TECHNICAL REPORT

ISO/TR 22869

First edition
2005-02-15

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

Reference number
ISO/TR 22869:2005(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.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).

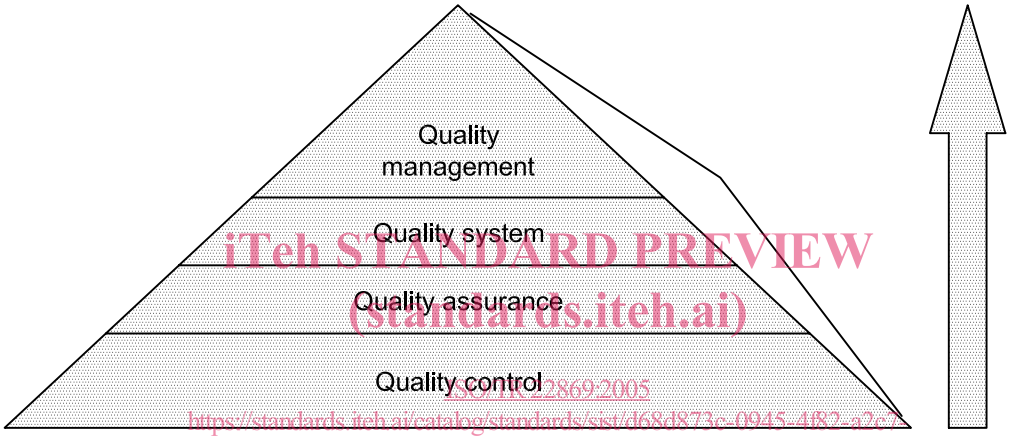


Figure 1 — The quality pyramid

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.

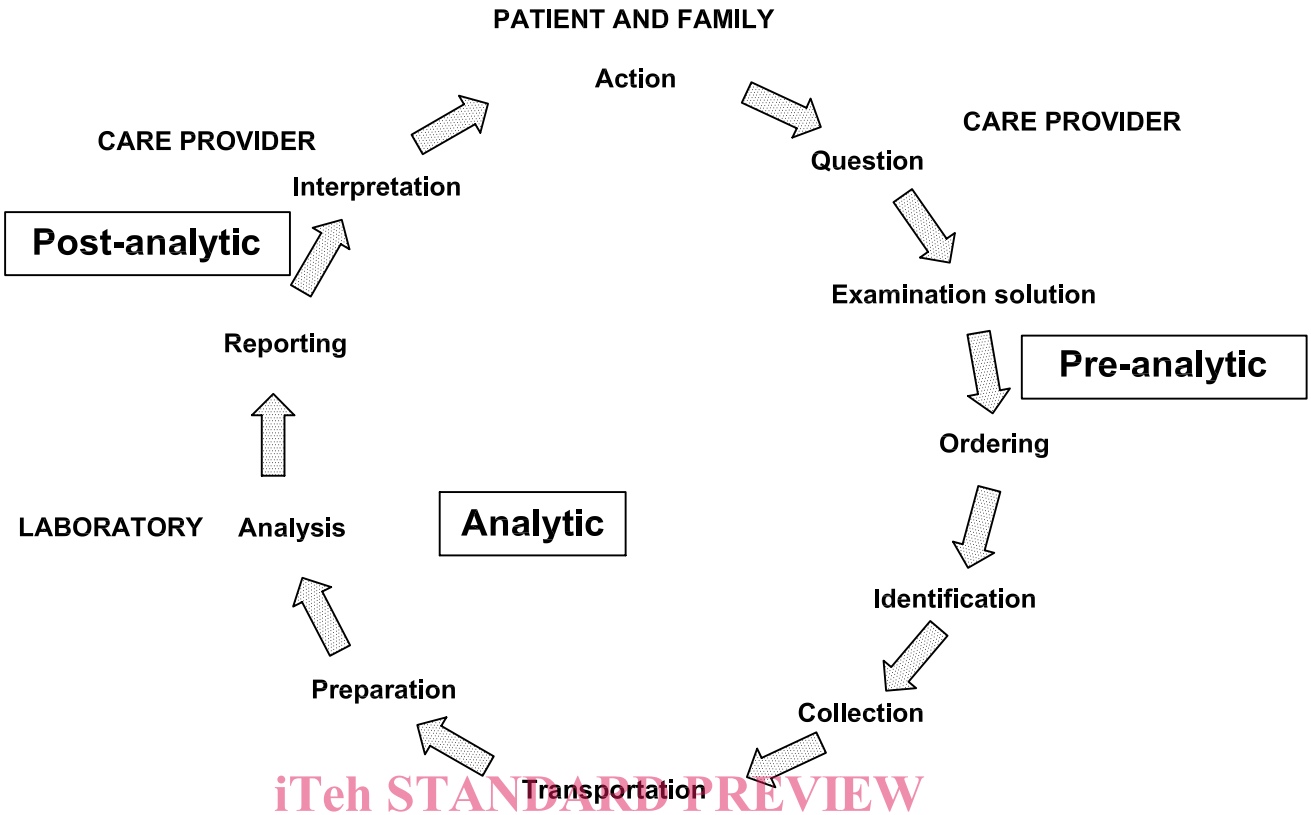


Figure 2 — Medical laboratory — Total examination cycle

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

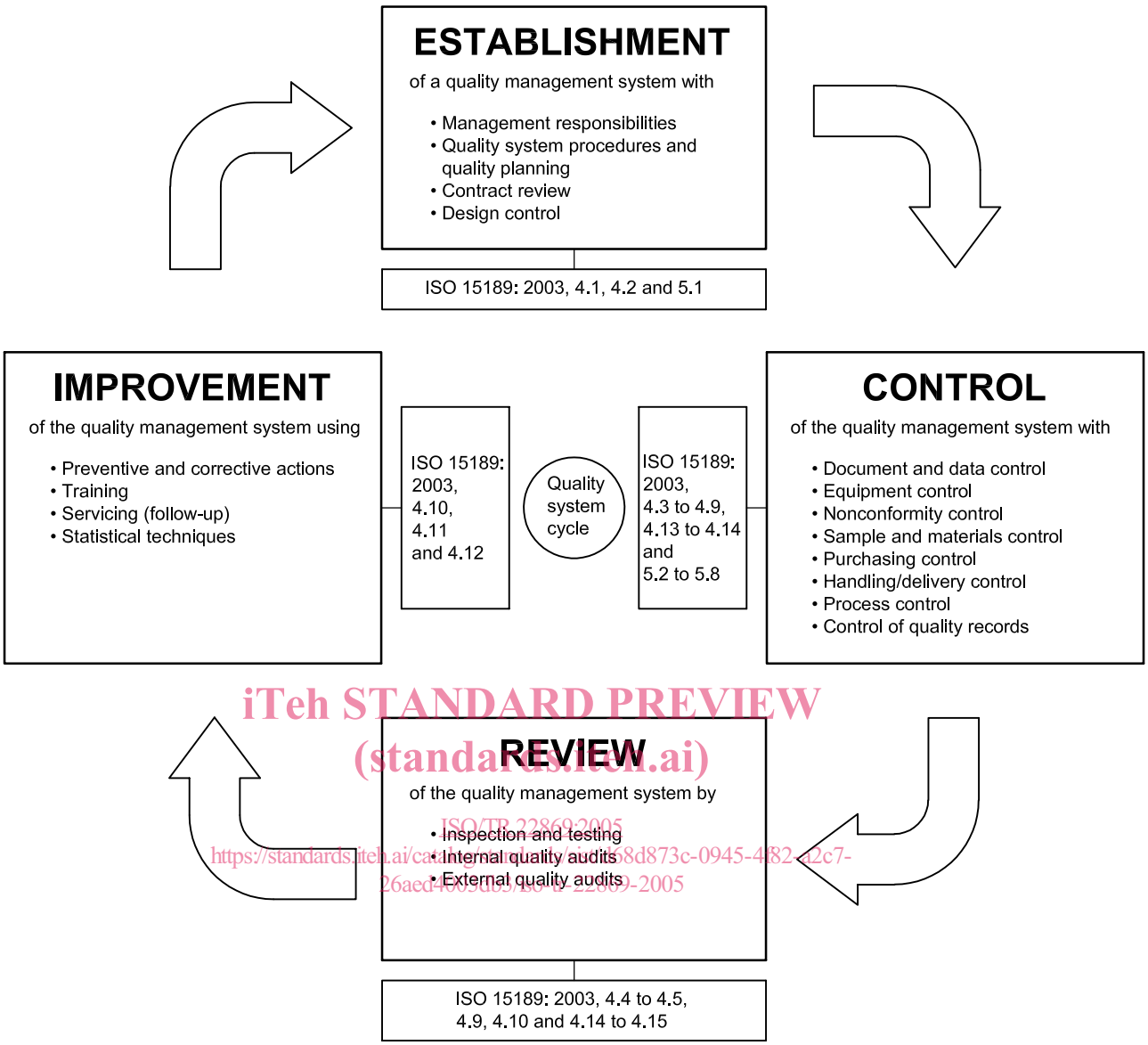
A critical step in the plan to meet all of the requirements of ISO 15189:2003 is to perform a self-assessment of the laboratory. A handy tool for such a pre-accreditation assessment is a checklist. Make sure that it encompasses all of the activities of the laboratory. If accreditation is being sought 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