ENGINEERING AND R&D SERVICES

HCL

Medical Device Risk Management: Transition to EN ISO 14971:2012

WHITE PAPER

2 Engineering experiences

Acceleration | Value | Technology

TABLE OF CONTENTS

© 2014, HCL Technologies. Reproduction Prohibited. This document is protected under Copyright by the Author, all rights reserved.

Abstract

The international standard EN ISO 14971:2009 – Application of Risk Management to Medical Devices has been amended to its next version EN ISO 14971:2012. The new version requires significant changes to the existing practices of risk management and has considerable impact on medical device manufacturers. The revised standard has shown greater harmony with European medical device directives. More importantly, requirements of the essential requirements checklists that in many ways contradicted the clauses of ISO 14971: 2007 have now been addressed through this transition.

This paper includes a deviations table that explains the changes made to the existing standard, and also the way existing clauses have been interpreted. HCL has technically understood the changes and developed its own process flow to support its clients, to implement these changes in a faster, economic and more effective way. Since the flow is very generic in nature, different clients can easily adapt and integrate this with their existing systems.

© 2014, HCL Technologies. Reproduction Prohibited. This document is protected under Copyright by the Author, all rights reserved.

Abbreviations

Sl. No.	Acronyms (Polymers)	Full form
1	ISO	International Organization for Standardization
2	EFTA	European Free Trade Association
3	ER	Essential Requirement
4	FMEA	Failure Mode Effects Analysis
5	EEC	European Economic Council
6	EN	Prefix to identify European Standards developed by the Standard Developing Organization – CEN (European Committee for Standardization)
7	ER	Essential Requirement as identified in the European Union directive
8	RCM	Risk Control Measure
9	ALARP	As Low As Reasonably Practicable
10	ALAP	As Low As Possible

© 2014, HCL Technologies. Reproduction Prohibited. This document is protected under Copyright by the Author, all rights reserved.

A harmonized version of the latest standard with European Medical Device Directives

Market Trends/Challenges

Compliance to ISO 14971: Application of Risk Management to Medical Devices is a mandatory regulatory requirement for medical device manufacturers. On 31st July 2012, its European adapted version, EN ISO 14971:2009 was replaced by the 2012 version – EN ISO 14971:2012. During this revision, some notable changes were introduced to bring greater harmony with the essential requirements of the European Medical Device Directives:

- 93/42/EEC - Medical devices
- 90/385/EEC - Active implantable medical devices
- 98/79/EC - In vitro diagnostic medical devices

This version of the standard has substantial differences from the ISO 14971:2007 standard. Manufacturers and conformity assessment bodies will need to feed the Essential Requirements into their risk management processes provided by the standard. Conformance with the revised version of the standard confers a presumption of conformity with some of the Essential Requirements and associated EFTA regulations. The major elements of the risk management process that were significantly affected as well as differently interpreted by the standard are listed below:

- ✓ Concept of As Low As Reasonably Practicable" (ALARP) to "As Far As Possible"
- ✓ Safety by design
- ✓ Mitigating negligible risks
- ✓ Design risk control options/measures
- ✓ Residual risk management
- ✓ Risk-benefit analysis
- ✓ Information for safety

© 2014, HCL Technologies. Reproduction Prohibited. This document is protected under Copyright by the Author, all rights reserved.

Solution

The following table shows the changes between the ISO 14971:2007 standard and the EN ISO 14971:2012 standard, and European ERs.

EN ISO 14971:2009	EN ISO 14971:2012 and European ERs
Mitigating negligible risks	
Negligible risks are acceptable and risk control need not be actively pursued; only non-acceptable risks have to be integrated into the overall risk-benefit analysis.	All the risks identified through risk management documents need to be reduced as much as **possible** regardless of their dimension and their "acceptability assessment" and need to be balanced together with all other risks, against the benefit of the device.
"As Low As Reasonably Practicable" Vs. "As Far As Possible"	
The concept of "**ALARP**" (As Low As Reasonably Practicable) has two parts: **Technical practicability** - The ability to reduce the risk regardless of the cost. **Economic practicability** - The ability to reduce the risk without making the provision of the medical device an unsound economic proposition.	The concept of **Practicability** has been modified to **Possibility** and explained as follows: • Risks to be reduced "**As Far As Possible**" without there being room for economic considerations. • Manufacturers and notified bodies may not apply the ALARP concept with regard to economic considerations.
Risk control options/measures	
The manufacturer shall "**use one or more** of the following risk control options in the priority order listed": 1. Inherent safety by design, 2. Protective measures in the medical device itself or in the manufacturing process, 3.Information for safety Any residual risk that remains after the risk control measure(s) are applied shall be evaluated using the criteria defined in the risk management plan. If the residual risk does not meet these criteria, further risk control measures shall be applied.	"**Conform to safety principles**, taking account of the generally acknowledged **state of the art**" and "**select the most appropriate solutions**" by applying cumulatively what has been called "control options" or "control mechanisms" in the standard. The manufacturer must **apply all** the "**control options**" and **may not stop his endeavors** if the first or the second control option has reduced the risk to an "acceptable level".

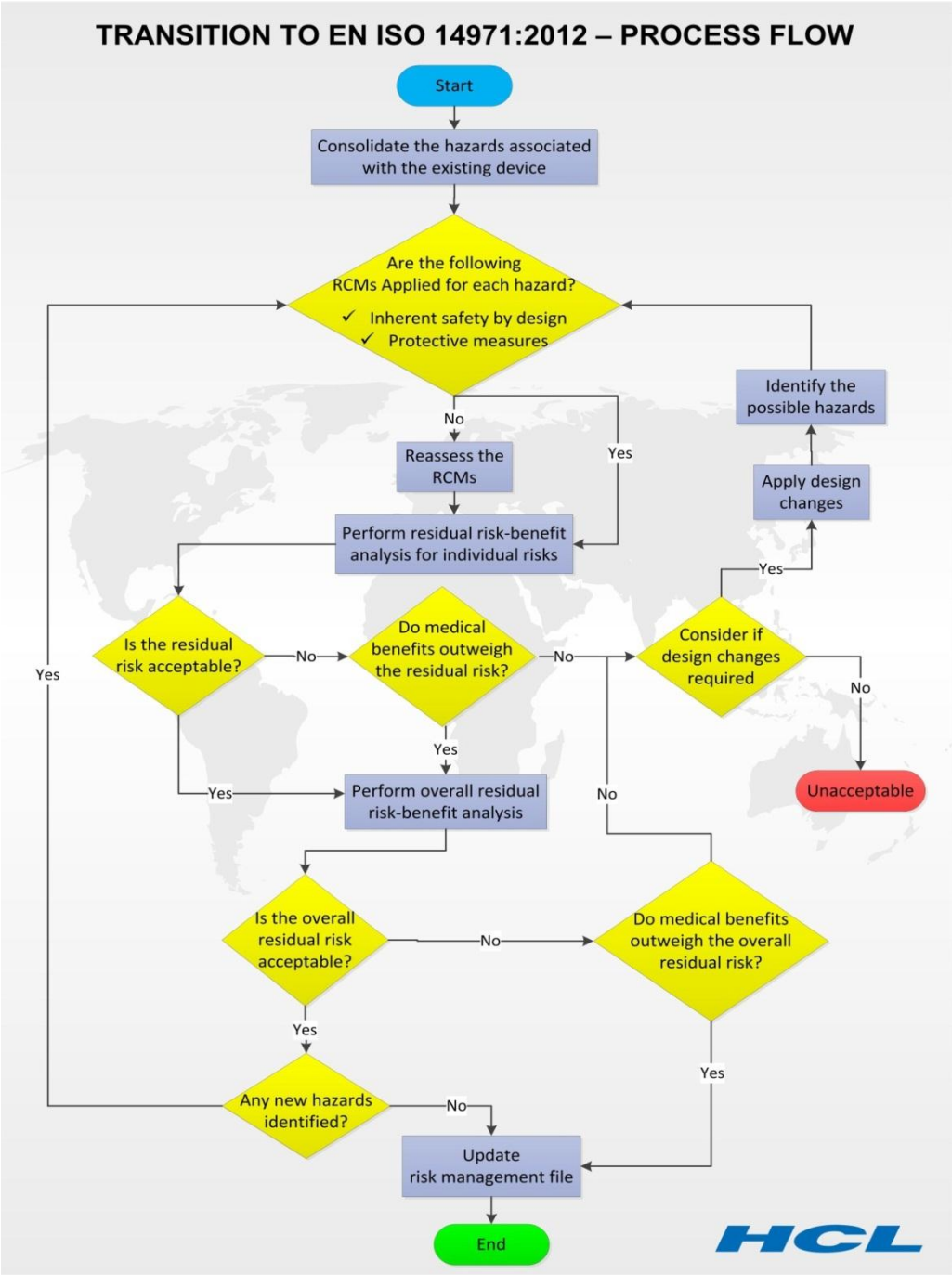
© 2014, HCL Technologies. Reproduction Prohibited. This document is protected under Copyright by the Author, all rights reserved.

EN ISO 14971:2009	EN ISO 14971:2012 and European ERs
Residual risk management and **risk-benefit analysis**	
Risk reduction **need not be performed** if the estimated risk(s) is so low.	Overall **risk-benefit analysis must take place** in any case, regardless of the application of criteria established in the risk management plan of the manufacturer.
If the **residual / overall residual risk** is judged unacceptable using the criteria established in the risk management plan and further risk control is impractical, the manufacturer shall **gather and review data and literature** on the medical benefits of the intended use/intended purpose to determine if they **outweigh** the residual / overall residual risk respectively.	The manufacturer must pursue the risk-benefit analysis for the individual risk and the overall risk-benefit analysis.
In both cases, the risk-benefit need not be pursued if the overall residual risk is judged acceptable when using the criteria established in the risk management plan.	Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.
Information for safety	
"**Information for safety**" to be a control option.	The user shall be informed about the residual risks - it is a **case of risk notification rather than risk mitigation** since the residual risks are not reduced further.

Process Flow

The following flow chart describes the flow of various activities that are performed as part of this transition. This flow ensures that no step is skipped during the process, and aids in building a proper documentation without any process related shortcomings.

© 2014, HCL Technologies. Reproduction Prohibited. This document is protected under Copyright by the Author, all rights reserved.



© 2014, HCL Technologies. Reproduction Prohibited. This document is protected under Copyright by the Author, all rights reserved.

HCL has developed process aids to easily implement changes which can further reduce cost and time

Design changes and in-vitro as well as in-vivo testing may be needed

Best Practices

- Medical device manufacturers have realized the importance of the revised standard and started implementing the changes in their processes. HCL has understood the market need and has come up with a process flow to support its global clients to implement these changes
- This process lets medical device manufactures understand and easily implement changes which can further reduce cost and time
- The process ensures effective deliverables in compliance with the revised standard
- It also ensures that the products get through quick regulatory clearance / renewal as it is simple and easy to implement

General Outcomes

- As part of this revised standard, there may be a chance to revise the designs if the existing control measures do not decrease the risk to an acceptable level
- In-vitro as well as in-vivo testing may be needed with newly implemented risk control measures
- Organization-wide trainings need to be conducted for relevant stakeholders to bring awareness about the changes in the risk management process
- Complete remediation of risk management files need to be performed with a thorough review to ensure that all the products, processes and practices are in compliance with the revised standard

© 2014, HCL Technologies. Reproduction Prohibited. This document is protected under Copyright by the Author, all rights reserved.

Ensuring compliance with an uncompromised quality of deliverables.

The above points involve considerable cost and time and are equally challenging to ensure compliance.

Conclusion

The outlined process explains an efficient and simple way for any medical device to comply with the latest EN ISO 14971:2012 standard. Though there are different strategies available in the market, our strategy simplifies the entire process and it is time saving and economical as well. This process has already been successfully implemented for a few medical devices (Class II and III devices).

HCL has vast experience in the medical devices domain, and has practical exposure to multiple international standards as well as regulatory affairs. With this deserving experience and technical knowledge, HCL can support its clients with greater confidence and deliver outputs with the highest possible quality.

© 2014, HCL Technologies. Reproduction Prohibited. This document is protected under Copyright by the Author, all rights reserved.

References

1. The ISO 14971: 2007 – Application of Risk Management to Medical Devices
2. EN ISO 14971:2009 – Application of Risk Management to Medical Devices
3. EN ISO 14971:2012 – Application of Risk Management to Medical Devices
4. www.bsigroup.co.uk

© 2014, HCL Technologies. Reproduction Prohibited. This document is protected under Copyright by the Author, all rights reserved.

Author Info

Avinash Donthula

Avinash has a Master's Degree in Clinical Engineering Technology from IIT Madras, India. He has over 2 years of experience in the Medical Devices domain.

Manoj Kumar Nagarajan

Manoj has a Bachelor in Engineering Degree and a Master's in Operations Management. He has over 15 years' experience in New Product Development and Sustaining Engineering with over 9 years' experience in the field of Medical Devices. He is leading an engagement for a large Medical Devices OEM across NPD, Sustaining, Quality and Manufacturing Engineering Services.

© 2014, HCL Technologies. Reproduction Prohibited. This document is protected under Copyright by the Author, all rights reserved.

Hello, I'm from HCL's Engineering and R&D Services. We enable technology led organizations to go to market with innovative products and solutions. We partner with our customers in building world class products and creating associated solution delivery ecosystems to help bring market leadership. We develop engineering products, solutions and platforms across Aerospace and Defense, Automotive, Consumer Electronics, Software, Online, Industrial Manufacturing, Medical Devices, Networking & Telecom, Office Automation, Semiconductor and Servers & Storage for our customers.

For more details contact**: ers.info@hcl.com**
Follow us on Twitter: http://twitter.com/hclers & LinkedIn: http://lnkd.in/bt8hDXM
View our blog-site: http://www.hcltech.com/blogs/engineering-and-rd-services
Visit our website: http://www.hcltech.com/engineering-rd-services