INTERNATIONAL STANDARD

ISO/HL7 16527

First edition
2016-04-01

Health informatics — HL7 Personal Health Record System Functional Model, Release 1 (PHRS FM)

Informatique de santé — Modèle fonctionnel d'un système de dossier de santé personnel, version 1 (PHRS FM)

Reference number
ISO/HL7 16527:2016(E)

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Contents

Page

Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 215, *Health informatics*.

Introduction

Notes to Readers

The HL7 Personal Health Record System Functional Model (PHR-S FM) was approved as a Draft Standard for Trial Use (DSTU) in July 2008. In September 2010 the PHR-S FM was presented to ISO TC215 as a New Work Item Proposal (NWIP) ballot and received comments from the international community. The comments from that ballot were used to update and improve the draft standard. In September 2013, the standand was updated, re-balloted, and the comments reconciled – resulting in the current version.

Information about HL7 is given in Annex F.

Changes from Previous Release

Not Applicable for Release 1.

Background

Personal Health Record (PHR) Versus a Personal Health Record System (PHR-S)

The PHR WG makes a clear distinction between a PHR and a PHR System (PHR-S). The PHR is the underlying record (e.g. data, information, pictures, sounds, graphs, or videos) that the software functionality of a PHR-S maintains. There has been much discussion surrounding the definition of a personal health record. The PHR-S FM does not attempt to define the PHR, but rather to identify system features and functions necessary to create and effectively manage PHRs. The PHR-S FM offers examples of data elements, but is not intended to provide details necessary to specify a data model.

The overarching theme of a PHR-S involves a patient-centric tool that is controlled, for the most part, by the individual PHR Account Holder. A PHR-S should be immediately available electronically and able to link to other systems. The PHR-S provides functionality to help an individual maintain a longitudinal view of his or her health history, and may be comprised of information from a number of sources – e.g. from providers and health plans, as well as from the individual. Data collected by the system is administrative and/or clinical, and the tool may provide access to health-related forms (e.g. Advance Directives) and advice (e.g. diet, exercise, or disease management). A PHR-S might also help the individual collect behavioral health, public health, patient-entered and patient-accessed data (including medical monitoring devices), medication information, care management plans and the like, and might be connected to providers, laboratories, pharmacies, nursing homes, hospitals and other institutions and clinical resources. This PHRS-FM is universal and therefore generic by design. There may be additional constraints in certain realms or regions. For example, in the US Realm, the management of laboratory results is subject to the Clinical Laboratory Improvement Amendments (CLIA) federal regulation.

At its core, the PHR-S should provide the ability for the individual to capture and maintain demographic, insurance coverage, and provider information. It should also provide the ability to capture health history in the form of a health summary, problems, conditions, symptoms, allergies, medications, laboratory and other test results, immunizations and encounters. Additionally, personal care planning features such as Advance Directives and care plans should be available. The system must be secure and have appropriate identity and access management capabilities, and must use standard nomenclature, coding and data exchange standards for consistency and interoperability. A host of optional features have been addressed over the course of this initiative, including secure messaging, graphical presentation of test results, patient education, guideline-based reminders, appointment scheduling and reminders, drug-drug interactions, formulary management, health care cost comparisons, document storage and clinical trial eligibility.

The effective use of a PHR-S is a key point for improving healthcare in terms of effective self-management, patient-provider communication and quality objectives.

Health informatics — HL7 Personal Health Record System Functional Model, Release 1 (PHRS FM)

1 Scope

The HL7 PHR-S FM defines a standardized model of the functions that may be present in PHR Systems.

It is beyond the scope of the PHR system to control the use (or intended use) of PHR data. On the contrary, it is within the scope of the PHR system to manage the authorization of an individual (or other application). Those parties are then responsible for using the data for appropriate (or intended) purposes. The system manufacturers specify "intended and permitted use of PHR data" in their Terms of Service and Terms of Use agreements.

This Functional Model is not:

- a messaging specification;
- an implementation specification;
- a conformance specification;
- a specification for the underlying PHR (i.e. the record itself);
- an exercise in creating a definition for a PHR;
- a conformance or conformance testing metric;
- a requirement specification for a single PHR system (see Annex D, Anticipated Uses).

The information exchange enabled by the PHR-S supports the retrieval and population of clinical documents and summaries, minimum data sets, and other input/outputs.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/TR 14292:2012, *Health informatics — Personal health records — Definition, scope and context*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
base functional profile
existing functional profile from which new (child) functional profiles are created/derived

3.2
conformance
fulfillment of a product, process, or service of specified requirements

3.3
conformance criteria
requirements indicating the behavior, action, or capability that constitutes implementation of the function

3.4
conformance clause
section of a specification that defines the requirements, criteria, or conditions to be satisfied in order to claim conformance

3.5
conformance statement
description of the function in a PHR system that has been implemented. It reflects the degree to which a PHR system has met the functional profile's requirements and may include optional functions and information

3.6
derived functional profile
functional profile that is created from a base functional profile, also known as a child functional profile

3.7
extension
ability for a PHR-S to incorporate additional functionality beyond what is defined in a functional profile

3.8
functional profile
subset of the PHR-S FM in which functions have been designated (sometimes in varying degrees) for certain PHR systems or sources or level of functionality

3.9
informative functional profile
registered functional profile that has successfully completed formal public scrutiny via the HL7 consensus process

3.10
inherited criterion
conformance criteria listed in a header function that will be inherited by all its children functions, and conformance criteria listed in a parent function that are inherited by all its children functions

3.11
registered functional profile
functional profile that has successfully completed HL7 EHR WG registration process and review

3.12
situational criterion
criterion that is required if the circumstances given are applicable

4 The Functional Model

4.1 Overview and Definition

The PHR-S FM is divided into three sections: Personal Health, Supportive, and Information Infrastructure. Functional profiles can be developed which identify various functions from one or more of these three sections in order to describe a given system, and allows for further characterization of that profile by the assignment of priorities to each function in the profile (see Figure 1). While the PHR-S FM should contain all reasonably anticipated PHR-S functions, it is not intended to comprise the entire list of all functions that may be found in any specific PHR-S. Again, functional profiles will be developed to constrain the functions for an intended use [see 5.1, Introduction (Reference)]. This document defines the PHR-S Functional Model and describes the general use of profiles and priorities (see Annex C, PHR Sources, for examples of stakeholders that might create profiles).

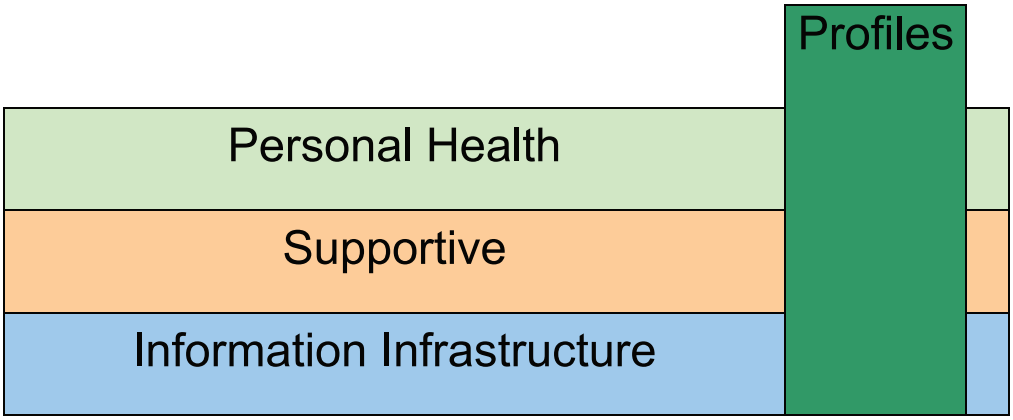

Figure 1 — PHR-S FunctionList Sections

As previously mentioned, the PHR-S FM is divided into three main sections: Personal Health, Supportive, and Information Infrastructure. Within the three main sections are a number of subsections (parent-child relationships). Each subsection is comprised of a number of individual functions. Functions describe the behavior of a system in consumer-oriented language and are intended to be recognizable to all key stakeholders of a PHR-S. Each function contains a Function Name, Function Statement, and Conformance Criteria (which are "normative" in an ANSI-accredited standard) as well as other associated information such as Description (which is reference information and is not a normative part of the ANSI-accredited standard).

The numbering of the functions maintains parent-child relationships between the sections and subsections (e.g. "PH.1.1 Account Holder Profile" is the parent of child "PH.1.1.1 Identify and Maintain a Patient Record"). In many cases the parent is fully expressed by the children (see Figure 2). In the aggregate, the PHR-S Functional Model is intended as the superset of functions from which a subset can be derived by a Stakeholder Community to illustrate what they need in a PHR-S for their setting. Only a subset of this inclusive set of functions (one or more PHR-S Functional Profiles) will apply to any particular PHR-S implementation.

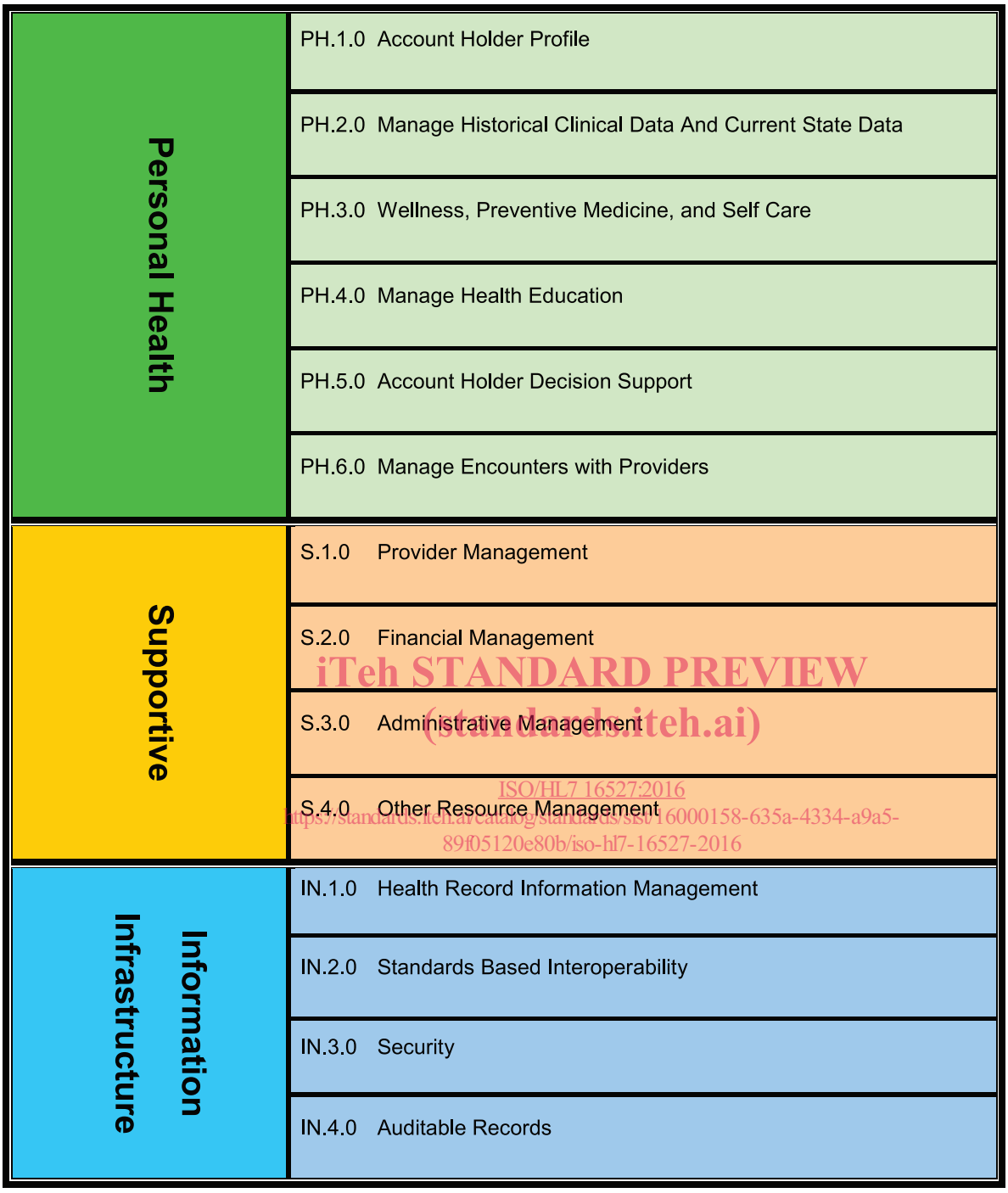

Figure 2 — PHR-S Functional Outline

4.2 PHR-S Functional Outline

4.2.1 The Functions and Their Use

The PHR-S Functional Model can be used to:

- Promote a common understanding of PHR functions upon which developers, vendors, users and other interested parties can plan and evaluate PHR functions.

- Provide the necessary framework to drive the requirements and applications of next level standards, such as PHR content, coding, information models, constructs and interoperability for information portability between sub-systems of a PHR-S and across more than one PHR-S.
- Establish a standards-based method by which each realm (country) can apply these PHR-S functions to care settings, uses, and priorities.
- Inform those concerned with new, additional, or other use of PHR data and national infrastructure what functions can be expected in a PHR-S.

4.2.2 Personal Health Section Functions

Description of Personal Health section functions: The Personal Health (PH) section functions are the subset of PHR-S functions that manage information and features related to self-care and provider based care over time. PH section functions can yield a summary record of an individual's care, including ad hoc views of the overall PHR.

Example of a Personal Health section function: A function to ensure that the individual PHR Account Holder's demographic information is captured and maintained so that the individual is unambiguously identified.

Actors for Personal Health section functions: As the subject of PHR information, the PHR Account Holder is the principal user of PH section functions.

4.2.3 Supportive Section Functions

Description of Supportive section functions: The Supportive section functions are the subset of PHR-S functions that assist the PHR Account Holder with administrative and financial requirements. Also included are PHR-S functions that provide input to systems that perform clinical research, promote public health and seek to improve the quality and outcome of health care delivered.

Example of a Supportive section function: A function that will electronically query local immunization registries to ensure that a person is currently registered and determine the person's immunization status.

Actors for Supportive section functions: The PHR Account Holder is the principal user of Supportive section functions, but under certain circumstances, health care providers might be expected to perform various Supportive section functions.

4.2.4 Information Infrastructure Section Functions

Description of Information Infrastructure section functions: The Information Infrastructure section consists of PHR-S functions that support Personal Health and Supportive section functions. These functions ensure that the PHR-S provides information privacy and security, interoperates with other information systems (including PHR and EHR systems), and helps make PHR-S features accessible and easy to use.

Example of an Information Infrastructure section function: A function to ensure that PHR data, such as an immunization record, can only be viewed and updated after an individual or system authenticates the user's identity within the PHR-S.

Actors for Information Infrastructure section functions: Information Infrastructure section functions are generally performed transparently by the PHR-S on behalf of (and without intervention of) PHR-S Account Holders and other users.

4.3 Common Major Concepts Across the Model

4.3.1 The "Action-Verb" Hierarchy

4.3.1.1 Consistency in the Conformance Criteria

Within the authoring group, there was an intentional effort to create language consistency in the conformance criteria. The "Action-Verb" Hierarchy diagrams below are used to create semantic harmony within the conformance criteria so that, for example, if the Personal Health Chapter has a conformance criterion using the Action-Verb "Update," that term has the same meaning as in the Supportive Chapter's conformance criteria.

The levels in the hierarchy are granular and have a parent-child relationship. For example, the diagram below reveals that the "Capture" of information covers local data entry ("Enter") and importation of data from an external source ("Import"). Similarly, under the "Maintain" section of the diagram, the term "Store" could invoke Action-Verbs listed below it. If the parent term is not used, then the respective verbs in the child will be cited individually in the criterion. If the term "Manage" is used, all of the applicable Action-Verbs included in the table are encompassed in that criterion. Authors are responsible for determining whether one or more of the sub-verbs are appropriate for a given function and must write conformance criteria that constrain the use of the Action-Verb hierarchy according to the intent of the profile being created.

4.3.1.2 The "Secure (System)" Category

The Secure System Category provides Action-Verbs for controlling access (authenticating and authorizing users), tracking activities (logging and auditing), and sustaining operations. This category has one parent, Secure (System), and three (3) intermediate children: Control Access, Track, and Sustain (Operations).

Secure (System)				
Control Access		**Track**		**Sustain (Operations)**
Authenticate	Authorize	Log	Audit	

Figure 3 — Secure (System)

4.3.1.3 The "Manage (Data)" Category

The data management Category provides Action-Verbs for the complete range of data handling actions by a system. The category has one parent, Manage (Data), and six (6) children with subsets: Capture, Maintain, Render, Exchange, Determine, and Manage-Data-Visibility.

Manage (Data)										
Capture	**Maintain**			**Render**			**Exchange**	**Determine**		**Manage-Data-Visibility**
Auto-Populate	Store	Update	Remove	Extract	Present	Transmit	Export	Analyze	Decide	De-Identify
Enter	Archive	Annotate	Delete				Import			Hide
Import	Backup	Attest	Purge				Receive			Mask
Receive	Decrypt	Edit					Transmit			Re-Identify
	Encrypt	Harmonize								Unhide
	Recover	Integrate								Unmask
	Restore	Link								
	Save	Tag								

Figure 4 — Manage (Data)

The hierarchical principle above was applied during the development of the PHR-S FM. The Action-Verbs and other terms used in the model are found in the model's Glossary (see Annex B). It is important to be consistent in the terminology used in the PHR-S FM conformance criteria to ensure consistent interpretation.

4.3.1.4 PHR Account Holder Privacy

It is the bias of this Model that consumer privacy rights be protected to the fullest extent possible. However, as an international model that attempts to describe functionality for many PHR system sub-types (e.g. integrated PHR/EHR systems, stand-alone PHR systems, or vendor-provided Web-based systems), statements concerning consumer control over information are frequently tempered by the phrase (with some variations) "in accordance with user role, organizational policy, or jurisdictional law." This phrase does not extend license to institutions to violate individual rights, but acknowledges that legitimate exceptions may exist to the general rule of PHR Account Holder control over their PHR information. In all cases, the model requires that the privacy policy of a PHR system be fully transparent to PHR Account Holders, and that a PHR-S has the ability to capture a PHR Account Holder's consent on how his or her personal information may be used and disclosed (see functions in IN.3.8, Patient Privacy and Confidentiality for additional detail.)

4.3.1.5 Functionality versus Implementation

It is important to note that many functions provide the capacity for functionality (e.g. provide for standards-based interoperability), but do not give implementation details. A function, when implemented, must be implemented within the context of the entire PHR-S FM. For example, implementation of many functions throughout the model are expected to conform to the security and audit functions found within IN.3 (Security) and IN.4 (Auditable Records), and functions performed "by the PHR Account Holder" may be actually performed by others as delegated by the Account Holder (see IN.3.2, Entity Authorization). Examples of PHR implementation contexts within the Mobile Device space can be found in Annex E, Mobile Device Impact on, and Issues related to, PHRs.

4.3.2 Relevant Standards

Relevant Standards:

- ISO/TR 14292 “Personal health records - definition, scope, context and global variations of use”

4.3.3 Consents, Authorizations, and Preferences

Consumers may desire to declare a consent, authorization, or preference differently in the PHR-S context than in the EHR-S context. The method of handling consents, authorizations, or preferences is not addressed by the PHR-S FM. Rather, such issues ought to be addressed during implementation. For example, such functionality could be implemented in a “services-aware” fashion if desired (for example, as a smart-cloud-type-query). Differences between multiple versions of consents, authorizations, or preferences may be best adjudicated by humans. The state of the art may not yet be adequate to handle such adjudication computationally.

4.3.4 Scope of Downstream Uses of PHR data

The PHR-S FM currently only envisions privacy, security, and confidentiality measures that extend to the initial PHR data-exchange recipient and not to (possible) subsequent recipients of the PHR data that might be passed on by the initial data-exchange recipient.

This PHRS-FM is universal and therefore generic by design. There may be additional constraints in certain realms or regions. For example, in the US Realm, the management of laboratory results is subject to the Clinical Laboratory Improvement Amendments (CLIA) federal regulation.

4.4 Type of Profiles

Characterization of a PHR profile based on its attributes:

- Scope and nature of content

  Some PHR systems do not contain any patient clinical data, but just have consumer health information, personal health journals, or information about benefits and/or providers.

  Of those PHR systems that have clinical information, some are populated by EHRs, some are disease specific, some include just specific subsets (e.g. lab reports), and some are comprehensive.

- Source of information

  Data in PHR systems may come from the consumer, patient, caregiver, healthcare provider, payer, or all of these.

- Custodian of the record

  The physical record may be operated by a number of parties, including the consumer or patient, an independent third party, a healthcare provider, an insurance company, or an employer.

- Data storage

  Data may be stored in a variety of locations, including an Internet-accessible database, a provider’s EHR-S, the consumer/patient’s home computer, a portable device such as a smart card or thumb drive, or a privately maintained database.

- Degree of Interoperability

  PHR system may be stand-alone or be interoperable with other EHRs/PHRs or somewhere in between.

- Party controlling access to the data

While consumers or patients always have access to their own data, they do not always determine who else may access it. For example, PHRs that are "views into a provider's EHR" follow the access rules set up by the provider. In some cases, consumers do have exclusive control.

5 Conformance Clause

5.1 Introduction (Reference)

The following is the HL7 EHR Work Group (EHR WG) -approved Conformance Clause for the PHR System Functional Model (PHR-S FM). As important background on conformance, please note the following:

a) This conformance clause defines what it means to conform to the PHR-S FM.

b) Conformance to the PHR-S FM is defined for functional profiles. A PHR system (PHR-S) does not directly conform to the PHR-S FM, rather it conforms to one or more functional profiles.

c) Conformance criteria are associated with every function in the PHR-S FM.

d) This conformance clause does not specify testing or validation procedures to determine whether a PHR-S conforms to a functional profile or whether a functional profile conforms to the PHR-S FM.

The technical and management staff of the U.S. National Institute of Standards and Technology (NIST), Information Technology Laboratory provided input and support for the development of this conformance clause.

5.2 Scope and Field of Application (Normative)

This *conformance clause* defines the minimum requirements for *functional profiles* claiming conformance to the PHR-S FM. It also identifies how PHR systems achieve conformance to the Functional Model (FM), which is via the system's conformance to a particular functional domain profile, multiple functional profiles, or combination of domain and companion profiles. This clause specifies:

- The purpose, structure, and use of conformance criteria that are to be included in the PHR-S FM and conforming functional profiles,
- The rules for defining conforming functional profiles of the PHR-S FM,
- The relationship between functional profiles and PHR systems,
- Sample conformance clauses and use case scenarios,
- Guidance on the conformance requirements that a functional profile might levy on PHR systems,
- Guidance on the purpose and use of a PHR system Conformance Statement.

While the conformance requirements for functional profiles can be found in this clause, they necessarily reference the PHR-S FM and other sources.

This conformance clause does not specify testing or validation procedures to assess a functional profile's conformance to the PHR-S FM. It also does not specify testing or validation procedures to determine whether a PHR system conforms to a functional profile or matches its Conformance Statement.

5.3 Concepts (Normative)

5.3.1 Functional Profiles

Creating a functional profile is a method for defining subsets of the PHR-S FM. A functional profile is a specification which uses the PHR-S FM to indicate which functions are required, desired, or implemented for certain PHR systems (e.g. systems characterized by their attributes such as source, custodian, technical approach, or level of functionality) or for other purposes (e.g. systems based