MEDICAL DEVICES IEC 60601 3RD EDITION THE SWITCH

THE TRANSITION FROM THE 2ND EDITION TO THE 3RD EDITION SERIES OF IEC 60601

At present choosing the edition that is the best fit for your device and markets of interest is a difficult decision. Some markets will switch exclusively to the 3rd edition series soon, while others have no foreseeable plans to make the switch.

The following table summarizes the switch to the general requirements standard IEC 60601-1, 3rd Edition:

COUNTRY OR REGION	AT PRESENT	MAY USE 3RD EDITION	MANDATORY USE OF 3RD EDITION	REMARKS
EU	2nd or 3rd edition	Yes, with the proper edition of the Part 1 & 2 standards	1 June 2012	
FDA (USA)	2nd or 3rd edition	Yes, along with other FDA Consensus Standards	30 June 2013	
USA NRTL	2nd or 3rd edition	Yes, with the proper edition of the required Part 1 & 2 standards	No date has been set	
HEALTH CANADA	2nd or 3rd edition	Yes, with additional Part 1 & 2 Recognized Standards	1 June 2012	
STANDARDS COUNCIL OF CANADA	2nd or 3rd edition	Yes, with the proper edition of the required Part 1 & 2 standards	No date has been set	
SFDA (CHINA)	2nd edition	No	No date has been set	
MHLW (JAPAN)	2nd edition	No	No date has been set	
CB SCHEME (IECEE)	2nd or 3rd edition	Some countries allow the option of using the 3rd edition	No date has been set	Most collateral 60601-1-x standards are now required
OTHER COUNTRIES	2nd or 3rd edition	Some countries allow the option of using the 3rd edition	No date has been set	

THE TIME TO SWITCH IS NOW

For markets such as the EU and when submitting to Health Canada and the FDA the mandatory date of June 1, 2012 leaves very little time to get a new device to market under the old edition. In fact, for some types of devices the mandatory date has passed. For example, ultrasonic imaging equipment had a mandatory date of October 1, 2010.

In addition, for the EU, older products currently on the market will need evidence that the Essential Requirements according to the Medical Device Directive are being met according to the EN 60601 3rd Edition series. SGS can perform a delta assessment from your existing 2nd edition data to address the changes that are more stringent in the 3rd edition.

CONTACT US

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DEVICES IN THE DESIGN PHASE

For these devices the recommended edition is 3rd, with a delta assessment to the 2nd edition for countries that will not currently accept 3rd. The time to learn about the requirements for the new edition is during the design phase, with design reviews being a strong recommendation.

Of primary importance during design reviews, and the full evaluation of the device, is the manufacturer's Risk Management File. A process audit to ISO 14971 for Risk Management is not adequate for the evaluation of specific devices; therefore, a device based review of the specific Risk management File is required by 60601.

There are many sub-clauses in the 60601 series where there must be a verdict in the Risk Management File that the specific concern in 60601 was addressed. If the Risk Management File is prepared without close consideration of 60601, it is guaranteed that many of the risks in 60601 will not be adequately addressed in the finished device.

THE CB SCHEME

The CB scheme recently created minimum requirements as to which collateral standards (60601-1-x) must be used. All collateral standards must be used except -1-2 for EMC, -1-6 for usability, and -1-9 for environmentally conscious design. The CB Scheme is based on the use of CB Test Certificates which provide evidence that representative specimens of the product have successfully passed tests in the SGS laboratories to show compliance with the requirements of the relevant IEC standard. A supplementary report providing evidence of compliance with declared national differences in order to obtain national certification or market acces may also be attached to the CB Test Report.

REGULATORY CERTIFICATION

In addition to testing services, SGS is a leading medical devices certification body with auditors and experts in over 35 countries who can support your market entry and approval in almost every part of the world. Regulatory certification available includes: EC Directives 93/42/EEC (MDD) and 98/79/EC (IVD) for CE marking; CMDCAS for Canada; JPAL for Japan; FDA site inspections for USA; INMETRO for Brazil and schemes for Taiwan, Australia and Hong Kong. Allowing SGS to offer you both testing and certification will minimize your time to market as testing and certification can be coordinated.

Get your medical devices to market faster when you know the way.

WHY SGS?

SGS is the world's leading inspection, verification, testing and certification company. Recognized as the global benchmark for quality and integrity, we employ 64,000 people and operate a network of more than 1,250 offices and laboratories around the world.

WHEN YOU NEED TO BE SURE

SGS