TECHNICAL REPORT

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Medical laboratories — Guidance on laboratory implementation of ISO 15189:2003

Laboratoires médicaux — Directives pour la mise en œuvre du laboratoire de l'ISO 15189:2003

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Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TR 22869 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

Introduction

This Technical Report provides guidance to laboratories on how to meet the requirements for competence and quality that are particular to medical laboratories contained in ISO 15189:2003 (in the French language, these laboratories are termed “laboratoires d’analyses de biologie médicale”, while in other languages they might be referred to using a term equivalent to the English “clinical laboratories”). This Technical Report describes the basic principles of a step-by-step process to build and maintain a quality management system within a medical laboratory. This Technical Report is equally applicable to newly established and existing laboratories. It encompasses both the management and technical requirements of ISO 15189:2003.

It is acknowledged that a country could have its own specific regulations or requirements applicable to professional personnel, their activities, and their responsibilities in this domain. In countries where accreditation requires adherence to a specific set of requirements, a laboratory seeking such recognition will need to obtain additional guidance from the accreditation body regarding conformity. This Technical Report also recognizes that each laboratory will be at a different starting point in implementing these requirements.

Therefore, each laboratory will need to determine where they are in relationship to building a quality management system that encompasses the various requirements for medical laboratories. Laboratory management needs to take the first step in building a quality system leading to compliance with ISO 15189:2003 by setting appropriate priorities based on their patient and client needs, their resources, and their local, regional and national mandates.

Medical laboratory services are essential to patient care and public health and therefore have to be available to meet the needs of all patients and the clinical personnel responsible for the care of those patients. Such services include arrangements for requisition, patient preparation, patient identification, collection of samples, transportation, storage, processing and examination of clinical samples, together with subsequent validation, interpretation, reporting and advice, in addition to the considerations of safety and ethics in medical laboratory work. Whenever allowed by national regulations, it is desirable that medical laboratory services include the examination of patients in consultation cases, and that those services actively participate in the prevention of disease in addition to diagnosis and patient management. Each service ought to also provide suitable educational and scientific opportunities for its professional staff.

While this Technical Report is intended for use throughout the currently recognized disciplines of medical laboratory services, those working in other health services and disciplines could also find it useful and appropriate. In addition, accreditation bodies that recognize the competence of medical laboratories may be able to use this Technical Report as the basis to assist laboratories in meeting requirements to establish a quality management system. International, national or regional guidance documents may also help a laboratory in meeting both local requirements as well as those in ISO 15189:2003.

This Technical Report provides guidance on how the requirements of ISO 15189:2003 fit within a medical laboratory’s quality management system and on the relationship between various ISO documents that concern building a quality management system and ISO 15189:2003. A detailed outline of how the elements of ISO 15189:2003 help define a quality management system is provided in Annex A. Finally, links to additional resources materials, including international and national standards setting and accreditation bodies, are provided in the Bibliography.

Medical laboratories — Guidance on laboratory implementation of ISO 15189:2003

1 Scope

This Technical Report provides guidance to medical laboratories describing how a medical laboratory can implement a quality system to meet the specific technical and management requirements for quality and competence in ISO 15189:2003. Bodies engaged in the recognition of the competence of medical laboratories may also be able to use this Technical Report as a basis to assist laboratories in establishing a quality system to meet national requirements, while at the same time conforming to appropriate International Standards. This guidance applies both to newly established and existing laboratories and encompasses both the management and technical requirements of ISO 15189:2003.

2 Normative references

The following referenced documents are valuable resources for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 15189:2003, *Medical laboratories — Particular requirements for quality and competence* (corrected and reprinted in July 2003)

3 Seeking accreditation for compliance with ISO 15189:2003

If accreditation to ISO 15189:2003 is the ultimate goal, seeking the advice of experts can help a laboratory avoid many of the pitfalls of either inadequate preparation or wasted effort. A preliminary audit of where the laboratory is on its pathway to building a quality management system and accreditation to a standard can be extremely helpful. A laboratory already adhering to best technical and management medical laboratory practices may only have to document its practices, while a laboratory just starting on the path of building a quality management system needs to recognize the time and resources required to achieve the goal of accreditation.

The focus of this Technical Report is to help a laboratory put in place a management system that will address both the management and technical requirements of ISO 15189:2003. As management implements a quality management system, it is necessary for management to consider ways to meet the technical requirements for personnel, environment conditions, equipment, and pre-examination, examination, and post-examination procedures described in the ISO 15189:2003.

4 Identifying resources to help a laboratory meet ISO 15189:2003 requirements

Each laboratory is likely to have a unique set of resources available to assist it in meeting requirements. Laboratory management can generally find help from other local laboratories who have already achieved compliance with requirements, or from professional laboratory organizations (local, regional, national and international), or from government, accrediting bodies (where permitted or provided), or international organizations offering quality assurance support for medical laboratories or from a consultant with appropriate expertise. If a laboratory is uncertain about a place to start, the country's Ministry of Health, or equivalent

national health organization may be the best place to begin. Also, refer to the Bibliography for additional resource materials.

5 Seeking support for building a quality management system to meet ISO 15189:2003 requirements

Laboratory management should recognize that there is a hierarchy of concepts used to describe a quality management system for health care services. These concepts, arranged from a manager's perspective, begin with a total quality management philosophy, which strives to achieve quality (safe, effective, timely and patient-oriented) service within the health care delivery system. This philosophy generally encompasses quality management, which strives to maintain coordinated and comprehensive efforts to meet the quality objectives of the health care system. These efforts are referred to as the "quality system", which includes all of the quality assurance activities (part of quality management focused on providing confidence that quality requirements will be fulfilled) (ISO 9000:2000) as well as quality control activities (part of quality management focused on fulfilling quality requirements) (ISO 9000:2000) (see Figure 1).

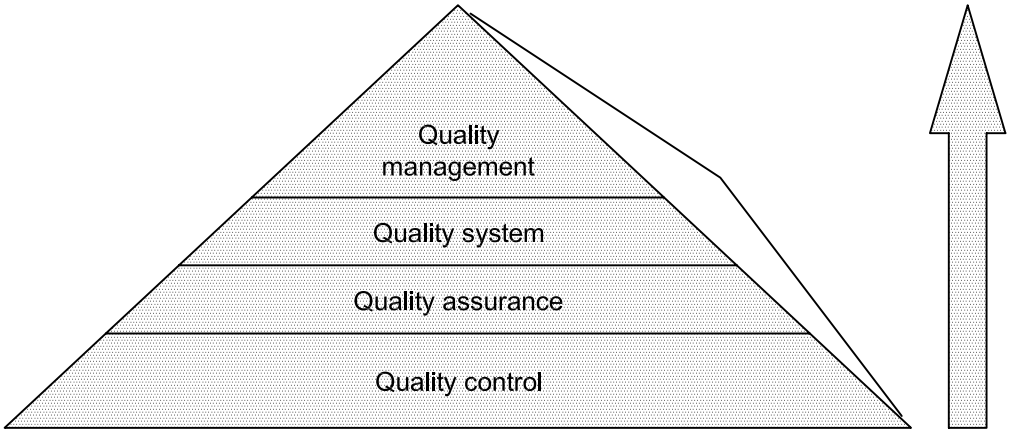


Figure 1 — The quality pyramid

In the absence of this hierarchal quality management scheme (quality pyramid) a laboratory may achieve highly accurate and reliable testing results that meet all of its analytical goals, but fail to deliver needed patient care results because of other flaws in the delivery of services in the health care system. For example, if the wrong test is performed on the correct patient sample or if the right test is performed on the wrong patient sample, the laboratory examination may be detrimental to patient care even if the results are analytically accurate and reliable. Since it is necessary that the quality system respond to a constantly changing health care environment, it is necessary for laboratory management to develop a plan for continuous improvement of its management practices (including staff training), and quality assurance, and quality control procedures to maintain a high level of readiness to respond to medical needs. Benefits of implementing a quality management system can include better resource allocation and reductions in operational costs.

Accreditation to ISO 15189:2003 incorporates and defines essential elements in the quality management system for medical laboratories. If a laboratory wants to be recognized as an organization that meets worldwide standards for quality, it needs to comply with this set of requirements. Achieving compliance within a framework of a quality system allows stepwise progress towards the goal of compliance with ISO 15189:2003, without wasting precious resources. A laboratory should stress to whomever it is accountable that their goal is to provide adequate laboratory service to support health care needs. Accomplishing compliance with ISO 15189:2003 within a quality management system permits an efficient way to meet service delivery and patient care goals. By implementing a quality management system the quality in an entire cycle of delivery of laboratory services can be assured (see Figure 2). It is necessary that this cycle be continuously examined for opportunities to improve laboratory services, for example, by reducing the number of samples the laboratory receives that are inadequate for testing.

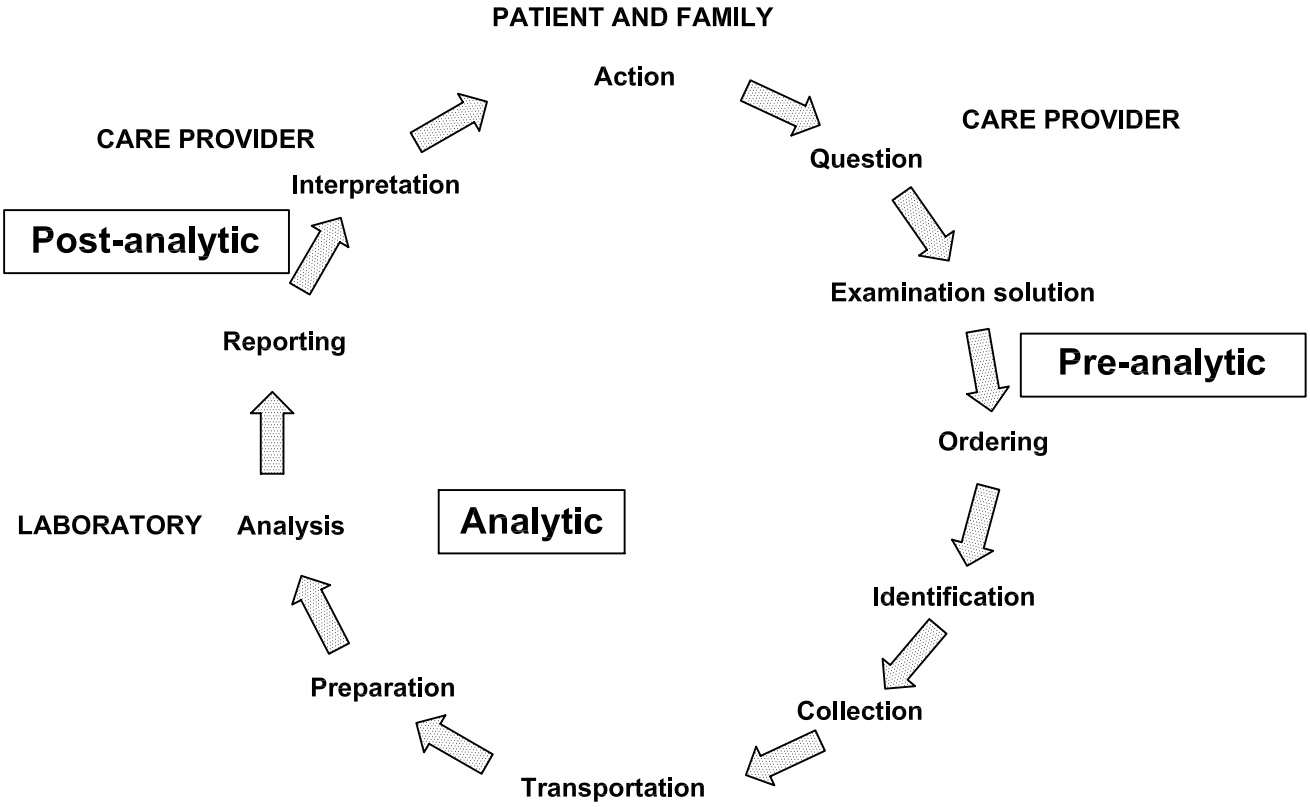


Figure 2 — Medical laboratory — Total examination cycle

6 Implementing a quality management system based on ISO 15189:2003

6.1 Components of a quality management system

Historically, the quality system essentials defined in ISO 9001:2000 come largely from concepts developed in the 1930s by Walter Shewhart, a pioneering statistician working at Bell Laboratories in the US. His four stages of problem solving (Plan, Do, Check and Act) are referred to as the "Shewhart cycle". This concept was effectively promoted by W. Edwards Deming in the 1950s to become a quality management tool referred to as the "Deming Wheel". These tools have been very effectively applied in many industries to enhance the efficiency and effectiveness of production as well as improve customer satisfaction with the products being produced. The benefits of applying quality management principles to the delivery of medical laboratory services have been recognized and are now being incorporated in many countries.

The application of quality system principles to the medical laboratory is the focus of ISO 15189:2003. It defines a quality management system, which encompasses an organization's policies, structure, processes, procedures and resources. When an organization's structure and other processes are aligned to meet the needs and requirements of users, a quality management system has been developed. It should be noted that in the supply chain terminology (supplier → organization → customer) used in the ISO 9001, a medical laboratory can refer to a supplier of items used by the medical laboratory, such as reagents, kits or devices, or to the medical laboratory as a supplier of testing services to care providers or their patients. The term organization can be used to refer to the laboratory itself or to the management structure within which the laboratory resides. The term customer is often used to refer to the individual who ordered a laboratory test, but can also be thought of as the patient.

Essential factors in the quality management system include: organization, personnel, equipment, purchasing and inventory, process control, documents and records, information management, occurrence management, internal and external assessment, process improvement, service and satisfaction and facilities and safety. Medical laboratory quality can be defined as a state that results from establishing a set of well-defined and well-executed processes. These processes create a system for the collection and examination of human samples and report of examination results that:

— supports diagnosis, disease prevention and control, and management of disease states;

— generates information having clinical utility and optimal impact on health outcomes;

— meets pre-determined targets for conformity;

— strives to be error free;

— strives to be timely, safe, efficient, and cost-effective; and

— promotes client satisfaction and continual improvement.

The initial management responsibility is to define the policies under which the laboratory will operate. Next, the policies are followed by defining processes describing what must be done to implement the policies. Finally, the processes are further defined by procedures that describe a set of actions to be taken to implement the policies and processes. This set of activities defines the quality management system, which establishes, controls, reviews and improves the total examination cycle over time. The relationship and correlation between the requirements in ISO 15189:2003 and achieving a quality management system in the laboratory is shown in Figure 3.

6.2 Assessment — Identifying deficiencies in a quality management system

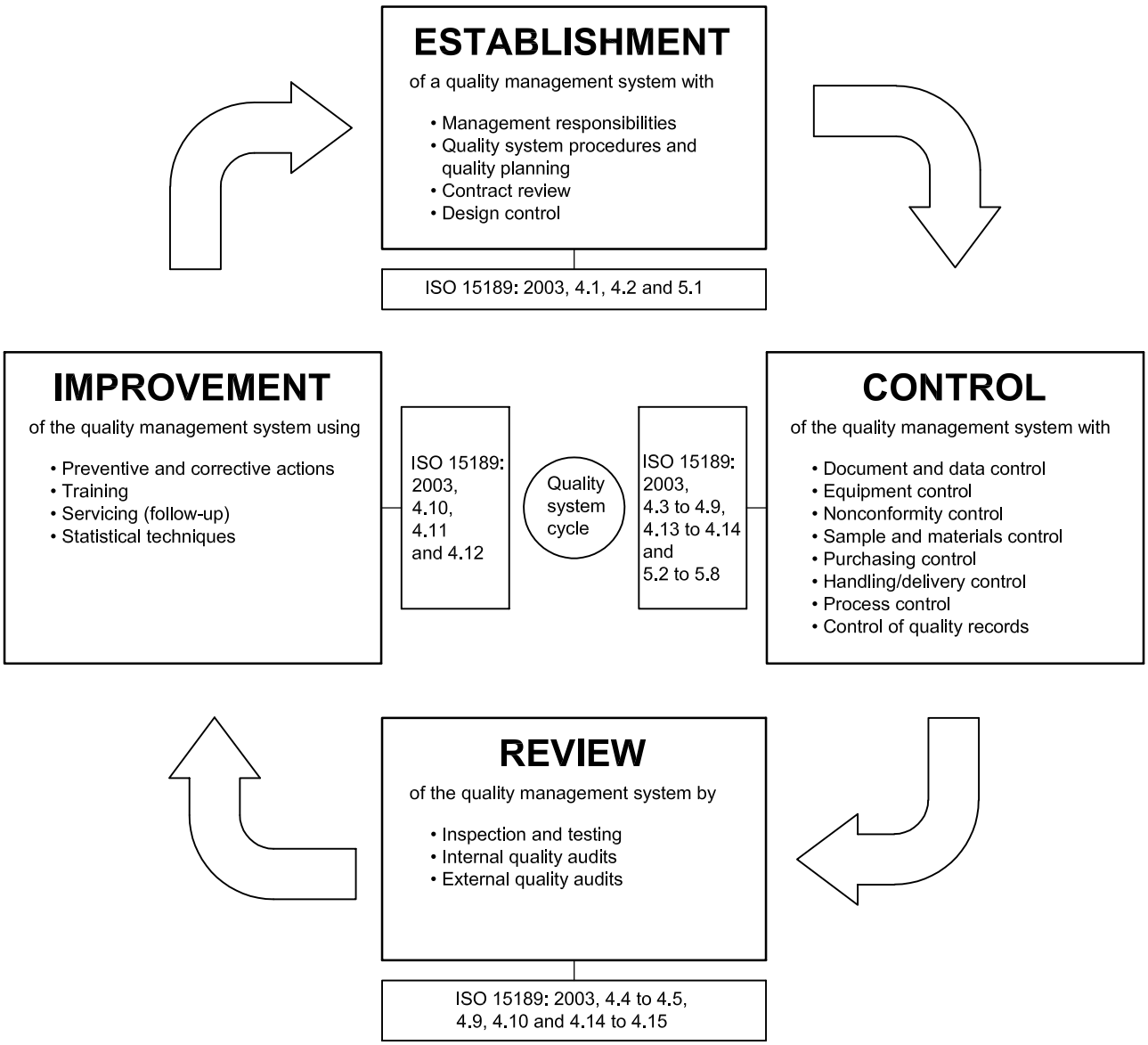
A critical step in the plan to meet all of the requirements of ISO 15189:2003 is to perform a self-assessment of the laboratory. A handy tool for such a pre-accreditation assessment is a checklist. Make sure that it encompasses all of the activities of the laboratory. If accreditation is being sought by a specific accreditation body, the pre-assessment checklist used by the accreditation body or one from a consultant who has expertise in assisting laboratories complying with that accreditation body's requirements might be most useful. This audit will help the laboratory identify its state of readiness to conform to ISO 15189:2003.

Since each laboratory will be at a different starting point, every laboratory will have its own road map to compliance with the standard. For example, a laboratory that has determined it meets most of the technical requirements for the facility (personnel, equipment, pre-examination, examination and post-examination procedures) described in ISO 15189:2003, Clause 5, might instead focus most of its efforts on meeting the management requirements in ISO 15189:2003, Clause 4.

Another way to approach compliance would be to determine which parts of the quality management system are missing. Assuming your facility, personnel and equipment are adequate, the first item to address is whether your laboratory has adequate quality control for its examination procedures. If not, this should be your starting point, since the validity of all measurements made in a laboratory could be questioned. If your quality control seems adequate then you should address the components that make up a comprehensive quality assurance system. As each part of a laboratory's overall management and technical capacity and capability is assessed, deficiencies in its quality system will be identified that must be changed in order to comply with ISO 15189:2003.

6.3 Planning — Correcting deficiencies in a quality management system

After a laboratory has assessed the deficiencies in its quality management system, the next step is to develop a corrective action plan. The plan should address the resources needed (money, personnel, equipment and time) to meet requirements in ISO 15189:2003. In some instances management policies, processes or procedures will need to be changed or modified. Correction of some deficiencies may require additions or changes that can only be accomplished by the laboratory management working with the laboratory's clients, funding organization, governmental agency, ministry of health, etc. In addition to achieving compliance, the laboratory should also find ways to eliminate or reduce risks and improve the efficiency of laboratory services. Therefore, the ultimate beneficiary of compliance is the patient. Correction of identified deficiencies is essential to ensuring that all health service goals are met.



NOTE Adapted from references [28] and [29].

Figure 3 — Relationship between implementation of a quality system cycle and ISO 15189:2003

6.4 Setting priorities

Priorities for a laboratory's services, i.e. the examinations (tests) to be offered, to whom, and when, are often set externally. However, when it comes to developing a quality management system to provide accurate and reliable examination (testing) to meet service demands, laboratory management has the ultimate responsibility. They should determine where there are deficiencies in complying with ISO 15189:2003 and seek the means to comply.

Each laboratory should establish a set of priorities in building its quality system. These should be based on an assessment of which factors are most likely to affect the efficiency and effectiveness of laboratory services. For resource-limited laboratories, the most critical factor may be the ability to provide adequately trained staff or acquire an environmentally controlled examination (testing) facility. All laboratories have resource limitations, and it is extremely important to assess where resources should be applied first to ensure quality testing services that meet the service needs of the clients and patients. Setting priorities based on preventing

the likelihood of non-conforming examination (testing) results may be helpful in planning where to focus efforts when resources are very limited. With respect to accreditation to ISO 15189:2003, all of ISO 15189:2003 requirements are to be met before the laboratory can be accredited, although the order in which components of ISO 15189:2003 are implemented or addressed can differ depending on the laboratory's resources and planning.

6.5 Implementation — Constructing a quality management system

Annex A provides a description of policies, processes and procedures that a laboratory needs to put in place to meet the managerial and technical requirements of ISO 15189:2003 within a quality management system. Specific elements of the standard are cross-referenced to illustrate how each element applies.

In constructing the laboratory's quality system, laboratory management should determine which policies are needed to support the processes and procedures to implement a specific requirement. As each of the four cornerstones of a quality management system (establishment, control, review and improvement) are implemented, the laboratory should assess its extent of compliance with requirements in the standard and seek the resources needed to fully comply. An initial internal audit of progress towards the goal of compliance is helpful in ensuring that resources are focused on the most important deficiencies.

6.6 Evaluating, improving and maintaining the quality management system

Regardless of the laboratory's starting point, conducting periodic internal audits of its quality system will help assure that the laboratory either continues to comply with ISO 15189:2003 or is making steady progress towards this goal. While internal audits are likely to identify many areas in need of improvement, there is added value to also having an external audit performed periodically.

An external audit can take several forms, including:

a) an assessment by an accrediting body;

b) an on-site evaluation by an expert or team of experts or from a local laboratory already accredited to ISO 15189:2003;

c) a comparison of examination (test) results with other laboratories to determine the accuracy of the laboratory's examination performance compared to other laboratories (ISO defines this as proficiency testing);

d) a sample rechecking scheme comparing one laboratory's results with the results of another laboratory on common testing materials or patient samples; or

e) participation in a national or regional benchmarking scheme to determine how the laboratory's practices and procedures compare with similar facilities.

Note that each of these approaches has some capacity to identify unmet management or technical requirements. The more comprehensive the laboratory's internal and external auditing processes are, the more likely the laboratory is to identify areas in need of improvement.

Other opportunities in improving and maintaining a quality management system for the laboratory can arise from monitoring laboratory service outcomes and from customer (health care staff and patient) evaluations. Input from these sources will enhance the laboratory's ability in identifying causes of non-conformity. Once the laboratory recognizes and implements a quality management system, an ongoing process will be in place for continued development and growth. The entire quality system will be able to respond to problems identified by customers, external quality assessment programs or internal or external audits with appropriate training and education and changes in technical or management practices. When all of this has been achieved, maintenance and improvement of the quality management system becomes the goal of the laboratory's management and technical operations.

Annex A
(informative)

Elements of ISO 15189:2003 for defining a quality management system

A.1 General

For medical laboratories, implementing a quality management system requires a clear understanding of where the laboratory is along the path toward implementation and the policies, processes, and procedures that are needed to complete implementation. The following table is intended to provide both a path forward and an outline of the steps to implement the quality management system. Because of the large differences in organizational structure of medical laboratories and the wide array of services being offered, a laboratory may need also to refer to sources of more technical guidance, provided by the resource material in the Bibliography. To address specific management and technical issues, numbers cited in the path of flow table refer to sections and annexes in ISO 15189:2003. Note that the bulleted items in Table A.1 could serve as a checklist for a laboratory to use in marking the laboratory's progress toward achieving implementation of a quality management system.

Table A.1 — Guidance on laboratory implementation of ISO 15189:2003 — Path of flow table

Policy	Process	Procedure
State intent and direction for:	**Activities that transform the intent into action:**	**Document instructions for:**
☐ Guidance and provision of laboratory services based on total quality management principles (4.1, 4.2)	☐ From the list below, determine core laboratory functions that will define intended services: — disease prevention, control, and surveillance; — integrated data management; — reference and specialized examinations; — environmental health; — laboratory improvement and regulatory compliance; — policy development; — emergency response; — health research; — training and education; — partnerships and communication	☐ Objectives of the quality management system and laboratory's commitment to quality defined in a quality policy statement [4.2.3 c), 4.2.3 f)] ☐ Scope and delivery of laboratory services (consult accreditation body) [4.2.3 a)] ☐ Who will be the customers and how they will be served (standard of service) [4.1.2, 4.2.3 b)] ☐ Quality manual that defines laboratory quality activities including but not limited to internal quality control policies and participation in an external quality assessment program (follow ISO 15189:2003 content and structure) (4.2.2 to 4.2.4)
☐ Conformance with regulatory requirements (4.1)	☐ Determine applicable regulatory requirements regarding laboratory location and function	☐ Regulatory requirements and an outline of how they will be met ☐ Assurance that laboratory is legally identifiable (4.1.1)

Table A.1 (*continued*)

Policy	Process	Procedure
State intent and direction for:	**Activities that transform the intent into action:**	**Document instructions for:**
☐ Financial analysis of resources needed to ensure a quality laboratory [4.1, 4.2, 4.4.1 b), 4.6.1]	☐ Consider and determine costs involved with: — facility: type, number and location; — equipment; — supplies (purchasing and inventory); — human resources; — maintenance, calibration, quality control, external quality assessment; — consultations, if needed	☐ Itemizing costs and total operational monies needed (annual budget) ☐ Procedures for purchase of supplies, equipment, and services such as: — volume purchasing; — sources, etc.
☐ Management structure (4.1.4, 4.1.5)	☐ Determine management hierarchy ☐ Determine duties and responsibilities ☐ Determine relationships to other organizations [4.1.5 e)] ☐ Determine possible conflicts of interest (4.1.4) ☐ Develop policies and procedures that ensure all laboratory staff are free of undue pressures that may adversely affect quality or customer confidence [4.1.5 b)]	☐ Laboratory commitment to quality management implementation (4.1.3) ☐ Technical and training requirements of staff [4.1.5 g)] ☐ Assigned responsibilities, authority, and interrelationships of all personnel [4.1.5 a), c), e), f), h), j)] ☐ Empowerment of laboratory staff to carry out all duties with appropriate authority and resources [4.1.4, 4.1.5 a)] ☐ Laboratory management autonomy [4.1.4, 4.1.5 e)] ☐ Mechanism for appointment of a laboratory quality manager [4.1.5 i), 4.1.5 j)]
☐ Document control (4.3)	☐ Define document control policies and procedures (4.3.1 to 4.3.3, 5.4.4) ☐ Establish a review process for all documents [4.3.2 a), 4.3.2 d)] ☐ Develop process to retain documents	☐ Create documents using required elements (4.3.1, 4.3.3, 5.4.4) ☐ Document control log [4.3.2 b), 4.3.2 c)] ☐ Document review, change, update

Table A.1 (*continued*)

Policy	Process	Procedure
State intent and direction for:	**Activities that transform the intent into action:**	**Document instructions for:**
☐ Personnel — technical requirements (5.1) ☐ Recruitment and retention program for qualified personnel as an Integral part of the commitment to quality	☐ Develop personnel policies and job descriptions of all laboratory personnel-include standards that meet laws, regulations and certification organizations ☐ Create personnel record requirements ☐ Establish responsibilities of lab director or designees (5.1.4) ☐ Develop legally compliant recruiting and hiring procedures ☐ Establish orientation program ☐ Create a continuing education program for all staff (5.1.9, 5.1.12) ☐ Develop policies for personal use of computer systems (5.1.8) ☐ Create safety and adverse incidents education program (5.1.10) ☐ Establish regular competency assessment program (5.1.11) ☐ Develop performance appraisal system, incentive and recognition program ☐ Create procedures for incident, accident and occupational hazard occurrences (coordinate human resource policies) ☐ Create grievance policies	☐ Job descriptions relevant to services offered (5.1.1, 5.1.3 to 5.1.6) ☐ Records including job descriptions, references, certifications, continuing education and personnel health records (5.1.2) ☐ Documenting activities ☐ Training records (5.1.11) ☐ Education and experience (5.1.12) ☐ Quality assurance training (5.1.6) ☐ Assure compliance with laws and regulations ☐ Orientation/training forms (5.1.6) ☐ Educational credit records ☐ Confidentiality and ethical standards of conduct (5.1.13, Annex B, Annex C) ☐ Annual safety training forms and incident reports ☐ Adverse incidents training (5.1.10) ☐ Records of competency assessment, results and corrective actions (5.1.11) ☐ Recognitions ☐ Retaining records of immunizations, accidents, injuries and incident involving personnel ☐ Recording any grievances and outcomes
☐ Pre-examination procedures (5.4)	☐ Establish examination request form requirements that provide pertinent information and satisfy regulatory or accreditation requirements (5.4.1) ☐ Create a primary sample collection manual (4.2.4, 4.3.1, 5.4.3) ☐ Establish criteria for primary sample collection, handling, tracking, transportation and retention (5.4.5) ☐ Establish a process to monitor transportation of samples (5.4.6) ☐ Establish review processes for examination requests, forms, sample collection procedures and examination methods employed (5.4.9, 5.4.10)	☐ Completing request form with required information [5.4.1, 5.4.3 c)] ☐ Proper sample collection and handling (5.4.2, 5.4.3): — general user's information; — labelling and safety instructions; — accepting, rejecting, tracking, accessioning and storage of primary samples (5.4.5, 5.4.12); — patient preparation instructions for caregivers; — urgent sample collections (5.4.11); — handling verbal or electronic test requests (5.4.13) ☐ Review of sample transport time, storage conditions and compliance with safety regulations

Table A.1 (*continued*)

Policy	Process	Procedure
State intent and direction for:	**Activities that transform the intent into action:**	**Document instructions for:**
☐ Examination procedures (5.5)	☐ Ensure that examination procedures are suitable and validated (5.5.1, 5.5.2) ☐ Establish procedures for all examinations (5.5.3) ☐ Create list of examinations, sample requirements and performance specifications for lab service users (5.5.6, 5.5.7)	☐ Validating procedures with management review, initially and periodically (5.5.2, 5.5.5) ☐ Procedure manuals and quick reference materials (5.5.3, 5.5.6) ☐ Performance records of quality control, calibrations and standardization results ☐ Review of quality control and external quality assessment results ☐ Recording corrective actions taken to assure quality of examinations
☐ Assuring quality of examination procedures (5.6)	☐ Establish traceability chain for each type of examination property (5.6.2) ☐ Establish protocols for internal quality control systems to achieve quality results (5.6.1) ☐ Enrol in interlaboratory quality assessment programs (5.6.4) ☐ Establish exchange of samples with other laboratories if needed (5.6.6, 5.6.7) ☐ Verify regulatory and/or accreditation requirements	☐ Identifying sources of examination uncertainty in examination measurements (5.6.2) ☐ Establish uncertainty budgets and estimate examination uncertainty for each type of examined property (5.6.2) ☐ Defining and reviewing biological reference values (5.5.5) ☐ Activities that document calibration and verification of examination systems (4.2.5, 5.6.3) ☐ Management review of results and documentation of corrective actions (5.6.4, 5.6.7, 5.8.10)
☐ Post-examination procedures (5.7)	☐ Establish protocols for review and release of examination results ☐ Establish protocols for storage conditions, retention times and safe disposal of samples after results are released	☐ Electronic or handwritten documentation for review of examination results ☐ Saving samples in designated storage areas after examination ☐ Safe disposal of samples
☐ Reporting of results (5.8, Annex B)	☐ Design formats for paper and electronic reports (5.8.1, 5.8.3 to 5.8.5) ☐ Create a retention procedure for all lab reports (5.8.6) ☐ Establish a report delivery system to ensure timeliness of result reporting (5.5.5, 5.8.2, 5.8.7, 5.8.9, 5.8.10, 5.8.16) ☐ Determine turnaround times for tests/examinations (5.8.11) ☐ Determine corrective actions needed for amended and altered reports	☐ Detailed list of required information for reports as specified in SOP's for individual examinations ☐ Guidelines for release of results (5.8.9, 5.8.13, 5.8.14) ☐ Electronic transmission schedules, crisis values requiring special notification, delivery schedules of manual reports, etc. ☐ List of turnaround times for all examinations — made available to users and laboratory staff (5.8.11) ☐ Recording report changes or corrections (5.8.15) ☐ Reporting examination results by telephone, fax or other methods, and consultations as applicable (5.8.12, 5.8.14)

Table A.1 (*continued*)

Policy	Process	Procedure
State intent and direction for:	**Activities that transform the intent into action:**	**Document instructions for:**
☐ Facility requirements including management commitment to adequacy of facility design to ensure quality testing environment (Accommodation and environmental conditions) (5.2)	☐ Establish criteria for adequate space and safety of all primary and secondary sample collection and examination sites (5.2.1 to 5.2.4, 5.2.8, 5.2.9)	☐ Control access to examination areas, reagents and samples (5.2.6, 5.2.7) ☐ Clean work area requirements and schedules (5.2.10) ☐ Following proper handling and disposal of bio-hazardous materials (5.2.10) ☐ Monitoring, recording and correcting environmental conditions affecting test results (5.2.5) ☐ Assure proper facilities and privacy for patients undergoing sampling and examination
☐ Laboratory equipment standards for purchase, maintenance, safe operation replacement and supplies required to achieve quality testing and supplies (5.3)	☐ Develop a program of performance standards for equipment, data integrity, safe handling (4.2.5, 5.3.1, 5.3.6 and Annex B) ☐ Establish equipment maintenance schedules, proper function monitors, and repair provisions (5.3.2)	☐ Equipment records operation validation (5.3.2 to 5.3.5, 5.3.14) ☐ Maintenance documentation, software updates, calibrations and repairs (4.2.5, 5.3.8 to 5.3.13) ☐ Safety requirements for all equipment and personnel (5.2.5, 5.3.6 to 5.3.8, 5.3.12) ☐ Handling defective equipment (5.3.7)
☐ Nonconformities (4.9)	☐ Develop procedures to respond to and correct problems (4.9.1) ☐ Develop program for assessing effectiveness of follow-up procedures ☐ Develop procedure of reporting and approval of deviations from SOP's	☐ Who is responsible for resolution, release of reports, examinations, etc. ☐ Taking corrective actions, documenting deviations and evaluating their impact on examination results ☐ Identification, corrective action, review and release of results or non-conforming activities ☐ Management review schedule
☐ Complaint resolution (4.8) (receiving and resolving all feedback from physicians, patients and other parties)	☐ Develop mechanism for resolution of complaints and responses to service users	☐ Recording all complaints, investigations and corrective actions
☐ Quality and technical records (4.13)	☐ Establish and implement procedures governing quality and technical records generated by the laboratory ☐ Verify compliance with local regulations	☐ Indexing of records ☐ Access/confidentiality ☐ Retention schedule ☐ Storage — archiving facility, environmental conditions and access control ☐ Records legibility ☐ Records retrieval and disposal
☐ Requests and contracts (4.4)	☐ Develop process for examination request form design and review ☐ Determine examination contract requirements	☐ Examination request form content and review interval ☐ Patient examination contracts and their review and renewal

Table A.1 (*continued*)

Policy	Process	Procedure
State intent and direction for:	**Activities that transform the intent into action:**	**Document instructions for:**
☐ Referral laboratories (4.5)	☐ Develop process for selection and review of referral laboratories ☐ Establish policies for handling and reporting results from referral laboratories	☐ Selection criteria ☐ Review and/or renewal of referral laboratories ☐ Maintaining a register of referral laboratories used ☐ Handling reports from referral laboratories
☐ External services and supplies (4.6)	☐ Establish purchasing procedures for services and materials ☐ Establish inventory control system	☐ Selection criteria based on quality, service, price and availability considerations ☐ Purchasing contracts, verification of materials, suppliers' quality and evaluation of materials and services
☐ Advisory services (4.7)	☐ Determine necessity and degree of consultative or advisory services needed	☐ Selection criteria ☐ Contractual requirements
☐ Internal audits (4.14)	☐ Plan, organize and perform internal audits ☐ Submit audit results for review by laboratory management	☐ Who will carry out audits ☐ Schedule of audits ☐ Reporting of results ☐ Follow-up of corrective actions taken
☐ Management review (4.15)	☐ Establish policies and time-lines for lab management review of the quality management system and all its medical services (4.15.1) ☐ List quality indicators to be reviewed (result turnaround time and laboratory service complaints may be good starting points) (4.15.2)	☐ Following a schedule for reviews ☐ Preparing reports of management review ☐ Reporting findings and actions of reviews ☐ Informing lab staff of review results and actions (4.15.4)
☐ Continual improvement (4.12)	☐ Management review of all operational procedures at intervals defined by quality management system ☐ Identify opportunities for improvement, implement quality indicators to monitor and evaluate patient care ☐ Audit areas of concern for improvement ☐ Provide education and training for lab personnel	☐ Management review schedule ☐ Action plans for improvement ☐ Reviews or audits of actions (improvement processes and procedures) NOTE ISO 14971 on risk management can help focus these activities which include employee involvement and improvement, encouragement of team work, management support, employee recognition, and recognition of accomplishments
☐ Corrective action (4.10)	☐ Establish procedures for investigation of problems ☐ Implement corrective changes ☐ Perform continuing audits of concern	☐ Recording results of investigations and corrective changes ☐ Reviewing results of corrective actions and submitting to management ☐ Monitoring results of corrective changes

Table A.1 (*continued*)

Policy	Process	Procedure
State intent and direction for:	**Activities that transform the intent into action:**	**Document instructions for:**
☐ Preventive action (4.11)	☐ Identify needed improvements and potential nonconformities ☐ List activities such as review of external quality assessment results	☐ Initiating preventive actions and controls to ensure improvements

Bibliography

Additional resource materials for laboratory quality management system development

Although this Technical Report is a guideline for laboratories wishing to comply with ISO 15189:2003, due to restrictions of space, it cannot provide details for all of the technical and managerial issues involved with operating a quality medical laboratory. For laboratories that may not have easy access to consultants but need assistance with such details as determining the uncertainty in laboratory testing, the determination of biological reference values, document control and other managerial skills, etc., the following resource materials should be of assistance.

[1] ISO 31 (all parts), *Quantities and units*

[2] ISO/IEC Guide 43-1, *Proficiency testing by interlaboratory comparisons — Part 1: Development and operation of proficiency testing schemes*

[3] ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*

[4] ISO 9001:2000, *Quality management systems — Requirements*

Determination of biological reference values

[5] Clinical and Laboratory Standards Institute (CLSI) website: http://www.clsi.org/

[6] NCCLS C28-A2: *How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline*. 2nd ed., NCCLS: Wayne, PA, 2000

[7] SOLBERG H.E. *Establishment and use of reference values*, In: BURTIS, C.A. and ASHWOOD, E.R., (eds), *Tietz Textbook of Clinical Chemistry*. 3rd ed., W.B. Saunders Co., Philadelphia, PA, 1999

Determining uncertainty in laboratory testing

[8] American Association for Clinical Chemistry website: http://www.aacc.org/

[9] International Federation of Clinical Chemistry and Laboratory Medicine website: http://www.ifcc.org/

[10] ISO 5725 (all parts), *Accuracy (trueness and precision) of measurement methods and results*

[11] *Guide to the expression of uncertainty in measurement* (GUM), BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML, 1993, corrected and reprinted in 1995

[12] NCCLS EP5-A, *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline*. NCCLS: Wayne, PA, 2nd ed., 2004

[13] NCCLS EP15-A: *User Demonstration of Performance for Precision and Accuracy; Approved Guideline*. NCCLS: Wayne, PA, 2001

[14] NCCLS GP29-A: *Assessment of Laboratory Tests When Proficiency Testing is Not Available; Approved Guideline*. NCCLS: Wayne, PA, 2002

Document control

[15] Clinical and Laboratory Standards Institute (CLSI) website: http://www.clsi.org/

[16] NCCLS GP2-A4, *Clinical Laboratory Technical Procedure Manuals; Approved Guideline*. 4th ed. NCCLS: Wayne, PA, 2002

Laboratory quality

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[21] EL-NAGEH, M., HEUCK, C., KALLNER, A. and MAYNARD, J. *Quality Systems for Medical Laboratories: Guidelines for Implementation and Monitoring*. WHO Regional Publications, Eastern Mediterranean Series 14, WHO-EMRO: Alexandria, Egypt, 1995

[22] National Pathology Accreditation Advisory Council, Australia website: http://www.health.gov.au/npaac

[23] Clinical and Laboratory Standards Institute (CLSI) website: http://www.clsi.org/

Managerial skills

[24] CDC. Core Functions and Capabilities of State Public Health Laboratories. MMWR: September 20, 2002, **51** (RR14, pp. 1-8)

[25] JURAN, J.M. *Juran On Leadership for Quality. New York*, NY: The Free Press, 1989

[26] MCCLOSKEY, L.A., COLLET, D.N. *TQM: A Primer Guide to Total Quality Management*. Methuen, MA: Goal/QPC, 1993

[27] Clinical and Laboratory Standards Institute (CLSI) website: http://www.clsi.org/

Quality system cycles

[28] BURNETT, D. *A Practical Guide to Accreditation in Laboratory Medicine*. ACB Venture Publications, London, UK, 2002. ISBN 0-902429-39-6

[29] National Pathology Accreditation Advisory Council *Guidelines for Quality Systems in Medical Laboratories*, Commonwealth of Australia. ISBN 0-642-73578-6)

Sources of International, national, and accreditation standards

[30] Canadian Standards Association website: http://www.csa.ca/

[31] Clinical Pathology Accreditation (UK) Ltd website: www.cpa-uk.co.uk/

[32] College of American Pathologists Laboratory Improvement Program website: http://www.cap.org/

[33] European Committee for Standardization (CEN) website: http://www.cenorm.be/cenorm/index.htm

[34] International Laboratory Accreditation Cooperation website: http://www.ilac.org/

[35] International Organization for Standardization website: http://www.iso.org/

[36] Israel Laboratory Accreditation Authority website: http://www.israc.gov.il/

[37] National Association of Testing Authorities, Australia website: http://www.nata.asn.au/

[38] Clinical and Laboratory Standards Institute (CLSI) website: http://www.clsi.org/

[39] United Kingdom Accreditation Service website: http://www.ukas.com/

[40] United States Clinical Laboratory Improvement Amendments 1988 at Centers for Medicare and Medicaid Services website: http://www.cms.hhs.gov/

[41] The Japan Accreditation Board for Conformity Assessment website: http://www.jab.or.jp/

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