Preparing Authority:

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G133 – A2LA Guide for Establishing Proficiency Testing Plans

A2LA document <u>R103 - General Requirements- Proficiency Testing for ISO-IEC 17025 Laboratories</u>, sections PT4 and PT5, specify that accredited laboratories must have a documented plan of how they intend to participate in appropriate and available PT and/or ILC programs to cover the tests/calibrations on their scope of accreditation and shall include participation within the accreditation cycle. A risk assessment of the level and frequency of the PT and/or ILC participation must also be completed.

There may be circumstances where A2LA may exempt a laboratory from needing to complete a risk assessment of their PT participation frequency, such as when there is a mandated frequency of PT participation by a regulator, an industry or professional sector, or Regional Cooperation Body (e.g., AOAC or TNI requirements).

This guidance document is designed to provide information on identifying sub-disciplines, performing an appropriate risk assessment, and developing a proficiency testing plan. Please refer to R103 and any applicable program specific requirement documents for additional proficiency testing requirements that may apply to certain areas.

One possible way towards developing a PT and/or ILC plan using a risk-based strategy is for a laboratory to identify relevant sub-disciplines regarding the activities listed on their scope of accreditation. A sub-discipline may contain more than one measurement technique, property, or product as long as equivalence and comparability can be demonstrated. The first consideration for a laboratory, when determining a sub-discipline, is that it should generally not contain different technical competences. Different technical competences can usually be identified by the need for different qualifications, training, and use of different equipment, knowledge, or experience¹.

The following subdisciplines were identified and reviewed by the relevant A2LA Technical Advisory Committees with responsibility in the respective fields (i.e., Construction Materials Advisory Committee (CMAC), Electromagnetic Advisory Committee (EMAC), Life Science Advisory Committee (LSAC), Measurement Advisory Committee (MAC), Materials and Transportation Advisory Committee (MTAC), and Forensics Examination Advisory Committee (FEAC)).

Acoustics and Vibration

There are currently no defined sub-disciplines under this field of accreditation.

Biological

Biological - General

Sub-disciplines include:

Sub-disciplines

Quantitative Bacteriology Quantitative Mycology Quantitative Virology Qualitative Bacteriology Qualitative Mycology

¹ EA-4/18:2021 - Guidance on the level and frequency of proficiency testing participation

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Qualitative Virology

Molecular Sub-typing Serology ELISA Sub-disciplines (cont.) PCR Microscopy Next Generation Sequencing Whole Genome Sequencing

Biological - Food Testing Program Requirements

Laboratories accredited to the A2LA Food Testing Program Requirements must meet the proficiency testing requirements specified in the AOAC Internationals' Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals – An Aid to the Interpretation of ISO/IEC 17025:2017. This document is available from AOAC International (*www.aoac.org*). For specific proficiency testing requirements please see <u>R204 - Specific Requirements - Food and Pharmaceutical Testing Laboratory</u> Accreditation Program.

Calibration

Disciplines/Sub-disciplines include:

| Disciplines | Sub-Disciplines | |
|-------------------------------|--|--|
| Acoustical | - Dosimeters, mastoids, sensors - Calibrators | |
| Chemical | - pH, conductance measuring devices, gas concentration | |
| Dimensional | - 1D – portable gauging and hand tools (calipers, height gages, indicators, micrometers, rulers, etc.) - 1D – artifacts, standards, and parts (angle blocks, external/internal cylinders, gage blocks, lasers, length bars, line scales, sine plates, sieves or mesh openings, spheres, stage micrometers, step gages, measurement of parts, etc.) - 2D – portable/fixed gauging and hand tools (bevel protractors, clinometers, levels, linear measuring machines, measuring microscopes, optical comparators, squareness testers, theodolites, etc.) - 2D – artifacts, standards, and parts (angle block, autocollimator, cones, cylinder squares, granite squares, index tables, optical polygons, optical squares, retroreflection prisms, sine bars, measurement of parts, etc.) - Form (external/internal cylinders, flatness standards, lenses, magnification, standards, optical flats/parallels/wedges, spheres, surface plates, etc.) - 3D – gauging (CMMs, theodolites, laser trackers, etc.) - 3D – artifacts, standards, and parts (ball plates, grid plates, etc.) - Other – (gears, groove depth standards, pitch masters, profilometers, roughness, standards, threaded devices, tip condition, etc.) | |
| Electrical – DC/Low Frequency | - Current - Voltage | |

- Power

| - Impedance | è |
|-------------|---|
|-------------|---|

- Inductance
- Capacitance
- Resistance
- Oscilloscope functions
- Process calibrators

Electrical – RF/Microwave

- Power, AM / FM / PM, Digital Modulation, Frequency
- Scattering Parameters (Reflection Coefficient / Transmission Coefficient / Attenuation / Gain / Insertion Loss)
- Noise and Phase Noise
- Antenna Factor, Antenna Gain, Field Strength
- Fiber Optic Parameters (Power, Wavelength, Loss, Spectral Width, Bandwidth, Dispersion)

Fluid

- Volume, density, specific gravity, mass/volume flow

Ionizing Radiation & Radioactivity

- Radiation protection/health physics survey instruments
- Radioactive source calibration

Mechanical

- Hardness (direct verification, indirect verification,
- geometry)
- Pressure, vacuum
- Torque, force, durometers, extensometers, strain gauges
- Acceleration, speed, vibration
- Scales & balances, mass

Optical

- Lasers, fiber optics
- Power, luminosity, radiance, irradiance, color

- Optical density

- Metallographs, photomicrographs

Thermodynamics

- Thermometers, ovens, furnaces
- Temperature indicating systems/environmental monitoring (RH, RTD's, thermocouples)
- Black body/IR

Time & Frequency

- Period, time, frequency

<u>Evaluation of Results:</u> The following equation is one example of a method for the evaluation of results from a laboratory's participation in a given measurement audit. See ISO 13528 for more examples of calculating performance statistics.

$$\left(E_{n}\right)_{i} = \frac{x_{i} - x_{pt}}{\sqrt{U^{2}\left(x_{i}\right) + U^{2}\left(x_{pt}\right)}}$$

where X_i and X_{pt} indicate the laboratory and reference measurement values respectively for the attribute in question and $U^2(X_i)$ and $U^2(X_{pt})$ represent the expanded uncertainties expressed at the 95% confidence level for the laboratory and reference laboratory respectively.² En values greater than 1 indicate that a laboratory's measurement result and associated uncertainty deviate significantly from the reference measurement result and associated reference uncertainty.

Chemical

Chemical - General

Sub-disciplines and material/matrices include:

Sub-disciplines
Chromatography: GC, GC-MS, HPLC, IC, TLC, LC-MS-MS, UPLC
Combustion: LECO
Conductivity
Microscopy: Optical, Electron, Atomic Force
pH
Spectroscopy: Alpha, Auger, AA, CVAA/GFAA, Gamma, Fluorescence, ICP, IR/FTIR, MS (MSD, MS/MS, etc.), NMR, OE, UV/Vis, XRD, XRF, NIR
Wet Chemistry

Materials/Matrices/Product Types Beverages, e.g., Wine Ceramics Composites Emissions Ferrous Alloy Families: Cast Fe, Carbon/Low Alloy/Tool Steel, Stainless and High Temperature Steel Food Manufactured Gases Natural Resources: Petroleum, Coal, Natural Gas, Minerals Non-Ferrous Alloy Families: Cu Alloys, Ni/Co Alloys, Al Alloys, Ti Alloys, Mg Alloys Plastics Rubber Soil Tobacco and Tobacco Products Vegetation Water

Chemical - Animal Drug Testing

² ISO 13528 – Statistical methods for use in proficiency testing by interlaboratory comparison

For specific proficiency testing requirements please see <u>R203 - Specific Requirements - Competition Animal Drug</u> <u>Testing Laboratory Accreditation Program for ISO-IEC 17025</u>.

Chemical - Food Testing

Laboratories accredited to the A2LA Food Testing Program Requirements must meet the proficiency testing requirements specified in the AOAC Internationals' *Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals – An Aid to the Interpretation of ISO/IEC 17025:2017.* This document is available from AOAC International (www.aoac.org). For specific proficiency testing requirements please see <u>R204 - Specific Requirements - Food and Pharmaceutical Testing Laboratory Accreditation Program</u>.

Chemical - Anti-Doping Testing

For specific proficiency testing requirements please see <u>R217 - Specific Requirements - World Anti-Doping</u> <u>Agency-WADA- Testing Laboratory Accreditation Program</u>.

Construction Materials

For specific proficiency testing requirements please see <u>R208 - Specific Requirements - Construction Materials</u> <u>Testing Laboratory Accreditation Program</u>.

Electrical

Sub-disciplines include: Electromagnetic Compatibility – EMC (*Radiated and Conducted Emissions testing*) Lighting

Environmental

Environmental – NELAC TNI

For specific proficiency testing requirements please see <u>R206 - Specific Requirements - Environmental Testing</u> <u>Laboratory Accreditation Program</u>.

Environmental - DoD Advanced Geophysical Classification Accreditation Program (DAGCAP)

For specific proficiency testing requirements please see <u>R224 - Specific Requirements - A2LA DoD Advanced</u> <u>Geophysical Classification Accreditation Program</u>.

Environmental – DoD ELAP or DOECAP

For laboratories pursuing compliance with the requirements of the <u>DoD/DOE Quality Systems Manual</u>, the applicable requirements listed in Volume 1, Module 1: Proficiency Testing apply.

Forensic

Disciplines (and sub-disciplines) include:

Failure Analysis: Electrical Safety, See sections IV – Chemical, XI – Mechanical, XII – Nondestructive and others as applicable.

Forensic Biology: Body fluid identification, DNA profiling, Animal DNA profiling, Relationship testing, Serology, See also – Biological section.

Controlled Substances: Botanical material, Controlled pharmaceuticals and drugs, Related chemicals and paraphernalia, Chemical Unknown (Solid), See also sections for Chemical and Environmental.

Latent Prints & Impressions: Fingerprints (development and/or comparison), Palm Prints (development and/or comparison), Footprints (development and/or comparison)

Firearms & Toolmarks*: Serial number restoration, Firearms examination / identification, Toolmark examination, See also – Mechanical section.

Trace Evidence*: Fiber / Hair analysis, Paint analysis, Glass, Tape Examination, Bulb Examination, Gun Shot Residue Analysis, Low Order Explosives (i.e., Flammability, Flashpoint, Ignition Temperature, Fire-promoting characteristics, Corrosion behavior), See also Chemical and – Mechanical sections.

Questioned Documents (Handwriting & Documents Examination) *: Copiers and copied material, Handwriting, Indentations, Paper, Printers and other printed objects, Security marks.

Forensic Toxicology: Blood Alcohol analysis, Breath alcohol simulator solution analysis, Urine testing, See also sections for Biology and Chemical.

Digital Forensics: Digital media examination (i.e., Write protection, Media imaging, establishing a hash value of the original media, creating a directory listing, Recovery of all active files, Deleted file recovery, Metadata recovery from documents, Text file recovery), Analog video examination, Digital video examination.

Crime Scene Inspection: Blood pattern analysis, Body fluid identification, Computer simulated crime scene.

*The listing of testing techniques under the above headings does not require that they be listed this way on a Scope of Accreditation. It is recognized that forensic disciplines perform similar analyses, and the allocation of these job duties will vary.

Geotechnical

Geotechnical - General

For specific proficiency testing requirements please see <u>R209 Specific Requirements - Harris County-City of</u> <u>Houston-Port Authority Geotechnical Engineering Testing Laboratory Accreditation Program</u>.

Geotechnical - Putting Green Materials

For specific proficiency testing requirements please see <u>R213 - Specific Requirements - Putting Green Materials</u> <u>Testing Laboratory Accreditation Program</u>.

Information Technology

There are currently no defined sub-disciplines under this scope of accreditation.

Mechanical

Sub-disciplines and material/matrices include:

Sub-disciplines Mechanical Tests: Tensile, Flexural, Compression Impact Tests: Izod, Charpy Thermal Tests: HDT, Vicat, DSC, Melt Flow, TGA, Ash Content Hardness: Rockwell, Brinell Microhardness: Knoop, Vickers Hardness: Other - (e.g., Shore A) Optical: Color, Gloss, Haze Corrosion/Environmental Simulation Metallographic Evaluation: Grain Size Material Properties: Specific Gravity, Viscosity Dimensional (please refer to the Dimensional section under III. Calibration) Others: Coefficient of Friction, Volume and Surface Resistivity

Materials/Matrices/Product Types

Plastic Rubber Metals Textiles

Nondestructive

There are currently no defined sub-disciplines under this scope of accreditation. For specific proficiency testing requirements please see <u>R212 - Specific Requirements - Nondestructive Testing Laboratory Accreditation</u> <u>Program</u>

Sustainable Energy

Sub-disciplines include: Lighting

Thermal

There are currently no defined sub-disciplines under this scope of accreditation.

Proficiency Testing Providers

As mentioned in A2LA R103, ISO/IEC 17025:2017 requires all laboratories, both applicant and accredited, to participate in appropriate and available PT provided by organizations administering acceptable programs. A2LA **strongly** recommends that laboratories participate in PT programs operated by accredited PT providers, however it is recognized that alternatives exist. Generally accepted guidelines for choosing acceptable PT and/or ILC programs are as follows:

- 1. A PT provider accredited to ISO/IEC 17043 by an accreditation body (AB) that is a signatory to the ILAC MRA for PT providers;
- 2. A PT provider accredited to ISO/IEC 17043 by an accreditation body that is a *non-signatory* of the ILAC MRA for PT providers;
- 3. Participation in ILC's organized for other purposes than determining laboratory competence (refer to ISO/IEC 17043, Introduction points h-j), and that have been evaluated and confirmed to be in accordance with ISO/IEC 17043, or;
- 4. Participation in competent ILC's organized in accordance with the requirements of ISO/IEC 17043, to determine the performance of accredited organizations by comparison with results of other laboratories.

Level and Frequency of Participation

The first step for the laboratories (accredited organization) should be to identify the sub-disciplines as identified above that apply for the tests/calibrations for which they are accredited.

Ideally a laboratory would participate in a specific PT for every measurement technique it uses and for every property measured in every product type, but it is recognized that doing so is not often feasible or economical for a number or reasons. When determining the level and frequency of participation in PT and/or ILC programs, the laboratory's risk assessment could include, but not be limited to the following considerations:

- Number of tests/calibrations/measurements undertaken;
- Turnover of technical staff;
- Experience and knowledge of technical staff;
- Source of traceability (e.g., availability of reference materials, national standards, etc.);
- Known stability/instability of the measurement technique;
- Significance and final use of testing/calibration data (e.g., forensic science represents an area requiring a high level of assurance)

To assist laboratories in formulating a PT Plan that meets the requirements of R103 and to facilitate an efficient means of tracking PT activities please see below as an example of how this information can be conveyed.

Risk Matrix

| | | Impact | | | |
|------------|---|-------------|-------------|-------------|--|
| | | 1 | 2 | 3 | |
| Likelihood | 1 | Low 1 | Low 2 | Medium 3 | |
| | 2 | Low 2 | Medium 4 | High 6 | |
| | 3 | Medium 3 | High 6 | High 9 | |

| Discipline | Subdiscipline | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | <u>Risk</u> <u>Level</u> |
|----------------------------------|----------------|--------|--------|--------|--------|--------|-----------------------------|
| Mechanical | Pressure | х | | | | 0 | 4 |
| | Mass | | | Х | | 0 | 3 |
| Chemical | pН | | | | Х | | 1 |
| Dimensional | 1D - Artifacts | | Х | | | | 2 |
| Fluid | Mass Flow | X | Х | Х | Х | | 9 |
| Electrical – | Current | | | | Х | | 1 |
| DC/Low Frequency | Voltage | | | Х | | | 1 |
| Electrical – RF/ Microwave | Attenuation | | х | | | | 2 |

O= Planned

X = Completed

In the example proficiency testing plan above, a low risk level of 1 was given to pH sub-discipline based on relative risk level to the laboratory (e.g., low demand for testing, simple test, budgets were recently recalculated)

Mass Flow was given a high risk level of 9 based on the relative risk level to the laboratory (e.g., a high turnover of technical personnel, repeated proficiency testing outliers, a recent customer complaint)

DOCUMENT REVISION HISTORY

| Date | Description | |
|----------|--|--|
| | Intro paragraph two - Added a paragraph on risk assessments when | |
| | PT participation frequency is mandatory | |
| 08/17/22 | Footnote 1 – updated EA 4/18 reference to 2021 | |
| | Calibration section – added example calculation for En values with | |
| | reference to ISO 13528 | |
| 09/05/23 | Re-write of Electric RF/Microwave section | |