CEN

WORKSHOP

AGREEMENT

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English version

Coding of Information and Traceability of Human Tissues and Cells

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties, the constitution of which is indicated in the foreword of this Workshop Agreement.

The formal process followed by the Workshop in the development of this Workshop Agreement has been endorsed by the National Members of CEN but neither the National Members of CEN nor the CEN Management Centre can be held accountable for the technical content of this CEN Workshop Agreement or possible conflicts with standards or legislation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

The objective of the CEN/ISSS Workshop on Coding of Information and Traceability of Human Tissues and Cells was to identify requirements concerning the coding of information and the traceability of human tissues and cells, and propose guidelines and recommendations to permit the implementation of the European Coding system within the time limit set by the European Tissues and Cells Directive 2004/23/EC (ECD). This CEN/ISSS Workshop commenced in April 2007 and held its final meeting in February 2008.

The Workshop counted over 70 participants from tissues, blood and eye banks, national ministries for healthcare, transplant organizations, universities and coding organizations mainly of Europe. A few representatives from Tissues banks in Canada, Australia, USA and Japan also followed the work.

The CEN Workshop Agreement (CWA) sets out the basic specification of a European coding system for human tissues and cells, and indicates how implementation of the system could be approached.

It went through a public comment phase from 15 December 2007 until 15 January 2008 and the endorsement period run from 9 April until 2 May 2008. The final text of this CWA was submitted to CEN for publication on 28 May 2008.

The CWA, and the associated Workshop proposals and recommendations, will be submitted to the European Commission and to the Committee of Member States that assists its management process under article 29 of the Directive 2004/23/EC.

This CEN Workshop Agreement is publicly available as a reference document from the National Members of CEN: AENOR, AFNOR, ASRO, BDS, BSI, CSNI, CYS, DIN, DS, ELOT, EVS, IBN, IPQ, IST, LVS, LST, MSA, MSZT, NEN, NSAI, ON, PKN, SEE, SIS, SIST, SFS, SN, SNV, SUTN and UNI.

Comments or suggestions from the users of the CEN Workshop Agreement are welcome and should be addressed to the CEN Management Centre.

List of organizations which have endorsed the CWA:

- NHSBT
- JACIE
- WMDA
- EBMT
- Danish National Board of Health
- Sanquin Blood Supply Foundation
- Hospices Civils de Lyon, Banque de Tissues
- NIBSC, UK Stem Cell Bank
- UCL Tissue Bank Brussels
- European Blood Alliance
- ICCBBA
- SNBTS
- EBA
- Autoridade Serviços Sangue e Transplantaçao (ASST), Portugal

- Scottish National Blood Transfusion Service, UK Standing advisory committee on Information Technology
- Centre of Tissue and Cell Banking, Poland
- Scottish National Blood Transfusion Service
- American Association of Tissue Banks
- Blood transfusion centre of Slovenia
- NHS Blood and Transplant
- Tissue Bank Lund
- Swedish National Board of Health and Welfare
- Sociedad Española de Transfusión Sanguínea
- Karolinska University Hospital, Sweden
- Central Tissue Bank Ghent University Hospital
- Danish Medicines Agency
- Spanish Organisation for Transplant (ONT)
- Bundesministerium für Gesundheit, Paul-Ehrlich-Institut
- Portuguese Institute of Blood
- Etablissement Français du Sang
- Agence de la Biomédecine, France
- Fondazione Banca degliOcchi del Veneto (Veneto Eye Bank Foundation)
- CNT (Italian National Transplant Centre)
- German Pharmaceutical Industry Association (BPI)
- Tissue Bank National Research Center ‘Demokritos’, Greece
- French Health Products and Safety Agency (AFSSAPS)

Introduction and Executive Summary

This CWA, and the associated Workshop proposals and recommendations, was submitted to the Commission and to the Committee of Member States that assists its management process under article 29 of the ECD in May 2008. The present document sets out the basic specification of a European coding system for human tissues and cells, and indicates how implementation of the system could be approached.

The background to this document is work already undertaken by the Expert Working Group of DG SANCO on coding of human tissues and cells (EG) established under Article 29 of the ECD.

The CWA work included analysis of existing relevant public activities (both inside and outside standardisation and including R&D projects) at European, national, regional and international levels, and also considered relevant international activities.

Having analysed in detail 3 candidate coding systems proposed by Member State (MS) representatives on the EG, the Workshop, the Project Team (PT), together with a panel including DG SANCO representatives and lawyers, recommended use of ISBT 128 as the basis for the EU coding scheme. It is considered a good match to requirements, but is not perfect in its current design:

- ISBT 128 was the only purely coding approach submitted;
- However each ISBT 128 Donation Code is associated with a single Facility Code either at national or local (~Tissue Establishment, TE) level;
- Both types of Facility (national & local) may need to be identified in some traceability models;
- There were philosophical, geographical, governance and sector objections to ISBT 128;

Further work identified the need for an additional component to be created to support both use of ISBT 128 and those organisations electing to retain existing coding schemes. This new component has been temporarily named in this document the "key code" (see 11.3). Because a donation event may result in tissues sent to different TEs ICCBBA offered a new component, incorporating Country code, Responsible organisation (e.g. CA) and TE, to be developed with the EU to meet international requirements:

- It would not invalidate existing ISBT 128 code structures but augment them;
- The "key code" could also be used with existing coding systems to provide unique identification and allow EU (potentially global) traceability of all materials from one donation event;
- The definition of the code elements would be a task for the EG.

The document also proposes that DG SANCO should establish a Committee to:

1. Ensure minimum agreed specifications are met;
2. Provide documents to support code implementation;
3. Provide training material.

The document further recommends that DG SANCO should establish Fora to Oversee EU definition with ICCBBA of, and be the points of reference/advice to MS/TEs for: 1) “Key code” (see 14.4.3); 2) Nomenclature (see 14.4.4); and 3) EU relationship with ICCBBA relating to ISBT128 (see 14.4.5).

MS need to consider: 1) Hardware, software and training requirements; 2) How TE codes and donation numbers are allocated, controlled and issued; 3) Translation tables for transition period; and 4) Policies for a possible period of dual labelling, labelling of imported and exported materials, and retrospective labelling of inventory.

During their work the PT noted that the traceability systems offered by Spain and Italy for MS use could, like those in use in some other MS, be very useful in combination with strong coding to achieve highest standards in strong traceability.

1 Scope

The background to this document is the DIRECTIVE 2004/23/EC (ECD), Article 25 provision requiring the Commission in cooperation with Member States to design a single European coding system to provide information on the main characteristics and properties of tissues and cells. This requirement is elaborated further in COMMISSION DIRECTIVE 2006/86/EC of 24 October 2006 implementing DIRECTIVE 2004/23/EC.

The present document therefore sets out the basic specification of a European coding system for human tissues and cells, and indicates how implementation of the system could be approached.

The CWA analyses the following issues:

- minimum requirement code systems to be used at European level;
- the basic process of donation, evaluation, procurement, processing, storage and distribution of Tissues and Cells.
- what a coding system can do;
- biovigilance schemes (including a review of dependencies);
- coding systems for human tissues and cells used in Europe;
- how existing systems can be made compatible with the harmonised European system;
- the implications of bringing local coding systems into the European system, and ways to resolve any difficulties;
- guidelines for the use of the harmonised European system in Member States (including management rules, labelling and electronic / telematic means);
- how the coding system should be maintained in the future.

The background to this document is work already undertaken by the Expert Working Group of DG SANCO on coding of human tissues and cells established under Article 29 of the ECD.

The document includes analysis of existing relevant public activities (both inside and outside standardisation and including R&D projects) at European, national, regional and international levels, and also takes due account of other relevant international activities.

The document also contains a proposed programme of further actions, both inside and outside the standardisation environment.

The draft and completed document, and the associated Workshop proposals and recommendations, was submitted to the Commission and to the Committee of Member States that assists its management process under article 29 of the ECD. Taking due account of the views expressed, as well as of the initial Workshop recommendations, the document may be progressed further towards a European (in CEN) or an International Standard (in ISO), and/or additional Workshop activities may be undertaken at later stages.

2 Normative references

See too the Informative References and Bibliography for additional materials including others referenced from the text.

DIRECTIVE 95/46/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data; OJ L 281, 23.11.1995, p. 31; available at: http://ec.europa.eu/justice_home/fsj/privacy/law/index_en.htm

DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to medicinal products for human use; OJ L 311/67; available at: http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_311/l_31120011128en00670128.pdf
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COMMISSION DIRECTIVE 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use; OJ L 159/46; available at: http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_159/l_15920030627en00460094.pdf

DIRECTIVE 2001/20/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 April 2001on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use; L 121/34; available at: http://europa.eu/eur-lex/pri/en/oj/dat/2001/l_121/l_12120010501en00340044.pdf

DIRECTIVE 2004/23/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells; OJ L 102; available at: http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!CELEXnumdoc&lg=EN&numdoc=32004L0023

COMMISSION DIRECTIVE 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells, available at: http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_038/l_03820060209en00400052.pdf

COMMISSION DIRECTIVE 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells; OJ L 102; available at: http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_102/l_10220040407en00480058.pdf

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SEC(2007) 705 COMMISSION STAFF WORKING DOCUMENT Accompanying document to the COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL ORGAN DONATION AND TRANSPLANTATION: POLICY ACTIONS AT EU LEVEL - Summary of the Impact Assessment, Brussels, 30.5.2007; available at: http://ec.europa.eu/health/ph_threats/human_substance/documents/organs_impact_sum_en.pdf