



Federal Ministry
of Health



IMDRF International Medical
Device Regulators Forum

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

Progress Report

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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 medical devices (processes or manufacturers) could come into regulatory compliance (e.g. with the essential principles).

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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. ...

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

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

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Initiated Actions:

1. Request for the nomination of national experts
2. Circulation of a first (incomplete) list of more than 720 valid international standards on Medical Devices (ISO/IEC) to USA, Canada, Australia, Japan, Brasil and the EU-Commission
3. Indication of the level of recognition of these standards (Y- fully recognized, N-not recognized, P-partially recognized) by the nominated national experts
4. First Compilation and Assessment of the provided answers

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First results:

- è all concerned 6 IMDRF members provided input to the project
- è a list with a clear indication of fully or partially recognized standards was provided by 5 of the 6 regions/countries
- è The number of fully recognized standards (out of 727 standards) varies between 222 and 18
- è The number of fully and/or partially recognized standards varies between 240 and 45
- è Out of the provided 727 standards there is no standard which is fully recognized by all participating regions/countries
- è There are 17 standards which are fully recognized by 4 out of 5 regions/countries

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Next Steps:

- è Completion of the survey (an additional list of around 430 standards is ready for distribution)
- è Verification and validation of the provided information/indications
- è Clarification and/or establishment of a common interpretation of the term “recognized standard” (including fully and partially recognized)
- è Finalisation of the information gathering phase Timeline: Spring 2013?
- è Publication of the list of recognized standards
- è 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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ISO 5840

ISO 10993-3

ISO 10993-4

ISO 10993-6

ISO 10993-7

ISO 10993-14

ISO 10993-15

ISO 10993-17

ISO 11135-1

ISO 11137-1

ISO 11607-1

ISO 11607-2

ISO 11737-1

ISO 14155

ISO 14937

ISO 17664

ISO 17665-1

List of Standards which are fully recognized by 4 out of 5 regions/countries



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