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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.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