#### **IUPAC Recommendations**

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# Vocabulary on nominal property, examination, and related concepts for clinical laboratory sciences (IFCC-IUPAC Recommendations 2017)

https://doi.org/10.1515/pac-2011-0613 Received June 29, 2011; accepted September 6, 2017

**Abstract:** Scientists of disciplines in clinical laboratory sciences have long worked on a common language for efficient and safe request of investigations, report of results, and communication of experience and scientific achievements. Widening the scope, most scientific disciplines, not only clinical laboratory sciences, rely to some extent on various examinations in addition to measurements. The 'International vocabulary of metrology – Basic and general concepts and associated terms' (VIM), is designed for metrology, the science of measurement. The aim of this vocabulary is to suggest definitions and explanations of concepts and a selection of terms related to nominal properties, *i.e.* properties that have no size.

**Keywords:** concept; examination; kind-of-nominal-property; nominal property; term; vocabulary.

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Article note: This document was prepared in the frame of IUPAC Project # 2004-023-1-700, extended 2008-019-1-700.

Supplementary information available online: In the online version of this article, located at https://doi.org/10.1515/pac-2011-0613, hyperlinks connect related terms and entries, allowing for direct navigation between them.

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## 1 Introduction

In a world of increased communication of examination results mediated by information technology, there is a need for a common vocabulary.

The International vocabulary of metrology – Basic and general concepts and associated terms (VIM) deals with metrology, defined as the science of measurement and its application [1]. According to VIM in 2.1, note 1, "Measurement does not apply to nominal properties," so they cannot be a subject for metrology. However, most scientific disciplines, not only clinical laboratory sciences, also rely – some predominantly - on the description of properties without size. Typical cases can be found in several recommendations and technical reports in Pure and Applied Chemistry (PAC) authored by the Committee-Subcommittee on Nomenclature for Properties and Units (C-SC-NPU) [2-6] that rely heavily on kinds-of-nominal-property, such as 'taxon' or 'sequence variation'. Some of these concepts have been covered earlier [7], but a vocabulary on nominal property should be useful in the development of the 4th edition of the VIM.

It is believed that concepts for non-measurable properties should be useful for practitioners and the scientific community in disciplines such as general chemistry, health science, clinical laboratory sciences, biology, engineering, biochemistry, food science, forensic medicine, molecular biology, environmental science, and physics.

The starting point and basis of this work have been the VIM, the definitions of which have been widely applied or adapted to nominal properties. However, a few concepts have different definitions from those given in VIM.

It should be noted that this vocabulary deals exclusively with nominal properties, i.e. with values that have no size, and not with ordinal quantities, including binary ordinal quantities, such as those with "no/ yes" or "0/1" values that can be ordered by size. The meaning of a nominal property value is given in the examination procedure.

The authors have a clinical laboratory sciences background, including several specialties. The examples, therefore, deal mostly with this discipline.

An earlier version of this document has been published [8]. Under the reviewing process for the present publication in PAC, many valuable comments have been received, notably from Jean Schwob. Professor Emil Bashkansky has provided helpful input to the discussions on statistics for nominal property values. Compared to the earlier version, the number of defined concepts has been reduced. Several basic concepts are now used as non-defined 'primitives', hopefully without reducing the understanding by laboratory practitioners. The term "examination" has been used instead of "nominal examination". Several of the remaining definitions have been corrected and improved.

The term "magnitude" as generally used by VIM has raised some discussion. In this document, the term has been replaced by "size" throughout.

#### 1.1 Conventions

#### **Terminology Rules**

The definitions and terms given in this vocabulary, and their formats, comply as far as possible with the rules of terminology outlined in ISO 704:2009 [9], ISO 1087-1:2000 [10], and ISO 10241-1:2011 [11]. In particular, the substitution principle applies; that is, it is possible in any definition to replace a term referring to a concept defined elsewhere in this vocabulary by the definition corresponding to that term without introducing contradiction or circularity.

#### **Format**

The format of terminological entries in this document is as follows:

**Entry number (bold) term (bold)** 

definition

**EXAMPLE 1 EXAMPLE 2** 

Note to example(s): Note 1 to entry: Note 2 to entry:

[SOURCE:]

#### **Document structure**

The concepts have been divided into three sections: Basic concepts related to 'examination' (Section 2), Concepts related to 'examination result' (Section 3) and 'Examination standards and reference examination procedures' (Section 4).

#### **Ouotation marks**

In this document, single quotation marks ('...') surround a term representing a concept, unless the term is in italics. Double quotation marks ("...") are used when only the term is considered, or for a quotation.

#### **Curly brackets**

The possible values in a set are separated by commas and surrounded by curly brackets,  $\{a, b, c, \ldots\}$ .

#### **Italic font**

Terms for concepts defined elsewhere in the document are printed in italic font followed by parenthetic entry number at the first appearance in an entry. Taxonomic terms in Latin, i.e. for genera, species, and subspecies, are also given in italics.

## 1.2 Scope

As previously stated, this vocabulary is written by clinical laboratory scientists and will be presented to JCGM-WG2 for its work towards a fourth edition of the VIM. Like VIM, it uses some general concepts without definition. These primitives include 'aspect', 'body', 'classification', 'code', 'component', 'device', 'equivalence', 'indication', 'instrument', 'material', 'object', 'phenomenon', 'property', 'reference', 'set', 'size', 'substance', 'system', and 'verification'.

This document encompasses a limited scientific field. Experts with other scientific backgrounds than the clinical laboratory are invited to consider the applicability of this vocabulary to activities in their domains.

# 2 Basic concepts related to 'examination'

## 2.1 nominal property

property of a phenomenon, body, or substance, where the property has no size

**EXAMPLE 1** Colour at a specified lighting of a given leaf of a plant. **EXAMPLE 2** Sequence variation of nucleotides of a given gene. **EXAMPLE 3** *Taxon* (2.4) of a bacterium in a given sample of urine. **EXAMPLE 4** Shape of the nucleus of a given white blood cell.

The concept 'nominal property' is defined as the opposite of 'quantity', i.e. the former Note 1 to entry:

concept lacks the essential characteristic of 'size' (or 'magnitude'). In such cases, ISO

704:2009-6.5.4 allows a 'negative definition' [9].

Note 2 to entry: The term "attribute" has sometimes been used to designate 'nominal property', but not

here.

Note 3 to entry: The term "qualitative property" is also used, but not here as it is ambiguous because

'ordinal quantity' is often included under that term.

Note 4 to entry: 'Nominal property' is sometimes termed "nameable property", but not here.

## 2.2 kind-of-nominal-property

defining aspect, common to mutually comparable nominal properties (2.1)

EXAMPLE 1 Colour at a specified lighting.

EXAMPLE 2 Sequence variation.

EXAMPLE 3 Taxon (2.4). EXAMPLE 4 Shape.

Note to entry: 'Kind-of-nominal-property' is sometimes termed "attribute", but not here.

[SOURCE: The definition of this concept is analogous to that of 'kind of quantity' in VIM 1.2.]

## 2.3 category

Kind-of-nominal-property (2.2) indicating a class among nominal properties (2.1) ordered according to nominal property values (3.1) of a specified nominal property value set (3.2) without relation to size

EXAMPLE Blood type A is a nominal property value within the blood group system ABO where the

nominal property value set is {A, B, AB, O}.

#### 2.4 taxon

category (2.3) indicating a class of organisms within a recognized hierarchically structured *nominal property* value set (3.2)

EXAMPLE In the system 'Blood' with the component 'Staphylococcus', the application of the kind-

of-nominal-property (2.2) 'taxon' could give the nominal property values (3.1) 'species Staphylococcus aureus, species Staphylococcus lugdunensis, and Coagulase negative staphylococci (CNS)'. The value set comprises all species and groups of Staphylococcus

that the procedure can identify.

Note to entry: Taxonomy is the science of classification and its applications, usually regarding organisms.

## 2.5 dedicated kind-of-nominal-property

kind-of-nominal-property (2.2) with a sort of system and any pertinent sort(s) of component(s)

EXAMPLE 1 The colour of the fluid within the central channel of the spinal cord of any person. The

colour might be affected by a cerebral haemorrhage.

**EXAMPLE 2** The sequence variation of nucleotides of the gene CYP2D6 in DNA from any person.

CYP2D6 is a gene coding for one of the enzymes within the cytochrome P450 oxidase

system, e.g. affecting drug metabolism.

EXAMPLE 3 The *taxon* (2.4) of the bacterium in a sample of expectoration from any person.

**EXAMPLE 4** The typical shape of the nuclei in monocytes (a type of leukocyte) in a sample of blood

from any person. The morphology of cells is studied under microscope after fixation

and staining of a thin blood film.

Note to examples: The dedicated kinds-of-nominal-property above correspond to EXAMPLES 1 – 4 of

kind-of-nominal-property.

A dedicated kind-of-nominal-property is not specified to any individual person, in con-Note 1 to entry:

trast to an individual nominal property, and it cannot have a nominal property value

(3.1).

In clinical laboratory report forms, dedicated kind-of-nominal-properties may be Note 2 to entry:

described according to an internationally recommended NPU syntax from IFCC-IUPAC [12]. The syntax is System(specification)—Component(specification); kindof-property(specification). The last "specification" might contain information on the examination procedure (2.12) or the nominal property value set (3.2) The initial capital

for System and for Component is mandatory.

Examples of the NPU syntax

Blood—Plasma; colour({milky, red, yellow}).

Erythrocytes(Blood)—Erythrocyte antigen; blood group({A, B, AB, O}).

For EXAMPLES 1 – 4N under the definition above, individual nominal properties can be written as follows (omitting patient identity and time but including the nominal property value for clarity):

- 1. Patient—Spinal fluid; colour(visual) = reddish
- DNA(Leukocytes)—CYP2D6 gene; sequence variation(allele specific PCR) = \*1/\*3
- 3. Expectoration—Bacterium; taxon(Phadebact coagglutination test)=Mycobacterium tuberculosis.
- Monocytes(Blood)—Nuclei; shape=oval

Note 3 to entry: The patient's name (or other identifier), location, and date and time of obtaining the

sample of the system under consideration shall always be given in the clinical labora-

tory report.

[SOURCE: The definition of this concept is analogous to that of 'dedicated kind-of-property' [7].]

#### 2.6 examination

process of experimentally obtaining one or more nominal property values (3.1) that can reasonably be attributed to a *nominal property* (2.1)

Examination of genotype by, e.g. allele specific PCR or melting point analysis. **EXAMPLE 1** 

**EXAMPLE 2** Erythrocyte antigen examined by agglutination reactions with known antibodies.

Note 1 to entry: The outcome of an examination is an *examination result* (3.4).

The activity of examination essentially consists in comparing the property consid-Note 2 to entry:

ered, i.e. the examinand (2.7) by way of an examining system (2.8), with the property

of a 'reference' of similar nature. Such a reference may be personal and subjective, such as a person's memory of a colour, or the reference may be objective, such as a nominal reference material (4.2).

[SOURCE: The definition of this concept is analogous to that of 'measurement' in VIM, 2.1.]

## 2.7 examinand

nominal property (2.1) intended to be examined

EXAMPLE 1 Morphology of cells in blood.

EXAMPLE 2 The taxon (2.4) of Entamoeba in faeces.

Note 1 to entry: The nominal property value (3.1) of an examinand may be different from that of the

property actually being examined due to changes of the system bearing the property

during the examination (2.6).

The examined value (3.5) may be obtained indirectly through examinations of other Note 2 to entry:

nominal properties, giving the examined value by using an algorithm which may

involve measurement results and examination results (3.4).

[SOURCE: The definition for this concept is analogous to that of 'measurand' in VIM, 2.3.]

## 2.8 examining system

set of one or more devices, including any reagent and supply, assembled and adapted to give information used to generate examined values (3.5) from a nominal property value set (3.2)

**EXAMPLE 1** Selective culture medium for the identification of *Candida albicans* in a biological fluid. EXAMPLE 2 Chromatograph and mass spectrometer for the identification of mass/charge ratios of

molecules.

**EXAMPLE 3** Instrument used for running a polymerase chain reaction (PCR) followed by restriction

fragment length polymorphism (RFLP) for the identification of a genotype.

Note to entry: A human eye may be an essential element of an examining system.

[SOURCE: The definition of this concept is analogous to that of 'measuring system' in VIM, 3.2.]

## 2.9 influence nominal property

nominal property (2.1) that, in an examination (2.6), does not affect the nominal property that is actually examined, but affects the relation between the nominal indication (2.13) on the examining system (2.8) and the examination result (3.4)

**EXAMPLE** Contaminating microbiological species may influence the nominal indication of a

nominal property related to the examined species.

Note to entry: A quantity might also influence a nominal property.

[SOURCE: The definition of this concept is analogous to that of 'influence quantity' in VIM, 2.52.]

## 2.10 examination principle

phenomenon serving as a basis of an examination (2.6)

**EXAMPLE 1** Selective amplification of a DNA sequence to compare for equivalence with a target

**EXAMPLE 2** Comparison of spectral properties of a component with properties of known

substances.

The phenomenon can be of a physical, chemical, or biological nature. Note to entry:

[SOURCE: The definition of this concept is analogous to that of 'measurement principle' in VIM, 2.4.]

#### 2.11 examination method

generic description of a logical organization of operations used in an examination (2.6)

**EXAMPLE 1** Polymerase chain reaction (PCR)-restriction fragment length polymorphism (RFLP).

**EXAMPLE 2** Infra-red spectrometry.

Note to entry: The laconic description in an examination method is insufficient to allow an examina-

tion with prescribed examination uncertainty (3.9), but aids in formulating one or more

examination procedures (2.12).

[SOURCE: The definition of this concept is analogous to that of 'measurement method' in VIM, 2.5.]

## 2.12 examination procedure

detailed description of an examination (2.6) according to one or more examination principles (2.10) and to a given examination method (2.11) and any decision algorithm necessary to obtain an examination result (3.4)

**EXAMPLE** Working instructions, or "standard operating procedure", at laboratory A to examine a

sample for a possible mutation in the gene for haemochromatosis (HFE).

Note 1 to entry: An examination procedure specifies the dedicated kind-of-nominal-property (2.5)

> involved, any sampling, examining system (2.8), nominal reference material(s) (4.2) needed, and the *nominal property value set* (3.2) used. The examination procedure also specifies how many examined values (3.5) that are necessary to obtain an examination

result and how to estimate the expected examination uncertainty (3.9).

Note 2 to entry: The information presented in an examination procedure is intended to be opera-

tional and should be sufficient for a trained operator to perform an examination

satisfactorily.

An examination procedure can include a statement concerning a target examination Note 3 to entry:

uncertainty (3.18).

[SOURCE: The definition of this concept and notes 2 and 3 to the entry are inspired by those of 'measurement procedure' in VIM, 2.6.]

#### 2.13 nominal indication

nominal property value (3.1) provided by an examining system (2.8)

[SOURCE: The definition is modified from VIM, 4.1.]

#### 2.14 blank nominal indication

nominal indication (2.13) obtained from an object similar to the one under investigation, except that the nominal property (2.1) of interest is supposed not to be present, or is not contributing to the nominal indication

**EXAMPLE** Nominal indication obtained by examining a serum containing immunoglobulins, but

no HLA-antibodies, when the component searched for is HLA-antibodies [13].

Note 1 to entry: A blank nominal indication shall not be confused with a quantity value below a detec-

tion limit.

Note 2 to entry: A blank nominal indication is necessary for quality assessment in some examination

procedures (2.12).

Note 3 to entry: A blank nominal indication, when the examination procedure is expected to produce a

nominal property value (3.1), is an erroneous nominal property value.

Note 4 to entry: The concept is often termed "negative control", but not here.

[SOURCE: The definition of this concept is analogous to that of 'blank indication' in VIM, 4.2.]

## 2.15 repeatability condition of examination

condition of examination (2.6) out of a set of conditions that includes the same examination procedure (2.12), same operators, same examining system (2.8), same operating conditions, same location, and replicate examinations on the same or similar objects over a short period of time

[SOURCE: The definition of this concept is analogous to that of 'repeatability condition of measurement' in VIM, 2.20.]

#### 2.16 intermediate precision condition of examination

condition of examination (2.6) out of a set of conditions that includes the same examination procedure (2.12), same location, and replicate examinations on the same or similar objects over an extended period of time, but may include other conditions involving changes

[SOURCE: The definition of this concept is analogous to that of 'intermediate precision condition of measurements' in VIM, 2.22.]

#### 2.17 reproducibility condition of examination

condition of examination (2.6) out of a set of conditions that includes different locations, operators, examining systems (2.8), and replicate examinations on the same or similar objects

Note to entry: The different examining systems may use different examination procedures (2.12).

[SOURCE: The definition of this concept is analogous to that of 'reproducibility condition of measurement' in VIM, 2.24.]

# 3 Concepts related to 'examination result'

## 3.1 nominal property value

feature common to equivalent individual nominal properties (2.1)

**EXAMPLE 1** 'Yellow' is a nominal property value for a nominal property of the kind-of-nominal-

property (2.2) 'colour' of a given Urine as system. There is no separate component.

**EXAMPLE 2** '\*1/\*3' is a nominal property value for a nominal property of the kind-of-nominal-prop-

> erty 'sequence variation' of the CYP2D6 gene in a given 'DNA' as system. The allele '\*1' is related to normal enzyme activity while the allele '\*3' is related to decreased enzyme

activity.

**EXAMPLE 3** The species Mycobacterium tuberculosis is a nominal property value for a nominal

> property of the kind-of-nominal-property taxon (2.4) of the component Mycobacterium in a given 'Expectoration' as system. Infectious diseases might be caused by several different species of *Mycobacterium*. The species can be examined in a sample from an

expectoration.

**EXAMPLE 4** 'Oval' is a nominal property value for a nominal property with of kind-of-nominal-

property 'shape' of the component 'Leukocyte nucleus' in a given Blood as system.

This shape is typical of immature forms of monocytes, such as promonocytes,

Note 1 to entry: Nominal property values can be words, alphanumerical codes, symbols, etc, but

cannot enter into algebraic equations and is not related to a quantity dimension or a

measurement unit.

Note 2 to entry: A nominal property value can consist of a set of items.

Example: The colours of the national flag of Switzerland are red and white.

Note 3 to entry: The term "nominal quantity value" and its short form "nominal value" are used, for

example in VIM 4.6, to indicate a concept concerning rounded or approximate quantity values. The term "nominal indication interval" is used in VIM 4.4 to indicate a concept

concerning rounded or approximate extreme indications.

[SOURCE: The first part of Note 1 to entry is from VIM, 1.30, Note 1.]

## 3.2 nominal property value set

set of possible nominal property values (3.1) for nominal properties (2.1) of a given kind-of-nominal-property (2.2)

**EXAMPLE 1** {milky, red, yellow} can be a nominal property value set for nominal properties with

the kind-of-nominal-property 'colour'.

**EXAMPLE 2** {A, B, AB, O} can be a nominal property value set of four nominal property values for

nominal properties with the kind-of-nominal-property 'blood group'.

A 'nominal property value set' can be ordered by convention, for example in alphabetic Note to entry:

order of words, or alphanumerical codes identifying nominal property values, or an

order reflecting a classification, but neither of these is an ordering by size.

**EXAMPLE 3** Nominal property value sets that are ordered by other means than size, e.g. numbering

of chromosomes and alphabetical list of country codes.

## 3.3 reference nominal property value

nominal property value (3.1) used as a basis for comparison with nominal property values of nominal properties (2.1) of the same kind-of-nominal-property (2.2)

A reference nominal property value can be a true nominal property value (3.6) of an Note to entry:

examinand (2.7), in which case it is unknown, or a conventional nominal property value

(3.7), in which case it is known.

[SOURCE: The definition and note of this concept are analogous to those of 'reference quantity value' in VIM, 5.18.]

## 3.4 examination result

set of nominal property values (3.1) being attributed to an examinand (2.7) together with any other available relevant information

**EXAMPLE** The gene for hemochromatosis (HFE) is examined for a possible mutation at c.187 from

> C to G. The result is C/C. If the probability of having an examination result that deviates from a conventional nominal property value (3.7) is close to zero, then the examination

uncertainty (3.9) is considered negligible.

An 'examination result' sometimes contains "relevant information" about the set of Note 1 to entry:

nominal property values, such that some may be more representative of the examinand

than others.

Note 2 to entry: 'Examination result' should not be confused with nominal property value set (3.2).

Note 3 to entry: An 'examination result' may be expressed as a single examined value (3.5) and an

> examination uncertainty. If there is no dispersion of nominal property values attributed to the examinand or if the examination uncertainty is considered to be negligible for a specified purpose, the examination result may be expressed as a single examined

value.

SOURCE: The definition and the first parts of Notes 1 and 2 for this concept are analogous to those of 'measurement result' in VIM, 2.9.]

## 3.5 examined value

nominal property value (3.1) representing an examination result (3.4)

The term "observed value" is sometimes used for 'examined value', but not here. Note to entry:

[SOURCE: The definition of this concept is analogous to that of 'measured quantity value' in VIM, 2.10.]

## 3.6 true nominal property value

nominal property value (3.1) consistent with the definition of a nominal property (2.1)

[SOURCE: The definition of this concept is analogous to that of 'true quantity value' in VIM, 2.11.]

## 3.7 conventional nominal property value

nominal property value (3.1) attributed by agreement to a nominal property (2.1) for a given purpose

**EXAMPLE** 'Red' for 'Blood(oxygenated)—Blood; colour'

[SOURCE: The definition of this concept is analogous to that of 'conventional quantity value' in VIM, 2.12.]

#### 3.8 examination trueness

fraction of examined values (3.5) identical to one or more reference nominal property values (3.3) among all the examined values provided

**EXAMPLE** The reference nominal property value is 'B'. The nominal property value set (3.2) of all

possible values is {A, B}. For nine of 10 examinations (2.6) the examined value is 'B'.

The examination trueness is therefore 0.9 (90%).

Note 1 to entry: Each examined value is either equivalent, or non-equivalent, to the reference nominal

property value.

Note 2 to entry: The examination trueness, in contrast to measurement trueness (VIM, 2.14), is a quan-

tity, and is complementary to examination uncertainty (3.9).

#### 3.9 examination uncertainty

fraction of examined values (3.5) that is different from a reference nominal property value (3.3) among all the examined values provided

**EXAMPLE 1:** The reference nominal property value is 'B'. The nominal property value set (3.2)

> of all possible nominal property values is {A, B}. For one of 10 examinations (2.6) the examined value differs from 'B'. The examination uncertainty is therefore 0.1

(10%).

**EXAMPLE 2:** A patient suffers from a urinary tract infection. The examination result (3.4) from the

> examination procedure (2.12) is growth of bacteria of the species E. coli in a sample of urine with 20% examination uncertainty. With knowledge and experience from the examination procedure it can be concluded that there is some probability that the true species of bacteria could be instead a Salmonella or Shigella species, while the probability that the reference nominal property value is some other species of bacteria is

very low.

Note 1 to entry: Examination uncertainty is a quantity that is complementary to examination

trueness (3.8).

Note 2 to entry: Examination uncertainty is a part of an examination result. Note 3 to entry: With exception of the situation where the examination uncertainty is zero, some

examined values differ from the reference nominal property value. In a comment to the examination result, the laboratory can provide information about other possible

nominal property values (3.1), based on the information available.

Note 4 to entry: The definition of this concept is not analogous to that of 'measurement uncertainty' in

VIM, 2.26.

#### 3.10 examination error

disagreement between an examined value (3.5) and a reference nominal property value (3.3)

EXAMPLE 1 The reference nominal property value is 'red' and the examined value is 'pink'.

Narrative expression: The examined value disagrees with the reference nominal property value, so that an

examination error is present.

EXAMPLE 2 The reference nominal property value is 'BCD' and the examined value is 'BCD'.

Narrative expression: The examined value agrees with the reference nominal property value, so there is no examination error.

Note 1 to entry: An examination error is either present or absent.

Note 2 to entry: Examination error is associated with an examined value, but not with an *examining* 

svstem (2.8).

Note 3 to entry: Examination error should not be confused with production error or mistake.

[SOURCE: Note 3 is analogous to that of 'measurement error' in VIM, 2.16, note 2.]

## 3.11 examination accuracy

closeness of agreement between an *examined value* (3.5) and a *true nominal property value* (3.6) of an *examinand* (2.7)

EXAMPLE The true nominal property value is 'A', the first examined value is 'B', and the second

examined value is 'A'.

Narrative expression: The first examined value is inaccurate, and the second examined value is accurate.

Note to entry: Examination accuracy is a feature of an individual examined value, but not of an *exam*-

ining system (2.8).

[SOURCE: The definition for this concept is inspired by that of 'measurement accuracy' in VIM, 2.13.]

#### 3.12 examination precision

closeness of agreement between *nominal indications* (2.13) on an *examining system* (2.8) or *examined values* (3.5) obtained by replicate *examinations* (2.6) on the same or similar objects under specified examination conditions

Note 1 to entry: Examination precision can be expressed numerically by measures of dispersion of

examined values such as Index of Qualitative Variation (IQV) [14] and the Shannon's

entropy [15], under specified examination conditions. IQV varies between 0 (no dispersion, all examined values in a single class) and 1 (two or more classes with identical frequency). Shannon's entropy varies between 0 (no dispersion, that is all examined values belong to a single category) and a maximum value equal to the logarithm (on basis 2) of the number of all categories.

**EXAMPLE** 

Examinations of a nominal property (2.1) were done with three different examining systems, used with respective specified examination procedures (2.12) under the same specified conditions. The nominal property value set (3.2) is {A, B, C, and D}. The frequency distribution of the examined values for examining systems 1, 2, and 3 were:

Possible examined values		Examined values	
	Examining system 1	Examining system 2	Examining system 3
A	8	6	6
В	1	2	4
C		1	
D	1	1	
Total number of examined values	10	10	10

In the example above the dispersion is lowest for Examining system 1, so that it has the lowest values for IQV and entropy. According to entropy, examination of system 2 has the highest degree of dispersion (data in four categories), while Examining system 3 has the greatest dispersion according to IQV. Methods have also been suggested for the investigation of differences in homogeneity of dispersion between groups [16].

Note 2 to entry: A proportion distribution of a set of examined values describes proportions of data

belonging to every possible nominal property value (3.1).

'Specified examination conditions' can, for example, be repeatability condition of Note 3 to entry:

examination (2.15), intermediate precision condition of examination (2.16), or reproduc-

ibility condition of examination (2.17).

Examination precision is used to define examination repeatability (3.13), intermediate Note 4 to entry:

examination precision (3.14), and examination reproducibility (3.15).

Note 5 to entry: Examination precision is a feature of an examining system used with a specified exam-

ination procedure.

[SOURCE: The definition and Notes 4 and 5 for this concept are analogous to those of 'measurement precision' in VIM, 2.15.]

## 3.13 examination repeatability

examination precision (3.12) under repeatability condition of examination (2.15)

Examination repeatability is a quantity. Note 1 to entry:

Note 2 to entry: Examination repeatability is a feature of an examining system (2.8) used with a speci-

fied examination procedure (2.12).

[SOURCE: The definition of this concept is analogous to that of 'measurement repeatability' in VIM, 2.21.]

## 3.14 intermediate examination precision

examination precision (3.12) under intermediate precision condition of examination (2.16)

Note 1 to entry: Intermediate examination precision is a quantity.

Note 2 to entry: Intermediate examination precision is a feature of an examining system (2.8) used with

a specified examination procedure (2.12).

[SOURCE: The definition of this concept is analogous to that of 'intermediate measurement precision' in VIM, 2.23.]

## 3.15 examination reproducibility

examination precision (3.12) under reproducibility condition of examination (2.17)

Examination reproducibility is a quantity. Note 1 to entry:

Note 2 to entry: Examination reproducibility is a feature of a set of *examined values* (3.5).

[SOURCE. The definition of this concept is analogous to that of 'measurement reproducibility' in VIM, 2.25.]

## 3.16 systematic examination error

fraction of examined values (3.5) with examination error (3.10) that in replicate examinations (2.6) remains constant or varies in a predictable manner

**EXAMPLE** The reference nominal property value (3.3) is 'B'. The following number of examined values

> were obtained in one set of examinations: 8 times 'B', 9 times 'C', 8 times 'D', 4 times 'E'. In another set the following values were obtained: 16 times 'B', 9 times 'C', and 4 times 'E'.

Narrative expression: The systematic examination error is that 'C' and 'E' are found in replicate examinations

and neither represents a reference nominal property value.

Systematic examination errors for examined values are quantities. Note 1 to entry:

Note 2 to entry: The systematic examination error for examined values can be expressed for a set of

examined values as examination bias (3.17).

Note 3 to entry: Systematic examination error is a feature of an examining system (2.8) used with a spec-

ified examination procedure (2.12).

[SOURCE: The definition of this concept is inspired by that of 'systematic measurement error' in VIM, 2.17.]

#### 3.17 examination bias

estimate of a systematic examination error (3.16)

**EXAMPLE** 53 examined values (3.5) were obtained with a reference examination procedure (4.4),

> 106 were obtained by Examination procedure 1 and with Examination procedure 2. Examination procedure 1 resulted in examined values with the same proportion distribution as for the Reference examination procedure, and the examined values have thus no examiation bias. The 106 examined values with Examination procedure 2 have

a different distribution compared to that of the reference nominal property values (3.3), and the examined values thus have an examination bias.

Possible examination values			Examined values	
	Reference examination procedure	Examination procedure 1	Examination procedure 2	
A	21	42	2	
В			40	
C	18	36	2	
D			36	
E	12	24	10	
F			5	
G	2	4	11	
Total number of examined values	53	106	106	

One estimate of examination bias for nominal properties (2.1) is the Bhattacharyya distance [17], which measures the similarity of two nominal data sets. It equals zero when two proportion distributions are identical as is the case when comparing Examination procedure 1 and Reference examination procedure. There is an examination bias between Examination procedure 2 and Reference examination procedure, because the proportion distributions are different.

Note 1 to entry: Examination bias is a quantity.

If the proportion distributions of the reference nominal property values and the exam-Note 2 to entry:

ined values are the same, there is no examination bias for the examining system (2.8). If

the distributions differ there is an examination bias.

In some publications on analytical chemistry, 'examination bias' is termed "lack of Note 3 to entry:

reliability", but this is not recommended here.

[SOURCE: The definition of this concept is analogous to that of 'measurement bias' in VIM, 2.18.]

## 3.18 target examination uncertainty

examination uncertainty (3.9) specified as an acceptable fraction and decided on the basis of the intended use of examination results (3.4)

Note to entry: Target examination uncertainty is a quantity.

[SOURCE: The definition of this concept is analogous to that of 'target measurement uncertainty' in VIM, 2.34.]

#### 3.19 nominal property value coverage set

subset of the nominal property value set (3.2) containing the true nominal property value(s) (3.6) of an examinand (2.7) with a stated probability, based on the information available

**EXAMPLE** A nominal property value coverage set for 'Urine(midstream)—Bacterium; taxon' could

be {Escherichia coli, Staphylococcus epidermidis} as specified in Bergey's manual.

[SOURCE: The definition of this concept is analogous to that of 'coverage interval' in VIM, 2.36.]

## 3.20 nominal property value coverage probability

probability that the set of true nominal property values (3.6) of an examinand (2.7) is contained within a specified nominal property value coverage set (3.19)

**EXAMPLE** The nominal property value coverage probability that the bacteria in the urine

belongs to the species Escherichia coli and Staphylococcus epidermidis is more than

95%.

[SOURCE: The definition of this concept is analogous to that of 'coverage probability' in VIM, 2.37.]

## 3.21 examination traceability

property of an examination result (3.4) whereby it can be related to a reference through a documented unbroken chain of examination calibrations (4.3), each contributing to the examination uncertainty (3.9)

An ISO Technical report (TR 79:2015) [18] characterizes reference materials for "qualita-Note to entry:

tive properties".

[SOURCE: The definition of this concept is analogous to that of 'metrological traceability' in VIM, 2.41.]

## 3.22 examinational comparability of examination results

comparability of examination results (3.4), for nominal properties (2.1) of a given kind-of-nominal-property (2.2), that are examined and traceable to the same reference

**EXAMPLE** Examination results for the colours of two different biological fluids are comparable

when they are both traceable to the same colour chart.

[SOURCE: The term and definition of this concept are analogous to those of 'metrological comparability' in VIM, 2.46.]

## 3.23 examinational compatibility of examination results

property of a set of examination results (3.4) for a specified examinand (2.7) of a given kind-of-nominal-property (2.2) that have overlapping nominal property value sets (3.2)

Let the nominal property value set for 'Patient-Urine; colour(proc.)' be {red, dark **EXAMPLE** 

'Red' is a compatible examination result because it is contained within the nominal property value set. 'Black' and 'white' are not compatible as they do not belong to the

nominal property value set.

Note 1 to entry: Two compatible examination results can be identical.

The definition of this concept is not analogous to that of 'metrological compatibility of Note 2 to entry:

measurement results' in VIM, 2.47.

## 4 Examination standards and reference examination procedures

## 4.1 examination standard

realization of the definition of a given nominal property (2.1), with stated nominal property value (3.1) and associated examination uncertainty (3.9), used as a reference

**EXAMPLE** A given examined value (3.5) for a bacterial taxon (2.4) can be compared for equiva-

lence with the stated nominal property value of an examination standard in the form

of typical bacteria of the species.

Note to entry: A 'realization of the definition of a given nominal property' can be provided by an

examining system (2.8) or a nominal reference material (4.2).

[SOURCE: The definition and note of this concept are analogous to those of 'measurement standard' in VIM, 5.1.]

#### 4.2 nominal reference material

material, sufficiently homogeneous and stable with reference to a specified nominal property (2.1), that has been established to be fit for its intended use in an examination (2.6)

**EXAMPLE 1** Colour chart with one or more specified colours.

**EXAMPLE 2** DNA compound containing a specified nucleotide sequence.

Note to entry: Nominal reference materials with or without assigned reference nominal property values

> (3.3) can be used for control of examination precision (3.12), whereas only nominal reference materials with assigned reference nominal property values can be used for the control of examination calibration (4.3) or evaluation of examination trueness (3.8).

[SOURCE: The definition of this concept and related examples are analogous to those of 'reference material' in VIM, 5.13, where the superordinate concept of both nominal reference material and measurement reference material is defined.]

#### 4.3 examination calibration

process that confers to one or more persons or to a device the capacity to provide nominal property values (3.1) from specified examinations (2.6) after having examined one or more examination standards (4.1)

**EXAMPLE** Identifying a bird after having studied certified pictures and sounds.

Note to entry: Examination calibration differs from that of calibration in VIM3 2.39, because in exami-

nation calibration there is no explicit mention of 'nominal indication' and 'examina-

tion uncertainty'.

## 4.4 reference examination procedure

examination procedure (2.12) accepted as providing examination results (3.4) fit for their intended use in assessing examination trueness (3.8) of examined values (3.5) obtained from other examination procedures for nominal properties (2.1) of the same kind-of-nominal-property (2.2), in examination calibration (4.3), or in characterizing nominal reference materials (4.2)

EXAMPLE 1 A reference examination procedure provided by a perfume firm to identify smells. EXAMPLE 2 The official examination procedure for car technical control (involving both measurements and nominal examination (2.6)).

[SOURCE: The definition of this concept is analogous to that of 'reference measurement procedure' in VIM, 2.7.]

## 4.5 primary reference examination procedure

reference examination procedure (4.4) used to obtain an examination result (3.4) without relation to an examination standard (4.1) for a nominal property (2.1) of the same kind-of-nominal-property (2.2)

[SOURCE: The definition of this concept is analogous to that of 'primary reference measurement procedure' in VIM, 2.8.]

#### 4.6 international examination standard

examination standard (4.1) recognized by signatories to an international agreement and intended to serve worldwide

**EXAMPLE** The WHO 1st international genetic reference panel for Factor V Leiden, Human gDNA: 03/254, 03/260, 03/248 [19].

[SOURCE: The definition of this concept is analogous to that of 'international measurement standard' in VIM, 5.2.]

#### 4.7 national examination standard

examination standard (4.1) recognized by national authority to serve in a state or economy as the basis for assigning nominal property values (3.1) to other examination standards for the same kind-of-nominalproperty (2.2)

**EXAMPLE** The examinand (2,7) 'HLA specific allo-antibodies in human blood plasma' is detected and identified according to a nationally agreed examination procedure (2.12) and nominal reference material (4.2).

[SOURCE: The definition of this concept is analogous to that of 'national measurement standard' in VIM, 5.3.]

## 4.8 primary examination standard

examination standard (4.1) established using a primary reference examination procedure (4.5), or created as an artefact, chosen by convention

[SOURCE: The definition of this concept is analogous to that of 'primary measurement standard' in VIM, 5.4.]

## 4.9 secondary examination standard

examination standard (4.1) established through examination calibration (4.3) with respect to a primary examination standard (4.8) for a nominal property (2.1) of the same kind-of-nominal-property (2.2)

[SOURCE: The definition of this concept is analogous to that of 'secondary measurement standard' in VIM, 5.5.]

#### 4.10 reference examination standard

examination standard (4.1) designated for the examination calibration (4.3) of other examination standards for nominal properties (2.1) of a given kind-of-nominal-property (2.2) in a given organization or at a given location

[SOURCE: The definition of this concept is analogous to that of 'reference measurement standard' in VIM, 5.6.]

## 4.11 working examination standard

examination standard (4.1) that is used routinely to calibrate or verify examining systems (2.8)

Note to entry: A working examination standard is usually calibrated with respect to a *reference exam*-

ination standard (4.10).

[SOURCE: The definition and note for this concept are analogous to those of 'working measurement standard' in VIM, 5.7.]

## 4.12 travelling examination standard

examination standard (4.1), sometimes of special construction, intended for transport between different locations

[SOURCE: The definition of this concept is analogous to that of 'travelling measurement standard' in VIM, 5.8.]

#### 4.13 transfer examination device

device used as an intermediary to compare examination standards (4.1)

Note to entry: Sometimes, examination standards are used as transfer examination devices.

[SOURCE: The definition and note for this concept are analogous to those of 'transfer measurement device' in VIM, 5.9.]

## 4.14 intrinsic examination standard

examination standard (4.1) based on a reproducible nominal property (2.1) of a phenomenon or substance

EXAMPLE For tri-dimensional shape, a crystal obtained from a solution of a pure compound.

Note to entry: A nominal property value (3.1) of an intrinsic examination standard is assigned by con-

sensus and does not need to be established by relating it to another examination stand-

ard of the same type.

[SOURCE: The definition and note for this concept are analogous to those of 'intrinsic measurement standard' in VIM, 5.10.]

#### 4.15 conservation of an examination standard

set of operations necessary to preserve the examinational properties of an *examination standard* (4.1) within stated limits

Note to entry: Conservation of an examination standard commonly includes periodic verification of

predefined nominal properties (2.1) or examination calibration (4.3), storage under suit-

able conditions, and specified care in use.

[SOURCE: The definition and note for this concept are analogous to 'conservation of a measurement standard' in VIM, 5.11.]

#### 4.16 examination calibrator

examination standard (4.1) used in examination calibration (4.3)

[SOURCE: The definition of this concept is analogous to that of 'calibrator' in VIM, 5.12.]

#### 4.17 certified nominal reference material

nominal reference material (4.2) accompanied by documentation issued by an authoritative body and providing one or more specified nominal property values (3.1) with examination uncertainty (3.9) and examination traceability (3.21), using valid examination procedures (2.12)

[SOURCE: The definition of this concept is analogous to that of 'certified reference material' in VIM, 5.14.]

# 5 Alphabetical index of terms

blank nominal indication # 2.14 category # 2.3 certified nominal reference material # 4.17 conservation of an examination standard # 4.15 conventional nominal property value # 3.7 dedicated kind-of-nominal-property # 2.5 examinand # 2.7 examination # 2.6 examination accuracy # 3.11

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true nominal property value # 3.6

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The combined membership of the IFCC Committee on Nomenclature, Properties and Units during the preparation of these recommendations (2004 - 2016) was as follows:

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**Acknowledgments:** The authors acknowledge that a former chairman of C-SC-NPU, Professor Robert Zender, made the first working draft, which provided ideas and parts for the present text.

## **Abbreviations**

**BIPM** Bureau Internationel des Poids et Mesures IEC International Electrotechnical Commission **IFCC** International Federation of Clinical Chemistry and Laboratory Medicine\* IUPAC International Union of Pure and Applied Chemistry **JCGM** Joint Committee for Guides in Metrology VIM International vocabulary of metrology – Basic and general concepts and associated terms WHO World Health Organization

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<sup>\*</sup>Formerly: International Federation of Clinical Chemistry

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