The Role of Standards in Medical Device Regulation

Asian Harmonization Working Party
Pre-Meeting Workshop

New Delhi, 4 November 2008

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Source: Rashtrapati Bhawan; Google Images; sivaspeaks.blogspot.com/2007/04/view-of-sunse…

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

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"

Source: ISO/IEC Information Centre; www.standardsinfo.net/info

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."

Source: ISO/IEC Information Centre; www.standardsinfo.net/info

International standardization

"With the increasing globalization of markets, international standards (as opposed to regioinal 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."

Source: ISO/IEC Information Centre; www.standardsinfo.net/info

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”

Source: Wikipedia, 22 Oct. 2008

What is a “standard”?

“Document,

Source: ISO/IEC Guide 2:2004: *Standardization and related activities – General vocabulary*

What is a “standard”?

“Document, established by consensus

Source: ISO/IEC Guide 2:2004: *Standardization and related activities – General vocabulary*

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.”

Source: ISO/IEC Directives, Part 1: Procedures for the technical work; 6th Ed., 2008

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”

Source: ISO/IEC Guide 2:2004

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What is an “international standard”?

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

Source: ISO/IEC Guide 2:2004: *Standardization and related activities – General vocabulary*

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”

Source: ISO/IEC Guide 2:2004: *Standardization and related activities – General vocabulary*

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"

Source: ISO/IEC Information Centre; www.standardsinfo.net/info

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; …

Source: ISO/IEC Information Centre; www.standardsinfo.net/info

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 …

Source: ISO/IEC Information Centre; www.standardsinfo.net/info

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”

Source: ISO/IEC Information Centre; www.standardsinfo.net/info

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"

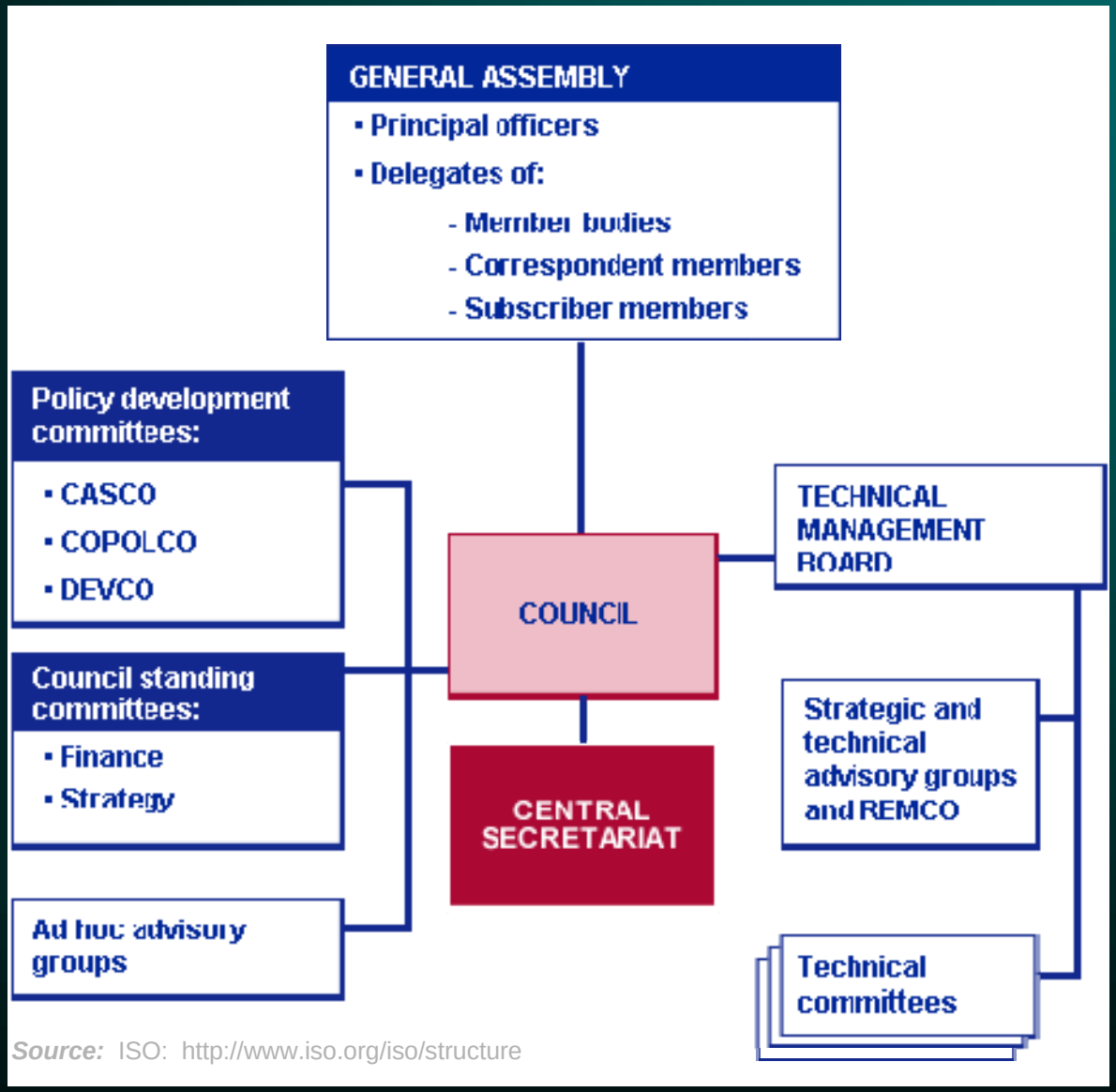
- Over the 40 years to 2002 a 1 percent increase in the number of Australian standards is associated with a 0.17 percent increase in productivity across the economy
- … standards can be considered, together with R&D expenditure, as contributing factors to the stock of knowledge, …. A 1 percent increase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

Who develops international standards?

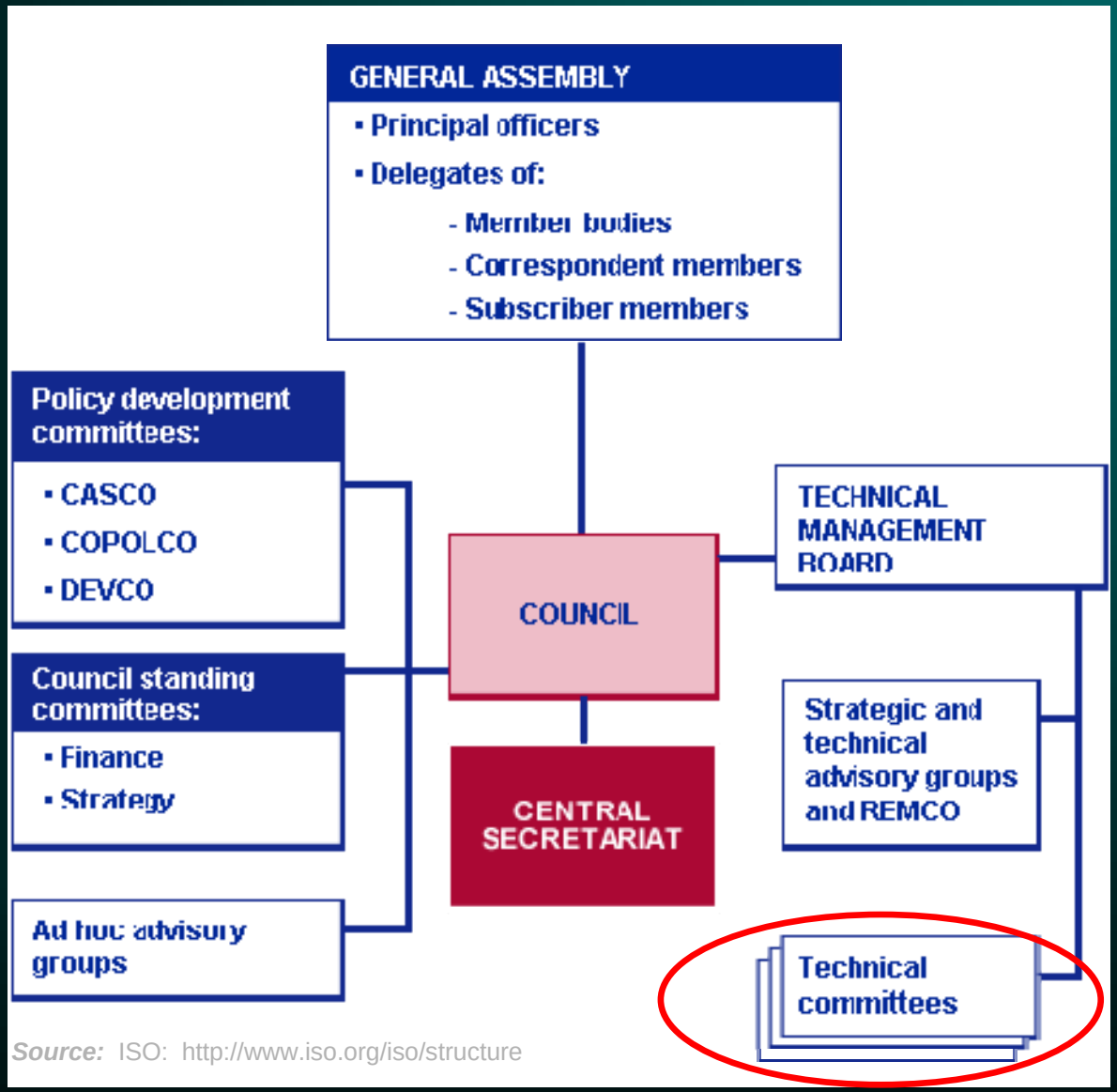
- International Organization for Standardization (ISO)
- International Electrotechnical Commission (IEC)
- International Telecommunication Union (ITU)

Who develops international standards?



Source: ISO: http://www.iso.org/iso/structure

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)

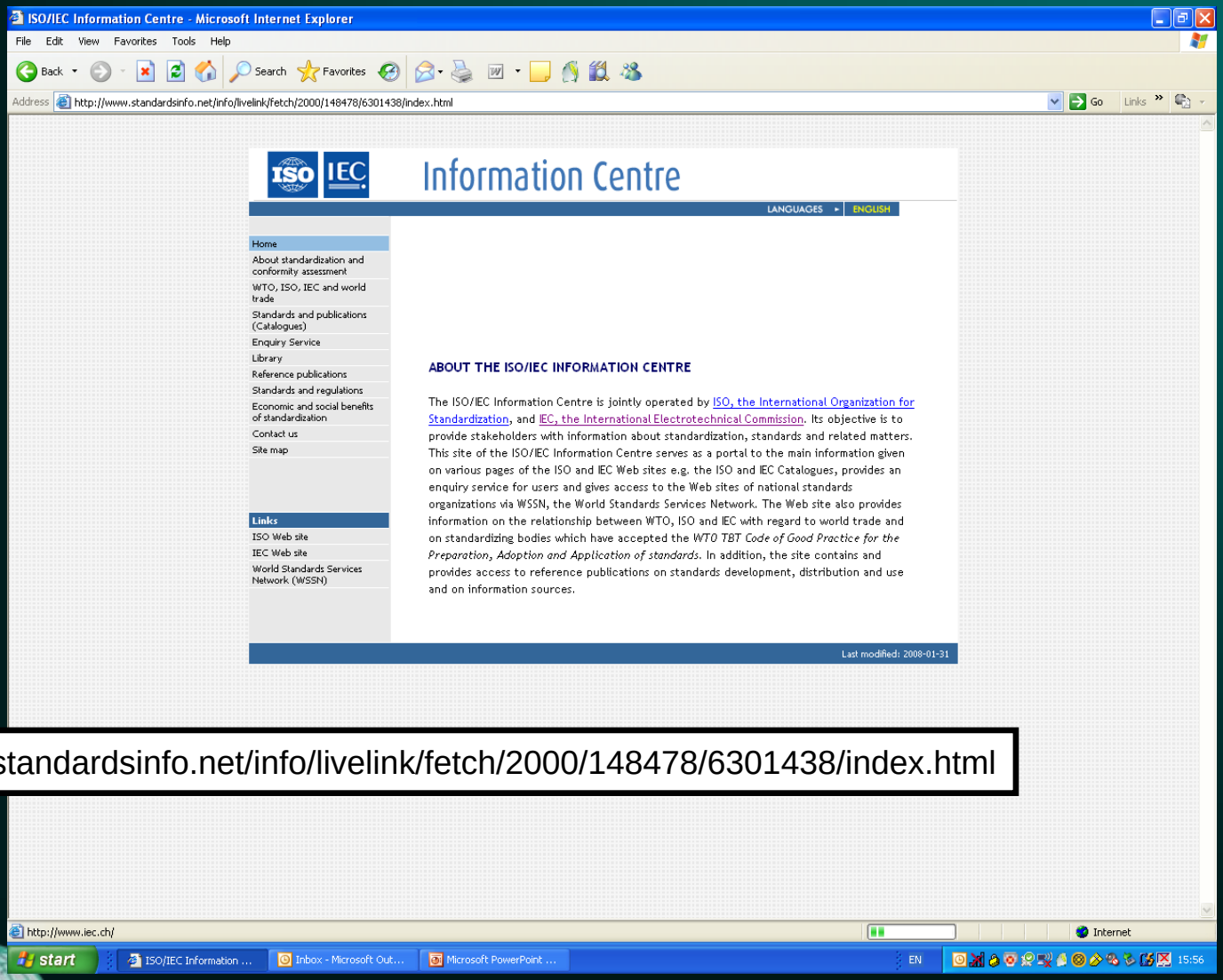
- Brunei Darussalam: Construction Planning and Research Unit
- Cambodia: Department of Industrial Standards of Cambodia
- PR China: Standardization Administration of China
- Hong Kong SAR: Innovation and Technology Commission
- India: Bureau of Indian Standards
- Indonesia: Badan Standardisasi Nacional
- 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



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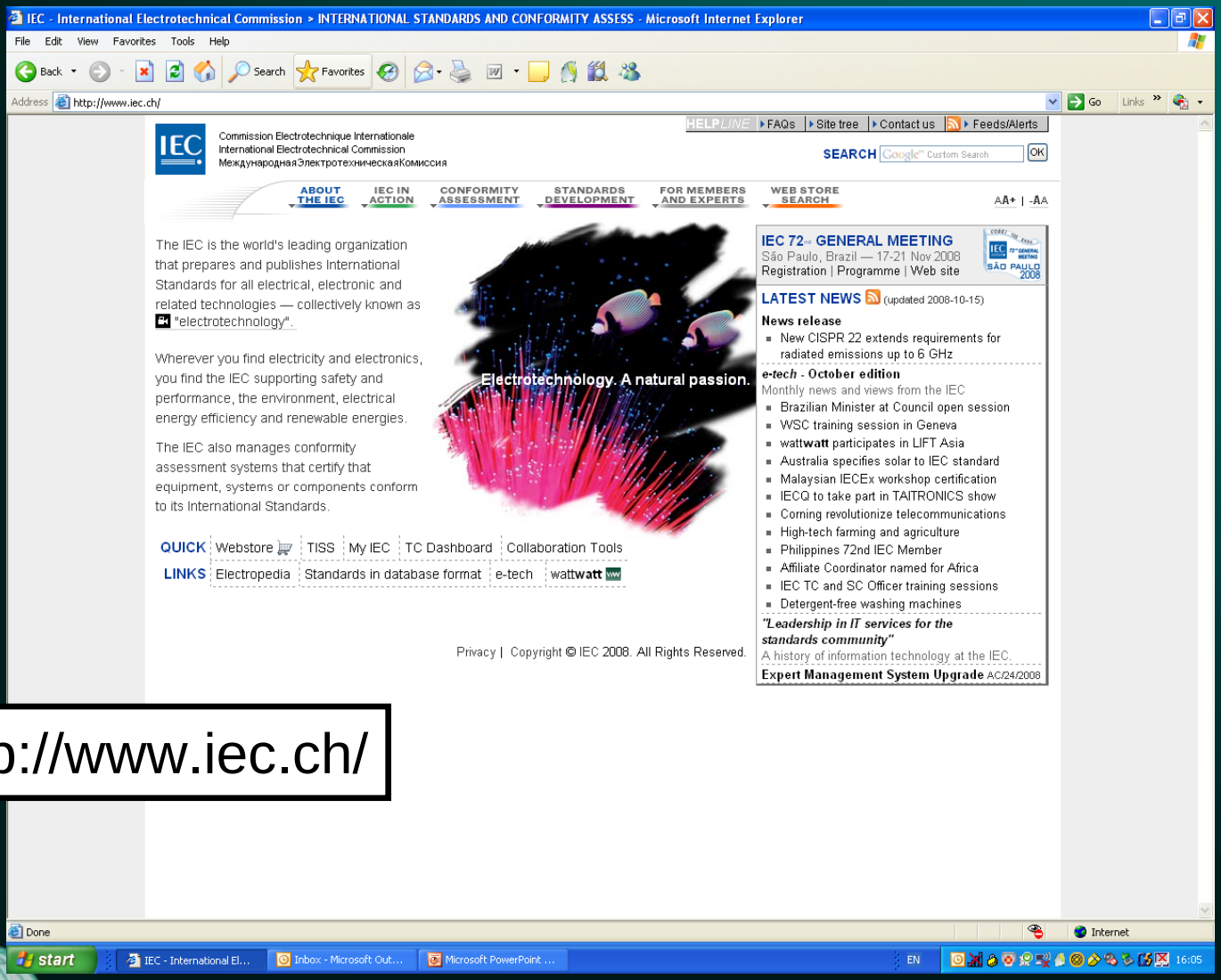
Sources of information – IEC



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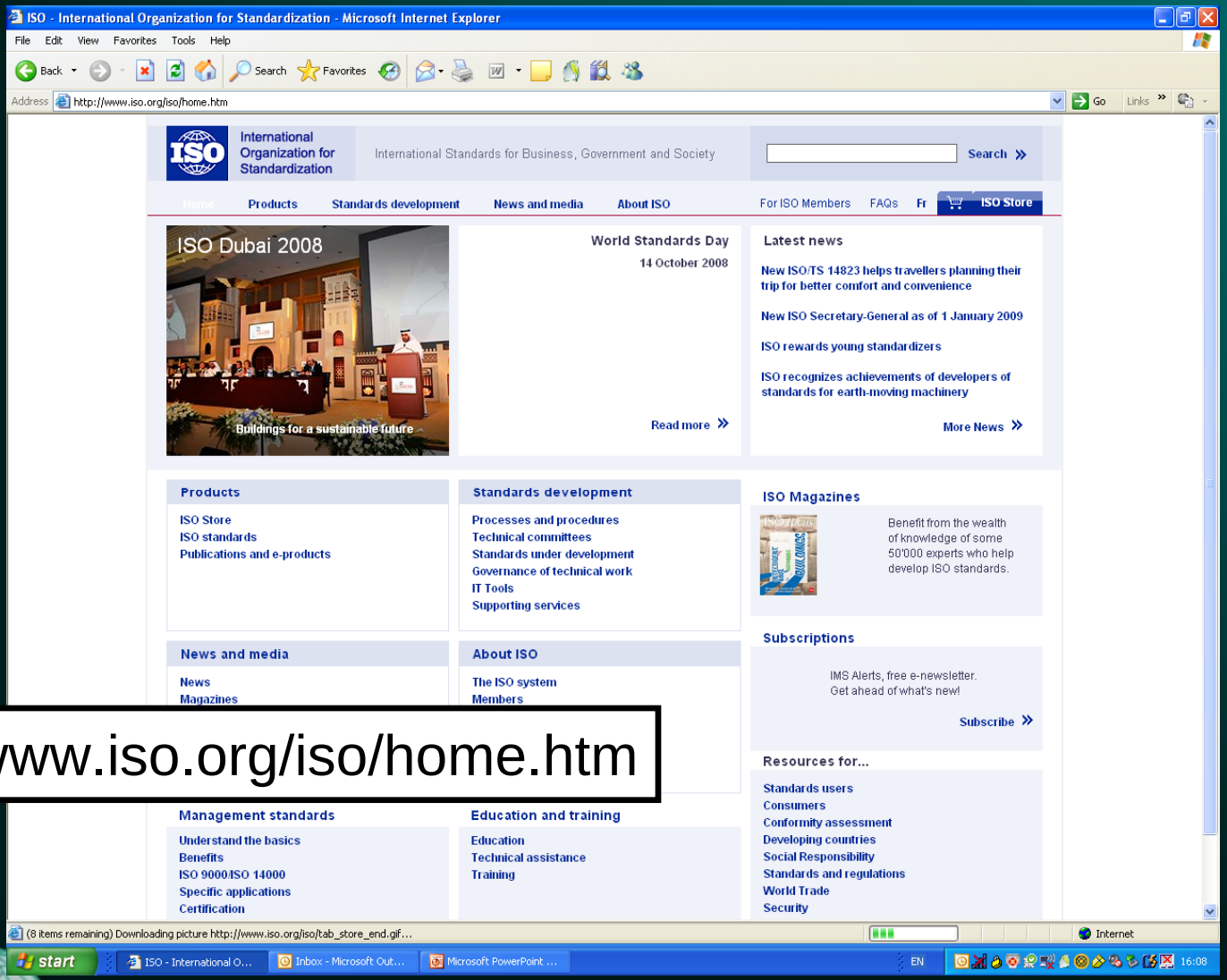
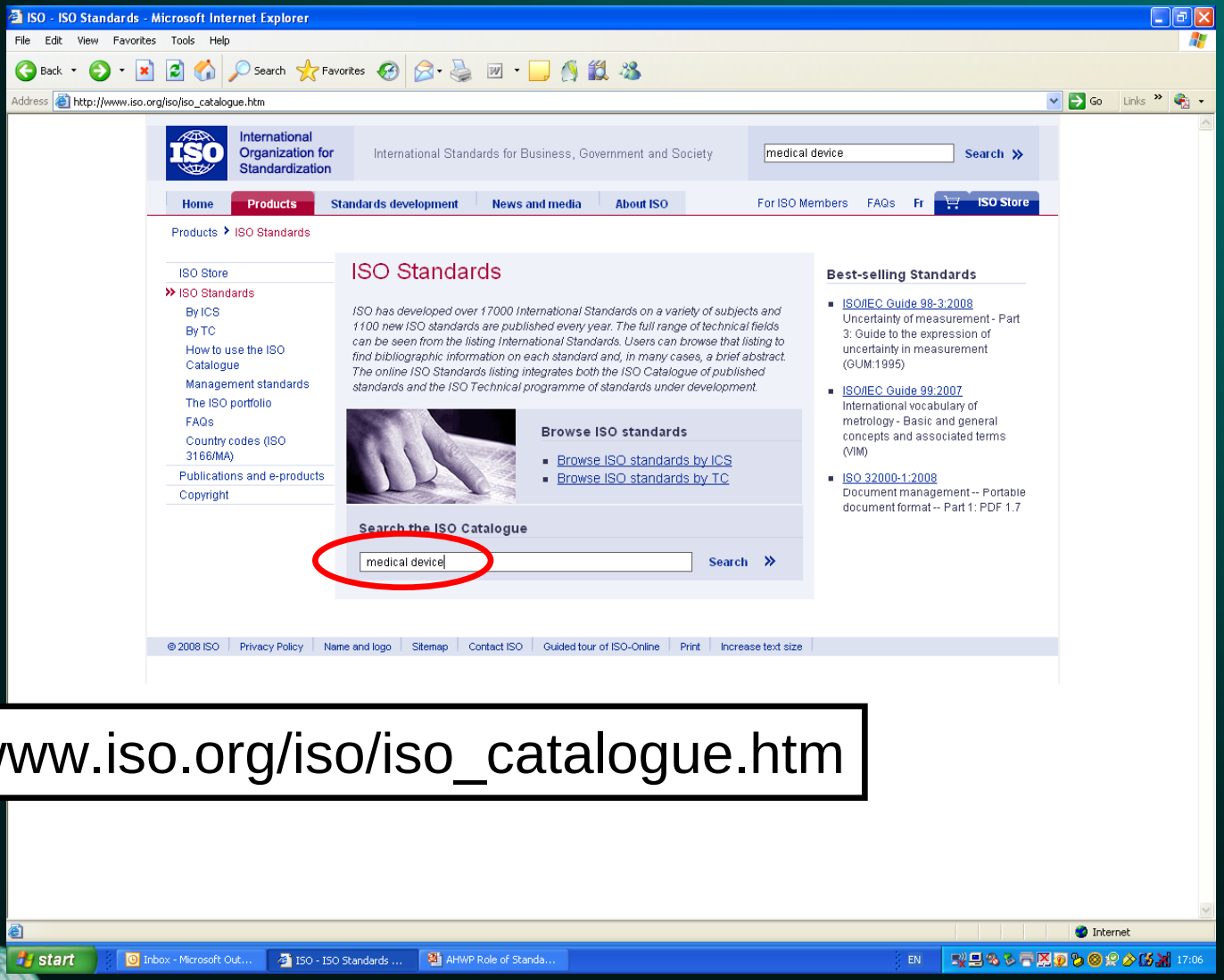
Sources of information – ISO



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

Finding standards – ISO



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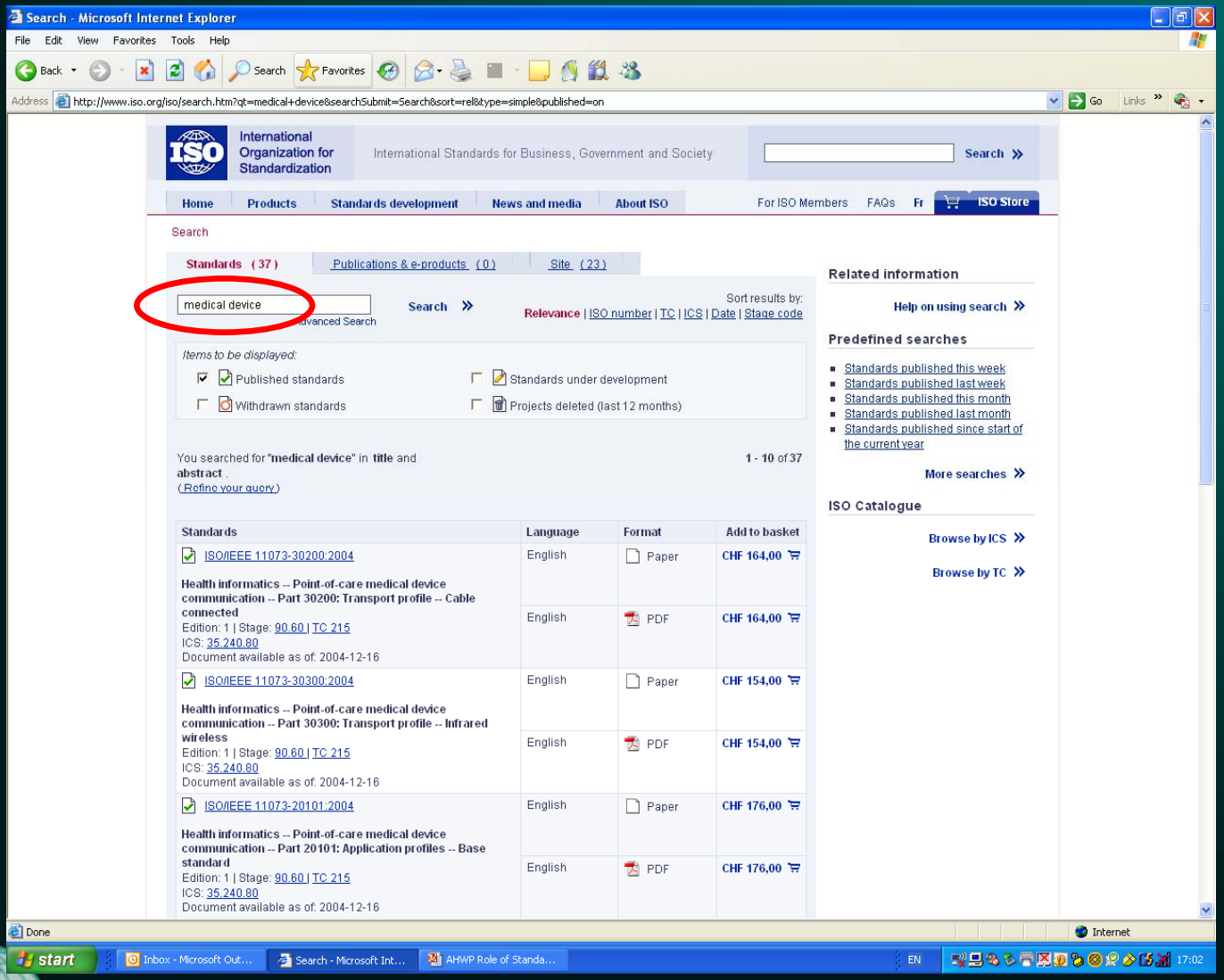

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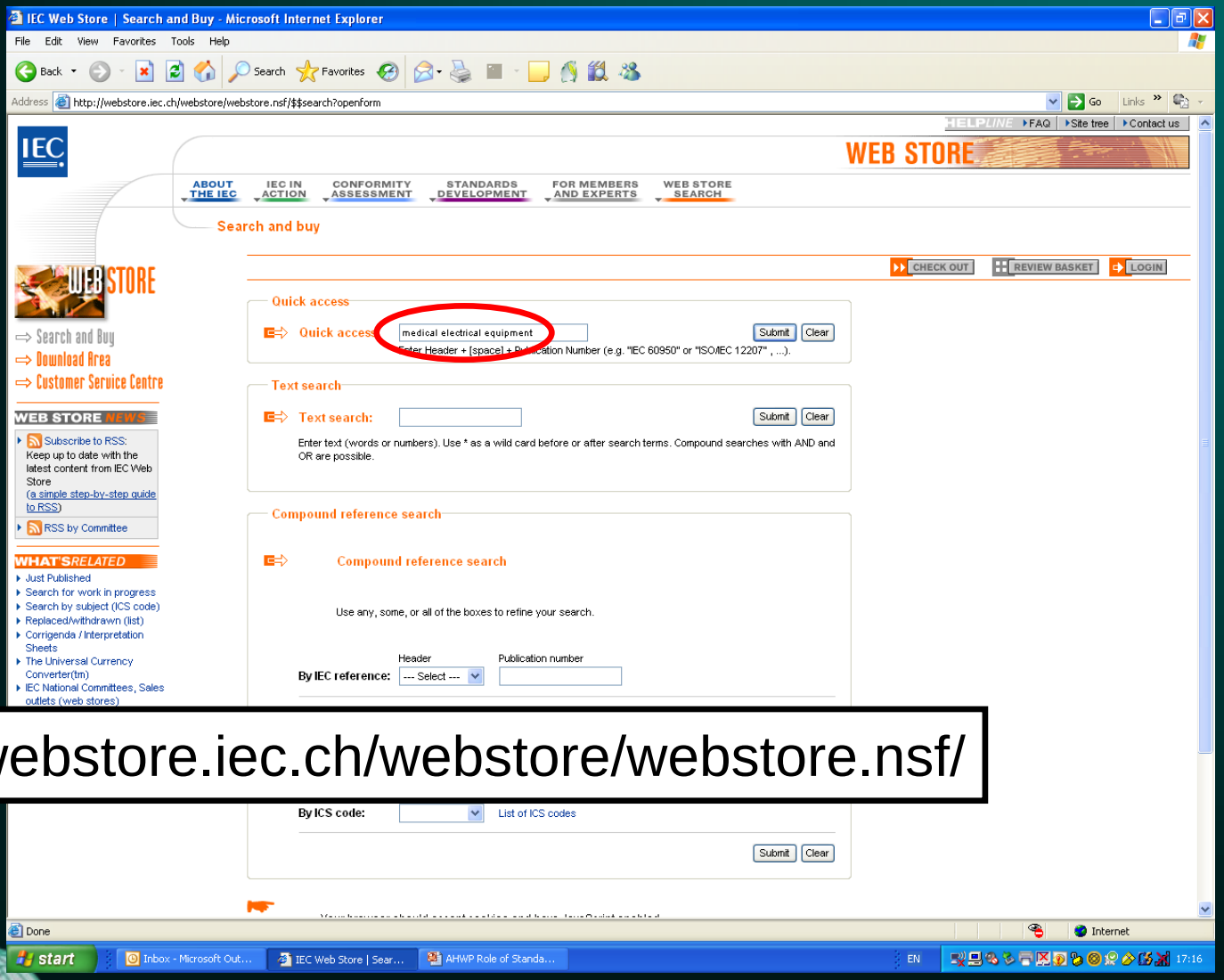

http://webstore.iec.ch/webstore/webstore.nsf/

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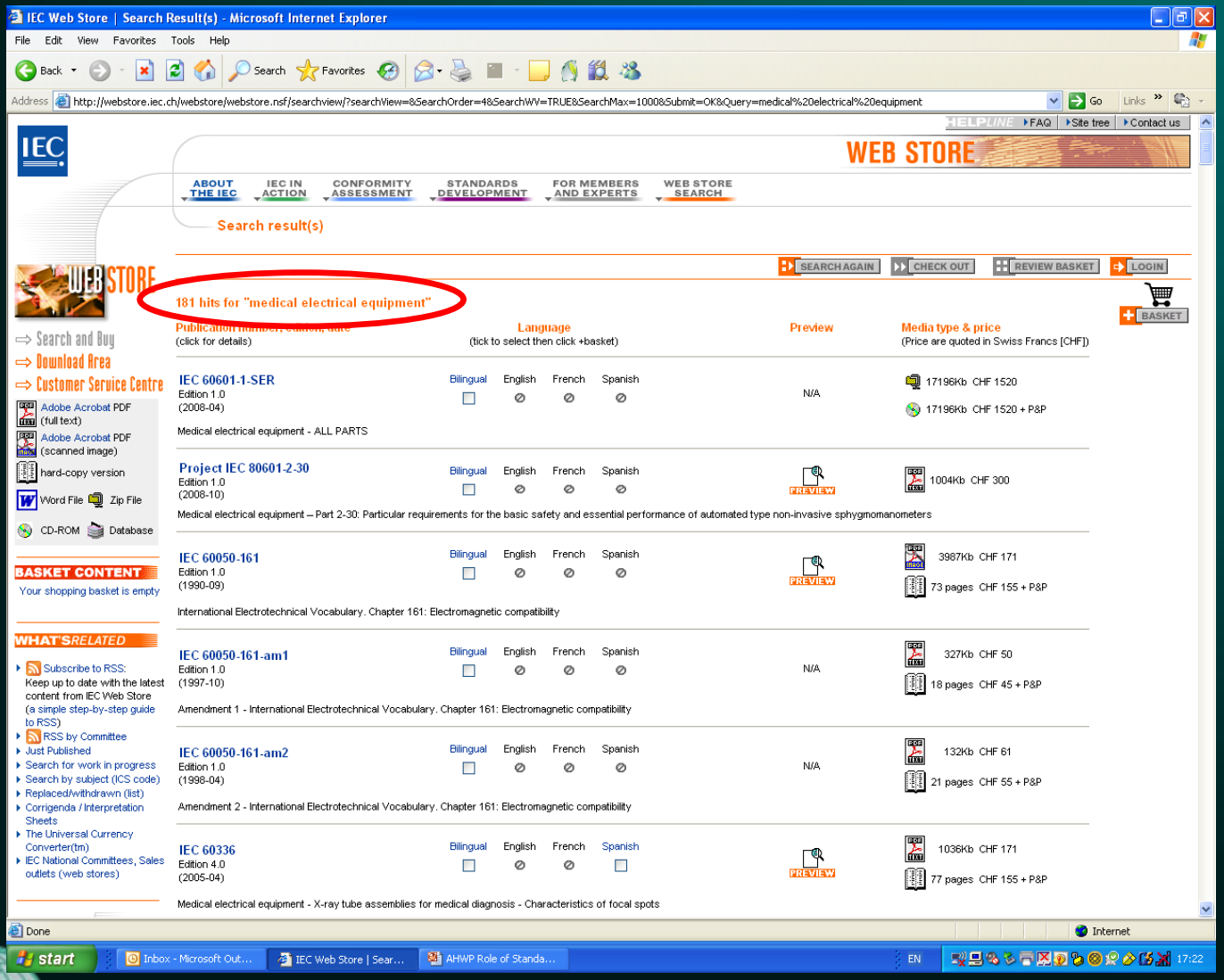


International medical device standards*

- 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)

* Partial listing; illustrative examples

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

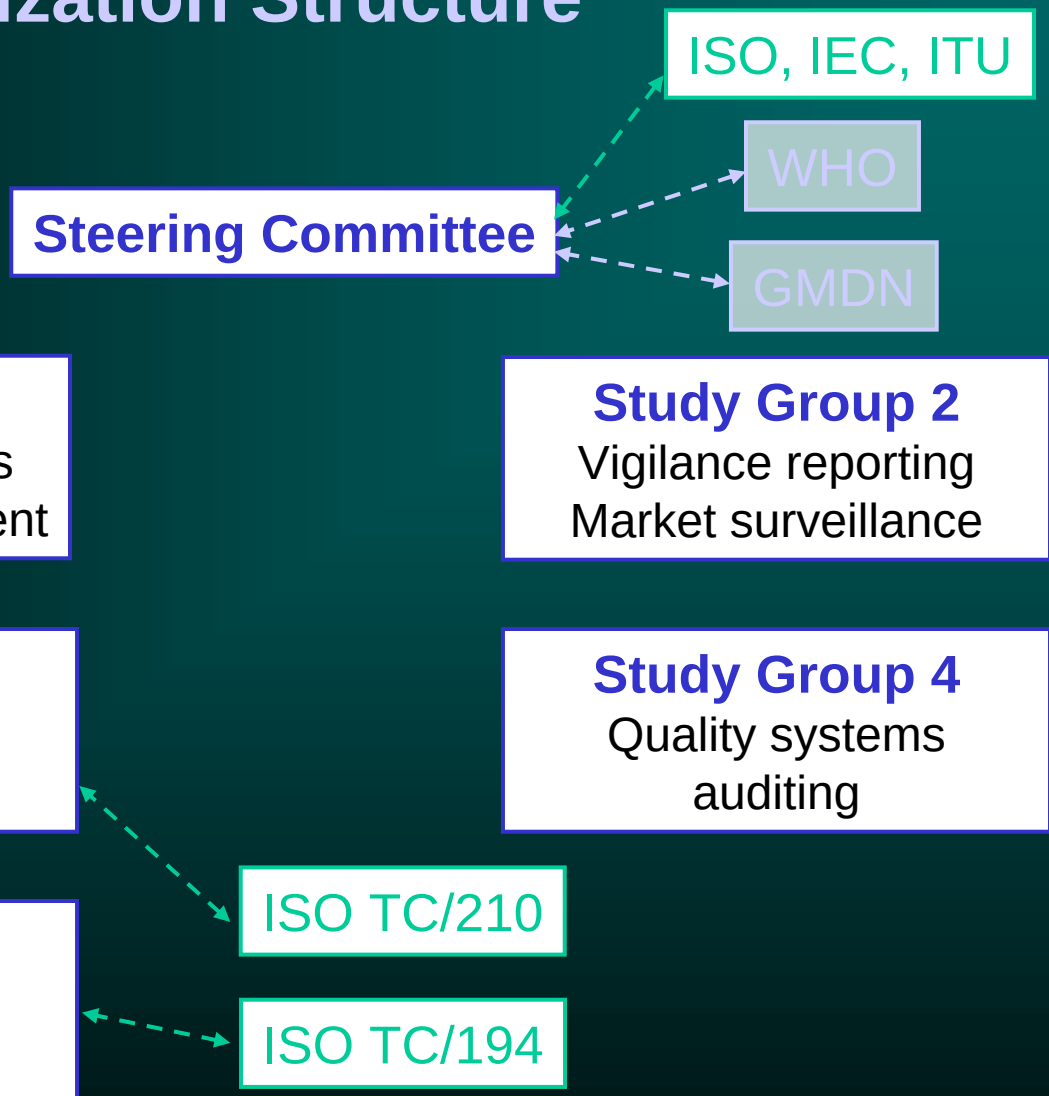
Study Group 2
Vigilance reporting
Market surveillance

Study Group 3
Quality system requirements

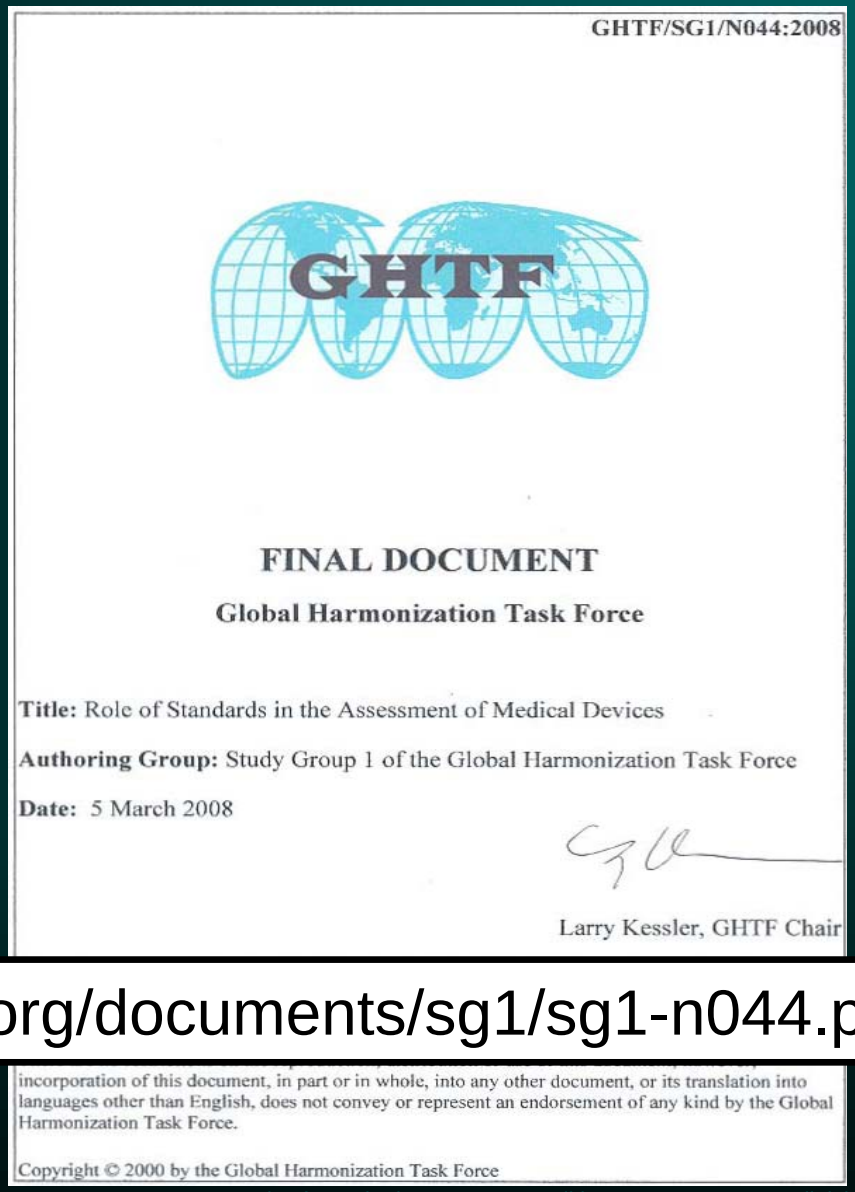
Study Group 4
Quality systems auditing

Study Group 5
Clinical evidence

GHTF Organization Structure



GHTF Guidance



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FINAL DOCUMENT

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

Questions?