, either concave or convex. The instrument simply verifies the uniformity of the surface, not the flatness.

Can a laboratory calibrate only 1 of these 2 parameters?

Only a plate which meets both the flatness specification and the repeat measurement specification truly meets the requirements of Federal Specification GGG-P-463c or ASME B89.3.7-2013 Granite Surface Plate standard. An endorsed calibration which is compliant with either of these standards must address both overall flatness and repeat measurement.

Author - Henry Alexander CMfgE CQE
Henry is the President and Chief Metrologist of Henry Alexander Engineering, Inc. providing system engineering services to accredited laboratories and those seeking accreditation. He is the former Calibration Program Manager of PJLA. He is a Lead Assessor of the ISO 17025:2005 standard and a member of the PJLA Technical Committee . ◆

Updates to ISO/IEC 17025:2005

ISO 17025 is still a work in progress and is now in the CD 2 stage. The FDIS expected release date is April 2017, with a final release by the end of 2017.

Some of the major changes include:

- ISO 9000 principles on resources and process
- Outcomes of processes – not procedures
- Follows new ISO 9000 philosophy requiring less documented procedures and policies and focuses more on the outcomes of a process

Example: no longer requires the laboratory to maintain a current job description (2005 – 5.2.4) but focuses on communicating to each person their duties, responsibilities and authorities (CD2 – 6.2.4).

- Additional rigor in assuring the quality of results
- Clarification/expansion of measurement decision risk

PJLA will keep organizations informed of the final changes and transition dates as we become more aware of them. ◆

PJLA Welcomes New Assessors to Our Team

Carl Maggiulli - *Calibration*

Kathleen Mitchell - *Environmental, Chemistry*

Luis LLeras - *Biological, Chemistry*

Heather Williams - *Chemistry, Biological, Proficiency Testing, RMP*

Enrique Servin - *Electrical and Mechanical Testing*

Raya Arya - *Calibration*

Nancy Bednarz - *Chemistry*

Venu Blakrishran - *Chemistry*

Michelle Harris-Bailey - *Biological, Chemistry*

Ron Winter - *Environmental, Chemistry*

Dan Hogan - *Calibration/Testing*

Larry Lagman - *Testing*

Fitri Sudradjat - *Testing*

PJLA is always looking for new assessors to join our team.
Contact us for more information. ◆

Perry Johnson Laboratory Accreditation, Inc.
755 W. Big Beaver, Suite 1340
Troy, Michigan 48084 USA

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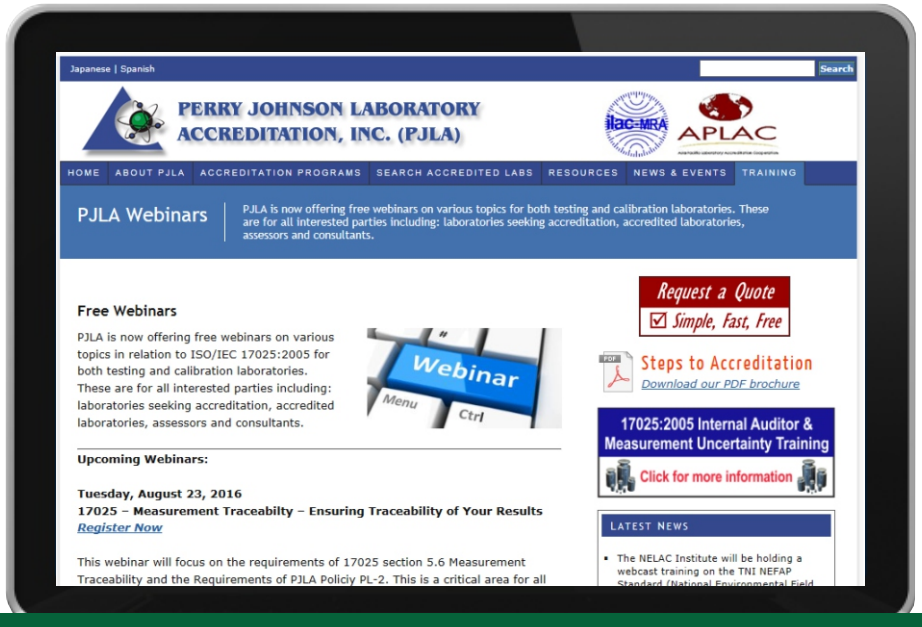
PJLA Offers FREE Training!

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. ◆



Upcoming Webinars:

Wednesday, September 14th
17025 – Corrective Action Requirements and Good Practice

Tuesday, October 4th
17025 – Reporting The Results – Ensure Compliance with 17025