

## STATUS OF DEVELOPMENT AND IMPLEMENTATION OF MEDICAL LABORATORIES ACCREDITATION IN SERBIA

### STATUS RAZVOJA I IMPLEMENTACIJE AKREDITACIJE MEDICINSKIH LABORATORIJA U SRBIJI

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**Summary:** Through the release of the SRPS ISO 15189:2008 standard entitled »Medicinske laboratorije: posebni zahtevi za kvalitet i kompetentnost« conditions have been created for medical laboratory accreditation in Serbia. The application of the ISO 15189:2007 standard is an accepted mechanism for improvement of the quality of medical laboratory services throughout EU today. In that way, different approaches to the quality improvement of medical laboratories have been harmonized. Functional organisation of the accreditation process of medical laboratories in most European countries is mainly carried out in cooperation with national accreditation bodies, medical experts appointed by scientist associations and health departments. This type of collaboration has proven successful in the United Kingdom, Germany, Hungary, France, Finland, Croatia, etc. The experiences of the Accreditation Board of Serbia (ABS) in medical laboratory accreditation according to the SRPS ISO/IEC 17025:2006 standard (5 laboratories have been accredited) and the positive experiences of European countries in accreditation process constitute the basis for the development of the program for medical laboratory accreditation in Serbia. The first step in this direction is the set-up of the Committee consisting of experts from different medical fields, ABS experts and representatives of the competent Ministry, as well as the definition of their tasks, such as: preparation of the necessary documentation, set-up and preparation of qualification criteria and training programs for assessors, participation in the development of the external quality assessment scheme through interlaboratory testing, liaison with the European organisations for accreditation, organisation of mutual assessments with national and international assessors, participation in decision making on accreditation and accreditation maintenance.

**Keywords:** accreditation, ISO standards, medical laboratories

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**Kratak sadržaj:** Objavlivanjem standarda SRPS ISO 15189:2008 »Medicinske laboratorije: posebni zahtevi za kvalitet i kompetentnost« stvoreni su osnovni preduslovi za njegovu primenu u Srbiji. Primena standarda ISO 15189 danas je prihvaćeni mehanizam za poboljšanje kvaliteta usluga medicinskih laboratorija u Evropi. Na taj način su harmonizovani do tada različiti pristupi poboljšanja kvaliteta medicinskih laboratorija. Funkcionalna organizacija procesa akreditacije medicinskih laboratorija u većini evropskih zemalja sprovodi se kroz saradnju nacionalnih akreditacionih tela, medicinskih eksperata delegiranih iz naučnih društava i resornih ministarstava. Takav tip saradnje pokazao se uspešnim u Velikoj Britaniji, Nemačkoj, Mađarskoj, Francuskoj, Hrvatskoj i dr. Naše iskustvo u akreditaciji medicinskih laboratorija prema standardu SRPS ISO/IEC 17025 (akreditovano je 5 laboratorija) i pozitivno iskustvo evropskih zemalja u procesu akreditacije su osnova za razvoj programa akreditacije medicinskih laboratorija u Srbiji. Prvi korak u tom nastojanju je formiranje komisije, sastavljene od eksperata iz različitih oblasti medicine, stručnjaka ATS-a i predstavnika nadležnog ministarstva, i definisanje njenih zadataka, kao što su: izrada potrebne dokumentacije, kvalifikacionih kriterijuma i programa obuke ocenjivača, učestvovanje u izradi šeme eksterne procene kvaliteta preko međulaboratorijskih ispitivanja, praćenje rada evropskih organizacija za akreditaciju, organizovanje zajedničkih ocenjivanja sa domaćim i stranim ocenjivačima i učestvovanje u odlučivanju prilikom dodeljivanja akreditacije.

**Ključne reči:** akreditacija, ISO standardi, medicinske laboratorije

## Introduction

Rapid economic and technological development has brought about the necessity to set up specific new regulatory requirements in the area of *in vitro* medical examination, and those requirements have been formulated as the terms of the ISO 15189:2007 standard entitled »Medical Laboratories – Particular Require-

ments for Quality and Competence« (1). Through the release of this international standard in Serbia as SRPS ISO 15189:2008 entitled »Medicinske laboratorije – Posebni zahtevi za kvalitet i kompetentnost« (2) as well as SRPS ISO/TR 22869:2008 »Medicinske laboratorije – Uputstvo za primenu ISO 15189:2003 u laboratorijama« (3), conditions have been created for establishing a quality system in medical laboratories. It is therefore our goal to develop a program for the accreditation of medical laboratories which would confirm competence in providing medical services.

### Significance of the ISO 15189 Standard

The development of the quality system in medical laboratories in the EU is based on adherence to the requirements of the international standards (primarily ISO standards), with a special emphasis on medical competence and validity. In the circumstances prior to the definition of ISO 15189, aiming to improve the quality of their services, medical laboratories in many countries formulated specific regulations pertaining to both pre- and postanalytical stages of the examination and included national requirements as well.

The most efficient way toward harmonization in the establishment of a quality system is the application of the same standards. The ISO 15189:2007, based on ISO/IEC 17025:2005 (4) and ISO 9001:2000 (5), was designed by the ISO Technical Committee TC212 in order to achieve a harmonized quality system in medical laboratories in the EU countries. The standard has been accepted by EA (European Accreditation) and ILAC (International Laboratory Accreditation Cooperation), while the CLIA (Clinical Laboratory Improvement Amendments) rules (6) have been also in accordance with it, which makes it a recognised standard not only in Europe but globally as well (7). A detailed account of the development of the ISO 15189 standard is presented in the paper by Majstorović and Majkić (8).

The requirements of the ISO 15189 standard may be applied in various fields of medical examination, which is set forth by the definition of the medical laboratory itself (2): »Laboratory for the biological, microbiological, immunological, chemical, immunohaematological, haematological, biophysical, cytological, pathological or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention and treatment of disease in, or assessment of the health of human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation«.

The process of developing the standard for medical laboratories has not been completed yet, particularly in terms of the requirements related to the *in vitro* medical examinations and the safety of the patients, personnel and the environment.

### The Structure of the ISO 15189:2007 Standard

Establishing a quality system in medical laboratories calls for fulfillment of specific requirements in order to produce accurate, precise and reasonable results.

The ISO 15189 standard is designed in the language of medical experts. It deals with management (Chapter 4) and technical requirements of a laboratory (Chapter 5); it also includes a consultant service team for laboratory examinations, interpretation of results and recommendation on further treatment (9, 10). The greatest changes in the ISO 15189 standard compared to the ISO/IEC 17025 are in the paragraphs: *4.5 Check-up in referral laboratories, 4.7 Advisory services, 4.12 Constant improvement, 5.4 Pre-examination procedures, 5.5 Examination procedures, 5.7 Post-examination procedures, 5.8 Reporting results, as well as recommendations outlined in Appendix B – Recommendations on the protection of laboratory information systems (LIS) and Appendix C – Ethics in laboratory medicine.* According to the interpretation of Libeer and Ehrmeyer (7), specific requirements of this standard refer to:

- Appropriate choice of tests for a patient
- Sampling instructions and patient preparation
- Preliminary storage and transport of samples to the test site
- Turn-around time and emergency testing
- Examination by referral laboratories
- Monitoring of biological reference intervals
- Information in reports and professional judgment
- Technical and medical competence
- Confidentiality aspects.

### Experiences in Medical Laboratory Accreditation in Europe

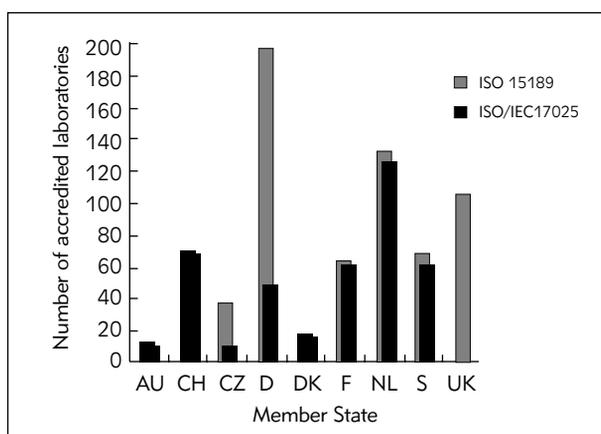
Although accreditation is optional in many European countries, in some of them the implementation of the quality system is supported by national legislations. Such are the cases of Austria, Belgium, Germany and Switzerland.

According to the ISO (International Organization for Standardization), accreditation is determined as: »a procedure by which an authoritative body gives formal recognition that an organization or a person is competent to carry out specific tasks«, whereas certification is defined as »a procedure by which a third party gives written assurance that a product, process, or service conforms to specific requirements« (7). Standard ISO 15189 is not intended for certification (1). In the U.S.A., the term »accreditation« refers both to authorization of laboratories and to certification of procedures and processes. The term »accreditation« should be used exclusively according to the ISO definition (7).

Implementation of the ISO 15189 standard is specific in respective European countries and it depends on a number of factors (laboratory status, available funds, etc.). However, what all the countries have in common is a national accreditation body that carries out the function of evaluation of the management system, while the assessment itself is left to experts in specific fields, as trained assessors.

Most medical laboratories in the EU have been accredited according to the ISO/IEC 17025, and/or ISO 15189 standards. The establishment of a quality system in medical laboratories in the EU according to the ISO 15189 standard is very efficient as shown in the data from the research carried out by the EC4 (European Community Confederation of Clinical Chemistry) working group in 2005 (11). At that time the total number of accredited medical laboratories was very small. The exceptions were the Netherlands and the UK, where there were over a hundred medical laboratories accredited according to the ISO 15189, whereas in the UK alone over 600 laboratories were accredited according to CPA (Clinical Pathology Accreditation) standards. In France at that time there were no laboratories accredited according to the ISO 15189, only those accredited according to the ISO 17025. As stated in the work of Spitzenberger and Edelhäuser (12), as soon as 2006, the situation in terms of numbers of accredited laboratories changed significantly and in Germany there were 150 laboratories accredited according to the ISO 15189 standard, as shown in *Figure 1*.

Today the process of accreditation in most European countries is mostly carried out in cooperation with national accreditation bodies, medical experts appointed by scientist associations and health departments. This type of collaboration has proven successful in the UK, Germany, Hungary, France and Croatia.



**Figure 1** Accredited medical laboratories according to the ISO 15189 standard (grey) and according to ISO/IEC 17025 (black), as stated by Spitzenberger and Edelhäuser 2006 (12).

In Germany, the Technical Committee consisting of experts from particular medical fields collaborates with accreditation bodies. Representatives of all the associations participate in the preparation of documents necessary for accreditation, in the training of assessors and the medical laboratory accreditation process itself. In the UK, CPA and the national accreditation body UKAS collaborate within the process of medical laboratory accreditation. CPA consists of representatives of scientific institutions. In Croatian Accreditation Agency (HAA) a working group for medical laboratories has been established (RS MedLab). It consists of the representatives from the Health & Welfare Ministry, Croatian Chamber of Medical Biochemists, other expert organisations and HAA.

### Status of Development of the Program of Medical Laboratory Accreditation in Serbia

Through the release of the SRPS ISO 15189:2008 standard conditions have been created for medical laboratory accreditation in Serbia. With the purpose of developing an accreditation program and adhering to the basic principles of the accreditation processes in the EU, within the Accreditation Board of Serbia (ATS) the Commission for development and implementation of medical laboratory accreditation program according to the new standard has been founded. It consists of eminent experts and professionals in various medical fields and ATS staff. The plan is for the Health Ministry to actively support the accreditation process and take part in the work of the Commission. The activities of the Commission are as follows: professional support to the ATS in development and implementation of the new standard requirements, creation of a pool of assessors, participation in defining qualification criteria and in designing assessor training programs, participation in development of the scheme of external quality assessment through interlaboratory testing (EQA/PT) according to the international criteria, liaison with the EA/LC, organisation of mutual assessments with national and international assessors, participation in decision making during accreditation and accreditation maintenance. Another task of the Commission is to prepare guidelines for transition of the laboratories already accredited according to the SRPS ISO/IEC 17025:2006 to the new standard SRPS ISO 15189:2008.

As ISO/IEC 17025 is a general standard for the testing and calibration of laboratory accreditation, the process of medical laboratory accreditation in Serbia has been carried out according to it since 2003. Five medical laboratories have been accredited, four of them for clinical biochemistry and one for microbiology.

The next step in the implementation of the medical laboratory accreditation program according to

the ISO 15189 standard is the establishment of the accreditation criteria based on the international standards, regulations and specific features of the fields. The existing ATS documentation with necessary alterations may partly be used in this procedure. New documents ought to be created, such as check lists, both for horizontal and vertical (specific for respective fields) assessment as well as guidelines for presenting the scope of accreditation.

Presentation of the activities of medical laboratories through the scope of accreditation is still an issue in the European accreditation organisations. The contents of the scope of accreditation should consist of fields of examination, types of tests, parameters under examination, sorts of samples and the documented method applied. Such scope of accreditation where examination methods are categorised by types of tests

may facilitate flexibility in the introduction of new methods within the types of tests for which the given laboratory has already been accredited.

Determination of the manner of selection, training and official appointment of assessors and experts participating in the assessment process requires particular attention.

### Conclusion

The establishment of the quality system in medical laboratories in Serbia according to the requirements of the ISO 15189 standard and certification of their competence for provision of services through the accreditation procedure guarantee high quality of their services.

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