Perry Johnson Laboratory Accreditation, Inc.

PJLA Accredited Laboratories and the Transition to ISO/IEC 17025:2017

The protocol for transitioning from ISO/IEC 17025:2005 to ISO/IEC 17025:2017 was announced in PJLA Update Notification #41, stating that laboratories must transition by **August 31, 2020** regardless of assessment due date. This deadline will allow for a buffer period to close any nonconformances that are identified during transition assessments. All laboratories must be accredited to the new standard by **November 29, 2020** and will be asked if they would like to transition during their normal routine visits.

As Perry Johnson Laboratory Accreditation, Inc. has been conducting transitional assessments to the 2017, we have started compiling data on the common areas PJLA assessors have been writing nonconformances:

Section 6.4 "Equipment" - At the forefront of this section, the requirement that laboratories have the required equipment to correctly perform laboratory activities is mentioned. This section now provides specifics as to when equipment is required to be calibrated. Reference to ISO 17034 has been included to emphasize the competence of reference material producers. Also specified in the 2005 standard, 2017 requires specified records to be maintained for equipment utilized within the laboratory.

Section 6.6 "Externally Provided Products and Services" - This section includes the previous concepts of subcontracting and purchasing, which are now compiled together within Section 6.6. This section offers organizations more flexibility in identifying suppliers that have been approved. Emphasis has been placed on procedures, however, and records are required to capture any actions that arise from evaluations, monitoring of performance, or re-evaluations of external providers.

Section 7.7 "Ensuring the Validity of Results" - Section 7.7 now has additional vehicles specified for the monitoring of results, which includes review of reported results, intra lab comparisons, and blind sample testing. In addition, this section now requires that a laboratory compare results with values obtained from outside of the organization where available and appropriate.

Section 7.8 "Recording the Results" - The 2017 standard puts more emphasis on reports that make statements of compliance. The concept of taking measurement uncertainty into account is nothing new in this area, but organizations are now required to record the decision rule used in taking uncertainty into account. In addition, the date of issue must now be captured on reports.

Section 7.2 "Selection Verification and Validation of Methods" - As always, a lab is required to use appropriate methods for Section 7.2.

Following **7.2.1.7**, the customer must accept deviations from the methods. Deviation in this context should be understood as a planned change or modification of the method.

The content of 5.4.3 and 5.4.4 of ISO/IEC 17025:2005 regarding developed methods and non-standardized methods have been erased. A "new" process to validate methods has been included as **7.2.2.1** and provides that method robustness is tested through a variation of controlled parameters, such as incubator temperature, volume dispensed, etc.

The previous **Note 3** in the 2005 Standard is now a requirement concerning the validation of methods when changes are made to the original validated method.

Additional records are now required to be maintained when methods need to be validated.