

ISO 15189:2003 — Its importance for the enlarged Europe

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Introduction

The basic idea of the European Union is freedom of movement of people, products and services. This is realised through harmonisation of practices, for example in the field of laboratory medicine, a patient wants to be sure that the result of a test can be trusted and is interpreted in the right way during his stay abroad. This has several implications for our profession. Within EC4, the European Communion Confederation of Clinical Chemistry and Laboratory Medicine, several working groups have contributed to the harmonisation of the profession, laboratory and laboratory data. Of course, international developments have been supported.

Quality and competence

The title of the ISO 15189 standard is "Medical laboratories — Particular requirements for quality and competence" (1). Several aspects of this title are important. The inclusion of the term "Competence" indicates that more than the existence of a valid quality system is considered. "Medical laboratories" indicates as well that it is written specifically for that field. The importance of these aspects will be indicated in the following sections.

Quality system

The quality of the analytical work had been a major focus for a very long time and as laboratory professionals, we have developed reference methods, international standards, and use quality control material to be sure about the internal variation coefficient of our methods and participate in External quality assessment schemes to understand the relationship between the performance of different laboratories. Still the physicians confronted us with mistakes. The quality approach taught us to consider the complete process. For a medical laboratory it meant the pre-examination procedures, the examination procedures and the post-examination procedures.

ISO 9001:2000 "Quality management systems — Requirements" (2) describes a very general approach to quality systems. It can be used to set up a quality system for different types of organisations. It is applied in hotels, garages, manufacturers of diagnostics and laboratories. It helps a lot to structure the different aspects in an

organisation. It pays specific attention to the critical points. It makes clear that mistakes should be examined to avoid repeating them. It helps to focus on the needs of clients (for the medical laboratory, this includes both patients and doctors). To ensure that a company has complied with this standard in setting up its quality system, it must be inspected and certified as compliant by a recognized certification body. In order to claim that it operates a quality system in accordance with ISO 9001:2000, a company must have received certification by a third party.

Competence in testing

This ISO 9000 approach is very general. If a customer receives a result from a laboratory that has tested for instance the amount of lead in a substance and this laboratory has an ISO 9001 certificate, it indicates that a quality system exists and that the laboratory does the testing according to written procedures but it does not give assurance about the competence with which the tests are performed.

To facilitate international trade it is necessary to ensure that tests on products performed by industrial testing laboratories in different countries are reliable and give comparable results.

It is therefore necessary to assess the competence of testing laboratories, as well as their quality systems. The standard ISO/IEC 17025:1999 "General requirements for quality and competence of testing laboratories" (3) has been developed for this purpose. This standard includes all aspects of the quality system, but adds specific demands concerning the analysis. The results should be traceable to international standards, external quality assessment should be done; validation of the test system is essential. The people who do the tests should be adequately trained. The analyses should be performed according to the best available methodology. Thus, specific demands concerning the competence of the laboratory are explicitly added. Again, inspection by a third party — in this case an accreditation body — is necessary. An important difference between this and a certification inspection is that the inspection team should include someone with experience in the field in which the laboratory is working. If the laboratory passes the inspection, it can claim to be accredited according to ISO 17025. Many accrediting bodies in Europe cooperate in the organization EA (European Cooperation on Accreditation). They perform mutual assessments. This gives confidence that the test results can be used internationally. Although it is quite possible that a laboratory with only an ISO 9000 certificate does the test as well as the one with a 17025 accreditation, the customer cannot be sure.

Competence in a medical laboratory

When the discussion about introduction of quality systems in medical laboratories started in the late nineteen-eighties, it focussed on which aspects were specific for medical laboratories. Different approaches were followed in different countries. To help in harmonisation in setting up of quality system and in the process of

accreditation, a Working Group on Accreditation was set up within EC4. In a survey held within Europe in the field of clinical chemistry, it was quite clear that there was a requirement to include pre- and post-examination aspects, and to make evident that a medical laboratory gives information and not just figures (4). The Essential Criteria (5) and Additional Essential Criteria (6) that were published by this Working Group contained all these items. The ISO Working Group that produced ISO 15189 included workers in the field of laboratory medicine, several of whom were members of the EC4 WG on Accreditation. It had input from different parts of the world and a major impact from the EC4 Essential Criteria. The utmost importance of this ISO 15189 is that it really covers all aspects of the work in a medical laboratory. It should mean that a medical laboratory which has been accredited according to ISO15189 by a competent accreditation body pays attention to all these different aspects. Its customers can be confident that the laboratory provides not only accurate test results, but also a good medical laboratory service.

In the ISO15189 all aspects of the generic ISO9001 are covered and the vast majority of the more specific ISO17025. It adds aspects specific for a medical laboratory, such as:

- working in a medical surrounding
- consultation function
- headed by a professional
- role of diagnostic manufacturer

Working in a medical surrounding

In a hospital environment, we have to deliver valid information about the patients during 24 hours every day of the year. Many of the results have to be available within a very short time, from minutes to an hour at the most for our stat samples. Our big volume test results are expected within a couple of hours. Only for a small volume of the tests we can take more time. To achieve this, we must not only have reliable apparatus, but also well trained technicians. They must not only be aware of analytics, but also of the clinical implications of the results. A laboratory professional must be available for consultation during the time tests are performed

The laboratory not only provides tests, but also service. This can involve the organisation of point of care testing. It can involve satellite laboratories for instance near intensive care. The laboratory professional should be responsible for the quality of the laboratory tests done in the hospital.

The taking of the samples from a patient is often critical, as is the transport. The medical laboratory should provide instructions that are critical. It should be rather stringent in the process of identification of the sample to a specific patient and refuse to give results if uncertainty exists.

When a test result has to be revised after it was available to a physician treating a patient, the doctor should be informed.

Consultation function

The medical laboratory professional should give advice concerning the tests which are adequate for certain categories and for individual patients, in consultation with the specialist who treats that specific patient. This is part of the pre-examination aspects of a laboratory,

which certainly are not restricted to technical aspects of phlebotomy, transportation and refrigeration.

The medical laboratory professional takes care that the analysis is done according to the state of the art, with the clinically required precision and accuracy. He is aware of drug interactions and other interfering factors. This is part of his role in the analytical process.

The medical laboratory professional discusses the results with the clinicians and is involved in discussion of patient cases and in the education of the clinicians concerning new developments in laboratory medicine. He is a member of the medical staff of the hospital. In the management review, which is part of the quality system, the adequacy of the test repertoire and delivered service in connection with patient care is an important aspect.

This is part of his role in the post examination aspects.

In the ISO 15189 these tasks of the medical laboratory professional are mentioned specifically. It means that during an accreditation the laboratory can show that these requirements are fulfilled. The professional should not only have been trained adequately to become registered for instance as a clinical biochemist, but he should also have taken part in post academic training to keep his registration. To make movement of professionals easier in the European Union, EC4 has set up a register of European Specialists in Clinical Chemistry and Laboratory Medicine.

Headed by a professional

ISO 15189 mentions that the responsibility of the laboratory director should include professional, scientific, consultative or advisory, organisational, administrative and educational matters. He (or she) should have the appropriate training and background to be able to discharge his/her responsibilities in specified items concerning all these aspects. This means that the professional responsibility of a medical laboratory can only be taken by a registered medical laboratory professional.

Role of diagnostic industry

ISO 15189 has a specific section (5.3) about laboratory equipment. It pays attention to the role these manufacturers play in providing instruction and in general as a partner in the process of providing relevant patients' results. In this aspect the introduction in Europe of CE marking for in vitro devices is relevant. It should give confidence that the results can be related to internationally accepted standards (traceability). It makes certain that relevant information about interactions is supplied and that a post marketing surveillance program is set up. One of the aims of EC4 is to stimulate work in this field of harmonisation of laboratory data. They will cooperate with industry in these matters

Setting up the quality system

Setting up a quality system in line with the ISO 15189 is a task which all medical laboratories in the enlarged Europe should try to accomplish. It is quite an effort, but worthwhile. It is a process which will take a couple of years. It has to be set up carefully. One of the medical laboratory professionals should be made responsible. Many people in the laboratory should be involved in preparing standard operating procedures, which are really used and kept up to date. One of the laboratory staff should be designated as Quality Manager and given enough time to fulfil this task. A Quality Manual should be set up and all documentation should be taken care of. In ISO 15189 all these aspects are mentioned. The problem with its structure is that it is based on that of the old ISO 9001:1994. Many

items which are certainly connected are worded under different paragraphs. For that reason, reading of the Essential Criteria will help to make it more understandable. Even more important is to realise that this whole effort is part of a continuous improvement process. The real meaning of a quality system is working on improvement by using the input of the customers, in our case the physicians and patients. This makes internal audit and the management review part of the mainstay of the quality system.

Accreditation

To make it clear to the customer that a laboratory has an adequate quality system and the competence to give reliable results and interpretation of their meaning for treatment of patients, an accreditation system has to be set up. It is quite clear that it can only be done when medical laboratory specialists are deeply involved in this process. For a medical laboratory the accreditation should be for a specific group of tests and not for specific tests in themselves. The frequency of the inspections should be in line with what gives added value. At this moment the EC4 Working Group on Accreditation is planning to produce a paper on essential criteria for assessments and assessors. This is of course in line with the guidelines produced by EA and ILAC (International Laboratory Accreditation Cooperation), but with specific attention to items specific for the medical laboratories. In these aspects close contact exists between members of this working group and of EA.

Multilateral Agreement

Many medical laboratories in countries in Europe are working on setting up a quality system according to ISO 15189. They should include specific items required by law in such a country to make it possible to use one system instead of several. Some countries like United Kingdom have already such a system. The systems used in several countries need not to be identical as long as they contain all specific aspects of the ISO 15189. Contacts between different countries and members of the working group exist.

It is important that the accrediting bodies use comparable guidelines during inspection. They should come to a form of mutual assessment and eventual recognition. For medical laboratory tests the same situation should exist as for testing laboratories in general, that results of accredited laboratories are recognised in all countries, in the enlarged Europe. This means a multilateral agreement under which each accrediting body agrees to recognise accreditation according to ISO 15189 by the other bodies.

Conclusion

ISO 15189 is the standard all medical laboratories in Europe should use to set up their quality system and use for accreditation.

It contains all aspects of importance to give confidence to our patients and medical doctors that we deliver good service.

In the end it should be possible that the doctor in Prague can use with confidence a result of a patient from a laboratory in Madrid.

References

1. ISO 15189:2003 Medical laboratories-Particular requirements for quality and competence
2. ISO 9001:2000 Quality management systems-requirements

3. ISO/IEC 17025:1999 General requirements for the competence of testing and calibration laboratories

4. Jansen RTP, Blaton V, Burnett D, et al. Quality and accreditation systems in clinical biochemistry in the European Union. *Eur J Clin Chem Clin Biochem* 1995;33:393-398

5. Jansen RTP, Blaton V, Burnett D, et al. Essential Criteria for quality systems in medical laboratories. *Eur J Clin Chem Clin Biochem* 1997;35:121-132

6. Jansen RTP, Blaton V, Burnett D, et al. Additional essential criteria for quality system of medical laboratories. *Clin Chem Lab Med* 1998;38:249-252