Collaboration Holds the Key to Clarity on EN ISO 14971:2012

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A consensus document to assist in implementing and utilizing EN ISO 14971:2012 is on the way.

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The EU Commission caused quite a stir in August 2012, when it announced the harmonization of the EN ISO 14971:2012 risk-management standard for the medical device industry with absolutely no transition period. Exacerbating the situation, of course, were the numerous challenges and widespread confusion around the modification to the existing standard ISO 14971:2007 (EN ISO 14971:2009)—not to mention inconsistent enforcement.

Published July of 2012 as an update to the 2009 version, the EN harmonized standard basically amends the Annexes ZA, ZB, and ZC for the three EU directives: the Medical Device, Active Implantable Medical Device, and In Vitro Diagnostic Medical Devices Directive.

Annexes ZA through ZC explain to medical device manufacturers how to comply with the Medical Devices Directives because the directives go beyond the base requirements of ISO 14971:2007. So, the annexes fill in those gaps with ISO 14971:2007 based on what the Medical Device Directives require. Remember: The regulation is what is required to be able to CE mark your medical device, and the use of the harmonized standard—EN ISO 14971:2012—is voluntary, per the three directives.

Without the use of harmonized standards, however, it is typically more difficult for the manufacturer—but not impossible—to prove to the notified body that it meets the intent of the applicable directive. One of the most significant issues with these annexes is that, according to EN ISO 14971:2012, companies have to reduce risk “as far as possible,” rather than reduce risk “as low as reasonably possible,” per ISO 14971:2007. While the change in verbiage appears minor, the difference between these two statements can actually have a major economic impact on a company, especially small medical device manufacturers.

Further complicating matters, many notified bodies didn’t enforce the standard when it first came out—and there’s still a wide variance of how it’s being enforced by the different notified bodies in terms of how and when it is required. Some notified bodies have issued their own set of criteria; others haven’t. Inconsistency seems to be the current state of these requirements.

There are more issues to consider, but these are some of the heavy hitters. An outcome of Annexes ZA through ZC is that you will need to update your quality system processes for risk management at a minimum. But the actual risk-management document for each product that is CE marked under the Medical Devices Directives will need to be updated as well. There may be additional issues that arise for a specific product that need to be considered, too.

Based on the release and impact of the EN ISO 14971:2012 harmonized standard, several European industry trade associations started developing guidance documents to address inconsistencies in how the requirements were being interpreted and implemented.

Toward the end of 2013, a couple of these industry trade associations came out with some guidance documents on how to implement the issues that are highlighted in the annexes of EN ISO 14971:2012. Team-NB, a voluntary membership trade association of some of the EU notified bodies for the Medical Devices Directives, also came out with a short, two-page position paper.

Unfortunately, these documents didn't totally clear the waters, so to speak. And they're not from the commission or the competent authorities. So, the general consensus was that they wouldn't have enough clout to effect change and they hadn't completely resolved inconsistencies.

With this in mind, COCIR, along with EDMA and Eucomed, met with the Notified Body Recommendation Group (NBRG) to discuss these issues. As it turned out, the notified bodies also were having concerns, weren't totally comfortable with where things stood with EN ISO 14971:2012, and weren't satisfied with the existing guidance documents from industry trade groups and the Team-NB position paper.

So, after discussions with these three other organizations, the NBRG decided it made sense to try and come up with a consensus document to assist in implementing and utilizing EN ISO 14971:2012. It agreed to set up a special risk-management working group (RM WG) specific to this issue. The RM WG consists of four notified bodies, six medical device companies, and members of COCIR, Eucomed, and EDMA.

The RM WG plans to have a final draft consensus guidance document for the implementation of EN ISO 14971:2012 by early April. The group will present the document to the NBRG, which will then determine whether or not it will publish this draft consensus document.

Critical to the success of this collaborative effort, however, is an industry survey that the NBRG RM WG has created, which asks for input from medical device companies on how they currently conduct their risk-management process and specifically how they align with EN ISO 14971:2012 processes. The survey (accessible here) is open to all medtech companies and should only take about 10 to 15 minutes to complete if you are familiar with your company's risk-management process. The survey is open until March 21, 2014; responses are completely anonymous.

The more industry feedback we receive on this survey, the better off industry will ultimately be. I'm hopeful that a better and clearer process will result from the use of this survey to help shape the NBRG RM WG consensus document. After all, survey results could conceivably reveal trends that may not have been obvious to the EU Commission, notified bodies, or the competent authorities that could help sway their attitudes and move this process and the proposed guidance document in a direction that industry will be happier with.

The impact of EN ISO 14971:2012 on the medical device industry is significant. So let's hope that this EN ISO 14971:2012 risk-management consensus document by NBRG is released as a reasonable set of clear recommendations and is done in a timely manner. It would be a

significant help to industry, after all, to have a consistent set of requirements that are reasonable, too.

Leonard (Leo) Eisner is the head of Eisner Safety Consultants. Eisner gave a presentation on the effort to develop a consensus document to assist in implementing and utilizing EN ISO 14971:2012 at MD&M West in February 2014. The slide deck from that presentation is available on his Web site.