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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.

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

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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 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. Currently (2012), the applicability of the second and ...

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DOES NOT INCORPORATE 2012 AMENDMENT,

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, Clause 14

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IEC 60601-2-39:2018 is also available as IEC 60601-2-39:2018 RLV which contains the International Standard and its Redline version, showing all changes of the technical content compared to the previous edition. IEC

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60601-2-39:2018 applies to the basic safety and essential performance of peritoneal dialysis medical electrical equipment.

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The 3rd edition of IEC 60601, issued in 2005, is 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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IEC TR 62348:2012 provides a tool to assist users of IEC 60601-1:2005 to assess the impact of the most significant changes in Amendment 1:2012, and to trace requirements between the third edition and the amended second edition.

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As mentioned in our Device Tip, the 3rd Edition of IEC

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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). The latest edition of the standard mandates (3) fundamental “new” requirements:

~~IEC 60601-1 3rd Edition, Part 1 Differences | Bob Duffy ...~~

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