

## A New International Standard: the introduction of ISO 15189:2022

### Introduction

The Institute of Biomedical Science (IBMS), Royal College of Pathologists (RCPATH), Association for Clinical Biochemistry & Laboratory Medicine (ACB) in collaboration with the United Kingdom Accreditation Service (UKAS) have produced this document to give an overview of the key changes included in the updated *ISO 15189:2022 - Medical Laboratories – Requirements for quality and competence* standard, and to guide healthcare professionals when implementing the new requirements in their service.

The existing requirements of the standard are largely unchanged, meaning that most (if not all) the existing quality management systems implemented in laboratories remain valid. The standard contains the minimum requirements for quality and competence and services are encouraged to view this as such, and that continuous improvement should always be sought.

The new International Standard will be used as criteria to award accreditation. The standard is aligned to the revised ISO 9001:2015 which in turn led to a revision of ISO 17025:2017 and now follows a similar structure in how it is organised. There are annexes comparing both ISO 9001:2015 to this version and the new standard to the 2012 version.

### The New Standard

The new standard is risk based, patient focused and encourages continuous improvement within medical laboratories. The introduction in the standard makes it clear that this is a patient centred standard. Throughout the document there are requirements that are designed to ensure that the risk to patients is central to the ethos of the laboratory's quality management design and processes.

One of the major changes from the 2012 standard is that this version is far less prescriptive, which means there is more flexibility as to how to meet and evidence the requirements set out in the document. The phrasing complies with the ISO directives so, for example, there are still "shall" and "should" statements ("shall" indicating a mandatory requirement, "should" indicating a strong recommendation). There is a greater use of qualifiers after "shall" statements. Clause 6.6.3 is an example of this, with a "shall" statement followed by the phrase "as appropriate" as a caveat at the end of the sentence.

This will require services to have an understanding as to what is appropriate for their local service and therefore if something is considered not to be appropriate - thus there is scope to justify the reasoning why this requirement is not met.

The second highlighted change from ISO 15189:2012 is that point of care testing (POCT) is now integral to this standard, which means ISO 22870:2016 will be withdrawn. There is an Annex to summarise these requirements and there are references to the requirements for POCT throughout the text. Laboratory supported POCT should be included in the scope of the management system and follow the requirements of the standard.

Notes included in the 2012 standard have been revised as there have been changes in the ISO directives used to inform standard writing. There can no longer be “shall” and “should” statements included in notes, so these have been moved into the main text.

There have also been a series of informative companion standards written and revised since the 2012 standard was published. For example, ISO/TS 20914:2019 describes how to calculate measurement uncertainty and provides a series of working examples.

As already described, the emphasis of the new version is on risk and how risks impact the patient. ISO 22367:2020 is a companion standard which covers the application of risk. One of the key concepts described in this document is how clinical decision making can be used as a factor when performing risk assessments.

## **Conclusion**

The IBMS, RCPATH and ACB welcome the new revision of this ISO standard and underline the importance of continually improving quality standards. The added flexibility to allow for clinically justifiable variation to these standards is important to ensure that medical laboratories can strive towards and meet the needs of patients and users within a fully accredited framework, wherever they receive our services.

## **Next steps**

With the release of the new standards, it is recommended that all medical laboratories perform a gap analysis, reviewing their local quality management system against the requirements of the new standard. This gap analysis must involve input from the wide range of laboratory staff, including staff in clinical advisory/interpretation roles, due to the importance of clinical decision making in many of the clauses.

The International Laboratory Accreditation Cooperation (ILAC) has set a transition period for accredited organisations, which requires the transition to the new standard to be completed within 3 years of publication. By the end of this period, all organisations accredited to ISO 15189:2012, and those also accredited to ISO 22870:2016, will need to have been assessed and be accredited to the updated version of ISO 15189.



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Medical Laboratories should work closely with their UKAS colleagues and partners to ensure smooth transition to the new standard. UKAS will work with its staff, technical assessors and accredited customers to support customers through the transition, and further details of the transition process will be made available in due course.