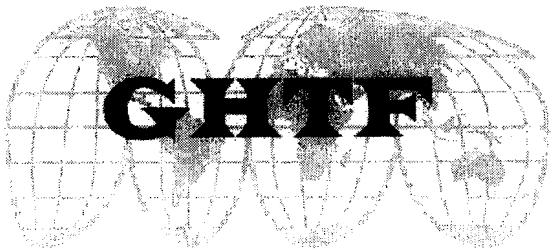

FINAL DOCUMENT

Global Harmonization Task Force

Title: Role of Standards in the Assessment of Medical Devices

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

Date: 5 March 2008

Larry Kessler, GHTF Chair

This document was produced by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

There are no restrictions on the reproduction, distribution or use of this document; however, incorporation of this document, in part or in whole, into any other document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the Global Harmonization Task Force.

Copyright © 2000 by the Global Harmonization Task Force

FDA-2008-D-0372

BKG

Table of Contents

1.0 Introduction 4
2.0 Rationale, Purpose and Scope 5
2.1 Rationale 5
2.2 Purpose 5
2.3 Scope 5
3.0 References 5
4.0 Definitions 6
5.0 General Principles 7
5.1 Recognition of Standards 7
5.2 Revision of Recognised Standards 8
5.3 Changes to the Recognition Status 8
5.4 Use of Recognised Standards when Designing and Supplying Medical Devices both during and after the Transition Period 9
5.5 Status of Devices Designed using the Superseded Version of the Recognised Standard and Supplied before the end of the Transition Period 9
5.6 Alternatives to Recognised Standards 9
5.7 Technical Documentation 10

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.

There are no restrictions on the reproduction, distribution, translation or use of this document. However, incorporation of this document, in part or in whole, into any other document does not convey or represent an endorsement of any kind by the Global Harmonization Task Force.

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 to demonstrate a device conforms to essential safety and performance principles. The GHTF published guidance on this subject entitled *GHTF/SG1/N012:2000 Role of Standards in the Assessment of Medical Devices.* It applied to the majority of medical devices but not to in vitro diagnostic (IVD) medical devices.

This document supersedes that previous version. It has been changed to:

- extend the scope to include in vitro diagnostic medical devices; and
- provide guidance on the use of recognised standards that have been revised or replaced.

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 the Chair of GHTF Study Group 1 whose contact details are available on the GHTF website.

Note: Where GHTF guidance documents are cited within this text, their titles are italicised for clarity.

2.0 Rationale, Purpose and Scope

2.1 Rationale

International consensus standards are a tool for harmonizing 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 demonstrating the device conforms to relevant essential safety and performance principles.

2.2 Purpose

To:

- encourage and support the development of international consensus standards for medical devices that may serve to demonstrate conformity with the *Essential Principles of Safety and Performance of Medical Devices* (hereafter referred to as 'Essential Principles');
- encourage manufacturers to conform with appropriate international standards;
- persuade Regulatory Authorities to introduce a mechanism for recognising standards that provide manufacturers with a method of demonstrating conformity with the GHTF harmonized 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/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/N11:2008 *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED).*

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 of 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.

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.

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

Standard: Document, established by consensus and approved by a recognised 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. *(ISO/IEC Guide2:2004, definition 3.2)*

Basic standard (also known as horizontal standard): Standard indicating fundamental concepts, principles and requirements with regard to general safety and performance aspects applicable to all kinds or a wide range of products and/or processes (e.g., standards concerning risk management, clinical investigation and the quality management system for the manufacture of medical devices).

Group standard (also known as semi-horizontal standard): Standard 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, stability of IVD reagents).

Product standard (also known as vertical standard): Standard 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 or for blood glucose meters for self testing).

Recognised standard: Standard deemed to offer the presumption of conformity to specific Essential Principles of Safety and Performance.

5.0 General Principles

International standards, such as basic standards, group standards and product standards, are a tool for harmonizing 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:

- RAs and industry should encourage, support and contribute to the development of international standards that may be useful in demonstrating conformity of medical devices with the Essential Principles[1].
- RAs should encourage the use of international standards[2].
- RAs should establish a mechanism for recognizing international standards to provide manufacturers with a method of demonstrating conformity with the Essential Principles. This mechanism should also include a procedure for 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 the public comments.
- If a manufacturer chooses not to apply a recognised standard in part or in full, then this is acceptable if conformity with the Essential Principles can be demonstrated by another means.
- It is preferable for harmonization purposes to use international standards but RAs should be prepared also to accept the use by manufacturers of global[3], national, regional or industry standards as a means of demonstrating conformity.
- Standards Bodies developing or revising standards for use with medical devices should consider the suitability of such standards for demonstrating conformity with the Essential Principles and should identify which of the Essential Principles they satisfy.
- Standards should represent the generally acknowledged state of technology and practice. However, 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

RAs should provide a method for the recognition of international voluntary standards and for public notification of such recognition. The process of recognition may vary from country to country. The method should include a mechanism of periodic review and realignment of nationally recognised standards to the international standards. Recognition

[1] International standards that may be useful in demonstrating conformity with the Essential Principles may be found in overview documents published by international standards organizations e.g., ISO/TR 16142:2006.
[2] This includes situations 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.

may occur by periodic publication of lists of standards that a RA has found will meet the Essential Principles.

Persons intending to market medical devices should obtain information from the relevant RA through official publications on recognised standards.

The use of standards by the manufacturer is voluntary. The term "recognised standard" does not imply that such a standard is mandatory (see also Section 5.7).

Conformity with recognised standards may be used by the manufacturer to demonstrate conformity with the relevant Essential Principles and/or specific premarket or post-market requirements of the RA. When used, the manufacturer should identify the version and date of the relevant recognised standard(s) in its technical documentation.

5.2 Revision of Recognised Standards

A revision of recognised standards may occur, for example, in the following circumstances:

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

5.3 Changes to the Recognition Status

The RA may cease to recognise a standard for various reasons, such as:

- safety concerns identified through post-market surveillance activities or user experience;
- the availability of a revised version of the standard.

Where the RA considers that, for safety reasons, a recognised standard ceases to give a presumption of conformity to the Essential Principles and a revised version has yet to become available, the RA should fix a date, which may be immediate, after which the standard will no longer give a presumption of conformity to an Essential Principle(s), and publish the withdrawal of recognition in accordance with its procedures for public notification of recognition of standards.

When withdrawing recognition of a standard for reasons other than safety, the RA should fix a date after which the standard will no longer give a presumption of conformity to an Essential Principle(s). When setting such a date, the RA should establish a transition period that should be adequate to allow manufacturers to respond in an appropriate manner. In such circumstances, the transition period should normally be in the order of 3 years. Depending upon the extent and nature of the revision, this transition period may be adapted, as appropriate. The RA should publish this information in accordance with its procedures for public notification of recognition of standards.

5.4 Use of Recognised Standards when Designing and Supplying Medical Devices both during and after the Transition Period

During the transition period both the prior and the revised version of the recognised standard give presumption of conformity with the Essential Principles, consequently either may be used when designing or supplying medical devices to the end user.

After the transition period, only the revised version of the recognised standard gives presumption of conformity with relevant Essential Principles. However, manufacturers may choose to use the superseded version of the recognised standard despite the loss of the presumption of conformity to the Essential Principles and may continue to design and/or supply medical devices to the end user according to the superseded standard. In such cases, in order to demonstrate that the medical device conforms to all relevant Essential Principles, the manufacturer is required to justify its decision to use the superseded standard through documented risk assessment, and take any risk mitigation action as appropriate.

The manufacturer's decision may be subject to review by a RA/CAB.

5.5 Status of Devices Designed using the Superseded Version of the Recognised Standard and Supplied before the end of the Transition Period

Where a medical device was designed according to the superseded version of the recognised standard to demonstrate conformity with one or more relevant Essential Principles and is either in the distribution chain or has been supplied to the end user before the end of the transition period, the manufacturer is not required to take any action unless there are safety implications, in which case the manufacturer should implement a risk mitigation strategy and take appropriate action to address these safety concerns.

5.6 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 conformity 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 agreed methods;
- internal manufacturer standard operating procedures developed by an individual manufacturer;
- 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 justified and may be subject to review by the RA/CAB, as appropriate.

5.7 Technical Documentation

The manufacturer should retain or be able to provide documentation to demonstrate that the device conforms 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 conformity with the Essential Principles has been achieved by other means, and/or
- 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 included in the Summary Technical Documentation (STED), and may, as appropriate, substitute for the source document itself.