Accreditation Insider

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ISO/IEC 17025:2017 – Transition Update

The new 17025 standard is making progress in the ISO community. At this time, the 17025:2017 FDIS version of the document has received a positive vote. The anticipated date for the standard to be released is Nov/Dec 2017. The FDIS version will be available for purchase shortly on the ISO.org website, which can be utilized for implementation if you wish to do so prior to the release of the final document.

The format of the new 17025 Standard will be changed significantly and be more in-line with new ISO 9000 formatting guidelines. The basic format is similar to other recently revised standards such as ISO/IEC 17020 (Inspection) and ISO 17034 (Reference Material Production). The new standard will be aligned with ISO 9001:2015 principles on resources and processes. There will be an Option A and B introduced in the new standard, which will primarily hinge on the laboratories established compliance in accordance to ISO 9001:2015. Informative Annexes have been added to aid in the interpretations of the standard as well metrological traceability.

In comparison to the ISO/IEC 17025:2005, the revised standard require labs to implement a risk based thinking process, which will enable some reduction in the former prescriptive requirements and performance based

(Transition Continued on PG 4)

Assessing Your Laboratories Technical Competence In Regards To The Requirements Of ISO/IEC 17025:2005, Section 5.3 Accommodation & Environmental Conditions

Michael Kramer - PJLA Calibration Program Manager

When assessing a laboratory to the technical elements specified in Section 5 of ISO/IEC 17025:2005, the quality management system needs to be written and comply with the requirements of the standard. Therefore, once a gap analysis or cross reference has been completed and determined that the quality management system is written and complies with ISO/IEC 17025:2005, the laboratory has in fact stated within their documentation how they will maintain compliance. In other words, the organization is stating what they are going to do.

This paper will focus on assessing laboratory compliance with ISO/IEC 17025:2005, Section 5.3. The quality management system as written is considered audit criteria. In other words, the laboratory has documented how they will comply with the standard. Audit criteria can be considered as anything that is written, seen, or heard when assessing a laboratory in regard to its operations. This paper will entail the actual review of objective

(17025 Continued on PG 5)

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 • Amy Wayne

Layout & Design:
Jason Millbrand

DoD ELAP QSM Version 5.1 Transition Update

Laboratories that are accredited under DoD ELAP should now be in the process of transitioning to the new QSM Version 5.1. All laboratories need to be assessed by January 2019 in order to stay within the program. If you have not already scheduled your assessment this year to the new standard, be prepared to be expected to meet these new requirements in 2018.

Additionally, please note PJLA's particular requirements for documentation submission. All documents must be submitted to your assessor and headquarters 30 days prior to your assessment. All relevant PT data should be submitted by your PT provider to pt@pjlabs.com in a .csv file. Failure to have these items submitted could result in PJLA removing items from your scope of accreditation.

Please ensure you have the latest and greatest revision of the QSM. This can be located directing on the Denix Website http://www.denix.osd.mil/edqw/accreditation/home along with any FAQs. We encourage that laboratories review this website frequently to be aware of any changes.

Laboratories that are being assessed to the Table B 15 requirements under the new standard need to review the changes in depth. Please ensure that you have two passing proficiency tests completed by an accredited third party provider, your procedures are updated and your data is reflective of the criteria as outline in the standard. Failure to meet the requirements will cause a delay in your scope to be updated to the Table B-15 criteria.

If you have any further questions regarding the DoD ELAP transition, please reach out to us at 1-877-369-5227. ◆

PJLA Welcomes A New Member To Our Team

PJLA is pleased to announce that we have added a new member to our team, Colleen Fitzgerald. Colleen will be assisting with various tasks to support our sales, accreditation, recruiting, and assessment processes. Colleen has over 14 years of experience working for the International Academy of Design & Technology and for ITT Technical Institute serving various administrative and executive support roles. ◆

COLLEEN FITZGERALD

PJLA To Offer Accreditation To DOECAP Laboratories By March 2018

As of September 2017, the DOE announced that they will be utilizing third party accreditation bodies (ABs) to conduct assessments for DOECAP. This will consist of an assessment to the DOD/DOE Combined Quality Systems Manual for Environmental Laboratories, Version 5.1., similar to the DoD Environmental Laboratory Accreditation Program (DoD-ELAP). At this time, the DOE is working on a Conditions and Criteria Document for the accreditation bodies, which will stipulate rules and criteria for assessments, training, DOE oversight, and AB credentials. It's expected that training will be conducted with our staff and assessors by November 2017 in order for us to have the program operating by March 2018.

PJLA attended the DOECAP workshop in Las Vegas on September 14-15, 2017 and presented on our experiences with DoD ELAP. This was well received and it was great to meet new potential clients and assessors. We look forward to this opportunity! ◆

PJLA Hosts Internal Auditor and Measurement Uncertainty Training Class

PJLA hosted our Fall ISO/IEC 17025:2005 Internal Auditor Course and Measurement Uncertainty training on September 19th-21st, 2017. This was conducted by PJLA Program Managers Mr. Michael Kramer and Mr. Douglas Berg. The class consisted of participants from across the United States, as well as Canada and the Bahamas. PJLA offers public classes biannually in the fall and in the spring at our Troy location. We we encourage all laboratories seeking accreditation to attend these courses in order to prepare for your assessment. These are also a great opportunity for accredited laboratories to train new staff on the requirements of ISO/IEC 17025:2005.

To learn more about our public classes, call 1-877-369-5227. ◆

PJLA Attended The Annual AOAC Meeting In Atlanta, GA

PJLA attended the annual AOAC meeting in Atlanta, GA during the week of September 24-27th. This was a great opportunity to network with customers, regulators, and industry experts within the food, pharmaceutical, and dietary supplement sectors. This was also a great opportunity to attend the various technical sessions on industry updates and accreditation. Some notable updates made during the ALACC meeting included the discussion on the changes to the *AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals*. It appears that the goal for this document will be updated to align with_the new ISO/IEC 17025:2017 standard by May 2018. All clients accredited to these guidelines will be notified early 2018 of the transition requirements. ◆

Left to Right: Larry Lagman - PJLA Food Testing Program Manager/ Lead Assessor, John Shumpert - GA Dept. of Agriculture, and Gary Steed - PJLA National Project Manager

(Transition Continued from pg 1)

requirements. The revision will allow greater flexibility in the requirements for processes, procedures, documented information, and organizational responsibilities. A definition of laboratory has been added along with the term decision rule, which describes how measurement uncertainty is taken into account when stating conformity with specified requirements. Other differences include the addition of requirements on externally provided products and services, which will incorporate requirements for both purchasing and subcontracting. The revised standard will also significantly expand on the requirement for documented processes associated with customer complaints.

PJLA will be provided a three year transition period to convert all laboratories to the new 17025:2017 standard by 2020. Our plan is to start offering accreditation to the new standard by February 2017. Laboratories already accredited can transition during this time either on their reassessment, surveillance or on a separate assessment.

PJLA will start offering transition training courses via on-line and face to face in early 2018. To ensure that you receive notification of upcoming training and events subscribe to our mailing list on our home page at www.pjlabs.com. Please note that earlier this year we provided a summary of the changes to the standard via webinar, which can be downloaded from our website at www.pjlabs.com/training/pjla-webinars/past-webinars. ◆

(17025 Continued from pg 1)

evidence along with additional audit criteria in making the determination whether compliance has, or has not been met.

Section 5.3 of ISO/IEC 17025:2005 specifies requirements for the accommodation and environment in which the test or calibrations are being performed. While assessing laboratory operations, there are requirements within this section which an auditor can see or hear and make a determination as to whether compliance is being meet. If there is anything witnessed within the working environment which would adversely affect the laboratories results should be a concern and noted by the auditor. Some items to consider are the lighting which the test or calibrations are undertaken, the actual cleanliness of the working area, any possibility of cross contamination, or vibration within the laboratory to name a few. Also the methods to control access to the laboratory operations may also be visually determined during the audit. If unauthorized personnel are seen entering the testing or calibration can be objective evidence in making the decision that perhaps the control of the area needs to be strengthened in order to preserve the integrity of the tests or calibrations which are being undertaken.

Specific tests or calibrations may in fact have specifications associated with them in regard to the laboratory environment in which these activities are carried out. These are to be monitored, controlled and recorded as required by the method being employed. This may include environmental conditions such as temperature and humidity. While assessing laboratory operations, these requirements should be known, and observed during the witnessing of tests or calibrations to determine if the laboratory is currently operating under the required parameters. Also, the auditor should determine if these have been monitored and captured as required during past tests or calibrations. Any objective evidence produced which shows tests or calibrations were performed outside the stated specification is in fact a nonconformance and perhaps even an indication that the control of nonconforming testing or calibration work procedures as specified in Section 4.9 of the standard, should have been implemented. ◆

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**

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. ◆

Tuesday, November 21, 2017:
17025 – 5.4.6 – Measurement Uncertainty – General Overview

Tuesday, December 19, 2017:
17025 – 5.2 – Personnel Requirements