



Perry Johnson Laboratory Accreditation, Inc.

Scopes of Accreditation Policy

1.0 INTRODUCTION

- 1.1 This policy has been developed by PJLA and its technical committee to ensure consistency among organization's scopes of accreditation. It establishes guidelines used by PJLA to determine the most accurate expression of an organization's conformity assessment activities deemed competent through accreditation. This includes policies for CABs including (Testing- general and medical and Calibration Organizations, Inspection Bodies, Reference Material Producers and Proficiency Testing Providers).
- 1.1.1 This document includes various appendices for accreditation programs which outlines various examples and criteria for scopes of accreditation, including Flexible scopes, based upon the requirements of ISO/IEC 17011:2017, ILAC G18 and ILAC P14 latest versions.
- 1.2 All applicant and accredited organizations shall adhere to this policy.

2.0 GENERAL

- 2.1 Scope of Accreditation
- 2.1.1 The scope of accreditation is the official and detailed statement of the activities for which the CAB is accredited. In ISO/IEC 17011:2017, sub-Clause 7.9.4, it is required that the accreditation body provide an accreditation certificate to the accredited conformity assessment body, which shall include a brief indication of, or reference to, the scope of accreditation.
- 2.1.2 All scopes of accreditation shall include the following regardless of the standard or program, per ISO/IEC 17011:2017, Section 7.8.1
- a) the identity and, where relevant, the accreditation body logo;
 - b) the name of the accredited conformity assessment body and the name of the legal entity, if different;
 - c) scope of accreditation;
 - d) locations of the accredited conformity assessment body and, as applicable, the conformity assessment activities performed at each location and covered by the scope of accreditation;
 - e) the unique accreditation identification of the accredited conformity assessment body;
 - f) the effective date of accreditation and, if applicable, its expiry or renewal date;
 - g) a statement of conformity and a reference to the international standard(s) and/or other normative document(s), including issue or revision used for assessment of the conformity assessment body.



Scopes of Accreditation

- 2.1.3 In addition, ISO/IEC 17011:2017, sub-clause Clause 8.2.1, requires that the accreditation body make publicly available information about the status of the accreditations, which shall be updated regularly. The information shall include scopes of accreditation, condensed and/or in full. If only condensed scopes are provided, information shall be given on how to obtain full scopes.
- 2.1.4 The formulation and assessment of the scope of accreditation represents the core of the accreditation process. The role of the Accreditation Body is to ensure (to an adequate degree of confidence) that the conformity assessment body has the competence to offer the service defined in the scope.
- 2.1.5 Footnotes are included on scopes of accreditation to identify CAB's capabilities for performing conformity assessment activities at customer locations, at fixed location and mobile units, as applicable. Additionally, the footnote section may be utilized to indicate when a CAB has a flexible scope, clarification of calibration measurement capabilities (CMC), or any other information to further define capabilities of the CAB.
- 2.1.6 Organizations may request a flexible scope which, provides benefits to the organization to add a method, matrix or analyte without having to request PJLA for an expansion to the scope, not including modifications to methodologies. CABs holding a flexible scope are required to have strict policies in place to validate flexible scope items. PJLA's criteria for applicant and accredited CABs applying for or maintaining a flexible scope is described in Appendix F of this policy as well as PJLA SOP-1 Accreditation Procedure. Only programs mentioned in Appendix F allow Flexible Scopes to be displayed on scopes of accreditation.
- 2.1.7 Applicant or accredited Organizations are responsible for providing PJLA with the most accurate and current information available regarding their scope of accreditation, in accordance with this policy.

3.0 References

- 3.1 ISO/IEC 17011:2017 Conformity assessment - General Requirements for accreditation bodies accrediting conformity assessment bodies
- 3.2 ILAC G18:12/2021 Guideline for describing Scopes of Accreditation
- 3.3 ILAC P14:09/2020 ILAC Policy for Measurement Uncertainty in Calibration
- 3.4 ILAC P15:05/2020 Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies
- 3.5 NIST Special Publication 811 2008 Edition-Guide for the Use of the International System of Units (SI)
- 3.6 ILAC G28:07/2018 Guideline for the Formulation of Scopes of Accreditation for Inspection Bodies



Scopes of Accreditation

APPENDIX A -CALIBRATION SCOPES OF ACCREDITATION-ISO/IEC 17025

1.0 GENERAL

- 1.1 The scope of accreditation is a formal document issued by PJLA to its accredited organizations. It contains information expressing the calibration parameters, ranges over which a calibration applies, the CMC (Calibration and Measurement Capability) associated with the calibration as well as pertinent information about the equipment, methods and references used in performing the calibration as required in ISO.IEC 17011:2017, clause 7.8.3, c. Below includes the requirements for the formatting of calibration scopes of accreditation.

2.0 CALIBRATION FIELD

- 2.1 Fields of accreditation shall be defined as listed below:

- Dimensional
- Electrical
- Time and Frequency
- Acoustic
- Mass, Force, and Weighing Devices
- Mechanical
- Chemical
- Thermodynamic
- Optical
- Ionizing Radiation and Radioactivity

- 2.2 Fields of accreditation shall be specified on the main certificate as well as certificate supplement.

3.0 MEASURED INSTRUMENT, QUANTITY OR GAUGE

- 3.1 This category represents the calibration that is being performed by the CAB. It should be specific to the instrument, gauge, or artifact which is being calibrated.

- 3.1.1 For example, analytical balances, indirect verification of Rockwell Hardness HRC, or Outside Micrometers.

4.0 RANGE (AND SPECIFICATION WHERE APPROPRIATE)

- 4.1 This category should define the range, which is the magnitudes between the lower and upper boundaries of the calibration parameter. For devices which are non-variable or nonadjustable, the range is reduced to a discrete value.



Scopes of Accreditation

- 4.2 CABs should exercise care in determining the lower limit of the range. Zero is not acceptable as the low end of a range when it cannot be physically attained as a valid measurement result or when a physical standard calibrated at zero magnitude is not possible. Another consideration is when the uncertainty becomes a significant component of the measurement result, the confidence in the validity of the result diminishes. For this reason, PJLA has established that the low end of the range for which it will accredit calibration disciplines typically should not be less than three times the CMC for that discipline or sub discipline.
- 4.3 PJLA will accept the range stated in one of the following three formats:
- 4.3.1 A fixed value:
- 4.3.1.1 This format is appropriate when the device to be calibrated has a fixed nominal value such as the length of an end standard, the stated value of an SRM (Standard Reference Material) or the temperature of a TPW (Triple Point of Water Cell) cell. In this case, the fixed value is understood to represent the expected nominal value of the device or specimen. When the range is expressed as a fixed value the fixed value typically should not be less than three times the CMC for that discipline or sub discipline
- 4.3.2 A range beginning with up to and ending with a fixed value:
- 4.3.2.1 This format is appropriate when the organization wishes to indicate the measurement capacity of equipment it can calibrate rather than stating its actual range of calibration capability for the calibration to which the range applies. In this case, it is understood that a non-zero low end of the range does exist, but there is no requirement that it be specified. Organizations should exercise care when using this format for representing the range of their calibration capability. It must be clearly understood by the organization that values of zero at the low end of the range are not permitted.
- 4.3.2.2 If a CAB elects this format, then any range beginning with up to within the sub-discipline cannot encompass like calibration points unless there is a change specified such as the resolution of the device under test, or the equipment used in the calibration. Additionally, there cannot be two like values specified with different CMCs unless there is a clear indication that there is a change.
- 4.3.3 A range between two fixed values:
- 4.3.3.1 This is appropriate when the device to be calibrated has the ability to measure “the absence of all magnitude or quantity” within the uncertainty of measurement associated with its calibration. In this case, the low end of the range represents the smallest calibrated standard used by the



Scopes of Accreditation

CAB in calibrating the device. The high end of the range represents the largest calibrated standard used by the CAB in calibrating the device. When the uncertainty becomes a significant component of the measurement result, confidence in the validity of the result diminishes. For this reason, PJLA has established that when the range is expressed as the interval between two fixed values the low end of the range for which it will accredit calibration disciplines typically should not be less than three times the CMC for that discipline or sub discipline. Additionally, there cannot be two like values specified with different CMCs unless there is a clear indication that there is a change. PJLA will consider exceptions to this policy on a case-by-case basis.

- 4.4 Care must be taken to ensure that measurement results produced as part of the calibration is expressed in acceptable units and that the expression of results is properly formatted. Mass measurements must be expressed in mass units and dimensional measurements must be expressed in dimensional units, etc. Please refer to NIST SP 811 for guidance in the use of appropriate units and formatting of measurement expressions. In those instances where use of U.S. Customary units (USC) is deemed appropriate NIST SP 811 will govern formatting and is a reliable source of conversion factors between the SI and USC units.

5.0 CALIBRATION AND MEASUREMENT CAPABILITY (CMC) EXPRESSED AS AN UNCERTAINTY:

- 5.1 PJLA grants accreditation on the organization's capability to perform a calibration. This capability is partially defined by stating the magnitude or range of values over which the calibration capability applies. The definition of the calibration capability is completed by specifying the CMC associated with the magnitude or range stated. The CMC is expressed as an expanded uncertainty with a coverage factor "k" = 2 resulting in an approximate 95% confidence level. The CMC stated in the proposed scope, is defined as "*the smallest uncertainty an organization can achieve within its scope of accreditation when performing a more or less routine calibration on a nearly ideal device being calibrated.*" The CMC stated on the scope supplement must be achievable by the organization when calibrating a nearly ideal UUT (Unit Under Test) and documentary evidence to that affect must be maintained.
- 5.2 Uncertainty occurs in one of three mathematical conditions:
- 5.2.1 The first is a set of values that remain constant over the stated range. CMC can be expressed on the scope of accreditation as an absolute uncertainty. In this situation, one value is appropriate for all points in the stated range.
- 5.2.2 The second is a set of values that are linear meaning that they vary in approximate direct proportion to the increase in magnitude of the stated range. CMC can be expressed on the scope of accreditation as a relative



Scopes of Accreditation

uncertainty equation. The equation takes the form $(1.21 + 1.34L)$ where L is a variable representing the magnitude of any value within the stated range. In this example, L represents length. Other variables may be used appropriate to the parameter being defined. Any variable used in this manner must be clearly defined in a footnote at the end of the scope of accreditation. An additional form of relative uncertainty statement is expressing the uncertainty as a percentage of the reading or a percentage of the reading plus a fixed or “floor” value. Although an absolute uncertainty can be used for uncertainties of condition 2, the value must be the largest for any point in the range, which means that the CMC for all other values in the range will be overstated. When an organization chooses to express its CMC as an RUS (Relative Uncertainty Statement) it may do so using either of the following formats:

- $72 \mu\text{V}/\text{V} + 2 \mu\text{V}$
- $0.016 \% \text{ of reading} + 8 \mu\text{V}$
- $0.021 \% \text{ of reading}$
- $(0.13 + 0.127\text{Wt}) \text{ g}$

As an alternative, the organization may propose an additional format for the relative uncertainty expression, any such formats developed by the organization shall be submitted to PJLA headquarters for approval. Once approval has been granted the organization may proceed to use the approved format. Although PJLA expresses no preference for a specific format, the organizations shall choose the format most appropriate for each calibration discipline and shall utilize the same format throughout specific calibration disciplines for expression of relative uncertainty statements. Any exception to this would need to be submitted to PJLA headquarters for review and handled on a case-by-case basis. Should the organization wish to expand the scope of disciplines for which they are accredited any added calibration activities whose CMC is expressed as a RUS shall use the format prevailing on the scope of accreditation prior to expansion for calibrations in the same discipline.

The third is a set of values that are non-linear, meaning that they vary at a non-uniform rate relative to the increase in magnitude of the stated range.

6.0 SIGNIFICANT DIGITS

- 6.1 The numerical value of the expanded uncertainty shall not be expressed more than two significant digits. Where the measurement result has been rounded, that rounding shall be applied when all calculations have been completed; resultant values may then be rounded for presentation.
- 6.2 The rule for rounding numbers used in stating the CMC is that the 2 digits immediately following the last desired significant digit shall be discarded if they are 5 percent or less of the last desired significant digit. If they exceed 5 percent of the last desired significant digit, then the last desired significant digit is increased in value by 1.



Scopes of Accreditation

6.2.1 See the following examples:

- 0.110 3 mV rounded to 2 significant digits is 0.11 mV
- 0.110 4 mV rounded to 2 significant digits is 0.11 mV
- 0.110 5 mV rounded to 2 significant digits is 0.11 mV
- 0.110 6 mV rounded to 2 significant digits is 0.12 mV

6.2.2 Where the measurement result has been rounded, that rounding shall be applied when all calculations have been completed.

6.2.3 Guidance on rounding provided in Section 7 of the GUM, shall be utilized.

7.0 CALIBRATION EQUIPMENT/REFERENCE STANDARDS USED

7.1 This field includes equipment or standards used to calibrate the device.

8.0 CALIBRATION MEASUREMENT METHOD OR PROCEDURES USED

8.1 This field includes the measurement method or procedure utilized for each calibration (i.e., ASTM, ISO, Internal SOP, WI etc.). The procedure or method specified shall be reflective of how the current ranges and CMCs were determined.

9.0 CALIBRATION SCOPE EXAMPLES

DIMENSIONAL

| MEASURED INSTRUMENT, QUANTITY OR GAUGE | RANGE (AND SPECIFICATION WHERE APPROPRIATE) | CALIBRATION OR MEASUREMENT CAPABILITY EXPRESSED AS AN UNCERTAINTY (\pm) | CALIBRATION EQUIPMENT AND REFERENCE STANDARDS USED | CALIBRATION MEASUREMENT METHOD OR PROCEDURES USED |
|--|---|---|--|---|
| Cylindrical Diameter Outside | 0.01 in to 1 in | 20 μ in | Universal Measuring Machine | GIDEP 17-20MD-39 |
| | 1 in to 5 in | (17.5 + 2.5L) μ in | | |
| Cylindrical Diameter Inside | 0.04 in to 0.5 in | 26 μ in | Gage Blocks/Sine Bar | WI-PRO-105 |
| | 0.5 in to 5 in | (24.75 + 2.5L) μ in | | |
| Protractors | 3 in to 12 in | (59 + 10L) μ in | | |



Scopes of Accreditation

| | | | | |
|---|-------------------------|----------------------------|---|---|
| Gage Blocks | 0.05 in to 1 in | 3.5 μin | Gage Block Comparator and Master Blocks NIST The Gauge Block Handbook | NIST The Gauge Block Handbook |
| | 1 in to 2 in | 5 μin | | |
| Gage Blocks Thread Plugs Pitch Diameter Thread Plugs Major Diameter | 2 in to 4 in | 7.9 μin | Gage Block Comparator and Master Blocks Measurement over wires with Supermicrometer ASME B1.2 Mil Std 45662A Manufacturer Specifications Supermicrometer ASME B1.2 Mil Std 45662A Manufacturer Specifications | NIST The Gauge Block Handbook ASME B1.2 Mil Std 45662A Manufacturer Specifications |
| | 0-80 to 4-12 | 140 μin | | |
| | 0-80 to 4-12 | 67 μin | | |
| Surface Plate Flatness Repeat Measurement | 10 in to 72 in diagonal | (51 + 1.2D) μin | Autocollimator | ASME B89.3 |

ELECTRICAL

| MEASURED INSTRUMENT, QUANTITY OR GAUGE | RANGE (AND SPECIFICATION WHERE APPROPRIATE) | CALIBRATION OR MEASUREMENT CAPABILITY EXPRESSED AS AN UNCERTAINTY (\pm) | CALIBRATION EQUIPMENT AND REFERENCE STANDARDS USED | CALIBRATION MEASUREMENT METHOD OR PROCEDURES USED |
|--|---|---|--|---|
| Equipment to Output DC Voltage | 0.3 μV to 200 mV | 4.5 $\mu\text{V/V} + 0.1 \mu\text{V}$ | Fluke 8508A | GIDEP / OEM Manual |
| Equipment to Measure DC Voltage | 1.2 μV to 220 mV | 7.5 $\mu\text{V/V} + 0.4 \mu\text{V}$ | Fluke 5720A | GIDEP / OEM Manual |
| Equipment to measure AC Voltage At the listed frequencies | | | Fluke 8508A | GIDEP / OEM Manual |
| 1 Hz to 10 Hz | 211 μV to 200 mV | 0.165 mV/V + 70 μV | | |
| 10 Hz to 40 Hz | 211 μV to 200 mV | 0.14 mV/V + 20 μV | | |
| 40 Hz to 100 Hz | 211 μV to 200 mV | 0.115 mV/V + 20 μV | | |
| 100 Hz to 2 kHz | 211 μV to 200 mV | 0.11 mV/V + 10 μV | | |
| 2 kHz to 10 kHz | 211 μV to 200 mV | 0.135 mV/V + 20 μV | | |



Scopes of Accreditation

ELECTRICAL

| MEASURED INSTRUMENT, QUANTITY OR GAUGE | RANGE (AND SPECIFICATION WHERE APPROPRIATE) | CALIBRATION OR MEASUREMENT CAPABILITY EXPRESSED AS AN UNCERTAINTY (\pm) | CALIBRATION EQUIPMENT AND REFERENCE STANDARDS USED | CALIBRATION MEASUREMENT METHOD OR PROCEDURES USED |
|---|---|---|---|---|
| Equipment to Measure Resistance Fixed Points | 150 $\mu\Omega$ | 40 $\mu\Omega$ | Fluke 5720A | GIDEP / OEM Manual |
| pH Simulation-Generate | 0.5 pH to 14 pH | 0.01 pH | | WI-SOP -PH02 ESI DB877 |
| Temperature Calibration, Indication and Control Equipment used with Thermocouple Type B | 600 °C to 800 °C | 0.44 °C | Fluke 5520A Electrical Simulation of Thermocouple Output | GIDEP / OEM Manual |

Due to regulatory requirements and Industrial practices, the following alternate format will be used for expressing the range of calibration capability for electrical parameters in the Japanese economy. Alternate formats for other calibration disciplines will be developed on an as needed basis.

Although differing in appearance, the information in the range statement must satisfy all requirements of PJLA PL-4 and define the exact same range of calibration capability.

When expressed in this format, the range is to be interpreted as in the following example:

In the **standard format** lines, 1, 2, 3, 4, 5 & 6 each express specific ranges of calibration capability from a minimum value to a maximum value.

In the **alternate format**, line 1 expresses the low end of the first range. Lines 2, 3, 4, 5, 6 & 7 identify the high end of 6 ranges.

The low end of each range in this example is the high end of the previous range.

Interpreted in this manner, the first range in the alternate format would be 1.1 μV to 100 mV, the second range would be 100 mV to 1 V etc.

Examination will indicate that these ranges are exactly equivalent to the first and second ranges in the standard format. The same is true for all remaining ranges.

Care must be taken when applying this alternate format to ensure that as expressed it defines exactly the same range of calibration capabilities as the range when expressed in the standard format.

| | | | | |
|---|-----------------------------|---|---------------|--------------------|
| Equipment to Output 1 DC Voltage 2 | 1.1 μV to 100 mV | 10.7 $\mu\text{V/V}$ + 1.07 μV | Agilent 3458A | GIDEP / OEM Manual |
| | 100 mV to 1 V | 5.86 $\mu\text{V/V}$ + 5.86 μV | | |
| | 1 V to 10 V | 5.59 $\mu\text{V/V}$ + 55.9 μV | | |
| | 10 V to 100 V | 7.93 $\mu\text{V/V}$ + 793 μV | | |



Scopes of Accreditation

| | | | | |
|--|---|---|---------------|--------------------|
| 3 Standard format 4 5 6 | 100 V to 1 000 V | 21.2 $\mu\text{V/V} + 2.12 \times 10^{-4} \mu\text{V}$ | | |
| Equipment to Output 1 DC Voltage 2 3 Alternate format 4 5 6 7 | 1.1 μV low end of range 100 mV 1 V 10 V 100 V 1 000 V | 10.7 $\mu\text{V/V} + 1.07 \mu\text{V}$ 5.86 $\mu\text{V/V} + 5.86 \mu\text{V}$ 5.59 $\mu\text{V/V} + 55.9 \mu\text{V}$ 7.93 $\mu\text{V/V} + 793 \mu\text{V}$ 21.2 $\mu\text{V/V} + 2.12 \times 10^{-4} \mu\text{V}$ | Agilent 3458A | GIDEP / OEM Manual |

TIME AND FREQUENCY

| MEASURED INSTRUMENT, QUANTITY OR GAUGE | RANGE (AND SPECIFICATION WHERE APPROPRIATE) | CALIBRATION OR MEASUREMENT CAPABILITY EXPRESSED AS AN UNCERTAINTY (\pm) | CALIBRATION EQUIPMENT AND REFERENCE STANDARDS USED | CALIBRATION MEASUREMENT METHOD OR PROCEDURES USED |
|--|---|---|--|---|
| Equipment to Generate Frequency | 50 mHz to 18 GHz | 1 part in 10^{11} of Freq. + 1 LSD of generator | GPS Disciplined Oscillator and Signal Generators | SOP-105-ELEC |
| Stopwatch Calibration | 7 200 s to 28 800 s | 0.05 s/day | Timometer | NIST-SP-960-12 |

ACOUSTIC

| MEASURED INSTRUMENT, QUANTITY OR GAUGE | RANGE (AND SPECIFICATION WHERE APPROPRIATE) | CALIBRATION OR MEASUREMENT CAPABILITY EXPRESSED AS AN UNCERTAINTY (\pm) | CALIBRATION EQUIPMENT AND REFERENCE STANDARDS USED | CALIBRATION MEASUREMENT METHOD OR PROCEDURES USED |
|---|---|---|--|---|
| Equipment to Generate Acoustic Level | 3.15 Hz | 0.11 dB | Pistophone reference standard | SOP-AC-11 |
| Calibration of Acoustic Calibrators 124 dB, re 2×10^{-5} Pa | 250 Hz | 0.05 dB | 1 inch reference microphone | SOP-AC-12 |



Scopes of Accreditation

MASS, FORCE, AND WEIGHING DEVICES

| MEASURED INSTRUMENT, QUANTITY OR GAUGE | RANGE (AND SPECIFICATION WHERE APPROPRIATE) | CALIBRATION OR MEASUREMENT CAPABILITY EXPRESSED AS AN UNCERTAINTY (\pm) | CALIBRATION EQUIPMENT AND REFERENCE STANDARDS USED | CALIBRATION MEASUREMENT METHOD OR PROCEDURES USED |
|---|---|---|--|---|
| Mass-Weights and Weight Sets | 50 kg | 20 mg | Class E2 mass set and Mass Comparators | Double Substitution with Air Buoyancy correction |
| Equipment to Source and Measure Force – Compression and Tension- Source and Measure | 200 lbf to 5 000 lbf | 1.2 lbf | Proving Rings and Morehouse Test Stand | ASTM E4 |
| Analytical Balances | 1 mg to 200 g | $(0.013 + 0.003Wt)$ mg | Class 1 weights | Euramet Calibration Guide No. 18 |

MECHANICAL

| MEASURED INSTRUMENT, QUANTITY OR GAUGE | RANGE (AND SPECIFICATION WHERE APPROPRIATE) | CALIBRATION OR MEASUREMENT CAPABILITY EXPRESSED AS AN UNCERTAINTY (\pm) | CALIBRATION EQUIPMENT AND REFERENCE STANDARDS USED | CALIBRATION MEASUREMENT METHOD OR PROCEDURES USED |
|--|---|---|--|---|
| Pressure-Pneumatic, Gage | 0.2 psi to 1 000 psi | 0.002 5% of reading | Ruska 2465 | T.O 33k6-4427-1 |
| Torque Wrenches | 45 lbf-in to 450 lbf-in | 0.026 lbf-in | Torque Transducer | DIN 51309 |
| Indirect Verification of Rockwell Hardness Testers HRA | 60 HRA to 70 HRA | 0.32 HRA | Rockwell Hardness Test Blocks | ASTM E 18 |



Scopes of Accreditation

| | | | | |
|---|--|--|--|-------------|
| Direct Verification of Durometer Hardness Tester Types A, B, C, D, E, O & DO Extension at zero reading Indentor Shape (Not all parameters apply to all of Durometer Types) Indentor Diameter Indentor Tip Diameter Indentor Tip Radius Indentor Tip Angle Durometer Indentor Spring Types A, B, E & O Types C, D & DO | 2.46 mm to 2.54 mm 0.55 N to 8.05 N 4.445 N to 44.45 N | 7.4 μ m 7.4 μ m 7.4 μ m 0.06° 1.4 N 1.4 N | Video Comparator 20x Video Comparator 20x Video Comparator 20x Video Comparator 20x Video Comparator 20x Load Cell Load Cell | ASTM D-2240 |
| Indirect Verification of Brinell Hardness Tester HBW 10/3000 | 92.5 HBW to 650 HBW | 4 HBW | Stage Micrometer | ASTM E-10 |

CHEMICAL

| MEASURED INSTRUMENT, QUANTITY OR GAUGE | RANGE (AND SPECIFICATION WHERE APPROPRIATE) | CALIBRATION OR MEASUREMENT CAPABILITY EXPRESSED AS AN UNCERTAINTY (\pm) | CALIBRATION EQUIPMENT AND REFERENCE STANDARDS USED | CALIBRATION MEASUREMENT METHOD OR PROCEDURES USED |
|--|---|---|--|---|
| pH meter/probe calibration | 4 pH to 10 pH | 0.027 pH | pH Buffer Solutions | EPA SOP EQ-01-08 |
| Conductivity meter | 5 μ S to 10 μ S | 0.47 μ S | Conductivity Solution | ASTM D1125 |



Scopes of Accreditation

THERMODYNAMIC

| MEASURED INSTRUMENT, QUANTITY OR GAUGE | RANGE (AND SPECIFICATION WHERE APPROPRIATE) | CALIBRATION OR MEASUREMENT CAPABILITY EXPRESSED AS AN UNCERTAINTY (\pm) | CALIBRATION EQUIPMENT AND REFERENCE STANDARDS USED | CALIBRATION MEASUREMENT METHOD OR PROCEDURES USED |
|--|---|---|--|---|
| Temperature Measurement Thermocouple Type J | -196 °C to -100 °C | 0.66 °C | SPRT and Dry Block Fluke 5520A | ASTM E220 |
| Temperature Measurement RTD Pt 395, 100 Ω | 100 °C to 300 °C | 0.45 °C | SPRT and Dry Block Fluke 5520A | ASTM E77 |
| Equipment to Measure Humidity @ 25 °C | 10 % RH to 95 % RH | 1 % RH | Two Pressure Humidity Generator | Thunder Scientific Manual |

OPTICAL

| MEASURED INSTRUMENT, QUANTITY OR GAUGE | RANGE (AND SPECIFICATION WHERE APPROPRIATE) | CALIBRATION OR MEASUREMENT CAPABILITY EXPRESSED AS AN UNCERTAINTY (\pm) | CALIBRATION EQUIPMENT AND REFERENCE STANDARDS USED | CALIBRATION MEASUREMENT METHOD OR PROCEDURES USED |
|---|---|---|--|---|
| Equipment to Measure Fiber Optics Power 10 nW to 100 μ W Fixed Points | 850 nm | 14 nm | Detector Based | WI-SOP-115 |
| Equipment to Measure Fiber Optic Wavelength | 600 nm to 1 700 nm | 0.2 nm | Spectrum analyzer and intrinsic source | WI-SOP-116 |
| Equipment to Measure Spectral Radiance- 300 nm to 1 600 nm | (1×10^{-9} to 1×10^{-5}) $Wcm^{-2} sr^{-1} nm^{-1}$) | 5 % | Detector and source based | WI-SOP-117 |
| Equipment to Measure Spectral Transmission (300 to 1500) nm | 10 % to 100 % | 3 % | Spectrophotometer | WI-SOP-118 |



Scopes of Accreditation

| | | | | |
|----------------------------------|-------------------|----------------|------------------------------|------------|
| White Light Meter Illuminance | 10 fcd to 500 fcd | 2 % of reading | Detector and source based | WI-SOP-119 |
|----------------------------------|-------------------|----------------|------------------------------|------------|

IONIZING RADIATION AND RADIOACTIVITY

| MEASURED INSTRUMENT, QUANTITY OR GAUGE | RANGE (AND SPECIFICATION WHERE APPROPRIATE) | CALIBRATION OR MEASUREMENT CAPABILITY EXPRESSED AS AN UNCERTAINTY (\pm) | CALIBRATION EQUIPMENT AND REFERENCE STANDARDS USED | CALIBRATION MEASUREMENT METHOD OR PROCEDURES USED |
|--|---|---|---|---|
| Radiation detectors | (1 to 9.999 X 10 ⁻⁶) counts/min | 1.2 % of reading | Pulser /Scaler, Radioactive reference sources; | Radiation Instrumentation Calibration Manual |
| Nuclear Density Gauge – Density | 1 175 kg/m ³ to 2 630 kg/m ³ | 0.3 % of Reading | Density Blocks | ASTM D7759 |
| Ionization Chamber Survey Meters | 0.05 mRem/hr to 2 000 mRem/hr | 5.2% of reading | Cs Isotope | SOP 101 |

EXAMPLE FOOTNOTES

- (Calibration and Measurement Capability) stated for calibrations included on this scope of accreditation represent the smallest measurement uncertainties attainable by the organization when performing a more or less routine calibration of a nearly ideal device under nearly ideal conditions. It is expressed at a confidence level of 95 % using a coverage factor *k* (usually equal to 2). The actual measurement uncertainty associated with a specific calibration performed by the organization will typically be larger than the CMC for the same calibration since capability and performance of the device being calibrated and the conditions related to the calibration may reasonably be expected to deviate from ideal to some degree.
- The term D represents diameter in inches or millimeters appropriate to the uncertainty statement.
- The term L represents length in inches or millimeters appropriate to the uncertainty statement.
- The term Wt represents weight in pounds or grams (including SI multiple and submultiple units) appropriate to the uncertainty statement.

APPENDIX B-INSPECTION BODY SCOPES OF ACCREDITATION-ISO/IEC 17020

1.0 GENERAL

- 1.1 The scope of accreditation is a formal document issued by PJLA to its accredited CABs. It contains information expressing the Inspection Body Type, Fields of Inspection, Types or Ranges of Inspection and the Specification, Standard Method, or Technique Used, as required in ISO/IEC 17011:2017, section 7.8.3, b. Below includes the requirements for the formatting of Inspection Body scopes of accreditation.

2.0 INSPECTION BODY TYPES

- 2.1 Inspection body will be defined as Type A, Type B, or Type C inspection body types. The following list criteria which will be used to determine inspection body type. The following Inspection Body types shall be placed on the main certificate. Additional details of the inspection body shall be provided in the supplement as detailed below in section 3.0-5.0.
- 2.1.1 Type A- An inspection body providing third party inspections.
- 2.1.2 Type B- An inspection body providing first party inspections, second party inspections, or both, which forms a separate and identifiable part of an organization involved in the design, manufacture, supply, installation, use or maintenance of the items it inspects, and which supplies inspection services only to its parent organization (in-house inspection body).
- 2.1.3 Type C- An inspection body providing first party inspections, second party inspections, or both, which forms an identifiable, but not necessarily a separate part of an organization involved in the design, manufacture, supply, installation, use or maintenance of the items it inspects, and which supplies inspection services to its parent organization or to other parties, or to both.
- 2.1.4 Annex A in ISO/IEC 17020 shall be used as guidance in the determination of independence requirements for each type of inspection body.

3.0 FIELDS OF INSPECTION

- 3.1 The scope of accreditation will define the specific inspection field which the inspection body is accredited. This is specified as a broad category of inspections in which the specific type or ranges of inspection will fall into:
e.g.
- Agricultural products



Scopes of Accreditation

- Asbestos – Surveying for asbestos on premises
- Building – Installation of Construction Products
- Bulk cargoes (e.g., petroleum, coal)
- Cargoes in containers and packages
- Cast products
- Chemical
- Construction – General Building
- Cranes
- Electrical
- Engineering
- Farmed Fish
- Fire Protection System and/or Fire-Resistant Construction
- Food processing factories (including bottled water, Red and White Meat, and Cutting)
- Foods
- Drugs, Dietary Supplements, Pharmaceuticals
- Forensic
- Forged products
- Gaming or Lottery Equipment and/or Systems
- Gas
- Legionella Risk assessments (bacteria)
- Mechanical/machinery
- Non-Destructive Testing by Personnel Certified to a Recognized Certification Scheme (See section 3.2.1)
- Operational Verification – Preparation on-going review & implementation of verification schemes throughout installation lifecycle
- Personal Protective Equipment
- Pipelines
- Pressure Systems (Major, Intermediate, Minor) to include Boilers, Pressure Vessels, Piping and Pipework
- Product Manufacturing
- Protective coatings
- Rolled products
- Social Care Providers - Adult
- Shellfish Purification Plants
- Structures (e.g., steel, concrete)
- Textiles
- Toys - Safety
- Welding

3.2. In some fields, such as non-destructive, it may be difficult to determine if testing or Inspection would be the most appropriate. PJLA has determined the following distinction between the two and recommend that CABs should select the most appropriate program based on their activities. Inspection is the examination of a product, process, service, or installation or their design and determination of its conformity with specific requirements or, on the basis of professional judgment, with general requirements.



Scopes of Accreditation

Typically, items would be inspected once all other activities have taken place in which testing may very well be a prerequisite prior to the inspection taken place. The inspection activity would not include the actual testing of the specific substance, artifact, or sample however the examination of the items after the testing has been completed. The completed testing may be one area which the inspection activity would encompass.

4.0 TYPE OR RANGE OF INSPECTION

- 4.1 The type or range of inspection should be specific as to what is being inspected or detected by the inspection body within the field of inspection. The following is a list of common types of inspections or ranges:

| Field | Type or Range of Inspection |
|---|--|
| Pressure Equipment | Boilers and Pressure Vessels |
| Fire Protection System and/or Fire-Resistant Construction | Sprayed Fire-Resistant Materials and Mastic and Intumescent Fire-Resistant Coating |
| Electric | Documentation and Packaging Inspection |
| | General and Detailed Visual Inspection |
| | Solvent test for remarking/resurfacing |
| | X-ray inspection |
| | XRF lead finish evaluation |
| | Inspection by Electron Microscope |

| Field | Type or Range of Inspection |
|---|--|
| Electric | Solderability |
| | Acceptability of Electronics Assemblies |
| | LCR Comparison to datasheet |
| Asbestos-Surveying for asbestos on premises | Management survey: (domestic, commercial premises) |
| | Refurbishment and demolition survey: (domestic, commercial premises) |
| Legionella Risk Assessments | Water Sampling for the purpose of Legionella Risk Assessment |
| | Total viability counts, Legionella and Pseudomonas |
| | Indicative water testing for the purpose of Legionella Risk Assessment, pH, conductivity, temperature, bromine, and chlorine |



Scopes of Accreditation

| | |
|---|--|
| | Total viability counts using dip slides |
| Cargoes: Transportation of Dangerous Goods and Used of Transportable Pressure Equipment | Periodic in-service inspection including: periodic inspection, intermediate inspection, and exceptional checks |

5.0 SPECIFICATION, STANDARD METHOD, OR TECHNIQUE USED

5.1 This section shall clearly indicate what the inspection body is using to perform inspections. Any exceptions to meeting full specifications or standards specified, shall be clearly noted. The following is a list of examples:

5.1.1 Pressure Equipment:

ANSI/NB 23 (ANSI/NB 369), (ANSI/ASME QAI-1), ASME Boiler & Pressure Vessel Code ANSI/ASME- Section I, III, IV, VIII div.1,2,3, X, XII, B31.1, ANSI/ASME B31.3, B31.5, PVHO, API 510, API 653, API 570 including Design Examinations and Jurisdictional requirements, as applicable

5.1.2 Fire Protection System and/or Fire-Resistant Construction:

NFPA 80, NFPA 105

5.1.3 Building – Installation of Construction Products:

Special Inspection as per 2014 NYC Construction Code provision inclusive of 1RCNY 101-06, 101-07, FCA Management System Documentation including Inspection Procedure, Version 1.2, Revised 12/04/2015.

5.1.4 Electrical:

IEEE 1680:2006 - Standard for Environmental Assessment of Electronic Products, IEEE 1680.2:2012 - Environmental Assessment of Imaging Equipment, IEEE 1680.3:2012 - Environmental Assessment of Televisions

5.1.5 Drugs, Dietary Supplements, Pharmaceuticals:

FDA Compliance Program Guidance Manual: Drug Manufacturing Inspections Program 7356.02 21 CFR 1 Subpart L – Foreign Supplier Verification Program



Scopes of Accreditation

APPENDIX C-TESTING SCOPES OF ACCREDITATION, INCLUDING MEDICAL TESTING-ISO/IEC 17025 and ISO 15189

1.0 GENERAL

- 1.1 The testing scope of accreditation is a formal document issued by PJLA to its accredited organizations. It contains the following information: field of test, items, materials, or products tested, specific tests or properties measured, specification, standard method or technique used in testing as required by the ISO/IEC 17011:2017 Sub-clause 7.8.3, item d. Below describes the formatting requirements of testing scopes of accreditation including medical.
- 1.2 Some testing programs (e.g., TNI-EL, DoD-ELAP, DOECAP-AP, Cannabis, ASCA), require program specific scope formats. Consult the applicable program's SOP-1 or specific regulatory requirements for program specific certificate scope formats.
- 1.3 At a minimum, the following items described below must be identified on the scope of accreditation: field of test, items, materials or products tested, component, characteristic, parameter tested, and the specification/standard method and the technology technique used.

2.0 FIELD OF TEST

- 2.1 The entry in this field shall represent the generic classification of the testing services provided by the organization from the list below:
 - 2.1.1 Acoustic Testing: Measurements of noise, vibration, and sound level testing.
 - 2.1.2 Biological: Biological, microbiological, and biochemical testing and measurement.
 - 2.1.3 Chemical: Chemical analysis and detection including instrumental and automated methods.
 - 2.1.4 Dimensional Inspection: Determination of dimensional parameter to establish magnitude or for comparison to defined nominal.
 - 2.1.5 Electrical: Tests of an electrical and electronic nature performed on instruments, equipment, appliances, components, and materials.
 - 2.1.6 Environmental: Tests for constituents in various environmental media.
 - 2.1.7 Mechanical: Tests, measurements, and evaluation of physical properties of materials, components, and assemblies.
 - 2.1.8 Non-Destructive: Examination of materials, components, and assemblies to detect discontinuities without damaging the originally submitted material, component or assembly. (See section Appendix B, 3.2.1)
 - 2.1.9 Optical Testing: Tests for the performance of fiber optic components, cable plants and systems.



Scopes of Accreditation

2.1.10 Thermodynamic: Tests of measurements and transformations of energy to heat.

2.2 Fields of accreditation shall be specified on the main certificate as well as the certificate supplement.

3.0 ITEMS, MATERIALS OR PRODUCTS TESTED

3.1 This category shall define the products, materials or other items tested (e.g., Metal Components, Wastewater or Plastic Components).

4.0 COMPONENT, CHARACTERISTIC, PARAMETER TESTED

4.1 This category describes the tests being performed. It shall be specific and fully describe the test or property measured (e.g. Lead, Mercury, Arsenic and Cadmium).

5.0 SPECIFICATION OR STANDARD METHOD

5.1 This category shall include the test methods or procedures utilized to perform the test. The test method may be an internationally recognized test method such as ASTM, SAE, AOAC, EPA, FDA, ISO, CMMEF, SMEWW, AWS, KTA, MSSSP, Mil-Std, Nav Sea, ASME or other accepted methods. This may also be a customer specified method or internal method. Whichever method is stated on the scope, the organization is expected to have available the most current version of that method.

6.0 TECHNOLOGY OR TECHNIQUE USED

6.1 This category shall identify the Technology or Technique used for performing the specific test (e.g. GC/MS, ICP, CMM).

7.0 RANGE AND DETECTION LIMIT (WHERE REQUIRED):

7.1 In cases where regulatory programs require scopes of accreditation to include ranges or detection limits, organizations must present the request to PJLA in writing, citing the requirement. If considered, an additional section to include them would be added.

7.2 The lower and upper boundaries of the range shall be provided. The use of zero as the lower boundary of the range shall be prevented, especially when a percent or multiplier is used.

7.3 Detection Limits can be expressed in quantitative or qualitative terms as necessary and clearly expressed in an easy-to-understand format.

7.4 The units, which define the measurement, must comply with acceptable units. Please refer to NIST SP 811 Appendix of this policy regarding the use of SI units.



Scopes of Accreditation

| FIELD OF TEST | ITEMS, MATERIALS OR PRODUCTS TESTED | COMPONENT, CHARACTERISTIC, PARAMETER TESTED | SPECIFICATION OR STANDARD METHOD | TECHNOLOGY OR TECHNIQUE USED |
|------------------------|---|---|---|--|
| Mechanical | Automotive Component | Mechanical Shock | USCAR-2; USCAR-20; USCAR-38; GMW 3172, GMW 3191 | Up to 100 G's, 11 ms Half Sine (Vertical and Horizontal Axis) |
| Dimensional Inspection | Fixtures, Gages, Tooling, Models, Molds, Parts and Components | X = Up to 4 267 mm Y = Up to 2 133 mm Z = Up to 1 524 mm D.L. = 0.025 mm | ASME Y14-5 2009 / ASME B89.4.1- 2008 Or Customer Specification | CMM |
| Electrical | Conducted Transient Immunity | +/- 300 V max | ISO 7637-2 (2011) | DMM |
| Electrical | SIR/MIR Testing | 1 Ω to 1 x 1 015 Ω 1 x 108 Ω to 1 x 1 014 Ω | IPC-TM-650 | DMM |
| Non-Destructive | Nut Products | Filth | AOAC 970.66 | Stereo Microscope / Compound Microscope |
| Non-Destructive | Metal Automotive Components | Pass/Fail Visual | ASTM E165 ASTM E1220 ASTM E 1417 ASTM E1418 | Liquid Dye Penetrant |
| Non-Destructive | Printed Wiring Boards, Components | 40 X to 10 000 X | ASTM B748; ASTM E766; ASTM E1508; MIL-STD-1580 | Scanning Electron Microscopy, Microscopic Evaluation |



Scopes of Accreditation

| FIELD OF TEST | ITEMS, MATERIALS OR PRODUCTS TESTED | COMPONENT, CHARACTERISTIC, PARAMETER TESTED | SPECIFICATION OR STANDARD METHOD | TECHNOLOGY OR TECHNIQUE USED |
|---------------|---|---|----------------------------------|---|
| Chemical | Air | Benzene | EPA TO-15 | Gas Chromatography Mass Spectrometry or GC/MS |
| | Water | Metals Lead Mercury Arsenic Cadmium | EPA 200.8 | Inductively Coupled Plasma Mass Spectrometry or ICP-MS |
| Biological | Food, Feed, Pharmaceuticals, and Dietary Supplements | Aerobic Plate Count | BAM Ch. 3 AOAC 990.12 | Quantitative Micro |
| Biological | Food, Feed, Pharmaceuticals, and Dietary Supplements Water | Escherichia coli EHEC | BAM Ch. 4 | Qualitative / Quantitative Micro (includes r t-PCR-direct detection) |
| | | Salmonella spp. | BAM Ch. 5 AOAC 2004.03 | Qualitative Micro Immunoassay (Rapid Screening) |
| | Food, Feed, Pharmaceuticals, and Dietary Supplements Water | Total Coliform, MPN | SMEWW Part 9000 | Quantitative Micro |
| | | | | |



Scopes of Accreditation

| | | | | |
|------------|--|--|--------------|---|
| Biological | Food, Feed, Pharmaceuticals, and Dietary Supplements | Pesticide Residue Chlorpyrifos-methyl Kresoxim-methyl Cyprodinil | AOAC 2007.01 | Liquid Chromatography - Mass Spectrometry and Tandem Mass Spectrometry or LC/MS/MS Gas Chromatography-Mass Spectrometry and Tandem Mass Spectrometry |
| Chemical | Food, Feed, Pharmaceuticals, and Dietary Supplements | Multi-Residue Antibiotics in Honey | LIB 4560 | Liquid Chromatography - Mass Spectrometry and Tandem Mass Spectrometry or LC/MS/MS |
| | | Metals Lead Mercury Arsenic Cadmium | AOAC 2013.06 | Inductively Coupled Plasma Mass Spectrometry or ICP-MS |
| | | Sulfites | AOAC 990.28 | Titrimetry |



Scopes of Accreditation

8.0 SCOPES OF ACCREDITATION FOR MEDICAL LABORATORIES-ISO 15189

8.1 GENERAL

- 8.1.1 The scope of accreditation for medical examinations based on ISO 15189 follows the same principles as the scope of accreditation of an ISO/IEC 17025 testing organization and as required by the ISO/IEC 17011:2017 Sub-clause 7.8.3, item d.

8.2 DISCIPLINE:

- 8.2.1 The discipline describes the medical laboratory testing area for the activity. Disciplines shall be specified on the main certificate as well as the certificate supplement.

Examples of possible disciplines:

| | | | |
|------------------|--------------------|---------------------|---------------|
| Microbiology | Hematology | Radiobioassay | Chemistry |
| Bacteriology | Immunochemistry | Cytology | Endocrinology |
| Mycology | ABO and Rh typing | Histocompatibility | Toxicology |
| Mycobacteriology | Anatomic Pathology | Cytogenetics | Urinalysis |
| Parasitology | Histopathology | Molecular Pathology | Immunology |

8.3 PROCESS OF EXAMINATION:

- 8.3.1 The process of examination is the test or examination to be performed on the test sample. The examination could be performed by various methodologies or technologies.

8.4 MEASUREMENT TECHNIQUES/ INSTRUMENT:

- 8.4.1 The Measurement Techniques/Instrument is the specific method or technology entered to define the test activity more narrowly. Examinations are often determined by the instrument (analyzer) used and in accordance with the manufacturer's instructions/protocol. Thus, a reference to the instrument (name of manufacturer and version/type) may provide unique identification of the method in the scope of accreditation.
- 8.4.2 This is an optional field if. If the Process of Examination field is sufficient to convey the test methodology., there may not be any added value to providing a particular methodology or testing system here. For those performing lab developed or branded test systems or assays, this field may be used to promote their method. For example, a genetic testing facility may examine samples using Next Generation Sequencing but have their own libraries or interpretative tools applied and branded for FDA approval. In that case, the lab may list the Process of Examination



Scopes of Accreditation

as Next Generation Sequencing and use their product name in the Measurement Techniques/Instrument field.

Example:

| Discipline | Process of Examination | Test Sample |
|------------------|---|---------------------|
| Mycobacteriology | Acid Fast smear exam <i>Examination is staining a smear of concentrated sputum</i> | Concentrated sputum |

| Property | Measurement Techniques / Instrument |
|--------------------------------|---|
| Detection of acid fast bacilli | A/O Stain <i>This is a specific technique for acid fast staining. Another lab may use Kinyoun Stain.</i> |

8.5 TEST SAMPLE

8.5.1 Test samples shall be a description of the material being examined or tested. The specimen collected may be blood, however the material being tested in the serum of that blood. Describing the test sample as serum indicates how the blood specimen should be collected to perform the test. This description may include additives necessary for preservation of a sample for testing. A test may permit the use of EDTA as an anticoagulant but may not be run if the anticoagulant is heparin.

8.6 PROPERTY

8.6.1 The property is what will be measured, detected, or identified by the examination or test, such as an analyte, pathogenic organism, mutation, gene, or antibody.

8.7 PARAMETER/RANGE

8.7.1 The parameter/range field is optional. This field describes the type of data generated by the test. This field may contain the detection or reporting range for a quantitative test for a particular analyte, such as a viral load test report. For qualitative examinations the field may convey that the test may be semi-quantitative scored as 1+ to 4+, or the test may detect only a presence or absence of a particular property. Some examination and test reporting formats are standard knowledge in the medical field so that the lab may not find value in providing an entry for this field.



Scopes of Accreditation

| DISCIPLINE | PROCESS OF EXAMINATION | TEST SAMPLE | PROPERTY | PARAMETER/RANGE | MEASUREMENT TECHNIQUES / INSTRUMENT |
|--------------|-----------------------------------|-------------|---------------------|--|---|
| Immunology | Serum Protein Immunology | Serum | CRP | - | - |
| Hematology | Blood Functional Test | Blood | HbA1c | 4.5% to 10.0% NGSP | EIA (Hitachi 7050) |
| Microbiology | Urine Culture with Identification | Urine | Pathogens (E. coli) | Presence/Absence | VITEK |
| Biochemistry | Automated system | Serum | YGT | CV _A : 8.2%, B _A : 12.8% | IFCC Traceable Method (Hitachi 7050 Type) |
| Hematology | Blood Test | Blood | RBC | CV:4.1% | See-Through Method (Sysmex XN-550) |

APPENDIX D-REFERENCE MATERIAL PRODUCER SCOPES OF ACCREDITATION-ISO 17034

1.0 GENERAL

- 1.1 The reference material producer scope of accreditation is a formal document issued by PJLA to its accredited CABs. It contains the following information: Type of RM, Reference material categories, items, matrix, material, or products; specific constituents or properties and approach used to assign property values.

2.0 RM/CRM (OR BOTH)

- 2.1 In accordance with ISO/IEC 17011:2017, a scope of accreditation must make the distinction between certified RMs or non-certified RMs when listing the specific types of RMs covered by the accreditation. ISO 17034:2016 section 3.4 “certified value - value, assigned to a property of a reference material that is accompanied by an uncertainty statement and a statement of metrological traceability, identified as such in the reference material certificate” (also ISO Guide 30:2015 2.2.3). If the material as described in the scope could be either an RM, CRM or both this needs to be identified on the scope.
- 2.2 This could be an optional field if other fields clearly indicated whether the particular reference material is a “reference material”, a “certified reference material” or both.

3.0 REFERENCE MATERIAL CATEGORIES

- 3.1 This category reflects the basic description of the nature of the reference material such as: chemical (organic, inorganic), metallurgical, mechanical, biological, medical, other terms related to their purpose in terms of analytics, such as single or multi-element, ion or multi-ion standards.
- 3.2 Reference material categories shall be specified on the main certificate as well as certificate supplement.

4.0 ITEMS, MATRIX, MATERIAL, OR PRODUCTS

- 4.1 This category reflects the characteristics of the material, such as: cylinder, vial, gas mixtures, neat materials, powders, alloys, etc.

5.0 SPECIFIC CONSTITUENTS OR PROPERTIES

- 5.1 This category describes the particulars of the material, either in general terms or more specific terms such as: analyte or element concentration,



Scopes of Accreditation

mixture concentration, element or chemical in a base gas, metals in films on a specific substrate, and the like.

6.0 APPROACH USED TO ASSIGN PROPERTY VALUES

6.1 This category refers to the characterization approach used, such as using a single reference measurement procedure in a single laboratory, characterization of a non-operationally defined measurand using two or more methods of demonstrable accuracy in one or more competent laboratories, etc. See ISO 17034 7.12.3 for additional information.

7.0 EXAMPLE REFERENCE MATERIAL SCOPES

| Type of RM | REFERENCE MATERIAL CATEGORIES | ITEMS, MATRIX MATERIALS OR PRODUCTS | SPECIFIC CONSTITUENTS OR PROPERTIES | APPROACH USED TO ASSIGN PROPERTY VALUES |
|------------|-------------------------------|---|-------------------------------------|---|
| RM/CRM | Metallurgical Materials | Ferrite Standards | Ferrite Content | single reference measurement procedure in a single laboratory |
| RM/CRM | Chemical Materials | High Pressure Gas Mixtures in Cylinders | Ethanol in Nitrogen | single reference measurement procedure in a single laboratory |
| RM/CRM | Chemical | Neat Materials | Analyte Identification and Purity | single reference measurement procedure in a single laboratory |

8.0 ALTERNATE SCOPES, STRUCTURE, CONTENTS

Other structures, formats and contents for reference material producer scopes may be appropriate as desired. These could arise out of comparative formats from other ILAC MRA recognized accreditation bodies, either with an organization's/CAB's existing scope from these bodies, rule or regulations for a particular program, regulatory agency preferred or required scopes or industry sector requirements or customary expectations. Descriptive, narrative scopes may also be appropriate and may especially be applicable for flexible scopes as discussed elsewhere in this document. However, such scopes should reflect the guidelines for reference material producer flexible scopes as contained in Appendix D of ILAC-G18 and meet the requirements of ISO/IEC 17011 section 7.8.3 f) for any/all reference material producer scopes at minimum.



Scopes of Accreditation

APPENDIX E-PROFICIENCY TESTING PROVIDER SCOPES OF ACCREDITATION-ISO 17034

1.0 GENERAL

- 1.1 The proficiency testing provider scope of accreditation is a formal document issued by PJLA to its accredited organizations. It lists the schemes that the proficiency testing provider is competent to provide, the type of proficiency test items, and the measurand(s) or characteristic(s) or (where appropriate) they type of measurand(s) or characteristic(s) to be identified, measured, tested or calibrated.
- 1.2 Proficiency Testing Provider shall be specified on the main certificate following specific details on the supplement as indicated below.

2.0 PT SCHEME/PROGRAM NAME

- 2.1 The scheme or program name can relate to testing, calibration or sampling and possibly to reference material production. They could be quantitative or qualitative. There could be one or more proficiency test items. There may be one of each specimen of each type (a round robin would be an example). It may be described by a specific test item, test type or matrix or type of material. Examples could be: Calibration, Electrical Calibration, Construction Materials, Construction Materials Testing, Dimensional Calibration, Dimensional Testing, etc.

3.0 PT ITEM TYPE

- 3.1 This category can be defined as a sample, a product, artifact, reference material, piece of equipment, measurement standard, a data set or other information used for proficiency testing, related to the scheme. The test items would be more specific and relate to specific tests, calibration, or groups of them. Within Construction Materials, the test items could be aggregate, soil, asphalt and the like. For Thermodynamic calibration it would normally be temperature or humidity. For Calibration it would the item types would be things like weight, mass, pressure, dimensional, temperature, volume, electrical (AC/DC voltage/amperage, resistance).

4.0 THE MEASURAND(S) OR CHARACTERISTIC(S) OR WHERE APPROPRIATE THE TYPE OF MEASURAND(S) OR CHARACTERISTIC(S) THAT ARE TO BE IDENTIFIED, MEASURED OR TESTED.

- 4.1 This category can be quantitative or qualitative information. The quantitative information typically provides detail relating to the PT items or quantities. It could also be a characteristic that may be quantitative or qualitative or provide specifics



Scopes of Accreditation

as to the proficiency test type items in terms of their identity or characteristics. The latter could be a specific type of gage or items, or the range or value relating to the specifics of the items type whether qualitative or quantitative.

5.0 EXAMPLES OF PROFICIENCY TESTING PROVIDER SCOPES

| PT SCHEME/PROGRAM NAME | PT ITEM TYPE | MEASURAND(S) OR CHARACTERISTIC(S) OR WHERE APPROPRIATE THE TYPE OF MEASURAND(S) OR CHARACTERISTIC(S) THAT ARE TO BE IDENTIFIED, MEASURED OR TESTED |
|--|--|--|
| Mass and Mass Related - Calibration | Pipette | 1 μ L to 10 mL |
| Length – Dimensional Metrology – Calibration | Micrometers – Dimensional | Up to 1 in |
| | Calipers – Dimensional | Up to 6 in Up to 12 in |
| Calibration | AC/DC Voltage, AC/DC Current, Resistance | Equipment to Measure DC Voltage, DC Current, Resistance Equipment to Output DC Voltage, DC Current, Resistance Equipment to Measure AC Voltage, AC current at the Listed Frequencies Equipment to Output AC Voltage, AC current at the Listed Frequencies, Temperature Calibration, Indication and Control Equipment used with Thermocouple and with RTD |
| | Pressure | Pressure Transducers, Pressure Transmitters, Manometers with digital or analogue indication, Mechanical Bourdon Tube Manometers. |
| Construction Material Testing | Bitumen | Determination of Ductility of Bituminous Materials Test |
| | | Determination of Penetration of Bituminous Materials Test |
| | | Determination of Softening Point of Bitumen Test |



Scopes of Accreditation

| | | |
|-------------------------------|-----------------------|--|
| Non-Destructive Testing (NDT) | Metallic Materials | Standard Practice for Liquid Penetrant Examination for General Industry |
| | | Standard Guide for Magnetic Particle Testing |
| | | Determination of ultrasonic pulse velocity |
| Chemical testing | Radioactivity testing | Determination of nuclides that emit gamma-ray by germanium semiconductor detector. |

8.0 ALTERNATE SCOPES, STRUCTURE, CONTENTS

- 8.1 Other structures, formats and contents for proficiency testing provider scopes may be appropriate as desired. These could arise out of comparative formats from other ILAC MRA recognized accreditation bodies, either with an organization's/CAB's existing scope from these bodies, rule or regulations for a particular program, regulatory agency preferred or required scopes or industry sector requirements or customary expectations. Descriptive, narrative scopes may also be appropriate and may especially be applicable for flexible scopes as discussed elsewhere in this document. However, such scopes should reflect the guidelines for proficiency testing provider flexible scopes as contained in Appendix E of ILAC-G18 and meet the requirements of ISO/IEC 17011 section 7.8.3 e) for any/all proficiency testing provider scopes at minimum.



APPENDIX F GUIDANCE FOR DEVELOPING AND USING A FLEXIBLE SCOPE

1.0 GENERAL

- 1.1 ISO/IEC 17011:2017 and *ILAC-G18 Guideline for describing Scopes of Accreditation* recognizes the use of flexible scopes of accreditation noting additional procedural requirements for Accreditation Bodies when assessing and managing them. PJLA utilizes these documents for the requirements as detailed below. The benefit of a flexible scope is that the CAB has the recognized ability to modify methodology or other parameters, validate or verify the changes and apply them without having to request an extension to its scope of accreditation. A flexible scope and a fixed scope can be separately described or combined on one accreditation certificate whatever is the most convenient or informative. Below are the requirements for conformity assessment bodies (CABs) applying for or maintaining a flexible scope of accreditation. Only programs listed below are offered a flexible scope. Failure to meet these requirements may result in the suspension of a flexible scope.

2.0 FLEXIBLE SCOPE TESTING LABORATORIES, INCLUDING MEDICAL-ISO/IEC 17025:2017 AND ISO 15189:2012

2.1 GENERAL

- 2.1.1 Organizations may apply for a flexible scope where a level of flexibility is justified in its operation. Organizations applying for and maintaining a flexible scope are held to additional requirements as detailed in this policy and additional time to the assessment may be allocated.
- 2.1.2 When an organization is granted a flexible scope, it can include additional activities in its scope of accreditation based on its own validations without additional evaluation by PJLA prior to performance of the activity. The possibility of adopting new standard methods, developing new in-house methods, and modifying existing methods under a flexible scope does not include introduction of new measurement principles of testing, or examination not previously covered by the scope of accreditation.
- 2.1.3 Organizations would need to apply for a scope expansion for new measurement principles of testing to be added to flexible scope of accreditation.



Scopes of Accreditation

- 2.1.4 A flexible scope can be established based on degrees of freedom for flexibility such as:
- Introduction of the testing of a new item, material, matrix, or product for an accredited test method;
 - Introduction of a new version of an accredited standard method (with no modifications);
 - Introduction of a new parameter/component/analyte to an accredited test method;
 - Introduction of a new measurement range to an accredited test method;
 - Introduction of a new version or modifications of an accredited non-standard method
 - Introduction of a new method that is equivalent to an accredited method (using same technology or technique)

2.2 REQUIREMENTS FOR MAINTAINING A FLEXIBLE SCOPE

- 2.2.1 Organization shall maintain information related to the application of their flexible scope for review during each assessment.
- 2.2.2 Records of competency and validation or verification of the application of their flexible scope and the data obtained must be retained and made available for review at each assessment or upon request.

3.0 FLEXIBLE REFERENCE MATERIAL PRODUCER SCOPES OF ACCREDITATION- ISO 17034

3.1 GENERAL

- 3.1.1 Reference Material producers may apply for flexible scope where a level of flexibility is justified in operation. Reference Material Producers applying for and maintaining a flexible scope are held to additional requirements as detailed in this policy and additional time to the assessment may be allocated.
- 3.1.2 When a Reference Material Producer is granted a flexible scope, it can include additional activities in its scope of accreditation based on its own validations without additional evaluation by PJLA prior to production of the reference material. Examples may include:

- Introduction of a new product for an accredited class or type of reference material
- Introduction of a new range for an accredited reference material
- Introduction of a new compound/analyte using an accredited class or type of reference material
- Introduction of a new version a standard method (with no modifications) for a test method used in the Reference Material Producers laboratory and referenced on the scope of accreditation
- Introduction of a new parameter/component/analyte for a method or a technology used in the Reference Material Producers laboratory and referenced on the scope of accreditation
- Introduction of a new measurement range to an accredited technology used in the Reference Material Producers laboratory and referenced on the scope of accreditation
- Introduction of a new version or modifications of a non-standard method for a technology used in the Reference Material Producers laboratory and referenced on the scope of accreditation
- Introduction of a new testing method that is equivalent to a method for a technology used in the Reference Material Producers laboratory and referenced on the scope of accreditation

3.2 REQUIREMENTS FOR MAINTAINING A FLEXIBLE REFERENCE MATERIAL SCOPE

- 3.2.1 Reference Material Producers shall maintain an updated list (or equivalent) of all reference materials for which accreditation is held for review by PJLA. This would include all reference materials on a conventional or flexible scope.
- 3.2.2 Reference Material Producers shall have fully documented and validated procedures for the reference materials produced under their scope of accreditations. The Reference Material Producers shall regularly review this list and associated substantiating evidence. Procedures and the responsibilities relevant to the development or revision of reference materials produced shall be reviewed periodically taking into account the results of internal and external quality control.
- 3.2.3 Reference Material Producers must be able to provide to PJLA documented evidence that the laboratory has complied with the requirements of ISO 17034:2017 for the reference materials produced on its scope(s) during assessments or upon request.
- 3.2.4 Records of the reference materials on the scopes must be retained and made available for review by PJLA to document the requirements of ISO 17034:2017 (section 6 and 7 particularly) and ISO/IEC 17011:2017 7.8.3 f). These records must be available for review by PJLA during the initial assessment, surveillance visits, and reassessments or on request.



Scopes of Accreditation

4.0 FLEXIBLE PROFICIENCY TESTING PROVIDER SCOPES OF ACCREDITATION-17043

4.1 GENERAL

- 4.1.1 Proficiency Testing Providers applying for and maintaining a flexible scope are held to additional requirements as detailed in this policy and additional time to the assessment may be allocated.
- 4.1.2 When a Proficiency Testing Provider is granted a flexible scope, it can include additional activities in its scope of accreditation based on its own validations without additional evaluation by PJLA prior to production of the reference material. Examples may include:
- Introduction of a new compound/component/analyte for an accredited scheme
 - Introduction of a new product of similar composition of an artifact used for an accredited scheme
 - Introduction of a new range for an accredited scheme

4.2 REQUIREMENTS FOR MAINTAINING A FLEXIBLE PROFICIENCY TESTING PROVIDER SCOPE

- 4.2.1 Proficiency Testing Providers shall maintain an updated list (or equivalent) of all PT schemes for which accreditation is held for review by PJLA. This would include all reference materials on a conventional or flexible scope.
- 4.2.2 Proficiency Testing Providers shall have fully documented procedures for PT schemes produced under their scope of accreditations. The Proficiency Testing Providers shall regularly review this list and associated substantiating evidence. Procedures and the responsibilities relevant to the development or revision of reference materials produced shall be reviewed periodically taking into account the results of internal and external quality control.
- 4.2.3 Proficiency Testing Providers must be able to provide to PJLA documented evidence that the laboratory has complied with the requirements of ISO/IEC 17043 for the PT schemes managed on its scope(s) during assessments or upon request.
- 4.2.4 Records of the PT schemes on the scopes must be retained and made available for review by PJLA. These records must be available for review by PJLA during the initial assessment, surveillance visits, and reassessments or on request.



Scopes of Accreditation

APPENDIX G- GUIDELINES FOR THE USE OF SI UNITS FOR THE SCOPE OF ACCREDITATION

1.0 GENERAL

- 1.1.1 The General Conference on Weights and Measures established the International System of Units (SI). It is the modern metric system of measurement used throughout the world. PJLA policy strongly encourages the exclusive use of SI units for stating ranges and CMC(s) on scopes of accreditation. This policy calls for the use of NIST SP 811 and the ISO 31 series of documents for direct guidance on the use of symbols and numbers. NIST SP 811 is a publication that was created to provide assistance to those who use SI units in their work. To make scopes of accreditation more accessible to the U.S. market, PJLA does allow the use of USC (US Customary) units of measure. Any scopes with USC units of measure will conform to the formatting of Appendix B of NIST SP 811.
- 1.1.2 It is the responsibility of the client to know and understand the requirements of the SI on their scope of accreditation. The NIST SP 811 is available on the Internet from the NIST website. The ISO 31 series of documents is available for purchase from the ISO website. The cost varies depending on which standards in the series you will need. If you choose to purchase these, we recommend at least acquiring the ISO 13-0, General Principles, and ISO 31-11, Mathematical signs and symbols for use in the physical sciences and technology.
- 1.1.3 The following pages contain a small sampling of guidelines and examples contained in the NIST SP 811.

| Rule: | Example: | Instead Of: |
|---|---|---------------------|
| Only units of the SI and those recognized by the SI are used. | 10 m 100 °C | 10 ft 100 °F |
| Abbreviations are avoided | s or second cm ³ or cubic centimeter | sec cc |
| Unit symbols are not modified in order to provide information about the quantity. | $V_{\max} = 1000 \text{ V}$ | $V = 1000 V_{\max}$ |

Scopes of Accreditation

| | | |
|--|---|--|
| The symbol “%” can be used in place of the number 0.01 | $x_{\beta} = 0.0038 = 0.38\%$ | $x_{\beta} = 0.25$ percent |
| Quantities are to be defined so that they can be expressed solely in acceptable units | The Ca content is 25 ng/L | 25 ng Ca/L |
| Unit and mathematical symbols and names are not mixed | m/s or meter per second | meter/s |
| Values for quantities are expressed in acceptable units using Arabic numerals and the SI symbols for units | The weight of the box was 35 kg. | The length of the box was thirty-five kilograms. |
| There is always a space between the quantity and the unit symbol, except when it is a plane angle | 189 kg 25 °C 357 Ω 24° (plane angle) | 189kg 25°C 357Ω 24 ° (plane angle) |

| Rule: | Example: | Instead Of: |
|---|------------------------------------|--|
| A thin space is used to separate digits with more than four per side of a decimal point | 123 586 257.004 1 | 123586257.0041 or 123,586,257.0041 |
| Quantity equations are preferred to numerical value equations | $l = vt$ | $\{l\}_m = 3.6^{-1} \{v\}_{km/h}$ $\{t\}_s$ |
| A quotient quantity is expressed using “divided by” instead of “per unit” | Pressure is force divided by area. | Pressure is force per unit area. |

| Rule: | Example: | Instead Of: |
|--|---|-------------------------------|
| The terms Normality and Molarity, symbols N and M respectively are obsolete. The preferred name is amount of substance concentration of B. | A solution having an amount of substance concentration of $c[(1/2)H_2SO_4]$ | A 0.5 N solution of H_2SO_4 |



Scopes of Accreditation

| | | |
|---|-----------------------|-----------------|
| Values of quantities are to be written so that it is clear to which unit symbols the numerical values of the quantities belong. | 51 mm x 51 mm x 25 mm | 51 x 51 x 25 mm |
| The word “to” is used to indicate a range of values instead of a dash. | 0 V to 5 V | 0 V – 5 V |

1. The word “weight” is used with the intended meaning clear. In science and technology, weight is defined as a force, for which the SI unit is the Newton. In commerce and everyday use, weight is used as a synonym for mass, for which the SI unit is the kilogram.
2. Standardized quantity symbols given in the ISO 31 series are used. Similarly, standardized mathematical signs and symbols such as those given in ISO 31-11 are used.
3. Due to ambiguity of definitions, the use of terms “PPM” and “PPB” are not acceptable.