IMDRF International Medical Device Regulators Forum

IMDRF Project:
"List of international standards recognized by IMDRF management committee members"

Progress Report

Dr. Matthias Neumann

Federal Ministry of Health, Germany

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IMDRF Project: "List of recognised standards"

Mandate:

2 Steps

1. Gathering information and creating a list of standards used for medical devices regulatory purposes that are recognized by IMDRF Management Committee members
2. Development of a procedure to continuously enhance the established list

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Background:

The GHTF regulatory model is based on the principle that the regulation defines the essential principles for safe and effective medical devices.

International Standards should specify (interpret) in detail how regulatory compliance (e.g. with the essential principles) for medical devices (processes or manufacturers) could be achieved.

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Background:

The GHTF paper "Role of Standards in the Assessment of Medical Devices" GHTF/SG1/N044:2008 states:

> 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. ...

- Regulatory Authorities should encourage the use of international standards.
- Regulatory Authorities 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. ...
- .....

Every Region should have established (or should be in the process of establishing) or is using a list of recognized or mandatory standards.

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Initiated Actions:

1. Request for the nomination of national experts
2. Circulation of a list of more then 1157 valid international standards on Medical Devices (ISO/IEC) to USA, Canada, Australia, Japan, Brazil and the EU-Commission
3. Indication of the level of recognition of these standards (Y- fully recognized/mandatory, N-not recognized, P-partially recognized or mandatory) by the nominated national experts
4. First Compilation and Assessment of the provided answers

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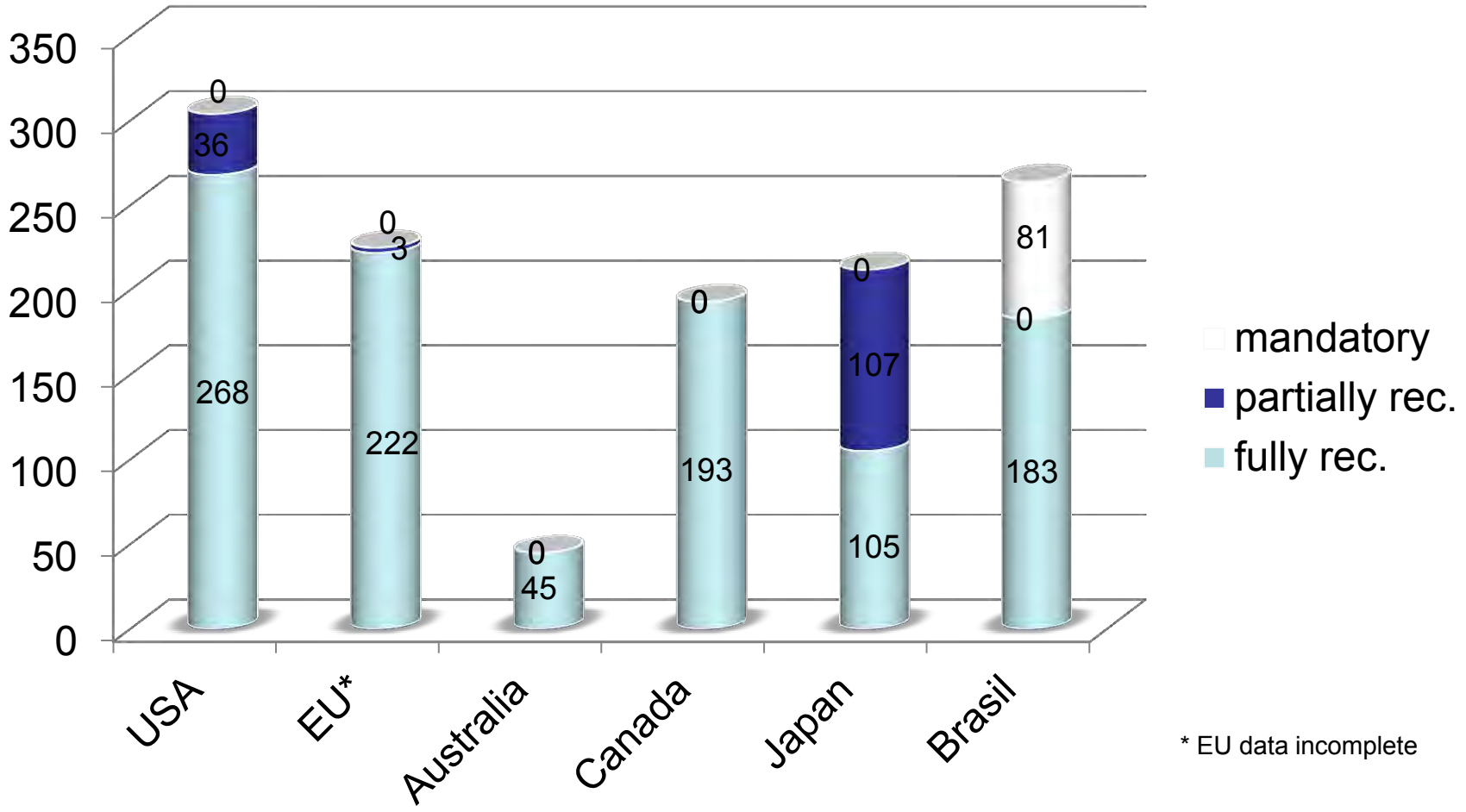
Results (March 2013):

- all concerned 6 IMDRF members provided input to the project
- a list with a clear indication of fully or partially recognized/mandatory standards was provided by 6 of the 6 regions/countries
- one region wasn't able to complete a second questionnaire (around 350 standards out of the 1157)
- The number of fully recognized standards (out of 1157 standards) varies between 268 and 45
- The number of partially and fully recognized standards varies between 304 and 45

Number of recognized/mandatory standards in IMDRF jurisdictions



* EU data incomplete

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Results (March 2013):

- There are 2 standards which are recognized/mandatory by all regions

  – ISO 10993-1: Biological evaluation of medical devices_- Part_1: Evaluation and testing within a risk management process 2009-10

  – ISO 14155: Clinical investigation of medical devices for human subjects_- Good clinical practice 2011-02

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Results (March 2013):

- There are 26 standards which are recognized/mandatory by 5 of the 6 regions

Standards recognised/mandatory in 5 of 6 IMDRF regions

ISO 10555-1	1995-06	Sterile, single-use intravascular catheters_- Part_1: General requirements
ISO 10555-1 AMD 1	1999-07	Sterile, single-use intravascular catheters_- Part_1: General requirements; Amendment_1
ISO 10555-1 AMD 2	2004-05	Sterile, single-use intravascular catheters_- Part_1: General requirements; Amendment_2
ISO 10993-1	2009-10	Biological evaluation of medical devices_- Part_1: Evaluation and testing within a risk management process
ISO 10993-3	2003-10	Biological evaluation of medical devices_- Part_3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-4	2002-10	Biological evaluation of medical devices_- Part_4: Selection of test for interactions with blood
ISO 10993-4 AMD 1	2006-07	Biological evaluation of medical devices_- Part_4: Selection of tests for interactions with blood
ISO 10993-5	2009-06	Biological evaluation of medical devices_- Part_5: Tests for in vitro cytotoxicity
ISO 10993-6	2007-04	Biological evaluation of medical devices_- Part_6: Tests for local effects after implantation
ISO 10993-7	2008-10	Biological evaluation of medical devices_- Part_7: Ethylene oxide sterilization residuals
ISO 10993-9	2009-12	Biological evaluation of medical devices_- Part_9: Framework for identification and quantification of potential degradation products
ISO 10993-12	2007-11	Biological evaluation of medical devices_- Part_12: Sample preparation and reference materials
ISO 10993-14	2001-11	Biological evaluation of medical devices_- Part_14: Identification and quantification of degradation products from ceramics
ISO 10993-15	2000-12	Biological evaluation of medical devices_- Part_15: Identification and quantification of degradation products from metals and alloys
ISO 10993-17	2002-12	Biological evaluation of medical devices_- Part_17: Establishment of allowable limits for leachable substances
ISO 11135-1	2007-05	Sterilization of health care products_- Ethylene oxide_- Part_1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11137-1	2006-04	Sterilization of health care products_- Radiation_- Part_1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11607-1	2006-04	Packaging for terminally sterilized medical devices_- Part_1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2	2006-04	Packaging for terminally sterilized medical devices_- Part_2: Validation requirements for forming, sealing and assembly processes
ISO 14155	2011-02	Clinical investigation of medical devices for human subjects_- Good clinical practice
ISO 14630	2008-01	Non-active surgical implants_- General requirements
ISO 17665-1	2006-08	Sterilization of health care products_- Moist heat_- Part_1: Requirements for the development, validation and routine control of a sterilization process for medical devices
IEC 60601-1	2005-12	Medical electrical equipment_- Part_1: General requirements for basic safety and essential performance
IEC 60601-1 Corrigendum 1	2006-12	Medical electrical equipment_- Part_1: General requirements for basic safety and essential performance; Corrigendum_1
IEC 60601-1-2	2007-03	Medical electrical equipment_- Part_1-2: General requirements for basic safety and essential performance_- Collateral standard: Electromagnetic compatibility_- Requirements and tests
IEC 60601-2-2	2009-02	Medical electrical equipment_- Part_2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

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By trying to globally harmonise requirements on medical devices the concept of the use of recognized standards in the different IMDRF jurisdictions needs to be further developed.

Currently existing hurdles:

1. The formal legal and administrative process to give a standard the official status of a recognised, harmonised or mandatory standard is too complex and time consuming
2. Legally problems related to the fact that the recognition of a standard could be interpreted as giving law making power to standards committee
3. Some IMDRF jurisdictions must transfer/implement the specific requirements of standards into the national regulation, which is time and ressources consuming
4. Assessment if standards are in compliance with the essential principles and the regional/national regulation is complex. (Therefore concentration on horizontal standards and product specific standards used for the assessment of high risk devices)

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Next Steps:

- Finalisation of the information gathering phase (EU data completion)
  Timeline: Summer 2013

- Publication of the list of recognized standards on the IMDRF website ??

- IMDRF resolution to further develop and promote the concept of recognized or mandatory international standards as a basis for providing regulatory compliance of medical devices

- IMDRF Management Committee assessment/decision: to establish (probably in cooperation with international standard organisations) a procedure to update, enhance the list of recognized standards

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