

IMDRF/Standards/N15FINAL:2014

Final Report:

“List of international standards recognized by IMDRF management committee members” Current as of: March 2014

Dr. Matthias Neumann

Mandate

Gathering information and creating a list of standards used for medical devices regulatory purposes that are recognized by IMDRF Management Committee members

Background

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

*GHTF/SG1/N044:2008: Role of Standards in the Assessment of 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.

Initiated Actions

1. Request for the nomination of national experts

2. Circulation of a list of 1102 valid international standards on Medical

Devices (ISO/IEC) to USA, Canada, Australia, Japan, Brasil,

China, Russia and the EU-Commission

3. Indication of the level of recognition of these standards (Y- fully recognized, N-not recognized, P-partially recognized or mandatory) by the nominated national experts

4. Compilation and assessment of the provided answers

An Excel sheet containing a list of 1102 IEC and ISO standards with

relevance to medical devices was developed.

Basis: database research covering the following ICS (International

Classification for Standards) notations.

• 11.100.20 (Biological evaluation of medical devices)

• 11.120.20 (Wound dressings and compresses)

• 11.140 (Hospital equipment)

• 13.140 Noise with respect to human beings. Including audiometry. Acoustics and acoustic measurement -> audiometer).

ICS (International Classification for Standards) notations.

• 11.100.10 (In vitro diagnostic test systems

• 11.080 (Sterilization and disinfection

• 11.040 (Medical equipment)

• 11.180 (Aids for disabled or handicapped persons)

• 11.060 (Dentistry)

For pragmatic reasons other medical devices (related) standards or standards of other international standardisation bodies have not been considered within this first phase of the project.

• All 8 IMDRF members provided input to the project

• a list with a clear indication of fully or partially recognized/mandatory standards was provided by 8 of the 8 regions/countries

• The number of fully recognized standards (out of 1102 standards)

varies between 261 and 44

• The number of partially and fully recognized standards varies between more than 390 and 44

• Three regions are using mandatory standards

Number of recognized/mandatory standards in IMDRF

jurisdictions

300

250

200

part.rec. and man.

150

mandatory

100

part. rec.

50 ful. rec.

0

USA EU Canada Japan Australia Brasil China Russia

Number of recognized/mandatory standards in IMDRF jurisdictions

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | recognised | partially | mandatory | partially recognised and mandatory |
| USA | 261 | 33 |  |  |
| EU | 222 | 3 |  |  |
| Canada | 181 |  |  |  |
| Japan | 104 | 105 |  |  |
| Australia | 44 |  |  |  |
| Brasil | 102 |  | 78 |  |
| China | 66 | 71 | 130 |  |
| Russia |  |  |  | 239 |

• There are 2 standards which are recognized/mandatory by 7 of the

8 regions

|  |  |  |
| --- | --- | --- |
| **Document reference** | **Publication[[1]](#footnote-1)** | **Title** |
| ISO 14630 | 2008-01 | Non-active surgical implants\_- General requirements |
| ISO 14971 | 2007-03 | Medical devices\_- Application of risk management to medical devices |

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17 standards which are recognized/mandatory by 6 of the 8 regions

|  |  |  |
| --- | --- | --- |
| **Document/reference** | **Publication** | **Title** |
| IEC 62304 | 2006-05 | Medical device software\_- Software life cycle processes |
| IEC 60601-2-20 | 2009-02 | Medical electrical equipment\_- Part\_2-20: Particular requirements for the basic safety and essential performance of infant transport incubators |
| IEC 60601-2-27 | 2011-03 | Medical electrical equipment\_- Part\_2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment |
| IEC 60601-2-29 | 2008-06 | Medical electrical equipment\_- Part\_2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators |
| IEC 60601-2-39 | 2007-11 | Medical electrical equipment\_- Part\_2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment |
| IEC 60601-2-44 | 2009-02 | Medical electrical equipment\_- Part\_2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography |
| 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 forinteractions with blood |

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17 standards which are recognized/mandatory by 6 of the 8 regions

|  |  |  |
| --- | --- | --- |
| **Document /reference** | **Publication** | **Title** |
| ISO 10993-6 | 2007-04 | Biological evaluation of medical devices\_- Part\_6: Tests for local effects after implantation |
| 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: Identificationand 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 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 14155 | 2011-02 | Clinical investigation of medical devices for human subjects\_- Good clinical practice |
| ISO 17664 | 2004-03 | Sterilization of medical devices\_- Information to be provided by the manufacturer for the processing of resterilizable medical devices |

Findings

The use of recognized standards can be a tool for harmonising requirements on medical devices in the different IMDRF jurisdictions.

The concept of the use of recognized/mandatory standards is currently implemented in the different IMDRF jurisdictions in different ways.

1. Simple mechanisms to establish a non-binding list of recognised standards

2. “Translation” of the standards into national legislation

3. Focusing on standards which are used by the regulators to perform tests

4. Complex mechanisms to give a standard the legal status of a recognised, harmonised or mandatory standard.

5. Concentration on horizontal standards and product specific standards used for the assessment of high risk devices. (Since the assessment if standards are in compliance with the essential principles and the regional/national regulation is too complex and resource binding).

Discussion Points for Regulatory Authorities

Efficient development and use of recognised standards requires that regulatory authorities have the resources to:

1. Be involved in standardization projects, and
2. Assess and implement the recognised standards under national legislation

Considerations:

- limited resources (for the assessment, for the implementation into the nat. regulation, for contribution to international standardization projects), and

- limited influence of regulatory bodies on

standardization projects

Thank you

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1. Some regions have recognized older versions of standards and are in the process of recognizing updated versions. [↑](#footnote-ref-1)