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ansi/aami/iso tir19218-2:2012 (an-

si/aami/iso tir  
19218-2:2012) Medical de-  
vices - Hierarchical coding  
structure for adverse  
events - Part 2: Evaluation  
codes Partial revision of  
ANSI/AAMI/ISO  
TIR19218:2005.Specifies  
requirements for a hi-  
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ture for characterizing the  
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with alternative methods  
for microbiological test-  
ing, causing it to be the  
only deviation from the  
ISO Hemodialysis Stan-  
dards.

with the fluid quality stan-  
dards, with the current AA-  
MI standards emphasizing  
compliance through the  
development and imple-  
mentation of a facility-spe-  
cific quality management  
program in contrast to the  
prescriptive approach in-  
cluded in ANSI/AAMI  
RD52:2004 and adopted  
in the CfC.

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60601-2-16:2012 Medical  
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mance of hemodialysis,  
hemodiafiltration and he-  
mofiltration equipment  
Red-line Format American  
National Standard EIE C  
his is a preview edition of  
an AAMI guidance docu-  
ment and is ... Objectives  
and uses of AAMI stan-  
dards and recommended  
practices

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

As a result, AAMI issued  
their own 2014 Standards  
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for microbiological test-  
ing, causing it to be the  
only deviation from the  
ISO Hemodialysis Stan-  
dards. The specific ISO cul-  
ture methods are still part  
of the AAMI Standard  
thereby allowing for a  
more precise cultivation  
technique that procedural

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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.

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@article{Ward2011News, title={New AAMI standards for dialysis fluids.}, author={Richard A. Ward}, journal={Nephrology news & issues}, year={2011}, volume={25 13 ...

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