The Nomenclature, Properties and Units
International System of Laboratory Terminology
(NPU Terminology)

A. Stakeholder Agreement

B. NPU Terminology Steering Committee:
Terms of Reference
The Nomenclature, Properties and Units International System of Laboratory Terminology (NPU Terminology)

A. Stakeholder Agreement

1. The NPU Terminology Stakeholders

There are three principal stakeholders in the NPU Terminology:

A. The International Union of Pure and Applied Chemistry, hereinafter referred to as “IUPAC” Secretariat, P.O. Box 13757, Research Triangle Park, North Carolina, 27709-3757, U.S.A.

B. The International Federation of Clinical Chemistry and Laboratory Medicine - hereinafter referred to as “IFCC” (c/o Seedamm Business Center - Churerstrasse 135, 8808 Pfäffikon, Switzerland)

C. The Danish Health Data Authority, (DHDA), an Agency under the Danish Ministry of Health – hereinafter referred to as “DHDA”, 5 Artillerivej, 2300 Copenhagen S, Denmark.

Collectively, these three stakeholders are hereinafter referred to as “The Parties”.

Other stakeholders include users of the NPU Terminology and committees established to oversee its governance, operation and development. These will be referred to elsewhere in this document but are not parties to the formal agreement.

2. NPU Terminology

The NPU Terminology is based on international recommendations and standards of terminology and metrology. It is applied to describe the wide range of substances involved and/or measured in human subjects as part of the investigation of health and disease. NPU Terminology provides a means to achieve international harmonisation of the description of clinical examination results. Therefore, it is of value to a range of stakeholders involved in the organisation and delivery of high quality laboratory medicine (clinical laboratory science) services. These may include:

D. National health authorities

E. National Release Centers

F. Laboratory directors and senior managers

G. Companies responsible for the manufacturing of products used in laboratory medicine

NPU Terminology has evolved over many years. Throughout that period publications on NPU Terminology and its application have appeared in the journals Pure and Applied Chemistry (“PAC”) and Clinical Chemistry and Laboratory Medicine (“CCLM”). The most recent article “Properties and units in the clinical laboratory sciences. Part XXIII. The NPU
terminology, principles, and implementation: A user's guide" was published in PAC Vol. 84, December 16, 2011.

The NPU database is the official repository of the NPU Terminology.

A more detailed explanation of the NPU Terminology and the NPU database is included in the Appendix to this document.

3. Basis of Stakeholder Agreement

The NPU Terminology was developed from 1987 under the Committee and Subcommittee on Nomenclature for Properties and Units (C-SC-NPU), a joint committee under the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and the International Union of Pure and Applied Chemistry (IUPAC).

The NPU Terminology has been used for electronic communication of laboratory information since 2000 in Denmark and Sweden, and I Norway since 2014. The NPU Terminology is in use in some laboratories outside the Scandinavian countries. The Danish Health Data Authority, has supported the development and maintenance of the terminology since 1998 in terms of financial and staff resources to ensure daily operations, tooling and competences to be in place. This has been conducted on an informal basis where the Danish Board of Health has been running the repository of the NPU Terminology and managed its international version since 2002. Since 2012 the Danish National eHealth Authority (DeHA) and in 2015 Danish Health Data Authority (DHDA) has taken on this function.

From the year 2020 the DHDA will claim for an annual fee from the National Release Centres using the NPU terminology and the related services. The Fee will be calculated on basis of an annual budget according to a distribution key from the year before.

The creation of a Steering Committee is one of the key points of the agreement. The Terms of Reference of the Steering Committee are set out in the accompanying document.

4. Definition of Stakeholder Agreement

4.1 Management of the International (English) Version of NPU Terminology

The Parties agree that the manager of the international (English) version of the NPU Terminology (currently DHDA) will:

A. Manage the international (English) version of the NPU Terminology

B. Receive and act on requests from National Release Centers for updates and changes to the international (English) NPU Terminology, in accordance with the NPU terminological principles.

C. Produce international (English) NPU publications of NPU Terminology, this includes responsibility for publication of updates and changes to the NPU Terminology

4.2 National Release Center (NRC)

The Parties agree that:

A. NRCs is the nationally recognized point of contact accepted by the Steering Committee
B. NRCs are responsible for communication between national users of the NPU Terminology, the DHDA managers and their representative in the Steering Committee

C. NRCs produce publications of NPU in national language version(s) for national use, containing all or part of the NPU Terminology

D. NRCs are responsible for maintaining, updating, and publishing their language version(s) correlated to the international (English) version in accordance with decisions made by the Steering Committee

4.3 Intellectual Property Rights

The Parties agree that:

A. IUPAC and IFCC are the owner of the exclusive, worldwide intellectual property rights associated with the NPU Terminology

B. DHDA is owner of property rights associated with the NPU hardware, website for publication of files and software to run operations.

C. DHDA has the non-exclusive right to offer technical and terminological services related to the NPU Terminology, its use and its publications, to NRCs and other stakeholders.

D. NRCs have the rights to translations of NPU Terminology in their language versions.

E. All other issues related to intellectual property rights will be determined by the Steering Committee (see Section 4.4)

F. IUPAC and IFCC will jointly explore the options to establish, maintain and increase the protection the intellectual property of the NPU Terminology

G. DHDA will make monthly updated NPU publications available for IUPAC and IFCC for publication on their websites.

The assignment of rights herein shall survive any termination of the cooperation between the Parties, including this Agreement.

4.4 Steering Committee

The Parties agree that:

A. A permanent and institutionalized cooperation in the development of the NPU Terminology and the NPU database will provide the best benefit to all Parties. Therefore the Parties agree to found a Steering Committee consisting of members from each of the Parties as well as from the C-SC-NPU and users of the NPU Terminology according to the agreed Membership of Steering Committee [App. B]

B. The Steering Committee shall be responsible for all aspects of:

   I. The governance, planning and external scientific and clinical links for the NPU Terminology.

   II. Support the continued development of NPU Terminology and if needed initiate projects. This function will be undertaken by C-SC-NPU reporting to the Steering Committee
III. The maintenance and update of the NPU database. This function will be performed by DHDA in accordance with the guidelines defined by the Steering Committee.

IV. Promotion of the NPU Terminology. This function will be performed by C-SC-NPU, IFCC and IUPAC in accordance with the guidelines defined by the Steering Committee

C. The detailed Terms of Reference of the Steering Committee shall be defined in a separate document (See Section B)

4.5 Liability
The Parties agree that:

A. They do not accept liability to each other for any omissions or errors in the published materials or data, for the use or validity of translations of all or part of the NPU, or for adverse consequences of the use of the NPU in any way, by any parties for any purpose.

B. The DHDA does not accept liability for any damage, including loss or corruption, to the NPU data.

4.6 Duration of the Agreement
The Parties agree that, subject to paragraph 4.7, this Agreement be valid for three years from the date of the final signature in Section 5 below

4.7 Termination of the Agreement
This Agreement can be terminated by any party (of the Parties) giving a 12 months written notice

5. Signatures of Acceptance of the Agreement 30.09.2019

IUPAC – represented by:
Colin Humphris

IFCC – represented by:
Graham Beastall

DHDA – represented by:
Karen Marie Lyng
Appendix A

Glossary of Terms that Apply to NPU Terminology and the NPU Database

For the purpose of this document the following definitions of central concepts apply:

**Terminology**
A set of designations applied to concepts belonging to one special language (ISO 23185:2009, 2.9)

**NPU Terminology**
Terminology developed jointly by IFCC and IUPAC for the kinds of (patient) property estimated in the field of clinical laboratory science, with designations and concept definitions in English

**NPU terminological principles**
Principles for the NPU Terminology described in the IFCC-IUPAC 'Properties and Units' series of Recommendations and Technical reports. They include the general information structure of the NPU terminology (syntax and general semantic rules) and specific semantic rules for different fields of laboratory science.

**NPU Terminology language version:**
NPU Terminology where concept definitions are systematically translated into another language for national use. This may be a translation of the full NPU Terminology or of a subset of it.

**NPU database**
The official repository for the NPU Terminology. It consists of NPU Terminology data (terms, references, definitions, ID codes, history and notes), and functions and user interfaces for administration of the NPU Terminology, and for access to the NPU Terminology by external users (website). At present the NPU repository is the Danish 'LabTerm' database, which is physically situated in Copenhagen, Denmark.

**NPU publications**
Any format of media, electronic or printed publication which makes NPU Terminology data available to users.

**NPU ShortSet**
NPU publication comprising the concept designations of the NPU Terminology, their ID codes and some related data. The NPU ShortSet is freely available as text files and may be accessed from the IUPAC and IFCC websites.

**NPU services**
NPU data, information and services freely available or available only to NRCs. Services freely available to all are e.g. access to the NPU terminological principles and the NPU
ShortSet. Services available only to NRCs are e.g. license to create and publish a NPU Terminology language version, access to having new concepts added to the NPU Terminology, and access to NPU data not in the NPU ShortSet

National Release Center

An institution responsible for translating and publishing a national language version of the NPU Terminology based on the international (English) version of the NPU Terminology (examples: Danish Release Center, Swedish Release Center and Norwegian Release Center).
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Appendix B

NPU Terminology Steering Committee: Terms of Reference

1. Overall Purpose

The NPU Terminology Steering Committee (hereinafter called Steering Committee) is responsible for all aspects related to the governance, operation, development and promotion of the NPU system of terminology.

The Steering Committee may establish subcommittees that are responsible for different elements of the NPU project. Those subcommittees report to the Steering Committee.

2. Membership of the Steering Committee

Members of the Steering Committee:

A. Two members appointed by IUPAC
B. Two members appointed by IFCC
C. Two members appointed by DHDA
D. Two members appointed by C-SC-NPU
E. Members nominated by each recognised NRCs of NPU

Individual members of the Steering Committee shall serve for a period of three years. An individual may serve for more than one term.

The Steering Committee shall elect a Chair, Vice Chair and Secretary on an annual basis from within the membership of the Steering Committee.

3. Quorum

A minimum of six members (60%) of the Steering Committee are required to attend a meeting (face to face or by conference call) in order for the meeting to be declared quorate and capable of taking decisions that are binding on all parties.

For a meeting to be quorate either or both of the Chair and Vice Chair shall be in attendance.

4. Voting Rights

All members of the Steering Committee shall have one vote.

Decisions shall be reached by a simple majority of the votes cast, with the exception of budget and funding decisions, which will require the approval of IUPAC, IFCC and DHDA.
In the event of a tied vote the Chair will not have a casting vote and the resolution will be recorded as failing to be approved.

5. Specific Roles

The specific roles of the Steering Committee are summarised in Figure 1. The substructure responsible for two of those roles is also included in the Figure 1.

![Figure 1]

NPU Terminology Steering Committee: Specific Roles

- Governance
- Development
- Maintenance
- External Links
- C-SC-NPU
- DHDA

5.1 Governance and Planning:
The Steering Committee will be responsible directly for all aspects of governance of the NPU Terminology. These will include but not be restricted to:

A. Resolution of disputes
B. Strategic planning
C. Rules and operating procedures
D. ‘Licensing’ of NRCs for translation and publication rights
E. Documentation
F. Promotion
G. Financial planning and accounting
H. Performance management and audit
I. Production of an annual report

5.2 Development
The Steering Committee will have responsibility for decisions relating to the further development of NPU Terminology and other related issues of terminology in e-health. The
C-SC-NPU will be responsible for the conception of ideas for development and for working these into a detailed proposal that will be submitted to the Steering Committee for final decision. The work of C-SC-NPU will include but not be restricted to:

A. Further development of terminological principles and the structure of NPU Terminology
B. Development of terminological models for new fields of laboratory medicine
C. Scientific collaboration and coordination with other international terminologies and organisations
D. Scientific collaboration with other experts in the areas of metrology, terminology and laboratory medicine
E. Presentations to national and international scientific conferences
F. Publication in peer reviewed journals

5.3 Maintenance and Technical Support

The Steering Committee will support a framework within which DHDA is able to take responsibility for the following functions:

A. Maintenance and security of the physical NPU database and the NPU data
B. Maintenance of NPU Terminology in accordance with NPU terminological principles
C. Updating of the NPU Terminology data and the NPU publications in response to requests from National Release Centres and approved users
D. Responding to technical enquiries about the content and operation of NPU Terminology and the NPU database form current or potential users
E. Transfer of NPU Terminology to approved sources (e.g. regular distribution of the NPU Short Set to IUPAC and IFCC for inclusion on their websites)
F. Provision of the required technical hardware
G. Provision of staff competent to undertake the above functions

5.4 External links

The Steering Committee will be responsible directly for establishing, maintaining and developing high level external links with other organisations, departments or individuals that have an interest in NPU Terminology or related issues of terminology in e-health. External links will include but not be restricted to:

A. International Health Terminology Standards Development Organisation (IHTSDO)
B. Government national health departments
C. Companies active in the area of laboratory medicine
6. Frequency and Format of Meetings

The Steering Committee will hold four scheduled meetings each year, one of which shall be designated the annual general meeting at which the annual report is approved and elections are held for officers for the following year.

Additional meetings of the Steering Committee will be held if requested by a majority of the members. At least two weeks' notice must be given to all members of the Steering Committee in the event of an additional meeting.

Meetings shall normally be held by telephone conference call or Skype. Face to face meetings may be arranged, when it is convenient to members and cost effective to do so.

7. Distribution and Approval of Documents

The agenda and supporting papers for any meeting of the Steering Committee shall be circulated (electronically) at least one week in advance.

The Minutes of any meeting of the Steering Committee shall be circulated in draft form no later than four weeks after the meeting. An amended draft shall be circulated and shall stand as unconfirmed Minutes until formal approval at the next meeting of the Steering Committee.

8. Complaints and Disputes

All complaints and disputes shall be referred to the Steering Committee for resolution. If there is not full agreement within the Steering Committee the Parties (as mentioned in the Stakeholder Agreement 1.A.B.C, will settle the case. The Steering Committee will regard the issues as confidential to its membership.

Notice of the complaint or dispute shall be submitted in writing in a form that is suitable for distribution to all members of the Steering Committee.

The complaint or dispute will normally be considered by the next scheduled meeting of the Steering Committee provided that this is at least one week away. A complaint or dispute may exceptionally be considered by an additional meeting of the Steering Committee in accordance with paragraph 6 above.

The Steering Committee may seek legal or other expert advice as a means to achieve resolution, bearing in mind the requirement to maintain confidentiality.

The decision of the Steering Committee shall be communicated in a timely manner to the individual or group who lodged the complaint or raised the dispute.