UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

TESTED & ACCEPTED

Implementing ISO/IEC 17025:2017

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The document was written by Dr. Stefanie Vehring based on the previous UNIDO issue "Complying with ISO 17025" (2009) by Dr. Alan G Rowley. Dr. Vehring participated in the Working Group on the latest revision of ISO/IEC 17025 (2017) and, since then, has been involved in training on the new version for various audiences.

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DISCLAIMER

Foreword

Developing countries are constantly striving to enhance their export competitiveness, strengthen their export base and become more integrated with international trade flows. To achieve this, they need to be able to access increasingly complex global markets with rigorous quality standards. In order to "make the grade" in exporting to these competitive markets, it is necessary to demonstrate compliance with global quality infrastructure (QI) markers: standardization to achieve compliance with international standards; metrology services to demonstrate accurate measurements; certification and accreditation to prove that goods and services have been tested according to agreed methods. Convenient and cost-effective conformity assessment services are also vital to demonstrate that products have been tested, inspected and certified prior to entering the market.

This publication provides practical guidance to ISO/IEC 17025, the international standard for the competence of testing and calibration laboratories. It is intended to aid laboratories to conform to the ISO/IEC 17025 requirements as well as when they transition to the revised 2017 standard.

Today it is widely acknowledged that a first step in facilitating acceptance of foreign-generated test results happens through accreditation, using an agreed set of general criteria for the competence of testing laboratories. Without consensus on accreditation, it is impossible to generate the cross-border confidence in product standards necessary to enable international trade.

The bedrock of our current international accreditation regime dates back to 1978, at the Second Conference on Facilitating Cross-border Acceptance of Test Results, which became known as the International Laboratory Accreditation Conference (ILAC) (later changed to a Cooperation in 1996 through the establishment of a network of mutual recognition agreements among accreditation bodies). A small group of national accreditation body leaders developed the first draft, which was presented to the International Organization for Standardization (ISO) for adoption as the ISO Guide 25. This formed the basis for the founding of ISO/IEC 17025.

Up to the present day, ISO/IEC 17025 enables laboratories to demonstrate that they operate competently, to an agreed framework, generating valid results, thereby promoting confidence in their work both nationally and around the world. ISO/IEC 17025

helps facilitate cooperation between laboratories and other bodies by generating wider acceptance of test results between countries. Test reports and certificates are accepted by one country to another without the need for further testing, which, in turn, accelerates and improves confidence in international trade.

The ISO Guide 25 was initially used to underpin bilateral mutual recognition arrangements (MRAs) between accreditation bodies. MRA signatories agree to accept each other's accreditations as equivalent and to promote acceptance of accredited results within their economies. In November 2000, ILAC converted the numerous bilateral and two regional multilateral arrangements into a global multilateral mutual recognition arrangement signed by 36 accreditation bodies from 28 economies, simplifying and enhancing the international acceptance of accreditation regimes significantly. The aim was to facilitate trade by promoting the acceptance of accredited test and calibration results for exported goods. The ILAC Mutual Recognition Arrangement (often referred to as the ILAC Arrangement) was the culmination of 22 years of intensive work aimed at establishing a multilateral regime in the field of laboratory policy. ISO/IEC 17025 is the foundation of that arrangement.

As the largest multilateral player in quality infrastructure development, with a proven track record of enhancing national capacities, the United Nations Industrial Development Organization (UNIDO) is the preferred partner of many developed countries (as donors) and developing countries (as recipients of international technical assistance) for ensuring that quality infrastructure specifications are met on a worldwide basis. Policymakers and practitioners turn to UNIDO for their transformative and tailored solutions, from specialized training to the transfer of technical knowledge.

For more than 50 years since its establishment, UNIDO has been supporting developing countries and countries in transition in the development of their quality infrastructure, through the setting up of National Standards Bodies (NSB) and National Metrology Institutes (NMI), and during the last two decades, the establishment of Accreditation Bodies (AB). During this time, UNIDO also has supported more than 1,000 Conformity Assessment Bodies (CABs) in 58 countries across the different regions in the world, helping developing countries to increase their productive capacities, export bases and, domestic and foreign investment. UNIDO helps laboratories committed to conform to ISO/IEC 17025, enabling them to reap tangible benefits for their operation and delivery of results. This supports effective decision-making be it for assuring product quality, protecting the health of consumers, ensuring safety, or promoting sustainability and protection of the environment.

UNIDO has been a partner of ILAC since its establishment and collaborates closely with ISO and its Committee on Conformity Assessment (CASCO). Today, UNIDO, ILAC and ISO are all members of the International Network on Quality Infrastructure (INetQI), an initiative that brings together the specialized quality infrastructure organizations operating at international level and that are active in promoting and implementing quality infrastructure activities (metrology, accreditation, standardization and conformity assessment) as a tool for sustainable economic development.

It is evident that establishing reliable quality infrastructure can substantially assist a country in pursuing a development path aligned with the SDGs, overcoming the challenges involved, and benefitting from the considerable opportunities generated through the achievement of the 2030 Agenda. Without a rigorous quality infrastructure domestic regime, a developing country will find it difficult to achieve the competitiveness needed to propel inclusive and sustainable industrialization (as embedded in SDG Goal 9) in particular.

As a leader in the field of quality infrastructure, UNIDO will have a big role to play in shaping the future of conformity assessment globally. By aligning its approach for quality infrastructure development and technical support to the demands of the digital era, it can ensure that it continues to provide a diversified and effective programmatic suite of technical cooperation, policy analysis and advice, and convening services for the benefit of its member states.

Li Yong

UNIDO Director General

Preface

Over the past 20 years, the United Nations Industrial Development Organization (UNIDO) has been the largest multilateral player in quality infrastructure development and a preferred partner of many developed (as donors) and developing countries (recipients of international technical assistance). It has a proven record of enhancing the national capabilities for standardization, metrology, conformity assessment, accreditation and market surveillance, allowing developing countries to increase their productive capacity, export base and domestic and foreign investment.

This publication is written as a guidance to ISO/IEC 17025, the international standard that specifies the general requirements for competence, impartiality and consistent operation of testing and calibration laboratories. It is intended to aid laboratories when establishing and maintaining ISO/IEC 17025 as well as when transitioning the implemented standard to the revised version of 2017.

Conformity with ISO/IEC 17025 provides a globally accepted basis for recognition of laboratories by customers, regulatory authorities, organisations and schemes using peer-assessment, accreditation bodies and others.

The standard specifies the technical requirements for competent laboratories. Requirements in order to ensure impartiality with regard to the outcome of the laboratory activities, e.g. testing a sample or calibrating an item, are of particular importance. Finally, ISO/IEC 17025 contains system requirements for managing consistent operation of laboratory activities.

This Guidebook should assist laboratories in identifying where they fulfil the requirements of ISO/IEC 17025 and in taking measures where fulfilment has yet to be achieved.

It follows the structure of the standard and provides clause by clause a description of the requirements along with further clarification and advice on the demonstration of fulfilment.

The guidance begins with key topics of each clause and the relation to corresponding requirements according to former ISO/IEC 17025 version of 2005.

Fundamental changes with the revised version of 2017 are summarised ahead of Chapter 5. Detailed cross-references between the two versions of ISO/IEC 17025 are given in Annex A.

Laboratories seeking accreditation by a recognised accreditation body will find the relevant documents of the International Laboratory Accreditation Cooperation (ILAC) indicated, where applicable, and referenced in the Bibliography. Also listed there are publications with basic references for ISO/IEC 17025, such as terminology documents or the management system standard ISO 9001, as well as further specifications, such as uncertainty of measurements, reference materials or management system audits.

An overview on the history and role of testing and calibration is given in Chapter 1.

Chapters 2 to 4 contain background information on trade (UN Sustainable Development Goals, World Trade Organisation, trade agreements), quality infrastructure (metrology, standardisation, conformity assessment, accreditation) and conformity assessment (testing, inspection, certification, validation, verification).

Abbreviations

BIPM	Bureau International des Poids et Mesures
CASCO	Committee on Conformity Assessment
CETA	Comprehensive Economic and Trade Agreement
CRM	Certified Reference Material
EC	European Commission
EU	European Union
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
ISO	International Standardisation Organisation
IT	Information technology
LIMS	Laboratory information management system
MLA	Multilateral Recognition Arrangement
MRA	Mutual Recognition Arrangement
OIML	Organisation Internationale de Métrologie Légale
QI	Quality Infrastructure
QP	Quality Policy
SDG	Sustainable Development Goals
SI	Système International d'unités
SOP	Standard operating procedure
SPS	Sanitary and Phytosanitary Measures
TBT	Technical Barriers to Trade
TF	Trade Facilitation
UN	United Nations
UNIDO	United Nations Industrial Development
VIM	International Vocabulary of Metrology
WTO	World Trade Organisation

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UNIDO – Quality Policy – Guiding Principles (2018)

ISO UNIDO – Building Trust – The Conformity Assessment Toolbox (2010)

ISO UNIDO – Fast Forward – National Standards Bodies in Developing Countries (2013)

ISO – Contributing to the UN Sustainable Development Goals with ISO standards (2018)

BIPM – SI Brochure – The International System of Units (2019)

EURACHEM Guide – The Fitness for Purpose of Analytical Methods (2014)

EURACHEM Guide – Quantifying Uncertainty in Analytical Measurement (2012)

Links

www.iso.org

www.unido.org

www.un.org/sustainabledevelopment

www.wto.org

www.iso.org/casco

www.ilac.org

www.eurolab.org

www.eurachem.org

www.eptis.org

Standards

ISO/IEC 17025 – General requirements for the competence of testing and calibration laboratories

ISO/IEC 17000 – Conformity assessment – Vocabulary and general principles

ISO/IEC Guide 99 (VIM) – International vocabulary of metrology – Basic and general concepts and associated terms (also known as JCGM 200)

ISO 9000 – Quality management systems – Fundamentals and vocabulary

QS-CAS-PROC-33 – Common elements in ISO/CASCO standards

ISO 9001 – Quality management systems – Requirements

ISO 15189 – Medical laboratories – Requirements for quality and competence

ISO/IEC 17043 – Conformity assessment – General requirements for proficiency testing

ISO 17034 – General requirements for the competence of reference material producers

ISO 10012 – Measurement management systems – Requirements for measurement processes and measuring equipment

ISO Guide 33 – Reference materials – Good practice in using reference materials

ISO Guide 80 – Guidance for the in-house preparation of quality control materials (QCMs)

ISO 19011 – Guidelines for auditing management systems

ISO/IEC Guide 98-3 – Uncertainty of measurement – Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)

ISO/IEC Guide 98-4 – Uncertainty of measurement – Part 4: Role of measurement uncertainty in conformity assessment

IEC Guide 115 – Application of uncertainty of measurement to conformity assessment activities in the electrotechnical sector

JCGM 106 – Evaluation of measurement data – The role of measurement uncertainty in conformity assessment

ISO 21748 – Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty evaluation

ISO 5725 ff. – Accuracy (trueness and precision) of measurement methods and results

Accreditation documents

ILAC G8 – Guidelines on decision rules and statements of conformity

ILAC G17 – Introducing the concept of uncertainty of measurement in testing in association with the application of the standard ISO/IEC 17025

ILAC G18 – Guideline for the formulation of scopes of accreditation for laboratories

ILAC G24 – Guidelines for the determination of calibration intervals of measuring instruments

ILAC P9 – ILAC policy for participation in proficiency testing activities

ILAC P10 – ILAC policy on traceability of measurement results

ILAC P14 – ILAC policy for uncertainty in calibration

The United Nations Industrial Development Organization (UNIDO)

THE UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION (UNIDO)

The United Nations Industrial Development Organization (UNIDO) helps developing countries and countries with economies in transition to develop an inclusive, competitive and environmentally sustainable industry to accelerate economic growth, reduce poverty and achieve the United Nations Sustainable Development Goals (SDGs). UNIDO's mandate is fully recognized in SDG-9, which calls to "Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation".

In pursuit of these objectives, UNIDO draws on global resources and expertise, and combines operational technical cooperation services with analytical, normative and convening activities, globally, regionally and locally.

UNIDO holds a special place in the United Nations system as the only organization with a mandate to promote industrial development worldwide. The Organization focuses on four inter-related thematic priorities:

» Creating shared prosperity

» Advancing economic competitiveness

» Safeguarding the environment

» Strengthening knowledge and institutions

In carrying out its mandate, UNIDO has considerably increased its portfolio of technical services over the past ten years. At the same time, it has also substantially increased its mobilization of financial resources, testifying to the growing international recognition of the Organization as an effective provider of industrial development services.

UNIDO has 170 Member States and is headquartered in Vienna, Austria, but operates worldwide, through its network of country and regional offices. Established in 1966, it became a specialized agency of the United Nations in 1985.

UNIDO's work in conformity assessment

The ability of developing countries to exploit commercial opportunities, to compete on global markets and to participate in international value chains is often challenged by their difficulties in demonstrating compliance with international quality requirements and trade rules. UNIDO helps to tackle these challenges by working with national, regional and international partners to strengthen the compliance capacity of public and private actors within the quality infrastructure system. UNIDO's unique approach offers developing countries and economies in transition opportunities to eradicate poverty and develop sustainably. UNIDO helps them to build up their industrial base as a platform for social inclusiveness, economic competitiveness, environmental sustainability and integrating with the global trading system.

UNIDO has a proven track record in developing quality infrastructure (QI) that acts as a multiplier for the efforts of developing countries to improve their industrial and economic performance as a basis for prosperity, health and wellbeing. The benefits of standardization in improving economic efficiency and providing access to world markets cannot be achieved without the ability to make reliable measurements and to be able to demonstrate that items conform to the requirements specified in the standards.

QUALITY INFRASTRUCTURE (QI) is the system comprising the organizations (public and private) together with the policies, relevant legal and regulatory framework, and practices needed to support and enhance the quality, safety and environmental soundness of goods, services and processes. The quality infrastructure is required for the effective operation of domestic markets, and its international recognition is important to enable access to foreign markets. It is a critical element in promoting and sustaining economic development, as well as environmental and social wellbeing. It relies on metrology, standardization, accreditation, conformity assessment, and market surveillance.

International Network on Quality Infrastructure (INetQI)

At the core of UNIDO's quality infrastructure mandate lies the firm belief that through enhancing conformity assessment capacities of developing countries, these countries will be able increase their potential for export, engage in global trade and thus boost their population's wellbeing. Against this background, quality infrastructure not only contributes to enhanced economic prosperity, but also to improving people's livelihoods and safeguarding the environment.

As part of their quality infrastructure, all economies need access to credible conformity assessment services. These are needed for a variety of purposes, including:

» Demonstrating that products, processes, services, commodities and personnel meet required specifications. These may include requirements specified under regulations (domestic or foreign), purchasers' specifications, trade agreements etc.

» Establishing and monitoring appropriate requirements for the protection of health, safety and the environment.

» Underpinning public infrastructure services in construction, energy, water and gas supplies, defence, transportation and communication systems.

» Protecting consumers through control of unfair trading practices.

» Demonstrating the credibility of forensic and justice systems.

» Ensuring the compatibility and interoperability of components in products and systems.

» Assisting the quarantining of harmful commodities, products, pests and diseases from entering an economy.

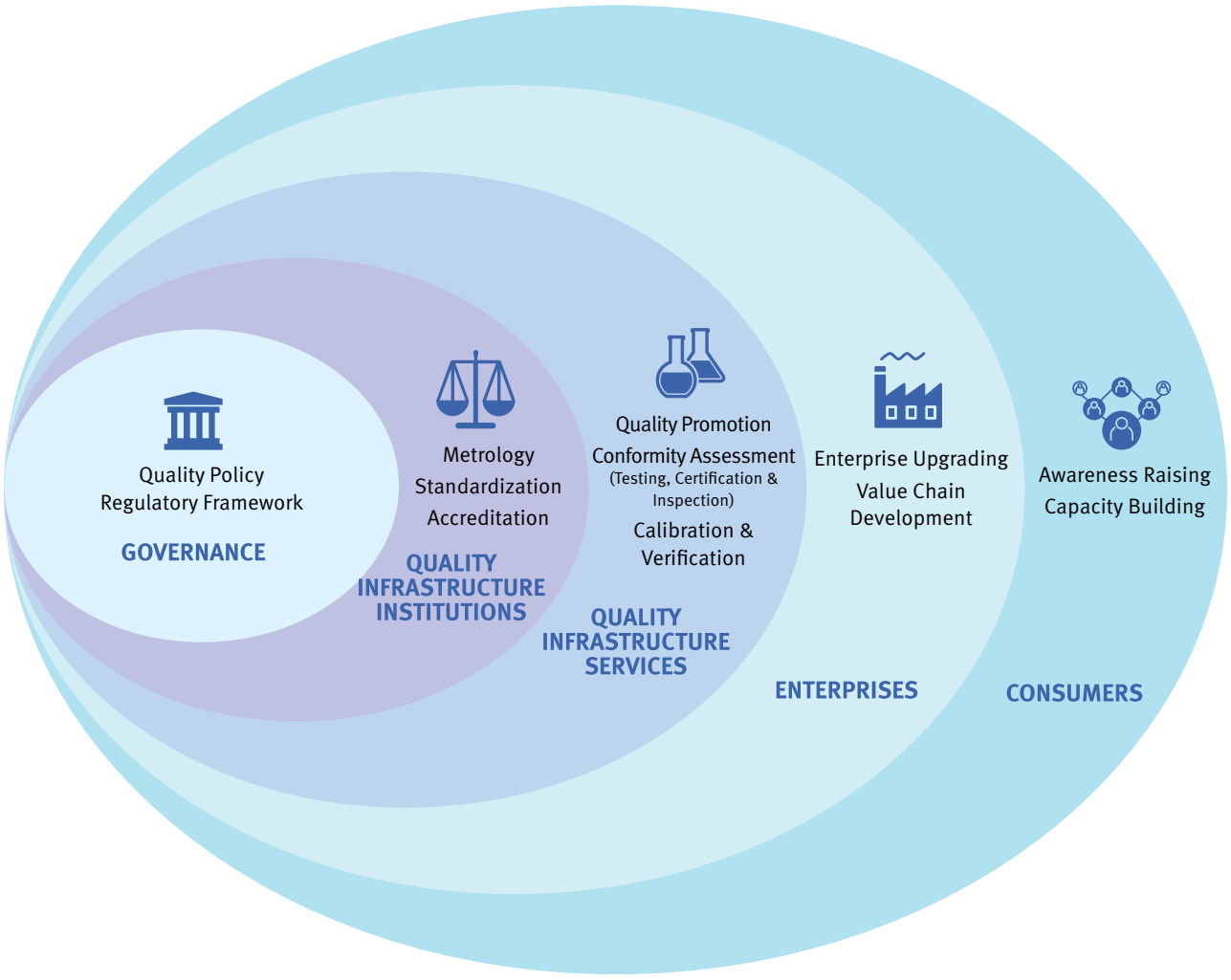
» Improving international trading opportunities by reducing technical barriers to trade and demonstrating compliance with specifications of international standards, technical regulations and commercial specifications.

Most societies recognise the domestic benefits of their quality infrastructure and many have established the appropriate national bodies and international relationships to support their system. However, national systems that are not harmonised regionally or internationally have the potential to introduce new technical barriers to trade. Both developed and developing countries are increasingly being expected to demonstrate that the products and services they produce are reliable, safe and environmentally responsible according to international standards. To achieve this aim, each economy requires an effective domestic technical capability (or access to foreign expertise) to underpin the conformity assessment services in their country.

Historically, UNIDO's approach to quality infrastructure development focused on strengthening the supply side capacity of quality infrastructure institutions, namely national standards bodies, national metrology institutes and accreditation bodies. Soon, this support was extended to include public and private providers of quality infrastructure services, most importantly conformity assessment bodies.

Today, UNIDO's approach to QI development is systemic and holistic, from building awareness to helping initiate, develop and strengthen a fit-for-purpose QI that runs efficiently and is cost-effective. UNIDO promotes good practices, capacity building and training, and fosters global cooperation in the development of standards- setting, measurement and

The Quality Infrastructure System



compliance along value chains. It works with partners from the public and private sectors, academia, national and international organizations engaged in standards development, and global metrology, standards and conformity assessment practice.

Throughout the past 20 years, UNIDO has strengthened the capacity of more than 1,000 Conformity Assessment Bodies (CABs) in 58 countries worldwide, including Asia, Africa, Central and South America, and South-Eastern Europe. On-the-ground support for testing and calibration laboratories accounts for approximately 75% of UNIDO's total technical assistance in the area of quality infrastructure development over the past two decades.

Most of the CABs supported (70%) were located in lower-middle-income countries such as Pakistan, Myanmar and Ghana. Low-income countries such as Malawi, Mozambique and Nepal make up for 19% of UNDIO technical assistance to CABs, followed by upper-middle income countries such as Namibia, Colombia and Thailand, accounting for 11%.

Out of the more than 1,000 CABs supported, approximately 26% have been supported towards and have been accredited, many of them in reference to ISO 17025. The subject guide book will serve as a valuable tool to support these efforts and assist developing countries towards the globally accepted accreditation of their testing services.

In its work, UNIDO combines a multitude of unique methodologies and tools, most of which are available free of charge on the UNIDO's Trade, Investment and Innovation Knowledge Hub (https://tii.unido.org). Some of the moist relevant tools are outlined below.

» Based on its experience of designing 26 national and three regional policies for developing and countries in transition, UNIDO with its partners in the International Network on Quality Infrastructure (INetQI), has developed a set of guiding documents for quality policy development. This set of three documents as well as an interactive online training on the subject matter, are available on the TII Knowledge Hub. This specific set of tools aims at supporting quality infrastructure practitioners and policy makers to design and develop robust, holistic, and demand-driven quality infrastructure systems.

» Developing timely and relevant policies is also recognised as the best approach to facilitate reforms and set strategic directions for conformity assessment. This allows for a holistic overview that incorporates the national and regional development vision, best international practices as well as market and sectoral needs. UNIDO's record in QI and laboratory capacity building allowed it to develop guidance on the development of a Laboratories Policy (LP) that helps countries to establish a fit-for-purpose, efficient and effective laboratory capability.

» Border rejections bear important and very specific information on compliance challenges of certain products and countries. UNIDO's unique tool on Rejection Analysis provides information on reasons for border rejections in major import markets (incl. EU, USA, Australia, Canada, Japan), allowing exporting nations to identify compliance bottlenecks for specific product groups and addressing them effectively.

» The Laboratory Network (LabNet) seeks to strengthen supply side capacities and at the same time create demand for conformity assessment services, through the provision of relevant information for CABs and those seeking conformity assessment services. This unique database brings together conformity assessment service providers and enterprises looking to prove that their products are fit-for-purpose.

» A guide on Setting up Accreditation Bodies in Developing Countries, jointly published with the International accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC).

» The Trade, Investment and Innovation Training Academy, also hosted on the Knowledge Hub, provides a number of interactive online trainings on relevant topics, such as 'Quality Infrastructure and Trade', 'Quality Policy' and 'Quality Management'. It also contains online trainings on 'E-commerce', 'Industry 4.0' and relevant topics in the areas of trade, investment and innovation.

UNIDO is constantly looking to improve its methodologies and complement the existing repertoire of tools with additional approaches.

New technologies call for change

Today, we are at the early stages of the Fourth Industrial Revolution (4IR), which brings digital, physical and biological systems together. From artificial intelligence to mobile supercomputing, the 4IR is transforming every part of our lives. Quality Infrastructure (QI) is no exception.

New technologies are constantly shaping the ways in which we work and live. Artificial intelligence, distributed ledger technologies, smart sensors, and next generation automation are at the heart of the new paradigm shift t. The Fourth Industrial Revolution is ushering in a structural transformation in the global economy and leading to a new division of labour and will eventually lead to a new geography of production. It is giving rise to the "factory of the future," in which digitally enhanced plant structures and processes increase productivity and flexibility in the factory but also throughout the supply chain.

These megatrends hold enormous opportunities and at the same time new pathways for achieving the 2030 Agenda for Sustainable Development are being unlocked by technological innovations. The 4IR has the potential to enhance global manufacturing output to meet the rising demands of a growing population for food, water, energy and materials, while protecting the environment. In other words, it can give rise to viable alternatives to the linear economy by decoupling

economic growth from resource constraints. The concept of circular economy is gaining increasing attention worldwide as a means to reduce dependency on primary materials and energy. In the circular economy, products are designed for durability, reuse and recyclability, and materials for new products come from old ones. At the same time, significant numbers of jobs and job sectors will be vulnerable to new technologies. The 4IR will exert a particularly strong influence on education and skill requirements, which is likely to be felt most in developing countries.

Amidst all of these disruptive changes, the desire for proven quality and safety from export markets will remain intact. Quality infrastructure must therefore adapt to remain a trust provider but also to help propel the technologically-driven paradigm change. Reactive policies and processes will become increasingly important to capture and accelerate the potential of these megatrends. Moreover, firms are changing their approach towards quality with a stronger emphasis on pre-empting than taking corrective actions. We are at a cusp of Quality 4.0, where companies can monitor their operations based on real-time data and predict quality issues and maintenance needs.

Of all the QI actors, conformity assessment bodies, including testing and calibration laboratories as well as inspection and certification bodies, are those that are most in contact with the industry and markets. CABs will have to embrace the ongoing transformation to enhance the services they provide by increasing optimization and flexibility. The use of new non-traditional models (drones for inspection, machine learning, smart sensors algorithms) can provide CABs with the opportunity to provide their services more efficiently and effectively, thereby reinforcing their role as "providers of trust".

CABs worldwide, and in developing countries in particular, will face big challenges to cope with demands of the 4IR. Conformity assessment, is rarely guided by a clear policy framework that can guide, reform, consolidate and maintain an effective system. In particular, developing countries continue to operate their conformity assessment based on outdated, incoherent and costly policy frameworks. There is a need for overarching quality policy frameworks to put in place long-term economic goals and lay out strategic directions, while outlining concrete and targeted policy measures that are fine-tuned to the specific needs of a particular economy.

In addition, outdated institutional frameworks hinder adequate allocation and use of resources, information sharing and often exacerbate shortcomings in service provision. Poor coordination of existing laboratories and overlapping mandates between laboratories that are sometimes established under different government agencies lead to wasting of resources, duplication of efforts and create obstacles for the private sector to identify the relevant conformity assessment providers.

Coping with the demands of the 4IR will be a particular challenge in developing countries, where systems and laboratories are not always as effective as they could be. Shortcomings can include outdated institutional frameworks, inadequate coordination of laboratories, poor information sharing and unnecessary duplication of efforts – ultimately leading to a waste of valuable resources. For private sector companies, it can be hard to find conformity assessment providers that are both relevant and competent. And the challenges don't end there: CABs in developing countries can also struggle to fulfil their mandated services – such as testing, inspections and certifications – due to a lack of equipment, facilities, and laboratory staff with the right knowledge or training.

Towards the Achievement of the Sustainable Development Goals (SDGs)

The UN's 17 Sustainable Development Goals (SDGs) represent a global call for action to protect the planet, ensure dignified lives for all people, and achieve inclusive economic development, peace and prosperity. The SDGs are universal, provide a holistic approach to future development and are intended to provide guidance to both public and private actors everywhere in the world.

National and regional QI institutions will continue to play a fundamental role in achieving the 2030 Agenda and the SDGs. The future of QI needs to be sustainable and consider prosperity, people and the planet.

To meet the challenges of this new era, there is a pressing need for quality infrastructure in general, and conformity assessment in particular, to adjust to the new paradigm. Technological innovations promise to transform not only the production methods and business models but also the way quality infrastructure is achieved. In order to keep up with the demands of technological change, quality infrastructure and conformity assessment services, which are critical to the enhancement of market accessibility in the digital era, also need to adapt and evolve.

We are entering a digital era where the rise of new technologies such as the internet of things (IoT), artificial intelligence (AI), additive manufacturing (3D printing) and blockchain will require new standards, as well as new quality requirements, to be developed to establish best practices and facilitate their sustainability. For instance, inspection by drones is already used to allow access to areas that may pose health, safety and environmental risks in a fast, cost-effective and safe way. Similarly, optical and laser systems are helping to advance non-contact metrology that is becoming increasingly intelligent and networked.

Amidst all these disruptive changes, the desire for quality and safety from export markets and consumers in those markets will remain intact. Digital and technological transformation in CABs also needs to be embraced, as the uptake of new technologies will likely enhance the services they provide, and increase optimization and flexibility. This will ensure that key players within the QI arena remain relevant and continue to be providers of trust in the existing but also new sectors, such as e-commerce.

It has been shown that establishing QI can substantially assist a nation in pursuing a development path aligned with the SDGs, overcoming the challenges involved, and benefitting from the considerable opportunities generated through achieving of the Sustainable Development Goals. As a leader in the field of QI, UNIDO will have a large role to play in the future of Conformity Assessment. By aligning its approach for QI development and technical support to the demands of the digital era, it can ensure its contributions remain both timely and sustainable.

UNIDO's activities will continue to stimulate knowledge transfer – particularly for CABs in developing countries – to ensure that no country is left behind. QI plays an essential role in supporting the achievement of the Sustainable Development Goals and UNIDO will cooperate with all relevant stakeholders to this end.

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1

Introduction

History of ISO/IEC 17025

Institutions for testing or calibration play a long-standing role in providing professional services and reliable results to market, authorities, research and production.

Standards have been developed not only to ensure repeatable and reproducible performance of these laboratories, but also to provide confidence in the quality of their work and the validity of their results.

The international standard ISO/IEC 17025 has been established as a basis to demonstrate the competence of laboratories.

Its preceding document, ISO/IEC Guide 25, consolidated in 1990 several international guides with acceptance criteria for testing facilities, published as early as 40 years ago.

The origin of ISO/IEC Guide 25 was the result of a conference on cross-border acceptance of test data. It was agreed by a small group of accreditation bodies to develop general criteria for the competence of testing laboratories to enable the acceptance of each other's accredited test data across national borders. It was also agreed to turn over the work to ISO.

With the aim to be implemented by national standardisation bodies to achieve harmonisation for bi-/multilateral agreements, ISO/IEC Guide 25 specified general requirements for the competence of calibration and testing laboratories.

The application evolved from providing a guidance document as a basis for harmonisation to providing standardised requirements as a basis for direct recognition of laboratories, published as ISO/IEC 17025 for the first time in 1999.

This international standard was compatible with ISO 9001 "Quality management systems – Requirements" and has been updated according to revisions of ISO 9001 in 2005 and 2017.

Core elements of ISO/IEC 17025 are management requirements for consistent operation together with requirements for impartiality of laboratories and their technical competence as organisation.

Its application is not limited to any sectors or differentiated with regards to internal versus independent laboratories.

Laboratory activities according to ISO/IEC 17025 can be transparently integrated in specific programmes or complex frameworks.

Testing and calibration laboratories are worldwide recognised according to this standard by accreditation.

In 2019, ca. 76,500 laboratories were accredited by bodies organised within ILAC (International Laboratory Accreditation Cooperation) as signatories to the respective mutual recognition arrangement (MRA).

Testing and Calibration

Determining the characteristics of a **test** item or material is one key activity in research and development, when seeking analysis and detection of unknown properties. Examples reach from material testing in construction to blood testing in order to prescribe a particular therapy.

Testing also serves for assuring established and intended qualities. This applies to doping control as well as to minimising the risk of producing, supplying or using faulty products. Failing the test would result in disqualification of an athlete, disregarding a batch of products as well as preventing threats to public safety or financial loss to a client.

Accurate and reliable results from a technically competent and impartial testing laboratory provide confidence and allow for recognition and eliminating the need for retesting, e.g. of shipped goods in the importing country.

Calibration is an operation that establishes a relation between the quantity values provided by measurement standards and corresponding indications (e.g. the display of a measuring instrument). In a second step, this information is used to establish a relation for obtaining a measurement result from an indication (e.g. using the displayed values with a correction factor when expressing as results).

It is important to note that the uncertainties of these values play a significant role when deducing relations and have to be taken into account carefully. This obligation becomes even more apparent, appreciating the potential of dissemination when using calibrated items or instruments as reference or standards.

Measurement results, which can be related to a reference (e.g. a national standard) through documented calibrations of the intermediate references (e.g. calibration standards) are traceable. Traceability within such an unbroken chain of calibrations ensures reliable results and sound conclusions, which are based thereupon.

All equipment in a laboratory, which has an impact on the validity of calibrations or tests, has to be calibrated in such a manner that there is an unbroken chain of comparisons which leads back from the equipment to a recognised international standard of measurement.

This is ideally achieved through central metrology institutes holding national standards for all measurements with links to the international measurement system. Laboratories and industry requiring calibrations can then go to their own national metrology laboratory to have their equipment calibrated in the knowledge that the calibration is internationally traceable.

Such national metrology systems do not exist in all countries, and in these cases calibration laboratories according to ISO/IEC 17025 can provide traceability by having calibrations performed, for example, by a national metrology laboratory in a nearby country.

Sampling is selection and/or collection of material or data regarding an object of conformity assessment. This selection can be on the basis of a procedure, an automated system, professional judgement, etc. Sampling is introduced in the 2017 version of ISO/IEC 17025 as stand-alone laboratory activity along with testing and calibration. This sampling activity is however associated with subsequent testing or calibration.

2

Trade

Sustainable Development Goals

The Sustainable Development Goals (SDG) were adopted in 2015 by countries of the UN as part of the 2030 Agenda for Sustainable Development.

The goals are interconnected and address the global challenges, including those related to poverty, inequality, climate, environmental degradation, prosperity, and peace and justice.

All elements of society, including local and national governments, business, industry and individuals are called for contribution in the corresponding actions to enhance peace and prosperity, eradicate poverty and protect the planet. To be successful, the process requires consensus, collaboration and innovation.

ISO standards are built around consensus, they provide a solid base on which innovation can thrive and are essential tools to help governments, industry and consumers contribute to the achievement of every one of the SDG.

World Trade Organisation Agreements

The Agreement on Technical Barriers to Trade (TBT) by the World Trade Organisation (WTO) aims to ensure that technical regulations, standards and conformity assessment procedures are non-discriminatory and do not create unnecessary obstacles to trade. At the same time, it recognises the WTO members' right to implement measures to achieve legitimate policy objectives, such as the protection of human health and safety or protection of the environment. The TBT Agreement strongly encourages members to base their measures on international standards as a means to facilitate trade.

Under the WTO Agreement on the application of Sanitary and Phytosanitary Measures (SPS), each Member of the WTO has obligations relating to transparency, e.g. countries are required to publish all sanitary and phytosanitary measures and notify changes to SPS measures. In implementing the agreement, countries are required to identify a single central government authority to be responsible for the notification requirements of the SPS Agreement and establish an enquiry point responsible for answering questions from other countries about SPS measures and related issues.

Bureaucratic delays and "red tape" pose a burden for moving goods across borders for traders. Trade facilitation, the simplification, modernisation and harmonisation of export and import processes, has therefore emerged as an important issue for the world trading system.

WTO members reached an agreement on Trade Facilitation (TFA) containing provisions for expediting the movement, release and clearance of goods, including goods in transit. It also sets out measures for effective cooperation between customs and other appropriate authorities on trade facilitation and customs compliance issues. It further contains provisions for technical assistance and capacity building in this area. Elements of the Quality Infrastructure (QI) system, such as standards, testing, inspection, certification and accreditation, play a fundamental role in supporting the TFA.

Conformity assessment in trade agreements

Globalisation results in an immense increase of trade, not only of manufactured goods but also wrought materials, semi-finished parts and services.

Any system that facilitates the worldwide movement of products, services and funds is of huge importance to economic growth. Even though national or regional legal frameworks, policies and safety concepts may differ, trade is supported by harmonised and standardised technical regulations and procedures in order to ensure consumer and environmental protection as well as reliable transfers and interoperable processing.

Competent and reliable assessment for conformity with these specifications provides confidence in the traded goods and allows for acceptance without double checking.

Assuring recognition of conformity assessment bodies and their work consequently plays a significant role in efficient trade agreements as well as in fully integrated internal markets.

In 2014, the European Union (EU) and Canada completed their bilateral negotiations regarding a Comprehensive Economic and Trade Agreement (CETA), which is provisionally in effect as of September 2017.

The Agreement targets to facilitate mutual market access and to intensify trade, for example by a new approach to conformity assessment.

Conformity assessment bodies registered in the EU will be able to assess certain products not just for the European but also for the Canadian market and vice versa. This means, that the legal and normative requirements applying in Canada can be assessed at a European body's own national location. Such a European body has to demonstrate its competence through valid accreditation by a local accreditation body, which is recognised by Canada.

Market surveillance

Market surveillance is undertaken by public authorities to ensure that products comply with the requirements set out in the relevant legislation, e.g. concerning health, safety or any other aspect of public interest protection.

National market surveillance has to identify and withdraw defective goods from the market.

Detecting unsafe nonconforming products can be achieved at points of entry at the external borders before they are placed on the market with effective information of border control by market surveillance authorities.

Testing, inspection and certification of products can complement market surveillance, where market surveillance authorities take account of them when performing checks on product characteristics. When checking quantities of pre-packed goods, legal metrology plays an important role.

3

Quality Infrastructure System

Quality Policy

A Quality Policy (QP) is the policy adopted at a national or regional level to develop and sustain effective and efficient means of supporting and enhancing the quality, safety and environmental soundness of goods, services and processes.

It is often related to a wider multisectoral development strategy and is an approach that is increasingly being adopted, usually at the national level, to further develop, consolidate, refine and appropriately sustain an effective and efficient national or regional Quality Infrastructure (QI) system.

QP also provides an overarching framework that links and underpins other national policies, e.g. development policy, trade policy, industrial and export policy, environmental policy, consumer protection policy, science, research and innovation policy, and investment policy.

The corresponding QI comprises public and private organisations, together with the policies, relevant legal and regulatory framework as well as practices. The QI is required for the effective operation of domestic markets and its international recognition is important to enable access to foreign markets.

Metrology

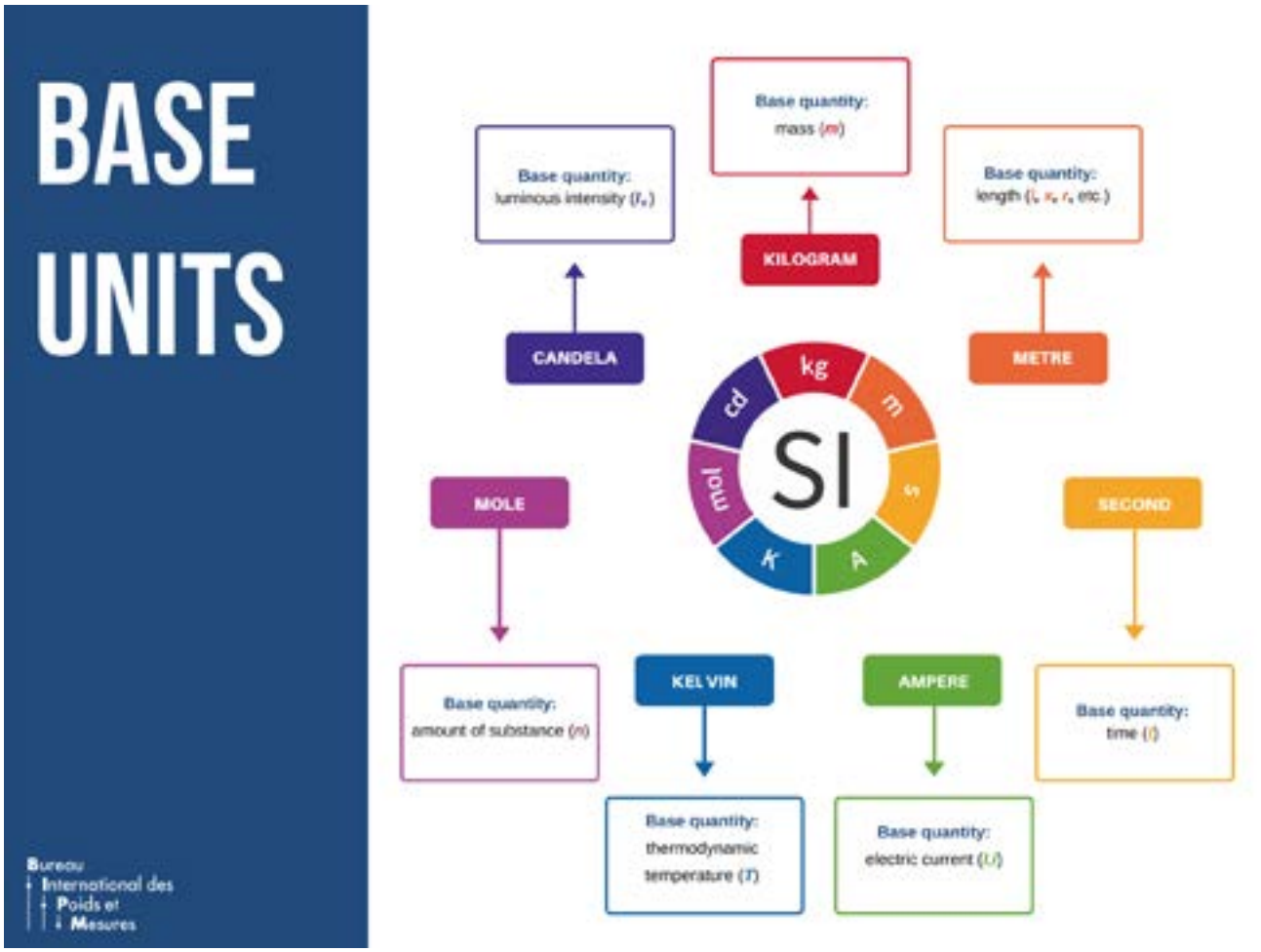
A basic element of QI is metrology, the science of measurement with its common definition of units for length, mass, volume, time and temperature. The realisation of these units with traceability of measurements made in practice to the reference standards allows for reliable and accurate results.

International organisations, such as the International Bureau of Weights and Measures (BIPM), provide the basis for a single, coherent system of measurements throughout the world, traceable to the International System of Units (SI).

Legal metrology involves the legislated use of metrology to ensure that fair weights and measures are applied in both national as well as import and export trade. Typical activities in this field include the calibration of measurement equipment, the type approval of measuring instruments used in trade (e.g. scales, fuel pumps), their ongoing verification and inspection and the application of sanctions in cases of noncompliance with legislation.

Standards used in legal metrology are developed by the International Organisation of Legal Metrology (OIML) and are adopted nationally, usually through the national standards body.

FIGURE 1: SI BASE UNITS



Standardisation

Standards provide specifications and requirements for objects like products, processes, procedures, systems as well as for services, persons or bodies.

Standardisation aims at harmonisation of conditions and compatibility, thereby avoiding technical barriers.

Standardisation bodies are involving all interested parties, participating by delegation, and issuing consensus based documents.

International standards for conformity assessment are developed jointly by ISO (International Organisation for Standardisation) and IEC (International Electrotechnical Commission) in the committee on conformity assessment (CASCO).

Conformity assessment

Wherever an object is characterised or specified by requirements, it can be assessed for its conformity with these specifications. For example, consumer products, working processes, management systems, persons or whole organisations are subjected to conformity assessment, ideally resulting in an attestation that the specified requirements are fulfilled.

The application of conformity assessment is differentiated according to the relation between the involved parties. First parties are considered the least independent and are usually the producer or provider. A second party keeps a relationship with the first party, for instance as customer or supplier. Only the third party fulfils the criteria of the highest independence with no engagement in design, manufacture, supply, installation, purchase, ownership, use or maintenance of the objects under assessment.
The principles and requirements of conformity assessment are specified by international standards (see ISO/IEC 17000 series) and implemented in various commercial and legal frameworks (e.g. the European Single Market).

Accreditation

The competence to carry out specific conformity assessment tasks can be evaluated and attested by third-party accreditation bodies.

An accreditation demonstrates the competence, impartiality and consistent operation of laboratories, inspection bodies, certification bodies for products, processes, services, management systems or persons as well as validation and verification bodies. In addition to these conformity assessment bodies, proficiency test providers and reference material producers can seek recognition by accreditation.

Rules for applying sector-specific competence criteria and for granting an accreditation are harmonised by regional and international accreditation organisations, such as IAF (International Accreditation Forum), and ILAC (International Laboratory Accreditation Cooperation). By mutual recognition arrangements within these organisations, conformity assessment bodies benefit from recognition of their accredited status as well as from recognition of their results within the scope of their accreditation.

Accreditation is referred as one tool to identify competent conformity assessment bodies in the WTO TBT agreement where acceptance of conformity assessment results across borders is an important issue.

In the European Union accreditation is deemed to be the preferred means of demonstrating the technical competence of conformity assessment bodies (see Regulation (EC) No 765/2008 for accreditation and market surveillance relating to the marketing of products).

Likewise, an accreditation can be required for various official authorisations of bodies to provide conformity assessment services as well as for contractors. The choice of a particular accreditation body can therefore depend on regulatory or economic conditions. For instance, it can be mandatory to use the home accreditation body, or else, it can be advisable to seek accreditation from a body either established in the economy of the target market or specialised in activities in the target sector.

The international standard ISO/IEC 17011 specifies requirements for accreditation bodies. Any organisation complying with this standard can be deemed to be competent and impartial as well as operating independently and consistently when assessing and accrediting conformity assessment bodies. Application of ISO/IEC 17011 is further specified in mandatory and informative documents by international and regional accreditation organisations (e.g. ILAC) in order to harmonise the operation of the signatories to their mutual recognition arrangements.

Defining the scope of an individual accreditation similarly depends on the particular conditions. It can be provided by the respective legal requirements, specified by an applicable programme as well as reflect the actual or intended activities of the conformity assessment body.

Enterprises and Consumers

Trade in products and services is increasing every day. The value chain is becoming ever more complex, and safety cultures vary between different economic areas. This is why participants in the market have to develop a common understanding of the characteristics of products and services that have to be present and the requirements that have to be fulfilled. Herein lies the importance of binding rules, often in the form of standards, which describe these characteristics.

Conformity of products is a prerequisite for a functioning market and for worldwide trade. Products are said to conform when they provide the promised performance and fulfil the requirements in reality. Confidence in safety is a prerequisite for the acceptance of innovation.

Increasing globalisation of the value chain and interlinking of international trade flows, worldwide higher safety and quality requirements and also

ever more complex technical products present new challenges to commercial and industrial organisations.

The earlier conformity assessments are carried out within the value chain, the more cost efficient production processes can be. Products and their components can be tested at their place of manufacture and therefore at a very early stage. This means that any corrections needed within the manufacturing processes can be identified in good time and any necessary adjustments can be carried out at the prototype stage.

Small and medium enterprises can make use of professional conformity assessment services when demonstrating that regulatory provisions and the requirements of standards have been fulfilled in the manufacture and marketing of products. This applies in particular when companies wish to open up new target markets abroad and therefore must ensure that their products fulfil all the local requirements. Product characteristics become more transparent and are comparable with competing products, which is the prerequisite for global trade.

Protection of consumers and of the environment rely on products only being placed on the market when complying with the applicable legislation.

Not only public interests, such as health and safety, but also specifics of the intended use or meeting the individual expectations can be assured by conformity with the relevant standards and requirements.

Fair competition and reliable information contribute to an increased choice and range of goods and services.

4

Conformity Assessment

Functional approach

According to ISO/IEC 17000, the functional approach to conformity assessment describes the demonstration that specified requirements are fulfilled as a series of the three functions (1) selection, (2) determination and (3) review, decision and attestation.

Selection activities involve planning and preparation for gathering evidence, i.e. collect samples or produce all the information needed as input for the subsequent determination function.

Determination involves activities to gather and create evidence in order to complete the relevant information on the object of conformity assessment or its sample.

This information is then **reviewed** to ascertain fulfilment of the specified requirements.

On this basis, the **decision** is taken whether or not conformity has been reliably demonstrated and eventually can be attested, e.g. by a certificate or supplier's declaration of conformity.

Conformity assessment can end with this attestation. Where needed, the three functions can be iterated in **surveillance** to maintain the validity of the statement.

Conformity assessment activities

Testing is the determination of one or more characteristics of an object of conformity assessment according to a procedure. The output of testing can include a statement on fulfilment of specified requirements or comments (e.g. opinions and interpretations) about the test results.

Inspection is the examination of an object of conformity assessment and determination of its conformity with detailed requirements or, on the basis of professional judgement, with general requirements. Applicable procedures or programmes can restrict inspection to examination only.

Certification is a third-party attestation of conformity assessment. It applies to all objects (products, services, processes, management systems, persons) with the exception of conformity assessment bodies themselves, for which accreditation is the equivalent third-party activity to assess the specified requirements.

Validation and **verification** are confirmations of declared information, that is provided as claims. Validation confirms the plausibility of a claim regarding a specific intended use in the future, verification confirms the truthfulness and correct declaration according to the specified requirements

CASCO Toolbox

The so called Toolbox developed by the committee on conformity assessment (CASCO) consists of international standards specifying conformity assessment, which can be applied as instruments individually or in combination.

For instance, certification of a product could take into account results of component testing or an inspection could require personnel with certified competence and qualification.

Likewise, the acceptance of results contributed by another conformity assessment body could be made dependent on accreditation of this body.

» ISO/IEC 17025 General requirements for the competence of **testing and calibration laboratories**

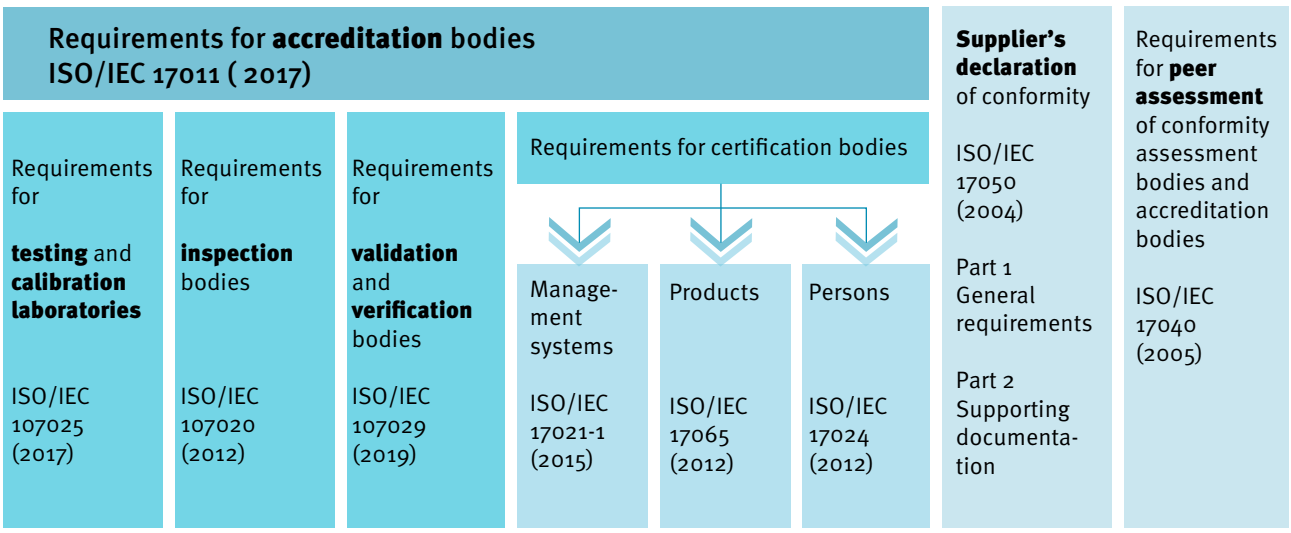
» ISO/IEC 17020 Requirements for the operation of various types of bodies performing **inspection**

» ISO/IEC 17029 General principles and requirements for **validation and verification** bodies

» ISO/IEC 17065 Requirements for bodies **certifying products, processes and services**

» ISO/IEC 17021-1 Requirements for bodies providing audit and **certification of management systems**

FIGURE 2: CASCO TOOLBOX



» ISO/IEC 17024 General requirements for bodies operating **certification of persons**

» ISO/IEC 17050 **Supplier's declaration** of conformity

» ISO/IEC 17011 Requirements for **accreditation** bodies accrediting conformity assessment bodies

» ISO/IEC 17040 General requirements for **peer assessment** of conformity assessment bodies and accreditation bodies

Also developed by CASCO for application in the context of conformity assessment are the following documents:

» ISO 17034 General requirements for the competence of reference material producers

» ISO/IEC 17043 General requirements for proficiency testing


No. 2543

5

ISO/IEC 17025

SUMMARY OF FUNDAMENTAL CHANGES WITH REVISED VERSION 2017

Verbatim quotations and referenced clauses are taken from ISO/IEC 17025:2017, unless otherwise specified.

Sampling is introduced as stand-alone laboratory activity along with testing and calibration

Former versions of the standard applied to testing and calibration laboratories, with the understanding that a laboratory could be either or both.

The scope of the new version allows for organisations specialised in sampling to be recognised for their sampling activities according to ISO/IEC 17025.

This sampling activity is associated with subsequent testing or calibration (see 3.6). Sampling as well as sample handling may still be required as process steps of testing and calibrating (see 7.3).

With the extended application, the laboratory is now explicitly required to define the range of its activities, i.e. stating to be a testing laboratory, a calibration laboratory, a sampling organisation or a combination thereof (see 5.3).

"Laboratory" as defined term is introduced

Using the three activities (i) testing, (ii) calibration and (iii) sampling associated with subsequent testing or calibration, a laboratory is defined as a body that performs at least one of these "laboratory activities" (see 3.6).

Outsourcing activities, for which the laboratory claims to conform with ISO/IEC 17025, on an ongoing basis is explicitly prohibited (see 5.3). This should prevent organisations merely brokering laboratory activities without being technically competent and appropriately organised.

With the basic concepts for testing (see ISO/IEC 17000) and calibration (see VIM, ISO Guide 99) as well as the introduced laboratory activity sampling (see 3.6), the definition of the laboratory as a body is now in line with conformity assessment bodies, such as inspection or certification bodies.

Concepts of impartiality and independence are differentiated

The convention to use the term "impartiality" when referring to the concept of objectivity or neutrality is specified as a defined term (see 3.1). This concept is differentiated from the term "independence", used for referring to freedom from the control or authority of another person or organisation.

The explicit reference to first-, second- or third-party laboratories, associated with the concept of independence, is no longer made in the scope of ISO/IEC 17025.

"Decision rule" as defined term is introduced

When issuing a statement of conformity, the laboratory has to apply certain criteria in order to decide whether or not the results fulfil the specified requirements, e.g. pass or fail a test.

Such decision rules have to take into account the measurement uncertainty of the results (see 3.7) as well as the risk of false statement (see 7.8.6).

Focus of the requirements is on the outcome rather than being prescriptive

Laboratories benefit from greater flexibility when implementing the new standard. This allows for individual solutions and probably less bureaucracy, but requires sound consideration of what is needed and that the consequential decisions are justified.

The guiding principles are to ensure quality of work and validity of results.

When deciding, for example, on the extent of documentation in the laboratory, training needs for personnel, calibration intervals for equipment or acceptance of external providers, the impact on the quality and validity has to be evaluated.

Seeking recognition according to ISO/IEC 17025 may require the laboratory to demonstrate the rationale for these decisions.

Risk based thinking is implemented

In line with the new version of ISO 9001 (2015), the requirements are weighted according to the risk of non-fulfillment and the potential effects. In this context, the formerly required "preventive action" is now part of this risk-based approach.

Similar to the evaluation of impact regarding the quality of work and validity of results, decisions and operations of the laboratory have to be guided by the potential influence on the intended effect.

The laboratory is responsible for deciding which risks and opportunities associated with its policies and procedures need to be addressed.

This applies particularly to

- risks to the laboratory's impartiality (see 4.1.4);
- risks caused by invalid methods (see 7.2)
- risks of false accept or false reject when providing statements of conformity (see 7.8.6);
- risks caused by nonconforming work (see 7.10);
- risks becoming apparent during corrective actions (see 8.7);
- risks to the effectiveness of the management system and risks of potential failure of the laboratory activities (see 8.5);
- risks identified and subjected to management reviews (see 8.9).

Helpful parameters when assessing risk are likelihood (What is the probability of a harmful event?) and significance (If something happens, how serious is the event?).

Also, it can be useful to establish certain risk categories. For example:

(i) no risk – no action required;

(ii) remote risk, serious harm very unlikely – random monitoring advised;

(iii) some risk, serious harm possible – monitoring required;

(iv) high risk, serious harm probable – action required;

(v) maximum risk, serious harm virtually certain – stop work.

Standard is restructured

Management requirements of the former Clause 4 are categorised with the new version as general, structural and management system requirements (see Clauses 4, 5 and 8).

Technical requirements of the former Clause 5 are now categorised as resource and process requirements (see Clauses 6 and 7).

Furthermore, the standard is formally updated with regard to terminology and references.Structure and content are aligned with current basic documents, such as ISO 9001:2015 and ISO/IEC 17000 series.

Requirements are oriented on the process of laboratory activities

The requirements follow a consistent approach, which is used throughout the new version of the standard:

1. the laboratory's requirements have to be documented,
2. the laboratory has to communicate accordingly to the persons and entities affected,
3. the laboratory has to ensure that the requirements are met and
4. appropriate records have to be retained.

Clause 7 consists of requirements for process steps corresponding to the sequence of the laboratory activities from performing contract review, selecting methods and obtaining samples to recording, quality control and issuing of results. Requirements for documentation, data and information management as well as handling complaints and nonconforming work are specified in this context.

Requirements regarding information technology (IT) and metrological traceability are updated

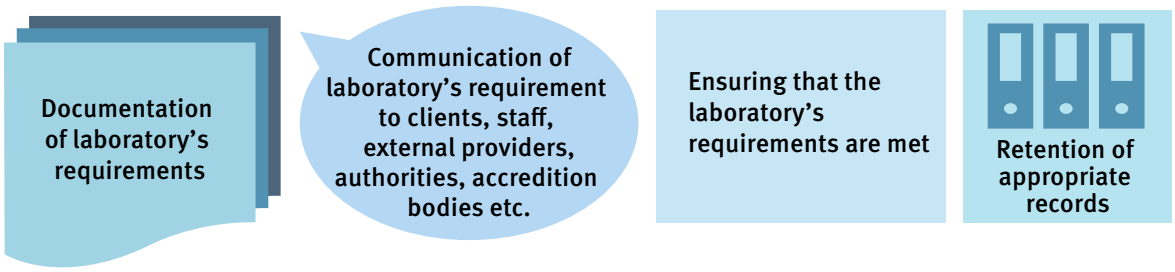
The standard reflects current practices and technologies in laboratories. This regards specific applications, e.g. for metrological traceability, as well as general developments in communication and administration.

For instance, reports can be issued electronically (see 7.8.1.2) or management of data and information can be computerised (see 7.11.2).

The term "quality manual" is no longer used. The requirements for an equivalent tool are essentially maintained and specified more generically for "management system documentation" (see 8.2) allowing for electronic and hyperlinked compilations of the relevant material.

ISO/IEC 17025:2005	ISO/IEC 17025:2017
1. Scope	1. Scope
2. Normative references	2. Normative references
3. Terms and definitions	3. Terms and definitions
4. Management requirements	4. General requirements
5. Technical requirements	5. Structural requirements
	6. Resource requirements
	7. Process requirements
	8. Management system requirements
Annex A Nominal cross-references to ISO 9001:2000	
Annex B Guidelines for establishing applications for specific fields	

FIGURE 3: PROCESS APPROACH TO SPECIFICATION OF REQUIREMENTS IN THE NEW VERSION OF ISO/IEC 17025



EXPLANATION OF CHANGES AND CONSEQUENCES, GUIDANCE TO APPLICATION

Verbatim quotations and referenced clauses are taken from ISO/IEC 17025:2017, unless otherwise specified.

Highlighted text indicates the requirements according to the standard.

Introduction

Changes with the new version

The statement regarding operation according to ISO/IEC 17025 being **in accordance with ISO 9001** is maintained, but the current wording is less binding ("...will also operate generally in accordance with the principles of ISO 9001"). A corresponding statement is not repeated in the Scope any more.

The accreditation organisations IAF and ILAC published a joint communiqué with ISO to emphasise this.

In line with ISO 9001:2015, laboratories are required to "plan and implement actions to address **risks and opportunities**". The laboratory is responsible to deciding which risks and opportunities need to be addressed.

Scope (Clause 1)

Changes with the new version

While the application of this standard to testing and calibration laboratories has not been changed, the scope has been fundamentally revised.

In **alignment with the ISO/IEC 17000 series**, the requirements are associated with "competence, impartiality and consistent operation" of laboratories.

Competence refers to the ability of the personnel to apply technical knowledge and skills as well as to the capability of the laboratory as an organisation being equipped and operational.

The consistency of the laboratory's operation relates to the required **management system**, which is a key element of the standard.

While **"impartiality"** is understood as objectivity or neutrality with regard to the assessed item, so that conflicts of interest do not exist or are resolved (see 3.1), the concept of **"independence"** describes freedom from the control or authority of another person or organisation. This detachment with regard to the assessed item is usually characterised by referring to first-, second- or third-parties.

ISO/IEC 17025 applies to all kinds of laboratories, regardless of their independence or further use of their results. However, the explicit reference to first-, second- and third-party laboratories and laboratories where testing and/or calibration forms part of inspection and product certification has been deleted.

Laboratories are referred to as "organisations performing **laboratory activities**", which are now specifically defined as testing, calibration, and sampling (see 3.6).

The application to organisations regardless of their **number of personnel**, therefore allowing for laboratories to be operated by a single person, is maintained.

Solutions for very small, i.e. single-person, laboratories are indicated, where extra persons are required. This applies to handling complaints (see 7.9.6) and internal audits (see 8.8).

The intended use for confirming a laboratory's competence or for **recognition purposes** (e.g. by customers, regulatory authorities, organisations and schemes using peer-assessment or accreditation bodies) remains unchanged.

The exclusion of application of this standard to regulatory and safety requirements is no longer part of the scope, neither are the explanatory notes or reference to accreditation according to ISO/IEC 17011.

References (Clause 2)

Changes with the new version

The normative basis for application of this standard has been unaltered.

The reference to the principles and terminology defined by **ISO/IEC 17000** and the vocabulary of metrology (**VIM**) according to ISO/IEC Guide 99 have been updated.

Terms & Definitions (Clause 3)

Changes with the new version

Unlike the 2005 version, which referred to the terminology documents VIM, ISO 9000 and ISO/IEC 17000, the standard now contains explicit terms and their definitions.

Most importantly, the term **"laboratory"** (see 3.6) is defined as body that performs at least one of three distinct "laboratory activities", being (i) testing, (ii) calibration and (iii) sampling, which is associated with subsequent testing or calibration.

With this definition, sampling is introduced as stand-alone activity along with testing and calibration. Consequently, sampling organisations could use ISO/IEC 17025 in managing their competence, impartiality and operations as well as seeking recognition.

When testing is performed as conformity assessment, hence the test results containing a decisive statement of conformity (such as "target value achieved" or "test failed"), a decision with regard to fulfilment of the specifications is required.

In this context, a **"decision rule"** (see 3.7) is defined in order to account for measurement uncertainty when stating conformity with a specified requirement.

The term **"impartiality"** is defined as "presence of objectivity" (see 3.1), which applies equally to first-, second- and third-party laboratory activities and is distinguished from the concept of "independence".

Other terms related to the concept of impartiality include freedom from conflict of interests, freedom from bias, lack of prejudice, neutrality, fairness, open-mindedness, even-handedness, detachment and balance.

For ensuring the quality of a laboratory's work by monitoring the validity of results, the term **"intralaboratory comparison"** (see 3.4) is defined as "organisation, performance and evaluation of measurements or tests on the same or similar items within the same laboratory in accordance with pre-determined conditions".

In the same context of monitoring the laboratory's performance, the terms **"interlaboratory comparison"** (see 3.3) and **"proficiency testing"** (see 3.5) are reproduced from ISO/IEC 17043.

Interlaboratory comparison is applying the concept of measuring or testing on the same or similar items by two or more laboratories. In case of calibration laboratories, these are normally referred to as "measurement audits".

Proficiency testing is using these means to evaluate the performance of participants against pre-established criteria.

ISO/IEC 17025 requires the laboratories to have a process for handling **complaints** (see 7.9).

In order to clarify the concept of "complaint", especially differentiating it from "appeals", the respective definition is reproduced from ISO/IEC 17000 (see 3.2).

Finally, the terms **"verification"** (see 3.8) and **"validation"** (see 3.9) are reproduced from VIM for application of this standard.

Verification is understood as the "provision of objective evidence that a given item fulfils specified requirements", hence directed at the test or calibration item itself. The item can be a process, measurement procedure, material, compound, or measuring system.

Examples are (i) a given reference material is confirmed to be homogeneous for the quantity value and measurement procedure concerned as claimed, (ii) performance properties or legal requirements of a measuring system are confirmed to be achieved, (iii) a target measurement uncertainty is confirmed to be met.

Validation is directed at the specified requirements, providing objective evidence that they are adequate for an intended use.

An example is validating a measurement procedure for the mass concentration of nitrogen in water also to be used for human serum.

Verification should not be confused with calibration.

Not every verification is a validation. While non-standard and in-house-developed methods require method validation, it can be essential to verify that the laboratory is able to apply already validated methods (e.g. standard methods) using the laboratory's equipment in its own environment and obtain the same outcome as provided with the validation data (e.g. the same results as by the standard method).

Impartiality (Clause 4.1)

Overview

Impartiality is fundamental to the trust, confidence and value of conformity assessment. It is important for laboratories, and their personnel, to be objective and to identify as well as manage conflicts of interest.

Threats to impartiality can result from various situations:

- Owning shares of a customer's organisation could create financial **self-interest** for personnel of the laboratory. Employment relationships between family members could create emotional or financial self-interest.
- When reviewing their own work, judgement or decisions, a **self-review** threat could occur.
- Close personal or professional relationships with a customer can result in a threat to impartiality because of **familiarity or trust**, being not sufficiently sceptical.
- When the laboratory's personnel feel openly or secretly coerced by a customer or by any other interested party (e.g. threatened with being replaced or reported over a disagreement with a customer) their impartiality can be affected by **intimidation**.
- When personnel has to act on behalf of or in opposition to a customer (e.g. in course of

resolving a complaint) this **advocacy** can threaten impartiality.

Independence, which is the extent of separation between the laboratory and others, who have an interest in the results, should be considered in the context of impartiality.

Laboratories according to ISO/IEC 17025 always had to undertake their activities impartially.

This means that there shall not be any commercial or financial pressures which might influence the quality of the work. However, this does not mean that a reasonable work rate cannot be expected from personnel. But paying them on the basis of the number of samples analysed could pose a considerable risk to impartiality.

With this clause (4.1) the formerly implicit requirements in this regard (see ISO/IEC 17025:2005, 4.1.4 and 4.1.5) are elaborated explicitly beyond organisational requirements, defined responsibilities, identification of conflicts of interest and transparency towards the customer.

The language for this clause is according to the harmonised text for common elements of CASCO standards.

Requirements

The laboratory shall be responsible for its impartiality (see 4.1.3) and the **laboratory management** shall be committed to impartiality (see 4.1.2).

The term "laboratory management" is understood as the highest management level of the laboratory, hence the "top management" of the entity. However, this might not be identical with the top management of the organisation the laboratory forms a part of (see 5.2).

A clear definition of authority and responsibilities in the laboratory's documentation can contribute here. The laboratory's management commitment to impartiality as a sort of policy statement places a responsibility on the laboratory to generate and report data objectively. This would be backed up by a statement that no personnel have authority to take any action or to require any action to be taken which interferes with the laboratory in discharging this responsibility, irrespective of the normal line of management. The laboratory personnel may then rely upon this stated policy to protect them from any undue influences.

The concept of impartiality is applied to **activities** and **structure** (see 4.1.1).

This means that where the laboratory is part of an organisation, which performs activities other than laboratory activities, the responsibilities of all personnel in the organisation who have influence on the laboratory work should be defined in order to identify potential conflicts of interest.

A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new customers, etc.

Risks to impartiality have to be identified, analysed and **managed on an on-going basis** (see 4.1.3, 4.1.4).

This includes addressing risks to impartiality regarding **relationships** of the laboratory or its personnel and conditions of work.

Identified risks to impartiality have to be eliminated or minimised (see 4.1.5).

A general measure to manage risks to impartiality could be as follows:

1. recognise a potential or present risk;
2. judge the risk level of it compromising impartiality;
3. determine and decide what level of risk is acceptable (risk assessment);
4. minimise risks of an unacceptable level, which can be managed, to an acceptable level;
5. eliminate risks of an unacceptable level, which cannot be managed.

Confidentiality (Clause 4.2)

Overview

To gain access to the information needed to conduct effective laboratory activities, the laboratory needs to provide confidence that confidential information will be protected and will not be disclosed.

All organisations and individuals have the right to have maintained as confidential any personal, intellectual property and proprietary information that they provide.

This principle always had to be realised in laboratories according to ISO/IEC 17025.

Respective requirements (see ISO/IEC 17025:2005, 4.1.5, 4.7.1 and 5.4.7) are consolidated in the current version and combined with resource requirements regarding the personnel (see 4.2.4).

The language for this clause is according to the harmonised text for common elements of CASCO standards.

Requirements

The concept of confidentiality is applied to **persons**, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf (see 4.2.4), as well as **systems**.

This means that all personnel have to be instructed to keep confidential anything, which they may learn as a result of their work and any information which they are given in order to help them to carry out their duties. It is not essential but generally recommended for the laboratory to require its personnel to sign a confidentiality agreement.

Likewise, it means that systems have to be operated and maintained to prevent any information loss or data leaks.

Stronger emphasis lies now on **customer awareness**. The **specific cases**, where confidentiality could be affected, are more detailed.

The customer has assigned the laboratory with its items, which could be a newly developed prototype, a consumer product as well as a product used by government agencies or authorities. The associated information and results are to be kept confidential between the laboratory's personnel and the customer and must not be discussed or made known to other parties.

The laboratory is formally and enforceable **responsible for managing** all information obtained or created in the course of its laboratory activities. All information is considered proprietary information to be kept confidential, unless it is made publicly available by the customer (see 4.2.1). This includes information about the customer obtained from sources other than the customer, e.g. through a complaint or by regulators (see 4.2.3).

A clear and distinguishable definition of which kind of information is considered confidential by the laboratory is recommended. This could be categorised as follows and accordingly marked or kept with restricted access:

» customer information: such as contact details, fees, quotation, confirmed purchase orders, sales orders, tender documents, contracts, agreements, confirmation emails;

» calculation or working formulas: such as testing working sheet, graphical illustration, customer's transferred analytical methods;

» documentation and records: such as materials list, batch records, laboratory records, standard operating procedures (SOP), test results, approved supplier list.

It is helpful to develop instructions for actions to be taken in case of doubts or compromised confidentiality and discuss confidentiality policies and issues with personnel in awareness trainings.

Disclosure of confidential information by the laboratory requires either an agreement with the customer (see 4.2.1) or a legal or a contractual arrangement, in which case the customer has to be notified of the information to be provided (see 4.2.2).

Structure (Clause 5)

Overview

This clause contains the requirements regarding the **organisational structure** of the laboratory (see ISO/IEC 17025:2005, 4.1 and 4.2).

The essential functions are retained, but the terms "technical management" and "quality manager" are no longer in use.

Legal entity

The form of the organisation of the laboratory is clarified by the term **"legal entity"**, being legally responsibility for its laboratory activities and allowing for the laboratory being a **defined part** of a legal entity (see 5.1).

This means that the laboratory needs to describe its precise organisational form.

Typical examples are:

» an independent commercial testing laboratory carrying out measurements for customers in return for a fee;

» a laboratory which serves a regulatory authority and provides data to that authority for enforcement purposes;

» a laboratory which is part of a bigger organisation and which provides an internal service solely within that organisation (including company quality assurance laboratories and laboratories providing in-house environmental control compliance monitoring).

This description should also include a statement of the ownership of the laboratory and its relationship to any parent or subsidiary organisations.

Governmental laboratories are deemed to be a legal entity on the basis of their governmental status.

Management

In any organisational form, the **management** with overall responsibility for the laboratory has to be identified (see 5.2). This can be identical with the laboratory management (see 4.1.2) but can also be a higher management level within the whole organisation.

The management makes decisions on policy and allocates resources. This will normally be the board of directors or an equivalent body with financial control.

Management structure

The organisation and **management structure** have to be defined (see 5.5).

This should make clear who is responsible and the scope of these responsibilities.

For example, if different technical areas have different managers, this needs to be specified with respect to the laboratory management and their range of responsibility clearly defined. It is generally expected that in any specific laboratory there will be a distinct laboratory manager, but in larger organisations with several technically distinct laboratories or legal entities there may be several laboratory managements (see 4.1.2) with specific technical briefs and with no overall management (see 5.2).

If the laboratory is part of an organisation that is involved in production or providing services, it is important to ensure the impartiality of the laboratory and avoid any conflicts of interest of personnel in this structure.

The description of the management structure should also make clear how supervision arrangements work.

Typical laboratory structures include technical staff and professional staff. The general division of work is that professional staff have responsibility for method selection, for development of new methods and for interpretation of data. Whereas the actual bench work is done by technical staff, although professional staff can also be involved.

Overall, the professional staff are responsible for the ultimate validity of results so the structure has to show how they discharge this responsibility by supervision of the technical staff. This does not necessarily mean direct supervision but will typically involve explaining how instructions are passed down to the bench and how data is passed back and checked.

In the case of each level of management or individual function, there should be job descriptions to describe the responsibilities to be discharged and the authority given, plus the supervisory responsibilities of each level. The usual practice is to include key job descriptions in the management system documentation, for example "laboratory manager" or "senior staff" with specific responsibilities, but to retain other job descriptions in a separate file or in personnel record files (see 6.2.2).

Responsibilities and authority (see 5.6) should match each other at all levels. If the responsibility for organising calibrations between two laboratories as means of an interlaboratory comparison, for example, is allocated to someone, this person must have the authority to require personnel to do the necessary work and to sanction appropriate expenditure.

When defining the organisation, each function should have an appropriate name (e.g. "chief chemist", "senior microbiologist", "materials scientist", "technical officer", "laboratory assistant") and show the reporting structure both going upwards and downwards (e.g. each chemist reports to a senior chemist and technical officers report to a materials scientist).

Range of laboratory activities

With the definition of laboratory activities, being testing, calibration and sampling, the laboratory is now required to identify its **range of laboratory activities** for which it conforms with ISO/IEC 17025 (see 5.3).

The continuous provision of laboratory activities by external organisations is explicitly excluded (see 5.3). Any claims of conformity of the laboratory with ISO/IEC 17025 are therefore restricted to this defined range (e.g. "calibration" or "sampling and testing").

Further specifications are made when seeking accreditation and defining the laboratory's scope of accreditation (e.g. field and type of testing, methods, test objects and parameters).

Applicable requirements

New text clarifies the **applicable requirements** for laboratory activities as consisting of the standard ISO/IEC 17025 as well as requirements by the laboratory's customers, regulatory authorities and organisations providing recognition, e.g. accreditation (see 5.4).

Also explicitly elaborated as a structural requirement of the new version are the **sites** at which the laboratory activities are performed. This includes all the laboratory's permanent facilities as well as sites away from its permanent facilities, associated temporary or mobile facilities, or a customer's facility (see 5.4).

Procedures

Use of the term "procedure", as distinguished from "process", indicates the requirement for the laboratory to maintain **documentation**.

The laboratory is required to document its procedures **to the extent necessary**, which means greater flexibility for the laboratory deciding what it needs in order to ensure the consistent application of its laboratory activities and the validity of the results (see 5.5).

For example, there should be a procedure which shows clearly enough how the customer's requirements are passed to the person who will actually do the test or calibration work. Likewise, the procedure showing how the data is checked and transcribed to the final report should to be documented to the extent that it can be followed consistently and the key aspects are clear (e.g. who is responsible for deciding whether the quality control criteria have been met and who can release the data).

For the following activities a procedure, hence **documentation**, is explicitly required:

- **personnel**: determining the competence requirements, selection of personnel, training, supervision, authorisation, monitoring competence of personnel (see 6.2.5);
- **equipment**: handling, transport, storage, use, planned maintenance and intermediate checks (see 6.4.3 and 6.4.10);
- **externally provided resources**: defining, reviewing and approving resources, evaluation, selection, monitoring of performance of provided resources, ensuring that externally provided resources conform to the applicable requirements, taking corresponding actions (see 6.6.2);
- **contracts**: reviewing requests and tenders (see 7.1.1);
- **laboratory activities**: describing methods and procedures (see 7.2.1.1), validation of methods (see 7.2.2.4);
- **test or calibration items**: transportation, receipt, handling, protection, storage, retention, and disposal or return (see 7.4.1);
- **quality control**: monitoring the validity of results (see 7.7.1);
- **complaints**: receiving, evaluating and making decisions (see 7.9.1);
- **nonconformities**: defining managing, immediate actions, evaluating significance, follow-up (see 7.10.1).

Responsibilities of personnel

The requirements for the resource **personnel** with relation to the organisational structure are also given in this clause.

The responsibilities, authorities and inter-relationships of personnel have to be specified by the laboratory (see 5.5) and the particular duties to be carried out, such as implementing, maintaining and improving the management system, are listed (see 5.6).

The function of a "quality manager" is no longer explicitly required by the new version of the standard. However, the persons responsible for administering the controlled document system, for compiling the documentations and for organising the review and internal audit have to be identified here.

These individuals are responsible for the effective enforcement of the management system's objectives and are also expected to advise the laboratory management on quality issues. Depending upon the organisation, these functions can be realised in a number of ways:

» In large organisations, a fulltime assignment to one person can also cover responsibility for other management systems, such as ISO 9001. In case this person lacks the required laboratory background, a representative with technical expertise can complement at laboratory level. These representatives can have a dual reporting line: the normal lines to the laboratory manager on technical issues and a line to the person in charge of the management system.

» Commonly found in medium-sized laboratories, a senior personnel from the tier below that of laboratory management is responsible for the management system issues. Occupying a management position below that of the laboratory management should present no problems provided it is stated in the documentation that, on matters of quality, the responsible persons have direct access to the level of the laboratory management. This allows for a line of action in the unlikely event that the managers below the laboratory management are contravening the objectives and attempting to subvert the responsible persons using line management authority.

» Alternatives to the scenarios already discussed include the use of a personnel who are not involved in laboratory work but who have the necessary technical background. Such persons are typically found amongst individuals who have been promoted into managerial posts from the laboratory. The laboratory management level may contain such individuals. The use of such a person not only provides an independent form of quality management but underlines the commitment of the highest level of the laboratory's management to the quality of work.

» In small organisations it may be difficult to separate the responsibility for the management system and technical management functions completely. Some laboratory managers can function as their own quality managers. In such cases the responsibilities should be clearly defined.

Responsibilities of laboratory management

While the content of the laboratory's management system is contained in Clause 8 of the new version, the general requirement for the laboratory to ensure the effectiveness and integrity of the **management system** is specified in this clause as responsibility of the laboratory management (see 5.7).

Although not explicitly required by the standard, there should be provision for **deputies** for all key functions so that their functions can still be discharged in their absence. The structural organisation of the laboratory (see 5.5) should ensure that the laboratory is never going to be paralysed because it is not clear who can give an authorisation or perform an activity in the absence of a particular person or function.

In small organisations it may not be practicable to have designated deputies for all functions. However, the allocated responsibilities, especially with authorising activities, should be carefully analysed and the implications of a particular absence should be considered. If this would create a problem in operating, arrangements should be made to cover the absence by showing where the responsibility is re-allocated.

The standard allows for using **external personnel** for functions requiring a certain separation, such as internal audits (see 8.8) or handling complaints (see 7.9.6).

Resources (Clause 6)

Overview

This clause contains the **"technical requirements"** (see ISO/IEC 17025:2005, 5.2, 5.3, 5.5 and 5.6) not categorised as requirements for the process of laboratory activities and relates to

» personnel (see 6.2),

» facilities (see 6.3),

» equipment (see 6.4),

» metrological traceability (see 6.5),

» externally provided resources (see 6.6).

The way these requirements are specified reflects the objective of the new version to be less prescriptive.

For instance, by generally requiring the laboratory to have **resources available** (see 6.1) the new version focusses less on the status or ownership of resources and more on the relevant requirements for those resources.

Examples are:

» 6.2.1 referring to all personnel, internal or external as opposed to requiring personnel to be employed

by or under contract (see ISO/IEC 17025:2005, 5.2.3);

» 6.4.1 requiring the laboratory to have access to equipment as opposed to requiring the laboratory to be furnished with all items (see ISO/IEC 17025:2005, 5.5.1).

The resource requirements follow a consistent approach, which is used throughout the standard:

1. the laboratory's requirements have to be documented,
2. the laboratory has to communicate accordingly to the persons and entities affected,
3. the laboratory has to ensure that the requirements are met and
4. appropriate records have to be retained.

Personnel

Probably the most important factor for the technical ability of a laboratory is competent personnel.

Requirements for **personnel** (see 6.2) are not significantly changed with the new version.

The individual requirements (see ISO/IEC 17025:2005, 5.2) are re-organised and the terminology is updated.

External as well as internal personnel with influence on the results are required to act impartially, to be competent and to work according to the laboratory's management system (see 6.2.1).

The laboratory has to document the **competence requirements** (see 6.2.2) and ensure that the acting personnel has the required competence (see 6.2.3).

A decision should be made on the qualifications and experience necessary to fill each of the levels of responsibilities, authorities and inter-relationships of personnel specified according to 5.5.

Criteria should not be too restrictive but demonstrate a genuine commitment to have properly trained and qualified personnel. Rather than listing qualifications and experience of the present personnel, the laboratory should think in terms of the minimum necessary qualifications and experience for each function and allow for using someone with appropriate experience and perhaps minimal or less formalised qualifications.

The list below provides a useful model, which effectively aligns personnel for technical operational purposes into several levels. Any individual may operate at more than one level.

» Personnel providing support and who never take responsibility for any data.

» Personnel who carry out routine work; such personnel do not evaluate the data for release but will normally be expected to do any initial checks required against precisely defined quality control criteria.

» Personnel who exercise professional judgements and evaluate data; normally those who can take responsibility for the release of data.

» Personnel responsible for training and evaluating the expertise of trainees.

» Personnel responsible for selecting and validating methods.

Ensuring that the acting personnel have the required competence involves identifying **training needs**, focussing on identifying the needs of the laboratory rather than on the professional development of individual personnel. This applies to increasing the existing personnel's competence in order to enhance the laboratory's flexibility and ability to cope with the workload as well as to consider training needs for planned expansion of the laboratory's range of laboratory activities (see 5.3).

Whenever there are changes in personnel, whether due to resignations or new recruitment, a review of the implications of these changes and any resulting training requirements should be made.

Likewise, training requirements should be considered when the laboratory is introducing new methods or instrumentation.

The specific **authorisations** have to be assigned (see 6.2.6) and the duties, responsibilities and authorities have to be **communicated** to the personnel (see 6.2.4).

The obligations for the laboratory to **document and record** are summarised (see 6.2.5).

Records on personnel in this context are different from normal personnel department records, which usually contain sensitive personal information. What has to be recorded here is accessible to the authorised laboratory personnel, internal auditors or external assessors (e.g. from an accreditation body).

In order to demonstrate competent personnel, the laboratory needs to record evidence of the individual formal qualifications, previous experience and training. The list of the activities for which the person has been trained should include not only laboratory activities for customers but any internal activities, such as in-house calibrations, auditing, and administrative activities (e.g. receiving samples).

Likewise, regular monitoring of the personnel's competence at each of the listed activities needs to be recorded.

Training records provide a source of reference that a person is trained and that this training is up to date not only for future allocation of tasks. This also allows for checking that the person doing the work was adequately trained when tracing back original observations to the person who generated it.

Obviously, the content of individual records will depend on the person's previous experience and known level of competence. However, irrespective of whether a new recruit is of the highest general competence, it will be necessary to ensure that this person is familiar with the laboratory's management system, the way laboratory activities are done (e.g. sample numbering and storage) and how results are recorded and reported in the particular laboratory.

The objective is to achieve a maximum of consistency

between measurements made by different personnel.

Most laboratories establishing personnel records will have existing personnel with known areas of competence. There is no need to create a retrospective record of training for these persons. An initial list of authorisations for existing personnel should note that they were regarded as competent at the start of the record.

Training of personnel to carry out particular laboratory activities must be an organised and formal process. The laboratory management should give the responsibility for carrying out the training to a specific person who is already authorised for the relevant laboratory activity. Training should be followed by a competence test before authorising a person for a particular laboratory activity. Ideally, the test uses items for which the results are already established (e.g. reference materials or items previously tested or calibrated).

The responsible personnel for managing competence and training must be satisfied that the documented procedure is being followed, that results and all other relevant observations are being properly recorded and that the results being obtained are correct as judged by the known values and normal quality control checks operated by the laboratory. The general criterion for the acceptability of personnel's competence should be that they can be confidently expected to follow the documented procedure and consistently produce data which falls within the laboratory's known performance.

In addition to authorisations to carry out laboratory activities, it may be necessary to have training and competence tests on particular instruments or routine operations.

Managing competence can be structured as a multi-tier system with equivalent multi-level authorisations. In such systems the initial assessment of competence leads to an authorisation to work unsupervised, but the work is then subjected to further checks (e.g. by a supervisor). Subsequently, a second competence assessment is conducted and, if this is satisfactory, the authorisation is extended to a second level and the checks and countersignature dispensed with.

Competence of personnel should be **monitored** according to the range of their responsibilities, the complexity and frequency of performing particular activities.

The general practice is that the authorisation to carry out a particular laboratory activity should be reviewed according to the same procedure as the competence test described above. A common strategy for this re-assessment is to have personnel carrying out one of the determinations which form part of the laboratory's interlaboratory comparison. The key reason for the re-assessment is to maintain consistency among data from different personnel. Areas where interpretation by personnel is an important factor may require more frequent re-assessment. It is good practice to plan re-assessment of each personnel's authorisation at the beginning of each year by the laboratory management.

If the review is unsatisfactory, the authorisation has to be withdrawn pending retraining of the personnel and performance of a satisfactory competence test.

Records which summarise how often personnel perform a laboratory activity and whether the data was acceptable or not according to the laboratory's normal requirements, can support monitoring competence on a regular basis and checking that personnel continue to have regular practice in the procedure.

Refresher training might be a reasonable requirement for laboratory activities not performed over the past year.

Facilities and environmental conditions

Requirements for **facilities** and **environmental conditions** (see 6.3) are not significantly changed with the new version.

The individual requirements (see ISO/IEC 17025:2005, 5.3) are re-organised and the terminology is updated.

The facilities and environmental conditions have to be suitable regarding the validity of the results of laboratory activities (see 6.3.1). Especially in calibration laboratories the stability of environmental conditions is vital to control measurement uncertainty within reasonable limits.

This applies to design and furnishing of the laboratory, such as surfaces, floors, air-conditioning, double-doored entry, changing or washing areas for personnel, as well as to segregated areas (e.g. for storage of references or pre-conditioning of samples).

The consideration of environmental factors, which might affect the generated data, usually includes temperature and humidity as well as possible cross-contamination (e.g. in areas with incompatible activities). Also relevant can be conditions free of dust, vibration, sound, radiation, or electromagnetic effects.

The laboratory has to **document** the respective requirements (see 6.3.2) and ensure that the facilities and environmental conditions meet these specifications (see 6.3.3 and 6.3.4).

This includes facilities outside the permanent control by the laboratory (see 6.3.5).

Specific requirements can apply to laboratory wear, sterility, stability of the environmental conditions, or doors and windows. In order to meet these requirements, a specific cleaning regime or continuous recording of conditions can be measures of control and monitoring.

In the case of laboratories where integrity of samples is particularly important (e.g. forensic laboratories) a formal chain of custody for samples can be needed.

The laboratory should have a procedure for taking appropriate action (e.g. stop work) when the conditions run out of specification.

A policy on access to the laboratory should be guided by the two principles of ensuring confidentiality (quality of work) and considering impact on data (validity of results), for example by contamination.

The public area of the organisation should be clearly separated from the laboratory by a physical barrier. Authorisation of access should differentiate between visitors and supporting services, such as cleaning staff or maintenance engineers. Possible considerations include, hazards for untrained persons, accompanying visitors and locking restricted areas.

Equipment

Like competent personnel, functional and reliable equipment contributes mainly to the technical ability of a laboratory.

Requirements for **equipment** (see ISO/IEC 17025:2005, 5.5) are revised in line with the objectives of the new version to be less prescriptive and detailed.

More information regarding reference material is included and general criteria for required calibration of equipment are provided, now applying equally to testing and calibration laboratories.

A **reference material** is any material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process of checking methods or apparatus. Two key types of reference materials are (i) single compounds or items of established purity or properties and (ii) matrix references, which are specific types of samples where accepted values of one or more determinands have been established.

Reference materials and certified reference materials are called “reference standards”, “calibration standards”, “standard reference materials”, “quality control materials”, etc.

ISO 17034 specifies general requirements for the competence of reference material producers, for which these organisations can seek recognition (e.g. by accreditation). Reference materials from producers meeting the requirements of ISO 17034 are provided with a product information sheet or certificate that specifies, amongst other characteristics, homogeneity and stability for specified properties and, for certified reference materials, specified properties with certified values, their associated measurement uncertainty and metrological traceability.

ISO Guide 33 provides guidance on the selection and use of reference materials.

ISO Guide 80 provides guidance to produce in-house quality control materials.

Metrological traceability is addressed in a separate clause (see 6.5) and no longer included in this clause on measurement and calibration of equipment (see ISO/IEC 17025:2005, 5.6).

The required access of the laboratory to equipment, which is specified as a more elaborate list of items, does not imply ownership by the laboratory (see 6.4.1).

The laboratory has to document the procedures and requirements for handling, transport, storage, use and maintenance of equipment (see 6.4.3), and ensure that the equipment meets these specifications (see 6.4.4). This includes equipment outside the permanent control by the laboratory (see 6.4.2).

All new equipment must be checked for correct functioning before being placed in routine service. This should include checks against the manufacturer’s specifications and checks to confirm that the equipment gives satisfactory results when used to make the measurements for which it is intended.

Where equipment needs calibration, this must also be done before it is put in service. Some pieces of equipment (e.g. balances) must be calibrated in situ, so even if these are shipped with a factory calibration certificate, calibration after installation and before use will be essential.

Equipment, hardware and software, has to be safeguarded from unauthorised changes and adjustments that could invalidate results.

Access to adjustable devices on equipment should be sealed so that tampering is clearly apparent. Software should be password protected.

Clear instructions to personnel ensure the operation of equipment only by competent and authorised personnel as well as disposition of equipment (e.g. in case of damaged or broken seals).

For **measuring equipment** an accuracy as well as measurement uncertainty are required in order to provide valid results (see 6.4.5).

Two criteria are identified that determine when measurement equipment has to be calibrated: (i) the measurement accuracy or measurement uncertainty affects the validity of the reported results and/or (ii) calibration of the equipment is required to establish the metrological traceability of the reported results (see 6.4.6).

A **calibration programme** is required (see 6.4.7) and the calibration status of the respective equipment has to be indicated (see 6.4.8).

When calibration intervals have to be determined by the laboratory, an initial calibration interval should be set based on the manufacturer’s recommendations, the frequency of use of the instrument, the accuracy required, the perceived risk of a loss of calibration and the magnitude of the impact, and local experience of similar instruments. The calibration is then checked at the end of this interval and, if it is still correct, the interval is confirmed as adequate. Alternatively, the interval is reduced if the check shows that recalibration is required. Records should be kept so that the laboratory can justify the interval chosen.

Some equipment is difficult to label in the conventional sense. In these cases, the calibration status could be indicated by means of a colour code or other marking.

The personnel should be instructed (see 8.2) that they must not use any equipment where the label shows that it is overdue for a check or calibration. Ideally, such equipment carries a label showing that it is not calibrated and hence not to be used for measurements where traceability is required.

The calibration programme can be a combination of service from the supplier and in-house checks and calibrations by the laboratory. The approach has to ensure proper and reliable functioning of the equipment. It should be conservative in order to pick up any calibration problems before they affect the validity of results.

ILAC G24 provides further guidance for the determination of calibration intervals for measuring instruments.

The requirements regarding **maintenance of equipment**, such as monitoring performance (see 6.4.9), intermediate checks (see 6.4.10), implementing reference values and correction factors (see 6.4.11), and unintended adjustments (see 6.4.12) have not significantly changed. Neither have the requirements regarding **records for equipment** (see 6.4.13).

Where equipment replaces or duplicates existing equipment, the checks should include a comparison of the results from each unit to establish the variations which might result.

Equipment undergoing checks (e.g. during calibration or after giving suspicious results) must either be segregated or clearly labelled as not to be used so that there is no possibility of it being inadvertently used for routine work until it is formally accepted.

The laboratory is no longer required to keep a master list of all equipment.

However, it is good practice to keep an **equipment log** for each item. It should start with details of the checks and calibrations carried out before the equipment is placed in service and continue with a detailed record of all calibrations, repairs, routine maintenance and performance checks. Any supporting documentation, such as service reports, calibration certificates and output from performance checks, should be attached. So that this record becomes a complete history of the equipment and its state of calibration as well as performance at any point in time can be demonstrated.

It could be useful to have a copy of operating procedures for the equipment as part of the equipment log. In cases where equipment operation is described adequately in the methods documentation (see 7.2), there is no need to repeat this information in the equipment log.

For smaller items of equipment, a composite log (e.g. covering all of the laboratory's thermometers) would be appropriate.

Historical information from an inventory of existing equipment (e.g. copies of service reports, calibration history, commissioning reports) could be included in the equipment log.

It is a good idea, especially in larger laboratories, to appoint an individual to be responsible for each piece or category of equipment, and this person should have a deputy.

As with any other piece of equipment, all **computers** must be introduced into use through a controlled system and must be subject to checks for correct functioning before being placed in routine use.

This applies to all hardware and software and especially to software written in-house or applications developed by personnel (e.g. on spreadsheets). Commercial off-the-shelf software in general use within its designated application range can be considered to be sufficiently validated. There should be records of the checks used to ensure correct functioning.

Each computer should have a log which shows the hardware and **software** installed. It is must also be possible to recreate the previous versions of any software in case an error or query arises and it is necessary to determine whether the software was responsible.

There should be a defined person who is responsible for authorising any software to be used in the laboratory. This person must ensure that it is checked to show that it does not corrupt data or other information before it is released for use. This requirement applies not only to new software but also to any updates or modifications as well as to applications such as spreadsheets.

Wherever possible, spreadsheets must be protected from alteration by using passwords reserved to the responsible and authorised personnel. Where this is not possible, a set of sample data should be available, which can be loaded before the spreadsheet is used, to check that the calculated values are determined correctly.

Computer networks can make control of software easier since work areas can be established with restricted access and often with different levels of access. Care will need to be taken where the workstation machines also have local drives. The laboratory will need to have a policy on whether local software will be permitted.

Metrological traceability

Requirements for **metrological traceability** (see 6.5) are revised to reflect the current practice in traceability and the terminology is updated.

According to VIM, metrological traceability is defined as the "property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty".

It therefore links a result of any particular measurement to the reference of the best possible measurement, eventually to the internationally accepted measurement references.

This concept ensures comparability of measurement results, both nationally and internationally, and provides confidence in implications derived from these results (e.g. medical diagnoses, safety warnings, forensic conclusions).

Measurement standards along the calibration chain are categorised as follows:

» National standards maintained by national metrological institutes

    - primary standards: cannot be calibrated by another measurement standard but are compared with other primary standards,
    - secondary standards: traceable to primary standards;
- Company standards
    - reference standards: most accurate standard used in the laboratory and protected carefully,
    - transfer standards: used as an intermediate to compare standards,
    - working standard: used frequently (e.g. for daily calibration of equipment).

When establishing metrological traceability the following aspects should be covered:

- What is the **quantity** to be measured?
- Are all calibrations going back to appropriate references in an **unbroken chain**?
- Is the **measurement uncertainty** evaluated for each step in the traceability chain?
- Is each step of the chain performed according to **appropriate methods**, with recorded measurement results and the associated measurement uncertainties?
- Is each step of the chain performed with the appropriate **technical competence**?
- Are any **systematic measurement errors** (sometimes called "bias") taken into account?

Direct realisation of the SI (Système international d'unités) units is added in the new version of the standard as an option to ensure traceable measurement results (see 6.5.2).

Explanatory notes (see ISO/IEC 17025:2005, 5.6.2) and further information are consolidated in a new Annex A to ISO/IEC 17025:2017.

The reference to little contribution to measurement uncertainty (see ISO/IEC 17025:2005, 5.6.2.2.1) is no longer explicit but covered by the risk-based approach to ensuring the validity of results.

Metrological traceability shall be ensured by an unbroken chain of calibrations (see 6.5.1).

Some equipment can be sent to a calibration laboratory for calibration and then shipped back to the laboratory, but many systems are either too bulky for this approach or need calibration on site.

Provided that it can achieve traceability, the laboratory can be self-sufficient in calibration and not use any external calibration services for its equipment.

Internal calibration would also have to be subject to an evaluation of its uncertainty by the laboratory just as though it were carried out by an external and accredited calibration service.

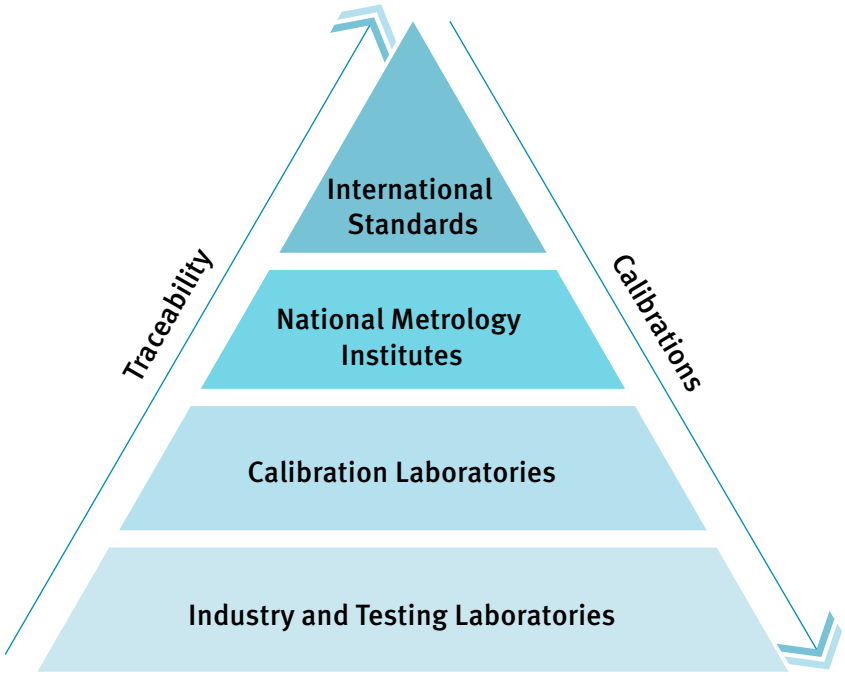
Traceability to SI units is achieved through one of three options (see 6.5.2):

(i) calibration by a competent laboratory,

(ii) certified reference materials by a competent producer or

(iii) direct realisation by comparison with national or international standards.

FIGURE 4: TRACEABILITY PYRAMID



Details of practical realisation of the definitions of the fundamental units of measurement are given in the SI brochure.

Accredited calibration services are generally considered to be competent.

If the calibration laboratory is not accredited, the laboratory will have to ensure that the calibrations are adequate and that traceability is intact. The key issues to demonstrate the latter are:

» references, which are properly calibrated and provide international traceability;

» calibration procedures, which are scientifically sound, of known performance characteristics;

» personnel, who are carrying out the procedures, are properly trained and competent in the calibrations performed.

When seeking recognition according to ISO/IEC 17025, it is advisable to contact the recognising body (e.g. the accreditation body) regarding the following questions:

» Is the calibration service accredited to ISO/IEC 17025 and is this accreditation covered by a mutual recognition agreement for calibration with the designated accreditation body for the laboratory?

» If the proposed calibration service is not accredited, does the designated accreditation body for the laboratory have any policy on the acceptance of calibrations from this calibration service?

» If the issue is still unresolved, what information would the designated accreditation body for the laboratory require to make a decision on the acceptability of calibrations from the proposed calibration service? This would normally concern examples of calibration certificates, information on how the calibration service establishes its traceability, what arrangements the calibration service has for measurement audit or comparisons with other calibration bodies and whether it has a management system.

If metrological traceability to the SI units is not technically possible, **appropriate references**, such as certified reference materials, reference methods or consensus standards, are specified to demonstrate metrological traceability (see 6.5.3).

In this case, measurements are traced back to the relevant reference rather than to a SI unit but provide acceptable metrological traceability in that they establish comparability between different laboratories.

However, the use of appropriate references to show that measurements are acceptably accurate is not a substitute for traceable calibration of instrumentation since this only tests the system at a single point.

The policy of accreditation bodies for traceability of measurement results is provided by ILAC P10.

Externally provided resources

Requirements for **externally provided resources** (see 6.6) combine the requirements for subcontracting and purchasing services (see ISO/IEC 17025:2005, 4.5 and 4.6.).

Externally provided **products** can include measurement standards and equipment, auxiliary equipment, consumable materials and reference materials.

Externally provided **services** can include calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services, and assessment and auditing services.

In all cases, **specifications** by the laboratory and corresponding **controls** are required since the new version of the standard focusses on the outcome and requires rather generically “suitable externally provided products and services” (see 6.6.1).

The laboratory is always responsible to the customer for the quality of externally provided resources.

The degree of scrutiny and evaluation of providers depends on the impact on the quality of the laboratory’s work and the validity of its results.

A practical approach is a list of approved external providers. Approval can depend on accepting evidence, such as certificates, accreditation, or proficiency testing results.

Otherwise supplies and services have to be checked by the laboratory for acceptance. With the impact on the validity of results as the guiding principle, the laboratory should check against the order specification or visit potential external providers to carry out an audit.

In practice, elements of both approaches will be used. Laboratories will have approved and trusted external providers but also carry out checks, often as an integral part of methods, for example reagent blanks or calibration checks.

The respective **procedures** to be documented and **records** to be retained are specified (see 6.6.2) and required **communication** to external providers is listed (see 6.6.3).

Such procedures should specify all necessary activities, from including the laboratory’s requirements in the purchasing information to inspecting shipments before releasing for laboratory use and re-evaluating providers. There should be a mechanism to prevent orders being placed or to ensure that sub-contracting is discontinued with not approved external providers.

The authorisation of personnel, who may release an order or sub-contract, should be clearly defined.

As a measure of controlling the quality of external resources (see 6.6.1), it is a good idea to instruct personnel to report quality problems to responsible personnel. This ensures that all of the information comes together at one point. It is not unusual in large organisations for a supplier to cause small problems in different departments which, when brought together, add up to considerable concern about the supplier’s overall suitability.

Process (Clause 7)

Overview

This clause contains the **"technical requirements"** (see ISO/IEC 17025:2005, 5.4, 5.7, 5.8, 5.9 and 5.10) not categorised as requirements for resources as well as **"management requirements"** (see ISO/IEC 17025:2005, 4.4, 4.7 and 4.13) not considered as requirements applying to the management system itself.

It relates to

» review of requests, tenders and contracts (see 7.1),

» methods (see 7.2),

» sampling (see 7.3),

» handling of items (see 7.4),

» technical records (see 7.5),

» evaluation of measurement of uncertainty (see 7.6),

» ensuring validity of results (see 7.7),

» reporting of results (see 7.8),

» handling of complaints (see 7.9),

» nonconforming work (see 7.10),

» control of data and information management (see 7.11).

The process requirements follow a consistent approach, which is used throughout the standard:

1. the laboratory's requirements have to be documented,
2. the laboratory has to communicate accordingly to the persons and entities affected,
3. the laboratory has to ensure that the requirements are met and
4. appropriate records have to be retained.

Review of requests, tenders and contracts

Requirements for **reviewing requests, tenders and contracts** (see 7.1) apply to all activities of the laboratory, including the three defined "laboratory activities" testing, calibration and sampling (see 3.6).

The purpose is to:

» clarify the customer's requirements;

» select the applicable methods;

» ensure that the laboratory has the necessary capability and resources;

» communicate aspects with the customer, such as provision of samples, deviations from standard procedures or accuracy levels of results, and decision rules for statements of conformity;

» seek the customer's approval (e.g. for in-house methods or externally provided resources). Addressing statements of conformity and the associated decision rule (see 3.7) is now required during review before taking up the laboratory's activities (see 7.1.3).

Decision rules are developed, verified and validated in a way that the decision is ideally based on objective evidence and less on individual knowledge or experience of personnel. They can require complex calculations to be performed by software.

Decision rules have to be appropriate and applicable either to the accuracy of the laboratory's methods and outcomes as well as to the customer's requirements for conformity. When agreeing on the decision rule, the associated risk for false accept or false reject has to be taken into account.

Further guidance on statements of conformity is provided by ISO/IEC Guide 98-4 and ILAC G8.

It is explicitly stated, that **deviations requested by the customer** shall not impact the integrity of the laboratory or the validity of the results (see 7.1.4).

If the laboratory perceives a decision rule prescribed by the customer to be inappropriate, it should be discussed during contract review.

In cases where a customer insist on a particular method in spite of the laboratory's reservations, the laboratory may proceed but should advise the customer of the limitations on the applicability of the data, which will result from the choice of method, and should reflect its views in any report issued.

Seeking **customer's approval** for engaging **external providers** is now required (see 7.1.1).

It is recognised that externally provided laboratory activities can occur when:

» the laboratory has the resources and competence to perform the activities, however, for unforeseen reasons is unable to undertake these in part or full;

» the laboratory does not have the resources or competence to perform the activities.

The rest of the requirements (see ISO/IEC 17025:2005, 4.4) are not significantly changed.

The sequence of events in contract review should be something like this:

1. A request is received from the customer.
2. The laboratory determines whether the request is clear in that it either identifies specifically the procedure required or makes clear the customer's objective in requesting the work.
3. The laboratory identifies whether the requested work is routine in the sense that it has a validated, documented and appropriate procedure. In that case, the laboratory can ensure it meets the customer's requirements. At most the laboratory has to ensure that it can cope with special conditions, such as large number of samples or very short time limit.

4. If the work is not identified as routine, then it will be necessary for the laboratory to determine whether it can accept it. This will require an assessment of whether the necessary equipment and expertise is available. A method will also have to be identified and arrangements made to validate it. The laboratory shall have a **procedure** for this review (see 7.1.1).

It should indicate the assigned responsibilities (see 5.5), for example who may determine whether work is routine and who decides whether a request for non-routine or high volume work will be accepted.

For internal or routine customers, reviews of requests, tenders and contracts can be performed in a simplified way.

A full contract review may not be required for routine samples from established customers. When the programme is set up initially, it could be sufficient to record the receipt of the work, the date and the identity of the person conducting the work as well as any significant changes.

It is a good idea to keep a set of documents in the sample reception office, which shows the current requirements for each regular customer. Such documents will form part of the controlled document system and are updated as necessary when customer requirements change.

Details of the request, such as inappropriate methods (see 7.1.2) as well as deviations from the contract (see 7.1.5), have to be **communicated** with the customer and outstanding issues have to be resolved before commencing laboratory activities (see 7.1.4).

Later **amendments** to the contract require a repeated review (see 7.1.6) and continuous cooperation with the customer ensures clarification of requests and monitoring the laboratory's performance (see 7.1.7).

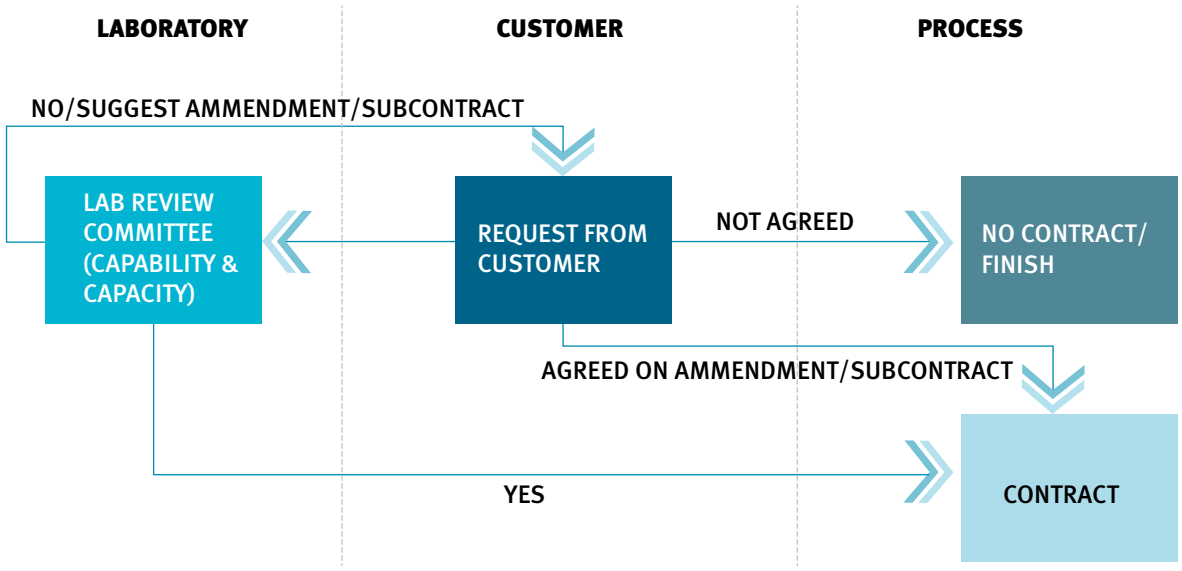
This can include providing reasonable access to relevant areas of the laboratory to witness customer-specific laboratory activities or preparation, packaging, and dispatch of items needed by the customer for verification purposes.

It may be necessary to revisit the contract review during the work as a result of changes requested by the customer or, more commonly, as a result of problems with the test or calibration items themselves. The laboratory is under an obligation to inform the customer of any deviations from the contract and to obtain approval.

Records of the review and discussions with the customer have to be retained (see 7.1.8).

They should identify who conducted the review, the customer details and contact information, and details of the work requested. Furthermore, the assessment of whether the work is routine or else the required validation should be recorded.

FIGURE 5: EXAMPLE FOR A SEQUENCE OF PROCESS STEPS IN THE CONTRACT REVIEW



Selection and verification of methods

Requirements for **methods** (see 7.2) are not significantly changed with the new version.

The individual requirements (see ISO/IEC 17025:2005, 5.4) are re-organised and the terminology is updated.

Method development is clarified with regard to method validation (see 7.2.1.6 and 7.2.2) and the term "method" is to be read as synonymous to "measurement procedure" according to VIM (see Note to 7.2.1.1).

International, regional or national standards as well as other recognised specifications that contain sufficient and concise information on how to perform laboratory activities do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used by the operating personnel in a laboratory. It can be necessary to provide additional documentation for optional steps in the method or additional details.

In practice, methods used by laboratories fall into one of three categories:

» **Standard methods** which are published as standard specifications (e.g. by ISO, ASTM American Society for Testing and Materials or other standardisation bodies) or are published in the scientific literature: Where the laboratory claims these as part of their scope they must be followed precisely without variation from the published specification. The laboratory will not have to carry out full method validation but will have to have data to show that it can achieve the level of performance which the standard specification claims for the method or, failing that, a level of performance appropriate for the purpose for which the measurement is being made.

» Documented **in-house methods** which are the laboratory's own methods: These must be subject to a high level of validation that the method is technically sound, suitable for the purpose claimed and acceptable to customers.

» Documented **in-house methods based on standard specifications**: This category makes up a major part of many laboratories' scopes. The amount of validation which a laboratory has to do will generally be reduced depending on the extent of the departure from the standard specification. Care needs to be taken, when reporting data from such methods, to recognise the variation from the standard specification. It is also necessary to ensure that customers are aware of the variation and accept the resulting data as still being suitable for their purposes.

All methods have to be **suitable, valid and up to date**, unless it is for some reason not appropriate or possible (see 7.2.1.1 and 7.2.1.3). The selected methods have to be **communicated** to the customer (see 7.2.1.4).

An issue which sometimes arises is, where a standard specification has been revised but the laboratory or its customers wish to continue to use the old version. The general rule is that customers of the laboratory who request a test to a particular standard specification are entitled to assume that the laboratory will use the current version and, if it is using an older version, then they must be informed and advised of the differences. Whether to proceed then becomes the customer's decision. On the other hand, if the customer specifies an older version, the laboratory must respect the customer's wishes, subject to the requirement to draw the customer's attention to any limitations introduced by this choice (see 7.1.4).

An out-of-date standard should be included amongst the laboratory's documentation only with care, and the document should be clearly marked with details of when it is appropriate to use, for example for work for a particular customer. The laboratory will have to demonstrate that there is no danger of the method being used in error as the current version.

Methods and relevant information have to be **available to personnel** (see 7.2.1.2) and the laboratory has to verify that it can perform the applicable methods and achieve the required **performance** (see 7.2.1.5).

This means that irrespective of whether the method is developed in-house or standard, the personnel must have documentation to enable it to be applied properly and consistently.

Publications of standard methods may be supplemented with additional information, such as instructions on the use with the laboratory's particular instrumentation or guidance on choices to be made or quality control samples to run.

In-house methods will need complete documentation.

Documentation of methods is issued as controlled documents (see 8.2).

Requirements are specified for method **development** (see 7.2.1.6), **deviations** as well as **changes** (see 7.2.1.7 and 7.2.2.2) and **validation** (see 7.2.2.1).

Customer acceptance of deviations should be agreed in advance in the contract.

Validation of methods

In **method validation** (see 7.2.2.1) the laboratory first needs to establish the extent to which it can reproduce procedures and hence show that it can deliver consistent data within known limits.

In order to avoid a bias in its data (i.e. being consistently wrong) the laboratory has to test itself against agreed reference points.

Validation can include procedures for sampling, handling and transportation of test or calibration items.

The equivalent to method validation in calibration is the establishment of the calibration and measurement capability. This is a measure of the smallest measurement uncertainty, which the laboratory can achieve for the specific calibration under ideal circumstances. Clearly, the reproducibility of the measurement is a key factor in limiting the measurement capability, but there must also be a

check to establish whether there is any bias which will also impose limitations.

The techniques used for method validation can be one of, or a combination of, the following:

» calibration or evaluation of bias and precision using reference standards or reference materials;

» systematic assessment of the factors influencing the result;

» testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed;

» comparison of results achieved with other validated methods;

» interlaboratory comparisons;

» evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method.

When validating methods by one or more alternative techniques, the apparent differences can be analysed statistically to confirm their significance.

How much validation is needed for a method depends on the requirement to be "adequate for **intended use**". It has to be shown that the method as applied by the laboratory is suitable for the purpose claimed or demanded by customers (see 7.2.1.1).

If the laboratory has developed the method itself, then appropriate validation can be a very complex process requiring a demonstration of the scope of applicability of the method in terms of samples and numerical range, selectivity, robustness in use, accuracy, precision, bias, linearity, detection limit, and any other relevant characteristics.

If the method is a standard published method, most of these factors will already have been investigated and specified as part of the method documentation. However, some verification will be required to establish that the performance of the method in that particular laboratory is satisfactory. There is no guarantee that the laboratory's skills or the performance of its instruments are of the same standard as those used to generate the standard validation data. The laboratory must always test its own capability directly.

The **performance** has to be according to the specifications (see 7.2.2.3) and the **records** to be retained are listed (see 7.2.2.4).

Performance characteristics can include, but are not limited to, measurement range, accuracy, measurement uncertainty of the results, limit of detection, limit of quantification, selectivity of the method, linearity, repeatability or reproducibility, robustness against external influences or cross-sensitivity against interference from the matrix of the sample or test object, and bias.

Deviating from the documented procedure is not a problem, provided the decision is made by an appropriately qualified person and that the details are recorded. If relevant to the interpretation of the results, the deviation must also appear on the report (see 7.8.2.1). The laboratory has to authorise personnel to approve deviations from standard methodology. The person authorising the deviation should be made responsible for ensuring that the necessary records are made.

Further guidance on method validation is provided by EURACHEM Guide "The fitness for purpose of analytical methods".

Sampling

Requirements for **sampling** (see 7.3) are not significantly changed with the new version (see ISO/IEC 17025:2005, 5.7).

The notes are consolidated and this process step is clarified with regard to "sampling" as the newly introduced laboratory activity (see 3.6).

Before any work is begun, the contract review process (see 7.1) must be complete. There must also be a check to confirm that any test or calibration items are appropriate for the procedure and in suitable condition. When received into the laboratory, further handling can be required (see 7.4).

A **sampling plan** and **sampling method** (see 7.3.2) are required, shall be available to personnel and contribute to ensuring the validity of subsequent results (see 7.3.1). Any deviations should be recorded.

The sampling plan describes the allocation, withdrawal and preparation of samples (e.g. from a matrix, or a batch of products). It should be based on appropriate statistical methods.

The sampling method describes the process of sampling and specifies the factors to be controlled in order to ensure the validity of results (e.g. to avoid contamination when selecting samples at sites or distortion during transport of samples).

Samples have to be unambiguously identified and the documentation on sample or item receipt should specify which personnel are authorised to receive and record items. The information recorded should include details of the condition of items on receipt and should identify the person making the register entry.

The person receiving the items should also be responsible for examining them to ensure that they are suitable for the intended test or calibration. If there are any problems, action must be taken to ensure that no work is done before the problems are resolved with the customer. A record must be kept of any communications with the customer, since such communications involve amendment to the contract review.

The **records** of sampling to be retained are listed in the standard (see 7.3.3).

Handling of test or calibration items

Requirements for **handling of items** (see 7.4) include now a **disclaimer** in the laboratory's report, indicating results that are possibly affected by deviations from specified conditions, which have been acknowledged by the customer (see 7.4.3).

Otherwise the requirements (see ISO/IEC 17025:2005, 5.8) are not significantly changed with the new version.

No work should be done until all matters of concern have been brought to the customer's attention and clarified to mutual satisfaction, i.e. the contract review is complete.

This includes problems with the items themselves or any lack of clarity about the work required.

A **procedure** of the laboratory for any handling of test or calibration items is required to ensure protection of their integrity (see 7.4.1).

The laboratory should have a clearly documented policy on where items are to be **stored**.

This may involve several storage locations for different types of items, but these should be clearly specified. Each storage location should have a log in which items can be signed out and back in again, such that a particular type of item will be found in the storage location or can be located by reference to the log. This record should identify the person taking the item and the date and time of removal. Similarly, return date and time should be recorded, if appropriate. The aim is to create a complete history of the custody of the item.

Retention of samples is less an issue for calibration laboratories, since items sent for calibration are invariably returned to the customer. In this case, the laboratory's obligation is to ensure that items are properly packed and transported to maintain the integrity of the calibration.

Testing laboratories and sampling organisations should have a clear policy on how long samples are kept. Wherever possible, samples should be retained for a period after the report is issued in case there are any queries which might be resolved by retest. If their retention makes no technical sense (e.g. for degrading materials) the laboratory should reserve the right to dispose of samples immediately.

Customers should be made aware (e.g. through the laboratory's standard terms of business) what the sample retention policy is so that there are no misunderstandings.

It should be clearly documented who may authorise sample disposal and all disposals should be recorded.

Test or calibration items have to be **unambiguously identified** (see 7.4.2) and specified **environmental conditions** for the items have to be controlled (see 7.4.4).

The purpose is to control the individual items from the collection site or customers dispatch through point of receipt at the laboratory and through storage until testing or calibration and, if applicable, until delivery to the customer.

All items must have a unique identifier which stays with them throughout their time in the laboratory. This "uniqueness" should be retained over the period for which the laboratory retains its records.

A system over which the laboratory does not have direct control, such as using the customer's sample description as an identifier, could lead to duplication. For the same reason, it is not adequate to retain a numbering system which repeats cyclically (e.g. at the start of a calendar year).

The numbering method can be chosen to suit the requirements of the laboratory, but it must be unambiguous, even when samples are divided. The laboratory sample number must be related to any customer identification details.

Technical records

Requirements for **technical records** (see 7.5) of this clause are differentiated from those for other types of records, which are addressed under the management system (see Clause 8).

No differentiation is made between electronic and manual records, otherwise no significant changes are made with the new version (see ISO/IEC 17025:2005, 4.13.2).

The key objective in keeping records should be to ensure that the source of any error can be traced and that any laboratory activity can be repeated in a manner as close to the original as possible. It must be possible to trace a result to the person who made the measurement and the equipment used and to identify precisely the method used. This means that data must be recorded at the time of observation, making it possible to check that the work was done by trained personnel using appropriate methods on correctly functioning and calibrated equipment.

It should be clear who is responsible for final quality control checks of technical records and effectively releasing data for inclusion in reports.

Manual records can make use of worksheets or laboratory journals and be either personal or method-specific.

Worksheets should not only provide space for recording results but should also require relevant calculations to be done on it (e.g. by an outline ready for the variables and the results to be written in). The objective is to have as much information as possible to support quality assurance and to provide for error tracking.

Laboratory journals and notebooks should be numbered and have numbered pages, which cannot be torn out without being detected. The holder of each journal should be recorded.

Instrument printouts should always be retained as part of the original observation records. The printout should show the sample number and the operator of the instrument. Where instruments record data in computer files, these should, preferably, have provision for recording the operator and the sample number to which the file refers.

In order to ensure consistency in practice and leaving no ambiguity about what constitutes the original observations, it is not recommended to record data in rough and then copy it over later. Data transfer steps are potential sources of error.

Electronic records making use of computer systems need to be properly managed and controlled, whether they be part of instrumentation or systems simply used to store and process data.

The **content of technical records** is specified in the standard, including factors affecting the results, date and the responsible personnel. Records for original observations, data and calculations are addressed (see 7.5.1).

The laboratory should decide which computer records constitute the original observations, i.e. the raw data recorded at the time of making the observation.

This will only be the case where data is logged into the computer directly from instruments or is entered at the bench. If data is recorded in notebooks or on worksheets prior to transfer to the computer, then these paper records are the original observations and the potential source of error by manually entering data into the computer has to be considered.

Technical records have to be **retained** and allow for **traceability** of amendments or to original observations (see 7.5.2).

Corrections to worksheets and journals must be made in such a way that the original version can be read.

Evaluation of measurement uncertainty

Requirements for **evaluation of measurement uncertainty** (see 7.6) are differentiated for testing and calibration.

Measurement uncertainty is understood as the margin of doubt about the results of any measurement. In order to evaluate this uncertainty, it has to be established (i) how big the margin of doubt is and (ii) with which certainty the true result lies within this margin (confidence level).

While the measurement "error" describes the difference between an actual measurement result and the true value, the "uncertainty" quantifies the doubt about the result.

Any error of unknown value, which cannot not be compensated by applying correction factors, is a source of uncertainty.

Likewise, the used standards, materials and equipment, the applied methods, environmental conditions or the operating personnel can contribute to the measurement uncertainty.

All laboratories are required to identify the contributions to measurement uncertainty for all measurements. When evaluation of measurement uncertainty is required, significant contributions have to be taken into account (see 7.6.1).

Laboratories are not required to evaluate a unique uncertainty every time a test or calibration is performed, provided the measurement uncertainty of the results has been established and verified and the laboratory can demonstrate that the identified critical influencing factors are under control (see 7.6.3, Note 2).

An indication of the associated uncertainty (i.e. the margin of doubt as well as the confidence level) is important when deciding whether the results are adequate for the intended use.

Evaluation of measurement uncertainty is required for all calibrations, including those the laboratory performs on its own equipment, i.e. "in-house" calibrations (see 7.6.2).

The policy of accreditation bodies for uncertainty in calibration is provided by ILAC P14.

A testing laboratory has to evaluate or at least estimate measurement uncertainty (see 7.6.3).

In those cases where a well-recognised test method specifies limits to the values of the major sources of measurement uncertainty and specifies the form of presentation of the calculated results, the laboratory is considered to have satisfied 7.6.3 by following the test method and reporting instructions.

For further information, see ISO/IEC Guide 98-3, ISO 21748, the ISO 5725 series, EURACHEM Guide "Quantifying uncertainty in analytical measurement" and ILAC G17.

Ensuring the validity of results

Requirements for **ensuring validity of results** (see 7.7) are specified separately for monitoring within the laboratory (see 7.7.1) and for approaches involving comparison with other laboratories (see 7.7.2).

Method validation (see 7.2.2) is typically an exercise undertaken when a laboratory develops or adopts a method. Once having established the performance characteristics of the method, it is necessary to put **quality control** measures in place to ensure that the demonstrated performance is maintained in routine use and to detect deviations from the ideal performance.

For instance, a laboratory might have a situation where all quality control samples are producing data within the acceptance limits but always on one side relative to the expected value. This situation bears investigation since there should be a random scatter about the expected value. This bias gives an early warning of a problem with the test or calibration system. What is really useful is that the problem has been detected before data is compromised.

All **monitoring activities** have to be planned and reviewed. Data from this analysis have to be used to control and improve laboratory activities, including taking action when results of analysed data are found to be outside pre-defined criteria (see 7.7.3).

Monitoring internal activities includes reference materials, working standards, intralaboratory comparisons and blind samples, replicate tests or calibrations with different methods or retained items, alternative calibrated instrumentation as well

as functional and intermediate checks of equipment (see 7.7.1).

A quality control plan should differentiate between activities on an on-going basis and quality control checks with particular frequencies and conditions.

Certified reference materials (CRM) are samples for which the test results are firmly established and agreed, ideally on an international basis. In order to be effective, a reference material must be typical of the samples which the laboratory tests on a routine basis.

For carrying out tests in complex matrices, which may affect the results, the laboratory can use **spikes** by taking a real sample and adding a known amount of the target in question.

Quality control samples for which the laboratory has established values and acceptance limits can be tested along with unknown samples as a performance check. Quality control samples should be calibrated against certified reference materials. In this instance they become transfer standards, and the quality control sample provides traceability.

Spikes and quality control samples, which are not calibrated against certified reference materials, do not provide traceability in themselves but demonstrate consistency of performance of the laboratory. Such consistency, when combined with satisfactory results from interlaboratory exercises showing that the laboratory normally agrees with its peers, comes a very close second to establishing true traceability and is, in many situations, the only possible option.

In the case of many methods, neither certified reference materials nor effective spikes are available. There could be **consensus standards**, recognised by all parties or industries concerned. Such standards may not be traceable in a strict sense but are used to ensure consistency of data within the industry sector and hence form a basis for agreement when testing against product quality standards.

Replicating determinations (e.g. with retained items) by the same method only provides confidence in the results, when the risk of repeating errors is carefully considered and systematic errors are excluded.

Determinations by **different methods**, which lead to comparable answers, are another approach to testing that is also recognised as a means of providing confidence in results.

In the case of some items, different methods may give different results. The method may effectively define what is measured, for instance the amount contained in a sample is defined by the amount extracted with a particular method.

In these cases, the "correct" result is defined in terms of a reference method which is tightly specified, and traceability effectively means traceability to the reference method.

The process of **calibration** involves the direct comparison of the item to be calibrated against a reference. It is, therefore, the reference itself which provides the guarantee of accuracy, and so it is critical that the reference itself is maintained and checked regularly.

This will often only be possible by sending the **reference for calibration**. However, in many instances, the calibration laboratory can work with a hierarchy of standards whereby a reference standard is maintained and used only for occasional checks on working standards.

Monitoring any activities involving other laboratories refers to participation in **proficiency testing** and other forms of **interlaboratory comparisons** (see 7.7.2).

ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirements of ISO/IEC 17043 are considered to be competent.

Even when effectively monitoring the consistency of the laboratory's own performance, it is in the interest of any laboratory to test this assumption from time to time by exchanging samples with other laboratories and comparing results.

Interlaboratory comparisons may be informal, in that a group of laboratories will exchange samples on an ad hoc basis, or may be formal exercises organised by the participating laboratories or a third party proficiency testing provider who circulates performance indicators.

Recognition of the laboratory's competence will normally not condition any particular level of performance in interlaboratory comparison, but will require the laboratory to have a procedure for evaluating the results from its participation and for responding to any problems revealed. There must also be records showing that the results were evaluated and what action was taken to remedy problems.

The policy of accreditation bodies for participation in proficiency testing is provided by ILAC P9.

Reporting of results

Requirements for **reporting of results** (see 7.8) are revised reflecting current approaches to reporting.

Data provided by a customer is addressed, including a disclaimer when those data can affect the validity of results (see 7.8.2.2).

Reporting **statements of conformity** is specified (see 7.8.6).

Reporting on sampling is specified (see 7.8.5) and differentiated from **test reports** (see 7.8.3) as well as **calibration certificates** (see 7.8.4).

The option to express opinions and interpretations with the reported results is introduced for calibration (see 7.8.7.1).

With these amendments and updates, the requirements (see ISO/IEC 17025:2005, 5.10) are essentially maintained.

It is explicitly required to **review and authorise** the results prior to release (see 7.8.1.1).

The instructions for **compiling reports** should identify the personnel responsible for putting reports together and authorising their release.

There should be a requirement by the laboratory that all reports are checked against the original observations and the customer's instructions before being issued. This should be done by the persons authorising release of the report since they take responsibility for its contents.

All checks should be recorded.

Reports can be issued as hard copies or by electronic means, provided that the requirements of ISO/IEC 17025 are met.

The common situation is that reports are signed documents. If authorised release is practised by other means (e.g. directly from the computer system), the report must still identify an individual who takes responsibility for the data and his or her position. In case of reports generated from a computer, it is essential to have security such that only authorised persons can generate reports. It is also essential to ensure that, once a report has been generated, it is not possible for an unauthorised person to alter the data in the computer and then to generate a changed version of the report.

When data are communicated outside the formal report, the laboratory should have a clear policy who is authorised, for instance to give results over the telephone, and that this should only be permitted once the data is ready for inclusion in a formal report.

Results have to be provided accurately, clearly, unambiguously and objectively, retained as technical **records** (see 7.8.1.2) and, if agreed with the customer, may be provided in a simplified way (see 7.8.1.3).

Reports should convey all information relating to the laboratory activity so that the results can be understood without further enquiry. The laboratory's customer may not be the end-user of a report.

If a laboratory is reporting within its own organisation or in the case of a specific agreement with a customer, the report may be abbreviated. All of the information required by the normal report format must still be available within the laboratory.

Sending reports requires preservation of confidentiality. For instance, reports should only be given to an individual who can be recognised by the laboratory as entitled to the results.

Common requirements for reports

The **required content for each report** is listed and includes title and issue date, identification of the laboratory and the customer, location and date of the activities, identification of items and methods, results and identification of results from external providers (see 7.8.2.1).

A statement that the report shall not be reproduced, except in full without approval of the laboratory, can provide assurance that parts of a report are not taken out of context.

When data is included in reporting, which result from activities not included in the laboratory's scope of accreditation, these results must be identified clearly. There shall be no misinterpretation of the laboratory's scope of accreditation or of data from external providers as having been generated in-house.

Most laboratories provide a **range of laboratory activities**, which is larger than their scope of accreditation. However, it is explicitly excluded to claim conformity with ISO/IEC 17025 for activities, which are externally provided on an ongoing basis (see 5.3).

It therefore has to be considered and aligned with the accreditation body's policy, whether including the accreditation body's symbol in the report is justified when the laboratory in practice reports on results within and beyond its accredited scope. If none of the reported data is within the scope of accreditation, the logo of the accreditation body and/or reference to accreditation shall never be used on the report. Commonly a disclaimer with clear marking of data beyond the scope is permitted.

The laboratory is responsible for the report, except for information provided by the customer. A **disclaimer** shall be put on the report when this information can affect the validity of results.

Information provided by the customer as well as results applying to samples provided by the customer have to be identified (see 7.8.2.2).

Specific requirements for test reports

Additional content for test reports is listed and includes test conditions, measurement uncertainty and, where applicable, opinions, interpretations and statement of conformity (see 7.8.3.1).

Specific requirements for calibration certificates

Additional content for calibration certificates is listed and includes calibration conditions, measurement uncertainty, metrological traceability and, where applicable, opinions, interpretations and statement of conformity (see 7.8.4.1). Unless agreed with the customer, the reported results shall not contain recommendations on calibration intervals (see 7.8.4.3).

Specific requirements for reporting sampling

Additional content for reports on sampling is listed and includes date, location and conditions of sampling, identification of the sampled item or material, sampling plan and method, information to evaluate measurement uncertainty of subsequent testing or calibration (see 7.8.5.1).

This also applies when the testing or calibration laboratory is responsible for the sampling activity (see 7.8.3.2 and 7.8.4.2).

Reporting statements of conformity

Providing a **statement of conformity** requires documentation of the corresponding **decision rule**

(see 7.8.6.1) as well as identification to which results the statement of conformity applies and which specifications, standards or parts thereof are met or not met (see 7.8.6.2).

Further guidance on statements of conformity is provided by ISO/IEC Guide 98-4 and ILAC G8.

Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.

Reporting opinions and interpretations

Opinions and interpretations expressed with the reported results have to be released by authorised personnel (see 7.8.7.1) and shall be clearly identified as such (see 7.8.7.2).

When not documented as part of the report and technical records but communicated directly, a record of this dialogue is to be retained (see 7.8.7.3).

It is important to distinguish opinions and interpretations from inspection statements according to ISO/IEC 17020, product certificates according to ISO/IEC 17065 and from statements of conformity as referred to in 7.8.6.

Laboratories are required to be able to show that they have a documented basis on which these professional judgements expressed as opinions and interpretations are made and that the qualifications and experience of the persons making them are appropriate.

Appropriate information would be reference to any general requirements, standards, technical requirements, or contractual specifications which are being used as a basis for opinions and interpretations. In the case of judgements based on individual's professional experience, the laboratory should be able to demonstrate (e.g. on the basis of the personnel records) that the person making the judgement is appropriately qualified.

Wherever possible, laboratories should have guidelines for any routine interpretations and judgements which have to be made in order to ensure that they are made consistently over time and by different individuals.

Amendments to reports

Changes, amendments or re-issues of reports have to be identified and referenced (see 7.8.8).

The rules for amendment of reports, once issued to the customer, are quite specific.

The original report cannot be destroyed and expunged from the system to be replaced by an extended or corrected version.

A completely new report (i.e. further document or data transfer) must be issued which complies with all of the normal reporting requirements, and it must be endorsed to show that it is an amendment, supplement or complete replacement of the previous version.

The laboratory must retain copies of the original and the amended versions as part of its records. Particular care is needed when report records are computerised to ensure that the new version does not overwrite and obliterate the original.

Even if an issued report is not changed, amended or re-issued, customers should be notified when the laboratory discovers a case where suspect data has been released. For example, if it emerges that an instrument is found to be out of calibration at a regular check and it is uncertain when it actually went out of calibration. The laboratory must determine and be prepared to report what effect the condition out of calibration could have had on final results by following its procedure for handling nonconforming work (see 7.10).

Complaints

Requirements for **handling complaints** (see 7.9) are according to the harmonised language for common elements of CASCO standards.

This includes the requirement to communicate (or else review and approve the respective communication) the outcomes to the complainant by individuals not involved in the original laboratory activities in question (see 7.9.6). This has practical implications for laboratories run by one person, similar to the conducting of internal audits by persons not being directly involved and auditing their own work. The use of external personnel is therefore permitted.

The laboratory is required to have a **documented process** for handling complaints (see 7.9.1) and a description of this process has to be available to any interested party upon request (see 7.9.2).

The laboratory has to validate and acknowledge a complaint (see 7.9.4 and 7.9.5) as well as communicate the outcome (see 7.9.6 and 7.9.7).

The process has to address receiving and investigating the complaint, actions to be taken in response to it as well as tracking and recording of complaints and of the corresponding actions (see 7.9.3).

When handling complaints, it is good practice to address the following questions:

- Who is complaining?
- What is the content of the complaint?
- Why is the issue giving rise to a complaint?
- Who is involved in the laboratory?
- Where did the laboratory activity in question occur?
- When did the laboratory activity in question occur?

Handling complaints, which concern more than one part of the laboratory, may involve a coordinating function (e.g. with responsibility for the laboratory's quality management).

Records of supporting evidence should be kept, even if the complaint has no substance.

If the complaint has substance, the laboratory

should be able to provide a record which shows the corrective action taken to resolve the problem and, most importantly, what has been done to reduce the likelihood of a recurrence.

Nonconforming work

A nonconformity is a non-fulfilment of a requirement.

Requirements for handling **nonconforming work** (see 7.10) implement the risk-based approach of the new version and contain more explicit details on records to be retained (see 7.10.2).

Otherwise the requirements (see ISO/IEC 17025:2005, 4.9) are not significantly changed.

Nonconforming work is any work which does not meet the applicable requirements (see 5.4), i.e. the laboratory's stated standards or the agreed customer requirements.

Any incident affecting the quality of work and the validity of results has to be evaluated for its significance. It should be used as a source of information on weak points in the management system.

The laboratory is required to have a **procedure** to be implemented in case of nonconforming activities or results with the applicable procedures and requirements. This is to ensure that defined responsibilities, actions according to established risk levels, evaluation of significance and decisions on acceptability as well as appropriate communication outside the laboratory are addressed (see 7.10.1).

It is recommended that laboratories have a coordinated approach to recording any such incidents, i.e. complaints, internally detected quality anomalies, detection of nonconforming work and other quality failures.

The **responsible personnel** (see 7.10.1) can then process these inputs and determine whether further action is required, for example response (see 7.9) or corrective action (see 7.10.3 and 8.7).

If the nonconformity could recur or relates to the requirements of the laboratory's management system, **corrective action** is to be taken (7.10.3).

The laboratory's management system contains the requirement for corrective actions in response to nonconformities (see 8.7).

With the guiding principle, that the corrective action shall be appropriate to the effects of the nonconformity, the following issues should be addressed when nonconforming work is detected:

- when laboratory activities have to be stopped,
- who has to be informed,
- who is responsible for the analysis,
- which corrective action must be taken and recorded,
- when the activities may be repeated or resumed (e.g. once the correction or corrective action has been implemented),
- who is responsible for determining that the problem has been resolved (e.g. that work may be started again).

Control of data and information management

Requirements for **control of data and information management** (see 7.11) extend and update the application according to current laboratory practice.

Data and information are the main outcome of laboratory activities and should be carefully managed.

The term "laboratory information management system" (LIMS) used in this clause includes both, computerised and non-computerised systems. Some of the requirements can be more applicable to computerised systems than to non-computerised systems.

The laboratory needs **access to the data and information** required to perform laboratory activities (see 7.11.1).

A functional laboratory **information management system** is used to collect, process, record, report, store, or retrieve data. Changes have to be authorised, documented and validated before implementation, this includes software configuration or modifications to commercial off-the-shelf software (see 6.4 and 7.11.2).

Original observations are first submitted to checks for **quality control** before they become available for incorporation into reports. Provided for a record of traceability, **changes** can be permitted to be made up to this point. However, once data has passed the quality control, only designated personnel, normally the laboratory management and senior professionals, should be able to authorise changes. This implies that computerised data must be protected from unauthorised alteration, either by being made read-only or by transfer to computers physically accessible only to authorised persons.

Once data has been released as a report, it would be a serious nonconformity if the laboratory's record of data failed to reflect the report content. Specific procedures must be followed when reports have to be amended, and the original and amended data must both be available (see 7.8.8).

It has to be possible at all times to tell which data is valid. For instance, when data has been altered on a computer, the corresponding work sheet has to be brought in line.

The laboratory information management system has to be protected, safeguarded, operated according to specifications and maintained. **System failures** and the appropriate immediate and corrective actions have to be recorded (see 7.11.3).

When it is possible to alter data without leaving a record of the alteration or of the original entry, all alterations must be traceable to the person carrying them out and must be made in such a way that the original value is retrievable.

The laboratory is under an obligation to ensure that it protects any data, which it holds, especially if this are

original observations or an essential part of records for traceability. This can involve regular back-ups of computerised systems or dual servers for data storage as well as physical archives protected from fire or humidity.

If off-site or external providers of information management are used, the laboratory has to ensure that they comply with the applicable requirements (see 7.11.4).

The network servers may be part of a general company network in larger organisations and not under direct control of the laboratory management but, for example, of the IT department.

Ensuring that the relevant requirements of ISO/IEC 17025 are fulfilled, the laboratory should have clear agreements on the respective responsibilities, such as

- making new software accessible to laboratory personnel; if necessary, the laboratory management should reserve the right to carry out checks on the software before accepting it,
- information of the laboratory of intended updates or other amendments of software used by the laboratory avoiding inadequate checks when both parties suppose the other to be responsible,
- ability to backtrack to the previous version of the software,
- keeping the log of software and updates,
- modes and levels of communication between the two parties, e.g. clarifying who is authorised to request software changes on behalf of the laboratory and avoiding response to requests from unauthorised personnel,
- arrangements for backing up the laboratory's data on the network.

Relevant information, such as instructions, manuals and reference data, has to be **available to personnel** (see 7.11.5) and calculations as well as data transfers have to be checked (see 7.11.6).

This applies to technical information as well as to management system documentation.

Computerised systems for information management can allow the laboratory to incorporate records of calibration intervals and training review in a manner that will prevent the entry of data generated on instruments past their calibration date or by personnel whose training review is overdue.

Most computerised systems provide for traceability by stamping data entries with the identity of the person entering the data derived from that person's computer user-name. In that case, it is important that personnel log on to the system under their own name. It also has to be considered that the person entering the data might not be the personnel who generated the results. In that case, the laboratory has to ensure traceability by linking the data entry to the responsible person carrying out the actual activity (e.g. a chemical analysis).

Management system (Clause 8)

Overview

A formal management system includes the laboratory's procedures regarding quality control of its generated results (i.e. checking that nothing has gone wrong) but is mainly oriented at providing quality assurance.

The procedures and management methods to this end are designed to minimise the chances of anything going wrong in the first place. The emphasis is on error prevention rather than on error detection. Another purpose of the management system is to provide for the maintenance of records in order to demonstrate even historically the laboratory's quality of work and validity of results.

Options

According to the harmonised text for common elements of CASCO standards, the revision now provides two distinct options (A and B) for establishing a management system (see 8.1).

Option A: A management system addressing as a minimum the requirements of Clauses 8.2 to 8.9

Option B: A management system in accordance with the requirements of ISO 9001 capable of supporting and demonstrating the consistent fulfilment of the requirements of ISO/IEC 17025, as a minimum the requirements of Clauses 8.2 to 8.9.

Laboratories need only conform to one of the options (not both).

Both options require that the management system is capable of supporting and demonstrating the consistent achievement of the requirements of ISO/IEC 17025 Clauses 4 to 7 and assuring the quality of the laboratory results (see 8.1.1). The intention is to achieve the same results with either of the two options.

Option B is helpful for many laboratories, which are part of a larger unit or organisation where ISO 9001 has been implemented. These laboratories would not need to implement a specific management system but could use the organisation's ISO 9001 system.

It has to be noted, that ISO 9001 contains requirements, which were not explicitly incorporated in ISO/IEC 17025. This regards, for example, the context of the organisation or its leadership (see ISO 9001:2015, Clauses 4 and 5).

In order to allow for equivalence of both options, the requirements of ISO 9001 that are relevant to the scope of laboratory activities have been incorporated in the standard. Laboratories that comply with Clauses 4 to 7 and implement Option A of Clause 8 will therefore also operate generally in accordance with the principles of ISO 9001.

However, a management system conforming with the relevant requirements of ISO 9001 (Option B) is not sufficient to demonstrate the impartiality and competence of the laboratory to produce technically valid data and results. This is accomplished through conformity with Clauses 4 to 7.

The concept of "documented information" according to ISO 9001 comprises documents, data and records.

Control of documents is covered by 8.3, control of records is addressed in 8.4 and 7.5.

The control of data related to the laboratory activities is covered by 7.11.

Option A is similar to the former version of ISO/IEC 17025 and aligned with the new version of ISO 9001:2015, especially regarding risk-based thinking.

The laboratory is responsible for deciding which risks and opportunities need to be addressed (see 8.5.1) but there is no requirement for formal methods for risk management or a documented risk management process (see 8.5.2).

The minimum requirements relate to

» management system documentation (see 8.2),

» control of management system documents (see 8.3),

» control of records (see 8.4),

» actions to address risks and opportunities (see 8.5),

» improvement (see 8.6),

» corrective action (see 8.7),

» internal audits (see 8.8),

» management review (see 8.9).

The terms "quality manual" and "master list" (see ISO/IEC 17025:2005, 4.2.2 and 4.3.2.1) are no longer used for management system documentation (see 8.2 and 8.3).

The concept of "preventive action" is now treated as **consideration of risks** and opportunities (see 8.5) as well as improvement (see 8.6), the term is no longer in use.

The laboratory is required to control the documents (see 8.3.1) where **documentation** is required or made by the laboratory to the extent necessary.

Management system documentation

Any **management system documentation** (see 8.2) has to serve the purpose of maintaining and, where necessary, improving quality.

It should ensure that quality management is applied comprehensively, appropriately and consistently. This includes establishing evidence such that if something should go wrong, the error can be tracked and modifications to the system can be made in order to reduce the likelihood of a recurrence, i.e. implementing corrective action which addresses the root cause of the problem.

Documentation is important but it is critical to realise that it is not, in itself, the management system.

The documentation is simply one of the tools of the system and has two main roles:

» it is a mechanism for defining the management system in order to be able to monitor whether it is being used;E

» it is a means of communication within the laboratory so that all personnel know their responsibilities and the procedures to be followed.

ISO/IEC 17025 requires the laboratory to implement its **policies and objectives** for fulfilling the standard at all levels (see 8.2.1).

This applies explicitly to the competence, impartiality and consistent operation of the laboratory (see 8.2.2).

There has to be evidence of the **laboratory's management commitment** in this regard (see 8.2.3).

Furthermore, all **information** relevant to the fulfilment of this standard, such as documentation, processes, procedures, systems and records, have to be at least **linked to the management system** (see 8.2.4).

Corresponding to their respective responsibilities, personnel need access to this documentation of the management system (see 8.2.5).

Although there is no longer a requirement for a formal "quality manual", all management system documentation, either electronically or as hard copy, should be compiled in a consistent and comprehensive manner.

It could make use of references to subsidiary documents (e.g. procedures or equipment logs) but has to contain all necessary information or clearly explain where such information is to be found.

This provides an appropriate basis for demonstrating the fulfilment of ISO/IEC 17025 (e.g. by accreditation) when the laboratory will be assessed against the requirements of the standard and its own management system documentation.

The **management system**, hence its documentation, consist of these main elements:

the laboratory's **policies and objectives** regarding the quality of its work, including the respective commitment of the highest management level or applicable regulatory documents;

» the **management structure** (see 5.5) which defines how responsibility and authority for dealing with problems of quality are allocated in the laboratory;

» the **procedures** which constitute the working management system (e.g. control of documents and records or dealing with nonconforming work).

In addition to the management system documentation, the laboratory has to document its **technical procedures**, such as test or calibration methods themselves (see 7.2) or operating details for the instrumentation (see 6.4).

The level of detail for these method documents should be such as to enable a trained practitioner to carry out tests and calibrations in a proper and consistent fashion.

Operating details can be provided either as part of the method description or as separate descriptions of operating procedures.

However, it is not essential for the laboratory to write up all methods and operating procedures. Where standard methods are used, the requirement for a method description can be met by making available to the personnel a copy of the standard specification.

Similarly, equipment operating instructions may be made available entirely in the form of manufacturers' manuals if these provide all of the information necessary.

A combination of the two approaches is often used, with documentation prepared by the laboratory being produced to refer to, amplify and clarify standard specifications and manufacturers' manuals.

In any case, the documentation has to be available and has to either contain all necessary technical information for carrying out the laboratory activities or make clear where the relevant information is to be found.

The emphasis must be such that all personnel have a source of reference to enable them to work properly and consistently.

An important function of the management system is that it should ensure this consistency. Consistency is particularly important since recognition (e.g. by an accreditation body) is granted to the laboratory and not to individual personnel.

A key feature is to start with a clear written definition of what everybody should be doing regarding both, quality management and technical procedures.

Control of management system documents

Control of documents relating to the fulfilment of the standard has to be in place (see 8.3.1) to ensure that documents are approved for adequacy, reviewed and updated, changes and versions are identified as well as unintended use is prevented (see 8.3.2).

The term "document" is interpreted with the broadest meaning as covering information in all forms, including computer files, software and other electronic or digital information.

In this context, "documents" can be policy statements, procedures, specifications, manufacturer's instructions, calibration tables, charts, text books, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copies or electronic files.

Documents include both, "technical" documents (e.g. protocols or equipment instructions) as well as "management system" documents (e.g. list of approved suppliers or complaints handling process).

The standard explicitly requires **documentation** for the following:

- range of laboratory activities (see 5.3);
- procedures (see 5.5);
- competence requirements for personnel (see 6.2.2);
- requirements for facilities and environmental conditions (see 6.3.2);
- equipment (see 6.4.3);
- chain of calibrations (see 6.5.1);
- externally provided products and services (see 6.6.2);
- review of requests, tenders and contracts (see 7.1.1);
- deviations from methods (see 7.2.1.7);
- sampling (see 7.3);
- handling of items (see 7.4);
- monitoring validity of results (see 7.7);
- decision rules for providing statements of conformity (see 7.8.6.1);
- basis for expressing opinions and interpretations (see 7.8.7.1);
- handling of complaints (see 7.9);
- handling of nonconforming work (see 7.10);
- changes to the laboratory information management system (see 7.11.2);
- management system (see 8.1.1 and 8.2).

All documents, which provide information or instructions for use in technical or management processes, have to be controlled, whether they are prepared by the laboratory, published material or externally provided information.

This includes the documentation of the management system itself (see 8.2) but also masters and templates used for record keeping, publications, notices, calibration tables, memoranda, drawings and plans.

The purpose of the document control is to allow appropriate and accurate documents to be **issued, amended and withdrawn**.

The laboratory's management should be aware of and **approve** the documents used by personnel to guide them in their work. All documents specifying procedures should be checked by someone with appropriate knowledge in order to ensure they are accurate, technically sound and unambiguous. There should be a record of the issuing of all copies of documents, so that if documents need to be reviewed, withdrawn or amended all copies can be subjected to the same procedure.

Any system established to achieve this should consider that documents may need to be issued and amended quickly and this should be done by the most appropriately qualified person.

If document issues and **revisions** do have cross-department implications and need some discussion, the procedure for reaching agreement should be streamlined and made efficient and not excessively bureaucratic.

If documentation is made available electronically, files must be read-only for users and only capable of being amended by authorised persons.

They should also be prevented from being printed without authorisation and recording, since this will generate unrecorded copies of the document, which will be missed by the updating process.

Likewise, the document control system has to be aware of every copy of a document in circulation in order to ensure that all are reviewed and updated when necessary.

Allowance could be made by the management system procedures for the **issuing of uncontrolled copies** of controlled documents, but only outside the organisation. For example, copies provided to customers normally will not need regular updates and could be marked as uncontrolled.

Uncontrolled copies of controlled documents should not be released within the laboratory and, if they are encountered by personnel, they are not to be used as work instructions.

The issuing and amendment of each controlled document is an assigned **responsibility** to an individual or specified group of individuals (see 6.2.6 and 8.3.2).

No other person may make alterations to the document or authorise its issue. The assigned individuals should be those with the relevant knowledge to evaluate the document, irrespective of line of management.

Relevant **displays of document control** (e.g. on the cover sheet of a hard copy) are:

» indication that the document is a controlled document;

» version number and/or the date of the current version, so that the most recent version can be clearly distinguished;

» individual identifier of the copy of the document, such as a copy number, the date of issue of the copy and either the name of the person to whom the copy was issued or the storage location for the copy;

» name, position and signature of the persons on whose authority the document is issued;

» expiry or review date for the document;

» information that the document is complete (e.g. total number of pages).

New or altered text could be identified in amended or revised documents or in attachments provided to communicate the amendments. This allows personnel to identify the key points and determine easily whether changes affect the way they carry out a procedure and when it is simply a textual change.

It is recommended to keep copies of all versions of each controlled document so that, if necessary, the content at any point in its history can be determined.

Also it may be necessary to retain copies of older versions of documents, for instance when customers wish the previous version of a standard method to be used.

Documents which are obsolete for general use but which are **retained for specific purposes**, must be suitably marked. The marking should either specify the scope of use of the document or simply warn that it is not for general use and refer the reader to an authority (e.g. senior laboratory personnel) who can provide information on when it is to be used.

There should be a procedure to ensure that **controlled documents are reviewed** from time to time.

Some published documents (e.g. ISO or national standards describing technical methods) are subject to revision by the issuing body. The laboratory will need a mechanism for ensuring that such revisions are noted and the laboratory's copies of the documents have been replaced with the updated versions. The simplest way is to have a list of all the documents in this category, check on a regular basis and record the checks.

Control of records

Control of records, which demonstrate the fulfilled requirements of the standard (see 8.4.1), has to be in place.

Records must be identifiable and kept in such a way that they can easily be retrieved if necessary. They have to be secure, held in confidence and reasonably protected from destruction (see 8.4.2).

Records contain technical, administrative as well as management system records and relate to:

» original observations (raw data), calculations and derived data (e.g. work sheets, instrument output), which should be dated and traceable to the person who made the observation or measurement and to the equipment used (see 6.3.3, 7.3.3, 7.4.3, 7.4.4, 7.5, 7.7.1);

» personnel qualifications, training and review of training (see 6.2.5);

» installation, maintenance, calibration and checks carried out on instruments and other equipment as individual equipment log for each major item of equipment or composite logs for smaller items (see 6.4.13);

» external providers (see 6.6.2);

» reviews of requests, tenders and contracts (see 7.1.8);

» validation, implementation and proper performance of methods (see 7.2.1.5 and 7.2.2.4);

» copies of all reports issued by the laboratory and relevant communication with the customer (see 7.8.1.2 and 7.8.7.3);

» complaints and response to nonconforming work, including details of follow-up and any corrective action taken (see 7.9.3 and 7.10.2);

» audits and reviews of the management system, including records of corrective action taken (see 8.7.3, 8.8.2, 8.9.2 and 8.9.3).

There should be a documented policy on the retention period of records. ISO/IEC 17025 does not require a specific time but a period consistent with the laboratory's contractual obligations.

A typical obligation is connected with an accreditation. The corresponding policy of the laboratory could be to retain most records for one accreditation cycle, hence disposal after re-assessment. Accreditation bodies themselves are required to retain records at least for the duration of the current cycle plus the previous full accreditation cycle.

Any records, which are relevant to ongoing issues, need to be kept for at least the duration of that issue. For example, records relating to individual items of equipment need to be kept for however long the equipment is in use plus whatever period is necessary to reach the next re-assessment.

Similarly, records of personnel are kept so long as they are employed plus the time to the next re-assessment.

Actions to address risks and opportunities

Risks are effects of uncertainty.

When assessing risks, these effects with respect to their likelihood and potential consequences are compared with criteria for acceptable impacts.

In association with the laboratory activities any **risks and opportunities** have to be considered (see 8.5.1).

This ensures the effectiveness of the management system, prevents or reduces failures and enhances the opportunities to achieve the objectives of the laboratory as well as improvement.

These considerations differ from corrective actions (see 8.7), which are a response to a nonconformity or a quality failure, i.e. to put right what has gone wrong and to make sure it does not go wrong again.

The objective is rather to identify where a quality failure or nonconformity is a possibility or where an opportunity is identified to strengthen the management system.

Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

Opportunities can lead to expanding the scope of the laboratory activities, addressing new customers, using new technology and other possibilities to address customer needs.

Actions to address risks and opportunities, which can be implemented in the management system and evaluated for their effectiveness, have to be planned (see 8.5.2).

Such actions could be in response to a scrutiny of the management system, which identifies areas where the system could be strengthened.

Any management system can always be improved. But there will be associated direct and indirect costs, for example reduced efficiency. The consideration of opportunities and potential benefits has to take these risks into account.

Although ISO/IEC 17025 specifies that the laboratory plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Laboratories can decide whether or not to develop a more extensive risk management methodology than is required by the standard (e.g. through the application of other guidance or standards).

Any actions shall each be **proportional to the potential impact** on the validity of the laboratory's results (see 8.5.3).

If the management decides not to take a particular opportunity for improvement on such a basis, justification should to be recorded.

Improvement

The laboratory has to identify opportunities for **improvement** and act accordingly (see 8.6.1).

Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results.

Actions can be in response to identified trends showing deterioration in performance. These include trends in data but also encompass general performance indicators (e.g. turnaround times).

Such identification of trends can be achieved through inviting internal auditors (see 8.8) to suggest areas for improvements to the management system beyond the audit findings and separately from the audit report. Likewise, personnel in general should be encouraged to offer suggestions for improvements in the management system or where the quality of work can be made more secure. This can be via an anonymous suggestions system if it suits the culture of the organisation to proceed this way.

There should be regular formal scrutiny of trends in data, especially quality control data (see 7.7), by the laboratory management. This should include interlaboratory proficiency testing results.

The objective should be to identify trends which indicate potential failures, for example bias developing on a Shewhart chart. This kind of scrutiny can be achieved by a regular meeting of senior laboratory personnel, for example the laboratory manager and senior scientists. The frequency of the meeting will depend on the volume of work, but monthly meetings are commonly held.

Finally, the laboratory is required to seek feedback

from customers to be analysed for improvement opportunities (see 8.6.2).

Examples of the types of feedback include customer satisfaction surveys, communication records and review of reports with customers.

Corrective actions

Corrections have to be taken when a **nonconformity** occurs. **Corrective actions** may be necessary to prevent or reduce re-occurrence of the nonconformity.

Internal audits (see 8.8) are one mechanism for determining whether corrective action is necessary, but there are other potential **sources of information** and all of these should be used.

Obvious sources are complaints from customers (see 7.9), information passed on from laboratory personnel about quality problems, detection of nonconforming work (see 7.10), and direct detection of quality failures as a result of monitoring (see 7.7.1). Interlaboratory proficiency testing (see 7.7.2) and feedback from external assessors and auditors (e.g. in course of accreditation or peer-review) would also come into the category of useful sources from outside the organisation.

The laboratory has to control and correct the nonconformity, including addressing its consequences.

The possible need for **eliminating the cause** has to be evaluated and effective actions have to be implemented accordingly. If necessary, further **update of the risks** and opportunities as well as **amendment of the management system** have to be made (see 8.7.1).

Corrective actions shall be **appropriate to the effect** of the occurred nonconformity (see 8.7.2).

This reflects the risk-based approach.

The laboratory has to keep **records** of the nonconformities and the corrections as well as the corrective actions (see 8.7.3).

Because of the variety of sources giving occasion for corrective action, it is useful to separate the record system for reporting quality problems from the system for planning and recording corrective action. This allows the same corrective action management and recording system to serve for all sources of information on quality problems. The audit, for example, is reported on a form dedicated to that purpose, and this is cross-referenced to the corrective action requests.

The corrective action record system should provide for the recording of the reason for the action and for a detailed description of the proposed corrective action, with an explanation of how it addresses the root cause of the problem.

The responsibility for the action should be assigned and a timescale agreed.

There should also be a record of the arrangements proposed to verify the effectiveness of the corrective action. This will normally mean some type of audit, possibly of restricted scope, covering only the immediate area of the quality system involved in the action.

A laboratory must take active steps to check that its management system is being operated properly and that it is achieving the required standard of quality.

Ensuring validity of results (see 7.7) provides some feedback on these issues but this is not, in itself, sufficient to meet the requirements of ISO/IEC 17025.

The management system has to be pro-active and ensure the quality of work. Moreover, the management system itself must be under constant scrutiny with regard to necessary corrections.

Internal audits and management reviews

ISO/IEC 17025 requires internal audits (see 8.8) and management review (see 8.9) of the system on a planned and regular basis, plus ongoing monitoring to detect **quality problems** and even to anticipate and prevent problems.

These are all strategies designed to detect actual or potential **nonconformities** with the management system before they affect data quality.

An **internal audit** checks on the basis of the management system that the documented instructions are followed, i.e. the implementation of the management system.

A **management review** checks on the basis of ISO/IEC 17025 and relevant policies and objectives of the laboratory that the management system is delivering what is required, i.e. the need for improvement.

Where there are no problems, these activities provide a record that the management system has been scrutinised and found to be satisfactory.

It is the responsibility of the personnel in charge of the management system (see 5.6) to organise audits and reviews as well as to check that any corrective action agreed is adequate, carried out and effective. Normally other personnel will be involved in actually carrying out audits.

The frequency of audit and review of the systems is not mandated in ISO/IEC 17025, but it is good practice to audit each aspect of the management system at least annually and, likewise, that management reviews will be conducted annually.

The management review and audit processes are distinct but interact in the sense that the review will consider, amongst other things, the audit reports. These will provide important information about where the management system is weak and in need of revision.

The audits and reviews should be treated as an important issue and not put off for any reason whatsoever. Experience shows that, once a programme falls behind, it is difficult to catch up.

Internal audits

The laboratory has to conduct **internal audits** on a regular basis. This reveals whether the management system is effectively implemented and conforms with all the applicable requirements, i.e. the laboratory's own as well as the requirements of the standard (see 8.8.1).

To put it simply, the documentation describes what is supposed to be done while the audit checks that it is actually being done and in the way specified.

ISO 19011 provides guidance for internal audits.

Internal audits of defined criteria and scope have to be in line with the laboratory's **audit programme** regarding frequency, responsibilities and procedures (see 8.8.2).

Within this programme, an annual plan should be prepared and the proposed timing of audits should be marked on the plan and, when an audit is complete, the actual date and name of the auditor should be added.

The **responsible personnel** should be given complete authority to ensure that the plan is adhered to.

Audits, in particular, are a crucial issue in an ISO/IEC 17025 management system since the whole philosophy is that the laboratory designs and implements the management system and then carries out audits to ensure that it is working properly. In the absence of audits, problems will only be detected when they lead to quality failures.

This is a quality control approach aimed at error detection, a management system according to ISO/IEC 17025 is focused on error prevention through quality assurance, and it is only through the audit that the laboratory can be sure that the system is working.

General practice is that an audit programme (see 8.8.2) should be organised on a rolling basis such that, in any one year, each aspect of the management system will be covered at least once.

In very small organisations (e.g. one-person-laboratories) where external auditors have to be used, one-off audits of the whole management system at once may be more practical.

It also good practice to conduct two **vertical audits** per year. In a vertical audit the auditor, rather than examining one aspect of the management system, tracks a specific sample or samples through the laboratory, from receipt to reporting of results, and checks that the procedures have been followed and all records kept.

When operating a new or amended management system, it is strongly recommended that the audit **frequency** be doubled during the first year (e.g. a six-month rolling audit programme supported by a six-monthly review).

The audit programme should be phased in during the implementation of the various elements of the management system and not postponed until it is all in place. This provides a valuable check on the elements of the management system as they are established. A settling-in period of two to three months should be allowed for each part of the system and then that part audited.

Auditors should be familiar with the principles of auditing and shall not audit an area of activity in which they are directly involved (e.g. their own work) or for which they have immediate supervisory responsibility.

An auditor need not have a detailed knowledge of the technical aspects of the work of the laboratory but some background is essential.

In most laboratories it is usually possible to do all auditing with **internal personnel**. However, people outside the laboratory (e.g. from other parts of the organisation to which the laboratory belongs) are often suitable. For instance, the personnel in charge of the management system could carry out most audits, and for areas where they are personally involved some other senior personnel are brought in to audit.

Especially in very small laboratories, it may be appropriate to use external auditors from outside the organisation.

Since the purpose of an audit is to check that what is actually happening matches the documentation, it is essential to agree on the documentation to be audited against before starting an audit.

The auditor should have an exact plan of what is going to be examined during the audit (e.g. a checklist of questions to be answered, documents to be examined and assessments to be made).

Results of the audit have to be reported to the relevant management level and records are to be retained (see 8.8.2).

The **audit report** must detail exactly what was examined during the audit and the findings of each examination. Date of the audit and auditors should be recorded.

Positive reports are required as well as negative ones, since the audit is as much concerned with establishing that the management system is working properly as it is with finding problems.

The auditor must be in a position to provide **objective evidence** for any conclusion reported. A general impression that "all is not well" in an area is not an adequate basis for a report.

If contentious disputes on what were the observed facts are expected, it could be a good idea for the auditor to obtain a confirmatory signature from laboratory personnel for the observations. This should be provided for as part of the audit procedure in the management system documentation.

In case of **nonconformities**, **corrections** and/or corrective actions have to be taken (see 8.8.2).

At the end of an audit, the auditor should hold an exit meeting with those involved, normally the laboratory management plus any other personnel with supervisory responsibility in the area audited. The auditor should give a verbal report on the findings, both positive and negative.

At this meeting there should be agreement on any correction and corrective action required and this should be recorded. The record should show what action was agreed, the person responsible for carrying it out and the timescale.

It is good practice to **summarise the results of audits**. Such summary should collate the numbers and types of nonconformities, classified by the area of

the management system to which they pertain. The summary should be presented at the management review meeting (see 8.9.2). It will highlight the areas of the management system which fail most frequently and so help to focus the review.

The summary can be particularly useful in multi-department laboratories where it brings all the audit findings together and can help to identify quality problems that are common to several departments. Such problems are often most effectively addressed at the higher management level rather than by individual departments.

Management reviews

The laboratory management has to **review the management system** periodically to ensure its continued suitability, adequacy and effectiveness as well as the fulfilment of the applicable requirements (see 8.9.1).

The objective is to decide whether the system is delivering what is required. The requirements will be, as a minimum, conformity with ISO/IEC 17025 but may also include any local policy requirements thought relevant by management.

Review is a management function where the key members of the laboratory management examine the **performance of the management system** as a whole. This could be the personnel in charge of the management system (see 5.6), the laboratory manager (see 5.7) and representatives of the management with overall responsibility for the laboratory, i.e. deciding on allocation of resources (see 5.2). The presence of such a representative is key since there may be resource implications in the findings of the committee. Any other persons who might make a contribution should be present. These would typically include senior professional staff and, perhaps, chief technicians. In a small laboratory with only two or three persons, it is usually most effective to involve everyone in the review.

It is the responsibility of the personnel in charge of the management system (see 5.6) to arrange the meeting. This includes distributing the agenda and all relevant information.

The **input to be taken into account** is listed in the standard (see 8.9.2) and relates to:

- audit reports and summaries, including reports by external assessors and any by customers;
- feedback from customers;
- the proposed audit and review programme for the following year;
- results of risk and opportunity identification;
- reports on quality failures and follow-up actions;
- outcomes of assurance of validity of results;
- reports on customer complaints and follow-up actions;
- results from participation in proficiency tests and other interlaboratory comparisons.

The purpose of the review meeting is to look at the performance of the management system over the past year and to decide on any modifications needed to secure improvements.

These could be changes to the management system documentation, plans for future accreditation scopes or participation in proficiency testing, requirements for personnel training, plans for future development of premises.

Records of the output have to be made, including decisions regarding provision of required resources and agreements on who will carry out each action and the timescale (see 8.9.3).

ANNEX A

Cross-references ISO/IEC 17025 2017 – 2005

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	7.8.5	5.10.3.2
	7.8.6.2 (new)	–
	7.8.7.1	5.10.5
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TENSION

UNITED NATIONS
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