

# FLEXIBLE SCOPE OF ACCREDITATION

## **SCOPE OF ACCREDITATION**

The scope of accreditation of a testing, calibration or medical laboratory is the official and detailed statement of the activities for which the laboratory is accredited.

## **ISO/IEC 17011 GENERAL REQUIREMENTS FOR ACCREDITATION BODIES ACCREDITING CONFORMITY ASSESSMENT BODIES**

- Accreditation body shall provide an accreditation certificate to the accredited laboratory, briefly identifying the scope of accreditation.
- Accreditation certificate or an annex to it shall identify:
  - the tests or types of tests performed
  - materials or products tested
  - the methods used (for testing laboratories)
  - the calibrations, including the types of measurements performed
  - benefits of accreditation
- 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 that the laboratory has the competence to offer the service defined in the scope.

## **ACCREDITED LABORATORIES MAY MODIFY METHODS**

- **ISO/IEC 17025** General requirement for the competence of testing and calibration laboratories, clauses 5.4.3 and 5.4.4
  - **ISO 15189** Medical laboratories - Particular requirements for quality and competence, clauses 5.5.1 to 5.5.3
- Such modifications require the laboratory to have a flexible scope of accreditation.

## **BENEFIT OF FLEXIBLE SCOPE**

- The basic consequence of a flexible scope and the benefit to the laboratory has the acknowledged flexibility, to modify methods, validate the changes and apply them without having to ask the accreditation body for extensions to the scope.
- Such modifications to methodology must not incorporate new measurement principles not previously covered in the scope of accreditation.

## **DESCRIPTION OF FLEXIBLE SCOPE**

Provides the possibility of describing major subdisciplines of the laboratory activities in a more general form.

The laboratory must anyway retain a current list of methods covered by accreditation including newly modified, introduced, or developed methods.



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### **Typical parameters for description of the scope of accreditation:**

| <b>Testing Laboratory</b>        | <b>Calibration Laboratory</b>                | <b>Medical Laboratory</b>                |
|----------------------------------|--|--|
| Testing field                    | Calibration field                            | Medical field                            |
| Type of test                     |  | Examination technique                    |
| Test object or product           | Calibration objects                          | Biological samples                       |
| Test parameter                   | Quantity, property                           | Components /Analytes or related groups   |
| Reference to standardized method |  |  |
| Internal method reference        | Internal calibration procedure reference     | Internal examination procedure reference |
|                                  | Calibration and Measurement Capability (CMC) |  |

It is allowed to include additional activities in its scope of accreditation on the basis of its own validations without evaluation by the accreditation body prior to operation of the activity.

### **FLEXIBLE SCOPE BASED ON DEGREES OF FREEDOM**

- **FLEXIBILITY CONCERNING OBJECT/MATRIX/SAMPLE**
  - allows for changes with respect to various products within a product area
- **FLEXIBILITY CONCERNING PARAMETERS/COMPONENTS/ANALYTES**
  - allows for changes with respect to parameters
- **FLEXIBILITY CONCERNING THE PERFORMANCE OF THE METHOD**
  - allows for changes in the performance of the method for a given specimen type and a given parameter, e.g., modification of measuring range and uncertainty
- **FLEXIBILITY CONCERNING THE METHOD**
  - allows adoption of methods that are equivalent to methods already covered by accreditation

