

# MEDICAL DEVICES

REGULATIONS, STANDARDS  
RISK MANAGEMENT,  
GLOBAL HARMONISATION

By

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# SCOPE

- Placing on the market and putting into service of medical devices
- Protection of health and safety of patients, users and third persons

Note: not covered: reimbursement issues, health insurance aspects



# The Philosophy

- -- provisions for the safety and health protection of patients, users, ... with regard to the use of medical devices should be harmonized in order to guarantee the free movement of such devices in the global market

5/9/02



# ----- **The Philosophy**

- -- medical devices should provide patients,... with a high level of protection and attain the performance levels attributed to them by the manufacturer; --- therefore the maintenance and improvement of the level of protection ... is one of the essential objectives of regulations

5/9/02



# PATIENT SAFETY

- -- take all necessary steps to ensure that devices may be placed on the market and put into service only if they do not compromise the safety and health of patient, and users---

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# The Philosophy

- -- when the Essential Principles include references to “minimizing” or “reducing” risk --  
----- these should be interpreted and applied ...  
to take account of technology and practice  
existing at the time of design--- and of technical  
and economical consideration compatible with  
a high level of protection ...



# ESSENTIAL PRINCIPLES

- Risk-Benefit assessment (when used as intended)
- Safety principles applied in design & construction
- Achievement of intended performance - performance defined
- Reliability/consistency of performance during defined lifetime of device
- Transport & storage must not effect performance
- Undesirable side-effects to be identified & quantified against intended performance



# ESSENTIAL PRINCIPLES

- Chemical, physical and biological properties
- Infection and microbial contamination
- Construction and environmental properties
- Devices with a measuring function
- Protection against radiation
- Requirements for medical devices connected or equipped with an energy source (including EMC)
- Information to be supplied by the manufacturer

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# **CONFORMITY ASSESSMENT** **BODIES**

**Inspection and Auditing, if appropriate is carried out by Regulatory Bodies or by Suitably Qualified Conformity Assessment Bodies appointed by the Regulatory Body (CAB's).**



# THE IMPORTANCE OF STANDARDS

- **Standards are a principal element of trade in general and a vital focus in meeting the regulatory ‘Essential Principles’ .**



**IN GENERAL,--- STANDARDS ARE  
NOT MANDATORY**

**THEY PROVIDE A PREFERRED ROUTE  
FOR ADDRESSING SPECIFIC  
‘ESSENTIAL PRINCIPLES’**



# 3 LAYERS OF STANDARDS

1 - HORIZONTAL MATTERS

2 - FAMILY STANDARDS

3 - DEVICE SPECIFIC STANDARDS



# How are Standards Prepared?



# HEALTH COMMITTEES

## Subjects covered by ISO/IEC/CEN/CLC etc

- Risk analysis
- Dentistry
- Sterilizers for medical purposes
- In-vitro diagnostic systems
- Ophthalmic optics
- Sterilization of Medical devices
- Non active medical devices
- Biocompatibility



# Health Committees

- **Medical Alarms and Signals**
- **Non-active surgical implants**
- **Aids for disabled persons**
- **Animal & Human tissues**
- **Working group quality systems**
- **Working group active implantable**
- **Electromedical equipment**



# HEALTH COMMITTEES

- **Respiratory and anaesthetics**
- **Disinfectants and antiseptic**
- **Rescue systems**
- **Medical informatics**
- **Terminology symbols and information provided with medical devices**
- **Nomenclature**
- **Clinical investigation of medical devices**



# VIENNA AGREEMENT

- Maximize cooperation
- Avoid duplication
- Mutual benefits from standardization at both levels



# POST-MARKET

“MANUFACTURERS MUST INSTITUTE AND KEEP UP-TO-DATE A SYSTEMATIC PROCEDURE TO REVIEW EXPERIENCE GAINED FROM DEVICES IN THE POST-PRODUCTION PHASE AND TO IMPLEMENT APPROPRIATE MEANS TO APPLY ANY NECESSARY CORRECTIVE ACTION”

5/9/2002



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# WHAT INFORMATION?

- Malfunction
- Deterioration in Performance
- Inadequacy of Labelling which might lead to: -  
Death or Serious Deterioration in state of  
Health of Patient Users



# **VIGILANCE FOR IVD'S**

## **INTRODUCES: -**

### **INDIRECT HARM -**

- Mis-Diagnosis
- Delayed Diagnosis
- Delayed Treatment

### **DIRECT HARM**

Caused by Agents in IVD

- Toxic Material
- Contact with Specimens etc.



# **Global Data Exchange**

## **Global Database on Medical Device incidents**

**PILOT PROGRAMME UNDERWAY  
IN STUDY GROUP 2 OF GHTE  
(ADMINISTERED BY CANADA)**



# Nomenclature System

## 12 main categories of devices

- Active implantable devices
- Anaesthetic & respiratory devices
- Dental devices
- Electro//medical & electro/mechanical medical devices
- Hospital hardware
- In vitro diagnostic devices

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# NOMENCLATURE SYSTEM

- Non active implantable devices
- Ophthalmic and optical devices
- Re-useable surgical instruments
- Single use devices
- Technical aids for disabled persons
- Diagnostic & therapeutic radiation devices

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# **The Assessment of Risk and its place in the field of Medical Devices**

6/20/00



# **ACCEPTANCE OF PRINCIPLE -**

**“AS LOW AS REASONABLY PRACTICABLE”**

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# **RISK CONTROL MEASURES**

- Inherent Safe Design
- Protection Measures Including Use Of Alarms
- Adequate Information Regarding Any Residual Risk



# LIKELIHOOD

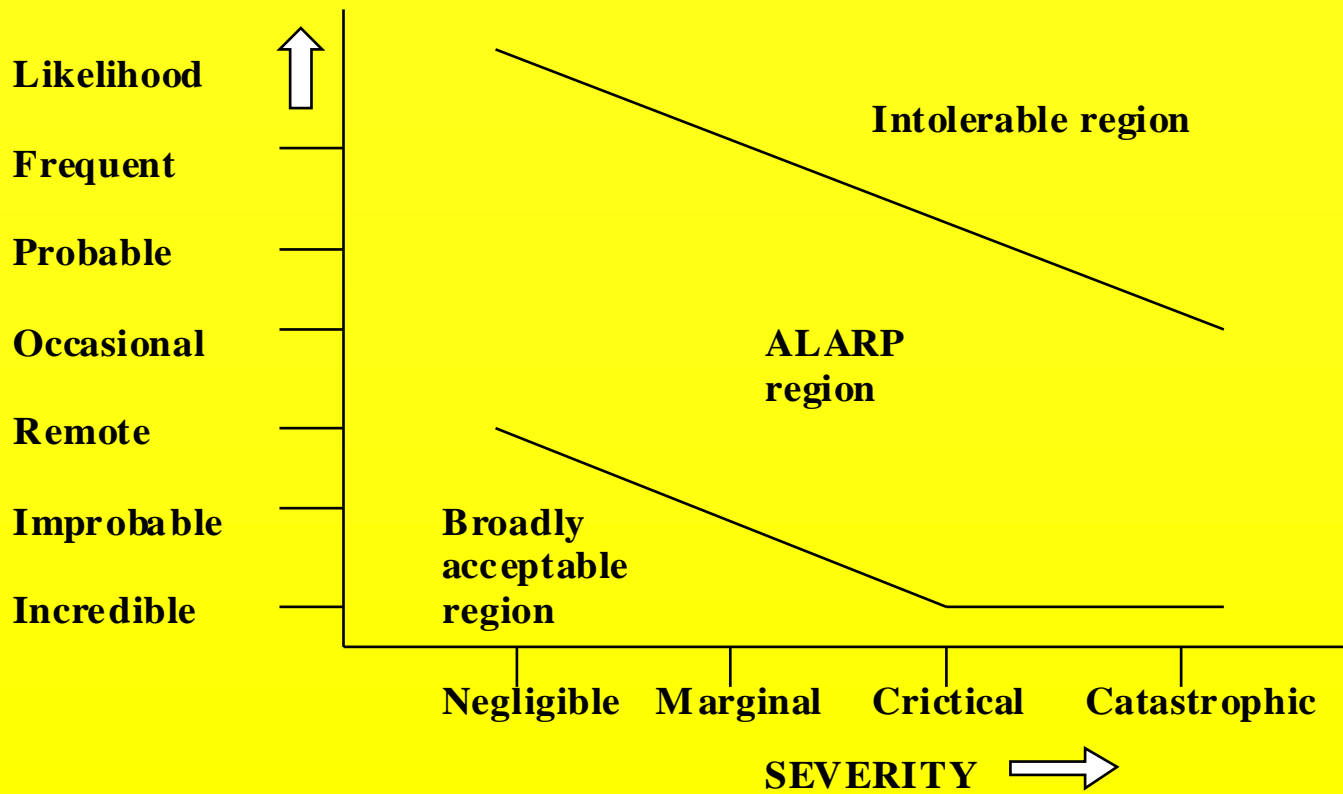
- Frequent
- Probable
- Occasional
- Remote
- Improbable
- Incredible



# SEVERITY LEVELS

- Catastrophic
- Critical
- Marginal
- Negligible





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# Terms of Reference of the Global Harmonisation Task Force

## Procedure 1

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 results are also available to inform interested countries who may be engaged in the development of such regulations.



# Global Harmonisation Task Force Study Group 1

Comparison of Regulatory Requirements

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Originally to compare existing regulations in  
Europe, USA, Canada, Japan, Australia



# Terms of Reference of the Global Harmonisation Task Force

## Objectives

The objective of the Global Harmonisation Task Force 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.



# SCOPE OF GHTF-SG1 PREMARKET TECHNICAL REQUIREMENTS

