A Review of the Upcoming Revisions to PJLA Policy PL-4 “Scopes of Accreditation”

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Who Are We?

Perry Johnson Laboratory Accreditation is cross-sector accreditation body recognized by the International Laboratory Accreditation Cooperation in the areas of testing, calibration, medical laboratories, inspection bodies, reference material producers and proficiency test providers

ISO/IEC 17025

ISO/IEC 17020

ISO 15189

ISO/IEC 17043

ISO 17034

Governmental/
Industry Schemes

PL-4 Updates

PJLA will update it's PL-4 policy regarding scopes of accreditation to not only address calibration scopes but now contains requirements for PJLA programs to include testing, inspection, proficiency testing providers, reference material producers, and medical.

PJLA

Perry Johnson Laboratory Accreditation, Inc.
Scopes of Accreditation Policy

PL-4 Scopes of Accreditation

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 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.

ISO/IEC 17011:2017 = Conformity Assessment — Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies

PL-4 Scopes of Accreditation

PL-4 will detail how testing organizations can request a flexible scope. This will provide 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.

APPENDIX A –CALIBRATION SCOPES OF ACCREDITATION

All previous requirements in the previous revision of PL-4 - *Calibration* Scopes of Accreditation are in place. To include requirements associated with defining the range of calibrations to include

- A fixed value
- A range beginning with up to and ending with a fixed value - - it is understood that a non-zero low end of the range does exist
- A range 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

APPENDIX A –CALIBRATION SCOPES OF ACCREDITATION

CMC - Calibration and Measurement Capability

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

Noted in PJLA PL-3 “Policy on Measurement Uncertainty” An actual uncertainty can not be reported which is less than the organizations CMC on the scope of accreditation.

APPENDIX A –CALIBRATION SCOPES OF ACCREDITATION

CMC can be stated on one of three mathematical conditions

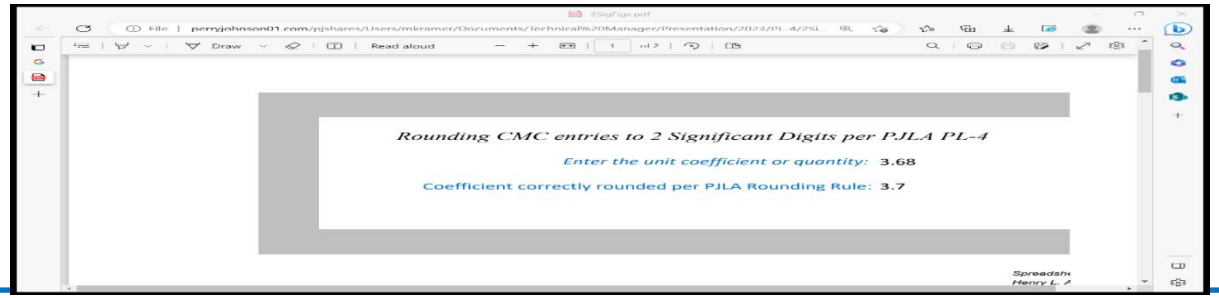
- remain constant over the stated range fixed
- set of values that are linear meaning that they vary in approximate direct proportion to the increase in magnitude of the stated range. -Examples are given as acceptable formats.
- The organization may propose an additional format for the relative uncertainty expression, *any such formats developed by the organization shall be submitted to PJLA headquarters for approval.*

APPENDIX A –CALIBRATION SCOPES OF ACCREDITATION

Significant Digits

The numerical value of the expanded uncertainty or as reported by the organizations CMC shall not be expressed more than two significant digits. 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.

PL-4 provides examples and PJLA website offers a calculator as a resource



APPENDIX A –CALIBRATION SCOPES OF ACCREDITATION

Revision - A new field of accreditation has been added to PJLA calibrations scope of accreditation.

Ionizing Radiation and Radioactivity

Examples of calibrations that will be included in the discipline includes Ionization Chambers Survey Meter, Contamination Instruments, Nuclear Gauges-Density, Radiation Survey Instruments, and Area Radiation Monitor Instruments.

APPENDIX A -CALIBRATION SCOPES OF ACCREDITATION

Calibration Equipment/Reference Standards Used

This field includes equipment or standards used to calibrate the device such as Fluke 5520A, Standard Thermometer and Dry Block, pH Buffer Solutions, or Torque Transducer.

APPENDIX A –CALIBRATION SCOPES OF ACCREDITATION

CALIBRATION MEASUREMENT METHOD OR PROCEDURES USED

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.

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APPENDIX A –CALIBRATION SCOPES OF ACCREDITATION

MEASURED INSTRUMENT, QUANTITY OR GAUGE

This needs to specify the instrument or gauge being calibrated and not just state the property being measured

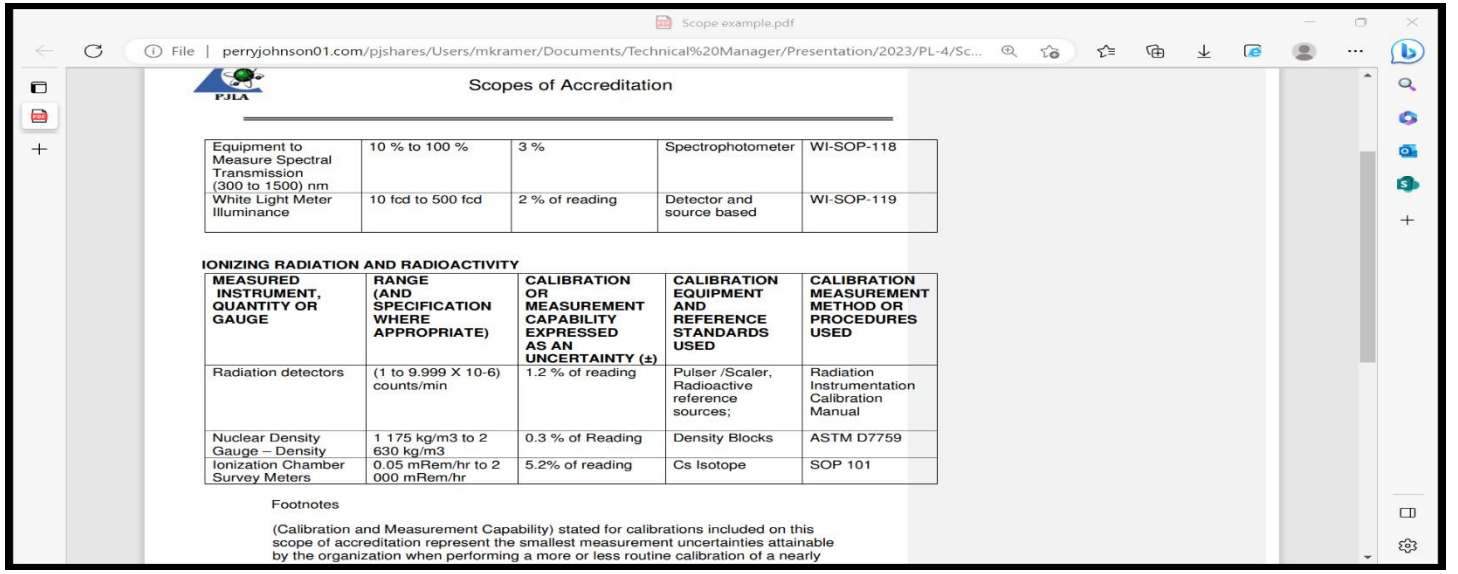
Torque - Torque Wrench Torque Tools

Pressure – Pressure Gauge, Pressure Transducer

Voltage- Equipment to Measure Voltage

APPENDIX A –CALIBRATION SCOPES OF ACCREDITATION

Calibration scopes examples has been expanded to include IONIZING RADIATION AND RADIOACTIVITY



Equipment to Measure Spectral Transmission (300 to 1500) nm	10 % to 100 %	3 %	Spectrophotometer	WI-SOP-118
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 (±)	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/m3 to 2 630 kg/m3	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

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

APPENDIX B-INSPECTION BODY SCOPES OF ACCREDITATION

Formerly PJLA had Work Instruction 9 which addressed Inspection Scopes of Accreditation.

APPENDIX B-INSPECTION BODY SCOPES OF ACCREDITATION

Inspection body will be defined as Type A, Type B, or Type C inspection body types

Fields of Inspection

Specific inspection field which the inspection body is accredited

- Bulk cargoes (e.g., petroleum, coal)
- Legionella Risk assessments (bacteria)
- Pressure Vessels, Piping and Pipework
- Fire Protection System and/or Fire-Resistant Construction

APPENDIX B-INSPECTION BODY SCOPES OF ACCREDITATION

PL-4 has added guidance in determining if the non-destructive field should be considered a test or inspection

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. 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. 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.

APPENDIX B-INSPECTION BODY SCOPES OF ACCREDITATION

Type or Ranges of Inspection

Should be specific as to what is being inspected or detected by the inspection body within the field of inspection.

Field	Type or Range of Inspection
Lifting Equipment	Hoists & Winches
Pressure Equipment	Boilers and Pressure Vessels
Petroleum Crude Oil Petroleum Products	Tank Gauging

APPENDIX B-INSPECTION BODY SCOPES OF ACCREDITATION

SPECIFICATION, STANDARD METHOD, OR TECHNIQUE USED

Should clearly indicate what the inspection body is using to perform inspections

- ASME Boiler & Pressure Vessel Code Sections I through XII, ASME B31
- U.S. Federal Specification RR –C-271F BS 3551:1962
- NIST SP 800-171
- COGSA [Carriage of Goods by Sea Act under 46USC (United States Code)]

Testing PL-4 Overview

- Scopes to include at minimum:
  - field of test,
  - items, materials or products tested,
  - component, characteristic, parameter tested,
  - the specification/standard method,
  - and the technology technique used.
- Important Note: Range
  - now optional or where required by the program

Examples

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	GC/MS
Non-Destructive	Cannabis Flower	Filth	In-house SOP16	Stereo Microscope / Compound Microscope
Biological	Food, Feed, Pharmaceuticals, and Dietary Supplements	Aerobic Plate Count	BAM Ch. 3 AOAC 990.12	Quantitative Micro
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)

Testing Flexible Scopes

- Can be established for various degrees of flexibility
  - 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;

Testing Flexible Scopes

- Can be established for various degrees of flexibility
  - 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)

Requirements for testing flexible scope

- Maintain a list of how flexible scope was applied

Technology/ Technique	Method	Matrix	Analyte	Date of competency	Date of last update or New date

- Records of verification or validation, as relevant
- Other records, as applicable

RMP PL-4 Overview

- Format Change
- Inclusion of approach used to assign property values
  - ISO 17034 7.12.3 (a-e)

Examples

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	Characterization of an operationally-defined measurand using a network of competent laboratories
RM	Chemical Materials	High Pressure Gas Mixtures in Cylinders	Ethanol in Nitrogen	single reference measurement procedure in a single laboratory
CRM	Organic Chemical	Neat Materials	Analyte Identification and Purity	single reference measurement procedure in a single laboratory

RMP Flexible Scopes

- 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 laboratory and referenced on the scope of accreditation,

RMP Flexible Scopes

- Introduction of a new parameter/component/analyte for a method or a technology used in the laboratory and referenced on the scope of accreditation,
- Introduction of a new measurement range to an accredited technology used in the 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 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 laboratory and referenced on the scope of accreditation.

Requirements for RMP Flexible scope

- List of all RMs
- Validation of any methods changed
- Evidence of compliance to ISO 17034
- Records available

PT PL-4 Overview

- No substantive changes in scopes

Examples

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
Construction Material Testing	Bitumen	Determination of Ductility of Bituminous Materials Test
Chemical testing	Metals Testing	Determination of Heavy Metals by ICP and ICPMS

PT Flexible Scopes

- 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

Requirements for PT Flexible scope

- List of all PT schemes
- Validation of any changes
- Evidence of compliance with ISO/IEC 17043
- Records available

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