Frank Oemig · Robert Snelick

Healthcare Interoperability Standards Compliance Handbook

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Conformance and Testing of Healthcare Data Exchange Standards

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Frank Oemig
Deutsche Telekom Healthcare
and Security Solutions GmbH
Mülheim
Germany

Robert Snelick
National Institute of Standards
and Technology (NIST)
Gaithersburg, MD
USA

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Foreword

Interoperability is essential for information to flow freely, accurately, efficiently, and securely between health information technology (HIT) systems and across healthcare networks—systems and networks that support hospitals and clinicians in the delivery of patient care. This information flow can enable the healthcare industry to achieve its goals related to preventive care, population health management, cost-effectiveness, and, that particularly elusive factor, patient safety.

Actually achieving interoperability through use of HIT has been compared, as far as the difficulty involved and the likelihood of it happening, to traveling to another planet; however, the initial building blocks needed for successfully realizing the information flow envisioned with true interoperability are identifiable today, including well-designed and clearly articulated data exchange standards and the test tools that evaluate conformance of HIT systems to those standards.

In *Healthcare Interoperability Standards Compliance Handbook: Conformance and Testing of Healthcare Data Exchange Standards*, Mr. Oemig and Mr. Snelick explain the challenges, methodologies, and mechanisms related to developing the standards and measuring the conformance of HIT systems. Having been co-chairs of the *HL7 Conformance and Guidance for Implementation/Testing Working Group* for numerous years, these authors are able to impart knowledge gleaned from real-world experience in development of conformance tools as well as from detailed discussions with clinical informatics experts in development of official standards that are in use today. With their in-depth understanding and their international perspective about the subject matter, the authors convey valuable information about the different families of data exchange standards—HL7 version 2.x, HL7 V3, and others—and about the need for an underlying system architecture and standards that provide the foundation for electronic communication of healthcare data at the national level in various countries and that also are flexible enough to allow for local adaptations and enhancements.

The format of interoperability standards documents themselves does not provide the means to disclose the details of the discussions that occur among the standards developers. In this book, however, the authors are able to give the readers insight

into the topics that are discussed as well as how the conclusions included in the standards were reached.

Using the basic interoperability guidelines, the foundation for which is provided in this book, the readers should be able to participate actively in efforts toward achieving the goals of compatible and interoperable implementations when applying the standards that are discussed herein. Furthermore, as the various concepts described are independent of these standards, the interoperability guidelines can be utilized with standards other than the ones highlighted in this text.

By providing this book as a source of up-to-date information about conformance testing and the development of testable data exchange standards, the authors are facilitating the healthcare industry's progress toward achieving HIT interoperability and reaching the goal of safer and more cost-effective patient care.

Gaithersburg, Maryland, USA

Sheryl L. Taylor, BSN, RN
IT Specialist, NIST

Preface

This book is organized into three parts. Part I, *Healthcare Information Technology*, outlines the motivation for writing the book, the background for the discussions, and the foundation upon which the subsequent parts of the book are based, and establishes the context for descriptions of the included conformance, interoperability, and testing concepts. Chapter 1, *Introduction*, gives an overview of the concepts, the targeted issues, and how the concepts are interrelated. This chapter describes a complete conformance testing process lifecycle from the development of standards to the certification of products. Chapter 2, *Architecture*, describes common architectures for distributed healthcare systems. The remaining concepts of the book are discussed against the backdrop of this context. Chapter 3, *Healthcare Data Exchange Landscape,* provides an overview of the Standards Development Organizations (SDO) and Standards Profiling Enforcement Organizations (PEO). In general, SDOs create the standards and PEOs apply the standards to address various workflows. Chapter 4, *Healthcare Data Exchange Standards*, provides a survey of the most relevant standards in use for healthcare data exchange today, while giving the reader a perspective on the standards-related technologies that are available along with the means to compare and contrast them at a high level. To explain the various data exchange concepts, case studies using specific standards are presented extensively throughout this book. Although any standard could have been used in the case studies, the HL7 v2.x standard is used for the most part since it is the most widely deployed standard, and the authors have extensive experience with it.

Part II, *Conformance*, focuses on the definition and explanation of conformance concepts and techniques for unambiguously specifying requirements, including applying the concepts of profiling. In the opinion of the authors, the lack of quality standard specifications is the biggest impediment to achieving interoperability among healthcare information systems. We encourage all standards developers to employ the concepts presented in Part II. Chapter 5, *Conformance Constructs*, provides a detailed explanation of conformance concepts that are applicable in a standard-agnostic manner to most standard specifications. This explanation sets the foundation for much of the discussion in later chapters, and the reader's

understanding of the information provided in this chapter is essential. Chapter 6, *Principles of Specifying Conformance*, describes how specifications should state requirements (conformance) in a general sense. This discussion includes the necessary conformance components and what they mean. A list of principles is given with explicit examples. Chapter 7, *Principles of Effective Profiling*, introduces the concept of profiling and how to use profiles effectively for managing standard specifications and for developing implementations. Chapter 8, *Profile Relationships*, gives an in-depth analysis of how profiles relate to each other in multiple dimensions (e.g., profile hierarchy and sender/receiver perspectives). A set of rules for creating and determining profile compliance and compatibility is given. Chapter 9, *Tools for Conformance Profiling*, provides a survey of the tools that help in effective application of the profiling mechanisms.

Part III, *Testing and Tools*, focuses on the concepts and techniques of conformance and interoperability testing. Principles of testing are discussed along with application of those principles via testing models, frameworks, architecture, tools, and testing programs. Parts I and II laid the foundation for a clear understanding of what conformance means, why it is necessary, and its benefits. Given that information as the background, how does anyone verify that implementers and users are applying the concepts appropriately in practice? *Testing and Tools* examines this topic by exploring the process, strategy, assessment, and instantiation of conformance and interoperability testing. A foundational chapter, Chap. 10, *Testing Models*, begins this part of the book by defining, in an abstract manner, the various testing models and describing the types of testing that can be performed within the models. Chapter 11, *Principles of Conformance Testing*, explains how to conduct conformance testing, including the creation and execution of test plans. Various types of conformance testing are examined. Chapter 12, *Conformity Assessment*, presents the assessment tables and interpretation of conformance for the conformance constructs presented in Chap. 5. The assessments provide the requirements for building validation tools to evaluate conformance. Through use of concrete examples, Chap. 13, *Testing Architectures*, provides a realization of the concepts and methodologies described in Chaps. 10 and 11. This realization includes a description of a testing infrastructure, testing framework, and an interoperability test bed. Case studies are provided to emphasize the utility of the modular approach. Chapter 14 builds upon this theme by providing a sampling of test tools created from the ideas (framework) explained in Chap. 13. Finally, Chap. 15 describes how testing programs operate and how they utilize the testing tools. An overview is given of the most prevalent testing and certification programs, such as the IHE Connect-a-thon and the ONC Health IT Certification Program that supports the CMS EHR Meaningful Use Programs.

Finally, Appendix, *Additional Healthcare Data Exchange Standards*, provides additional background information about some of the data exchange standards that are in use worldwide.

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Certain commercial products or materials are identified in this book in order to explain a concept or to provide realistic examples adequately. Such identification is not intended to imply recommendation or endorsement by the National Institute of Standards and Technology, nor is it intended to imply that the products or materials identified are necessarily the best available for the purpose.

Copy-Editor

We can't thank Sheryl Taylor (NIST) enough for the detailed edits she made in multiple drafts of the book, improving the readability and content immensely.

Contributors

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HL7 Conformance Working Group

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Robert Snelick Acknowledgments

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Frank Oemig Acknowledgments

I would like to thank my mentor and long-time friend Bernd Blobel for an uncountable number of discussions in this domain. Without his outstanding support I wouldn't be in the position I am in today.

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Finally, I would like to thank my wife Anja and our children Alina and Fabian for their continuous support and encouragement, especially when I have to start a new trip to USA.

After several years of work and huge amount of intermediate versions of the individual chapters the first release of our book is ready.

Dedication

The authors would like to dedicate this book to friend and colleague Pete Rontey. Pete was a leader in establishing conformance principles and implemented those principles in his development of the highly successful messaging workbench (MWB). We recall fond memories of Pete at the HL7 working group meetings discussing conformance issues over a cold beer (or two…). This one is for you Pete!

Mülheim, Germany — Frank Oemig
Gaithersburg, USA — Robert Snelick

Contents

About the Authors

Frank Oemig, Ph.D., FHL7 has studied computer science and theoretical medicine at the Universities in Dortmund and Bochum (both located in Germany) in the mid-eighties. Although he concentrated on artificial intelligence (AI) he also worked for a software company developing programs for radiology departments, diagnosis coding and other healthcare related problems. Having said that, Mr. Oemig has been active in the healthcare domain for more than 30 years.

Immediately after finalizing his diploma thesis and leaving his first employment in a research department he started concentrating on ICT—information communication technology—in healthcare. One of his first topics was enabling a subsystem to receive patient related data. During that time (1993) he started a more intensive work with HL7 v2.1 in Germany. When joining the internal HL7 community in 1998 he became one of the first international co-chairs for the Personnel Management Work Group which he led together with Bernd Blobel till 2003. Since 2005 Frank is one of the co-chairs to the Conformance and Guidance for Implementation and Testing Work Group (CGIT, formerly known as Conformance WG).

Frank is also co-founder of IHE in Germany, initiator of HL7 Switzerland, HL7 Austria, HL7 Luxembourg and HL7 Bosnia & Herzegovina.

For more than 9 years Frank has worked for Agfa Healthcare GmbH, Bonn, Germany, a vendor company being the HIS leader in Germany. Now he is employed by Deutsche Telekom Healthcare and Security Solutions GmbH, a subsidiary of T-System International.

Using all that knowledge, Frank could intensify his engagement with HL7 by writing a Ph.D. thesis about knowledge representation in healthcare using formal ontologies. The most important result was the development of a communication standards ontology (CSO) formally allowing to bridge different communication standards like HL7 v2.x and Version 3.

Mr. Oemig has published approximately 180 of his works, including articles in journals, papers for conferences, and chapters for technical books.

Robert Snelick, M.Sc. has a B.S. (Computer Science) from Clarion University of Pennsylvania (1986) and a M.S. (Computer Science) from the Johns Hopkins University (1991). Mr. Snelick has been employed at the National Institute of Standards and Technology (NIST) since 1986. He began working in the healthcare technology domain in 2004. Mr. Snelick is currently the project lead and chief architect for the NIST HL7 v2 Testing Framework and Tools, the Implementation Guide Authoring and Management Tool (IGAMT), and the Test Case Authoring and Management Tool (TCAMT).

Mr. Snelick is active in standards development organizations such as HL7, IHE, and ONC S&I Framework. He has served as a co-chair for HL7 Conformance working group for the past eight years, is a member of the IHE Testing and Tooling Committee, and is the S&I Framework Validation Suite Chair for the Laboratory domain. His technical focus is on improving the specification of conformance requirements and the testing of implementations for conformance and interoperability. Mr. Snelick's proposals have led to numerous improvements to the HL7 v2 conformance model and to the increased efficiency and rigor in conformance and interoperability testing.

Mr. Snelick has lead the development of the test procedures and test tools to support the ONC 2012, 2014, and 2015 Edition Health IT Certification measures that included HL7 v2 standards. He has also led tool development efforts to support testing activities at the CDC, IHE, AIRA, HL7, HITSP, and CCHIT.

Prior to working in the healthcare information technology domain, Mr. Snelick conducted research and development in performance evaluation of parallel and supercomputing, cluster computing, interactive digital television, biometrics, and multi-model biometrics methods and testing.

Mr. Snelick has published over 30 of his works, including articles in journals, papers for conferences, and chapters for technical books.

Acronyms

ACB	Authorized Certification Body
ACK	Acknowledgement
ACR	American College of Radiology
ACRNEMA	American College of Radiology—National Electrical Manufacturers Association predecessor of the DICOM standard defined by ACR and NEMA
ADT	Abrechnungsdatentransfer (xDT)—aka financial transaction ⇒ QMS
ADT	Admission, Discharge and Transfer ⇒ HL7
AHIC	American Health Information Community
AHML	Australian Healthcare Messaging Laboratory, University of Ballarat, Australia, www.ahml.com.au
AMS	Abstract Message Syntax ⇒ HL7 v2.x
ANSI	American National Standards Institute
API	Application Programming Interface
ART	Advanced Requirement tooling ⇒ ART-DECOR
ASC	Accredited Standards Committee
ASCII	American Standard Code for Information Interchange
ASIP	Agence des systèmes d'information partagés de santé ⇒ ASIP Santé
ASTM	American Society for Testing and Materials
ATL	Accredited Testing Laboratory
ATL	Archetype Type Library
B2B	Business to Business
BDT	Behandlungsdatentransfer (xDT)—aka administrative data transfer ⇒ QMS
BNF	Backus Naur Form
BOM	Byte Order Mark
BPEL	Business Process Execution Language

CCOW	Clinical Context Object Working Group ⇒ HL7
CDA	Clinical Document Architecture ⇒ HL7
CDC	Center for Disease Control and Prevention
CEHRT	Certified EHR Technology
CEN	Comité Européen de Normalisation, http://www.cen.org
CGIT	Conformance and Guidance for Implementation/Testing, an HL7 Work group, www.hl7.org
CHI	Canada Health Infoway
ClaML	Classification Markup Language ⇒ ISO
CLIA	Clinical Laboratory Improvement Amendments
CMET	Common Message Element Types ⇒ HL7 V3
CMS	Centers for Medicare and Medicaid Services
CORBA	Common Object Request Broker Architecture
CT	Computer Tomography
CTS	Common Terminology Services ⇒ HL7, OMG
CTS2	Common Terminology Services, Release 2 ⇒ HL7, OMG
D2D	Doctor-to-Doctor Communication
DECOR	Data Elements, Codes, OIDs and Rules ⇒ ART-DECOR
DICOM	Digital Imaging and COmmunication in Medicine, www.rsna.org
DIMSE	DICOM Message Service Element
DIN	Deutsches Institut für Normung, German branch of CEN
DITA	Darwin Information Typing Architecture ⇒ OASIS
D-MIM	Domain Message Information Model ⇒ HL7 V3
DMP	Dossier Médical Personnel ⇒ ASIP Santé
DQA	Data Quality Assurance
DRG	Diagnosis Related Group
DSTU	Draft Standard for Trial Use ⇒ HL7, IHE, now replaced by STU
EBCDIC	Extended Binary Coded Decimal Interchange Code
ebRIM	Electronic business Registry Information Model ⇒ OASIS
ebXML	Electronic business XML ⇒ OASIS
ECCF	Enterprise Compliance and Conformance Framework ⇒ HL7, SAIF
EDI	Electronic Data Interchange
EDIFACT	Electronic Data Interchange For Administration, Commerce and Transport
EHR	Electronic Health Record
EHR-S	Electronic Health Record System
ELR	Electronic Laboratory Reports
ER7	Encoding Rules 7, the standard encoding format for HL7 v2 messaging ⇒ HL7
ESB	Enterprise Service Bus
EU	European Union
EUP	EHR Usability Protocol, www.nist.gov

FHIR	Fast Healthcare Interoperability Resources ⇒ HL7
GCM	Generic Component Model
GDT	Gerätedatentransfer (xDT), aka of device data transfer ⇒ KBV
GELLO	An OCL-Like Common Expression Language ⇒ HL7
Gematik	"Gesellschaft für Telematik im Gesundheitswesen", http://www.gematik.de
GLIF	Guideline Interchange Format ⇒ HL7
GMSIH	Groupement pour la Modernisation du Système s'Information Hospitalier
GP	General Practitioner
H.PR.I.M.	Harmonie et Promotion de l'Information Médicale
HAPI	HL7 API, a Java-based toolkit
HDF	HL7 Development Framework ⇒ HL7
HIMSS	Healthcare Information and Management Systems Society
HIS	Hospital Information System
HISSP	Health Information System Strategic Plan
HIT	Health(care) Information Technology
HITSP	Health(care) Information Technology Standards Panel
HL7	Health Level Seven, Inc., www.hl7.org
HL7v2.6	HL7 Version 2.6 ⇒ HL7
HL7v2.7	HL7 Version 2.7 ⇒ HL7
HL7V3NE2008	HL7 Version 3 Normative Edition 2008 ⇒ HL7
HLLP	Hybrid Lower Layer Protocol
HPC	Health Professional Card
HTML	Hyper Text Markup Language
IATM	International Association for Testing and Materials
ICT	Information and Communication Technology
IE	Information Entity ⇒ DICOM
IEEE	Institute of Electrical and Electronics Engineers
IG	Implementation Guide
IHE	Integrating the Healthcare Enterprise, www.ihe.net
IHTSDO	International Health Terminology Standards Development Organization, www.ihtsdo.org
IOM	Institute of Medicine's
IP	Internet Protocol
ISO	International Standardisation Organisation, http://www.iso.org
IT	Information Technology
ITB	Interoperability Test Bed
ITI	IT-Infrastructure: IHE Domain, ⇒ IHE, www.ihe.net
ITS	Implementation Technology Specification ⇒ HL7 V3
JSON	Java Script Object Notation
KADT	Kurärztliche Abrechnungsdaten (xDT)
KBV	"Kassenärztliche Bundesvereinigung", a German institution being responsible for handling the reimbursement of general practitioners, www.kbv.de

KdÖR	www.kbv.de/html/ita.php
KH-IT	Bundesverband der Krankenhaus-IT-Leiterinnen/Leiter e.V., professional association of head of IT departments in hospitals, www.kh-it.de
KV	"Kassenärztliche Vereinigung", diverse branches of the KBV in the different German federal states
LDT	Labordatentransfer (xDT)—aka laboratory data transfer ⇒ KBV
LIS	Laboratory Information System
LOI	Laboratory Order Interface, www.healthit.gov
LOINC	Logical Observation Identifier Names and Codes, www.loinc.org, www.regenstrief.org
LRI	Laboratory Results Interface, www.healthit.gov
LTPAC	Long Term and Past Acute Care
MDF	Message Development Framework, 1999 ⇒ HL7
MDHT	Model Driven Health Tool ⇒ HL7 V3
MIF	Model Interchange Format ⇒ HL7 V3
MLLP	Minimal Lower Layer Protocol ⇒ HL7 v2
MR	Magnetic Resonance
MSH	Message Header ⇒ HL7 v2
MU	Meaningful Use ⇒ CMS
NATA	National Association of Testing Authorities
NCPDP	National Council for Prescription Drug Programs
NEMA	National Electrical Manufacturing Association, a US trade organization
NHS	National Health Service (UK)
NICTIZ	Nationaal ICT Instituut in der Zorg, www.nictiz.nl
NIST	National Institute of Standards and Technology, www.nist.gov
OASIS	Organization for the Advancement of Structured Information Standards, www.oasis-open.org
OCL	Object Constraint Language
OHT	Open Health Tools
OMG	Object Management Group, www.omg.org
ONC	Office of the National Coordinator
OSI	Open Systems Interconnection
PACS	Picture Archiving and Communication System
PAM	Patient Administration Management ⇒ IHE IT-Infrastructure
PCC	Patient Care Coordination: Domain ⇒ IHE
PCD	Patient Care Devices: Domain ⇒ IHE
PDF	Portable Document Format, http://www.pdfassociation.org
PDF/A	PDF Archive
PDO	Profile Development Organization
PDQ	Patient Demographics Query ⇒ IHE IT-Infrastructure
PET	Positron Emission Tomography

PHAST	Association Réseau Phast, L'Information de santé Standardisée, http://www.phast.fr
PIF	Patient Identity Feed ⇒ IHE ITI XDS
PIX	Patient Information Cross Referencing ⇒ IHE IT-Infrastructure
QMS	Qualitätsring Medizinische Software, www.qms-standards.de
QRPH	Quality, Research and Public Health ⇒ IHE
REST	Representational State Transfer
RIM	Reference Information Model
RM-ODP	Reference Model for Open Distributed Processing
RSNA	Radiological Society of North America, www.rsna.org
RTF	Rich Text Format
RTM	Rosetta Terminology Mapping ⇒ IHE PCD
SAEAF	Services Aware Enterprise Architecture Framework (old term ⇒ SAIF)
SAIF	Services Aware Interoperability Framework (new term ⇐ SAEAF)
SAML	Security Assertion Markup Language ⇒ OASIS
SCIPHOX	Standardized Communication in Physician Offices and Hospitals using XML, www.sciphox.de, relinked to www.hl7.de
SCP	Service Class Provider ⇒ DICOM
SCU	Service Class User ⇒ DICOM
SDA	Structured Document Architecture ⇒ HL7
SDO	Standards Developing Organisation
SFM	Service functional model
SGML	Standard Generalized Markup Language ⇒ OASIS
Snomed CT	Snomed Clinical Terms ⇒ IHTSDO
SNOMED	Systemized NOmenclature in MEDicine ⇒ IHTSDO
SOAP	Service oriented access protocol
SOP	Service Object Pair ⇒ DICOM
SPL	Structured Product Labeling
STU	Standard for Trial Use ⇒ HL7
SUT	System under test
SWF	Scheduled Workflow ⇒ IHE Radiology
TCP/IP	Transmission Control Program/Internet Protocol
TeveGe	"Telematikgesellschaft für ein vernetztes Gesundheitswesen", www.tevege.de
UCS	Universal Multiple-Octet Coded Character Set
UCUM	Unified Code for Units of Measure
UDDI	Universal Description, Discovery and Integration ⇒ OASIS
UDP/IP	User Datagram Protocol/Internet Protocol
UID	Unique Identifier
UML	Unified Modeling Language, www.omg.org
UN/EDIFACT	United Nations Electronic Data Interchange for Administration, Commerce and Transport