

# Accreditation Insider

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

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## *ISO 15189:2022 Medical Laboratories – Requirements For Quality And Competence Have Now Been Revised!*

Attention all 15189 accredited or applicant laboratories! The new 15189:2022 standard has now been released and available for purchase on the ISO or ANSI websites. All organizations accredited to the prior version will have 3 years to transition to the new standard or by December 6, 2025. PJLA is currently working on updating our working documents to the new standard criteria and will start accepting new applications and requests for standard transitions by June 1, 2023. In order to meet the transition deadline, all 15189:2012 accredited laboratories must conduct a transition assessment no later than August 5, 2025, regardless of routine assessment schedules.

### **Brief Overview of the standard Changes**

- Alignment with ISO/IEC 17025:2017 resulted in the management requirements now appearing at the end of the document;
- Requirements for point-of-care testing (POCT), previously in ISO 22870, have been incorporated; (Note ISO 22870 will no longer be offered independently of 15189);
- Increased emphasis on risk management. ◆



## *FDA LAAF Checklist & Update*

PJLA has now updated our website to include our assessor checklist in accordance with the FDA LAAF requirements and are currently accepting applications from laboratories interested in becoming an FDA LAAF accredited laboratory. The FDA is anxious to obtain competent laboratories under this program in order to issue an official ruling to owners and consignees requiring the use of FDA LAAF laboratories. Laboratories are encouraged to review information on FDA LAAF and apply to PJLA for an assessment. ◆



# EPA 1633 Draft – DoD/DOE Update

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PJLA will no longer be required to identify Draft EPA Method 1633 as Modified on scopes of accreditation for additional analytes not listed in the method. The DoD and DOE have taken the position as long as the laboratory a) complies with all requirements of Draft EPA Method 1633 and DoD/DOE QSM Appendix B Table B-24; (b) can demonstrate the analyte does not interfere with determination of other analytes of concern in that method; and (c) has developed and employed QC acceptance criteria for determination of the target analyte. PJLA will revise certificates and scope of accreditation that currently identify EPA Method 1633 as Modified for additional analytes and will be submitting the revised accreditation certificates and scopes to the DoD and DOE. ♦



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## Join Our Team!

Join Perry Johnson Laboratory Accreditation, Inc.'s team of **ISO/IEC 17025** professionals who provide the best accreditation experience possible.

### ISO/IEC 17025 Assessors

We are currently seeking experienced **ISO/IEC 17025 Assessors** to join our assessment staff for the following programs:

#### Testing

- Biological
- Chemical
- Dimensional Inspection
- Electrical
- Mechanical
- Microbiological
- Acoustic
- Thermodynamic
- Environmental

#### Calibration

- Acoustic
- Chemical
- Dimensional
- Electrical
- Mechanical
- Mass/Weighing
- Optical
- Thermodynamic
- Time & Frequency

For immediate consideration, email us at [pjlabs@pjlabs.com](mailto:pjlabs@pjlabs.com) or send your resume to:

**Perry Johnson Laboratory Accreditation, Inc.**

755 West Big Beaver Road, Suite 1325, Troy, Michigan 48084



## *HYTORC International Starts ISO/IEC 17025:2017 Accreditation Globally With PJLA*

**H**YTORC International, a global leader in calibration, service, and manufacturing, has announced their pursuit of ISO/IEC 17025:2017 Accreditation for all international locations. "This is an exciting and important time for HYTORC," said Pietro Barcia, Senior Quality Assurance Manager. "The commitment to ISO 17025 Accreditation shows our customers and our team that we are serious about operating at the highest levels of quality and accuracy around the globe."

HYTORC has operated an ISO/IEC 17025:2017 Accredited program in the United States for several years. Tracy Szerszen, President of PJLA, stated, "We value our relationship with HYTORC and their decision to entrust us with the additional Accreditations of their international locations. They have been a wonderful customer for years and we are excited for this next level of their global business unit expansion."

From HYTORC's Senior Quality Assurance Manager:

"HYTORC is committed to delivering the most outstanding levels of service through the calibration processes to ensure its customers total compliance to the requirements of ISO/IEC 17025:2017. HYTORC is pleased to announce that the accreditation process to ISO/IEC 17025:2015 has begun for the following locations: Australia, Singapore, Japan, Saudi Arabia, Indonesia, United Arab Emirates, Dubai, and South Africa."

For more information on HYTORC International, please contact Pietro Barcia at [pbarcis@hytorc.com](mailto:pbarcis@hytorc.com). ♦

# HYTORC



## *Congratulations!*

**C**ongratulations to Tracy Szerszen, Perry Johnson Laboratory Accreditation, Inc. President, for being awarded Executive of the Year by PJLA founder, Perry Johnson, at this year's annual training. We also offer congratulations to our PJLA Assessor of the Year, Rae Cote and congratulations to our PJLA Employee of the Year, Melissa Chahine. ♦



Melissa Chahine



# 2022 Annual Assessor Training

The 2022 Annual Assessor Conclave was another great success. Perry Johnson Laboratory Accreditation, Inc. virtually welcomed PJLA assessors on December 9-10, 2022, for their annual December training. Tracy Szerszen, Tamara Norris, Doug Berg, Julie Snelling, Leeza Akimenko and Mike Kramer educated our core group of assessors on topics like common findings, program changes, and recent updates to relevant standards and programs. Some, but not all, of the many items on the agenda this year included Food Safety AOAC & FDA LAAF training, New & Updated Forms, FDA ASCA, EOA Assessments, and Inspection Body 17020 Updates.

We would also like to say a special thank you to our two guest speakers, Mark Ruefenacht from ASTM and Jerry Bambach from UNC and RTD Calibration and Customer Considerations, as well as a thank you to all PJLA staff for all their efforts coordinating another successful annual assessor conclave. ♦



## 2022 Top 10 Common Findings

1. 6.4 Equipment
2. 7.8 Reporting of Results
3. 6.2 Personnel
4. 8.8 Internal Audits
5. 6.6 Externally Provided Products and Services
6. 7.6 Evaluation of Measurement Uncertainty
7. 8.7 Corrective Actions
8. 7.7 Ensuring the Validity of Results
9. 8.6 Improvement
10. 7.2 Selection, Verification, and Validation of Methods



**Pittcon**<sup>®</sup>  
Conference and Exposition

Philadelphia, PA  
March 18-22, 2023  
Visit PJLA at booth #624



PJLA recently attended the Emerald Conference.  
Above: PJLA's Brett McMillen with Matt Sica.  
Below: Matt Sica speaking with Absolute Standards.



## Assessors In The Field



Goodman Manufacturing Company, L.P. d/b/a Dalkin Manufacturing Company, L.P. with PJLA Assessors, Filipe Narcio and RK Varma



## PJLA Podcasts – Now On Spotify



- Requirements for Internal Audits in ISO/IEC 17025:2017
- Streamlining Laboratory Efficiency with Greg Cencer
- A Look at ISO/IEC 17025:2017 – Section 8.9 Management Review Requirements and Utilization

## Look Out For PJLA's FREE Online Webinars!

For our full schedule and to register for upcoming webinars visit our website at [www.pjlab.com/training/pjla-webinars](http://www.pjlab.com/training/pjla-webinars).

### Testimonial:

*"I have been attending these webinars offered for various sections of new ISO/IEC 17025:2017 standards. I enjoy the presentations and the contents have been very useful and applicable for me who work in the Quality Assurance Section of our laboratory. I have a direct involvement with our laboratory Quality System (QS) including creating and updating of our Quality Manual, performing internal audits, and providing QS trainings as examples of some of the related tasks.*

*I also would like to take this opportunity and thank Mr. Kramer for the great job he does in creating and presenting these webinars. The availability of the webinars for future access are a very useful resource to use for future reference, refresher to learn more about each topic, etc."*

– Fathieh Shafiee

Program and Policy Analyst Advanced Quality Assurance  
Section Bureau of Laboratory Services/Division of  
Management Services Wisconsin Department of  
Agriculture, Trade and Consumer Protection

- **Wednesday, March 29, 2023 – 1:00pm EST**  
**A Look at ISO/IEC 17025:2017 – Review of Section 8.5 "Actions to Address Risks and Opportunities"**

*Presented By: Michael Kramer, PJLA Calibration Program Manager and Lead Assessor*

- **Thursday, December 22, 2022 – 1:00pm EST**  
**A Review of ISO/IEC 17025:2017 Requirements in Section 7.2 "Selection, Verification and Validation of Methods"**

*Presented By: Michael Kramer, PJLA Calibration Program Manager and Lead Assessor*

PJLA is hosting a series of FREE, educational podcasts.  
[Click Here](#) to listen to any of our previously recorded podcasts