**Integrating the Healthcare Enterprise**



**IHE <PCC>**

**Technical Framework Supplement**

**<Remote Patient Monitoring   
(RPM)>**

**Draft in preparation for Public Comment**

<The IHE Documentation Specialist will change the title to just “Draft for Public Comment” upon publication for public comment; leave “as is” until then.>

Date: <Month xx, 20xx>

Author: <Author Name or Technical Committee Name>

Email: <domain\_name@ihe.net>

<Instructions to authors are encapsulated in angled brackets as “< … >” and denoted with italicized text. These instructions are to be deleted in their entirety prior to publication.>

<Use of capitalization: Please follow standard English grammar rules-only proper nouns and names are upper case. For example, “Modality Actor” is upper case, but “an actor which fulfills the role of a modality” is lower case. Do not use upper case to emphasize a word/topic.>

<Note: There are editing conventions, such as diagram numbering and how to use Microsoft Word tools, etc., at <http://wiki.ihe.net/index.php?title=Writing_Technical_Frameworks_and_Supplements>. Please review this prior to beginning a new Supplement. This is especially useful for first time authors.>

<This Supplement Template is intended for the development of new Profiles or for making significant changes to Profiles, such as adding formal Options. Simple changes to existing Supplements or Profiles should be made using the Change Proposal (CP) process. See the Technical Framework Development section at <http://wiki.ihe.net/index.php?title=Process#Technical_Framework_Development> for more guidance on Supplements vs. CPs.>

<All of the sections in this document are required. Sections may not be deleted. The outline numbering is intended to be consistent across Profiles and across Domains, so do not adjust the outline numbering. If there is no relevant content for a section, simply state “Section not applicable”, but leave the numbering intact. Sub-sections may be added for clarity.>

*<This Supplement Template includes templates for Volumes 1 (Profiles), 2 (Transactions), 3 (Content Modules), and 4 (National Extensions).>*

*<Volumes 1, 2, and/or 3 are developed together for Public Comment and Trial Implementation submission. Volume 4, National Extensions, is typically developed at a later point in time, usually at Trial Implementation or later. Templates for all four volumes are included in this document for the sake of completeness. If you are beginning a new profile, you are strongly discouraged from using National Extensions and should instead focus on optional data sets or other alternatives. For more information, see* [*http://wiki.ihe.net/index.php?title=National\_Extensions\_Process*](http://wiki.ihe.net/index.php?title=National_Extensions_Process)*.>*

**Foreword**

This is a supplement to the IHE <Domain Name> Technical Framework <VX.X>. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

*<For Public Comment:>* This supplement is published on <Month XX, 201x> for Public Comment. Comments are invited and may be submitted at [http://www.ihe.net/<domain>/<domain>comments.cfm](http://www.ihe.net/Technical_Framework/public_comment.cfm). In order to be considered in development of the Trial Implementation version of the supplement, comments must be received by <Month XX, 201X>.

*<For Trial Implementation:>* This supplement is published on <Month XX, 201X> for Trial Implementation and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the <Domain Name> Technical Framework. Comments are invited and may be submitted at [http://www.ihe.net/<domain>/<domain>comments.cfm](http://www.ihe.net/%3cdomain%3e/%3cdomain%3ecomments.cfm).

This supplement describes changes to the existing technical framework documents.

“Boxed” instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume.

Amend section X.X by the following:

Where the amendment adds text, make the added text bold underline. Where the amendment removes text, make the removed text bold strikethrough. When entire new sections are added, introduce with editor’s instructions to “add new text” or similar, which for readability are not bolded or underlined.

General information about IHE can be found at: [www.ihe.net](http://www.ihe.net).

Information about the IHE <Domain Name> domain can be found at: <http://www.ihe.net/Domains/index.cfm>.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at: <http://www.ihe.net/About/process.cfm> and <http://www.ihe.net/profiles/index.cfm>.

The current version of the IHE <Domain name>Technical Framework can be found at: <http://www.ihe.net/Technical_Framework/index.cfm>.

*<Comments may be submitted on IHE Technical Framework templates any time at* [*http://ihe.net/ihetemplates.cfm*](http://ihe.net/ihetemplates.cfm)*. Please enter comments/issues as soon as they are found. Do not wait until a future review cycle is announced.*

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# Introduction to this Supplement

<Provide a brief overview of the volumes/sections of the Technical Framework that get changed/ added by this supplement. Provide 200 words or less describing this supplement.>

## Open Issues and Questions

1. How should we partition this profile? At present, it is one profile containing content from PCC and PCD. Should it be restructured as was done for Radiology Clinical Decision Support/PCC Guideline Appropriate Ordering? Is this a PCC or PCD profile in the end?
2. Related to #1: Should **Communicate PCHA Data** be aPCD or PCC transaction**?**
3. Comments from Paul Schluter
4. A few suggestions:

1.  Indicate that several deployment options are shown, in each of the three horizontal bands.  A short description of each as a subcaption in small italic text would help the reader understand what is going on.

2.  PCD DOR and PCD DOC are defined by the IHE PCD domain.  You need a unique labels for your device data observation source and consumer; it should not be the same as those that have been used by IHE PCD for years.

3**.  Use shaded vertical lines to highlight that the PCHA data transaction(s), IHE PCD DEC (of** which we have many, in addition to the basic PCD-01), and PCC document sharing.

## Closed Issues

<List the closed issues/questions with their resolutions. These are particularly useful for recording the rationale for closed issues to forestall unnecessary rehashing in the future and/or to make it easier to identify when a closed issue should be re-opened due to new information.>

<Note: The sections following this Introduction will eventually be added as Final Text to Volumes 1 – 4 of the Technical Framework. The material above this note (the Introduction, and Open and Closed Issues section) will be deleted when this Supplement is moved to Final Text.>

# General Introduction

Update the following Appendices to the General Introduction as indicated below. Note that these are not appendices to Volume 1.

Appendix A - Actor Summary Definitions

**Sensor Data Consumer** This actor receives sensor data from Personal Healthcare Devices (PHDs)



Appendix B - Transaction Summary Definitions

Add the following transactions to the IHE Technical Frameworks General Introduction list of Transactions:

**Communicate PCHA Data** <PCD-xx> – This transaction contains the discrete data from the remote Personal Health Device, such as device identification data, data related to the settings and calibration of the device, and the sensor data itself. To qualify as PCHA data certain time stamping requirements must be met; e.g. all stored data must be time stamped and any device containing timestamps in the measurements must expose its sense of current time and its time synchronization (if any).

|  |  |
| --- | --- |
| Transaction | Definition |
| **Communicate PCHA Data** | This transaction uses either the IEEE 11073-20601 protocol or the Bluetooth Low Energy attribute protocol to transfer sensor data to a Device Observation Consumer over a variety of transports for personal devices. |

Glossary

Add the following glossary terms to the IHE Technical Frameworks General Introduction Glossary:

|  |  |
| --- | --- |
| Glossary Term | Definition |
| RPM | Remote Patient Monitoring |
| PCHA | Personal Connected Health Alliance (Formally Continua) |
| PCHA Data | Data arriving over the Continua-specified PCHA Transaction from PHD devices. This data is typically provided by sensors and contains sufficient information to generate the non-demographic components of and enterprise time requirements for the IHE PCD-01 or PHMR modules. |
| PHMR | Personal Healthcare Monitoring Report. A C-CDA document designed primarily to record medical measurements taken on a patient by a sensor device. |
| PHD | Personal Health Device such as a pedometer, glucometer, blood pressure cuff, thermometer, etc. |
| IEEE-11073-20601 | Optimized Exchange Protocol. A transport-agnostic packet-based protocol for exchanging health data. Currently used only over local transports (PHCD USB, ZigBee, HDP Bluetooth, NFC) |
| IHE PCD Data | PCHA sensor data expressed in the form of a PCHA-compliant IHE PCD-01 document. |
| LAN | Local Area Network: A transaction using ZigBee transports to transfer sensor data in the form of IEEE 11073 20601 data packets |
| PAN | Personal Area Network: A transaction using PHDC USB or HDP Bluetooth transports to transfer sensor data in the form of IEEE 11073 20601 data packets OR a transaction using the Attribute protocol over Bluetooth Low Energy transports to transfer sensor data. |
|  |  |
|  |  |
| TAN | Touch Area Network. A transaction using Near Field Communication transports to transfer sensor data in the form of IEEE 11073 20601 data packets |

Volume 1 – Profiles

## <*Copyright Licenses>*

<General copyright licenses and permissions are listed in the IHE Technical Frameworks General Introduction. Add information on any standards referenced in the profile that are not already addressed in the permission section.>

Add the following to the IHE Technical Frameworks General Introduction Copyright section:

## <*Domain-specific additions>*

<Some domains have specific sections, added as subsections to Sections 1 or 2, in their Technical Frameworks. These types of additions are allowed as long as they do not adjust the overall numbering scheme which needs to remain consistent across domains. If there are such additions, they should be included here.>

Add to Section …

<Reserve a subsequent section number in the current domain Technical Framework Volume 1 (DOM TF-1). Replace the letter “X” with that section heading number. This number should not change when this supplement is added to the Final Text Technical Framework. In this manner, references should be able to be maintained going forward.>

# X Remote Patient Monitoring (RPM) Profile

The Remote Patient Monitoring Profile describes a standardized means to transmit measurements taken by personal health devices in a remote setting to a health care provider, including remote home monitoring, sub-acute therapy devices and wearable technologies. Remote in this case means outside of a care provider facility and is typically in the patient’s home. In this manner, a patient’s status can be monitored without repetitively travelling to a provider facility until deemed necessary, reducing interference in their day to day lives. In addition patients can be in an environment that they are more familiar and comfortable with. The reduction of personal stress and overall expense is especially beneficial in the case of independent living support, chronic disease management and post-operative recovery.

This profile is, for all practical purposes, an expression of the already existing set of standards and interfaces defined by PCHA for the delivery of remote patient data taken by Personal Healthcare Devices to the care provider in terms of IHE actors and transactions. No new standards or transactions are proposed.

The typical technology used to support remote monitoring includes:

* A Personal Health Device (PHD) which produces various health-related measurements through different kinds of sensors, and
* A collector that gathers data from one or more PHDs and forwards the information to the health information exchange, and
* The health information exchange that stores and makes the data accessible to healthcare providers such as the physician or care coordinator, and
* An electronic health record or care management system that provides healthcare providers or coordinators with access to the patient’s health record and monitoring data.

Personal health devices include sensors such as a weight scale, SpO2 sensors, blood pressure cuffs, and medication dispensers. These devices connect to a data collector using a variety of personal networking protocols, such as Bluetooth®, ZigBee®, and USB connections. Personal health devices tend to use embedded systems to handle data communication, and have limited capabilities. They may not even have a clock to keep track of the date and time a measurement is taken.

Collectors are typically applications built into devices such as a set-top box attached to a cable or local area network, or a mobile device such as a cellular phone, tablet or personal computer. These applications collect data from one or more PHDs and send them on to the healthcare provider via a health information exchange.

The personal health devices data is time stamped with a consistent enterprise time. This time stamping is typically not done by the PHD sensor device but by the Device Observation Reporter actor obtaining the PCHA data from Sensor Data Consumer.

The Remote Patient Monitoring Profile uses transactions that include the transport of data content based on IEEE 11073 terminologies for remote patient monitoring devices. Please see the list of terminologies in Appendix A.

## X.1 RPM Actors, Transactions, and Content Modules

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A at <http://www.ihe.net/Technical_Framework/index.cfm>.

The intent of the RPM profile is to standardize the representation of device observations and the transactions necessary to get the device observations to the health care provider. This standardization ensures plug and play operation for each component participating in the RPM profile from the sensor device (Device Observation Source) used by the remotely located patient to the EHR document reader used by the health care provider.

The profile consists of the following actors:

1. Device Observation Source actor which is typically the Personal Health Device (PHD) sensor
2. Sensor Data Consumer actor that receives the data from the sensor device. In this profile, the Sensor Data Consumer must be grouped with either a Device Observation Reporter or Content Creator.
3. Device Observation Reporter actor that generates a PCD-01 document from the PCHA data
4. Device Observation Consumer actor that receives clinical data from the Device Observation Reporter actor. In this profile the Device Observation Consumer actor is typically grouped with a Content Creator actor that creates PHMR content modules from IHE PCD-01 data. However in some use cases the PCD-01 document may suffice
5. Content Creator actor that generates a PHMR content module and makes that Content available to a Content Consumer
6. Content Consumer actor that receives a PHMR content module

and transactions:

1. PCHA Data transaction communicates sensor data to the appropriate consumer
2. PCD-01 Communicate PCD Data transaction communicates PCD-01 data to the appropriate consumer
3. PCC Document Sharing transaction distributes the PHMR content module by an agreed upon technique (such as XDSb or XDM) to an appropriate consumer

and Content Module:

1. Personal Healthcare Monitoring Report (PHMR).

*<Workflow/Transport Instructions>*

<If this profile does not define workflow or transport transactions, delete the following text and diagram until the “Content Module Instructions” below.>

<Continue here for workflow and/or transport profiles:>

Figure X.1-1 shows the actors and actor groupings directly involved in the RPM Profile and the relevant transactions between them in its various combinations. It is envisioned that the primary workflow is the four-module version where the Device Observation Source actor is one component, the Sensor Data Consumer and Device Observation Reporter actor group is a second component, the Device Observation Consumer and Content Creator actor group is a third component and the Content Consumer is the fourth component. Alternative deployments of this profile that combine the above components such that the total number of transactions is reduced are also shown using boxes with thinner lines in Figure X.1-1. For the most part, costs and maintenance issues make the alternative deployments less attractive. However with the increased ubiquity of mobile devices, combining the Device Observation Source and Device Observation Reporter actors onto these mobile platforms is a likely development.

PCHA Data

Transaction

Transaction 1 [1] ↓

Device Observation Source

PCD-01 Communicate

PCD Data

Device Observation Reporter

PCC

Document Sharing

Sensor Data Consumer

Content

Consumer

Content Creator

Device Observation Consumer

Device Observation Source

Device Observation Reporter

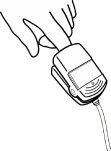
Content Creator

Sensor Data Consumer

Content Creator

Figure X.1-1: RPM Actor Diagram

The equivalent PCHA end-to-end data flow that is analogous to the four component deployment in Figure X.1-1 is shown in the Figure X.1-2. It should be noted that PCHA also defines the same alternative deployments as shown in Figure X.1-1 except for the Device Observation Source and Content Creator combination.

treadmill.pnghouse.pngusbBluetooth[v7_n_zigbee](http://images.google.com/imgres?imgurl=http://images.vnunet.com/v7_images/generic/medium/v7_n_zigbee.gif&imgrefurl=http://www.v3.co.uk/vnunet/analysis/2132125/zigbee-homes-short-range-wireless&usg=__Lt3B48Kw-SBQbLXMVKqFrHoiWSs=&h=110&w=185&sz=3&hl=en&start=7&tbnid=Ww8WGf99xQZ2bM:&tbnh=61&tbnw=102&prev=/images?q=ZigBee+logo&gbv=2&hl=en)[](http://images.google.com/imgres?imgurl=http://alabut.com/nonsense/images/w3c.jpg&imgrefurl=http://alabut.com/nonsense/archive/2007_03_01_index.html&usg=__Z-PsQzjVqNttrVx46ni5uIwxPQg=&h=173&w=140&sz=6&hl=en&start=4&um=1&tbnid=_N2x6-vfVJfzfM:&tbnh=100&tbnw=81&prev=/images?q=W3C&gbv=2&hl=en&um=1)

Health Records

Telehealth Service Center

Aggregation Manager



Devices  
*aka Agents*



***Continua***

***WAN***

***Continua***

***HRN***

***Continua***

***PAN***

***Continua***

***LAN***



Figure X.1-2: PCHA End-to-end Flow Diagram

Table X.1-1 lists the transactions for each actor directly involved in the RPM Profile. To claim compliance with this Profile, an actor shall support all required transactions (labeled “R”) and may support the optional transactions (labeled “O”).

<Actors from other profiles represented in dotted boxes, such as Actor C in the example above, should not be listed in Table X.1-1.>

Table X.1-1: RPM Profile - Actors and Transactions

| Actors | Transactions | Optionality | Reference |
| --- | --- | --- | --- |
| Device Observation Source | Communicate PCHA Data [PCD-xx] | R | PCC TF-2: 3.Y1 |
| Sensor Data Consumer | Communicate PCHA Data [PCD-xx] | R | PCC TF-2: 3.Y1 |
| Device Observation Reporter | PCD-01 Communicate PCD Data | R | PCC TF-2: 3.Y2 |
| Device Observation Consumer | PCD-01 Communicate PCD Data | R | PCC TF-2: 3.Y2 |
| Content Creator | PCC-1 Document Sharing | R | PCC TF-2: 3.Y2 |
| Content Consumer | PCC-1 Document Sharing | R | PCC TF-2: 3.Y2 |

Table X.1-2: RPM Profile - Actors and Content Modules

| Actors | Content Modules | Optionality | Reference  *<this should be a reference to a location in Volume 3)* |
| --- | --- | --- | --- |
| Content Creator | PHMR | R | PCC TF-3: 6.3.1.D |
| Content Consumer | PHMR | R | PCC TF-3: 6.3.1.D |

The Content Creator Actor in this profile depends upon the Consistent Time Profile. Table X.1-3 defines the dependency:

Table X.1-3: Content Module Dependencies

| Integration Profile | Depends on | Dependency Type | Purpose |
| --- | --- | --- | --- |
| Remote Patient Monitoring Profile (RPM) | Consistent Time | The Content Creator Actor implementing this profile must implement the Consistent Time Profile | Required for consistent time-stamping of the PHMR content module. |

### X.1.1 Actor Descriptions and Actor Profile Requirements

The RPM profile consists of the following actors:

1. Device Observation Source actor which is typically the Personal Health Device (PHD) sensor
2. Sensor Data Consumer actor that receives the data from the sensor device. In this profile, the Sensor Data Consumer must be grouped with either a Device Observation Reporter or Content Creator actor.
3. Device Observation Reporter actor that generates a PCD-01 document from the PCHA data
4. Device Observation Consumer actor that receives clinical data from the Device Observation Reporter actor. In this profile the Device Observation Consumer actor is typically grouped with a Content Creator actor that creates PHMR content modules from IHE PCD-01 data. However in some use cases the PCD-01 document may suffice.
5. Content Creator actor that generates a PHMR content module and makes that Content available to a Content Consumer.
6. Content Consumer actor that receives a PHMR content module.

A manufacturer implementing components that claim conformance to this profile could consist of one of the following actors or actor groups:

1. A Device Observation Source
2. A Sensor Data Consumer grouped with a Device Observation Reporter
3. A Device Observation Reporter Consumer grouped with a Content Creator
4. A Content Consumer capable of reading a PHMR
5. A Device Observation Consumer grouped with a Content Creator
6. A sensor acting as a Device Observation Reporter
7. A sensor acting as a Content Creator

These seven components do not rule out an implementation where a manufacturer implements, for example, a Sensor Data Consumer grouped with both a Device Observation Reporter and Content Creator. Such a component could provide both a PCD-01 document and/or PHMR content module.

Due to resource requirements, costs, and maintenance efforts, it is envisioned that the most common set of components satisfying the end-to-end nature of this profile will consist of one or more Device Observation Source components and a Sensor Data Consumer grouped with a Device Observation Reporter component for each patient, and a Device Observation Consumer grouped with a Content Creator component serving several patients sharing PHMR content modules with several Content Consumers.

The three transactions involved in this profile utilize multiple transports.

The PCHA Data transaction specified by the PCHA H.811 - TAN-PAN-LAN Interface guidelines currently supports the following transports and protocols

* IEEE 11073-20601 packets over
  + HDP Bluetooth
  + PHCD USB
  + ZigBee
  + NFC
* Assorted Health device profiles overs Bluetooth Low Energy Attribute protocol

The guidelines place further requirements upon these protocols and transports than defined in the respective IEEE 11073 20601 and corresponding specialization specifications and the Bluetooth Low Energy health device profiles and services. The Device Observation Source actor implementing this transaction must provide what is referred to as PCHA data in this specification. The PCHA data is required to have certain device information and (conditionally) timing information to allow generation of observation data that can be coordinated and corrected to a UTC synchronized time source by the Sensor Data Consumer / Device Observation Reporter actor group if the Device Observation Source has not already done so. In particular, any stored measurements MUST provide a time stamp, and any Device Observation Source actor providing a timestamp in any measurement (stored or live) MUST provide its sense of current time.

The PCD-01 Communicate PCD Data transaction communicates observation data in the form of a PCD-01 document to an appropriate consumer. The transaction uses one of the following transport methods:

* Continua PCHA hData Observation-Upload
* Continua PCHA SOAP Observation-Upload

As specified in the PCHA H.812.1 - Observation Upload and PCHA H.812 - WAN Interface guidelines. The SOAP Observation-Upload uses the web services based IHE CommunicatePCDData SOAP action over TLS authenticated with SAML. The hData Observation-Upload uses RESTful transports over TLS authenticated by oAuth. How the SAML or oAuth tokens are obtained is not specified by this profile but is a business decision made by the communicating partners.

The PCC Document Sharing transaction uses the transport methods specified by the PCHA H.813 - HRN Interface guidelines. These transports communicate the PHMR C-CDA content module to the consumer.

Details of these requirements are documented in Transactions (Volume 2) and Content Modules (Volume 3). This section documents any additional requirements on profile’s actors.

#### X.1.1.1 Device Observation Source

Typically the Device Observation Source actor is a Personal Health Device (sensor) which captures measurements about a patient. These measurements are communicated to the Device Observation consumer using one or more of the protocols and transports specified in the PCHA Communicate Device Data transaction to the Device Observation Consumer actor, described below.

#### X.1.1.2 Sensor Data Consumer

The Sensor DataConsumer actor receives data from the sensor, augments it and forwards it towards the healthcare provider. In this profile, the Sensor DataConsumer must be grouped with either a Device Observation Reporteror Content Creator actor to handle the forwarding of the information.

The Device Observation Reporter associates the sensor data with a time stamp, and the patient identity. PHD sensors typically can be used by multiple patients (e.g., a weight scale), and so the device observation consumer me be needed to distinguish which patient the device is currently measuring. Additionally, sensors often do not keep track of time and date, and so the Device Observation Reporter must time stamp the measurements. The Device Observation Reporter should, but is not required to support the IHE Time Client actor of the Consistent Time protocol. These devices may be wirelessly connected devices which get their time from the cellular network, rather than from an NTP or SNTP server.

**X.1.1.3 Device Observation Reporter**The Device Observation Reporter actor is responsible for transmitting augmented sensor observations one step closer to the healthcare provider.

#### X.1.1.4 Device Observation Consumer

The Device Observation Consumer accepts augmented device observations. It must be grouped with a Content Creator actor, and it uses that actor to forward these observations to the healthcare provider.

#### X.1.1.5 Content Creator

The Content Creator actor formats sensor data in the Personal Health Monitoring Report (PHMR) format, a form suitable for consumption by EHR, HIE and other Health IT systems, and which is also human readable.

#### X.1.1.6 Content Consumer

The Content Consumer actor is used by the healthcare provider to access stored sensor data associated with a patient in the Personal Health Monitoring Report (PHMR) format.

## X.2 RPM Actor Options

<Modify the following Table listing the actors in this profile, the options available for each, and references to sections that state requirements for compliance to each Option. For actors with no options, state “No options defined” in the Options column.>

<Note: Options are directly carried over to the Integration Statements which are published by vendors for review by buyers. Too many options can be confusing for readers.>

< Try to **minimize** options for Actors and only use if necessary.>

<Several options for Content Consumers are defined in PCC TF-2 section 3.1.1-3.1.4. It is recommended that these options are reused for content module definitions, but read the option definitions thoroughly to be certain that they apply. If they do apply in their entirety, you will need to define a corresponding option in this profile. The recommended naming convention for a similar, but different, option is, for example, “View Option - <profile acronym>, etc., “View Option – CIRC”.>

Options that may be selected for each actor in this profile, if any, are listed in the table X.2-1. Dependencies between options when applicable are specified in notes.

Table X.2-1: <Profile Name> - Actors and Options

| Actor | Option Name | Reference  *<either reference TF-3 or the applicable X.2.x subsection below table>* |
| --- | --- | --- |
|  |  |  |

Note: *<Conditional or required options must be described in this SHORT note, for longer notes use section X.2.1.>,*

### X.2.1 <Option Name>

<Consider including a high level description of the option.>

<e.g., The Content Consumer actor is required to support at least one of the View or Discrete Data Import options. The Document Import and Section Import options also require the View option.>

<Repeat this section (and increment numbering) as needed for additional options.>

## X.3 RPM Required Actor Groupings

*<Describe any requirements for actors in this profile to be grouped with other actors.>*

*<Note that this section effectively combines the previous “Profile Dependencies” Section (formerly Vol. 1, Section 2.1) and the previous “Groupings” section.>*

*<This section is for REQUIRED Actor Groupings (although “required” sometimes allows for a selection of one of several). To suggest other profile groupings or helpful references for other profiles to consider, use Section X.6 Cross Profile Considerations. Use X.5 for security profile recommendations.>*

An Actor from this profile (Column 1) shall implement all of the required transactions and/or content modules in this profile ***in addition to*** all of the transactions required for the grouped actor (Column 2).

If this is a content profile, and actors from this profile are grouped with actors from a workflow or transport profile, the Content Bindings reference column references any specifications for mapping data from the content module into data elements from the workflow or transport transactions.

In some cases, required groupings are defined as at least one of an enumerated set of possible actors; this is designated by merging column one into a single cell spanning multiple potential grouped actors. Notes are used to highlight this situation.

Section X.5 describes some optional groupings that may be of interest for security considerations and section X.6 describes some optional groupings in other related profiles.

<All Actors from this profile should be listed in Column 1. If no mandatory required grouping exists, “none” should be listed in Column 2. If the content module actor is bound to a transport or workflow actor it will be listed **with at least one** binding reference. Do not use “XD\*” as an actor name.>

<In some cases, required groupings are defined as at least one of an enumerated set of possible actors; to designate this create a row for each potential actor grouping and merge column one to form a single cell containing the profile actor which should be grouped with at least one of the actors in the spanned rows. In addition, a note should be included to explain the enumerated set. See example below showing Document Consumer needing to be grouped with at least one of XDS.b Document Consumer, XDR Document Recipient or XDM Portable Media Importer>

<The author should pay special consideration to IT and security profiles in this grouping section. Consideration should be given to Consistent Time (CT) Client, ATNA, as well as other profiles. For the sake of clarity and completeness, even if this table begins to become long, a line should be added for each actor for each of the required grouping for IT and security. Also see the ITI document titled ‘Cookbook: Preparing the IHE Profile Security Section’ at http://www.ihe.net/Technical\_Framework/index.cfm for a list of suggested IT and security groupings.>

<The Bindings column is used when a Content Module profile actor is grouped with a workflow or transport actor. Otherwise, mark it as “--”.>

Table X.3-1: RPM - Required Actor Groupings

| <this Profile Acronym> Actor | Actor to be grouped with | Reference | Content Bindings Reference |
| --- | --- | --- | --- |
| Sensor DataConsumer1 | Device Observation Reporter | <reference the section where the actors are defined in that profile, e.g., <Domain Acronym TF-1: x.x.x> | <Reference to CM bindings section  e.g., <Domain Acronym TF-3:Z.xxx > (e.g., PCC TF-2 :4.1) |
| Device Observation Consumer | Content Creator | <reference the section where the actors are defined in that profile, e.g., <Domain Acronym TF-1: x.x.x> | <Reference to CM bindings section  e.g., <Domain Acronym TF-3:Z.xxx > (e.g., PCC TF-2 :4.1) |
| Device Observation Source | None |  |  |
| Device Observation Reporter | None |  |  |
| Content Creator | None |  |  |
| Content Consumer | None |  |  |

1 The Sensor Data Consumer is required to be grouped with *either* the Device Observation Reporter or Content Creator actor. It *may* be grouped with both.

## X.4 RPM Overview

The RPM profile describes a set of standardized means to deliver patient health measurements and monitoring data in a remote setting to a health care provider. The delivery route can take one of several paths. However, given costs and technological constraints, it is envisioned that most use cases will follow the delivery paths as illustrated in Figure X.4-1.

In this case there are several monitored patients, each with their own set of sensor devices and a local collector of those sensor observations. Each collector then sends its clinical data to a single back end server that generates the content appropriate for one of several consumers.

PHCA Data Transaction

Transaction 1 [1] ↓

Dev Obs Src

Actor A

Content Consumer

Actor F

Sensor-Data-Cons

Actor F

Dev-Obs-Cons

Actor F

PCD-01 Communicate PCD Data

PCC-1 Document Sharing

Transaction 1 [1] ↓

Sensor-Data-Cons

Actor F

Sensor-Data-Cons

Actor F

Dev Obs Src

Actor A

Dev Obs Src

Actor A

Dev Obs Src

Actor A

Dev Obs Src

Actor A

Dev Obs Src

Actor A

Dev Obs Src

Actor A

Dev Obs Src

Actor A

PHCA Data Transaction

Transaction 1 [1] ↓

Dev-Obs-Rep

Actor F

Dev-Obs-Rep

Actor F

Dev-Obs-Rep

Actor F

Content Creator

Actor F

Content Consumer

Actor F

Content Consumer

Actor F

Dev Obs Src

Actor A

Figure X.4-1: RPM Operational Diagram

There are a couple of reasons that the RPM profile is likely to be implemented as indicated in Figure X.4-1. First is that the collector of sensor observations is typically done on low-footprint hardware, such as a mobile phone, tablet, or set-top box. Supporting the Content Creator actor is resource and power demanding making such collectors more expensive. Second is that the amount of supplementary information needed to support the headers of the PHMR content module is quite large compared to the amount of supplementary information needed to support the Device Observation Source actor. The task of maintaining and configuring this information then needs to be done for each patient on more expensive hardware if implemented on the local collector. Having a single high end back-end server handling multiple patients and the Content Creator is likely less expensive and easier to maintain.

Home sensor devices also need to be low footprint, where the bulk of their expense is the sensor itself and the hardware necessary to support transaction protocols and external configuration is minimized. Since many of the sensor devices may be borne on the patient, making the sensor as small and as unobtrusive as possible also limits hardware resources and power demands. These demands make the PCHA data transaction the most likely solution.

*<Volume 2 documents each transaction/content module in isolation. This section shows how the transactions/content modules of the profile are combined to address the use cases.>*

*<Use Cases are informative, not normative, and “SHALL” language is not allowed in use cases.>*

### X.4.1 Concepts

The RPM profile as defined in this document is the first stage in providing a standardized means of monitoring patients outside the care provider facilities. This profile currently specifies the transfer of monitoring data from the remote site to the health care facility. PCHA is currently implementing standards for two-way monitoring in the form of consent, questionnaires, IEEE 11073 20601 command and control, and automated persistent sessions. It is anticipated that these standards will either provide enhancements to this profile or be the basis for additional profiles related to the remote monitoring of patients.

### X.4.2 Use Cases

The generic use case for this profile is any situation in which the health care provider judges that the patient will benefit from being able to be medically and environmentally monitored outside of the health care facility (typically the home). Quality of life and reduction in costs are also important factors in the judgment.

#### X.4.2.1 Use Case #1: Chronic Disease Management

Chronic Disease Management allows compromised individuals managing disorders such as diabetes, hypertension, heart disease, sleep apnoea, etc. to go through their daily lives with as minimal intrusion as possible. The RPM profile allows a greater number of such people to live as normal a life as possible.

##### X.4.2.1.1 Chronic Disease Management Use Case Description

People can become physically and medically compromised for several reasons. However, in many cases these people would be able to live a fairly normal and functional life with minimal intrusion if as much of the continuous monitoring could be done on the person without visits to a professional facility. The patient can transfer monitoring measurements to the health care provider at a pre-determined frequency using the RPM. The health care provider can then decide whether additional monitoring and thus a visit to the provider are warranted.

##### X.4.2.1.2 Chronic Disease Management Process Flow

<http://ihe.net/uploadedFiles/Documents/PCC/IHE_PCC_Suppl_RCK.pdf>

A patient suffers from hypertension and is at high risk for stroke. The patient needs to take certain medications each day and ideally needs to lose some weight. The health care professional’s institution already has the infrastructure to create, read, and distribute IHE compatible Electronic Heath Records (EHRs) as C-CDAs. The health care professional provides the patient with a blood pressure cuff from BP Manufactures, Inc., a weight scale from WS Solutions, and a medication monitor from AMM GBH containing next month’s daily medication doses. All the devices are PCHA compliant. The patient also receives a PCHA compliant set top box from AHD Magic, Inc. The patient was given the choice to use either a set top box or a mobile tablet, the latter of which would display the patient’s measurements as received. The patient chose the set top box because the patient is technology challenged and did not want to turn on the device and/or activate the application to see the measurements as they were uploaded from the devices. The chosen set top box is pre-configured to communicate with a PCHA compliant server application developed by Medical Application Services, fulfilling the role of a Sensor Data Consumer. This application has been installed on a system at the health care provider’s facility. The server application has a web interface that allows the health care provider to generate an account for a given patient. The account will contain information about the given patient that the health care facility requires for its record keeping. A user name and password is required to access this account and that information has been configured into the patient’s set top box. When the server application receives data from this patient it then knows to generate a PHMR that is delivered to an XDSb respository the health care provider can access.

The patient has been instructed on how to use the devices and to plug in the set top box in the area where the devices are to be used. Each morning the patient is to take a blood pressure reading, a weight measurement, and the daily medications. When the patient performs these tasks, a PCHA compliant message is sent to the set top box which gives a beep of approval and converted to an IHE PCD-01 document. The first time this is done, the set top box requests the back end server application for a SAML token using the user name and password configured by the health care provider’s facility. If correct, the set top box receives the token from the server application and sends the PCD-01 document in a TLS-secured IHE CommunicatePCDData SOAP action authenticated with the SAML token. The server application validates the token and if valid, converts the data to a PHMR module and sends it to the XDS respository using the IHE XDSb provide and register document set transaction where the health care provider can now read it.

In this manner the health care provider can monitor the patient and make medical decisions based on it, allowing the patient to go about his/her daily tasks with minimal intrusion. Remote monitoring does not preclude the patient from directly contacting the health care provider.

Measurements sent to local collector

Sensor

Data

Consumer

*Internal: PHCA data*

*to PCD-01*

Device Observation

Source

BP

WS

MM

Device Observation Reporter

Device Observation

Consumer

Content

Creator

PCD-01 sent to remote server

*Internal: PCD-01 to PHMR*

*module*

Content

Consumer

PHMR module sent to consumer

Health care provider reads results

Patient takes measurements and meds

Figure X.4.2.2-1: Basic Process Flow in RPM Profile

Pre-conditions:

<Very briefly (typically one sentence) describe the conditions or timing when this content module would be used.>

Main Flow:

<Typically in an enumerated list, describe the clinical workflow when, where, and how this content module would be used.>

Post-conditions:

<Very briefly (typically one sentence) describe the state of the clinical scenario after this content module has been created including examples of potential next steps.>

#### X.4.2.2 Use Case #2: Post-Operative Recovery

Remote Post-Operative recovery allows a patient to recover from the effects of surgery or other traumatic procedures (such as chemotherapy) amongst family and friends in a familiar environment.

##### X.4.2.2.1 Post-Operative Recovery Use Case Description

A patient that has had surgery, or chemotherapy, or radiation treatment, or has undergone some other medically traumatic event will often need to be monitored for potential complications. In some cases (such as a broken bone) the potential for complications is so low that it is standard procedure that recovery is at home. In many other cases monitoring is needed but it is fairly simple, and any complications that might be detected from the monitoring will not be acute. Nevertheless the patient is either required to stay at the facility to receive this monitoring or is required to frequently visit the facility to be monitored, both of which are inconvenient and expensive. If the patient can be provided with the monitoring equipment, recovery can take place in the home and visits to the facility take place only when warranted.

##### X.4.2.2.2 Post-Operative Recovery Process Flow

A patient has just undergone heart surgery. The surgery appears to have gone well and the patient shows no signs of complications. The care giver provides the patient with a PCHA-compliant weight scale from ViktMasters AB, blood pressure cuff from MedMax Gmbh, pulse oximeter from POSpecialists, Inc, and medication monitor from AMM Masters AB, and installs a PCHA complaint application hosting device application from Medical Mjukvaror AB on the patient’s mobile phone. The Medical Mjukvaror AHD application is configured to transfer the data to an application obtained from Medical Servers, Inc. running on the facilities back end server. The health care staff has configured an account for the patient on this server. The care giver instructs the patient to take a weight measurement, blood pressure measurement, and pulse oximeter reading twice a day along with medication instructions; once in the morning, and once in the evening. Taking additional weight measurements during other times of the day is encouraged. The patient is instructed to first turn on the mobile device, start the installed Medical Mjukvaror AHD application, and then use the three provided devices to take the measurements. Medications are dispensed from a special pill box. The patient is given a few practice sessions with the devices, the use of the medication dispenser, and mobile phone application. Everything goes smoothly though it takes some extra effort to get used to taking blood pressure measurements. The patient sees the measurements displayed and medications taken on the mobile device and an indication that the data is dispatched to the care provider. The care provider then accesses the data from the examination room terminal and shows the patient the sent measurements.

Once home the patient follows the care giver’s instructions; turn on the mobile device, start the PCHA complaint application, and then take the three instructed measurements and the prescribed medications. All devices use the PCHA Data transaction over Bluetooth to transfer the measurements and medication indications to the mobile device.

The mobile device then uses the SOAP Observation upload transaction and sends this data as a PCD-01 document to the backend server. The backend server then converts the PCD-01 document to a PHMR module using the supplementary information entered for this patient in the patient’s account and uses XDSb Provide and Register Document Set transaction to send the document to the care provider’s repository where it can be examined with the facilities’ existing infrastructure.

## X.5 RPM Security Considerations

Personal Health Devices are typically simple applications embedded with a sensor that communicate to more complex devices through secure wireless personal networking protocols, or connected to devices through a wired USB connection under the control of the user. While they can store data (e.g., a glucose monitor), many rarely store data for other than a short period of time, and only that data that is measured by the sensor. In addition, Personal Health Devices rarely have personally identifiable information as there is currently no standardized means to transmit such information using the Communicate PCHA transactions. The devices are subject to typical security concerns, such as theft or loss. The main security concern for these devices is their communication channel with other actors. This profile mandates the use of secured network communications when the device is accessed or transmits data through wireless protocols. This mitigates the risk of data interception, interference, or alteration in transit. It is presumed that the device is under user control when it is attached via a wired connection, and so no encryption is required in this case.

Unlike sensors, data collectors may store both sensor data, as well as personally identifiable information, and will communicate it to upstream systems. Like PHDs, these devices are also subject to theft and loss. These devices are required to synchronize time using either native protocols (e.g., through the cellular network that the device is attached), or through use of the IHE Time Client Actor from the Consistent Time profile, and to encrypt any upstream network transmissions using Transport Layer Security and authenticate the user via SAML or oAuth. While audit logging is not required to enable certain kinds of devices the ability to function, they may consider using the Secure Node or Secure Application actor from the IHE ATNA profile to ensure that communications are audited, users are authenticated, and transmissions are secured between known entities.

Back office, departmental and EHR systems used by the healthcare provider to access the sensor data or translate it to a persistent, human readable format will need to be further secured. See the Security Considerations section for IHE transport protocols used by the Content Creator and Content Consumer actors (e.g., XDS and XDM) for further details related to those transports. Those transports typically mandate grouping with the Secure Node or Secure Application actors from ATNA.

## X.6 RPM Cross Profile Considerations

<other profile acronym> - <other profile name>  
A <other profile actor name> in <other profile name> might be grouped with a <this profile actor name> to <describe benefit/what is accomplished by grouping>.

Volume 2 – Transactions

Add section 3.Y

## 3.Y <Transaction Name [Domain Acronym-#]>

*<The “Y” in the heading should be the same as the # in the [Domain Acronym -#] title>*

### 3.Y.1 Scope

This transaction is used to *<…describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>*

### 3.Y.2 Actor Roles

<Optional: if desired, in addition to the table, add a diagram as shown below to illustrate the actors included in this transaction, or delete the diagram altogether.>

Actor ABC

Actor ABC

Actor DEF

Actor DEF

Figure 3.Y.2-1: Use Case Diagram

Table 3.Y.2-1: Actor Roles

|  |  |
| --- | --- |
| **Actor:** | <Official actor name; list every actor in this transaction.> |
| **Role:** | <Very brief, one phrase, description of the role that this actor plays in this transaction.> |
| **Actor:** |  |
| **Role:** |  |
| **Actor:** |  |
| **Role:** |  |

*<The assignment and use of Role Names in transaction specifications has proved to be very effective/efficient in Radiology, especially when existing transactions are re-used by additional actors. Following is an alternative example of the Role section. Delete which ever form of the role section you choose not to use.>*

The Roles in this transaction are defined in the following table and may be played by the actors shown here:

Table 3.Y.2-1 Actor Roles

|  |  |
| --- | --- |
| **Role:** | *<Role Name:><Only unique within this transaction. Typically one word. The Role Name is analogous to SCU or SCP in DICOM Services.>* |
| **Actor(s):** | The following actors may play the role of *<Role Name>*:         *<Actor Name>: <optionally, the situation where the Actor would play this Role if needed for clarity.>*” |
| **Role:** | *<e.g., Requestor:*  *Submits the relevant details and requests the creation of a new workitem.>* |
| **Actor(s):** | *<e.g., The following actors may play the role of Requestor:*  *Workitem Creator: when requesting workitems*  *Workitem Performer: when performing unscheduled workitems>* |
| **Role:** | *<e.g., Manager:*  *Creates and manages a Unified Procedure Step instance for the requested*  *workitem.>* |
| **Actor(s):** | *<e.g., The following actors may play the role of Manager:*  *Workitem Manager: when receiving a new workitem for its worklist.>* |

Transaction text specifies behavior for each Role. The behavior of specific Actors may also be specified when it goes beyond that of the general Role.

### 3.Y.3 Referenced Standards

<e.g., HL7 2.3.1 Chapters 2, 3>

<e.g., DICOM 2008 PS 3.3: A.35.8 X-Ray Radiation Dose SR IOD>

### 3.Y.4 Interaction Diagram

<The interaction diagram shows the detailed standards-based message exchange that makes up the IHE transaction.>

Actor A

Actor A

Message 1

Message 1

Actor D

Actor D

Message 2

Message 2

#### 3.Y.4.1 <Message 1 Name>

<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>

<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>

##### 3.Y.4.1.1 Trigger Events

<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>

##### 3.Y.4.1.2 Message Semantics

<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>

<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”).>

<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>

##### 3.Y.4.1.3 Expected Actions

<Description of the actions expected to be taken as a result of sending or receiving this message.>

<Describe what the receiver is expected/required to do upon receiving this message. >

<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>

<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

#### 3.Y.4.2 <Message 2 Name>

<One or two sentence summary of what Message 2 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>

<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>

<Repeat this section as necessary based on the number of messages in the interaction diagram.>

##### 3.Y.4.2.1 Trigger Events

<Description of the real world events that cause the sender (Actor A) to send Message 1(e.g., an operator or an automated function determines that a new workitem is needed).>

##### 3.Y.4.2.2 Message Semantics

<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>

<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”).>

<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>

##### 3.Y.4.2.3 Expected Actions

<Description of the actions expected to be taken as a result of sending or receiving this message.>

<Describe what the receiver is expected/required to do upon receiving this message. >

<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>

<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

### 3.Y.5 Security Considerations

<Description of the transaction specific security consideration; such as use of security profiles.>

#### 3.Y.5.1 Security Audit Considerations

<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >

##### 3.Y.5.1.(z) <Actor> Specific Security Considerations

<This section should specify any specific security considerations on an Actor by Actor basis.>

Appendices

<Detailed cross transaction relationships or mapping details are described in an appendix in Volume 2x. Volume 2 appendices may be informational or normative. Immediately after the title of a Volume 2 appendix, provide a very explicit statement defining whether this new appendix is informative or normative.>

Appendix A – <Appendix A Title>

Appendix A text goes here.

* 1. <Add Title>

Appendix A.1 text goes here

Appendix B – <Appendix B Title>

Appendix B text goes here.

* 1. <Add Title>

Appendix B.1 text goes here.

Volume 2 Namespace Additions

Add the following terms to the IHE General Introduction Appendix G:

<Please explicitly identify all new OIDs, UIDs, URNs, etc., defined specifically for this profile. These will be added to the IHE TF General Introduction namespace appendix when it becomes available. These items should be collected from the sections above, and listed here as additions when this document is published for Trial Implementation. This section will be deleted prior to inclusion into the Technical Framework as Final Text, but should be present for publication of Public Comment and Trial Implementation.>

Volume 3 – Content Modules

# 5. Namespaces and Vocabularies

Add to section 5 Namespaces and Vocabularies

| codeSystem | codeSystemName | Description |
| --- | --- | --- |
| 2.16.840.1.113883.6.24 | ISO/IEEE 11073-10101 Medical Device Communication Nomenclature | See <http://www.hl7.org/oid/index.cfm?Comp_OID=2.16.840.1.113883.6.24> for more details. |

Add to section 5.1.1 IHE Format Codes

| Profile | Format Code | Media Type | Template ID |
| --- | --- | --- | --- |
| Personal Health Monitoring Report (PHMR) | **urn:ihe:pcc:phmr:2015** | Text/xml | *TBD* |







## 6.3.1 CDA Document Content Modules

Add to section 6.3.1 CDA Document Content Modules

#### 6.3.1.D Personal Healthcare Monitoring Report (PHMR) Document Content Module

##### 6.3.1.D.1 Format Code

The XDSDocumentEntry format code for this content is **urn:ihe:pcc:phmr:2015**

##### 6.3.1.D.2 Parent Template

This document is a specialization of the IHE PCC Medical Document template (OID = 1.3.6.1.4.1.19376.1.5.3.1.1.1).

##### 6.3.1.D.3 Referenced Standards

All standards which are reference in this document are listed below with their common abbreviation, full title, and link to the standard.

Table 6.3.1.D.3-1: PHMR - Referenced Standards

| Abbreviation | Title | URL |
| --- | --- | --- |
| PHMR | Personal Health Monitoring Report | *TBD* |
| CDA | HL7 Clinical Document Architecture | *TBD* |















































Appendices

Appendix J – hData Transport

This appendix should describe briefly the hData transport details by referencing the PCHA specifications.

J.1 <Add Title>

Appendix J.1 text goes here

Volume 3 Namespace Additions

Add the following terms to the IHE Namespace:

<Please explicitly identify all new OIDs, UIDs, URNs, etc., defined specifically for this profile. These will be added to the IHE TF General Introduction namespace appendix when it becomes available. These items should be collected from the sections above by the author, and listed here as additions when this document is published for Trial Implementation. This section will be deleted prior to inclusion into the Technical Framework as Final Text, but should be present for publication of Public Comment and Trial Implementation.>