IAF-ILAC-ISO/CASCO JOINT WORKING GROUP ON IMAGE AND INTEGRITY OF CONFORMITY ASSESSMENT

OBJECTIVES AND ROLES OF "ACCREDITATION" AND "CERTIFICATION" OF LABORATORIES

1 Background

For laboratories and users of laboratory services, occasionally there is misunderstanding and confusion about the objectives and functions of "accreditation" based on ISO/IEC 17025:1999 *General requirements for competence of testing and calibration laboratories*, and "certification" of laboratories based on ISO 9001:2000, *Quality management systems – Requirements*.

This communiqué was prepared by the IAF-ILAC-ISO/CASCO Joint Working Group on Image and Integrity of Conformity Assessment to clarify the key distinctions between the two different types of recognition of laboratories by either accreditation bodies or certification bodies.

It is important to note that there are differences in both the emphasis of the standards (ISO/IEC 17025 and ISO 9001) and in the processes used to determine compliance with them.

2 What do the Standards Specify?

ISO/IEC 17025 was developed as a special purpose standard for laboratories to specify the general requirements for their *technical competence*. While the Standard is generic it also recognises that for accreditation purposes (i.e. for independent recognition of a laboratory's competence to perform specific tests, or calibrations) the Standard may require development of guidelines to explain its use in specific areas of testing or measurement.

ISO/IEC 17025:1999 has two major components, namely *management requirements* and *technical requirements*. The *management requirements* are written in language relevant to laboratory operations but were developed to meet the systems requirements of ISO 9001:1994 and ISO 9002:1994[1].

For accreditation against ISO/IEC 17025 the *emphasis* is to establish the *technical competence* of a laboratory for a *defined set of tests, measurements or calibrations*. In doing so, however, compliance with the Standard's management requirements is also assessed. However, accreditation against ISO/IEC 17025 should not be interpreted to be the same as certification against ISO 9001.

[1] ISO/CASCO is currently reviewing ISO/IEC 17025 *management requirements* for possible alignment with ISO 9001:2000.

ISO 9001:2000 is a generic standard for quality management systems applicable to all organisations irrespective of type, size or product or service provided. Therefore, it is also applicable to laboratories, even though its language is generic. Its purpose is to specify a quality management system that will allow an organisation to demonstrate its ability to provide product that meets customer and applicable regulatory requirements. It also aims to enhance customer satisfaction, including processes for continual improvements and assurance of conformity.

In applying ISO 9001:2000 to a laboratory's operations, the emphasis for certification bodies is to establish compliance with *quality management systems* requirements. Unlike ISO/IEC 17025, it does not contain technical requirements for laboratory personnel and operations and, as such, certification against ISO 9001:2000 should not be interpreted to mean that it demonstrates the technical competence of a laboratory to produce valid data and results.

3 What are the Differences between the Processes used for Laboratory Accreditation and Certification?

Apart from the different emphasis of the two Standards, there are some fundamental differences in the processes used by accreditation bodies and certification bodies to establish compliance with ISO/IEC 17025:1999 and ISO 9001:2000 respectively.

Because laboratory accreditation aims to recognise *specific technical competence*, the assessments of laboratories are conducted by teams comprising relevant technical experts and assessors able to evaluate compliance with the management systems requirements of ISO/IEC 17025. While the management system requirements are an important component of a laboratory's assessment for accreditation, the major *emphasis* is on determining the *specific technical competence* of personnel and the availability of all the technical resources needed to produce reliable data and results for specific test methods. Often the accreditation process will also use objective data from proficiency testing programs to assist accreditation decisions. (Proficiency testing programs are described in detail in ISO/IEC Guide 43: Parts 1 and 2:1997).

For certification of a laboratory against ISO 9001:2000, the assessment team will consist of auditors with detailed experience in assessment of quality management systems. They may have the technical expertise (or be supported by technical experts) to enable them to apply the generic requirements of the Standard to the operations of laboratory services, but the *emphasis* is on determining compliance with the *quality management system requirements*.

4 Accreditation or Certification of a Laboratory or Both?

Some laboratories are not stand-alone facilities. They may form part of a larger organisation, which may have a need to be certified against ISO 9001:2000, while the laboratory's testing or calibration functions may also need to be accredited against ISO/IEC 17025

The decision to seek accreditation or certification of a laboratory (or both) will depend on the overall needs of each laboratory and the expectations of its customers, regulators or other interested parties for their reassurance about the specific technical competence of a laboratory or about its compliance with quality management systems only.