IMDRF International Medical Device Regulators Forum

IMDRF Working Group

Improving the Quality of International Standards for Regulatory Use

Progress Report

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New Work Item Proposal - Two stages

1. Mapping of technical issues and concerns, with regard to regulatory aspects of standards developed by some major international standardization committees and Explore possibilities for improvement & discuss with stakeholders and SDOs

2. Describe possible actions to take by IMDRF in order to influence and support the development or amendment of standards for regulatory purposes

Conclusion:

Standards are not as useful for regulatory purposes as they could be

Conclusion:

Improvement is necessary and in principle possible (actions needed by SDOs and IMDRF)

Conclusion:

Better co-operation and coordination within the IMDRF necessary with regards to international standardisation projects

Areas of Opportunities

- Participation levels by Regulatory Authorities
- Decision-making in the standards development process
- Usefulness of standards for regulatory use
- Consideration of regulatory and technical environment for product testing during development of a standard
- **others**

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Discussion with ISO and IEC

Geneva 22nd February

Meeting with

Frans Vreeswijk IEC CEO

Kevin McKinley ISO CEO

Conclusions:

- An appropriate and much closer co-operation between ISO/IEC and IMDRF could significantly contribute to improvements
- ISO/IEC will consider if and how a Memorandum of Understanding between ISO/IEC and IMDRF could be formulated to achieve at least that,
  - IMDRF RA experts do have full access to all relevant documents
  - IMDRF is consulted at the NWIP stage for regulatory blessing.
  - IMDRF can provide an co-ordinated input into the standard development process at TC/SC level independent from National Committees
  - IMDRF can propose NWIP

Conclusions

With regards to the presented options to increase effectiveness of RA involvement into international standardisation processes ISO/IEC indicated that there are no possibilities to introduce only for medical devices standards major abbreviations from general ISO/IEC principles like veto-rights for RAs or IMDRF, however within those limits several areas have been identified to optimise the standardisation process for medical devices standards for regulatory use:

- ISO/IEC will continue and enhance their activities to encourage each relevant TC/SC and the National Committees to ensure a proper participation of all concerned stakeholders (in particular RA, users, academics). For doing so the introduction of methods to analyse the composition of TC/SC will be considered.
- IEC and ISO will consider options to make the impact assessment to be provided together with an NWIP more meaningful so that the assessment of the NWIP can be done more efficiently

Conclusions

- ISO and IEC will continue and intensify the encouragement of TCs and SCs to focus their work better on regulatory needs
- TC and SC will take care that test procedures described in standards are validated and or the information about those validations will be made more efficiently available
- ISO and IEC reported that inside of the SDOs discussions have been started on the pros and cons of standards mixing system and test requirements
- It was indicated that the best way to ensure that IMDRF RA positions are very well reflected in the standardisation process would be a close co-operation between IMDRF and ISO/IEC, early involvement and a kind of IMDRF recognition process

Conclusions

- ISO and IEC indicated that they will consider options on how to deal with standards where RA are indicating serious gaps or failures causing unsafe devices in the field.

- IMDRF, ISO and IEC underline the need that TC and SC require better training on global regulatory requirements. An IMDRF guide containing in particular the IMDRF RA expectation would be of great value

Currently discussed model

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MoU

IEC

ISO

SC

TC

TC

TC

TC

TC

TC

SC

TC

TC

FDA

Pmda JAPAN

HSA

EU

Australia Goverment
Department of Health and Ageing
Therapeutic Goods Administration

Health Canada

CFDA

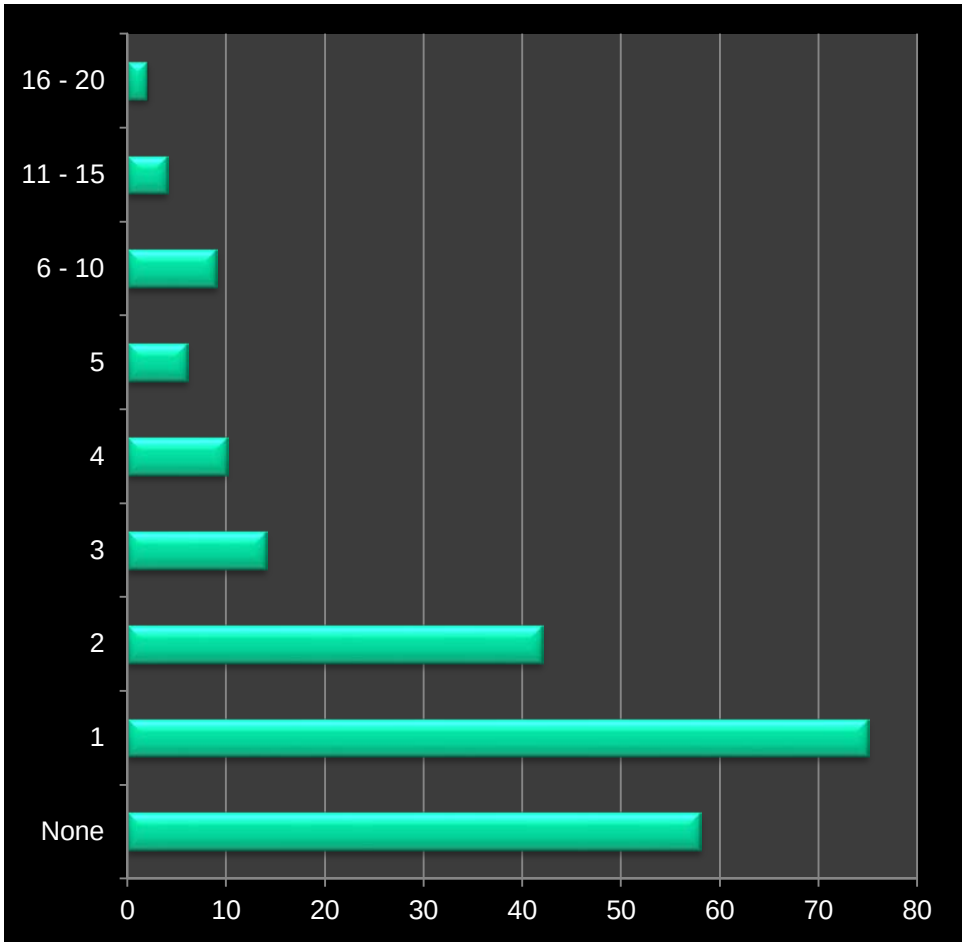
ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ

ANVISA

Number of IMDRF RA experts in ISO/IEC Teams

- 222 respondents
- Caution: responses are self-identified/counted
- ‘None’ responses 58
- Most participate in only 1 (75)
- Second highest is 2 teams (45)
- Frequency

None	58
1 team	75
2 teams	42
3 teams	14
4 teams	10
5 teams	6
6 – 10	9
11 – 15	4
16 – 20	2

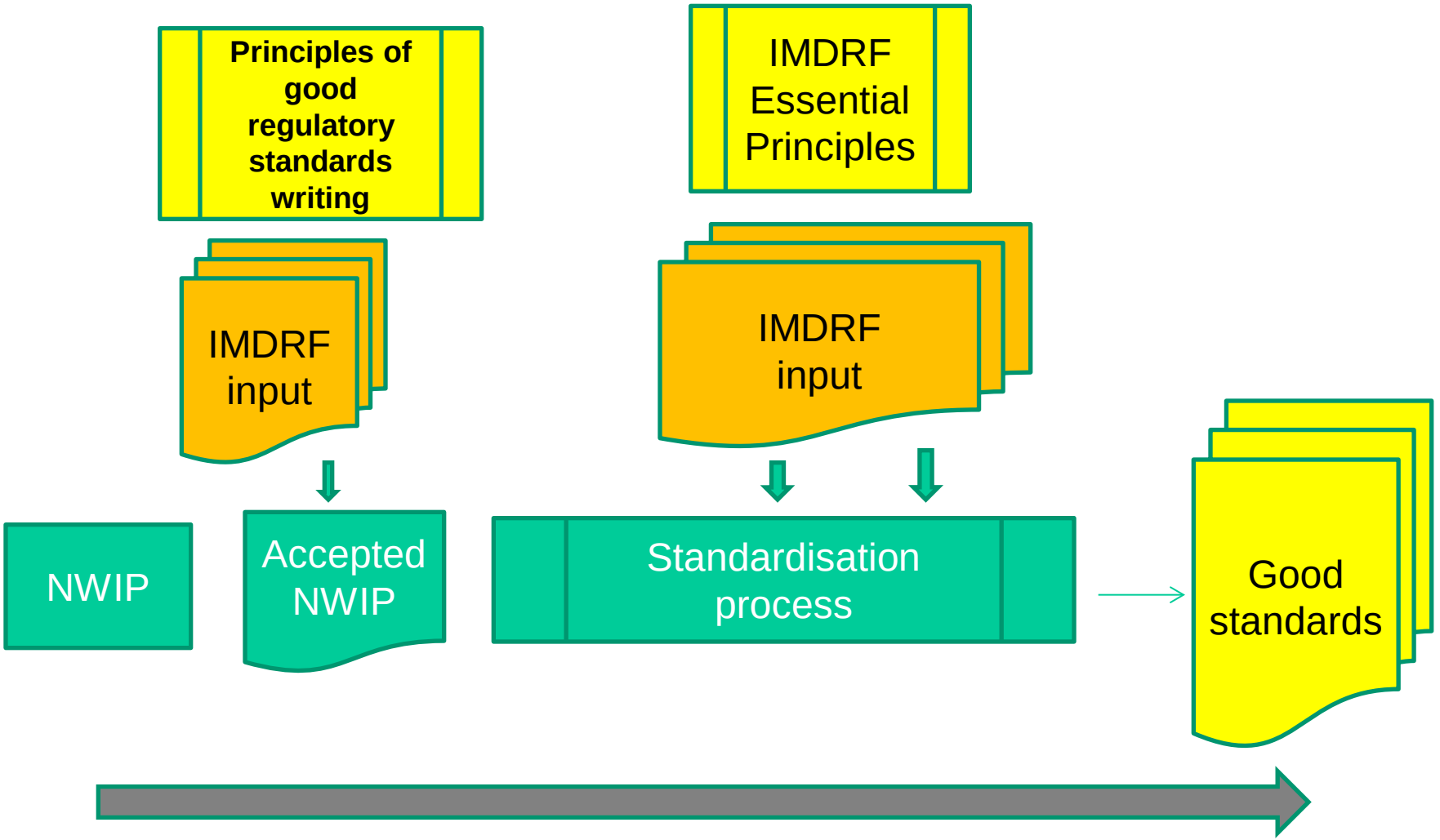


ISO Teams

None	34
TC 45 Rubber and rubber products	2
TC 69 Application of statistical methods	0
TC 69/SC 4 Applications of statistical methods in product and process management	0
TC 76 Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use	2
TC 83 Sports and other recreational facilities and equipment	0
TC 84 Devices for administration of medicinal products and catheters	5
TC 94 Personal safety -- Protective clothing and equipment	0
TC 106 Dentistry	3
TC 106/SC 1 Filling and restorative materials	1
TC 106/SC 2 Prosthodontic materials	1
TC 106/SC 3 Terminology	0
TC 106/SC 4 Dental instruments	1
TC 106/SC 6 Dental equipment	2
TC 106/SC 8 Dental implants	1
TC 106/SC 9 Dental CAD/CAM systems	0
TC 121 Anaesthetic and respiratory equipment	4
TC 121/SC 1 Breathing attachments and anaesthetic machines	2
TC 121/SC 2 Airways and related equipment	0
TC 121/SC 3 Lung ventilators and related equipment	5
TC 121/SC 4 Terminology and semantics	2
TC 121/SC 6 Medical gas systems	1
TC 121/SC 8 Suction devices for hospital and emergency care use	0
TC 121/AG 1	0
TC 126 Tobacco and tobacco products	0
TC 150 Implants for surgery	19
TC 150/SC 1 Materials	7
TC 150/SC 2 Cardiovascular implants and extracorporeal systems	12
TC 150/SC 3 Neurosurgical implants	6
TC 150/SC 4 Bone and joint replacements	4
TC 150/SC 5 Osteosynthesis and spinal devices	5
TC 150/SC 6 Active implants	9
TC 150/SC 7 Tissue-engineered medical products	4
TC 157 Non-systemic contraceptives and STI barrier prophylactics	4
TC 159 Ergonomics	0
TC 168 Prosthetics and orthotics	0
TC 170 Surgical instruments	3
TC 172 Optics and photonics	3
TC 172/SC 5 Microscopes and endoscopes	3
TC 172/SC 7 Ophthalmic optics and instruments	8
TC 172/SC 9 Electro-optical systems	0
TC 173 Assistive products for persons with disability	1
TC 173/SC 3 Aids for ostomy and incontinence	0
TC 176 Quality management and quality assurance	1
TC 194 Biological and clinical evaluation of medical devices	22
TC 194/SC 1 Tissue product safety	3
TC 198 Sterilization of health care products	13
TC 209 Cleanrooms and associated controlled environments	0
TC 210 Quality management and corresponding general aspects for medical devices	22
TC 212 Clinical laboratory testing and in vitro diagnostic test systems	9
TC 215 Health informatics	3
TC 217 Cosmetics	0
TC 229 Nanotechnologies	5
TC 249 Traditional Chinese medicine	1
TC 272 Forensic sciences	1
TC 276 Biotechnology	4
TC 299 Robotics	3
TC 304 Healthcare administration	1
Other (please specify)	0

IEC Teams

None	117
TC 21 Secondary cells and batteries	1
TC 21/SC 21A Secondary cells and batteries containing alkaline or other non-acid electrolytes	2
TC 56 Dependability	1
TC 61 Safety of household and similar electrical appliances	0
TC 61/SC 61B Safety of microwave appliances for household and commercial use	0
TC 62 Electrical equipment in medical practice	13
TC 62/SC 62A Common aspects of electrical equipment used in medical practice	13
TC 62/SC 62B Diagnostic imaging equipment	14
TC 62/SC 62C Equipment for radiotherapy, nuclear medicine and radiation dosimetry	1
TC 62/SC 62D Electromedical equipment	17
TC 65 Industrial-process measurement, control and automation	0
TC 65/SC 65A System aspects	0
TC 76 Optical radiation safety and laser equipment	0
TC 77 Electromagnetic compatibility	1
TC 87 Ultrasonics	2
TC 106 Methods for the assessment of electric, magnetic and electromagnetic fields associated with human exposure	1
TC 110 Electronic display devices	1
TC 113 Nanotechnology for electrotechnical products and systems	0
Other (please specify)	0


Principles of good regulatory standards writing
IMDRF Essential Principles
IMDRF input
IMDRF input
NWIP
Accepted NWIP
Standardisation process
Good standards

Next Steps

- Further analysis of the feasibility of an IMDRF Standardisation network
- Analysis of potentially needed additional measures (e.g. review of the GHTF essential principles, guidance on good regulatory standards writing)
- Final report

Thank you for your attention !