60601 3rd Edition Transition Solution

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While many companies are concerned with the impact the 3rd edition of IEC 60601-1 will have on their medical device products, what they first need to determine is which products will actually be impacted. Preparing products for the new standard does not need to rely heavily on valuable resources. This article looks at the considerations prior to transitioning a product for the new standard.

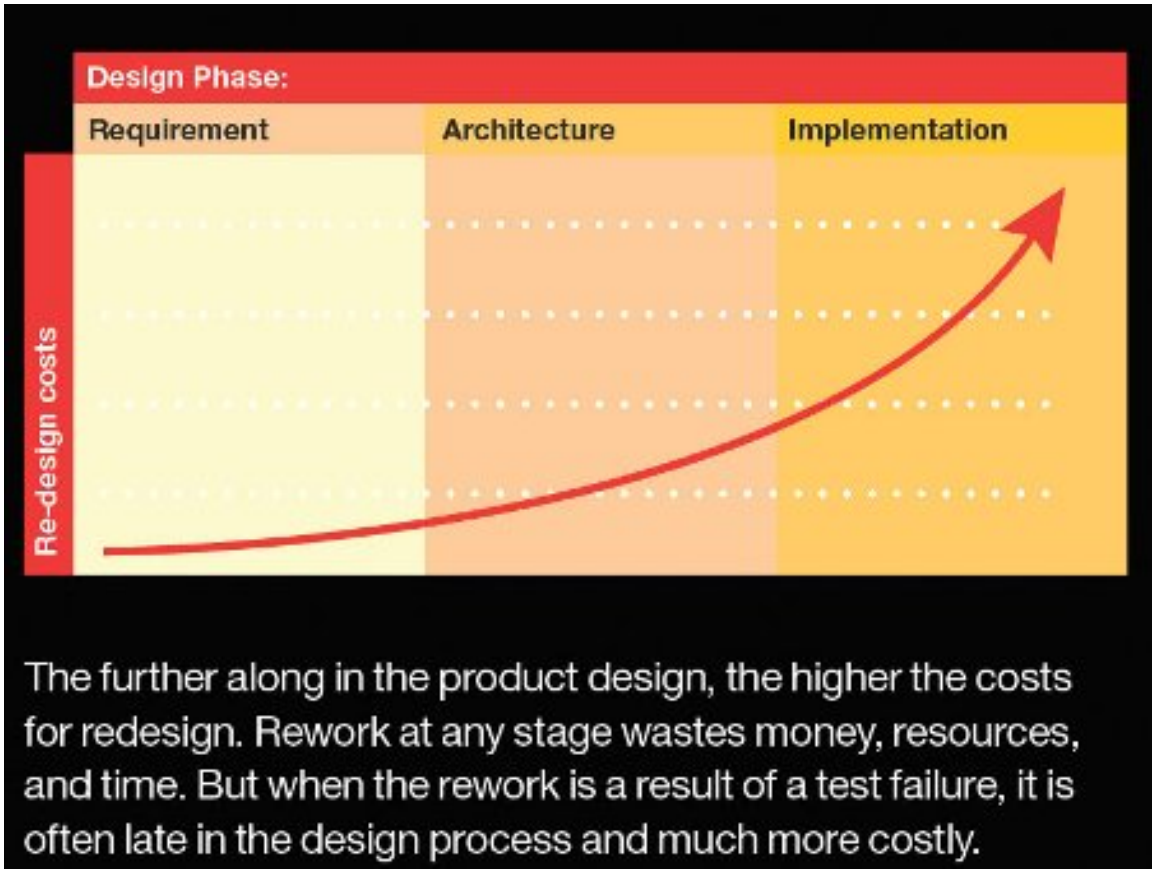

Figure 1: Cost of redesign over the design cycle of a medical device

The 3rd edition of IEC 60601-1 represents a major change in the way in which the safety of electro-medical devices is assessed. As such, it has taken several years since its 2005 publication for the world's major regulatory agencies to officially recognize the standard. Now, the EU, Canada, and FDA have publically recognized the standard and published transition dates, with the EU and Canada setting June 2012 and FDA establishing a June 2013 transition date. Other countries, such as Japan and Brazil, have made it as far as translating the standard, but regulatory

authorities in those countries continue to recognize the 2nd edition of IEC 60601 without setting transition dates for the 3rd edition. Medical device manufacturers in particular are heavily reliant on sales in global markets to recoup the regulatory and R&D expenses it takes to bring a medical device to market; as the need to design and certify products to two very different set of requirements can increase costs and timelines dramatically, the global adoption status of the IEC 60601 3rd edition has the potential to make a major business impact on some medical device companies.

Many design and certification engineers working for medical device companies that sell devices to global markets have become used to the convenience of being able to work with one certification agency, and test their devices to one internationally harmonized standard to support global regulatory submissions. Even though there are now multiple editions of the standard, the good news is that there are certification agencies that have the ability to assess a device for conformity to both the 2nd and 3rd editions of IEC 60601, so companies can continue to work with one certification body regardless of their global product strategy.

For existing devices that were designed considering the requirements in the 2nd edition only, companies may have to redesign these devices in order to comply with the 3rd edition. With the 3rd edition, the product itself is not the only concern, as the product manufacturer's risk management is an integral part of the standard and must also be considered. Therefore, part of the business decision regarding when and if to upgrade an existing device is also dependent on the company's existing systems and/or ability to apply risk management retroactively, if needed.

IEC 60601 3rd Edition Resources

Click here [1]for UL's dedicated webpage for 60601 Transition.

Click here [2]for the UL/IEC 60601 general webpage.

Check out a Q&A with UL on IEC 60601 3rd Edition. "Q&A with UL" contains valuable information for companies looking to demonstrate conformity to the 3rd edition of IEC 60601. Leveraging UL's global reach and expertise in the 3rd edition, the document contains over 70 questions from medical companies around the world and responses by UL experts, by topic. Click here [3] for a free copy (look under "Additional resources")

Click here [4]for a complete list of UL University webinars and public workshops, including two- and three-day "Designing for compliance to IEC 60601-1 3rd edition" workshops.

Click here [5]for on-demand learning. "IEC 60601-1

3rd edition: Overview and adoption update." One hour overview that you can view at home or in the office, on-demand.

Click here [6]for a white paper entitled, "The 3rd edition Update—Major Regulatory Decisions on the Third Edition of IEC 60601-1," which provides an overview of the adoption status by country.

Article: [6]"A review of market entry requirements for risk management, with special emphasis on FDA and ISO 14971 compliance"

Article: [6]"Choices – IEC 60601-1 3rd Edition and Component Selection"

The following is a list of several key factors to consider as companies make the choice whether or not to upgrade an existing product to the 3rd edition.

- Steps to Determining Which Products to Upgrade
- Determine what markets are being sold into now, what edition of the standard is recognized in each market, and the relevant transition dates.
- Review what products/models are sold in which countries and to what standards they have already been assessed.
- Determine each product's position in its lifecycle and estimate its future sales life.
- Identify which products will be discontinued.
- Identify products developed without a risk management process.
- Consider feasibility in retroactively establishing risk management.
- Remember to look at existing software.
- Decide which products need to continue to be sold in which markets.
- Identify differences in standards and which products need to be upgraded.
- Determine the impact of redesign—resources required, regulatory approvals that need to be repeated, repeat testing, etc.
- Consider impact of brand perception, market loss, etc. if products are no longer available in each market.

Create a plan/timeline for redesign, certification upgrade, or discontinuation of products in each market.

Once existing products and markets have been reviewed, it is time to assess certification options for new product development. With new devices, getting the certification agency involved early in the new product development process can help identify applicable standard requirements, identify design challenges, and mitigate test failures that can help the evaluation stay on schedule. And with the risk management considerations specific to IEC 60601 3rd edition, it may be

prudent for businesses to have the certification body look at the risk management system even before new products are designed or existing products are redesigned to address any gaps that will affect certification. By identifying the target markets early in the product development process, companies also have the advantage of "designing-in" national differences and requirements specific to those countries, including 2nd edition specific requirements, ultimately saving time and resources. Figure 1 illustrates the value of getting the certification agency involved early in the design process, which is especially relevant with the complexity of the 3rd edition.

The cost of certification failure:

- Resources—Approximately 80% of medical devices consist of components made by other companies, often selected without considering safety certifications, resulting in costly rework and delays.
- Rework—Failures often result in fast fixes that meet certification requirements, but may be expensive and difficult to manufacture.
- Time—Companies that have failing products take longer to complete the assessment, which results in less time on the market.
- Opportunities—Schedule creep results in missed opportunities, wasted design time, and reduced ROI.

UL [3] is a leading provider of services to help medical companies gain access to global markets. Services include integrated systems registrations for ISO 13485, Canada CMDCAS-Recognized Registrar, Europe Notified Body, Japan - PAL, Brazil - INMETRO, ISO 14971, IEC 60601 and 61010, CB Scheme, China SFDA Application, and Training. UL also provides sterility, packaging validation, CRO, and biocompatibility for implantable, inactive, and ophthalmic devices.

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