EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods
Cosmetics and Medical Devices

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Standardization mandate to CEN concerning the development of European standards relating to colour coding systems intended for specimen receptacles used for in vitro diagnostic medical devices

GENERAL

Article 5 of the Directive 98/79/EC on in vitro diagnostic medical devices lays down that devices in conformity with national standards transposing harmonised standards, the references of which have been published in the Official Journal, shall have a presumption of conformity with the essential requirements in Article 3 of that Directive.

EN 14254: 2004 and EN 14820: 2004 are harmonised standards under this Directive, giving a presumption of conformity with the relevant essential requirements.

This present mandate is a *specific* mandate to amend these particular standards in order to incorporate a colour coding system:

– EN 14254: 2004 "In vitro diagnostic medical devices - Single-use receptacles for the collection of specimens, other than blood, from humans"

– EN 14820:2004 - Single-use containers for human venous blood specimen collection

These amendments will present a colour coding system used in healthcare settings.

Several standardization mandates are already issued in the field of medical devices.

- Mandate BC/CEN/CENELEC/09/89 concerns active implantable devices
- Mandate BC/CENELEC/02/89 concerns horizontal aspects of medical devices.
- Mandate BC/CEN/03/023/93-08 is a general mandate to produce level 1, 2 and 3 standards. This mandate is further extended by mandate M/295.
- Mandate BC/CEN/03/91 concerns specifically condoms.

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- M/252 covers the specific requirements for In-Vitro diagnostic devices.

I BACKGROUND

During the drafting stage of the revision of EN 14820 and EN 14254 in 2003 a consensus regarding a colour coding system could not be reached.

The CEN/TC 140 noted that in that respect that:

- A number of countries strongly required colour coding of receptacles for their perceived safety of patients;
- Two well-established colour codes are in common use;
- Any changes by manufacturers will increase the cost of production and as a consequence the price of receptacles to users;
- Therefore it had not been possible to make any agreed recommendations on colour codes of receptacles and so these documents had been prepared without a recommended colour code as the only possible means of obtaining consensus by Standards bodies.[1]

II MOTIVATION AND NEEDS

At present, it is recognized, and endorsed by the Medical Device Expert Group in December 2004, to request the acceptance of movement towards a common colour code system intended for specimen receptacles used for in vitro diagnostics, to be required for European use, despite earlier difficulties due to the existence of alternative colour codes. The difficulties experienced in the past when trying to obtain consensus are considered to be overcome.

It has become common understanding that there is a need for a mandate for a common coding system. With regards to safety implications in an area of free circulation of healthcare professionals (nurses, doctors and laboratory personnel) a common colour coding system is safer than several contradicting codes. Consequently, a distinguishing common colour coding system is in the interest of patient safety.

III DESCRIPTION OF MANDATED WORK

CEN is requested to examine and deal with the specific needs and requirements for a common colour coding system for medical devices, and to prepare revisions to the relevant harmonised European standards accordingly.

At least the following elements should be taken into account:

- to examine the option to move towards the system used in the United States as codified in NCCLS Document H1 – A5, tubes and additives for blood specimen collection - fifth edition; approved standard (vol. 23 no. 33);

- to evaluate and determine a transition time built in to allow for changeover;

[1] CEN/TC 140, EN 14820:2004 “Single-use containers for human venous blood specimen collection” at the introduction.

- it should also be encouraged that this single common code is to be accepted at ISO, possibly by means of the Vienna Agreement for a joint adoption.

IV EXECUTION OF THE MANDATE

1. An indication of a target date for a draft amendment and for the final adoption will be provided by CEN. At this date, the three linguistic versions (German, English, French) shall be available as well as the correct titles in the other official languages of the European Union.

2. CEN will communicate to the European Commission when it intends to subject the outcome of the mandate to a formal vote. This date may not exceed the time period of 6 months after acceptance of this mandate.

2. The work will be carried out in close consultation with the Commission, taking into account the fact that the concerned directives are already applied.

3. Within 6 months after the adoption the amended EN harmonized standard will be transposed into national standards. Divergent national standards will be withdrawn in the Member States of the European Union.

4. Acceptance by CEN of this mandate will initiate the standstill period referred to article 7 of the Directive 98/34/EC of 22 June 1998 (OJ no. L204 of 21 June 1998).

5. If, during the drafting of the standards, the structure of this programme would need to be modified, CEN will have to inform the Commission who will then inform the Committee for Standards and Technical Regulations. This new or modified work will normally be included in the present mandate.

6. The Commission reserves the right to specifying more precisely, if necessary, the terms of the mandate.

7. The work following this mandate may be updated by common agreement if that proves to be necessary during the course of the work.

8. The harmonised standard should include an annex providing information with regard to the relationship between its clauses and the essential requirements of the Directive.

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