Introduction

The following is the EHR Technical Committee approved, non-balloted, pre-final Conformance Clause. It is anticipated that the final version of the 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

Also note that although the term *profile* is used in this document, the more accurate designation is *functional profile* of the EHR System Function 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 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. Scope and Field of Application

This *conformance clause* defines the minimum requirements for *profiles* claiming conformance to the EHR System Functional Model. It also identifies how an EHR Systems can have conformance to the Functional Model, which is via that systems' conformance to a particular profile. This clause 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 EHR systems,
- sample conformance clauses and use case scenarios,

- guidance on the conformance requirements that a profile might levy on EHR systems,
- guidance on the purpose and use of an EHR system Inventory Statement.

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

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 EHR system conforms to a profile or matches its Inventory Statement.

2. Concepts

2.1 Profiles
Creating a profile is 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 systems or Healthcare Delivery Settings.

Profiles can be created by anyone. 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 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 base (existing) profile. NOTE: Profiles that undergo formal public scrutiny via a standards setting organization's consensus process (for HL7, Informative ballot at the committee level) will be designated as *SDO balloted profiles*. Though none are planned in the 2005 near-term for the US realm, it is feasible that another SDO like ASTM or an international HL7 affiliate realm may create and/or submit such a profile.

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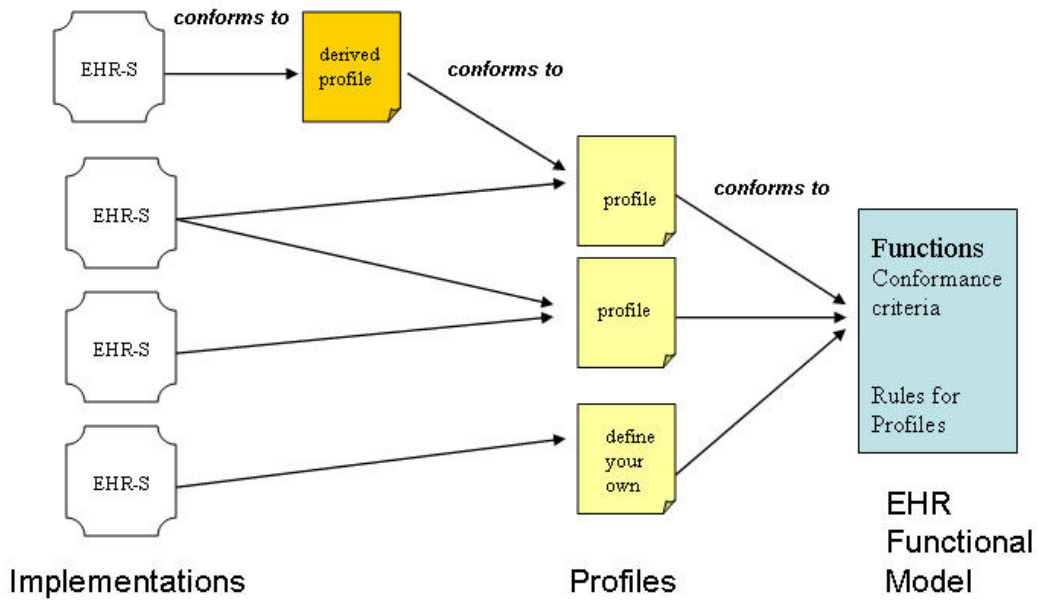
Figure 1 Conformance Relationships

3. Normative language
The following keywords 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'.
- **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'.

This document consists of normative, informative, and reference sections. The normative contect explains how a profile may achieve conformance to the Functional Model. Informative and reference sections of this document consist of examples, extended explanations, and other matter that contains information that should be read to acquire a proper understanding of conformance and this conformance clause.

4. Conformance Criteria

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. A conformance criterion usually specifies a testable property of an EHR System, although there may be desirable conformance criteria that represent system properties that, for practical purposes, are difficult or impossible to test.

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 optional to mandatory – as long as the profile does not thereby become less restrictive than the Functional Model. Profiles may also add additional criteria.

5. Functional Model Structure and extensibility

The Functional Model is represented as a hierarchical list of functions, consisting of functional headers and functions. The headers are indicated by an ID and Name, whereas functions contain at a minimum the following: ID, Name, Statement, Description, and Conformance Criteria. 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). Functions at the same level are called 'siblings'. A function that is not a parent to another function is considered a 'leaf'. Figure 2 illustrates this hierarchical structure.
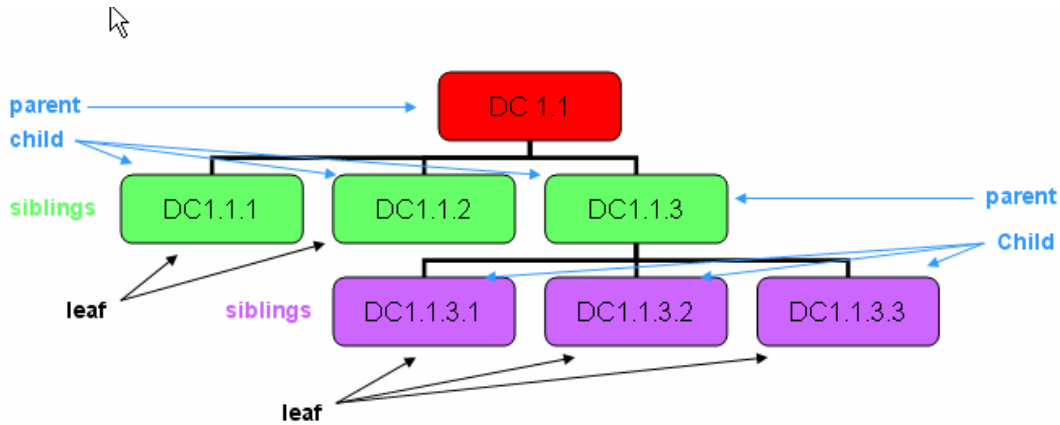

Figure 2 Functional Model hierarchical structure

Profiles either:
- Select functions from the Functional Model for inclusion in the profile,
- Deem a function in the Functional Model as not applicable, thus not select it for inclusion in the profile,
- Determine that there is no applicable function in the Functional Model to represent a functional need in the profile.

To accommodate changes in technology as well as profiles' needs, the Functional Model is designed for extensibility. *Extensions* provide for the incorporation of additional functions in the profile beyond what is defined in the Functional Model. To minimize the impact of extensions on such things as conformance, the ability to compare profiles, the development of support tools, etc., a set of rules for adding new functions is defined (see Section 6.2).

6. Profile Conformance

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

6.1 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, version and date of the profile,
3. contain a conformance clause which
   a. defines the requirements that EHR systems shall satisfy in order to claim conformance to the profile,
   b. defines the requirements that profiles derived from the profile (i.e., derived profiles) shall satisfy in order to claim conformance to the profile.
   c. specifies that functions designated as 'Essential Now' shall be implemented by conformant EHR systems.
   d. specifies that functions designated as 'Essential Now' shall be included in any derived profiles.
4. identify functions from the Functional Model that are applicable to the profile. For each function indicate whether it is mandatory (i.e., Essential Now or Essential Future) or Optional.
5. for each function, derive conformance criteria based on the Functional Model's conformance criteria. There shall be at least one criterion for each function that is mandatory (a "shall" criterion). If no profile-specific conformance criterion are listed, then the profile inherits the Functional Model's conformance criteria, and

the first statement in the inherited criterion becomes an implicit "shall" statement, if no others exist.
6. adhere to the rules for creating new functions in profiles in Section 6.2.
7. be structured in accordance with the structural requirements defined for the Functional Model in Section 5.

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. add additional conformance criteria beyond those in the Functional Model.
4. enforce common resolution of ambiguous semantics of the Functional Model.
5. make the profile public (e.g., published on a web site) 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. modify the name, statement, or description of any function 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 shall promote it into their profile).

6.2. Rules for Creating New Functions in Profiles
If a function is not adequately specified for a profile and/or does not exist, the profile **may** create new children functions according to the following rules.
1. Whenever possible, conformance criteria shall 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 profile's inherited conformance criteria into two critera in the profile, one being mandatory, the other optional.
2. When a 'leaf' function exists but is too broadly specified in the Functional Model or base 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 profile, a new 'sibling' 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 profiles.

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

6.3. Rules for derived profiles
Derived profiles claiming conformance to one or more base profiles **shall:**
1. adhere to all the rules for profiles as specified in Section 6.1 and 6.2,
2. identify the base profiles from which it is derived,
3. for each function inherited from a base profile, retain and not change mandatory conformance criteria to optional

6.4 Inventory Statement
An *Inventory Statement[1]* provides information about an EHR system, by presenting in a uniform manner the functions that have been implemented by the EHR system. An Inventory Statement pro-forma typically takes the form of a questionnaire or checklist, to be completed for each EHR system.

An Inventory Statement pro-forma provides a concise summary of a profile. It follows a standard layout, thus providing EHR system vendors and users a quick overview of the 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., additonal functionality beyond what is in the profile) or specializations that have been made. Once completed for an EHR system, the Inventory Statement provides information that can be used in assessing the EHR system's conformance to a specific profile. Additionally, organizations wishing to acquire an EHR system may complete an Inventory Statement to indicate the functions that are required and/or desired in an EHR system

Profiles may want to include an Inventory Statement pro-forma. Providing this pro-forma helps to ensure consistency among completed Inventory Statements. It 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 Inventory Statement and the tests for these functions (which are unimplemented) would not be executed.

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[1] The term 'inventory statement' may be known to many as a vendor's conformance statement. It is called an inventory statement here, to emphasis that it is a list of functions that are implemented or desired and not a report of conformance results.

7. Use cases and samples (Reference)

7.1 Profile use cases

Example 1: Care Setting
It is determined that a new care setting profile is needed to reflect the care setting specific requirements. To help ensure widespread use and uniformity, the profile authors elect to undergo the HL7 consensus process (submitting the profile as an "Informative" document for a committee level ballot).

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 made public by publishing it on various web sites. Additionally, the profile is submitted to HL7's EHR technical committee 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 '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 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. He adds a description and a conformance clause (see samples in section 7.2). This is his profile. If he 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 profile is comprised of 'Essential Now' and 'Essential Future' and/or 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 Inventory Statement (a concept most vendors are already familiar with). A vendor may create multiple profiles.

7.2 Sample Profile Conformance Clauses

To aid profile developers in developing a conformance clause for their profile, as required by Section 6.1 rule #3, the following are examples are offered.

Sample 1: conformance clause for a care-setting profile

This profile defines the conformance requirements for EHR systems and derived profiles. To conform to this 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 profile is conforming if it follows the Rules for 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 Inventory Statement structured according to the rules and policies defined in the 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 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 s those designated '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.

Sample 3: conformance clause for a vendor system profile

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: conformance clause for a vendor system profile

Conformance is defined for BuyMyEHR. 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 may be implemented in future profiles.

8. Definitions

Balloted profile – a profile that has been voted upon according to a standard setting organization's consensus process.

Base profile – an existing profile from which new 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.

Derived profile – a profile that is created from a base profile, (i.e., child profile).

Extension – the ability to incorporate additional functionality beyond what is defined in the specification.

Inventory Statement – a pro-forma that lists in a uniform manner all the functions in a profile and may allow for the inclusion of optional functions and information. When completed, it can be used to express the degree to which an EHR system has met the profile's requirements, by indicating which functions have been implemented.

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.