

Integrating the Healthcare Enterprise



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IHE Cardiology Technical Framework Supplement

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Intravascular Imaging Option for Cath Workflow (CATH)

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Trial Implementation

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Foreword

25 This is a supplement to the IHE Cardiology Technical Framework V4.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published on May 21, 2013 for Trial Implementation and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the
30 results of testing. Following successful testing it will be incorporated into the Cardiology Technical Framework. Comments are invited and may be submitted at <http://www.ihe.net/cardiology/cardiologycomments.cfm>.

This supplement describes changes to the existing technical framework documents.

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

<i>Amend section X.X by the following:</i>
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40 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.

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

45 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 Cardiology Technical Framework can be found at: http://www.ihe.net/Technical_Framework/index.cfm.

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CONTENTS

	Introduction to this Supplement.....	4
55	Open Issues and Questions	4
	Closed Issues.....	4
	General Introduction.....	5
	Appendix A – Actor Summary Definitions	5
	Appendix B – Transaction Summary Definitions.....	5
60	Appendix D – Glossary.....	5
	Volume 1 – Profiles	6
	3.2 Cath Workflow Integration Profile Options.....	6
	3.3 Cath Scheduled Process Flow	7
	3.4 Cath Workflow Use Cases	7
65	3.4.11 Case C11: Change modality during procedure.....	7
	Appendices.....	9
	Appendix A – The Cardiac Catheterization Procedure in Perspective.....	9
	Appendix B – Challenges of Workflow Management in Cardiac Catheterization.....	9
	B.2 Organizing the Workflow: Requested Procedures and Procedure Steps	9
70	B.2.4 Clinical Protocols and Procedure Step Protocols	9
	B.3 Multi-Modality and <i>Ad Hoc</i> Scheduling.....	11
	Volume 2 – Transactions	12
	4 IHE Transactions.....	12
	4.2 Modality Images/Evidence Stored [CARD-2].....	12
75	4.2.6 Intravascular Imaging Option	12
	4.4 Retrieve Images/Evidence [CARD-4]	12
	4.4.1 Intravascular Imaging Option.....	12
	Appendices.....	14
	Volume 2 Namespace Additions	14
80	Volume 3 – Content Modules.....	15
	Volume 4 – National Extensions	16

Introduction to this Supplement

- 85 This supplement adds an option to support Intravascular Imaging to the CATH Workflow profile. This includes support for an additional Modality and a new use case, which describes the workflow to change a modality during the procedure.

Open Issues and Questions

- 90 1. What types of compression have to be supported for the IVOCT SOP classes?

Closed Issues

- 95 1. Image Displays can receive an Image in either one or both of the IVOCT SOP Classes (For Presentation or For Processing). The current assumption is that if an Image Display receives the same image in both SOP Classes, the For Presentation objects will be displayed. Is this assumption correct? Yes, the For Presentation objects will be displayed.

General Introduction

100

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

There are no new actors defined in this supplement

Appendix B – Transaction Summary Definitions

There are no new transactions defined in this supplement

105

Appendix D – Glossary

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

Glossary Term	Definition
<u>IVOCT</u>	<u>Intravascular Optical Coherence Tomography</u>

Volume 1 – Profiles

110 *Modify Table 3.2-1 as specified below*

3.2 Cath Workflow Integration Profile Options

115 Many Actors have Options defined in order to accommodate variations in use across domains or implementations. Options that may be selected for this Integration Profile are listed in the table 3.2-1 along with the Actors to which they apply. Certain of these Options are required for implementation by actors in this Profile (although they may be truly optional in other Profiles).

Table 3.2-1: Cath Workflow - Actors and Options

Actor	Option Name	Optionality	Vol & Section
ADT Patient Registration	<i>No options defined</i>	-	-
Order Placer	<i>No options defined</i>	-	-
Department System Scheduler/Order Filler	Multi-modality Procedure Update	R	CARD TF-2: 4.1
	PPS Exception Management	O	RAD TF-2: 4.7
	Availability of PPS-Referenced Instances	O	RAD TF-3: 4.49
Acquisition Modality	Patient Based Worklist Query	O	RAD TF-2: 4.5
	Broad Worklist Query	R (see note)	RAD TF-2: 4.5
	PPS Exception Management	O	RAD TF-2: 4.7
Image Manager/ Image Archive	PPS Exception Management	O	RAD TF-2: 4.7
	Intermittently Connected Modality	R	CARD TF-2: 4.3
	Cardiac Cath	R	CARD TF-2: 4.2
	Availability of PPS-Referenced Instances	O	RAD TF-3: 4.49
	<u>Intravascular Imaging</u>	<u>O</u>	<u>CARD TF-2: 4.2.6</u>
Image Display	<u>Intravascular Imaging</u>	<u>O</u>	<u>CARD TF-2: 4.4.1</u>
Performed Procedure Step Manager	<i>No options defined</i>	-	-
Evidence Creator	<i>No options defined</i>	-	-

Note: The Broad Worklist Query option is required to support Case C7, and facilitates effective workflow in the multimodality environment.

120 The Acquisition Modality and Image Manager/ Image Archive will likely support a variety of DICOM SOP Classes. It is expected that this level of optionality will be documented by a reference in the IHE Integration Statement (see Appendix C).

Add the IVOCT as shown below.

125 3.3 Cath Scheduled Process Flow

- *Storage Commitment:* The Image Manager/Archive accepts responsibility for stored images and evidence, allowing the modality to delete the data from its local storage. The Image Manager/Archive shall support mobile devices, such as intravascular ultrasound (IVUS), **Intravascular optical coherence tomography (IVOCT)** and intracardiac echocardiography (ICE), that may be intermittently connected to the network and temporarily unable to receive Storage Commitment messages.

Modify Section 3.4 as follows

3.4 Cath Workflow Use Cases

135 *Add a new Use case for Change modality during procedure as shown below.*

3.4.11 Case C11: Change modality during procedure

140 **Clinical Context: It is not uncommon in the cath lab environment that it becomes necessary to introduce a new catheter-based modality for the procedure taking place. In a diagnostic case or an interventional case, the physician may change the diagnostic catheter to an IVUS catheter that is used for intravascular ultrasound imaging to detect significant insights into pathological processes of the vasculature.**

IHE Context: This case describes the process flow for continuing a procedure in one room with several modalities. For continuity of clinical data, it is critical that this be treated as a single Requested Procedure, i.e., it uses the same Study Instance UID.

145 **The basic process is that the first modality in the room will issue a Modality Procedure Step Completed or Discontinued when it is finished being used. The second newly introduced modality needs to obtain the patient demographics and study IDs. Since IVUS or IVOCT are rarely scheduled in advance and are introduced after the catheterization starts, the modality may issue a broad Modality Worklist query (not constrained to its own AE Title) to obtain any Scheduled Procedure Step for the study to obtain the patient demographics and study IDs.**

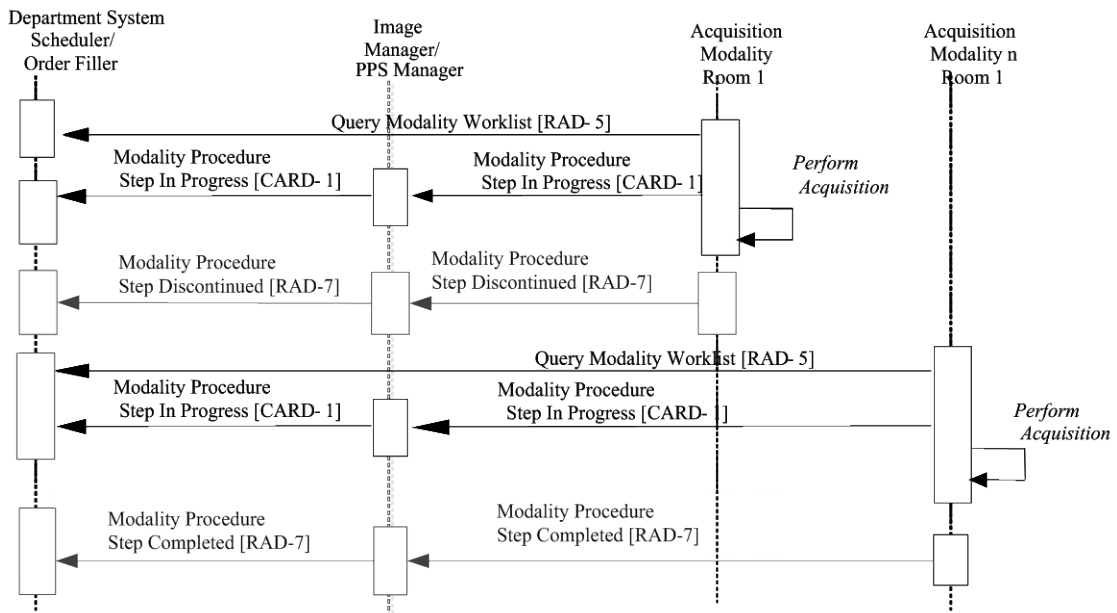
150 **Alternatively, the DSS/OF can always assign Scheduled Procedure Steps for each potential modality (including IVUS or IVOCT), which will simply be ignored if those devices are not required for the study. Then the modality can link its Modality Performed Procedure Step to that Scheduled Step.**

If the second modality is located in a different room, it may issue a Modality Worklist query for procedures scheduled for the room where the current procedure is being

160 **performed, or for any active cath procedure, and then disconnect from the network and move into the target room. The second modality can perform the procedure by selecting an appropriate received Scheduled Procedure Step.**

165 **Note that the absence of Modality Procedure Step Completed or Discontinued does not impact the ability to continue the procedure using additional equipment. The Modality Procedure Step Completed or Discontinued from any modality may be sent at any time. Each modality is required to send a Modality Procedure Step Completed or Discontinued update to complete its Modality Procedure Step in Progress. The order in which the Modality Procedure Step Completed or Discontinued updates are sent from the modalities does not matter. The updates from the modalities are independent of each other.**

Note that there is no comparable case covered in the Radiology Technical Framework.



170 **Figure 3.4-10: Change Equipment during Procedure – Case C11**

Appendices

<i>Modify Appendix A as follows</i>

Appendix A – The Cardiac Catheterization Procedure in Perspective

175 None

<i>Add the IVOCT in Appendix B as shown below.</i>
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Appendix B – Challenges of Workflow Management in Cardiac Catheterization

180 **B.2 Organizing the Workflow: Requested Procedures and Procedure Steps**

B.2.4 Clinical Protocols and Procedure Step Protocols

185 As described in B.1 above, there are protocols that represent the clinical activities of the cath procedure. Table B.2-1 provides a sample list of Protocols for Diagnostic and Interventional procedure steps.

Table B.2-1: Cath Clinical Protocols

Diagnostic
Left Heart Catheterization
Right Heart Catheterization
Coronary Angiography
Pulmonary Arteriography
Aortography
Renal Arteriography
Femoral Arteriography
Carotid Arteriography
Left Ventriculography
Right Ventriculography
Fluoroscopic evaluation of valve function
Intracardiac echocardiography
Intravascular ultrasound imaging
<u>Intravascular Optical Coherence Tomography</u>

Interventional
Intracoronary thrombolysis
Balloon angioplasty
Stent deployment
Rotational atherectomy
Brachytherapy
ASD/VSD Closure
Valvuloplasty

190 Scheduled and Performed Procedure Steps are modality-specific, and their associated protocols would similarly be modality-specific, rather than clinical procedure-related. Nevertheless, it is possible for appropriate modalities to report protocols of Performed Procedure Steps that distinguish between Diagnostic and Interventional procedure phases. The IHE Technical Framework provides flexibility for the configuration of modality protocols to meet the desired workstep status tracking for a user institution.

195 A real world example of the use of Procedure Step protocols can be demonstrated by a Requested Procedure for a cardiac catheterization. For that Requested Procedure there will be at least one procedure step scheduled for each modality, but there may be multiple procedure steps representing separate Diagnostic and Interventional clinical phases for each modality. This could result in the set of Scheduled Procedure Steps for the single Requested Procedure shown in Table B.2-2.

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Table B.2-2: Scheduled Procedure Step Example

SPS Number	Modality	SPS Protocol
1	HD	Diagnostic Heart Catheterization Hemodynamics
2	XA	Diagnostic Heart Catheterization Angiography
3	HD	Interventional Heart Catheterization Hemodynamics
4	XA	Interventional Heart Catheterization Angiography
5	IVUS	Interventional Heart Catheterization Intravascular Ultrasound
6	<u>IVOCT</u>	<u>Intravascular Optical Coherence Tomography</u>

205 Note that when the procedure is performed there are several possible combinations of Performed Procedure Steps related to the Scheduled Procedure Steps. There may be one PPS for every SPS. There may be no (zero) PPSs for some of the SPSs (e.g., the interventional phase was deemed not necessary, or an IVUS was never performed). There may be one PPS for all the SPSs assigned to a modality (e.g., the hemodynamics system does not support separation of an exam into multiple PPSs). Conversely, an Acquisition Modality could perform several PPSs for a single SPS (e.g., the XA system performs quantitative analysis on the images and reports that as a separate PPS from the image acquisition).

210

It should be noted that all of the combinations of SPS:PPS must be handled by a Department System Scheduler/Order Filler.

B.3 Multi-Modality and *Ad Hoc* Scheduling

215 The cardiac cath lab is inherently multi-modality (hemodynamics, x-ray, IVUS, **IVOCT**, etc.), and therefore more prone to data entry errors and patient safety issues. It is critical that the exact same patient is selected on all pieces of equipment. A goal of IHE is to have a single selection of a patient on a single piece of equipment, and then ensuring that patient’s information is available at all of the other pieces of equipment within the cath lab, thereby eliminating data entry errors.

220 This goal is further complicated by the frequent *ad hoc* assignment of rooms to specific patient procedures to accommodate the large proportion of emergent cases. The specific lab to be used is often not determined until the patient is wheeled into one.

225 The Department System Scheduler/ Order Filler (DSS/OF) is responsible for procedure scheduling. In the multi-modality cath lab, this means creating a Scheduled Procedure Step for each modality that may participate in the procedure. When a particular room and time can be assigned for a procedure, there is no problem with using the simple Modality Worklist information model definition of an SPS that presumes a specific assigned resource; however, this is seldom possible in the real world. And even when such scheduling can be done, it may be overridden by an emergency case.

230 To accommodate *ad hoc* scheduling, the DSS/OF may therefore typically schedule a procedure with an SPS for a “generic resource” that could be selected by the modality in any particular room.

235 To facilitate the single selection of a patient within the environment of generic resource scheduling, the Technical Framework has specified a *Multi-Modality Procedure Update* function of the DSS/OF. The DSS/OF shall be able to designate one or more modalities in each lab (typically the hemodynamics system) as a “selector”; that modality is expected to select the patient in the lab by choosing a Modality Worklist SPS, and starting a PPS. When that modality sends its first Modality Procedure Step In Progress for a particular Requested Procedure, the DSS/OF schedules SPSs for that Requested Procedure (and patient) for all modalities in that lab.

240 The other modalities in that lab can then obtain coordinated patient and Requested Procedure identifiers using the Query Modality Worklist transaction.

245 **Note:** There may be a time delay between the Modality Procedure Step In Progress from the first modality and the availability of SPSs for the other modalities in the Modality Worklist. It is expected that this delay would be measured in seconds or minutes, not hours. In the cath lab, there is typically a delay between the first modality’s MPPS and that of the other modalities, usually sufficient to accommodate the delay in the DSS/OF. However, for clinical reasons, the other modalities may need to start their data acquisition without waiting for the Study Instance UID provided in the Modality Worklist, and will therefore use a different Study Instance UID. It is highly desirable to avoid the proliferation of Study Instance UIDs in a single procedure. This version of the IHE Cardiology Technical Framework does not deal with reconciliation of multiple Study Instance UIDs.

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Volume 2 – Transactions

4 IHE Transactions

This section defines each IHE transaction in detail, specifying the standards used, the information transferred, and the conditions under which the transaction is required or optional.

255 4.2 Modality Images/Evidence Stored [CARD-2]

This transaction is identical to Modality Images Stored [RAD-8] and Evidence Documents Stored [RAD-43] (see RAD TF-2: 4.8 and RAD TF-3: 4.43), with the addition of several options.

Add the following Section to the Technical Framework.

260 4.2.6 Intravascular Imaging Option

Image Manager/ Image Archive supporting the INTRAVASCULAR IMAGING option are required to support all of the SOP classes listed in Table 4.2-10 below.

Table 4.2-10: Intravascular Imaging SOP Classes

SOP Class UID	SOP Class Name
<u>1.2.840.10008.5.1.4.1.1.14.1</u>	<u>Intravascular Optical Coherence Tomography Image Storage – For Presentation</u>
<u>1.2.840.10008.5.1.4.1.1.14.2</u>	<u>Intravascular Optical Coherence Tomography Image Storage – For Processing</u>

265

4.4 Retrieve Images/Evidence [CARD-4]

This transaction is identical to Retrieve Images [RAD-16] and Retrieve Evidence Documents [RAD-45] (see RAD TF-2: 4.16 and RAD TF-3: 4.45), with the addition of several options.

270 *Add a new section as shown below.*

4.4.1 Intravascular Imaging Option

Image Display actors supporting the INTRAVASCULAR IMAGING option are required to support the SOP classes as defined in Table 4.4-8 below.

275

Table 4.4-8: Intravascular Imaging Option

<u>SOP Class UID</u>	<u>SOP Class Name</u>	<u>Requirement</u>
<u>1.2.840.10008.5.1.4.1.1.14.1</u>	<u>Intravascular Optical Coherence Tomography Image Storage – For Presentation</u>	<u>R</u>
<u>1.2.840.10008.5.1.4.1.1.14.2</u>	<u>Intravascular Optical Coherence Tomography Image Storage – For Processing</u>	<u>O</u>

If an Image Display receives both a For Processing and a For Presentation SOP Class for the same image, the Image Display shall display the For Presentation Image SOP Class.

Appendices

280

Volume 2 Namespace Additions

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

NA

285

Volume 3 – Content Modules

There are no Content Modules defined in this supplement.

Volume 4 – National Extensions

Add appropriate Country section

NA