

# The Role of Standards in Medical Device Regulation

Asian Harmonization Working Party  
Pre-Meeting Workshop

New Delhi, 4 November 2008

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



# Introduction

- International standards are a basic element of GHTF “global regulatory model”
- General overview of technical field
- Material from many sources
- Context

## International standardization

“International standards, and their use in technical regulations on products, production methods and services play an important role in sustainable development and trade facilitation through the promotion of safety, quality and technical compatibility. ...”



*Source:* ISO/IEC Information Centre; [www.standardsinfo.net/info](http://www.standardsinfo.net/info)

# International standardization

“... The benefits that are derived are significant. Standardization contributes to the basic infrastructure that underpins society including health and environment while promoting sustainability and good regulatory practice”

## International standardization

“International standards, or national or regional adoptions of international standards, assist in the operation of domestic markets, and also increase competitiveness and provide an excellent source of technology transfer. They play an integral role in the protection of consumers and the environment.”

## International standardization

“With the increasing globalization of markets, international standards (as opposed to regional or national standards) have become critical to the trading process, ensuring a level playing field for exports, and ensuring imports meet internationally recognized levels of performance and safety.”

# What is a “standard”?

“A technical standard is an established norm or requirement. It is usually a formal document that establishes uniform engineering or technical criteria, methods, processes and practices”

# What is a “standard”?

“Document,



# What is a “standard”?

“Document, established by consensus

## What is a “standard”?

“Because ISO standards are voluntary agreements, they need to be based on a solid consensus of international expert opinion”

“Consensus, which requires the resolution of substantial objections, is an essential procedural principle and a necessary condition for the preparation of International Standards that will be accepted and widely used.

Although it is necessary for the technical work to progress speedily, sufficient time is required before the approval stage for the discussion, negotiation and resolution of significant technical disagreements.”

# What is a “standard”?

Consensus: “general agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments”

“Consensus need not imply unanimity”

# What is a “standard”?

“Document, established by consensus and approved by a recognized body,

# What is a “standard”?

“Document, established by consensus and approved by a recognized body, that provides, for common and repeated use,

# What is a “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,

# What is a “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

# What is a “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.



# What is a “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,

# What is a “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”

# What is a “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”

# What is an “international standard”?

“Standard that is adopted by an international standardizing/standards organization and made available to the public”

# What is a “regulation”?

“Document providing binding legislative rules, that is adopted by an authority”

Technical regulation: “Regulation that provides technical requirements, either directly or by referring to or incorporating the content of a standard, technical specification or code of practice

NOTE: A technical regulation may be supplemented by technical guidance that outlines some means of compliance with the requirements of the regulation, i.e., deemed-to-satisfy provision”

# Relationship between standards and regulation

“ISO and IEC standards can be used to support and simplify the process of development and application of technical regulations”

## International standards

- “Support the technical aspects of societal and environmental policies and contribute to sustainable development across the world;
- Offer the same level of consumer protection whether applied in a mature or an evolving economy;
- Allow products to be supplied and used across different markets, facilitating regulatory compliance and enhancing the market access opportunities for small enterprises; ...

## International standards

- “Reflect the state of the art and serve as a vehicle for the dissemination of new technologies and innovative practices;
- Can become national standards after a national public enquiry process carried out by a country’s standards body, which can reduce the need for the regulator to hold national consultations;
- Can be used as a basis for national technical regulations without causing unnecessary technical barriers to trade ...



## International standards

- “Offer a complete range of tools for the various modes of conformity assessment;
- Are used for conformity assessment to enhance confidence in products, systems, processes, services or personnel;
- Are developed using procedures which ensure that the thousands of standards available avoid duplication and conflict with each other”

## Benefits of international standards

“This report, for the first time, puts a dollar value on the impact of standards across some of our most important industries and also measures the economy wide benefits. ... And the result is clear: standards are helping generate profits and creating jobs in Australia”

- Over the 40 years to 2002 a 1 percent increase in the number of Australian standards is associated with a 0.17 percent increase in productivity across the economy
- ... standards can be considered, together with R&D expenditure, as contributing factors to the stock of knowledge, .... A 1 percent increase in this joint stock of knowledge leads to a 0.12 percent increase in economy-wide productivity”

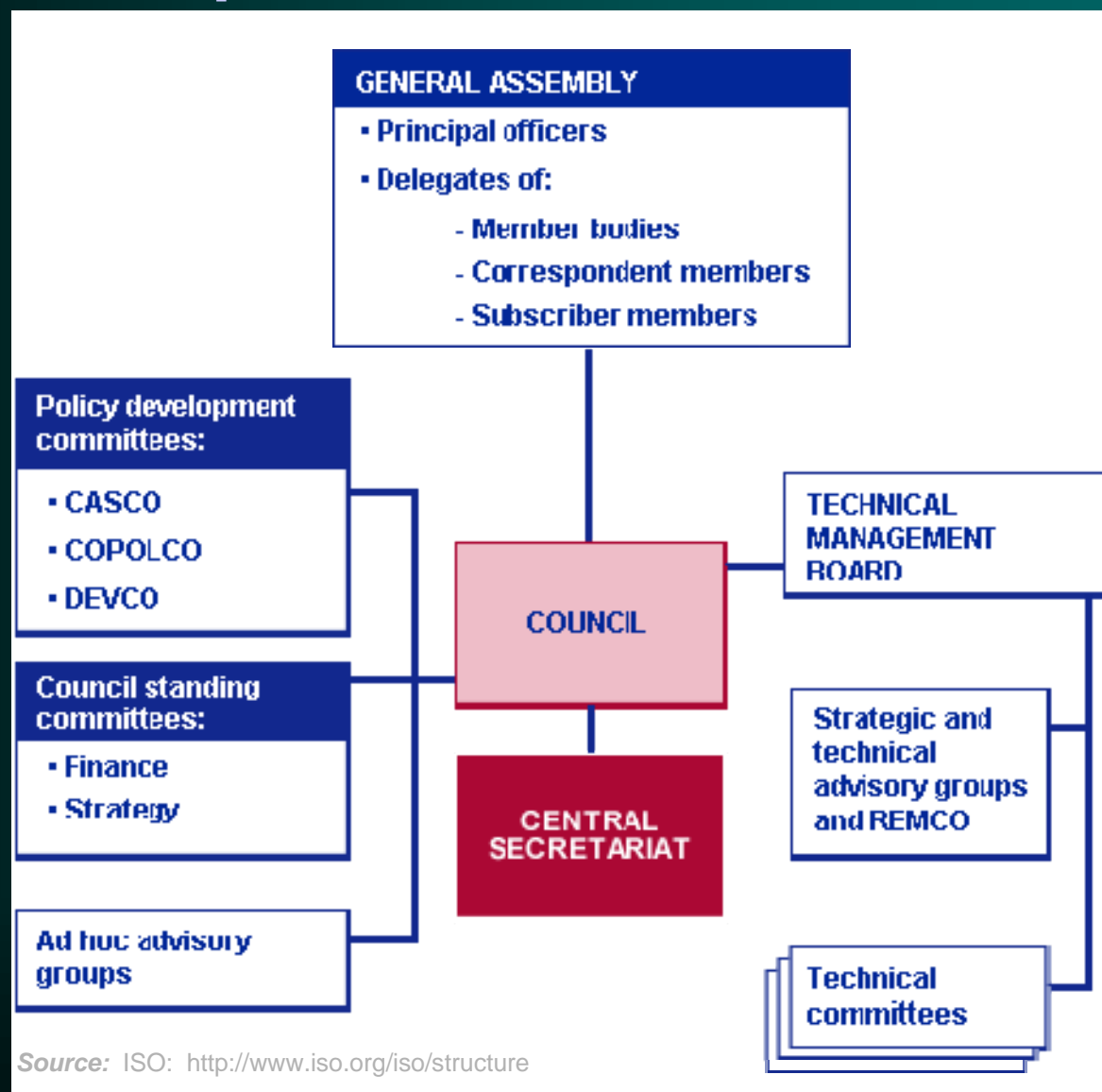


*Source:* ISO/IEC Information Centre; [www.standardsinfo.net/info](http://www.standardsinfo.net/info)

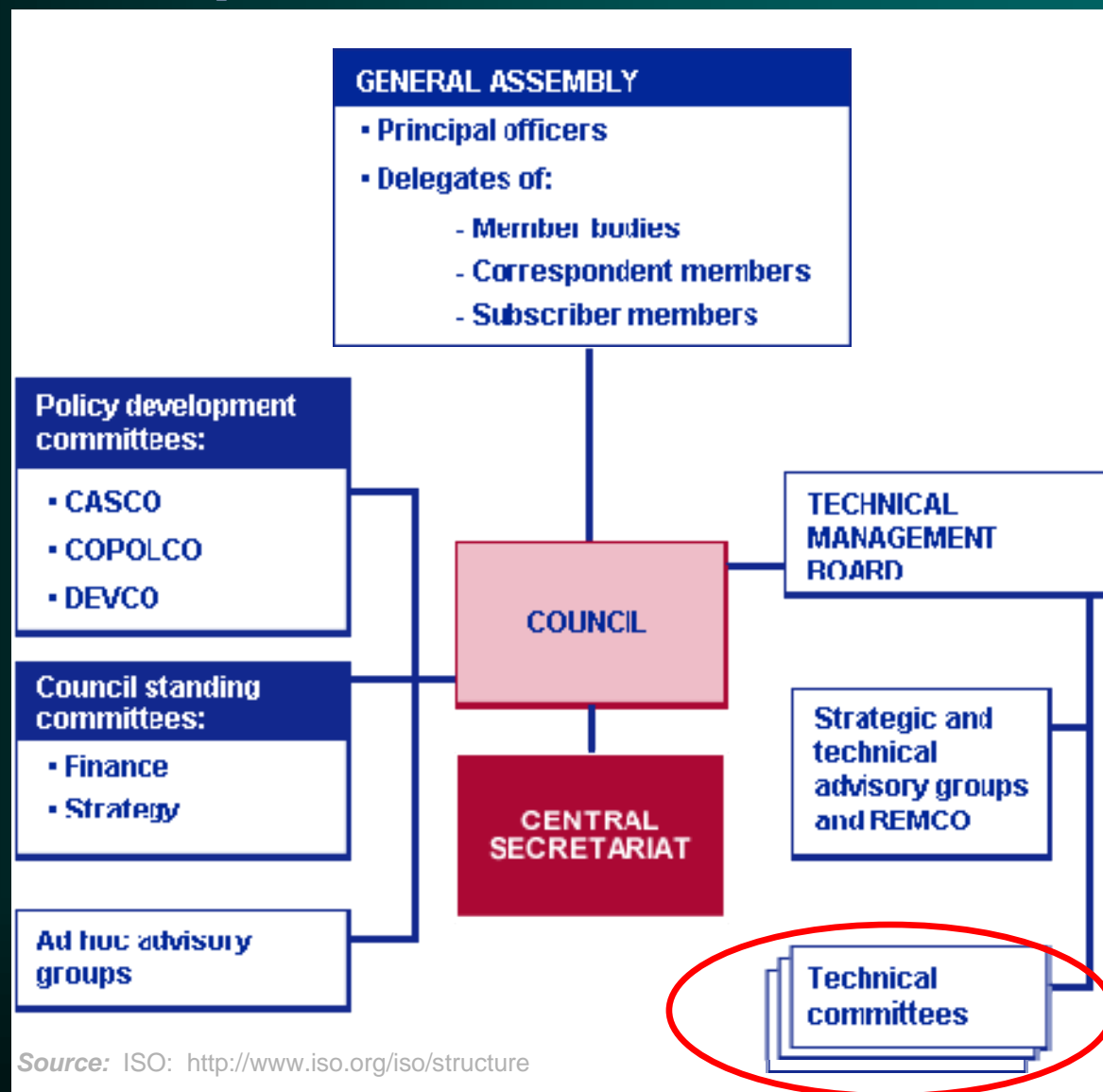
# Who develops international standards?

- International Organization for Standardization (ISO)
- International Electrotechnical Commission (IEC)
- International Telecommunication Union (ITU)

# Who develops international standards?



# Who develops international standards?



# Who develops international standards?

## Standardization Body Technical committees:

- Experts from industrial, technical, and business sectors
- Representatives of government agencies, testing laboratories, consumer associations, non-governmental organizations, and academia
- Participate as national delegations, chosen by national member body

# Who develops international standards?

## AHWP member economy standardization bodies (ISO)

- Brunei Darussalam: Construction Planning and Research Unit
- Cambodia: Department of Industrial Standards of Cambodia
- PR China: Standardization Administration of China
- Hong Kong SAR: Innovation and Technology Commission
- India: Bureau of Indian Standards
- Indonesia: Badan Standardisasi Nasional
- Korea: Korean Agency for Technology and Standards
- Lao PDR: Department of Intellectual Property, Standardization and Metrology
- Malaysia: Department of Standards Malaysia
- Philippines: Bureau of Product Standards
- Saudi Arabia: Saudi Arabian Standards Organization
- Singapore: Standards, Productivity and Innovation Board
- South Africa: South African Bureau of Standards
- Thailand: Thai Industrial Standards Institute
- Vietnam: Directorate for Standards and Quality



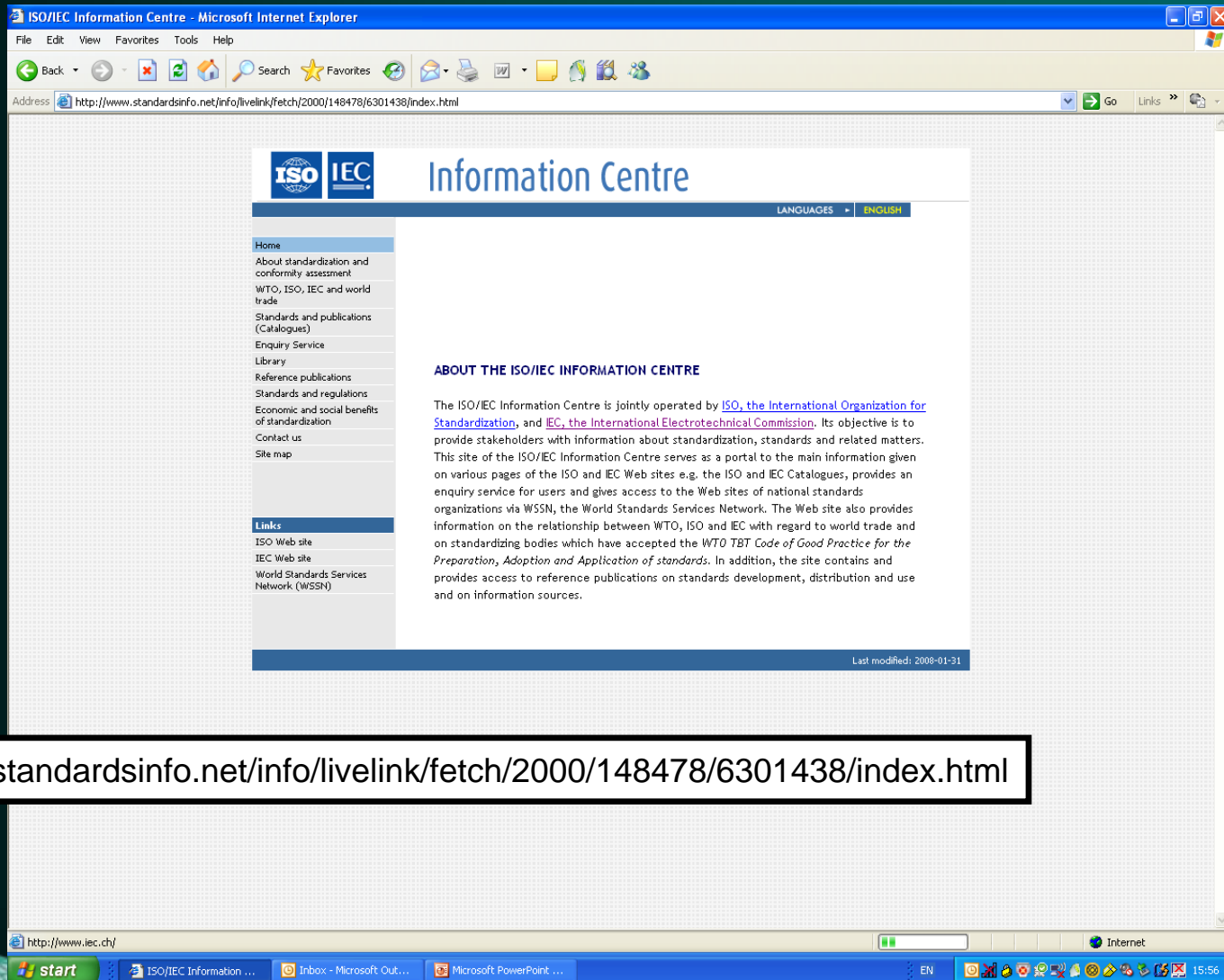
# How are international standards developed?

## Stages

- Proposal – confirmation of need
- Preparatory – technical solution development
- Committee – consensus development
- Enquiry – circulation to all ISO member bodies for voting and comments
- Approval – for adoption
- Publication (3 official languages)
- Periodic confirmation/revision/withdrawal

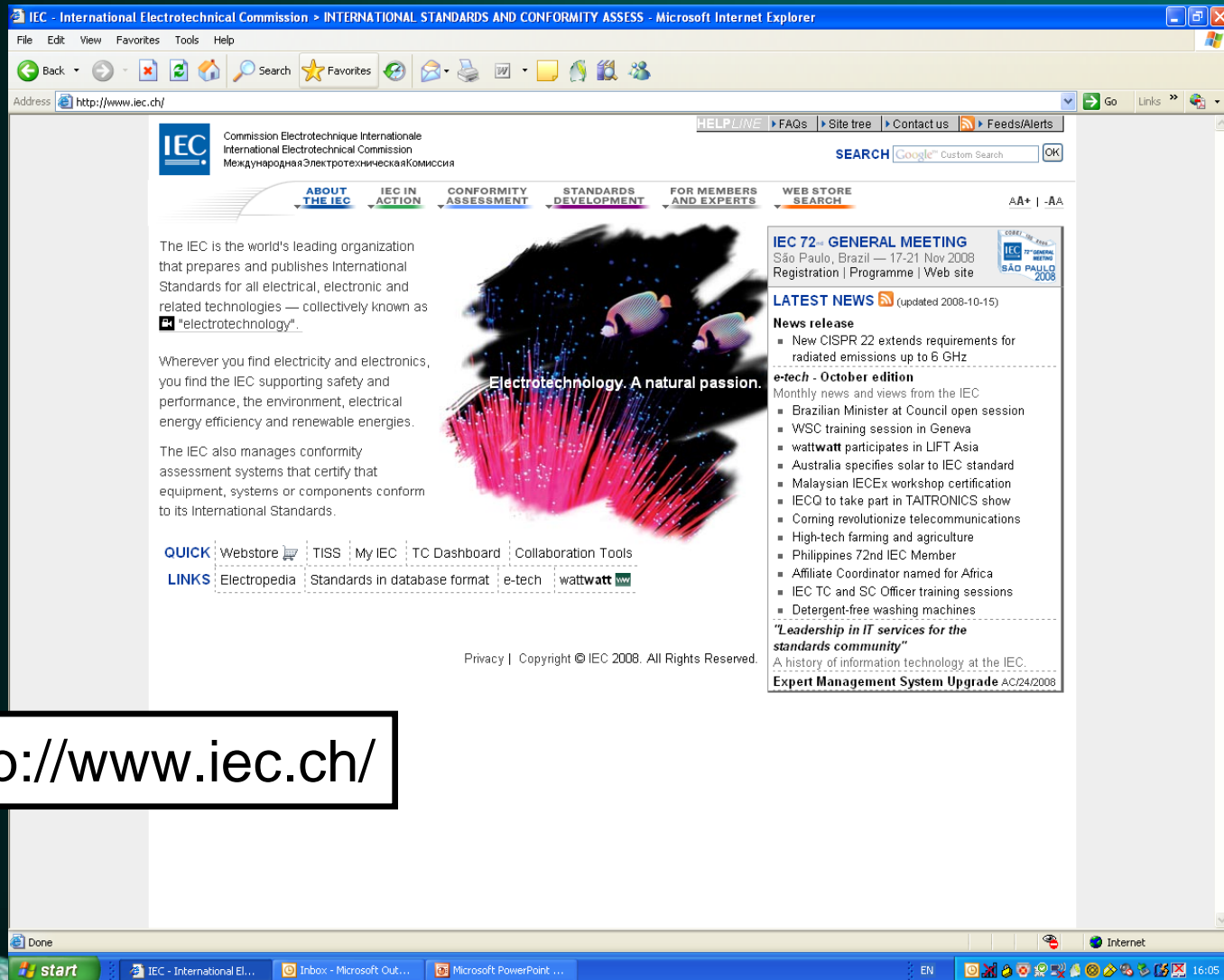


# Sources of information – ISO IEC



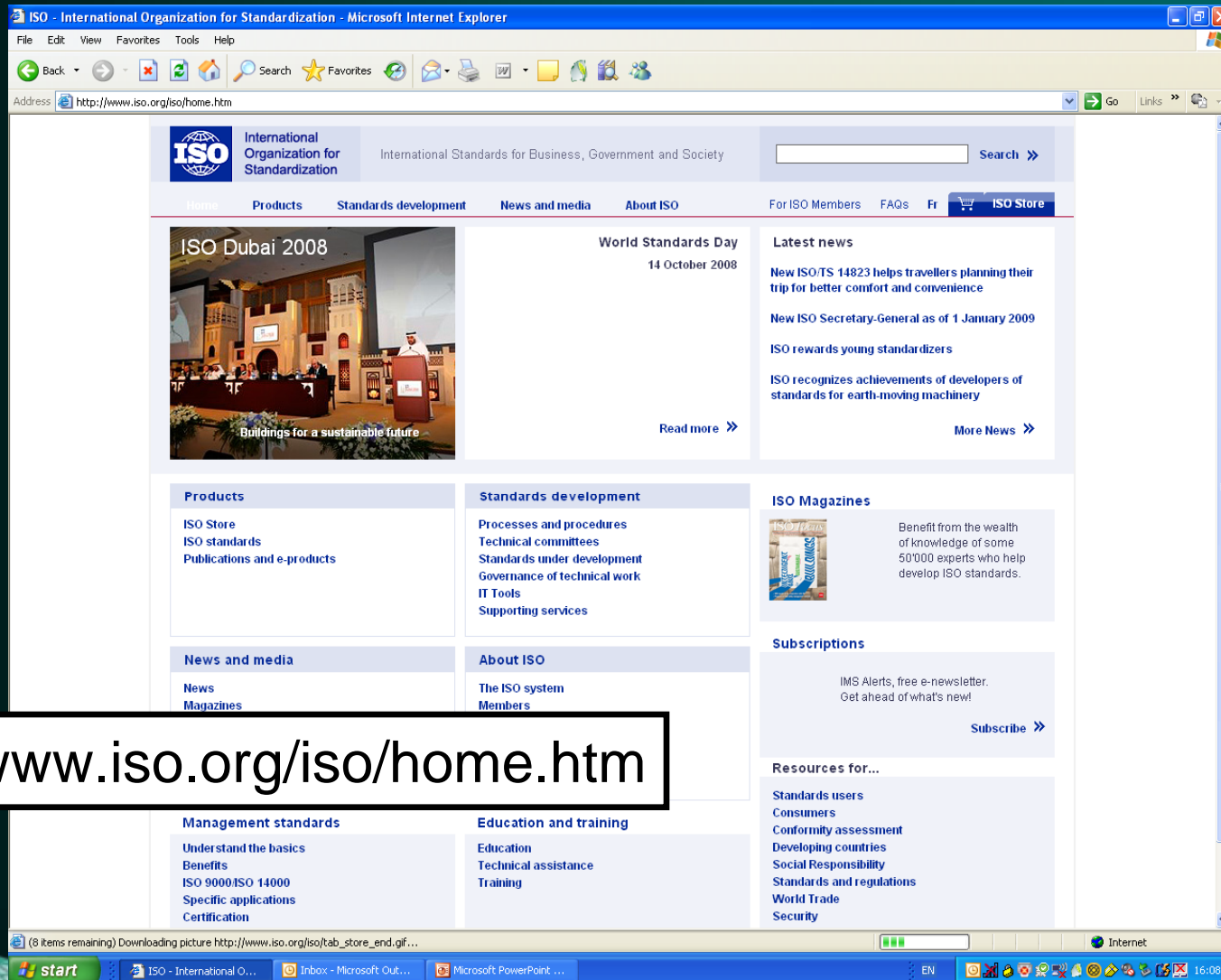
<http://www.standardsinfo.net/info/livelink/fetch/2000/148478/6301438/index.html>

# Sources of information – IEC



<http://www.iec.ch/>

# Sources of information – ISO



ISO - International Organization for Standardization - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Refresh Print Mail Print Preview

Address <http://www.iso.org/iso/home.htm> Go Links

**ISO** International Organization for Standardization International Standards for Business, Government and Society

Home Products Standards development News and media About ISO For ISO Members FAQs Fr **ISO Store**

**ISO Dubai 2008**

World Standards Day 14 October 2008

Latest news

New ISO/TS 14823 helps travellers planning their trip for better comfort and convenience

New ISO Secretary-General as of 1 January 2009

ISO rewards young standardizers

ISO recognizes achievements of developers of standards for earth-moving machinery

Buildings for a sustainable future

Read more

More News

**Products**

ISO Store  
ISO standards  
Publications and e-products

**Standards development**

Processes and procedures  
Technical committees  
Standards under development  
Governance of technical work  
IT Tools  
Supporting services

**ISO Magazines**

Benefit from the wealth of knowledge of some 50'000 experts who help develop ISO standards.

**Subscriptions**

IMS Alerts, free e-newsletter. Get ahead of what's new!

Subscribe

**Resources for...**

Standards users  
Consumers  
Conformity assessment  
Developing countries  
Social Responsibility  
Standards and regulations  
World Trade  
Security

**News and media**

News  
Magazines

**About ISO**

The ISO system  
Members

**Management standards**

Understand the basics  
Benefits  
ISO 9000/ISO 14000  
Specific applications  
Certification

**Education and training**

Education  
Technical assistance  
Training

(8 items remaining) Downloading picture [http://www.iso.org/iso/tab\\_store\\_end.gif](http://www.iso.org/iso/tab_store_end.gif)...

start ISO - International O... Inbox - Microsoft Out... Microsoft PowerPoint ... EN 16:08

<http://www.iso.org/iso/home.htm>

# Finding standards – ISO



ISO - ISO Standards - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites

Address [http://www.iso.org/iso/iso\\_catalogue.htm](http://www.iso.org/iso/iso_catalogue.htm) Go Links

**ISO** International Organization for Standardization International Standards for Business, Government and Society

medical device Search >>

Home Products Standards development News and media About ISO For ISO Members FAQs Fr ISO Store

Products > ISO Standards

ISO Store

>> ISO Standards

By ICS

By TC

How to use the ISO Catalogue

Management standards

The ISO portfolio

FAQs

Country codes (ISO 3166/MA)

Publications and e-products

Copyright

## ISO Standards

ISO has developed over 17000 International Standards on a variety of subjects and 1100 new ISO standards are published every year. The full range of technical fields can be seen from the listing International Standards. Users can browse that listing to find bibliographic information on each standard and, in many cases, a brief abstract. The online ISO Standards listing integrates both the ISO Catalogue of published standards and the ISO Technical programme of standards under development.



**Browse ISO standards**

- Browse ISO standards by ICS
- Browse ISO standards by TC

**Search the ISO Catalogue**

medical device Search >>

### Best-selling Standards

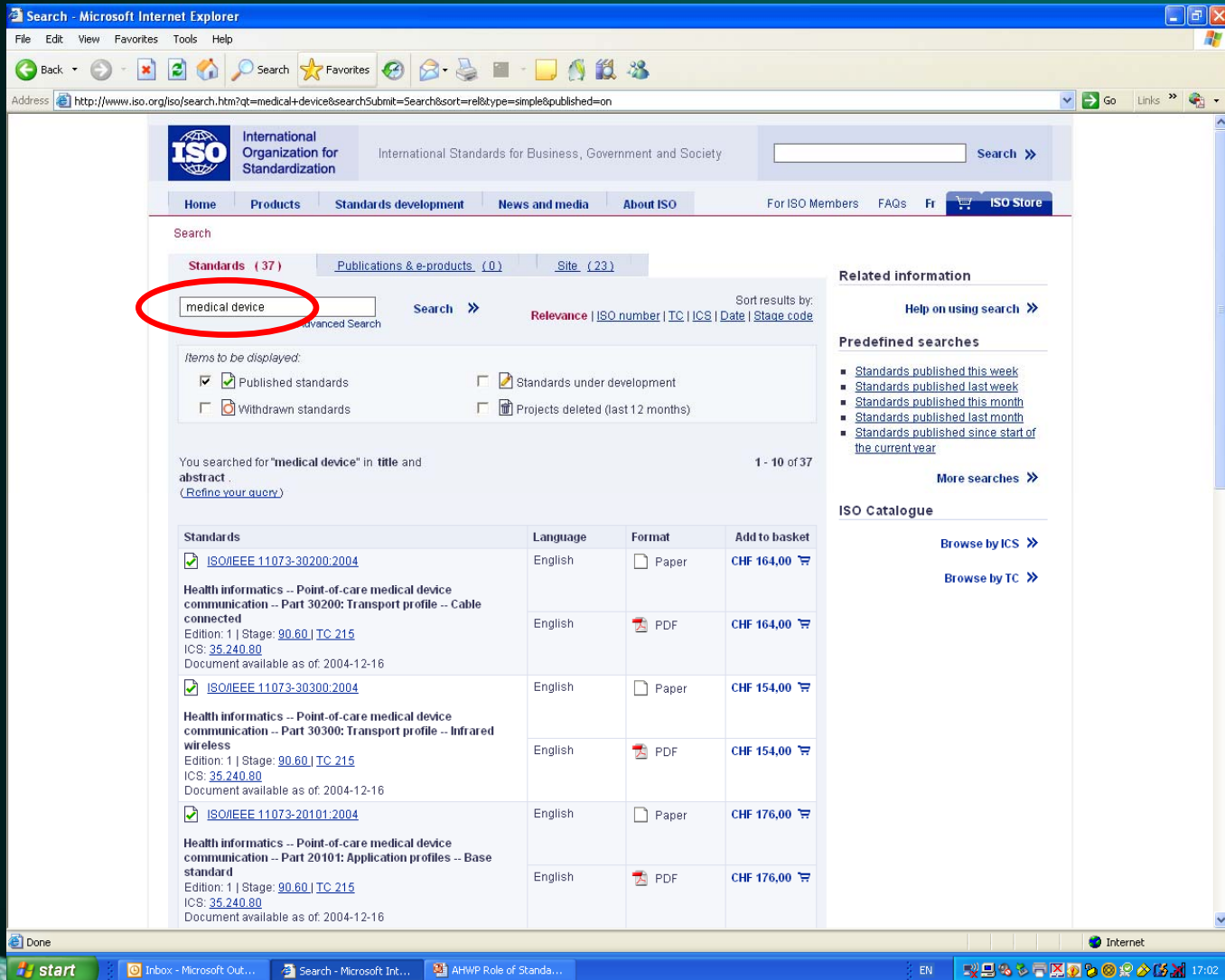
- [ISO/IEC Guide 98-3:2008](#)  
Uncertainty of measurement - Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)
- [ISO/IEC Guide 99:2007](#)  
International vocabulary of metrology - Basic and general concepts and associated terms (VIM)
- [ISO 32000-1:2008](#)  
Document management -- Portable document format -- Part 1: PDF 1.7

© 2008 ISO Privacy Policy Name and logo Sitemap Contact ISO Guided tour of ISO-Online Print Increase text size

start Inbox - Microsoft Out... ISO - ISO Standards ... AHWP Role of Standa... EN 17:06

[http://www.iso.org/iso/iso\\_catalogue.htm](http://www.iso.org/iso/iso_catalogue.htm)

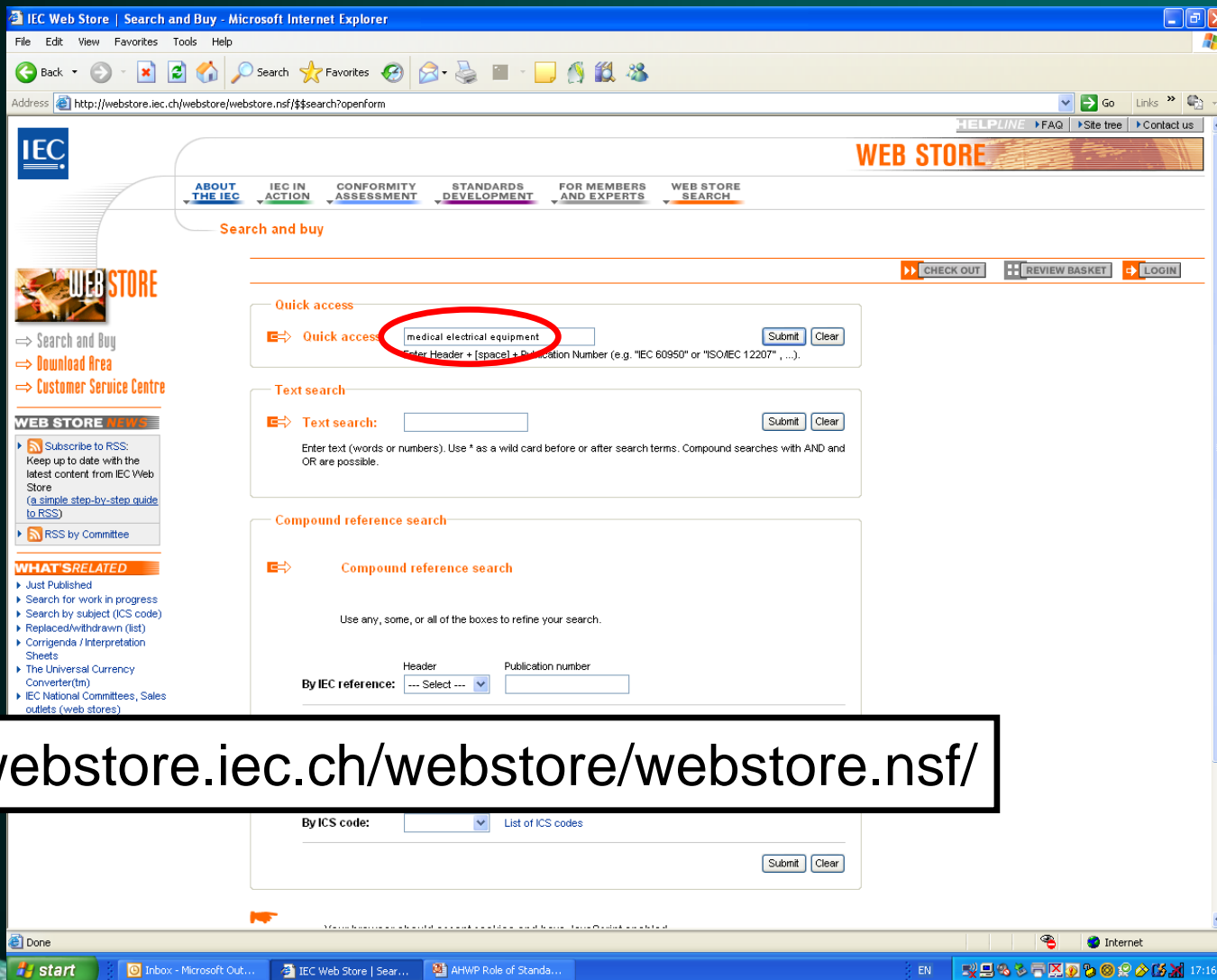
# Finding standards – ISO



The screenshot shows the ISO website search results for the query "medical device". The search bar is highlighted with a red circle. The results are sorted by Relevance and show 1-10 of 37 items. The first four items are listed in a table below.

Standards	Language	Format	Add to basket
<a href="#">ISO/IEEE 11073-30200:2004</a> Health informatics -- Point-of-care medical device communication -- Part 30200: Transport profile -- Cable connected Edition: 1   Stage: <a href="#">90.60</a>   <a href="#">TC 215</a> ICS: <a href="#">35.240.80</a> Document available as of: 2004-12-16	English	Paper	CHF 164,00
<a href="#">ISO/IEEE 11073-30300:2004</a> Health informatics -- Point-of-care medical device communication -- Part 30300: Transport profile -- Infrared wireless Edition: 1   Stage: <a href="#">90.60</a>   <a href="#">TC 215</a> ICS: <a href="#">35.240.80</a> Document available as of: 2004-12-16	English	PDF	CHF 154,00
<a href="#">ISO/IEEE 11073-20101:2004</a> Health informatics -- Point-of-care medical device communication -- Part 20101: Application profiles -- Base standard Edition: 1   Stage: <a href="#">90.60</a>   <a href="#">TC 215</a> ICS: <a href="#">35.240.80</a> Document available as of: 2004-12-16	English	Paper	CHF 176,00
	English	PDF	CHF 176,00

# Finding standards – IEC



IEC Web Store | Search and Buy - Microsoft Internet Explorer

Address: <http://webstore.iec.ch/webstore/webstore.nsf?search?openform>

WEB STORE

Search and buy

Quick access

Quick access:

Text search

Text search:

Compound reference search

Compound reference search

Use any, some, or all of the boxes to refine your search.

By IEC reference:

By ICS code:

Done

start

Inbox - Microsoft Out...

IEC Web Store | Search...

AHWP Role of Stands...

EN

Internet

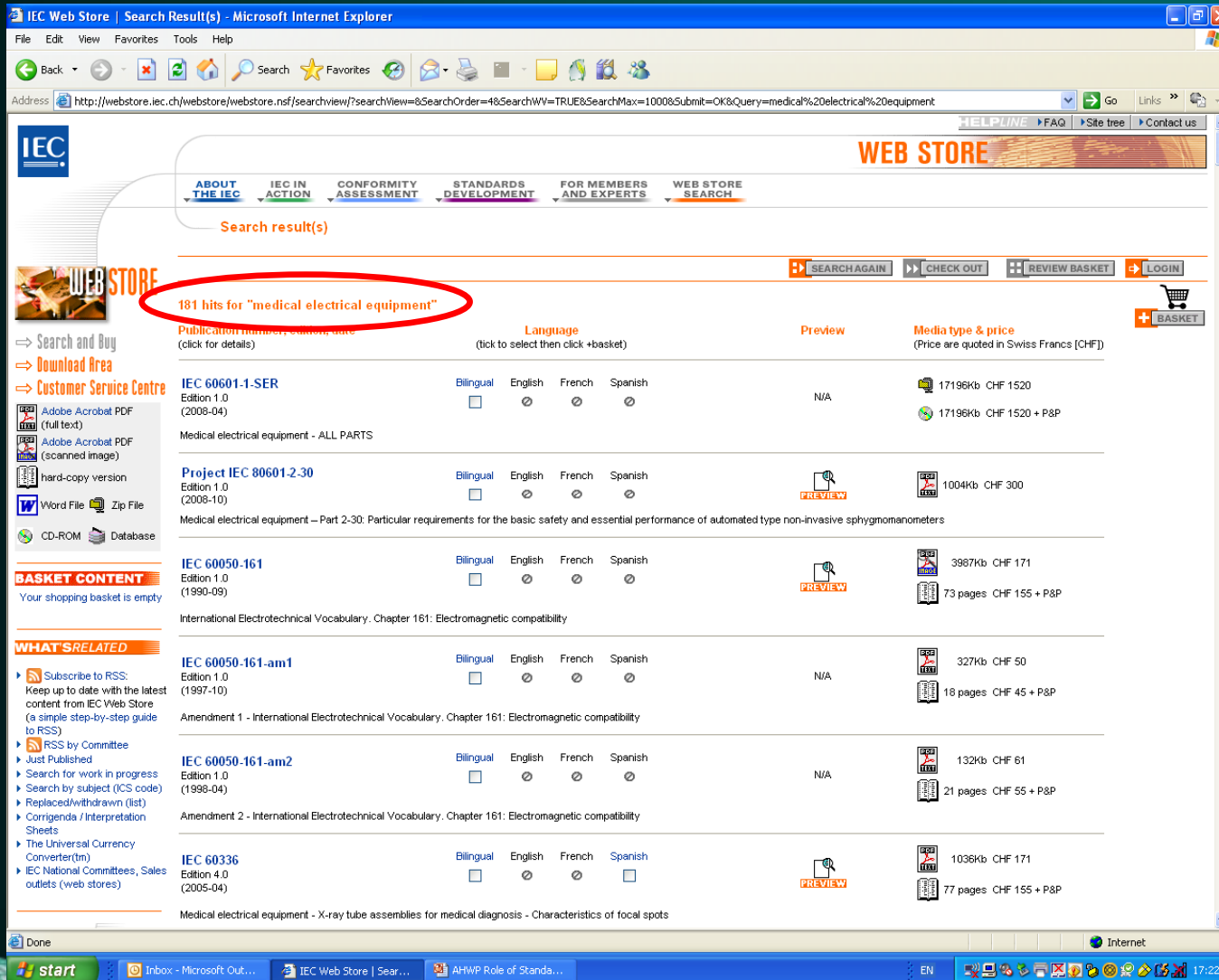
17:16

<http://webstore.iec.ch/webstore/webstore.nsf/>





# Finding standards – IEC



The screenshot shows the IEC Web Store search results for the query "medical electrical equipment". The search results are displayed in a table with columns for Publication number, Language, Preview, and Media type & price. The results are sorted by relevance.

**Search result(s)**

181 hits for "medical electrical equipment"

Publication number, edition date (click for details)	Language (tick to select then click +basket)	Preview	Media type & price (Price are quoted in Swiss Francs [CHF])
<b>IEC 60601-1-SER</b> Edition 1.0 (2006-04) Medical electrical equipment - ALL PARTS	Bilingual <input type="checkbox"/> English <input checked="" type="checkbox"/> French <input checked="" type="checkbox"/> Spanish <input checked="" type="checkbox"/>	N/A	17196Kb CHF 1520 17196Kb CHF 1520 + P&P
<b>Project IEC 80601-2-30</b> Edition 1.0 (2008-10) Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated type non-invasive sphygmomanometers	Bilingual <input type="checkbox"/> English <input checked="" type="checkbox"/> French <input checked="" type="checkbox"/> Spanish <input checked="" type="checkbox"/>	<a href="#">PREVIEW</a>	1004Kb CHF 300
<b>IEC 60050-161</b> Edition 1.0 (1990-09) International Electrotechnical Vocabulary. Chapter 161: Electromagnetic compatibility	Bilingual <input type="checkbox"/> English <input checked="" type="checkbox"/> French <input checked="" type="checkbox"/> Spanish <input checked="" type="checkbox"/>	<a href="#">PREVIEW</a>	3987Kb CHF 171 73 pages CHF 155 + P&P
<b>IEC 60050-161-am1</b> Edition 1.0 (1997-10) Amendment 1 - International Electrotechnical Vocabulary. Chapter 161: Electromagnetic compatibility	Bilingual <input type="checkbox"/> English <input checked="" type="checkbox"/> French <input checked="" type="checkbox"/> Spanish <input checked="" type="checkbox"/>	N/A	327Kb CHF 50 18 pages CHF 45 + P&P
<b>IEC 60050-161-am2</b> Edition 1.0 (1998-04) Amendment 2 - International Electrotechnical Vocabulary. Chapter 161: Electromagnetic compatibility	Bilingual <input type="checkbox"/> English <input checked="" type="checkbox"/> French <input checked="" type="checkbox"/> Spanish <input checked="" type="checkbox"/>	N/A	132Kb CHF 61 21 pages CHF 55 + P&P
<b>IEC 60336</b> Edition 4.0 (2005-04) Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Characteristics of focal spots	Bilingual <input type="checkbox"/> English <input checked="" type="checkbox"/> French <input checked="" type="checkbox"/> Spanish <input type="checkbox"/>	<a href="#">PREVIEW</a>	1036Kb CHF 171 77 pages CHF 155 + P&P

**BASKET CONTENT**  
Your shopping basket is empty

**WHAT'S RELATED**

- Subscribe to RSS: Keep up to date with the latest content from IEC Web Store (a simple step-by-step guide to RSS)
- RSS by Committee
- Just Published
- Search for work in progress
- Search by subject (ICS code)
- Replaced/withdrawn (list)
- Corrigenda / Interpretation Sheets
- The Universal Currency Converter(tm)
- IEC National Committees, Sales outlets (web stores)

## International medical device standards\*

- Quality management systems (ISO 13485)
- Sterilization (ISO 11737)
- Biological evaluation (ISO 10993)
- Risk management (ISO 14971)
- Clinical investigations (ISO 14155)
- Packaging for sterilized medical devices (ISO 11607)
- Health informatics (ISO 11073)
- Medical device software (ISO 62304)
- Label symbols (ISO 15223)
- Implants for surgery (ISO 14708)
- Cardiovascular implants (ISO 25539)

\* Partial listing; illustrative examples



## International medical device standards\*

- Medical electrical equipment – General requirements for basic safety and essential performance (IEC 60601)
- Usability engineering (IEC 62366)
- Software life cycle processes (IEC 62304)
- General testing procedures (IEC/TR 62354)

# International medical device standards

- May be broadly subdivided into three categories:
  - Product (quality and safety)
    - “Horizontal”: apply across product categories
    - “Vertical”: product category specific
  - Process (conditions under which products and services are to be produced, packaged, or refined)
  - Management systems

# GHTF Organization Structure

## Steering Committee

### Study Group 1

Regulatory systems  
Premarket assessment

### Study Group 2

Vigilance reporting  
Market surveillance

### Study Group 3

Quality system  
requirements

### Study Group 4

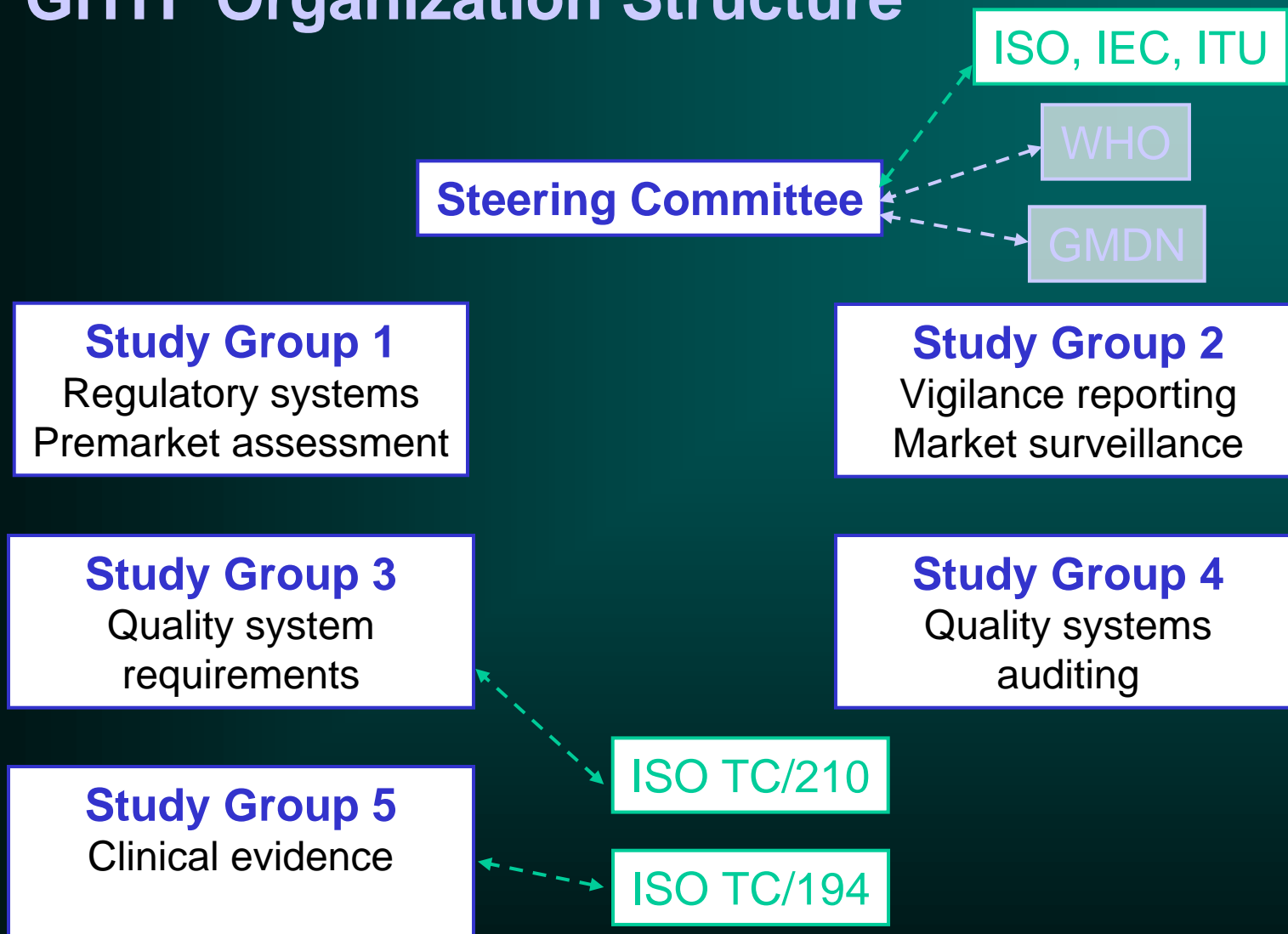
Quality systems  
auditing

### Study Group 5

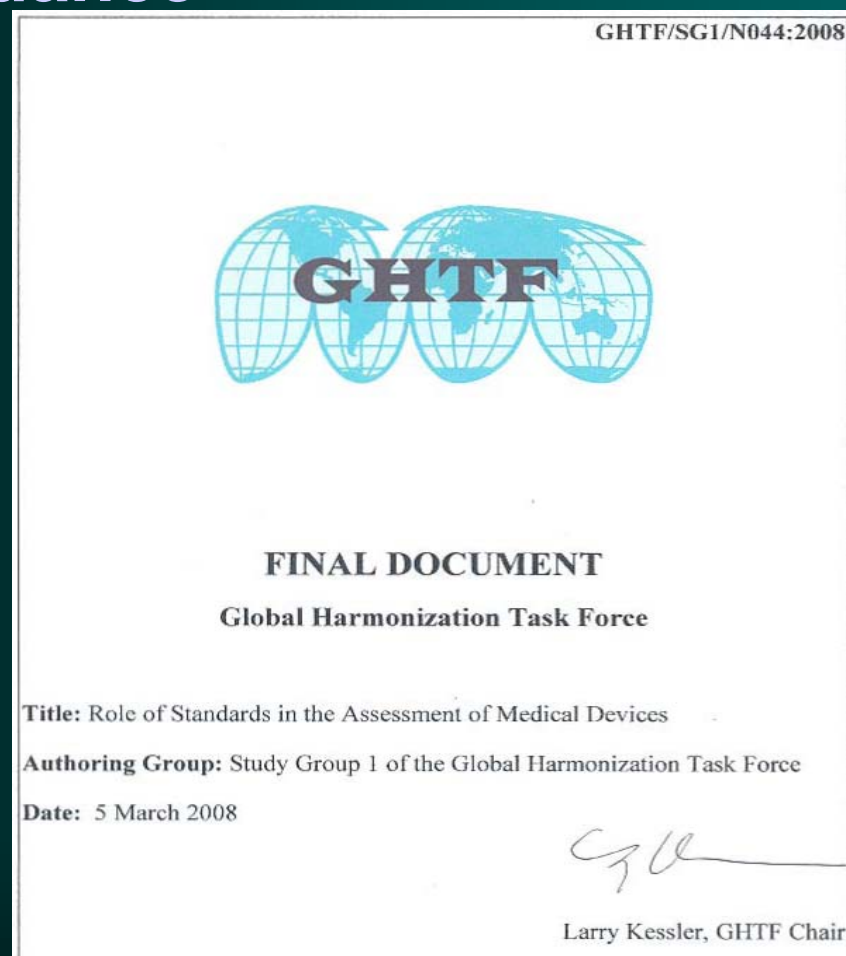
Clinical evidence



# GHTF Organization Structure



# GHTF Guidance



<http://www.ghtf.org/documents/sg1/sg1-n044.pdf>



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

# Questions?

