IMDRF International Medical Device Regulators Forum

How standards are used for regulatory purposes among IMDRF members

Tatiana Pika
member of Standards Working Group,
Roszdravnadzor

Standards are '…the distilled wisdom of people with expertise in their subject matter and who know the needs of the organizations they represent – people such as manufacturers, sellers, buyers, customers, trade associations, users or regulators'.*

* https://www.bsigroup.com/en-GB/standards/Information-about-standards/what-is-a-standard/, accessed 15 June 2017

Standards Working Group (SWG) Members

- Scott Colburn/FDA/USA, Chair
- Ying Huang/TGA/Australia
- Fabio Quintino/ANVISA/Brazil
- Kevin Day/Health Canada
- Jia Zheng/SDA/China
- Maurizio Andreano/DITTA/Siemens
- Peter Linders/DITTA/Philips
- Naoki Marooka/DITTA/Shimadzu
- Erik Hansson/European Commission
- Matthias Neumann/European Union
- Jeff Eggleston/GMTA/Medtronic
- Hideki Asai/GMTA/Hitachi
- Hiroshi Ishikawa/PMDA/Japan
- Madoka Murakami/PMDA/Japan
- Vladimir Antonov/Roszdravnadzor/Russia
- Tatiana Pika/Roszdravnadzor/Russia
- Christopher Lam/HSA/Singapore
- Kookhan Kim/MFDS/Korea
- Heungil Ryu/MFDS/Korea
- Kyunghyun Kim/MFDS/Korea
- Gail Rodriguez/FDA/USA

Role of Standards (IMDRF Model)

Role of Standards in the Assessment of Medical Devices Study Group 1 Final Document GHTF/SG1/N044:2008

Main purpose: demonstrating conformity with the Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (IMDRF GRRP WG/N47 FINAL:2018)

Methods:
- use of recognized standards;
- use of non-recognized standards;
- other methods.

Use of recognized standards (IMDRF Model)

Recognition of Standards

The method should include a mechanism of periodic review and realignment of nationally recognized standards to the international standards.

The term “recognized standard” does not imply that such a standard is mandatory.

Use of recognized standards

Recognised standard - standard deemed to offer the presumption of conformity to specific Essential Principles of Safety and Performance.

Use of recognized standards (IMDRF Model)

Revision of Recognized Standards

- a requirement in a specific standard is determined to be inadequate to ensure conformity to a specific Essential Principle;
- one or more of the Essential Principles has changed,
- changes in the state of technology or accepted practice necessitate revising the technical specifications in the standard.

Changes to the Recognition Status

- safety concerns identified through post-market surveillance activities or user experience;
- the availability of a revised version of the standard.

IMDRF Model

Alternative solutions to demonstrate conformity with the Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

- national and international standards that have not been given the status of a "recognized standard" by the Regulatory Authority;
-industry agreed methods;
- internal manufacturer standard operating procedures developed by an individual manufacturer;
- other sources that describe the current state of technology and practice related to performance, material, design, methods, processes or practices.

Use of recognized standards among IMDRF members

Recognized and voluntary	Recognized; voluntary and mandatory	Recognized and mandatory
Russia (EEU)	China	Korea
USA		Brazil**
Europe		
Australia		
Singapore*		
Canada*		
Japan*		

* have one mandatory standard or section of the standard (linked to regulatory framework)

** only informal recognition program

Standards Recognition and Use

Work Item goal: advance harmonized use of standards

- Two objectives
  - Compare RAs' recognition and utilization policies
  - Update list of commonly recognized standards
- Two elements
  - Survey
  - Checklist of recognized standards

Recognition Program Details

- 7 of the 10 respondents (70%) report that they have a formal standards department or function within their RA
- The lack of a formal department notwithstanding, 9 (90%) have in place formal systems – policies and processes
- Systems identify, recognize and maintain an approved list of standards and encourage their use by manufacturers in device submissions

Recognition Program Details, cont'd

- Most, whether formal or informal, maintain a list of recognized standards that manufacturers may declare conformity to for purposes of device submissions
- Two respondents' programs are regional programs
- One RA has in place an ad hoc team that plans to transform itself into a formal department in the near future

Recognition Program Details, cont'd

- Many responses appear to be a 'hybrid' program, with both formal and informal aspects (e.g., a formal list of recognized standards, but an informal staff and process for producing the list)
- Several mention that they expect further formalization of their standards program in the future
- RAs report both rules/regulations and statutes as the authority for their programs
- National Bodies participate directly in 6 of 10 RAs' programs (more regulations than statutes)

Managing a Recognition List

- 60% of respondents report they are required to seek outside input into which standards will be recognized.
- Most require a public consultation, at least for list publication
- Others permit input from the public
- 90% publish the list of recognized standards; all of those make the list of recognized standards available to all
- Frequency of list updates ranges from ‘case by case basis’ to ‘periodically’ to ‘at least five yearly’

How to Gain Recognition

- Again, a wide spectrum of expectations for requesting recognition; some require specific forms and others simply accept a request
- Some have ad hoc or technical teams consider the addition of new standards; some will accept requests from anyone

Partial v Complete Recognition

- 100% (10 respondents) allow partial recognition

Conformity Assessment

- 100% of respondents allow Declarations of Conformity (DoCs)
- 9 of 10 (90%) sometimes require additional documentation to the DoC
  - Generally based upon device risk
  - Testing reports are the most often required documents
- 90% accept test results from other countries in support of a DoC

Thank you for your attention!

Tatiana Pika
member of Standards Working Group,
Roszdravnadzor