

Review

European medical laboratory accreditation. Present situation and steps to harmonisation

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Abstract

Accreditation of medical laboratories in Europe is primarily according to ISO15189. The percentage of accredited laboratories is still small. The time spent on an assessment is quite different between countries. More important is the way the assessment process is carried out. Harmonisation in accrediting medical laboratories is the main task of the Health Care Committee within EA (European cooperation of Accreditation). The EFCC Working Group on Accreditation strongly contributes as the representative of laboratory professionals. An important item is the use of flexible scope. The intention is that all tests within a medical discipline are offered for accreditation. This is not yet normal practice. Other items concern accreditation of point-of-care testing (POCT) – reliability of the pre-analytical phase, when the phlebotomy is not done by the laboratory, and practical use of uncertainty and verification. Also the diversity in time spent for an assessment is discussed. The added value of accreditation is strongly dependent upon the assessors who have an important task. Their training and calibration needs continuous input. The medical laboratory professionals should participate in all aspects concerning the quality system, starting with the standard, working on the guidelines, the assessment itself, and input in the accreditation bodies.

Keywords: accreditation; assessor; ISO15189; point-of-care testing (POCT); quality.

Introduction

ISO15189-2007 “Medical laboratories – Particular requirements for quality and competence” (1) is well accepted at the moment. It is the primary standard used for accreditation

of medical laboratories in Europe. A recent questionnaire organised in 2011 by ENAC, the Spanish accreditation body, confirms this (Table 1). However, the percentage of laboratories which are actually accredited is still low in most countries (Table 2).

Currently, accreditation is only mandatory in France. The added value of accreditation is recognised by more countries as indicated by the fact that it is obligatory for high-risk tests, i.e., molecular genetics in Belgium, newborn in Germany, and human genetics in Swiss.

The point of view of the Working Group (WG) on Accreditation and ISO/CEN Standards of the European Federation of Clinical Chemistry and Laboratory Medicine (EFCC) concerning the way accreditation should be carried out was published in 2007 (2). It stresses that the accreditation of a medical laboratory should be primarily directed at the service and includes the whole range of tests within that service. Accreditation of a restricted number of the tests is contrary to the intention of ISO15189 when applied to a general laboratory.

Harmonisation of accreditation in Europe needs attention. Many items are discussed in the Health Care Committee of the EA. In this committee representatives of the National Accreditation Bodies Diagnosed (European Diagnostic Industry), and laboratory professionals try to reach consensus.

Flexible scope

According to the accreditation bodies originally set up in the UK (CPA) and in the Netherlands (CCKL) specifically for accreditation of medical laboratories, accreditation was only possible if all tests are included. The patient expects that all tests are done properly. Furthermore, tests which are done less frequently need extra attention, because it is not routine. This same point of view is held by the Australian pathology accreditation system. There is close cooperation between the Australian medical laboratory associations (National Pathology Accreditation Advisory Council), the accreditation body (National Association of Testing Authorities), and the in vitro diagnostic regulator (Therapeutic Goods Administration). Their system covers the whole chain of medical laboratory services. It includes accreditation of sample taking centres, laboratories, and the doctors who receive the test results. Laboratories are only reimbursed when they are accredited. Also in the USA the quality demands for a specific test only depends on its classification according to CLIA.

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Table 1 Standard used for accreditation of medical laboratories by national accreditation bodies. Based on a questionnaire by ENAC 2011.

Only ISO15189	ISO15189 and ISO17025
CY	CZ
LV	DE
MT	DK
NL	EE
HR	FI
ES	FR
TR	GR
	IE
	NO
	PT
	RS
	CH

Only 15189, 42%; mainly 15189, 37%; both standards, 21%.

It was the intention of the WG on Accreditation when discussing flexible scope to include all tests. Generally, it is accepted by the EA (3) and also sustained by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), as stated on their website:

1. The scope of accreditation should normally cover the substantial majority of the overall service provided by the laboratory within a medical field.
2. It is recognised that some national accreditation bodies (NABs) cannot enforce this. Nevertheless these NABs should encourage medical laboratories to cover the majority of their examinations within each medical field in their scope.
3. The flexible scope of accreditation is preferred. The laboratory shall maintain a list of all individual examinations for which it is accredited.
4. At the first level the scope of accreditation shall be defined as a medical discipline, such as, e.g., clinical chemistry, haematology, etc.
5. For each medical field mentioned in the scope it is expected that the laboratory provides a full service, which includes all pre-examination, examination, and post-examination aspects that are essential to provide an effective and efficient laboratory service to the patients. Within this it is expected that a medical laboratory is able to demonstrate its competence in interpreting the results of the examinations performed.

In actual practice accreditation bodies in Europe, Asia and South America stress that they cannot enforce all tests to be covered within a specific service. They cannot refuse to

accredit a laboratory for a small number of tests. They correctly indicate that in such a case the quality system of the whole laboratory will be assessed. But the competence part, and thus proper performance, is not checked for those tests which are not offered for accreditation. Officially, by law, they are right, and it is possible for a client to find out which tests are accredited and which not.

However, the ISO15189 was set up to provide better services for the patients and they can expect that all these tests are carried out according to the same quality principles.

Concerning the discussion about the first level of the scope on the accreditation certificate, generally the medical discipline, one should be aware of the possibility for reference laboratories and those doing molecular diagnostic tests to put in specific tests. For molecular diagnostic tests it is important they are accredited according to ISO15189 (1) and not ISO17025 (4). The consultative part should be warranted.

The WG agrees that all tests which are accredited should be available for a client. This can be on the laboratory website. How detailed the name of the test should be is under discussion. At least it should be traceable to Logical Observation Identifiers Names and Codes (LOINC), but should the name of the manufacturer of the test be added as well? And, what about small revisions of such a test by the laboratory? In particular for tumour markers, it is important that the doctor is aware of the differences between the tests offered by the manufacturers.

Pre-analytical aspects

In a recent conference, which is published in *CCLM* (5), it was clear that not only the majority of the mistakes are still made in the pre-analytical field, but also that the percentage of haemolysed samples strongly depends on which department did the phlebotomy. In the opinion of the WG it is not sufficient for a laboratory, who wants to be accredited according to ISO15189, to show that they have sent the right instructions to the sampling stations. According to ISO15189 this is acceptable. But it states as well, that when the samples are received in the laboratory they should be checked before acceptance. This involves not only administrative aspects such as a missing name, but also quality aspects such as transportation time (visible from the date of the sampling and receipt), transportation conditions (visible from the temperature: refrigerated, frozen, room temperature, and in other conditions: centrifuged, etc.). An analytically valid test on a corrupted sample gives completely wrong information to the doctor. In the opinion of the WG on Accreditation the laboratory must have a service level agreement with those involved

Table 2 Approximate percentage of medical laboratories accredited according to an ISO standard. Based on a questionnaire of EFCC 2009, but updated with the results of the ENAC questionnaire of 2011.

0%	0, 1%–5%	6%–15%	16%–30%	31%–50%	51%–75%
MT, SI 4	AT, CH ES, FR, HU, IT LV, RS 9	CZ, DE, EI, LT 2	BE, EE 2	–	NL, UK, SE 3

in the pre-examination aspects, to carry out an audit and interfere actively when problems occur. In testing laboratories, accredited according to ISO17025, a disclaimer about not being responsible for the sampling is normally added to the analytical result. It would not be in line with ISO15189 if this is applied to medical tests.

In Australia the phlebotomy has to be accredited which makes the chain stronger. In Spain the phlebotomy service is under supervision of the medical laboratory. In The Netherlands most samples were taken under supervision of the laboratory, but it is changing. In many countries the sampling is outside the jurisdiction of the laboratory. Phlebotomy by nurses, doctors or primary care centres can be more efficient. For an accredited laboratory, it should be only acceptable if the laboratory has gathered information about adherence to the pre-examination instructions.

This point concerning assessment of the pre-analytical phase is one of the actual discussion items within the EA Health Care Committee.

Point-of-care testing (POCT)

Having immediate results is the primary reason of POCT, but the quality of these results is important as well. The ISO 22870:2006 "Point-of-care testing (POCT); Requirements for quality and competence" (6) is strongly related to ISO15189. Originally, it was intended to be included in ISO15189. The EA and ILAC (International Laboratory Accreditation Cooperation) clearly state that for accreditation of POCT a relation with a laboratory accredited according ISO15189 is needed. The WG on Accreditation shares this opinion.

A third party evaluation of POCT is important. The competence aspect should be taken seriously. It includes the intention of a test: for glucose in hand held glucose meters it is mostly monitoring. A deviation of the true value of 10% is acceptable. For HbA_{1c} an acceptable deviation is much smaller, but this is also true for a glucose used for diagnostic purposes. Also the pre-examination aspects and awareness about interferences are important.

Accreditation of POCT should only take place if it gives the confidence that "state of the art" results are provided. This competence part is best warranted by a formal connection with an accredited medical laboratory and adhering to the ISO22870. Although accreditation of POCT is the best option, if it concerns the quality system only, certification according to ISO9000 and not accreditation is appropriate.

Specific items

In the Health Care Committee of EA practical problems concerning the explanation of ISO15189 in the assessment process are discussed. A question and answer list is composed gradually.

An important item is the use of the uncertainty concept in medical laboratories. According to ISO17025 it is an obligation, but as well according to ISO15189 it should be

calculated and presented to the doctor when relevant. Different approaches for calculating uncertainty exist. In many countries in Europe the demands set by their NABs became confusing. In a recent meeting consensus was reached. For the medical laboratory the measurement uncertainty is most relevant. The top down approach for calculation is most fit. When performing a validation or verification of a test the relevant aspects are already measured. This includes the standard deviation and traceability to a standard. If the bias can be restricted, the base of the uncertainty is primarily the standard deviation. This Australian approach (7, 8) was recently accepted in the Health Care Committee. For the medical laboratories an acceptable uncertainty can be calculated, based on the within patient biological variation, and it should be lower than one quarter.

If validation of a test is already done by the manufacturer or published in the literature, the amount of work in the laboratory before introducing this test is substantially less. It only needs to verify the performance in the laboratory. This is possible if the validation reports of the diagnostic manufacturers are available including clarity about the traceability. This is part of the input given by the EFCC concerning the new IVD directive in the EU: the value of CE registration.

In the new edition of ISO15189 clear discretion will be made between validation and verification. Verification is assuring that the quality claims of the manufacturer are valid in the laboratory. It can only be applied if the kit instructions are completely followed, and if the validation report of the manufacturer is available in the laboratory.

A completely different discussion is the use of ISO15189 for accreditation in other fields like radiology and nuclear medicine. As laboratory professionals we support these possibilities. In fact in some countries it is already practised.

Variation in assessment

At this moment differences exist in the way assessment for medical laboratories is practised in the European countries. Not only in frequency of assessment and surveillance visits, but also in the hours spent by the assessment team. This became clear in a questionnaire sent to all European NABs in 2009. One of the questions was about the number of assessors and time needed for the assessment of a specified laboratory with a medium amount of clinical chemistry and haematology and who did the phlebotomy. The results are shown in Tables 3 and 4. Although these results are from 2009, in the discussions about specific cases in the EA Health Care Committee it was clear that it has not changed substantially. These differences still exist.

Some of the differences originate from the difference in the content of clinical chemistry in different countries. It is sometimes restricted to one medical discipline and sometimes includes nearly the whole range of medical laboratory services.

Still unexplainable differences exist. Apart from the economic consequences, it is questionable if this is a real problem concerning the validity of accreditation. In real practice

Table 3 Number of assessors for an assessment visit in a specified laboratory based on a questionnaire of EFCC in 2009, but still valid in 2011 as discussed in the committee.

1 LA+1 TA	1 LA+2 TA	1 LA+3 TA	1 LA+4 TA
DE 1	AT, BE, CH, DK, EE, ES, FI, MT, NL, NO, PT, RO, RS, SE 14	FR, GR, IE, HR, HU, PL 6	UK, LV 2

LA, lead assessor; TA, technical assessor.

an assessment team will, within a couple of hours, have an idea if a quality system is really functioning. Do they critically rate their quality system and competences: internal audits, a clear quality plan, training of the technicians and laboratory specialists, validation of tests and systems, documentation, etc.? Time is needed to find the hard evidence concerning non-consistencies. Nearly always an assessment is a “random sample”, but is still a good indicator of the overall practice.

An important aspect to assess is the way the laboratory handles its non-consistencies. Not only those found during previous external assessment, but as well, or primarily, those found during their internal audits. It is not just solving the specific case, but trying to detect the root cause, find out the extent (also in other areas), correct this root cause and perform an internal audit to be sure that the problem was solved. Such an internal audit system is not only directed on actual non-consistencies but also on potential ones.

Quality is principally the responsibility of the laboratory itself: they should be competent and have a real quality system. It should cover all aspects important for the medical laboratory service: pre-examination, examination and post-examination.

The competence part is not only related to the state of the art methods, the adequate reaction on internal and external quality control, the validation of the methods, with attention for their traceability. It also concerns the competence of the people who do the tests and are responsible. For the technicians it includes their original background education, their qualifications for the specific tasks they perform, their requalification if a specific task has not been done for a specified time, and their continual education. For the medical laboratory specialist it involves their registration as such in their specific countries, and their re-registration. Their responsibilities include consultation concerning the test results they deliver, participating in patient pathology conferences, if applicable. It also concerns active reporting of new developments to their clients, involvement in making them aware of new tests, not only their advantages, but also their restrictions. In these aspects an active role of the professional medical laboratory societies is justified.

Assessor tasks

Having a good quality system makes laboratories better. The value of accreditation is that competent people from an independent third party confirm it, help to find blind spots, and to stay focussed. The continuation of the added value of accreditation, as perceived by the laboratories is clearly dependent upon the assessors. The lead assessors should really be focussed on the functioning of the quality system of the laboratories, and the technical assessors on the competence aspects as described in the standard. About the selection of assessors and their training guidelines exist for a long time. EAL G7 (9) and ILAC G3 (10) “Guidelines for training courses for assessors used by laboratory accreditation schemes”. In ILAC-G11:07 (11) “Guidelines on qualification and competence of assessors and technical experts” not only demands concerning different competence aspects is worded, but as well the respective roles in the assessment process.

For the lead assessor the main tasks are: quality system, continuous quality improvement, customer satisfaction, complaint system, validation system, management review and internal audits. It concerns mainly Chapter 4 of ISO15189. In the opinion of the WG on Accreditation it is more important that the lead assessor has experience with quality systems, does frequent assessments and has the ability to lead a team, than being a medical laboratory professional.

For the technical assessors it is essential to be competent in the field which is accredited. This means not only being registered as a laboratory professional, but having actual experience with the type of tests which are assessed. Professional associations should play a role in their selection. In actual practice this happens already in most countries. Their main tasks are: competence of technical personnel, state of the art methods, correct pre-examination procedures, use of internal and external quality control, standard operating procedures correct and used, traceability, uncertainty, reference values, validation of methods and last but not least the consultancy function of the laboratory.

For the lead assessor and the technical assessors the “soft issues” are important. It has already been stated years ago that

Table 4 Total hours spent by the assessors for an assessment of a specified laboratory based on the questionnaire of EFCC in 2009, but validated in 2011 in the HC Committee.

48 h	56 h	64 h	72 h	80 h	≥90 h
DE, GR 2	EE 1	ES, IE, RO, RS 4	AT, BE, CH, FI 4	FR, NL, NO, PT, SE 5	DK, HR, LV, MT, PL 5

the assessors should have specific personal qualifications: open mindedness, diplomacy, being observant, perceptiveness, decisiveness, self reliance, integrity, ability to negotiate, self control and the ability to work in a team. Most important is an open mind, realisation that things can be done differently, the possibility to work in a team and to differentiate between an incident and a real system error.

This should not only be handled in the training of the assessors, but also be monitored. An accreditation body should have data concerning the competence of all assessors: their training, their presence in meetings for calibration, their up-to-date technical competences, and their functioning in actual practice.

Training assessors

For an accreditation body their most valuable asset is the assessors. One of their most important tasks is the calibration of these assessors. It is very frustrating for a laboratory if different assessments lead to completely different outcomes. This is especially if the noted non-consistencies are considered by the audited laboratories as minor points or just the opinion of that specific expert. Care should be taken when conclusions are drawn from isolated good or bad findings. An incident should not be used to conclude that everything else is generally good or bad. A badly performed assessment can jeopardise the whole value of accreditation.

For that reason the EA Health Care Committee has set up a Task Force to find out the best practises concerning training and calibration in the different countries. It concerns the organisation and content of the ongoing training, identifying and analysing the top 10 non-consistencies, and the organisation of functioning feed back with the professional laboratory organisations about what should be considered as non-consistencies in relation with ISO15189. It is hoped that a course could offered for the trainers of the assessors.

Accreditation vs. inspection

The use of checklists for assessment is quite often discussed in quality committees and between assessors.

Of course a laboratory preparing for accreditation should know what it can expect. This can be made available in the form of checklists indicating which items will be addressed and the amount of documentation that should be available. These lists are useful for the assessors.

Before a visit on site an assessor receives and often studies the documents. As indicated by the accreditation bodies it concerns the Quality Manual, Management Review, list of Standardised Operating Procedures (SOPs), some examples of SOPs, etc. This will certainly result in specific questions which will be asked, and handlings which will be viewed in the laboratory. It is important to make notes and it can be in the form of a checklist.

However, an assessor should not follow a list exclusively. It is more relevant to follow certain paths, to react on what is

noticed, taking in mind what the demands of the standard are, and what level of competence is to be expected. A checklist could be helpful, but if it is used exclusively it is an inspection not an accreditation.

Involvement of laboratory professionals

Medical laboratory professionals should be involved in all levels of the accreditation process. It starts with the work in ISO in its Technical Committees. ISO TC212, who prepares the ISO15189, started originally because of the need felt by the professionals for a specific standard for medical laboratories. At this moment the influence of accreditation bodies and metrologists from standard institutes in preparing the new edition is growing. The laboratory professionals have to take care about their input. Often guidelines are needed for the explanation of the standards. In composing these guidelines the laboratory professionals should be in the lead, and be aware of another danger. A guideline composed by experts tends to address everything, include everything and to be directed to an ideal situation. However, time and funds in the laboratories are restricted. A guideline should be helpful for the general situation in the general laboratory and as well in the less developed countries. For that reason it is important to restrict these documents to the essentials, or to indicate that not all aspects have to be fulfilled. The name given by the WG on Accreditation to their original work in setting up a quality system was essential criteria (12).

Voting about the ISO standards is undertaken by the National Standard Bodies. It is important to have good connections with these bodies, and to be involved in the different committees they have. At the minimum, the laboratory societies should have input in the comments and voting procedures.

Accreditation bodies edit guidelines concerning many aspects of their procedures. This happens at all levels: ILAC, EA and NABs. A stakeholder agreement is signed between ILAC and IFCC, which makes it possible to be involved. For EA the EFCC is a registered stakeholder, and is actively involved in the Health Care Committee. This has been discussed extensively in this paper. On the national level the national societies should take care to be present in the relevant committees of their accreditation bodies.

Involvement in the assessment process is warranted. For the competence part the contributions of the laboratory specialists is essential. The quality committees of the professional societies should be involved in the calibration of the assessors and the decision about which professional guidelines are obligatory during the assessment.

Conclusions

Accreditation according to ISO15189 can make laboratories better. It is important that all aspects of this standard are included: pre-examination, examination and post-examination. This involves advice concerning relevant tests, their

sampling and transportation, the analysis and availability of results in time, their reporting and consultancy if needed. It will contribute strongly to patient safety.

This can only be accomplished if the original intention of ISO15189 is followed. It means accreditation of all tests within a service, and involvement of the pre-examination aspects also if this is performed outside the medical laboratory organisation, inclusion of POCT, and real attention for the consultative activities by the laboratory professionals.

This can be accomplished if the assessors are well trained and continuously calibrated. The lead assessor needs to pay attention to all the important aspects of the quality system and the technical assessor need to pay attention to the competence parts concerning the analyses, but also concerning the professionals, with attention for relevant non-conformities.

The professional societies must accept their responsibility and ensure they are involved in all aspects of this process – in the composition of the standards and guidelines, in the discussion within the national standard bodies, and in the accreditation bodies on national and international level. The medical laboratory professionals must be prepared to be trained and to operate as technical assessors. If completed properly accreditation will continue to contribute strongly to the quality of all laboratories.

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