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In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Presentation of reference measurement procedures

Dispositifs médicaux de diagnostic in vitro — Mesure des grandeurs dans des échantillons d'origine biologique — Présentation des modes opératoires de mesure de référence

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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 3.

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 15193 was prepared by the European Committee for Standardization (as EN 12286:1998) and was adopted, under a special “fast-track procedure”, by Technical Committee ISO/TC 212, *Clinical laboratory testing and* in vitro *diagnostic test systems*, in parallel with its approval by the ISO member bodies.

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 140 "In vitro diagnostic medical devices", the secretariat of which is held by DIN.

The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and the European Confederation of Laboratory Medicine (ECLM) have contributed to its preparation.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 1999, and conflicting national standards shall be withdrawn at the latest by May 1999.

This European Standard is based on ISO/DIS 78-2 with special consideration of the requirements for biological materials and for reference measurement procedures. prEN 12287 "In vitro diagnostic medical devices – Measurement of quantities in samples of biological origin – Description of reference materials" specifies requirements of importance to the calibration and quality assurance of reference measurement procedures.

Annexes A and B are for information only.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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Introduction

Reference measurement systems are needed for producing useful and reliable results of measurement, whether in science, technology, or routine service so as to be comparable and ultimately traceable to measurement standards 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 characteristics of measuring systems – comprising measuring instruments, auxiliary equipment as well as reagents,

– in demonstrating the functional interchangeability of different routine measurement procedures purporting to measure the same quantity,

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

– in detecting analytical influence quantities in patient samples.

For clinical laboratory measurements, in particular, it is vitally important to acute and continuous patient care that the 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 values are to be stated by the supplier;

– 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.

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1 Scope

This European Standard specifies requirements for the drafting of a reference measurement procedure.

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

This European Standard is applicable to 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.

2 Normative references

This European Standard incorporates by dated or undated reference provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to, or revisions of, any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN ISO 3696 Water for analytical laboratory use – Specification and test methods (ISO 3696 : 1987)

ISO 6353-2 Reagents for chemical analysis – Part 2: Specifications – First series

ISO 6353-3 Reagents for chemical analysis – Part 3: Specifications – Second series

ISO/IEC Directives – Part 2 : 1992 Methodology for the development of International Standards

International Vocabulary of Basic and General Terms in Metrology (VIM), 2nd edition, Geneva: ISO, 1993 [1] [2]

Guide to the Expression of Uncertainty in Measurement, 1st edition, Geneva: ISO, 1993 [1]

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3 Definitions

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For the purposes of this European Standard, the definitions given in "International Vocabulary of Basic and General Terms in Metrology" and in "Guide to the Expression of Uncertainty in Measurement" apply together with the following:

3.1 primary sample: Collection of one or more parts initially taken from a system and intended to provide information about the system or to serve as a basis for a decision about the system.

NOTE: In some cases, the information provided also applies to a larger system or a set of systems of which the sampled system is an element.

3.2 laboratory sample: Primary sample or a subsample of it as prepared for sending to or as received by the laboratory and intended for measurement.

3.3 analytical sample: Sample prepared from the laboratory sample and from which analytical portions may be taken.

NOTE: The analytical sample can be subjected to various treatments before an analytical portion is taken.

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[1]) This document has been prepared by a joint working group consisting of experts appointed by:

BIPM	International Bureau of Weights and Measures
IEC	International Electrotechnical Commission
IFCC	International Federation of Clinical Chemistry and Laboratory Medicine
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
IUPAP	International Union of Pure and Applied Physics
OIML	International Organization of Legal Metrology.

[2]) The abbreviation VIM is used in this standard.

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3.4 analytical portion: Portion of material taken from the analytical sample and on which the measurement or observation is actually carried out.

NOTE: The analytical portion is taken directly from the primary sample or laboratory sample if no preparation of these is required. The analytical portion sometimes is dissolved to give an analytical solution before being exposed to the measuring device.

3.5 analytical solution: Solution prepared by dissolving, with or without reaction, an analytical portion in a gas, liquid, or solid.

3.6 matrix (of a material system): All components of a material system, except the analyte.

3.7 reference measurement procedure: Thoroughly investigated measurement procedure shown to yield values having an uncertainty of measurement commensurate with its intended use, especially in assessing the trueness of other measurement procedures for the same quantity and in characterizing reference materials.

3.8 analytical specificity: Ability of a measurement procedure to determine solely the measurable quantity it purports to measure.

3.9 analytical interference: Systematic error of measurement caused by an influence quantity which does not by itself produce a signal in the measuring system, but which causes an enhancement or depression of the value indicated.

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3.10 influence quantity: Quantity that is not the measurand but that affects the result of the measurement. [2.7 of VIM]

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3.11 measurand: Particular quantity subject to measurement. [2.6 of VIM]

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4 Presentation of a reference measurement procedure

4.1 Elements of a written reference measurement procedure

The presentation of a reference measurement procedure shall comprise at least the elements listed as mandatory (M) in table 1. The order of the elements listed in table 1 may be changed and additional elements, such as an abstract, etc. may be added as appropriate.

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Table 1: Elements of the presentation of a reference measurement procedure

Element	Type [1])		Subclause in this European Standard
	M	O	
Title page	I		
Contents list		I	
Foreword	I		
Warning and safety precautions	I		4.2
Introduction		I	4.3
Title	N		
Scope	N		4.4
Normative references	N		
Definitions		N	
Symbols and abbreviations		N	
Terminology		N	4.5
Principle and method of measurement	N		4.6
Check list		N	4.7
Reagents	N		4.8
Apparatus	N		4.9
Sampling and sample	N		4.10
Preparation of measuring system and analytical portion	N		4.11
Operation of measuring system	N		4.12
Data processing	N		4.13
Analytical reliability	N		4.14
Special cases	N		4.15
Validation by inter-laboratory studies	N		4.16
Reporting	N		4.17
Quality assurance		I	4.18
Bibliography (Annex)		I	4.19
Dates of authorization and revision	I		4.20

[1]) Symbols for type of element in a European Standard:
M mandatory, O optional; I informative, N normative.

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4.2 Warning and safety precautions

4.2.1 Attention shall be drawn to any danger associated with a type of sample, reagent, equipment or activity, and all necessary precautions shall be described, including precautions for disposal. Regional, national, and local legislation and regulations may apply.

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4.2.2 This information shall be printed in capital letters or in bold type as follows:

a) immediately after the title of the European Standard if the danger to be encountered is due to the product being analysed, e. g. native material of biological origin;

b) in the description of the reagents, after the name of the reagent or material if the danger to be encountered is due to a particular reagent or material, e. g. a carcinogen, a radioactive material;

c) as a cautionary statement in the first clause of the practical reference measurement procedure, e. g. for a measurement using flammable gas.

Warning notes and safety precautions shall be unnumbered.

NOTE: The source text presenting the dangers to health should be quoted where appropriate.

4.3 Introduction

The introduction shall comprise the following items, as appropriate, in any order:

a) the nature of the quantity measured by the reference measurement procedure in terms of system, component, and kind-of-quantity;

b) a brief statement of its role in health care, if appropriate;

c) method of measurement and rationale for its choice;

d) place in a hierarchy of measurement procedures and traceability;

4.4 Scope

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The scope shall define the subject and aspect(s) covered, indicating any known limits of applicability. This element shall not contain requirements.

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NOTE: The scope could include the following items:

a) types of sample material to which the reference measurement procedure applies and whether limitations exist;

b) limits for values of quantities that can be measured by the reference measurement procedure and which can depend on other components;

c) interfering components – such as drugs, metabolites, additives, microbial growth – or other interfering factors;

d) mention of allowable modifications to the basic reference measurement procedure, e. g. as necessary to eliminate an unusual and identifiable interference (details of modified procedure to be given in a separate clause "Special cases" (see 4.15));

e) objectives of measurement for which the reference measurement procedure is suited.

4.5 Terminology

4.5.1 Concepts

If appropriate, this clause shall describe all elements essential for the understanding of the reference measurement procedure.

NOTE 1: This can include, for example

a) a system of related concepts, e. g. isoenzymes of lactate dehydrogenase according to electrophoretic mobility;

b) a term that may be used with special meaning, unfamiliar to some potential readers, e. g. "quantity" for "property" or "amount of substance" for the base kind-of-quantity with the unit mole;

c) a current term that may not be used for a given reason, e. g. "parts per million (ppm)" is avoided in favour of "mass fraction, in milligram per kilogram" or "volume fraction, in cubic centimetre per cubic metre (or microlitre per litre)" (see also 4.8.4).

NOTE 2: The clause "Terminology" is complementary to the clause "Definitions" and sometimes also to the clause "Symbols and abbreviations" (see table 1), and the terms are often incorporated in either or distributed between both.

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4.5.2 Nomenclature

The names of chemical compounds, biological components, quantities, units and symbols used shall be in accordance with European or International Standards, if available, or the latest recommendations of the appropriate international organization(s) (see [20]. When more than one name is recommended by authoritative sources, a single name may be chosen. The chosen name and synonyms shall be listed with the relevant standard or recommending organization.

4.5.3 Trivial names

If a trivial name of a reagent is used it shall be given in parentheses following the systematic name the first time the systematic name appears in the text.

4.6 Principle and method of measurement

4.6.1 The principle of measurement shall be given in the reference measurement procedure, e. g. molecular absorption of visible light applied in a procedure for measuring the concentration of bilirubins in a liquid solution.

4.6.2 The method of measurement shall be described. If appropriate, the reasons for the choice of a certain step shall be given. Essential reactions shall be indicated if they help in understanding the text or the calculations. The reactions shall, if appropriate, be expressed in ionic form.

4.7 Check-list

4.7.1 Appropriateness

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If included, the check-list shall list the items and conditions that are required to perform the measurements.

NOTE: A check-list is especially useful if the document is large. It is particularly applicable to reagents (see 4.8) and to apparatus (see 4.9). The full descriptions and instructions for preparation of reagents would be given later in the text or as an annex.

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4.7.2 Reagents

If reagents are incorporated in the check-list, they shall be listed by systematic or trivial name.

NOTE: This clause should be drawn up in the following systematic order:

a) products (excluding solutions) used in their commercially available form;

b) solutions, suspensions, or powders (excluding reference materials) with their approximate concentrations stated;

c) calibration materials such as solutions with defined concentrations;

d) indicators;

e) solvents (water, organic solvents);

f) control materials.

4.7.3 Apparatus

The main pieces of apparatus shall be listed, together with their type and any particular requirements such as officially calibrated instruments (e. g. balances and volumetric devices).

4.7.4 Auxiliary equipment

Other items of apparatus, not listed in accordance with 4.7.3, shall be listed, together with their type and other appropriate information such as material, grade, calibration, size and any other particular performance requirements.

4.7.5 Special laboratory requirements

Any physical, environmental, and safety requirements, necessary to the measurement, shall be fully defined.

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