The Journal Of The International Federation Of Clinical Chemistry And Laboratory Medicine

eJIFCC

PRACTICAL APPLICATION OF ISO 15189 BY ACCREDITATION BODIES -

A comparison with ISO/IEC 17025

Bella Ho, Hong Kong Accreditation Service

Introduction

ISO 15189:2003 is an international standard developed particularly for the medical laboratories. Though it is based upon ISO/IEC 17025:1999 and ISO 9000:2000, it is a standalone standard for medical laboratories with a title particularly referred to "quality and competence". The ISO 15189 requirements are however, harmonised with those of ISO/IEC 17025. Under the International Laboratory Accreditation Cooperation (ILAC) Multilateral Mutual Recognition Arrangement (MLA), accreditation of medical laboratories against ISO 15189 and ISO/IEC 17025 are both acceptable.

The standard, since its publication in 2003, is gaining more and more acceptance by accreditation bodies worldwide as the standard for medical laboratories and has been adopted as the accreditation criteria used by many economies, including New Zealand, Canada, Israel, Hong Kong, Thailand, etc. It is also known that many economies including Malaysia, China, Japan, are also planning to start accreditation of medical laboratories using this new standard. A number of accreditation bodies currently offering accreditation for medical laboratories against ISO/IEC 17025 are also planning to start using this new standard in the next few years.

The Hong Kong Accreditation Service is among one of the accreditation bodies first adopting the use of ISO 15189 to accredit medical laboratories. As the accreditation of medical laboratories is a new area of service offered by the Hong Kong Accreditation Service, application documents have been prepared to guide the laboratories in seeking for accreditation. Though ISO 15189 has been developed based on ISO/IEC 17025 and that the essential requirements in ISO/IEC 17025 are also included in ISO 15189, there are differences in emphasis and the latter has been written in a language more familiar to the medical community.

For those economies where the medical laboratories are not yet accredited to any ISO standards, ISO 15189 represents a good start. For those that have been using ISO/IEC 17025 for accrediting medical laboratories for some years, accreditation to ISO 15189 is a lot easier and the key is to know the difference. A detailed comparison of ISO/IEC 17025:1999 and ISO 15189:2003 is given in Annex A.

Management Requirements

Basically the management requirements as stipulated in ISO 15189 and ISO/IEC 17025 are similar except that a new clause of "Continual improvement" has been introduced in ISO 15189. The minor differences found in the wordings of the management requirements of ISO 15189 and ISO/IEC 17025 are in fact further elaboration on the actual application of the standards requirements and the expectation of quality service. The essence is the same in the two standards.

"Continual improvement" is a requirement from ISO 9000:2000 which came out one year after ISO/IEC 17025:1999. The aim of continual improvement of a quality management system is to improve the service provided and to enhance the satisfaction of service users.

Opportunities for improvement could be identified from various sources such as feedback from service users, audits, management review, etc. Despite having a separate clause in ISO 15189, the concept of continual improvement is embedded in the quality management system required under ISO/IEC 17025. Notwithstanding this, Clause 4.12.4 under Continual improvement requires laboratory management to implement quality indicators such as turnaround time, blood usage, etc. for systematically monitoring and evaluating the laboratory's contribution to patient care, this is a requirement specific for medical laboratories.

Technical Requirements

While there is no major difference in the basic principles behind the technical requirements of the two standards, ISO 15189, in a way, has additional requirements that are specific to the medical testing laboratories and emphasis has been put on patient care. The following focussed on the differences of requirements between ISO 15189 and ISO/IEC 17025 and the practical application of the new standard.

Personnel Requirement

A much-expanded section has been devoted to describe the responsibilities and functions of the laboratory director(s). Clause 5.1.3 stated that "the laboratory shall be directed by **a person or persons** having executive responsibility and the competence to assume responsibility for the services provided". This implied the acceptance of team management with responsibilities and competence emphasised.

The standard does not specify whether the laboratory director should be medically qualified or the academic or professional qualifications one must attain for fulfilling the role. The academic or professional qualifications required of a laboratory director or directors would need to be considered according to local situation where local application documents would be helpful. This is particularly valid for some economies where only limited number of pathologists or highly academically qualified personnel, are

eJIFCC2004Vol15No4pp128-135

available. Factors to take into consideration include, but are not limited to, the set up of the whole medical system, the local education system and opportunities, public expectation, local economy and whether the accreditation scheme is voluntary or mandatory. While balancing all the factors, one important feature that an accreditation scheme has to maintain is the quality service that an accredited laboratory could offer. The "competence" of the personnel and the management's commitment are the key contributing factors to quality service, which should not be compromised due to availability of pathologists.

This also leads to the consideration of whether visiting pathologists who may have no responsibilities for the daily operation of the laboratory could provide adequate medical coverage. There is no fast and hard rule on what is adequate. Accreditation bodies would need to be flexible when assessing a laboratory's competency while placing priority on patient care. It should also be recognised that for the interpretation of certain tests, the results of examinations have to be evaluated in conformity with the clinical information available regarding the patient and for these tests, the input from pathologists is inevitable.

Continual Professional Development

Though ISO/IEC 17025 also requires the laboratory to identify training needs of personnel and to provide relevant training, the emphasis on continual education is much greater in ISO 15189. The requirement of continual professional development for all staff, including those making professional judgements, is mentioned more than once in ISO 15189. There is also particular requirement for staff to receive relevant training in quality assurance and quality management as well as health and safety.

Continual professional development is in fact not uncommon to the medical community, who always realise the need to keep up with advances in science. Seminars, workshops, scientific conferences, journal clubs, case studies, etc. are often organised by scientific or professional organisations; laboratory personnel would not have difficulties to fulfil this requirement except documentation is now required. Support and encouragement from the management would be required for active participation in such activities. To provide continuing education program to staff at all levels is a responsibility of the laboratory management.

Safety Requirement

There is no particular safety requirement mentioned in ISO/IEC 17025 though assessors may still attend to safety issues during assessment, it may not always be possible to raise non-conformities against ISO/IEC 17025 on unsafe conditions observed.

Laboratory safety is important for the medical testing laboratories, not only to the laboratory personnel, but also to the patients, visitors and the general public e.g. in case of SARS episodes in 2004 which have been related to laboratory exposure. Hence ISO 15189 not only requires laboratory personnel to be trained in safety issues, the new standard also requires patients, employees as well as visitors, including those engineers for repairing work, to be protected from potential risk. Attention is also drawn to the safety for the carrier and the general public during transportation of samples. Safety requirements are covered under *Clauses 5.1 Personnel, 5.2 Accommodation and environmental conditions, 5.3 Laboratory equipment, 5.4 Pre-examination procedures and 5.7 Post-examination procedures*.

ISO 15190 is a related standard on requirements for safety in medical laboratories, first published in October 2003. The standard is not yet included in ISO 15189 as a normative reference because of its late publication, but medical laboratories meeting the requirement of ISO 15189 are expected to refer to this safety standard.

Laboratory Equipment

A definition for laboratory equipment has been provided in NOTE under *Clause 5.3 Laboratory Equipment* to include instruments, reference materials, consumables, reagents and analytical systems. This definition broadens the calibration and maintenance programme of equipment to cover demonstration of proper function of reagents and analytical systems.

Preventive maintenance is in fact a term more appropriate than calibration to most medical equipment and analytical systems. Much of such equipment is maintained or calibrated, if required, by manufacturers which are not accredited calibration laboratories. It would be impractical at this stage, to require all maintenance and calibrations to be conducted by accredited laboratories. Nevertheless, proper maintenance and calibration, despite being carried out by manufacturers, has to be insisted upon, wherever necessary. Where calibration of standard laboratory equipment e.g. temperature monitoring device or volume measuring equipment, is involved and such equipment affects quality of results, calibrations should be conducted by accredited calibration laboratories.

Pre-examination Procedures

Samples in non-medical testing laboratories are often tested as received. Though ISO/IEC 17025 also has requirements on *Sampling*, they are applicable only for laboratories responsible for sample collection. The requirements now covered in *5.4 Pre-examination procedure* of ISO 15189 are applicable to all medical testing laboratories.

All medical testing laboratories are required to provide a primary sample collection manual for service users, which include information for patients, sample collectors, and sample reception staff. Though sample collection may be carried out by nursing staff in hospital wards or by medical doctors in clinics, the responsibility of proper sample collection falls onto the laboratory. Apart from providing the necessary instructions, the laboratory is also expected to have frequent communication and liaison with responsible personnel to ensure that the instructions are understood and followed.

Measurement Uncertainty and Traceability

Measurement uncertainty is only mentioned in *Clause 5.6.2* in ISO 15189 where there is a conditional statement of "where relevant and possible". It is understood that the application of Measurement Uncertainty for medical testing is still under development. There is much concern among the medical laboratories that there is not enough guidance of estimating uncertainty in the medical field. A classical ISO approach to measurement uncertainty may not be appropriate for medical testing.

Though it is generally acknowledged that the results produced by medical laboratories should be traceable to reference materials and/or reference measurement procedures of higher order, whenever these are available, it is inevitable that there is a lack of reference materials/reference measurement procedures for medical testing. To tackle this issue, an agreement between Bureau

International des Poids et Mesures (BIPM), International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and International Laboratory Accreditation Corporation (ILAC) has been signed, establishing the Joint Committee on Traceability in Laboratory Medicine (JCTLM).

The JCTLM has published a list of about 150 reliable, internationally recognized Certified Reference Materials of higher order on the websites of BIPM and IFCC. Reference Materials and Measurement Procedures included in this category are those that provide values that are traceable to the SI units; e.g. electrolytes, enzymes, drugs, metabolites and substrates, non-peptide hormones and some proteins.

Another list will soon be published, on the international conventional reference materials, i.e. where the measurand(s) is/are not SI-traceable and/or no internationally recognized reference measurement procedure is available; e.g. WHO reference materials for coagulation factors, nucleic acids, and some proteins.

At the present stage, medical laboratories are encouraged to consider factors contributing to uncertainty of results where possible and relevant, particularly in the discipline of clinical chemistry. A practical and reasonable approach to Measurement Uncertainty would be adopted when accrediting medical laboratories.

External Quality Assurance Programmes

Clause 4.2.2 of ISO 15189 requires that the quality management system shall include internal quality control and participation in organised inter-laboratory comparisons, which is a clause not found under the management requirements of ISO/IEC 17025. An expanded section on inter-laboratory comparisons is included under *Clause 5.6 Assuring quality of examination procedures* .

Though a number of well-established external quality assurance programmes (EQAPs) for medical testing are available worldwide, there are always some tests that are not covered by any programmes, e.g. SARS detection. Besides, not many of these programmes are accredited and whether they are in substantial agreement with ISO/IEC Guide 43-1 as required in *Clause 5.6.4 of ISO 15189*, are not clear. Some of these programmes are highly reputed, yet they are expensive and their status is not clear. If locally organised inter-laboratory comparisons are available and could be demonstrated to be in substantial agreement with ISO/IEC Guide 43-1, participation in such local schemes should be equally acceptable for accreditation purpose. There is, however, general feeling that sector specific requirements for proficiency testing providers, particularly for medical testing, is required.

For medical testing, it is generally accepted that the frequency of participation in EQAPs should be much more frequent than the minimum frequency of once per four years as stated by ILAC. There is no specific guideline laid down for medical testing. However, the medical sector does expect a higher frequency of participation for quality service. The test areas to be covered in the quality assurance programmes are, however, usually considerably larger than the non-medical testing laboratories. The participation in more than one programme is often required for adequate coverage. Hence accreditation bodies could take a practical and reasonable approach to the requirement of participation in inter-laboratory comparisons, taking into consideration the scope of service provided by the laboratory.

Establishment of Alert/Critical Intervals and Turnaround Time

Establishment of critical/alert levels for all examinations and turnaround time that reflect clinical needs are specific requirements for medical testing in *Clause 5.8 Reporting of results*. For non-medical testing results, the limits are often those specified in a certain standard or legislation. Laboratories interpret their results according to these defined limits or client's specifications. For medical testing results, the alert/critical intervals could be dependent upon population, sex, age or method; hence laboratories would need to determine their own alert/critical levels according to the clinical needs. This need and requirement is well understood by the medical laboratories.

There is no definition provided in ISO 15189 regarding turnaround time. It could be interpreted as time of sample collection to receipt of examination results by the requester or when samples are received by the laboratory to issue of results. Arguments may arise when sample collection is not under the direct control of the laboratory, for example, in case of sample collection in hospital wards. Both interpretations would be acceptable provided there is justification that the defined turnaround time reflects clinical needs. It should also be noted that there is a requirement to monitor the transportation of the samples to ensure that the samples are received within an appropriate time frame. The essence of this "turnaround time" requirement is on clinical needs and patient care.

Conclusion

The requirements specified in ISO 15189 are not difficult to implement. Though the essence of ISO 15189 and ISO/IEC 17025 are the same, the way that the requirements are presented in ISO 15189 are more easily understood by the medical community and are considered as more relevant and appropriate to laboratory medicine. Though there are areas included in ISO 15189 which are unfamiliar to the medical community e.g. MU and traceability, the concepts are not totally rejected and efforts have been put in developing further guidance to the medical community. It is envisaged that ISO 15189 would gain wide acceptance by the medical community and it would soon be used as the prime standard for accrediting medical laboratories.

Annex A

Comparison of management and technical requirements in ISO 15189 and ISO/IEC 17025

ISO 15189:2003		ISO/IEC 17025:1999	
Clause	Requirement	Clause	Requirement
4	Management requirements	4	Management requirements
4.1	Organisation and management	4.1	Organisation
4.1.1 to 4.1.5	Legal entity; services provided; compliance with the standard; conflict of interest; management responsibility	4.1.1 to 4.1.5	*Similar requirements*
4.2	Quality management system	4.2	Quality system
4.2.1	Quality system implementation	4.2.1	*Similar requirements*
4.2.2	Quality assurance - *new*		
4.2.3	Quality Policy Statement – (a) and (e) are additional	4.2.2	*Similar but not the same*
4.2.4	Quality manual	4.2.3 and 4.2.4	*Similar but not the same*
	2nd paragraph – *new*		
	Suggested table of content – *new*		
4.2.5	Equipment calibration and maintenance programme - *new*		
4.3	Document control	4.3	Document control
4.3.1 to 4.3.3	Documentation system; control procedures; document identification	4.3.1 to 4.3.3	*Similar requirements*
4.4	Review of contracts	4.4	Review of request, tenders or contracts
4.4.1 (a) to (c)	Policy and procedures	4.4.1 (a) to (c)	*Similar requirements*
		Paragraph after (c)	Difference in contract shall be resolved before work commences
4.4.2 to 4.4.5	Review records; referred work; deviation; contract amendment	4.4.2 to 4.4.5	*Similar requirements*
4.5	Examination by referral laboratories	4.5	Subcontracting of tests and calibrations
4.5.1	Evaluation and selection	4.5.1	*Similar requirements*
	Select referral lab with "the advice of users of lab services where appropriate"	4.5.2	Approval of subcontracting from client
4.5.2	Periodic review – *new*		
4.5.3	Register of referral lab and record of referred work	4.5.4	Register of subcontractors

4.5.4	Responsibility	4.5.3	*Similar requirements*
2nd part of 4.5.4	Identify additional interpretative remarks provided by the referring lab	5.10.6	Identify results from subcontractors
4.6	External services and supplies	4.6	Purchasing services and supplies
4.6.1 to 4.6.4	Policy and procedures; verification; inventory control; evaluation	4.6.1 to 4.6.4	*Similar requirements*
4.7	Advisory services	4.7	Service to the client
	- advice on examinations, meeting with service users		- cooperation, communication, feedback
4.8	Resolution of complaints	4.8	Complaints - *Similar requirements*
4.9	Identification and control of nonconformities	4.9	Control of nonconforming testing and/or calibration work
4.9.1 (a) to (g)	Policy and procedures	4.9.1 (a) to (e) and Note	*Similar requirements*
4.9.1 (h)	Documentation and review of each episode - *new*		
4.9.2	Root cause analysis	4.9.2	*Similar requirements*
4.9.3	Release of NC results - *new*		
4.10	Corrective action	4.10	Corrective action
4.10.1 to 4.10.4	Procedure; documentation; implementation; monitoring; additional audit	4.10.1 to 4.10.5	Similar requirements, but need to designate authorities for implementation
4.11	Preventive action	4.11	Preventive action
4.11.1 to 4.11.2	Identification; action; control	4.11.1 to 4.11.2	*Similar requirements*
4.12	Continual improvement - *new* Procedures review; action plan; evaluation, quality indicators; continual professional development		
4.13	Quality and technical records	4.12	Control of records
4.13.1 to 4.13.3	Procedures; storage; retention	4.12.1 to 4.12.2	*Similar requirements*
4.14	Internal audits	4.13	Internal audits
4.14.1 to 4.14.3	Audit elements; implementation; review	4.13.1 to 4.13.4	*Similar requirements*
4.15	Management review	4.14	Management review
4.15.1, 4.15.2 (a) to (h)	Review, action plan and interval; review areas (a) to (h)	4.14.1 with Notes 1,2,3	*Similar requirements*
4.15.2 (i) to (m)	Review areas (i) to (m) - *additional*		
4.15.3	Contribution to patient care		
4.15.4	Records and action within appropriate time	4.14.2	*Similar requirements*
5.	Technical requirements	5.	Technical requirements
		5.1	General
		5.1.1 to 5.1.2	Contributing factors to MU
5.1	Personnel	5.2	Personnel
5.1.1	Organisational plan, job description for all personnel	5.2.4	*Similar requirements*, but job description for managerial, technical and key supporting personnel

5.1.2	Personnel records	2nd part of 5.2.5	*Similar requirements*
5.1.3 and Note	Laboratory director(s) – responsibility and competence	5.2.1 and Note 1	Competence of operators; qualification requirement
5.1.4 to 5.1.6	Responsibilities of laboratory director; adequate staff resources; quality management training – *new*		
5.1.7	Task oriented authorisation	1st part of 5.2.5	*Similar requirements*
5.1.8	Data access policy - *new*		
5.1.9	Continual education program for all staff	5.2.2	Staff training plan
		5.2.3	Contracted staff
5.1.10 to 5.1.11	Safety training; periodic retraining and reassessment - *new*		
5.1.12	Professional judgement; Continual professional development - *additional*	Note 2 of 5.2.1	Persons providing opinions and interpretation
5.1.13	Patient data confidentiality - *new*		
5.2	Accommodation and environmental conditions	5.3	Accommodation and environmental conditions
5.2.1 to 5.2.3	Laboratory space and resources; design and safety; sample collection facilities - *new*		
5.2.4 to 5.2.7	Appropriateness; environmental monitoring; incompatible activities; lab access	5.3.1 to 5.3.4	*Similar requirements*
5.2.8 to 5.2.9	Communication within lab; sample storage		
5.2.10	Housekeeping; Storage/disposal of dangerous material - additional	5.3.5	*Similar requirements*
5.3	Laboratory equipment	5.5	Equipment
Note	Definition of lab equipment – *new*		
5.3.1	Equipment availability	5.5.1	*Similar requirements*
5.3.2 to 5.3.5	Performance validation and calibration programme; equipment identification; records; authorised operator	5.5.2 to 5.5.5, 5.6.1	*Similar requirements*
	Maintenance programme – *additional*		
5.3.6, 5.3.12	Safe handling of equipment for safe working condition and prevent contamination	5.5.6	Safe handling of equipment for proper functioning and to prevent contamination
	(including hazardous materials - *additional*)		
5.3.7	Defective equipment	5.5.7	*Similar requirements*
5.3.8	Safety for engineers – *new*		
5.3.9 to 5.3.10	Status indication; functional check on re-installation	5.5.8 to 5.5.9	*Similar requirements*
		5.5.10	Intermediate checks
5.3.11	Protection of electronic data	5.4.7.2	*Similar requirements*
5.3.13 to 5.3.14	Correction factors; safeguard from adjustment	5.5.11 to 5.5.12	*Similar requirements*

5.4	Pre-examination procedures	5.7	Sampling – different issue
		5.8	Handling of test and calibration items
5.4.1 to 5.4.4	Request form; instructions for sample collection; primary sample collection manual and its control – *new*		
5.4.5 to 5.4.6	Sample identification and suitability; sample transportation	5.8.1 to 5.8.3	*Similar requirements*
5.4.7 to 5.4.9	Sample log	5.8.1 to 5.8.3	*Similar* sample log requirements
	Acceptance / rejection criteria; sample volume review - *new*		
5.4.10	Request review	4.4.1	*Similar requirements*
5.4.11, 5.4.13	Sample reception; verbal requests - *new*		
5.4.12, 5.4.14	Sample traceability; sample storage Specified retention time- *additional*	5.8.2, 5.8.4	*Similar requirements*
5.5	Examination procedures	5.4	Test and calibration methods and method validation
5.5.1	Method appropriateness and preferred procedures	5.4.1, 5.4.2	*Similar requirements*
5.5.2	Method validation Method evaluation and periodic review - *additional*	5.4.3, 5.4.4, 5.4.5	Similar validation required for laboratory-developed methods and non-standard methods
5.5.3 1st and 2nd para	Documentation and availability	5.4.1 2nd para	Documentation and availability
	- including control on card files and instructions for use – *additional*		
5.5.3 3rd, 4th and 5th para	Procedure information and review – *new*		
5.5.4	Performance specifications	5.4.5.1	*Similar requirements*
5.5.5, 5.5.6	Regular review of biological reference intervals; list of examination procedures for service users – new		
5.5.7	Inform users of changes	4.4.4, 4.4.5	*Similar requirements*
5.6	Assuring quality of examination procedures	5.6	Measurement traceability
		5.9	Assuring the quality of test and calibration results
5.6.1	Internal quality control system	5.9 1st para	*Similar requirements*
5.6.2	Uncertainty of results and contributing factors - *where relevant and possible*	5.4.6.2, 5.4.6.3 5.6.2.2	Estimation of uncertainty of measurement by testing laboratories
5.6.3	Calibration programme and traceability	5.6.1 5.6.2.2.2	Calibration programme Traceability
		5.6.2.1	Specific requirements for calibration
		5.6.3	Reference standards and reference materials
5.6.4, 5.6.5, 5.6.6	External quality assurance programmes; inter-laboratory comparisons; comparability of results	5.9 (a) to (e)	Quality control procedures
	Inter-laboratory comparison programs in substantial agreement with ISO/IEC Guide 43 - *additional*		
5.6.7	Document, record and act on comparison results - *new*		

5.7	Post-examination procedures		
5.7.1 to 5.7.3	Results review; sample storage and disposal		
5.8	Reporting of results	5.10	Reporting the results
		5.10.1	General
5.8.1	Report formatted in discussion with user	5.10.8	Report design – minimise misunderstanding
5.8.2	Report receipt - *new*		
5.8.3	Information in reports– specific to medical testing reports	5.10.2, 5.10.3	Information in reports; information for interpretation of test results
		5.10.4	Calibration certificates
5.8.4, 5.8.5	Results description; identification of compromised samples - *new*		
5.8.6	Retention of reported results	4.12.2.1	Retention of records
5.8.7 to 5.8.11	Notification of critical results; "alert/critical" intervals; interim results; actions for critical results; turnaround times and notification of delayed results - *new*		
		5.10.5	Opinions and interpretations
5.8.12	Results from referral lab	5.10.6	Results from subcontractors
5.8.13	Document procedures and authorisation of report release - *new*		
5.8.14	Phone or electronic results policy	5.10.7	Electronic transmission of results – meet requirements in ISO 17025
5.8.15	Alteration of reports – policy and procedures, alteration record, legible original entries	5.10.9	Amendments to test reports and calibration certificates – clearly identified as supplementary report and reference to original report
5.8.16	Records of result revision - *new*		