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Accreditation of medical laboratories in the European Union

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Abstract

Background: Using a questionnaire, the EC4 (European Communities Confederation of Clinical Chemistry and Laboratory Medicine) has collated an inventory of the accreditation procedures for medical laboratories in the EU.

Results and discussion: Accreditation of medical laboratories in the countries of the EU is mostly carried out in cooperation with national accreditation bodies. These national accreditation bodies work together in a regional cooperation, the European Cooperation for Accreditation (EA). Professionals are trained to become assessors and play a prominent role in the accreditation process. The extent of the training is diverse, but assessors are kept informed and up-to-date by annual meetings. The frequency of assessments and surveillance visits differs from country to country and ranges from 1 to 4 years. More harmonisation is needed in this respect, based on a frequency that can be pragmatically handled by laboratory professionals. In the majority of EA bodies, accreditation is carried out on a test-by-test basis. Many professionals would prefer accreditation of the entire service provided within the actual field of testing (i.e., haematology, immunology, etc.), with accreditation granted if the majority of tests offered within a service field fulfil the requirements of the ISO 15189 standard. The scope of accreditation is a major point of discussions between the EC4 Working Group on Accreditation and representatives of accreditation bodies in the EA Medical Laboratory Committee.
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Keywords: accreditation; ISO standards; medical laboratory; quality.

Introduction

The International and European standard for quality requirements in medical laboratories, ISO EN 15189: 2003, entitled ''Medical laboratories – particular requirements for quality and competence'', has been available for 3 years now and is widely accepted in the medical laboratory community (1). Many laboratories are working on its implementation, and request accreditation of their service to be judged according to this standard. Previously, different approaches were followed. Some countries started with accreditation according to the ISO 17025:1999 standard, entitled ''General requirements for the competence of testing and calibration laboratories'' by national accreditation bodies that were members of the European Cooperation of Accreditation (EA) (2). In many countries, these bodies are now also offering accreditation according to ISO 15189.

Other countries have started to set up professional accreditation bodies specifically for medical laboratories, e.g., CPA (UK), CCKL (The Netherlands), and NACCL (Czech Republic). They have incorporated in their requirements all aspects of ISO 15189. Because of the freedom of movement of people, services and

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goods within and outside the EU, these bodies also seek international recognition. Such a mutual lateral agreement can be accomplished by cooperation with accreditation bodies linked to the EA.

The EC4 (European Communities Confederation of Clinical Chemistry and Laboratory Medicine) Working Group (WG) on Accreditation has published Essential Criteria to stimulate harmonisation of quality systems in the different EU countries (3, 4). These essential criteria were used extensively when the ISO 15189 standard was formulated. The WG is now very active in harmonising the accreditation of medical laboratories within Europe. One of the aims of this WG is to produce essential criteria for assessors and assessments, but before doing so a survey was carried out in 2005 to explore the current status of accreditation in EU countries. The questionnaire was sent to representatives of clinical biochemistry and laboratory medicine societies of EU countries.

Results and discussion

Out of 25 societies, 19 returned the survey questionnaire by December 2005. The answers represent the situation as of April 2005. At the time of the survey, accreditation of medical laboratories in Ireland was carried out by CPA (UK) Ltd. Greece had not yet started the accreditation of medical laboratories. Austria and Germany indicated that their societies were not involved in the accreditation of medical laboratories.

Responses from the national accreditation bodies were not available in most countries. In Italy, while the scientific societies recognise the value of ISO 15189:2003 as the accreditation standard for medical laboratories, major problems have been experienced in identifying the accreditation body. The answers returned by the Hungarian society were presented jointly and validated by the national accreditation body. Results are presented in Tables 1–10. Y means yes and N means no. If no answers were given, the items were left blank.

For the assessment of medical laboratories, the relevant ISO standard 17011 and related guidelines are generally followed very well in each country (5). Because accreditation is carried out by accreditation bodies who are members of EA, this is not surprising, but independent organisations, such as CPA and CCKL, are also following these standards and guidelines.

The current status regarding the selection, training and evaluation of assessors in EU countries is demonstrated in Tables 1–5. Table 1 indicates quite clearly that in most cases the accreditation body selects the assessors. In some countries, professional laboratory organisations support this process. In terms of professional requirements, assessors are high-level medical laboratory professionals (clinical biochemists at consultant level) with at least 4–5 years of experience (Table 2). Sometimes highly trained technologists or quality officers are also members of the assessment team (Table 1). The ISO 10011:1993 guidelines state that, apart from professional skills, the personality

Table 1 Selection and recruitment of assessors.

Selection and recruitment of assessors	AT*	BE	CZ	DE*	ES	FI	FR	GR**	HR	HU	IE	LV	NL	NO	PL	SE	SL	SK	UK
Selection by accreditation body		Y			Y	Y	Y		Y	Y		Y	Y	Y	Y	Y	Y	Y	
Selection by professional societies			Y		N						Y		Y		Y				Y
Assessors are laboratory specialists		Y	Y		Y	Y	Y		Y	Y	Y	Y	Y	Y		Y	Y	Y	Y
Assessors are laboratory technologists					N						Y		Y		Y				Y
Attitudinal aspects play a role		Y	N		N		Y			Y		Y	Y	Y	N	Y	Y	Y	

*No society involvement in laboratory accreditation. **Not yet started accreditation.

Table 2 Professional experience of assessors.

Professional experience before acceptance as assessor	AT*	BE	CZ	DE*	ES	FI	FR	GR**	HR	HU	IE	LV	NL	NO	PL	SE	SL	SK	UK
2 years																			
3 years													Y						
4 years					Y							Y					Y		
5 years			Y				Y			Y						Y		Y	

*No society involvement in laboratory accreditation. **Not yet started accreditation.

Table 3 Assessor training.

Training of assessors	AT*	BE	CZ	DE*	ES	FI	FR	GR**	HR	HU	IE	LV	NL	NO	PL	SE	SL	SK	UK
Trained according to ISO standards		Y	Y		Y	Y	Y		Y	Y		Y	Y	Y	Y	Y	Y	Y	
Trained by EA-linked body		Y	Y		Y	Y	Y			Y		Y		Y	Y	Y	Y	Y	
Trained by professional organisation					N				Y		Y		Y						Y
Training includes role-playing		Y	N		Y	Y	Y		N	Y	Y	Y	Y	Y	Y	Y	Y		
Trained by observing an assessment		Y			N	Y	N			Y	Y	Y	Y	Y	Y	N	Y		Y
Yearly updates		Y			Y	Y	Y		Y	Y	Y	Y	Y	Y		Y	Y	Y	Y
Information on specific items		Y	Y		Y	Y	Y		Y	Y	Y	Y	Y	Y	Y	Y	Y		Y

*No society involvement in laboratory accreditation. **Not yet started accreditation.

Table 4 Duration of assessor training.

Duration of assessor training	AT*	BE	CZ	DE*	ES	FI	FR	GR**	HR	HU	IE	LV	NL	NO	PL	SE	SL	SK	UK
2 days					Y		Y				Y							Y	Y
3 days													Y			Y			
4 days		Y				Y													
5 days									Y	Y		Y		Y			Y		
>5 days			Y												Y				

*No society involvement in laboratory accreditation. **Not yet started accreditation.

Table 5 Evaluation of assessors.

Appraisal of assessors	AT*	BE	CZ	DE*	ES	FI	FR	GR**	HR	HU	IE	LV	NL	NO	PL	SE	SL	SK	UK
Part of the training		Y	N				Y		Y	Y	N	Y	N	Y		Y	Y	Y	N
Done by the accrediting body		Y	Y		Y		Y		N	Y	Y	Y	Y	Y		Y	Y	Y	Y
Performance monitored		Y			Y	Y			Y	Y	Y	Y	Y	Y		Y		Y	Y

*No society involvement in laboratory accreditation. **Not yet started accreditation.

Table 6 The assessment process.

Assessment process	AT*	BE	CZ	DE*	ES	FI	FR	GR**	HR	HU	IE	LV	NL	NO	PL	SE	SL	SK	UK
Accrediting body provides information		Y			Y	Y	Y		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Information requested before visit		Y			Y	Y	Y		N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Competence graded by laboratory specialist		Y	Y		Y	Y	Y		Y	Y	Y	Y	Y	Y		Y	Y	Y	Y
Quality systems graded by laboratory specialist		Y	Y		N					Y	Y		Y				Y	Y	Y
Quality systems graded by quality specialist		Y			Y		Y					Y		Y	Y	Y			
Accreditation granted per test		Y			Y	Y	Y			Y		Y		Y		Y		Y	
Accreditation granted per service			Y		N				Y		Y		Y		Y				Y

*No society involvement in laboratory accreditation. **Not yet started accreditation.

Table 7 Frequency of assessments.

Interval between assessments	AT*	BE	CZ	DE*	ES	FI	FR	GR**	HR	HU	IE	LV	NL	NO	PL	SE	SL	SK	UK
1.5 years							Y								Y				
2 years			Y						Y										
3 years		Y								Y									
4 years											Y	Y	Y			Y		Y	Y
5 years														Y			Y		

*No society involvement in laboratory accreditation. **Not yet started accreditation.

Table 8 Frequency of surveillance visits.

Frequency of surveillance visits	AT*	BE	CZ	DE*	ES	FI	FR	GR**	HR	HU	IE	LV	NL	NO	PL	SE	SL	SK	UK
None			Y				Y				Y		Y						Y
Every 1.5 years		Y																	
Every year					Y	Y				Y		Y		Y		Y	Y	Y	

*No society involvement in laboratory accreditation. **Not yet started accreditation.

Table 9 Grading of non-conformities.

Grading scale for non-conformities	AT*	BE	CZ	DE*	ES	FI	FR	GR**	HR	HU	IE	LV	NL	NO	PL	SE	SL	SK	UK
1																			
2					X		X				X								X
3		X								X		X	X	X					

*No society involvement in laboratory accreditation. **Not yet started accreditation.

Table 10 Number of accredited laboratories.

Accreditation	AT*	BE	CZ	DE*	ES	FI	FR	GR**	HR	HU	IE	LV	NL	NO	PL	SE	SL	SK	UK
ISO 15189		22 (10%)	3 (0.3%)		3								122 (30%) +98 applied		4		0	6 (4%)	101 (9%) fully, 116 partially; old CPA: 606 (55%) fully, 276 partially
ISO 17025			2			? (1%)	90 (3%)			6[a] (3%)		5 (4%)		15		85%			

Results are presented as number of laboratories (% of total). [a]In Hungary it is possible to accredit medical laboratories according to ISO 17025 and/or 15189. At the time of the survey, however, all accredited laboratories used the ISO 17025 standard. [b]In the UK, the laboratory service is accredited and it is possible to grant accreditation to the whole service or to part of it only. In the latter case, the laboratory is granted partial accreditation. Up to the date of our survey, most laboratories were accredited according to the old CPA standards fully or partially. However, laboratories had started to use the new ISO 15189-aligned CPA standards as well, and 101 laboratories were fully and 116 laboratories partially accredited. *No society involvement in laboratory accreditation. **Not yet started accreditation.

and attitude of assessors are also very important in the assessment process (6). An assessor is expected to be unprejudiced, open-minded, and able to work in a team. Not all countries have formalised these aspects in their requirements for assessors yet (Table 1).

For the training of the assessors, ISO standard 10011 and the ILAC G3 or EAL G7 guidelines (6–8) are followed (Table 3). Training is mostly carried out by EA-linked national accrediting bodies. The duration of the training is quite diverse (Table 4). This, of course, partly depends upon the previous experience and training of the professionals, as well as on the experience of the accrediting body. In countries that have a long tradition of accrediting medical laboratories (e.g., Sweden, UK, The Netherlands) the duration of training is shorter than in countries in which the accreditation system is relatively young (e.g., the new Central-Eastern European EU countries). The training process follows the guidelines, and in most countries involves role-play and training in practice, but the survey did not collect information on the actual training content (Table 3). Updating of assessors, either in the form of regular yearly refresher courses or by providing special workshops on key topics, seems to be a regular activity in all countries (Table 3).

Appraisal of assessors is often carried out during the training course and, in nearly all cases, by monitoring performance at assessment visits thereafter (Table 5). The accreditation bodies use different techniques for evaluating assessor performance (customer questionnaire, feedback from co-assessors or lead assessors, reading draft reports by the director of the accreditation body, etc.).

Results of the survey on the assessment process are presented in Tables 6–10. Assessment of the quality management system itself is mostly carried out by medical laboratory specialists, but in some cases by people specialised in quality systems only (Table 6). Grading of competence and non-conformities is taught at the training and annual refresher courses, and is carried out by laboratory specialists in all countries (Table 6), but there is a difference in the grading system used across countries (Table 9). The duration of an assessment and the number of assessors are highly dependent on the size of the laboratory, and the complexity of the different disciplines it incorporates.

The most important differences exist in relation to the scope of accreditation (Table 6) and to the frequency of the assessment and surveillance visits (Tables 7 and 8). Concerning the scope, it has to be recognised that a medical laboratory performs hundreds of different tests at the request of doctors and for the benefit of patients. Owing to numerous guidelines on best medical practice, there are certain testing protocols and diagnostic algorithms, as well as clinical experience and doctors' and patients' preferences, that also guide the request patterns of health professionals and thus the diagnostic service of laboratories. Pathophysiology of disease also drives this process and therefore laboratory testing is specialised to certain fields, such as clinical biochemistry, haematology, immunology, etc. Every year many new tests are introduced into the laboratory repertoire to keep pace with advances in research and technology and user requirements for diagnostic services. Laboratory tests are validated before use in routine practice, and many new tests are mostly performed with the same types of instruments and techniques that are already used in the laboratories. Certain test groups and laboratory techniques require the same pre-analytical, analytical and post-analytical procedures, and combined interpretation of several test results or test groups may be required for accurate diagnosis in a clinical context. When accrediting medical laboratories, it has to be recognised that making a medical diagnosis is a highly sophisticated professional activity in which the analytical performance of a test is only a small part. Clinical decisions on accurate diagnosis depend on many clinical, pre-analytical, analytical and post-analytical factors, and often on a combination of different test results. Therefore, laboratories are required to provide a complex service that encapsulates all these variables and takes into consideration the needs and demands of both clinicians and patients. Thus, in most laboratories, specific sections or units are organised for the field of service, covering a certain range of tests or test groups in order to deliver a complex, highly efficient and high-quality service to its users.

For these reasons and because of the complex nature of clinical diagnosis, from the start of accreditation, the UK and The Netherlands choose to grant accreditation according to fields of services, e.g., haematology, clinical biochemistry, medical microbiology, molecular genetics, etc. The EA-linked bodies, based on their long-term experience with industrial laboratories, started with accreditation per test, with the possibility of collecting these tests under the flexible scope of service field. Considering the relationship between the aims of accreditation and the definition of a medical laboratory service and medical tests, then the provision of accreditation of the service area by field of discipline seems to be a more customer-focused and professionally acceptable method.

The arguments for this ''service approach'' as opposed to the ''test approach'' are as follows:

- The prime aim of accreditation of medical laboratories is to prove, by objective evidence, that the laboratory is competent to provide a medical diagnostic service to its customers, including healthcare staff and patients.
- A medical diagnostic service incorporates a whole range of activities, from advising doctors on selection of the most appropriate tests for the actual diagnostic problem, instructions on sampling and pre-analytical variables, to testing by analytical methods and then reporting and interpreting test results in the clinical context. Thus, the diagnostic service provided by the laboratory is far broader than just performing analysis of a certain measurand.
- Individual medical tests are seldom used in isolation for diagnostic purposes. It is often a combi-

nation of test results and the pattern of results that, together with the patient's history, signs and symptoms, provide the diagnosis.
- Often certain test results prompt further testing according to predefined medical algorithms, which are highly dependent on patient characteristics and the original question posed by the clinician. Therefore, individual medical tests accredited in isolation tell little about the competence of the laboratory in providing a high-quality diagnostic service.
- Medical tests are often based on the same methodological principles, so grouping them into fields of service area is commonly done according to method groups. Within such method groups, the laboratory has to show its competence for validating one test, as well as many tests.
- Accreditation based on the service area stresses the need for technical competence in managing the inspection visit and, in general, the whole accreditation programme.

Based on the above characteristics of medical laboratories, the EC4 WG proposes a paradigm shift in the way the scope of accreditation is determined and that assessments are carried out by accrediting bodies. The primary consideration in determining the scope of the service provided, and therefore the scope of assessments carried out by accrediting bodies, must be the needs and requirements of the clinicians (and their patients) who use the laboratory's services. Of course the question then arises as to what is the definition of a service area of a medical laboratory. For example, what does a haematology service mean? As the needs and requirements of clinicians (and their patients) will vary from situation to situation, so will the content of the service provided. In some laboratories the haematology service may include only full blood cell counts, while in another laboratory it could also incorporate blood films or bone marrow preparations and flow cytometric analysis of different cellular markers, as well as biochemical or immunochemical tests for the diagnosis of iron metabolism, etc.

Members of the EC4 WG accept the principle that the actual tests involved in an accredited field of service should be clearly defined and stated and also made publicly available, so that customers are sufficiently and explicitly informed about the content of that service. To sum up arguments for both approaches, we strongly believe that if the service area of laboratories is accredited in a complex fashion, together with an explicit statement of what tests that service incorporates in the given laboratory, then accreditation will better reflect the competence of the laboratory in fulfilling the medical needs of its customers.

The frequency of assessments is another important aspect of the accreditation process. ISO 17011 requires an assessment within a maximum of 5 years and preference is given to more frequent assessments every 4 years (5). All countries fulfil these criteria (Table 7). The standard also states that a regular surveillance procedure is needed to ensure that a valid quality management system is maintained in the meantime (5). On-site surveillance visits may be required, but much of the routine quality improvement activities can be left to the responsibility of the accredited laboratory. ISO 17011 indicates that the first surveillance visit after the first assessment should preferably be within 1 year (5). The EC4 group suggests that the frequency of surveillance visits is reconsidered. A system similar to that in the UK, i.e., one surveillance 2 years after accreditation status is achieved and re-assessment after 4 years, seems to be a reasonable scheme. Table 8 indicates that in most countries surveillance is carried out annually. Not only is this frequency expensive, but it also creates difficulties for the accreditation bodies in finding competent and willing assessors to meet the demand. A formal cost-benefit analysis would be required to investigate the effectiveness and to justify the frequency of the current surveillance programmes.

The number of accredited laboratories varies between EU countries. In 20% of the countries EN/ISO 15189 is used exclusively, while in the remaining countries both standards (i.e., ISO 15189 and 17025) are available (Table 10). In the UK, the original CPA standards are now replaced by the new EN/ISO 15189-aligned CPA guideline. The total number of accredited laboratories is relatively high, and the proportion accredited according to ISO 15189 is already 9%. In The Netherlands, 30% of all types of medical laboratories and 70% of clinical biochemistry laboratories are accredited to EN/ISO 15189. In Sweden, the rate of accredited laboratories is even higher at 85%, most of which are accredited to ISO/IEC 17025, but some also to EN/ISO 15189 (Table 10).

Our survey has also revealed that, while there are several variations in the approaches to accreditation of medical laboratories in the EU, EN/ISO15189 has been accepted in all EU countries as the standard for medical laboratory services, and that there is a need for uniform implementation of the accreditation concept, using the same standards in all countries. The EC4 WG is willing to support these processes in the future by promoting harmonisation and training, and by co-operating with the EA and national accrediting organisations.

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