

Proposed Draft

**For the HL7 EHR System Functional Model
Draft Standard for Trial Use, Published July 2004**

CONFORMANCE CLAUSE

**For Public Comment
December 2004**

Copyright 2004 by Health Level Seven, ® Inc. ALL RIGHTS RESERVED. Any reproduction of this material in any form is strictly forbidden without the written permission of the publisher. Health Level Seven and HL7 are trademarks of Health Level Seven, Inc.

TABLE OF CONTENTS

Introduction	1
Conformance Clause	1
1.0 Scope and Field of Application	1
2.0 EHR Functional Model Conformance Model	2
3.0 Normative Language	2
4.0 Conformance Criteria	2
5.0 Profile Conformance.....	3
5.1 Rules for Profiles	3
5.2 Conformance Statements	4
6.0 Use Cases and Samples.....	4
6.1 Profile Use Cases	4
6.2 Sample Profile Conformance Clauses	5
7. Definitions.....	6

Introduction

The following is the proposed draft Conformance Clause. It is anticipated that this Conformance Clause will be part of a future, formal update of the **HL7 EHR System Functional Model and Standard – Draft Standard for Trial Use (EHR-S DSTU)**. An updated version of this Conformance Clause, at some point, would become part of the normative portion of the Standard Overview chapter of the EHR-S DSTU.

As important background on conformance, please note the following:

1. Conformance criteria are needed to move the EHR-S DSTU toward a normative standard.
2. There needs to be a methodology for expressing conformance criteria.
3. As agreed at the September, 2004 EHR TC meeting in Atlanta, a Conformance Criteria Work Group was established to assess the issues and options, and to recommend the approach for the development of conformance criteria

The technical and management staff of the U.S. National Institute of Standards and Technology, Standards and Conformance Testing Group (NIST) provided orientation and education to EHR TC members on conformance. With significant input and support from NIST, we have developed two key documents as progress with the conformance criteria component of moving the DSTU toward a normative standard: 1) this proposed draft conformance clause, and 2) a conformance criteria crafting guide.

It is expected that use of these materials by the EHR TC to draft criteria, along with industry feedback on these drafts, will be the basis for further refinements and improvements of the draft conformance clause below, and approach to creating quality conformance criteria.

Conformance Clause

1.0 Scope and Field of Application

This *conformance clause* defines the minimum requirements for *profiles* and implementations claiming conformance to the EHR System Functional Model Standard. It specifies:

- the purpose, structure and use of conformance criteria that shall be included in the Functional Model and conforming profiles,
- the rules for defining conforming profiles of the Functional Model,
- the relationship between profiles and implementations,
- sample conformance clauses and use case scenarios,
- guidance as to the conformance requirements that a profile could levy on EHR systems claiming conformance,
- guidance on the purpose and use of vendor Conformance Statements.

While the conformance requirements can be found in this clause, they necessarily reference normative text within the System Functional Model Standard and other references.

This conformance clause does not specify testing or validation procedures to assess a profile's conformance to the Functional Model. It also does not specify testing or validation procedures to determine whether an implementation conforms to a profile or matches its Conformance Statement

2.0 EHR Functional Model Conformance Model

Conformance to the Functional Model is defined in terms of profiles. Conformance of implementations (i.e., EHR systems) to the Functional Model is defined in terms of conformance to a particular profile of the Functional Model. An implementation conforms to the Functional Model if it conforms to a profile. Thus, profiles claim conformance to the Functional Model and implementations claim conformance to one or more conforming profiles. Figure 1 illustrates the relationship between the Functional Model, profiles and implementations with respect to conformance.

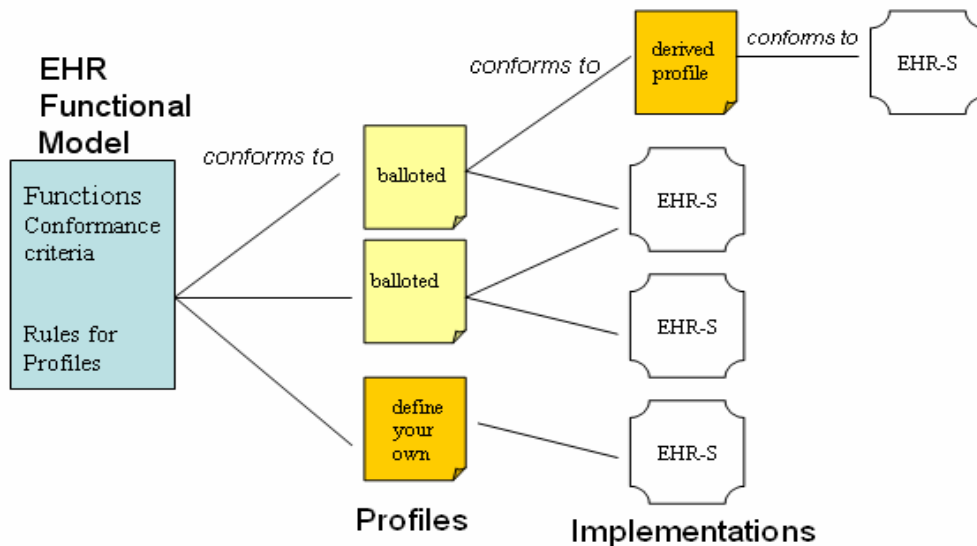


Figure 1 Conformance Relationships

3.0 Normative Language

The following keywords will be used to convey conformance requirements.

- **Shall** - to indicate a mandatory requirement to be followed (implemented) in order to conform.
- **Should** - to indicate an optional recommendation that is particularly suitable, without mentioning or excluding others.
- **May** - to indicate an optional, permissible action.

Note that the keyword “must” is synonymous to “shall”. Either keyword may be used, however, pick one and use it consistently.

4.0 Conformance Criteria

Every function in the Functional Model has associated with it a set of conformance criteria. These *conformance criteria* form the basis for determining if the function has been implemented. The criteria are derived from the Functional Model function name, statement and description.

Profiles also have conformance criteria associated with every function in the profile. The profile’s criteria are either (1) adapted from the Functional Model criteria with care-setting and application specific information or (2) if no care-setting or application specific criteria are present, inherited directly from Functional Model. Profiles may change Functional Model criteria to match the needs and priorities of the profile’s constituency, - e.g., by making it more specific, changing it from

PROPOSED DRAFT CONFORMANCE CLAUSE FOR EHR-S DSTU V1 – 2004-12-20

optional to mandatory – as long as the criteria remains consistent with that of the Functional Model (meaning they are not a substantive change to the Functional Model criteria) . Profiles may also add additional criteria.

5.0 Profile Conformance

Profiles are a method for defining subsets of the Functional Model. A profile is a specification which uses the Functional Model to indicate which functions are required, desired, or implemented for certain EHR-S implementations or Healthcare Delivery Settings.

Profiles can be created by anyone. Profiles can represent the functionality required and desired for a care setting, application, or reflect the functionality incorporated in a vendor's EHR system. Profiles that undergo public scrutiny and the HL7 consensus process are designated as *HL7 balloted profiles*. Once a profile is defined it can be implemented by EHR systems or it may trigger the creation of derived profiles. A *derived profile* is a profile that is created from an existing profile, inheriting functions from the existing (base) profile.

A profile claiming conformance to the Functional Model **shall** meet all requirements specified in the Rules for Profiles.

5.1 Rules for Profiles

Profiles that adhere to the Rules for Profiles can claim conformance to the version of the EHR-S Functional Model from which it was derived.

Profiles claiming Functional Model conformance **shall**:

1. identify the Functional Model with version/date, from which the profile is derived,
2. include a description and/or definition of the profile,
3. contain a conformance clause which
 - a. defines the requirements that implementations shall satisfy in order to claim conformance to the profile,
 - b. defines the requirements for that profiles derived from the base profile shall satisfy in order to claim conformance to the profile,
 - c. specifies that functions designated as 'Essential Now' shall be implemented by the EHR-S and shall be included in any derived profiles.
4. identify functions from the Functional Model that are applicable to the profile by
 - a. designating a minimum function set (MFS).
The total set of functions in a profile may be designated the MFS. Alternatively, the profile may contain a MFS and additional functions.
 - b. indicating whether the function is essential (now or future), optional, or not applicable.
5. for each function, derive conformance criteria based on the Functional Model conformance criteria. There shall be at least one criterion for each function that is mandatory. If a conformance criterion is not created, then the profile inherits the Functional Model's conformance criteria.
6. be structured in accordance with the structural requirements defined in the Functional Model, e.g., hierarchy of functions.
7. make the profile public.

Profiles claiming conformance to the Functional Model **may**

1. apply care setting dependent semantics to functions by creating a new child function from an existing function (or creating a new derivative function ??)
2. contain conformance criteria more specific and limited in scope than those of the Functional Model.

PROPOSED DRAFT CONFORMANCE CLAUSE FOR EHR-S DSTU V1 – 2004-12-20

3. add additional conformance criteria beyond those in the Functional Model.
4. identify degrees of conformance (i.e., conformance levels). For example, equating Level 1 to 'Essential Now', Level 2 to Essential Future, etc.
5. enforce common resolution of ambiguous semantics of the Functional Model.
6. make the profile public, via submission to HL7 for posting per EHR TC guidelines TDB (i.e., publish the profile so interested parties can see/use it)

Profiles claiming conformance to the Functional Model **shall not**

1. specify any requirements that would contradict or cause non-conformance to the Functional Model.
2. make optional conformance criteria that are mandatory in the Functional Model.
3. modify any requirements of a function not selected for the profile (i.e., all unselected functions default to the Functional Model's criteria. If a profiling group wants to change something, they must promote it into their profile).

5.2 Conformance Statements

An implementation of a profile need not employ all the optional functions in the profile. A *conformance statement* can be used to record the functions that are supported in an implementation. Both mandatory and optional functions can be recorded. The conformance statement provides an overview of the functions supported by a particular implementation, including which optional functions and capabilities are supported and what additional extensions or specializations have been added.

Profiles may want to require implementers to complete a conformance statement as part of their conformance claim. The profile may include a template of the conformance statement. Providing the template makes it conducive to completing and helps to ensure consistency among completed conformance statements.

6.0 Use Cases and Samples

6.1 Profile Use Cases

Example 1: Care Setting

A new care setting profile is needed to reflect the care setting specific requirements. To ensure widespread use, the profile will undergo the HL7 consensus process.

After looking at current balloted profiles, the decision to create a new profile is made. Each function in the EHR System Functional Model is examined and those that are relevant to the care setting are chosen. From these functions, a small set of 'core' functions are selected as being essential and mandatory. For each function, conformance criteria is developed either adapting the Functional Model conformance criteria or in a few cases, using the Functional Model criteria as is. To complete the profile, a description of the profile, including its intended use and audience as well as a conformance clause is written. The profile is submitted to HL7 for review, comment and ballot.

Example 2: Community of Interest derived profile

A community of interest (e.g., regional health information exchange network) wants a profile to reflect their specific needs.

The Community of Interest doesn't want to create a new profile from scratch. Using the Ocean Informatics Profiling Tool, they find an existing profile that is very close to what they want. Using this profile as the base, they accept all the functions designated as

PROPOSED DRAFT CONFORMANCE CLAUSE FOR EHR-S DSTU V1 – 2004-12-20

'Essential Now' in the MFS, reject functions designated as 'Future' and add several more functions. For each function, they review the conformance criteria and adapt the criteria to reflect their situational information

Example 3: Vendor profile

A vendor with an EHR system wants to claim conformance to the EHR System Functional Model Standard.

The vendor identifies and lists all the functions that are in his product. He adds a description and a conformance clause (see samples in section 6.2). This is his profile. If he has actually implemented all the functions listed, then this is equivalent to the MFS, 'Essential Now'. If functions that are currently implemented and those that will be implemented in the future are listed, then the profile is comprised of a MFS and optional future functionality. Finally, the vendor adds conformance criteria for each function, inheriting directly (without change) the criteria in the Functional Model. This is appealing in that, the vendor has the opportunity to list his current functionality and if desired, indicate future plans. In essence, this is similar to a vendor conformance statement (a concept most vendors are already familiar with). It should be the case that a vendor's profile is equal to a vendor's product (or is greater than the vendor's product)

6.2 Sample Profile Conformance Clauses

Sample 1: for a care-setting profile

This profile defines the conformance requirements for systems and derived profiles. To conform to this profile, the Minimum Function Set must be implemented. A system is conforming if it implements all the functions designated as 'Essential Now' with mandatory conformance criteria. A derived profile is conforming if it contains all the functions in the Minimum Function Set and follows the Rules for Profiles.

Mandatory conformance criteria are indicated by the keyword **must**. Optional conformance criteria are indicated by the keywords **should** or **may**.

Implementations must provide a Conformance Statement structured according to the rules and policies defined in the profile.

Sample 2: for an application

E-Application is an application that if included in a care-setting specific system must conform to this profile. E-Application is an application that has a defined set of attributes of which the Minimum Function Set is required of any system claiming this e-Application functionality.

Two levels of conformance are designated:

- Level 1 – Core Conformance is comprised of the functions in the Minimal Function Set designated as 'Essential Now'.
- Level 2 – Advanced Conformance comprises the entire Minimal Function Set (i.e., all 'Essential Now' and all 'Future' functions).

A system may claim conformance to either Level 1 or Level 2 if it implements all the mandatory criteria for the functions at the conformance level for which the claim is being made.

Sample 3: for a vendor system (vendor profiling all current functionality)

Conformance is defined for My-EHRsystem. All functions in this profile are mandatory, are deemed as 'essential', and have been implemented in order to conform to this profile.

Sample 4: for a vendor system (vendor profiling both current and future functionality)

Conformance is defined for VendorEHR. To conform to this profile, all functions labeled as 'supported' shall be available and have been implemented. Functions labeled 'future' are optional, in that they are present for informational purposes only and must be implemented in future profiles.

7. Definitions

Base standard – a standardized base specification, i.e., HL7 EHR-S Functional Model Standard.

Conformance – the fulfillment of a product, process, or service of specified requirements.

Conformance criteria – statements of requirement indicating the behavior, action, capability that constitutes implementation of the function

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

Conformance statement – a statement associated with a specific implementation of a profile of the EHR-S Functional Model.

Balloted profile – a profile that has been voted upon according to the HL7 consensus process.

Derived profile – a profile that is created from an exiting profile.

Profile - a subset of the Functional Model, in which functions have been designated (sometimes in varying degrees) for certain EHR-S implementations or Healthcare Delivery Settings.

Proposed Draft

**A Guide to Creating Conformance Criteria
For the HL7 EHR System
Functional Model and Profiles**

HOW TO GUIDE WITH DOs AND DON'Ts

**For Public Comment
December 2004**

Copyright 2004 by Health Level Seven, ® Inc. ALL RIGHTS RESERVED. Any reproduction of this material in any form is strictly forbidden without the written permission of the publisher. Health Level Seven and HL7 are trademarks of Health Level Seven, Inc.

Table of Contents

INTRODUCTION 1

STEPS 1

PRINCIPLES 5

INTRODUCTION

The following is a guide for creating conformance criteria for the HL7 EHR-S DSTU Functional Model (denoted hereafter *FM*) and its profiles. Please bear in mind that these recommendations are meant as “help notes”, and as such, are not meant as binding directives. A set of basic steps are presented, followed by general principles to keep in mind as you create the criteria. Discussion assumes that the reader is familiar with the HL7 EHR-S Functional Model (*FM*) and is knowledgeable about EHR-S healthcare delivery settings and implementations.

Although primarily addressing conformance criteria for the *FM* level, this guide can also be employed in developing conformance criteria for *profiles*. The same basic steps and principles apply. Of course, FM conformance criteria constitute but one set, whereas there can be any number of profiles and their respective conformance criteria sets. In addition, profile criteria must adhere to constraints imposed by FM conformance criteria. Profiles should either derive their conformance criteria from FM criteria (if they exist) or use the FM criteria directly (again, if they exist). The HL7 EHR Working Groups listed at http://www.hl7.org/special/committees/list_sub.cfm?list=ehr are certainly happy to discuss aspects of an application or care setting profile. Please coordinate your efforts with them, especially regarding terminology that could be or is in the EHR TC Glossary [add reference as available].

STEPS

1. Read the function carefully

The conformance criteria will be created from the function *statement* and *description*. You may need to unroll the ‘rollups’ into more specific descriptions of the function, since some of these rollups may

- Contain cryptic hints that have to be amplified and made explicit
- Lack detail on an important function or concept

Examples

The *statement* for FM I.1.5 states that one must “Secure all modes of EHR data exchange”. Clearly much more is intended, for the informal *description* is 105 words long. S.2.2, Report Generation, is another function with a short statement and a long description: 149 words.

2. Extract out general concepts and premises

From the function *statement* and *description*, try to extract out overall concepts, underlying assumptions and meaning that must hold true. (Steps 3 and 4 address decomposing statement and description texts to extract specific details.)

Example

Workflow tasks (regardless of application or care setting) must start, progress, and terminate. Otherwise the system is unsound.

3. For each function *statement*: Separate into meaningful sentences - *i.e.*, distinct criteria

Read each function *statement* and capture the facts. What is the system being asked to do?

- Identify the actor.
Example: Because the FM concerns an EHR *System*, many criteria will identify the actor by opening with the phrase “The system ...”. Profile conformance criteria will show more variety because they address more specialized areas. (compare columns (1) and (2) below, Fig. 1).
- Identify the interaction (action) – *e.g.*, condition to hold true, behavior, or actions to take.
Examples: Create something; supply specific information (see Fig. 1, below)
- Is this mandatory or optional? – *e.g.*, *shall*, *must*, or an imperative sentence indicates mandatory, whereas *should* or *may* indicates optionality. (See # 5 and 6 below)

Write one or more short, clear, complete sentences to capture this information. Use one sentence for each concept or fact. These sentences are the criteria.

There should be at least one criterion that is mandatory – *i.e.*, has a ‘shall’ in it.

Figure 1. Example Criteria for (1) FM and (2) Profile.

FM Function Identification	FM Statement	(1) Conformance Criteria for FM	(2) Conformance Criteria for Profile using FM
DC.1.1.3 Manage Summary Lists	Create and maintain patient-specific summary lists that are structured and coded where appropriate.	<ul style="list-style-type: none"> • The system shall create and maintain a summary list for each patient • The system shall be capable of including structure and codes 	<ul style="list-style-type: none"> • A minimal set of patient identifying information (name, gender, DOB) must be visible in the user interface throughout the process of creating a prescription.
S.1.3.1 Provider demographics	Provide a current directory of practitioners that, in addition to demographic information, contains data needed to determine levels of access required by the EHR security system	<ul style="list-style-type: none"> • The system shall provide a directory of practitioners that has demographic information on providers • The system shall contain data needed to determine levels of access required by the EHR security system 	<ul style="list-style-type: none"> • For the Prescriber, the following information must be supplied either by user entry or through a supporting system: Name, Gov’t license number, Address, Phone Number, System access level. • For the Prescriber, the following information should be requested: Identification such as DEA number, National Provider ID, and/or Health Plan ID number.

4. *For each function description:* Separate into meaningful sentences - *i.e.*, criteria
Read each function *description* sentence. What is the system (or actor) being asked to do?
- Identify actors – *e.g.*, the system, prescriber, patient

—How to Guide with DOs and DON'Ts —

- Identify the interaction (action) – e.g., condition to hold true, behavior, or actions to take
- Is there a list of items given? Must all these be implemented or are these choices? Must one of the items be chosen or can none be chosen?
- Is there a range given? Create criteria for the minimum and maximum values.
- Are these examples? Examples can be captured as optional criteria
- Is the sentence conditional upon something being in place or an action? If so, don't forget to preface the criteria with, 'If x, then ...'
- Is this mandatory or optional? – e.g., *shall*, *must*, or an imperative sentence indicates mandatory, *should* or *may* indicates optionality. Tread carefully, when making a criteria mandatory (shall), if it was created from the function *description*. Remember this part was not balloted. (See #4 and #5 below).
- Once you have considered each sentence individually, now think about the combination of these sentences – does combining some of these sentences yield a new situation, behavior or action that needs to be captured?
- Is there a general concept that also applies, even though it wasn't explicitly described? – e.g., must have connectivity, ability to maintain and update?

Example:

S1.3.1 Provider demographics	The system should allow updating of provider demographics
------------------------------	---

Write one or more short, clear, complete sentences to capture this information. Remember, one sentence for each concept or fact.

Examples

FM Function Identification	FM Description	Conformance Criteria
DC.1.1.3 Manage Summary Lists	Patient summary lists can be created from patient specific data and displayed in a summary format. The functions below are important, but do not exhaust the possibilities	<ul style="list-style-type: none"> • The system should display summary list in a summary format • The system should include at least the following in the summary list: problem list, medication list, allergy and adverse reaction list
S1.3.1 Provider demographics	Provider demographics may include any credentials, certifications, or other information that may be used to verify that a provider is permitted to perform certain service	<ul style="list-style-type: none"> • The system should be capable of capturing credentials, certifications and other verification information • The system should allow updating of provider demographics

5. Indicate clearly whether mandatory or optional

Look carefully at the language used by the function *statement* and *description*. How do you know mandatory or optional elements? The FM text may or may not use 'must', 'shall' and 'should'. Sometimes, an imperative sentence is used to indicate a requirement (e.g., "Include this."). Additionally, it may be the case that 'must' was used in error and was not the intent.

6. Make at least one of the criteria mandatory (i.e., 'shall' or 'must')

Try to find at least one criterion that is the core or basis of the function – that is, without this criterion you don't have that function. Make this a mandatory criterion. Its best if this criterion is taken from the function's *statement* rather than its *description*.

For profiles, if a FM conformance criterion is mandatory (worded 'shall' or 'must'), then it is also mandatory in the profile. If a FM conformance criterion is optional—'should' meaning *recommended*, 'may' signifying *at user discretion*—then the profile may make the criterion mandatory ('shall' or 'must').

7. Check for dependencies and co-relations

Some functions will depend on or relate to other functions in the FM. Follow these chains of function dependency to ascertain that details in the chain are appropriate and captured. Record function dependencies and other important linkages.

Example: S1.3.1 Provider demographics relates to I1.2 Entity Authorization

Some functions specify general categories or need more information to be testable eventually. This information will come from care settings, applications, realms, etc. It is helpful to indicate the type of additional information needed.

Examples

DC1.1.3.2 Manage medication lists – which lists?

S1.3.1 Provider demographics - what demographics – credentials, certifications, other?

Congratulations - you have created conformance criteria.

By the way, use this exercise of creating criteria as a feedback loop to improve the FM – to find and correct ambiguities, inconsistencies, etc. in the original text.

PRINCIPLES

Follow the below principles when creating conformance criteria:

1. **Do** restrict each conformance criterion to one atomic, simple statement.
 - Address one feature at a time.
 - Keep each criterion as simple as possible. Multiple one-feature criteria will be easier to test (and trace back should a test fail) than one multi-part criterion.
 - Order features in a natural progression, beginning with easiest. This makes your document easier to read and later testing and trace-back more sensible (see next item). If an implementation can't support an 'easy' criterion, then it is unlikely to support a more complex one.
 - Ensure traceability of criteria to a function. Each criterion must be directly traceable to wording (*name* or *statement* or *description*) of the function in the FM.
2. **Do** make criteria technology neutral.
3. **Do Not** change the functionality of the EHR-S FM.
4. **Do Not** mix important terminologies.
 - Use an EHR-S Glossary agreed upon by all.
 - Keep the balance of your text self-contained, with as few footnotes and external references as practical.
 - Choose either “shall” or “must” to signify requirement, use “should” for recommendation (but not requirement) and “may” for neutral choice. Don't mix sets of terms that assign different interpretations to the same words.
5. **Do** constrain optionality and cardinality.
 - Describe what features, values, attributes, etc. are to be measured and what the range indications are for success or failure.
Example: ...occurs zero or more times
 ...required when <Person> used
6. **Do** indicate explicit dependencies and constraints.
7. **Do Not** state how to test.
8. **Do Not** rely upon formatting or context to convey intentions such as mandatory or optional. For example, instead of employing italic or bold face, use the English imperative “shall” or “must”, whichever is chosen as standard terminology.
Example: Not “..*this* feature *is* required,” but rather, “..shall require feature A31.”