

Choices – IEC 60601-1 3rd Edition and Component Selection

Abstract — When the 3rd edition of IEC 60601-1 was published, it marked the beginning of a new era. The standard now incorporates the concept and application of risk management in the design and production of devices. Implementation of risk management has implications for not only the end-product manufacturer, but component providers as well, and further cascades through the entire supply chain. All parties now face a series of choices and opportunities in determining how best to ensure, for the entire lifetime of a device, that basic safety and essential performance are preserved. This article explores some of those choices and their consequences.

Background

The publication of the 3rd Edition of IEC 60601 sparked debate and discussion about the need to perform a risk management assessment of component power supplies that will be used in medical electrical equipment.

In reality, this is not a new concern. Many regulators have long required manufacturers to incorporate risk management in the design and production of medical devices. For example, the U.S. Food and Drug Administration's (FDA) quality system regulation (QSR) requires manufacturers to, (as noted in 21 CFR 820.30 (c) - Design Inputs):

"... ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient ..."

And in 21 CFR 820.30 (g) - Design Validation:

"... shall include software validation and risk analysis (emphasis added) ..."

In practice, some manufacturers have relied on third-party certification to ensure adequacy of design of supplied components. With certain qualifiers, the FDA has acknowledged this approach. According to the preamble to the 1996 quality systems regulation (comment No. 103):

"... [FDA] cautions manufacturers against relying solely on certification by third parties as evidence that suppliers have the capability to provide quality products or services ... third party certification should not be relied on exclusively in initially evaluating a supplier; if a device manufacturer has established confidence in the supplier's ability to provide acceptable products or services,



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