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Abstract — When the 3rd edition of IEC

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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.

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Introduction The 3rd Edition of IEC 60601-1 represents a shift in philosophy from the 2nd Edition, including a greater emphasis on risk management and essential performance. As with any other standard change, a

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failure to implement these new requirements in a timely manner could cause costly delays in getting your device to market.

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Some key changes are:
the outline and the

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numbering scheme of

the clauses and

subclauses were

changed, risk

management was made

much more relevant and

the concept of essential

performance was added.

Currently (2012), the

applicability of the

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in various states of adoption by regulatory bodies around the world. IEC 60601-1 is the harmonized standard for medical electrical equipment recognized by public health authorities in most countries.

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As mentioned in our Device Tip, the 3rd Edition of IEC 60601-1 is now in effect. Issued in 2005, European and Canadian companies were given until June 1, 2012 to comply with the new standard (US companies have until 6/30/13 to comply).

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