HL7 EHR WG

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How-To Guide for Creating Functional Profiles

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Introduction

Background and Assumptions

This 'How-to Guide' offers guidance for using the EHR-S FM Profiling Designer **tool** to create functional profiles that conforms to the HL7 EHR-S Functional Model (denoted hereafter *FM*). A conforming functional profile is one that adheres to the rules specified in the FM Conformance Clause, (Section 6). Please note that this 'How-to guide' is not a replacement for the Conformance Clause. You are encouraged to read Section 6 carefully. Section 6 is also included in the EA Learning Center in section 'Overview & Definitions'. For the remainder of this section, the term *profile* will be used as shorthand for *functional profile*.

This document offers *guidelines* — not binding directives. It will walk you through the basic steps involved in creating a conforming functional profile, including the development of a conformance clause and conformance criteria. The How-to Guide offers a few general principles to keep in mind as you create the functional profile. Also, it provides guidance on how and why you should consider balloting the profile you created. It assumes that you are familiar with the FM and are knowledgeable about the requirements associated with a particular EHR-S healthcare delivery setting.

Building a Conforming Functional Profile

The goal of this guide to assist in the development of a conforming profile, by making it easier to define the components that comprise the profile. In particular, all conforming profiles contain general information about the profile, a conformance clause, and functions and their criteria. This guide addresses each of these components by leading you through the steps and decisions needed to write the necessary text or criteria for that component. It describes many of the profile rules from the Conformance Clause, giving you more insight into what they mean and how to comply with them.

This guide will help you provide the minimal information needed in a conforming profile to satisfy the rules. You can also add additional information, restrictions, etc., into your profile as long as you do not add anything that violates or contradicts the rules described in the Conformance Clause.

Functional profiles that undergo formal public scrutiny via the HL7 consensus process as an Informative EHR WG ballot at the committee level will be designated as "HL7 Informative functional profiles".

We recognize that it is not an easy task to write accurate, clear, and unbiased profiles. It takes planning, organization, expertise, and foresight about the needs and use of EHR systems within your profile setting. It is worth the time to create a conforming profile, since conforming profiles:

- provide traceability back to a specific version of the FM
- promote consistency among conforming profiles
- enable comparisons between conforming profiles
- foster interoperability of EHR systems.
- promote market awareness and adoption of the profile and FM standard
- help to influence the FM to ensure realistic, implementable functionality and profile rules

The development of a functional profile with support of the **tool** makes the conformance with the FM easier. The items listed above are automatically met because of the use of the FM Profile Design tool.

The EHR Profile Design Tool

As described a HL7 conforming profile means that you satisfy the rules for profiles found in the Conformance Clause. The EHR Profile Designer tool will support you to follow those rules.

The FM Profile Designer tool is developed as an extension of Enterprise Architect (EA). EA was chosen because of its availability to the HL7 community, experience with tool development, and its import – export capabilities. If you want to develop a new Functional Profile you choose your Base Model from which you want to derive the new Functional Profile. This Base Model can be the FM, the Personal Health Record-System Functional Model (PHR-S FM) or an existing Functional Profile[1]. A Profile Definition is used to transform the base model into a functional profile. Conformance Clause offers validation rules that produce conforming functional profiles; these rules have been instantiated into the EA tool. Profile Definitions can be validated using the EA tool.

Use of Model Automated eXchange (MAX)

Because many HL7 Work Groups use a Unified Modeling Language (UML) modeling tool, there is a common need to import data into and export data from the model tool repository. Enabling model content import/export capabilities also enhances the modeler's productivity. The goal of the MAX toolkit project is to enable the import, export, and re-import of a user-defined subset of model elements specified in a UML modeling tool. eXented Markup Language Metadata Interchange (XMI) is the default definitive means by which models and model packages are imported and exported by UML modeling tools. The Clinical Interoperability Council (CIC) and Tooling Workgroups are co-sponsors of the Model Automated Exchange (MAX) toolkit project.

MAX is intended to support capabilities not easily supported by XMI alone. Specifically MAX addresses the desire to limit a model import/export to a subset. In this context of the How-to Guide this is a subset of the FM elements. The use of MAX for the FM has defined the ability to import/export using the structure of the FM. Currently in MAX, the only UML modeling tool being addressed is Enterprise Architect from Sparx System. The output of MAX is used in other tools to create different publication formats.

To create a new Functional Profile you will need the MAX file of the Base Model. This is all described in the Learning Center of EA in section 'Create a Functional Profile', chapter 'Load the Base Model'. Contact HL7 to obtain the MAX file.

Organization of This Guide

This section is organized into two parts.

- Part 1 focuses on creating the profile, including steps to follow and a set of principles to keep in mind
- Part 2 addresses the ballot process

The Frequently Asked Questions, FAQ and Lessons Learned are described in a separate section.

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[1] At this moment, September 2014, only the EHR-S FM can be chosen as the Base Model. In the (near) future also the PHR-S FM or an existing functional profile can be chosen.

It is not necessary to read this section and complete the steps in the order they are presented. Rather, you may find it more suitable to work on the sections in the EHR-S FM in parallel or in an iterative manner or by starting with the conformance criteria section. As you will notice, a major portion of this section focuses on constructing conformance criteria for profiles. This is because we think it is a difficult, time consuming, and critical aspect in creating a profile.

For More Help…

The HL7 EHR WG Working Groups listed at

http://www.hl7.org/Special/committees/ehr/index.cfm

are happy to discuss aspects of a care-setting profile. Please coordinate your efforts with them, especially regarding terminology that could be or is in the EHR WG Glossary.

PART 1. Creating a Functional Profile

1.   Getting Started

You will need the following:

1. The official publication of the EHR-S FM standard. This is a pdf document on the HL7 International website: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=269

2. You will need the MAX file of the EHR-S FM; <EHRS_FM_R2 date_Final.max>. You can obtain this file by emailing the co-chairs of the EHR WG. Contact information is on http://www.hl7.org/Special/committees/ehr/leadership.cfm

3. In the future this can also be the PHR-S FM or an existing Functional Profile.

In particular:

From the official publication, you will be using chapter 6 which contains the conformance clause.

From the MAX file the different sections in the EHR-S FM, Care Provision, Care Provision Support, Population Health Support, Administration Support, Record Infrastructure and Trust Infrastructure.

In this How-to Guide you will find guidance and rules organized around four topic areas:

- general profile information;

- creating a conformance clause;

- selecting functions;

- creating conformance criteria.

Each area provides a set of steps to help you achieve the goal – a conforming Functional Profile. Many of the steps, discussions, and examples in the guidance are based on practical experience of people developing profiles as well as discussions among the HL7 EHR Work Group on what items in Chapter 6[2]: Conformance Clause mean and how to apply them.

The Functional Profile is created with the support of the EHR-S FM Profiling tool. The rules that are described in chapter 6 Conformance Clause are implemented in the tool as validation rules. An error or warning message will appear if you run the validation on the Functional Profile.

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[2] Chapter 6 of the normative standard April 2014.

How to use the tool for creating a Functional Profile see the User Guides section ' Create a Functional Profile, chapter 'Creating a Functional Profile'. The user guides are in Ea Learning Center or can be obtained by contacting the co-chairs of the EHR WG[3].

In this part you will find how to create a project in Enterprise Architect for the new Functional Profile and how to load the Base Model.

2. Providing General Profile Information

A basic requirement of all Functional Profiles is to have a unique identify and to convey general information about the profile.
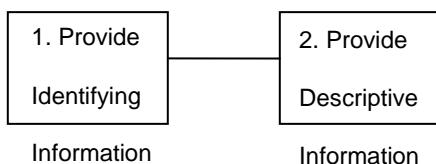
Figure 1. Steps in Providing General Information.

Steps

2.1. Provide Identify Information

➢ Identify the profile. Besides the profile name, include a version number and the date that it becomes effective (i.e., publication date, date of issuance). The date is significant, not only to help distinguish this profile from another profile, but also because it is used to define the time frame of the Essential Now priority. How to identify the profile in the EHR Profile Design tool is described in the EA Learning Center, section 'Create a Functional Profile', chapter 'Provide General Information';

➢ Identify the Functional Model that you are using as the basis for the profile. This is the FM that the profile will claim conformance to. Use the complete citation of the FM, including its version and date.

   ▪ In the **tool** this is done by entering the reference information in the metadata. This is described in the EA Learning Center, section 'Create a Functional Profile', chapter 'Provide General Information'. Using the **tool** and the FM as the Base Model creates automatically a link or traceability between the Functional Profile and the Base Model. Thus, it is always possible to get back to the source of the function and its Base Model criteria.

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[3] In this guide is referred to the EA Learning Center. However, if this doesn't work ask the co-chairs of the EhR WG for the user guides.

➢ If you are basing your profile on an already existing Functional Profile or Profiles, then you need also identify those Functional Profiles. This is usually the case if the profile you are creating is a derived profile.
- At this moment, September 2014, this is not possible with support of the **tool**.
- If you are using a max file of a Functional Profile based on the EHR-S FM R2 as the Base Model for the new Derived Functional Profile the tool will automatically creates a link to the Base Model.

➢ If you are basing your profile on the PHR-S FM, then you need also identify the PHR-S FM.
- At this moment, September 2014, this is not possible with support of the **tool**.

➢ If you are also using other standards or specifications as references or within criteria, then you also need to identify them. Don't forget to include all relevant information, including the document's full title, version, data, and the organization that published the document.
- In the **tool** this is done by entering these references in the metadata. This is described in the EA Learning Center, section 'Create a Functional Profile', chapter 'Provide General Information'.
- Or include these references in an Overview chapter that accompanies the Functional Profile.

2.2. Provide Description Information

Let readers know what the Functional Profile is about so that they can determine if it is relevant to them. It sets the stage for what follows, for why the profile is created, and for how to use the profile. Include a description and definition of the care setting or application area targeted by the profile. It is always helpful to describe the rationale, scope, and audience of the profile. Providing examples of what is in scope and what is out of scope is one way to do this. A part of this can be described in an Overview chapter that comes with the profile. You can ask the EHR WG co-chairs for the template.

- If you use the EHR Profile Designer **tool**, a part can be described in the metadata. This is described in the EA Learning Center, section 'Create a Functional Profile', chapter 'Provide General Information'.

2.3. Provide country and language code

If you are creating a Realm Functional Profile, you shall provide the country and language code in the Profile Metadata. These codes are according to both the ISO-3166 2-letter Country Codes and the ISO-639 Language Codes. There is a value set[4] where you can choose from.

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[4] September 2014. Not the whole value set is implemented yet.

3.   Creating the Conformance Clause

The conformance clause provides the answer to the important question: what is required to claim conformance? It provides communication between the profile creators, EHR system developers, certification and testing organizations, users, and the community as to what is required and gives meaning to the phrase, "conforming system" or "conforming functional profile". Moreover, it facilitates the consistent application of conformance within a profile and across related profiles.

1. Define Normative	→	2. Define Priority timeframe	→	3. Define Requirements	→	4. Determine Extensibility
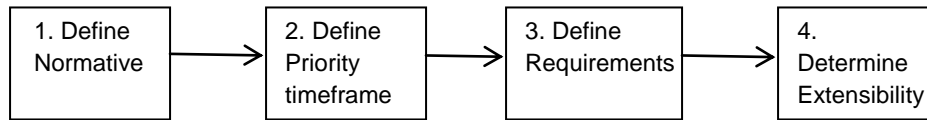
Figure 1. Steps in Creating a Conformance Clause

Steps

3.1.   Define Normative Keywords

Readers need to be able to differentiate requirements in the profile from non-requirements. Use a consistent set of keywords (aka normative verbs) to convey conformance requirements and tell the reader what that is. In the FM, we used the ISO preferred keywords and defined them as follows:

- **SHALL** – indicates a mandatory, required action. Synonymous with 'is required'.
- **SHOULD** – indicates an optional, recommended action that is particularly suitable, without mentioning or excluding other actions. Synonymous with 'is permitted and recommended'.
- **MAY** – indicates an optional, permissible action. Synonymous with 'is permitted'

The easiest thing to do is just to copy this into your profile and label the section Normative Language. This is described in an Overview chapter that comes with the profile.

If you have additional or different keywords, then add them to this list. For example, you may wish to add 'Shall Not', 'Required', 'Optional' and their definitions. Only include the keywords that you use.

- If you use the **tool** for the development of a profile, then the use of other keywords than SHALL, SHOULD and MAY, is not possible at this moment (September 2014).

Within the profile, distinguish these keywords with distinctive formatting, such as upper case and/or bold. This helps to quickly find them as well as providing a good way to differentiate the normative keywords apart from when they are used in an informative sentence.

- In the Base Model this formatting is used. Using the **tool** and the Base Model and inherit functions and criteria this formatting is automatically inherit as well.
- When creating new conformance criteria with the **tool**, you need to be aware of using distinctive formatting for the normative keywords. How to create new conformance criteria is described in section 'How-To Guide for Creating Functional Profiles', chapter 'Create Conformance Criteria'.

If you are planning to ballot your Functional Profile through HL7 you may want to consider labeling parts within the profile document as Normative, Informative, or Reference. Normative content is the prescriptive part of the specification, whereas informative and reference are for informational purposes and assist in the understanding and use of the profile. It is recommended that you discuss any ballot considerations with your HL7 Affiliate, HL7 International Headquarters or the HL7 International EHR Workgroup.

3.2.   Define Priority Timeframe

All functions are assigned a priority – Essential Now, Essential Future, or Optional.

- In the **tool** you can assign a priority on function and criteria level. Assigning priority is done while defining the Profile Definition. How to do this is described in the EA Learning Center, section 'Create a Functional Profile', chapter 'Create Profile Definition'.

The terms Essential Now and Essential Future are used by some in the EHR community; however, not everyone reading the profile is familiar with these terms. Thus, include a definition of these terms in your profile.

- In the **tool** this is done in the metadata, 'Priorities Description'. This is described in the EA Learning Center, in section 'Create a Functional Profile', chapter 'Provide General Information'.

For the definitions of the priorities you can use the definitions in the standard.

Essential Now (EN):
Indicates that the implementation of the function is mandatory, as of the profile issuance date. Remember, a function labeled EN means that it is a mandatory function, that is, all systems must implement it and all derived profiles must inherit this function.

Essential Future (EF):
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. It is like a hybrid priority, combining priorities Essential Now and Optional. Initially, Essential Future is equivalent to Optional and then at the specified timeframe, Essential Future becomes equivalent to Essential Now.

You will need to qualify the timeframe for Essential Future – when is the future? Is it a date in the future? Is it a set number of months and if so, when does the clock start ticking? Is it an event? Thus, somewhere in your profile, we suggest the conformance clause, it is essential that you define the timeframe for when Essential Future functions are no longer optional. A timeframe can be a specific date (e.g., month/day/year), a time allotment (e.g., 18 months after profile publication, year-2008) or an event (e.g., republication of this profile).

- In the **tool** this can be done in the metadata, 'Priorities Description'. This is described in the EA Learning Center, in section 'Create a Functional Profile', chapter 'Provide General Information'.

It is permissible to have multiple timeframes defined for EF. This provides a way to indicate different timeframes for different functions – very useful for giving a roadmap of when you want functions to be implemented. For example, label some functions EF-2008 and other functions EF-2009. The format is always: EF-xxx, where xxx is the qualifier.

Optional:

A priority of Optional means just that – the function is optional and does not need to be implemented. This means that derived profiles do not need to include this function. It also means that EHR systems can ignore this function. However, if a system does implement the function, the function must be implemented correctly, including implementing all criteria containing the keyword 'shall'.

Yes, you need to use the terms Essential Now, Essential Future, and Optional. What if you don't like these priority terms or you don't need them since you have another way to designate mandatory and optional functions? Simple. Just explain this and provide your alternative designations along with a mapping of your alternative designations to the FM priority designations. Including a rationale for using alternative designations is recommended.

Priorities vs. criteria – what's the difference?

Priorities pertain to the timing of when the function gets implemented by the system. Criteria (those statements with 'shall', 'should' or 'may') define what it means to actually implement or support the function within a system.

- In the **tool** this question and the answer to it is also included in the FAQ in the EA Learning Center, section FAQ.

3.3.   Define Requirements for Claims

State what the profile defines conformance for. Do this with a statement such as, "This name-of-care-setting profile defines conformance for EHR systems and profiles derived from this name-of-care-setting profile.

This is where you could indicate any special grouping of functions, for example a minimal set of functions that always get implemented or get inherited by derived profiles; or a set of functions that depend on each other – so that if you implement one of them, you must implement them all.

- This is described in the 'Overview' chapter that comes with the profile.

What are the rules for an EHR system to claim conformance? Must all the functions be implemented or only some of the functions. If only some functions, which ones? The priorities Essential Now and Essential Future can be used to indicate the timeframe for when functions are to be implemented. Are there any special circumstances where different EHR systems would implement a different set of functions? If so, then that needs to be explicitly described. Are there conformance designations, such as levels of conformance? An example of a profile that defines 2 levels of conformance as well as other conformance clause examples can be found in Annex 1 of this chapter.

Make sure that when you define your profile, its functions and priorities that at least one function is required to be implemented by the EHR system.

What are the rules for derived profiles to claim conformance?

Include a statement such as "all derived profiles SHALL include all functions designated as Essential Now". If there is a minimal set of functions for the profile, make sure that it gets inherited by the derived profile (note: these are probably the functions designated as Essential Now).

▪ This is described in the 'Overview' chapter that comes with the profile.

3.4.   Determine Extensibility

Extensibility provides the ability to add functionality or criteria beyond what is defined in the FM.

In the conformance clause you are writing, you may want to discuss whether derived profiles are allowed to add new children functions or new criteria. You also may want to discuss whether EHR systems are allowed to add new functionality. That is what this section is about – that is, what to say in your profile's conformance clause.

▪ How you can add children functions and criteria to your profile using the **tool** is explained in the EA Learning Center, section 'Edit the Functional Model/ Profile', chapter 'Adding EHR-S FM FP components'.

What about derived profiles?

Do you want to allow derived profiles to add new children functions? *[6.6].*

- If this is a profile that others will build upon, e.g., a minimal function set profile which provides a foundation from which derived profiles will start; then yes.
- If this is profile from which derived profiles are to be a proper subset (i.e., no adding of functions); then no.

If you want to allow derived profiles to create new children functions, indicate this and point to the instructions of how to create new children functions in the learning center of the **tool**.

If you want to prevent derived profiles from creating new functions, explicitly state this. It is also helpful to explain why derived profiles cannot add functionality. Reasons may include:

- Believing the profile is complete, self-sufficient and doesn't need additional functionality, or
- By being a subset, the derived profile is not a new specification but a constrained version of the base profile; or
- Being less of an impediment to predictability and interoperability among profiles by not introducing differences between profiles and the EHR systems that implement them.

▪ How to use the **tool** to develop a derived profile is not in scope in September 2014. This still needs to be planned.

What about EHR systems?

EHR systems will most probably include functionality beyond what is specified in the profile. It is important that this additional functionality in the EHR system does not contradict or negate the functionality specified by the profile and thus, interfere with (break) conformance to the profile. Consider including in the conformance clause the following statement:

Additional functionality SHALL NOT contradict nor cause the non-conformance of functionally defined in the profile.

4. Selecting Functions

In the development of a Functional Profile all functions in the Base Model need to be reviewed. Important questions in the review are:

- Is the function applicable or not?
- Is the function and the included criteria complete?

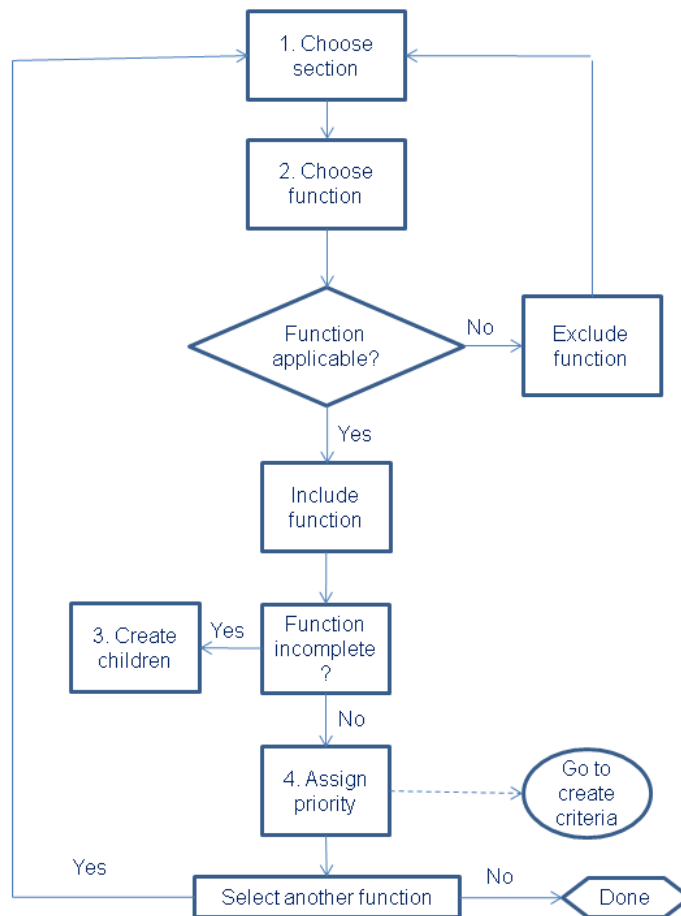The process of selecting functions is as follows:

Figure 1. Selecting a function for a Functional Profile.

Steps

4.1. Choose section

Choose in the Base Model the section from which the project team wants to choose a function. See in the EA Learning Center, section 'Create a Functional Profile', chapter 'Create Profile Definition'.

4.2. Choose function

Choose a function from the FM that meets your profile's functional needs. Read the statement, description and criteria and determine if this function is applicable to your profile.

- If the function is not applicable, exclude the function for your functional profile and look at the next function.
- If the function is applicable as is, include the function for your functional profile and go to Step 4.
- If the function is not quite right – e.g., it may be missing functionality or not adequately specified – continue to the next step '4.3 Create children'.

In the EA Learning Center, section 'Create a Functional Profile', chapter 'Create Profile Definition' is described how to choose a function and include or exclude this function for you functional, profile. In this guide is also described how to edit the description text of a function and how to edit the text of a criterion.

In the EA Learning Center, section 'Edit the Functional Model/ Profile', chapter 'Adding EHR-S FM FP components' is described how to add functions and/or criteria.

Nomenclature alignment

Do not change the name of a function or its statement, except to align it to realm specific nomenclature. *In* non-U.S. realms, there may be some words in the FM that do not mean the same thing as was intended. For example, a 'provider' in the U.K. refers to the 'provider organization' which is more limited than what is intended when used in the FM. Thus, limited, but controlled localization is allowed. If you change a function name or statement, append the ISO 3166 2-letter country code to the function ID, e.g., DC#.#GB, S#.#.#FR.

- In the **tool** you SHALL not add the ISO country code to the ID of the function. Because changes are made by a country with a certain language both the ISO-3166 Country Codes and ISO-639 Language Codes **SHALL** be added to the Profile Metadata. There is a value set in a dropdown menu were the country and language code can be selected (not fully implemented in September 2014). More about the Profile Metadata can be found in chapter 'Provide General Information'.
- The traceability to the base model is guaranteed when using the **tool** and the change indicator in the profile indicates if the function was changed or not.
- How to change the functions name or statement is described in the EA Learning Center, section 'Create a functional Profile', chapter 'Create the Profile Definition for the new functional profile'.

The HL7 affiliate for each realm should establish a list of the functions and/or statements that are modified with a mapping to the FM function name and statement. This will help to ensure consistent use for profiles in that realm as well as promote awareness of these modifications. Profiles are encouraged to include this mapping in an appendix.

Alternately, if the name or statement isn't quite right, you can explain this in the function's 'Description' and provide the name or statement changes here. This is the only way to indicate variations of a different function name or statement in U.S. profiles.

- In the **tool** the mapping to the FM or Base Model is established automatically by creating the Profile Definition from the Base Model. The traceability is included in the Profile Definition and in

the Functional Profile created from the Profile Definition. If functions and/or statements are modified, a note can be made. The changes in the name and/or statement of a function is described in the EA Learning Center, section 'Create a Functional Profile', chapter 'Create Profile Definition'.

FM ID alignment

In your profile, try to keep the same function IDs as those in the FM. If this isn't possible, then renumber as necessary, but retain the 'CP, CPS, AS, RI and TI prefixes.   Needing to renumber can happen since you are selecting functions and perhaps adding new children functions.

To maintain traceability back to the FM, we recommend keeping track of the mapping between your IDs and the FM's IDs.

- If you use the **tool** to create the new Functional Profile, the functions IDs are kept the same as in the Base Model. Also the traceability to the Base Model is established automatically when using the **tool** by creating the Profile Definition from the Base Model.

4.3. Create children

We realize that the FM may not accommodate all the varied, unique, and evolving needs of users in specific care settings, practice areas, or realms. Profiles are the place where these needs can be taken care of. This means that if you need to add a new child function or add additional criteria, you can. New criteria could be added to further constrain the function. Only new children functions (created by splitting a function or adding a sibling function) are allowed. A sibling function is a child function that has a brother or sister. Remember, all children functions must have a parent. Note that any addition of non-children functions would be outside the scope of a conforming HL7 EHR-S profile and consequently not part of the claim of conformance for that profile.

- The addition of new functions is described in the EA Learning Center, section 'Edit the Functional Model/ Profile', chapter 'Adding EHR-S FM FP components'.

a) Use conformance criteria.

Try to avoid splitting a function or creating a sibling function - use conformance criteria instead. This is the preferred method. Adding conformance criteria usually works for functions that are too broad or not adequately specified. Consider constraining an existing criterion or adding a new criterion that reflects the capability you need. The addition of conformance criteria is described in the EA Learning Center, section 'Edit the Functional Model/ Profile', chapter 'Adding EHR-S FM FP components'.

b) Split a function.

If using conformance criteria doesn't do the job, then you can split a function to create new children functions. Only leaf functions (i.e., those that do not have other functions under it) can be split. In the EA Learning Center you can read more about splitting a function in section 'Overview & Definitions', chapter 'Rules for Creating New Functions in Functional Profiles'.

The conformance criteria in the original leaf function get distributed among its new children functions. There are various ways to do this including:

- put all the original criteria in one child and create new criteria in the other children
- distribute the original criteria across all the children
- put the 'shall' criteria in all the children and create new criteria where needed

Don't forget:

- all children functions need to have at least 1 'shall' criteria
- all children functions need to be assigned a priority

You should end up with the original leaf function becoming a parent with children – hence a non-leaf function. Figure 2 illustrates a function that has been split to create three new children.
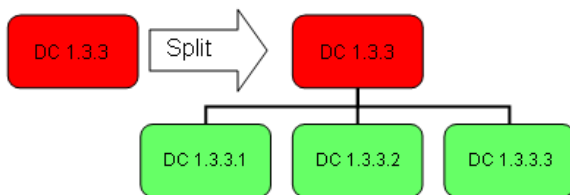
Figure 2. Splitting a function

c) Create a sibling.

Another way to add a function is to add a sibling, that is, add a new child function to a parent that already has children. Don't forget to add criteria for this new child function and include at least one 'SHALL' criterion. . In the EA Learning Center you can read more about splitting a function in section 'Overview & Definitions', chapter 'Rules for Creating New Functions in Functional Profiles'.
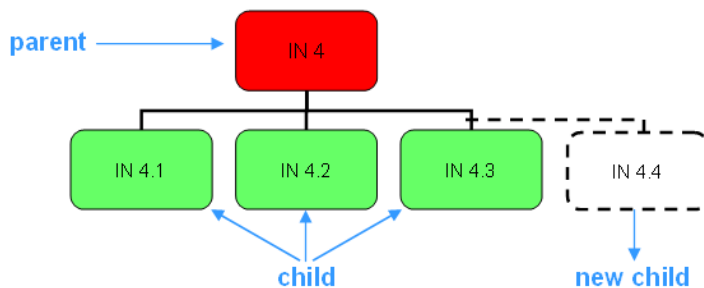
Figure 3. Adding a new child function

Function IN 4.4 is added as a new child which is a sibling to IN 4.1, IN 4.2, and IN 4.3.

You cannot add a sibling that does not have a parent (see Figure 4). Specifically, you cannot add a sibling at the topmost level of the FM.
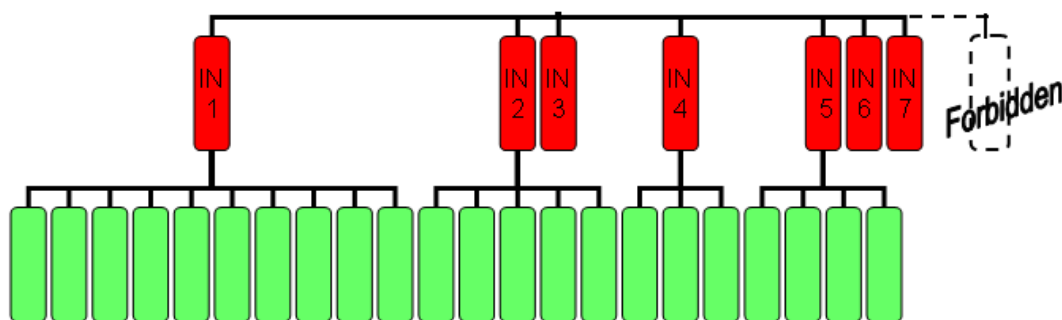
Figure 4. Illegal addition of a child

These are the only way to add new functions to a profile or if allowed, a derived profile and still end up with a conforming profile. The addition of non-children functions is nonstandard. If there are non-children functions associated with the profile, there needs to be a clear distinction that they are not part of the conforming profile and they SHALL NOT change the behavior of functions or facilities defined by the conforming profile.

When you develop a Functional Profile with the **tool** the adding of functions can be done with support of the **tool**. In the validation of the Profile Definition and the Compiled Profile will check if the addition of functions is done according to the instructions above.

4.4. Assign a Priority

Now that you have selected a function, assign a priority to it. See for a description on priorities The EA Learning Center, section How-to Guide for creating functional profiles', chapter 'Creating the Conformance Clause'.

The assignment of a priority to a header, function or criteria can be supported with the **tool**. The default in the **tool** for this is 'Essential Now', EN. This can be seen in the Tagged Values of a header, function or criterion. The description of how to assign a priority can be found in the EA Learning Center, section 'Create a Functional Profile', chapter 'Create the Profile Definition for the new functional profile'.

All functions, including header functions are assigned a priority. When assigning a priority to a header function – think through the implications. Priorities are not subject to inheritance – that is, a priority assigned to a parent does not necessarily get assigned to a child. If you want priorities to be inherited by children functions, then use the conformance clause to state this. The conformance clause on priorities can be described in the Profile Metadata. See the EA Learning Center, section 'Create a Functional Profile', chapter 'Provide General Information'. In fact, to improve clarity, use the conformance clause either way - to state whether priorities are or are not inherited.

- In the **tool** you can assign a priority to a header, function and/or criterion. The priorities can be different. That is that the priority of a function can be EN, but for some criteria it can be EF.

  Example situations – priorities not inherited:

  1. Header CP.3 Manage Clinical Documentation = EN means that manage clinical documentation is mandatory.

You could (try to avoid this) assign all children of CP.3 a priority of Optional. This could result in no CP.3 functions being implemented. Bad!

2. Header CPS.9 Support Care Coordination & Reporting = Optional, CPS.9.2 Support for Inter-Provider Communication = EN and both CPS.9.5 Ad Hoc Query and Rendering and CPS.9.6 Information View = Optional. This means that all (header and children) CPS.9 Support Care Coordination & Reporting are optional and need not be implemented. But, if S3.2 <u>is</u> implemented, then CPS.9.2 Support for Inter-Provider Communication must also be implemented. The other children functions (CPS.9.5 and CPS.9.6) may or may not be implemented.

It can be a challenge to assign the right priority, especially when your profile will be used across a wide diversity of settings or specialties.

Consider how widespread the need for this function is – is it used by everyone or just a segment of your stakeholders?   Consider the availability of the function – is it widely supported in most systems? Consider the criticality of having the function – is it something that must be part of the system?

Remember: Any function assigned Essential Now SHALL be inherited with the Essential Now rating by all subsequent derived profiles.

When a function seems to apply to some but not other types of care settings or organizations within a specialties' scope, consider giving the function an 'optional' priority and explain why you did this.

4.5. Go to Create Criteria

You can either create conformance criteria for each function as you select or create it, or you may want to select a set of functions prior to creating criteria, or establish the entire set of functions and then create criteria. It doesn't matter how you do it, as long as you eventually have criteria for each function.

- In the **tool** you can keep track of functions in which you want to create criteria in a later stage by using the functionality Project Status of EA. How to use this is described in the EA Learning Center, section 'Edit the Functional Model/ Profile', chapter 'Project Management'.
- How to create criteria with support of the **tool** is described in the EA Learning Center, section 'Edit the Functional Model/ Profile', chapter 'Adding EHR-S FM FP components'.

5.   Creating Conformance Criteria

Basis for a Profile's Conformance Criteria

In general, profiles inherit conformance criteria directly from the FM (Base Model) or derive conformance criteria that are based on the FM's conformance criteria. Similarly, a *derived profile* uses conformance criteria taken directly or derived from its *base profile(s)* and the FM's conformance criteria. If your goal is to develop conformance criteria for a profile, we encourage you to review the following steps carefully.

Structure of Conformance Criteria

Conformance criteria in the FM (Base Model) and those that you will create can be structured as follows:

1. Simple form: Actor followed by normative verb followed by action or property

   Example:
   The system **SHALL** capture demographic information as part of the patient record.

2. Conditional form:
   If condition, then Actor followed by normative verb followed by action

The way this works is that if the condition is true, then the following text applies. If the condition is not met (i.e., false) then ignore the rest of the sentence.

   Example
   IF an interchange agreement description specifies the use of a certain standard, THEN the system SHOULD exchange information using the standard specified by the interchange agreement description according to scope of practice, organizational policy, and/or jurisdictional law. (TI.5.4#02).

3. 'Dependent Shall' form: Actor followed by normative verb followed by action/interaction followed by 'according to scope of practice, organizational policy or jurisdictional law'. See the paragraph on 'Dependent SHALL' later in this chapter and Chapter 6 Conformance clause, paragraph 6.5.2 for a more thorough explanation. This chapter is also in the Learning Center; section 'Overview & Definitions, chapter 'Conformance criteria'.

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

```
┌─────────┐   ┌──────────┐   ┌──────────┐   ┌──────────┐      ╱╲              ┌──────────┐
│  5.1    │   │5.2 Refine│   │5.3       │   │5.4 Draft │    ╱Criteria╲  Yes   │5.5 Specify│
│         │──▶│          │──▶│Identify  │──▶│criteria or│──▶│  text   ├──────▶│the        │
│Function&│   │Concepts &│   │actors &  │   │inherit    │   ╲standards╱       │standards  │
│its       │   │assumptions│  │interactions│ │from FM   │    ╲based ╱         └──────────┘
│Criteria │   └──────────┘   └──────────┘   └──────────┘       ╲╱                   │
└─────────┘        ▲                                           │No                  │
                   │REFINE                                     ◀────────────────────┘
```


<the figure needs to be improved!>
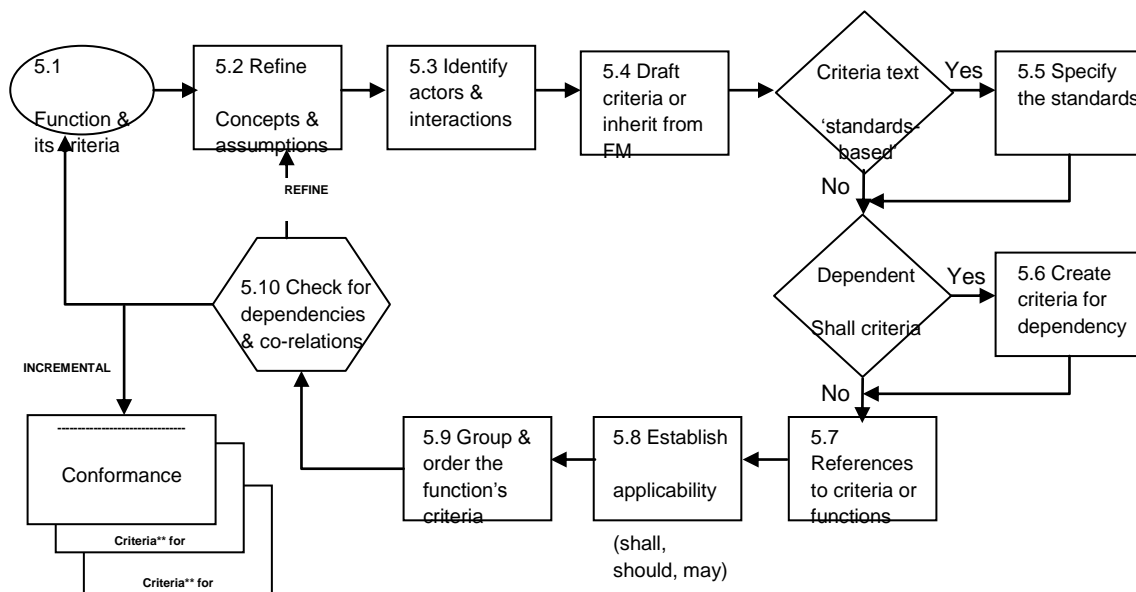
Figure 1. Steps in Establishing Conformance Criteria for Profiles

Steps

5.1.   Start with a Function and Its Conformance Criteria

Once you have a function, review its conformance criteria carefully. For each of that function's conformance criterion, consider:

- Using it "as is" (via inheritance), in the **tool** the criteria are included by default, so you don't have to do anything.
- Making it more specific and/or more applicable to your profile (see Step Inherit or Create the Function's Conformance Criteria). See the EA Learning Center, section 'Create a functional Profile', chapter 'Create the Profile Definition for the new functional profile'.
- Making it mandatory if it was optional (see Step Establish Applicability – Shall, Should, or May). See the EA Learning Center, section 'Create a functional Profile', chapter 'Create the Profile Definition for the new functional profile'.
- Rejecting it – not inheriting it. Because the criteria are included by default in the **tool**, you explicitly exclude the criterion in the Profile Definition. See the EA Learning Center, section 'Create a functional Profile', chapter 'Create the Profile Definition for the new functional profile'.

A profile must inherit all the FM function's mandatory (i.e., 'shall') criteria, if there are any. If there are no mandatory criteria, at least one resultant criterion associated with the profile function needs to be made mandatory. This can be done by changing an existing optional criterion to a 'shall' criterion or creating a new 'shall' criterion. The rules for this are described in the EA Learning Center, section 'Overview &

Definitions', chapter '[Functional Profile Conformance](#)'[5].

Remember – don't forget to look at the criteria found at the section header and/or functional header levels. These criteria get inherited (i.e., apply) by all functions within that section or under that function header.

5.2.   Refine General Concepts and Assumptions

From the selected function's *Conformance Criteria*, *Statement* and *Description*, try to refine the overall concepts, underlying assumptions, and the meaning that must hold true for your profile. Often these concepts are unwritten, with the assumption that the reader knows the basic premises or concepts that comprise a profile. When crafting conformance criteria, however, it is a good idea not to rely on unwritten assumptions and describe the profile in terms of it successfully conforming to the conformance criteria that you select, derive, or generate for the profile.

Example
It is implicitly assumed, but not always stated, that workflow tasks must start, progress, and terminate – regardless of care setting. Without each of these phases, a workflow task is unsound. Well-formed conformance criteria address each phase explicitly.

- How to do this with the **tool** is described in the EA Learning Center, section 'Create a functional Profile', chapter '[Create the Profile Definition for the new functional profile](#)'.

5.3.   Identify Needed Actors and Interactions

Next, you'll be starting the process to tailor a (general) function of the FM to a (specific) functional requirement of your profile. The objective is to start thinking about a function's criteria and how to evolve them to reflect the profile's needs. Having read a selected FM function's Conformance Criteria, Statement and Description which depicts a generalized function that covers all profiles, ask, "*Who* is being asked to do *what* for my specific profile with regard to this function?" Thus, you'll need to:

- Identify the specific actors.
  The system is the most obvious 'actor', but may not be the only one**.** The FM is comprised of many functions where the system is the actor. As a result many FM conformance criteria start with the phrase "The system …". However, from the point of view of your profile, there may be additional actors (such as clinicians, managers, technical staff, and administrators). Therefore, the actors listed in the conformance criteria for profiles maybe more precise than in the FM ~~more variety than FM~~ conformance criteria because profiles usually address and refine specialized care settings or a specialized scope of practice.

- Identify the interactions (with what possible components).
  Think about the action or influence resulting from the function. What gets accomplished by having this function? Does this function interact with or affect a particular component (e.g. registry,

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network). Is the function providing a capability, causing or enabling an action to occur, changing a behavior or affecting a component (e.g. sending a notification to a particular registry)? Another way to think about this is via the actor (e.g., does the actor perform a certain action when a given condition arises or supply specific information when a given condition arises)?

- Determine applicability – mandatory or optional status
  When addressing applicability of each criterion, think about whether the profile's conformance criteria will be mandatory or optional, and if optional, is it something that is recommended. This determination will drive the normative keyword chosen (see Step Establish Applicability – Shall, Should, or May). Remember, you cannot take a mandatory criterion from the FM and reduce its status to optional. A mandatory criterion must remain mandatory.

5.4.   Inherit or Create the Function's Conformance Criteria

If you are inheriting any conformance criteria directly from the FM, you don't have to do anything in the **tool**. This is because all conformance criteria are included in the Profile Definition by default when you include a function.

If you are modifying conformance criteria from the FM, then in essence you have a 'jump' start to creating new criteria. Continue reading this section.

When selecting and adopting criteria from the FM, what you select and create should not fundamentally alter the intent of the function. See paragraph 4.2 Choose function. Take care that the criteria you select does not weaken the function.

If you are not inheriting conformance criteria for your profile, you must create it. When doing so, use short, succinct sentences. If you have to decide between being concise or being clear, be clear. — And if you need extra space in order to state a criterion precisely, do so. In general, use one sentence for each concept or fact. If you have a list of items, consider creating separate criteria for each. However, it may make sense to keep the list intact within a single criterion. When a criterion involves choosing among items, indicate clearly how many must be chosen, e.g., exactly one, at least one, or more than one. Consider what it means to implement the function for the profile and how the function should be refined, constrained, or extended.

To build distinct criteria:

a. Identify actors. (See description above).
b. Identify the interaction or components (for example, condition to hold true, behavior, or actions to take).
c. Think about what the system will do automatically and what it will provide the ability for an authorized user to do.
d. Consider how many items of a given list must be implemented. Is it legitimate to select zero items? Only one item? One or more items? Must all of the items be implemented or can the user choose certain items?
e. Consider whether a certain range must be specified or whether conformance criteria ought to be written to test minimum and maximum values.
f. Consider whether a criterion is conditional upon something being in place or on whether an action has occurred. If so, indicate the condition, for example, by prefacing the criterion with, "IF x, THEN …".

g. Consider whether the requirement is mandatory or optional. (See Step Establish Applicability – Shall, Should, or May).
h. Consider whether the function's importance and/or immediacy needs to be indicated by assigning it a priority (namely, essential now, essential future, or optional).
i. Once you have expressed each criterion in individual sentences, consider whether some of those sentences ought to be combined. Also, consider whether certain combinations yield new situations, behaviors, or actions that need to be captured.
j. Consider whether a general concept applies to the function, even though it wasn't explicitly described, for example, a system that needs connectivity, or a system that needs the ability to be maintained and updated. Draft one or more short, clear, complete sentences to capture such information.

Remember, compose one sentence for each concept or fact that will be tested for conformance.

Use words with agreed-upon meanings

Make sure that everyone shares a common understanding of your technical words. Break down words that imply multiple components – that is, words connoting or denoting compound actions or items. Be specific and careful with the words you use in your conformance criteria. Some words seem to be synonyms, but aren't. For example:

- Manage vs. maintain
- Display vs. present
- Vocabulary vs. terminology
- Sex vs. gender
- Practitioner vs. provider vs. clinical personnel.

The word "manage" is a higher order verb than "maintain," "capture," "render," "exchange," "determine," or "Manage-Data-Visibility,". "Manage" is therefore used in the Name, but the more detailed, explanatory verbs are used in the FM function's statement, description, and conformance criteria. In your conformance Criteria, if you have the word 'manage', replace it with a verb that describes the actual action the criterion should perform, see Figure 1. This may cause the addition of new conformance criteria because the word "manage" was too nebulous and sometimes needs to be broken into multiple criteria.

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

Table 1. Verb hierarchy.

Other words to watch for:

- User, clinician, person, and other terms referring to an individual/role. In the FM criteria, provider was used rather than clinician.
- Data vs. information. In the FM, data was used rather than information.
- Capture is a higher order verb. Use it in other areas when you really mean input from a number of methods (e.g., from a device, key entry, etc.). Use the detail level verbs when a certain input method is required.
- Integrate can be viewed as (1) "Low" level integration (i.e. document received and indexed appropriately for retrieval) – state action as "**receive and store**"; or (2) "High" level integration (i.e. data elements able to be used) – state action as "**integrate into the patient record**"

If there are words that need to be defined, identify them, share them with the group, and offer them for inclusion in the glossary.

Clean up the wording

Think through each criterion and whether it is something that the system should do automatically or not.

- In each conformance criterion, search for such verbs as "able," "enable," "facilitate," "support," "allow," and others where it is unclear what measurable action the conformance criterion is performing. Change these verbs/instances to the phrase, "provide the ability to". This will cause the entire sentence to be reworded, and/or change the order of conformance criteria.
- Some criteria are written such that the system would automatically perform that step, when it really should provide the ability for an authorized user to do so. These criteria will need to be changed using the "provide the ability to" format.
- It is rare that a criterion that already uses the "provide the ability to" format should be changed to one in which the system should do the activity automatically. However, in those instances, convert the criterion by removing the "provide the ability to" phrase.

5.5. Specify the Standards in 'Standards-Based'

Within a function's criteria, there may be criteria that include the text 'standards-based'. For example,

> CP.1.1#11 The system SHOULD provide the ability to capture patient history adhering to a **standards-based** form or template according to scope of practice, organizational policy, and/or jurisdictional law.

This criterion, although appropriate in the FM and perhaps some profiles (e.g., those that are purposely general to allow constraints and specificity to be done by its derived profiles), is effectively useless unless all parties involved in building, testing, buying, using, and interfacing with the system have a common understanding of what is meant by 'standards-based'. Basically, which standards? Just saying standards-based isn't enough to ensure interoperability.

Each high-level statement about standards conformance (e.g., support standards-based encryption mechanisms) needs to be replaced with the specific standards, specifications, profiles, etc., to which conformance is required (6.7.1.2#3 of the EHR-S FM standard April 2014). The more detail you can

provide the better - Include as much specificity regarding the standard, specification, etc., as possible, e.g., version(s), declarations of which optional features to include/exclude, declarations of which profiles apply, any other conditions or limitations that pertain to conformance. Another thing to consider is to include statements (e.g., a service agreement) on maintaining conformance to updated or successor versions of the standard you are referring to.

The reason this rule (6.7.1.2#3) is not a 'shall' rule is that there may be reasons not to replace standards-based' with the specific standards, for example: a general profile from which derived profiles will define the standards or a profile for an RFP and the desire is to have the RFP bidders state the standards they use in their system. If the reason is the former (i.e., allowing derived profiles to specify the standards), consider adding a requirement or rule in your conformance clause that derived profiles 'shall' replace the text 'standards-based' with the specific standards.

5.6. 'Dependent SHALL'

'Dependent SHALL' criteria are used to call attention to criteria that we want you as profile developers to examine carefully with respect to situational conditions such as policy, organizational, and/or legal implications (6.5.2 in the EHR-S FM standard, April 2014). It is used for criterion that under certain circumstances should be 'SHALL' criterion. Your job is to determine for each dependent shall criterion what if any jurisdictional laws apply, are there any organizational policies, and is there any scope of practice considerations – for example, constraints needed for behavioral health. Chapter 6, 6.5.2 Conformance Clause describes how to interpret and apply the 'dependent shall'.

When you encounter a 'dependent SHALL':

1. Review the criterion while you are creating the Profile Definition, don't change it. See in EA Learning Center, section 'Create a Functional Profile', chapter 'Create the Profile Definition for the new functional profile'.
2. Determine if there are scope of practice concerns, organizational policies, or jurisdictional laws that apply.
3. If yes, then using the 'dependent SHALL' as the basis, create a new criterion that reflects the dependencies that apply. Although you can create a single criterion to reflect all the dependencies, consider creating separate criteria for each dependency – it is usually clearer to understand. How to create new criteria is described in the EA Learning Center, section 'Edit the Functional Model/Profile, chapter 'Adding EHR-S FM FP components'.
4. Add additional criteria if you want. See item 3.

The reasons you need to include the 'dependent SHALL' in the profile are:

- It is a 'shall' and 'shalls' always transfer to the profile and any derived profiles.

To make sure it doesn't get lost when morphing it into a more specific criterion. We want to preserve it so that it can be seen and used by derived profiles and other profile users as well as be intact if there are future dependencies that arise and need to be reflected by the criterion.

The explanation of the dependency or why there is no dependency can be located with each criterion or put in an appendix or other section (the Overview chapter that comes with each profile). Multiple criteria can reference the same explanation.

Examples:

Let's assume we are building an ambulatory U.S. profile that will be used within behavioral health (BH) programs.

Extracting from FM function TI.1.2 Entity Authorization:

TI.1.2#01   The system SHALL provide the ability to manage sets of access-control permissions granted to an entity (e.g., user, application, device) based on identity, role, and/or context according to scope of practice, organizational policy, and/or jurisdictional law.

TI.1.2#03   The system SHALL provide the ability to manage roles (e.g., clinician versus administrator) and contexts (e.g., legal requirements versus emergency situations) for authorization according to scope of practice, organizational policy, and/or jurisdictional law.

In the profile, these three criteria are included by default if you use the **tool**.
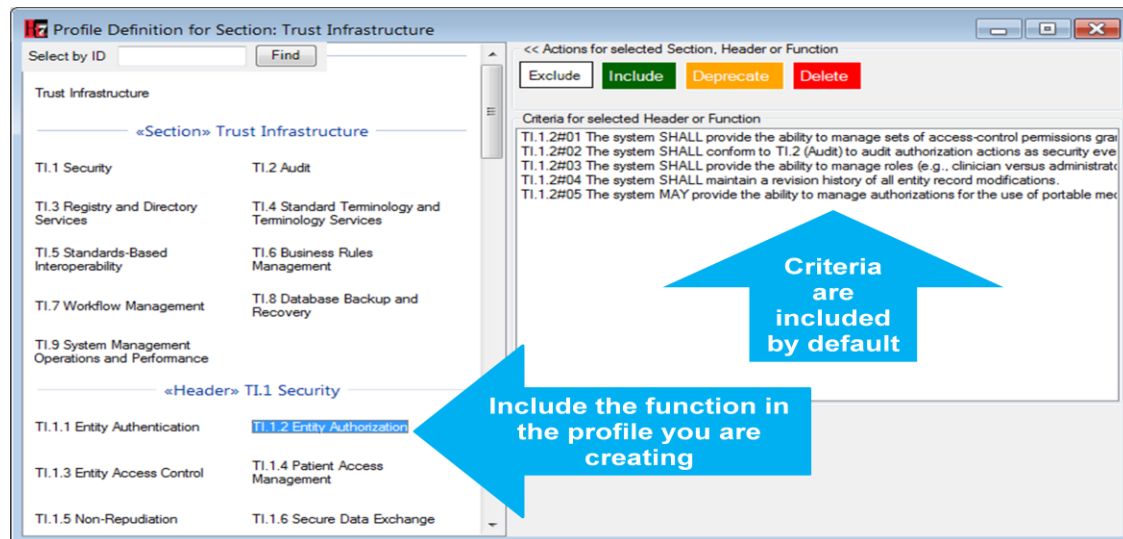
Figure 2. Edit profile for Profile Definition.

For this profile, dependencies exist, as follows:

Change an existing criteria that modifies TI.1.2#1 to account for HIPAA.

> TI.1.2 Entity Authorization: d) The system SHALL provide the ability to manage sets of access-control permissions granted to an entity (e.g., user, application, device) based on identity, role, and/or context in accordance with HIPAA.

Add a new criterion that 'raises' the dependent shall TI.1.2#03 to a 'shall' (without dependency), thus it is always in effect and not contingent on any situational conditions.

> TI.1.2 Entity Authorization: e) The system SHALL provide the ability to manage roles (e.g., clinician versus administrator) and contexts (e.g., legal requirements versus emergency situations) for authorization.

To complete the profile, add an explanation for criteria d) and e) in the ChangeNote[6] and include the full citation for HIPAA in the Profile Metadata or Overview chapter.

5.7. *Referencing Other Criteria or Functions*

It may be the case that a given function depends on another function or on a specific criterion associated with another function. You need to indicate such dependencies and refer to the associated function or criterion.

Take care to consider the ramifications of referencing another function –

- Are all the referenced function's criteria applicable?
- What about the normative keywords used with the referenced function's criteria – any SHALL criteria are automatically mandatory; but look also at the optional (SHOULD and MAY) criteria, do you still want them to be optional?
- What about the referenced function's priority? Is it the same or different than the 'calling' function? If it is different, does it make sense to have the different priorities?

Take care to consider the ramifications of referencing a criterion in another function –

- Does the referenced function have the normative verb ('shall', 'should' 'may') that is appropriate for the 'calling' function?
- Does the referenced criterion make sense when looking at all the 'calling' functions criteria?
- Does the referenced criterion make sense when taken out of context of its function?

If the criterion references another function in the profile, then provide the function name and its ID.

Case 1: If Criterion-W requires that another function (call this F-1) be implemented and W explicitly names function F-1, then all the 'Shall' criteria of function F-1 apply.

Example:

RI.1.1.4 Attest Record Entry Content; RI.1.1.4#01 The system SHALL conform to function TI.1.1 (Entity Authentication).

This criterion requires function TI.1.1 Entity Authentication, and thus, all 'shall' conformance criteria for function TI.1.1 are also required and automatically become part of satisfying function RI.1.1.4 Attest Record Entry Content. Think of it like this – the 'shall' criteria of IN.1.1 are virtually appended to the list of criteria for RI.1.1.4.

5.8. *Establish Applicability – Shall, Should, or May*

Now you must decide whether the criterion is mandatory or optional. Look carefully at the language used by the selected function's *conformance criteria*, and also its *Statement* and *Description*.

- You must make at least one of the selected function's conformance criteria mandatory (chapter 6 in the EHR-S FM standard, April 2014, paragraph 6.7.1.1#5a (Functional Domain Profiles) and 6.7.5#4a (Functional Companion Profiles)).

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[6] The ChangeNote is on the Edit Profile form in figure 2 and can be seen when you click on a criterion.

- If there are 'shall' criteria, the profile inherits all of these (chapter 6 in the EHR-S FM standard, April 2014, paragraph 6.7.1.1#5b and 6.7.5#4b.

You can't pick and choose – you inherit them all. If there are no 'shall' criteria in the FM, then you must make at least one of the optional criteria mandatory or create a new mandatory criterion (see Figure 3, , third column) (chapter 6 in the EHR-S FM standard, April 2014, paragraph 6.7.1.1#5d.

'Shall' criterion express a core or basic feature of the function – that is, without the criterion you don't have needed functionality. If a profile criterion is mandatory, then some part of it is also mandatory in a further, derived profile.

> Remember: all functional criteria rated as 'shall' in your profile SHALL be inherited with that 'shall' rating by all subsequent derived profiles.

'Shall' is used when a criterion is the essence of the function – that is, you don't have the function without this feature or capability. 'Should' and 'may' indicates optional features, capabilities, etc. associated with that function.

Remember:

- A FM 'shall' always remains as a 'shall' in the profile. (chapter 6 in the EHR-S FM standard, April 2014, paragraph 6.7.1 and 6.7.5)
    - A FM 'should' can
    - remain as a 'should' in the profile,
    - be changed to a 'shall' or 'may' in the profile,
    - be omitted from the profile.
- A FM 'may' can
    - remain as a 'may' in the profile,
    - be changed to a 'shall' or 'should' in the profile,
    - be omitted from the profile.

Conformance criteria **corresponding to function** (left box) of FM

Conformance criteria **for a profile** based on FM criteria and profile factors

a. xxxxx *Shall xxxxx xxx xxxxx xxxxx*

a. xxxxx *shall xxxxx*
c. xxxxx *shall xxx*
Profile requires at least one "shall" criterion per FM function

SHALL

Function from FM

Name xxxxxx
Statement
xxxxxxx
xxxxxxxxxxxxxxx
Description
xxxxxx
xxxxxxxxxxxxxxx

b. xxxxxx *should* xxxxx xxxxxxxxx
c. xxxxx *should xxxxx*

d. xxxxx, xxxx *should* xx xxxxxxxx
dd. xxxxx, xxx *[dd. derives from d within profile context]*

SHOULD

d. xxxxx, xxxx *may* xx xxxxxxxx
e. xxxx xxxx *may xxx*

b. xxxxxx *may xxxxx* xxxxxxxxx
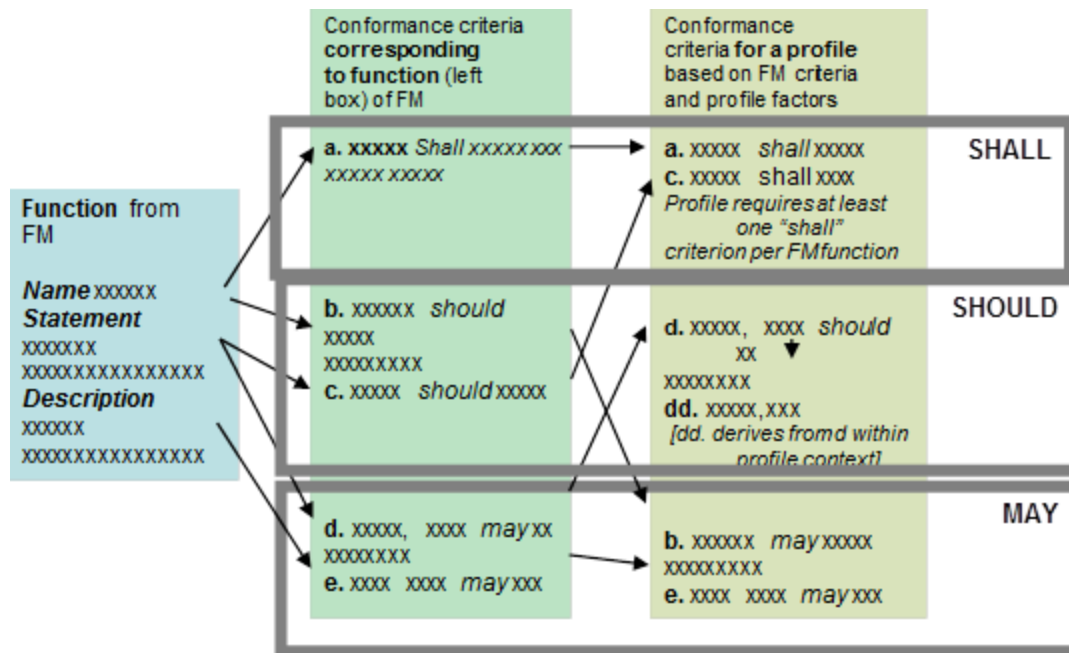**e.** xxxx xxxx *may xxx*

MAY

Figure 3. Level of applicability: FM Function to FM Function Criteria to Profile Criteria

To draw attention to the normative verbs, convention is to capitalize the verbs 'shall', 'should', and 'may' in the Conformance Criteria and anywhere else that the verb is used to indicate requirements or prescriptive information.

5.9.   Group and Order the Function's Criteria

Now that you have created a set of criteria, it makes sense to group related criteria together. You can also make the order in which the criteria are listed significant. Try to group them into logical, related sets.

We recommend ordering the criteria according to a natural and logical flow. For example, input should come before processing, which comes before reporting, etc. When you read down the column, your thought processes should not be interrupted and you should clearly see the function's behavior from one step to the next.

If there seems to be a missing step between two criteria, it may mean that new criteria may need to be developed.

In a Functional Domain profile, you MAY make the order of the conformance criteria significant. However, we don't recommend placing all the 'shalls' first, followed by the 'shoulds', and then the 'mays'. That results in an artificial order and the reader's thoughts are greatly interrupted. The reader may be confused, causing them to put the criteria in order mentally before assessing whether or not the verbs should be what they are. Putting such an effort on the reader could result in an incorrect conclusion that the function is disorganized, and that there is "something missing." One does not want this reader reaction when seeking to provide understanding or seeking agreement on the applicability and merits of the use of the profile (potentially seeking an affirmative vote).

- The ordering of the criteria can be done by changing the sequence number of the criteria. This is described in the EA Learning Center, section 'Edit the Functional Model/Profile', chapter 'Moving EHR-S FM FP components'.

It's better to have the conformance criteria in their natural order with the 'shalls', 'shoulds', and 'mays' interspersed as the order of the criteria dictates. It's an easier mental operation for the reader to say, "Yes, this is the next criterion that should follow, and it should be a 'should'. All makes sense to me."

Criteria traceability

We recommend that you keep track of the origins of the criteria – and whether it is modified or unchanged from that within the FM and/or base profile. This may be important when questions arise as to where did it come from, why did you choose or modify it, etc. It can also be helpful to have traceability back to the FM criteria for when you revise your profile or for derived profiles.

- The traceability of criteria is done by the **tool**. For every header, function and criterion the traceability to the base model is in the Tagged values. In the compiled profile it is indicated if the header, function or criterion was changed or not for the profile.

Creating Inherited criteria

If you find that there are criteria that are common among all sibling functions, consider making them 'over-arching', inherited criteria. Inherited criteria is a fancy way of saying that you are putting all the criteria that apply to all siblings in the functional header or in the section header, rather than repeating the criteria in each sibling. It is basically a shorthand efficient way to list the criteria, without having to duplicate the same criteria in each sibling or child function. The criteria at the higher level of the hierarchy are inherited (i.e., apply) by all the children and any grandchildren. There are no exceptions to this – that is, the criteria are inherited by all functions below the header. Figure 4 illustrates this concept.

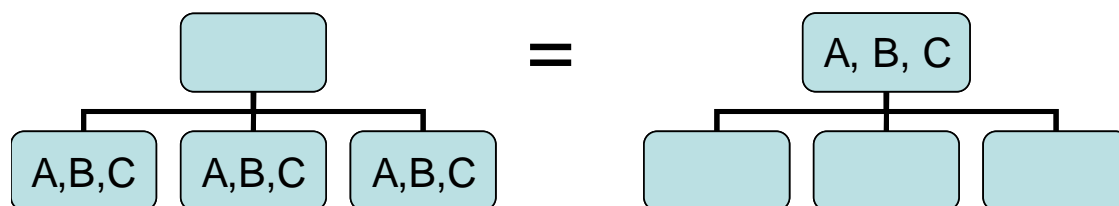Figure 4. Inherited criteria.

In Figure 4, A, B, C are criteria. Rather than rewriting these criteria in each child, put it in the parent. This is not only convenient, but may help in reducing errors associated by having the same criteria repeated in all the children. . This is described in the EA Learning Center, section 'Edit the Functional Model/Profile', chapter 'Moving EHR-S FM FP components'.

5.10. Check for Dependencies and Co-relations

As we have seen, some functions specify general categories or need more information to be testable. This information comes from care settings, specialties, realms, etc. Go ahead and provide the additional information in the criteria or if necessary add a child or split a function.

Examples

- CP.1.3 Manage Medication List – which lists?
- AS.1.1 Manage Provider Registry or Directory – what identifies – credentials, certifications, licenses, or other?

Other functions will depend upon or relate to other functions, either in the FM or in your profile. Follow the chains of functional dependency to ascertain that details in the chain are appropriate and are captured. Record functional dependencies and other important linkages.

> **FM Example:** CP.1.1#03 *The system SHOULD conform to function CPS.2.1 (Support externally-sourced Clinical Documents) to capture, store and render previous external patient histories.*

On a function by function basis, review the conformance criteria once again. Review also the relationships of the function. In the **tool** you can use the view Traceability of EA to see the relationships. On a function by function basis, read the function and its related function together (e.g., Manage assessments to Support for standard assessments to Support for patient context enabled assessments) using the traceability view in EA. You should get the feeling of completeness or comprehensiveness (e.g., first the system let me set it up, then use it for direct care, then for retrospective decision making). If you don't, it may imply that there are missing functions or components of existing functions. Revise the functions as necessary.

CONGRATULATIONS. You have created conformance criteria for a function in your profile. By the way, use this exercise of creating criteria as a feedback loop to improve your profile (also the FM) and its conformance criteria: the fewer ambiguities, inconsistencies, etc., in texts, the better.

6. Principles when creating profile conformance criteria

Apply the following principles when creating profile conformance criteria:

1. **Do** restrict each conformance criterion to an atomic, simple statement by.
   - Addressing one feature at a time.
   - Keeping each criterion as simple as possible. Multiple single-feature criteria are easier to test than a multi-part criterion. Also, identifying the source of a failure to achieve conformance for a given function is easier when criterion are not multi-part.
   - Group criteria into logical sets. Consider ordering them 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 should be directly traceable to wording (*name* or *statement or description*) of the function in the FM.
   - Obey conformance clause rules for splitting conformance criteria

2. **Do** make your profile conformance criteria technology-neutral.

3. **Do not** change the functionality of the FM. Your profile will refine it.

4. **Do not** weaken the intent of the criteria with ineffective criteria selection or ordering. When adopting FM criteria into the profile, take care that you don't alter or weaken the fundamental intent of the function.

5. **Do not** change a 'shall' criterion from the FM to a 'should' or 'may' criteria in your profile.

6. **Do not** mix important terminologies.
   - Use an FM Glossary agreed upon by all.
   - Keep the balance of your text self-contained, with as few footnotes and external references as practical.
   - Avoid sets of terms that assign different interpretations to the same words.

7. **Do** constrain options and allowed values.
   - Describe features, values, attributes, etc. to be measured and indications of success or failure.
     Examples: … shall offer A, B, or C, and no others

                        … occurs one or more times

8. **Do** indicate explicit dependencies and constraints.
     Example: … *Gender* ('M', 'F', or 'NA') shall be required whenever *Person* option is used.

9. **Do not** state how to test.

10. **Do** use "shall" to signify *required*, "should" for *recommended but not obligatory* and "may" for optional, a neutral choice.

11. **Do not** rely upon formatting or context to convey intentions. For example, instead of employing italic or bold face, use the English imperative "shall".
    Example: Not "… *this* feature *is* required," but rather, "… shall require feature A31."

PART 2: Functional Profile Registration and Balloting

WHAT is it?

Two mechanisms exist to facilitate public awareness of functional profiles:

1. Registration of a functional profile
2. Balloting a functional profile

Both of these activities take place under the auspices of the HL7 EHR Technical Committee (EHR TC).

Registration of a functional profile is a mechanism for listing a conforming functional profile on an HL7 web site. It involves self-attestation of conformance by those submitting the functional profile and a subsequent review by the EHR TC.

Balloting a functional profile is a thorough consensus process in which the functional profile has been subjected to rigorous review. The functional profile is given a designation to indicate it has successfully completed the HL7 ballot process. There are two levels of balloting – technical committee and membership. Balloting occurs first at the technical committee level and if successful and so desired, the TC can conduct a ballot at the HL7 membership level.

WHY Bother?

Registration indicates that the submitter of the functional profile believes that it conforms to the HL7 EHR-S Functional Model. Registration can facilitate the adoption of the profile by making it publicly available for use – to be implemented to be used as the basis of a derived functional profile. Registration can help minimize the proliferation of profiles by making people aware of the ones that exist and thus, minimize the need to create new and different profiles. Basically, reuse rather than create new. Also, having a list of functional profiles can serve as an educational **tool** – e.g., to be used as examples to those building a functional profile or to show the type of functionality applicable to a particular care setting, application, etc.

Balloting at the TC level indicates that the Technical Committee has formally reviewed and approved the functional profile. This means that the TC believes that the functional profile conforms to the HL7 EHR-S Functional Model and that the functions and criteria contained in the functional model are appropriate. Upon successful completion of the HL7 ballot process, the functional profile would be listed on the HL7 site as an HL7 Informative functional profile. This allows organizations to refer to a consensus based functional profile. It is also a required first step if the goal of the functional profile submitter and/or the TC is to pass membership ballot and become an HL7 normative standard. Only HL7 standards can become ANSI standards and subsequently submitted for consideration as an ISO standard. Note: the ANSI and ISO processes would need to be followed in order to obtain standardization from these organizations.

Balloting at the HL7 membership level indicates that the full HL7 membership has formally reviewed and approved the functional profile.   This provides for a wider community to review and formally agree that the functional profile conforms and is appropriate. This is not a trivial process and requires support from the TC to progress the functional profile through the process. Upon successful completion of the HL7 ballot process, the functional profile will be listed on the HL7 site as a HL7 standard. Being a de-jure standard could give the functional profile additional stature and make it eligible for reference in other standards, legislation, etc.

WHO can do it?

Any stakeholders with an interest in the functional profile can register it. Typically, this will be the developers of functional profiles or the organizations taking ownership for the functional profile or a community of interest for using the profile.

Any stakeholder can submit a functional profile to the HL7 EHR TC as an HL7 project proposal for a TC support for ballot submission. Stakeholders are encouraged to work with the TC, helping the TC understand the motivation for the functional profile as well as the rationale for the included functions and criteria. As a functional profile is balloted, it is extremely important to have stakeholder's interests represented in the TC. Similarly, stakeholders need to work with the TC if the functional profile is to undergo an HL7 membership ballot.

WHEN can it happen?

Registration can occur at any time. Balloting will only occur at specified times and limited to no more than twice a year. The reason for the limit on balloting is that it is a time consuming and often resource intensive event – e.g., requiring structuring of the ballot, recording and resolution of all comments, and other administrative efforts.

HOW to register a functional profile?

Step 1:   Complete the checklist provided by the HL7 EHR WG. This checklist is used to document that the functional profile was developed following the Rules for Profiles and that it is a conforming functional profile. Through a self-attestation statement, which is part of the checklist, the submitter declares that the functional profile is a conforming functional profile and specifies the version and date of the Functional Model to which it conforms.

Step 2.   Submit the checklist and file (or URL) for the functional profile to the HL7 EHR WG.

Step 3.   The submitter is notified that the functional profile was received and has been posted with the label '**Registration Pending'**.

Step 4.   The EHR WG reviews the checklist and functional profile to ensure that required information is provided and complete. The WG does not evaluate the appropriateness or quality of the functions or criteria in the functional model, but does make sure that the rules for profiles have been followed.

Step 5.   The functional profile is listed as **Registered**.

NOTE: it is anticipated that the registration process will be facilitated via web forms and automated **tool**s to review the submission – though it will initially be manual.

HOW to ballot a functional profile?

Step 1.   Make friends with members of the HL7 EHR WG.

Step 2.   Provide the functional profile to a HL7 EHR WG chair or member, as part of requesting that it undergo a TC ballot.

Step 3.   A formal HL7 project request is prepared for WG review and approval.

Step 4.   If the project request is approved, the WG follows the HL7 consensus process. [GET REFERENCE]

Step 5.   As the balloting process progresses, the submitter and/or other stakeholders need to stay involved. The success of the ballot depends on this, since it is the stakeholders who can answer questions that arise from the ballot and may need to modify the functional profile to incorporate the accepted comments.

Step 6.   Once all comments are satisfactory resolved, the functional profile is designated as a WG Balloted functional profile.

The process for HL7 membership ballot is basically the same as a WG ballot except this time the pool of eligible voters on the ballot is larger. Again, it is critical that stakeholders stay involved and work with the WG to get a successful result.

PART 3: FAQ and Lessons Learned

The following are taken from questions we have received and lessons learned from profile development groups. In some cases, we share with you the text produced by the profile groups as they figured out how to build their profiles.

1. ***How do we get started?***
   a. You will need the EHR-S Functional Model R2 (April 2014) – in particular, Chapter 6: Conformance Clause.
   b. You will also need the max version of the EHR-S FM R2 in where the sections, functions and conformance criteria are described.
   c. You will need Enterprise Architect, EA, installed on your computer.
   d. You will need the EHR Profile Designer tool for creating Functional Profiles. This is an extension for EA. Install this on your computer.
   e. Decide on the scope, audience and objective of the profile. Start with this so that everyone is on the same page – but revisit it as you develop the profile and modify it, as you see fit. How to use the **tool** for this is described in 'Provide General Information'.
   f. Pick functions from the FM by reading through all the functions.
   g. Include or exclude functions and criteria for your Functional Profile. See 'Create the Profile Definition for the new functional profile'.
   h. Assign priorities and criteria to the functions. See Create the Profile Definition for the functional profile as in g. Some groups like to do this at the same time, other groups assign priorities and then tackle the criteria.
   i. Write the conformance clause. The conformance clause often evolves as you develop the profile, that is, you think about the things to be defined as you encounter them. For example, rules that you want to impose on derived profiles or defining different levels of conformance (e.g., 2 levels: core = a minimal set of functions and advanced = core + an additional set of functions). See 'Provide General Information' in e.
   j. Reread and review everything – making sure it is clear, consistent and nothing is missing.

2. ***What is the difference between priorities and criteria?***

   Priorities pertain to the timing of when the function gets implemented by the system. It is a way for you, as profile creators to indicate a timeline or roadmap for implementation.

   Criteria are developed for each function, regardless of its priority. The criteria define what it means to actually implement or support the function within an EHR system. They provide the basis for articulating the features or capabilities of the function. Basically, what you can expect if that function is implemented. The criteria can be designated mandatory or optional. This is done by using they keywords SHALL, SHOULD or MAY.

Function	Priority	Criteria
Function 1	Essential Now (EN)	1a) Criteria with a SHALL 1b) Criteria with a SHALL 1c) Criteria with a SHOULD
Function 2	Essential Future (EF)	2a) Criteria with a SHALL 2b) Criteria with a SHOULD 2c) Criteria with a MAY 2d) Criteria with a MAY
Function 3	Optional	3a Criteria with a SHALL 3b) Criteria with a SHOULD 3c) Criteria with a MAY

Table 1 . Illustration of difference between priority and criteria.

Function 1 is Essential Now (EN) and an EHR system is required to implement the function and satisfy criteria 1a and 1b. Criteria 1c is optional and may also be satisfied, but there is no penalty if it is not. On the other hand, the priority Essential Future (EF) makes Function 2 optional – the EHR system does not have to implement this function until the date indicated in the EF definition. However, Essential Future functions can be implemented prior to the date when they are required to be implemented. So, when Function 2 is implemented (now or in the future), criteria 2a needs to be satisfied. The other criteria (2b, 2c, 2d) remain optional. Function 3 is always optional and it follows that if Function 3 is implemented, then criteria 3a needs to be satisfied.

3. *Do we assign a priority to each criterion?*

No. Priorities are only assigned to a function and is used to indicate the timing of when that function needs to be implemented.

However, with the **tool** it is possible to assign priorities on criteria and function level. If the priority is assigned on function level, then the priority for each criterion in that function has the same priority as assigned to the function. The function can have a priority Essential Now, but one or more criteria can have another priority. As in table 1 above criteria 1c is optional and can have the priority Optional in a function that has the priority Essential Now.

4. How do we determine a function's priority?

(The following is extracted from a profile group's development process)

To determine a function's priority, ask:

- Is this function already being implemented? If yes, how widely across all your stakeholders? If yes, but not widely, why not? What would it take to implement it more widely?
- If the function is not yet being implemented, what would be required to develop and implement it? Is this dependent upon software vendors? If so, do they have it on their roadmap? Is it dependent on development of other relevant standards? Is it dependent on other events or organizations?

Based on these answers: consider

- 'Optional', if the function is applicable to only a few of your stakeholders and unlikely to be needed more widely in the near future.
- 'Essential Future', if the function is either
    - o Implemented in only a few stakeholders now, but is likely to be needed by most organizations in the near future.
    - o Likely to be needed by most stakeholders in the near future but not implemented now because necessary software functionality needs to be developed. In this case, define 'future' in terms of the time needed for software development and implementation to occur.
    - o Likely to be needed by most stakeholders in the future but not implemented now because related supporting standards (i.e., interoperability standards, security standards) are not in place. In this case, define 'future' in terms of the necessary standards or other environmental changes that must happen first.
- 'Essential Now', if the function is implemented widely now.

5. Are priorities assigned to header functions?

Yes.

5a. Are these priorities inherited by children of the header functions?

Not necessarily. Children functions can have the same or different priorities than their parents. If you want inheritance of priorities, you need to indicate this explicitly. The conformance clause is a good place to state this.

5b. Can I have an EN header function with only one of its children assigned EN?

Yes.

5c. Can I have an EN header function with no children assigned EN, i.e., children with EF or Optional priorities?

> Yes. But exercise caution here. Although permissible, we advise you to avoid having all leaf children assigned optional priority. This could result in no functions being implemented or the implementation of a non-standard function (i.e., a function not included in your profile). As an exercise, work through the implications of the priorities you assign to make sure they are what you intend.

5d. Can I have an Optional header function and EN children or children assigned EN, EF and Optional.

> Again, yes. This means that if this header function is not implemented, then ignore it and all its children. If it is implemented, then all EN children must be implemented, optional children may or may not be implemented, and EF children depend on the timeframe of the EF as to whether they must be implemented or are optional.

NOTE: the **tool** will give you a warning if running a validation on your functional profile if the priorities assigned on a function and its criteria are not consistent. But as you have read above this is possible.

6. Should we inherit all a function's criteria?

(The following is extracted from a profile group's development process)

Not necessarily. You must inherit all 'shall' criteria that are contained in the functions you have selected from the FM. However, you can pick and choose from the other criteria and you can also change the verb (i.e., 'should' to 'shall' or 'may' and 'may' to 'shall' or 'should'). To determine this, ask: Is this criterion

- A 'must have'? – Make it a 'shall'.
- Recommended, but not a 'must have'? – Make it a 'should'.
- Recommended for most, but a 'must have' for some? Make it a 'should' and indicate in a note which stakeholders this is a 'must have'. This will signal those stakeholders that if they create a derived profile, they should consider elevating this to a 'shall'.
- Recommended, but may not be achievable or useful by all systems? – Make it a 'should' and indicate in a note the circumstances.
- Mildly useful to most stakeholders? – Make it a 'may'.
- A good thing to have and don't feel strongly about? – Make it a 'may'.

7. We are creating a generic profile that will be used across diverse settings.

> What should we do when functions and/or criteria apply to some organizations but not others?

> *(The following was extracted from a profile group who is developing a generic profile from which they expect derived profiles to be built.)*

The challenge is to set both the priority of the function and its criteria so that is can be applied to the appropriate care settings and/or specialty. The following are two approaches to consider for handling this.

Approach 1

1. Make any functions as 'Optional' if there is wide diversity among types of organizations as to how essential the function is. Include in a notes section the types of organizations for which the function seems Essential and encourage those types of organizations to indicate such if/when they develop their own derived profiles from the more generic one.

> IMPACT:

a. If instead of Optional an Essential priority is used in the generic profile, all the organizations for which the function is inapplicable will henceforward be required to include it in their EHR.
b. On occasion, an 'if/then' conditional statement to address the variation in need across organizations can be used. However, care needs to be taken to ensure that the 'if/then' statement appropriately targets all the organizations or situations the group is trying to capture. Moreover, use of conditional statements can lead to a cumbersome profile that does not read well. For example, a statement such as 'IF caresetting 1, caresetting 2 and caresetting 3, THEN Function (Essential Now), else Function (Optional). Clearly the list of caresettings can get very long and there is a possibility that a care setting is mistakenly left out.

2. Rate any functional criteria as 'should' or 'may', not 'shall', if there is wide diversity among types of organizations as to how applicable and vital the functional criteria are. Include in a notes section the types of organizations for which the functional criteria warrants a 'shall' and encourage those types of organizations to indicate such if/when they develop their own derived profiles from the more generic one.

> IMPACT:

a. If instead of 'should' or 'may' a 'shall' verb is used in the generic profile, all the organizations for which the function is inapplicable will henceforward be required to include it in their HER and stipulate it as a 'shall'.
b. On occasion, an 'if/then' conditional statement to address the variation in need across organizations can be used. See 1b above for cautions.

Approach 2

1. If there is a wide diversity among types of organizations as to how applicable and essential the function is, then categorize the organizations according to how they differ in their need for the function in question. Then set up copies of the function in question and its functional criteria for each organizational category. Then rate the function and its functional criteria separately for each organizational category.

IMPACT:

    a.   This will result in a hybrid profile that will include some functions of a profile generic to all organizations within a specialty area and some functions of a derived profile that will be more setting-specific.

    b.   One of the obvious advantages of this approach is that it will give a head start to types of organizations that will want to develop derived profiles from the generic one. A second advantage is that it will make clear what priority is intended for which types of organizations.

    c.   A major disadvantage of this approach involves more work which translates to more time and related resources.

Profile groups may use a combination of approaches, of which these are just two possibilities.

NOTE: More Frequently Asked Questions on the **tool** can be found here.

Annex 1. Sample Functional Profile Conformance Clauses

To aid functional profile developers in developing a conformance clause for their functional profile 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.