PJLA Update Notification

Update Notification #80

Update Notification Release Date: 12/31/2024

Form/Procedure/Policy: Update to PJLA Policies PL-1 and PL-2

Attention All Applicant and Accredited Organizations:

PJLA has updated PL-1 Proficiency Testing Policy and PL-2 Traceability Policy. Please note these are mandatory policies that all conformity assessment bodies (Laboratories (Testing, Calibration, Medical Testing) Inspection Bodies, Proficiency Testing Providers and Reference Material Producers shall follow. Below is a summary of these changes and implementation dates.

PL-1 Proficiency Testing Revision 1.17 -Effective Immediately

1. Alignment with ILAC-P9:01/2024

 The updated policy incorporates requirements from ILAC-P9:01/2024, ensuring conformity with global accreditation practices. This includes refined participation criteria for Proficiency Testing (PT) and Inter-laboratory Comparisons (ILC) and clarifies the process for Intra-Laboratory Comparisons and Repeatability studies.

2. Clarified Definitions and Approved Approaches

- Enhanced definitions for PT, ILC, and intra-laboratory comparisons have been added for improved clarity.
- A prioritized list of acceptable PT activities has been introduced, emphasizing third-party accredited providers, inter-laboratory comparisons, and alternatives like repeatability studies, pending prior approval.

3. Risk-Based Planning and Documentation Enhancements

- CABs are now required to include risk evaluations in their PT plans. This encompasses complexity of tests, calibration frequency, and staff expertise.
- Updated documentation requirements mandate a rolling four-year schedule for PT activities, ensuring comprehensive scope coverage.

4. Revised Frequency Requirements

- Initial accreditation now requires participation in at least one PT or ILC within the preceding 12 months, with specific provisions for medical laboratories.
- Annual PT participation is required for all accredited CABs, with defined sampling rules for scopes with multiple fields.

5. Strengthened Records Requirements

- Requirements for records identify requires specific to all activity types.
- Clarity is provided for investigating and addressing results outside predefined performance criteria, emphasizing timely corrective action and documentation.

6. Clarity on Corrective Action Framework

• Clarity is provided for investigating and addressing results outside predefined performance criteria, emphasizing timely corrective action and documentation.

In summary, the updates in this policy were not significant and should not highly impact CAB's when implementing. Please note that all CABs shall have available the latest revision of this policy as part of their external document control system.

PL-2 Traceability Policy Revision 1.13-Effective Immediately

1. Alignment with Updated Standards

- Revision 1.13 incorporates references to ILAC-P10:07/2020 for metrological traceability.
- Emphasis on traceability through recognized National Metrology Institutes (NMIs) and Designated Institutes (DIs) per **BIPM KCDB** guidelines.

2. Expanded Guidance on Calibration Providers

- Clarification on acceptable calibration providers, including NMIs and ISO/IEC 17025-accredited laboratories.
- Added provisions for CABs to use NMIs outside the CIPM MRA, provided appropriate evidence is submitted and approved.

3. Enhanced Requirements for In-House Calibrations

- Greater detail on requirements for CABs performing in-house calibrations:
 - Maintenance of appropriate environments.
 - o Competence records for personnel.
 - Documented procedures and traceability evidence.

4. Certified Reference Materials and Traceability Options

- Expanded options for establishing metrological traceability when SI units are not feasible:
 - Use of Certified Reference Materials (CRMs) produced under ISO 17034 accreditation.
 - Introduction of reference materials validated for intended use with defined uncertainties.

5. Strengthened Documentation and Evidence

- Additional emphasis on maintaining an unbroken chain of traceability:
 - Documented evidence for each step in the traceability chain.
 - Clear calculation of measurement uncertainty across the chain.

6. Case-by-Case Approval for Non-Accredited Providers

- Introduced provisions for using non-accredited calibration providers:
 - Completion of LF-123 Traceability Form.
 - Mandatory assessor approval and documentation during assessments.

7. Improved Calibration Intervals and Risk Management

 CABs are now required to evaluate and document calibration intervals based on risks and operational variables.

This revision reflects PJLA's commitment to continuous improvement, aligning with evolving standards and enhancing the proficiency testing framework for its accredited bodies. For further details, please refer to the full policy document available through PJLA's website.

Thank you!