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Professional paper

THE NEW ISO AND CEN STANDARDS FOR QUALITY AND ACCREDITATION OF MEDICAL LABORATORIES[1]

Desmond Kenny, Dublin, Ireland

Department of Clinical Biochemistry, Our Lady's Hospital for Sick Children, Crumlin, Dublin 12, Ireland

Summary: The new international standard EN ISO 15189:2003 »Medical laboratories – particular requirements for quality and competence«, after many delays, was finally published in February 2003. This standard has been developed specifically to address requirements for accreditation of medical laboratories. It takes into account the special constraints imposed by the medical environment and the essential contribution of the medical laboratory service to patient care. It recognizes that medical laboratories provide not only testing of patient samples, but also advisory, interpretative and educational services. It also acknowledges the role of diagnostics manufacturers in maintaining the quality of medical laboratory services. The international standard ISO/IEC 17025 »General requirements for the competence of testing and calibration laboratories« is already used in some countries for accreditation of medical laboratories. This is a standard which was developed mainly for use in industrial testing laboratories, and has serious deficiencies when used in the medical environment. While still in draft form, 15189 was already approved by ILAC (International Laboratory Accreditation Co-operation) as a suitable basis for accrediting medical laboratories. It is expected that this document will be used widely in Europe and throughout the world as the preferred standard for this purpose. An informal survey of FESCC member societies shows that 15189, alone or in combination with other standards, will be used in almost all European countries for accreditation of medical laboratories. A further complementary standard, ISO 15190 »Medical laboratories – requirements for safety« has now been published. A standard for quality and competence in Point Of Care Testing (POCT) is under development, and will be published as a new Annex to EN ISO 15189. These standards will for the first time provide a common basis for the development of quality systems and requirements for competence in medical laboratories throughout the world.

Key words: medical laboratories, clinical laboratories, quality management, accreditation, standards

Introduction

ISO is the International Organization for Standardization. The ISO members are the national standards institutes of 146 countries worldwide. **CEN** (Comité Européen de Normalisation) is the European standardization body. CEN full members are the national standards bodies of the EU and EFTA countries (the standards bodies of the ten new EU member states became full members of CEN well in advance of their accession to the EU on 1 May 2004). The national standards bodies of Albania, Bulgaria, Croatia, Romania, the Republic of Macedonia, and Turkey are CEN Affiliates. The national standards body of Serbia & Montenegro (SCG) is a Corresponding member of CEN. The most important condition for full membership of CEN is agreement that European Standards (EN) will be adopted as national standards.

ISO and CEN work is done by Technical Committees (TCs). Each TC has a number of Working Groups (WGs) under its control. The two most important Technical Committees in relation to Laboratory Medicine are **CEN/TC 140** »In vitro diagnostic medical devices« and **ISO/TC 212** »Clinical laboratory testing and *in vitro* diagnostic test systems«. These two Technical Committees work very closely together, and their most important standards are both International Standards of ISO and European Standards of CEN (ISO standards are identified by numbers prefixed with the letters »ISO«; CEN standards are identified by numbers prefixed with the letters »EN«).

[1] ISO = International Organization for Standardization; CEN = Comité Européen de Normalisation; EN = European Standard (European Norm); »EN ISO« indicates that the document is a European and International Standard.

Examples of the work of the two TCs are:

15189 Quality systems / Accreditation (published)
15190 Safety in medical laboratories (published)
15195 Requirements for reference laboratories (published)
17511 Metrological traceability of calibrators (published)
18153 Calibration of enzyme assays (published)
22869 Guidance on use of 15189 (Technical Report) (draft)
22870 POCT (Annex for 15189) (draft)
20776 Standardization in antimicrobial susceptibility testing (new approved work item)

Also, a series of standards aimed mainly at manufacturers and relating to the EU Directive on In Vitro Diagnostics has been prepared by CEN/TC 140.

For the medical laboratories, the most important product of these committees is **EN ISO 15189: 2003** (1) »Medical laboratories – particular requirements for quality and competence«. This is the first international standard which has been developed specifically to address the requirements for accreditation of medical laboratories.

15189 is based on ISO/IEC 17025 [2], the standard for accrediting »testing and calibration laboratories« but with many additional requirements for medical laboratory services (not confined to the testing process), with a large input from the EC4 »Essential Requirements« documents (3–5). It also includes elements of the ISO 9000 series.

While still in draft form, it was approved by ILAC (International Laboratory Accreditation Co-operation) as a suitable basis for the accreditation of medical laboratories.

The need for EN ISO 15189

Why do we need a laboratory accreditation standard? Is ISO 9001:2000 not enough? ISO 9001 (6) is about quality management systems, and is applicable to all kinds of organizations including medical laboratories. However, it does not address the technical issues. For this we need a standard which deals with the competence of the organization in providing a medical laboratory service of a high standard.

EN ISO 15189:2003 was approved in November 2002 in the final votes in CEN and ISO. In both the CEN and ISO voting, the results were unanimous – all countries voted »yes«. The standard was finally published (in English) in February 2003 (and a corrected version published in July 2003).

A further complementary standard, ISO 15190 »Medical laboratories – requirements for safety« (7) was published in late 2003.

A standard for quality and competence in Point Of Care Testing (POCT) is under development, and will be published as a new Annex to EN ISO 15189.

Comparison of EN ISO 15189 and ISO/IEC 17025

Before EN ISO 15189 was developed, the standard ISO/IEC 17025 (2) »General requirements for the competence of testing and calibration laboratories«[2] was used in some countries as a basis for accreditation of medical laboratories, despite its serious deficiencies when used in the medical environment. Should it still be used now that a standard specifically developed to cover the needs of medical laboratories is available?

The Scope clause of 17025 says:

1.1 This International Standard specifies the general requirements for the competence to carry out tests and/or calibrations …1.2 This International Standard is applicable to all organizations performing tests and/or calibrations. These include, for example, first-, second- and third-party laboratories, and laboratories where testing and/or calibration forms part of inspection and product certification…

Do medical laboratory services really come within this scope? The »tests« mentioned in 17025 are usually tests on products or materials to see if they meet with particular specifications or regulations (*con-formity assessment*). On the other hand – »Medical laboratories do not deal with a production line but rather with human life with multiple factors influencing the results and having a big impact on human health care«

To demonstrate the difference in emphasis between the two standards we can compare some corresponding clauses from the two standards. These are shown in *Tables I* to *VIII*.

Looking at the *Introductions* from the two documents (*Table I*), we see that in 17025, the emphasis is on the validity of the test results. Of course, in the medical laboratory we must also produce valid results, but there are also important requirements which must be considered if we are to provide a medical laboratort service of high quality.

Under the heading of *Management requirements* (*Table II*), in 15189 the emphasis is on the patient, in contrast to the corresponding subclause of 17025.

Comparing subclause 4.7 of the two standards (*Table III*), we can see that the relationship with the users of the service is quite different for the medical laboratory (15189) from that of »testing and calibration laboratories« (17025).

[2] or its predecessors, ISO Guide 25 (8) and EN 45001 (9)

Table I Introduction

17025 **Introduction** This International Standard ... contains all of the requirements that testing and calibration laboratories have to meet if they wish to demonstrate that they operate a quality system, are technically competent, and are able to generate technically valid results.
15189 **Introduction** This International Standard ... provides requirements for competence and quality that are particular to medical laboratories ...Medical laboratory services are essential to patient care and therefore have to be available to meet the needs of all patients and the clinical personnel responsible for the care of those patients...

Table II Management requirements

17025 ***Management requirements – Organization*** **4.1.2** It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this International Standard and to satisfy the needs of the client, the regulatory authorities or organizations providing recognition.
15189 **Management requirements – Organization and management** **4.1.2** Medical laboratory services, including appropriate interpretation and advisory services, shall be designed to meet the needs of patients and all clinical personnel responsible for patient care.

In dealing with nonconformities (*Table IV*) it is necessary under 15189 that the professional staff of the medical laboratory must have the competence to consider the medical significance of their work.

In conducting management reviews (*Table V*) we can see that the emphasis in 15189 is on the patient.

In 15189 there is a very strong emphasis on the requirement that the medical laboratory service should be directed by a person or persons with an appropriately high level of competence (*Table VI*, subclause 5.1.3). The responsibilities of the director are given in great detail (5.1.4). There is no corresponding text in 17025. 15189 has sections on the pre- and post-examination phases, which are not dealt with adequately in 17025 (*Table VII*).

The contribution of the diagnostics manufacturers in maintaining the quality of medical laboratory services is explicitly acknowledged in 15189 (*Table VIII*). There is no corresponding text in 17025.

Table III Communicating with the users of the service

17025 4.7 Service to the client The laboratory shall afford clients or their representatives cooperation to clarify the client's request and to monitor the laboratory's performance in relation to the work performed ...NOTE 1 Such cooperation may include … providing the client or the client's representative reasonable access to relevant areas of the laboratory for the witnessing of tests and/or calibrations performed for the client …
15189 4.7 Advisory services Appropriate laboratory professional staff shall provide advice on choice of examinations and use of the services … Where appropriate, interpretation of the results of examinations shall be provided. There should be regular documented meetings of professional staff with the clinical staff regarding the use of the laboratory services and for the purpose of consultation on scientific matters. The professional staff should participate in clinical rounds, enabling advice on effectiveness ...

Table IV Nonconformities

17025 **4.9 Control of nonconforming testing and/or calibration work** **4.9.1d** where necessary, the client is notified and work is recalled
15189 **4.9 Identification and control of nonconformities** **4.9.1c** the medical significance of the nonconforming examinations is considered, and where appropriate, the requesting clinician informed

Table V Management review

17025 **4.14 Management reviews** **4.14.1** In accordance with a predetermined schedule and procedure, the laboratory's executive management shall periodically conduct a review of the laboratory's quality system and testing and/or calibration activities …
15189 **4.15 Management review** **4.15.1** The laboratory management shall review the laboratory's quality management system and all of its medical services, including examination and advisory activities, to ensure their continuing suitability and effectiveness in support of patient care ...

Table VI The Laboratory Director

17025 **Personnel** [*Laboratory Director not mentioned*]
15189 **Personnel** 5.1.3 The laboratory shall be directed by a person or persons having executive responsibility and the competence to assume responsibility for the services provided. ... Competence is here understood as the product of basic academic, postgraduate, and continuing education, as well as training and experience of several years in a medical laboratory. 5.1.4 The responsibilities of the laboratory director or designees shall include professional, scientific, consultative or advisory, organizational, administrative, and educational matters ... The laboratory director or designees for each task should have the appropriate training and background to be able to discharge the following responsibilities … a) provide advice ... about the choice of tests, the use of the laboratory service and the interpretation of laboratory data; b) serve as an active member(s) of the medical staff for those facilities served, if applicable and appropriate; c) relate and function effectively … with 1) ... accrediting and regulatory agencies, 2) ... administrative officials, 3) the healthcare community, and 4) the patient population ...; d) define, implement and monitor standards of performance and quality improvement ... e) implement the quality management system ... f) monitor all work ... to determine that reliable data are being generated; g) ensure that there are sufficient qualified personnel with adequate documented training and experience ... h) plan, set goals, develop and allocate resources appropriate to the medical environment; i) provide effective and efficient administration of the medical laboratory service, including budget planning and control with responsible financial management ... j) provide educational programs for the medical and laboratory staff and participate in educational programs of the institution; k) plan and direct research and development ...; l) select and monitor all referral laboratories for quality of service; m) implement a safe laboratory environment ...; n) address any complaint, request or suggestion from users of laboratory services; o) ensure good staff morale. The laboratory director need not perform all responsibilities personally. However, it is the laboratory director who remains responsible for the overall operation and administration of the laboratory, for ensuring that quality services are provided for patients.

Table VII Pre- and post-examination procedures

17025 [*some correspondences with 5.8* »Handling of test and calibration items«]
15189 5.4 Pre-examination procedures 5.7 Post-examination procedures (pre- and post-analytical phases)

Survey on likely implementation of 15189 in Europe:

In March 2003 a questionnaire (*Table IX*) was sent to 35 member societies of FESCC asking for their views on whether 15189 would be used and how it would be used as a basis for accreditation of medical laboratories in Europe. Information was received from 26 countries, and this is summarised in *Tables X* and *XI* (the information is incomplete; in some of the 26 countries the future situation is not yet clear). The most notable finding was that 26 out of 26 national societies said »Yes« to Question 1.

Conclusion

If a medical laboratory has to choose between the 15189 and 17025 standards as a basis for accreditation, 15189 has many advantages and is strongly recommended by the author and by EC4. If both standards are used, 15189 should be the primary document.

Table VIII Role of the diagnostics manufacturers

17025 [*no corresponding text*]
15189 **5.3 Laboratory equipment** 5.3.2 … a documented and recorded programme of preventive maintenance and calibration … which, at a minimum, follows manufacturer's recommendations. ... manufacturer's instructions, operator's manuals, or other documentation ... may be used to establish requirements for compliance with relevant standards ... 5.3.4 … Manufacturer's instructions may be used to establish acceptance criteria, procedures, and frequency of verification for maintenance and/or calibration ... 5.3.6 Equipment shall be maintained in a safe working condition ... Manufacturer's specifications or instructions or both shall be used, as appropriate. **5.5 Examination procedures** 5.5.3 … The procedure shall be based in whole or in part on the instructions for use ... written by the manufacturer, provided that they are in accordance with 5.5.1 and 5.5.2 and that they describe the procedure as it is performed in the laboratory ... **5.6 Assuring quality of examination procedures** 5.6.3 … means for providing confidence in the results shall be applied including ... documentation of statements regarding reagents, procedures or the examination system when traceability is provided by the supplier or manufacturer.

Table IX Questionnaire to FESCC member societies

Q1. In the future, will ISO 15189 be used as the basis for accreditation of medical laboratories in your country? [YES/NO] *If the answer is YES, please also answer the following questions (it may be necessary to answer YES to more than one question):*
In your country – **Q2**. will 15189 be used alone as the basis for accreditation of medical laboratories? [YES/NO] **Q3.** will 15189 be used in conjunction with other ISO standards? [YES/NO] [*please say which standards*] **Q4.** will 15189 be used in conjunction with national guidelines or standards? [YES/NO]

Table X Responses to questionnaire – summary

Information from 26 countries: **All 26 said »yes« to Question 1** Of the 26 : most countries will use 15189 in conjunction with another ISO standard (17025 and/or 9001:2000) some countries will offer laboratories a choice between 15189 and 17025 some countries will use 15189 in conjunction with a national guideline/standard a few countries said »Yes« but still have some problems to solve before it can be implemented

Table XI Responses to questionnaire – differences between countries

Information from 26 countries: 4 countries will give laboratories a choice to use 15189 or 17025 14 will use 15189 in conjunction with another ISO standard (17025 / 9001) 16 will use 15189 in conjunction with national guidelines 3 countries will definitely use 15189 alone 1 other country will probably use 15189 alone several who will use 15189 in conjunction with other standards consider 15189 to be the most important document.

NOVI ISO I CEN STANDARDI ZA KVALITET I AKREDITACIJU MEDICINSKIH LABORATORIJA

Desmond Kenny, Dublin, Ireland

Department of Clinical Biochemistry, Our Lady's Hospital for Sick Children, Crumlin, Dublin 12, Ireland

Kratak sadržaj: Novi međunarodni standard EN ISO 15189:2003 »Medicinske laboratorije – posebni zahtevi za kvalitet i kompetentnost« posle dužeg odlaganja je konačno objavljen februara 2003. godine. Ovaj standard je razvijen specifično za zadovolji zahteve za akreditaciju medicinskih laboratorija. Uzima u obzir specijalni položaj medicinske laboratorije i doprinos iste u zbrinjavanju pacijenata. Ovaj standard prepoznaje da medicinske laboratorije ne samo da obezbeđuju ispitivanje uzoraka pacijenata, već obezbeđuju savetodavnu, edukativnu i konsultantsku ulogu. Takođe se naglašava uloga proizvodžača dijagnostičkih sredstava u održavanju kvaliteta rada medicinskih laboratorija. Međunarodni standard ISO/IEC 17025 »Opšti zahtevi za kompetentnost ispitinih i kalibracionih laboratorija« se takođe koristi u pojedinim zemljama za akreditaciju medicinskih laboratorija. Ovaj standard koji je uglavnom razvijen za potrebe industrijskih ispitinih laboratorija ima niz nedostataka kada se primenjuje za potrebe medicinskih laboratorija. Još dok je bio u pripremi standard 15189 je bio priznat od ILAC (Međunarodna Laboratorijska Ko-operacija) kao pogodan za medicinske laboratorije. Očekivanja su da će ovaj standard biti primenljiv širom Evrope i sveta kao primarni standard za ovu oblast. Neformalna istraživanja među članicama FESCC-a pokazuju da 15189, sam ili u kombinaciji sa drugim standardima, može da se koristi u većini zemalja za akreditaciju medicinskih laboratorija. Drugi komplementarni standard, ISO 15190 »Medicinske laboratorije – zahtevi za bezbednost« je sada u pripremi. Standard za kvalitet i kompetentnost u tzv. »Point-of-Care« ispitivanju (POCT) je u pripremi, i biće objavljen kao novi aneks EN ISO 15189. Ovi standardi će po prvi put da obezbede osnovu za razvoj sistema kvaliteta i zahteve za kompetentnost medicinskih laboratorija širom sveta.

Ključne reči: medicinske laboratorije, kliničke laboratorije, menadžment kvalitetom, akreditacija, standardi

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