FUTURE OF ISO 13485 AND UPDATE ON ISO 14971

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1. Introduction
2. What again is ISO’s HLS (high-level structure)?
3. Future of ISO 13485 (Medical devices -- Quality management systems -- Requirements for regulatory purposes)
4. Update on revision of ISO 14971 (Medical devices -- Application of risk management to medical devices)
5. Take Aways
ISO 13485:
- Ed. 3 published on 1 March 2016
- Is a management system standard (MSS), type A
- Is—in principle—subject to ISO HLS

ISO 14971:
- Ed. 2 published in 2007
- Revision almost done – publication expected in 2019
- Comes with ISO/TR 24971 and new Guide 63
- Is not an MSS ...
What is ISO’s High-Level Structure?

- HLS represents common part of ISO’s Management System Standards (MSS)
- HLS aims to ‘standardize’ MSSs
- HLS aims to support development of MSSs
- HLS aims to facilitate implementation of multiple MSSs in an organization
- HLS is not just a structure, also normative text
- HLS was designed for enterprise management systems
- HLS is mandatory for all ISO MSSs
Conceptual model of ISO HLS
ISO/IEC Directives Part 1 - Annex SL, Appendix 2: High level structure, identical core text, common terms and core definitions

NOTE In the Identical text proposals, XXX = an MSS discipline specific qualifier (e.g. energy, road traffic safety, IT security, food safety, societal security, environment, quality) that needs to be inserted

Over 10 pages of normative core text …

So HLS is not just a structure

OTAGMSS* and a BBMSS**

* on-line tool for automatic generation of management system standards (not yet available)
** BBMSS: beer brewery management system standard
So, in principle, ISO 13485 must be made HLS compliant with the next revision

(And also normatively reference ISO 9001)
However:

- Normative language in HLS does not fit well regulatory purposes
- HLS is in revision, target effective date: 2022
- Likelihood of substantive change is minimal
- At ISO 13485 workshop in Seoul (Nov 2018), many stakeholders requested (at least) 5 year stability
- Systematic review of ISO 13485 starts next month
Ambition of the ISO/TC 210 leadership: maintain the usefulness of ISO 13485 for the purposes it had for the last 25+ years

Note: “Requirements for regulatory purposes” is in the title
Revision of ISO 14971:2007 comes with:

- Revision of ISO/TR 24971:2013 (Medical devices – Guidance on the application of ISO 14971)
- Update of ISO/IEC Guide 63:2012 (Guide to the development and inclusion of aspects of safety in international standards for medical devices)

*(text in collaboration with Dr. Jos van Vroonhoven, JWG1 convener)*
Major changes in ISO 14971:2019

- New Clause 2 on normative references, per ISO/IEC Directives
- Steps in risk analysis are re-arranged in more logical order
- New defined terms “benefit”, “reasonably foreseeable misuse”
- Emphasis on benefits in evaluation of overall residual risk
- Instruction to mfrs. to disclose significant residual risks
- More detailed requirements for production and post-production activities

FDIS ballot April/May 2019; publication of standard in 2019
Major changes in ISO/TR 24971:2019

• Complete revision of ISO/TR 24971:2013
• Clause numbering is equal to that in ISO 14971
• Additional annexes to clarify specific topics
• Some annexes of ISO 14971:2007 moved to TR, merged with existing guidance in ISO/TR 24971:2013,
• Updated and supplemented with more guidance

DTR ballot late spring 2019; publication expected in 2019

• Guide is intended for writers of standards for medical devices, when developing/revising standards
• Current Edition (2012) was based on ISO 14971:2007
• Edition 3 is basis for ISO 14971:2019 and for other standards
• Definitions in Guide 63 are aligned with GHTF/IMDRF and with ISO 14971:2019 and ISO 13485:2016

Dguide approved (2x100%!); publication expected soon
TAKE AWAYS

• Future of ISO 13485 not yet fully clear
• ISO/TC 210 will strive for continued usefulness
• Close alignment with IMDRF is important
• Outcome of systematic review expected mid 2019

• Revision of ISO 14971 and associated documents (ISO/TR 24971 and ISO/IEC Guide 63) almost done
• No fundamental change in process approach
THANK YOU!

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