Gap Analysis Techniques for Easy Medical Device 60601 3rd Edition Electrical Safety Testing

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For those unfamiliar, all medical devices (i.e., equipment that is intended to diagnose, treat, or monitor a patient; make physical or electrical contact with a patient; transfer energy to or from a patient; and/or detect energy transfer to or from a patient) must be electrical safety tested. I found a common misconception in that many manufacturers/designers do not realize that Class I devices, commonly thought of as a low risk and typically do not require regulatory clearance before being marketed (neglecting special cases such as sterile equipment or those with a measuring function), must also comply.

Most users would agree that mandatory electrical safety testing is a good thing before devices are allowed on the market. *IEC 60601 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance* is the name of the Technical Standard that is widely recognized (at least Australia, Brazil, Canada, EU, Japan, USA and New Zealand all have more or less equivalent national versions) as the de-facto standard to demonstrate safety of electrical medical devices. The majority of healthcare regulatory bodies now require a manufacturer to demonstrate compliance to the 3rd edition of this standard, which introduces the concept of risk management and is not purely prescriptive testing.

In Part 1 of this blog, I'll describe the background and approaches we at StarFish Medical [1] took for more modern devices with a comprehensive technical file, with five top tips. In Part 2 [2], I'll describe how we recertified for older devices where the design documentation was less comprehensive, with seven top tips.

Background

Previously, the electrical safety standards (starting with 60601-1, 1st edition, published in 1970) were very prescriptive, explicitly stating to the engineers what was and what was not permissible, such as the minimum clearance between electrical conductors, maximum allowed temperatures, etc., and was based on observable or testable aspects of a device presented for compliance testing. Since then, the scope of the standard has become broader over time, and 60601-1, 2nd edition (published in 1988) covered mechanical, fire, radiation, and other hazards, and introduced the concept of three approaches (insulation, protective earthing, and protective impedance) to design in at least two methods of patient and operator protection from the outset.

Now, IEC 60601-1 Edition 3 (published in 2005) takes this to a new level, the rights and wrongs of which are discussed elsewhere [3], as many of the risk management requirements specified in ISO 14971 are now reviewed as part of the compliance test. Whether the intent of the IEC 60601-1 working committee was for compliance to be required for all devices currently marketed or only new devices is unknown. Many healthcare regulatory authorities provided quite a generous transition period from 2nd edition to 3rd edition, but the majority now require 3rd edition compliance for at least all new submissions (i.e., Health Canada deadline for last allowed 2nd edition testing for new medical device submissions was May 31, 2012; the FDA require 3rd edition testing for all new devices and substantial changes to previously marketed devices from July 1, 2013; but in Europe, the deadline for 3rd edition testing, including existing devices already marketed, was June 1, 2012—otherwise the CE mark would be invalid. The deadline for Brazil is January 1, 2014, and Japan has not yet set a deadline. However, whether testing labs such as UL will continue to allow their logo to be affixed to devices without 3rd edition testing, or whether hospital bio-medical electronics equipment service departments will mandate 3rd edition compliance, remains to be seen.

Gap Analysis

Over the course of the past year, StarFish Medical has worked on several 3rd edition projects, and I wanted to relay the experience and processes we developed. Generally, if the product is “new” (i.e., less than five years old), and especially if already CE marked under the MDD (which requires ISO 14971 risk management), then things were in generally good shape. As stated, 60601 Edition 3 requires risk management to be considered in addition to the electrical safety testing. We found relatively new designs already have a comprehensive risk management file in line with ISO 14971, and it was just a matter of some tweaking.

From this, following are five simple tips for modern device submissions:

1. Read the Standards! It is surprising how many people developing a medical device have never looked at the appropriate standards. Although dry, 60601-1 3rd edition, collateral standards, and usability/software standards can be at least skimmed through quite quickly, which allows a more meaningful conversation with your chosen testing house

2. Depending on your company's internal strategy, a gap analysis approach may be a quicker, lower cost route to demonstrate 3rd edition compliance, provided no major changes have occurred to the design between tests. Essentially, all the expensive inspection as well as physical and environmental testing will most likely already be covered by the 2nd edition test report. Query with your test house if they prefer a gap analysis approach, or whether their internal process requires whole testing to be completed. Some test houses may not like performing a gap analysis if the 2nd edition testing was undertaken by a rival test house; if not, there can be little compliant.
3. Review your existing 60601-1 2nd edition test house report in conjunction with IEC TR 62348, which provides a cross-reference and permits a gap analysis to be undertaken. A quiet room, spreadsheet, and coffee are highly recommended.
4. Most test houses provide a checklist whereby you point out clauses in your documentation that highlight specific queries—the more comprehensive this checklist is, the more effort you may need to complete it, but the more streamlined the submission will be.
5. Interview your test house. In the old days, many test houses were government run, and some have not yet realized they have transitioned to a commercial, fee-for-service environment. The more direction they give, the more you know what they want to see. A communicative test house is infinitely preferable to a monosyllabic test house. Having said that, consider paying for test house consultancy time (i.e., a dry run) before submission, as a few hundred dollars spent on consultancy and a quick, clean test report is better than endless requests for further information or even worse, a failure report. If you are still not getting the feedback you need to prepare an effective submission, consider another test house. For example, in a previous role, initial discussions with a local test house raised concerns on Essential Performance, so we eventually opted for a foreign headquartered test house with in-house medical doctors who understood our clinical data much better.

In part 2 of this blog [2], I discuss tips on how we addressed 3rd edition testing for older devices, where the available documentation was usually not as comprehensive as a more modern submission. In the meantime, I would be delighted to hear about your tips and experiences in the comments sections.

Links:
[1] http://www.starfishmedical.com/
[2] http://www.mdtmag.com/blogs/2013/08/tips-legacy-medical-device-submissions-60601-3rd-edition-electrical-safety-testing-part-2
[3] http://www.mdtmag.com/blogs/2013/04/60601-ed-3-what-happened