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)
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INTRODUCTION

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
FUTURE OF ISO 13485

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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