



**CYPRUS ACCREDITATION BODY
CYSAB**

**Accreditation
of Medical Laboratories**

**CYPRUS ORGANIZATION
FOR THE PROMOTION OF QUALITY (CYS)**

Operational Framework of Medical Laboratories

Medical Laboratories represent a very basic infrastructure in the field of health services. The operational framework of the (usually) small private medical laboratories is regulated by the relevant legislation. In the case of hospital laboratories, the operation of the laboratory within a larger organization differentiates the operational framework. The materialization of specific activities and procedures requires a close and efficient cooperation on quality aspects with the other departments of the hospital. The issue of legal entity and the provision of opinions and diagnosis by the proper medical personnel in the framework of services provided to the patient, affects the implementation of the management system. The operation of private hospital polyclinics is similar to the ones in the public sector. However, some of their characteristics are the same with those of small laboratories.

The use of the Standard ISO 15189

The Standard ISO/IEC 17025 was prepared with the perspective to be used in all testing and calibration laboratories, regardless of the specific sector. However, it should be noted that in each case, relevant technical documents and practical codes that reflect the specific needs apply as well. Health services sector and specifically medical laboratories gave rise to specific discussions that led to the preparation of the Standard ISO 15189:2003. This Standard has been issued as a Cyprus Standard and has been recently revised (CYS EN ISO 15189:2007). It represents many similarities to ISO/IEC 17025. However, it includes main differences regarding clauses that reflect the particularities of the sector.

What are the differences between the two Standards

- Terminology
 - In the case of medical laboratories, the term "patient" is used for the customer.
 - The procedure is divided in pre-examination, examination and post-examination.
- Subcontraction is not referred to. There is a reference to laboratories for a second opinion named "referral laboratories". The laboratory turns to these when it judges that some results (that are considered to be critical due to their nature and role in diagnosis meaning) need support/confirmation through this second opinion.
- Particular emphasis is given to the pre-examination phase which already refers, mainly, to the sampling procedure and the protection of samples prior to testing.
- In most cases, samples are unique.
- A detailed code of ethics is included. Samples are a property of the patient and results contain the patient's personal data and any other handling/release is given only upon the patient's permission.

The need to assure reliability

In Cyprus so far there are approximately ten laboratories that are either accredited or are in the procedure towards accreditation. The realization of a reliable operation and the understanding of the accreditation's benefits, are expected to lead to an increase of interest towards accreditation in the next few years. A driving force towards this direction would be the probable incorporation of the clinical laboratories in the National Health Insurance System (NHIS), provided that their results are in compliance with the specifications regarding quality assurance.

CYSAB's Policy for Clinical Laboratories

Following the policy of the other national accreditation bodies in the European place, CYSAB declares ready to provide its accreditation services to clinical and hospital laboratories, depending on their selection between the Standards CYS EN ISO/IEC 17025 and CYS EN ISO 15189. The latter Standard is unambiguously better adjusted regarding the terminology and the philosophy of the health sector; besides, it was prepared to fit this purpose. A number of CYSAB's staff is trained for the needs of the Standard CYS EN ISO 15189 and has already started accrediting clinical laboratories based on this Standard. Already a number of accreditation certificates are given to these laboratories. CYSAB's active participation in the activities of the European co-operation for Accreditation (EA), and more specifically in the Laboratory Committee Working Group assures the continuous update feedback as well as the participation in the modulation of these activities. This participation is essential in order to remind and record the particularity of the small countries as well as to use the European and the International experience.

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