EUROPEAN COMMISSION
DIRECTORATE-GENERAL III INDUSTRY
Industrial affairs II: Capital goods industries
Pressure vessels, medical equipment and metrology

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MO95

PROGRAMMING MANDATE TO CEN/CENELEC RELATING TO IN VITRO DIAGNOSTIC MEDICAL DEVICES

I. Motivation

This standardization request relates to the proposal for a directive on in vitro diagnostic medical devices (COM (95)130).

This mandate invites CEN and CENELEC to draw up a work programme to define the European standards needed to ensure the optimal functioning of the forthcoming directive on in vitro diagnostic medical devices (including in particular reagents, instruments and complete systems).

To do this it is necessary to establish priorities taking account of:

- the need, with regard to design, manufacturing and use of the in vitro diagnostic medical device.
- the advanced state of standardisation work taking place in Europe and at international level; and
- the need for standards to facilitate application of the requirements of the directive and the necessity of having these standards in good time;

A standardisation request will be established on the basis of the work programme emanating from this mandate.

The programme will include details of harmonised standards to be developed which when used by manufacturers of medical devices will enable the manufacturer to claim compliance with the specific essential requirements included in the IVD directive proposals as addressed by such standards.

Other standards may be developed within this programme which may not specifically address essential requirements and so may not assume the status of a harmonised standard, but which may be helpful in providing detailed interpretation for specific procedures for the manufacturer of medical devices.

II. Programming request

1) Programme objective

The Commission hereby requests CEN and CENELEC to prepare for this sector a joint and mutually agreed comprehensive and coherent work programme of standards. This programme should contribute to clear understanding of the purpose of standardisation, avoid duplication of work, permit an optimal organisation of resources, and allow the identification of needs for horizontal and vertical standards to provide a coherent approach.

The programme must also indicate which of the standards should have the status of a harmonised standard.

It is also requested that need should be indicated for appropriate revisions to standards which have been completed or those still in the process of elaboration in order for them to assume the status of harmonised standards by taking into account the necessary requirements foreseen in the proposed directive.

The mandate should take account of the existing mandates :

- BC/CEN/CENELEC/09/89;
- BC/CENELEC/02/89;
- BC/CEN/03/91;
- BC/CEN/CENELEC/03/323/93-08;

and ongoing standardisation activities related to the Directives 90/385/EEC on Active Implantable Medical Devices and 93/42/EEC on Medical Devices.

2) Elements to be taken into consideration

a) The harmonised standards to be prepared :

- Shall be suitable for giving presemption of conformity with legal requirements to the necessary extent without rephrasing these requirements in other terms;
- Shall not deal with matters explicitly covered by the draft legislation;
- Shall prescribe methods by which conformity with their requirements can be determined.

b) For each standard the following information shall be indicated:

- Title;
- Indication of the scope of the standard;

- Any relevant reference documents (e.g., existing international or national standards, research reports, etc.);
- Whether it involves the revision of an existing standard or one in an advanced stage of preparation;
- The timetable for the development, adoption and implementation of the standard;
- The body that will be responsible for the work;
- Priority to be allocated within the programme;
- Whether or not the subject of the standard is partly covered by another mandate for standardisation.

c) It is accepted that certain of these standards may be drawn up by ISO or IEC and accepted under the Vienna Agreement.

III. BODIES TO BE ASSOCIATED

The programme shall be developed with the participation and assistance of concerned parties (e.g. industry, professionals, consumers, assessment bodies, etc.).

IV. TIMETABLE

The standardisation programme shall be presented to the Commission by March 1996.

V. Presentation by CEN and CENELEC of the programme starts the standstill period referred to in Article 7 of Council Directive 83/189/EEC of 28 March 1983 (OJ N° L 109 of 26 April 1983).