UC 577,1; 61 ISSN 0354-3447

Jugoslov Med Biohem 24: 187–192, 2005 *Pregledni članak*[1]
Review article

ACCREDITATION

Willem Huisman[2]

Clinical Chemical Laboratory, Medical Centre Haaglanden, PO Box 432, 2501CK, The Hague, The Netherlands

Summary: ISO 15189 is very well accepted as the principle standard for accreditation of medical laboratories in the European countries. In cooperation with the EA linked national accreditation bodies mutual lateral agreement is well accepted for this standard. It makes it possible that the accreditation is accepted in other countries. Medical laboratory professionals play a key role in the assessment process. Their choice, training and constant education are essential to ascertain that accreditation adds value in the treatment of the patients. It should contribute to the continuous improvement of all laboratories. Some preliminary results of a questionnaire concerning the present status of accreditation in the countries of the European Union are presented. It shows quite diversity in the accreditation process in relation to the interval between assessment visits and the frequency of surveillance visits. The Working Group on Accreditation of the EC4 will use the input of this questionnaire and the content of some ILAC and EA guidelines, to offer Essential Criteria on some of these aspects.

Key words: accreditation, assessors, cooperation with EA, questionnaire concerning accreditation

Introduction

Quality has always been of utmost importance in medical laboratories. Originally it was focussed on the quality of the analytical results, and schemes for proficiency assessment exist already for many years. Furthermore, our societies have worked on reference methods and set up reference laboratories. Traceability is also an important aspect of the ISO standards. It became clear that other aspects should be considered as well. A common division concerning quality is: pre-examination, examination and post-examination aspects. Different approaches for setting up a (total) quality system in the medical laboratory were initiated. This has led to various systems for certification and accreditation.

Medical laboratory professionals from different fields of our discipline and from many countries have cooperated to compose a standard accepted by ISO (International Organisation for Standardisation) and CEN (Comité Europe de Normalisation): the EN ISO 15189:2003 Medical laboratories-Particular requirements for quality and competence. This standard follows the essentials of the ISO 9000:2000 in relation to the demands put on the quality system itself. It is comparable to the ISO 17025 in relation to the competence required in performing the laboratory tests, but now specifically focussed on a medical laboratory (1, 2). This standard should be used for setting up a quality system and form the cornerstone during accreditation of medical laboratories. Nearly the complete December 2004 (15 no 4) of the eJIFCC (the electronic journal of the IFCC) is devoted to the ISO 15189. The diverse contribitions were edited by Desmond Kenny and David Burnett.

Address for correspondence:
Willem Huisman
Clinical Chemical Laboratory
Medical Centre Haaglanden
PO Box 432, 2501CK,
The Hague, The Netherlands

[1] Presented on Symposium for Balkan region on Education, Management and Standards in Laboratory Medicine, Belgrade, June 10–12th, 2005.

[2] Chairman Working Group on Accreditation and Quality Systems of EC4.

Who performs the accreditation?

The meaning of accreditation is in a definition of ILAC (International Laboratory Accreditation Cooperation): »Process whereby an organisation performing one or more of the functions outlined above (for instance testing) can demonstrate its competence by conforming to appropriate internationally or nationally accepted standards or codes of practice and being able to show a competent third party accreditation body that it does so; usually by peer review.«

In this definition one finds different important aspects:

1 *appropriate* internationally or nationally accepted standards. According to ILAC this can be ISO 17025 or ISO 15189 for a medical laboratory. According to FESCC and EC4 the only appropriate standard is ISO 15189. One of the main reasons, that in different countries an organisation specifically meant for accreditation of medical laboratories according nationally accepted standards was set up, was that the ISO 17025 does not cover some very important aspects of a medical laboratory.

2 a *competent* third party. An independent party which follows the standard set by ISO for an accreditation body: ISO 17011:2004 Conformity assessment-General requirements for accreditation bodies accrediting conformity assessment bodies. This third party body should use assessors competent in the field of the medical laboratory they assess, which means professionals.

3 usually by *peer review*. This phrase highlights the importance of professionals as assessors. Furthermore this is quite customary in the medical field.

As long as an accreditation body fulfils the criteria of ISO 17025 one can speak of an accredited laboratory in that specific country. To make it valid in another country the accrediting body must have an agreement with the accrediting body in that other specific country. This is the important concept of MLA (Mutual Lateral Agreement) or Multilateral Mutual Recognition Arrangement. It had already been set up by ILAC for accreditation bodies using ISO 17025 for testing laboratories, and can be used by these same organisations when using ISO 15189. In Europe they form the EA (European cooperation of Accreditation). In nearly every country they have one specific accrediting body, for instance in the UK UKAS. For MLA EA cooperates also with accrediting bodies outside Europe.

Thus we have to decide between

1. Accreditation along 15189 is done by specific medical laboratory accrediting organisations and the accreditation is restricted to only the specific countrie(s) it serves.
2. These specific organisations set up their MLA system to make the accreditation valid in another country. For this it has to follow strict ISO rules.
3. These specific organisations set up a close cooperation with the EA linked body of that country and MLA is part of the deal. This can have different formats between cooperation or forming a specific division.
4. The EA linked body does the accreditation according to ISO 15189 in close cooperation with the professional organisations. Also in this format a specific division for medical laboratories could be formed.

These different options have been discussed quite often during the past 5 years in the EC4 Working Group on Accreditation. In their opinion MLA is important. The EU is about free movement of people and services, and this should be applied to the health sector as well. Thus option 1 is not a real one. The preferred option is a specific division in the EA linked national accreditation body, or a close cooperation in those countries which have already set up their specific bodies as in the United Kingdom. Only if the role of the medial laboratory societies is ignored by EA, option 2 is an alternative.

To further options 3 and 4 the EC4 has joined from its start the Committee on accreditation of medical laboratories of the EA. This is a joined group of representatives from accreditation bodies and professionals. After a difficult start the cooperation between EA representatives and professionals looks very promising at this moment.

Whatever option is chosen, professionals should be trained to become lead or expert assessors. For specific decisions concerning what is meant by conformity or non-conformity on many aspects of the standard, the professionals should play a crucial role. In the above cited definition of accreditation peer review is mentioned. In the future, when an accreditation becomes important for a laboratory to get funds, such decisions should be as uniform as possible and not depend upon the personal opinion of one specific assessor. Apart from the important role of the director of the accreditation body, professional organisations have a role in the calibration of the assessment. For instance concerning aspects of traceability in medical laboratories cooperation is set up between BIPM (Bureau International de Poids et Mesures), IFCC (International Federation of Clinical Chemistry and laboratory medicine) and ILAC. They have set up working groups for different measurands.

In the article by Bella Ho (2), member of the Hong Kong Accreditation Service, many examples of the practical application of ISO 15189 by accreditation bodies are given. The role of the professionals is important. For testing laboratories also this is quite common. Organisations like Eurochem help with the explanation of specific items.

The accreditation process

ISO 17011 describes the requirements for an accreditation body. The title of this standard is »General requirements for accreditation bodies accrediting conformity assessment bodies«. It gives the criteria concerning its quality system, its training of assessors the assessment process and the way the decision about accrediting should be taken, of course with a possibility of appeal.

The requirements stated are very comparable to those for setting up a quality system in a medical laboratory.

– Accreditation Body

It starts with general requirements concerning structure, impartiality, confidentiality

– Management

It states familiar demands concerning its management system and the need for a quality manual, standard operating procedures, document control, non-conformities and corrective actions, internal audits and management review.

– Human resources

An important part forms the competence of the personnel, not only those who work exclusively for the accreditation body, but as well those involved in the assessment process. There should be attention for selection, training and monitoring, and records of the assessors.

– Accreditation process

Of course the whole process should be transparent. It concerns: criteria and information, application, resource review, subcontracting assessment, preparation for assessment, document and record review, on site assessment, analysis of findings and report, decision about accreditation, appeals, surveillance activities and re-assessment.

– Responsibilities of the accreditation body

I will not focus on the general aspects concerning the setting up of such an accreditation body for medical laboratories. These were followed in the UK by CPA and in The Netherlands by CCKL. In the present situation, we hope it can be done mostly by the national EA linked accrediting bodies. I will pay attention to some aspects in which the medical laboratory specialists are involved.

1. Who are fit to become an assessor?

2. How should they be trained?

3. How can the judgement concerning conformity be calibrated?

Different guidelines of ILAC and EA explain some specific items like the qualification and training of assessors, the scope of accreditation, use of proficiency testing, scoring of non conformities, etc. I mention some of these guidelines.

Choosing assessors

Because assessment is some form of peer review, and not an on-site-visit of a person who only uses a list to see if things are followed, the quality of the assessors must be accepted by the professionals in the laboratory. Some helpful documents are:

EA G8 (1994): Guidelines for selection of participants to courses for training of assessors involved in assessment of laboratories applying for accreditation

ILAC G11 (1998): Guidelines on assessor qualifications and competence

One has to distinguish

– Professional criteria, because an assessor for accreditation has to be a professional

At least a couple of year experience as consultant or scientist in a medical laboratory; expertise in the fields the laboratory applies for accreditation, for instance, immunology, DNA etc.

– Personal qualifications

Open mindedness – willingness to consider alternative ideas or point of views

Diplomacy – tact and skill in dealing with people

Being observant – constantly and actively aware of physical surroundings and activities

Perceptiveness – ability to use instinct to understand and adapt to situations

Tenacity – persistence, the ability to stay focussed, oriented towards objectives

Decisiveness – ability to make decisions based on logical reasoning and analytical skills

Self-reliance – ability to act on one's own

Integrity-fair, truthful, sincere, honest and discrete

Ability to negotiate skilfully

Self control

Ability to work in a team

Of course it is difficult to find people who fulfil all these criteria, but communication skills and open mindedness are essential, especially for the lead assessor.

Training of the assessors

After the selection of the professionals fit for the task, an extensive training has to be accomplished. Also in this field guidelines exist.

ILAC G 3 (1994): Guidelines for training courses for assessors used by laboratory accreditation schemes.

EAL G 7 (1993): Guidelines for training courses for assessors used by laboratory accreditation schemes

EAL G 10 (1993): Programme for course for tutors for assessor training.

In these guidelines is indicated that 36-hour training is needed (4 days) in a group of 15 till 20 persons with 2 tutors. It should contain lectures, group discussions, and exercises.

In this course should be paid attention to:

– Common introduction about quality assurance and quality control
– Background of the accreditation scheme
– Knowledge of ISO 15189
– Quality system and quality manual
– Procedures for and performance of internal audits and reviews
– Calibration and traceability of measurements
– Proficiency testing and internal quality control schemes

Human aspects of assessment

– techniques for conducting the assessment
– questioning techniques
– gathering information in an objective, friendly and professional method

Administration and pre- assessment procedures

– Conduct of the assessment
– Reporting non-compliance's
– Exercises through cases

During this course the potential assessors are appraised concerning different aspects

– knowledge and understanding of the accreditation scheme
– ability to work as a member of a team
– ability to communicate and deal with human relations
– potential leadership (to act as a lead assessor in the future)

Apart from the original training, which has to be completed successful one has to act as an observer during one real assessment.

Calibration of the assessment process

One of the main tasks of the accrediting body is to take care that the assessment process is comparable between the different laboratories they assess. This is mainly done by the director of this body, and he can use experts in the field. Uniformity should occur concerning the grading of the non conformities which certainly will be discovered by the assessors. Information concerning these aspects will be sent to all assessors. Another possibility is yearly conferences of the assessors and the discussion of cases.

Also in this field an ILAC guideline exists.

ILAC G20 (2002): Guidelines on grading of non-conformities.

This, of course, is in line with the way assessment is generally done.

They discern 3 grades

Grade 1: very serious indeed. The accreditation process is immediately suspended.

Grade 2: quite significant. Corrective action must be completed before accreditation is given or renewed. The corrections must be shown in writing or during a re visit.

Grade 3: minor. It does not affect the outcome or quality system at that moment. But if not repaired, the system can deteriorate. These items will be checked during the next re assessment visit.

Especially non-conformities, which are related to the technical activities and results, are considered as quite serious.

Instances of grade 1 are

– no professional staff present, because the former ones have left and not replaced by qualified ones
– cross contamination of samples is possible
– serious error in calibration is identified, but not acted on, whereas the reports are send out
– no action undertaken on consecutive outliers in proficiency testing, which are not related to a matrix problem in the proficiency samples.

Instances of grade 2 are

– one recent proficiency testing was an outlier and not yet acted, whereas this in normally done in that laboratory as indicated in documentation
– internal audit some months overdue
– the most recent management review is dot yet done
– not all technical personnel acquainted with the Westgard rules.

Instances of grade 3 are

– a photocopy of an obsolete SOP is found in a drawer
– a SOP which is not changed is not updated within the indicated time.

Questionnaire concerning accreditation of medical laboratories

One of the main tasks of our Working Group is to accomplish some harmonisation of the practice of accreditation. The intention is to publish Essential Criteria concerning the process of choosing and training the assessors, and for the assessment process itself. The ILAC and EA guidelines are very helpful for this purpose.

Interesting as well is to know the present situation in Europe. For this purpose a questionnaire was send to all clinical chemical societies of the member states of the European Union.

The preliminary results, with answers of 13 countries from which 2 indicated they could not reply right now, are:

Choice of standard

For accreditation nearly all (10) countries use ISO 15189 and a smaller number (5) ISO 17025 as well.

Selection of assessors

The selection of assessors is either the task of the accreditation body (8) alone or in combination with the professional society (3).

Mostly the assessors are laboratory professionals with extensive (3–10) year's experience. For assessment of the quality system mostly laboratory professionals are used (9), but sometimes experts concerning quality systems (2). Attitudinal requirements are indicated in 6 cases, especially concerning communication skills.

Training of the assessors

The training is mostly done by an EA linked body (8), but sometimes by the professional organisations. Also in these instance ILAC G3 and EAL G7 are followed

The duration of the training is quite divers. From 2–6 days, but in the majority (7) it is 4 or 5 days. It depends partly on the role these professionals play during the assessment process. For technical assessors it is shorter than for lead assessors. For updating the assessors in all instances information about specific items is provided (10) and in 6 cases there is a yearly update through a meeting as well.

The assessment process

Information is required before an on site visit takes place. At least a quality manual, but also proficiency testing, examples of audits and standard operating procedures. The number of assessors depends upon the size of the laboratory, the extensiveness of its testing repertoire and in one case the first assessment requires more people than re assessments.

The duration of the assessment visit is divers, from 1–3 days, but in the majority it takes 2 days, representing 4–9 days in man power.

The assessment is granted for 1–1.5 (2), 2 (2), 3 (2), 4 (4), or 5 (1) years.

In most of the cases per test, but a laboratory can also choose for flexible scope (3), which gives more liberty to make small changes. In some countries accreditation is granted for a broader scope, especially in those countries, where the process was initiated by the professional bodies.

In most cases where an accreditation was granted for more than 2 years a surveillance visit was organized every 1–1,5 year. Till now this is not done in UK, The Netherlands and Czech Republic. Grading of non-conformities is not clear yet

Number of accredited laboratories

The % of laboratories which have been accredited is quite divers. In most countries is has just started. In France 90 laboratories are accredited, representing 2.5%, and in Belgium 22 laboratories representing 10%. Unfortunately the numbers for Sweden are not mentioned. In The Netherlands 122 laboratories from 14 disciplines are accredited representing 30.5%. In the UK a change takes place from laboratories accredited conforming the original CPA system (609) to the new CPA standards which are equivalent to ISO 15189 (101 at this moment), also from all types of disciplines just started.

Conclusion

For the accreditation of medical laboratories the ISO 15189 is very well accepted. The percentage of laboratories which have been accredited is still rather low. Even when the accreditation of medical laboratories is done by EA linked accreditation bodies, quite diversity exists in the frequency of the assessment visits, in the frequency of the surveillance visits and in the duration of these assessment visits. The ISO 17011 allows such diversity. It states that the maximum interval between assessments is 5 years. To prevent de-arrangement of the system a surveillance process should be set up, and a surveillance visit could be part of it. In all cases the professional laboratory workers play a crucial role. This is of utmost importance, because only in this way competence can be judged. In Australia, where a system of cooperation between professionals and an accrediting body already exists for more than 15 years, and accreditation is granted for 3 years, the result for the quality of the medical laboratory system is judged as positive.

In the article of Ho (2) the importance of continuous improvement is indicated as well. Setting up a quality system in line with ISO 15189 is an expensive process and so is the accreditation. The higher the frequency of the assessment and surveillance visits, the higher are not only the costs, but also the difficulty of finding enough competent assessors. Accreditation should not be restricted to a few big laboratories, but form a mechanism to improve the quality of all medical laboratories, like proficiency testing does. For that reason the EC4 Working Group will focus on what they consider as Essential Criteria for assessors and assessment.

Especially with respect to non-conformities it is important to avoid the views of hobbyists as assessors. The natural way of an accreditation process is that only the best practises are valued as »conform«, even if other practises are still quite acceptable. The management review of a laboratory should provide information on the added value of all steps of the quality system, also in relation to its costs. In the latest version of the CCKL standard, which in The Netherlands is used for accreditation and which incorporates the whole ISO 15189, »Value for Money« of the quality system is added as an important aspect of this management review. We should never forget that a quality system and accreditation are not purposes on itself but they should contribute to a good health system for our patients.

AKREDITACIJA

Willem Huisman

Predsedavajući Radne grupe za akreditaciju i sistem kvaliteta EC4
Clinical Chemical Laboratory, Medical Centre Haaglanden, PO Box 432, 2501CK, The Hague, The Netherlands

Kratak sadržaj: ISO 15189 je dobro prihvaćen kao glavni standard za akreditaciju medicinskih laboratorija u evropskim zemljama. U saradnji sa EA nacionalna akreditaciona tela prihvatila su ovaj standard za praktičnu primenu. To je omogućilo da akreditacija bude prihvaćena i u drugim zemljama. Stručnjaci iz medicinskih laboratorija imaju ključnu ulogu u sprovođenju ovog procesa. Njihova stalna edukacija i obuka je od posebne važnosti za postizanje značanosti akreditacije pri tretmanu pacijenata. Ovaj proces će značajno doprineti kontinuiranom poboljašnju u svim laboratorijama. Ovde se prikazuju preliminarni rezultati upitnika koji se odnosi na sadašnju situaciju akreditacije u zemljama Evropske zajednice. Oni ukazuju na različitosti u akreditacionom procesu u odnosu na interval između preispitivanja i nadzornih poseta. Radna grupa za akreditaciju EC4 iskoristi će rezultate ovog upitnika i sadržaje ILAC i EA uputstava će koristiti kako bi ponudila važne kriterijume u odnosu na neke od navedenih aspekata.

Ključne reči: akreditacija, procena, saradnja sa EA, upitnik vezan za akreditaciju

References

1. Huisman W. ISO 15189:2003-Its importance for the enlarged Europe http://www.ifcc.org/ejifcc/vol15 no4/150412200406.htm
2. Ho B. Practical applications of ISO 15189 by accreditation bodies http://www.ifcc.org/ejifcc/vol15no4/150412200403.htm

Received: April 11, 2005

Accepted: April 14, 2005