Frank Oemig · Robert Snelick

Healthcare Interoperability Standards Compliance Handbook



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Conformance and Testing of Healthcare Data Exchange Standards



Frank Oemig
Deutsche Telekom Healthcare
and Security Solutions GmbH
Mülheim
Germany

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

ISBN 978-3-319-44837-4 DOI 10.1007/978-3-319-44839-8 ISBN 978-3-319-44839-8 (eBook)

Library of Congress Control Number: 2016949613

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Printed on acid-free paper

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The registered company is Springer International Publishing AG
The registered company address is: Gewerbestrasse 11, 6330 Cham, Switzerland

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 vi Foreword

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

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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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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

The section "EHR Certification and Meaningful Use Programs" in Chap. 15 was contributed by Sheryl Taylor of NIST. We are delighted that Sheryl shared her knowledge about the CMS Meaningful Use and ONC Health IT Certification Programs and the associated testing efforts. Another special thank you goes to those persons and institutions/organizations that have provided us with supportive material which we are allowed to use to underline our statements and explanations: Bernd Blobel, Kai Heitmann, Ioana Singureanu, Pete Rontey, Sheryl Taylor, Ted Klein, Friedemann Schulz von Thun, HL7 International, National Electrical Manufacturers Association (NEMA), IHE-Integrating the Healthcare Enterprise, International Standardization Organization (ISO), Deutsches Institut für Normung (DIN), ASTM, OASIS, IETF, United Nations, DVTk, Hprim Santé, Phast, ART-DECOR Experts Group, Lantana Consulting Group, Furore, Qualitätsring Medizinische Software, and finally Australian Healthcare Messaging Laboratory (AHML).

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Reviewers

We would like to thank Craig Newman, who was the technical reviewer for the book. Craig provided thoughtful and detailed comments that led to many clarifications, improvements, and additional content.

We would like to thank other reviewers who also provided comments that led to many quality improvements in one or more chapters: Bernd Blobel, Peter Geibel, Ted Klein (contributed to, and reviewed various sections in vocabulary), Riki Merrick, Nathan Bunker, John Garguilo and Marek Vaçlavik.

Finally, we would like to thank those who partially reviewed specific sections for their correctness: Francois Macary/Franck Gener/Olivier Boux (InteropSante, ASIP.SANTE, Hprim Santé, PN13), Michel Rutten (Forge profile editing tool), Kai Heitmann (ART-DECOR), Reinhold Mainz (xDT standards family), Nicolas Canu (PN13), Ewout Kramer (FHIR), Liora Alschuler/Rick Geimer/Sean P. McIlvenna (Trifolia), and Andreas Schultz (EDIFACT).

HL7 Conformance Working Group

We would like to thank the members of the HL7 Conformance, Vocabulary, and Order and Observations Working Groups for the many fruitful and insightful conversations through the years that helped formulate many of the concepts and principles documented in this book.

Robert Snelick Acknowledgments

I would like to thank the numerous colleagues with whom I have worked at NIST. Many of the concepts explained in this book were generated from our projects. Caroline Rosin is the senior developer for the suite of laboratory conformance HL7 v2 testing tools. Harold Affo is the architect and senior developer of the NIST HL7 v2 testing framework. He is also the project lead and architect of the NIST Implementation Guide Authoring and Management Tool (IGAMT). Woo Jungyub is the architect and senior developer of the NIST Test Case Authoring and Management Tool (TCAMT). Sydney Henrard, Salifou Malick, and Hossam Tamri have developed and refined the validation engine over many years. Sandra Martinez is the tool analyst for the Immunization and Vital Records domains. I would like to thank Sheryl Taylor for her unyielding work ethic and for sharing her knowledge of clinical informatics as we developed the three iterations of ONC certification test procedures and test tools. Others who also contributed as tool analysts or

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developers include Len Gebase, Sheryl Taylor, Roch Bertucat, Nico Couzier, and Mike Indovina. NIST management, past and present, must be thanked for their forward-thinking vision in establishing the conformance testing project and for providing a first-class working environment.

I would also like to thank the NIST contractors, associates, and collaborators, of whom there are too many to name. I would especially like to thank the subject matter experts who provided domain expertise, test data, and feedback during the process of the tool development: Rob Savage, Craig Newman, Nathan Bunker, and Eric Larson (Immunization); Riki Merrick, Eric Haas, and Bob Dieterle (Laboratory); and others in the various domains. I am appreciative of the efforts of the S&I Framework Laboratory Work Group, through which many of the profiling ideas and concepts were proposed, applied, vetted, and refined. I would also like to thank my colleagues at the CDC, HL7, and IHE.

And, finally, I would like to thank my wife Donna for always being there for me and to thank my children Victoria, Austin, and Connor for their support and patience; it is finally finished!

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.

A lot of my work is supported not only by my employer, but also HL7 Germany. Here I would like to say thank you to my friends and colleagues Kai, Christof, Sylvia, Bernd (2x), Alex, Markus, Mathias, Daniel, Peter (2x), Marek, Simone, Ralf and Tarik. I am sorry if I missed anyone here.

Furthermore, I appreciate the discussions with my friends from the international and national community and would like to thank them for their patience with me. I know it is not that easy.

Another special thank you goes to Sheryl, who has done an incredible job in taking care of my English. As a non-native speaker it was a great exercise for me, and I have learned a lot.

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.

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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 Gaithersburg, USA Frank Oemig Robert Snelick

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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 com-

munication 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.

xxvi About the Authors

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 \Rightarrow

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

 $transfer \Rightarrow OMS$

BNF Backus Naur Form BOM Byte Order Mark

BPEL Business Process Execution Language

xxviii Acronyms

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

Canada Health Infoway CHI

Classification Markup Language ⇒ ISO ClaML Clinical Laboratory Improvement Amendments **CLIA** Common Message Element Types ⇒ HL7 V3 **CMET CMS** Centers for Medicare and Medicaid Services **CORBA** Common Object Request Broker Architecture

CT Computer Tomography

Common Terminology Services ⇒ HL7, OMG CTS

Common Terminology Services, Release 2 ⇒ HL7, OMG CTS2

D₂D Doctor-to-Doctor Communication

Data Elements, Codes, OIDs and Rules ⇒ ART-DECOR DECOR **DICOM**

Digital Imaging and COmmunication in Medicine,

www.rsna.org

DICOM Message Service Element DIMSE

DIN Deutsches Institut für Normung, German branch of CEN Darwin Information Typing Architecture ⇒ OASIS **DITA** Domain Message Information Model ⇒ HL7 V3 D-MIM

DMP Dossier Médical Personnel ⇒ ASIP Santé

Data Quality Assurance DOA DRG Diagnosis Related Group

Draft Standard for Trial Use ⇒ HL7, IHE, now replaced by **DSTU**

STU

EBCDIC Extended Binary Coded Decimal Interchange Code

Electronic business Registry Information Model ⇒ OASIS ebRIM

ebXML. Electronic business XML ⇒ OASIS

ECCF Enterprise Compliance and Conformance Framework \Rightarrow HL7,

SAIF

EDI Electronic Data Interchange

EDIFACT Electronic Data Interchange For Administration, Commerce and

Transport

EHR Electronic Health Record

Electronic Health Record System EHR-S Electronic Laboratory Reports **ELR**

Encoding Rules 7, the standard encoding format for HL7 v2 ER7

messaging \Rightarrow HL7

ESB Enterprise Service Bus European Union EU

EHR Usability Protocol, www.nist.gov **EUP**

Acronyms xxix

FHIR Fast Healthcare Interoperability Resources ⇒ HL7

GCM Generic Component Model

GDT Gerätedatentransfer (xDT), aka of device data transfer \Rightarrow KBV

GELLO An OCL-Like Common Expression Language ⇒ HL7 Gematik "Gesellschaft für Telematik im Gesundheitswesen".

http://www.gematik.de

GLIF Guideline Interchange Format \Rightarrow 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 $2.6 \Rightarrow$ HL7 HL7v2.7 HL7 Version $2.7 \Rightarrow$ 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 \Rightarrow 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

xxx Acronyms

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 \Rightarrow HL7 V3 MIF Model Interchange Format \Rightarrow HL7 V3 MLLP Minimal Lower Layer Protocol \Rightarrow HL7 v2

MR Magnetic Resonance

MSH Message Header \Rightarrow HL7 v2 MU Meaningful Use \Rightarrow 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

Acronyms xxxi

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

 \Rightarrow 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.h17.de

SCP Service Class Provider \Rightarrow DICOM SCU Service Class User \Rightarrow 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 \Rightarrow IHTSDO

SNOMED Systemized NOmenclature in MEDicine ⇒ IHTSDO

SOAPService oriented access protocolSOPService Object Pair ⇒ DICOMSPLStructured Product LabelingSTUStandard for Trial Use ⇒ HL7

SUT System under test

SWF Scheduled Workflow \Rightarrow 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