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BSI Medical Device Newsletter June 2015

Welcome to the June Medical Device Newsletter 2015.

Report on the update of the Revision of the Medical Device Directives

Gert Bos, BSI Head of Regulatory & Clinical Affairs.

Voices in Brussels corridors are not agreeing, but the overall tendency is towards positive compromises being reached in the Council.

The last few elements of debate, including, the scrutiny on Notified Bodies for clinical evaluation of high risk medical devices and implants continue. Detailed discussions on dedicated IVD topics have been held and are expected to continue over the next few weeks.

A growing number of Competent Authorities as well as EU Commission representatives have indicated that a positive outcome of the EPSCO (Employment, Social Policy, Health and Consumer Affairs Council configuration) Council meeting on 19th June, 2015 will be favourable to complete the council work. If positive, the first reading will continue, a significant amount of time for negotiations is foreseen, and the presumption is for six key meetings to held between September 2015 and early 2016.

Should all the above progress, as currently planned, the first reading will close, and an early adoption in the second reading would complete the process by June 2016. Live streaming of the EPSCO Council meeting will reveal what is in place for the future on key elements; full disclosure of the council amendments is expected to reach the public domain around six weeks later.

Revision of ISO 13485, Quality Management System.

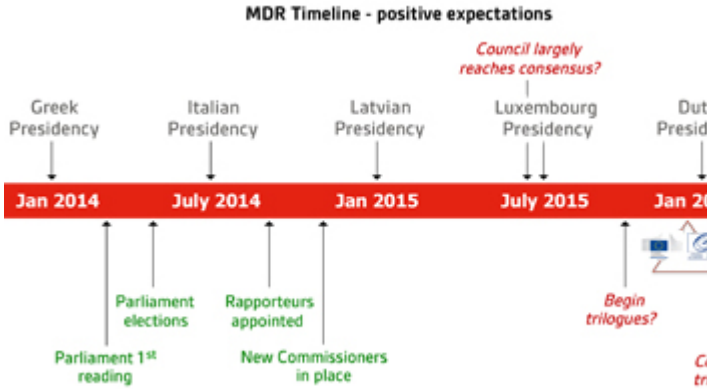
Next steps for ISO 13485.

The next planned meeting of ISOTC 210 WG1 (ISO Technical Committee working on the revision of the standard), is scheduled for June 2015 in Denver. From this meeting it is expected that a Final DIS (FDIS) will be compiled and issued with a two month voting period.

The expected time line will give a final publication toward the very end of 2015. Keep up to date with the development of the standard via our revision website.

If you missed the webinar in May, Paul Sim talked through the current status of the revision and how the standard will proceed, you can listen back to the webinar.

An exciting summer lays ahead of us….. More detail to



follow as insight progresses.

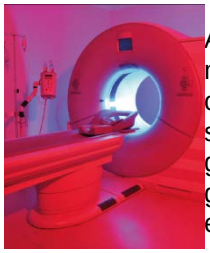
New BSI Webinars available.

To help you to keep up to date with a rapidly changing regulatory environment we are publishing a webinar schedule for the whole of 2015. The full list of webinars can be seen on our website, and the following webinars are now open for registration:

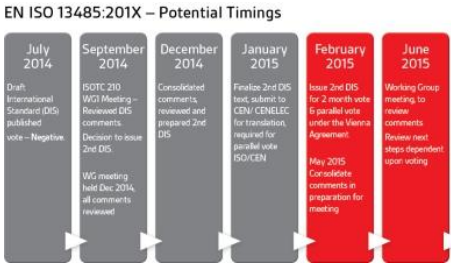
- Requirements for a 'Person Responsible for Regulatory Compliance'
- 23 June 2015 - 16:00 GMT
- Clinical evaluation, clinical investigations, do you have enough evidence?
- 7 July 2015 - 16:00 GMT
- ISO 13485 AND ISO 9001, with both changing are you prepared?
- 28 July 2015 - 16:00 GMT
- Will your product be reclassified under the new MDR? Lessons you need to hear
- 9 September 2015 - 16:00 GMT

If you missed any of the past webinars on the Revision of the MDD and AIMD, and the overview on ISO 14971 Risk Management, you can listen back via the website.

What is an Active Medical Device?



An active medical device means any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy.



BSI Whitepapers.

Did you miss any of our published whitepapers?

The proposed EU regulations for medical and in vitro diagnostic devices.

Generating clinical evaluation reports: A guide to effectively analysing medical device safety and performance.

Effective post-market surveillance.

What you need to know about the FDA's UDI system final rule.

Engaging Stakeholders in the Home Medical Device Market.

Negotiating the Innovation and Regulatory Conundrum.

The growing role of human factors and usability engineering for medical devices.

The EN 60601 family of standards is of major importance for all electrical medical equipment for demonstrating compliance with the Essential Requirements of the Medical Device Directives.

The classification of medical devices in the European Union is outlined in Annex IX of the Council Directive 93/42/EEC. There are four classes, ranging from low risk to high risk.

- Class I (including Is & Im)
- Class IIa
- Class IIb
- Class III

A manufacturer confirms compliance with the MDD by means of a Declaration of Conformity. This declaration is issued by the manufacturer, but for products in Class Is, Im, IIa, IIb or III, they also require and assessment by a Notified Body such as BSI. This means whatever type of device a manufacturer wishes to market in Europe, where CE marking is a legal requirement, BSI have the technical expertise to assist and provide appropriate conformity assessment services. Look at our active medical devices services for further details .

Meet BSI in Person.

For a the full list of speaking events please see the events website.

BSI Global Medical Devices LinkedIn Group.

This group is for professionals who design, develop, manufacture or distribute medical devices or related services, or are involved in developing medical device standards or regulations.

Don't forget to sign up if you haven't already.

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