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In 2005, the third edition of IEC 60601-1 was published. It was the result of a comprehensive review of the second edition (dating from 1988). Some key

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changes are: the outline and the numbering scheme of the clauses and subclauses were changed, risk management was made much more relevant and the concept of essential performance was added.

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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

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to comply with the new standard (US companies have until 6/30/13 to comply). The latest edition of the standard mandates (3) fundamental “new” requirements:

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