

# Technical Information Report

## AAMI TIR45: 2012/(R)2018

Guidance on the use of  
AGILE practices in the  
development of medical  
device software



# Guidance on the use of AGILE practices in the development of medical device software

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**AAMI**

**Abstract:** Over the past several years, **AGILE** software development has become an accepted method for developing software products. There have been questions from both manufacturers and regulators as to whether (or which) **AGILE** practices are appropriate for developing medical device software. Enough medical device manufacturers have implemented **AGILE** practices in their software development so that answers to these questions can be documented. Having clear guidance of which practices have been found to be appropriate will be very useful for all developers of medical device software. This TIR will provide recommendations for complying with international standards and U.S. Food and Drug Administration (FDA) guidance documents when using **AGILE** practices to develop medical device software.

**Keywords:** AGILE, software

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## Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation. The code in the US column, “(R)20xx” indicates the year the document was officially reaffirmed by AAMI. E.g., ANSI/AAMI/ISO 10993-4:2002/(R)2009 indicates that 10993-4, originally approved and published in 2002, was reaffirmed without change in 2009.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

| International designation                                                         | U.S. designation                                                                                                                                                    | Equivalency                                                                                                 |
|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| IEC 60601-1:2005<br>IEC 60601-1:2005/A1:2012<br>IEC Technical Corrigendum 1 and 2 | ANSI/AAMI ES60601-1:2005/(R)2012<br>ANSI/AAMI ES60601-1:2005/A1:2012<br>ANSI/AAMI ES60601-1:2005/C1:2009/(R)2012 (amdt)<br>ANSI/AAMI ES60601-1:2005/A2:2010/(R)2012 | Major technical variations<br>A1 identical<br>C1 identical to Corrigendum 1 & 2<br>A2 applies to AAMI, only |
| IEC 60601-1-11:2010                                                               | ANSI/AAMI HA60601-1-11:2011                                                                                                                                         | Major technical variations                                                                                  |
| IEC 60601-1-2:2007                                                                | ANSI/AAMI/IEC 60601-1-2:2007/(R)2012                                                                                                                                | Identical                                                                                                   |
| IEC 60601-2-2:2009                                                                | ANSI/AAMI/IEC 60601-2-2:2009                                                                                                                                        | Identical                                                                                                   |
| IEC 60601-2-4:2010                                                                | ANSI/AAMI/IEC 60601-2-4:2010                                                                                                                                        | Identical                                                                                                   |
| IEC 60601-2-16:2012                                                               | ANSI/AAMI/IEC 60601-2-16:2012                                                                                                                                       | Identical                                                                                                   |
| IEC 60601-2-19:2009                                                               | ANSI/AAMI/IEC 60601-2-19:2009                                                                                                                                       | Identical                                                                                                   |
| IEC 60601-2-20:2009                                                               | ANSI/AAMI/IEC 60601-2-20:2009                                                                                                                                       | Identical                                                                                                   |
| IEC 60601-2-21:2009                                                               | ANSI/AAMI/IEC 60601-2-21:2009                                                                                                                                       | Identical                                                                                                   |
| IEC 60601-2-24:1998                                                               | ANSI/AAMI ID26:2004/(R)2009                                                                                                                                         | Major technical variations                                                                                  |
| IEC 60601-2-25:2011                                                               | ANSI/AAMI/IEC 60601-2-25:2011                                                                                                                                       | Identical                                                                                                   |
| IEC 60601-2-27:2011                                                               | ANSI/AAMI/IEC 60601-2-27:2011                                                                                                                                       | Identical                                                                                                   |
| IEC 60601-2-47:2012                                                               | ANSI/AAMI/IEC 60601-2-47:2012                                                                                                                                       | Identical                                                                                                   |
| IEC 60601-2-50:2009                                                               | ANSI/AAMI/IEC 60601-2-50:2009                                                                                                                                       | Identical                                                                                                   |
| IEC/TR 60878:2009                                                                 | ANSI/AAMI/IEC TIR60878:2003                                                                                                                                         | Identical                                                                                                   |
| IEC/TR 61289:2011                                                                 | ANSI/AAMI/IEC TIR61289:2011                                                                                                                                         | Identical                                                                                                   |
| IEC/TR 62296:2009                                                                 | ANSI/AAMI/IEC TIR62296:2009                                                                                                                                         | Identical                                                                                                   |
| IEC 62304:2006                                                                    | ANSI/AAMI/IEC 62304:2006                                                                                                                                            | Identical                                                                                                   |
| IEC/TR 62348:2006                                                                 | ANSI/AAMI/IEC TIR62348:2006                                                                                                                                         | Identical                                                                                                   |
| IEC/TR 62354:2009                                                                 | ANSI/AAMI/IEC TIR62354:2009                                                                                                                                         | Identical                                                                                                   |
| IEC 62366:2007                                                                    | ANSI/AAMI/IEC 62366:2007                                                                                                                                            | Identical                                                                                                   |
| IEC 80001-1:2010                                                                  | ANSI/AAMI/IEC 80001-1:2010                                                                                                                                          | Identical                                                                                                   |
| IEC/TR 80001-2-1:2012                                                             | ANSI/AAMI/IEC 80001-2-1:2012                                                                                                                                        | Identical                                                                                                   |
| IEC/TR 80001-2-3:2012                                                             | ANSI/AAMI/IEC 80001-2-3:2012                                                                                                                                        | Identical                                                                                                   |
| IEC/TR 80002-1:2009                                                               | ANSI/IEC/TR 80002-1:2009                                                                                                                                            | Identical                                                                                                   |
| IEC 80601-2-30:2009 and Technical Corrigendum 1                                   | ANSI/AAMI/IEC 80601-2-30:2009 and ANSI/AAMI/IEC 80601-2-30:2009/C1:2009 (amdt) – consolidated text                                                                  | Identical (with inclusion)<br>C1 Identical to Corrigendum 1                                                 |
| IEC 80601-2-58:2008                                                               | ANSI/AAMI/IEC 80601-2-58:2008                                                                                                                                       | Identical                                                                                                   |
| ISO 5840:2005                                                                     | ANSI/AAMI/ISO 5840:2005/(R)2010                                                                                                                                     | Identical                                                                                                   |
| ISO 7198:1998                                                                     | ANSI/AAMI/ISO 7198:1998/2001/(R)2010                                                                                                                                | Identical                                                                                                   |
| ISO 7199:2009 and Amendment 1:2012                                                | ANSI/AAMI/ISO 7199:2009 and Amendment 1:2012                                                                                                                        | Identical                                                                                                   |
| ISO 8637:2010                                                                     | ANSI/AAMI/ISO 8637:2010                                                                                                                                             | Identical                                                                                                   |
| ISO 8638:2010                                                                     | ANSI/AAMI/ISO 8638:2010                                                                                                                                             | Identical                                                                                                   |
| ISO 10993-1:2009                                                                  | ANSI/AAMI/ISO 10993-1:2009                                                                                                                                          | Identical                                                                                                   |

| International designation             | U.S. designation                                                | Equivalency                |
|---------------------------------------|-----------------------------------------------------------------|----------------------------|
| ISO 10993-2:2006                      | ANSI/AAMI/ISO 10993-2:2006/(R)2010                              | Identical                  |
| ISO 10993-3:2003                      | ANSI/AAMI/ISO 10993-3:2003/(R)2009                              | Identical                  |
| ISO 10993-4:2002 and Amendment 1:2006 | ANSI/AAMI/ISO 10993-4:2002/(R)2009 and Amendment 1:2006/(R)2009 | Identical                  |
| ISO 10993-5:2009                      | ANSI/AAMI/ISO 10993-5:2009                                      | Identical                  |
| ISO 10993-6:2007                      | ANSI/AAMI/ISO 10993-6:2007/(R)2010                              | Identical                  |
| ISO 10993-7:2008                      | ANSI/AAMI/ISO 10993-7:2008/(R)2012                              | Identical                  |
| ISO 10993-9:2009                      | ANSI/AAMI/ISO 10993-9:2009                                      | Identical                  |
| ISO 10993-10:2010                     | ANSI/AAMI/ISO 10993-10:2010                                     | Identical                  |
| ISO 10993-11:2006                     | ANSI/AAMI/ISO 10993-11:2006/(R)2010                             | Identical                  |
| ISO 10993-12:2012                     | ANSI/AAMI/ISO 10993-12:2012                                     | Identical                  |
| ISO 10993-13:2010                     | ANSI/AAMI/ISO 10993-13:2010                                     | Identical                  |
| ISO 10993-14:2001                     | ANSI/AAMI/ISO 10993-14:2001/(R)2006                             | Identical                  |
| ISO 10993-15:2000                     | ANSI/AAMI/ISO 10993-15:2000/(R)2006                             | Identical                  |
| ISO 10993-16:2010                     | ANSI/AAMI/ISO 10993-16:2010                                     | Identical                  |
| ISO 10993-17:2002                     | ANSI/AAMI/ISO 10993-17:2002/(R)2008                             | Identical                  |
| ISO 10993-18:2005                     | ANSI/AAMI BE83:2006/(R)2011                                     | Major technical variations |
| ISO/TS 10993-19:2006                  | ANSI/AAMI/ISO TIR10993-19:2006                                  | Identical                  |
| ISO/TS 10993-20:2006                  | ANSI/AAMI/ISO TIR10993-20:2006                                  | Identical                  |
| ISO 11135-1:2007                      | ANSI/AAMI/ISO 11135-1:2007                                      | Identical                  |
| ISO/TS 11135-2:2008                   | ANSI/AAMI/ISO TIR11135-2:2008                                   | Identical                  |
| ISO 11137-1:2006                      | ANSI/AAMI/ISO 11137-1:2006/(R)2010                              | Identical                  |
| ISO 11137-2:2012                      | ANSI/AAMI/ISO 11137-2:2012                                      | Identical                  |
| ISO 11137-3:2006                      | ANSI/AAMI/ISO 11137-3:2006/(R)2010                              | Identical                  |
| ISO 11138-1:2006                      | ANSI/AAMI/ISO 11138-1:2006/(R)2010                              | Identical                  |
| ISO 11138-2:2006                      | ANSI/AAMI/ISO 11138-2:2006/(R)2010                              | Identical                  |
| ISO 11138-3:2006                      | ANSI/AAMI/ISO 11138-3:2006/(R)2010                              | Identical                  |
| ISO 11138-4:2006                      | ANSI/AAMI/ISO 11138-4:2006/(R)2010                              | Identical                  |
| ISO 11138-5:2006                      | ANSI/AAMI/ISO 11138-5:2006/(R)2010                              | Identical                  |
| ISO/TS 11139:2006                     | ANSI/AAMI/ISO 11139:2006                                        | Identical                  |
| ISO 11140-1:2005                      | ANSI/AAMI/ISO 11140-1:2005/(R)2010                              | Identical                  |
| ISO 11140-3:2007                      | ANSI/AAMI/ISO 11140-3:2007/(R)2012                              | Identical                  |
| ISO 11140-4:2007                      | ANSI/AAMI/ISO 11140-4:2007/(R)2012                              | Identical                  |
| ISO 11140-5:2007                      | ANSI/AAMI/ISO 11140-5:2007/(R)2012                              | Identical                  |
| ISO 11607-1:2006                      | ANSI/AAMI/ISO 11607-1:2006/(R)2010                              | Identical                  |
| ISO 11607-2:2006                      | ANSI/AAMI/ISO 11607-2:2006/(R)2010                              | Identical                  |
| ISO 11658:2012                        | ANSI/AAMI/ISO 11658:2012                                        | Identical                  |
| ISO 11663:2009                        | ANSI/AAMI/ISO 11633:2009                                        | Identical                  |
| ISO 11737-1:2006                      | ANSI/AAMI/ISO 11737-1:2006                                      | Identical                  |
| ISO 11737-2:2009                      | ANSI/AAMI/ISO 11737-2:2009                                      | Identical                  |
| ISO/TS 12417:2011                     | ANSI/AAMI/ISO TIR12417:2011                                     | Identical                  |
| ISO 13022:2012                        | ANSI/AAMI/ISO 13022:2012                                        | Identical                  |
| ISO 13408-1:2008                      | ANSI/AAMI/ISO 13408-1:2008/(R)2011                              | Identical                  |
| ISO 13408-2:2003                      | ANSI/AAMI/ISO 13408-2:2003                                      | Identical                  |
| ISO 13408-3:2006                      | ANSI/AAMI/ISO 13408-3:2006                                      | Identical                  |
| ISO 13408-4:2005                      | ANSI/AAMI/ISO 13408-4:2005                                      | Identical                  |
| ISO 13408-5:2006                      | ANSI/AAMI/ISO 13408-5:2006                                      | Identical                  |
| ISO 13408-6:2006                      | ANSI/AAMI/ISO 13408-6:2006                                      | Identical                  |
| ISO 13408-7:2012                      | ANSI/AAMI/ISO 13408-7:2012                                      | Identical                  |