SLOVENSKI PREDSTANDARD

oSIST prEN ISO 15193:2006

november 2006

Diagnostični medicinski pripomočki in vitro - Merjenje količin v vzorcih biološkega izvora - Zahteve za vsebino in predstavitev referenčnih merilnih postopkov (ISO/DIS 15193:2006)

In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference measurement procedures (ISO/DIS 15193:2006)

ICS 11.100.10

Referenčna številka
oSIST prEN ISO 15193:2006(en)

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN ISO 15193

August 2006

ICS

English Version

In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference measurement procedures (ISO/DIS 15193:2006)

Dispositifs médicaux de diagnostic in vitro - Mesurage des grandeurs dans des échantillons d'origine biologique - Exigences relatives au contenu et à la présentation des modes opératoires de mesure de référence (ISO/DIS 15193:2006)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 140.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

This draft European Standard was established by CEN in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. prEN ISO 15193:2006: E

Foreword

This document (prEN ISO 15193:2006) has been prepared by Technical Committee CEN/TC 140 "In vitro diagnostic medical devices", the secretariat of which is held by DIN, in collaboration with Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems".

This document is currently submitted to the parallel Enquiry.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

DRAFT INTERNATIONAL STANDARD ISO/DIS 15193

ISO/TC **212** Secretariat: **ANSI**

Voting begins on: **2006-08-10** Voting terminates on: **2007-01-10**

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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 modes opératoires de mesure de référence

[Revision of first edition (ISO 15193:2002)]

ICS 11.100.10

ISO/CEN PARALLEL ENQUIRY

This draft International Standard is a draft standard developed within the European Committee for Standardization (CEN) and processed under the CEN-lead mode of collaboration as defined in the Vienna Agreement. The document has been transmitted by CEN to ISO for circulation for ISO member body voting in parallel with CEN enquiry. Comments received from ISO member bodies, including those from non-CEN members, will be considered by the appropriate CEN technical body. Should this DIS be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month FDIS vote in ISO and formal vote in CEN.

In accordance with the provisions of Council Resolution 15/1993 this document is circulated in the English language only.

Conformément aux dispositions de la Résolution du Conseil 15/1993, ce document est distribué en version anglaise seulement.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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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 DIS 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).

Introduction

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

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

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

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

— in detecting analytical influence quantities in patient samples.

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

— 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 the ISO/IEC Guide 15.

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

1 Scope

This International Standard specifies requirements for the content and format of a reference measurement procedure.

NOTE 1 It is intended that an experienced laboratory worker, following a measurement procedure, written in accordance with this International Standard, can be expected to produce measurement results with a measurement uncertainty not exceeding the stipulated interval.

This International Standard applies to reference measurement procedures providing values of differential or rational quantities. For nominal properties and ordinal quantities, see Annex A.

This International Standard is valid for any person, body, or institution, involved in one of the various branches of laboratory medicine, intending to write a document to serve as a reference measurement procedure.

NOTE 2 Full descriptions of measurement methods are usually published in the scientific literature. Such publications should describe methods in sufficient detail so that they can be used as the basis of a documented measurement procedure.

NOTE 3 The terms 'standard' and 'international standard' are used with two meanings: A written text or a material, substance or device. In this document the term 'International Standard' is always a document from ISO whereas 'international measurement standard' designates a material standard. The term 'International Standard' is used by WHO for reference materials.

2 Normative references

The following referenced documents are indispensable 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.

International vocabulary of basic and general terms in metrology, BIPM/IEC/IFCC/ISO/IUPAC/IUPAP/OIML[1]

Guide to the expression of uncertainty in measurement, BIPM/IEC/IFCC/ISO/IUPAC/IUPAP/OIML, 1993

ISO 78-2:1999, *Chemistry – Layouts for standards – Part 2: Methods of chemical analysis*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in the *International vocabulary of basic and general terms in metrology* and in the *Guide to the expression of uncertainty in measurement* and the following apply:

[1] The abbreviation VIM is used in this International Standard.