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GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

FUTURE OF ISO 13485 AND UPDATE ON ISO 14971

Monday 18th March 2019, Moscow (Russia)

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PRESENTATION OUTLINE

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**

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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 …

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ISO HLS

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

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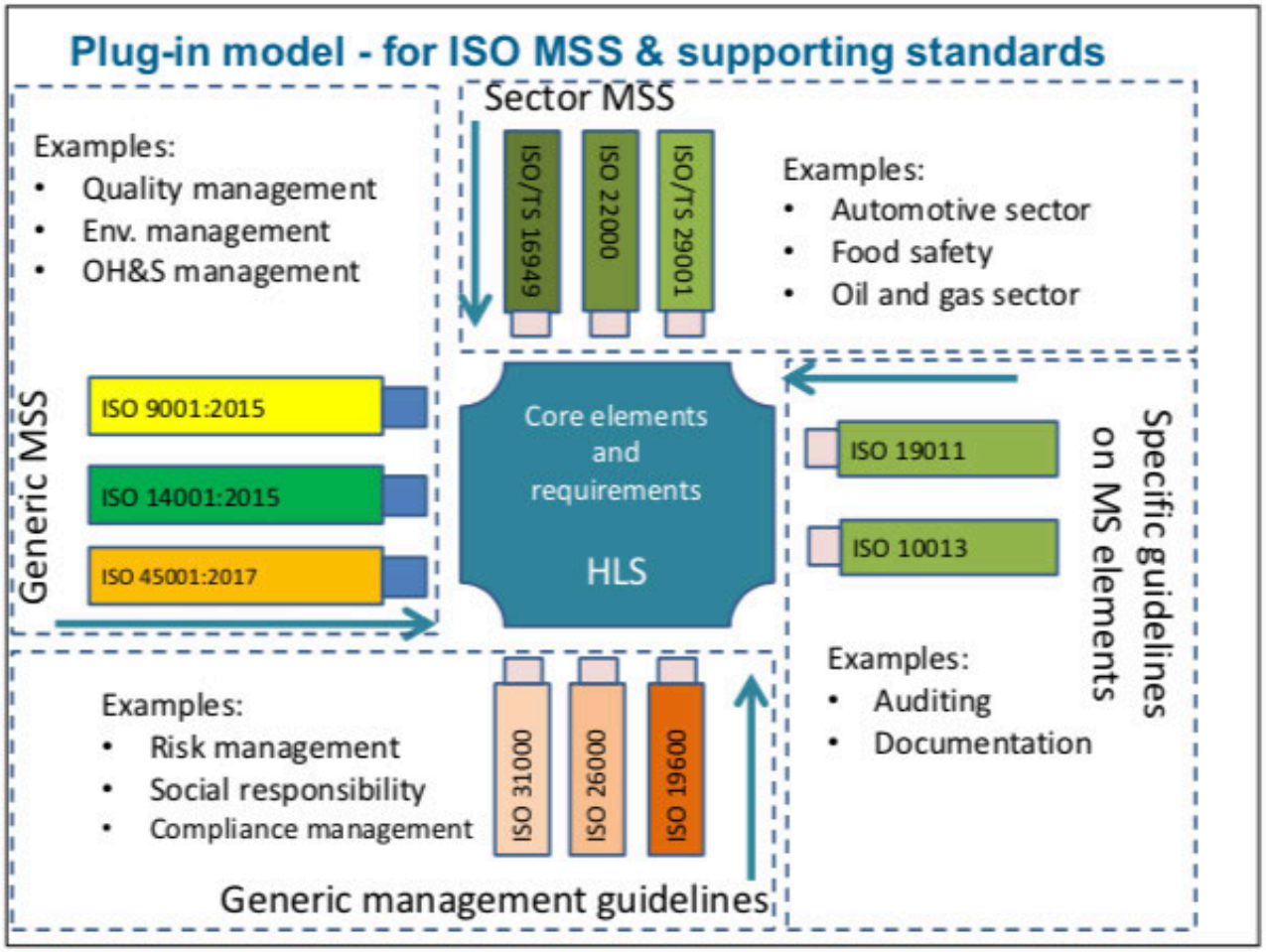
ISO HLS

Conceptual model of ISO HLS



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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*

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FUTURE OF ISO 13485

So, in principle, ISO 13485 must be made HLS compliant with the next revision

(And also normatively reference ISO 9001)

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FUTURE OF ISO 13485

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

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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

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REVISION OF ISO 14971

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)

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REVISION OF ISO 14971

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

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REVISION OF ISO 14971

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

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REVISION OF ISO 14971

Notes on ISO/IEC Guide 63:2019

- 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

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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

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