Reference Material Producer (RMP)
Accreditation Procedure

PJLA offers third-party accreditation services to Conformity Assessment Bodies (i.e. Testing and/or Calibration Laboratories, Reference Material Producers, Field Sampling and Measurement Organizations and Inspection Bodies). This procedure outlines PJLA's accreditation process and criteria administered to conformity assessments bodies producing **reference material or certified reference material (ISO 17034). This is a Supplemental Procedure to PJLA's Accreditation Procedure (SOP-1). Both procedures shall be followed for the entirety of this accreditation program.**

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1.0 SUBSTANCE OF THE AGREEMENT

1.1 PJLA is recognized by both the ILAC and the APAC MRAs as operating in conformance to ISO/IEC 17011.

2.0 MANUAL/ORGANIZATION

2.1 PJLA maintains a quality manual and operating procedures and work instructions to document its quality system to comply with ISO/IEC 17011. These and other related documents (including this one) state all of the requirements for organizations seeking accreditation under the RMP program. PJLA will follow its organization procedures as specified in these documents in the removal, suspension or withdrawal of an organization's accreditation status based on the organization's failure to meet requirements of the program on an ongoing basis or at the organization's request.

3.0 TRAINING AND QUALIFICATION

3.1 PJLA maintains a training, qualification and on-going continuing education program for assessors to comply with ISO/IEC 17011. New and experienced assessors are required to meet the requirements contained in this document. PJLA may, at its option, utilize the training of other accrediting organizations. PJLA will also recognize appropriate training conducted by federal, state, or local entities, academic/educational institutions or qualified private organizations if available and equivalent.

3.2 RMP assessors will possess a Bachelor's degree (or higher) in a scientific/technical discipline or have equivalent experience in testing and/or calibration, production/quality control, statistics, reference material production or distribution. Initially, assessors in the beginning of the program will not have to be witnessed or supervised if they have completed at least four other on-site assessments and have been determined to be proficient by PJLA. To be qualified all assessors will have to participate in at least four on-site assessments under the supervision of a qualified assessor. If the assessor is already a qualified assessor for another PJLA program, then the assessor will only need to be witnessed or supervised for one on-site assessment, at a minimum. Any supervised assessment shall be documented on an Assessor Evaluation Form (LF-100).

3.3 All assessors shall complete a basic training course that addresses the requirements of ISO 17034, ISO Guides 31, and 35 (or successor documents) and pass a written test. They shall also complete or have on record completion of at least one technical discipline as described in the previous paragraph. Annual

refresher training will be provided to address (for example): regulations; accreditation processes and procedures and requirements; records and documents; data analysis, reduction and reporting; sampling and measurement methods and techniques; and other topics to improve assessment and communication skills.

3.4 All qualifications and training will be documented in the assessor files.

4.0 ASSESSMENTS AND DOCUMENTATION

4.1 PJLA will perform on-site assessments of organizations' quality systems to include the applicable ISO/IEC 17025 requirements, ISO 17034 and related documents, (or successor documents). Each assessment will include the completion of a checklist that follows the requirements of ISO 17034. The completed checklist and other pertinent documentation will be kept per 8.0 below.

4.2 The basis for the assessment of the RMP will be ISO 17034 (or successor document). The applicability of ISO/IEC 17025 requirements is done on a case-by-case basis depending on the functions and activities the RMP performs. When the RMP performs measurement, calibration and testing activities, the requirements of ISO/IEC 17025 would apply. If the RMP (or a subcontractor) is accredited by an ILAC MRA for the activities performed, this will be sufficient evidence of technical competency. If the RMP is not accredited for such activities where the requirements of ISO/IEC 17025 would apply, PJLA will include the assessment for these activities against the requirements of ISO/IEC 17025 as well as those contained in ISO 17034 (or successor document).

5.0 PROFICIENCY TESTING (ACCREDITATION PROCESS)

5.1 PJLA requires all Conformity Assessment Bodies, (CABs), applying or maintaining accreditation under the PJLA RMP program to participate in applicable and available proficiency testing (PT) programs from an approved (PT) provider to each scope of accreditation sought. This (PT) program must comply with PJLA Policy PL-1 and other related program specific requirements such as ILAC P9 for the tests or calibrations performed. This requirement also extends to (CAB) subcontractors performing analytical testing activities in the characterization, determination of homogeneity or stability, shelf life, or ongoing monitoring of reference materials. This requirement holds true whether the subcontractor is accredited or unaccredited. If appropriate (PT) programs are not applicable or available then proficiency can be demonstrated by a variety of means such as (but not limited to): internal quality control check samples or programs; studies to establish method detection limits, precision, accuracy, and

demonstrations of capability; internal self-monitoring and audits of the measurement activities; or inter-organization studies.

6.0 ACCREDITATION INTERVAL/CYCLE (ASSESSMENT PROCESS)

6.1 PJLA currently accredits (CABs) for a two-year accreditation cycle, supplemented with yearly on-site surveillance assessments. While no change in this interval is anticipated, for the PJLA RMP program, it will not exceed the times and conditions allowed in ISO 17011. Accreditation and re-accreditation assessments involve the off-site review of documentation and performance information and an on-site assessment that address all applicable elements of ISO/IEC 17025 and all elements of ISO 17034. This includes subcontractor locations where warranted.

7.0 ANALYSIS OF FINDINGS AND REPORT

7.1 PJLA will follow its documented procedures in the conduct of the assessments, documentation of findings (non-conformities/observations), and on-site reports. PJLA assessors are expected to leave the documentation of findings and the report with the organization at the conclusion of the closing meeting. Also, the lead assessor is expected to send this documentation to PJLA HQ within 14 days of the end of the assessment (with allowances for travel, weekends, particular circumstances, etc.). Consistent with current PJLA requirements all non-conformities must be closed or resolved with correction and containment, root cause, implementation of corrective action, and objective evidence or an assessable plan with objective evidence of implementation of the plan within 60 days of the closing meeting. All non-conformities must be so resolved prior to recommending accreditation or extending reaccreditation.

8.0 RECORD RETENTION (RECORDS/COMPLAINTS)

8.1 PJLA currently retains records from three (3) to five (5) years (depending on the record), minimum. These records will include all complaints received from customers and others about (CABs) accredited by PJLA in the RMP program. Specific program requirements may supersede these retention periods, but only by increasing them.

9.0 DELEGATION (SUBCONTRACTING OF ASSESSMENT ACTIVITIES)

9.1 PJLA will not delegate (whole or in part) the responsibility of (CAB) assessment to another organization, which is not itself recognized under the ILAC MRA. This

will not extend to the assessors themselves, many/most of who are independent contractors. PJLA confidentiality and conflict of interest policies will be enforced.

10.0 SUBCONTRACTING OF (CAB) ACTIVITIES

10.1 (CABs) accredited by PJLA may subcontract activities described under the scopes of their accreditation and for which they are recognized consistent with ISO 17034. In accordance to the Standard they shall not subcontract out production planning, the assignment and decision of property values, determination of their uncertainties, authorization of property values, and the issuance of certificates. Other provisions of ISO/IEC 17025 regarding subcontracting will, of course, also be enforced in that the RMP would need to determine the competence of the subcontractor for the work performed and have records of the qualifications and evaluation of the subcontractor(s). PJLA will review how the RMP selects subcontractors particularly for critical activities where the subcontractor generates measurements for the characterization of property values, homogeneity, and stability.

10.2 An on-site assessment of the subcontractor by the RMP is not normally needed if the testing or calibration subcontractor is accredited to ISO/IEC 17025 for the specific test or calibration, and the degree of the review done by the RMP of the contract or arrangement with its subcontractor is appropriate and at a minimum includes a review of:

10.2.1 the measurement required;
10.2.2 the test and/or calibration method(s) used;
10.2.3 the required measurement uncertainty;
10.2.4 metrological traceability;
10.2.5 the reporting requirements;
10.2.6 the performance of proficiency testing activities (where suitable and applicable), and
10.2.7 attention by the subcontractor to performing the work with the required technical thoroughness

10.3 When the testing or calibration subcontractor is not accredited, the same issues should be addressed, but an on-site assessment by the RMP may be required with records available for review.

11.0 CERTIFICATES OF ACCREDITATION

11.1 PJLA only issues certificates of accreditation upon the final approval of the Executive Committee. These certificates will contain the effective date and the scope of accreditation consistent with PJLA polices and work instructions.

11.2 If an RMP does certain activities that are outside the scope of its accreditation, it shall not claim that it is accredited for producing the RM concerned, and cannot use an endorsed certificate/statement/report for such a RM.

11.3 A listing of all accredited RMP (CABs) will be published on the PJLA site to include the: (CAB) name, address, contact, phone number, scope of accreditation. Any changes to the (CAB's) status will be indicated on the PJLA website.

12.0 PARTICIPATION AND MAINTENANCE OF RECOGNITION

12.1 PJLA will participate in meetings with APAC as scheduled and announced, to help in the evaluation, maintenance and improvement of the APAC RMP program. PJLA will undergo periodic re-evaluation as an AB as required upon the granting of full recognition by APAC. This may involve other interested parties as observers in the evaluation process.