

**Standards and Regulatory Highlights:**

The AAMI Medical Device Data Systems (MDDS) TIR is out for ballot and the AAMI TIR SW 1 *Guidance on the use of agile practices in the development of medical device software* should be issued shortly.

The European Commission has issued a final guidance on stand alone software entitled: "GUIDELINES ON THE QUALIFICATION AND CLASSIFICATION OF STAND ALONE SOFTWARE USED IN HEALTHCARE WITHIN THE REGULATORY FRAMEWORK OF MEDICAL DEVICES."

The AAMI course April 2-4 in Maryland will have 2 FDA instructors, John Murray and Richard Chapman. This is an excellent opportunity to get several FDA perspectives from both compliance and the office of Device Evaluation. Alan Kusnitz of SoftwareCPR® will be the lead instructor.

SoftwareCPR® News:

We have upgraded our website graphics to provide a more professional look. We hope this will also make it easier to navigate and access the extensive content ranging from an annotated version of the FDA software submission guidance to a full set of IEC 62304 training templates. If you have any problems or questions on the new site we would appreciate your feedback.

We provide a service to help you develop **Safety/Assurance Cases**. This includes use of your existing risk management documentation to more efficiently generate summaries in the form of assurance cases for premarket submissions.

Our commitment to compliant yet efficient use of **Agile Methods** continues along with our belief that this can actually lead to safer medical device software when properly done. Brian Pate is a lead expert in this area and is available for consulting and training. Part of our approach, for groups that already have some Agile exposure, is to hold workout sessions to address gaps in Agile fashion expediting process improvements.

We continue to expand our risk based code review and **static analysis services** and have recently **added the LDRA tool** as part of this service.

We have established a new premium subscription service called **Software STANDARDS NAVIGATOR led by Sherman Eagles**. This provides real time insight, guidance, monthly reports, and access to public draft standards as well as some consulting or training time each year. Click [TOPICS](#) and then click the Standards Navigator topic to get further information.

We can bring courses on **Efficient Use of Medical Device Software Standards, FDA Software Medical Device Software Validation and Submissions, Assurance/Safety Cases, Risk Management, Validation of Regulated Automation, 21 CFR Part 11**, and other topics tailored to your needs directly to your facility.

Please be sure to check out our "topic" pages. Try these out by clicking (<http://www.softwarecpr.com/topicsframepage.htm>). Paid subscribers should log in and then will have access to all educational documents while others will have only limited access. Remember that additional documents are available by browsing or searching the library.

Newsletter Instructions

The **NEW** items listed on the following pages are organized according to their location in the **REFERENCE** section of www.softwarecpr.com. Some sections of this newsletter provide a complete index, others just recently added items. If you have trouble finding an item of interest, send email to office@softwarecpr.com. **Note: Items with the “S” symbol on the website including most of items in the Educational Documents category are only accessible to those with valid logins.** If you are not a subscriber, and would like more information on becoming one, click the Subscription Info link on the home bar of www.softwarecpr.com.

SoftwareCPR® Consulting and Annual Subscriptions

SoftwareCPR® provides training in FDA regulation, risk management, and software validation. Alan Kusnitz of SoftwareCPR® has provided in-house training to FDA and Health Canada and is on the AAMI Software Committee and involved in international software standards. Sherman Eagles chairs many of the international software working groups. Several other SoftwareCPR® partners have been involved in development of FDA recognized standards for medical device software and EU software guidance. Consider having us update you on current regulatory expectations.

SoftwareCPR® also performs auditing, consulting and crisis management for all aspects of FDA regulation including quality systems, design control, and premarket submissions as well as hands-on support for risk management and validation. **Remember if you are a paid subscriber you can submit questions** on the website for guaranteed response from one of our experts, obtain word copies of any of our posted educational aides, and can receive all of our bulletins and newsletters.

If you are not a paid subscriber more information about the value of subscribing, including the premium **Standards Navigator** subscription, is available by clicking the Subscription Info link on the home bar of www.softwarecpr.com.

<p align="center"><u>Software Regulatory News</u> (recently added news updates only)</p>	<p align="center"><u>FDA Documents</u> (recently added or updated software related items only)</p>
<p>2/2/2012 - EU Guidance Classification of Standalone Software. 1/27/2012 - UL 1998 Revisions out for comment 1/5/2012 - AAMI 2012 Standards Week Committee Meetings. 10/28/2011 - FDA RAPS Software Presentation Oct 2011. 10/27/2011 - IEC Software and Network Advisory Group 10/25/2011 - AAMI Agile Methods TIR out for comment 10/19/2011 - FDA Pacemaker Pulse Generator Draft Guidance 10/4/2011 - FDA Regulatory Science for Medical Devices 9/25/2011 - SoftwareCPR.com September 2011 Newsletter 9/23/2011 - Safety Assurance Case Update</p>	<p>FDA Quality Manual Software Validation text FDA Infusion Pump Software Safety Research Manufacturer remote access to medical devices FDA RAPS Software Presentation Oct 2011. FDA Pacemaker Pulse Generator Draft Guidance FDA Regulatory Science for Medical Devices Safety Assurance Case Update</p>

<p style="text-align: center;">LIBRARY</p> <p style="text-align: center;">SoftwareCPR® Educational Material</p> <p>(RECENTLY ADDED OR UPDATED ITEMS ONLY) BROWSE OR SEARCH THE WEBSITE LIBRARY or TOPICS FOR THESE AND MANY OTHERS</p>	<p style="text-align: center;">Conferences and Public Training</p> <p>(a few recent and upcoming FDA software related conferences)</p>
<ul style="list-style-type: none"> • <i>\$All Recall Excerpts in one pdf file\$</i> • <i>\$All Warning Letter Excerpts in one pdf file\$</i> • Manufacturer remote access to medical devices 	<p>3/1/2012 - *IT Networks incorporating Medical Devices & Software*</p> <p>4/2/2012 - *AAMI SW Validation Requirements*</p> <p>4/25/2012 - *BOSCON 2012 - Medical Device Assurance Cases*</p> <p>5/14/2012 - *AAMI Assurance Case Course*</p> <p>5/21/12 *Agile Methods Compliance Workshop*</p> <p>6/2/12 *An Overview of the New AAMI Recommended Practices for MDDS*</p> <p>10/22/2012 - *AAMI Assurance Case Course*</p> <p>2012 - *SoftwareCPR Tailored Training at your site*</p> <p><i>*Conferences with SoftwareCPR® speakers are in bold</i></p>

<p style="text-align: center;">Warning Letters</p> <p style="text-align: center;">(recently added software- related FDA warning letters)</p>
<p>2/29/2012 - \$All Warning Letter Excerpts in one pdf file\$</p> <p>2/29/2012 - Omron (Dalian) Co., Ltd. blood pressure monitors</p> <p>2/29/2012 - Scottcare Corporation</p> <p>1/25/2012 - CuraeLase, Inc.</p> <p>12/14/2011 - Galloway Technologies, LLC</p> <p>12/9/2011 - Beckman Coulter, Inc. in vitro diagnostic products</p>

Recalls

(recently added software-related recalls published by FDA)

2/29/2012 - \$All Recall Excerpts in one pdf file\$
 2/26/2012 - Brilliance 64, Ingenuity CT Tomography, CI II
 2/26/2012 - Leica M822 Surgical Microscope Control SW, CI II
 2/26/2012 - Philips Computed Tomography X-Ray Systems, CI II
 2/26/2012 - Spacelabs Medical Ultraview SL Command Mod, CI II
 2/26/2012 - Vitrea Enterprise Suite, CI II
 2/18/2012 - GEMINI TF 16 PET/CT System, CI II
 2/18/2012 - Pinnacle3 Radiation Therapy Planning System, CI II
 2/18/2012 - Volcano pcFM Software Kit, CI II
 2/9/2012 - STERIS SYSTEM 1E, CI II
 2/3/2012 - Siemens syngo.plaza VA20A Server Farm setup, CI II
 2/3/2012 - Syngo Imaging XS, CI II
 1/27/2012 - NicVue Software version 2.9.2 and 3.0.1 , CI II
 1/27/2012 - RayStation Version 2.0.0.15 , CI II
 1/25/2012 - CareFusionNicolet® Cortical Stimulator, CI I
 1/18/2012 - GE LOGIQ E9 Diagnostic Ultrasound Systems, CI II
 1/11/2012 - Brilliance Tomography X-Ray System, CI II
 1/11/2012 - Extended Brilliance Workstation-NM, CI II
 1/11/2012 - IMPAX Cardiovascular Results Management SW, CI II
 1/11/2012 - Odyssey A radiation treatment plan system CI II
 1/11/2012 - SoftLab GUI, CI II
 1/11/2012 - SoftReports version 1.1.8.2.4, CI II
 1/5/2012 - cobas c 311 Analyzer, CI II
 1/5/2012 - SCC Soft Computer SoftMic, CI II
 12/28/2011 - LATITUDE Patient Management System Software, CI II
 12/28/2011 - Philips GEMINI TF Diganostic Imaging, CI II
 12/27/2011 - CareFusion AVEA Ventilators, CI I

12/22/2011 - IMPAX CardioVascular (CV) Admin Tool, CI II
 12/22/2011 - IMPAX CV Echo Measurement Import, CI II
 12/22/2011 - Philips Multi Diagnost Eleva , CI II
 12/16/2011 - Elekta Synergy XVI R.4.5 & R4.6 Product Use, CI II
 12/16/2011 - SCC Soft Computer, Softlab Lab Info System, CI II
 12/16/2011 - Siemens Symbia Series SPECT System, CI II
 12/9/2011 - Draeger Infinity(R) Monitors, CI II
 12/9/2011 - Infinity Acute Care System Monitoring Solutio CI I
 12/9/2011 - Norland Illuminatus Software, CI II
 12/9/2011 - SA BASE Software, CI II
 12/8/2011 - Medtronic Arctic Front Catheter, CI II
 11/23/2011 - Mako Surgical RIO Robot Unit, CI I
 11/18/2011 - Straumann coDiagnostiX, version 8.0, CI II
 11/10/2011 - Beckman SYNCHRON CX Systems, CI II
 11/10/2011 - Philips MDC PACS - release R2.3 SP1, CI II
 10/27/2011 - PCR Eleva Radiological Image Processing Syst CI II
 10/27/2011 - Plum A+ and A+3 Infusion Pumps, CI II
 10/24/2011 - CareFusion EnVe Ventilators, CI I
 10/24/2011 - Philips GEMINI Diagnostic Imaging Systems, CI II
 10/6/2011 - ADVANTAGE WINDOWS (Workstation), CI II
 10/6/2011 - Boston Scientific, LATITUDE Patient Mgmt Sys CI II
 10/6/2011 - HLA Fusion Software Version, CI II
 10/6/2011 - MEDITECH Blood Bank Software Client Server, CI II
 10/6/2011 - MEDITECH Blood Bank Software, CI II
 10/6/2011 - MEDITECH Blood Bank, CI II
 9/29/2011 - Toshiba AQUILION, CI II

Industry Papers/Presentations

(RECENTLY ADDED OR UPDATED ITEMS ONLY)
 BROWSE OR SEARCH THE WEBSITE LIBRARY or
 TOPICS FOR THESE AND MANY OTHERS

2/28/2012 - *Build and Validate Safety Article*
 1/13/2010 - *Australian DOD Software Reliability Paper*
 11/29/2009 - *IEEE Article - 10 rules for safe code*
 11/29/2009 - *NASA Fault Tolerance Paper*
 11/11/2009 - *SEI Safety Assurance Case Medical Device Example*
 Nov 2010 *Reprint of JMDR FDA Software Regulation Overview article*

Standards and Non-US Regulations

(RECENTLY ADDED OR UPDATED ITEMS ONLY)
 BROWSE OR SEARCH THE WEBSITE LIBRARY or
 TOPICS FOR THESE AND MANY OTHERS

- *Manufacturer remote access to medical devices*
- *UL 1998 Revisions out for comment*
- *New Standards Work Item for Standalone Software*
- *Radiotherapy Treatment Planning Systems Standard*
- *AAMI proposes Human Factors Software Standard*
- *ASME Forms Medical Device V&V committee.*
- *FDA Recognizes HE75 Human Factors Standard*
- *IEC 61508 association*