



FINAL DOCUMENT

Title: Role of Standards in the Assessment of Medical Devices

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A handwritten signature in black ink that reads "Beth Pierson".

Beth Pierson, GHTF Chair

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**GLOBAL HARMONIZATION TASK FORCE
STUDY GROUP 1**

ROLE OF STANDARDS IN THE ASSESSMENT OF MEDICAL DEVICES

This document has been developed to encourage and support global convergence of regulatory systems and the means of achievement. It is intended for use by medical devices regulators, Conformity Assessment Bodies and industry, and will provide benefits in establishing, in a consistent way, an economic and effective approach to the control of medical devices in the interest of public health. The document will be of value to countries developing or amending regulations. The regulatory requirements of some countries may not, at present, reflect the contents of this document.

ROLE OF STANDARDS IN THE ASSESSMENT OF MEDICAL DEVICES

**GENERAL PRINCIPLES
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International standards are a building block for harmonized regulatory processes to assure the safety, quality and performance of medical devices.

To achieve this purpose, the following principles are recommended:

- Regulatory Authorities and industry should encourage and support the development of international standards for medical devices to demonstrate compliance with “the Essential Principles of Safety and Performance of Medical Devices”¹ (referred to hereafter as the Essential Principles).
- Regulatory Authorities developing new medical device regulations should encourage the use of international standards.
- Regulatory Authorities should provide a mechanism for recognizing international standards to provide manufacturers with a method of demonstrating compliance with the Essential Principles.
- When an international standard is not applied or not applied in full, this is acceptable if an appropriate level of compliance with the Essential Principles can be demonstrated.
- While it may be preferable for harmonization purposes to use international standards, it may be appropriate for Regulatory Authorities to accept the use of national/regional standards or industry standards as a means of demonstrating compliance.
- Standards Bodies developing or revising standards for use with medical devices should consider the suitability of such standards for demonstrating compliance with the Essential Principles and to identify which of the Essential Principles they satisfy.
- The use of standards should preferably reflect current, broadly applicable technology while not discouraging the use of new technologies.
- Standards may represent the current state of art in a technological field. However, not all devices, or elements of device safety and/or performance may be addressed by recognised standards, especially for new types of devices and emerging technologies.

¹ As developed by the Global Harmonization Task Force Study Group 1

"Recognised" Standards²

Regulatory Authorities should have or develop a procedure for "recognition" of voluntary standards and public notification of such recognition. The process of recognition may vary from country to country. An organisation may be created/designated by a country or community to develop recognised voluntary standards (e.g. CEN in Europe), or recognition may occur by publication of existing voluntary standards that a Regulatory Authority has found will meet specific premarket requirements (e.g. USA).

² In European Directives "recognised" standards are known as "harmonized" standards.

Persons intending to market medical devices should obtain information from the relevant Regulatory Authority, Conformity Assessment Body or other authorised third party, or through official publications, on any standards recognised by the Regulatory Authority.³

The term “Recognised Standard” does not imply that such a standard is mandatory.

Compliance with recognised standards may be used (if the manufacturer chooses) to demonstrate compliance with the relevant Essential Principles for Safety and Performance of Medical Devices and/or specific premarket requirements and/or other requirements of the Regulatory Authority.

Alternatives to Recognised Standards

The use of standards is voluntary, except in those particular cases where certain standards have been deemed mandatory by the Regulatory Authority. Manufacturers should be free to select alternative solutions to demonstrate their medical device meets the relevant Essential Principle. Manufacturers may use “non-recognised” standards, in whole or in part, or other methods. Alternative means of demonstrating compliance with the Essential Principles may include, for example:

- national and international standards that have not been given the status of a "recognised standard" by the Regulatory Authority;
- industry standards;
- internal manufacturer standard operating procedures developed by an individual manufacturer and not related to international standards;
- current state of the art techniques related to performance, material, design, methods, processes or practices.

The acceptability of such other solutions should be demonstrated.

Technical Documentation

The manufacturer should retain or be able to provide documentation to demonstrate that the device complies with the selected standard or alternative means of meeting the Essential Principles.

Documentation may include for example, the standard itself (or the alternative means used), how it was applied, deviations, test results and/or other outputs.

When a standard is not applied, or is not applied in full, the manufacturer should retain, and submit where appropriate, data or information to demonstrate:

- that compliance with the Essential Principles has been achieved by other means, and if applicable,
- that the parts of the standard that were not applied were not pertinent to the particular device in question.

³ International standards that may be useful in demonstrating compliance with the Essential Principles may be found in overview documents of international standards organizations e.g., ISO TR16142

A declaration of conformity to a recognised standard may be documented in a Summary Technical File⁴, and submitted where appropriate, in lieu of the technical documentation. The format of the declaration of conformity may vary from country to country but it is desirable that a common format be developed.

GENERAL INFORMATION ON USE OF STANDARDS

General Considerations

General Considerations

The following considerations should be kept in mind when developing a regulatory programme using voluntary standards:

- Standards represent the opinion of experts from industry, regulators, users and other interested parties.
- Standards are based on current scientific knowledge and experience.
- Innovation may present unanticipated challenges to experience.
- Rigid and mandatory application of standards may deter innovation.
- Operation of a quality system, subject to assessment, has become widely acknowledged as a fundamental and effective tool for the protection of public health.
- Quality systems include provisions that address both innovation and experience.
- Such provisions include field experience, risk analysis and management, phased reviews, documentation and record keeping as well as the use of product and process standards.

Types of Standards

Standards are created and published by national or international standards organisations or by Regulatory Authorities. Examples of international standards bodies are IEC and ISO, of regional bodies are CEN and CENELEC, and of national bodies are Deutsches Institut fuer Normung, the British Standards Institute, the American National Standards Institute, ASTM, AAMI, the Japanese Industrial Standards Committee and European and national Pharmacopoeias.

Standards are produced for different reasons and are used in some countries as regulatory requirements rather than being voluntary.

Various terms are used to describe the characteristics of a standard. These are not necessarily mutually exclusive. For example:

- **basic safety standards** (also known as horizontal standards) - standards indicating fundamental concepts, principles and requirements with regard to general safety aspects applicable to all kinds or a wide range of products and/or processes (e.g., standards concerning risk assessment and control of medical devices);
- **group safety standards** (also known as semi-horizontal standards) – standards indicating aspects applicable to families of similar products and/or processes making reference as far as possible to

⁴ Refer to the GHTF document: Summary Technical File for the Pre-Market Documentation of Conformity with Requirements for Medical devices (GHTF.SG1.N011R9)

basic safety standards (e.g., standards concerning sterile or electrically-powered medical devices);
and

- **product safety standards** (also known as vertical standards) – standards indicating necessary safety aspects of specific products and/or processes, making reference, as far as possible, to basic safety standards and group safety standards (e.g., standards for infusion pumps or for anaesthetic machines).

APPENDIX 1 – SOURCES OF STANDARDS
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International standards may be obtained from national standard bodies and possibly at a financial cost. Information is available also from the ISO and IEC Internet web sites.

IEC: International Electromedical Commission
International Electromedical Commission

Address: Central Office of the IEC
3, rue de Varembe
P.O. Box 131
CH-1211 Geneva 20
Switzerland

Telephone: (+41) 22 919 02 11

Fax: (+41) 22 919 03 00

Web Site: <http://www.iec.ch>

ISO: International Organisation for Standardization
International Organisation for Standardization

Address: 1, rue de Varembe
Case postale 56
CH-1211 Geneve 20
Switzerland

Telephone: (+41) 22 749 01 11

Fax: (+41) 22 733 34 30

e-mail: central@iso.ch

Web Site: <http://www.iso.ch>

CEN: CEN Central Secretariat

Address: rue de Stassart, 36
1050 Brussels
Belgium

Telephone: (+32) 2 519 68 11

Fax: (+32) 2 519 68 19

Web Site: <http://www.stri.is/cen>

**CENELEC: Comite Europeene de Normalisation Electrotechnique
Comite Europeene de Normalisation Electrotechnique**

Address: Comite Europeene de Normalisation Electrotechnique
Rue de Stassart, 35
B-1050 Brussels
Belgium

Telephone: (+32) 2 519 68 71

Fax: (+32) 2 519 69 19

Web Site: <http://server.cenelc.be>

Others: see links to above organizations for other national or regional standardization organizations.