QUALITY MANUAL: MODEL ACCORDING EC4 ESSENTIAL CRITERIA

1. GENERAL INFORMATION

1.2. DEFINITIONS AND ABBREVIATIONS
0. CONTENTS
1. INTRODUCTION
   1.1. SCOPE
   1.2. AIMS
   1.3. PUBLICATION CREDITS
   1.4. REFERENCES
   1.5. RELATED DOCUMENTS
   1.6. ABBREVIATIONS
   1.7. RELATED DEFINITIONS
2. ABBREVIATIONS
3. DEFINITIONS
1. INTRODUCTION

Used terms should be defined (2-4).
Abbreviations should be avoided, and if used, be explained (2-4).

1.1. SCOPE

All the Quality Manual

1.2. AIMS

To fulfil the following clauses:

<table>
<thead>
<tr>
<th>ISO 15189</th>
<th>ISO 9000: 2000</th>
<th>ISO 17025</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Terms and definitions</td>
<td>3. Terms and definitions</td>
<td></td>
</tr>
</tbody>
</table>

1.3. PUBLICATION CREDITS

EC4 WG

1.4. REFERENCES


1.5. RELATED DOCUMENTS
2. ABBREVIATIONS

2.1. SCIENTIFIC AND TECHNICAL ABBREVIATIONS

HPLC: High Performance Liquid Chromatography
GC: Gas Chromatography
GC/MS: Gas Chromatography / Mass Spectrometry
LIS: Laboratory Information System

2.2. INSTITUTION-SPECIFIC ABBREVIATIONS:

CC: Clinical Chemist
CLA: Collective Labour Agreement for Hospital Employees
CSC: Computer System Controller
GM: Group Manager
HHS&EM: Hygiene, Health, Safety and Environmental Management
HIS: Hospital Information System
HLDA: Haematological Laboratory Diagnostics Association
MERC: Medical Ethical Review Committee
MES: Medical Electronics Service
MO: Maintenance Officer
PAS: Program Access
PAU: Purchase Administrative Unit
QHS&E: Quality, Health, Safety and the Environment
QO: Quality Officer
SCC: Senior Clinical Chemist
SLA: Senior Laboratory Technician
TD: Technical Department
UCI: User Class Identification
VDU: Video Display Units

1.3. OTHER ABBREVIATIONS:

BAGA: Hazardous Wastes Designation Decree
BIG: Individual Health Care Professions Act
CBTS: Central Blood Transfusion Service Laboratory of the Dutch Red Cross
EQA: External Quality Assurance
GLP: Good Laboratory Practice
GMP: Good Manufacturing Practice
GPIS: General Practitioners Information System
HLT: Higher Laboratory Training
ILT: Intermediate Laboratory Training
IFCC: International Federation of Clinical Chemistry
IUPAC: International Union of Pure and Applied Chemistry
IVD: In Vitro Diagnostics
KNMG: Royal Netherlands Society for the Advancement of Medicine
LI: Labour Inspectorate
MAC: Maximum Acceptable Concentration
MCA: Multi-component Analysis, HLQAF section
NBAC: National Binding Analysis Committee
NVKC: Nederlandse Vereniging voor Klinische Association
PCCE: Postgraduate Clinical Chemistry Education
RIATL: Reference Institute for Anticoagulant Testing Laboratories
RI&E: Risk Inventory and Evaluation
RIVM: National Institute of Public Health and Environmental Protection
SOP: Standard Operating Procedure
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>VCL</td>
<td>Virtual Central Laboratory</td>
</tr>
<tr>
<td>WDC</td>
<td>Work Duration Curtailment</td>
</tr>
<tr>
<td>WGBO</td>
<td>Medical Treatment Contracts Act</td>
</tr>
<tr>
<td>WME</td>
<td>Medical Experimentation Act</td>
</tr>
</tbody>
</table>
3. DEFINITIONS

accuracy of measurement: closeness of the agreement between the result of a measurement and a true value of the measurand (9, definition 3.5). NOTE 1: The term accuracy is also applied to sets of results of measurements and to measurement procedures. NOTE 2: The concept accuracy of measurement is described by trueness of measurement and precision of measurement. Thus, accuracy is not a synonym for trueness or for precision. NOTE 3: The concept, accuracy, relates to a combination of systematic effects and random effects that contribute individual components of error of measurement. NOTE 4: Accuracy cannot be given a numerical value, but can be expressed on an ordinal scale such as (poor, fair, good). NOTE 5: (11, definition 3.4) substitutes the concept "true value" by "accepted reference value".

analyte: component indicated in the name of a measurable quantity (6, definition 4.4). NOTE 1: Analyte and component are different concepts from measurable quantity and measurand which furthermore require indication of system and kind-of-quantity. NOTE 2: The term analyte has also been used specifically for the component of a solution applied to the sensor of a measuring system and providing the output signal. This component may not be identical to that of the measurand.

analytically false negative result: result of a measurement below the limit of detection when the analyte under consideration is present in the sample at a concentration above the limit of detection. NOTE 1: Here, the adjective "negative" is not used in the mathematical sense. NOTE 2: A complementary concept is "analytically true positive result".

analytically false positive result: result of a measurement above the limit of detection when the analyte under consideration is present in the sample at a concentration below the limit of detection. NOTE 1: Here, the adjective "positive" is not used in the mathematical sense. NOTE 2: A complementary concept is "analytically true positive result".

analytical performance characteristic (merit (deprecated)): property in the set of properties that is necessary for assessing the reliability of a measurement procedure and its suitability for any given purpose and where each property can be given an experimentally determined value. EXAMPLES: Analytical sensitivity; repeatability standard deviation; limit of detection.; NOTE: An analytical performance characteristic is a measurable quantity.

analytical sample: sample prepared from the laboratory sample and from which analytical portions may be taken (6, definition 4.1 1). NOTE The analytical sample may be subjected to various treatments before an analytical portion is taken.

analytical specificity: A term which expresses qualitatively the extent to which other substances interfere with the determination of a substance according to a given procedure. Specific is considered to be the ultimate of selective, meaning that no interferences are supposed to occur (17).

analytical sensitivity: The slope of the calibration curve. If the curve is in fact a 'curve', rather than a straight line, then course sensitivity will be a function of analyte concentration or amount. If sensitivity is to be a unique performance characteristic (17).

applied medical research: see: clinical medical trials.

authorisation: final process of the analytical service where the qualified staff

bias of measurements (bias; inaccuracy (deprecated)) difference between the expectation of the results of measurement and a true value of the measurand.. NOTE 1: Bias of measurements is equal to the systematic error of measurement that may be composed of one or more systematic error components. Its value is unknown. NOTE 2: An estimator is the "sample bias of measurements" that is the difference between the average and a conventional true value (or accepted reference value. NOTE 3: ISO (11, definition 3.13) defines bias as the difference between the expectation of the results and an accepted reference value (the latter including true value, assigned value, certified value, consensus value, and (when such are not available) the expectation itself).

biological reference value: value of a measurand in an individual belonging to a defined reference sample group of individuals (6, definition 4.20). NOTE 1: Reference values may have to be classified according to factors of influence such as the diurnal variation, sex, race, or age of the population studied. When applicable, a distribution of values is expressed in term of reference limits (upper and lower). The source of material upon which they are based and the procedure for their determination should be documented. NOTE 2: A biological reference interval usually refers to the central 95-percentile of the distribution of reference values.

calibration: the set of operations which establish, under specified conditions, the relationship between values indicated by the analytical instrument and the corresponding known values of an analyte (17). See calibration material.

calibration material: a material of known composition or properties which can be presented to the analytical instrument for calibration purposes (17).

calibration sample: the test portion or test solution used for calibration of an analytical procedure. The calibration sample is normally of known weight or volume and is prepared according to specifications (17).
central 0.95 - interfractile interval: closed interval of values between the 0.025- and 0.975-fractiles of a set of values. NOTE: If the limits are derived from a sample of values, the employed type of non-parametric or parametric statistics should be indicated.

certification report: document giving detailed information, supplementary to that contained in a reference material certificate, e.g. the preparation of the material, methods of measurement, factors affecting accuracy of measurement, statistical treatment of results of measurements, and the way in which traceability was established (14, definition 4.3).

clinical chemist: member of the staff who has the responsibility for a definite area of the Clinical Chemistry Department.

clinical laboratory: a room or building (space) fitted out for scientific examinations (testing) of materials taken from patients for the purposes of diagnosis and treatment (6, definition 3.61). (See: medical laboratory).

clinical/medical trial protocol: written procedure which contains all the details about an experimental procedure.

clinical/medical trials: any experimental action or process undertaken to discover something not yet known or to demonstrate something known.

clinical specificity: proportion of non diseased individuals correctly identified by a diagnostic procedure from all the non diseased individuals.

clinical sensitivity: proportion of patients correctly identified by a diagnostic procedure from all the patients.

component: definable part of a system (6, definition 3.31). EXAMPLE: Glucose (in a portion of urine), process of coagulation (in a sample of blood).

computer systems controller: a member of the staff of the Clinical Chemistry Department, or from the Maintenance Department, who has the responsibility to maintain the laboratory hardware and software systems.

conformity: fulfilment by a product, process or service of specified requirements (13, definition 12.1).

control chart: chart, with upper and or lower control limits, on which values of some statistical measure for a series of samples or subgroups are plotted, usually in time or sample number order (11, definition 3.3.1). NOTE 1: The chart frequently shows a central line to assist detection of a trend of plotted values toward either control limit. NOTE 2: In some control charts, the control limits are based on the within-sample or within-subgroup data plotted on the chart; in others, the control limits are based on adopted measurement standard values or specified values applicable to the statistical measures plotted on the chart.

controlled copies: documents from the quality manual issued and validated by authorised persons.

corrected result of a measurement: result of a measurement after correction for systematic errors of measurement (8, definition 3.4).

correction: value added algebraically to the uncorrected result of a measurement to compensate for systematic error of measurement (8, definition 3.15). NOTE 1: The correction is equal to the negative of the estimated systematic error of measurement. NOTE 2: Some systematic errors may be estimated, and compensated for by applying appropriate corrections as specified in the measurement procedure. However, since the systematic error of measurement cannot be known completely, the compensation cannot be assuredly complete, and an element of uncertainty of measurement is introduced.

detection limit: the minimum single result which, with a stated probability, can be distinguished from a suitable blank value. The limit defines the point at which the analysis becomes possible and this may be different from the lower limit of the determinable analytical range (17). See relative detection limit.

document: a piece of written or printed matter that provides a record or evidence of events (6, definition 3.30).

durable goods: laboratory equipment such as machines, apparatus and inspection and measuring devices, as well as resources such as refrigerators, centrifuges, water baths, mixers, stoves and freeze-dryers.

Environmental Action Plan a plan setting out all measures necessary for the exercise of environmental management, including organisational matters, fulfilment of licence conditions, information and training activities, modification of internal procedures and test and control programmes.

error of measurement: result of a measurement minus a true value of the measurand (8, definition 3.10). NOTE 1: To obtain an estimate, a conventional true value of the measurand is substituted for an (unknown) true value. NOTE 2: Error of measurement in a result of a measurement is the sum of random error of measurement and systematic error of measurement. Each type of error may be the outcome of contributions from several sources. These two types cannot be separated unless sets of results are available; in that case, the systematic error may be estimated (see 6, definition 4.131). NOTE 3: The known parts of the systematic error of measurement may be compensated for by applying appropriate corrections or correction factors. NOTE 4: Modern descriptions of uncertainty of measurement avoid the concepts "sources of error" and the (unknown) "systematic error" and "random error"; the respective concepts "sources of uncertainty", "systematic effect" and "random effect" are preferred. The correction for a recognized systematic effect introduces an uncertainty as does the random effects.
examination: activity leading to a value on a nominal, ordinal, difference, or ratio scale. NOTE In some countries and disciplines (e.g. microbiology) examination is the total activity of a number of tests (6, definition 3.34).

examination procedure: set of operations, described specifically, used in the performance examinations according to a given method ( Cf. measurement procedure).

experimental testing: testing with methods or with purposes different to previously established in the standard operating procedures.

extent of risk: the number of people who might be exposed to the hazard and the consequences for them.

external quality assessment: see: laboratory proficiency testing.

hazard: something with the potential to do harm, for example, chemical substances, biological agents, equipment or methods of working (5).

hazardous waste: Materials defined as hazardous waste pursuant to the Environmental Management Act, which came into force on 1 January 1994. Such materials were previously referred to in the 1993 Chemical Waste Act as “chemical waste”; the change was made to bring Dutch legislation into line with international terminological usage. Section 1.1, subsection 1, of the Environmental Management Act provides for materials to be classed as hazardous waste by Order in Council.

imprecision of measurements: dispersion of independent results of measurements obtained under specified conditions. NOTE 1: Imprecision of measurements, when applied to sets of results of measurements, depends solely on the dispersion of random error of measurement and does not relate to a true value of the measurable quantity. NOTE 2: Imprecision is usually expressed numerically as the repeatability standard deviation, an intermediate precision standard deviation, or a reproducibility standard deviation of the results of measurements. NOTE 3: Imprecision can be expressed on an ordinal scale such as (small, medium, large); NOTE 4: Imprecision is the inverse of precision of measurements.

inaccuracy of measurement: discrepancy between the result of a measurement and a true value of a measurand. NOTE 1: Inaccuracy of measurement, when applied to sets of results, describes a combination of systematic effects and random effects that contribute individual components of error of measurement. NOTE 2: Inaccuracy is related to uncertainty of measurement. NOTE 3: Inaccuracy can be measured on an ordinal scale such as (small, medium, large). NOTE 4: Inaccuracy is the inverse of accuracy of measurement; the latter concept is preferred.

internal quality control: operational techniques and activities within a laboratory that are used to fulfil requirements for quality. NOTE 1: In the clinical laboratory, internal quality control is aimed both at monitoring a process to assess whether results of measurement are reliable enough to be released and at eliminating causes of unsatisfactory performance at relevant stages of the quality loop. NOTE 2: Internal quality control in the broad sense applies to all steps of activity for production of results of measurement, from assessing clinical needs, via collection of sample, and measurement of a measurable quantity to reporting of result.

interval: set of all values lying between and sometimes including one or both of the lower limiting value and higher limiting value. NOTE 1: If both limits are excluded, the interval is open; if both are included, it is closed. NOTE 2: The definition given corresponds to a statistical usage, e. g. confidence interval and statistical coverage interval. In general metrology, interval is also used to mean the difference between the higher and the lower limiting values, whereas the set is called "range", e. g. range of indication.

laboratory director: the person who governs the policy of a laboratory. NOTE A specific person may be director of a number of similar or dissimilar institutions (6, definition 3.50). (See: laboratory management).

laboratory specimen: material obtained from an individual with the purpose of assay its components or properties.

laboratory management: collective body of those persons who manage the activities of the laboratory headed by the laboratory director (6).

laboratory manager: a person who carries out the administration of a laboratory in accordance with a policy. NOTE The policy is usually prepared by the laboratory director in consultation with the laboratory manager (6, definition 3.50).

laboratory proficiency testing (external quality assessment): determination of laboratory measurement performance by means of inter-laboratory measurement comparisons (13, definition 12.6). NOTE 1: Here, this concept is distinguished from two other types of inter-laboratory study: method-performance study and material-certification study. NOTE 2: The term "external quality assessment" (EQA) is sometimes preferred if proficiency testing is thought to convey an unintended impression of an official regulatory function.

laboratory report: see report of measurement.

laboratory sample: primary sample or a subsample of it as prepared for sending to or as received by the laboratory and intended for measurement. NOTE: The laboratory specimen is the final material collected and the laboratory sample is initial material in the analytical phase.

laboratory supervisor: head of technicians, whose has responsibility in planning the day to day work.
DEFINITIONS

limit of detection (minimum detectable value; sensitivity (deprecated)): result of a measurement by a given measurement procedure for which the probability of an analytically false negative result is 0, given the probability or of an analytically false positive result. NOTE 1: IUPAC recommends default values for α and β equal to 0.05. NOTE 2: A value for the limit of detection cannot usually be derived from theory. NOTE 3: If the measurement indicates a value below the limit of detection, the numerical value may be stated as “zero or less than that of the limit of detection”, not as “zero”. NOTE 4: If the found value of a sample is above the limit of detection, but below the lower limit of determination, the analytical result can only be expressed as an inequality.

linearity: (linear range) concentration range over which the intensity of the signal obtained is directly proportional to the concentration of the species producing the signal (17).

lower limit of determination: minimum quantifiable value lowest result of a measurement, that can be obtained by a stated measurement procedure, and that can be given with a statement of uncertainty of measurement.

measurable quantity: (measurable property, quantity) attribute of a phenomenon, body, or substance that may be distinguished qualitatively and determined quantitatively (8, definition 1.1). NOTE 1 Phenomenon, body, or substance corresponds to the concept of system as used in clinical laboratory sciences. Qualitatively refers to the need to define a quantity before it can be measured. NOTE 2 Measurable quantity is described by three concepts, here called kind-of-quantity, component, and system. NOTE 3 “quantity” is often used as a short term.

measurand: particular quantity subject to measurement (8, definition 2.6). EXAMPLE Vapour pressure of a given sample of water at 20 °C. NOTE The specification of a measurand may require statements about other quantities such as time, temperature and pressure.

measurement set of operations having the object of determining a value of a measurable quantity (8, definition 2.1). NOTE: The terms method of measurement, measurement procedure, “test”, “assay”, measurable quantity, and result of measurement are not synonyms for measurement.

measurement procedure: set of operations, described specifically, used in the performance of measurements according to a given method of measurement (8, definition 2.5). NOTE 1: A measurement procedure is usually sufficiently detailed to enable an operator to carry out a measurement without significant additional information. NOTE 2: The terms “method of measurement”, “test”, “test method”, “assay”, measurable quantity, and measurement are not synonyms for measurement procedure. NOTE 3: Terms also used are “analytical protocol” and “standard operating procedure”.

measuring interval: (measuring range): closed interval of possible values allowed by a measurement procedure and delimited by the lower limit of determination and the higher limit of determination (6, definition 4.74).

Medical Ethical Review Committee: Institution body which has the responsibility to review, authorised and monitor experimental projects.

medical laboratory: (clinical laboratory) a facility- for the biological, -microbiological, serological, chemical, immunohaematological, haematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

merit: see: analytical performance characteristic.

method of measurement: logical sequence of operations, described generically, used in the performance of measurements (8, definition 2.4). NOTE: The terms “test”, “assay”, measurement procedure, measurable quantity, and measurement are not synonyms for method of measurement.

minimum detectable value: see: limit of detection, sensitivity (deprecated).

mistake (blunder): Unauthorized departure from the prescribed measurement procedure. NOTE: The mistake can take the form of an omission or an incorrect action and may be due to insufficient understanding, perception, interpretation, judgement, or attention. This is to be distinguished from error of measurement.

non-conformity: non-fulfilment of a specified requirement.

Outpatients’ Specimens Collection Unit: premises where specimens are obtained.

post-examination procedure: steps starting in chronological order from formatting and interpretation by the medical laboratory, reporting of result, storage of samples, transmission of the examination result, ending after the primary human sample has been discarded.

precision of measurements: closeness of agreement between independent results of measurements obtained under stipulated conditions (11, definition 3.14). NOTE 1: See imprecision, NOTES 1 and 4. NOTE 2: Precision is usually expressed numerically by statistical measures of imprecision of measurements, see imprecision, NOTE 2. NOTE 3: Precision of measurements cannot be given a numerical value, but can be expressed on an ordinal scale.
such as (low, medium, high). NOTE 4 Imprecision of measurements is the dispersion of independent results of measurement obtained under specified conditions. (6, definition 4.47).

**principle of measurement**
scientific basis of a measurement (8, definition 2.3). EXAMPLES: The thermoelectric effect applied to the measurement of temperature; the molecular light absorption applied to the measurement of amount-of-substance concentration.

**pre-examination procedure:** steps starting in chronological order from the clinicians' request, including the examination requisition, preparation of the primary sample, transportation to and within the laboratory and ending when the analytical examination procedure starts. NOTE: for histopathology, such procedures also include gross description and selection, tissue processing, freezing, cryostat sectioning, chemical fixation, decalcification, dehydration, embedding, and sectioning. For cytopathology, such procedures applied to cells include the preparation of imprints, mononuclear smears and blood smears, air drying, and/or chemical fixation.

**primary sample:** see: specimen, sample.

**production (batch)** batch definite amount of some commodity or service produced at one time under conditions that are presumed uniform (11, definition 1.3.4).

**qualification:** accomplishments and academic awards necessary to fit a person for a position or purpose (COD) (6, definition 3.78)

**quality:** totally of characteristics of an entity that bear on its ability to satisfy stated and implied needs. (12, definition 2.1) (6, definition 3.79)

**quality assurance:** all the planned and systematic activities implemented within the quality system, and demonstrated as needed, to provide adequate confidence that an entity will fulfil requirements for quality (12, definition 3.5). NOTE There may be both internal and external purposes for quality assurance: (a) internal quality control: within an organization, provides confidence to the laboratory management; (b) external quality assessment: in contractual or other situations provides confidence to the customers or others.

**quality manual:** set of documents describing the quality system of the Clinical Chemistry Department.

**quality officer:** the member of the staff in charge to establish and maintain the quality system on behalf of the laboratory management. The quality officer has the highest range in the laboratory, directly under the laboratory director.

**quality system:** organizational structure, procedures, processes, and resources needed to implement quality management. (12, definition 3.6) (6, definition 3.83).

**quantity:** short term of measurable quantity.

**reference measurement laboratory:** laboratory that performs reference measurement procedures and provides results with stated uncertainties (see: subcontractor)

**reference values:** see biological reference value

**referred laboratory** laboratory organization to which a sample is submitted for an examination procedure and report (see: subcontractor).

**relative detection limit:** (Often incorrectly referred to as sensitivity). Smallest amount of material detectable (3 s-criterion) in a matrix relative to the amount of material analysed — given in atomic, mole or weight fractions (17).

**repeatability** precision under circumstances which are as consistent as possible (same laboratory, laboratory technician, run, etc.). The standard deviation can be calculated from independent analysis results obtained using identical material or from independent duplicate analyses using different materials.

**repeatability conditions** conditions where independent results of measurement are obtained with the same measurement procedure on the same measurand by the same measuring system, used under the same conditions, at the same location over a short period of time.

**repeatability of results of measurements** closeness of the agreement between the results of successive measurements of the same measurand carried out under repeatability conditions (8, definition 3.6). NOTE: Repeatability of results of measurements can be measured on an ordinal scale such as (low, medium, high). It is inversely expressed in terms of the dispersion of the results of measurements, usually as the repeatability standard deviation.

**report of measurement:** document that presents the name of the measurand, and result of measurement, together with an expression of the uncertainty of measurement, the values of relevant influence quantities, information necessary for the identification of the sample, the requester, and the organisation or laboratory issuing the report, and sometimes interpretative remarks.

**reproducibility:** precision under variable circumstances. A statement of reproducibility must indicate the nature of the circumstances in question. EXAMPLE: different laboratories, days/weeks or laboratory technicians etc.
reproducibility of results of measurements: closeness of the agreement between the results of measurements of the same measurand carried out under the changed conditions of measurement that must be specified (8, definition 3.7). NOTE 1: A valid statement of reproducibility of results of measurements requires specification of the conditions changed. The changed conditions may include: principle of measurement, method of measurement, observer, measuring system, calibration material, location, conditions of use of measuring system, time (8, definition 3.7, NOTES 1 and 2). NOTE 2: In 16 definition 4.1.15 and 11, definition 3.21 the concept "reproducibility conditions" is defined with the principle and method of measurement kept constant. NOTE 3: Reproducibility of results of measurements can be measured on an ordinal scale such as (low, medium, high). It is inversely expressed in terms of the dispersion of the results of measurements, for example as the reproducibility standard deviation. NOTE 4: Results of measurements are here usually understood to be corrected results of measurements.

result of a measurement: value attributed to a measurand, obtained by measurement (8, definition 3.1). NOTE 1: When the term result of a measurement is used, it should be made clear whether it refers to (a) the uncorrected result of a measurement; (b) the corrected result of a measurement; (c) a single observation or an average of the values obtained by several observations. NOTE 2: A complete statement of the result of a measurement includes information about the uncertainty of measurement and about the values of relevant influence quantities.

risk: the likelihood that some harm can come from the particular hazard.

robustness: the property of a method which makes it not sensitive to so called noise.

safety officer: the member of the staff who has the responsibility to establish and maintain the health, safety and environment program.

sample: one or more parts taken from a system and intended to provide information on the system, often to serve as a basis for a decision on the system or its production (6, definition 4.11.4). EXAMPLES: A volume of serum taken from a larger volume of serum; a simple random subset of measured values of a measurable quantity taken from a set of such values. NOTE 1: The single part forming a cohesive entity and taken from one place and at one time is also called a "sampling unit" or an "item". NOTE 2: Unless otherwise specified, the sample is assumed to be representative of a "static system", that is a system having no appreciable change in relevant measurable quantities during the time of consideration. NOTE 3: When a "dynamic system" is concerned, as is often the case in the clinical laboratory sciences, the calendar time of sampling is a mandatory item of specification to the system of interest. Such a special type of sample has been called a "specimen", but this term is not used here. The term specimen has also been used in laboratory medicine as a synonym for a sample, as defined here, of biological origin, or for an entire macroscopic parasite. NOTE 4: The system from which a sample is taken may not be of the same type as that of the measurand. EXAMPLE: A given blood sample may serve for measurement of pH in plasma and haemoglobin concentration) in erythrocytes. NOTE 5: The definition given above covers a sample from any type of system. ISO gives two definitions that apply more to data and materials respectively. (a) sample: One or more sampling units taken from a population and intended to provide information on the population; (b) sample: Representative quantity of material extracted from a batch of reference material. NOTE 6: In some countries the term specimen is used for primary sample (or a subsample of it) which is the sample prepared for sending to or as received by the laboratory and intended for measurement (6, definition 4.95).

sampling: process of drawing or constituting a sample (11, definition 2.1.2).

sampling procedure: operational requirements and or instructions relating to the use of a particular sampling plan, that is the planned procedure of selection, withdrawal, and preparation of one or more samples from an inspection lot to yield knowledge of the characteristic(s) of the lot (11, definition 2.3.2). NOTE: In laboratory medicine, the "inspection lot" usually is a person.

sensitivity: (deprecated), see: limit of detection (minimum detectable value).

specimen: in some countries the term specimen is used for primary sample (6, definition 4.95).

standard operating procedures: documents from the quality manual describing the details of an analytical, instrumental or administrative procedure.

subcontractor: laboratories to which specialised or infrequently requested assays are sent (see reference measurement laboratory, referral laboratory). reference measurement laboratory system: demarcated part or phenomenon of the perceivable or conceivable universe, material or immaterial, that may be regarded as a set of elements and a set of relationships between these elements (6, definition 4.130).

test: technical operation that consists of the determination of one or more characteristics of a given product, process or service according to a specific procedure (13, definition 13.1). NOTE In medical laboratories this is usually part of an examination (see: examination) (6, definition 3.92).

turnaround time: interval between collection of the primary sample either by laboratory personnel or receipt from an external source and the reporting of results to the requesting health care provider (time from sample to report) or interval between receipt of the request and the reporting of results to the requesting health care provider (time from request to report).

traceability A property possessed by a test result or measured value of a standard which can be related to a fixed reference by an uninterrupted series of equations whose uncertainty is known.
**user:** the clinician or other health care worker who requests examination of a sample by a medical laboratory.

**validation:** confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled (12, definition 2.18).

**variation coefficient:** [percent] expression of dispersion statistical parameter, consisting of the standard deviation divided by the mean, times 100.

**verification:** confirmation by examination and provision of objective evidence that specified requirement have been fulfilled (12, definition 2.18).