



ISO TC215 WG7 Health Informatics - Devices

2010.05.10 – 13, Rio de Janeiro, Brazil

Convenor: Todd Cooper

Vice Convenor: Thomas Norgall

Secretary: Patty Krantz

Meeting Overview

- ✓ Detailed review of the WG7 Work Program spreadsheet / coordinated updates with multi-organizational leads for joint projects
- ✓ ISO/IEC JWG7 80001 Status Review
- ✓ ISO CS / IEEE 11073 Issues
- ✓ MFER NWIP Ballot Results Review
- ✓ “Lower layers” Project Reports
- ✓ Urinalysis Personal Health Device Proposal

Meeting Overview

- ✓ Coordination with other WGs:
 - 80001 Updates (WG4)
 - Device - Detailed Clinical Model (DCM) Coord.
 - Patient Safety & Quality TF
 - Telehealth (WG2)
 - Software as a “medical device” Discussions
 - ✓ “Alert information in health records”
 - ✓ CDSS WIs
 - ✓ “observables” (WG6)
 - ✓ JIC (WG9) projects



Convenor: Todd Cooper (U.S.A.)
(2nd Term 2008 – 2011)

✓ Elections to be held in 2011 Plenary Meeting

Vice Convenor: Thomas Norgall (Germany)

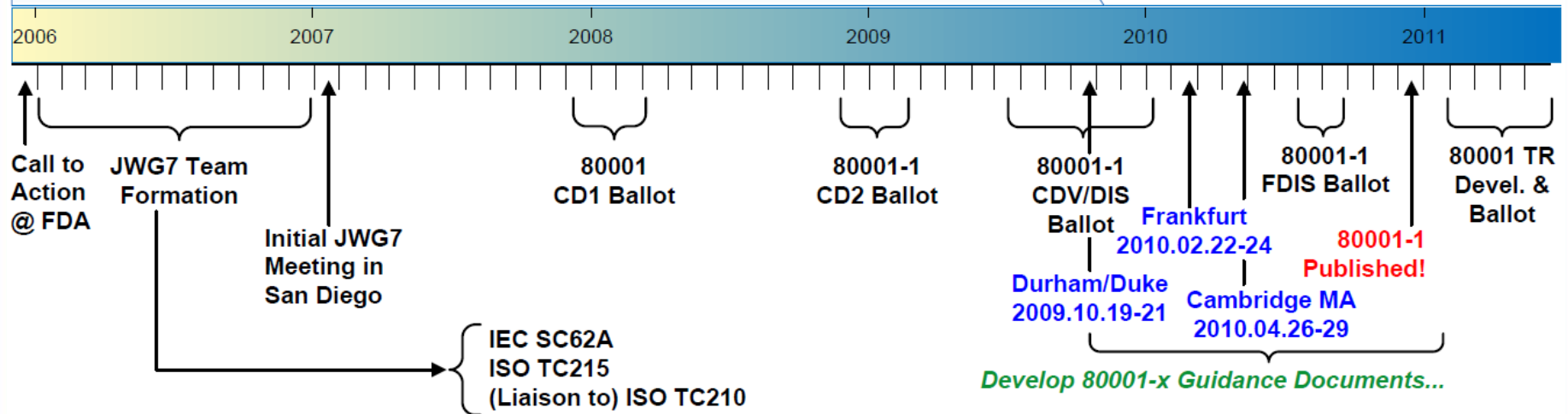
Secretary: Patty Krantz (U.S.A.)

ISO/IEC JWG7 - 80001

ISO/IEC JWG7 Past, Present & Future

2010.05.12

(r6)



Note: For Pre-History: [Ask Oliver Christ!](#)

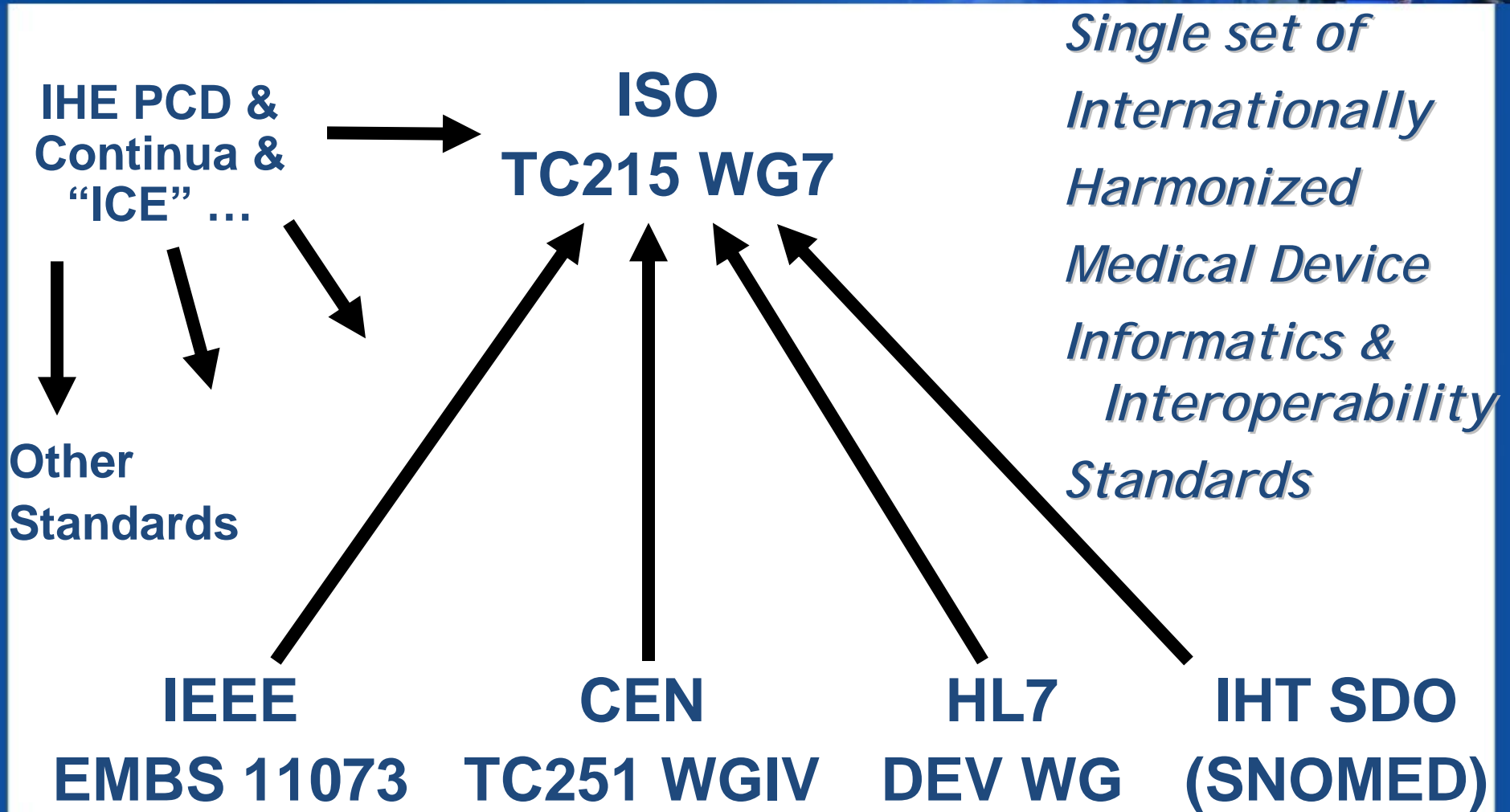
- ✓ **80001-1 passed CDV/DIS Ballot 2010.01.08**
- ✓ **FDIS text currently out for French translation**
- ✓ **FDIS ballot scheduled for 2010 JUL-SEP**
- ✓ **Publication target @ 2010.11**

Additional 80001 guidance ...

- ✓ *Guidance for HDOs*
- ✓ *Step by Step Risk Management of Medical IT-networks; Practical Applications and Examples*
- ✓ *Guidance for wireless networks*
- ✓ *Guidance for the communication of medical device security needs, risks and controls*

1. *3 of 4 Durham Preliminary WI's have mature drafts*
2. *All (4) planning final round of informal draft reviews*
3. *Submit NWIPs for all (4) late 2010.09 pending successful 80001-1 FDIS ballot*
4. *TR ballots / publication completion ~ mid-2011*

Health Informatics - Devices



ISO/IEEE 11073 – ISO CS Issues

- ✓ Issue Summary:
 - Document Renaming (@ FDIS!)
 - Changed PHD doc names
 - No noticed / consensus beforehand
 - Renaming inconsistent w/ IEEE & 11073
 - Document Renumbering
 - Numbering part of published ISO & IEEE Stds
 - Long history of “-xyzz” in ISO & IEEE
 - Previously harmonized from x.y.z to xyzz!
 - Extensive cross-referencing w/ other standards and specifications (incl. Continua spec’s)

ISO/IEEE 11073 – ISO CS Issues

- ✓ Issue Summary:
 - PSDO Agreement & “fastrack” Processing
 - Previous process facilitated *joint* development and timely consensus formation
 - New process ... inhibits
 - Document types supported: IS only?!
 - Mixed document types in a single series not allowed
- ✓ Resolutions express WG7 and the 11073 community’s strong need to maintain the successful processes and conventions

WG7 Resolution (Part 1):

Resolved that ISO/TC215 approves the WG 7 recommendation that the ISO/TC 215 Secretariat communicate to ISO Central Secretariat that WG7 in coordination with IEEE EMBS 11073 and other liaison groups, including Integrating the Healthcare Enterprise (IHE) Patient Care Devices (PCD) Domain and the Continua Health Alliance, strongly desires to maintain the core elements of the effective and efficient processes that have been in place for many years starting with the ISO/IEEE Pilot Project established in the late 1990's, namely that processing of ISO/IEEE 11073 work items:

1. Maintain both the 11073 document titles and numbering scheme when IEEE approved work items are brought to ISO TC215 for "fast track" processing;
2. Implement the PSDO process so as to facilitate the timely joint consensus development that has been successfully employed for these joint documents (see related resolution);
3. Remove the restriction of a single document type within a series # (i.e. allow IS, TS, and TRs within 11073)
4. Remove the restriction on IS-only under the PSDO to allow IS, TS & TRs

WG7 Resolution (Part 2):

WG7 asks ISO Central Secretariat and IEEE to resolve the current issues per the key points above ASAP. Until then, we ask that there be no publication of any 11073 standards that have been approved, and that all further projects be held back from submission for ISO processing until these issues are resolved, including the *IEEE 11073 Health informatics – Personal health device communication – Device specialization –*

- 11073-10404 Pulse oximeter (revision)
- 11073-10407 Blood pressure monitor
- 11073-10417 Glucose meter (revision)
- 11073-10418 INR analyzer
- 11073-10419 Insulin pump
- 11073-10420 Body composition analyzer
- 11073-10421 Peak expiratory flow monitor (peak flow)
- 11073-10472 Medication monitor

WG7 Resolution:

Resolved that ISO/TC215 approves the WG 7 recommendation that subject to approval of IEEE and ISO CS staffs, resolve that the following standing process be enacted:

- 1) approved IEEE 11073 PARs are lodged onto the ISO TC215 work program as ISO/IEEE 11073 preNWIPs;
- 2) all ISO/IEEE 11073 preNWIPs are circulated to ISO TC215 for a period of 30 days to allow for the nomination of contributing ISO experts;
- 3) all IEEE 11073 drafts approved by the IEEE-SA Standards Board Review Committee, and previously notified as ISO/IEEE 11073 preNWIPs, will be accepted for fast-track FDIS.

2010.10 Rotterdam Planning

- ✓ Continued 11073 Coordination
- ✓ Device DCM Development
- ✓ 80001 HDO Guidance TR Development
- ✓ Joint Meeting w/ CEN TC251 WGIV
- ✓ “Software as a Medical Device” Workshop?

Note: Core 11073 technical meetings will be held in conjunction w/ HL7 & IEEE 11073 sessions the preceding week in Cambridge Mass.



Joe Morrissey
1962 - 2010

WG7 Resolution:

Resolved that ISO/TC215 accepts the report of ISO/TC 215 WG 7.