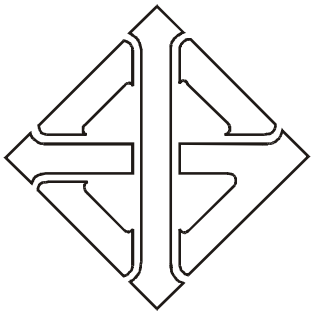

มาตรฐานผลิตภัณฑ์อุตสาหกรรม

THAI INDUSTRIAL STANDARD

มอก. 2277 – 2549

ISO 15195 : 2003

ห้องปฏิบัติการทางการแพทย์ – ข้อกำหนดสำหรับห้องปฏิบัติการที่ทำการวัดค่ามาตรฐานอ้างอิง

LABORATORY MEDICINE - REQUIREMENTS FOR REFERENCE MEASUREMENT LABORATORIES

สำนักงานมาตรฐานผลิตภัณฑ์อุตสาหกรรม

กระทรวงอุตสาหกรรม

ICS 11.100

ISBN 974-1508-43-3

มาตรฐานผลิตภัณฑ์อุตสาหกรรม

ห้องปฏิบัติการทางการแพทย์ – ข้อกำหนดสำหรับห้องปฏิบัติการที่ทำการวัดค่ามาตรฐานอ้างอิง

มอก. 2277 – 2549

สำนักงานมาตรฐานผลิตภัณฑ์อุตสาหกรรม
กระทรวงอุตสาหกรรม ถนนพระรามที่ 6 กรุงเทพฯ 10400
โทรศัพท์ 0 2202 3300

ประกาศในราชกิจจานุเบกษา ฉบับประกาศและงานทั่วไป เล่ม 123 ตอนที่ 83 ง
วันที่ 24 สิงหาคม พุทธศักราช 2549

เนื่องจาก ห้องปฏิบัติการทางการแพทย์ที่ทำการวัดค่ามาตรฐานอ้างอิง ต้องปฏิบัติตามขั้นตอนการทดสอบที่สามารถอ้างอิงได้ และ เสนอผลการวัดที่แม่นยำ และสามารถทวนสอบไปยังวัสดุอ้างอิง (reference material) ระดับชาติหรือระดับสากล ดังนั้นเพื่อให้บรรลุวัตถุประสงค์ดังกล่าวข้างต้นโดยไม่ต้องคำนึงถึงสถานที่และเวลาที่ทำการทดสอบ จึงกำหนดมาตรฐานผลิตภัณฑ์อุตสาหกรรม ห้องปฏิบัติการทางการแพทย์ – ข้อกำหนดสำหรับห้องปฏิบัติการที่ทำการวัดค่ามาตรฐานอ้างอิง ขึ้น

มาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้กำหนดขึ้นโดยรับ ISO 15195 : 2003 Laboratory medicine – Requirements for reference measurement laboratories มาใช้ในระดับเหมือนกันทุกประการ (identical) โดยใช้ ISO ฉบับภาษาอังกฤษเป็นหลัก

มาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้กำหนดขึ้นเพื่อให้ทันกับความต้องการของผู้ใช้ และจักได้แปล เป็นภาษาไทยในโอกาสอันสมควร หากมีข้อสงสัยโปรดติดต่อสอบถามที่สำนักงานมาตรฐานผลิตภัณฑ์อุตสาหกรรม

คณะกรรมการมาตรฐานผลิตภัณฑ์อุตสาหกรรมได้พิจารณามาตรฐานนี้แล้ว เห็นสมควรเสนอรัฐมนตรีประกาศตามมาตรา 15 แห่งพระราชบัญญัติมาตรฐานผลิตภัณฑ์อุตสาหกรรม พ.ศ. 2511

ประกาศกระทรวงอุตสาหกรรม

ฉบับที่ 3496 (พ.ศ. 2549)

ออกตามความในพระราชบัญญัติมาตรฐานผลิตภัณฑ์อุตสาหกรรม

พ.ศ. 2511

เรื่อง กำหนดมาตรฐานผลิตภัณฑ์อุตสาหกรรม

ห้องปฏิบัติการทางการแพทย์–ข้อกำหนดสำหรับห้องปฏิบัติการ

ที่ทำการวัดค่ามาตรฐานอ้างอิง

อาศัยอำนาจตามความในมาตรา 15 แห่งพระราชบัญญัติมาตรฐานผลิตภัณฑ์อุตสาหกรรม พ.ศ. 2511 รัฐมนตรีว่าการกระทรวงอุตสาหกรรมออกประกาศกำหนดมาตรฐานผลิตภัณฑ์อุตสาหกรรม ห้องปฏิบัติการทางการแพทย์–ข้อกำหนดสำหรับห้องปฏิบัติการที่ทำการวัดค่ามาตรฐานอ้างอิง มาตรฐานเลขที่ มอก. 2277– 2549 ไว้ ดังมีรายการละเอียดต่อท้ายประกาศ นี้

ประกาศ ณ วันที่ 26 เมษายน พ.ศ. 2549

สุริยะ จึงรุ่งเรืองกิจ

รัฐมนตรีว่าการกระทรวงอุตสาหกรรม

มอก. 2277–2549
ISO 15195 : 2003

มาตรฐานผลิตภัณฑ์อุตสาหกรรม
ห้องปฏิบัติการทางการแพทย์ – ข้อกำหนดสำหรับห้องปฏิบัติการที่ทำการวัดค่ามาตรฐานอ้างอิง

บทนำ

มาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้กำหนดขึ้นโดยรับ ISO 15195 : 2003 Laboratory medicine – Requirements for reference measurement laboratories มาใช้ในระดับเหมือนกันทุกประการ (identical) โดยใช้ ISO ฉบับภาษาอังกฤษ เป็นหลัก

ขอบข่าย

มาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้ระบุข้อกำหนดสำหรับห้องปฏิบัติการทางการแพทย์ที่สามารถวัดค่าที่อ้างอิง โดยการแสดงผลความไม่แน่นอนของค่าที่วัดได้

เอกสารอ้างอิง

ISO 15193, In vitro diagnostic medical devices – Measurement of quantities in samples of biological origin – Presentation of reference measurement procedures

ISO 15194 : 2002, In vitro diagnostic medical devices – Measurement of quantities in samples of biological origin – Description of reference materials

ISO 17511, In vitro diagnostic medical devices – Measurement of quantities in biological samples – Metrological traceability of values assigned to calibrators and control materials

ISO 18153, In vitro diagnostic medical devices – Measurement of quantities in biological samples – Metrological traceability of assigned values for catalytic concentration of enzymes in calibrators and control materials

International vocabulary of basic and general terms in metrology (VIM). BIPM, IEC, IFCC, ISO, IUPAC IUPAP and OIML, (1993)

Guide to the expression of uncertainty in measurement (GUM). BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML, (1993)

หมายเหตุ *เอกสารอ้างอิงข้างต้นที่ไม่ระบุปีที่ประกาศใช้ ให้ใช้เอกสารฉบับล่าสุดในการอ้างอิง และให้ใช้เฉพาะฉบับที่ระบุไว้ในมาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้เท่านั้นในกรณีที่ระบุปีที่ประกาศใช้*

คำศัพท์และบทนิยาม

รายละเอียดให้เป็นไปตามมาตรฐาน ISO 15195 : 2003 ข้อ 3

ข้อกำหนดระบบการบริหารจัดการ

รายละเอียดให้เป็นไปตามมาตรฐาน ISO 15195 : 2003 ข้อ 4

ข้อกำหนดด้านวิชาการ

รายละเอียดให้เป็นไปตามมาตรฐาน ISO 15195 : 2003 ข้อ 5

Laboratory medicine — Requirements for reference measurement laboratories

1 Scope

This International Standard gives the specific requirements for reference measurement laboratories in laboratory medicine. Examinations of properties with results reported on a nominal or ordinal scale are not included.

This International Standard is not applicable to routine medical laboratories.

NOTE 1 It is the laboratory's responsibility to comply with the relevant legal health and safety requirements.

NOTE 2 Requirements for routine medical laboratories are specified in ISO 15189.

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.

ISO 15193*, In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Presentation of reference measurement procedures*

ISO 15194:2002, *In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Description of reference materials*

ISO 17511, *In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values assigned to calibrators and control materials*

ISO 18153, *In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of assigned values for catalytic concentration of enzymes in calibrators and control materials*

International vocabulary of basic and general terms in metrology (VIM). BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML, 1993[1)]

Guide to the expression of uncertainty in measurement (GUM). BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML,1993[1)]

---

1) This vocabulary has been prepared simultaneously in English and French 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

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 (VIM)* and the following apply.

3.1
accuracy of measurement
closeness of the agreement between the result of a measurement and a true value of the measurand

[VIM:1993, 3.5]

NOTE 1 According to ISO 5725-1, accuracy of measurement is related to both trueness of measurement and precision of measurement.

NOTE 2 Accuracy cannot be given a numerical value in terms of the measurand, only descriptions such as “sufficient” or “insufficient” for a stated purpose.

NOTE 3 An estimate of an inverse measure of accuracy is “deviation”, defined as “value minus a conventional true value”.

NOTE 4 Instead of “a true value” in the definition above, ISO 3534-1 uses the concept “the accepted reference value”, which can be a theoretical (true), assigned, consensus, or procedure-defined value.

NOTE 5 In this International Standard the concept “accuracy of measurement” is related to both **trueness of measurement** (3.10) and **precision of measurement** (3.4) whereas the EU Directive on *in vitro* diagnostic medical devices uses the term “accuracy” instead of “trueness”.

3.2
certified reference material
CRM
reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes its traceability to an accurate realization of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence

[VIM:1993, 6.14]

3.3
measurable quantity
attribute of a phenomenon, body, or substance that may be distinguished qualitatively and determined quantitatively

[VIM:1993, 1.1]

3.4
precision of measurement
closeness of agreement between independent results of measurement obtained under stipulated conditions

NOTE 1 Adapted from ISO 3534-1:1993, 3.14.

NOTE 2 “Precision of measurement” is a qualitative concept.

NOTE 3 The degree of precision is usually expressed numerically by statistical measures of imprecision of measurement such as “standard deviation” and “coefficient of variation” that are inversely related to precision.

NOTE 4 “Precision” of a given measurement procedure is subdivided according to the specified precision conditions. “Repeatability” relates to essentially unchanged conditions and is often termed “within-series precision” or “within-run precision.” “Intermediate precision” refers to conditions where there is variation in one or more of the factors time, calibration, operator, and equipment — usually within a laboratory. “Reproducibility” relates to change in conditions, i.e., different laboratories, operators, and measuring systems (including different calibrations and reagent batches) and is often termed “interlaboratory precision”.

NOTE 5 The definition used in this International Standard is consistent with related ISO standards. The definition for precision of measurement as stated in ISO 3534-1:1993, 3.14, reads as follows: closeness of agreement between independent test results obtained under stipulated conditions.

3.5
reference material
material or substance, one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of a measuring system, the assessment of a measurement procedure, or for assigning values to materials

[VIM:1993, 6.13; ISO Guide 30:1992, 2.1]

3.6
reference measurement laboratory
laboratory that performs a reference measurement procedure and provides results with stated uncertainties

NOTE ISO/IEC 17025 uses the term “calibration laboratory”.

3.7
reference measurement procedure
thoroughly investigated measurement procedure shown to have an uncertainty of measurement commensurate with the intended use, especially in assessing the trueness of other measurement procedures for the same quantity and in characterizing reference materials

NOTE 1 Adapted from ISO 15193.

NOTE 2 When several reference measurement procedures exist for a given measurable quantity, it can be possible to arrange them in a hierarchy according to size of uncertainty of measurement. A primary reference measurement procedure is sometimes termed a “definitive method of measurement”, but not by VIM:1993.

NOTE 3 The Consultative Committee on Amount of Substance (CCQM) of BIPM has defined a “primary method of measurement” as a method having the highest metrological qualities, whose operation can be completely described and understood, for which a complete uncertainty statement can be written down in terms of SI units, and whose results are, therefore, accepted without reference to a standard of the quantity being measured. For amount of substance, the following principles of measurement were identified as suitable for primary measurement procedures: isotope dilution-mass spectrometry, coulometry, gravimetry, titrimetry, and determination of colligative properties such as freezing point depression. BIPM, Comité Consultatif pour la Quantité de Matière, 1995.

NOTE 4 The Analytical Chemistry Division of IUPAC describes an allied concept, “absolute method”, wherein calculations are based on universal quantities and fundamental physical constants only.

3.8
traceability
property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or International Standards, through an unbroken chain of comparisons all having stated uncertainties

[VIM:1993, 6.10]

3.9
true value of a quantity
value consistent with the definition of a given particular quantity

NOTE 1 This is a value that would be obtained by a perfect measurement.

NOTE 2 True values are by nature indeterminate.

NOTE 3 The indefinite article “a,” rather than the definite article “the,” is used in conjunction with a “true value” because there may be many values consistent with the definition of a given particular quantity.

[VIM:1993, 1.19]

NOTE 4 ISO 3534-1:1993 instead of “a true value,” uses the concept “the accepted reference value,” which can be a theoretical (true), assigned, consensus, or procedure-defined value.

3.10
trueness of measurement
closeness of agreement between the average value obtained from a large series of results of measurements and a true value

NOTE 1 Adapted from ISO 3534-1:1993, 3.12.

NOTE 2 “Trueness of measurement” is a qualitative concept.

NOTE 3 The degree of trueness is usually expressed numerically by the statistical measure “bias” that is Inversely related to trueness.

3.11
uncertainty of measurement
parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand

[VIM:1993, 3.9, GUM:1993, B.2.18]

NOTE 1 The parameter may be, for example, a standard deviation (or a given multiple of it), or the half-width of an interval having a stated level of confidence.

NOTE 2 “Uncertainty of measurement” comprises, in general, many components. Some of these components may be evaluated from the statistical distribution of the results of series of measurements and can be characterized by “experimental standard deviations”. The other components, which can also be characterized by standard deviations, are evaluated from assumed probability distributions based on experience or other information.

NOTE 3 It is understood that the result of the measurement is the best estimate of the value of the measurand, and that all components of uncertainty, including those arising from systematic effects, such as components associated with corrections and reference standards, contribute to the dispersion.

3.12
validation
confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

[ISO 9000:2000, 3.8.5]

3.13
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

[ISO 9000:2000, 3.8.4]

4 Management system requirements

4.1 Organization and management

The laboratory shall be organized and operated so that its independence of judgement and its integrity shall not be influenced by commercial, financial, or other conflicts of interest.

The laboratory management shall specify the responsibility, authority, and interrelation of all personnel who manage, perform, review and approve work affecting the quality of reference measurements.

The management of the laboratory shall designate a quality manager and nominate a deputy to serve in his or her absence.

4.2 Quality management system

The laboratory shall establish and maintain a quality management system documented in a quality manual. This shall describe the objectives, the quality policies, and quality control programmes which enable the laboratory to assure the quality of its reference measurement results with the stated level of uncertainty of measurement according to the *Guide to the expression of uncertainty in measurement* (GUM).

The contents of the quality manual shall be available to and implemented by the personnel of the laboratory as appropriate.

The quality management system shall consist of the following elements documented in the quality manual:

a) an introduction;

b) a description of the legal identity of the laboratory;

c) a quality policy;

d) an organizational chart, identifying the laboratory within the organization;

e) a description of the within-laboratory organization and distribution of responsibilities of the director and the staff of the laboratory;

f) a description of the premises, services and any environmental control of the laboratory;

g) all safety requirements;

h) a listing of reference materials used;

i) a description of the major equipment of the laboratory and its maintenance and validation procedures;

j) a listing of the quantities for which the laboratory offers reference measurements;

k) documentation in accordance with the requirements of ISO 15193 of reference measurement procedures applied by the laboratory;

l) a description of the internal quality control and external quality assessment procedures;

m) a statement of the metrological services provided by the laboratory;

n) policies and procedures to avoid involvement in any activities that might diminish confidence in its competence, impartiality, judgement, or operational integrity;

o) procedures to be followed for feedback, corrective action, and reporting whenever non-conformity or error is detected;

p) policies and procedures for addressing deviations from approved measurement procedures;

q) procedures for dealing with complaints and for recording resulting actions;

r) procedures for protecting the confidentiality and proprietary rights of a customer;

s) procedures for internal audit and review;

t) a procedure for control and maintenance of documentation;

u) compliance with requirements of regulatory authorities;

v) a statement concerning any accreditation status and accrediting body;

w) a procedure to be followed for signature of certificates.

4.3 Personnel

The management of a reference measurement laboratory is responsible for defining and providing a documented list of general and specified skills and training requirements for the laboratory personnel.

The personnel shall have appropriate theoretical background and adequate practical experience in the relevant field of reference measurement technology.

The director and any deputy director of a reference measurement laboratory shall have relevant academic education, training and adequate experience to be able to ensure that reference procedures are performed correctly.

The laboratory staff shall include well-trained personnel knowledgeable in the policies and practices of the laboratory as well as in the technical equipment, materials necessary to provide metrological traceability and statements of uncertainty, and in all relevant calibration and quality control procedures.

The personnel of the laboratory should be assessed by an accrediting body or national metrology institute, i.e. in terms of their education, training, experience and ability to perform measurements.

Personnel shall only carry out measurements when properly trained according to documented training procedures and when recognized by the laboratory management are competent to perform the reference measurement procedure; the only exception being for training purposes or under direct supervision.

The laboratory management shall ensure that the training of the personnel is kept up-to-date.

The laboratory shall maintain records of the professional qualifications and training of all technical personnel.

4.4 Measurement documentation and records

The reference measurement laboratory shall establish and maintain a documentation system containing the quality manual, all relevant safety regulations, as well as descriptions of reference measurement and calibration procedures. All documents shall be approved by the laboratory management and shall be readily available to the staff of the laboratory. All documents shall be uniquely identified and periodically reviewed according to an established scheme and revised if necessary.

Entries in laboratory notebooks and worksheets shall be in a durable and retrievable form and signed by the analyst or otherwise identified by the name or code of the analyst. They shall contain the date of measurement, the analyst, quantity, sample identification, specific observations before and during measurements, quality control data, primary data (e.g. absorbance readings, peak areas or heights, isotope ratios) and calculations of results. Incorrect entries shall be corrected (but still be legible), signed or otherwise identified and dated by the person making the correction. Records shall be stored and retained in a written document or on electronic media in a durable and readily retrievable form for a period of time as specified by regulatory authorities or by the customer.

An audit procedure shall be established to allow identification of factors affecting uncertainty of the results.

4.5 Contracting

Each request from a customer for assigning a reference measurement procedure value shall be checked by the laboratory management to ensure that the laboratory has the capability and resources to meet the requirements with respect to the agreed level of uncertainty and to perform the measurements within the agreed time, prior to signing a contract.

If subcontracting is necessary, the reference measurement laboratory as defined in this International Standard shall retain primary responsibility and shall ensure that the subcontractor is competent to perform the relevant work and complies at least with the requirements of this International Standard. The customer shall be informed about any subcontracting.

5 Technical requirements

5.1 Premises and environmental conditions

Laboratory facilities and environmental conditions shall be such as to enable correct performance of reference measurement procedures.

Effective separation between neighbouring areas in which incompatible activities take place shall be provided, e.g. to prevent cross-contamination.

Where appropriate, environmental conditions relevant for the magnitude of the measurement results and their uncertainties shall be controlled, monitored and documented in the records.

5.2 Handling of samples

The laboratory shall have a written procedure for the identification (including chain of custody where appropriate), registration and labelling of samples on which measurements have to be performed by the reference measurement laboratory and for any subsampling procedures.

In order to avoid deterioration or damage to the samples during transport for which the reference measurement laboratory is responsible, documented procedures and appropriate storage facilities shall be available.

5.3 Equipment

The laboratory shall be equipped with all items of equipment required for the correct performance of its listed reference measurement procedures. All equipment relevant to the measurements concerned shall be capable of achieving the accuracy required.

When processed signals (e.g. by built-in microprocessors) are used, calibration and transformation functions should be known, verified and validated either by the manufacturer or independently (see Reference [13]).

All equipment used in the reference measurement procedure shall be regularly inspected and maintained by authorized personnel. A program for calibration and verification of the functioning of the equipment shall be established. Relevant environmental conditions shall be maintained. Equipment operation manuals shall be kept up-to-date and readily available. Each item shall be uniquely identified. The use and maintenance of each major item of equipment shall be recorded in a log that contains:

— the type of measurement, control, or maintenance procedure performed;

— the status of calibration and verification;

— the date of measurement or maintenance;

— the operator who performed measurement or maintenance;

— reasons for maintenance (prevention, or malfunction repair);

— where relevant, specific operating conditions;

— unusual observations which shall require investigations where necessary.

A warning notice shall be affixed on equipment if it is not to be used (e.g. intended for disposal or for repair).

For the basic quantities such as mass, volume, and temperature, the laboratories shall have either calibrated devices available or shall calibrate the balances and volumetric equipment themselves. The calibration of each item shall be linked to the national standard (realization of the SI unit) held by a national metrology institute. Calibrations shall be performed within the required levels of uncertainty of measurement and recorded.

When the uncertainty of weighing of reference materials or other items necessary for calibration is a significant element in the combined uncertainty, corrections for the lift of the materials in the air according to their density relative to that of the test weight pieces (correction for the buoyancy) should be applied when this is relevant for the result or its uncertainty. Temperature, atmospheric pressure and humidity should be taken into account, as relevant.

Special care should be taken in calibrating volumetric equipment by weighing corresponding amounts of water or other appropriate liquids, taking into account the liquid's density at the relevant temperature and atmospheric pressure. For the weighing procedure, calibrated balances and weight pieces should be used.

For the accurate sampling of small volumes, it is recommended to use positive displacement volumetric equipment and calibration of the pipetted volume by a gravimetric procedure.

5.4 Reference materials

A reference measurement laboratory shall use appropriate reference materials.

The description of a reference material shall follow ISO 15194 as far as possible.

These materials should be internationally recognized and issued by national metrology institutes or international organizations.

A given reference material may be used either as calibration material or as a control material, but the same reference material should not be used for both purposes in a given situation in a particular laboratory.

The reference materials shall be adequately labelled and stored according to the instructions of the certificate.

Information on the shelf life of the reference materials shall be given in accordance with ISO 15194:2002, 5.9.4 and 5.11.2.

5.5 Reference measurement procedures

The reference measurement procedures are usually complex. They are generally developed and published by individual laboratories and approved by international professional scientific organizations or national metrology institutes, collaborating in the International Committee for Weights and Measures (CIPM). A procedure to be accepted as a reference measurement procedure shall be designed, described, and applied so that traceability of its results to a higher reference procedure or a higher reference material is achieved with the level of uncertainty of measurement as required.

The presentation of a reference measurement procedure shall follow ISO 15193.

Before reference measurements are offered to a customer, the laboratory shall demonstrate, for example, by accreditation, that it can properly operate the reference measurement procedure and that the equipment and reagents used are appropriate.

5.6 Metrological traceability — Uncertainty of measurement

Reference measurement laboratories shall demonstrate that their measurement results are traceable to a reference material or reference measurement procedure of highest available order by an unbroken chain of comparisons as specified in ISO 17511 and ISO 18153.

Measurements and calibrations shall be designed and operated in such a way as to ensure that the results are traceable where possible to the SI units (Système International d’Unités) of measurement. This may be achieved by the use of an appropriate primary reference material.

If traceability expressed in an SI unit cannot be attained, the traceability chain ends at a lower level of the metrological hierarchy.

Each reported measurement result shall be accompanied by an uncertainty statement estimated and expressed in accordance with the GUM.

5.7 Quality assurance

The analytical goals shall be defined in relation to the customer's needs and shall take into consideration that the metrological level is appropriate to enable the customer to fulfil medical requirements. The way of assessing conformity with quality control rules shall be documented. Internal quality control shall be performed by measuring a sufficient number of matrix control samples in each analytical series in order to provide sufficiently powerful control rules to fulfil the customer's requirements.

Preferably, certified reference materials with a matrix similar to the samples to be investigated should be used.

The measurement value obtained on the control material shall agree with its assigned value within the measurement capability claimed by the laboratory.

In order to supplement internal quality control, the laboratory shall regularly check its performance characteristics by taking part in appropriate interlaboratory comparisons for relevant types of quantity (preferably in a network of reference measurement laboratories) organized by national metrology institutes, accrediting bodies, or international scientific organizations.

5.8 Reporting results

5.8.1 Minimum requirements for reporting

The result of a reference measurement shall be issued in the form of a report or certificate. This shall contain at least the following elements:

a) the title of the document;

b) the name and address of the issuing organization;

c) the accrediting body, if appropriate;

d) the type and the source of material received;

e) the unique identification and the serial number(s) of material;

f) the number of subsamples investigated;

g) the name and the address of customer;

h) the order number;

i) the number of pages of the report or the certificate;

j) the date of the report or the certificate;

k) the measurement procedure applied;

EXAMPLE Accredited reference measurement procedure for the measurement of the amount-of-substance concentration of creatinine in human serum by isotope dilution-mass spectrometry.

l) the results of the individual measurements;

EXAMPLE Results from different series of measurement using separate calibration procedures.

m) the reported reference measurement value;

n) a statement on the traceability of the reported or the certified value;

o) an expression of uncertainty of measurement in accordance with the GUM;

p) any information on the geographical validity (national, regional) of the report or the certification document.

The document shall be signed only by authorized personnel and the director or his/her deputy of the reference measurement laboratory.

5.8.2 Optional elements

When appropriate or requested by the customer, the technical report or certificate shall contain the following:

a) any legal disclaimer;

b) interpretations of the results;

c) use of the values for calibration or for verification;

d) professional judgement of other uses of the results;

e) copyright restrictions;

f) a statement that the report or the certificate complies with this International Standard, i.e. ISO 15195, if applicable.

Annex A
(informative)

Cross-references to ISO/IEC 17025:1999

Table A.1 — Correspondence between this International Standard and ISO/IEC 17025:1999

Clause, subclause of this International Standard	Clause, subclause of ISO/IEC 17025:1999
1	1
2	2
3	3
4.1	4.1
4.2	4.2
4.3	4.1.5, 5.2
4.4	4.3
4.5	4.4, 4.5
5.1	5.3
5.2	5.8
5.3	5.5, 5.6.1, 5.6.2.1
5.4	5.6.3
5.5	5.4
5.6	5.4.6, 5.6
5.7	5.9
5.8	5.10

Bibliography

[1] ISO 3534-1:1993, *Statistics — Vocabulary and symbols — Part 1: Probability and general statistical terms*

[2] ISO 5725-1, *Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions*

[3] ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*

[4] ISO 15189:2003, *Medical laboratories — Particular requirements for quality and competence*

[5] ISO/IEC 17025:1999, *General requirements for the competence of testing and calibration laboratories*

[6] ISO Guide 30:1992, *Terms and definitions used in connection with reference materials*

[7] ISO/IEC Guide 58, *Calibration and testing laboratory accreditation systems — General requirements for operation and recognition*

[8] SIEKMANN, L., DOUMAS, B.T., THIENPONT, L. and SCHUMANN, G. Networks of reference laboratories. *Eur J Clin Chem Clin Biochem*, **33**, 1995, pp. 1013-1017

[9] BÜTTNER, J. The need for accuracy in laboratory medicine. *Eur J Clin Chem Clin Biochem*, **33**, 1995, pp 981-988

[10] DYBKAER, R. Vocabulary for use in measurement procedures and description of reference materials in laboratory medicine. *Eur J Clin Chem Clin Biochem*, **35**, 1997, pp. 141-173

[11] QUINN, T.J. Primary methods of measurement and primary standards. *Metrologia*, **34**, 1997, pp. 61-65

[12] THIENPONT, L., FRANZINI, C., KRATOCHVILA, J., MIDDLE, J., RICOS, C., SIEKMANN, L., STÖCKL, D. Analytical quality specifications for reference methods and operating specifications for networks of reference laboratories. *Eur J Clin Chem Clin Biochem*, **33**, 1995, pp. 949-957

[13] WICHMANN, BA. *Measurement system: Validation of measurement software. Best practice guide No. 1*. National Physical Laboratory, April 2000