Jan 2018 - Joint HL7/IEEE WG NOLA

Monday, January 29, 2018   10:16 AM

To help prepare for HL7's Working Group Meeting, please note the following information:

A copy of the HL7 Working Group On-Site Meeting Schedule can be found here: Onsite Guide. Hard copies will also be available at the registration desk.

You can also find the same information available on our Event Mobile App here: EventMobi App

Meeting Minutes Draft Version 1.0, Thursday, February 1, 2018
Please NOTE: the following notes are draft and pending members/leadership review and vetting (Draft V1.0, as of Thursday Q3, February 1, 2018)
Please provide IEEE PoCD Secretary (John Garguilo, john.garguilo@nist.gov) any proposed updates/edits/corrections
Apologies in advance for any "fat fingers" or misrepresentations which may be provided in these draft meeting notes.

IEEE Portion of Meeting (presiding)
IEEE 11073 General Committee Chair: Ken Fuchs
IEEE 11073 PoCD Chair: John Rhoads
IEEE 11073 PoCD Secretary: John Garguilo

HL7 Portion of Meeting (presiding)
HL7 Healthcare Device Co-Chair: John Rhoads
HL7 Healthcare Device Co-Chair: John Garguilo

Draft Master Attendee List
John Garguilo, NIST, john.garguilo@nist.gov
John Rhoads, Philips Healthcare
Stefan Schlichting, Draeger, stefan.schlichting@draeger.com
David Gregorzyk, Draeger, david.gregorezyk@draeger.com
Martin Rosner, Philips, martin.rosner@philips.com
Masato Tanaka, Nihon Kohden, masato.tanaka@
Bjorn-Eric Erlandsson, HL7-Sweden, beerlekth.se(??)
To be completed…

Notes Key:
Yellow Highlight: Date/Day and Quarter of Meeting)
Red Highlight with box to right: Action Item

Q1 Monday, January 29, 2018

Welcome and Introductions (Ken Fuchs, John Rhoads)
Meeting Hotel/Room: (Hilton Riverside Hotel, New Orleans, LA)
IEEE Licensing & Copyright - nondisclosure clause, and rules of behavior review
See attendee list for in room attendees
On-line (via WebEx): Beth Puma(?) KP; Jan Wittenber; Marcos (??); Stefan Karl (Philips);

New to group - Ray??
Kostas ?? - FDA - question about WG…

Agenda review (Rhoads) - see Agenda draft version 0.6
IEEE 11073 / HL7 HCD – Draft 0.6

AM	IEEE Q1	Welcome, Introductions, Rules **x73 in DE Federal Register Listing Standards Maintenance (PoCD)** ISO TC215 Reviews **PHD/PCHAlliance/Continua "Europe Rolling Plan" - HISA & x73**	Chair Andersen Bennett Fuchs Wittenber Bennett

► IEEE 11073 Highlights (K. Bennett)

See Kathryn's slide set (posted to HCD WG "Documents" tab/site)
- Ballot Highlights
- Executive Summary
- EU Opportunities
    - Bjorn Andersen working with Andreas Grode at Gematik
    - Martin Rosner - Amalgamation Results
        - Prioritizing comments resolution
- Bjorn volunteered at Kathryn's call for volunteer (along with Stephan Schlichting)
- Kathryn showed a nice slide (see at end of her slide set) on the upcoming 2018 IEEE Standards Association Governance Meetings Schedule (SAGM)

► AAMI UL 2800 Standard Update (Fuchs)
- Preliminary (informal) draft was made for review - so may be getting close to a publication
- Standard itself is somewhat process oriented
- Infusing overall interoperability as a complement to Risk Mgmt., Security - however nothing really specific as one might develop a product…
- Develop a concept of SSEPO - (Safety, Security, Central Performance and Objectives) things related to safety security and performance of interoperability
    - Each of these is a large topic - the group has concentrated on the process objectives - one problem is there are many potential systems that can be developed so coming up with an "interoperability model" is quite difficult… thus the management process has been the focus (vs. the technical interoperability part)
    - Goal is to have a balloted Std by EOY (about ~200 pages of content + 10-15 annexes) - so the guess is a document should emerge in the next 2-3 months
- John Rhoads mentioned that there was theme for IoT
    - "OCF" (Open Connectivity Foundation) led by Doug Bogia - and Continua/PCHA - but nothing materialized
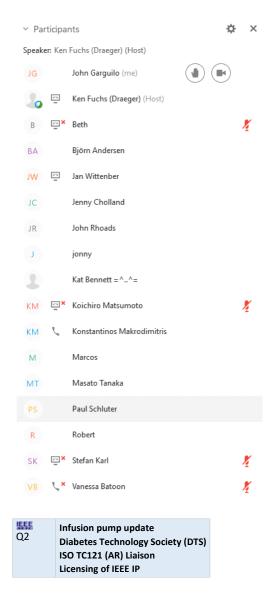
Break 10:30 - 11:00 am

Note: Ken Fuchs updated Agenda to make IEEE Licensing linked

Q2: Monday
Attendees: To be completed
On WebEx:

Q2
Infusion pump update
Diabetes Technology Society (DTS)
ISO TC121 (AR) Liaison
Licensing of IEEE IP

► Infusion Pump: Discussion on moving to get a definitive technical nomenclature definition - as well as a containment

Need to look into "Leading the charge" from Pump group (IHE-PCD)
Suggestion to get more from this group (prior to Spring F2F - IHE-PCD (typically a one-day pre-meeting with Pump Group prior to PCD F2F)… however the one-time weekly call has not met for past several months (since last Fall 2017 F2F)
Issue: having the appropriate leadership is important to drive such areas (often there's no vendor willing to dedicate this kind of resource &/or work commitment).
☐ Action Item: John Rhoads will talk to Tom Kowalchick (IHE-PCD Co-chair) regarding if someone should be budgeted

► Diabetes Tech Society (DTS)

► ISO TC121 (AR) Liaison
- Letter was received (by Ken Fuchs) from ISO/TC 121 seeking to establish a Liaison between IEEE 11073 Standards Committee and ISO TC 121 - from Colleen Elliott ISO/TC 121 Secretariat cc: Dr. Steven Dain, Chair - ISO/TC 121 indicating (primarily) for purposes of exchanging/sharing (draft) standards (as well as technical reports)
☐ - Action Item: Kathryn Bennett will check in with IEEE to determine 'category' to which this/such a "liaison" could be established.
- Motion put forward that this group accept and exchange (limited to approved drafts) 11073 standards as a liaison between ISO/TC 121 and IEEE 11073 Standards Committee; Result: Unanimous: "Approved"
  - o Deliverables are (approved) draft standards or technical reports and bi-directional
    - ▪ Discussion: (Jan Wittenber) TC 121 does not have in their charter to address "interoperability"; there are some items that confuse the issue of terms within the scope of TC 121 (e.g., respiration) - this group is more interested in the clinical side (w.r.t. terminology)
      - ☐ Jan expressed concerned that (ISO/TC 121) sharing of standards may not be "apples to apples" (e.g. given, 19223).
      - ☐ Jan suggested that (meeting the needs of each groups charter) may not be fully vetted at this point.

- □ Vetted working documents + approved drafts that lead to developed standards.
- □ Ken Fuchs suggested that a "formal liaison" indicates/eludes to notification of standards work.
- □ Request that IEEE PHD get vote to leadership (Co-chairs: Daidi and Michael Kirwin).
- □ Jan noted that part of this understanding is that the documents would be limited to IEEE Central Desktop, password protected, and access controlled by IEEE members.
- □ Establish an "official liaison" (such as John Rhoads, Ken Fuchs, or Jan Wittenber) - Steve Dain would be the contact person from TC 121 perspective - Ken suggested that he be the IEEE liaison and formally respond
  - ▪ Motion by John Rhoads, second by Paul Schluter
  - ▪ Favor: 10 Neg: 0   Abstain: 3; "passed"
  - ▪ Follow-on information: Ken Fuchs responded to ISO/TC 121 and agreeing to be the lead from IEEE; Dr. Steve Dain will be from the ISO/ TC 121 Side.

► Licensing "Terms of Use"
  - ○ The IEEE terms of use aren't prominently displayed (e.g., can't see directly when going to site's homepage)
  - ○ 11073 website (11073.org) does have "Conditions of Use"
    - ▪ https://11073.weebly.com/existing-standards.html
  - ○ Kathryn had IEEE review 11073.org (PoCD/PHD Standards --> Conditions of Use)
    - ▪ Only one question was still being vetted (note: question not identified(?))
  - □ ○ Suggested to add on NIST's RTMMS website (https://rtmms.nist.gov) terms of conditions "For official 11073 Conditions of Use refer to 11073.org"(Garguilo)
  - ○ Note: Malcolm has taken a new position at a Turkish University and no longer at Brunell University
  - □ ○ Add reference to FHIR implementation Guide from HL7's site
  - □ ○ Kathryn noted potential move to "Wordpress" web site creation tool would resolve any URL issues and site formally built and maintained by Malcolm Clarke. (future action item??) Post meeting update: Malcolm is hoping to remain involved, pending funding…

► Item: (Bjorn Anderson): Positive indication received from German Government for funding (in Germany) - Michael K. and Bjorn will be the project leads - research project funded for standardization efforts (specifically for SDC - included three Universities).
Bjorn noted project duration slated for 2-years but funding could be extended (i.e., same base funding({amount} over longer period of time) to develop 'Device Specializations'… T.B.D…
  - ○ Goal is to wrap up two Device Specializations and then progressively refine into what could become officially balloted standards (within the PHD scope).
  Bjorn's student to date has worked with Michael Faughn (NIST contractor) to leverage DIM Tool. Bjorn expressed appreciation of Michael's time and talents to enable student and leverage modeling expertise and NIST tooling.

Q3: Monday
Agenda:

IEEE Q3	Information Model: NIST Tooling DIM 10201 Dialysis Project Update

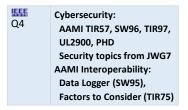Attendees: to be completed…
On WebEx:

► NIST DIM Editor Update and Presentation (Michael Faughn)
See slide set posted to HL7 HCD WG "Documents" tab/site

Michael also walked through the standards document created programmatically (and in some cases by hand) which reside on the IEEE iDeskTop space...

Discussion on the variations and representing the DIM (what's needed by who) - how many "views" are there? How does one ensure models are consistent between those?....(included in Michael Faughn's presentation)

Q4: Monday

IEEE Q4	Cybersecurity:
	   AAMI TIR57, SW96, TIR97,
	   UL2900, PHD
	   Security topics from JWG7
	AAMI Interoperability:
	   Data Logger (SW95),
	   Factors to Consider (TIR75)

Attendees: To be completed...

Cybersecurity Activities:
- Noted that group meets bi-weekly (recent day change from Thursdays to Wednesdays)
- PHD is attempting threat and pre-mitigation models which are applied to device specializations (-104xx series)
- Christof is hoping to circulate a white paper in the next few weeks

Review of Cyber activity groups provided by Jan Wittenber and Ken Fuchs (no slides presented)
Noted that the PHD Cybersecurity Tiger Team meets once every other week, on Wednesdays.

► Joint with O&O

Sign in sheet handled by O&O (non O&O members, e.g., HCD signed paper sheet, O&O using piloted HL7 Confluence site to record meeting attendance)
Attendees: See O&O
HCD WG Attendees: Michael Faughn, John Garguilo, Bjorn Anderson, Paul Schluter, John Rhoads, Ken Fuchs, Stephan Schlichting, Jan Wittenber Koichiro, Mosato, (Jan Wittenber via WebEx)

Comment review:
13562 - motion was made - declining Todd Cooper's comment as a "non-persuasive" motion
14881 - motion was made - declining Todd Cooper's comment as a "non-persuasive" motion and suggested moved to the Conformance WG as it a more infrastructural issue and too specific (conformance) for O&O
Discussion included question: For HL7 - could this not be accommodated in the OBX-3 (OBX-3.1- OBX-3.6)
www.hl7.org/fhir/
http://www.hl7.org/fhir/observation-vitalsigns.html

Issue - Scope: Which resources?

★ Hans suggested a Monday Call following WG meetings (due to lack of time in this quarter). Calls are 1 PM - 2 PM (Eastern Time) and suggestion/request was made to have key HCD/devices WG members on phone to figure this out. Some HCD members agreed to atten d (and hoping Todd Cooper and Jan Wittenber too are able to join call).
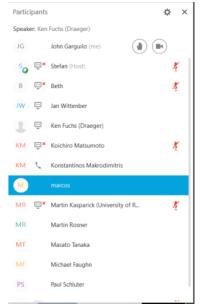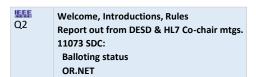
Attendees: to be completed…
Present: Stephan S, Ken Fuchs, David G., Martin Kasparick, name of person not noted(??), Kathryn Bennett, Bjorn Anderson, Mas ato Tanaka, Koichiro Matsumoto, Michael Faughn, Paul Schluter, John Garguilo
Participants on WebEx (note: some present in room - John Garguilo, Ken Fuchs, Koichiro Matsumoto, Martin Rosner, Masato Tanaka, Michael Faughn, Paul Schluter, Konstantinos Makrodimitris)
On WebEx:

IEEE Q2	**Welcome, Introductions, Rules**
	Report out from DESD & HL7 Co-chair mtgs.
	11073 SDC:
	  Balloting status
	  OR.NET

HL7 HCD Co-chair and Domain Steering Division Report Out (Garguilo)
- Re-categorization of Steering Division 'pillars' within the Technical Steering Committee's (TSC) Domain Steering Division (DSD
  - HCD was targeted to be in the new "Administrative" pillar - John Rhoads and John Garguilo expressed concerns with the draft designation and suggested HCD be part of the "clinical" pillar as this area (of the four pillars) is most appropriate.

- HL7 going to more automated (less paper-based) systems including 'Confluence' for recording attendance and notes at WG meetings, JIRA for tracking issues, etc.
- Two PSS discussed in DSD - not applicable or relevant to HCD (refer to HL7 DSD's meeting minutes)

► 11073 SDC (Schlichting)
See Stefan's slide set posted to HL7 HCD WG's "Documents" tab/site.
- Stefan outlined the document and some of the recent changes to documentation / standard
- Of particular note - refer to "The Glue" (section 7. SDC Participant Model Binding) slide for highlighted items (including):
  - 11073 nomenclature becomes mandatory.
- Requires Saftey Classifications for all Operations
- The Glue - starting balloting end of February/Beginning of March 2018
- What is next?
  - ☐ ○ Setup project for an Implementation Guide for SDC (Schlichting)
  - ☐ ○ Setup project for an nomenclature for remote control commands(Schlichting)

Kathryn Bennett sent an email to IEEE PoCD and PHD co-chairs/leadership with the following consideration.
Please consider a bucket motion, a PoCD and a PHD motion, or 5 individual motions to occur prior to the close of IEEE business to Sponsor approve the following drafts to progress into the sponsor balloting process:

P11073-10407 Revision
P11073-10408 Revision
P11073-10415 Revision
P11073-10471 Revision
P11073-20701

Please note that all 5 invitations have been submitted. I am not able to approve initial ballots until sponsor approval has been given.

Thank you!

Kind regards,

Kathryn M. Bennett
Program Manager, IEEE Standards Association
Telephone: +1 732 850 1768
Email: K.Bennett@ieee.org

Q3 Tuesday, January 30, 2018

IEEE Q3	Terminology: **IEEE P11073-10101b** - parameters (NMT, TPTD-CCO, infusion?, dialysis?) - event and alert nomenclature - additional body and measurement sites **IEEE -10103 IDCO** **Recent updates to the harmonized Rosetta (hRTM2a)** **10101 to LOINC mapping updates**	Schluter
		Abhyankar

► Terminology (Paul Schluter)
- See Paul's slide set
- 10101b likely not to be balloted for another 3 or so months
- Swapna Abhyankar - 639 mappings (+49 up from the 590 on RTMMS)
  - There was a comment (Cooper) no one reviewed the mappings? Should there be a more rigorous review process?
  - FHIR Vital signs and mappings (both generic and specific)
  - How do we handle "equivalency factor"? i.e., how accurately does a LOINC term map
    - Dr. Abhyankar discussed the issue and question of how one defines some kind of "equivalency factor" between MDC and LOINC terminology mappings

Q4 Tuesday, January 30, 2018

Attendees: to be completed…

WebEx on-line members for Q4

Q4	Other: UDI, MDAP CMI, Roadmap & Planning

Terminology (Paul Schluter), Part 2: Term Approval Process
- Define codes by "expert group" and lock in the numeric codes (Ref_ID, Discriminator {Min, Max, Mean}, Context Free Code

New Term Ref ID and Code Assignments

Background for this discussion, motivated by the desirability of assigning numeric codes at the earliest possible time.

- Use the NIST RTMMS as the authoritative numeric code validator (and/or generator) for new terms to guarantee non-overlap between multiple organizations, e.g. IEEE 11073 PoCD, IEEE 11073 PHD, IHE PCD Rosetta, PCHA/Continua, MDPnP, OR.NET and others.
- If the assigned Reference ID, Disc, Part::Code is discarded during balloting, retired as a "zombie term" and cannot be re-used.
- Terms that are assigned codes must have complete definitions, UoMs, enur values and other information when they are submitted as an Excel workshe formatted exactly as it would appear in the published standard.

Is this a good idea?

- *Yes,* if we can keep the number of "zombie terms" to a small number (e.g. < 1 to 3% of new terms defined).
- *No,* we could end up with a 'free-for-all' if this is uncontrolled without any degree of editorial review and curation.

IEEE 11073 GC, New C
2018

- Code and Term Assignment Process

Code and Term Assignment Process

① Proposed 0^MDCX terms that have not been approved by a recognized working group, let alone by the larger IEEE 11073 community.

② Provisional terms that have been approved by a recognized working group (e.g. IEEE 11073 PoCD, PHD, IHE PCD Rosetta or Profile/Supplement WG, PCHA/Continua, MDPnP, OR.NET and others) may have numeric codes assigned to them prior to IEEE balloting. The status of each term (proposed, provisional, published) will be maintained on the NIST RTMMS.

③ Published terms are those that have been balloted, approved and published as an IEEE 11073 standard.

Note: If a provisional term is rejected during IEEE balloting, the { Reference ID, Disc, Part::Code } 3-tuple will be retired as a "zombie term" and the Part::Code shall not deployed in messages nor recycled for use with another term in the future (enforced by NIST test tools). Proposed and provisional terms are subject to change and are not final until published in an IEEE 11073 standard.

CF_CODE10^REFID	RTMMS Status	Meaning
0^MDCX_term	① Proposed	Proposed term
nnnnn^MDC_term	② Provisional	Assigned numeric code (could become zombie)
nnnnn^MDC_term	③ Published	IEEE 11073 Balloted, Approved and Published

Term Provenance and WGs

The provenance of 'Published' and 'Provisional' terms will be indicated in the RTMMS using the IEEE filename, an IHE PCD Content Profile/Supplement/Module or other designator.

Identifier	Working Group or IHE PCD Content Profile/Supplement/Module
10101a-2015	An approved and published IEEE 11073 PoCD or PHD Standard
10101b-D1	A draft IEEE 11073 standard (first ballot draft)
20601-2014-Cor1	A corrigenda (use IEEE-SA filename conventions)
PCD-PIV-IPEC	An IHE PCD Profile (PIV and IPEC)
PCD-MEM-LS	An IHE PCD Supplement (MEM Location Services)
PCD-WCM	An IHE PCD Content Module (e.g. Waveform Content Module)

Provisional Term Information

Column Name	Description
REFID	Proposed IEEE 11073 Reference ID
Disc	Proposed IEEE 11073 Discriminator Set Identifier(s) [1, 2]
PartCode	Proposed IEEE 11073 Partition and Code, unless assigned by RTMMS [3]
Description	Proposed IEEE 11073 Description
UOM_MDC	IEEE 11073 Units of Measure
UOM_UCUM	UCUM Units of Measure
Enum_Values	Enumerated Value(s)
External_Sites	Measurement Site(s)

Notes:
1. MVC, MMM, SDM, RCE, RCN, LAT, UoM, UoM1, 1 discriminator sets defined in ISO/IEEE 11073-10101a-2015.
2. LEAD disriminator set is defined in ISO/IEEE 11073-10102-2012 aECG.
3. Part::Code can be proposed (and verified by RTMMS) or can be assigned by RTMMS.
4. { REFID, Disc, PartCode } is reserved forever, unless deprecated and prohibited from future use as a 'zombie'.
5. UOM_MDC and UOM_UCUM, Enum_Values and External_Sites are conditional.

Summary and Deployment

IEEE 11073 terms can have the following deployment status:
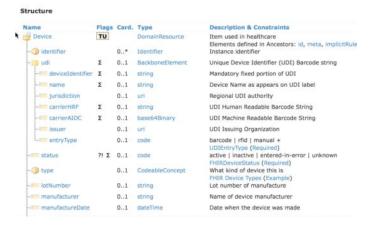
Status	Meaning	Example (OBX-3)
Private	Private, upper 4K of partition	131072^MDCGE_EEG_COHERENCE_INDEX^MDC
Proposed	Proposed 0^MDCX_ term	0^MDCX_ECG_QT_DISPERSION^MDC
Provisional	Assigned numeric code, could become zombie	68321^MDC_ATTR_SAMPLE_COUNT^MDC
Published	IEEE 11073 Balloted, Approved and Published	147842^MDC_ECG_HEART_RATE^MDC

Support for 'provisional' terms was recently implemented on the NIST RTMMS and was used to assign new MDC_ATTR attributes and MDC_EVT events for IHE PCD WCM and MEM-LS.

IHE PCD PIV and IPEC terms can also be viewed as 'provisional' and the same process can be used for IEEE 11073 Personal Health Device (PHD) terms as well.

(end of Schluter's Presentation)

► UDI Discussion (Rhoads)
- First appeared in HL7 Version 2.7 and elaborated in 2.8.2
- FHIR definition presented (different from V2)

Structure

Name	Flags	Card.	Type	Description & Constraints
Device	TU		DomainResource	Item used in healthcare
				Elements defined in Ancestors: id, meta, implicitRule
identifier		0..*	Identifier	Instance identifier
udi	Σ	0..1	BackboneElement	Unique Device Identifier (UDI) Barcode string
deviceIdentifier	Σ	0..1	string	Mandatory fixed portion of UDI
name	Σ	0..1	string	Device Name as appears on UDI label
jurisdiction		0..1	uri	Regional UDI authority
carrierHRF	Σ	0..1	string	UDI Human Readable Barcode String
carrierAIDC	Σ	0..1	base64Binary	UDI Machine Readable Barcode String
issuer		0..1	uri	UDI Issuing Organization
entryType		0..1	code	barcode | rfid | manual + UDIEntryType (Required)
status	?! Σ	0..1	code	active | inactive | entered-in-error | unknown FHIRDeviceStatus (Required)
type		0..1	CodeableConcept	What kind of device this is FHIR Device Types (Example)
lotNumber		0..1	string	Lot number of manufacture
manufacturer		0..1	string	Name of device manufacturer
manufactureDate		0..1	dateTime	Date when the device was made

► MDAP Item (left over from prior agenda)
► Roadmap Discussion
- Proposal 10101-2004 + 10101a revision or keep as an amendment (document not as easy to use)
  - Downside of revision is that others could add on (e.g., PHD which don't yet have terms fully vetted)
- Afterwards (later on in time) do 10101b as a revision
- Recommendation/suggestion from Kathryn (beyond revision) - at some point - Since Paul already has an open amendment (10101b), withdrawal the amendment and create a revision
- Paul Schluter agreed to work on 10101-2004 +10101a revision (required by 10 year rule + extension (which gives to calendar end of 2018).
- Ken Fuchs agreed to help do the "administrative" part to enable Paul Schluter to work on ballot process
- Jan Wittenber (currently listed as Chair) should designate Ken Fuchs as "ballot coordinator" for 10101 revision
- Jan W. made note that 2004 document was updated already to be nearly editorially (IEEE-SA editorial) compliant
- No other deadlines eminently looming
- Call for members to review 11073-10201 DIM document (ad-hoc tiger team is being formed to get a ballotable version of that). The remaining work are mainly the figures /graphics (to be integrated with the textual part that Michael Faughn is programmatically producing from the updated Model - roughly page 35 - 135). Figures need to be reviewed by group (potentially needing some editing)
  - 11073-10201 update has to be submitted by Oct 16, 2018 (six-month ballot period is the typically time estimate)
  - Goal should be (suggested) to submit document in March (which would give May meetings a place and time for resolution)
- 11073-20101 - No resource or expectation to upgrade - in past meeting it was agreed to submit as it is, therefore is re-ballot as is… SDC has essentially superseded where this document was headed. If nothing is done, document goes "inactive". No clear direction decided at this point. John Rhoads and Ken Fuchs will further evaluate.

Email from Kathryn providing clarification on standard status:
1) Revise unchanged document - requires a full ballot process
2) Do nothing and allow the standard to go into inactive-reserved status
- inactive-reserved: removed from active status through an administrative process for standards that have not undergone a revision process within 10 years.
- An inactive standard can be revised at any time. The inactive standard will remain inactive. Any active standard created by revising an inactive-withdrawn or inactive-reserved standard will be the revision approved by the IEEE-SASB, and will be identified using that approval date.
- Inactive standards are available for purchase from the IEEE Standards Store. Purchasers should note that inactive standards are not maintained, so they may contain significant obsolete or erroneous information, and are used AT THEIR OWN RISK.

Comment was noted, by Bjorn Anderson, that as long as RTMMS has consistent and well vetted terms, where the paper standard re sides…

IEEE 11073Meeting Adjourned (5:05 PM, 30 January 2018)

Q1 Wednesday, January 31, 2018

Pre-meeting: to review PSS's (three of them) - see confluence.hl7.org
Attending: Rob Snelick, John Garguilo, Harold Affo, Craig Newman, Hans Buteneuck(sp?), Frank Oemeg(sp?), ??(Publishing), Wayn e

PSS's:
1) Conformance
2) V2+
3) IGAMT: V2 Tooling

Agreed to meet on WebEx: Every other week on Friday

Welcome and Introductions
Intellectual Property Policy

DEV WG Agenda Review

Review of Projects, Status:
~~Dialysis (already discussed with O&O)~~
PC Cross-Paradigm PSS
FHIR Projects Update

Attendees: to be completed:
On WebEx:

∨ Participants

Speaker: John Garguilo (Host)

		John G (2) (me)
JG	🖥	John Garguilo (Host)
JR		John Rhoads
B	📞	Beth
BA		Björn Andersen
CC	📞	Chris Courville
	🖥✗	J.-Uwe Meyer (MT2IT)
	📱✗	J.-Uwe Meyer (MT2IT)
JW	🖥	Jan Wittenber
		Ken Fuchs (Draeger)
KM	🖥✗	Koichiro Matsumoto
MR		Martin Rosner
MT		masato tanaka
PS		Paul Schluter
SK	🖥✗	Stefan Karl
SL		Stephen Lowe

✓ Discuss May Meeting room requirements with group
  •

► Review of Projects (from HCD site)
  • 1369
  • 1351
  • 1343
  • 1335
  • 1277
  • 1153
  • 979 - no update - not sure of if even a viable project at this point
  • 898 - On hold pending Laura's leadership
  • 897 - On hold pending Laura's leadership
  • 850 - IG for CDA - Martin Hurrell - on Hold status pending the AWG reforming
  • 773 - V2.9 Message Standard - continue to work on advancing this version of the standard
  • 513 - IG for CDA - project should be removed…

Jan Wittenber asked about where 'Dialysis' project stands… John R. responded it may be with O&O but there would need to be a Project Scope Statement, Project Plan, etc… (Patrick lead of that effort?) - no project found…
Project 1309 - Cross Paradigm -

► Administrative items:
  • Co-chair report out
    HL7 HCD Co-chair and Domain Steering Division Report Out (Garguilo)

- ✓ Re- categorization of Steering Division 'pillars'
  - ○ HCD was targeted to be in the new "Administrative" pillar - John Rhoads and John Garguilo suggested HCD be part of the "clinical" pillar as this area (of the four pillars) is most appropriate.
- ✓ HL7 going to more automated (less paper-based) systems including 'Confluence' for recording attendance and notes at WG meetings, JIRA for tracking issues, etc.
- • Two PSS discussed in DSD - not applicable or relevant to HCD

- • Meeting room requirements for May '18 WG meetings in Cologne
  - • Will need room for 30 on Tuesday
  - • Rooms for 25 on Q3 Monday - Q3 Thursday
  - • John G. or Todd Cooper will reserve rooms

- • John Rhoads provided an update for Confluence (vs. Wiki Media) which HCD will start using…
  - • Advantages - centralized, meeting minutes and notes entered and viewable by all - common formatting available
  - • Tracking system is JIRA

Q2 Wednesday, January 31, 2018

Devices on FHIR :
PoCD IG Ballot Comment Resolution
Q2

Attendees: to be completed…
On WebEx:

Attendees: Ken Fuchs, Bjorn, Kathryn, Kochi, Mat, Martin, David G., Stefan Schlichting, John G, John R, Michael Faughn
New: Dan ?? (VA - Ioana works for him); Dale Nelson (Accenture - working out); Konstantinos Makrodimitris (Liaison for PHD from FDA)
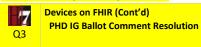
- ► PoCD DoF IG review
  - • Stefan Karl provided an overview PoCD IG
    - ○ Showed extensions (and constraints of the Profile to accommodate 11073 specification)
  - • John Rhoads led a review of ballot comments (see ballot comment source - TBD - where is this located??)
    - ○ Item 1:
    - ○ Item 2: Deferred (Beth Plumo)
    - ○ Item 3: Deferred (Beth Plumo)
    - ○ Item 4 : Stefan addressed comment - Suggested to be tabled and added to harmonization effort
    - ○ Item 5: To date it's been hard for a receiver to parse every scenario - however it is reasonable to have consumer at least accept the information

and ack it… Comments
- ○ Item 6: typo - accepted change
- ○ Item 7: Comment Use Cases can be expanded as FHIR enables a whole new class of device-content-enabled applications… Item comment reasonable
- ○ Item 8: Language Code
- ○ Item 9: recommended WCM
- ○ Item 10:
- ○ Item 11:
- ○ Item 12: Why UDI a separate identifier - answer - because UDI can't be included as typical identifier… for further evaluation
- ○ Item 13: Need to have a representative set of states for receiving system - for PHD harmonization…
- ○ Item 14: first class attributes of this profile making the distinction between a device interfaced via a Gateway or device directly connecting… Perhaps identifying somehow that "I'm from a gateway" - another harmonization with PHD
- ○ Item 15: expectations for systems storing but also exposing Device Data?
- ○ Item 16: add to RTMMS modeling information…
- ○ Item 17: Tied to item 16 - potentially an extension (would fall out of the 80% rule?)
- ○ Item 18: Color codes issue again (same as prior comment)
- ○ Item 19: Already Optional - perhaps a comment from an early version that's already been updated?
- ○ Item 20: Can be considered, but hard to distinguish a waveform from a numeric - Stefan S believes it would only be needed
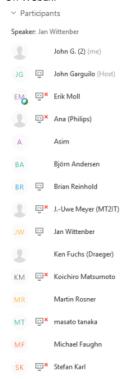
End of Q2

Q3 Wednesday, January 31, 2018

Devices on FHIR (Cont'd)
PHD IG Ballot Comment Resolution
Q3

Attendees: to be completed..
On WebEx:

∨ Participants

Speaker: Jan Wittenber

- John G. (2) (me)
- JG — John Garguilo (Host)
- EM — Erik Moll
- Ana (Philips)
- A — Asim
- BA — Björn Andersen
- BR — Brian Reinhold
- J.-Uwe Meyer (MT2IT)
- JW — Jan Wittenber
- Ken Fuchs (Draeger)
- KM — Koichiro Matsumoto
- MR — Martin Rosner
- MT — masato tanaka
- MF — Michael Faughn
- SK — Stefan Karl

New: Muhammad Asim, Philips, Muhammad.asim@philips.com

Erik Moll (on-line) presented requested
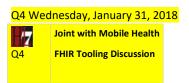
Discussion of solving issues one-by-one
Discussion of changing the FHIR spec (given maturity level 2) - reexamination of current specification.
Note: if targeting DTU Version 4
Discussion point: Merge Device Component with Device (get "production spec" in "Device")

PCHA Requested changes on HL7 FHIR resources
- Can Device and DeviceComponent be merged in the next FHIR release?
  - If a merge cannot be achieved, can UDI be added to DeviceComponent?
- Can there be an attribute in DeviceComponent and/or Device that can carry multiple device types?
  - E.g. DeviceComponent.type with 1..* multiplicity

- Question: would a mapping of the IEEE Metric objects to FHIR DeviceMetric resources be useful?

Production Spec + Properties proposal update to O&O - attempt to get clarification/change proposal to HCD on Thursday… then O&O
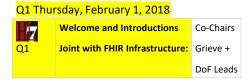
Q4 Wednesday, January 31, 2018

	Joint with Mobile Health
Q4	FHIR Tooling Discussion

Attendees: To be completed
On WebEx:

Participants

Speaker: John Garguilo (Host)

		John G. (2) (me)
JG		John Garguilo (Host)
A		Asim
BA		Björn Andersen
		J.-Uwe Meyer (MT2IT)
JW		Jan Wittenber
		Ken Fuchs (Draeger)
KM		Koichiro Matsumoto
MR		Martin Rosner
MT		masato tanaka
MF		Michael Faughn
PS		Paul Schluter
SK		Stefan Karl

Matthew Graham presented cMHAFF slide set (posted to website)

Michel Rutten demonstrated the process for
https://Registry.fhir.org
Simplifier.net - cloud in which registry is stored

Q1 Thursday, February 1, 2018

	Welcome and Introductions	Co-Chairs
Q1	Joint with FHIR Infrastructure:	Grieve +
		DoF Leads

Introductions and Agenda Review

- ► Joint Meeting with FHIR
- • John R. presented background and key discussion points for FHIR - (from lively discussion from yesterday)
- • Design goals for both device Classes

Design goals for both device classes

- • Full observation traceability to device and, where applicable, subsystem
- • Details of device state, in some cases potentially dynamic state, for devices and subsystems relevant for devices with communications capabilities, but not relevant for many other kinds of devices in FHIR use cases. Desirable to separate those from largely static information in Device resource. Provided for by DeviceComponent and DeviceMetric resources.
- • Simple access to information by implementers, as uniform as possible between the device classes

Personal Health Devices special concerns

Because of the relatively simplicity of the information offered by Personal Health Devices and a strong perceived imperative to minimize data complexity, code, and bandwidth:

- • PHD proposal was to omit use of Device resource. Implementers and and some PoCD participants objected that this would make accessing PHD data different than other device data. In particular, it seemed natural for PHDs to found by Device resource like other categories of devices.

Alternate PHD proposal discussed yesterday in HCD WG meeting

- • Asserts that two data items now in DeviceComponent, productionSpecification (carrying details like firmware and software versions) and properties (carrying IEEE 11073-20601 and Continua properties such as timekeeping and time accuracy capabilities of the PHD and its certification status) are all that is needed to add to the information already provided for in Device resource, allowing DeviceComponent and DeviceMetric to be omitted for PHD devices.
- • **Ask that these items be added to the definition of Device. Proponents strongly assert that doing this would be greatly preferable to them than to provide for them through extensions.**
- • Consensus of HCD members is that this would mitigate the concerns of those of impementers wanting all classes of devices to be not too dissimilar.

Grahame

What are plans for FHIR Connectathon in May (Cologne Meeting)? He also asked why no one participated in this (NOLA) meeting this time…

☐ Next Action Items on FHIR - A lot of work to do for FHIR Planning - TBD Wednesday 9:30 AM Eastern Call

Discussion (by Paul) on size/bandwidth - send a first message with the detailed information (in FHIR)

- ► NIST Tooling status and report out from IHE-PCD 2018 Connectathon held week of 15-19 January 2018

Note: Updated slide set provided by PHD (Martin Rosner) and uploaded to HL7 HCD "Documents" site.

Q2 Thursday, February 1, 2018

Q2	**FHIR Planning** **IGAMT & TCAMT**

- ► Updated Agenda to Add item from Jan Wittenber regarding an email exchange with Rebecca Poindexter

- Jan showed IHE-PCD-like document for Dialysis
- Need to again get Dialysis Group to add Ref_id (which at one point contained the MDC terms were stripped out)
- Start a little "mini-project" to get DIM hierarchy defined…

On Wed, Jan 31, 2018 at 12:25 PM, Poindexter, Rebecca <rebecca.l.poindexter@medtronic.com> wrote:
Notes from today:

Monique Washington (Monique.Washington@davita.com) is taking over from Eric Arther

Data objects spreadsheet finalized (included as part of HL7 guidance)

Received update from Patrick and Lorraine on HL7 guidance, whole team was going to review and return back with comments (Nov 1, 2017, see attached) – for manufacturers and providers. Nobody has completed this activity yet to date that we know of.
- *forward email to Monique - DONE

- Comments by end of February to Dan Rubery for companies to send out review comments

- Dan Rubery to combine for Patrick/Lorraine, 1 week to combine then send to ICode

- Dan to identify if there are any issues to bring back to the team BEFORE sending to Icode

- Dan to provide an example of treatment for HL7 using his device logs

- ICode to update doc then send final version with tracked changes to this team for final approval to proceed to HL7 committee

- When is the next submission to HL7? Monique to get this from Patrick/Lorraine, Monique to publish schedule w/ dates and ensure it aligns w/ the next HL7 meeting

- Monique to send reminders to keep us on track!

 IEEE – Eric and Jan and Terri were going to meet to add just the few remaining
- Monique to help continue this w/ Jan and Terri – start this next week

- Email follow-up to team to communicate update

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Q3 Thursday, February 1, 2018

Q3 **Carry-over DEV topics**
HL7 DEV General Planning
Adjourn

Motion to Adjourn: Moved: John Rhoads, Second: Paul Schluter; Result: Accepted
--Adjourn--

Q4 Thursday, February 1, 2018
No meeting