Second edition
2009-05-01

In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for content and presentation of reference measurement procedures

Dispositifs médicaux de diagnostic in vitro — Mesurage des grandeurs dans des échantillons d'origine biologique — Exigences relatives au contenu et à la présentation des procédures de mesure de référence

Reference number
ISO 15193:2009(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.

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 15193 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 140, In vitro *diagnostic medical devices*, in collaboration with Technical Committee ISO/TC 212, *Clinical laboratory testing and* in vitro *diagnostic test systems*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 15193:2002), which has been technically revised.

Introduction

Reference measurement systems are needed to produce useful and reliable measurement results, whether in science, technology or routine service, so as to be comparable and ultimately metrologically traceable to measurement units and/or measurement standards and/or measurement procedures of the highest metrological level. Reference measurement procedures play a crucial role in this metrological system because they can be used for the following:

a) in assessing performance properties of measuring systems – comprising measuring instruments, auxiliary equipment as well as reagents,

b) in demonstrating if there is a functional interchangeability of different routine measurement procedures purporting to measure the same quantity,

c) in assigning quantity values to reference materials that are then used for purposes of calibration or trueness control of routine measurement procedures, and

d) in detecting analytical influence quantities in patient samples.

For medical laboratory measurements, in particular, it is vitally important to both patient care and health screening that the measurement results reported to the physicians and patients are adequately comparable, reproducible and accurate. In some cases, it is advisable that a reference measurement procedure be given in the form of a standard, namely when it is related to technical requirements:

— that are specified in standards, technical specifications, or technical regulations, etc.,

— for which quantity values are to be stated by the supplier, and

— that have a direct relationship to the performance of a product or process.

The advantages of having such a standard are listed in ISO/IEC Guide 15.

In Clause 3 of this International Standard, concepts are indicated by *italicized text*.