
# PROPOSED DOCUMENT

## Global Harmonization Task Force

**Title:** Role of Standards in the Assessment of Medical Devices (revised)

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

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# Table of Contents

## Preface

The document herein was produced by the Global Harmonization Task Force, a voluntary group of representatives from medical device regulatory authorities and the regulated industry. The document is intended to provide non-binding guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.

# 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 those regulatory means considered the most suitable.

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, as appropriate taking into account their existing legal framework, or by nations with developing regulatory programmes. Eliminating differences between jurisdictions decreases the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments.

This guidance document is one of a series that together describe a global regulatory model for medical devices. It describes the role of technical standards both during the design of a medical device and subsequently to demonstrate a device conforms to essential safety and performance criteria. The GHTF published guidance on this subject in 1999 entitled *Role of Standards in the Assessment of Medical Devices GHTF/SG1/N012 of November 18, 1999.* It applied to the majority of medical devices but not to *in vitro* medical devices. This revision includes

- added guidance for *in vitro* medical devices,
- guidance on revision or replacement of recognised standards,

and **supersedes the previous version.**

This document is intended for use by 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 or amending existing ones are encouraged to consider the adoption of this guidance and the principles it embodies, as this will help to reduce the diversity of schemes worldwide and facilitate the process of harmonization.

The regulatory requirements of some countries may not, at this time, align fully with this guidance.

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 Rationale, Purpose and Scope

## 2.1 Rationale

International consensus standards are a building block for harmonized regulatory processes to assure the safety, quality and performance of medical devices. This document provides guidance on the use of standards by a manufacturer when designing a medical device and, subsequently, when demonstrating the device conforms to relevant essential safety and performance criteria. A consistent approach within different jurisdictions decreases the cost of regulatory compliance and allows patients earlier access to new technologies and treatments.

## 2.2 Purpose

To:

- encourage and support the development of international consensus standards for medical devices to demonstrate compliance with the *Essential Principles of Safety and Performance of Medical Devices* (hereafter referred to as 'Essential Principles');
- encourage manufacturers to comply with appropriate international standards;
- persuade Regulatory Authorities to introduce a mechanism for recognising standards that provide manufacturers with a method of demonstrating compliance with the GHTF harmonised Essential Principles;
- support the concept that in general, the use of standards is voluntary and manufacturers have the option to select alternative solutions to demonstrate their medical device meets the relevant Essential Principles.

## 2.3 Scope

This document applies to all products that fall within the definition of a medical device that appears within the GHTF document *Information Document Concerning the Definition of the Term 'Medical Device'*, **including** those used for the *in vitro* examination of specimens derived from the human body.

# 3.0 References

## GHTF Final Documents

GHTF/SG1/N15:2006 *Principles of Medical Devices Classification.*

GHTF/SG1/N29:2005 *Information Document Concerning the Definition of the Term 'Medical Device'.*

GHTF/SG1/N40:2006 *Principles of Conformity Assessment for Medical Devices.*

GHTF/SG1/N41:2005 *Essential Principles of Safety and Performance of Medical Devices.*

GHTF/SG1/N43:2005 *Labelling for Medical Devices.*

## International Standards

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

ISO/TR 16142:2004 *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 of evidence generated and procedures undertaken by the manufacturer, under requirements established by the Regulatory Authority, to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to the *Essential Principles of Safety and Performance for Medical Devices*.

**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 Regulatory Authority 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)*

**Standard:** Document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

**NOTE:** Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.
*(Source – ISO/IEC Guide2:2004, definition 3.2)*

**Basic 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, clinical investigation and the quality management system for the manufacture of medical devices).

**Group 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 standards (e.g., standards concerning sterile medical devices, electrically-powered medical devices or risk of infection due to IVD reagents); and

**Product standards (also known as vertical standards):** Standards indicating necessary safety and performance aspects of specific products and/or processes, making reference, as far as possible, to basic standards and group 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. Standards represent the opinion of experts from all interested parties, including industry, regulators, users and others.

To achieve harmonization, the following principles are recommended:

- Regulatory Authorities and industry should encourage, support and contribute to 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 should encourage the use of international standards[2].
- Regulatory Authorities should provide a mechanism for recognizing international standards to provide manufacturers with a method of demonstrating compliance with the Essential Principles. This mechanism should include also withdrawal of recognition. Preference should be given to standards developed in accordance with principles of procedural transparency, and rules that require public comment, periodic revisions, and the consideration and resolution of all negative votes.
- If a manufacturer chooses not to apply a recognised standard in part or in full, then this is acceptable if an appropriate level of compliance with the Essential Principles can be demonstrated.
- It is preferable for harmonization purposes to use international standards but Regulatory Authorities should be prepared also to accept the use by manufacturers of global[3], national, regional 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 should identify which of the Essential Principles they satisfy.

[1] In European Directives 'recognised standards' are known as 'harmonized standards'. In USFDA Regulations, a recognized standard is listed on the annually published USFDA list of "Recognized Medical Device Standards".
[2] These include standards where an international standard has been adopted as a national standard.
[3] Standards that, while not being international standards, have gained acceptance in many parts of the World.

- Standards should represent the generally acknowledged state of technology and practice. The preference for the use of recognised standards should not discourage the use of new technologies. Not all devices, or elements of safety and/or performance, may be addressed by recognised standards, especially for new types of devices and emerging technologies.

## 5.1 Recognition of Standards

Regulatory Authorities should have, or should develop, procedures for "recognition" of international voluntary standards and for public notification of such recognition. The process of recognition may vary from country to country. These procedures need to include a mechanism of regular review and realignment of locally recognized standards to the international standards. Recognition may occur by publication of lists identifying existing voluntary standards that a Regulatory Authority has found will meet specific premarket requirements.

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.[4]

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

Compliance with recognised standards may be used by the manufacturer 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.

## 5.2 Revision or Replacement of Recognised Standards

Recognised standards may be revised or superseded from time to time for various reasons, for example:

- changes in state of technology and accepted practice necessitate revising the technical specifications in the standard;
- a requirement in a specific standard is determined to be inadequate to ensure conformity to a specific Essential Principle, e.g. there is a safety implication;
- one or more of the Essential Principles has changed.

In general, the updated standard will become recognised, and recognition of the superseded document is withdrawn after a reasonable transition period established by the RA/CAB. The transition period should be adequate to allow manufacturers to respond in an appropriate manner. In normal circumstances, the transition period should be 3 years and should not exceed 5 years unless there are exceptional circumstances that justify a longer transition period.

Where the recognised standard has been revised to address safety concerns, the manufacturer is expected to implement a risk mitigation strategy and take appropriate action to address these concerns.

[4] International standards that may be useful in demonstrating compliance with the Essential Principles may be found in overview documents published by international standards organizations e.g., ISO TR16142

During the transition period both the existing and the revised version of the recognised standard give presumption of conformity with the Essential Principles.

Devices designed and manufactured, using either version of the recognised standard, and first introduced to the market prior to the end of the transition period, remain in compliance with the Essential Principles.

Devices first introduced to the market after the end of the transition period should comply with the revised version of the recognised standard.

However, manufacturers choosing to continue to use a superseded version of a recognised standard after the transition period, either for a newly introduced or already marketed device, lose presumption of conformity to the Essential Principles and should take account of this decision in a risk assessment and accompanying documentation. The manufacturer's decision is subject to review by a Conformity Assessment Body or Regulatory Authority, if appropriate.

Devices already in use (i.e. devices that were sold to users before or during the transition period) and compliant with a superseded version of a recognised standard, remain in compliance with the Essential Principles of Safety and Performance unless it has been demonstrated otherwise through post-market activities. Where it is considered that there are safety implications, the manufacturer should implement a risk mitigation strategy and take appropriate action to address all safety concerns.

### 5.3 Alternatives to Recognised Standards

The use of standards is voluntary. Manufacturers should have the option to select alternative solutions to demonstrate their medical device meets the relevant Essential Principles. 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;
- other sources that describe the current state of technology and practice related to performance, material, design, methods, processes or practices.

The acceptability of such other solutions should be demonstrated.

## 5.4 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, how it was applied, deviations, test results, relevant pass/fail criteria when these are not specifically stated in the standard 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[5], 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.

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

# Appendix

# Appendix A: Sources of Standards

International standards may be obtained from national standard bodies and possibly at a financial cost.

**IEC: International Electrotechnical Committee**

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**

Address: 1, rue de Varembe
P.O. Box 56
CH-1211 Geneve 20
Switzerland

Telephone: (+41) 22 749 01 11

Fax: (+41) 22 733 34 30

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

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