Essential Principles of Safety and Performance of Medical Devices

4th APEC-Funded Seminar on
Harmonization of Medical Device Regulation

The Role of Regulators, Industry, and Distributors in Harmonization of Medical Device Regulation in the Asia/Pacific Region

Kuala Lumpur, 6 March 2008

M. Gropp, Medtronic, Inc., Minneapolis, USA

Only medical devices that are safe and perform as intended should be allowed in the market

- ☐ Agree
- ☐ Disagree

Presentation overview

- Introduction
- Purpose
- Overview of main points of Essential Principles guidance document

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Working Towards Harmonization in Medical Device Regulation

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Welcome to the Global Harmonization Task Force Website

The Global Harmonization Task Force was conceived in 1992 in an effort to achieve greater uniformity between national medical device regulatory systems. This is being done with two aims in mind: enhancing patient safety and increasing access to safe, effective and clinically beneficial medical technologies around the world.

A partnership between regulatory authorities and regulated industry, the GHTF is comprised of five Founding Members: European Union, United States, Canada, Australia and Japan. The chairmanship is rotated among the Founding Members and presently resides with the United States.

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- SG2 Participants (21 February 2008)
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- GHTF/APEC Training - 5-7 March 2008 - Kuala Lumpur, Malaysia (14 January 2008)
- SG4 Participants (10 January 2008)
- Steering Committee Chair Page and Member List (21 November 2007)
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SG1 - Final Documents

Title	Description	Posted Date	Size	Comments To
SG1-N15:2006 PDF Word	Principles of Medical Devices Classification	31 August 2006	27 pages	
SG1-N40:2006 PDF Word	Principles of Conformity Assessment for Medical Devices	31 August 2006	16 pages	
SG1-N43:2005 PDF	Labelling for Medical Devices	29 August 2005	10 pages	
SG1-N29R16:2005 PDF	Information Document Concerning the Definition of the Term "Medical Device"	21 July 2005	6 pages	
SG1-N41R9:2005 PDF	Essential Principles of Safety & Performance of Medical Devices	21 July 2005	6 pages	
SG1-N012R10 PDF Word	Role of Standards in the Assessment of Medical Devices	15 March 2000 *Re-posted: 23 October 2000	10 pages, 50Kb-PDF 73Kb-Word	

*Reposted dates indicate when the document was reposted with a standard format cover sheet.

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GHTF/SG1/N41R9:2005

FINAL DOCUMENT

Title: Essential Principles of Safety and Performance of Medical Devices

Authoring Group: GHTF Study Group 1

Endorsed by: The Global Harmonization Task Force

Date: May 20, 2005

Abraao Carvalho, 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.

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.

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Document history

"The GHTF has identified as a priority the need to harmonize essential safety and performance criteria for a medical device that allow the manufacturer to demonstrate its product is suitable for its intended use.

This goal was achieved through the publication of guidance on the subject entitled *Essential Principles of Safety and Performance of Medical Devices* (SG1/N020 of June 30, 1999) that applied to the majority of medical devices but not to *in vitro* diagnostic devices. …"

Document history

"…. This current document supersedes that earlier one. The major difference between them is the expanded scope; this document now includes medical devices for the *in vitro* examination of specimens derived from the human body."

Rationale

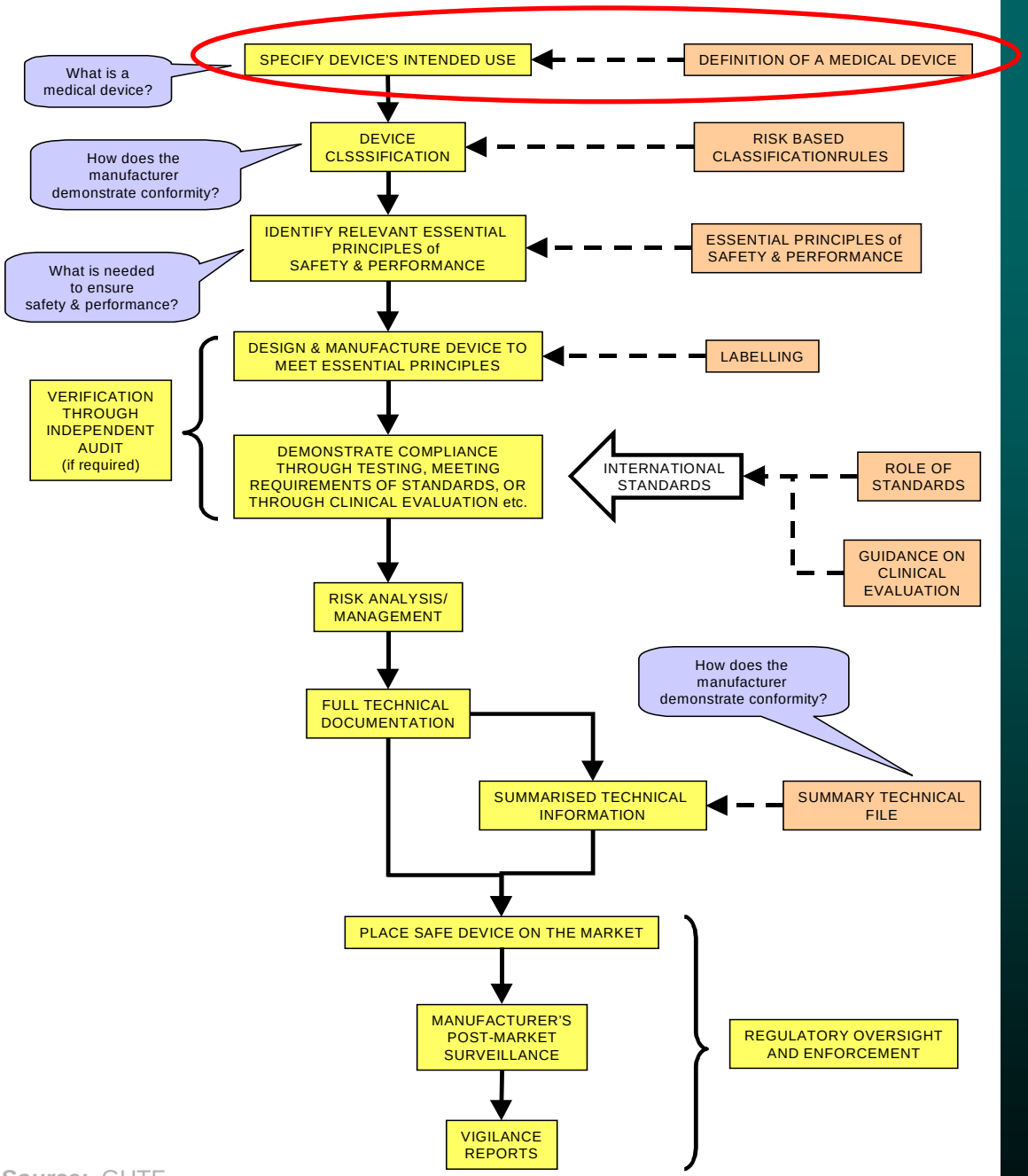
"Consistent identification, selection and application of safety and performance principles to a medical device offers significant benefits to the manufacturer, user, patient or consumer, and to Regulatory Authorities since it allows its manufacturer to design, manufacture and demonstrate the device is suitable for its intended use. ..."

Rationale

"… Moreover, eliminating differences between jurisdictions decreases the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments."

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."


What is a medical device?
SPECIFY DEVICE'S INTENDED USE
DEFINITION OF A MEDICAL DEVICE
How does the manufacturer demonstrate conformity?
DEVICE CLSSSIFICATION
RISK BASED CLASSIFICATIONRULES
What is needed to ensure safety & performance?
IDENTIFY RELEVANT ESSENTIAL PRINCIPLES of SAFETY & PERFORMANCE
ESSENTIAL PRINCIPLES of SAFETY & PERFORMANCE
DESIGN & MANUFACTURE DEVICE TO MEET ESSENTIAL PRINCIPLES
LABELLING
VERIFICATION THROUGH INDEPENDENT AUDIT (if required)
DEMONSTRATE COMPLIANCE THROUGH TESTING, MEETING REQUIREMENTS OF STANDARDS, OR THROUGH CLINICAL EVALUATION etc.
INTERNATIONAL STANDARDS
ROLE OF STANDARDS
GUIDANCE ON CLINICAL EVALUATION
RISK ANALYSIS/ MANAGEMENT
How does the manufacturer demonstrate conformity?
FULL TECHNICAL DOCUMENTATION
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SUMMARY TECHNICAL FILE
PLACE SAFE DEVICE ON THE MARKET
MANUFACTURER'S POST-MARKET SURVEILLANCE
VIGILANCE REPORTS
REGULATORY OVERSIGHT AND ENFORCEMENT

Source: GHTF

Purpose

"To describe six **general requirements** of safety and performance that apply to all medical devices.

To provide a comprehensive list of **design and manufacturing requirements** of safety and performance, some of which are relevant to each medical device. …" [emphasis in original]

Purpose

"… These are grouped as:

- Chemical, physical and biological properties
- Infection and microbial contamination
- Manufacturing and environmental properties
- Devices with a diagnostic or measuring function
- Protection against radiation
- Requirements for medical devices connected to or equipped with an energy source
- Protection against mechanical risks …

Purpose

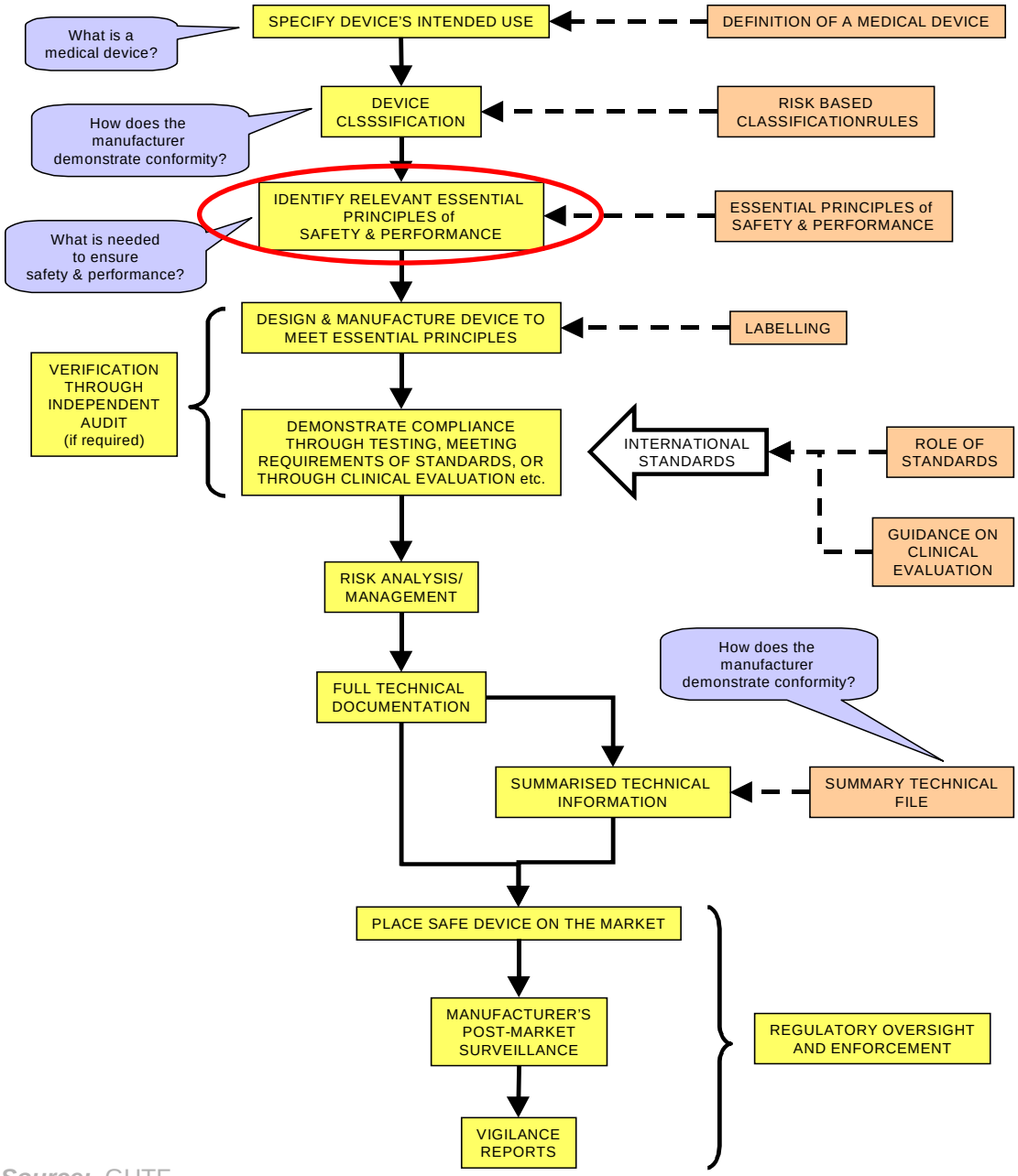
"… These are grouped as: (continued)

- Protection against the risks posed to the patient by supplied energy or substances
- Protection against the risks posed to the patient for devices for self-testing or self-administration
- Information supplied by the manufacturer
- Performance evaluation including, where appropriate, clinical evaluation"

Purpose

"The manufacturer selects which of the design and manufacturing requirements are relevant to a particular medical device, documenting the reasons for excluding the others.

The Regulatory Authority and/or Conformity Assessment Body may verify this decision during the conformity assessment process." (or audit)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Source: GHTF

General requirement 1

"Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, …"

General requirement 1 (continued)

"… provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety."

General requirement 2

"The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art.

When risk reduction is required, the manufacturer should control the risk(s) so that the residual risk(s) associated with each hazard is judged acceptable. …"

Reference: ISO 14971:2001: *Medical devices – Application of risk management to medical devices*

General requirement 2 (continued)

"The manufacturer should apply the following principles in the priority order listed:

- identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse,
- eliminate risks as far as reasonably practicable through inherently safe design and manufacture
- reduce as far as is reasonably practicable the remaining risks by taking adequate protection measures, including alarms,
- inform users of any residual risks"

General requirement 3

"Devices should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions within the scope of the definition of a medical device applicable in each jurisdiction."

General requirement 4

"The characteristics and performances …. should not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions."

General requirement 5

"The devices should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected under transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer."

General requirement 6

"The benefits must be determined to outweigh any undesirable side effects for the performances intended"

Conformity assessment

"Refer to … *Principles of Conformity Assessment for Medical Devices* and the work of GHTF Study Group 5 for further information on the use of clinical evaluation to demonstrate compliance with these Essential Principles."

Summary

- Essential Principles form foundation of harmonised global regulatory model
- Comprehensive in scope
- Cover safety and performance
- Define design requirements
- Do not define methods of achieving, demonstrating, or documenting conformity
    - Often covered by international standards

Summary

- Manufacturer must apply all general principles and all relevant specific principles
- Flexible to accommodate advances in the state of the art and new medical devices / technologies / intended uses
- Recognise risks and benefits associated with medical devices
- Are founded on risk management principles
- Intimately linked to manufacturer's quality system for design, manufacture, and risk management

Questions?