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Nomenclature system for medical devices for the purpose of regulatory data exchange - Rationale

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CEN REPORT

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Nomenclature system for medical devices for the purpose of regulatory data exchange - Rationale

This CEN Report was approved by CEN on 22 October 1997. It has been drawn up by the Technical Committee CEN/TC 257.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Introduction

This report has been prepared to aid understanding of the decisions made by CEN/TC 257/SC 1 - Coding systems and nomenclature for medical devices - in preparing the following documents.

prENV XXXX	Nomenclature - Recommendations for an interim system and rules for a future system
prEN 1874	Nomenclature - Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange

CEN/TC 257/SC 1 was formed in January 1994 to produce a European nomenclature system after a request to CEN from the CEC (Commission of the European Communities).

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1 Background

1.1 Initial assumptions

Development of a regulatory data set should be progressed by Euromedies (European Medical Device Information Exchange System).

The identification of device type using the manufacturer and model was considered to be a vital part of the final system as was the regulatory data set.

It was agreed that device type identification would not be standardized by CEN/TC 257/SC 1.

1.2 Summary

This CEN report describes how the work of CEN/TC 257/SC 1 was progressed and gives proposals for the further development of the nomenclature system as follows:

a) it gives the outline of a European nomenclature and coding system that will facilitate the collation of regulatory data and will provide a structure for some of the information to be exchanged within the Euromedies system;

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NOTE: It is expected that this will lead to publication of EN 1874 - Nomenclature - Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange.

b) it provides a framework for proposals for projects to generate and maintain the nomenclature system; and

c) it gives guidance to potential users of the nomenclature system on the course of action to be taken whilst the European nomenclature system is being generated.

NOTE: It is expected that this will lead to publication of ENV XXXX - Nomenclature - Recommendations for an interim system and rules for a future system.

2 Overview

2.1 General

An agreed, widely used nomenclature system to identify and describe, in general terms, medical devices is needed to allow collation and data exchange across Europe in support of

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the implementation of the Medical Device Directives and to support global harmonization efforts.

2.2 Setting up the nomenclature system

The following factors were considered in developing the system:

a) the requirements, of the CEC, for a decentralized regulatory system and one CA (Competent Authority) per EU (European Union) member;

b) national and multi-national manufacturers;

c) the use of several languages;

d) the need to interface with established nomenclature systems;

NOTE: For example systems in America and Australia.

e) global harmonization initiatives;

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f) the implementation by national governments of the Medical Device Directive on 1 January 1995; and

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g) the availability of resources.

2.3 Tools of data exchange

In developing an effective European nomenclature system the following factors were considered:

a) experience and terms developed from existing systems;

b) the preparation of a nomenclature structure by CEN/TC 257/SC 1;

c) the preparation of a defined data set by Euromedies; and

d) the preparation of an electronic data exchange system and protocols by Euromedies.

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2.4 Responsibilities in the regulatory cycle

The responsibilities of the manufacturer, Notified Body (NB) and Component Authority (CA) are shown in table 1.

2.5 Uses of a European nomenclature system

The European nomenclature system is intended to facilitate data exchange via Euromedies and aggregation of data in a consistent manner for the following purposes:

a) vigilance reports;

b) data exchange between notified bodies;

NOTE: In particular certification information.

c) clinical investigation data exchange between competent authorities;

d) notification of class I devices; and

e) post market surveillance.

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Table 1: Responsibilities in the regulatory cycle

Responsibility						
Organization	Design and classification	Clinical investigation	CE marking - Tests and inspections	Notification of class I and custom devices	Post market surveillance	Vigilance/safeguard action
Manufacturer	x	x	x	x	x	x
Competent Authority		x		x		x
Notified body			x			
NOTE: x indicates responsibility.						

2.6 Other potential users

It is expected that the system will have potential application by purchasers, researchers, standards organizations, hospital and healthcare facilities and other parties interested in medical devices.

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3 Review of existing nomenclature systems

3.1 General

At present many systems exist. They all have various strengths and weakness. The criteria used for the generation and inclusion of new terms are not usually published. The existing nomenclature systems do not usually go down to device type level. Two widely used, well established systems are considered in 3.2 and 3.3.

3.2 FDA system: standard production nomenclature system

NOTE: Annex A gives examples from the FDA system.

3.2.1 General

The FDA system is divided into two levels: the top level is divided between 19 panels (see 3.2.2) and the nomenclature group level (see 3.2.3) which contains more than 4500 preferred terms.

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3.2.2 Top level

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The top level is divided between 19 panels based on clinical speciality. The panels give advice on maintenance of the system. Medical officers and the gatekeeper assign devices to panels depending on the device's intended use. The panels oversee the nomenclature group terms within its remit.

3.2.3 Nomenclature group level

The nomenclature group level is based on device intended use. This level contains other attributes including: FDA class; applicable regulation and device definition. The system is available only in English.

Maintenance of the whole system requires 1.5 person - years per annum plus work by panels.

3.3 ECRI system: Universal medical device nomenclature system

NOTE: Annex B gives examples from the ECRI system.

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3.3.1 General

The ECRI system has a single level, known as the nomenclature group level (see 3.3.2), that contains more than 4400 preferred terms. The ECRI system has been used as the basis of other systems. For example in Australia a structured version of the Universal medical device nomenclature system is used with the addition of a top level containing approximately 70 terms.

3.3.2 Nomenclature group level

The nomenclature group is based on the most prominent device feature, for example: intended use or technology. The system has been translated into many languages. Maintenance of the system requires 3 person years per annum.

4 Recommendations for nomenclature system design

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4.1 Review of options

4.1.1 Architecture

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The choices available are hierarchical or multiaxial. After consideration of the requirements of the relevant directives a hierarchical structure with arributes was proposed. As the number of levels in the structure has consequences on system generation and maintenance a survey of the Directives was made (see annex C).

4.1.2 Relationship between levels

The relationship can be one to many, many to many, etc.

4.1.3 Use of each level

The levels should be used for purposes such as: administration, regulation, purchasing, aggregation and QA.

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4.1.4 Criteria for division within a level

Levels could be divided for the following reasons:

a) clinical use;

b) technology;

c) trade association;

d) physical size of level;

e) price; and

f) regulatory classification.

Experience of FDA and ECRI systems has shown that a single criterion is difficult to apply.

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4.2 Structure

4.2.1 General

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A three level system was proposed as it fulfilled the requirements of the relevant directives (see annex D). The properties expected of each level are given in 4.2.2 to 4.2.4.

4.2.2 Top level - category

This level would be used to facilitate the management of the nomenclature system and to provide a first level search criterion. It would be expected to contain fewer than 20 categories. The categories are divided on the basis of knowledge sets or professional disciplines. Annex E contains the initial categories proposed by CEN/TC 257/SC 1.

4.2.3 Middle level - Generic group

This level will contain the actual nomenclature. It will be used to collect together device types with common features or functions. As with existing systems it would be expected to contain between 5000 and 10 000 terms. The basis of division of the generic group requires development, possibly by CEN/TC 257/SC 1. Attributes may be defined in CEN/TC 257/SC 1 but would be expected to contain factors such as 'active' and 'implant'.