

ISO 15189 Accreditation: Requirements for quality and competence of medical laboratories, experience of a laboratory I

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Abstract

Aim: Medical laboratories are the key partners in patient safety. Laboratory results influence 70% of medical diagnoses. Quality of laboratory service is the major factor which directly affects the quality of health care. The clinical laboratory as a whole has to provide the best patient care promoting excellence.

Methods: International Standard ISO 15189, based upon ISO 17025 and ISO 9001 standards, provides requirements for competence and quality of medical laboratories. Accredited medical laboratories enhance credibility and competency of their testing services. Our group of laboratories, one of the leading institutions in the area, had previous experience with ISO 9001 and ISO 17025 Accreditation at non-medical sections. We started to prepare for ISO 15189 Accreditation at the beginning of 2006 and were certified in March, 2007. We spent more than a year to prepare for accreditation.

Results: Accreditation scopes of our laboratory were as follows: clinical chemistry, hematology, immunology, allergology, microbiology, parasitology, molecular biology of infection serology and transfusion medicine. The total number of accredited tests is 531. We participate in five different PT programs. Inter Laboratory Comparison (ILC) protocols are performed with reputable laboratories. 82 different PT Program modules, 277 cycles per year for 451 tests and 72 ILC program organizations for remaining tests have been performed. Our laboratory also organizes a PT program for flow cytometry. 22 laboratories participate in this program, 2 cycles per year. Our laboratory has had its own custom made WEB based LIS system since 2001. We serve more than 500 customers on a real time basis. Our quality management system is also documented and processed electronically, Document Management System (DMS), via our intranet.

Conclusion: Preparatory phase for accreditation, data management, external quality control programs, personnel related issues before, during and after accreditation process are presented. Every laboratory has to concentrate on patient safety issues related to laboratory testing and should perform quality improvement projects.

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Accreditation of medical laboratories

Accreditation means that medical laboratories have been assessed against internationally recognized standards to demonstrate their competence, impartiality and performance capacity. Reputation and competence of accrediting bodies are assurances of laboratories. Accreditation gives international recognition.

The international standard ISO 15189 “Medical Laboratories—Particular Requirements for Quality and Competence” is the basis for accreditation of Medical Testing Laboratories [1]. This standard is based upon ISO/IEC 17025 and ISO 9001. This standard requires

medical laboratories to demonstrate a quality system, technical competency and to be able to generate technically valid results.

The use of an international standard for recognizing competence has led to increased confidence in testing laboratories and facilitated the acceptance of test results by authorities around the world. National Accreditation Bodies have specific protocols for accreditation of medical laboratories. Candidate laboratory has to fulfill the application procedure requirements first. Then, accreditation body prepares an inspection plan. It has to be approved by the applicant laboratory. If necessary, pre-assessment visit may be performed.

Assessment and pre-assessment visits include the following steps; opening briefing, examination of records, sample handling, interview with technicians, demonstrations of tests

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and techniques, examination of equipment calibration and maintenance, review of quality documentation, written report of assessor's findings, and finally, closure meeting.

The laboratory responds to any deficiencies indicated by assessor's findings. The laboratory has to send a written corrective action response in due time. Accreditation body examines all documents and sends their report to Accreditation Body's Council for a vote. Accreditation is granted when all concerns are solved, fees are paid and affirmative votes are received. A certificate of ISO 15189 Accreditation containing annexes, scope and list of accredited services, will be issued.

Preparation for accreditation

Medical laboratory quality systems can be based on different standards or protocols, such as ISO 15189, ISO 17025, ISO 9001, JCI, EFQM Model, and WHO Health Promoting Hospitals. The laboratory has to decide to which system it should apply [2]. The most recent, internationally accepted Accreditation System is the ISO 15189 Standard [1]. Previously, medical laboratories were accredited according to ISO/EN 45001, ISO/IEC 17025 standards.

Top management of the candidate laboratory has to be committed to accreditation and fully support the team in every aspect. Large spectrum servicing laboratories have to establish an accreditation team. Coordination of these activities may be too large and detailed task for one manager. One person should be devoted and responsible for the development and maintenance of the Quality System Documents.

Candidate laboratory has to obtain an official copy of ISO 15189: 2007. The laboratory may not have an established quality system. If this is the case, the laboratory will need a consultant for preparation. Every laboratory can prepare them, but it may take a long time and may not be prepared as required. Without a consultant, it may be a waste of time and money. It is advisable, but not necessary.

Content of the standard should be understood very well. Criteria should be discussed by the maximum possible number of related staff. Weak and strong points of the existing practice should be identified. Weaknesses must be revised.

Organizational arrangements, practices and procedures have to be examined to see whether they meet the requirements of the standard. Improvements have to be made on the basis of evaluation, if necessary. This stage is the most critical issue of preparation for accreditation. You have to evaluate your system. Decide on the correction. Document it and follow it up in a sufficient period of time. Then, you can decide whether your laboratory is ready for accreditation application or not. It may take more time, effort and money than you expect, to adopt the existing practice to the requirements of the standard.

Our group of laboratories is quite experienced in accreditation. Different laboratories of the group received ISO/EN 45001 accreditation in 1991, ISO 9001 certification in 1996, ISO/IEC 17025 accreditation in 2005. We did get support from consultants during previous work. Centro Laboratory was performing almost as an accredited laboratory and did not need to get professional support.

Quality manual

Quality Management System has to be described in the Quality Manual. It also has to contain basic procedures and referrals to supportive documents. It has to be basic and simple. If the quality manual is prepared with a broad content of technical and practical documents, it will become almost impossible to make necessary revisions.

The structure of the documentation, roles and responsibilities of technical management and quality manager have to be defined in the Quality Manual.

Quality manual of a medical laboratory must contain following items according to the standard:

1. Introduction
2. Description of medical laboratory
3. Quality policy
4. Staff education and training
5. Quality assurance
6. Document control
7. Records, maintenance and archiving
8. Accommodation and environment
9. Instruments, reagents and consumables management
10. Validation of examination
11. Safety
12. Environmental aspects
13. Research and development
14. List of examination procedures
15. Request protocols, primary sample, collection and handling of laboratory samples
16. Validation of results
17. Quality control, including ILC
18. Laboratory information system
19. Reporting of results
20. Remedial actions and handling of complaints
21. Communication and other interactions with patients, health professionals, referral laboratories and suppliers.
22. Internal Audits
23. Ethics

Determination of scope

Candidate laboratory has to determine "Scope of Accreditation" and the areas and names of tests, which will be specifically examined by expert assessors. The laboratory has to participate in PT or ILC for tests listed. This is the only way that the laboratory can present the proof of performance.

It is advisable to start with a limited scope at the beginning. Then the laboratory can expand the scope in the future.

Our laboratories do participate in four international and one national PT programs. 72 Tests are evaluated with Inter Laboratory Comparison programs. Total number of accredited tests is 531.

Scope of medical testing laboratories may cover the following areas:

–Microbiology, Mycology, Virology, Parasitology, Bacteriology

- Chemistry; Routine chemistry, Endocrinology, Toxicology, Urinalysis
- Hematology
- Pathology; Histopathology, Cytology
- Immunohematology
- Diagnostic Immunology
- Clinical Cytogenetics
- Molecular Genetics
- Others

Critical role of proficiency testing and Inter Laboratory Comparisons

Accredited test methods must be validated. Technicians, instruments, reagents and other factors affecting the test results have to be checked. The laboratory has to prove the correctness of test results. Proficiency testing programs test results must be ready for evaluation of assessors. It is difficult to find a Proficiency Testing (PT) Program for each test parameter, especially for the rare analysis. The laboratory has to organize or participate in Inter Laboratory Comparison (ILC) Programs for this type of tests. The laboratory can be sure and be able to prove the accuracy and trueness of its test results via participating in such programs.

The laboratory has to apply internal Quality Control (QC) Programs. This must be done to prove daily performance quality. Application procedures, data evaluation, corrective and preventive actions have to be determined in Quality System documents.

The laboratory must define internal QC program protocols and criteria for repetition of tests. The laboratory also has to participate in PT and ILC programs after the initial decision of accreditation for each test to be accredited. This is one of the first things to be done. If the laboratory does not participate in acceptable PT programs prior to accreditation and decides to participate in these programs at a later stage, it is going to be very difficult. PT programs usually have 2–3 cycles per year. It is very important to take corrective actions if the laboratory gets out of range results. All of these activities need time; during the period of heavy work load of accreditation it is not possible to fulfill the requirements within 3–4 months. The applicant laboratory has to be very well aware of this issue and has to start right from the beginning.

Application procedure

All accreditation Bodies have same basic principles for application procedure. ISO/IEC 15189:2007 standard is the basis.

1. Applicant laboratory obtains official copy of the standard.
2. Initial contract has to be signed by two parties.
3. Accreditation Body sends a check list and list of other requested documents. The laboratory can perform a self assessment to verify compliance with all requirements of the standard using this check list.
4. The applicant laboratory completes and returns this form and other required documents with necessary fee payments.

5. Accrediting Body reviews the application. If it is sufficient to continue, assessors will be assigned according to the scope of the application. Candidate laboratory has to confirm assessors. If not, accreditation body will nominate other assessors.
6. Scheduling of the on-site assessment will be decided by the laboratory and the lead assessor.
7. Pre-assessment can be performed depending on the request of the laboratory.
8. The laboratory has to perform a general rehearsal for the accreditation assessment. Internal audit results and management reviews have to be checked finally to ensure that the arrangements and procedures described in the quality manual fit the real situation. This examination has to be done carefully.

Accrediting body assessment visit

On-site assessment is undertaken at the laboratory. All key personnel should be available for the interview during the assessment period. Assessors may request the laboratory to perform some of the tests as part of the assessment process.

Assessors visit the candidate laboratory on the date previously determined. Lead assessor, assessors, laboratory manager and key responsible personnel of the laboratory attend the opening meeting. It may take one to one and half hour. Assessors have a short discussion after this meeting. Then, examination of records and the technical inspection start. All procedures and related documents are examined starting from sample reception to patient report discharge. Sample handling, interview with technicians, demonstrations of tests and techniques, examination of equipment calibration and maintenance, review of quality documentation, document management system, and all other criteria of the standard have to be examined.

At the completion of on-site assessment, the laboratory management is provided with an assessment report by the assessment team. This report includes; the assessment team's recommendation regarding the granting of accreditation for all or part of the scope. Major or minor non-conformities should be defined in the assessment report. The laboratory manager signs the report and gets a copy of it for remedial action. The deadline of corrective action and requested data will be determined and explained. Finally all attendants of the opening meeting perform a closure meeting, to conclude the accreditation assessment.

The laboratory performs all remedial actions indicated in the assessment report. If the matters are minor non-conformities, corrective actions can be confirmed through submission of supporting documents. Further on-site assessment may be needed for major cases. Assuming that the remedial actions are found acceptable, a recommendation for accreditation will follow. A formal notification letter and a Certification of Accreditation will be issued within 3–4 months.

The laboratory will be reassessed again at intervals not exceeding 2 years after accreditation has been granted. The purpose is to ensure that the requirements of the standard are continued to be met by the accredited laboratory after the

accreditation period. The laboratory may expand or reduce the scope of accreditation at future assessments.

Accreditation body assessors' audits are very important and are useful tools for quality improvement of laboratories. It is always possible to make mistakes in daily routine. Every laboratory should educate its staff on the importance of audits, and motivate them to learn as much as possible from this process.

All information provided by the laboratory to the accreditation body and assessors has to be kept confidential. Our laboratory accreditation visit had one lead assessor and three assessors in the fields of clinical chemistry, microbiology and immunology. We did not need pre-assessment. First assessment ended up with an approval of our ISO 15189 Accreditation.

Accredited laboratory personnel

The practical impact of the laboratory accreditation on the technical staff is a very important issue. Do they feel that the quality improved? What are the main advantages and disadvantages for them? Does it cause more work pressure? Do they prefer to work in an accredited or non-accredited medical laboratory?

Dr. Alain Verstraete prepared a one page, multiple choice inquiry form [3]. It was submitted to the personnel of two private laboratories in Belgium. Majority of personnel in all surveyed laboratories reported that the work load increased (85–90%).

Surprisingly, minority of staff thought that the quality of the test results improved (15–28%) after the accreditation. After a year, this percentage almost doubled, from 28% to 46%. Possibly, technicians believed that the quality was already good before the accreditation. Another possibility is that much more attention is paid to formalities than to the quality of the test results at the beginning of accreditation process. After a certain period of time, formalities become more routine and the technical expertise, due to getting good results from PT programs, becomes the main concern. The advantages of working in an accredited laboratory for the staff are as follows: better documentation, easy traceability of causes of errors, better understanding of the analysis performed.

The biggest disadvantage of working for an accredited laboratory according to technical staff is the increase in paper work. Discrepancy between the written procedures and the reality and greater emphasis on the formalities were also important disadvantages for working staff. The number of people who mentioned the discrepancy between reality and written procedures, reduced by 50% 1 year later. Despite the mentioned disadvantages, majority of technical staff prefer to work in an accredited laboratory. Common idea is that technical staff, involved in the accreditation process, becomes more sophisticated and experienced in an accredited laboratory environment.

Patient safety

Laboratory data are an integral part of the physicians' decision-making process. Reduction of laboratory errors and

the improvement of quality in medical laboratories play a significant role in improving the quality of health care. Laboratory personnel and their performance play a crucial role in patient safety.

Most of the medical errors are preventable and most have little to do with the work done in the laboratory. Laboratory quality management plans, pre-analytic, analytic and post-analytic stages are key elements in patient safety. Every step has a critical role. Test results will be useless or possibly harmful, if testing is not performed on a valid sample. Sample needs to be collected from the correct patient, under correct conditions, into a correct container, which is labeled and handled correctly [4].

Personnel standards, certification and continuing education, proficiency testing, laboratory accreditation, safety goals, quality forums, health information technology, and electronic records are critical issues for patient safety. Accreditation bodies, government authorities, laboratories and suppliers should continuously improve the quality of laboratory practice and safety of patients [5].

Conclusion

The activity of laboratory accreditation has been around for so many years. Laboratory accreditation is a formal recognition by a third party authority of a laboratory's capability to perform testing. The objective is to encourage the laboratories to enhance management system, technical capability and competitiveness. Laboratory accreditation is a voluntary scheme. The accrediting body will perform on-site audit of the applicant laboratory. The applicant laboratory meeting the requirements of the standard will be accredited. The accreditation body will then perform periodic surveillance audits and re-audits.

A committee for periodic review of procedures has to be organized from amongst the working staff of the laboratory. The numbers of complaints documented in quality systems are usually unrealistic. Real numbers may be ten times more. But still, it helps a lot. Evaluation of complaints stimulates the communication and helps in the improvement of members of the staff.

Preparation–implementation period for accreditation may require 2 years of tedious and frustrating work. Getting accreditation is feeling of satisfaction to people who participated in the process. Post-accreditation settlement period may also take 2 years. The staff will have much better understanding after this period.

Accreditation means that the serving laboratory has been successful at meeting the requirements of international accreditation standards. The patient, customer reduces the risk of selecting an incompetent laboratory and paying for that kind of service, or more seriously, for invalid results. Accredited laboratories also have a responsibility to the society. Each laboratory has to concentrate on patient safety issues related to laboratory testing and can perform quality improvement projects to reduce patient harm due to laboratory errors.

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