

PJLA Update Notification

Update Notification # 37

Update Notification Release Date: 2/8/17

Form/Procedure/Policy: PJLA Policy Updates-PL-1, PL-2, PL-3, PL-4

PJLA Applicant/Accredited Organizations:

PJLA has recently updated PL-1, PL-2, PL-3, and PL-4. An overview of these changes are listed below. Since none of these changes will critically impact accredited or applicant organizations, the implementation of these will be assessed at your next assessment. Please ensure to retain a copy of the PL documents from our website at <http://www.pjlab.com/resources/pjla-documents>.

PL-1 Proficiency Testing Policy

- Section 1.0 removed the term 17025 in order for the policy to apply for additional standards PJLA accredits
- Section 2.0-Added/Reworded to specify that the section if for 17025 only
- Section 3.1-Added criteria for initial assessments that PT data supplied should not be more than 12 months prior to the initial assessment
- Section 5.0-Added/Reworded to specify General Criteria for all laboratories under PJLA's accreditation Program
- Annex A-Added new section to include PJLA's criteria for the accreditation of medical laboratories to ISO 15189 including the requirements for frequency, quantity and PT plan development
- Changed font, re-numbering, formatting
- Added wording in regard to reflect the policy is general and other programs such as the DoD ELAP may be more stringent etc.

PL-2 Traceability Policy

- No major changes to any content. The only modifications were the additions of references throughout the document to include the ISO 15189 standard and its relevant sections in regard to traceability
- Changed font, re-numbering, formatting

PL-3 Measurement Uncertainty

Section-1.0- Added a reference to ISO 15189

Section 1.4-deleted since it was duplicative to other areas of the document

Section 2.0- Added a section for Terms for Measurement Uncertainty and also CMC calibration measurement capability

Section 3.3- rephrased the statement “The organization shall then prepare an uncertainty budget **where applicable and appropriate**”

-Section 4.0 added bolded titles to inform users that this section pertains to Calibration Labs Only

-Section 5.0 added bold title to inform users that this section pertains to testing & calibration labs performing in house calibration only

-Section 6.0 added bold title to inform users that this section pertains to testing labs only

- Section 7.0 added bold title to inform users that this section pertains to Reference Material Producers only

-Section 8.0 added bold title to inform users that this section pertains to medical labs only (15189)

-formatting, grammatical, re-numbering throughout the document

PL-4 Calibration Scopes of Accreditation Policy

-Section 3.2 editorial edits

- 3.3-expanded on the definition of range including the allowance for zero or up to as well as guidelines on the use of ranges; removed the wording that the CMC should not be three times less for the discipline or sub discipline

-Appendix A –added additional examples and criteria for PJLA’s allowance to modify this policy based on international markets (i.e. Japan)

-Changed font, re-numbering, formatting

Thank you!