GENERAL INTRODUCTION

The subject of this Guide is concerned mainly with testing laboratories – chemical, pharmaceutical, microbiological, geotechnical, food, nuclear etc. that are accredited to ISO 17025. This standard addresses: 'General requirements for the competence of testing and calibration laboratories'.

Staff in other laboratories, such as calibration, medical (accredited to ISO 15189) and those that are GLP compliant should find many of the sections in this Guide applicable to their operations.

Laboratories that are seeking accreditation to ISO 17025 or certification to ISO 9001 and laboratories already certified to ISO 9001 should also find many of the sections relevant to their activities.

The standard will be referred to in this Guide as ISO 17025; the date of publication will be added, where necessary, for clarity.

Many thousands of laboratories are now '***accredited'***, '***certified'*** or '***compliant'*** to one or more of the following standards:

- ISO 17025:2017 General requirements for the competence of testing and calibration laboratories. (Accreditation)
- ISO 15189:2012 Medical Laboratories – Requirements for quality and competence. (Accreditation)
- ISO 9001:2015 Quality Management Systems, Requirements. (Certification)

The Good Laboratory Practice Regulations 1999. (UK) Statutory Instrument (SI) No. 3106. Amended by SI 2004 / 0994. In the UK, the GLP Monitoring Authority has published to UK GLP Regulations 1999. Other countries have the same / similar GLP Regulations.

Every year, new laboratories are seeking accreditation / certification or to become compliant, while many established laboratories are extending their testing or calibration scopes of activities.

Note 1: *The contents of the above Standards / Regulations are periodically updated; please ensure that you are working to the current or appropriate document.*

This Guide to the operation of ISO 17025:2017 aims to give all staff - managers, supervisors and analysts practical means for the successful operation and improvement of many, if not all, of the aspects of the new standard. It also looks to increase underpinning knowledge and understanding of laboratory operations by providing associated text alongside the sections of

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the standard. This should help laboratory staff to increase their effectiveness and so reduce negative laboratory aspects like rework, customer complaints and queries, while increasing laboratory productivity, customer satisfaction and employee skills and motivation.

It is written in an A to Z format to address all the activities in ISO 17025:2017 as well as the additional, associated aspects. The additional text is referenced against the most appropriate ISO 17025 sub-clauses.

There is a cross-references table that correlates the sections in this Guide with the sub-clauses in ISO 17025:2017 and with sections of the previous version of the standard, ISO 17025:2005.

National or Regional equivalents to ISO / IEC 17025, such as BS EN ISO / IEC 17025, will be referred to in this Guide as just the ISO prefix, with the publication date of 2017, where this is required for clarity.

The A to Z format is designed to have a significant amount of material on a topic in one place and so allow readers to target aspects of interest one at a time.

The ISO 17025:2017 Standard.

The standard can be said to have several aims, with the objective of promoting confidence in the operation of laboratories. Some examples of the key aims are below.

- It highlights the important activities in producing customer data and information that is ‘fit for purpose’.
- It requires laboratories to document some of its procedures, with the aim of reducing the variation in how they are practised.
- It provides a mechanism for laboratories to demonstrate that they can generate valid results / information, and therefore compete on equal terms with other accredited laboratories.
- It is a key driver to help improve the overall performance of laboratories, both testing and calibration.
- Compliance with the standard enables laboratories to gain formal third-party recognition by being accredited to this international standard.
- Laboratories that conform to this international standard will also operate in accordance with the principles of ISO 9001:2015.

Note 2: It can be said that the most suitable ISO standard for testing and calibration laboratories is accreditation to ISO 17025: 2017.

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To be accredited either by the National Accreditation Body or the Body of another country, where there is no National Body available, a laboratory is required to be a 'Legal Entity' or a defined part of a 'Legal Entity'. This means that it can be held legally responsible for its activities. ISO 17025 recognises that a government laboratory is deemed to be a 'Legal Entity'.

On occasion, an Accreditation Body, which accredits a company's laboratory in its home country may also accredit that company's laboratory in a second country, where there is a National Body. This is normally the case where a company has several laboratories spread over more than one country.

Changes to the structure of the standard and other changes.

There are some significant changes from ISO 17025:2005 to the 2017 version of the standard. The actual structure of the standard has changed, see immediately below. Other changes are given below under the heading 'Main changes to the standard'.

The structure of the standard has changed from having two main sections, a Management one and a Technical one, containing fifteen and ten parts respectively, to having the aspects in the standard grouped into five clauses in the format of a 'Business Model'.

The new ISO 17025 has, the *operational activities* grouped together under five main headings, given below:

- **General Requirements, Clause 4.**
- **Structural Requirements, Clause 5.**
- **Resource Requirements, Clause 6.**
- **Process Requirements, Clause 7 and**
- **Management Requirements, Clause 8.**

Clauses 1, 2 and 3 are 'Scope', 'Normative references' and 'Terms and Definitions' respectively.

Some details from the previous ISO 17025 are contained in the new standard, albeit in some cases under different headings.

ISO 17025:2017 depicts a business model using just the 11 sections in Clause 7, Process Requirements. ISO 9001:2015 has two business-type diagrams at the beginning of the standard. The first shows the elements of a single process, without using sections of the standard; the second places clauses 4 to 10 onto a 'Plan-do-check-act' cycle.

A general business model developed by the European Foundation for Quality Management (EFQM) shows an example business model as nine connected parts, which are grouped into

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two main sections termed ‘Enablers’ and ‘Results’, essentially ‘Inputs’ and ‘Outputs’. See the depictions of the business models in the above two ISO standards and see: www.EFQM.org.

The structure of the new ISO 17025 standard may be said to better illustrate a business model by grouping the related components of a business into five clauses as opposed to a longer listing of the requirements in the previous standard. Nevertheless, it is important to view and understand how the composition of each of the five clauses in ISO 17025:2017 contributes to the overall functioning of a laboratory business.

Note 3: A key difference between the two ISO standards above and the EFQM model is that neither of the former standards address financial aspects of a business, the EFQM model does. A significant difference between ISO 17025 and ISO 9001 is that the former has both a management part and a technical part, ISO 9001 has just a management part as it is a generic management standard for all types of businesses.

Main changes to the standard.

- Clause 4, General requirements, includes sub-Clauses 4.1 and 4.2 ‘Impartiality’ and ‘Confidentiality’ respectively. These activities are new to the standard, but should have always been practised, now they are stated requirements.
- Clause 5, Structural requirements. There is no specific requirement in ISO 17025:2017 for a member of staff to be designated as the ‘Quality Manager’. Quality management requirements are still identified in the standard and it is implicit that a responsible person(s) is to carry them out.
- Sub-clause 6.6, ‘externally provide products and services’ now includes subcontracting.
- With sampling, sub-clause 7.3, the laboratory is required to have a sampling plan when it carries out any type of sampling for subsequent testing or calibration.
- Also associated with sampling is the inclusion in sub-clause 7.6, Measurement Uncertainty, of the requirement to consider the uncertainty of measurement associated with sampling. This is in addition to that for testing. In the author’s opinion, the standard does not make it clear whether the measurement uncertainty is only when the laboratory carries out sampling activities or if it is for sampling carried out by other organisations, who then forward the samples to the laboratory for analysis. Realistically, the laboratory can only evaluate measurement uncertainty when it has carried out the sampling itself or provided a sampling plan and method to a competent body to carry out the activity on their behalf.
- Clause 8 gives the option to use one of two management systems for compliance to ISO 17025. Sub-clause 8.1.2, Option A, use of sub-clauses 8.2 to 8.9 of ISO 17025,

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or, a management system in accordance with the requirements of ISO 9001:2015, termed Option B. This option essentially fulfils at least the intent of the management system requirements in sub-clauses 8.2 to 8.9 of ISO 17025.

- Sub-clause 8.5, 'Actions to address risks and opportunities' is new to the standard. Part of this activity essentially addresses 'Preventive Action'.
- The management requirements in Clause 8 does not include 'Preventive Action'. This has been addressed by the new sub-clause, 8.5, 'Actions to address risks and opportunities'.
- Sub-clause 8.9, Management reviews carries a different example agenda to the 2005 version. There are additions like 'changes in internal and external issues'; 'fulfilment of objectives' and 'status of actions from previous management reviews'. Deletions include no actual mention of PT Schemes; this requirement is included in item 'n', 'outcomes of the assurance of the validity of results'. Also, there is no specific requirement for reports into the management review from senior staff. The contents of the agenda do include all the key items on which senior staff may comment.

The new ISO standard will not prevent laboratories from making additions to the example agenda, if they so wish.

For those laboratories that are just certified to ISO 9001 and wish to be accredited to ISO 17025, it may result in some of them documenting aspects, in say clause 5 of ISO 17025, Structural requirements, when they are already covered in ISO 9001. Two examples of this are given below.

The first could be: 'Defining the organisation and management structure of the laboratory' in Structural requirements sub-clause 5.5 of ISO 17025, when this aspect is already covered by sub-clause 5.3, 'Organisational roles, responsibilities and authorities', in ISO 9001 certification.

A second example could be: 'Documenting procedures' in Structural requirements sub-clause 5.5 of ISO 17025, when this aspect is addressed in sub-clause 4.3 of ISO 9001, 'Determining the scope of the quality management system'.

Accreditation versus Certification.

Some laboratories are certified to the ISO 9001 standard for testing and / or sampling. ISO 9001 is solely a management standard, as it is designed for all types of businesses; ISO 17025 has management and technical requirements.

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Should an ISO 9001 business (vehicles, pharmaceuticals, foods, beverages etc.) require a technical or a health and safety / data etc. input, appropriate standards are selected and incorporated into the overall management system.

Nevertheless, ISO 9001 does address a small amount of technical content, such as staff training requirements and analysis of data. The 'data' item for laboratories covers aspects such as analytical / internal quality control (AQC / IQC) and proficiency testing schemes (PTS) or Inter-laboratory comparison (ILC) schemes.

Maintaining Conformance with the ISO standards above.

Laboratories should comply with all the necessary sections of these standards, all the time, to fully maintain accreditation / certification. Inevitably, for various reasons, laboratories may not comply with some of the aspects of a standard some of the time. Therefore, internal audits are carried out by the business and external audits carried out by the accreditation / certification bodies as well as by customers, on a periodic basis. Any nonconformances, where found, should be investigated and corrected. A root cause analysis should be carried out prior to putting in place an appropriate corrective action to help prevent the reoccurrence of the original nonconformance.

Minor nonconformances may or may not affect the validity of data / information. For instance, a pipette, which was two days past its re-calibration date or an analytical balance, which had not been check calibrated on a working day may have affected data if found to be out of specification when check-calibrated. If these two items after being check-calibrated were found to be still within specification, then the data would be satisfactory.

It is not good practice to exceed traceable calibration or check-calibration dates for equipment.

Where equipment has been used past a given time and a check has shown that is has moved out of specification, this would mean that all the test data, where this equipment had been used, back to the last compliant check, may not be fit for purpose. In this instance, an assessment would need to be made about the validity of the data. Where it could be shown that the variances in the results were not significant and, for instance, the new results were within the uncertainty of measurements, it may still be appropriate to report them as accredited. If this were not the case, the work could not be reported as accredited and the customer should be advised as to the possible outcomes. These could be: repeat the work, report the work as not accredited and with a comment, or resample, if possible.

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The customer may not wish to pay for unaccredited work or for any re-testing or re-sampling.

Where nonconformances are thought to be of a major nature, that is, where sizeable volumes of reported data are almost certainly suspect, management should consider contacting any affected customers. For instance, with large data errors, test results may be compromised. Consideration should also be given to suspending the accreditation / certification of the relevant tests or calibrations until the process is again compliant. (Although this move alone will not improve the validity of data)

GLP Compliant.

Laboratories that are GLP compliant will be periodically assessed for conformance, like other laboratories, which are Accredited or Certified to ISO standards, but the 'Accreditation Body' for GLP will normally be different to those that accredit or certify other laboratories to the three ISO standards mentioned above. (17025, 15189 & 9001)

Within this Guide are several appendices that are linked to some of the topics.

Note 4: A selection of appropriate references are put at the end of each section. These can be augmented by others from the following organisations, given below.

There is also a full listing of references in the bibliography.

Eurachem. www.eurachem.org.

The International Accreditation Co-Operation, ILAC. www.ilac.org

The European Accreditation Co-Operation, EA. www.european-accreditation.org

The Asia Pacific Laboratory Accreditation Co-Operation, APLAC. www.aplac.org

Documentation from your National Accreditation Body (NAB), which will normally have been adapted from ILAC, APLAC, EA and other documents.

The ISO 17025:2017 standard itself has a range of useful references, some of which are given in this Guide.

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