NIST

National Institute of Standards and Technology
Technology Administration, U.S. Department of Commerce

Helping the Cause of Medical Device Interoperability:
A standards-based testing approach based on identifying and obtaining testable assertions

VERSION (1.4) 09/28/2010

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Keywords

Conformance Testing; Interoperability; Health care Information Technology; Medical devices; Testable Assertions

Abstract

We present a black-box messaging test approach employed to achieve a level of rigor which improves, if not assures - given no optionality, correct data exchange. In particular, verifying that physiological information derived and communicated via messaging from a source medical device (e.g., an infusion pump) or healthcare information system, to another medical device (e.g., a patient monitor) or healthcare information system which consumes or make use of the data is syntactically and semantically correct. Our approach for developing a test system to validate messages is based on constraining identified and recognized specifications. The test system validation performed uses codified assertions derived from the specifications and constraints placed upon those specifications. To first show conformance which subsequently enables interoperability, these assertions, which are atomic requirements traceable by clause to the base specifications, are employed by our medical device test tools to rigorously enforce standards to facilitate safe and effective plug-and-play information exchange.

1 Introduction

At the U.S. Department of Commerce's (DoC) National Institute of Standards and Technology (NIST) researchers are collaborating with medical device experts to facilitate the development and adoption of standards for medical device communications throughout the healthcare enterprise as well as integrating it into the electronic health record. We have developed test tools[1] and a modeling application, including a corresponding electronic representation of an international standard's information model[2], which provides several important capabilities leading toward device interoperability[3].

Conformance testing is a key step leading to, although not guaranteeing, interoperability[4]. Sparked by involvement over the past several years of working with medical device domain experts and vendors who participate in Standards Development Organizations (SDOs) and use established standards such as *Health Level 7*[5] (HL7) and *ISO/IEEE 11073 Health informatics – Point-of-care medical device communication*[6] and *Personal health device communication*[7], an approach used to identify testable assertions derived from such standards and constrained by important use cases is presented.

The black-box messaging test approach addresses how we define and get to a level of rigor which improves, if not ultimately assures – given no optionality, correct data exchange. In particular, verifying that physiological information derived and communicated from a source medical device (e.g., an infusion pump) or healthcare information system, to another medical device (e.g., a patient monitor) or healthcare information system which consumes or makes use of the data is syntactically and semantically correct. In other words, the structure of information exchanged within the healthcare system is compliant to a defined specification(s) and the information meaning conveyed and interpreted by the consumer is exactly the same and as intended by the source.

The reality that medical devices need to communicate with tens, if not hundreds, of other devices of varying makes, models, and modalities has large market and substantial healthcare implications. Acute point-of-care settings such as a hospital's intensive care unit, a patient's bedside, or personal telehealth location require each class of medical device to use the same terminology and data organization to seamlessly and reliably communicate physiological data. Healthcare communication standards that address plug-and-play medical device interoperability are critical. While providing the groundwork to enable device communication, standards are developed in an open ended manner (and for good reason). It is our contention, through experience in software testing, that only until standards and defined specifications are constrained (ultimately removing all optionality to create *profiles*) that the desired "guarantee" of syntactic and semantic correctness can be achieved.

Conformance test methodologies are being employed by NIST via software test tools to help get closer to that "guarantee". These tools are publicly available and being used by the medical device industry to ensure that critical devices correctly implement the medical device standards. A consortium of medical device vendors using these test methodologies to successfully meet a level of compliance to standards sufficient to achieve truly efficient interoperability is the Integrating the Healthcare Enterprise – Patient Care Device (IHE-PCD) domain[8]. Correct implementation of standards lead to effective exchange of critical physiologic data derived from the patient at the device and exchanged throughout the healthcare enterprise. As more and more devices are able to achieve "plug-and-play" capabilities, clinicians are empowered to focus more on the patient and less on the devices. The ability to reliably and effectively integrate data from a

broad range of point-of-care devices will ultimately lead to a reduction in medical errors and the associated loss of life.

2   Background

2.1   Medical Device Communication Standard

The ISO/IEEE 11073 Health Informatics – Point of Care and Personal Health Medical Device Communication standards (x73) defines a set of information objects and functions needed for medical device communication. Such a family of standards was developed to address the critical need of enabling medical devices to share physiologic data between devices and computerized healthcare information systems. Two primary parts of these standards used in our approach pertain to the *Domain Information Models* (DIM)[9,10] and *Nomenclature[11]*. The DIM provides the objects and object relationships necessary to abstractly define a device (see Section 4.2 discussion regarding device containment hierarchy). It defines the overall set of information objects as well as the attributes, methods, and access functions which are abstractions of real-world entities in the domain of medical devices and device communication. Nomenclature defines terminology and codes used across classes of medical devices.

2.2   IHE-PCD Integration Profiles, Technical Frameworks, and Integration Statements

IHE-PCD participant vendors define 'use cases' in which at least one 'actor' is a regulated Patient Care Device. IHE *Integration Profiles* are defined and provide the necessary detail to enable demonstration, through implementation (i.e., specific implementations of established standards to achieve integration goals), of important use cases. The IHE-PCD Integration Profiles, defined in IHE-PCD *Technical Framework* documents[12], organize and leverage the integration capabilities that can be achieved by coordinated implementation of communication standards such as HL7 and x73. They provide precise definitions of how standards are constrained and may be implemented to meet specific clinical needs[13].

Based on these specifications which constrain the reference standards, the IHE conducts cyclical interoperability testing events; NIST test tools are used in the IHE-PCD domain to evaluate conformance to the specified Integration Profiles and executed test cases. If successful, industry participants publish IHE '*Integration Statements*' to indicate their system's conformance which can be useful for medical device procurers during their evaluation.

Currently within the IHE-PCD participants are actively working on several Integration Profiles[14] including **Device Enterprise Communication** (DEC) with options to **Patient Identity Binding** (PIB) and **Subscribe to Patient Data** (SPD) which provides a subscription/data filtering mechanism; **Alarm Communication Management** (ACM); **Point-of-care Infusion Verification** (PIV) addressing infusion safety issues such as "five rights of Medication Safety"[15]; **Implantable Device Cardiac Observation** (IDCO); and **Rosetta Terminology Mapping** (RTM) which provides a mapping between proprietary device semantics to the x73 nomenclature and associated co-constraints (e.g., associated reference identifier, terminology code, unit(s) of measurement, lead sites where measurements may be taken, and enumerations).

2.3   The Need for Conformance Test Tools

Conformance and interoperability testing of medical device data communication is essential leading to long term value propositions which include:
- Integrity of data – automatic population of all information systems – reducing medical errors
- Automating systems to capture clinical data into Electronic Health Records (EHRs) thus saving time for clinicians

- Access to patient data across devices and systems so custom communication interfaces can be eliminated thus allowing for best of breed and even plug-and-play devices
- Improving agility of enterprises to meet varied patient loads
- Improving life-cycle cost of ownership

To address real-world semantic interoperability the transfer of data must be (in many cases) near real-time data from a gateway to an Electronic Medical Records (EMR) system in a rich, accurate, and consistent manner. To first show conformance which subsequently enables such interoperability, test tools that rigorously enforce defined specifications to facilitate safe and effective plug-and play interoperability are necessary.

3 Our Approach: Constraining Specifications To Derive Testable Assertions

Our approach for developing a test system to validate messages is based on constraining identified specifications. The validation is defined by assertions derived from the specifications and constraints placed upon the specifications. The premise at getting to any level of rigor is that specifications are complete (as possible) and constrain open ended assertions. The more well-formed, formal, and complete the specifications the greater level of rigor can be achieved by the test system.
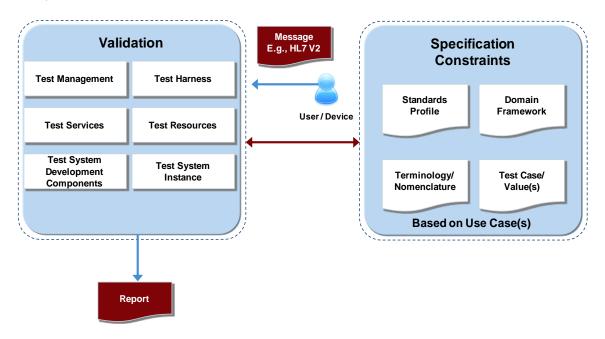

Figure 1: Constraining Specifications to Enable Rigorous Testing

Figure 1 shows the specifications used by our test tooling to address message validation in the IHE-PCD domain environment. Messages being exchanged contain physiologic observations. The messages (i.e., defined using HL7 version 2) are tested against the specifications which define the standards used, any domain specific specifications, terminology and nomenclature employed and any specific values or value sets being conveyed as identified in test cases.

It is unrealistic to assume all standards and specifications are correct or mature to a level of 'complete'. However as specifications are implemented and a collaborative, iterative, feedback process occurs - so too can the rigor-level and coverage provided by the test tools via updates,

enhancements and issue resolution. Should we consider different enterprise-level testing outside of IHE, other specifications as made available by the domain could be integrated in a similar manner into the test tooling.

Based on the specifications and any constraints identified in those specifications, messages are validated by the test system which employs various test components. For example, an HL7 message derived from an infusion pump (or generated from the pump system or gateway) is evaluated against the HL7 standard for its syntax and semantics, the x73 standard for terminology, terminology co-constraints, and information model (i.e., the device object hierarchy), and the test case for any specific values or attributes.

4   Specification Ingredients Employed In Our Testing Approach

The recipe for correctly effecting validation of messages in our approach calls for specification ingredients as shown in Figure 2. Given the IHE-PCD domain and integration goals, these specifications include the HL7 Version 2 standard for message definition and value sets, the x73 standard for medical device nomenclature, the IHE-PCD Technical Framework documents for message transaction definition, and the IHE-PCD test cases for specific value definition.

These specifications define and lead to what we call "testable assertions", which are atomic test requirements traceable to the aforementioned specifications. Identified test assertions are codified into "context validation" files. Context validation files are defined in XML and provide the precise assertions that the test system uses as input to a validation engine which performs the validation service (and in the future, other services such as message generation). Each testable assertion references the specific clause in the base specification, or ingredient of our recipe. Test reports are generated by the test tool identifying the specific error within the message along with a reference to the clause from which the assertion is based.
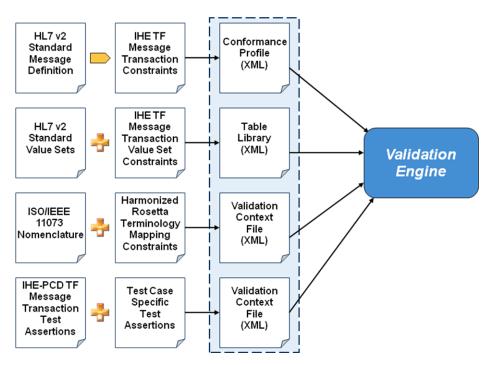

Figure 2: Origin of Test Assertions

4.1 HL7 Standard, Value Sets, and IHE Technical Framework Assertions

Validation of the device information carried within the HL7 messages occurs at both the syntactic and (low-level) semantic levels. Messages are validated against defined value sets and what we refer to as "failure types". The test tool uses validation context files codified in XML (see Figure 2) to perform message validation checks against the HL7 V2 standard, value set tables, and any further constraints defined by IHE-PCD with the Technical Framework documents (e.g., "local" value sets not defined in HL7) for message transactions. Validation of failure types include:

- **VERSION** (e.g., the HL7 version and IHE-PCD Technical Framework Integration Profile)
- **MESSAGE_STRUCTURE_ID** (e.g., the HL7 message type [MSH.9 element] defined in the profile shall match what's in the message)
- **MESSAGE_STRUCTURE** (e.g., the message shall have a valid HL7 message structure - including correct usage, correct cardinality, and correct element name)
- **USAGE** (e.g., HL7 'R' elements should be present; 'X' elements should not be present in the message)
- **CARDINALITY** (e.g., elements shall be present at least the minimum times and at most the maximum times specified in the conformance profile)
- **LENGTH** (e.g., the value of the element shall have a length equal or less than the value specified in the profile)
- **DATATYPE** (e.g., for the HL7 data types 'NM', 'DT', 'DTM', 'SI' and 'TM', the value of the element shall match the regular expression defined in the standard)
- **DATA** (e.g., the value of the element shall match a constant specified in the profile, a value set specified in a table, or a value or a regular expression specified in the message validation context [derived from a test case])
- **TABLE_NOT_FOUND** (e.g., an error when a referenced table can't be found in the table files HL7 or local defined set of allowable tables)

The above attributes defined in HL7 are often referred to as 'HL7 Conformance Profiles'. 'HL7 Conformance Profiles' are produced using third party software and define the constraints desired when implementing HL7 messages. 'HL7 Conformance Profiles' may be used as input into the test tools and become testable assertions enforced by the validation engine.

4.2 Common Medical Device Information Model and Nomenclature Assertions

In considering and developing our test approach one of the overarching goals is to achieve semantic interoperability – communicate medical device data using a single unified nomenclature and semantic model that can be rigorously defined and enforced to facilitate safe and effective plug-and play interoperability.

This is where the aforementioned x73 Domain Information Model and Nomenclature are an essential ingredient. Today, nearly all vendors have an internal (and often proprietary) representation of device and corresponding device generated information. Vendors can correctly and consistently map information that has been generated, either by the same or another device make or model or system, by applying a common model and nomenclature based on recognized standards. Furthermore from a black-box testing perspective in which medical device observations are exchanged via messaging, rigorous validation can be applied using those very same standards which are constrained via profiles by communicating entities. Profiles may include 'device profiles' as defined in x73 (x73-103xx[16] series of device specializations for point-of-care health devices - such as an infusion pump or ventilator or x73-104yy[17,18,19,20,21,22,23,24,25] series of device specializations for personal health devices - such as a weight scale or pulse oximeter) or 'Integration Profiles' as defined by the IHE-PCD domain.

One of the IHE-PCD domain Integration Profiles, *Rosetta Terminology Mapping*, identifies the nomenclature and provides a 'containment hierarchy' to abstractly represent medical devices as defined in the x73 standard. This Integration Profile provides the testable assertions of device information carried within the observation segments (i.e., HL7 Version 2 "OBX segments"). These constraints or test assertions lead to test validation context files as depicted in Figure 2 and provide traceability to the x73 standard's nomenclature and information model.

4.3 IHE-PCD Transaction and Test Case Defined Assertions

IHE-PCD domain defines the technical framework documents and test cases (see Figure 2) in which vendors are evaluated against. The framework documents define and constrain (at the HL7 usage level) 'transactions' (i.e., HL7 messages). IHE-PCD defined Test cases identify specific values required in vendor implementations and demonstrated during the test event(s). The corresponding validation context information contained in the test cases is codified in XML as testable assertions.

5 Advancing the Approach

The presented test approach of validating static messages by constraining specifications is foundational. However, there is much work to be done to achieve greater levels of rigor. Test tool enhancements are forthcoming to advance functionality from a static message checker over what we refer to as in an "instance test environment", which essentially evaluates message against the specification(s) from which the message is based (e.g., conformance testing an HL7 V2 message) to an "isolated system test environment". Ultimately we strive to provide a test infrastructure providing a "peer-to-peer environment"[26].

Isolated system type testing involves real scenarios in which transactions exchanged as well as *behavior* exhibited by the system under test (SUT) are evaluated by the test system. Typically this involves a meaningful scenario in which transaction exchange occurs between the SUT and test system, thus isolating the SUT. Protocol conformance and functional behavior (including features and operation) are evaluated by the test system according to identified specifications. For example, each step within a scenario may involve one or more messages transmitted to/from the SUT to/from the test system. The test system views the SUT as a black box, evaluating transactions and behavior (i.e., expected syntax and semantic content).

Peer-to-peer system testing involves multiple (two or more) SUTs interacting, with the test system involved as a proxy. In addition to the functionality of isolated system testing, peer-to-peer includes the complete application environment to achieve interoperability testing. Peer-to-peer test environment may include interacting with many services including a database, network communication, other hardware, applications or systems as appropriate.

Another software application[27,28,29] we developed at NIST allows users to define medical device profiles in strict accordance to the x73 standard. The resultant XML file provides abstract representations of real devices defined using x73 nomenclature and with an x73 DIM containment hierarchy. Using the application's interface a user can define and constrain the device abstract representation to a particular class of device and furthermore to the specific make and model. We are considering approaches to integrate this device representation with the message validation test tools. Such integration would enable validation of specific device classes for each IHE-PCD use case that is appropriate for that device class. Conformance testing device classes, makes, and models is important as devices exhibit variant behavior, even if when applied to the same test case (within a use case, Integration Profile, or scenario).

In related efforts NIST has developed validation tooling being used in several other domains (including the Health and Human Services' National Health Information Network, the IHE IT Infrastructure domain[30] Cross Enterprise Document Sharing [XDS][31], Patient Identifier Cross Referencing [PIX][32], and Patient Demographics Query [PDQ][33]).

Developing our initial set of test tools has been enhanced through our involvement with industry consortium. As active participants in IHE, standards development organizations and other consortium, NIST researchers have gained invaluable insight into the needs and issues of medical device vendors, clinicians, clinical engineers, and in general the healthcare community. We continue to focus our attention on open consensus forums and processes based on open consensus standards. We are actively monitoring other related work[34],[35] and efforts using related medical device standards[36], focused on critical issues such as patient safety and device risk analysis. We believe our approach offers benefits to most of these efforts, if not all. As we continue to build upon and enhance the test tooling, the likely hood of interoperability increases. It is our hope that "as we build it, they will come…"

[1] "NIST HL7 V2 Tools – IHE-PCD Connectathon 2011 Test Tool", website: http://xreg2.nist.gov:8080/PCD-HL7WebCon/, (accessed September 2010).

[2] "ISO/IEEE 11073-P10202 Health informatics – Point-of-care medical device communication – Part 10202: Nomenclature XML Schema" (Institute of Electrical and Electronics Engineers Standards Association, Manager, Standards Intellectual Property, 444 Hoes Lane, Piscataway, NJ 08854, E-mail: stds.ipr@ieee.org, web: www.ieee.org.

[3] "NIST Medical Device Testing Project", website: http://xw2k.nist.gov/medicaldevices/index.html, (accessed September 2010).

[4] "Conformance Testing and Interoperability: A Case Study in Healthcare Data Exchange". L. Gebase, R. Snelick, M. Skall. Published in the 2008 Software Engineering Research and Practice (SERP08) conference proceedings (Editor: H.R. Arabnia), WORLDCOMP'08 July 14-17, 2008, Las Vegas, Nevada, pp143-149.

[5] Health Level Seven International Website, www.hl7.org, accessed September 2010.

[6] "ISO/IEEE 11073 Health informatics – Point-of-care medical device communication" – (family of standards) Institute of Electrical and Electronics Engineers Standards Association, Manager, Standards Intellectual Property, 444 Hoes Lane, Piscataway, NJ 08854, E-mail: stds.ipr@ieee.org, web: www.ieee.org.

[7] "ISO/IEEE 11073 Health informatics – Personal Health medical device communication" – (family of standards) Institute of Electrical and Electronics Engineers Standards Association, Manager, Standards Intellectual Property, 444 Hoes Lane, Piscataway, NJ 08854, E-mail: stds.ipr@ieee.org, web: www.ieee.org.

[8] "Integrating the Healthcare Enterprise", websites: http://www.ihe.net/pcd/index.cfm, http://wiki.ihe.net/index.php?title=PCD, (accessed September 2010).

[9] "ISO/IEEE 11073-10201 Health informatics – Point-of-care medical device communication – Part 10201: Domain information model" (Institute of Electrical and Electronics Engineers Standards Association, Manager, Standards Intellectual Property, 444 Hoes Lane, Piscataway, NJ 08854, E-mail: stds.ipr@ieee.org, web: www.ieee.org.

[10] "ISO/IEEE P11073-20601 Draft Standard for Health informatics – Personal health device communication – Application profile – Optimized exchange protocol", 2008, Institute of Electrical and Electronics Engineers Standards Association, Manager, Standards Intellectual Property, 444 Hoes Lane, Piscataway, NJ 08854, E-mail: stds.ipr@ieee.org, web: www.ieee.org.

[11] "ISO/IEEE 11073-10101 Health informatics – Point-of-care medical device communication – Part 10101: Nomenclature", Institute of Electrical and Electronics Engineers Standards Association, Manager, Standards Intellectual Property, 444 Hoes Lane, Piscataway, NJ 08854, E-mail: stds.ipr@ieee.org, web: www.ieee.org.

[12] "IHE-Patient Care Devices Technical Framework", 2009-2010, Revision 1.1 Trial Implementation, website http://www.ihe.net/Technical_Framework/index.cfm#pcd, (accessed September 2010).

[13] "Integrating the Healthcare Enterprise-Patient Care Domain IHE Profiles", websites: http://www.ihe.net, and http://www.ihe.net/profiles/index.cfm, (accessed September 2010).

[14] "IHE Patient Care Device Domain, IHE PCD Profiles", website http://www.ihe.net/pcd/index.cfm, (accessed September 2010).

[15] Suite101.com, *Five Rights of Medication Safety, Avoid Serious Errors by Observing These Tips*, December 9. 2007, website: http://www.suite101.com/content/five-rights-of-medication-safety-a37494, accessed September 2010.

[16] MDCIG/IEEE-ISTO IEE 1073 – Baseline Profile Demonstration Project, Messaging Specification Document, Version 1..14, Annex A, pages 161-166, February 20, 200, Institute of Electrical and Electronics Engineers Standards Association, Manager, Standards Intellectual Property, 444 Hoes Lane, Piscataway, NJ 08854, E-mail: stds.ipr@ieee.org, web: www.ieee.org.

[17] *ISO/IEEE P11073-20601 Draft Standard for Health informatics – Personal health device communication – Application profile – Optimized exchange protocol*, 2008, Institute of Electrical and Electronics Engineers Standards Association, Manager, Standards Intellectual Property, 444 Hoes Lane, Piscataway, NJ 08854, E-mail: stds.ipr@ieee.org, web: www.ieee.org.

[18] *ISO/IEEE P11073-10404 Draft Standard for Health informatics – Personal health device communication – Device Specialization – Pulse Oximeter*, 2008 Institute of Electrical and Electronics Engineers Standards Association, Manager, Standards Intellectual Property, 444 Hoes Lane, Piscataway, NJ 08854, E-mail: stds.ipr@ieee.org, web: www.ieee.org.

[19] *ISO/IEEE P11073-10407 Draft Standard for Health informatics – Personal health device communication – Device Specialization – Blood pressure monitor*, 2008, Institute of Electrical and Electronics Engineers Standards Association, Manager, Standards Intellectual Property, 444 Hoes Lane, Piscataway, NJ 08854, E-mail: stds.ipr@ieee.org, web: www.ieee.org.

[20] *ISO/IEEE P11073-10408 Draft Standard for Health informatics – Personal health device communication – Device Specialization – Thermometer*, 2008, Institute of Electrical and Electronics Engineers Standards Association, Manager, Standards Intellectual Property, 444 Hoes Lane, Piscataway, NJ 08854, E-mail: stds.ipr@ieee.org, web: www.ieee.org.

[21] *ISO/IEEE P11073-10415 Draft Standard for Health informatics – Personal health device communication – Device Specialization – Weighing scale*, 2008, Institute of Electrical and Electronics Engineers Standards Association, Manager, Standards Intellectual Property, 444 Hoes Lane, Piscataway, NJ 08854, E-mail: stds.ipr@ieee.org, web: www.ieee.org.

[22] *ISO/IEEE P11073-10417 Draft Standard for Health informatics – Personal health device communication – Device Specialization – Glucose*, 2008, Institute of Electrical and Electronics Engineers Standards Association, Manager, Standards Intellectual Property, 444 Hoes Lane, Piscataway, NJ 08854, E-mail: stds.ipr@ieee.org, web: www.ieee.org.

[23] *ISO/IEEE P11073-10441 Draft Standard for Health informatics – Personal health device communication – Device Specialization – Cardiovascular Fitness*, 2008, Institute of Electrical and Electronics Engineers Standards Association, Manager, Standards Intellectual Property, 444 Hoes Lane, Piscataway, NJ 08854, E-mail: stds.ipr@ieee.org, web: www.ieee.org.

[24] *ISO/IEEE P11073-10442 Draft Standard for Health informatics – Personal health device communication – Device Specialization – Strength Fitness*, 2008, Institute of Electrical and Electronics Engineers Standards Association, Manager, Standards Intellectual Property, 444 Hoes Lane, Piscataway, NJ 08854, E-mail: stds.ipr@ieee.org, web: www.ieee.org.

[25] *ISO/IEEE P11073-10471 Draft Standard for Health informatics – Personal health device communication – Device Specialization – Independent living activity hub*, 2008, Institute of Electrical and Electronics Engineers Standards Association, Manager, Standards Intellectual Property, 444 Hoes Lane, Piscataway, NJ 08854, E-mail: stds.ipr@ieee.org, web: www.ieee.org.

[26] *Testing Environments for Assessing Conformance and Interoperability,* R. Snelick, L. Gebase. Published in the 2010 Software Engineering Research and Practice (SERP10) conference proceedings (Editors: H.R. Arabnia, H. Reza, L. Deligiannidis), WORLDCOMP'10 July 12-15, 2010, Las Vegas, Nevada, pp219-225.

[27] *Medical Device Communication: A Standards-based Conformance Testing Approach*, John J. Garguilo, Sandra Martinez, and Maria Cherkaoui. Published in the 9th International HL7 Interoperability Conference 2008 Proceedings, (Editor: Euroline Congress) IHIC 2008, October 8-11, 2008, Crete, Greece, pages 170-173.

[28] *Moving Toward Semantic Interoperability of Medical Devices,* J. Garguilo, S. Martinez, R. Rivello, and M. Cherkaoui. Published in the 2007 Joint Workshop on Hi-Confidence Medical Devices, Software, and Systems / Medical Devices Plug-and-Play Interoperability conference proceedings - Interoperability Challenges (Editor: S. Kawada), HCMDSS/MD PnP 2007, June 25-27, 2007, Cambridge, Massachusetts, pages 13-19.

[29] "NIST Medical Device Communication Testing Project, Test Tools, ICSGenerator", website: http://xw2k.nist.gov/medicaldevices/testtools.html, (accessed September 2010).

[30] "IHE Information Technology Infrastructure Domain", website: http://www.ihe.net/IT_infra/committees/index.cfm

[31] "NIST XDS Public Registry Test Facility", website: http://ihexds.nist.gov/, (accessed September 2010).

[32] "NIST HL7 V2 Testing Toolkit" Web Site: http://hl7v2tools.nist.gov/, (accessed September 2010)

[33] "NIST HL7 V2 Testing Toolkit" Web Site: http://hl7v2tools.nist.gov/, (accessed September 2010)

[34] "CIMIT: Center for Integration of Medicine and Innovative Technology", website: http://www.cimit.org/, (accessed September 2010).

[35] "IHE ICE-PCD (Integrated Clinical Environment – Patient Care Device) Analysis Committee", website: http://wiki.ihe.net/index.php?title=IHE_PCD_ICE-PCD_Analysis_Committee, (accessed September 2010).

[36] ASTM 2761-2009 Medical Devices and Medical Systems – Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) – Part 1: General requirements and conceptual model.