



DRAFT MEETING MINUTES

Dated 2010-05-19

Reference **ISO/TC 215/ WG7 – N 0297**

**ISO/TC 215 PLENARY AND WG MEETINGS**  
**ISO/TC215 — HEALTH INFORMATICS WG7 — DEVICES**

*WG7 Secretariat:*

PATTY KRANTZ (ANSI)  
[patty.krantz@medtronic.com](mailto:patty.krantz@medtronic.com)

*WG7 Convenor, IEEE11073 Co-Chair, HL7 DEV WG Co-Chair:*

TODD COOPER (ANSI)  
[t.cooper@IEEE.org](mailto:t.cooper@IEEE.org)

*Host organisation:*

ISO/TC215

*Meeting dates:*

2010/05/9 to 2010/05/13  
(Sunday, May 9 – Thursday, May 13, 2010)

*Place:*

**Windsor Barra Hotel**  
Av. Sernambetiba, 2630 Barra da Tijuca  
Zip code 22620-170 - Rio de Janeiro/ RJ - Brazil  
Fone: 55 21 2195-5000 - Fax: 55 21 2195-5050

*Host:*

Brazilian Association for  
Standardization (ABNT)  
Rua Minas Gerais, 190  
**BR-01244-010 – São Paulo/SP**  
Tel: +55 11 30 17 36 34  
Fax: +55 11 30 17 36 33  
E-mail: [isotc215brasil@abnt.org.br](mailto:isotc215brasil@abnt.org.br)  
Web: [www.abnt.org.br/](http://www.abnt.org.br/)

ISO/TC215 WG7 Meeting Attendance – see end of document

<b>Sunday 9 May 10: not WG7 specific</b>		
<b>Quarter</b>	<b>Topic</b>	<b>Notes</b>
Q1 – Q3	<ol style="list-style-type: none"> <li>1. Operations and Harmonization Meeting</li> <li>2. Executive Council</li> <li>3. JIC Information session; JIC Harmonization Open Forum; Unconference</li> </ol>	

<b>Monday 10 May 2010: Status update and strategy day</b>		
<b>Quarter</b>	<b>Topic</b>	<b>Notes</b>
Q1	4. Opening Plenary	
Q2	5. Welcome, roll-call, approval of agenda	All participants were introduced. Agenda reviewed (N0298) and reports added. Final agenda to be posted and will also be reflected in the meeting minutes.
	6. Status on JWG7 IEC 80001-1 and technical reports	See slides within agenda slide deck from Todd Cooper (N0298)  Todd also reviewed portions of the draft TR: <i>Step by Step Risk Management of Medical IT-NETWORKS; Practical Applications and Examples</i> . This draft is available upon request.

Monday 10 May 2010: Status update and strategy day		
Quarter	Topic	Notes
	7. ISO/IEEE 11073 – ISO CS Issues	<p>Issue summary:</p> <ul style="list-style-type: none"> <li>• Document renaming (at FDIS!)               <ul style="list-style-type: none"> <li>○ Changed PHD doc names</li> <li>○ No notice/consensus beforehand</li> <li>○ Renaming inconsistent w/IEEE &amp; 11073</li> </ul> </li> <li>• Document Renumbering               <ul style="list-style-type: none"> <li>○ Numbering part of published ISO &amp; IEEE standards</li> <li>○ Long history of “-xyzz” in ISO &amp; IEEE</li> <li>○ Previously harmonized from x.y.z to xyzz</li> <li>○ Extensive cross-referencing w/other standards and specifications (incl. Continua spec’s)</li> </ul> </li> <li>• PSDO Agreement &amp; “fastrack” Processing               <ul style="list-style-type: none"> <li>○ Previous process facilitated JOINT development and timely consensus formation</li> <li>○ New process ... inhibits</li> </ul> </li> <li>• Document types supported: IS only?!</li> <li>• Mixed document types in a single series not allowed</li> </ul> <p>WG7 Feedback to ISO CS: ISO is violating agreement between IEEE and ISO; Go back to CS and then escalate to TMB; Note that IEEE and IEC do not have issues such as this.</p> <p><b>Resolution drafted (see closing plenary report N0302)</b></p>
	8. Patient Safety and Quality report	<p>Todd Cooper provided a high level overview of report (N0299)</p> <ul style="list-style-type: none"> <li>• Reviewed Scope clause (what is in and out of scope)</li> <li>• Review of existing standards</li> </ul> <p>Patty Krantz to attend the Q3 session on this Task Force (see report out item 12)</p>
	9. IEEE 11073 Lower Layers chair update	<p>Malcolm Clarke provided a lower layers chair update (lower layers report.ppt document N0300)</p>
Q3 & Q4	<p>10. JWG7 IEC 80001-1 report out of WG4</p> <p>11. Joint meetings with Patient Safety &amp; Quality Task Force, WG1-DCM, WG2b-Telehealth</p>	<p>Joint meeting with WG4. Todd Cooper provided a more detailed report out on draft technical report on security</p> <p>WG7 members attended various concurrent WG sessions in Q3 and Q4.</p>

Tuesday 11:		
Quarter	Topic	Notes
Q1	<b>12. Report out of joint meetings from Monday</b>	<p>WG7 &amp; WG4: WG7 report out on IEC 80001-1</p> <p>Patient Safety &amp; Quality Task Force report: ISO/TC 215 Task Force on Patient Safety and Quality is commissioned by the ISO/TC 215 Executive Council (Resolution of ISO/TC 215 April 30, 2009). They are not looking at the development of devices and HIT software (out of scope, there are already standards in place). However, Patty Krantz requested that IEC 62304 and ISO 14971 be added to the list of existing standards. This task force is looking at clinical use of health information and how health informatics may be employed to develop standardized models for representing quality healthcare processes. They are leveraging the ISO 9000 framework. Their conclusion/recommendation: "Therefore, to develop a Health Informatics Framework that systemically supports quality care, it is recommended that a process control model be adopted." Going forward, Patty Krantz will stay engaged in this task force.</p> <p>Telehealth: draft 13131: The majority of this session was spent discussing definitions and scope. Outcome: definitions remain a problem (telehealth, telemedicine) but Malcolm provided a recommendation; scope - they don't know where they are going yet. Malcolm Clarke will stay engaged in this group (WG2 Architecture breakout group B (WG2B)).</p>
	<b>13. Review of MFER Ballot results</b>	<p>Reviewed results of the four NWIP ballots - none of which had the required number of experts nominated to pass NWIP ballot.</p> <ul style="list-style-type: none"> <li>• 11073-92205</li> <li>• 11073-92206</li> <li>• 11073-92301</li> <li>• 11073-92302</li> </ul> <p>Todd Cooper, Melvin Reynolds, and Masaki Hirai will resolve comments with possible new NWIPs by the October 2010 meeting.</p>
	<b>14. Review of Work Program items</b>	<p>The ISO/TC215 work program (WP) spreadsheet was reviewed. The work of updating the WG7 WP to align with IEEE status and reflect current ISO/TC215 status was taken off-line. Patty will continue to work with Mr. Mike Kroll to get the proper updates posted to the ISO/TC215 site.</p>
	<b>15. SAMD</b>	<p>Patty Krantz provided a high level report of SaMD activities. SaMD met May 4 to review the new version of the draft SW Manual on Classification and Qualification. This document was drafted by a sub-group of the medical device expert group on Borderline and classification in order to clarify in which cases or under which conditions software used in a healthcare environment could be qualified as medical device and where appropriate to clarify their classification. The purpose of this document is to define the criteria for the qualification of standalone software as medical device and to provide with some useful and clear examples. Software embedded in medical devices is outside the scope of this guideline.</p>

Tuesday 11:		
Quarter	Topic	Notes
Q2	<b>16. WG7 Leadership</b>	Todd Cooper's convenership term is up next year (2011). If you are interested in learning more about this role then please contact Todd Cooper.
	<b>17. Review of future Meetings</b>	Please see the list of meetings below. Note that there is a new date for the 2011 ISO/TC215 Plenary meeting (so that it does not conflict with HL7)
	<b>18. Urinalysis PHD</b>	Presentation from Dr. Kwak (N0301) Through IEEE new PAR (Sun Ki Lee worked on glucose meter). WG7 adjourned.

**Next 'Devices' Meetings (does not include interim project / task meetings):**

- \* IEEE 11073 PHD 15 June 2010 - Belfast (coupled with CONTINUA)
- \* CEN/TC251 Plenary meeting, 16 June, 2010 - Brussels (part with CENELEC/TC62)
- \* 24th Annual HL7 Plenary & Working Group meeting, 3-8 Oct 2010 - Cambridge, MA, USA (send query to begin building agenda for this, meet here or in Rotterdam?)
- \* ISO/TC215 Joint working groups. 10-13 Oct 2010 - Rotterdam, Netherlands CEN TC251 WGIV (plan meeting here if not meeting in Apr?! Coordinate CEN/TC251 with Alpo Varri; possible topic: Maureen Baker of JWG7 80001TR; adjusted NWIPs for MFER)
- \* HL7 Working Group Meetings. 9-14 January 2011 - Sydney, Australia
- \* HL7 Working Group Meeting, 15-20 May 2011 - Orlando, FL USA
- \* ISO/TC215 Plenary and joint Working Groups, 23-27 May 2011 Finland
- \* 25th Annual HL7 Plenary & Working Group meeting, 11-16 September 11, 2011 - San Diego, CA
- \* HL7 Working Group Meetings. 15-20 January 2012 - San Antonio, Texas

WG7 Devices  
Monday May 10

Q2



WINDSOR BARRA  
Hotel & Congresses

Name

organization

e-mail

Patty Krantz

USA - ANSI

patty.krantz@medtronic.com

MALCOLM CLARKE

UK-BSI

malcolm.clarke@brunel.ac.uk

Marin Kojler

Sweden - SIS

marin.kojler@telia.com

Yun S Kwak

Korea

yekwak@knu.ac.kr

Masaaki Hirai

Japan

Masaaki.Hirai@mifty.com

Marcelo Antunes

Brazil

marcelo@sqrconsulting.com.br

Q3

WG7 hosts w4 for 8001-1 report

Masuyoshi Yachida

Japan

yachida@rdc.rich.co.jp

Taizo Hirata

Japan

taizo.hirata@siemens.com

Shinichiro Nishida

Japan

snishi@shimadzu.co.jp

Yasushi Okada

Japan

yasushi.okada@ts.med.co.jp

Hideyuki Miyohara

Japan

Miyohara.Hideyuki@ap.  
MitsubishiElectric.co.jp

Ms Knadzir Steier Amerl NY

knadzir@nsh.gov.ny

ROSS FRASER

CANADA

ROSS.FRASER@  
SEKT-APT.SOFTWARE.COM

Sheila Monteiro

Brazil

sheila@datasis.gov.br

Kanjo Malme

BRASIL - MSAUDE

malme@datasis.gov.br

Jane Milles

IHTSDO

jmi@iht.sdo.org

Nicholas Oughtbridge

UK-BSI

Nicholas.oughtbridge@nhs.net

Anely Bond

Australia

anely.bond@uehcta.gov.au

Bernd Blobel

Germany

bernd.blobel@klinik.uni-regensburg.de

Kyo IL Chung

Korea

Kyo:il@etri.re.kr

Yun Sik Kwak

Korea

yekwak@knu.ac.kr

Masaaki Hirai

Japan

Masaaki.Hirai@mifty.com

ELAINE SAWATSKY

CANADA

ELAINE.SAWATSKY@TECUS.NET

Marcelo Antunes

Brazil

marcelo@sqrconsulting.com.br

WG7

Tuesday  
May 11, 2010



**WINDSOR BARRA**  
Hotel & Congress

Q1 → Q2

<u>Name</u>	<u>ORGANIZATION</u>	<u>EMAIL</u>
Patty Krantz	USA - ANSI	patty.krantz@medtronic.com
Malcolm Clarke	UK - BSI	malcolm.clarke@brunel.ac.uk
Karin Heyfer	SE - SIS	karin.heyfer@teli.no.com
SHARON STANFORD	USA - ANSI	STANFORDS@ADA.ORG
Marcela Antunes	Brazil-ABNT	marcelo@sgconsulting.com
Masaaki Hirai	JAPAN JISC	Masaaki-Hirai@misty.com
MIKE KROZ	USA-ANSI	MIKROZ@HMS.ORG
Todd Casper	USA-ANSI	T.Casper@icee.org
Yun Sik Kwak	Korea	see previous page