

# HL7 EHR TC

## Electronic Health Record - System Functional Model, Release 1 February 2007

# Chapter Two: Conformance Clause

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## Chapter 2: Introduction (*Reference*)

The following is the EHR Technical Committee approved, Conformance Clause. As important background on conformance, please note the following:

1. This conformance clause defines what it means to conform to the EHR-S Functional Model.
2. Conformance to the Functional Model is defined for functional profiles. An EHR system does not directly conform to the Functional Model, rather it conforms to one or more functional profiles.
3. Conformance criteria are associated with every function in the EHR-S Functional Model.
4. This conformance clause does not specify testing or validation procedures to determine whether an EHR system conforms to a functional profile or whether a functional profile conforms to the EHR-S Functional Model.

The technical and management staff of the U.S. National Institute of Standards and Technology, Information Technology Laboratory (NIST) provided orientation and education to EHR TC members on conformance. With significant input and support from NIST, we have developed two key documents: 1) this conformance clause, and 2) a profile development “How To” guide.

## Conformance Clause

### 1. *Scope and Field of Application (Normative)*

This *conformance clause* defines the minimum requirements for *functional profiles* claiming conformance to the EHR System Functional Model. It also identifies how EHR systems achieve conformance to the Functional Model, which is via the system’s conformance to a particular functional profile. This clause specifies:

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

While the conformance requirements for functional profiles can be found in this clause, they necessarily reference the Functional Model and other sources.

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

## 2. Concepts (Normative)

### 2.1 Functional Profiles

Creating a functional profile is a method for defining subsets of the Functional Model. A functional profile is a specification which uses the Functional Model to indicate which functions are required, desired, or implemented for certain EHR systems, Healthcare Delivery Settings, or for other purposes (e.g. profile for legal EHR).

Functional profiles can be created by healthcare community stakeholders with interest in using and/or providing a functional profile for an EHR system. Functional profiles can represent the functionality required and desired for a care setting or application, or reflect the functionality incorporated in a vendor's EHR system. Once a functional profile is defined it can be implemented by EHR systems or it may trigger the creation of derived functional profiles. A *derived functional profile* is a functional profile that is created from an existing functional profile, inheriting functions from the base (existing) functional profile.

A formal process exists for registering and balloting functional profiles. Functional profiles that are submitted to the HL7 EHR TC with an attestation of conformance to Chapter 2: Conformance Clause of the HL7 EHR-S Standard and successfully complete review by the TC are designated as "*Registered functional profiles*". Registered functional profiles that undergo formal public scrutiny via the HL7 consensus process as an Informative EHR TC ballot at the committee level will be designated as *HL7 Informative functional profiles*. HL7 Informative functional profiles are eligible to undergo full membership ballot via the HL7 consensus process. *For additional information on registering and/or balloting functional profiles, see the reference information in the How To Guide for Profiles.*

### 2.2 Conformance Model

Conformance to the Functional Model is defined for functional profiles. A functional profile conforms either (1) directly to the Functional Model or (2) to another conforming functional profile. An EHR system does not conform directly to the Functional Model; rather, it conforms to a functional profile. Thus, functional profiles claim conformance to the Functional Model and EHR systems claim conformance to one or more conforming functional profiles. Figure 1 on the next page illustrates this relationship.

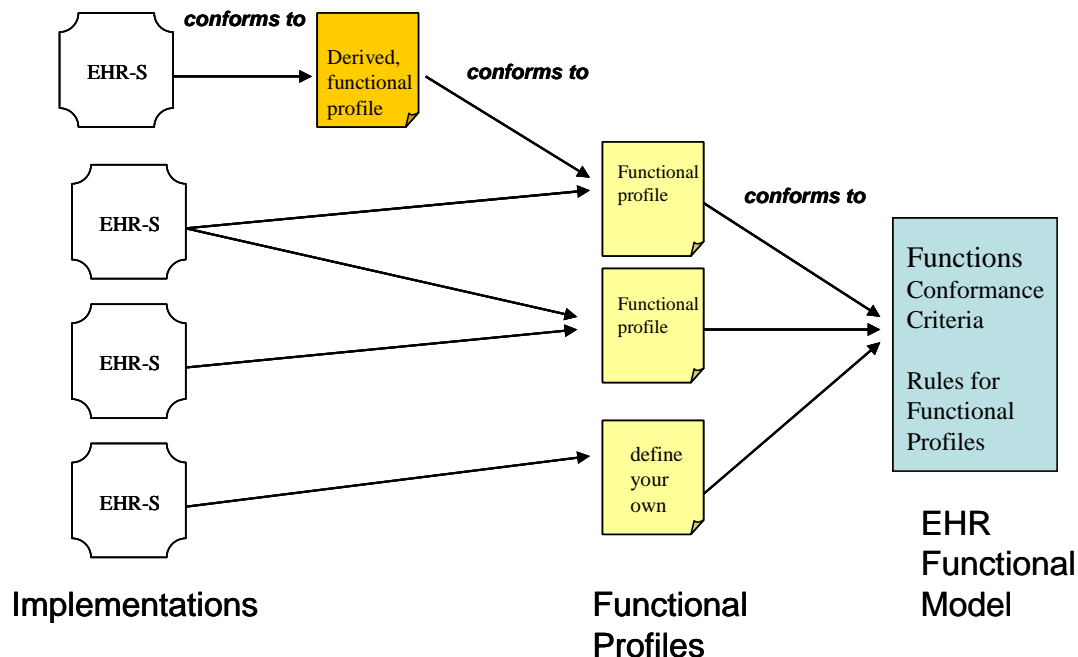


Figure 1 Conformance Relationships

### 3. Normative Language (Normative)

The following keywords (i.e., normative verbs) **SHALL** be used to convey conformance requirements.

- **SHALL** – to indicate a mandatory requirement to be followed (implemented) in order to conform. Synonymous with 'is required to'.
- **SHALL NOT** – to indicate a prohibited action. Synonymous with 'prohibited'.
- **SHOULD** - to indicate an optional recommended action, one that is particularly suitable, without mentioning or excluding others. Synonymous with 'is permitted and recommended'.
- **MAY** - to indicate an optional, permissible action. Synonymous with 'is permitted'.

The EHR-S Functional Model (i.e., all chapters) contains normative, informative, and reference sections. In this conformance clause chapter, the normative content defines how a functional profile achieves conformance to the Functional Model.

### 4. Conformance Criteria (Normative)

Every function in the Functional Model is associated with a set of conformance criteria. These *conformance criteria* form the basis for determining whether the function has been implemented.

#### 4.1 Criteria in the Functional Profile

Functional profiles also have conformance criteria associated with every function in the functional profile. The functional 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. Functional profiles **MAY**

change Functional Model criteria to match the needs and priorities of the functional profile's constituency, e.g., by making it more specific, or changing it from 'may' or 'should' to 'shall'. The functional profile **SHALL NOT** be made less restrictive than the Functional Model by changing 'shall' criteria to 'may' or 'should' criteria. Functional profiles **MAY** also add additional criteria.

#### 4.2 'Dependent SHALL' Criteria

Conformance criteria that contain the keyword 'shall' **and** a dependency on situational conditions are called 'dependent shall' criteria. The 'dependent shall' **SHALL** contain the phrase "in accordance with scope of practice, organizational policy, or jurisdictional law" or other appropriate grammatical tie-in words (e.g., 'based on' rather than 'in accordance'). A 'dependent shall' criteria is used to highlight only these (i.e., scope of practice, organizational policy or jurisdictional law) conditions. A 'dependent shall' criterion is a mandatory criterion for functional profiles and situational for EHR systems. Specifically,

- All functional profiles **SHALL** inherit the criterion, if the function appears in the functional profile.
- An EHR system **SHALL** implement the criterion only if the criterion is applicable per the stated dependency in the functional model

#### 4.3 Referencing Other Criteria or Functions

There is often a link between functions and their criteria with other functions and criteria. For example, a given function may depend on another function or on a specific criterion associated with another function.

A criterion in the functional profile that references another function in the functional profile **SHALL** reference that function by indicating its name and ID, as "X.n.n (Name)". If the referenced function is required to be implemented, then all the 'shall' criteria of this referenced function apply.

A criterion in the functional profile that references a specific criterion in another function **SHALL** reference that function by rewriting the referenced criterion as one of its own and indicating the function from where it came.

## 5. Functional Model Structure and Extensibility (Normative)

### 5.1 Hierarchical Structure

Functions **MAY** be contained (i.e., nested) within other functions. A nested function is a ‘child’ to its ‘parent’ (i.e., the function that contains it). A child **SHALL** always have a parent. A function that is not a parent to another function is considered a ‘leaf’. Figure 2 illustrates this hierarchical structure.

The Functional Model is represented as a hierarchical list of functions, consisting of functional headers and functions. Headers include an ID, Name and “H” in the column labeled “Type”. Headers **MAY** contain conformance criteria only if the criteria apply to all its descendent functions (i.e., children, grandchildren, etc.). A function of type H (i.e., header function) is always parent function. Functions contain at a minimum the following: ID, Name, Statement, Description, and Conformance Criteria and have a “F” in the “Type” column. Conformance criteria listed in a header function **SHALL** be inherited by all its children functions. Similarly, conformance criteria listed in a parent function **SHALL** be inherited by all its children functions.

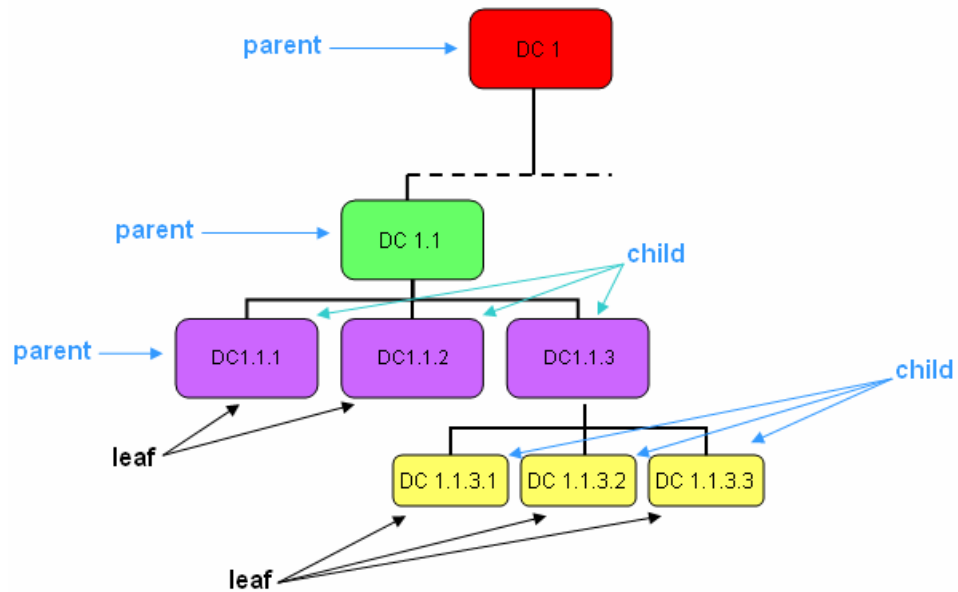


Figure 2 Portion of the Functional Model hierarchical structure

Functional profiles either:

- Select functions from the Functional Model for inclusion in the functional profile,
- Deem a function in the Functional Model as not applicable, thus do not select it for inclusion in the functional profile,
- Add a new child function when it has been determined that there is no applicable function in the Functional Model to represent a functional need in the functional profile.

### *5.2 Naming Convention*

Functional profiles **SHALL NOT** change the name or statement of a function except to allow for alignment to realm specific nomenclature. In these cases, the International Organization for Standardization (ISO) country code (ISO 3166 Country Codes) **SHALL** be appended to the function ID in the functional profile. It is recommended that the HL7 Affiliate for the respective realm coordinate and the profile maintain a mapping of the Functional Model function name and/or statement and the realm-adjusted name and/or statement.

### *5.3 Priorities*

Functional profiles indicate the importance and/or immediacy of a functional profile by associating a priority with a function. Three priorities have been defined, Essential Now, Essential Future, and Optional.

- Essential Now indicates that the implementation of the function is mandatory, as of the profile issuance date.
- Essential Future indicates that the implementation of the function is currently optional but will be mandatory at some future time, which is specified by the functional profile
- Optional indicates that the implementation of the function is optional.

Any or all of these priorities **SHALL** be used in a functional profile. If the Essential Future priority is used, then functional profiles are required to define the timeframe associated with implementing functions. A timeframe **MAY** be a date, time allotment (e.g., year 2008 or 4 months after functional profile publication), or event (e.g., republication of this functional profile). A functional profile **MAY** define multiple timeframes for the Essential Future priority. If multiple timeframes are defined, then the timeframe **SHALL** be used to qualify each occurrence of the Essential Future priority (e.g., EF-2008, EF-2009).

### *5.4 Extensibility*

To accommodate changes in technology as well as functional profiles' needs, the Functional Model is designed for extensibility. Incorporation of additional functions in the functional profile beyond what is defined in the Functional Model is accommodated through a set of rules for adding new functions as defined in Section 6.2.

## **6. Functional Profile Conformance (Normative)**

A functional profile claiming conformance to the Functional Model **SHALL** meet all requirements specified in the Rules for Functional profiles.

### 6.1 Rules for Functional Profiles

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

#### 6.1.1 Functional profiles claiming Functional Model conformance **SHALL**:

1. Identify the Functional Model with version/date, from which the functional profile is derived,
2. Include a description, version and issuance date of the functional profile,
3. Contain a conformance clause which
  - a. Defines the requirements that EHR systems must satisfy in order to claim conformance to the functional profile,
  - b. Defines the requirements that functional profiles derived from the functional profile (i.e., derived functional profiles) must satisfy in order to claim conformance to the functional profile.
  - c. Specifies that functions designated with the priority 'Essential Now' **SHALL** be implemented by conformant EHR systems.
  - d. Specifies that functions designated with the priority 'Essential Now' **SHALL** be included in any derived functional profiles.
  - e. If Essential Future is used, defines the meaning of 'Essential Future', including specifying the timeframe for when these functions are required to be implemented.
  - f. Requires that at least one function, regardless of its priority, be implemented in order for an EHR system to claim conformance to the profile.
4. Identify functions from the Functional Model that are applicable to the functional profile. For each function, indicate its priority (i.e., Essential Now, Essential Future or Optional)
5. For each function, derive conformance criteria based on the Functional Model's conformance criteria.
  - a. In the functional profile, there **SHALL** be at least one criterion for each function that is mandatory (a 'shall' criterion).
  - b. If there are 'shall' criteria (for the function in the Functional Model), then those criteria **SHALL** also exist for the function (in the functional profile). Additionally, if the function is split (in the functional profile), then the parent's 'shall' criteria **SHALL** appear in at least one child of that function.
  - c. If, as yet there is no 'shall' criterion (for the function in the Functional Model), then at least one of the 'should' or 'may' criterion **SHALL** be made mandatory, i.e., a 'shall' criterion.
  - d. Adhere to the rules for referencing functions or criteria in Section 4.3.
6. For any function in the functional model where one or more criteria are 'dependent shall' criteria, the functional profile for that function **SHALL**
  - a. Replicate verbatim each 'dependent shall' in the functional profile, regardless of whether the dependent situation applies or not.
  - b. When the dependent situation applies, create 'shall' criteria that apply the dependency to the 'dependent shall' criterion, resulting in one or more new, constrained versions of the 'dependent shall' criterion.
  - c. State the specific scope of practice, organizational policy, and/or jurisdictional law which applies or state why these dependencies do not apply.
7. Adhere to the rules for creating new functions in functional profiles in Section 6.2.
8. Be structured in accordance with the structural requirements defined for the Functional Model in Section 5.

#### 6.1.2 Functional profiles claiming conformance to the Functional Model **MAY**:

1. Create additional functions according to the rules specified in Section 6.2.
2. Contain conformance criteria more specific and limited in scope than those of the Functional Model.

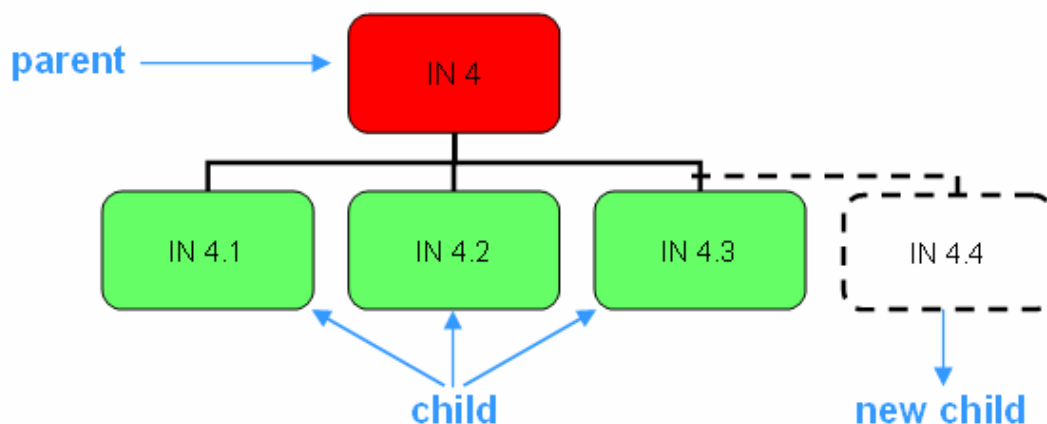
3. Replace the text 'standard(s)-based' found in some criteria with specific standards and/or specifications named at the most discrete level of designation.
4. Change a 'should' criterion to a 'shall' or a 'may' criterion.
5. Change a 'may' criterion to a 'shall' or a 'should' criterion.
6. Ignore a 'should' or 'may' criterion in the functional model (i.e., not include it in the functional profile).
7. Add additional conformance criteria beyond those in the Functional Model.
8. Make the order of the conformance criteria significant (e.g., put all 'shall' criteria first).
9. Enforce common resolution of ambiguous semantics of the Functional Model.
10. Make the functional profile public (e.g., published on a web site) so interested parties can see/use it.
11. Submit the functional profile for registration review by the HL7 EHR Technical Committee.

#### 6.1.3 Functional 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. Modify the name or statement of any function in the Functional Model, except to allow for alignment with realm specific nomenclature as specified in Section 5.2.
3. Change a mandatory conformance criteria to an optional criteria (i.e., replace the 'shall' within the criteria to 'should' or 'may') of any function in the Functional Model.
4. Modify any requirements of a function not selected for the functional profile (i.e., all unselected functions default to the Functional Model's criteria. If a profiling group wants to change something, they **SHALL** promote it into their functional profile).

### 6.2. Rules for Creating New Functions in Functional Profiles

If a function is not adequately specified for a functional profile or does not exist, the functional profile **SHALL** only create new children . Figure 3 illustrates the addition of a new child function.



**Figure 3 Creating a new function**

The following rules specify the method for creating new functions.

1. Whenever possible, conformance criteria **SHOULD** be used to avoid creating a new function. This may be done, for example, in cases where the original function's conformance criteria are too broad: divide the Functional Model's or base functional

- profile's inherited conformance criteria into two criteria in the functional profile, one being mandatory and the other optional.
2. When a 'leaf' function exists but is too broadly specified in the Functional Model or base functional profile for conformance criteria to adequately constrain it, then the function **MAY** be split as follows:
    - a. The original 'leaf' function is retained as the parent of its newly created children functions,
    - b. The original 'leaf' function's conformance criteria **SHALL** be distributed among its children functions.
  3. When no candidate function exists to express the requirements of a functional profile, a new child function **MAY** be created (e.g., adding a new kind of summary list under the summary list's parent).
  4. 'Non-leaf' functions **SHALL NOT** be split. This preserves the structure of the underlying functional model in the functional profiles.

If new children functions are created by a functional profile, then these new functions **SHOULD** be forwarded to the HL7 EHR TC for review. The EHR TC **MAY** use this as input for changes to the Functional Model (e.g., inclusion, relaxation of conformance criteria).

### 6.3. Rules for Derived Functional Profiles

Derived functional profiles claiming conformance to one or more base functional profiles **SHALL**:

1. Adhere to all the rules for functional profiles as specified in Section 6.1
2. Adhere to the rules for creating new functions as specified in Section 6.2, if not prohibited by the base functional profile.
3. Identify the base functional profiles from which it is derived.
4. For each function inherited from a base functional profile, retain and not change mandatory conformance criteria to optional conformance criteria.

### 6.4 Conformance Statement

Functional profiles **MAY** want to require that a conformance statement be produced for systems claiming conformance to the profile. A *Conformance Statement* provides information about an EHR system, by presenting in a uniform manner the functions that have been implemented by the EHR system. A blank (i.e., yet to be completed) Conformance Statement typically takes the form of a questionnaire or checklist, to be completed for each EHR system.

A Conformance Statement provides a concise summary of a functional profile. It follows a standard layout, thus providing EHR system vendors and users a quick overview of the functional profile's functions. Moreover, it can also be used to highlight optional functions and capabilities supported by the EHR systems as well as document any extensions (i.e., additional functionality beyond what is in the functional profile) or specializations that have been made. An EHR system's Conformance Statement provides information that can be used in assessing the EHR system's conformance to a specific functional profile. Additionally, organizations wishing to acquire an EHR system **MAY** produce a Conformance Statement to indicate the functions that are required and/or desired in an EHR system

Functional profiles **MAY** want to include a blank Conformance Statement in order to promote consistency among completed Conformance Statements. Conformance Statements can be useful in determining the chances of interoperability between two EHR systems, by comparing the functions supported by each EHR system. Additionally, for conformance testing purposes, it can be used to facilitate the selection of tests that would be applicable to a particular EHR system being tested. For example, if an EHR system did not implement functions designated as

'Essential Future', this would be evident in the Conformance Statement and the tests for these functions (which are unimplemented) would not be performed.

## **7. Use Cases and Samples (Reference)**

### *7.1 Functional Profile Use Cases*

#### **Example 1: Care Setting**

It is determined that a new care setting functional profile is needed to reflect the care setting specific requirements. To help ensure widespread use and uniformity, the functional profile authors elect to undergo the registration review followed by the HL7 consensus process (i.e., submitting the registered functional profile for an "Informative" committee level ballot). If successful, the result will be designated a HL7 Informative Functional Profile.

After looking at current list of HL7 informative functional profiles, the decision to create a new functional 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 functional profile, a description of the functional profile, including its intended use and audience as well as a conformance clause is written. The functional profile is made public by publishing it on various web sites. Additionally, the functional profile is submitted to HL7's EHR technical committee for registration review, comment and ballot.

#### **Example 2: Community of Interest derived functional profile**

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

The Community of Interest doesn't want to create a new functional profile from scratch. After looking at the list of Registered Functional Profiles, they find an existing functional profile that is very close to what they want. Using this functional profile as the base, they accept all the functions designated as 'Essential Now', 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 functional profile**

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

The vendor identifies and lists all the functions that are in his product. The vendor adds a description and a conformance clause (see samples in section 7.2). This is the vendor's functional profile. If the vendor has actually implemented all the functions listed, then this is equivalent to 'Essential Now' and these functions are mandatory. If functions that are currently implemented and those that will be implemented in the future are listed, then the functional profile is comprised of 'Essential Now' and 'Essential Future' and/or optional 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 the 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). A vendor may create multiple functional profiles.

## 7.2 Sample Functional Profile Conformance Clauses

To aid functional profile developers in developing a conformance clause for their functional profile, as required by Section 6.1 rule #3, the following examples are offered. Note: in these examples, the keywords 'shall', 'should', and 'may' are capitalized and bold. This is a convention to draw attention to the keywords.

### Sample 1: conformance clause for a care-setting functional profile

This functional profile defines the conformance requirements for EHR systems and derived functional profiles. To conform to this functional profile, all 'Essential Now' functions **SHALL** be implemented. 'Essential Now' functions are considered mandatory functions. An EHR system is conforming if it implements all the functions designated as 'Essential Now' and the mandatory conformance criteria associated with that function. A derived functional profile is conforming if it follows the Rules for functional profiles.

Mandatory conformance criteria are indicated by the keyword 'shall'. Optional conformance criteria are indicated by the keywords 'should' or 'may'.

EHR systems **SHALL** provide a Conformance Statement structured according to the rules and policies defined in this functional profile.

### Sample 2: conformance clause for an application

E-Application is an application that if included in a care-setting specific system **SHALL** conform to this functional profile. E-Application is an application that has a defined set of attributes of which a minimum set of functions is required of any system claiming this e-Application functionality. Two levels of conformance are designated:

- Core Conformance is comprised of the functions in the minimal set of functions that are designated as 'Essential Now'.
- Advanced Conformance comprises the entire minimal set of functions (i.e., all 'Essential Now' as well as those designated 'Essential Future' functions).

A system **MAY** claim conformance to either the Core or Advanced Conformance levels, if it implements all the mandatory criteria for the functions at the conformance level for which the claim is being made.

Functions designated with the priority 'Essential Now' indicate core functionality. These functions are required to be implemented in order to claim conformance to E-Application, regardless of the level of conformance (i.e., core or advanced) to which the claim is made.

Functions designated with the priority 'Essential Future' indicate advanced functionality. These functions are required to be implemented in order to claim advanced level conformance. 'Essential Future' functions become mandatory 18 months after publication of this functional profile and thus, required for immediate implementation in order to claim conformance at either the core or advanced levels.

### Sample 3: conformance clause for a vendor system functional profile

Conformance is defined for My-EHRsystem. All functions in this functional profile are mandatory, are deemed as 'essential now', and **SHALL** be implemented in order to conform to this functional profile.

### Sample 4: conformance clause for a community of interest functional profile

Conformance is defined for BuyMyEHR. To conform to this functional profile, all functions labeled as 'essential now' **SHALL** be available and have been implemented. Functions

labeled 'essential future' are optional, in that they are present for informational purposes only and **MAY** be implemented in future functional profiles.

## **8. Interpreting and Applying 'Dependent SHALL' (Reference)**

The following example of a Functional Model 'dependent shall' criterion will be used to illustrate concepts throughout this section.

Functional Model criterion: *The system **SHALL** enable EHR-S security administrators to grant authorizations to principals according to scope of practice, organizational policy, or jurisdictional laws.*

### **8.1 General Concepts**

The purpose of the 'dependent shall' is to allow functional profiles to constrain a Functional Model 'shall' criteria based on situational conditions such as policy and legal implications. Specifically, the 'dependent shall' criteria in the Functional Model are 'shall' criteria + a dependency, where the dependency is defined by:

- Scope of practice which applies to the EHRs user's scope of practice and refers to best practices within the user's discipline – which may be care setting specific or not.
- Organizational policy which refers to a plan or course of action intended to influence and determine decisions, actions, and other matters of a group of persons organized for a particular purpose within an association and structure through which individuals cooperate systematically to conduct business.
- Jurisdictional law which refers to the territorial range of authority or control with the power, right, or authority to interpret, apply, and declare the body of rules and principles governing the affairs of a community and enforced by a political authority; a legal system.

The structure of the 'dependent shall' criteria in the Functional Model is the same as the 'shall' criteria except with the addition of the phrase "in accordance with scope of practice, organizational policy or jurisdictional law" or other appropriate grammatical tie-in words (e.g., based on rather than in accordance). Note that all three dependencies are present in the Functional Model 'dependent shall' criteria. It is the functional profile that narrows it to any one dependency or any combination of the three. Moreover, in the functional profile, the specific scope of practice, organizational policy, and/or jurisdictional law which necessitates evoking the 'dependent shall' is explicitly identified.

For example: (derived from the Functional Model criterion above)

Functional Model criterion: *The system **SHALL** enable EHR-S security administrators to grant authorizations in accordance with HIPAA.*

The difference between a 'shall' criterion and a 'dependent shall' criterion is shown in Table 1 below.

	'SHALL' Criterion	'Dependent SHALL' Criterion
Be present in the functional profile	Yes, either verbatim or modified (e.g., constrained or refined)	Yes, verbatim. If dependency exists, add additional criteria reflecting the dependency.
Implemented by EHR systems	Yes.	Situational - only implement if the dependency exists. Specifically, EHR system does not implement the 'dependent shall' criterion (as copied from the FM), but does implement additional 'shall' criteria created to reflect the dependency.

**Table 1 Differences between 'shall' and 'dependent shall'**

### 8.2 Rationale for 'Dependent SHALL'

The reason for using a 'dependent shall' in the Functional Model is to highlight these criteria and bring them to the attention of the reader – both developers of functional profiles as well as other users. These criteria are considered to be special cases, where there are one or more dependencies that affect these criteria, across multiple care settings. Using the 'dependent shall' ensures that developers of all functional profiles address the criterion and consciously decide whether the criterion in question is applicable, based on the stated dependency.

Regardless of whether a dependency exists or not, the 'dependent shall' is copied verbatim into the functional profile. The reasons for this are:

- Adherence to the rule that a 'shall' criterion is always inherited by the functional profile.
- Consistency with handling the 'dependent shall' under all conditions (i.e., when there are dependencies and when there are not).
- Retention of the 'dependent shall' so that it is present for derived profiles.
- Retention of the 'dependent shall' so that it remains effective for this profile if future requirements change (i.e., the dependency may not be applicable at this present time, but may be applicable in the future due to changes in scope of practice, organizational policy or jurisdictional law).

### 8.3 How to Apply the 'Dependent SHALL'

The way to interpret and apply a 'dependent shall' criterion in a functional profile is as follows:

- Copy the criterion into the functional profile.
- Review the criterion and determine if any of the dependencies are applicable to the functional profile.
- Dependency exists  
If one or more dependencies are applicable to the functional profile (e.g., there are jurisdictional legal requirements), add one or more 'shall' criteria that refine and further constrain the 'dependent shall' with respect to the dependencies.

For the new criteria, add an explanation and/or citing for the dependency. For example, jurisdictional legal requirements for this functional profile are defined by Federal Regulations (see 45 CFR Parts 160, 162 and 164 – The HIPAA Security Rule. The

explanation or citing may be in an appendix. It is likely that multiple criteria will reference the same explanation or citing.

Examples:

Functional Profile criteria

1. The system **SHALL** enable EHR-S security administrators to grant authorizations to principals in accordance with HIPAA\*.
2. The system **SHALL** enable EHR-S security administrators to grant authorizations for roles in accordance with 42 CFR Part 2\*.

Dependency Explanation

\*For a U.S. realm functional profile, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as well as other jurisdictional legal requirements or other more stringent requirements would be applied to 'dependent shall' criteria in the functional profile.

FM	Dependency Applicable?	Applicability	Functional Profile
Dependent SHALL	Yes	Mandatory	Copy SHALL from FM
		Mandatory	Add additional criteria to reflect the dependencies. Use 'shall'.
		Mandatory	Add explanation or citing
		Optional	Add additional criteria derived from 'dependent shall'. Use 'shall', 'should' or 'may'.

Table 2 Summary of actions when dependency exists

- No Dependency exists  
If no dependency is applicable to the functional profile (i.e., there are no scope of practice, organizational policies or jurisdictional legal requirements that apply), then document the rationale for deciding that no dependencies apply. This explanation may be in an appendix. It is likely that this explanation will apply to multiple 'dependent shall' criteria.

FM	Dependency Applicable?	Applicability	Functional Profile
Dependent SHALL	No	Mandatory	Copy SHALL from FM
		Mandatory	Add explanation
		Optional	Add additional criteria derived from 'dependent shall'. Use 'shall', 'should' or 'may'.

Table 3 Summary of actions for when no dependencies

- Add additional criteria – regardless of whether a dependency exists or not.  
It is always permissible for a functional profile to add new criteria. Add new criteria that are derived from the 'dependent shall'. Use any keyword: 'shall', 'should' or 'may' (see Section 3) in these new criteria.

Examples:

1. The system **SHOULD** enable EHR-S security administrators to grant authorizations to principals.
2. The system **MAY** enable EHR-S security administrators to grant authorizations for roles.

3. The system **SHOULD** enable EHR-S security administrators to grant authorizations within contexts.

4. The system **SHALL** enable EHR-S security administrators to grant authorizations for roles for organizations with 10 employees or more.

## 9. Definitions (Reference)

Additional terms are listed in the HL7 EHR-TC Functional Model Glossary.

Base functional profile :	An existing functional profile from which new functional profiles are created/derived.
Conformance:	The fulfillment of a product, process, or service of specified requirements.
Conformance criteria:	Requirements 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 description of the function in an EHR system that have been implemented. It reflects the degree to which an EHR system has met the functionality has met the functional profile's requirements and may include optional functions and information.
Derived functional profile:	A functional profile that is created from a base functional profile, (i.e., child functional profile).
Extension:	The ability for an EHR-S to incorporate additional functionality beyond what is defined in the Functional Profile.
Functional profile:	A subset of the Functional Model, in which functions have been designated (sometimes in varying degrees) for certain EHR systems or healthcare delivery settings.
Informative functional profile:	A registered functional profile that has successfully completed formal public scrutiny via the HL7 consensus process.
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.
Registered functional profile:	A functional profile that has successfully completed HL7 EHR Technical Committee registration process and review.
Situational criterion:	Criterion that is required if the circumstances given are applicable.