JAHIS

Integrating the Healthcare Enterprise

IHE Endoscopy Technical Framework Year 4: 2009-2010（Upper/Lower Gastrointestinal Tract）

Volume I Integration Profiles

Trial Implementation Version

Rev. 2.0

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Contests.

Foreword

Integrating the Healthcare Enterprise (IHE) is an initiative designed to stimulate the integration of the information systems that support modern healthcare institutions. Its fundamental objective is to ensure that in the care of patients all required information for medical decisions is both correct and available to healthcare professionals. The IHE initiative is both a process and a forum for encouraging integration efforts. It defines a technical framework for the implementation of established messaging standards to achieve specific clinical goals. It includes a rigorous testing process for the implementation of this framework. And it organizes educational sessions and exhibits at major meetings of medical professionals to demonstrate the benefits of this framework and encourage its adoption by industry and users.

The approach employed in the IHE initiative is not to define new integration standards, but rather to support the use of existing standards, HL7, DICOM, IETF, and others, as appropriate in their respective domains in an integrated manner, defining configuration choices when necessary. When clarifications or extensions to existing standards are necessary, IHE refers recommendations to the relevant standards bodies.

This initiative has numerous sponsors and supporting organizations in different medical specialty domains and geographical regions. In North America the primary sponsors are the American College of Cardiology (ACC), the Healthcare Information and Management Systems Society (HIMSS) and the Radiological Society of North America (RSNA). IHE Canada has also been formed. IHE Europe (IHE-EUR) is supported by a large coalition of organizations including the European Society of Cardiology (ESC), European Association of Radiology (EAR) and European Congress of Radiologists (ECR), the Coordination Committee of the Radiological and Electromedical Industries (COCIR), Deutsche Röntgengesellschaft (DRG), the EuroPACS Association, Groupement pour la Modernisation du Système d'Information Hospitalier (GMSIH), Société Française de Radiologie (SFR), and Società Italiana di Radiologia Medica (SIRM).

IHE in Japan (IHE-J hereafter) is promoted by the IHE-J (Chairman: Yutaka Ando), with the sponsorship of the Ministry of Economy, Trade and Industry (METI); the Ministry of Health, Labor, and Welfare; and MEDIS-CD; cooperation organizations include the Japan Industories Association of Radiology Systems (JIRA), and the Japan Association of Healthcare Information Systems Industory (JAHIS), Radiolofy Society (JRS), Japan Society of Radiology Technilogy (JSRT), and the Japan Association of Medical Informatics (JAMI). IHE in gastrointestinal endoscopic domain is promoted by the Endoscopy committee.

The IHE Technical Frameworks for the various domains (IT Infrastructure, Cardiology, Laboratory, Radiology, etc.) define specific implementations of established standards to achieve integration goals that promote appropriate sharing of medical information to support optimal patient care. They are expanded annually, after a period of public review, and maintained regularly through the identification and correction of errors. The current version for these Technical Frameworks may be found at www.acc.org, www.rsna.org/IHE, or http://www.himss.org/IHE.

The IHE Technical Frameworks identify a subset of the functional components of the healthcare enterprise, called IHE Actors, and specify their interactions in terms of a set of coordinated, standards-based transactions. They describe this body of transactions in progressively greater depth. This volume I provides a high-level view of IHE functionality, showing the transactions organized into functional units called Integration Profiles that highlight their capacity to address

specific clinical needs. The subsequent volumes provide detailed technical descriptions of each IHE transaction.

This IHE Gastrointestinal Endoscopy Technical Framework Year 4 is submitted for Public Comments through May 2010, per the schedule announced in December 2009.

The IHE-J Endoscopy Technical Committee (IHE ENDO TC) will address these comments and expects to publish a revised version in June 2010.

1 Introduction

1.1 Overview of Technical Framework

This document, the IHE Endoscopy Technical Framework (IHE ENDO-TF), defines specific implementations of established standards to achieve integration goals for endoscopy. Such integration promotes appropriate sharing of medical information to support optimal patient care.

The ENDO-TF is expanded annually, after a period of public review, and maintained regularly through the identification and correction of errors. The current version, rev. 2.0, specifies the IHE transactions defined and implemented as of December 2009. The latest version of the document is available via IHE-J

The ENDO-TF identifies a subset of the functional components of the healthcare enterprise, called IHE actors, and specifies their interactions in terms of a set of coordinated, standards-based transactions. It describes this body of transactions in progressively greater depth. The present Volume I provides a high-level view of IHE functionality, showing the transactions organized into functional units called Integration Profiles that highlight their capacity to address specific clinical needs. Volume II provides detailed technical descriptions of each endoscopy-specific IHE transaction.

The ENDO-TF is part of a related set of IHE Technical Frameworks, comprised of the following domain-specific documents:

- IHE Endoscopy Technical Framework
- IHE Cardiology Technical Framework
- IHE IT Infrastructure Technical Framework
- IHE Radiology Technical Framework
- IHE Laboratory Technical Framework

The IHE Endoscopy Integration Profiles rely heavily on, and reference, the transactions defined in those other IHE Technical Framework documents. For the conventions on referencing other frameworks, see Section 1.6.4 within this volume.

1.2 Overview of Volume I

The remainder of section 1 further describes the general nature, purpose and function of the Technical Framework. Section 2 introduces the concept of IHE Integration Profiles that make up the Technical Framework.

Section 3 to 4 and the subsequent sections of this volume provide detailed documentation on each Integration Profile, including the clinical problem it is intended to address and the IHE Actors and Transactions it comprises.

The appendices following the main body of the document provide concept of relationship and scope of each integration profile, explanation of original integration profile ‘ENDO’ so that the readers may easier to understand the entire picture composed of current profiles.

1.3 Audience

The intended audience of this document is:

- Clinicians interested in the technical aspects of integrating healthcare information systems
- Technical staff of vendors participating in the IHE initiative
- IT departments of healthcare institutions
- Experts involved in standards development

1.4 Relationship to Standards

The IHE Technical Framework identifies functional components of a distributed healthcare environment (referred to as IHE Actors), solely from the point of view of their interactions in the healthcare enterprise. At its current level of development, it defines a coordinated set of transactions based on the HL7, DICOM, and various Web standards. As the scope of the IHE initiative expands, transactions based on other standards will be included as required.

In some cases, IHE recommends selection of specific options supported by these standards; however, IHE does not introduce technical choices that contradict conformance to these standards. If errors in or extensions to existing standards are identified, IHE's policy is to report them to the appropriate standards bodies for resolution within their conformance and standards evolution strategy.

IHE is therefore an implementation framework, not a standard. Referencing IHE as a standard is inappropriate. Conformance claims by product must still be made in direct reference to specific standards. In addition, vendors who have implemented IHE integration capabilities shall use an IHE Integration Statement to describe the conformance of their product to the specifications in the IHE Technical Framework. The purpose of an IHE Integration Statement is to communicate in a uniform manner to the users of the corresponding product the IHE capabilities it has been designed to support. Vendors publishing IHE Integration Statements accept full responsibility for their content. By comparing the IHE Integration Statements from different implementations, a user familiar with the IHE concepts of Actors and Integration Profiles should be able to determine whether and to what extent communications might be supported between products. See Appendix B.8 for the format of such IHE Integration Statements. IHE encourages implementers to ensure that products implemented in accordance with the IHE Technical Framework also meet the full requirements of the standards underlying IHE, allowing the products to interact, although possibly at a lower level of integration, with products that have been implemented in conformance with those standards, but not in full accordance with the IHE Technical Framework.

1.5 Relationship to Real-world Architectures

The IHE Actors and transactions described in the IHE Technical Framework are abstractions of the real-world healthcare information system environment. While some of the transactions are traditionally performed by specific product categories (e.g. HIS, Electronic Patient Record, RIS, PACS, Clinical Information Systems or imaging modalities), the IHE Technical Framework

intentionally avoids associating functions or actors with such product categories. For each actor, the IHE Technical Framework defines only those functions associated with integrating information systems. The IHE definition of an actor should therefore not be taken as the complete definition of any product that might implement it, nor should the framework itself be taken to comprehensively describe the architecture of a healthcare information system.

The reason for defining actors and transactions is to provide a basis for defining the interactions among functional components of the healthcare information system environment. In situations where a single physical product implements multiple functions, only the interfaces between the product and external functions in the environment are considered to be significant by the IHE initiative. Therefore, the IHE initiative takes no position as to the relative merits of an integrated environment based on a single, all-encompassing information system versus one based on multiple systems that together achieve the same end. To illustrate most dramatically the possibilities of the IHE Technical Framework, however, the IHE demonstrations emphasize the integration of multiple vendors' systems based on the IHE Technical Framework.

1.6 Conventions

This document has adopted the following conventions for representing the framework concepts and specifying how the standards upon which the IHE Technical Framework is based should be applied.

1.6.1 Actor and Transaction Diagrams and Tables

Each integration profile is a representation of a real-world capability that is supported by a set of actors that interact through transactions. Actors are information systems or components of information systems that produce, manage, or act on categories of information required by operational activities in the enterprise. Transactions are interactions between actors that transfer the required information through standards-based messages.

The tables of Actors and Transactions given in sections 3 and 4 indicate which Transactions each Actor in a given profile must support.

In some cases, a profile is dependent on a pre-requisite profile in order to function properly and be useful. For example, Cath Workflow depends on the Consistent Time Profile (from the IHE IT Infrastructure framework) being implemented as a pre-requisite. These dependencies can be found by locating the desired profile in Table 2.1-1 and seeing which profiles are listed as required pre-requisites. An Actor must implement all required transactions in the pre-requisite profiles in addition to those in the desired profile.

1.6.2 Process Flow Diagrams

The descriptions of Integration Profiles that follow include Process Flow Diagrams that illustrate how the profile functions as a sequence of transactions between relevant actors.

These diagrams are intended to provide a "big picture" so the transactions can be seen in the context of the overall workflow. Certain transactions and activities not defined in detail by IHE are shown in these diagrams in *italics* to provide additional context on where the relevant IHE transactions fit into the broader scheme of healthcare information systems.

These diagrams are not intended to present the only possible scenario. Often other actor groupings are possible, and complementary transactions from other profiles may be interspersed.

In some cases the sequence of transactions may be flexible. Where this is the case there will generally be a note pointing out the possibility of variations.

The convention used in these diagrams is that the arrow on the line for the transaction points from the initiator of the transaction to the destination. It does not mention push/pull attribute of the message.

1.6.3 Normative versus informative contents of the Technical Framework

Most parts of the Technical Framework describe required or optional characteristics of Integration Profiles, Actors and Transactions: these are normative. For a better understanding of the text, there also exist illustrating parts in the Technical Framework that are informative and non-normative.

According to IETF RFC 2119, certain words indicate whether a specific content of the Technical Framework is normative: either required (e.g. “must”, “required”, “shall”) or optional (e.g. “may”, “recommended”). Informative content does not contain these key words.

1.6.4 Technical Framework Referencing

When references are made to a section within the same Technical Framework volume, a section number is used by itself. When references are made to other volumes or to a Technical Framework in another domain, the following format is used:

<domain designator> TF-<volume number>: <section number>, where

<domain designator> is a short designator for the IHE domain (ITI = IT Infrastructure, RAD = Radiology, CARD = Cardiology, LAB = Laboratory, ENDO = Endoscopy)

<volume number> is the applicable volume within the given Technical Framework (e.g., 1, 2, 3), and

<section number> is the applicable section number.

For example: ITI TF-1: 3.1 refers to section 3.1 in volume 1 of the IHE IT Infrastructure Technical Framework, RAD TF-3: 4.33 refers to section 4.33 in volume 3 of the IHE Radiology Technical Framework.

1.6.5 Transaction Referencing

When references are made to a Transaction, the following format is used:

<domain designator>-<transaction number>, where

<domain designator> is a short designator for the IHE domain (ITI = IT Infrastructure, RAD = Radiology, CARD = Cardiology, LAB = Laboratory, ENDO = Endoscopy)

<transaction number> is the applicable transaction number as specified in the Technical Framework for that domain.

Transactions may also be referenced by name, but only after that transaction name has been identified with its domain and transaction number within that section of the document.

1.7 IHE Endoscopy Current Year Scope

This document refers to Year 4 of the IHE Endoscopy initiative. The current IHE ENDO TF addresses the following primary feature:

- The ENDO Workflow Integration Profile describes the mechanisms used to manage and distribute the workflow in the endo lab that for studying the upper and lower gastrointestinal tract.

1.8 Comments

JAHIS welcomes comments on this document and the IHE initiative. They should be directed to the person in charge at the investigating organization, IHE-J, as follows:

IHE-J
http://www.ihe-j.org/index.html
Secretariat Organization: JAHIS
Secretary E-mail : Sec.IHE.Endo.a@gmail.com

1.9 Copyright Permission

Health Level Seven, Inc., has granted permission to the IHE to reproduce tables from the HL7 standard. The HL7 tables in this document are copyrighted by Health Level Seven, Inc. All rights reserved.

The National Electrical Manufacturers Association (NEMA) has granted permission to the IHE to incorporate portions of the DICOM standard.

Material drawn from these documents is credited where used.

1.10 IHE Technical Framework Development and Maintenance Process

The Technical Framework is continuously extended and maintained by the Endoscopy Committee, in cooperation with the other domain-specific Technical Committees. The Development and Maintenance Process of the Framework follows a number of principles to ensure stability of the specification both vendors and users may rely upon in specifying, developing and acquiring IHE compatible products.

The process is intended to address the need for extensions, clarifications and corrections while maintaining backward compatibility of framework definitions as to support implementations claiming conformance to any previously defined Integration Profile and its Actors.

To maintain stability of the IHE Technical Framework, modifications occur in a regular annual cycle (Figure 1.10-1) according to one of two controlled paths: new development, and maintenance.

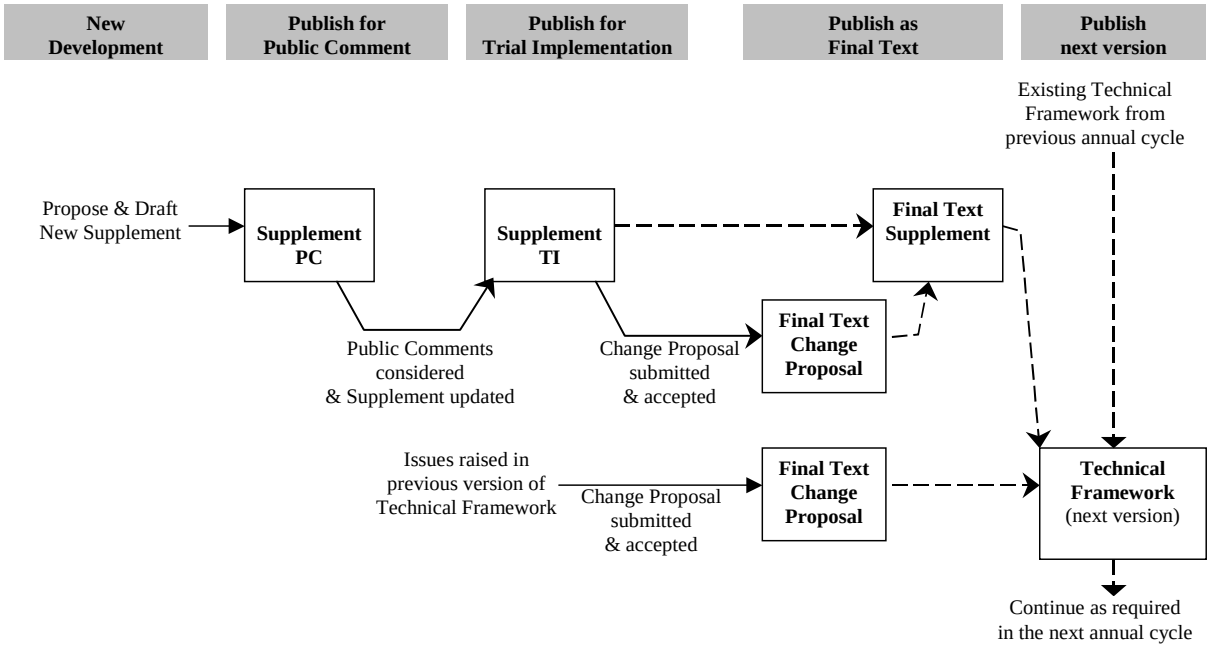

Figure 1.10-1. The figure shows the process of developing and maintaining the Technical Framework during an annual cycle. Dashed arrows indicate the assembly (merging) of text.

1.10.1 New Development – Extending the Existing Technical Framework

Each year, new functionality to be developed is identified by the IHE Endoscopy Planning Committee. The Technical Committee performs the necessary analysis and design work and generates new text for the Technical Framework.

Generally, new functionality is published in the form of a Supplement. The scope of a Supplement is to make one of the following additions to the Technical Framework:

- A new Integration Profile, usually including the introduction of new Actors and Transactions.
- New Actors in an existing Integration Profile: These may be either Actors previously defined elsewhere in the Technical Framework, or new ones not yet defined. Transactions identifying the new actors responsibilities in this profile are identified or defined and may be designated as required or optional. To avoid causing compatibility problems for systems that have already implemented that profile, no new required Transactions are added for existing Actors in the profile.
- New Options in an existing Integration Profile: These usually add optional Transactions for existing actors in the profiles, or add optional features within existing Transactions.
- Major conceptual changes: They do not change the behavior of existing Integration Profiles but may imply changes or additions to Actors or Transactions in the future.

The publication process consists of certain phases and is clearly indicated on each document.

First, the text is published for **Public Comment** (with a "PC" designation). During the Public Comment period (typically 30 days), the text and a comment submission facility are available on the IHE Website. Following this period, the Technical Committee will review the comments.

Updated text of Supplements is then published for **Trial Implementation** (with a "TI" designation), based on the modifications resulting from the comments received.

IHE provides a process for vendors to test their implementation of the Trial Implementation specifications of IHE Actors and Integration Profiles. The IHE testing process, culminating in a multi-party interactive testing event called the Connect-a-thon, provides vendors with valuable feedback and provides a baseline indication of the conformance of their implementations. It also serves as a validation of the technical approach of the Trial Implementation specifications.

After trial implementations have been judged to have sufficiently exercised the new functionality (e.g., due to experience from the Connect-a-thon), and the text is considered sufficiently stable, the new text will be published as **Final Text** (with a "FT" designation).

Final Text Supplements will be merged at the end of the annual development cycle with the current version of the Technical Framework resulting in a new version of the Technical Framework with an increased version number.

1.10.2 Maintenance of existing Technical Framework content

Despite the best efforts of the Technical Committee, a published current version of the Technical Framework or Trial Implementation documents may contain text that is incorrect, incomplete or unclear. Such issues are handled as Change Proposals and cover:

- Corrections: technical issues causing non-interoperability of implementations are fixed without introducing changes in functionality of a stable Integration Profile.
- Clarifications: text that can be misunderstood or is ambiguous is made easier to understand or disambiguated, without introducing any technical changes.

The publication process is the same for both Corrections and Clarifications, and addresses both changes to Trial Implementations and changes to a current version of the Technical Framework.

Submitted Change Proposal results from issues raised by users, vendors or Technical Committee members, e.g. from experiences with Trial Implementation or Final Text Integration Profiles or at a Connect-a-thon. The resulting Change Proposal document should explicitly state:

- the parts of the Technical Framework requested to be changed,
- a problem description,
- a rationale why the change is considered necessary, and
- a solution or approach to the problem.

The Technical Committee regularly considers Change Proposals which are then either accepted or rejected.

A **Rejected Change Proposal** is published with a rationale from the Technical Committee explaining why the change is not appropriate.

An **Accepted Change Proposal** is assigned to a member of the Technical Committee as a work item for further investigation with the goal to produce adequate clarifications or corrections. The resulting text will again be reviewed by the Technical Committee before being approved.

Once approved, a **Final Text Change Proposal** is published by the Technical Committee, and then is to be considered as effective. It will be merged into the next version of the Technical Framework

at the end of the annual development cycle. Submitting a Change Proposal to a Final Text Change Proposal or a Final Text Supplement is not possible.

1.10.3 Use of Technical Framework

The current version of the Technical Framework is considered the primary reference document. Final Text Supplements and Final Text Change Proposals from the current annual cycle complement this document. Past Final Text documents are retained to provide convenient summaries of differences to prior versions of the Technical Framework or Trial Implementation versions of Supplements.

During the annual development and maintenance cycle, it is recommended to use Technical Framework documents for implementations as follows:

- Product Implementations
  Products implemented based on Trial Implementation text are expected to review the subsequent Final Text and update their products as necessary. Further, it is expected that vendors will monitor Final Text Change Proposals and make any corrections relevant to their product in a timely fashion.
- Connect-a-thon Implementations
  Testing at the Connect-a-thon will be based on the current version of the Technical Framework for the appropriate IHE Domain, plus any relevant Supplements for Trial Implementation and Final Text Change Proposals.

2 Integration Profiles

IHE ENDO Integration Profiles, depicted in Figure 2-1, offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. Integration Profiles describe real-world scenarios or specific sets of capabilities of integrated systems. An Integration Profile applies to a specified set of actors and for each actor specifies the transactions necessary to support those capabilities.

Integration Profiles provide a convenient way for both users and vendors to reference a subset of the functionality detailed in the IHE Technical Framework. They enable users and vendors to be more specific than simply requesting or promising overall IHE support, without laborious restatement of the details regarding IHE actors and transactions defined by the IHE Technical Framework.

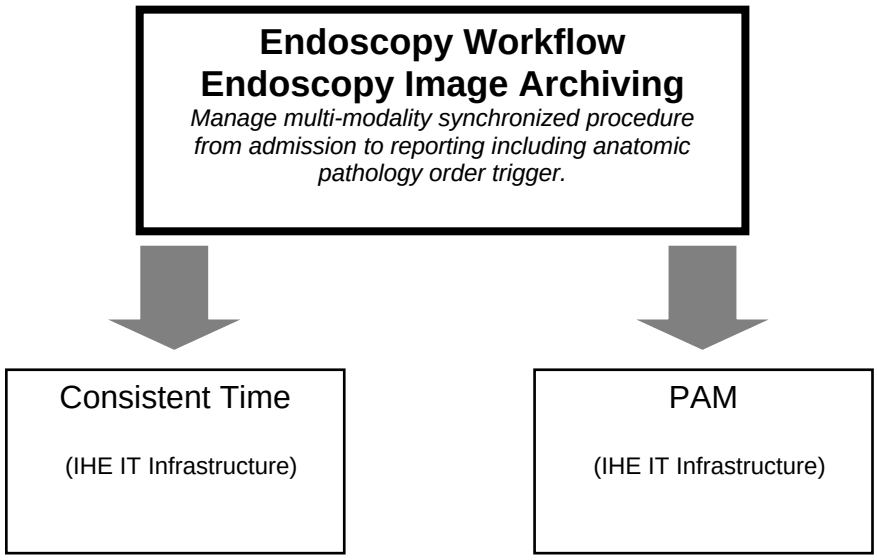

Figure 2-1. IHE ENDO Integration Profiles and Dependencies

2.1 Dependencies between Integration Profiles

In general, IHE Integration Profiles do not operate independently. Objects that serve as useful input to one profile may have been produced as a result of implementing another profile.

Figure 2-1 provides a graphical view of the dependencies between Integration Profiles. The arrows in the diagram point from the dependent profile to the profile(s) on which it relies.

Note especially that the supporting profiles come from other IHE domains.

Table 2-1-1 defines the required dependencies between the Integration Profiles in a tabular form.

There are of course other useful synergies that occur when different combinations of profiles are implemented, but those are not described in the table below. For instance, actors of the various endoscopy profiles may implement profiles of the IT Infrastructure domain for user or node authentication, audit trails, patient identifier cross-referencing, etc.

Table 2.1-1. ENDO Integration Profiles Dependencies

Integration Profile	Depends on	Dependency Type	Comments
Endoscopy Workflow Endoscopy Image Archiving	ITI-TF Consistent Time	The DSS/Order Filler and Acquisition Modality actors are required to be grouped with Time Client actors	
	ITI-TF PAM	Each actors of EWF are required to be grouped with one of them.. Patient Demographics Supplier, Patient Demographics Consumer, Patient Encounter Supplier, Patient Encounter Consumer	

Vendor products support an Integration Profile by implementing the appropriate actor-transactions as outlined in the Integration Profile in sections 3 and 4. A product may implement more than one actor and more than one Integration Profile.

An actor must implement all required transactions in the pre-requisite profiles in addition to those in the desired profile.

Actors (see section 2.2) are information systems or components of information systems that produce, manage, or act on information associated with operational activities in the enterprise.

Transactions (see section 2.3) are interactions between actors that transfer the required information through standards-based messages.

2.2 Integration Profiles Overview

In this document, each IHE Integration Profile is defined by:

- The IHE Actors involved
- The specific set of IHE Transactions required for each IHE Actor.

These requirements are presented in the form of a table of transactions required for each actor supporting the Integration Profile. Actors supporting multiple Integration Profiles are required to support all the required transactions of each Integration Profile supported. When an Integration Profile depends upon another Integration Profile, all transactions required for the dependent Integration Profile have been included in the table.

Note that IHE Integration Profiles are not statements of conformance to standards, and IHE is not a certifying body. Users should continue to request that vendors provide statements of their

conformance to relevant standards, such as DICOM and HL7. Standards conformance is a prerequisite for vendors adopting IHE Integration Profiles.

Also note that there are critical needs for any successful integration project that IHE cannot address. Successfully integrating systems still requires a project plan that minimizes disruptions and describes fail-safe strategies, specific and mutually understood performance expectations, well-defined user interface requirements, clearly identified systems limitations, detailed cost objectives, plans for maintenance and support, etc.

2.2.1 Endoscopy Workflow (EWF)

The Endoscopy Workflow outlines a series of workflows incorporating endoscopy procedure steps wherein an endoscopy is first ordered from the hospital information system located outside of the endoscopy department, the endoscopy conducted, a report prepared detailing the results and finally an order filed to the outside department for a pathological report.

2.2.2 Endoscopy Image Archiving (EIA)

The Endoscopy Image Archiving defines a workflow for the acquisition and archiving of images during an endoscopy. (In this document, we are just drawing attention to its requirement with detail to be added in accordance with future plans.)

3 Endoscopy Workflow (EWF)

The Endoscopy Workflow specifies a series of workflows where endoscopy is conducted on the order from the hospital information system located outside of the endoscopy department and the result returned to the system.

The EOF(Endoscopy Order Filler) receives an order from the Order Placer to administer an endoscopy and the endoscopy report creator prepares an endoscopy report. When the endoscopy procedure is over, the EOF notifies the hospital information system located outside of the endoscopy department of the endoscopy status and places an order for the triggering of a pathological biopsy.

We have defined an independent actor to generate endoscopy execution information, because execution information can be input either as a part of a report or a part of an OF.

We also considered returning status of both “Execution data input was done” and “Endoscopy report input was done” to OP independently by “Endoscopy Execution Information Notification” and “Observation Report Notification” transactions.

3.1 Actors/Transactions

The Actors and the Transactions of the EWF are presented in figure 3-1-1.

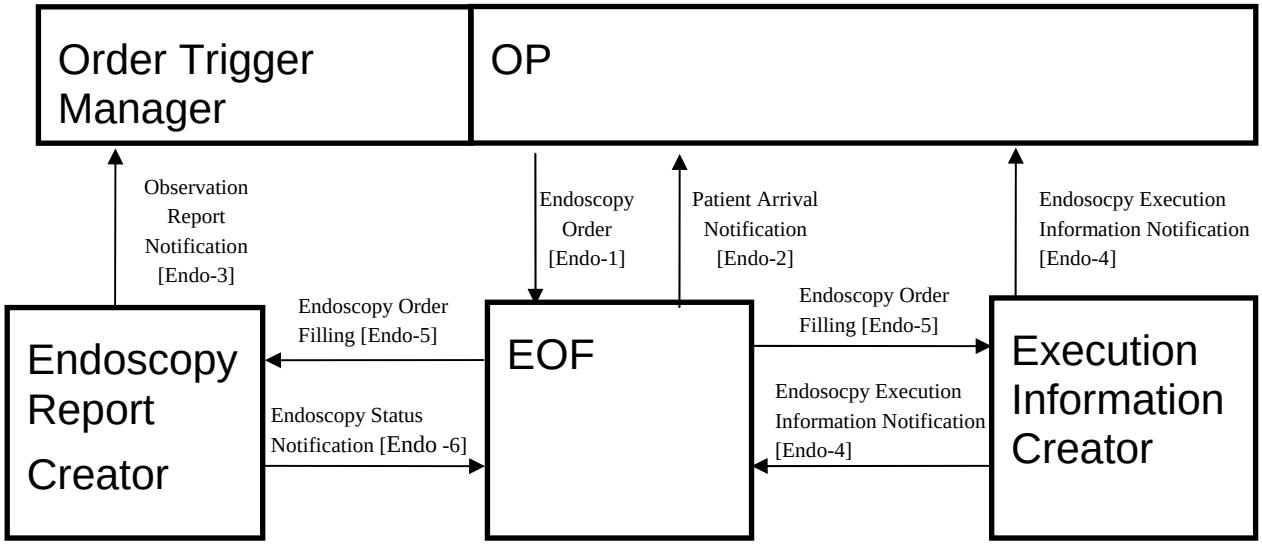

Figure 3.1-1 Endoscopy Workflow Diagram

The Optionalities of Actors and Transactions are presented in table 3-1-1.

Table 3.1-1 Endoscopy Workflow – Actors and Transactions

Actors	Transactions	Optonality	Section
Order Placer (OP)	Endoscopy Order [Endo-1]	R	ENDO-TF 2.4.1
	Patient Arrival Notification [Endo-2]	R	ENDO-TF 2.4.2
	Endosocpy Execution Information Notification [Endo -4]	R	ENDO-TF 2.4.4
Endoscopy Order Filler (EOF)	Endoscopy Order [Endo-1]	R	ENDO-TF 2.4.1
	Patient Arrival Notification [Endo-2]	R	ENDO-TF 2.4.2
	Endosocpy Execution Information Notification [Endo -4]	C	ENDO-TF 2.4.4
	Endoscopy Order Filling [Endo-5]	C	ENDO-TF 2.4.5
	Endoscopy Status Notification [Endo-6]	C	ENDO-TF 2.4.6
Order Trigger Manager	Observation Report Notification [Endo-3]	R	ENDO-TF 2.4.3
Endoscopy Report Creator	Observation Report Notification [Endo -3]	R	ENDO-TF 2.4.3
	Endoscopy Order Filling [Endo-5]	C	ENDO-TF 2.4.5
	Endoscopy Status Notification [Endo-6]	C	ENDO-TF 2.4.6
Execution Information Creator	Endosocpy Execution Information Notification [Endo -4]	R (to OP) C (to EOF)	ENDO-TF 2.4.4
	Endoscopy Order Filling [Endo-5]	C	ENDO-TF 2.4.5

In the table above, the transactions labeled “R” are required. The transactions labeled “C” are conditionally required with the condition of second stage implementation as described in Appendix A.

3.2 Endoscopy Workflow Integration Profile Options

The Actors and Options of the Profile are shown in the table 3.2.1.

Table 3.2.1 Endoscopy Workflow – Actors and Options

Actor	Option Name	Optionality	Vol & Section
Order Placer (OP)	*No options defined*	-	-
Endoscopy Order Filler (EOF)	*No options defined*	-	-
Order Trigger Manager	*No options defined*	-	-
Endoscopy Report Creator	*No options defined*	-	-
Execution Information Creator	*No options defined*	-	-

3.3 Endoscopy Workflow Process Flow

The Process Flow from an endoscopy order and execution to the performed information notification is presented below. The OP places an order to prepare the endoscopy. The EOF notifies the OP of patient arrival after which changes of order by the OP are prohibited. Upon the completion of the observation report, the Endoscopy Report Creator notifies the Order Trigger Manager of the necessary information for a pathology order of a specimen. Upon the completion of Execution Data Entry, the Execution Information Creator notifies the OP of the performed information. Then the EOF identifies the Exam End when it receives the task completion notification from the Endoscopy Report Creator and Execution Information Creator.

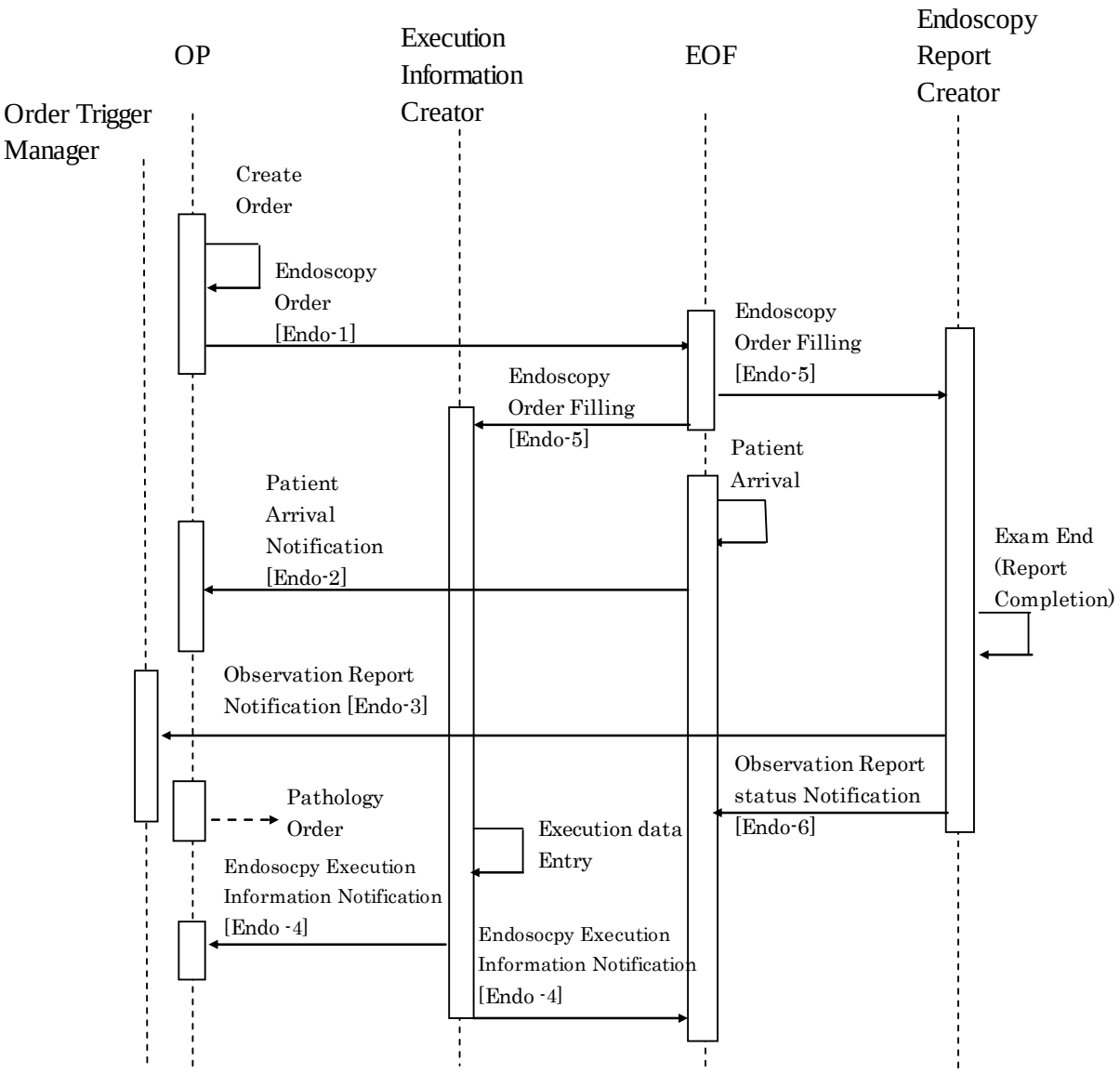

Figure 3.3-1 EWF Process Flow

(The case that the endoscopy observation report is completed before execution data is entered.)

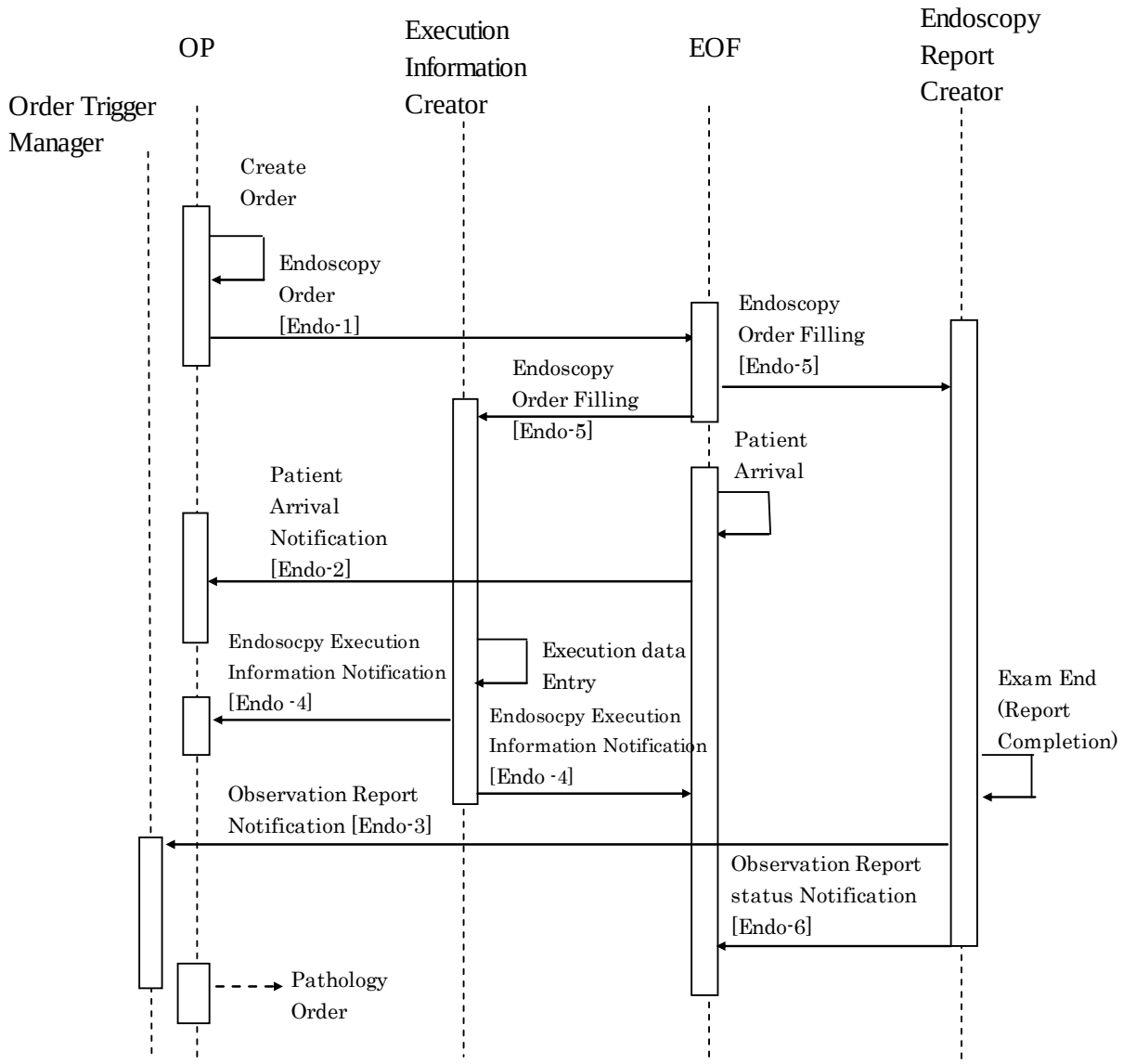

Figure 3.3-2 EWF Process Flow

(The case that execution data is entered before the endoscopy observation report is completed.)

4 Endoscopy Image Archiving (EIA)

The Endoscopy Image Archiving defines a workflow for storing images if some images are taken during an endoscopy. In this version, we are merely naming the subsection so that it can be mapped out in accordance with future agendas.

Appendix A The relationship between the Implementation Roadmap and the Integration Profile of Endoscopy IHE.

The Integration Profile based on the originally-defined Endoscopy Workflow is presented in Appendix B. Ultimately, the goal of the current Integration Profile is the same as that of the original profile.

However, since there are cases where the implementation progresses in steps the Profile needed to reflect these progressive aspects as well as implementation of the system as a whole. The order of priority was difficult to determine when the Integration Profile was defined as one large profile covering entire workflow and when each of the component transactions were regarded as being required.

Therefore, we have decided to present a Roadmap of implementation, in which the Integration Profile was divided. The Implementation Roadmap is a three-stage process as shown below.

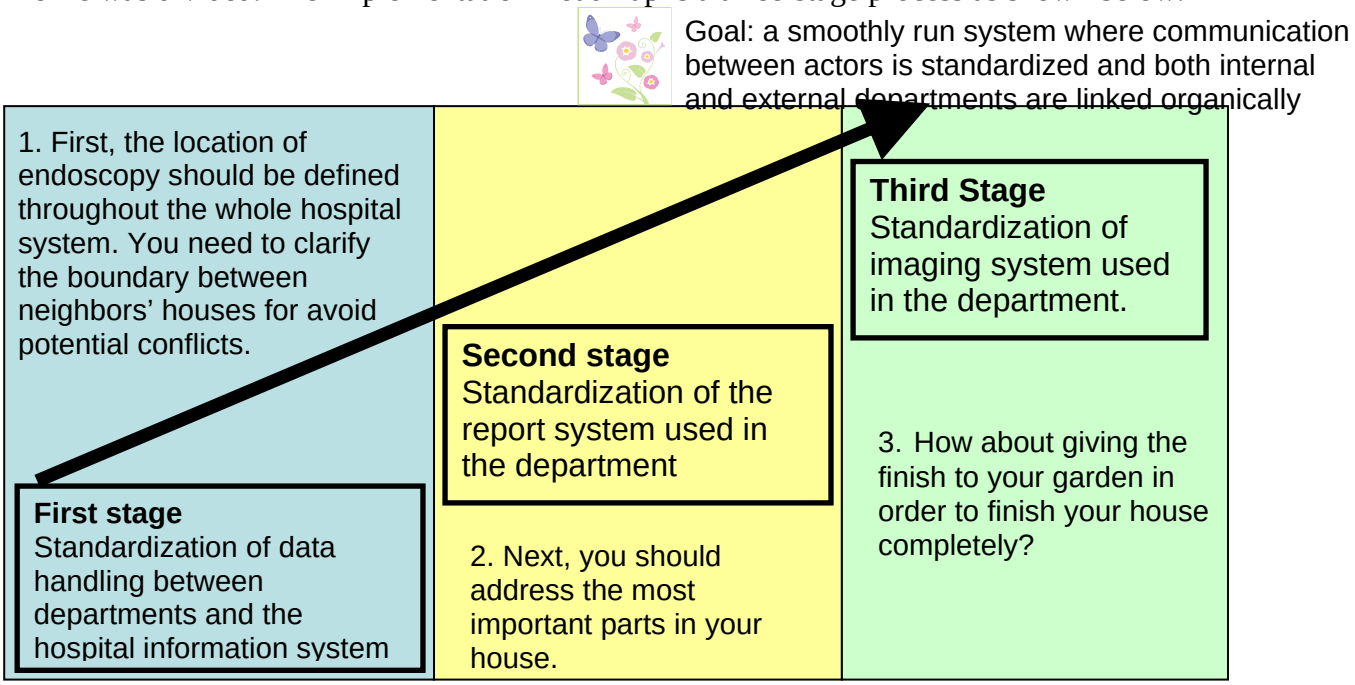

Figure A-1 Implementation Roadmap

In the first stage, the workflow focusing on data handling between department system and the hospital information system was defined. In order for a smooth and manageable introduction of the IT system throughout the whole hospital, priority should be given to general data handling, such as how orders are treated and how information from departments is received, rather than focusing on department specific requirement. The required transactions defined in the Endoscopy Workflow (EWF) are the Integral Profiles which correspond to this stage.

In the second stage, the workflow focusing on the data handling of procedure reports within departments was defined. An endoscopy is completed when the report is filled in. Considering the

total flow comprising the whole endoscopy procedure, the report workflow is, after the workflow between departments and the hospital information system, most important. Endoscopy Workflow (EWF) also represents this stage where those transactions are defined as conditional.

The endoscopy procedure includes steps where an order is received, the procedure carried out and an observation report generated. These steps are considered as a workflow since once a reporting procedure has been completed, the workflow is considered as completed. However, the reporting part is defined as conditional because the report is considered as the second stage in the above Implementation Roadmap.

Finally, the third stage defines a workflow focusing on the image information communication which is acquired during the endoscopic procedure. The Endoscopy Image Archiving（EIA）is made up of the Integration Profiles which is correspond to this stage.

Appendix B Original Integration Profile for Endoscopy 'ENDO'

The Integration profile for Endoscopy "Endo" in this Appendix has been described in the White Paper which was generated after receiving public comments in 2006.

Subsequently, we have decided to divide the large profile described here into multiple profiles and adjust transactions to reflect the needs of implementers who may chose the implementation steps specified in Appendix A. The original profile is still available here as Appendix B, because it describes the endoscopy-specific requirements and the differences from the other domains.

B.1 Upper Gastrointestinal Endocopy Workflow (ENDO workflow)

Upper and Lower Endoscopy is complex, especially from a workflow perspective. Evidence-gathering activities may begin before an order is placed; in fact, orders are often not created for an endoscopic procedure in case of emergency. There may be a variety of imaging, measurement, and reporting systems that need to coordinate to use the same patient identifier, and to assure that the evidence produced is all associated with the same procedure. Further, the procedure itself may include both diagnostic and interventional or therapeutic aspects, and may extend over a long time period.

The ENDO Workflow Integration Profile establishes the continuity and integrity of basic patient data in the context of the endoscopic procedure. This profile deals specifically with consistent handling of patient identifiers and demographic data, including that of emergency patient presentation where the actual patient identity may not be established until after the beginning of the procedure, or even a significant time after the completion of the procedure. It also specifies the scheduling and coordination of procedure data across a variety of imaging, measurement, and analysis systems, and its reliable storage in an archive from where it is available to support subsequent workflow steps, such as reporting. It also provides central coordination of the completion status of steps of a potentially multi-phase (diagnostic and interventional) procedure.

B.2 Actor Descriptions

Actors are information systems or components of information systems that produce, manage, or act on information associated with operational activities in the enterprise. The following are the actors defined by IHE and referenced throughout the rest of this document, as well as in other domain Technical Framework documents.

It is acknowledged that some of the terms used as modifiers for the actor names are not used consistently (e.g., Image Manager, which also manages non-image objects). At this point, the benefit in doing extensive renaming to gain consistency is outweighed by the risk of introducing significant confusion that would result from renaming many of the existing actors that are shared across multiple domains. Therefore the actor names will remain as defined below.

Acquisition Modality – A system that acquires and creates medical images or waveforms while a patient is present. In the ENDO TF, it signifies an endoscopy system. A modality may also create other evidence objects such as Structured Report Documents containing measurements.

ADT – A system responsible for adding and/or updating patient demographic and encounter information (Admission/Discharge/Transfer). In particular, it registers a new patient with the Order Placer and Department System.

Department System Scheduler/Order Filler – A department-based (for instance, Endoscopy or Radiology) information system that provides functions related to the management of orders received from external systems or through the department system's user interface. Extended features for endoscopy include producing the order data that are used to send a request for a biopsy to the pathology department and relaying the status of the pre-procedure and post-procedure treatments as the order progress information back to the Order Placer.

Image Archive – A system that provides long term storage of evidence objects such as images, presentation states, Key Image Notes and Evidence Documents.

Image Creator – A system that processes images and generates new images. It is not included in the Scheduled Workflow (SWF) because the endoscopic procedure does not normally involve image processing. In cases where image processing is involved, it is supported by a different profile.

Image Display – A system that offers browsing of patients' studies. In addition, it may support the retrieval and display of selected evidence objects including sets of images, presentation states, Key Image Notes, and/or Evidence Documents.

Image Manager – A system that provides functions related to safe storage and management of evidence objects. It supplies availability information for those objects to the Department System Scheduler.

Order Placer – A hospital or enterprise-wide system that generates orders for various departments and distributes those orders to the correct department. Extended features for endoscopy include producing the order data that are used to send a request for a biopsy to the pathology department and receiving the status of the pre-procedure and post-procedure treatments as the order progress information.

Performed Procedure Step Manager – A system that re-distributes the Modality Performed Procedure Step information from the Acquisition Modality to the Department System Scheduler/Order Filler and Image Manager. Extended features for endoscopy include managing the order for a request for a biopsy from the endo lab to the pathology department and managing the information on the status of the pre-procedure and post-procedure treatments of endoscopy.

Report Creator – One who creates structured reports.

Report Manager – One who manages structured reports and stores them in the repository.

Report Repository – One who stores and manages the structured reports in the repository and retrieves them upon request.

Report Reader – One who queries, acquires, and displays the structured reports.

Specimen Manager – One who generates a number for each specimen when a biopsy of the acquired specimen is ordered and sent to the pathology department.

The following table shows which actors are used in which Integration Profiles.

Table B.2-1. Integration Profile Actors

Integration Profile / Actor	ENDO
Acquisition Modality	X
ADT Patient Registration	X
DSS/OF	X
Image Archive	X
Image Creator	
Image Display	X
Image Manager	X
Order Placer	X
Performed Procedure Step Manager	X
Report Creator	X
Report Manager	X
Report Repository	X
Report Reader	X
Specimen Manager	X

Note: The Time Client actor is not formally part of the Endo Workflow Profile, but it must be grouped with certain actors in that Profile.

B.3 Transaction Descriptions

Transactions are interactions between actors that transfer the required information through standards-based messages. The following are the transactions defined by IHE and referenced throughout the rest of this document. Those transactions specified in other domain Technical Framework documents are identified with the domain identifier and transaction number.

Patient Registration – The ADT system registers and/or admits a patient and forwards the information to other information systems. [RAD-1]

Placer Order Management – The Order Placer informs the Order Filler of the initiation or cancellation of an order. The Placer/Filler Order Management transaction will sometimes be referred to as "-New" when a new order is being initiated, or as "-Cancel" when an existing order is canceled. [RAD-2]

Order Filler Management – The Order Filler registrates or cancel the order. The Order Filler informs the Order Placer of the initiation, cancellation, or change in the status of an order. The Placer/Filler Order Management transaction will sometimes be referred to as "-New" when a new order is being initiated, or as "-Cancel" when an existing order is canceled. Extended features for endoscopy include notification of the order placement for a biopsy to the pathology department and the status of the pre-procedure and post-procedure treatments as the order progress information. [RAD-3]

Procedure Scheduled – The Image Manager is notified of a registration of a test. Schedule information is sent from the Department System Scheduler/Order Filler to the Image Manager. [RAD-4]

Modality Worklist Provided/Query Modality Worklist – The modality orders a retrieval/acquisition of a test. Based on a query entered at the Acquisition Modality, a modality worklist is generated listing all the items that satisfy the query. This list of Scheduled Procedure Steps (SPS) with selected demographic information is returned to the Acquisition Modality [RAD-5].

Modality Procedure Step In Progress – The beginning of an endoscopic procedure is notified. Extended features for endoscopy include information on the progress of endoscopic procedures including the pre- and post-procedure treatments. An Acquisition Modality notifies the Performed Procedure Step (PPS) Manager of the start of a new Procedure Step and the PPS Manager informs the Department System Scheduler/Order Filler and Image Manager. [ENDO-7, derived from RAD-6]

Modality Procedure Step Completed – The completion of an endoscopic procedure is notified. Extended features for endocopy includes the notification at the completion of the procedure including post-procedure treatment. An Acquisition Modality notifies the Performed Procedure Step (PPS) Manager of the completion of a Procedure Step and the PPS Manager informs the Department System Scheduler/Order Filler and Image Manager. [RAD-7]

Modality Images/Evidence Stored – The endoscopic images are archived. An Acquisition Modality sends acquired or generated images to the Image Archive. [ENDO-8, derived from RAD-8 and RAD-43]

Modality Presentation State Stored – The presentation-state information of endoscopic images is archived. An Acquisition Modality sends the acquired or generated information on the presentation state of the image to the Image Manager.[RAD-9]

Storage Commitment – The storage assurance of the data including the endoscopic image data is confirmed. A requestor (Acquisition Modality) requests that the Image Manager confirm ownership for the specified DICOM objects (images) that the requestor stored in the Image Archive, thus allowing the sender to delete those objects now owned by the Image Manager. [Endo-9, derived from RAD-10]

Image Availability Query – The availability of a specified image is confirmed. The Image Manager confirms the availability of the specified image.[RAD-11]

Patient Update – The notification that the patient data is updated. The ADT Patient Registration System informs the Order Placer and the Department System Scheduler/Order Filler of new information for a particular patient. The Department System Scheduler may then further inform the Image Manager. [RAD-12]

Procedure Update – The notification that the endoscopy order is updated. The Department System Scheduler/Order Filler sends the Image Manager updated order or procedure information. [RAD-13]

Query Images – The query of endoscopic images. An Image Display queries the Image Archive for a list of entries representing images by patient, study, series, or instance. [RAD-14]

Query Presentation State – The presentation state of the endoscopic images (GSPS) is queried.[RAD-15]

Retrieve Images – The retrieval of endoscopic images. An image display device requests specific images or a combination of images in the image archive in order to acquire them. [Derived from ENDO-10 and RAD-16]

Retrieve Presentation State – The presentation state of an endoscopic image (GSPS) is retrieved.[RAD-17]

Creator Image Stored – The storage of new image data. New image data are stored in the Image Archiving System.[RAD-18]

Creator Presentation State Stored – The presentation-state data of an endoscopic image (GSPS) is stored**.**[RAD-19]

Creator Procedure Step Progress – The Image Creator notifies the PPS manager of the beginning of the image processing of a specific image.[RAD-20]

Creator Procedure Step Completed – The Image Creator notifies the PPS manager of the completion of the image processing of a specific image.[RAD-21]

Report Submission – The Report Creator sends a report to the Report Manager. [RAD-24]

Report Ready – The Report Manager notifies the Report Creator that the report is ready to generate. [RAD-24]

Report Issuing – The acknowledged report that includes the image data is submitted to the Report Repository. [RAD-25]

Query Reports – The query of a report for loading. [RAD-26]

Retrieve Reports – The retrieval of a queried report. [RAD-27]

Pre-procedure PPS– It notifies the status of the pre-procedure (i.e. started, completed, etc.) based on endoscopy order. Work list that will be used by not only acquisition modality. It will be handed to PPS manager as extended work list. The data entry will be done by operators utilizing the terminal in department. [ENDO-1]

Specimen PPS – It notifies the status that biopsy has been done. It send the unique specimen ID that represents both each specimen and the number of the specimen.[ENDO-2]

GPPPS report finished – It notifies the status that the endoscopy procedure report has been completed. It also represents pathology order when biopsy was done and Specimen PPS was notified. [ENDO-3]

Post-procedure PPS – It notifies the status of the post-procedure (i.e. started, completed, etc.) based on endoscopy order. Work list that will be used by not only acquisition modality. It will be handed to PPS manager as extended work list. The data entry will be done by operators utilizing the terminal in department. [ENDO-4]

Demand for Path. Order PPS – The status notification that biopsy has been done, required information for pathology order has been completed and existence of the demand for pathology order. OP refers the status and the information contained and sends pathology order. [ENDO-5]

Table B.3-2 shows which transactions are used in which Integration Profiles.

Table B.3-2. Integration Profile Transactions

Integration Profile / Transaction	ENDO
Patient Registration [RAD-1]	X
Placer Order Management [RAD-2]	X
Filler Order Management [RAD-3]	X
Procedure Scheduled [RAD-4]	X
Modality Worklist Provided/Query Modality Worklist [RAD-5]	X
Modality Procedure Step In Progress [ENDO-7、RAD-6 より派生]	X
Modality Procedure Step Completed [RAD-7]	X
Modality Images Stored [ENDO-8、RAD-8 および RAD-43 から派生]	X
Modality Presentation State Stored [RAD-9]	X
Storage Commitment [ENDO-9、RAD-10 から派生]	X
Image Availability Query [RAD-11]	X
Patient Update [RAD-12]	X
Procedure Update [RAD-13]	X
Query Images [RAD-14]	X
Query Presentation State [RAD-15]	X
Retrieve Images [ENDO-10、RAD-16 から派生]	X
Retrieve Presentation State [RAD-17]	X
Creator Image Stored [RAD-18]	X
Creator Presentation State Stored [RAD-19]	X
Creator Procedure Step Progress [RAD-20]	X
Creator Procedure Step Completed [RAD-21]	X
Report Submission [RAD-24]	X
Report Issuing [RAD-25]	X
Query Reports [RAD-26]	X
Retrieve Reports [RAD-27]	X
Pre-procedure PPS [ENDO-1]	X
Specimen PPS [ENDO-2]	X
GPPPS report finished/Order to Path. [ENDO-3]	X
Post-procedure PPS [ENDO-4]	X
Demand for Path. Order PPS [ENDO-5]	X

Note: The Maintain Time transaction is not formally part of the Endo Workflow Profile, but it is required for the Time Client actor grouped with certain actors in that Profile.

B.4 Product Implementations

Developers have a number of options in implementing IHE actors and transactions in product implementations. The decisions cover four levels of optionality:

- For a system, select which actors it will incorporate. (Multiple actors per system is acceptable).
- For each actor, select which Integration Profiles it will participate in.
- For each actor-profile, select which optional transactions will be implemented. All required transactions must be implemented for the profile to be supported. (Refer to the Integration Profile Tables in sections 3-5)
- Finally, for each transaction, select which optional features will be supported. (Refer to the transaction descriptions in ENDO-TF Volume II, or the appropriate domain TF)

Implementers should provide a statement describing which IHE Actors, IHE Integration Profiles, optional transactions and optional features are incorporated in a given product. The recommended form for such a statement is defined in Appendix C.

In general, a product implementation may incorporate any single actor or combination of actors. However, in the cases specified below, the implementation of one actor requires the implementation of one or more additional actors:

- The Image Archive shall be grouped with the Image Manager, and the Image Manager shall be grouped with the Image Archive.
- The Image Manager participating in the ENDO Workflow Integration Profiles shall be grouped with a Performed Procedure Step Manager. The grouped Performed Procedure Step Manager shall be capable of being disabled via configuration.
- The Department System Scheduler/Order Filler participating in the ENDO Workflow shall be grouped with a Performed Procedure Step Manager. The grouped Performed Procedure Step Manager shall be capable of being disabled via configuration
- The DSS/Order Filler and Modality Acquisition Actors participating in the ENDO Workflow Integration Profile shall be grouped with the Time Client Actor of the Consistent Time Profile

When multiple actors are grouped in a single product implementation, all transactions originating or terminating with each of the supported actors shall be supported (i.e., the IHE transactions shall be offered on an external product interface). The exceptions to this rule are any transactions defined between actors in the required groupings defined above.

For example, the Procedure Step In Progress/Completed transaction does not need to be supported between the Performed Procedure Step Manager and the Image Manager when these are grouped together in a single system.

When two or more actors are grouped together, internal communication between actors is assumed to be sufficient to allow the necessary information flow to support their functionality; for example, the Image Manager provides necessary information updates to the Image Archive to support its Query/Retrieve functionality. The exact mechanisms of such internal communication are outside the scope of the IHE Technical Framework.

B.5 Gastrointestinal Endoscopy Workflow (ENDO Workflow)

The ENDO Workflow Integration Profile establishes the continuity and integrity of basic patient data in the context of the endoscopic procedure. This profile deals specifically with consistent handling of patient identifiers and demographic data, including that of emergency patient presentation where the actual patient identity may not be established until after the beginning of the procedure, or even a significant time after the completion of the procedure. It also specifies the scheduling and coordination of procedure data across a variety of imaging, measurement, and analysis systems, and its reliable storage in an archive from where it is available to support subsequent workflow steps, such as reporting. It also provides central coordination of the completion status of steps of a potentially multi-phase (diagnostic and interventional) procedure.

This profile has much in common with the IHE Radiology Scheduled Workflow, Patient Information Reconciliation, and Evidence Document Integration Profiles, but deals more explicitly with the multi-modality coordination, and with endo-specific data requirements. See **Rad TF-1: 3.4** for the integrated workflow data model adopted by the IHE Technical Framework for HL7 messages and DICOM information objects. This data model offers three major levels of control for workflow:

- **Order**: A request for a Departmental Service
- **Requested Procedure**: Unit of work resulting in one or more reports, with associated codified, billable acts.
- **Scheduled and Performed Procedure Step**: the smallest unit of work in the workflow that is scheduled (work to do) or performed (work done).

A clear understanding of the workflow data model is essential to interpreting the Endo Workflow Integration Profile.

Although the major cases for ENDO workflow are described in the following subsections, it is beneficial to also see the corresponding workflows in radiology. Rad TF-1: 3.3 has a description of the “normal” scheduled workflow when all three levels of control in the data model are fully utilized for known patients, and Rad TF-1: 4.3 and 4.4 describes workflows when the patient is unknown and/or the ordering and scheduling process is short-circuited (e.g., in the emergency case). Even in this latter case, all three levels of control are present and used, although not to their full extent.

B.5.1 Actors/Transactions

Figure B.5.1-1 diagrams the actors involved with this profile and the transactions between actors.

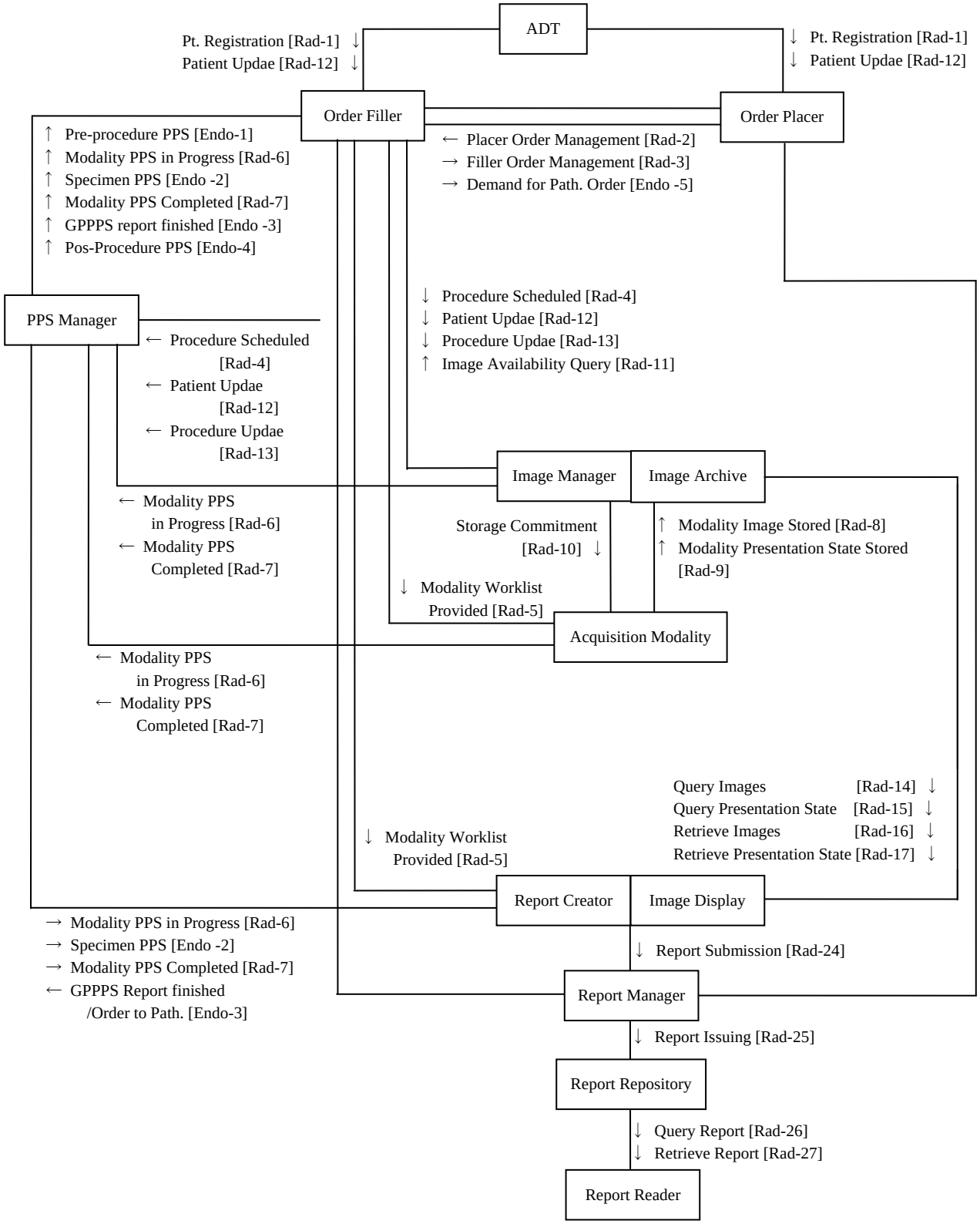

Figure B5.1-1. ENDO Workflow Diagram

Note that this diagram maintains the actor and transaction names specified in the Radiology Technical Framework (RAD-TF) for consistency of definitions.

Table B5.1-1 lists the transactions for each actor directly involved in the Endo Workflow Integration Profile. In order to claim support of this Integration Profile, an implementation must perform the required transactions (labeled "R"). Transactions labeled "O" are optional. A complete list of options defined by this Integration Profile that implementations may choose to support is listed in Section B5.2.

Table B5.1-1. Endo Workflow - Actors and Transactions

Actors	Transactions	Optionality	Section
ADT Patient Registration	Patient Registration [Rad-1]	R	RAD-TF 2: 4.1
	Patient Update [Rad-12]	R	RAD-TF 2: 4.12
Order Placer	Patient Registration [Rad-1]	R	RAD-TF 2: 4.1
	Patient Update [Rad-12]	R	RAD-TF 2: 4.12
	Placer Order Management [Rad-2]	R	RAD-TF 2: 4.2
	Filler Order Management [Rad-3]	R	RAD-TF 2: 4.3
	Demand for Path. Order PPS [Endo-5]	R	ENDO-TF 2: 4.5
DSS/OF	Patient Registration [Rad-1]	R	RAD-TF 2: 4.1
	Placer Order Management [Rad-2]	R	RAD-TF 2: 4.2
	Filler Order Management [Rad-3]	R	RAD-TF 2: 4.3
	Procedure Scheduled [Rad-4]	R	RAD-TF 2: 4.4
	Query Modality Worklist [Rad-5]	R	RAD-TF 2: 4.5
	Modality Procedure Step In Progress [Rad-6]	R	RAD-TF 2: 4.1
	Modality Procedure Step Completed [Rad-7]	R	RAD-TF 2: 4.7
	Patient Update [Rad-12]	R	RAD-TF 2: 4.12
	Procedure Updated [Rad-13]	R	RAD-TF 2: 4.13
	Pre-procedure PPS [Endo -1]	R	ENDO-TF 2: 4.1
	Specimen PPS [Endo -2]	R	ENDO-TF 2: 4.2
	GPPPS report finished/Order to Path. [Endo -3]	R	ENDO-TF 2: 4.3
	Post-procedure PPS [Endo -4]	R	ENDO-TF 2: 4.4
	Demand for Path. Order PPS [Endo -5]	R	ENDO-TF 2: 4.5
Acquisition Modality	Query Modality Worklist [Rad-5]	R	RAD-TF 2: 4.5
	Modality Procedure Step In Progress [Rad-6]	R	RAD-TF 2: 4.6
	Modality Procedure Step Completed [Rad-7]	R	RAD-TF 2: 4.7
	Modality Images/Evidence Stored [Rad -8]	R	RAD -TF 2: 4.2
	Modality Presentation State Stored [RAD-9]	R	ENDO-TF 2: 4.9
	Storage Commitment[RAD-10]	R	ENDO-TF 2: 4.10
Image Manager/ Image Archive	Procedure Scheduled [Rad-4]	R	RAD-TF 2: 4.4
	Modality Procedure Step In Progress [Rad-6]	R	RAD-TF 2: 4.6
	Modality Procedure Step Completed [Rad-7]	R	RAD-TF 2: 4.7
	Patient Update [Rad-12]	R	RAD-TF 2: 4.12
	Procedure Updated [Rad-13]	R	RAD-TF 2: 4.13
	Query Images [Rad-14]	R	RAD-TF 2: 4.14

	Query Presentation State [RAD-15]	R	RAD-TF 2: 4.15
	Retrieve Images [RAD-16]	R	RAD-TF 2: 4.16
	Retrieve Presentation State [RAD-17]	R	RAD-TF 2: 4.17
Performed Procedure Step Manager	Modality Procedure Step In Progress [Rad-6]	R	RAD-TF 2: 4.6
	Modality Procedure Step Completed [Rad-7]	R	RAD-TF 2: 4.7
	Pre-procedure PPS [Endo -1]	R	ENDO-TF 2: 4.1
	Specimen PPS [Endo -2]	R	ENDO-TF 2: 4.2
	GPPPS report finished/Order to Path. [Endo -3]	R	ENDO-TF 2: 4.3
	Post-procedure PPS [Endo -4]	R	ENDO-TF 2: 4.4
Image Display	Query Images [Rad-14]	R	RAD-TF 2: 4.14
	Retrieve Images [ENDO-10]	R	ENDO-TF 2: 4.4
Specimen Manager	Query Modality Worklist [Rad-5]	R	RAD-TF 2: 4.5
	Specimen PPS [Endo -2]	R	ENDO-TF 2: 4.2
Report Creator	Query Modality Worklist [Rad-5]	R	RAD-TF 2: 4.5
	Modality Procedure Step In Progress [Rad-6]	R	RAD-TF 2: 4.6
	Modality Procedure Step Completed [Rad-7]	R	RAD-TF 2: 4.7
	Specimen PPS [Endo -2]	R	ENDO-TF 2: 4.2
	GPPPS report finished/Order to Path. [Endo -3]	R	ENDO-TF 2: 4.3
Report Manager	Report Submission [Rad-24]	R	
	Report Issuing [Rad-25]	R	
Report Repository	Report Issuing [Rad-25]	R	
	Query Report [Rad-26]	R	
	Retrieve Report [Rad-27]	R	
Report Reader	Query Report [Rad-26]	R	
	Retrieve Report [Rad-27]	R	

このプロファイルに対する前提条件となる可能性のある他のプロファイルについては、**エラー! 参照元が見つかりません。**を参照すること。

B.5.2 Endo Workflow Integration Profile Options

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 B5.2-1 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 B.5.2-3 ENDO Workflow – Actors and Options

Actor	Option Name	Optionality	Vol & Section
ADT Patient Registration	*No options defined*	-	-
OP	*No options defined*	-	-
DSS/Order Filler	Multi-modality Procedure Update	R	ENDO-TF 2: 4.1
	PPS Exception Management	O	RAD-TF 2: 4.7
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	ENDO-TF 2: 4.3
	ENDOScopic Cath	R	ENDO-TF 2: 4.2
Image Display	*No options defined*	-	-
Performed Procedure Step Manager	*No options defined*	-	-

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

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).

B.5.3 Endo Scheduled Process Flow

Each process flow is introduced with an overview of the end-user issue addressed ("Clinical Context") and the approach taken in the Technical Framework ("IHE Context").

Clinical context: This reflects the situation where a patient is admitted to the facility, and a endo procedure is ordered and scheduled, similar to a radiology procedure. Note that while Scheduled Workflow is the normal or expected situation in radiology, there might be some exceptions in the Endo workflow. See also Appendix A which discusses the endo procedure and its relationship to the overall episode of care.

IHE Context: This section describes the "normal" scheduled workflow when all three levels of control (order, requested procedure, and scheduled/performed procedure steps) in the IHE data model are fully utilized to request a procedure for known patients. In fact, orders are often not generated for an endoscopic procedure in acute cases, but this process flow provides the basis for understanding the specific use cases described in section B5.4. In fact, this workflow, plus a patient information reconciliation step, constitutes case C1 in section B5.4

For comparison with radiology, see RAD-TF 1:3.3.

Note : Order Change Flow (RAD-TF 1:3.3.3) and the Exception Management Workflow (RAD-TF 1:3.3.4) may be used as elaborated there, and are not further described in the Endoscopic Technical Framework. The functionality of those data flows is specified within the specific transactions invoked by the ENDO-TF.

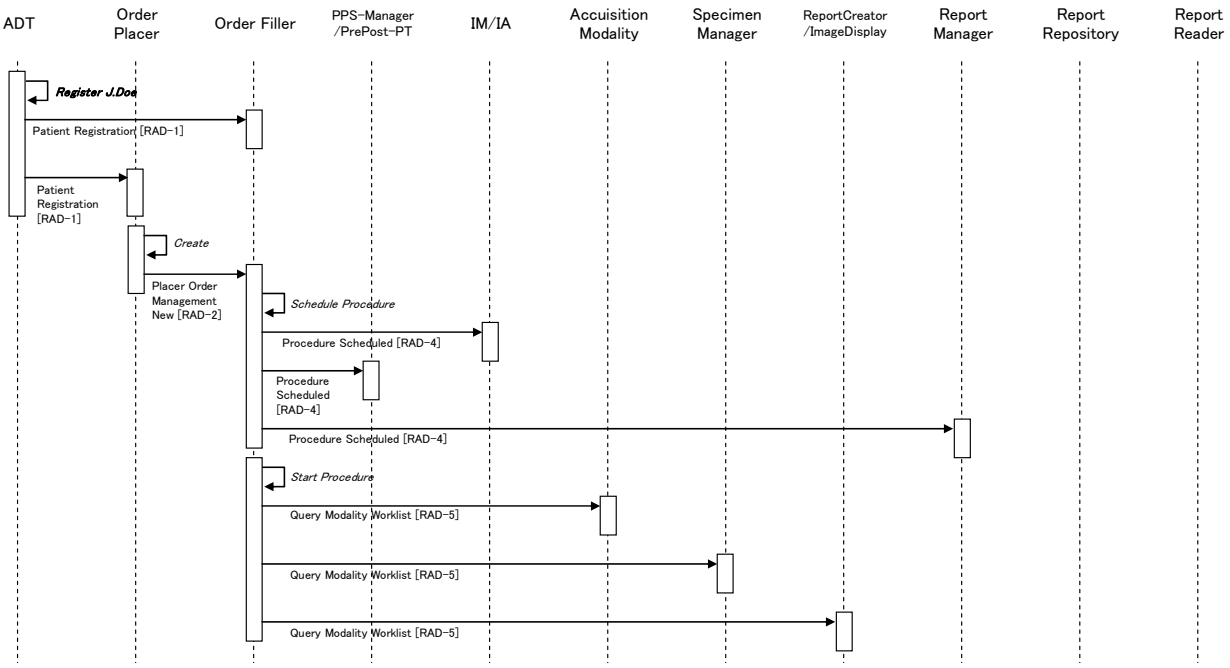

Figure B5.3-2 Schedued Workflow*: Administrative Process Flow

The following should be noted in relation to the Administrative process flow:

- *Patient Registration*: The Patient Registration data is broadcast to several systems, including the Order Placer and the Department System Scheduler/Order Filler (DSS/OF).
- *Create Order*: The Order Placer is the repository for all patient orders.
- *Schedule Procedure*: The DSS/OF associates the order with one or more Requested Procedures that have to be performed to satisfy the order. Each Requested Procedure prescribes a number of actions that have to be performed by Acquisition Modalities. Actions are specified in Scheduled Procedure Steps (SPS) based on timing and sequencing, and on modality. Scheduled Procedure Steps are scheduled, i.e., assigned a time slot and performing resource (modality), and are made available for Modality Worklist Query.
- *Start Procedure*: The DSS/OF may have an optional function to start the Endo Procedure, typically to allow the collection of patient data specifically tied to the procedure but outside the scope of any particular modality. This may result, for instance, in the “Arrived” status being set in the associated SPSs. The purpose of this action is to start a procedure from a non-modality actor.
- *Query Modality Worklist*: The Modality Worklist (MWL) query may be broad (get a list of scheduled procedures from which one will be selected), or patient-specific (provided with sufficient query keys to get back the scheduled procedure for a single patient). The latter case may be facilitated by entering the Patient ID from a bar-coded wristband into the MWL query (as an institution’s endoscopic standard operating procedure).
- *Select Patient*: In the event of a single SPS in the MWL response, a modality may optimize the Select Patient function to select that SPS without further explicit user action.
- Those messages that the Order Fillers send simultaneously to the PPS Manager, IM/IA, the Report Manager, the Order Manager, and the Specimen Manager are the same transactions as described in Procedure Scheduled [RAD-4].

- During administrative processing, Procedure Scheduled [RAD-4] is necessary for both the Report Manager and the Specimen Manager to prepare the report after endoscopy.

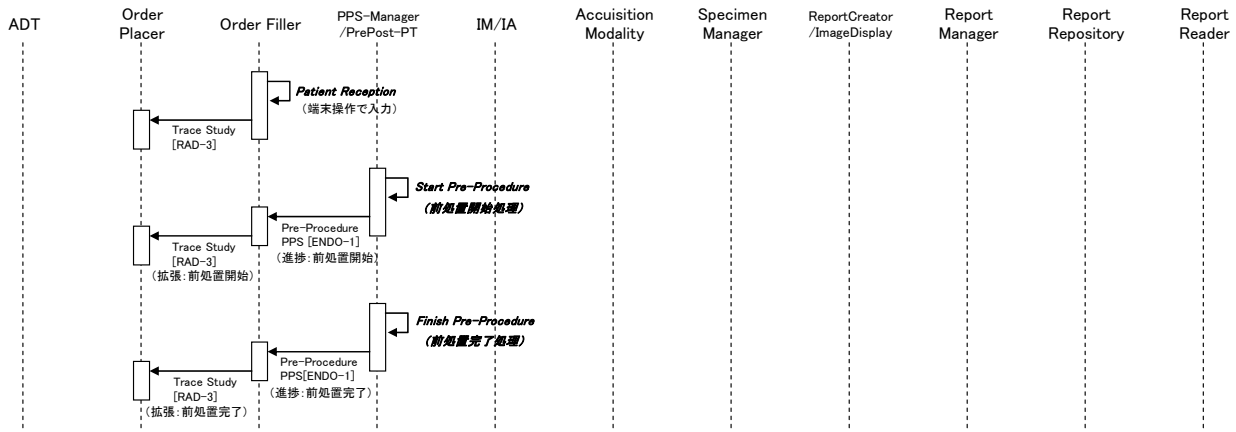

図 B.5.3-3-1. Scheduled Workflow: Procedure Performance Process Flow (1/3)

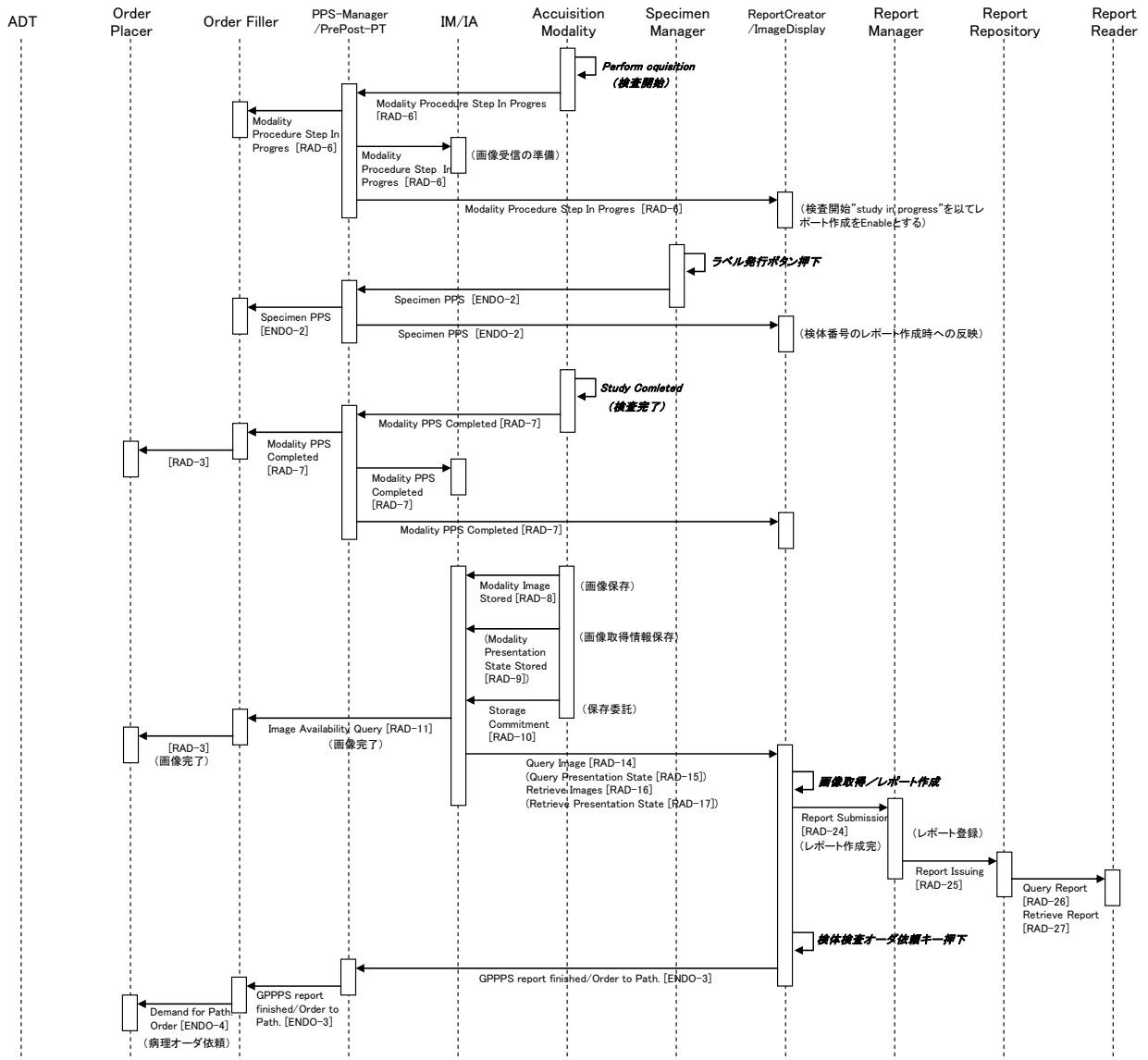

Figure B.5.33.3-2-2. Scheduled Workflow: Procedure Performance Process Flow (2/3)

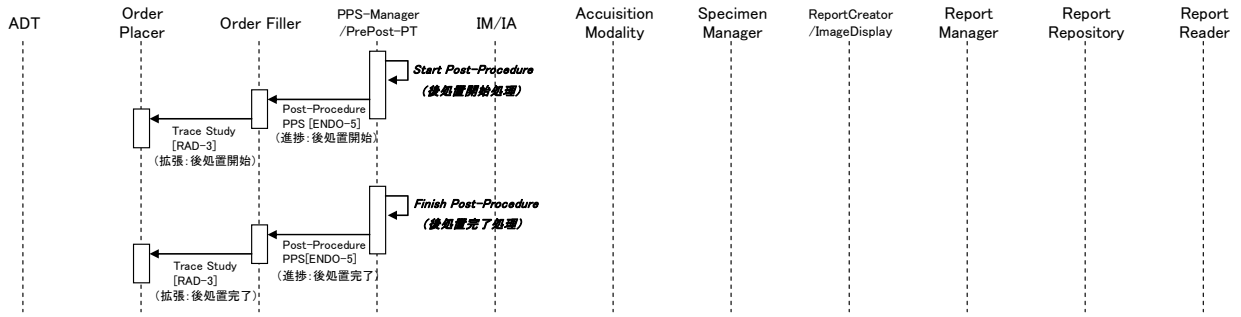

Figure B5.33.3-2-3. Scheduled Workflow: Procedure Performance Process Flow (1/3)

The following should be noted in relation to the Procedure Performance process flow:

- *Modality Procedure Step In Progress* and *Update Schedule*: Initial Procedure scheduling may be vague (i.e., not exactly specify a time or endo lab), or the procedure may be performed in a room different from the one in which it was scheduled. If the DSS/OF has not started the procedure, upon receipt of first MPPS In Progress for the endo lab, which includes the patient ID/name and the modality Station AE Title (which allows it to be linked to a specific endo lab), the DSS/OF updates the Scheduled Procedure Steps for all the modalities in that same endo lab to reflect the current active case (i.e., that first MPPS serves as "current patient / lab selection").
- *Query Modality Worklist*: MWL queries from modalities in that endo lab subsequent to the Update Schedule process may be able to use a broad query with sufficient request keys that would return in the MWL response only a single SPS for the current patient, allowing optimization of modality start-up.
- *Perform Acquisition*: Each Modality may produce a variety of images and other evidence (waveforms, analysis reports, etc.) that are stored to the Image Manager/Archive. The Image Manager/Archive must support all the object types (beyond just images) as specified by the ENDO Option .
- *Modality Procedure Step Complete (MPS)* and *End Procedure*: Modality Procedure Step Complete also includes Modality Procedure Step Discontinued. The simple transmission of a Complete or Discontinued does not indicate that a modality is then available, due to multi-step procedures (diagnostic/interventional) and multi-modality cross-dependencies in a procedure room. It is a function of the DSS/OF (outside the scope of this document) to determine when to end the procedure, and declare the modality resources in the room are available for another procedure.
- *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 those with caster wheels, which may be intermittently connected to the network and temporarily unable to receive Storage Commitment messages.
- *Filler Order Management - Status Update*: Status Update transactions may be sent to the Order Placer at several points in the workflow, although only the update after the first Modality Procedure Step In Progress and the last Modality Procedure Step Complete are shown.
- Those messages that the PPS Manager send simultaneously to IM/IA, the Report Manager, the Order Manager, and the Specimen Manager are the same transactions as the transaction Modality PPS Completed [RAD-7].
- The above chart shows the process workflow that includes a biopsy specimen. With no specimens included, several relevant transactions are able to be omitted. Those examples will be shown in the following section.
- Note that reporting is required for endoscopic procedures.The report is to be completed immediately after the test or operation. The endoscopic procedure is not complete until both the report and patient recovery are finished, which is different from the radiographic procedure.

B.5.4 ENDO Workflow Use Cases

This section describes the specific use cases and process flows defined for the ENDO Workflow Profile.

Clinical Context: Currently, the most common scenario of performing endoscopy is that a consulting medicine recommends that the patient undergo endoscopy, and makes the arrangements by phone for the procedure. This is a simple logistical arrangement with the endo lab, which sometimes involves a formal electronic scheduling activity (this function is served instead by the ubiquitous “whiteboard”). At this point, one of three paths may be used: the procedure is ordered at the Order Placer system, the procedure is ordered at the departmental system, or the procedure begins without an order in the endo lab.

Note that in operations typical of current practice in the endo lab, there is little (if any) interaction between the department information systems and a hospital Order Placer system. One of the goals of IHE is to facilitate better integration between those two worlds, and enable the Order Placer system to provide a uniform system of order management for the departments. The clinical context of the ENDO Workflow Profile encourages the evolution from current practice to a more highly integrated enterprise workflow.

IHE Context: Many of the use cases include the set of transactions necessary for post-hoc updating of patient information. In the Radiology Technical Framework, this is specified in a separate Patient Information Reconciliation Profile, but because the ENDO workflow needs to deal with this in some of the cases, patient updating has been included in the basic ENDO Workflow Profile. However, the specific data flows for such reconciliation are indicated in the Process Flow Diagrams in blue.

The use cases parallel those defined in the Radiology Patient Information Reconciliation Profile (RAD-TF 1:4.4). To facilitate comparison for those readers familiar with RAD-TF, the differences between the radiology Process Flow Diagrams and those in endoscopy are shown in green in the figures of the following subsections.

There are six specific Use Cases defined for ENDO Workflow, C1 through C6, whose variations occur based on whether or not and where a patient is registered, as well as whether or not and where an order is placed. These variations are listed in the table below. ENDO use cases C1 through C6 correspond closely to RAD-TF Patient Information Reconciliation use cases 1 through 6. Additional use cases, Case C7: No Pathology Order without Biopsy Specimen and C8: Suspension/Cancel of the Procedure, are not shown in the Table.

Table B.5.4-4.ENDO Workflow Cases

Order Placement / **Patient Registration**	**Order Placed at Order Placer**	**Order Placed at Order Filler**	**Order Not Placed**
Patient Registered at ADT	**Case C1**	**Case C2**	**Case C3**
Patient Registered in the Department (see note)	Not Applicable - the Order Placer requires the patient registration from the ADT system	**Case C4**	**Case C5**
Patient Updated	**Case C6**	**Case C6**	**Case C6**

Note: Patient is registered in the department either in the DSS/OF system, or manually (temporary ID assigned on paper and manually entered into the modality).

Note: The transactions for Modality Image/Evidence Stored and Storage Commitment are not shown in the following subsections, and select Order Status Update transactions are not shown, as they do not impact the process control workflow. Also only selected transactions for "Modality N" (i.e., representing multiple additional modalities in the lab) are shown to indicate the multi-modality nature of the Process Flow.

Also note that the Performed Procedure Step Manager as shown on the Process Flow diagrams is presumed to be grouped with the Image Manager for the purpose of presentation. In actual implementations it may be grouped with the Department System Scheduler/Order Filler with corresponding changes in the flow of PPS related transactions between the Image Manager and Department System Scheduler/Order Filler.

B.5.4.1 Case C1: Patient Registered at ADT and Procedure Ordered at the Order Placer

Clinical Context: This corresponds to the more traditional Radiology Structured Workflow, where an order is placed in the hospital ordering system for endoscopy. It also accounts for the special situation where an emergency identifier has been created for the patient (so that the patient is registered in the ADT and has been assigned a unique identifier). Since the order is placed before the procedure begins, common identifiers can be used to enable the coordinated presentation and electronic distribution of all of the information related to the endoscopy.

IHE Context: This case includes the full scheduled workflow when all three levels of control (order, requested procedure, and scheduled/performed procedure steps) in the IHE data model are fully utilized to request a procedure (see section B5.3).

The patient may be registered at the ADT system as a known patient with complete demographics, or with incomplete demographics, including the case of a totally unidentified patient for whom only a Patient ID and a temporary name are assigned. To the subsequent systems in the ENDO Workflow, it is irrelevant to procedure performance whether or not the complete demographics are known. This case thus includes both identified and unidentified patients, registered at the ADT system, for whom Orders are created at the Order Placer, and whose procedures are scheduled at the Department System Scheduler/Order Filler (DSS/OF).

For unidentified patients the ADT system is a single point of patient reconciliation in the enterprise. When the real patient identity is known, the ADT is responsible for reconciliation of its own records, as well as informing the Order Placer and DSS/OF about corresponding changes. The ADT sends a Patient Update message to both the Order Placer and DSS/OF. The DSS/OF sends the Patient Update message to the Image Manager.

Parts of figure B5.4-1 are omitted by wavy double lines because the shown procedures are the same as those shown in figures B5.3-1, B5.3-2-1, B5.3-2-2, and B5.3-2-3.

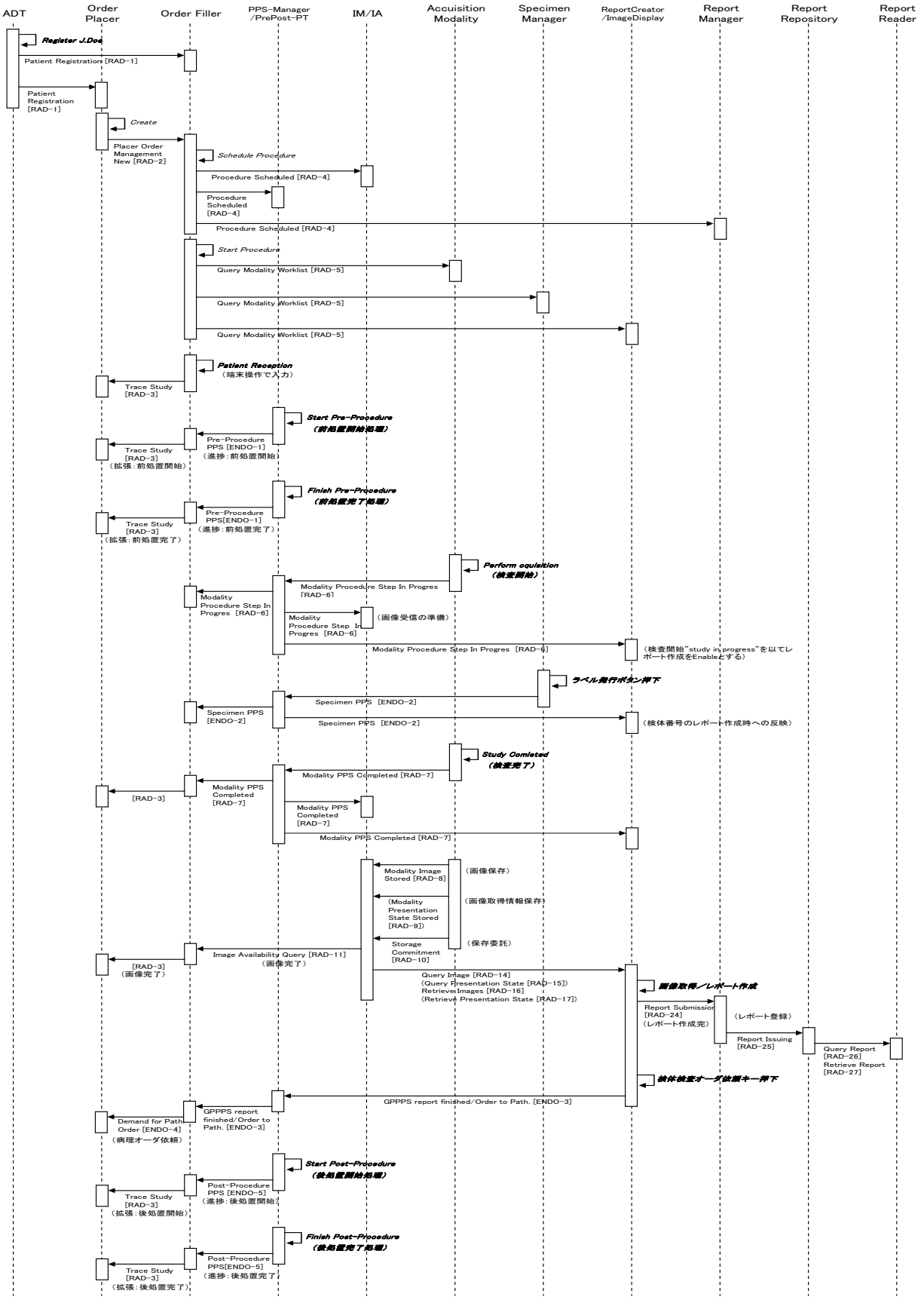

Figure B.5.4-4. Patient Registered at ADT and Ordered at the Order Placer – Case C1

Significant Transactions :

- To reconcile the patient information, the ADT may register a new patient and merge the temporary patient with the correct patient, and send both Patient Registration [RAD-1] and Patient Update [RAD-12] (Merge) transactions to the Order Placer and DSS/OF.
- If a permanent Patient ID was assigned, then the ADT may only send a Patient Update [RAD-12] transaction with proper information.

B.5.4.2 Case C2: Patient Registered at ADT and Procedure Ordered at DSS/OF

Clinical Context: This scenario is closely akin to Case C1, however, an order is not placed in the traditional hospital ordering system, but rather, the procedure information is entered at the Departmental System, which then submits the information to the hospital ordering system. This workflow is typical of many institutions, and alleviates the need to have an Order Placer system (HIS) terminal in the department or endo lab.

IHE Context: This case is based on case C1. However, in this situation the order for a procedure for a registered patient is generated by the Department System Scheduler/Order Filler and submitted to the Order Placer. Procedures are scheduled normally and acquisition systems use Modality Worklist.

If the patient information requires subsequent reconciliation, the ADT sends the Patient Update messages to both the Order Placer and Department System Scheduler/Order Filler. The Department System Scheduler/Order Filler sends the Patient Update message to the Image Manager as in case C1.

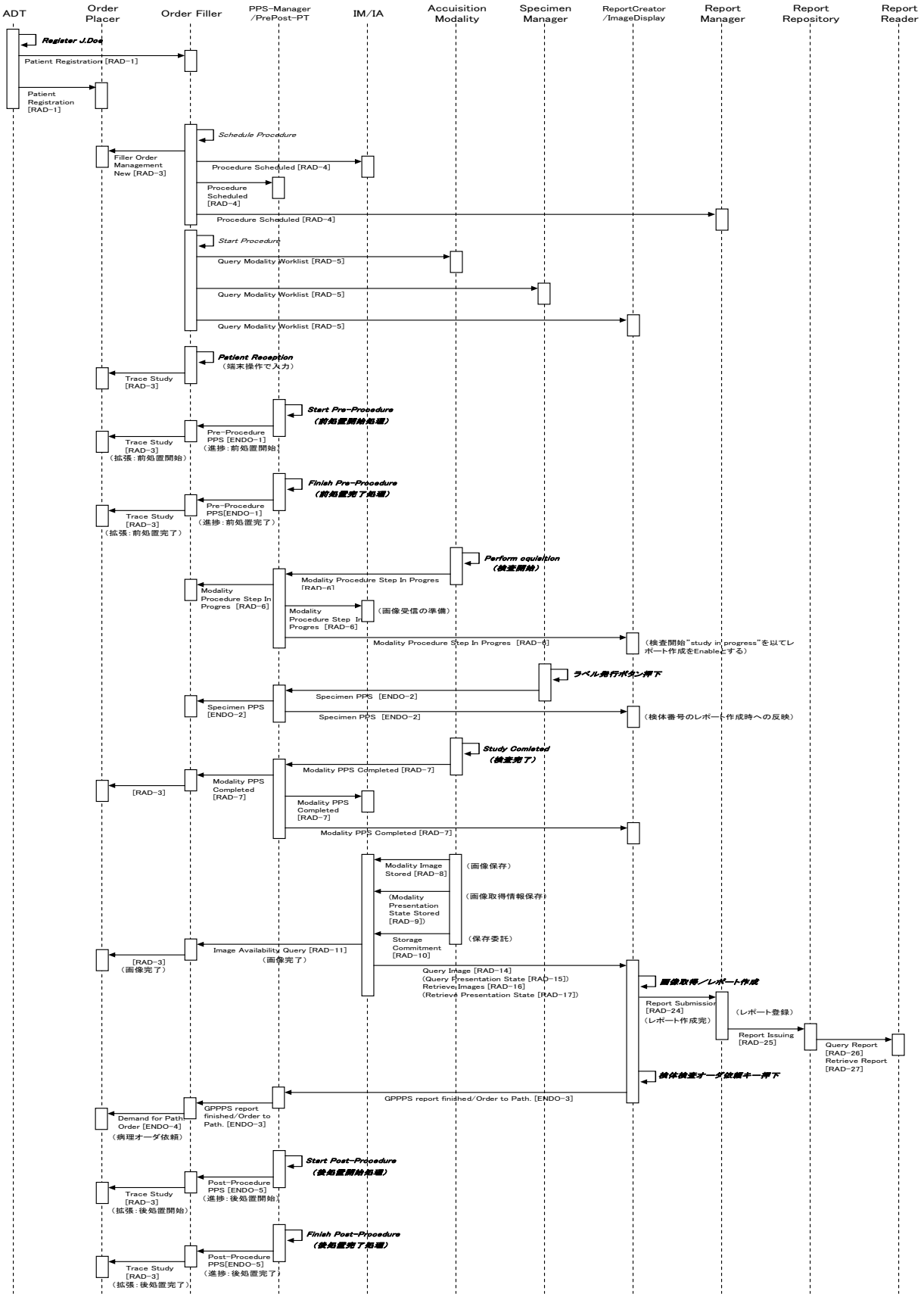

Figure B5.4-5. Patient Registered at ADT and Ordered at DSS/OF – Case C2

Significant Transactions:

- A Filler Order Management (New Order) transaction [RAD-3] is sent from Department System Scheduler/Order Filler to the Order Placer.

B.5.4.3 Case C3: Patient Registered at ADT and Procedure Not Ordered

Clinical Context: This scenario is similar to case C2, but the procedure information is not entered at the departmental system (e.g., due to time constraints). One of the participating modalities will therefore need to initiate the process of creating the common procedure identifiers. The identifiers are created at the departmental system based on an action taken by the first modality to start the procedure (typically the endoscopic system); they are then available for subsequent modalities to share. The amount of detail in the procedure information will be limited to what is provided by the first modality, e.g., if it does not provide a coded procedure type, it will necessarily appear as a "generic endo procedure". It is desirable whenever possible to use case C1 or case C2 process flows.

IHE Context: As in cases C1 and C2, this uses a permanent Patient ID generated by the ADT for a registered patient (identified, or unidentified). However, no order entry or scheduling takes place before an Acquisition Modality begins performing the procedure. The permanent Patient ID is entered at the Acquisition Modality (typically, from a patient wristband; a barcode reader may minimize the occurrence of data entry errors).

This case differs from the corresponding Radiology use case. The endoscopic procedure is basically a single modality, but in rare cases where multiple modalities are utilized, it is essential for all devices to use a common set of identifiers for both the patient and the study. Therefore, upon receiving the first Modality Procedure Step In Progress, the DSS/OF will automatically create a Requested Procedure for endoscopy, and its associated Scheduled Procedure Steps for all modalities in the same endo lab (room), utilizing the Study UID provided by the first Modality Procedure Step In Progress. The other modalities in that lab can then obtain coordinated identifiers using the Query Modality Worklist transaction.

When the Requested Procedure is automatically created, the DSS/OF generates and submits an order to the Order Placer, as in case C2, using a generic endoscopic procedure code, and then sends a Procedure Scheduled to the Image Manager.

Notes: 1. The difference from the Radiology TF is that the DSS/OF creation of a Requested Procedure occurs upon the MPPS In Progress (N-CREATE) message, not the MPPS Completed message; this allows multi-modality synchronization to the same Requested Procedure.
2. Also, the DSS/OF does not wait for the Order Placer to return a response with an Order Placer Number before creating the Requested Procedure, as this may delay expeditious creation of SPSs to enable time-critical multi-modality start-up in the endo lab.

If the patient information requires subsequent reconciliation, the ADT sends the Patient Update messages to both the Order Placer and Department System Scheduler/Order Filler. The Department System Scheduler/Order Filler sends the Patient Update message to the Image Manager as in case C1.

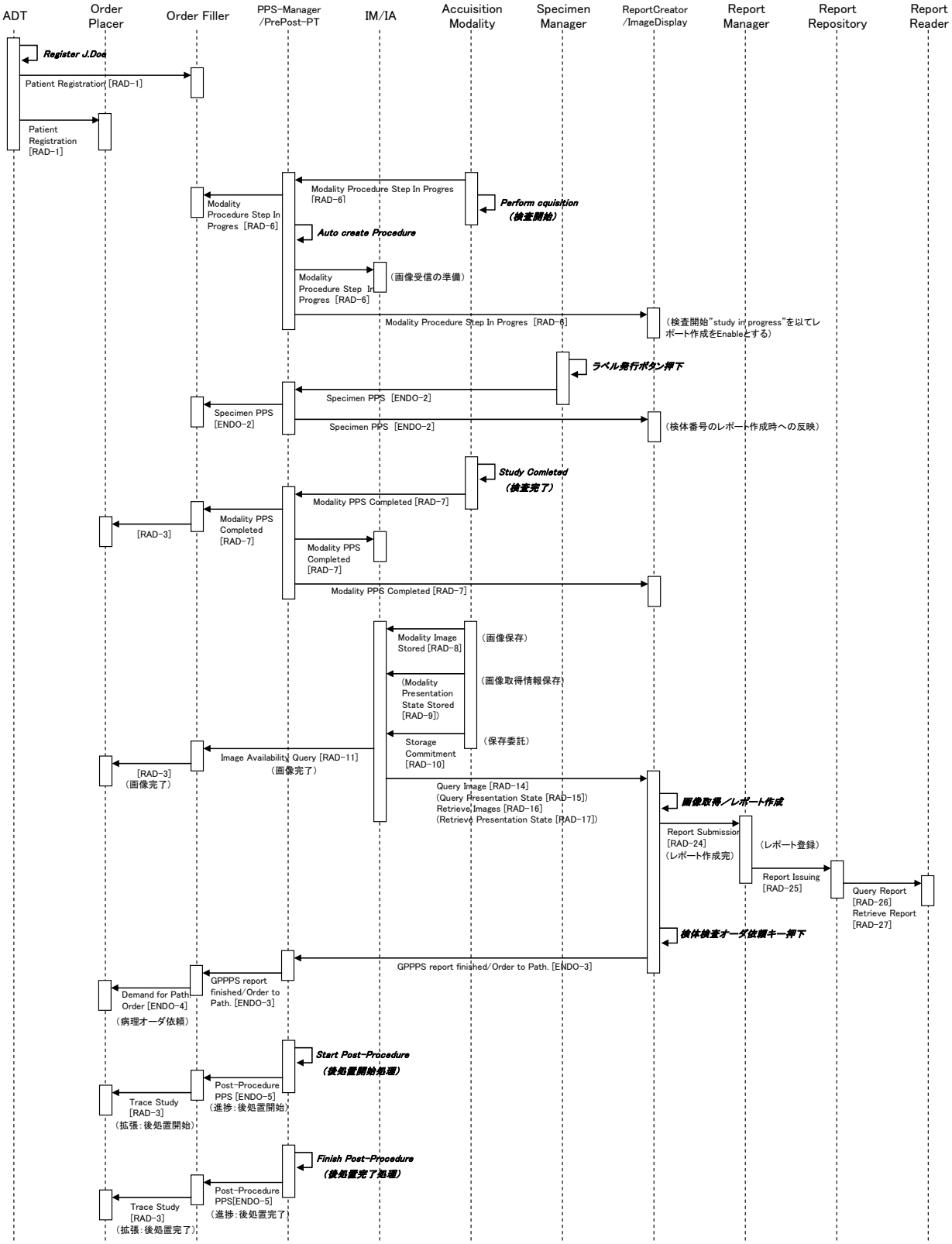

Figure B5.4-6. Patient Registered at ADT and Procedure Not Ordered – Case C3

Significant Transactions:

- From the first acquisition modality's perspective, the difference between this and cases C1 and C2 is that the MWL query (not shown) will not return a response for the current patient. An unscheduled Performed Procedure Step will need to be created.
- On receiving a Modality Procedure Step In-progress [ENDO-1], the Department System Scheduler/Order Filler recognizes it as an unscheduled case, but can match the Patient ID to ADT information previously received.
- Using the information from the MPPS transaction, which includes the patient ID and the modality station AE Title, the DSS/OF creates a new Requested Procedure, and also creates Scheduled Procedure Steps for all the modalities in that same endo lab to reflect the current active case. Note that since the patient is registered, the DSS/OF will have received the demographics associated with the patient ID.
- The Department System Scheduler/Order Filler sends a Filler Order Management (New Order) transaction [RAD-3] to the Order Placer, then a Filler Order Management (Status Update) indicating the in-progress state, and sends a Procedure Scheduled transaction [RAD-4] to the Image Manager.
- Subsequent Modality Worklist queries [RAD-5] from equipment in this endo lab will receive the appropriate scheduled procedure steps including the necessary patient/study identifiers.
- The identifier is generated from the actions of the procedural modality. Therefore, the pre-procedure processes are omitted in the system flow.

B.5.4.4 Case C4: Patient Registered at DSS/OF and Procedure Ordered

Clinical Context: This is a variation of Case C2 where the order is being placed in the department. This accommodates the emergency case when there is not enough time to register the patient in the hospital system, or the event that the ADT system is unavailable (e.g., after hours). In this scenario, however, the patient identifier is not available from the hospital ADT. A temporary patient identifier is created at the department level, and the procedure information can be entered. The Order Placer system cannot be notified yet (while the patient ID is still temporary). At some later time, the registration will occur at the ADT system, at which time the reconciliation with the temporary patient ID can happen (manually at the department system). The Order Placer system can then also be notified.

IHE Context: In this case, no valid Patient ID is available to the Department System Scheduler/Order Filler from the ADT system. The DSS/OF assigns a temporary Patient ID and a temporary name and schedules the required procedure. The scheduled procedure with the temporary Patient ID is conveyed to the Image Manager.

Note: The Department System Scheduler/Order Filler must ensure that the assigned temporary Patient ID is unique within its scope.

However, unlike case C2, the DSS/OF does not send the Filler Order Management (New Order) transaction to the Order Placer when the Requested Procedure is created, since the temporary Patient ID is out of the ADT domain scope of the Order Placer. Similarly, a Filler Order Management - Status Update transaction is not sent based on the first MPPS In Progress.

Procedure performance at the modalities proceeds as normal based on Modality Worklist.

When patient information becomes known, the ADT system sends new patient information to both the Order Placer and the Department System Scheduler/Order Filler. The Department System Scheduler/Order Filler (typically using a manual process) reconciles received patient information with that associated with the temporary Patient ID and merges the permanent patient record with its own temporary one and sends a Patient Update transaction to the Image Manager. At the same time, the Department System Scheduler/Order Filler generates and submits an order to the Order Placer using the permanent Patient ID, notifies the Order Placer that the order is completed, and updates the Image Manager with the Order Placer Number for the order.

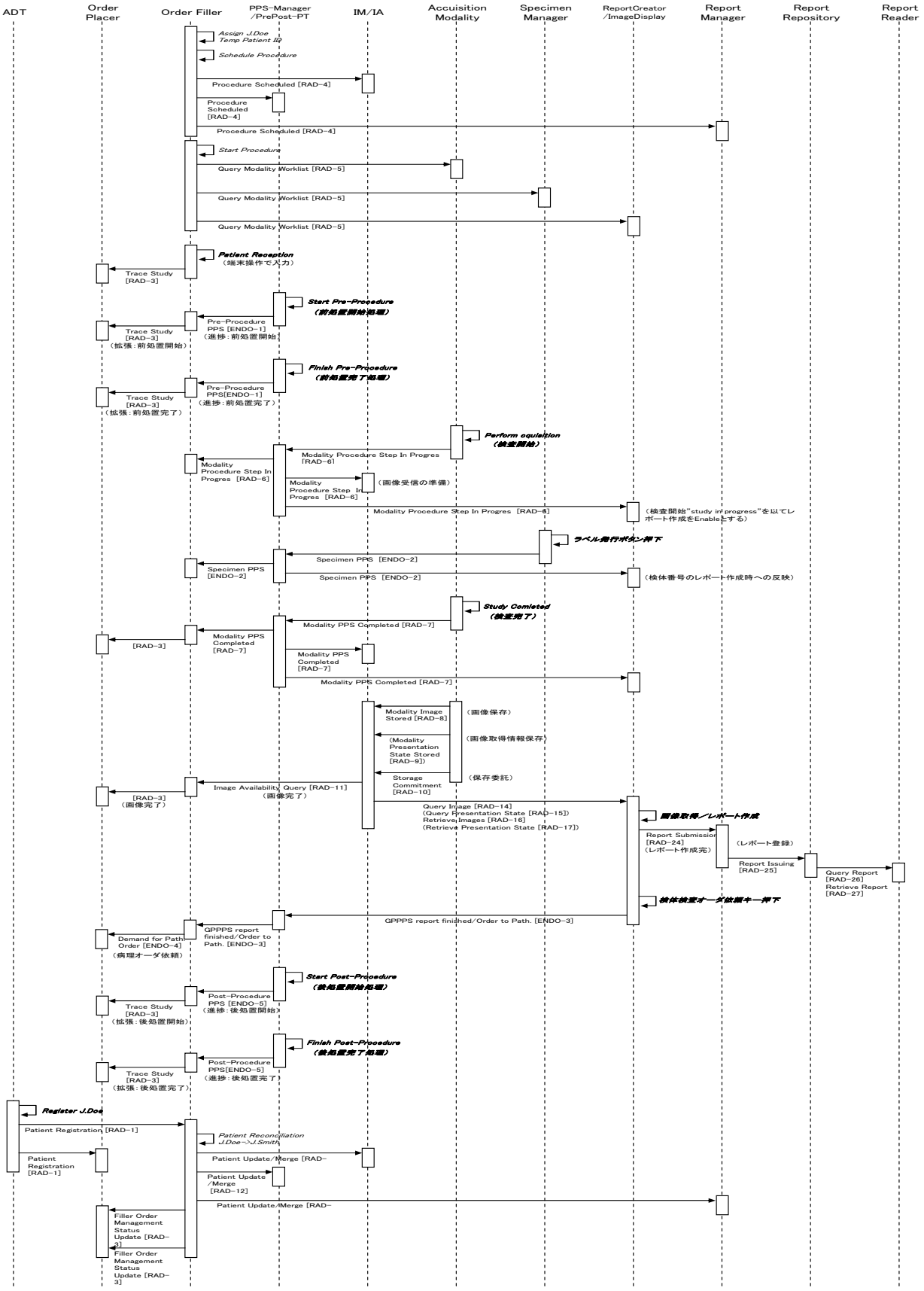

Figure B5.4-7. Patient Registered at DSS/OF and Procedure Ordered – Case C4

Significant Transactions:

- Patient information is reconciled internally by the Department System Scheduler/Order Filler using the Patient Registration from ADT.
- The Department System Scheduler/Order Filler sends the Patient Update [RAD-12], and Procedure Update [RAD-13] transactions to the Image Manager.
- The Department System Scheduler/Order Filler sends the Filler Order Management (New Order and Status Update) transactions [RAD-3] to the Order Placer.

B.5.4.5 Case C5: Patient Not Registered

Clinical Context: This is a combination of Cases C3 and C4 (above). In this case, the patient has not been registered in the ADT system *and* there is no order placed ahead of time in either the Order Placer system or the departmental system. This can occur in an emergency situation where there is either no patient information available or there is not enough time available to create it. It might also occur in the less emergent setting where the ADT or other key component of the HIS is unavailable. All of the activities of Cases C3 and C4 need to take place. A temporary patient ID assigned by the department is entered at the first modality to start the procedure; that modality forwards the patient and procedure information to the departmental system for sharing with the other modalities. This procedure information cannot be sent yet to the Order Placer system. When a valid identifier is available from the ADT, the departmental system can complete the process of reconciling the patient IDs and notifying the Order Placer system.

IHE Context: In this case, no valid Patient ID is available to the Department System Scheduler/Order Filler from the ADT system, and no ordering or scheduling is done before the procedure is performed. A temporary ID and name are entered at the Modality (not from a patient wristband, since that would be a valid ADT system Patient ID, and is covered in case C3). The Patient ID and name are selected according to the locally defined rules; for example, selected from the predefined pool of “Patient ID–patient name” pairs. The rules for selecting temporary Patient ID shall guarantee its uniqueness within the scope of Department System Scheduler/Order Filler.

As in case C3, it is essential for all devices to use a common set of identifiers for the patient and study. Therefore, upon receiving the first Modality Procedure Step In Progress, the DSS/OF will automatically create a Requested Procedure for the endoscopy, and its associated Scheduled Procedure Steps for all modalities in the same endo lab (room), utilizing the Study UID provided by the first Modality Procedure Step In Progress. The other modalities in that lab can then obtain coordinated identifiers using the Query Modality Worklist transaction.

Note: See note on time delay between the Modality Procedure Step In Progress transaction from the first modality, and the availability of SPSs in the Modality Worklist in Appendix B.

The DSS/OF sends a Procedure Scheduled message to the Image Manager. However, as in case C4, the DSS/OF does not send the Filler Order Management (New Order) transaction to the Order Placer when the Requested Procedure is created, since the temporary Patient ID is out of the ADT domain scope of the Order Placer.

Note: The difference from the Radiology TF is that the DSS/OF creation of a Requested Procedure occurs automatically upon receipt of the MPPS In Progress (N-CREATE) message, not after manual reconciliation following the MPPS Completed message; this

allows multi-modality synchronization to the same Requested Procedure. Since the Requested Procedure and (temporary) Patient identifiers are known, the Image Manager can be notified of a Procedure Scheduled.

When patient information becomes known, the ADT system sends new patient information to both the Order Placer and the Department System Scheduler/Order Filler. As in case C4, the Department System Scheduler/Order Filler (typically using a manual process) reconciles received patient information with that associated with the temporary Patient ID and merges the permanent patient record with its own temporary one and sends a Patient Update transaction to the Image Manager. At the same time, the Department System Scheduler/Order Filler generates and submits an order to the Order Placer using the permanent Patient ID, notifies the Order Placer that the order is completed, and updates the Image Manager with the Order Placer Number for the order.

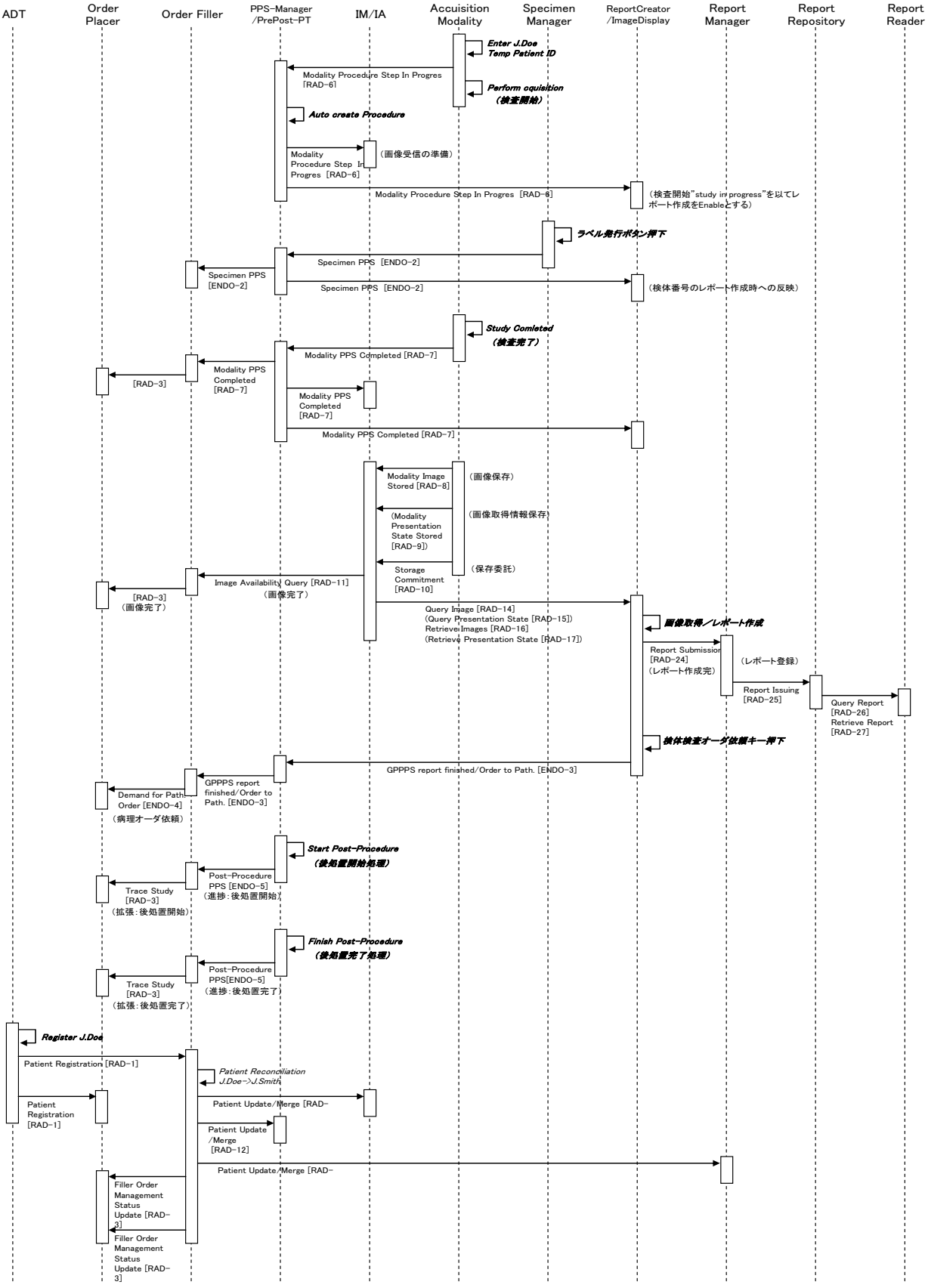

Figure B5.4-8. Patient Not Registered – Case C5

Significant Transactions:

- From the first acquisition modality's perspective, the difference between this and case C3 is that the MWL query (not shown) will not return a response for the current patient, and there is no ADT system-issued Patient ID. An unscheduled Performed Procedure Step will need to be created with a locally created Patient ID.
- On receiving a Modality Procedure Step In-Progress [ENDO-1] transaction, the Department System Scheduler/Order Filler recognizes it as an unscheduled case, and in contrast to case C3, cannot match the Patient ID to ADT information previously received.
- Using the information from the MPPS transaction, which includes the temporary patient ID and the modality station name, the DSS/Order Filler creates a new Requested Procedure, and also creates Scheduled Procedure Steps for all the modalities in that same endo lab to reflect the current active case. It sends a Procedure Scheduled [RAD-4] to the Image Manager.
- Patient information is reconciled internally by the Department System Scheduler/Order Filler using the Patient Registration from the ADT.
- The Department System Scheduler/Order Filler sends a Patient Update/Merge transaction [RAD-12] to the Image Manager.
- The Department System Scheduler/Order Filler sends Filler Order Management (New Order and Status Update) transactions [RAD-3] to the Order Placer.
- Using the information from the placed order, the Department System Scheduler/Order Filler sends a Procedure Update [RAD-13] transaction to the Image Manager containing the new official Order Placer number.

B.5.4.6 Case C6: Patient Updated During Procedure

Clinical Context: An unidentified patient may be registered at the ADT system and brought into the endo lab with temporary patient demographics. While the procedure is in progress, the ADT system is able to obtain the correct patient demographics, and sends an update message. In this situation, some of the information may be obtained with the original (temporary) patient demographics, and some with the revised demographics. This case identifies how reconciliation occurs.

IHE Context: Updates may need to occur after the initial Patient Registration and Order Placement has occurred. The Modality may have requested information from the Department System Scheduler before the update has occurred and continue to send the images with the original Patient Registration and Order information. The Image Manager will need to update the patient information in items stored in the Image Archive, as well as items that it may continue to receive from the modalities.

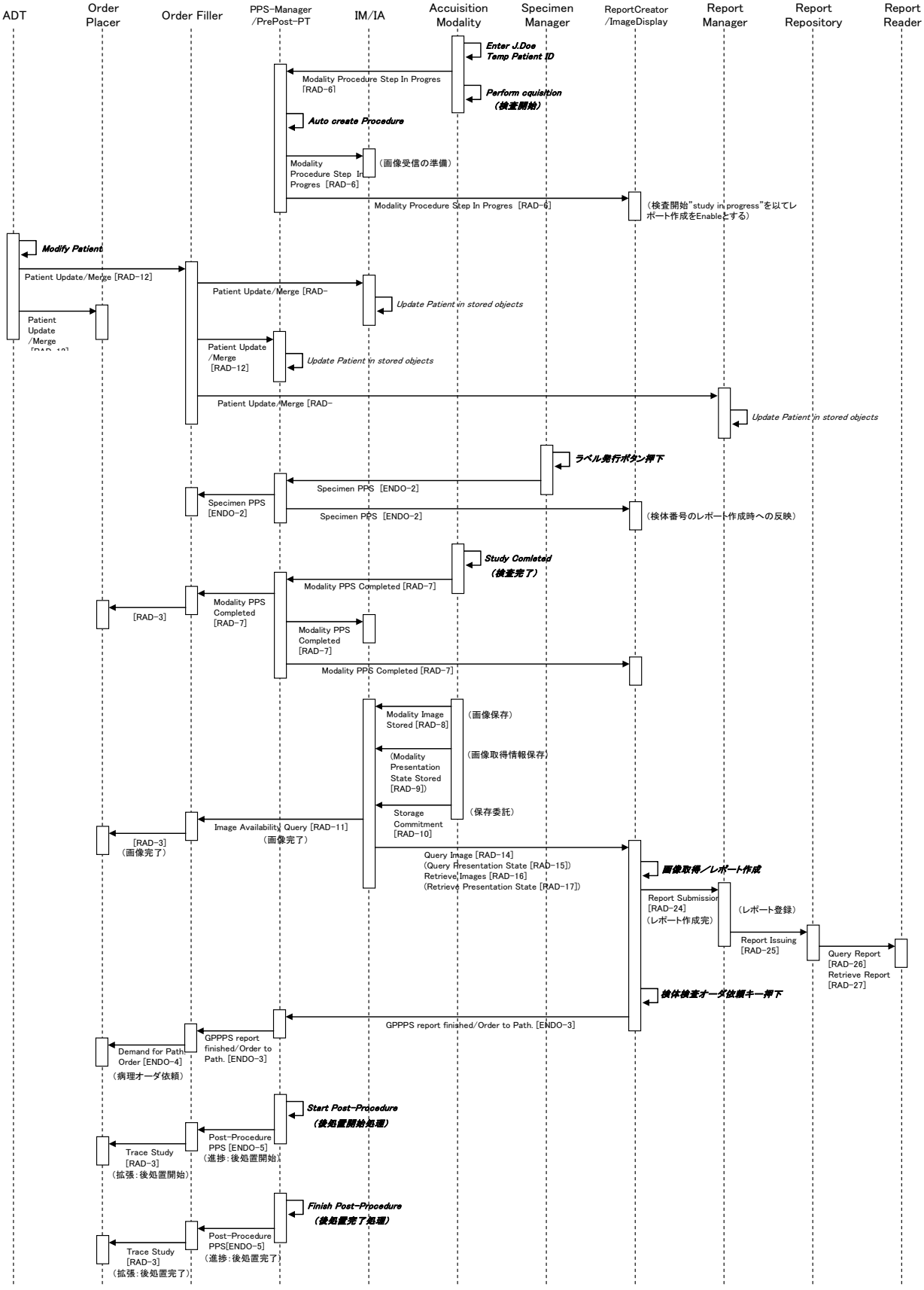

Figure B5.4-9. Patient Updated during procedure – Case C6

Significant Transactions:

- The Modality may continue to send information using the original patient information even after the patient update has occurred.
- The Image Manager must continue to reconcile Patient Information even after the Patient Update transaction has been completed.

Only partial transactions are shown. Other transactions are performed according to the other profile use case requirements.

B.5.4.7 Case C7: No Pathology Order due to the Lack of Biopsy Specimens

Clinical Context: There are cases where no biopsy specimens are collected during the endoscopic procedure. The collection is not decided prior to the procedure but is determined during the procedure and is dependent upon the individual circumstances. Therefore, endoscopy must be performed with an assumed preparation of biopsy specimen collection. However, it is only after the procedure that one can know whether biopsy specimens were collected.

IHE Context: This case describes the process flow in cases where no pathology order was placed because no biopsy specimens were collected during the endoscopic procedure.

The need for specimen collection is determined during the procedure, so preparatory steps for a pathology order should be followed at the beginning of the endoscopic procedure.

In cases where no specimens were collected, biopsy incidence is not recorded by the Specimen Manager and the pathology ordering process is not initiated prior to the completion of the procedure.

Only these two steps in the pathology ordering process are omitted while the rest of the process is the same as in cases where pathology ordering takes place.

Note that there are no corresponding cases in the Radiology Technical Framework.

Only partial transactions are shown. Other transactions are performed according to the other profile use case requirements, in particular.

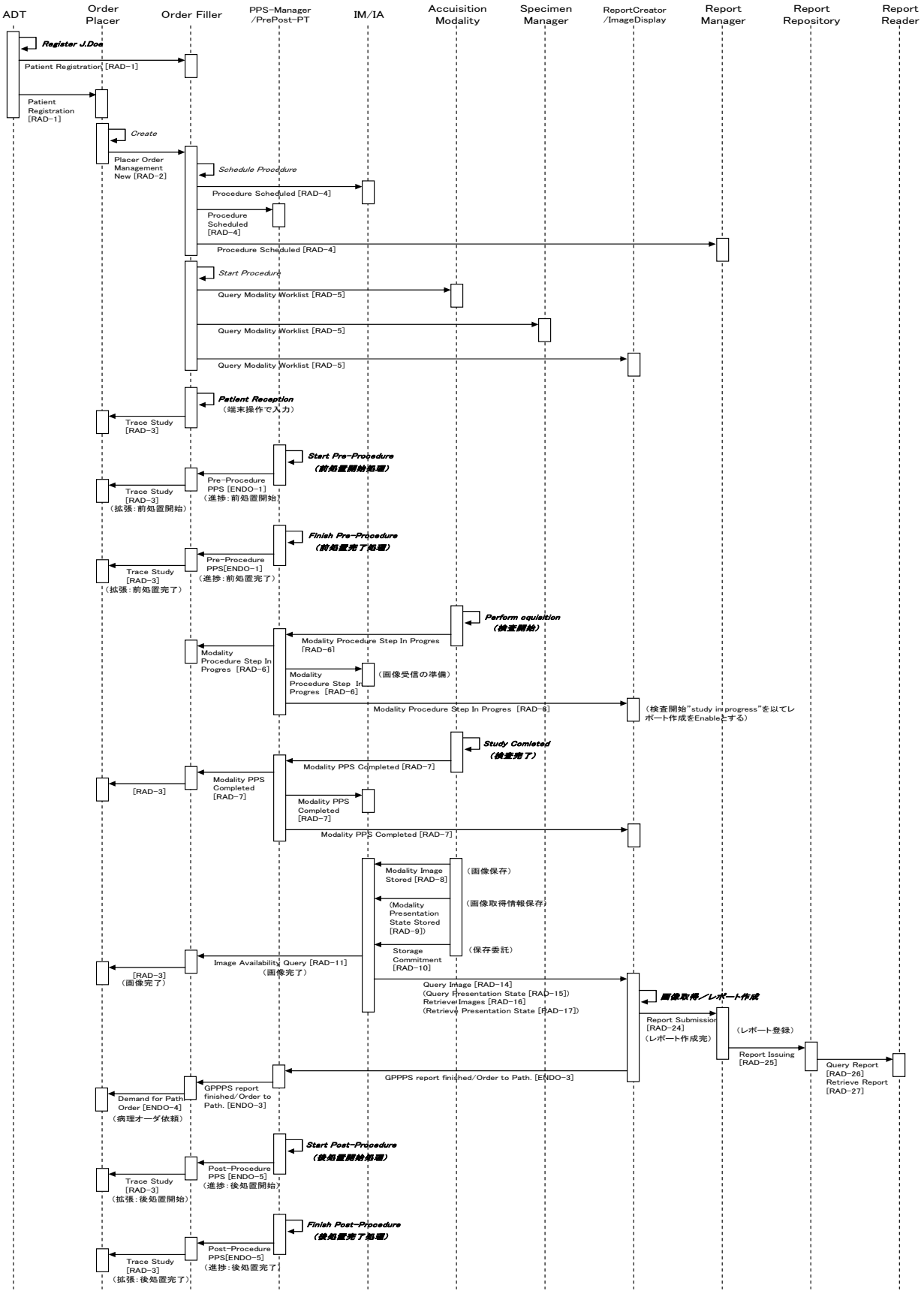

Figure B5.4-10. No Pathology Ordering due to the lack of Biopsy Specimens – Case C7

B.5.4.8 Case C8: Suspension/Cancel Procedure

Clinical Context: When an endoscopic procedure is cancelled, it is important for the information systems to keep track of the cancellation to be able to respond to queries that the endo lab personnel will continue to receive regarding that patient.

IHE Context: This case describes the process flow for canceling an endoscopic procedure prior to its start. The procedure is ordered either by the Order Placer system, or by the DSS/OF, as shown in Figure 3.4-8. The DSS/OF assigns the Requested Procedure ID and Study Instance UID, schedules the procedure, and notifies the Image Manger.

If the procedure is cancelled in the department, the DSS/OF notifies the Order Placer system and the Image Manger. All three systems - DSS/OF, Order Placer, and Image Manger – may maintain information about the cancelled Order and Requested Procedure for an implementation- or institutionally-determined length of time.

It should be noted that the system may manage the progress of the endoscopic pre-procedure process flow because there are cases where the preparation has already been completed by the time the procedure is either suspended or cancelled.

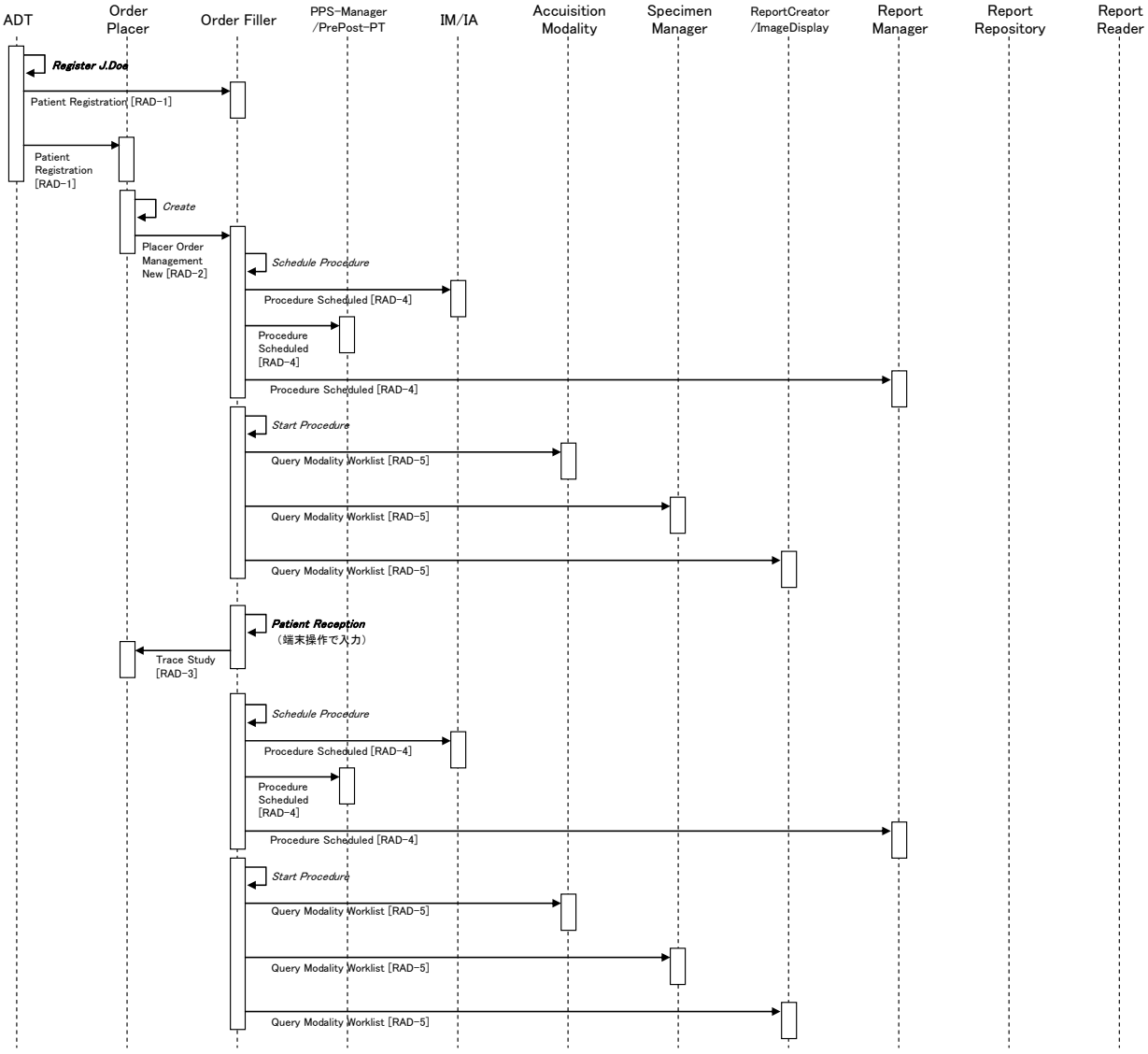

Figure B5.4-11. Suspension/Cancel Procedure – Case C8

B.6 (Appendix. A) Endoscopic Procedure in Perspective

A vast range of devices are categorized as endoscopes, ranging from laparoscopes to capsule endoscopy systems . Some are used as casually as a stethoscope where no reservations are needed while others are used as interventions or occasionally treated as operations. Such applications are so varied that it is impossible to group all their workflows together. In initiating the activity of an IHE-J investigation of endoscopic workflow, we decided to focus on gastrointestinal endoscopy. We believe this subject is effective for the purpose of the IHE because gastrointestinal endoscopy is a routine test and is often operationally independent as a department. The terms “endoscope” or “endoscopy” in this document should be interpreted as “gastrointestinal endoscope” or “gastrointestinal endoscopy” unless otherwise mentioned.

In this appendix, we used the current Radiology Scheduled Workflow (SWF) model to investigate whether the basic IHE concepts can apply to endoscopy. The concepts proposed by the IHE featured HL7 for linking ordering systems and DICOM for imaging systems.

The endoscopy workflow shares part of the radiology workflow steps, including ordering, registration, study (image generation), and reporting. Since the endoscopy procedures are varied, we chose an outpatient upper gastrointestinal endoscopy case as a model scenario.

B.6.1 Characteristics of the Endoscopy Workflow

B.6.1.1 Positioning of Endoscopy

In radiology world, the scope of the procedure is from ordering to image capture. Image study and generating report are independent outside framework. However, in endoscopy, generating report should be the scope of endoscopy procedure. The differences are shown as the differences in captured information, managed information and detail data structures in the workflow. For instance, status information of the pre/post-procedure and pathology order relating information including order would be done or not.

As mentioned in the previous section, endoscopy is performed by physicians and the findings are recorded either during or immediately after the procedure. It is a medical procedure rather than a study. It is a traditional medical practice for various procedures to be performed under a physician’s direction. Consequently, the endoscopic procedure presents significant mismatches in the conventional framework of the ordering and departmental systems under which the procedure is performed upon receipt of an order. This discrepancy is defined more specifically by a summary of differences between the orders placed through the ordering system and clinical practice at Chiba University Hospital. The percentage of discrepancies between order and practice observed for one month in June 2004 was 1.2% for radiology and 48.4% for endoscopy. This figure may be considerably biased because the number of routine endoscopic studies is lower at the university hospital than in general practice. It is sufficient to show how frequently the procedure changes in endoscopy. The radiology study type where the procedure was most frequently changed was angiography (26.8%). Similar to endoscopy, angiography is often used for as a treatment procedure in which the steps are modified as required by patient status.

Possible causes for changing procedures in endoscopy include the following: necessity of the pre-procedure treatment, including sedation, analgesia, and suppression of tract movement; necessity of the post-procedure treatment related to the pretreatment; and requirement of biopsy sample collection and the order for pathological study.

Taking the above facts into consideration, we are proposing the detailed management of the endoscopy scheduled workflow (SWF), including both pre- and post-procedure treatments. As to the materials (i.e., agents and medical devices) used in their respective phases, we excluded the relationships of both orders and accompanying performance records from the scope of this Endoscopy SWF investigation. We have not prepared the idea of comprehensive workflow to overcome the variety of procurement methods (i.e., hospital logistics) that depend on the particular institution.

B.6.2 Differences in Image Position between Endoscopy and Radiology

Endoscopic images differ greatly in meaning from radiological images. Generally, radiological images are captured by technologists for presentation to physicians for diagnostic interpretation. Radiological images are therefore tools for diagnosis. On the other hand, endoscopic images are captured and saved by physicians, but are not necessarily used later for diagnosis, because in most cases, diagnosis is performed while the images are being captured. In endoscopy, the motion images during the endoscopic procedure are used for diagnosis. In this sense, the still endoscopic images may be comparable to the key images in radiology because they both provide images that are relevant to diagnosis. Endoscopic images are regards as memorandum rather than diagnosis objects.

It is only in recent years that the endoscopy system came to be equipped with an image saving function. Since the classic models do not necessarily provide that function, endoscopy does not enjoy a satisfactory digital image storage environment. This situation is also a result of a lack of incentives that are equivalent to the addition of digital storage in radiology to the reimbursement system. Some people do not feel obliged to store endoscopic images. However, the present tendency is to store as much medical data as possible, and therefore, we will not discuss storage obligation.

Most of the endoscopic images are secondary captured images with a VGA-level resolution. Since they are not considered useful for diagnosis, an irreversible, “lossy” compression storage format is acceptable. Under these conditions, still image storage will not be a heavy burden for the present capacity of PACS memory. The future increase in memory capacity will enable network storage of endoscopic movie images that are presently stored locally in many institutions.

B.6.3 Positioning of the Endoscopic Report

Similar to endoscopic images, endoscopy reports differ significantly from those of radiology. In radiology, reporting is required only after the images are generated, while in endoscopy, reporting is required upon completion of the procedure. Reporting is an obligation in endoscopy regardless of whether images are generated or whether the procedure is successful. When endoscopy is considered a medical procedure, reporting is necessary because all medical procedures require recording. Nevertheless, an endoscopic report should not be regarded in the same way as a

radiology report, which records the findings from the acquired images, but should rather be regarded as a record of the medical procedure that happens to be accompanied by images. The IHE-J ENDO Workgroup integrated, therefore, the reporting workflow into the Endoscopy SWF. Considering the other IHE technical frameworks, we expect that there may be different views, but for clarification, we added an explanation in the Endoscopy SWF that the workflow includes the reporting step.

Especially the large hospitals where endoscoic procedures are concurrently done have plural procedure rooms. In the case, usually reporting terminals are set in each procedure room with modality. Physicians usually generate procedure report just after the procedure. In radiology, image capturing process and report generating process are independent. Readers are expected to understand the difference. Also please be noticed that because of the difference, the positioning of the Report relating actors (e.g. Report Manager).

For reporting gastrointestinal endoscopy, the Minimal Standard Terminology (MST) is proposed by the World Organization of Digestive Endoscopy. This glossary is edited so that various ranges of information on gastrointestinal endoscopic procedures can be recorded in a structured form. It is translated into approximately ten different languages, including Japanese, and is recommended by the Japan Gastrointestinal Endoscopy Society for use in writing endoscopic reports. It might be out of the IHE framework to make such a terminological issue, but the standardization will be far more effective if the information describing the method as well as the procedural flow is standardized. The MST is practical for the development of an ordering system because it includes a useful terminology table that provides the reason for the test. Reporting systems that use a standard glossary should be constructed with utmost care because it will not be user-friendly unless medical concepts, entering policies, and test policies are both universal and optimal. Both the healthcare professionals and vendors should unequivocally consider using the MST.

In this document, the scope of the procedure start in ordering and end in generating procedure report, not image capturing, that is usual in radiology. In endoscopy, generating report are required as end of the procedure, on the other hand image capturing is not mandatorily required. (Of course, in practice, images are usually taken. However, point is, physician diagnose with motion picture. He can diagnose without still images. Also imagine utilizing fiber scope that has no image capturing function.) In general, the report is generated just after the procedure in the procedure room, therefore, the characteristics of endoscopy report relating functions are similar to that of acquisition modality or specimen manager, report creator generates report.

B.6.4 The Pre/Post-Procedure Management

Endoscopy procedure workflow contains pre-procedure and post-procedure. The workflow does not always include modality, rather contains a lot of manual process. Therefore, manual data entry is required to manage pre/post-procedure.

This function should be realized as implementation of e-PPS Manager. E-PPS Manager handles pre/post-procedure relating data as a part of endoscopy procedure.

In the discussion if e-PPS manager is defined as an actor in this document, we concluded to define it as an independent actor explicitly in ENDO workflow, because recent medical environment starts including PDA terminal to enter various pre/procedure relating data where multi vendor devices may be used and they may require interoperability.

B.6.5 The difference in Upper GI Endoscopy and Lower GI Endoscopy

The ENDO workflow represents GI endoscopy that includes both upper and lower GI endoscopy.

We carefully analyzed both upper and lower GI endoscopy procedure if any differences or similarity and concluded some differences exist in specific medicine for organ cleaning, but no differences as workflow. Therefore, we define one GI endoscopy workflow that include both upper and lower GI endoscopy.

The ENDO workflow also include ERCP (endoscopic retrograde cholangio-pancreatography) where doctors use contrast medium with thin tube through endoscope. Doctors use both endoscope and radiology devices. In the case, concept is to adapt existing radiology IHE workflow for radiology part and ENDO workflow for endoscopy part. This approach does not always reflect insurance charging mechanism (especially in Japan), however, we concluded to adopt this approach to simplify the workflow rather than defining independent ERCP workflow. If local insurance system does not match the workflow, the insurance charging process should be separately studied in national extension.

B.6.6 Biopsy Orders for the Pathology Department

B.6.7 The posisioning of the Pathology Order

The endo lab must forward a request to the pathology department so that biopsy specimens are sent to the pathology department for study. The requesting form should contain information found in the above-mentioned report. In the Cardiac Catheterization Workflow (CATH), which is considered similar to the ENDO workflow, the relationship to the pathology study is not discussed. Therefore, this relationship comprises an essential part of endoscopy management, albeit a new addition to past IHE workflows.

The steps needed for collaboration with the pathology department are as follows:

- Allocate a specimen number to each biopsy specimen.
- Record the original site of the specimen in the report
- Request the Order Placer to place a Pathology Order, including information on specimen collection.
- Record in the Pathology Department System information stating that this pathology study was ordered by endoscopy and generate a pathology report that corresponds to the specimen number.

The above steps enable a link between the endoscopy report and the relevant pathology report, in addition to a record of this linking information for referencing the endoscopic and pathological findings for future correspondence. The department systems at present function only within the department; the reports generated from these systems will be able to be used interdisciplinarily by

this change. However, a departmental system with an external ordering function for another department is not universally available at present. Considerable revision may be required for both the ordering and departmental systems to implement this functionality. Inter-operability of this system will be one of the most demanded functions in the future since each system would be able to fulfill significant functions independently.

B.6.8 Requirement of Pathology Order

Order number and specimen number shall be unique in pathology order.

In general, hospital IT system has a mechanism to generate unique order ID number. It is recommended that the mechanism is also used for pathology order.

In this document, all the order is considered to be done by Order Placer to describe the model as simple as possible. However, it is not a requirement to have only single Order Placer in one facility. Order Placer should be set center of the system or each department may have Order Placer. It should be an implementation matter.

The point is generating unique order ID number for pathology order, not a location of Order Placer. Even in the case to implement Order Placer in endoscopy department system, it is significant to utilize hospital wide mechanism of generating unique order ID number.

It is understood that the requirement of unique order ID number for specimen is implementation matter and this document does not define the mechanism of generating unique specimen ID number. Usually in Japan, specimen number is generated in pathology department. There is no hospital wide unique specimen ID number generating system that can be used both endoscopy and pathology department. Even though, uniqueness requirement is applicable. The pathology department can generate unique ID utilizing both unique order number and its own number.

Here in this document, requirement for specimen number is simply to be unique. We will not describe the hospital wide mechanism of generating unique specimen number so pathology department may generate the number.

Example;

Specimen ID number = Endoscopy Order number + branch number

Specimen ID number = Endoscopy Order number + Endoscopy specific serial number

Specimen ID number = Endoscopy Order number + branch number & Endoscopy specific serial number

B.6.9 Pathology Order Mechanism

As described above, all the order should be done by Order Placer. The trigger of the order placing is that Order Placer notices the status of Order Filler, in stead of Order Filler send Filler Order message to Order Placer. If Order Filler has a status of existence of specimen and the completion of procedure report, it is regarded as trigger.

e-PPS manager watches the status of the Specimen Manager and the Report Creator to notice the status change to the Order Filler. Once Order Filler finds the status change, Order Filler notices the

status of existence of pathology order to Order Placer. The Order placer places pathology order with necessary information based on the notification from the Order Filler.

B.6.9.1 The positioning of Specimen Manager and Label Printer

In this document, the requirement of Specimen manager is regarded same to that of Acquisition Modality from simplification point of view. There is a similarity that both of Acquisition Modality and Specimen Manager proceeds same procedure based on same procedure work list. Only difference is that Acquisition Modality generates images, on the other hand, Specimen Manager generates specimen label through Label Printer. Therefore, they work on same model that something is generated from a device based on work list during procedure.

The numbering of specimen ID has already stated above. As for image ID, it is understood that DICOM rule is applied and unique ID number is expected for each image. Same concept is expected for the numbering of specimen label ID.

Of course if physician take no specimen in the procedure, no specimen label is generated by Specimen Manager even Acquisition Modality generates image ID. It is no problem because the Specimen Manager and the Acquisition Modality generate their output independently.

B.7 (Appendix. B) Challenges of Workflow Management in Endoscopy

B.7.1 Clinical Context: Diagnostic and Interventional Procedures

In Radiology, clinicians order very specific studies after evaluation of the patient's history, physical findings, and the results of other studies. However, requests for endoscopy are handled clinically in a very different fashion. The referring clinician typically requests an endoscopist consultation (or perhaps a more specific intervention consultation). The exact procedure(s) to be performed are generally selected in the endo laboratory itself, as the initial information is gathered. Clinical activities are selected as deemed appropriate by the performing physician. Moreover, unlike Radiology, the selected activities ("protocols") are more clinically oriented, as opposed to being modality oriented.

For logistical and administrative purposes, procedures are divided somewhat arbitrarily into "Diagnostic" and "Interventional", despite the fact that the demarcation line between the two categories may be indistinct. It is rare, however, that an ordering physician would make the distinction ahead of time and specifically order one or the other, except in the case of an order for interventional follow-up to a diagnostic exam (e.g., due to resource limitations at the time of the diagnostic exam).

B.7.2 Organizing the Workflow: Requested Procedures and Procedure Steps

In the past (pre-IHE), a common (but not universal) practice in the cath lab has been to create a new DICOM Study for the x-ray angiography (XA) data when the activities move from Diagnostic to Interventional. This is indicative of an administrative desire to identify a distinction between those two phases in a cath procedure. This is a less than ideal method, but in that environment the only available "hammer" for that "nail" was the DICOM XA Study.

Similarly in endoscopy, activities may move from diagnostic to interventional. Although the distinction between these two phases is easily made, it is not necessary.

However, IHE provides several tools for managing the workflow and organizing the data, principally the Requested Procedures, Scheduled Procedure Steps (SPS), and Performed Procedure Steps (PPS). Moreover, IHE address the full multi-modality context of the endo lab, not just XA. This section describes the required use of these IHE constructs.

The SPS and PPS are the smallest units of the workflow that are scheduled or performed, whose status is tracked, and that are associated with protocolsAs described in B.1 above, there are protocols that represent the clinical activities of the endo procedure.

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.

B.7.3 Multi-Modality and *Ad Hoc* Scheduling

The endoscopic lab is inherently a single modality and is rarely a multiple modality (e.g., hemodynamics, x-ray, IVUS, etc.). Therefore, our Technical Framework does not propose a workflow that involves multiple modalities.

A multi-modality lab is 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 endo lab, thereby eliminating data entry errors. 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.

The Department System Scheduler/ Order Filler (DSS/OF) is responsible for procedure scheduling. In the multi-modality endo 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.

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.

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

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 measured in seconds or minutes, not hours. In the endo 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 Endoscopy Technical Framework does not deal with reconciliation of multiple Study Instance UIDs.

B.7.3.1 Unscheduled Case

The need for consistent patient and Requested Procedure identifiers is just as important, if not more so, in the Unscheduled Case, where there is no available Requested Procedure to be shared across the multiple modalities (see endo use cases C3 and C5).

The Technical Framework requires that the *Multi-Modality Procedure Update* function of the DSS/OF also includes an automatic creation of a Requested Procedure if the MPPS from the selector modality is unscheduled. Creation of this Requested Procedure is a necessary prerequisite for the creation of the SPSs for all modalities in the lab.

As noted above, the Requested Procedure generally represents the unspecialized "Endoscopic Consultation". It is possible, therefore, to have a default Procedure type (code and/or description) that may be used to auto-create the Requested Procedure. The DSS/OF may also be able to select an appropriate Procedure type from a set, based on attributes such as protocol in the received MPPS.

This approach differs somewhat from the approach in the Radiology Technical Framework. RAD-TF 2: 4.6.4.1.3 states:

> If the Requested Procedure ID is transmitted empty (Unscheduled Performed Procedure Step case), the Department System Scheduler/Order Filler and the Image Manager shall **create an exception** that must be **manually** resolved to link the Performed Procedure Step to the appropriate procedure.

The Radiology Technical Framework intent is to force eventual reconciliation to associate the PPS with an appropriate Requested Procedure.

The fact that the Endoscopy Technical Framework uses this condition as a trigger for the DSS/OF to **automatically** create a Requested Procedure (and the multi-modality Scheduled Procedure Steps) contradicts the **letter** of the radiology framework (i.e., manual reconciliation), but **not the intent** (i.e., reconciliation of the unscheduled PPS with a Requested Procedure).

It is the opinion of the Endoscopy Technical Committee that the difference in approach between Radiology and Endoscopy Technical Frameworks does not represent a significant deviation in required or intended usage of the MPPS In Progress transaction, and that the *Multi-Modality Procedure Update* option sufficiently characterizes the necessary functionality.

B.7.4 Modality Procedure Step Complete/Discontinue

This Technical Framework requires each modality in the multi-modality end lab to individually select an SPS from the Modality Worklist to start its PPS/acquisition. Likewise, each modality must complete or discontinue any PPSs it has started.

The same functionality that facilitates single patient selection for all modalities, also facilitates *incorrect* single patient selection. If the patient selection is incorrect on the initial piece of equipment, the patient will be incorrect on all the modalities in the end lab that have used SPSs based on that initial selection. It is then crucial to "discontinue" that patient on all endo modalities, thereby reducing misidentification errors.

B.7.5 Start and End Procedures

The ENDO Workflow Profile focuses on the workflow within the lab itself. However, given the interventional nature of endoscopy, this Profile cannot ignore the immediate pre- and post-endoscopy activities that occur within the endo lab *suite*. The endo lab environment poses challenges due to its multi-modality nature discussed above, but also to its multi-*location* nature – a

single endo procedure may transition across as many as three different rooms, each with its own equipment (a procedure preparation area, a diagnostic/interventional lab, and a recovery holding area).

Pre-endo activities can include gathering critical lab information in advance, verifying the existence of all blood analysis and other results necessary prior to beginning an endo procedure, lab set up, notification of patient arrival, discussions with and signatures from patient, etc. Post-procedure activities include monitoring the patient for adverse events, completing the exams on all equipment, cleaning the room, canceling procedure steps which were not actually completed, etc. The ENDO Workflow Profile cannot account for all of these activities, but does recognize that they exist.

For that reason there may be an optional “Start Procedure” function on the DSS/OF for the ENDO Workflow. Specifically, the Start Procedure function can provide the advantages of:

- Registering patient arrival to set the status (0040,0020) in the associated SPSs
- Using patient arrival status to reduce the worklist for broad queries provided to the labs (when an individual room/suite assignment has not been made)
- Ensuring that all pre-procedure information which is gathered will be accurately combined with the procedure information from the lab
- Specify the lab/suite where the procedure will take place, which in turn, may simplify the selection the same patient on all equipment within a suite (a potential patient safety feature)

The corresponding optional “End Procedure” function on the DSS/OF can provide the advantages of :

- Verify the exam was manually completed on each piece of equipment.
- Cancel all SPSs for the Requested Procedure which, in turn, may help signify that the room is no longer occupied (and even possibly indicate ready for cleaning or other post-procedure activities)
- Trigger sending an Order Status Update message to the Order Placer

For these reasons, the DSS/OF internal Start Procedure and End Procedure functions are included in the Cath Workflow Use Cases, and it is highly recommended that such functionality be supported in DSS/OF implementations.

B.7.6 Grouped Procedures

B.7.6.1 What are Grouped Procedures?

Grouped procedures are not absolutely necessary for endoscopy, but such procedures are described in the IHE Radiology Technical Framework (RAD-TF-1:4.6). The Grouped Procedure case provides a mechanism for facilitating workflow when an operator combines the acquisition steps of two or more separate Requested Procedures, often for the sake of acquisition efficiency and patient comfort. Viewing images and reporting, however, must still be done on the individual Requested Procedures. Through the Grouped Procedure, a single acquired image set (Study) is produced, but

the workflow transactions allow separate viewing and interpretation of the image subsets related to each of the Requested Procedures.

Grouped procedures in IHE Radiology are confined to a single modality, e.g., CT head and spine. Each Modality Performed Procedure Step (MPPS) is related to multiple Scheduled Procedure Steps (SPSs) and Requested Procedures.

One of the issues with Grouped Procedures is the identification of the Requested Procedures in relation to the "performed Study". DICOM identifies Requested Procedures by Study Instance UID, and typically the images produced are stored under that same Study UID. In the Grouped case, this is not possible, since there are multiple Requested Procedures.

In the classic, single-modality Grouped case, study UIDs are relatively straightforward. Each Requested Procedure (RP) identifies its own Order Filler-specified Study Instance UID. The modality selects the multiple Scheduled Procedure Steps (SPSs) associated with the various RPs. As there are *multiple* RP study UIDs referenced, the modality creates its own "I-Study" Study Instance UID to store the images/evidence associated with the Grouped procedures acquisition (MPPS). Now all the images/evidence associated with the acquisition are contained under the single "I-Study" UID, but this contains references to the multiple RP Study UIDs. (See RAD-TF-2, Appendix A for further description of the Data Model used in Grouped cases.)

B.6.9.2 Why Grouped Case is a Problem with Multimodality Studies?

Endoscopy is a natural candidate for grouped procedures; there are typically multiple procedures which should be billed and reported separately (i.e., the diagnostic and interventional phases of the endoscopy), but which share equipment, and for patient safety and efficiency the procedures are performed together.

However, a multi-modality processing brings complications to the classic grouped procedure approach outlined previously.

In the classic case, each modality creates its own I-Study UID to store the images/evidence it creates in a Grouped case. But I-Study UIDs are (by definition) unique per modality, thus in a multi-modality procedure the images/evidence relating to the procedure would be scattered across multiple I-Study UIDs, one per modality. This negates the workflow benefits associated with all data related to the procedure sharing a common I-Study UID.

B.7.7 The Approach Adopted by IHE Endoscopy

IHE endoscopy generates one report per study.

An additional pathology report is considered separately from the endoscopy report because pathology is an independent department.

However, the co-existence of a general diagnostic report and a report by a special protocol that includes a clinical study should be accepted.

IHE Endoscopy *strongly advises* the use of a ***single Requested Procedure for endoscopy***, even though there may be two reports (diagnostic and interventional) and separate billing resulting from

the procedure. This allows all data for the procedure to be collected under the single Study Instance UID of the Requested Procedure.

There are several supporting arguments for this choice.

First, even in IHE Radiology (in the most recent version), there is not a strict 1:1 correspondence between Requested Procedure and reporting/billing. The classic counter-example is mammography, where the exam will be read independently by two radiologists, who produce two independent reports, but it is still a single Requested Procedure. The production of multiple reports is an internal process of the Reporting Workflow. The endoscopy case can be treated similarly - it is a single Requested Procedure, but the reporting process will produce two documents. (IHE Endoscopy will address reporting and charge posting in subsequent years).

Second, endoscopy is clinically a single procedure - the patient gets on the table once; the procedure log conveys a continuous record of the patient from before entering the endo lab until after leaving it; and the interventional data cannot be interpreted without the diagnostic data. The clinical use of the endo exam data after the procedure similarly needs to be viewed as a whole to provide context for any single item of data. As a result it makes little sense to separate the exam into two Requested Procedures, which then need to be grouped for effective clinical practice.

Third, a single Requested Procedure simplifies the operations for a diagnostic endo that changes to an interventional - with or without a change of rooms. There is no need to worry about modalities (e.g., IVUS) that join the procedure only in the interventional phase having different study information than those that joined at the start of the diagnostic phase.

Even with a single Requested Procedure, it is possible (but optional) for separate MPPSs to be created for data collected by a modality in the diagnostic and interventional phases. These MPPSs can be derived from a single diagnostic/interventional Scheduled Procedure Step for the modality, or from separate diagnostic and interventional SPSs. Conversely, with a single Requested Procedure, if the Order Filler schedules separate diagnostic and interventional SPSs, a modality can fulfill both with a single MPPS (this is not a Grouped Procedure case, since the SPSs are from the same Requested Procedure).

However, an institution can still implement two Requested Procedures, but this would require all the modalities to close out the data acquisition for the diagnostic phase, and start a new interventional study. The Grouped Procedure case thus needs to be forbidden for the multi-modality endo lab use case.

B.8 (Appendix. C) IHE Integration Statements

IHE Integration Statements are documents prepared and published by vendors to describe the intended conformance of their products with the IHE Technical Framework. They identify the specific IHE capabilities a given product is designed to support in terms of the key concepts of IHE: Actors and Integration Profiles (described in Volume I, section 2 of the Technical Framework).

Users familiar with these concepts can use Integration Statements as an aid to determine what level of integration a vendor asserts a product supports with complementary systems and what clinical and operational benefits such integration might provide. Integration Statements are intended to be used in conjunction with statements of conformance to specific standards (e.g. HL7, DICOM, W3C, etc.).

IHE provides a process for vendors to test their implementation of IHE Actors and Integration Profiles. The IHE testing process, culminating in a multi-party interactive testing event called the Connect-a-thon, provides vendors with valuable feedback and provides a baseline indication of the conformance of their implementations. The process is not, however, intended to independently evaluate, or ensure, product compliance. In publishing the results of the Connect-a-thon, and facilitating access to vendors' IHE Integration Statements, IHE and its sponsoring organizations are in no way attesting to the accuracy or validity of any vendor's IHE Integration Statements or any other claims by vendors regarding their products.

IMPORTANT -- PLEASE NOTE: Vendors have sole responsibility for the accuracy and validity of their IHE Integration Statements. Vendors' Integration Statements are made available through IHE simply for consideration by parties seeking information about the integration capabilities of particular products. IHE and its sponsoring organizations have not evaluated or approved any IHE Integration Statement or any related product, and IHE and its sponsoring organizations shall have no liability or responsibility to any party for any claims or damages, whether direct, indirect, incidental or consequential, including but not limited to business interruption and loss of revenue, arising from any use of, or reliance upon, any IHE Integration Statement.

B.8.1 Structure and Content of an IHE Integration Statement

An IHE Integration Statement for a product shall include:

1. The Vendor Name
2. The Product Name (as used in the commercial context) to which the IHE Integration Statement applies.
3. The Product Version to which the IHE Integration Statement applies.
4. A publication date.
5. The following statement:

   "This product is intended to implement all transactions required in the IHE Technical Framework to support the IHE Integration Profiles, Actors and Options listed below:"
6. A list of IHE Integration Profiles supported by the product and, for each Integration Profile, a list of IHE Actors supported. For each integration profile/actor combination

one or more of the options defined in the IHE Technical Framework may also be stated. Profiles, Actors and Options shall use the names defined by the IHE Technical Framework Volume I. (Note: The vendor may also elect to indicate the version number of the Technical Framework referenced for each Integration Profile.)

Note that implementation of the integration profile presumes implementation of all required transactions for an actor; options include optional transactions or optional functions for required transactions.

The statement shall also include references and/or internet links to the following information:

7. The specific internet address (or universal resource locator [URL]) where the vendor's Integration Statements are posted
8. The specific URL where the vendor's standards conformance statements (e.g., HL7, DICOM, etc.) relevant to the IHE transactions implemented by the product are posted.
9. The URL of the IHE Initiative's web page for general information on IHE (www.rsna.org/IHE).

An IHE Integration Statement is not intended to promote or advertise aspects of a product not directly related to its implementation of IHE capabilities.

B.8.2 Format of an IHE Integration Statement

Each Integration Statement shall follow the format shown below. Vendors may add a cover page and any necessary additional information in accordance with their product documentation policies.

IHE Integration Statement			**Date**	12 Oct 2002
Vendor	**Product Name**		**Version**	
Any Medical Systems Co.	IntegrateRAD		V2.5	
This product implements all transactions required in the IHE Technical Framework to support the IHE Integration Profiles, Actors and Options listed below:				
Integration Profiles Implemented	**Actors Implemented**		**OptionsImplemented**	
Scheduled Workflow	Image Manager/Image Archive		none	
	Image Display		none	
	Image Creator		Performed Procedure Step	
	Order Filler		PPS Exception Management	
Simple Image and Numeric Report	Report Creator		none	
Internet address for vendor's IHE information: www.anymedicalsystemsco.com/ihe				
Links to Standards Conformance Statements for the Implementation				
HL7	www.ihe-j.jp			
DICOM	www.anymedicalsystemsco.com/dicom/integrateRAD.pdf			
MFER	ecg.heart.or.jp			
Links to general information on IHE				
In North America: www.ihe.net	In Europe: www.ihe-europe.org	In Japan: www.ihe-j.org		

B.9 (Appendix. D) GLOSSARY

Terms Specific to this Document

Actor: An entity within a use case diagram that can perform an action within a use case diagram. Possible actions are creation or consumption of a message

Evidence Documents: Evidence Documents represent the uninterpreted information that is primarily managed and used inside the imaging department, although distribution outside the imaging department is not precluded. Evidence documents are non-image information and include things such as measurements, CAD results, procedure logs, etc and are to be encoded as DICOM SR documents.

Evidence Objects: All objects generated as a result of performing procedure steps on systems in an imaging department. These objects are used by the reading physician in the process of creating a diagnostic report and are managed inside the imaging Department. Examples of evidence objects include: Images, Presentation States, Key Image Notes and Evidence Documents.

Expected Actions: Actions which should occur as the result of a trigger event

Interaction Diagram: A diagram which depicts data flow and sequencing of events

Process Flow Diagram: A graphical illustration of the flow of processes and interactions among the actors involved in a particular example

Role: The actions of an actor in a use case.

Scope: A brief description of the transaction.

Trigger Event: An event such as the reception of a message or completion of a process, which causes another action to occur.

Use Case: A graphical depiction of the actors and operation of a system.

DICOM Terms

Basic Text SR Storage SOP Class: See DICOM Supplement 23

DICOM Model of the Real World: See DICOM PS 3.3

Enhanced SR Storage SOP Class: See DICOM Supplement 23

Grayscale Softcopy Presentation State Storage SOP Class: See DICOM PS 3.4

Grayscale Standard Display Function: DICOM PS 3.14

Imaging Service Request: See DICOM PS 3.3

Modality: See DICOM PS 3.3

Modality Worklist SOP Class: See DICOM PS 3.4

Modality Performed Procedure Step: See DICOM PS 3.3

Modality Performed Procedure Step Information Module: See DICOM PS 3.3

Modality Performed Procedure Step Relationship Module: See DICOM PS 3.3

Modality Performed Procedure Step SOP Class: See DICOM PS 3.4

N-Event Report: See DICOM PS 3.7

Patient: See DICOM PS 3.3

Patient Identification Module: See DICOM PS 3.3
Print Presentation LUT SOP Class: See DICOM PS 3.4
Procedure Plan: See DICOM PS 3.3
Procedure Type: See DICOM PS 3.3
Protocol Code: See DICOM PS 3.3
Requested Procedure: See DICOM PS 3.3
Requested Procedure Module: See DICOM PS 3.3
Requested Procedure ID: See DICOM PS 3.3
Results Information Object Definition: See DICOM PS 3.3
Scheduled Procedure Step: See DICOM PS 3.3
Scheduled Procedure Step Module: See DICOM PS 3.3
Storage Commitment SOP Class: See DICOM PS 3.4
Structured Reporting Information Object Definitions: See DICOM PS 3.3
Structured Reporting SOP Classes: See DICOM PS 3.4
Structured Reporting Templates: See DICOM PS 3.16
Unique Identifier (UID): See DICOM PS 3.5

HL7 Terms

ADT: See HL7 version 2.5
Filler: See HL7 version 2.5
Observation: See HL7 version 2.5
Placer: See HL7 version 2.5
Universal Service ID: See HL7 version 2.5

Acronyms and Abbreviations

ACC: American College of Cardiology
ASE: American Society of Echocardiography
ECG: Electrocardiogram
ESC: European Society of Cardiology
HIMSS: Healthcare Information and Management Systems Society
HIS: Hospital Information System
ICE: Intracardiac Echocardiography
IHE: Integrating the Healthcare Enterprise
IOD: Information Object Definitions
IT: Information Technology
IVUS: Intravascular Ultrasound
MWL: Modality Worklist
MPPS: Modality Performed Procedure Step

NEMA: National Electrical Manufacturers Association
OID: Object Identifier
PACS: Picture Archive and Communication System
PPS: Performed Procedure Step
RID: Retrieve Information for Display
RIS: Radiology Information System
RSNA: Radiological Society of North America
SCU: Service Class User
SCP: Service Class Provider
SPS: Scheduled Procedure Step
SR: Structured Report
TEE: Transesphogeal Echocardiography
TTE: Transthoracic Echocardiography
UID: Unique Identifier
UUID: Universally Unique Identifier
XA: X-ray Angiography

B.10 (Appendix. E) Security Environment Considerations

IHE compliant systems usually process private healthcare information. This is subject to national privacy regulations, and possibly other state and contractual requirements. The IHE profiles do not fully define the security mechanisms necessary to protect this information. The ITI-TF Audit Trail and Node Authentication (ATNA) Profile provides one component of this solution.

IHE assumes that actors will be installed on nodes with the following characteristics:

- Each node has a security policy and procedure that applies to its operation.
  This is assumed to be part of the healthcare enterprise security policy.
- Any user (human, or application process) external to the node boundaries is submitted to an access control procedure in which the user/application will be authenticated.
- All required audit trail events are captured and recorded.

The profiles in this framework assume the following environment:

- Physical Security Environment
    - The equipment is assumed to be located in a physically protected and actively monitored area. This is normally the case with modality equipment because of other patient safety, privacy, and operational concerns. Similarly, the HIS systems and various archives are normally protected. Equipment like PACS workstations are sometimes placed in unprotected areas, but it is usually located where hospital staff monitors and limit access. It assumes that the threat of equipment modification is protected against by means of the physical security mechanisms.
    - The network equipment that connects the computers is also assumed to be physically protected against unauthorized connections and unauthorized modifications. In the treatment areas of most hospitals the network equipment is in ceilings, cableways, locked cabinets, and other protected areas. There is usually staff present to monitor that no unauthorized activity is taking place.
    - Local procedures and operations will be in place to ensure that the physical security assumptions are valid for other areas of the hospital, such as administrative offices, that may be at greater risk.
    - Remote locations, especially home offices, are not physically protected. Other means will be used to provide equivalent protection. This may include the use of technology such as VPN connections or HTTPS encryption. Use of encryption or VPN is not a complete replacement for physical security but may be part of an overall protection system.
    - The home computer that is used for both personal and professional purposes is difficult to protect. It will be protected from inadvertent modification by malicious software or its use will be prohibited.
- Network Security Environment
    - In addition to the physical security of the network, there will be protection against network access by unsupervised systems. This is typically provided by mechanisms such as firewalls and VPNs.

The threat profile is assumed to be:

- Accidental and inadvertent misuse
- Individual abuse for personal gain, malice, revenge, or curiosity. The abusers are assumed to have only limited access to the underlying systems and software. They are not expert at the internal structure of the systems.
- Random untargeted abuse, such as from an Internet hacker.

The threat profile also assumes that the following threats are either not present or otherwise protected.

- Individual abuse by a system administrator, system developer, or other expert.
- Military or hostile government action
- Organized criminal attack

IHE addresses only those security requirements related to IT systems within the scope of IHE healthcare applications. It does not address security requirements for defending against network attacks, virus infection, etc.

IHE does not mandate the use of encryption because the performance impact of current encryption algorithms is excessive. Most hospital networks provide adequate security through physical and procedural mechanisms. The additional performance penalty for encryption is not justified for these networks. The profiles permit the use of encryption so that it can be used as part of an overall security plan.