Factsheet –
Specifying accreditation in Regulation

In many economies, regulators may be national, state, provincial, or even municipal in their scope. They may be public authorities or represent private sector specifiers. Many regulators are already using accreditation effectively to support their regulatory and policy objectives. However, there are some that do not possess sufficient information, which can lead to the incorrect application or specification of accreditation requirements.

The following sets out how to accurately and fully specify the accredited services from external testing and calibration laboratories and inspection bodies, covered by the ILAC Arrangement (MRA). All four paragraphs are needed to ensure that a party providing external testing, calibration, medical testing and inspection services has met the relevant international standard and ILAC requirements for competence, and are providing reliable data and reports.

This text can be provided to Regulators and specifiers to assist them in their drafting of Regulation or specification.

"1. The laboratory shall be accredited in accordance with the requirements of ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories* (for testing or calibration laboratory) or with ISO 15189, *Medical laboratories – Particular requirements for quality and competence (for medical laboratories)* or the inspection body shall be accredited in accordance with the requirements of ISO/IEC 17020, *General criteria for the operation of various types of bodies performing inspection.*

2. The testing (or calibration) laboratory's scope of accreditation to ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratorie*s shall encompass testing (or calibration) of (list the test method(s) or parameter(s) that are required for the testing or calibration work being required or specified). The same applies to scopes of medical laboratories and inspection bodies.

3. The accreditation of a testing, calibration or medical laboratory or inspection body shall be issued by an accreditation body (AB), operating in accordance with ISO/IEC 17011, *General requirements for accreditation bodies accrediting conformity assessment bodies* and signatory to the ILAC Arrangement.

4. Additional requirements can be laid down by the regulator (e.g. the lab must participate in specific PT programs). The accreditation body shall evaluate compliance with these additional requirements."

The first paragraph stipulates that the **service provider** be accredited to ISO/IEC 17025, ISO 15189 or ISO/IEC 17020, while the second paragraph requires that the **tests, calibrations, or examinations** requested be listed on the scope of accreditation for the laboratory or inspection body´s scope of accreditation. If this requirement is not met, the laboratory could claim, for example, that it is ISO/IEC 17025 compliant even though it is not actually accredited for the tests or calibrations specifically required.

The third paragraph stipulates that the AB should be an ILAC MRA signatory. It emphasises the importance of purchasing conformity assessment services accredited by an AB with the appropriate credentials without which it is not possible to be confident that the laboratory or inspection body has been accredited by an AB competent to carry out the assessment. There are ABs that claim to be compliant with ISO/IEC 17011. Holding ILAC MRA signatory status indicates that the AB has been periodically peer-evaluated against the requirements of ISO/IEC 17011 and additional ILAC requirements.

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