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# Work Instruction for Testing Scopes of Accreditation Including Flexible Scopes

The scope of accreditation is a formal document issued by PJLA to its accredited laboratories. It contains information for which accreditation has been granted in regards to the types of tests performed, techniques used and detection limits.

It is the responsibility of the laboratory to prepare its proposed scope of accreditation before the initial assessment. The proposed scope of accreditation will be reviewed by the PJLA assessor onsite for accuracy and completeness. Once the assessor has agreed with the proposed scope of accreditation, both the laboratory and the assessor will sign the proposed scope and submit it to PJLA for review with the assessment package. Please note that the submitted scope of accreditation can be modified by PJLA after technical review of the assessment package. Once the accreditation is granted, PJLA will issue a final certificate. The final certificate will be made available to the public through the PJLA website.

The following information should be used to complete the scope of accreditation LF-1 Application or LF-64.

# APPENDIX A

**Certificate Required Fields/Format**

**Field of Test:**

The entry in this field needs to represent the generic classification of the testing services provided by the laboratory. When completing this field, the entry needs to broadly describe the discipline that is to follow in the adjacent columns. Appendix A of this work instruction includes a listing of appropriate fields to be used based on the types of testing that is being provided by the laboratory. Should you find that your testing areas do not fit into the fields listed below, please notify PJLA staff to assist you with completing this section of your scope of accreditation.

**Testing Field:**

1. Biological: Biological, microbiological and biochemical testing and measurement.
2. Chemical: Chemical analysis and detection including instrumental and automated methods.
3. Dimensional Inspection
4. Electrical: Tests of an electrical and electronic nature performed on instruments, equipment, appliances, components and materials.
5. Environmental: Tests for constituents in various environmental media.
6. Mechanical: Tests, measurements and evaluation of physical properties of materials, components and assemblies.
7. Non-Destructive: Examination of materials, components and assemblies to detect discontinuities without damaging the material, component or assembly.

**Items, Materials or Products Tested:**

Define the products, materials or other items that you test using the technology defined in column three. For example: Metals, Waste Water or Plastic Components.

**Specific Tests or Properties Measured:**

The entry in this field needs to represent the tests you are performing. This entry needs to be specific and fully describe the test or property so as to indicate the capabilities of the laboratory.

**Specification, Standard Method or Technique Used:**

Enter all of the test methods that are used when performing tests in the technologies related to the third column. The test method may be an internationally recognized test method such as ASTM, SAE or other accepted methods. This may also be a customer

specified method or internal method. Whichever method is stated on the scope, the laboratory is expected to have available the most current version of that method.

Range (Where Appropriate) and Detection Limit:

Provide the lower and upper boundaries for the range of the parameter. Beware of including a zero as the lower boundary, especially when a percent or multiplier is used

Detection limit for the product in the manner to be tested must be provided. Detection Limit can be expressed in quantitative or qualitative terms as necessary. The capabilities of the laboratory need to be clearly expressed in an easy to understand format.

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

**Format:**

A separate line entry is needed for each parameter/discipline and/or each range listed for that parameter. For each line entry, a separate line must be used for each range.

The format of the example table must be followed. This includes font (Times New Roman), font size (10), column order and column headings, and placement of notes. Blank Boxes and boxes containing the phrase "N/A" will only be accepted for the range of the parameter and not the detection limit, where applicable.

| FIELD OF TEST | ITEMS, MATERIALS OR PRODUCTS TESTED | SPECIFIC TESTS OR PROPERTIES MEASURED | SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED | RANGE (WHERE APPROPRIATE) AND DETECTION LIMIT |
|---|---|---|---|---|
| Environmental | Waste Water | Sodium Content | EPA 10528 | 0.001 mg/dl to 0.15 mg/dl 0.000012 mg/dl |
| Mechanical | Automotive Components | Chipping Resistance | SAE 4500A | ± 5% |

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# APPENDIX B

## Guidelines for the use of SI units for the scope of accreditation

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 requires the use of SI units to be used for reporting results of measurements on scopes of accreditation. This policy calls for the use of NIST SP 811 for direct guidance on the use of symbols, numbers and the use of the SI Units.

It is the responsibility of the client to be aware of the appropriateness of the SI unit on their scope of accreditation as applicable. In some cases, U.S. customary units may be more appropriate. The NIST SP 811 can be retrieved from www.nist.gov .

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<br>100 °C | 10 ft<br>100 °F |
| Abbreviations are avoided | S or second<br>$cm^3$ or cubic centimeter | sec<br>cc |
| ppm, ppb and ppt are avoided | 2 ng/kg<br>1.1 nm/m | 2 ppt<br>1.1 ppb |
| Unit symbols are not modified in order to provide information about the quantity. | $V_{max}$ = 1000 V | V = 1000 $V_{max}$ |
| 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 | 189 kg<br>25 °C<br>357 Ω | 189kg<br>25°C<br>357Ω |

| | | |
|---|---|---|
| when it is a plane angle | 24° (plane angle) | 24 ° (plane angle) |
| 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 $H_2SO_4$ |
| 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 is ISO 31-11 are used.

# Appendix C

**Guidelines for developing and using a flexible scope**

PJLA utilizes ILAC-G18:04/2010 Guidelines for the Formulation of Scopes of Accreditation for Laboratories, to accredit a laboratory using a flexible scope. When a laboratory is granted a flexible scope, it is allowed to include additional activities in its scope of accreditation on the basis of its own validations without evaluation prior to operation of the activity. The possibility of introducing new, modified or laboratory developed methods under a flexible scope does not include introduction of new measurement principles of testing, calibration or examination not previously covered by the scope of accreditation.

A flexible scope can be established based on degrees of freedom for flexibility such as (from ILAC G18:04/2010):

- *Flexibility concerning object/matrix/sample*

This means flexibility that allows for changes with respect to various products (e.g. change in matrices) within a product area. For example this covers electrothermal/graphite tube atomic absorption spectroscopy which is extended from determination of cadmium in fruit, jams and other fruit products for the determination of cadmium in cereals and bakery products. Another example is mechanical testing of various components (e.g. wheels, suspensions) for automotive applications.

- *Flexibility concerning parameters/components/analytes*

This means flexibility that allows for changes with respect to parameters. An example is the extension of cadmium determination in food to other trace metals by electrothermal/graphite tube atomic absorption spectroscopy.

- *Flexibility concerning the performance of the method*

This means flexibility that allows for changes in the performance of the method for a given specimen type and a given parameter. This includes for example, the modification of measuring range and uncertainty.

- *Flexibility concerning the method*

This means flexibility which allows adoption of methods that are equivalent to methods already covered by accreditation. An example is the extension of in-plane displacement field measurement by 2D-

ESPI (electronic speckle pattern interferometry) to three dimensional distribution of the displacement by 3D-ESPI.

Laboratories receiving this type of accreditation are not granted for a specific measurement procedure and limits of the flexibility are clearly set. A flexible scope and a fixed scope can be separately described or combined within one accreditation whatever is the most convenient or informative. In all cases, the laboratory must retain an updated list of all methods for which accreditation is held, including newly modified, introduced or developed methods for review by the PJLA.

Laboratories maintaining a flexible scope of accreditation must have, where it is applicable, fully documented procedures for the validation of method modifications (including modifications of parameters and matrices) and for the verification of additional methods to be covered under the flexible accreditation scope.

This is means the laboratory must provide to PJLA documented evidence that the laboratory has complied with the requirements of ISO/IEC 17025 clause 5.4.5 Validation of Methods, in the laboratory's procedures. The appropriateness and robustness of the laboratory's validation procedures will be assessed by PJLA prior to accreditation being granted for a flexible scope. Records of validation and verification of additional methods and the data obtained must be retained and made available for review at assessment. Modifications and up-dates of the test methods or development activities including all the underlying results and other relevant data must be controlled and maintained. This could normally be in the form of a validation and/or verification report. ISO/IEC 170025:2005 5.4.5.2)

The list of methods maintained by the laboratory must be organized by the technologies listed on their flexible scope that includes the following information about the method performance as appropriate:

1. Detection Limit(s) of parameters/components/analytes,
2. Range, accuracy and precision of the values obtainable,
3. The uncertainty of the results,
4. Selectivity of the method,
5. Linearity,

6. Limit of repeatability and/or reproducibility,

7. Robustness against external influences, cross sensitivity against interference from the sample matrix.

8. Raw data used to determine the above information.(ISO/IEC 17025:2005 5.4.5.3)

The appropriateness would involve considerations as to whether the additional method is itself a standard method, the intended use of the method and the customer's needs. (ISO/IEC 17025:2005 5.4.1-5.4.5)

Procedures and responsibilities relevant to the development or revision of methods covered by accreditation must be reviewed periodically by the responsible management and take into account the results of internal and external quality control.

The responsible staff (including those responsible for quality management) shall regularly review the modified, revised or newly developed methods. Procedures and responsibilities linked to the development or revision of accredited methods shall be reviewed periodically by the responsible management taking into account the results of internal and external quality control such as inter-laboratory comparisons.

These records must be available for review by the PJLA during the initial assessment, surveillance visits, and reassessments or on request.

**References:**

-ILAC G18:04/2010 Guidelines for the Formulation of Scopes of Accreditation for Laboratories

-ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories

-NIST Special Publication 811 2008 Edition-Guide for the Use of the International System of Units (SI)