

ISO 15189 accreditation: Requirements for quality and competence of medical laboratories, experience of a laboratory II

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Abstract

Objectives: Our laboratory was accredited for 531 tests according to ISO 15189 standard (*ISO 15189:2003 Medical laboratories - Particular requirements for quality and competence specifies the quality management system requirements particular to medical laboratories*) in 2007. An ambitious and young group of laboratory personnel has spent efforts with commitment and dedication to complete the heavy work of preparation and passed through assessment with success. We herewith share our experience of the accreditation, the stages we have been through; our solutions to obstacles which we came across during the process.

Design and methods: Our approaches to topics of environmental conditions, document management system (CentroDMS), use of the laboratory information system (CentroLIS), corrective/preventive actions and measurement uncertainty are summarized in this article.

Results: Experience of our laboratory in different areas of ISO 15189 accreditation is presented in summary.

Conclusion: Accreditation of medical laboratories increases the quality of the results, motivates the laboratory personnel and is beneficial for all interested bodies. Continuous improvement and dedicated people are the key elements for continuation of the quality assurance in an accredited medical laboratory.

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The most critical issue, for ISO 15189 accreditation is that, it requires hard work and commitment at all levels, from the top management to the most junior person in the laboratory. There are responsibilities to be completed by each and every member of the laboratory, and all need to be done in harmony. 4P rule (Plan, Prepare, Practice, and Performance Evaluation) is the rule to follow for successful implementation of the ISO 15189.

Our laboratory is a referral laboratory accepting samples from other laboratories and hospitals. Hence, a total quality management approach centered on customer satisfaction is adopted. Our laboratory had been performing many aspects of the accreditation requirements, but some of them were not in standardized written form. So what we have done was, to make a plan and delegate the responsibilities for preparatory work

with a time plan to be followed. We have established an accreditation team (steering committee) whose members were general director, technical manager, department chiefs, quality manager, financial manager and some head technicians. We gathered at weekly meetings and reviewed our progress. Some of these meetings were difficult ones, because interpretation of the ISO 15189 was sometimes different from one person to another. We discussed almost every single detail of the requirements [1]. I am going to write some of these discussions here and how we have come to mutual agreements on them.

After a careful review of the standard by each member of the accreditation team, a SWOT analysis (a strategic tool used to evaluate Strength, Weaknesses, Opportunities, and Threats involved in a project) of the current situation was performed. We have listed what we have and what we have to improve. We found out that we comply with most of the requirements, but we did not always have the written evidence to prove it. So we started to make a translation of the requirements and prepared our own check lists.

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Environmental conditions

The medical laboratory must have adequate space and a safe environment to perform testing. There must be adequate lighting, ventilation, water, waste and refuse disposal. We have reviewed the space, design and storage facilities in our laboratory. Since we already had an electrical current generator, centralized air conditioning (heat adjustable in different parts of the laboratory), and fire extinguishing system; there was little to be done for the improvement of environmental conditions. Work areas are kept clean and well maintained. Precautions and special care is taken to prevent cross contamination in bacteriology, molecular biology and flow cytometry laboratories.

An updated layout of the laboratory was drawn by a professional. We made small changes in our microbiology department for the isolation of bacteriology laboratory. We were following and recording the temperature of freezers, heat incubators etc. All of these instruments were serviced and calibrated by an accredited calibration laboratory. We improved our forms, simplified the procedures and quality department unified the documentation [2]. We spent efforts to unify our labeling in each laboratory department on solution bottles, benches, cabinets etc. We did not have the names of eligible personnel to use a certain system on visible sight; we prepared labels to be posted on the systems stating the names of eligible personnel to use that particular system, department chief responsible for that particular system, part number of the system and technical service person's name and communication information. We had the guiding signs in the building, but we increased the numbers. We did many training on laboratory safety, recording and follow up of environmental conditions, fire escape, earth quake rescue and emergency care. Our related teams received trainings for fire, emergency care and earth quake rescue from professional organizations and gave internal trainings afterwards.

Equipment

Laboratory equipment is defined as instruments, reference materials, consumables, reagents and analytical systems. Every laboratory should have adequate equipment to perform testing to meet its stated laboratory mission, and so does our laboratory. Our laboratory has the necessary policies and procedures that specify the regular monitoring of the instrument calibration and preventive maintenance. All of the records, calibration certificates, verifications and related information are kept under record at the technical department. To comply with the requirements of the standard, the accuracy and precision of instruments and kits claimed by the manufacturers are verified.

Functional equipment are vital for producing reliable test results, minimizing instrument breakdown, lowering repair costs, preventing delays in reporting test results and maintaining productivity. By establishing a good instrument program, we are able to maintain a high level of performance with longer instrument life, reduced interruption of services due to break-

downs and failures which lead to improved customer satisfaction. It is also important in improving the technical personnel's confidence and knowledge.

We have established instructions for selection, acquisition, installation, calibration, validation/verification, maintenance, service/repair, retiring or disposition of equipment. Trouble-shooting tips are included in the equipment SOP's in detail.

We have assigned responsibilities for all of the above mentioned issues of equipment management. All of the personnel are trained on equipment management requirements and responsibilities. Under the supervision of the technical manager, department chiefs monitor equipment management activities by routinely reviewing all record, ensuring all procedures are followed and updated, when necessary.

CentroLIS

CentroLIS is the internet based laboratory information system of our laboratory. All of the patient, sample, analysis, internal quality control, and stock information are held in this data base. A terminal of CentroLIS is connected to customers, so that they can follow up the flow of the work themselves.

The standard requires that the computer software should be validated and precautions must be taken to protect the integrity and privacy of the patient data archived in electronic formats. Access to the CentroLIS is restricted to prevent alteration and destruction of data by unauthorized people. Reports, sample and test information can be observed by the personnel, for their related department on CentroLIS. Each manual assay result is entered in to the system by the technician who performs the test. Head technician approves the result on line after technician control. Then, the department chief controls and electronically signs the result. All other instruments are directly linked to LIS, and transfer data without human interference until the department chief's approval. During the accreditation process, we made some very minor changes to the CentroLIS program. Traceability of internal controls on the system, for most of the analyzers is the latest feature of the CentroLIS.

CentroLIS is periodically reviewed for auto verification. All of the entries and approvals are traced, system changes are performed by IT department after approval of the general manager, data storage policy is well documented, after modifications, trainings to personnel are performed by IT department and any errors detected during the use or back up are documented and followed via corrective/preventive action forms.

Document management system

One of the first and important things to be done was to inform the laboratory workers about the requirements of ISO 15189 which meant focused and concentrated training on all aspects of the requirements. A heavy workload was to be planned for the chief of departments and head technicians, because they had to keep up the good work for daily routine and prepare SOP's (Standard Operation Procedures) at the same

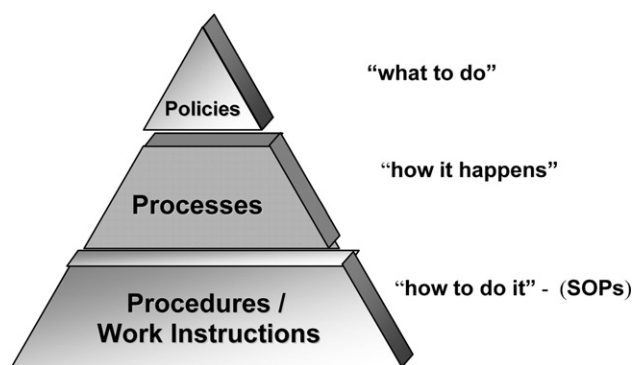


Fig. 1. Hierarchy of documents.

time. It is sometimes quite difficult to put into writing some of the things that are performed daily on routine basis. Even so, to have instructions and SOP's are very important in medical laboratories since verbal instructions can be forgotten with time, not heard, misunderstood or ignored. SOP format was established with many details in it, which was simplified later on (Fig. 1).

Each department has provided a schedule of their own for the completion of the SOP's which took almost a year (We must state that our laboratory is ISO 15189 accredited for 531 tests). Format, contents and references to be included were discussed in weekly department meetings, questions and suggestions were evaluated at the weekly quality management team meetings, solutions and changes were implemented, afterwards. A document management system (CentroDMS) was established to avoid the huge amount of paper waste and centralize the documentation. All of the documents were entered in to this system by the person initiating the document and approvals were completed on line in DMS. The quality manager was responsible for the system. By this approach, it was easy to follow up the progress at all levels and documents were available at all stages to DMS users. The DMS has a follow up and record system, approvals, refusal of updates, revision times etc. which can be followed up by the quality manager and the related departments. Right now, we also circulate forms and internal announcements through the DMS. At first announcement of the DMS system by quality assurance department, we all thought that it would be time consuming to look up DMS every day, but quality manager kept calling and asking to electronically sign the documents, and now it is a habit to look at DMS during the day and electronically read and sign all of the documents sent for our approval or notice. Revision dates, revision numbers and all of the related signs are followed up by the system which makes the system work smoothly.

Corrective/preventive actions

During the process of samples to sources the variations that can be attributed, are human, equipment, methods, materials or environment. Process variations are due to either common causes or special causes. Control charts and written documentation aid in distinguishing these two types of variations. Goal is

to control and reduce variation, stabilize and improve the process. In turn, the customers receive a high quality service with a high degree of certainty.

Section 4.11 of ISO 15189 covers corrective and preventive actions. For corrective action, it deals with determining the underlying cause of any problems, documenting changes made as a result of investigations into corrective actions, monitoring the effectiveness of corrective actions and auditing where an investigation suggests that there is non-compliance. For preventive action, it deals with identifying where preventive action is necessary and determining what actions should be taken. Preventive action consists of risk assessment and implementing quality improvements.

On the eight month of preparations, accreditation team decided that to make the system alive, we need to start the Corrective/Preventive Action system [1]. A form for Corrective/Preventive Action was prepared, after the training of the personnel. Quality department expected to receive many CPA forms. But during the first two months, very few forms were received. That was because the personnel thought that to write CPA forms was to complain about co-workers. After giving a number of trainings, personnel were convinced that CPA forms were to improve our service quality and made us see the troublesome areas ourselves. Just to give an idea on the use of CPA forms, while we had 20 CPA forms per month in 2006, we now have 26 CPA per month. Increase in the number of CPA forms, made us think that Centro personnel understood and absorbed the benefits of using CPA forms. During 2007, we had 311 CPA forms, which broke down as 94% corrective and 6% preventive action. 41% of our CPA forms were created by Quality Assurance Department during the internal assessments. Additional in house trainings were required for 28% of the CPAs, 15% were promptly corrected, for 8%, we had to provide additional information to our customers and 12% required re-assessment (2007 year end report by Quality Assurance Department).

One thing we must say about CPA forms is, if used correctly, they provide valuable information on laboratory, customers and personnel. It is also a channel of communication between the quality department and laboratory personnel. It will be good to mention that this year we have started to have an award system for the person who contributes to the improvement of our laboratory through suggestions on work flow or in any area of the daily work for continuous quality improvement. This has been encouraging for the participation of personnel in the daily affairs of the laboratory.

Measurement uncertainty

One of the most difficult parts of our implementation of ISO 15189 was measurement uncertainty. Terminology itself was somewhat difficult to understand. It was Uncertainty of Measurement in some references while some guidelines were published under the Measurement Uncertainty name. Confused, but determined to clarify the "Measurement Uncertainty", we read what is available on the matter, took some courses, and came to the conclusion that we need to decide for each and

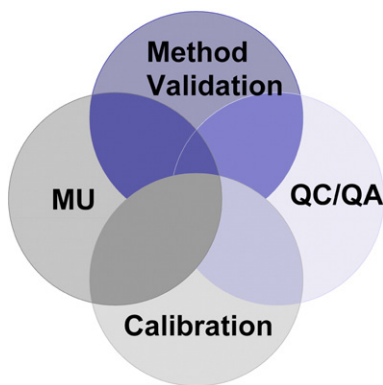


Fig. 2. Venn Diagram of overlapping functions for valid measurements. MU: Measurement Uncertainty, QC: Quality Control, QA: Quality Assurance.

every test separately on how to calculate measurement uncertainty. Measurement Uncertainty is currently defined as a “parameter that characterizes the dispersion of the quantity values that are being attributed to a measurand, based on the information used” in International Vocabulary of Basic and General Terms in Metrology. Guide to Uncertainty of Measurement (GUM) has strict definitions which are truly valid for chemical measurements, but most of them do not apply to clinical laboratory [3].

After many discussions on available information, we decided to calculate the measurement uncertainty as described in GUM for the methods with quantitative results, solutions and materials which are prepared in our laboratory such as atomic absorption tests (trace elements in blood, etc). When we calculate MU values for atomic absorption laboratory, we took all of the factors that affect the results into consideration by reviewing all steps of the tests [4–6]. Measurement uncertainty overlaps with other functions of the process, such as method validation, calibration and quality control/quality assurance (Fig. 2).

For the test analytes with ready to use kits on automation systems and known MU values, the value can be used as it is, but we prefer that MU be calculated from control runs in a certain period of time, such as 200 runs in 6 months. For some tests, we calculate MU from consecutive external quality control results obtained through recognized PT programs. To be able to do this, at least six consequent set of results should be evaluated [7,8].

If we should list the general sources of measurement uncertainty, they are:

1. Pre analytical factors,
2. Intra individual variation,
3. Assay imprecision,
4. Specimen processing variables,
5. Pathological Processes,

MU calculation should be done by personnel who are thoroughly familiar with the test, who know the calibration and understand the capacity and limitations of the equipment and the influences of the external factors. While making the

calculations, personnel should base all of the calculations on evidence.

However, measurement uncertainty in clinical laboratories is still a topic of discussion in medical laboratory community and it has its own uncertainties which need to be clarified along the way of implementation during routine.

A standard — ISO/AWI 25680 is being prepared by ISO (International Standard Organization) for “Estimation and reporting of measurement uncertainty”. This standard will outline the principles of estimating measurement uncertainty for quantity values obtained in medical laboratories, based on data obtained from metrological experience, publications, manufacturers’ information, and supplementary experiments — all necessary ingredients during the validation of any measurement procedure. It will be developed as a joint activity of ISO/TC 212 and CEN/TC 140.

Conclusion on measurement uncertainty can be summarized as follows:

- Studying of measurement uncertainty in clinical laboratories is important not only for the laboratories but also for the clinicians. It helps them use the results on a laboratory report more effectively.
- Reporting measurement uncertainty will help reduce over interpretation of results by the clinicians.
- Methods of MU calculation will vary upon the type of test, and is to be decided by each laboratory itself.
- Regulatory authorities need to imply to laboratories that, where available, laboratory results should include the measurement uncertainty values.

Continuous improvement

Continuous improvement is a requirement of ISO 15189. It deals with establishing procedures for ensuring that continual improvement occurs (evaluating the actions, implementing the changes, providing educational and training opportunities).

Continuous improvement is achieved at our service to customers through audits, corrective/preventive actions, addressing particular questions, risk assessment and review of critical events. As will be discussed in another part, documented education and training is an important asset for continuous improvement.

Once implemented, ISO 15189 accreditation makes life in the laboratory easy in many ways. The difficult part is to have an actual, living system which is acknowledged by all of the laboratory personnel. It is beneficial for customers (both for the patients and the doctors), because every information related to sample analysis can be traced back easily. It is beneficial for the management, because it provides day by day information on all issues of laboratory. It is beneficial for the laboratory personnel, because all aspects of the work are documented and responsibilities are assigned. The most important issue for accreditation is to be motivated. The joy and excitement that our colleagues experienced after our successful assessment was something to be remembered for a life time.

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