PROPOSED DOCUMENT

Global Harmonization Task Force

Title: Role of Standards in the Assessment of Medical Devices (including *In Vitro* Diagnostic Devices)

Authoring Group: Study Group 1 of the Global Harmonization Task Force

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Preface

This document was produced by the Global Harmonization Task Force, a voluntary consortium of representatives from medical device Regulatory Authorities and Trade Associations from around the world. The document is intended to provide non-binding guidance to Regulatory Authorities for use in the regulation of medical devices and has been subject to consultation throughout its development and endorsement by the current Chair. Endorsement by the Chair signifies acceptance by consensus amongst members of the GHTF Steering Committee, as a document to be promoted by all members of the GHTF.

The primary way in which the Global Harmonization Task Force (GHTF) achieves its goals is through the production of harmonized guidance documents suitable for implementation or adoption by member Regulatory Authorities or by nations with developing regulatory programmes.

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1.0 Introduction

The objective of the Global Harmonization Task Force (GHTF) is to encourage convergence at the global level in the evolution of regulatory systems for medical devices in order to facilitate trade whilst preserving the right of participating members to address the protection of public health by regulatory means considered to be most suitable. This is achieved by identifying and developing areas of international co-operation in order to facilitate progressive reduction of technical and regulatory differences in systems established to regulate medical devices.

The GHTF has identified an important role for technical standards both during the design of a medical device and to demonstrate a device conforms to essential safety and performance criteria. This role was described in the GHTF publication on the subject entitled *Role of Standards in the Assessment of Medical Devices (SG1/N012 of November 18, 1999)*. **This current document supersedes that earlier one.** The major difference between them is to expand the scope of application to include medical devices for the *in vitro* examination of specimens derived from the human body.

Eliminating differences between jurisdictions decreases the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments.

This guidance document has been prepared by Study Group 1 of the Global Harmonization Task Force (GHTF). Comments or questions about it should be directed to either the Chairman or Secretary of GHTF Study Group 1 whose contact details may be found on the GHTF web page.

2.0 Scope

This document applies to all products that fall within the definition of a medical device that appears within the GHTF document *Information Concerning the Definition of the Term 'Medical Device' (SG1/N029).*

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 Regulatory Authorities, 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.

Regulatory Authorities that are developing regulations for medical devices and are considering the role of technical standards in assessing whether devices comply with the essential principles for safety and performance are encouraged to consider the adoption of this guidance, as this will help to reduce the diversity of schemes world-wide and facilitate the process of harmonization.

The regulatory requirements of some countries may not, at present, reflect the contents of this document.

3.0 Informative References

Final documents

SG1/N009 *Labelling for Medical Devices*

SG1/N020 *Essential Principles of Safety and Performance of Medical Devices*

Superseded document

SG1/N012 *Role of Standards in the Assessment of Medical Devices.*

Documents available for public comment at 5 October 2002

SG1/N011 *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices.*

SG1/N015 *Medical Devices Classification.*

SG1/N029 *Information Document Concerning the Definition of the Term 'Medical Device'.*

SG1/N043 *Labelling for Medical Devices (including In Vitro Diagnostic Devices).*

Documents being prepared for public comment

SG1/N040 *Premarket Conformity Assessment for Medical Devices.*

International standards

ISO 14971 *The Application of Risk Management to Medical Devices.*

ISO/TR 16142:1999 *Medical Devices – Guidance on the Selection of Standards in Support of the Recognized Essential Principles of Safety and Performance of Medical Devices.*

4.0 Definitions

Conformity assessment: The systematic examination to determine the extent to which a medical device fulfils specified requirements. *(Source – EU-Canada MRA)*

Conformity Assessment Body (CAB): A body engaged in the performance of procedures for determining whether the relevant requirements in technical regulations or standards are fulfilled. A CAB is authorized to undertake specified conformity assessment activities by a RA that will ensure performance of the CAB is monitored and, if necessary, withdraw designation. *(Source – EU-Canada MRA)*

Regulatory Authority (RA): A government agency or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements. *(Source – EU-Canada MRA)*

Risk: Combination of the probability of occurrence of harm and the severity of that harm. *(Source – ISO/IEC Guide 51:1999)*

Standards

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 basic safety standards (e.g., standards concerning sterile medical devices, electrically-powered medical devices or risk of infection due to IVD reagents); 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, for anaesthetic machines, for blood glucose meters for self testing or specifications detailing technical product requirements for certain IVD devices).

Recognised standards[1]: Standards deemed to offer the presumption of conformity to specific essential principles of safety and performance.

5.0 General Principles

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:

[1] In European Directives recognised standards are known as harmonized standards.

- 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" (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.

5.1 Recognised Standards

Regulatory Authorities should have, or should develop, procedures for "recognition" of voluntary standards and for 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).

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.[2]

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

[2] 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

Medical Devices and/or specific premarket requirements and/or other requirements of the Regulatory Authority.

5.2 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.

5.3 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.

A declaration of conformity to a recognised standard may be documented in the Summary Technical Documentation that demonstrates conformity to the Essential Principles of Safety and Performance of Medical Devices, 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.

6.0 General Information on Use of Standards

6.1 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.

6.2 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 in application.

Appendix

Appendix A: Sources of Standards

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

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: hppt://www.iec.ch

ISO: 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: hppt://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

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.cenelor.be

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