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*IEC 60601-2-16 Ed. 4.0 b:2012 Document History. AAMI/IEC 60601-2-16:2012 currently viewing. August 2012 Medical electrical equipment, Part 2-16: Particular requirements for basic safety and essential performance of hemodialysis, hemodiafiltration and hemofiltration equipment*

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*ansi/aami/iso tir19218-2:2012 (ansi/aami/iso tir 19218-2:2012) Medical devices - Hierarchical coding structure for adverse events - Part 2: Evaluation codes Partial revision of ANSI/AAMI/ISO TIR19218:2005. Specifies requirements for a hierarchical coding structure for characterizing the results of the analysis or evaluation of adverse events relating to medical devices.*

*ANSI/AAMI/ISO TIR19218-2:2012 (ANSI/AAMI/ISO TIR 19218-2 ...*

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*As a result, AAMI issued their own 2014 Standards with alternative methods for microbiological testing, causing it to be the only deviation from the ISO Hemodialysis Standards. The specific ISO culture methods are still part of the AAMI Standard thereby allowing for a more precise cultivation technique that procedural*

*AAMI Water Quality Standard for Hemodialysis*

*Contact: Gavin Stern, [gstern@aami.org](mailto:gstern@aami.org), 1-703-647-2781 The International Organization for Standardization (ISO) has released a redesignated and revised series of five standards that provide healthcare professionals and manufacturers with guidance for ensuring the quality and safety of dialysis fluids for hemodialysis and related therapies.*

*AAMI Adopts Updated Series of Dialysis Standards | AAMI*

*(AAMI) attempts to harmonize with interna-tional standards, adopting them as U.S. standards. In 2014, AAMI published the ANSI/AAMI versions of the 2011-14 ISO versions of the hemodialysis and related therapies standards (i.e., 23500, 11663, 13958, 13959, 26722) with the addition of a U.S. deviation. The U.S. deviation added back the Tryptic*

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*with the fluid quality standards, with the current AAMI standards emphasizing compliance through the development and implementation of a facility-specific quality management program in contrast to the prescriptive approach included in ANSI/AAMI RD52:2004 and adopted in the CFC.*

*Dialysis Water and Dialysate ... - The AAMI Store*

*ANSI/AAMI/ISO 13958:2009 Concentrates for hemodialysis and related therapies (revision of RD61) As a result of some of the challenges these standards caused to the US hemodialysis community, the AAMI RDD Committee approved and released a US deviation to the International ANSI/AAMI/ISO documents as stated above and has since published the following:*

*AAMI - Dialysis Water Solutions*

*AAMI TIR45:2012 (R2018) Guidance on the use of AGILE practices in the development of medical device software. Over the past several years, AGILE software development has become an accepted method for developing software products.*

*AAMI TIR45:2012 (R2018) - American National Standards ...*

*@article{Ward2011NewAS, title={New AAMI standards for dialysis fluids.}, author={Richard A. Ward}, journal={Nephrology news & issues}, year={2011}, volume={25 13 ...*

*New AAMI standards for dialysis fluids. | Semantic Scholar*

*ANSI/AAMI/ IEC 60601-2-16:2012 Medical electrical ... for basic safety and essential performance of hemodialysis, hemodiafiltration and hemofiltration equipment Red-line Format American National Standard EIE C his is a preview edition of an AAMI guidance document and is ... Objectives and uses of AAMI standards and recommended practices*

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