HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

NIST
Medical Device Communication Testing

Semantic interoperability of Medical Devices

Test Tool Update
Joint IEEE / HL7 May WG Meeting @ Madrid, Spain

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National Institute of Standards and Technology

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- ## Nicolas Crouzier(Contractor-Dakota) +
  ## (*Note: Ismail Mellouli (GR) term ended 30 April '17*)
  - RTMMS,
  - HL7 V2 Tools

- ## Michael Faughn, Jan Wittenber (Contractors - *Prometheus Computing, LLC w/* Art Griesser)
  - DIM Modeling + "DIM Editor/Medical Device Profiler"

- ❖ Note: As part of US Federal Government, all NIST work products are freely and publically available

- Work Area & Status Updates

- HL7 V2 IHE-PCD Tooling Status & Updates

- DIM Editor work updates, tool review, discussion topics

Conformance Tooling Suite

- *HL7 V2 (2.6) IHE-PCD Validation Tools*
  - IHE-PCD Pre-Connectathon: http://ihe-pcd-precon.nist.gov/
  - IHE-PCD Connectathon, http://ihe-pcd-con.nist.gov/
- Rosetta Terminology Mapping Management System (*RTMMS*) https://rtmms.nist.gov
- DIM Work - 'DIM Editor/Profiler' and ISO/IEEE 11073 UML Model
  - Development Tool: dim.prometheuscomputing.com
- NIST HL7 V2 Portal: http://hl7v2tools.nist.gov/portal/#/tools
  - IGAMT – Implementation Guide Authoring Management Tool
  - TCAMT – Test Case Authoring Management Tool

Conformance Tooling Portal

- IHE-PCD Pre-Connectathon, "Isolated Environment"
  http://ihe-pcd-precon.nist.gov/

- IHE-PCD Connectathon, "Instance Environment"
  http://ihe-pcd-con.nist.gov/

- Enhancements to Pre-Connectathon, Connectathon Tools
  to support IHE-PCD Cycle 11, now Cycle 12; mainly CPs

- *Key test events*
  - Supported IHE-Europe Connectathon (April 2016)
  - Supported IHE-Korea Connectathon (Aug 2016)
  - Supported IHE-Japan Connectathon (Sept 2016)
  - Supported IHE-North America Connectathon (Jan 2017)
  - IHE Europe – May 2017
  - (New) IHE Australia – August 2017 ?? (may be cancelled?)

- Cycle 12 underway - CP updates (as accepted) to be coded for
  2017-18 (mainly from IHE-PCD; 1 April 2017 – 31 March 2018)

- **143** existing User Accounts (as of 9 May 2017)
  - Contributing Orgs, SDO (leads/Co-chairs), Reviewers
  - In total since tool made publically available (2011)

Recorded or stored by NIST tool registered user

- Cycle 11: 14 Users, 95 Tests Executed/Stored
  - 13 Unique Companies
- Cycle 10: 17 Users, 124 Tests Executed/Stored
- Cycle 9: 17 Users, 106 Tests Executed/Stored
  - Recorded or stored by NIST tool registered user
- Cycle 8: 22 Users, 115 Tests Executed/Stored
- Cycle 1-7: 42 Users, 99 Tests Executed/Stored*

  *Cycles 1-7 not all test were stored in tool – 99 tests are primarily from cycle 7

- IHE-PCD: NIST "Isolated Environment" Test Tools
  - HL7 V2.6
  - Supports 8 Integration Profiles (number of test cases, some duplicated amongst actors)
    - DEC – Device Enterprise Communication (10)
      - SPD – Filter (4)
      - POI – Pulse Ox (3)
    - PIV – Patient Infusion Verification (9)
    - IPEC – Infusion Pump Event Communication (6)
    - IDCO – Implantable Device Cardiac Observation (4)
    - ACM – Alert Communication Management (2)
    - RDQ – Retrospective Data Query (1)
    - MEMDMC – Device Management Communication (1)
    - MEMLS – Location Services (1)
    - *OMS, RTLS/CMS, Security white papers/WGs*

- 64 Test Cases {31 Unique} (across all 'Actors')

Rosetta Terminology Mapping Management System (*RTMMS*)
ISO/IEEE 11073-10101

- RTMMS Deployment Update and service status
  - -10101b Work underway, 10101c (future TBD)
  - -10101a added + harmonized co-constraints (e.g., units, enums, body sites): **590** LOINC mappings to MDC terms!
  - IEEE Agreement to make available the "Works" (5 key nomenclature attributes)
  - Latest numbers…

- Many thanks to lead Paul Schluter, Principal Engineer, GE Healthcare! ☺

- https://rtmms.nist.gov

RTMMS by the numbers; 9 May 2017 (@Madrid WG Mtgs)

	Oct 2015	Jan 2016	May 2016	Sept 2016	Jan 2017	May 2017
Rosetta Terms	1642	1648	1731	1733	1763	1764
hRTM (Harmonized)	693	804	879	880	911	911
Groups	226	317	323	323	337	337
Unit Groups	8	8	12	12	12	12
Units (MDC)	515	524	547	551	552	552
Units (UCUM)	520	526	540	545	548	548
Enumeration Groups	39	43	43	43	43	43
Enumerations	317	317	403	403	436	436
Organizations Registered	61	65	70	71	78	91

Terms being or to-be vetted

("Term Approval" tab for 'SDO' user)

- "Proposed Terms": 186
- "Ready Terms Table":79
- "Mapped Terms": 79
- "Proposed Units": 188
- "Proposed Enumerations": 178

- ISO/IEEE 11073 '*Domain Information Model Editor*' -> "DIM Editor"
  - Progress/Update/Status (Michael Faughn)
  - UML Defined 11073-10201 DIM basis for tooling
  - Issues list (actively/weekly addressing and resolving)
    - » Tool continues to improve performance and usability
  - ❖ DIM Editor tool – Medical Device subject matter experts wanted!
  - Auto producing ISO/IEEE documentation (to meet SDO's templates)
    - No major hurdles – from IEEE and w/ document generation
    - Michael provided a sample – Kathryn B. circulated w/in IEEE and accepted
  - Continue weekly TCons (Thursdays @ 2 pm Eastern) – all welcome!

- ❖ Michael traveling (but working) through July 2017

http://hl7v2tools.nist.gov/portal/#/tools

- IGAMT – Implementation Guide Authoring Management Tool

- TCAMT – Test Case Authoring Management Tool
  - *Currently being used for MU domains (e.g., Lab, Immunization, Syndromic Surveillance)…*
  - *Development work underway on IHE-PCD HL7 V2 Messages:*
    - *PCD-01 (ORU^R01) + PCD-03 (RGV^R015)…*
  - *Initial Goal: Develop first version of IG for PCD-01 (TF Vol. II)*
    - *Focus on IHE-PCD TF Vol. II/III (+ IHE-PCD test cases in TCAMT)*
    - *Base device profiles*
  - *(?? On hold for first release) Contributing to CAsC 'Virtual Machine' (conformity Assessment ISO 17025)*
    - *TCAMT focus on relatively small number of CAsC Identified Test Cases (presently from IHE-PCD, cycle 10)*
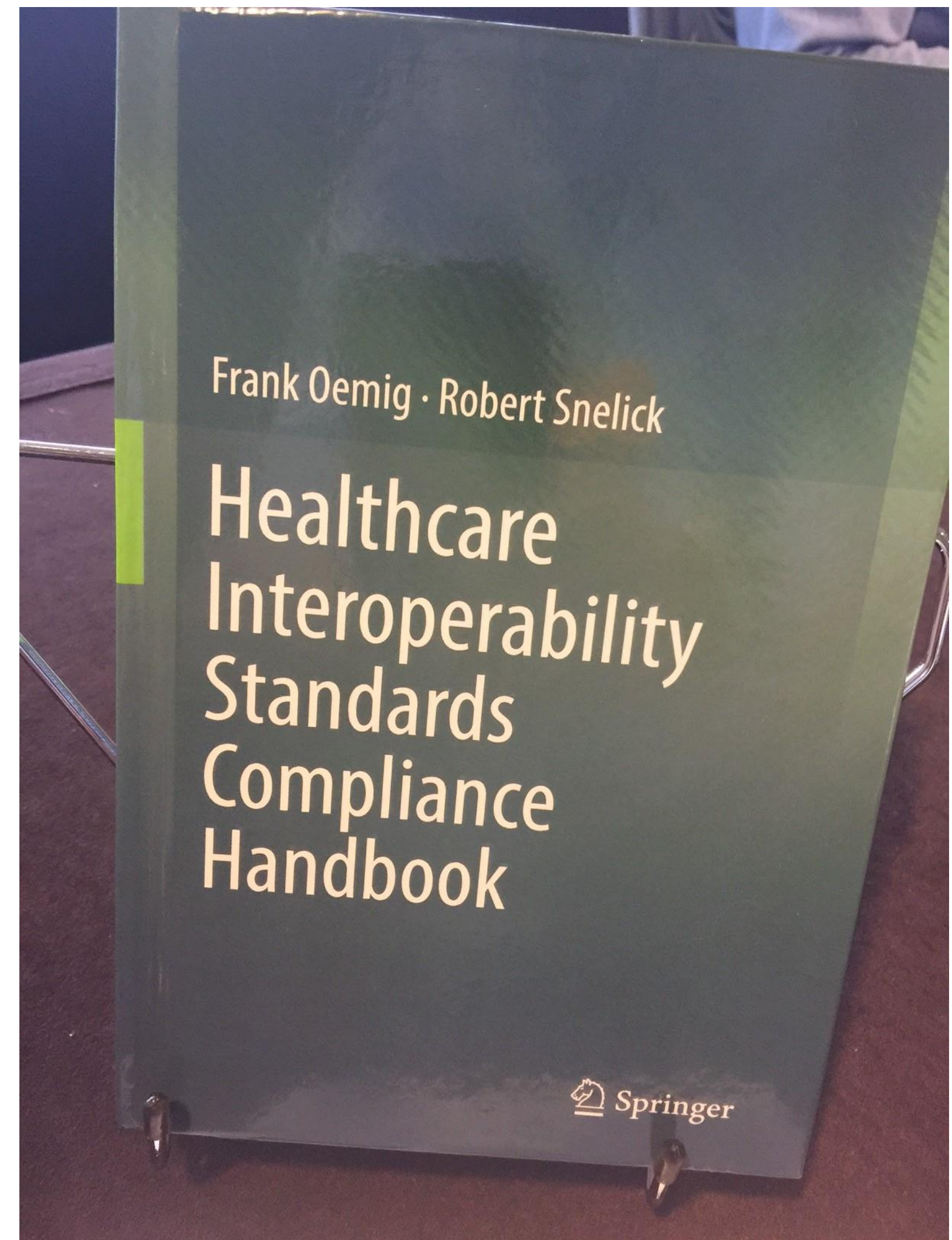 - *Begin producing IGs for device baseline profiles/specializations*

- Underlying 'Framework':
  HL7 profile→IGAMT→TCAMT→Tool
  - "Resource Bundle" generated to automatically update tool instance
  - *Developed initial version of PCD-01 (ORU^R01, ACK^R01) and PCD-03 (RGV^O15, ACK^O15)… additional constructs (e.g., support of "conditionals" such as OBX-2 [Value Type] and OBX-5 [Observation Value] in development)*
  - *Initial Goal: Develop first version of IG for PCD-01 (TF Vol. II)*
    - *Focus on IHE-PCD TF Vol. II/III*
    - *Continue to grow IGs for Volume IIIs (Device Specializations)*

- Underlying 'Framework': HL7 profile→IGAMT→TCAMT→Tool
  - Tool to create Implementation Guides and conformance profiles
  - Tool to create test plans, test cases, and associated test data
  - Testing Infrastructure and test framework to build testing tools
- Rethink "normal" approach
  - Requirements are captured with tools that internalize the requirements as <u>computable artifacts</u> (<u>*not as typically done*</u> – using natural language and subsequently interpreting the requirements to create test plans and test assertions)…
- Approach entry in tools (IGAMT + TCAMT) from a 'Quality' perspective by SME

- New Conformance Book released (Jan '17) by publisher
- Authors:
  - Rob Snelick (NIST)
  - Frank Oemig (HL7 – Germany)
  - CGIT HL7 WG co-chairs
- Available through Springer (order form at HL7.org or at Springer Web Site)

Yes!

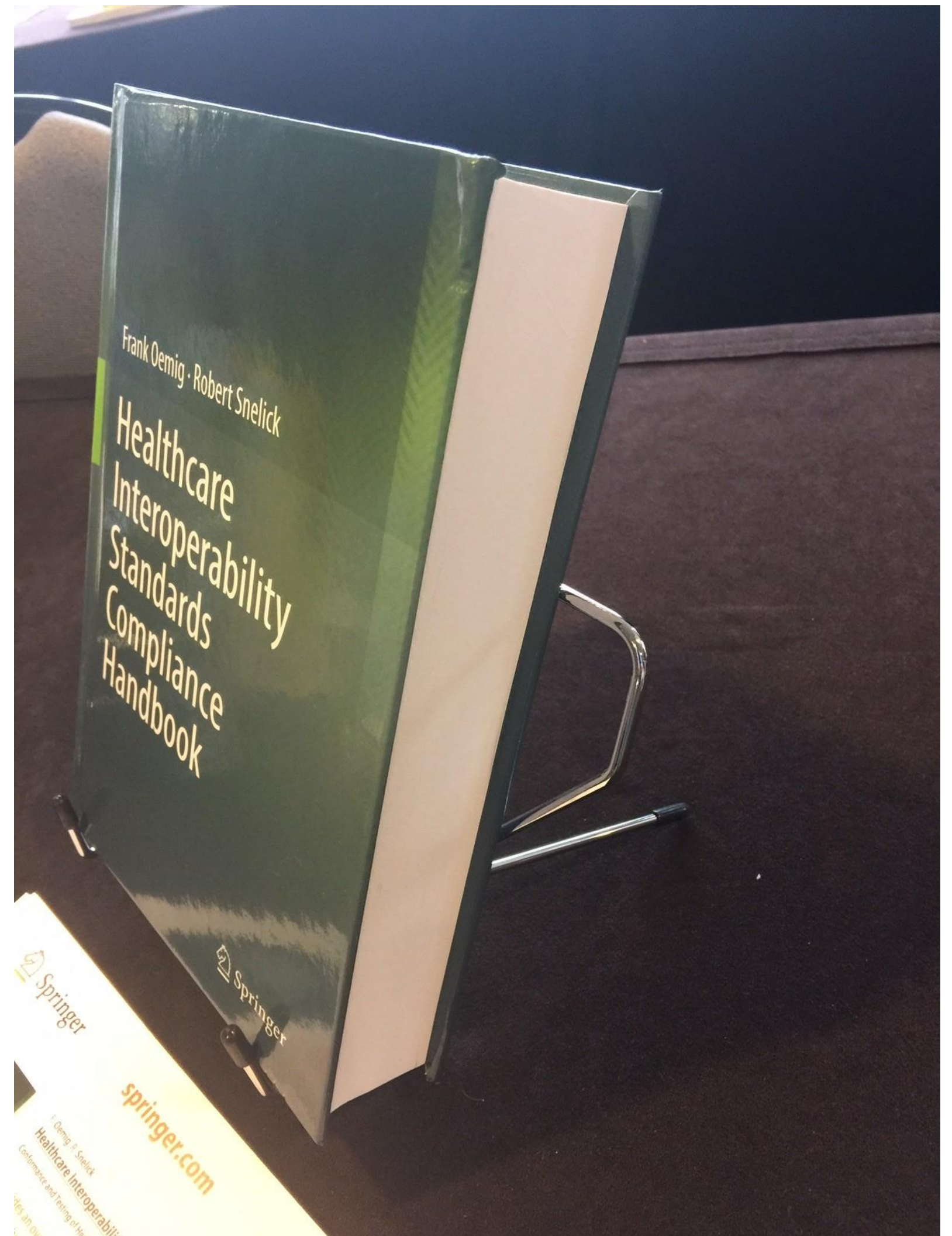Conformance ***IS Hard Work***

- ***700+ pages***
- ***~3 inches thick***
- ***Good educational source***
- ***HL7 (v2) focus***

Meetings + Activities: past, on-going and future

- Weekly "DPI" Meetings on Thursdays @ 2pm (w/ Jan Wittenber)
- ✓ Joint HL7 HCD / IEEE 11073 WG Mtgs., San Antonio, TX (Jan 2017)
- ✓ IHE North American Connectathon, Cleveland (23-27 Jan 2017)
  - NIST Connectathon Tool used for static validation
    - John G., Nicolas C., Ismail M., and Sandra Martinez serving as test monitors
    - John G. to participated ("Staff") in IHE's education series ("Connectathon 101")
      - presented session on how PCD tests…
    - NIST's IHE-PCD V2 Tool Tutorial
      (recorded fall 2015 for cycle 10 – on IHE wiki)
- ✓ HIMSS'17 – Orlando (Feb.2017)
- ~~NIST supporting IHE CaSC effort by providing PCD tooling~~
  - ~~Validation tooling to be part of CaSC "Virtual Machine"~~
- ✓ IHE-PCD F2F: Spring 2017 (San Diego @ Qualcomm)
  - Past Fall F2F, Boca Raton (Oct 2016)
- Joint HL7 HCD / IEEE 11073 WG Mtgs., Madrid, Spain (May 2017)

- IHE-PCD Cycle 12 (2017-18)
  - New HL7 V2 Tooling framework (same functionality and execution)
    - ➤ Generate tooling from resource bundle (files output from IGAMT and TCAMT)
  - Test Cases/demographics reviewed – used as basis for tooling 2017-18
  - CPs as introduced + requirements added into tooling
    (see PCD wiki: http://wiki.ihe.net/index.php?title=PCD_CP_grid)
  - Consider ACM WCTP validation service (from TF Vol 2)
  - Continue to support IHE (Inter-)National Test Events
  - Roadmap of activities updated… see PCD wiki

http://wiki.ihe.net/index.php?title=Patient_Care_Devices

RTMMS Technology Update
(Coming soon (??) – Early Summer '17)

- Updating tool (interface and dBase)

- 'AngularJS' for the front end (user interface).

- 'Node.js' for the backend and MongoDB for the NoSQL database.

Terminology Additions Continuing…

- 10101a (~240 terms) + co-constraints; 10101b near completion…

Informational Update

- MDC / LOINC mappings view (i.e., tab in interface)
  – 590… another ~150 mappings recently added as provided to NIST
  – Thanks to Dr. Swapna Abhyankar (Regenstrief)

- DIM Editor/Profiler 11073-10201

→ Finish implementation of r/w permissions in web application

→ Improve integration with RTMMS

→ Improve report new terms, etc.

→ Comprehensive audit of updated DIM model / application with respect to 11073:10201© 2004

→ Easier access to metadata and information from the DIM standard for device profile users

→ Deploy to NIST server (from Prometheus Computing)

→ Release Device Profiling app for general use

→ Conformance statements from the profile editor

→ Work with Open SDC (11073 Web Services) on similar tool

Key Goal:

→ Build library of template 'Device Specializations'

❖ See Michael Faughn's slides

- Devices on FHIR
- DoF Validation Service
  - Evaluating and researching FHIR validation services
  - Key goal: develop framework (similar to HL7 V2)

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Thank You or your attention ☺

- Questions
- Discussion