

## **Calibration Systems, ISO/IEC 17025, ISO 10012 or both?**

Trevor offers answers to metrology and accreditation questions and in this issue he considers the relative roles of ISO/IEC 17025:2017 and ISO 10012:2003 in providing assurance of the work undertaken in a calibration system.

The role of a calibration system in any organisation calibrating measuring instruments and standards is to ensure that calibrations conducted are valid, consistent, and meeting the user's needs. That system may be for a calibration laboratory existing for the purpose of selling its calibrations or may be for a small part of a larger organisation needing calibrations within its own organisation, as would be the case of a manufacturer, either of measuring instruments or of any goods needing to meet a technical specification.

The standard ISO 9001 specifies management system features, previously known as "quality system", which should ensure consistent fulfilment of requirements. It may be applied in any industry or commerce situation and is very broad in application. It is revised and modernised every few years and presently features a risk-and-opportunity-based approach which is necessarily less prescriptive than hitherto. There are sectorial interpretations for some industries and these are more focused on that industry's needs. The standard ISO 10012:2003 might be considered as such an interpretation for organisations with calibration systems. Certainly, if ISO 10012 is followed then that management system should comply with ISO 9001 for that work. It is presently under review and may be republished with a version featuring risk and opportunity to match the latest ISO 9001.

The essential difference between ISO 9001/10012 and ISO/IEC 17025 is that the later contains competence criteria as well as management system features. It is used by accreditation bodies to accredit the competence of calibration laboratories as it also contains technical requirements to be met by a competent calibration supplier giving valid results.

Features manifest in a competent calibration supplier would include all these below:

**A management system** ensuring consistency of application, understanding and implementing customer requirements. It features contract review, internal audits, complaint handling and more. It is usually described in some form of quality manual. This is covered by 9001/10012 or similar as well as in 17025.

**Technical Competency** as provided by staff training, competency criteria, suitable equipment and environment, validated and verified methods and procedures, uncertainty budgets (no result is valid without knowledge of how uncertain that result is!) and more. This is described in 17025.

**Quality Assurance Measures** to ensure that valid results are actually obtained in practice. "The proof of the pudding" by taking part in interlaboratory comparisons with other laboratories. This is an important feature to provide confidence and to be compliant with 17025.

DIAGRAM

The diagram shows the main features of a credible calibration system. A management system demonstrating the consistent fulfilment of the technical requirements of ISO/IEC 17025 is required. That management system is described in ISO 17025 itself or use may be made of ISO 9001 as a basis.

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