Accreditation of medical laboratories using ISO 15189:2003

April 2003

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Accreditation of medical laboratory examinations in the widest sense is becoming important as a management tool and a means to create confidence in results.

The International Standard ISO/IEC 17025:1999 provides the general requirements for quality management system and technical competence, but the medical laboratorians have felt that the involvement with patients and clinicians make special considerations necessary, particularly for the pre- and postexaminational phases.

Consequently, the ISO Technical Committee 212 "Clinical laboratory testing and in vitro diagnostic test systems" has now produced a stand-alone ISO 15189:2003 "Medical laboratories - Particular requirements for quality and competence".

The management part corresponds to the requirements for certification of the quality system, whereas the technical part describes the requirements for personnel, premises, equipment, procedures, quality assurance, and reporting.

Annexes have correlation tables with ISO 9001:2000 and ISO/IEC 17025:1999 as well as recommendations on protection of laboratory information systems and on ethics.

The standard is intended to cover the needs of all types of medical laboratory from classical clinical chemistry to transfusion medicine and histopathology.

A supplementary document, ISO 22869 "Guidance on application of ISO 15189", is planned as a specifying aid to the undoubtedly considerable, but also rewarding task of preparing for accreditation.

Introduction

Acceptance of and confidence in laboratory examination results by second parties - "examined once, accepted everywhere" - may be achieved by demonstrating competence through accreditation of examination procedures by a third party.

The concept of "accreditation" is defined in the International Organisation for Standardization/ International Electrotechnical Commision (ISO/IEC) Guide 2:1996 as the "procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks".

Accreditation is gaining ground among different types of laboratory for several reasons, such as legal requirements for some examinations, requirements from the pharmaceutical industry, competitive advantage, and managerial control.

Accreditation of medical laboratories (historical perspective)

For a quarter of a century, at the international level the relevant standards to follow in accreditation have been successive editions of ISO later ISO/IEC Guide 25 "General requirements for the technical competence of testing laboratories", or the European Standard EN 45001 "General criteria for the operation of testing laboratories".

These two documents have now been replaced by the much more detailed International Standard ISO/IEC 17025:1999 "General requirements for the competence of testing and calibration laboratories", which also became a European Standard (EN) in 2000.

When accreditation of examinations in Northern European medical laboratories became relevant in the 1990s, laboratories felt that the ISO/IEC Guide 25:1990 was insufficiently applicable, especially regarding the pre- and postanalytical phases.

Consequently, the European Cooperation for Accreditation of Laboratories (EAL) and the European Confederation of Laboratory Medicine (ECLM) published an EAL-G25/ECLM-1 "Accreditation for medical laboratories" in 1997.

This document presented in parallel selected sentences or summary statements of Guide 25 and respective recommended interpretations. Such a structure impractically requires the simultaneous use of two documents.

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Year	Title	Comments
1990's	ISO/IEC Guide 25: 1990"General requirements for the technical competence of testing laboratories"	or EN 45001
1997	EAL-G25/ECLM-1 "Accreditation for medical laboratories"	Published by EAL/ECLM
1999	ISO/IEC 17025:1999 "General requirements for the competence of testing and calibration laboratories"	Became an EN in 2000
2003	ISO 15189:2003 "Medical laboratories - Particular requirements for quality and competence"	Prepared by ISO Technical Committee 212 "Clinical laboratory testing and in vitro diagnostic test systems"

TABLE I. History of accreditation standards

Contents of ISO 15189:2003

The International Standard is a comprehensive text of vi + 39 pages. Consequently, the following has to be a summarizing and highlighting presentation.

Introduction

Most medical laboratories, in contrast to other analytical laboratories, have

- preanalytical obligations towards patients regarding their preparation and identification, and transport of samples
- postanalytical obligations towards healthcare personnel regarding validation, reporting, interpretation, and advice

Furthermore, there are considerations of safety, ethics, and prevention of disease.

Scope, normative references, terms and definitions

The scope essentially only quotes the title of the standard as given above and is thus much shorter than in ISO/IEC 17025. The list of normative references includes ISO 9001:2000 and ISO/IEC 17025:1999 together with several ISO vocabularies, whereas background material is listed in a 57-item Bibliography.

Seventeen central concepts are defined, sometimes by quote from the "International vocabulary of basic and general terms in metrology" (VIM:1993); ISO/IEC 17025 has none, but refers to ISO/IEC Guide 2 and VIM.

Management requirements

Clause 4 of the standard describes the requirements for a quality management system based on ISO 9001:2000, but structured according to ISO/IEC 17025:1999. The normative Table A.1 lists the correlation between ISO 9001 and 15189.

4.1 Organization and management

The goal of medical laboratories in particular are immediately set out by stating that "Medical laboratory services, including appropriate interpretation and advisory services, shall be designed to meet the needs of patients and all clinical personnel responsible for patient care" (4.1.2).

Otherwise, the elements of management responsibilities for design, implementation, maintenance, and improvement of the quality management system (QMS) are listed, including confidentiality, training, and appointment of a quality manager.

4.2 Quality management system

Documentation is an important point, which is initially quite burdensome and exceeds classical routine paperwork in extent and detail.

It comprises policies, processes, programmes, procedures, and instructions, which must be communicated and understood, as well as internal quality control and external quality assessment.

The governing document is a quality manual describing in general i.a. quality policy (including scope, standard of service, and adherence to ISO/IEC 17025), QMS, roles and responsibilities of technical management and quality manager, resources, list of and validation of examination procedures, interaction with surroundings, internal audits, and ethics.

The listing of contents is more detailed than in ISO/IEC 17025.

4.3 Document control

This subclause is quite detailed about procedures, review, archiving, retention, amendments, and identification. All very useful when implemented and maintained, but laborious to get started.

4.4 Review of contracts

Procedures must be established to ensure that contracts to provide service are kept updated.

4.5 Examination by referral laboratories

A quite difficult and sensitive responsibility of a referring laboratory is to define and ensure the competence and quality of referral laboratories and consultants, and to transmit and comment their results to the requester. The requirements are detailed.

4.6 External services and supplies

Policies and procedures shall be documented for the selection, verification, and use of purchased external services, equipment, and consumables as well as for evaluation of suppliers.

4.7 Advisory services

The professional staff is responsible for advice to clinicians on choice of samples and examinations and use of services together with any interpretation of results.

There should be regular meetings between professional and clinical staff on the use of services and on scientific matters, and professional staff should participate in clinical rounds to enable general and case-specific advice.

Such activities clearly are special for the medical laboratory.

4.8 Resolution and complaints

There shall be a policy and procedure for the recording and resolution of complaints and other feedback from patients, clinicians, and further parties.

4.9 Identification and control of non-conformities

Policy and procedure shall be established to treat deviations from the requirements of the QMS or clinician, including consideration of medical significance, any recall of data, documentation, prevention, and review.

4.10 Corrective action

Procedures shall describe an investigative process to find underlying causes of a problem. An appropriate corrective action requires a risk analysis, record, monitoring, and audit.

4.11 Preventive action

Necessary preventive actions against non-conformities of technique or QMS require planning, implementation, and monitoring.

4.12 Continual improvement

All procedures shall be regularly reviewed by management to identify opportunities for improvement in QMS or technical practices followed by planning, implementation, and monitoring.

Furthermore, the laboratory's contribution to patient care shall be evaluated by quality indicators, which may point to a need for improvement. This item does not appear as a subclause in ISO/IEC 17025.

4.13 Quality and technical records

There shall be procedures for the identification, collection, indexing, access, retrievable safe storage for a stipulated period, maintenance, and safe disposal of quality and technical reports; a long list of type examples is given.

4.14 Internal audits

Compliance with all managerial and technical parts of the QMS shall be verified by the quality manager or designated personnel through internal audits at defined intervals, emphasizing areas important to patient care.

The outcome shall be documented, followed by

corrective or preventive actions, and reviewed by management.

4.15 Management review

The QMS and its medical services shall be reviewed periodically by management to ensure their continuing suitability and effectiveness for patient care and to introduce planned improvements; a long list of examples is presented.

The findings and actions shall be recorded and communicated to the staff.

Technical requirements

Clause 5 describes the requirements for competence based on ISO/IEC 17025:1999 and with nearly identical structure as shown in the normative Table A.2.

5.1 Personnel

Management shall have an organizational plan, personnel policies, job descriptions, as well as records of educational and professional qualifications, training, experience and competence of all personnel; elements of such records are listed.

The laboratory director shall have executive responsibility and competence relevant to the services provided, and may serve as member of the clinical staff; an impressive list of tasks is given relating to all managerial and operational aspects of the laboratory and its surrounding entities; the tasks are much more detailed than in ISO/IEC 17025.

Requirements are presented in general as to number of personnel and their education, training, authorization, competency, and confidentiality of information regarding patients.

5.2 Accommodation and environmental conditions

General advice is given on space, design, services, facilities, environmental conditions, storage, housekeeping, and access as well as the comfort and safety for patients and personnel.

5.3 Laboratory equipment

Equipment, including materials, reagents, and consumables, shall be verified, regularly monitored, and maintained. Each item shall be recorded in detail as listed and provided with operating instructions to ensure correct and safe operation.

Defective equipment shall be labelled and any effect on previous examinations shall be investigated.

Stand-alone or incorporated computers and their software must be documented, validated, maintained, and protected.

5.4 Pre-examination procedures

The items on a request form, traceable to an identified individual, are listed and supplemented by a primary sample collection manual, which is also detailed. The problems with uncertain identification of samples and any instability are discussed.

Requirements of primary sample transport, recording, validation, and storage are mentioned.

This subclause is much more explicit than in ISO/IEC 17025.

5.5 Examination procedures

The selection, validation, documentation, and review of examination procedures are emphasized, and their structure is listed, including interference, biological reference interval, and interpretation of examination results.

Performance specifications shall relate to the intended use.

5.6 Assuring quality of examination procedures

The internal quality control shall verify the intended

performance. The laboratory shall determine the examination uncertainty, taking important components into account, from sampling to change of operator.

Calibration shall ensure metrological traceability to SI units, natural constants, or other stated references.

Participation in available interlaboratory comparisons is mandatory and should check the entire process from pre- to postexamination.

The emphasis on (examinational) traceability and uncertainty is new to most medical laboratories and will require updated information from the manufacturers of equipment and calibrators, and considerable investigations by the laboratorians.

5.7 Postexamination procedures

Examination results must be reviewed in the light of clinical information before release. Storage and safe disposal of samples must proceed according to regulations and policy.

5.8 Reporting of results

The elements of a report are listed, including biological reference intervals, interpretation, and comments. The representation of each examinand and its result should follow the recommendations of international scientific organizations with regard to nomenclature and syntax.

There shall be procedures for release of examination results and for notification of healthcare personnel about delayed and critical or dangerous findings, and records of the actions undertaken. Transcription of examination results from referral laboratories shall be verified.

Annex B (informative): Recommendations for protection of laboratory information systems (LIS)

In order to protect patients from harm by loss or change of examination results and information, the integrity of comprehensive computer systems should be ensured by established policies. The recommendations given do not cover small computers and integral dedicated microprocessors.

Advice is given on location, services, environment, procedure manual, security, authorized use, and interchange with other systems. The integrity of data transfer to, through, and from the LIS should be ensured together with review of calculations and check against absurd or impossible examination results.

The recommendations include data storage, data retrieval, and backup, as well as testing and alarm systems.

General principles for handling hardware, software, and maintenance, including written procedures, documentation, and management are stated with emphasis on the integrity of patient data.

Annex C (informative): Ethics in laboratory medicine
The medical laboratory is obliged to ensure that the patient's welfare and interest are paramount and a section on ethics is therefore relevant.

Collection of information about the patient should only be as extensive as necessary and be made known to the patient.

Collection of primary samples requires adequate privacy and the patient's informed consent whenever possible.

Examinations should be carried out according to professional expectation.

Examination results attributable to a specific patient are confidential and should be reported to the requesting physician; procedures should detail the circumstances for other recipients.

Advice on selection and interpretation of examinations is part of the laboratory service.

Results with serious implications should not be

communicated directly to the patient without adequate counselling.

Access, storage, and retention of information and materials as well as use of samples for unrequested examination should be governed by procedures.

Laboratories, of course, should avoid conflicts of interest.

Supplementary document

The wording of ISO 15189 is necessarily rather general. To aid the medical laboratories, ISO/TC 212 therefore plans to produce a "Guidance on application of ISO 15189" (ISO 22869) with some specifications.

Conclusions

The ISO 15189 is specifically aimed at the accreditation of various types of medical laboratory.

Whereas the ISO/IEC 17025 is primarily concerned with the examinational phase of differential and rational properties having magnitudes, ISO 15189 is also relevant for the pre- and postexaminational phases, for non-standard and laboratory-developed examination procedures, and for nominal properties, such as descriptions of blood groups or histological preparations - all aspects that are important in laboratory medicine.

The comprehensive text includes two main clauses: on the quality management system, equivalent to requirements for certification, and on the additional technical requirements necessary for accreditation. The annexes on protection of LISs and ethics give useful information.

Any medical laboratory seeking recognition of its competence through accreditation should be well served by choosing this International Standard as a basis.

The process will entail considerable work on management system, routines, documentation, and procedures.

The process will require inquisitive and sustained support by all personnel.

The outcome should be a more transparent, robust, and continuously improving service beneficial to both patients and laboratory.