

# Accreditation of laboratories: can the laboratory quality system meet the requirements and challenges of the future laboratory business

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The operational environment of testing laboratories has changed a great deal during the past five to ten years, and the changing process is expected to continue. Laboratories are forced to operate more and more in open competition and in the normal business environment of the private sector. These changes extend many expectations on the management of the future laboratory. Originally scientifically oriented laboratories must adopt business management and leadership components in their operation. One of these components is the third party audited and certified quality system (QA-system). ISO 9000 has been widely used as a quality standard by the industrial and process laboratories as a part of the host organization. On the other hand, the EN 45001 standard series has been tailored especially for testing laboratories featured by their specific requirements. There is a distinct difference between these standards, the former aims at certification and the latter at accreditation. However, there is an evident need to bring these standards closer to each other in order to avoid additional costs due to multiple audits and certifications. The new ISO Guide 25 is an attempt to get an internationally accepted standard for laboratory QA-system fulfilling both the requirements of the ISO 9000 and

the EN 45001. The new ISO Guide 25 includes sampling at least to some extent as a part of the laboratory processes. This aspect is welcome, considering an essential role of sampling in the entire chain: sampling — sample pre-treatment — analysis.

However, insufficiencies still remain in the standard. It is still very technically oriented. Not neglecting the essentiality of for example calibration, there is an evident need for a holistic view of the entire laboratory management and operation process. One of the critical issues will be the management of the laboratory — client interface, where most of the method development ideas and needs are born. To guarantee, that the laboratory is not only doing the things right, but also doing right things, well organised communication between laboratory and client is essential. The development of the laboratory must be seen as a continuous process of improvement, where all staff members contribute. The systematic self audit exercises are good tools in helping to focus on the most urgent development projects.

By adding the systematic development of the personnel and benchmarking to the leading international laboratories, the laboratory management approaches the Total Quality Management concept (TQM). Fulfilling the requirements of the ISO Guide 25 or EN 45001 is a must, but unfortunately not enough.

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