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Pressure vessels, medical equipment and metrology

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M/252

Standardization mandate to CEN/CENELEC concerning the development of European standards relating to in vitro diagnostic medical devices

I. BACKGROUND AND MOTIVATION

This standardization mandate relates to the proposal for a European Parliament and Council Directive on in vitro diagnostic medical devices.

There are four standardization mandates already authorized in the field of medical devices as follows :

1 Mandate : BC/CEN/CENELEC/09/89

Standardization mandate jointly to CEN and CENELEC concerning the preparation of European standards relating to horizontal aspects in the field of medical devices (These standards relate to both the Active Implantable Medical Devices Directive and the Medical Devices Directive)

2. Mandate : BC/CENELEC/02/89

Standardization mandate to CENELEC concerning the preparation of European standards relating to active implantable medical devices with reference to Council Directive 90/385/EEC of June 1990 . This mandate covered the requirement for harmonised standards covering particular (vertical) matters within the scope of this Directive.

3. Mandate : BC/CEN/03/91

Standardization mandate to CEN concerning the preparation of particular European standards relating to condoms. These are medical devices and fall within the scope of the Directive on Medical Devices.

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4. Mandate : BC/CEN/CENELEC/03/023/93

This standardization mandated addressed to CEN and CENELEC aims at developing European standards of levels 1, 2 and 3. It concerns a broad range of medical devices but concentrates more specifically on the products covered by Directive 93/42/EEC; nevertheless, some standards of level 1 concern all the medical devices covered by the Council Directives 90/385/EEC and 93/42/EEC.

The present standardization mandate is formulated to complement the earlier requests in the context of the directive on in vitro diagnostic medical devices.

This directive is meant to cover a range of products which can be divided in two large categories :

* systems, instruments and devices which in many cases function with the help of an electrical energy source;

* reagents which are chemical or biological substances, often single-use products used in conjunction with the devices referenced above or with other devices.

The very large majority of the standards concerned are of level 1 or 2 due to the nature of the devices covered.

These standards must be produced so that their application will provide a route for the presumption of conformity with specific essential requirements included in the Directive. It is understood that it may be necessary to refer to more than one standard in order to address the relevant essential requirements pertinent to a given medical device.

This standardization mandate continues the principles already established by the previous mandates for the preparation of harmonised standards and seeks to request that, wherever possible, the standards should deal with matters addressing the essential requirements at a “horizontal” level (level 1) or at the level of “families” of products (level 2). In this way, only where there are requirements that are not covered in one of these “horizontal” or “group” standards, will they be requested by means of a particular product harmonised standard.

The three levels of standards within this “Hierarchical” approach are :

Level 1 - basic standards	these “horizontal standards” cover common requirements for all or a wide range of medical devices
Level 2 - group or “family” standards	these “semi-horizontal standards” cover requirements for a related “family” of medical devices, where such requirements are typical for a number of products
Level 3 - product standards	these standards cover requirements for a specific type of medical device

The preparation of level 3 standards is considered appropriate and necessary in the case of specific products where the level 1 or level 2 standards do not adequately address the relevant essential requirements in order to ensure an appropriate level of protection of health and safety.

Wherever relevant, these standards should address the methodology to be used to achieve the essential requirements rather than the specification of particular design or manufacturing solutions which may restrict technological evolution.

The existence of such standards will eliminate potential difficulties which otherwise may be experienced by industry in the manufacture of in vitro diagnostic medical devices when asked to provide justification as to complying with the essential requirements of the directive concerned.

It is thus important that appropriate European standards should be available, wherever possible, before the implementation date for the directive.

In the course of this work relevant international standards (ISO and CEI, amongst others) and other international documents should be identified and, where appropriate, these should be adopted, after incorporating amendments as necessary, to meet the listed directive requirements.

Wherever possible efforts should be made to withdraw documents no longer relevant or suitable in this area.

II. STANDARDIZATION MANDATE

Having identified the needs and also taking into account the programme of work suggested by CEN and CENELEC, the Commission assigns to CEN/CENELEC the task of establishing standards EN in the following areas :

II.1 LIST A

Level 1 standards

1. Performance evaluation plans and methods for IVD MDs including those for self-testing;

2. Description and validation of "special microbiological states" for IVD MDs;

3. Testing of stability of IVD MDs (with particular attention to accelerated stability testing);

4. Presentation of reference measurements procedures (including aspects related to interferences)

5. Description of reference materials;

6. Demonstration of traceability through reference measurement procedures and/or reference materials;

7. Sampling procedures used in the manufacture of IVD MDs - Statistical and systematic considerations;

8. Elimination or reduction of risk of infection related to IVD MDs;

9. Symbols and colour codes to be used for IVD MDs;

10. External quality assessment schemes in relation to medical laboratories (EQAS)[1].

Level 2 or 3 standards

11. Requirements for labelling of IVD reagents for professional use;

12. Requirements for labelling of IVD reagents for self-testing;

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[1] This standard would not necessarily become a "harmonised standard" within the meaning of the directive.

13. Requirements for user manuals for IVD instruments for professional use;

14. Requirements for user manuals for IVD instruments for self-testing;

15. Requirements for marking of IVD instruments;

16. Performance criteria for culture media;

17. General requirements for IVD MDs for self-testing;

18. Blood glucose meters for self-testing;

19. Standardization of enzyme measurements[1] ;

20. Specimen containers.

II.B LIST B

Level 1 standards

1. Amendment to standard EN 61010-1:1993 : "Safety requirements for electrical equipment for measurement, control and laboratory use". Part 1 : general requirements

Level 2 or 3 standards

1. Amendment to standard EN 61010-2-020:1994 : "Safety requirements for electrical equipment for measurement, control and laboratory use". Part 2-020 : particular requirements for laboratory centrifuges

2. Amendment to standard EN 61010-2-045:199x :"Safety requirements for electrical equipment for measurement, control and laboratory use". Part 2-045 : particular requirements for washers desinfectors and other equipment incorporating washing equipment for the treatment of medical materials, and for laboratories processes

3. Amendment to standard EN 61010-2-061:1996 : "Safety requirements for electrical equipment for measurement, control and laboratory use". Part 2-061 : particular requirements for laboratory atomic spectrometers with thermal atomization and ionization

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[1] This standard would not necessarily become a "harmonised standard" within the meaning of the directive.

4. EN 61010-2-081:199x : “Safety requirements for electrical equipment for measurement, control and laboratory use”. Part 2-081 : Particular requirements for automatic and semi-automatic operating analytical equipment”

III. EXECUTION OF THE MANDATE

1. A list of provisional titles for the identified work programme presented in a systematic manner will be provided by CEN and CENELEC before the end of September 1997, including target dates for draft standards and for final adoption.

2. The work will be carried out in close consultation with the Commission, including the allocation of priorities so as to achieve the completion of the work and the adoption of harmonised standards before the end of September 2001.

3. Within 6 months after their adoption the EN harmonised standards will be transposed into national standards. Divergent national standards will be withdrawn in the Member States of the European Union taking into account the transitional period indicated in the Directive.

4. Acceptance by CEN and CENELEC of this mandate will initiate the standstill period referred to in Article 7 of the Directive 83/189/EEC of 28 March 1983 (OJ no. L 109 of 26 April 1983).

5. If, during the drafting of the standards, the structure of this programme would need to be modified, CEN and CENELEC 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.

The present mandates may be modified by common agreement if that proves to be necessary during the course of the work.