The European Association Medical devices - Notified Bodies

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TEAM-NB Position Paper

EN ISO 14971:2012

Background

On 31 July 2012 EN ISO 14971:2012, Medical devices — Application of risk management to medical devices, replaced EN ISO 14971:2009 as the European harmonised standard. The 2009 version was considered obsolete as of the same date. The 2012 version allows the presumption of conformity to the applicable Essential Requirements of the three Medical Device Directives, 90/385/EEC, 93/42/EEC and 98/79/EC. EN ISO 14971:2012 applies only to manufacturers placing devices on the market in Europe; for the rest of the world, ISO 14971:2007 remains the applicable standard.
We describe below the steps TEAM-NB members plan to verify where relevant if requirements of EN ISO 14971:2012 have been met. This should help manufacturers update their risk management procedures and files to maintain compliance with the Essential Requirements of the directives, when building on the presumption of conformity.

What is the difference between EN ISO 14971:2012, EN ISO 14971:2009 and ISO 14971:2007?

There has been no change to the Normative Text of the standard; the Normative Text contains the requirements and is the same in all three versions. Only the Annex Zs of EN ISO 14971 have changed in the 2012 version. The new Annex Zs describe where the EN ISO 14971 standard does and does not meet the requirements of the European Directives. The Annex Zs describe these differences as Content Deviations for each Directive.
What does this mean for future Notified Body Quality System or Technical Documentation Audits and Design Dossier Reviews?
The role of the Notified Body is to assess compliance to the Directives, focusing on risk management and whether clinical benefits outweigh risk to patients and users. Manufacturers should have read the new harmonised standard and can then choose to use the harmonised standard to help meet the requirements of the Directives. The latest harmonised version has clarified the gaps.
Notified Body Assessors and Technical Specialists will be asking questions in upcoming audits and reviews that ensure that manufacturers who place devices on the market in Europe are aware of the gaps between the requirements of the standard and those of the Directives, and that manufacturers have undertaken (or are undertaking) any actions needed to address these.

Key questions will include:

1. Are all design solutions conform with the safety principles given in the essential requirements and EN ISO 14971? (inherent safe design > protection measures > information)
2. Have manufacturers shown that risks have been reduced as much as possible?
3. Have manufacturers conducted a risk benefit analysis for all risks?
4. As publication of residual risks in the information given to the user does not reduce the risk, but publication of residual risks and warnings used as risk control measure may be beneficial, have residual risks been correctly placed on IFUs or provided in training, and have manufacturers evaluated whether those warnings are effective (refer to IEC 62366).

The wording in the Directives has not changed and some manufacturers will have procedures and risk management files that already comply. Others may have corrective actions to take. Please be ready at your next Notified Body QMS or Technical File Assessment to share evidence to show that EN ISO 14971:2012 Annex Z has been considered in your compliance to the Essential Requirements for newer devices and to share your plans for evaluating and addressing the impact of EN ISO 14971:2012 Annex Z on older and legacy devices that will continue to have CE Marking applied.