Integrating the Healthcare Enterprise

IHE Radiology (RAD)
Technical Framework

Volume 1
IHE RAD TF-1
Integration Profiles

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1   Introduction

This document, Volume 1 of the IHE Radiology (RAD) Technical Framework, describes the clinical use cases, actors, content module, and transaction requirements for the Radiology
430 profiles.

1.1 Introduction to IHE

Integrating the Healthcare Enterprise (IHE) is an international initiative to promote the use of standards to achieve interoperability among health information technology (HIT) systems and effective use of electronic health records (EHRs). IHE provides a forum for care providers, HIT
435 experts and other stakeholders in several clinical and operational domains to reach consensus on standards-based solutions to critical interoperability issues.

The primary output of IHE is system implementation guides, called IHE profiles. IHE publishes each profile through a well-defined process of public review and Trial Implementation and gathers profiles that have reached Final Text status into an IHE Technical Framework, of which
440 this volume is a part.

For general information regarding IHE, refer to www.ihe.net.

1.2 Introduction to IHE Radiology (RAD)

IHE Radiology was formed in 1998 to address issues of interoperability and information sharing that impact the quality of care in medical imaging. It has developed and documented standards-
445 based solutions to these problems and organized testing and education to foster their adoption. IHE solutions are now available in hundreds of commercial radiology-related information systems and are implemented in care sites around the world.

IHE Radiology is sponsored by the Radiological Society of North America.

1.3 Intended Audience

450 The intended audience of IHE Technical Frameworks Volume 1 (Profiles) is:

- Those interested in integrating healthcare information systems and workflows
- IT departments of healthcare institutions
- Technical staff of vendors participating in the IHE initiative

1.4 Prerequisites and Reference Material

455 For more general information regarding IHE, refer to www.ihe.net. It is strongly recommended that, prior to reading this volume, readers familiarize themselves with the concepts defined in the IHE Technical Frameworks General Introduction.

Additional reference material available includes:

1.4.1 Actors

460 Actors are information systems or components of information systems that produce, manage, or act on information associated with operational activities in the enterprise.

For information on actors for all domains and their brief descriptions, see IHE Technical Frameworks General Introduction, Appendix A - Actors.

1.4.2 Transactions

465 Transactions are interactions between actors that transfer the required information through standards-based messages.

For information on transactions defined for all domains, their transactions numbers, and a brief description, see IHE Technical Frameworks General Introduction, Appendix B - Transactions.

1.4.3 IHE Integration Statements

470 IHE Integration Statements provide a consistent way to document high level IHE implementation status in products between vendors and users.

The instructions and template for IHE Integration Statements can be found in the IHE Technical Frameworks General Introduction, Appendix F - Integration Statements.

IHE also provides the IHE Product Registry (http://www.ihe.net/IHE_Product_Registry) as a
475 resource for vendors and purchasers of HIT systems to communicate about the IHE compliance of such systems. Vendors can use the Product Registry to generate and register Integration Statements.

1.5 Overview of Technical Framework Volume 1

Volume 1 is comprised of several distinct sections:

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- Section 1 provides background and reference material.
- Section 2 presents the conventions used in this volume to define the profiles and provides an overview of the defined profiles.
- Sections 3 and beyond define Radiology profiles, actors, and requirements in detail.

The appendices in Volume 1 provide clarification of uses cases or other details.

485 For a brief overview of additional Technical Framework Volumes (TF-2, TF-3, TF-4), please see the IHE Technical Frameworks General Introduction, Section 5.

1.6 Comment Process

IHE International welcomes comments on this document and the IHE initiative. Comments on the IHE initiative can be submitted by sending an email to the co-chairs and secretary of the Radiology domain committees at radiology@ihe.net. Comments on this document can be submitted at Radiology Public Comments.

1.7 Copyright Licenses

IHE technical documents refer to, and make use of, a number of standards developed and published by several standards development organizations. Please refer to the IHE Technical Frameworks General Introduction, Section 9 - Copyright Licenses for copyright license information for frequently referenced base standards. Information pertaining to the use of IHE International copyrighted materials is also available there.

1.8 Trademark

IHE® and the IHE logo are trademarks of the Healthcare Information Management Systems Society in the United States and trademarks of IHE Europe in the European Community. Please refer to the IHE Technical Frameworks General Introduction, Section 10 - Trademark for information on their use.

1.9 Disclaimer Regarding Patent Rights

Attention is called to the possibility that implementation of the specifications in this document may require use of subject matter covered by patent rights. By publication of this document, no position is taken with respect to the existence or validity of any patent rights in connection therewith. IHE International is not responsible for identifying Necessary Patent Claims for which a license may be required, for conducting inquiries into the legal validity or scope of Patents Claims or determining whether any licensing terms or conditions provided in connection with submission of a Letter of Assurance, if any, or in any licensing agreements are reasonable or non-discriminatory. Users of the specifications in this document are expressly advised that determination of the validity of any patent rights, and the risk of infringement of such rights, is entirely their own responsibility. Further information about the IHE International patent disclosure process including links to forms for making disclosures is available at http://www.ihe.net/Patent_Disclosure_Process. Please address questions about the patent disclosure process to the secretary of the IHE International Board: secretary@ihe.net.

1.10 History of Document Changes

This section provides a brief summary of changes and additions to this document.

Date	Document Revision	Change Summary
2020-09-18	19.0	Integrate Scheduled Workflow.b as a Final Text profile. Integrate the DBT Extensions Supplement into Final Text. Incorporate Change Proposals from 2019 CP Ballots. Refer to IHE RAD CP Tracking for details. Update TF Volumes to move all transaction definitions to Volume 2 and align Volume 3 with the current template.
2022-03-10	20.0	Integrate Management of Radiology Report Templates (MRRT) as a Final Text profile. Incorporate Change Proposals from 2020-2021 CP Ballots. Refer to the IHE RAD CP Tracking for details.
2023-06	21.0	Integrate Radiation Exposure Monitoring for Nuclear Medicine (REM-NM) as a Final Text profile. Incorporate Change Proposals from CP Ballot 2023A and CP-RAD-460. Refer to the IHE RAD CP Tracking Sheet and IHE Radiology's Incorporated CPs for details.
2024-06	22.0	Integrate the following as Final Text: • Basic Image Review (BIR) Profile • Web-based Image Capture (WIC) Profile • Web-based Image Access (WIC) Profile • Cardiac Option into the Nuclear Medicine Imaging (NMI) Profile Incorporate Change Proposals from CP Ballot 2023B and 2024A. Refer to the IHE RAD CP Tracking Sheet and IHE Radiology's Incorporated CPs for details.
2024-07	22.1	For Volume 1only (this volume) three figures that were not rendering properly were updated. No other changes were made.

2 Integration Profiles

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IHE Integration Profiles offer a common language that healthcare professionals and vendors can use to discuss integration needs of healthcare enterprises and the integration capabilities of information systems in precise terms. Integration Profiles specify implementations of standards that are designed to meet identified clinical needs. They enable users and vendors to state which IHE capabilities they require or provide, by reference to the detailed specifications of the IHE Radiology Technical Framework.

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IHE Integration Profiles are defined in terms of IHE actors (defined in Volume 1), transactions (defined in Volume 2), and content modules (defined in Volume 3). Actors are information systems or components of information systems that produce, manage, or act on information associated with clinical and operational activities in healthcare. Transactions are interactions between actors that communicate the required information through standards-based messages. Content modules define how the content used in a transaction is structured. A content module is specified so as to be independent of the transaction in which it appears.

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The Profiles can be considered in three classes: Content Profiles which address the management of a particular type of content object; Workflow Profiles which address the management of the workflow process by which content is created; and Infrastructure Profiles which address departmental issues. Figure 2-1 shows some IHE Profiles organized around these classes.

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The Content Profiles describe the creation, storage, management, retrieval and general use of a particular type of content object. Content Profiles are "workflow neutral". The profile addresses how the object is created, stored, queried and retrieved, but does not address the workflow management process.

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The Workflow Profiles address managing workflow process, which typically involves providing worklists, and reporting/monitoring the progress and completion of workitems. Within this context, one or more content objects are generally created according to their content profile.

545
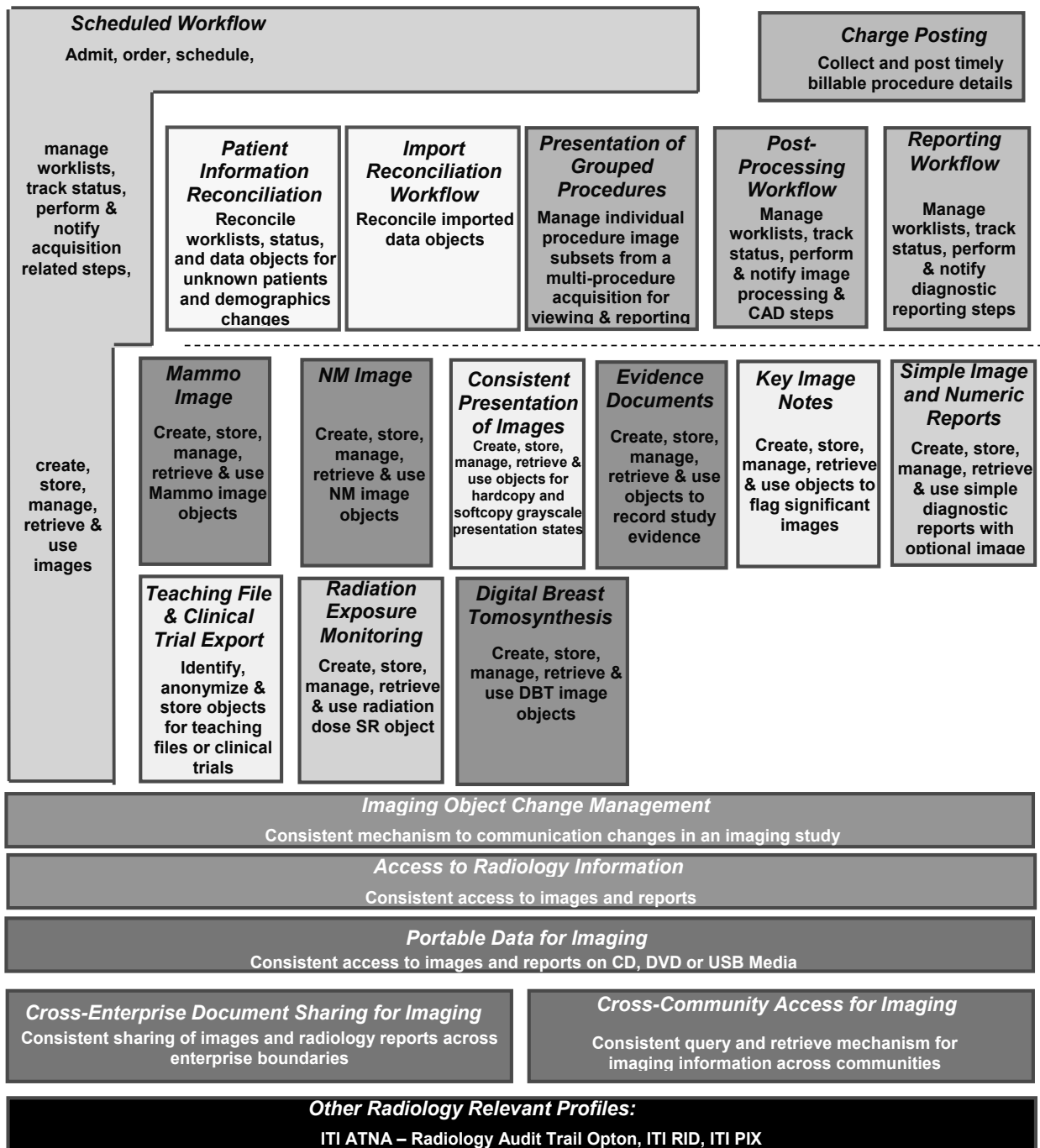
Figure 2-1: Example IHE Integration Profiles

Vendor products support an Integration Profile by implementing the appropriate actor(s) and transactions. A given product may implement more than one actor and more than one integration profile.

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IHE profiles which have reached the status of *Final Text* are published as part of the domain's Technical Framework Volumes 1-4. Prior to Final Text status, IHE profiles are published independently as *Profile Supplements* with the status of *Public Comment* or *Trial Implementation*.

555   For a list and short description of Radiology profiles, see the IHE Wiki at https://wiki.ihe.net/index.php/Profiles#IHE_Radiology_Profiles. The list includes all of the profiles in this document (Final Text) and may include profiles in the Trial Implementation and Public Comment stage.

2.1 Required Actor Groupings (Dependencies)

560   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.

In some cases, a profile is strictly dependent on one or more profiles in order to function. For example, Presentation of Grouped Procedures depends directly on the features of Scheduled Workflow and Consistent Presentation of Images in order to function.

565   In other cases, a profile is dependent on one of a class of profiles in order to be useful. For example, Charge Posting depends on at least one of the workflow profiles (Scheduled Workflow, Post-Processing Workflow and/or Reporting Workflow) being present in order for it to have something useful to post. Similarly, each workflow profile is of little value unless at least one relevant content profile is also implemented. Of course, the more content profiles are supported,
570   the more forms of input and output can be managed by the workflow.

To express these dependencies, the IHE Technical Framework relies on the concepts of *required actor groupings*.

Required actor groupings may be defined between two or more actors in IHE Profiles. Actors are grouped to combine the features of existing actors. This allows reuse of features of an
575   existing actor and does not recreate those same features in another actor. Internal communication between grouped actors is not specified by IHE. An example of grouped actors in the IHE Radiology Scheduled Workflow Profile is the grouping between the Image Manager and Image Archive.

Additionally, required actor groupings may cross profile boundaries. For example, an XDS-I.b
580   Imaging Document Source is required to be grouped with an ATNA Secure Node. Required actor groupings are defined in each profile definition in Volume 1. To comply with an actor in an IHE profile, a system must perform all transactions required for that actor in that profile. Actors supporting multiple Integration Profiles must support all of the transactions of each profile.

Note: In early versions of IHE Technical Framework documents, required actor groupings were
585   referred to as "Profile Dependencies". Table 2.1-1 defines the required dependencies between these profiles. In newer profiles, these "dependencies" are specified in a "Required Actor Groupings" section within each profile in Volume 1, and are not repeated in Table 2.1-1.

Table 2.1-1: IHE Radiology Integration Profiles Dependencies

Integration Profile	Depends on	Dependency Type	Comments
Consistent Presentation of Images	*None*	*None*	-
Key Image Notes	*None*	*None*	-
NM Image	*None*	*None*	
Mammography Image	*None*	*None*	
Evidence Documents	*None*	*None*	-
Simple Image and Numeric Report	*None*	*None*	-
Access to Radiology Information	One or more of: {Scheduled Workflow Consistent Presentation of Images, Evidence Documents, Key Image Notes, Simple Image and Numeric Reports} Patient Information Reconciliation	Required for Content output

Conditionally Required for the Multi Source Option | Supporting the image related transactions of Scheduled Workflow counts as a content profile |
Scheduled Workflow	*None*	*None*	-
Presentation of Grouped Procedures	Scheduled Workflow	Required for workflow	-
	Consistent Presentation of Images	Required for Content output	-
Post-Processing Workflow	Scheduled Workflow	Required for workflow management	-
	One or more of: {Scheduled Workflow, Evidence Documents, NM Image}	Required for Content input	Supporting the image related transactions of Scheduled Workflow counts as a content profile
	One or more of: {Scheduled Workflow Consistent Presentation of Images, Evidence Documents, Key Image Notes}	Required if any output is produced	Supporting the image related transactions of Scheduled Workflow counts as a content profile
Reporting Workflow	Scheduled Workflow	Required for workflow management	-
	One or more of: {Scheduled Workflow, Evidence Documents, NM Image}	Required for Content input	Supporting the image related transactions of Scheduled Workflow counts as a content profile.
	Simple Image and Numeric Reports	Required for Content input/output	-
Charge Posting	One or more of: {Scheduled Workflow, Post-Processing Workflow, Reporting Workflow, Import Reconciliation Workflow}	Required for charge trigger input	-

Integration Profile	Depends on	Dependency Type	Comments
Patient Information Reconciliation	Scheduled Workflow	Required for workflow/content to manage	Patient Information Reconciliation is an extension to this profile requiring that the workitems and/or content be updated.
Portable Data for Imaging	*None*	*None*	-
Basic Image Review	*None*	*None*	
Import Reconciliation Workflow	Scheduled Workflow	Required for Workflow (including Scheduled Import Option)	Support the workflow related transactions of Scheduled Workflow.
	Patient Demographics Query [ITI]	Required for Unscheduled Import Option	Patient Demographic information is obtained using Patient Demographic Query.
Teaching File and Clinical Trial Export	*None*	*None*	-
Radiation Exposure Monitoring	*None*	*None*	-
Imaging Object Change Management	Scheduled Workflow	Required for workflow management	Defines how Image Manager/Image Archive can obtain scheduled worklist in order to correct the modality worklist selection of the acquired instances. Support communication of procedure steps and storage commitment when Change Requester is grouped with Acquisition Modality, Image Manager/Image Archive or Evidence Creator. Support Image Manager to Image Manager change management if Multiple Patient Identity Resolution Option is supported.
	Patient Information Reconciliation	Required for reconciliation workflow	Support the patient information reconciliation mechanisms for the actor that is grouped with the Change Requester.

Integration Profile	Depends on	Dependency Type	Comments
Digital Breast Tomosynthesis	*None*	*None*	-
Management of Radiology Report Templates	*None*	*None*	-

2.2 Security Implications

IHE transactions often contain information that must be protected in conformance with privacy laws, regulations and best practices. This protection is documented in the Security Considerations section of each profile, which communicates security/privacy concerns that the implementers need to be aware of, assumptions made about security/privacy pre-conditions and, where appropriate, key elements of a risk mitigation strategy to be applied.

2.3 Profiles Overview

A brief overview of each IHE Radiology profile is provided on the IHE wiki at https://wiki.ihe.net/index.php/Profiles#IHE_Radiology_Profiles.

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.

As mentioned earlier, there is a class of Profiles that deal primarily with data content. Most types of content belong to the family of Evidence Objects. Currently this means Images, Presentation States, Key Image Notes and Evidence Documents. Evidence Objects are generated as a result of performing procedure steps on systems in the radiology department. These objects are used by the Radiologist in the process of creating a Radiological Diagnostic Report and are managed inside the Radiology Department. Evidence Documents represent the uninterpreted information that is primarily managed and used inside Radiology, although distribution outside Radiology is not precluded. In contrast, the diagnostic reports described in the Simple Image and Numeric Reports Profile represent the interpreted information which is the primary output of the Radiology department and are available for wide distribution.

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
625 objectives, plans for maintenance and support, etc.

2.3.1 Scheduled Workflow (SWF)

The Scheduled Workflow Integration Profile establishes the continuity and integrity of basic departmental imaging data acquired in an environment where examinations are generally being ordered. It specifies a number of transactions that maintain the consistency of patient and
630 ordering information as well as defining the scheduling and imaging acquisition procedure steps. This profile also makes it possible to determine whether images and other evidence objects associated with a particular performed procedure step have been stored (archived) and are available to enable subsequent workflow steps, such as reporting. It may also provide central coordination of the completion of processing and reporting steps as well as notification of
635 appointments to the Order Placer.

2.3.2 Patient Information Reconciliation (PIR)

The Patient Information Reconciliation Integration Profile extends the *Scheduled Workflow Integration Profile* by offering the means to match images, diagnostic reports, and other evidence objects acquired for a misidentified or unidentified patient (for example, during a
640 trauma case) with the patient's record. In the example of the trauma case, this integration profile allows subsequent reconciliation of the patient record with images that are acquired (either without a prior registration or under a generic registration) before the patient's identity could be determined. Thus images, diagnostic reports and other evidence objects can be acquired and interpreted immediately and later, when the patient's official registration and order information
645 is entered into the ADT, Order Placer and Order Filler Systems, this information is matched with the acquired image set, greatly simplifying these exception-handling situations.

2.3.3 Consistent Presentation of Images (CPI)

The Consistent Presentation of Images Integration Profile specifies a number of transactions that maintain the consistency of presentation for grayscale images and their presentation state
650 information (including user annotations, shutters, flip/rotate, display area, and zoom). It also defines a standard contrast curve, the Grayscale Standard Display Function, against which different types of display and hardcopy output devices can be calibrated. It thus supports hardcopy, softcopy and mixed environments.

2.3.4 Presentation of Grouped Procedures (PGP)

655 The Presentation of Grouped Procedures Integration Profile (PGP) addresses what is sometimes referred to as the linked studies problem: viewing image subsets resulting from a single acquisition with each image subset related to a different requested procedure (e.g., CT chest, abdomen and pelvis). It provides a mechanism for facilitating workflow when viewing images and reporting on individual requested procedures that an operator has grouped (often for the sake

660 of acquisition efficiency and patient comfort). A single acquired image set is produced, but the combined use of the scheduled workflow transactions and the consistent presentation of images allow separate viewing and interpretation of the image subsets related to each of the requested procedures.

2.3.5 Access to Radiology Information (ARI)

665 The Access to Radiology Information Integration Profile specifies a number of query transactions providing access to radiology information, including images and related reports, in a DICOM format as they were acquired or created. Such access is useful both to the radiology department and to other departments such as pathology, surgery and oncology.

2.3.6 Key Image Note (KIN)

670 The Key Image Note Integration Profile specifies transactions that allow a user to mark one or more images in a study as significant by attaching to them a note managed together with the study. This note includes a title stating the purpose of marking the images and a user comment field. Physicians may attach Key Image Notes to images for a variety of purposes: referring physician access, teaching files selection, consultation with other departments, and image quality
675 issues, etc.

2.3.7 Simple Image and Numeric Report (SINR)

The Simple Image and Numeric Report Integration Profile facilitates the growing use of digital dictation, voice recognition, and specialized reporting packages, by separating the functions of reporting into discrete actors for creation, management, storage and viewing. Separating these
680 functions while defining transactions to exchange the reports between them enables a vendor to include one or more of these functions in an actual system.

2.3.8 Basic Security (SEC) - DEPRECATED

This profile has been superseded by the ITI Audit Trail and Node Authentication (ATNA) Integration Profile and the Radiology Audit Trail Option on ATNA.

685 ### 2.3.9 Charge Posting (CHG)

The Charge Posting Integration Profile specifies the exchange of information from the Department System Scheduler/Order Filler to the Charge Processor regarding charges associated with particular procedures, as well as communication between the ADT/Patient Registration and Charge Processor Actors about patient demographics, accounts, insurance, and guarantors. The
690 Charge Posted Transaction contains all of the required procedure data to generate a claim. Currently, these interfaces contain fixed field formatted or HL7-style data. The goal of including this transaction in the Radiology Technical Framework is to standardize the Charge Posted Transaction to a Charge Processor, thus reducing system interface installation time between clinical systems and Charge Processors. Additionally, the Charge Posted Transaction reduces the
695 need of the billing system to have knowledge of the radiology internals. The result is that the Charge Processor will receive more complete, timely and accurate data.

2.3.10 Post-Processing Workflow (PWF)

700 The Post-Processing Workflow Integration Profile addresses the need to schedule, distribute and track the status of typical post-processing workflow steps, such as Computer-Aided Detection or Image Processing. Worklists for each of these tasks are generated and can be queried, workitems can be selected and the resulting status returned from the system performing the work to the system managing the work.

NOTE: *As of June 2012, IHE introduced a new Trial Implementation Profile: Post-Acquisition Workflow (PAWF). The use cases addressed are largely the same as PWF, but the underlying*
705 *mechanisms are improved. The PWF Profile documented in this section has been deprecated by the Radiology Domain and is now replaced by PAWF. When the PAWF Profile becomes Final Text, the contents of Section 12 will be removed. In the interim, new implementations should be based on PAWF, found at https://profiles.ihe.net/RAD.*

2.3.11 Reporting Workflow (RWF)

710 The Reporting Workflow Profile addresses the need to schedule, distribute and track the status of the reporting workflow tasks such as interpretation, transcription and verification. Worklists for each of these tasks are generated and can be queried; workitems can be selected and the resulting status returned from the system performing the work to the system managing the work.

2.3.12 Evidence Documents (ED)

715 The Evidence Documents Profile defines interoperable ways for observations, measurements, results and other procedure details recorded in the course of carrying out a procedure step to be output by devices, such as acquisition systems and other workstations; to be stored and managed by archival systems; and to be retrieved and presented by display and reporting systems. This allows detailed non-image information, such as measurements, CAD results, procedure logs, etc.
720 to be made available as input to the process of generating a diagnostic report. The Evidence Documents may be used either as additional evidence for the reporting physician or in some cases for selected items in the Evidence Document to be included in the diagnostic report.

2.3.13 Portable Data for Imaging (PDI)

The Portable Data for Imaging Integration Profile specifies actors and transactions that allow
725 users to distribute imaging related information on interchange media. The intent of this profile is to provide reliable interchange of evidence objects and diagnostic reports for import, display or print by a receiving actor. The CD format with uncompressed content was chosen as the baseline. Options for the support of DVD media and USB, JPEG and JPEG 2000 lossless and lossy compression on CD, DVD and USB media are also defined.

730 ### 2.3.14 NM Image (NMI)

The NM Image Integration Profile specifies how Acquisition Modalities and workstations should store NM Images and how Image Displays should retrieve and make use of them. It defines the basic display capabilities Image Displays are expected to provide, and also how result screens,

735   both static and dynamic, such as those created by NM Cardiac Processing Packages, should be stored using DICOM objects that can be displayed on general purpose Image Display systems.

2.3.15 Teaching File and Clinical Trial Export (TCE)

The Teaching File and Clinical Trial Export Profile addresses the need to select DICOM instances, series or studies (which may contain images, key image notes, reports, evidence documents and presentation states) that need to be exported for teaching files or clinical trials.

740   It defines an actor for making the Export Selection, which would typically be grouped with an Image Display or Acquisition Modality, and an actor for processing the selection, which is required to support a configurable means of de-identifying the exported instances. Additional options are provided for de-identification of pixel data, remapping of identifiers to pseudonymous values, export of additional teaching file information, and delaying export for a

745   variety of reasons.

2.3.16 Cross-Enterprise Document Sharing for Imaging (XDS-I.b)

The Cross-Enterprise Document Sharing for Imaging (XDS-I.b) Integration Profile specifies actors and transactions that allow users to share imaging information across enterprises. This profile depends on the IHE IT Infrastructure Cross-Enterprise Document Sharing (XDS.b)

750   Profile. Cross-Enterprise Document Sharing for Imaging (XDS-I.b) defines the information to be shared such as sets of DICOM instances (including images, evidence documents, and presentation states), diagnostic imaging reports provided in a ready-for-display format.

Since the XDS-I.b Profile depends on and extends the IT Infrastructure XDS.b Profile including the use of terms defined in XDS (e.g., XDS Affinity Domain, submission set, etc.) the reader of

755   XDS-I.b is expected to have read and understood the XDS Profile.

2.3.17 Mammography Image (MAMMO)

The Mammography Image Profile specifies how DICOM Mammography images and evidence objects are created, exchanged and used. It describes how Acquisition Modalities transfer Full Field Digital Mammography (FFDM) Images, how CAD systems act as Evidence Creators, and

760   how Image Displays should retrieve and make use of images and CAD results. It defines the basic display capabilities Image Displays are expected to provide, and which attributes should be used to implement those capabilities.

2.3.18 Image Fusion (FUS)

Image Fusion is a Trial Implementation Profile.

765   ### 2.3.19 Import Reconciliation Workflow (IRWF)

The Import Reconciliation Workflow Integration Profile (IRWF) specifies how data Importers obtain local demographics, coerce patient and procedure attribute values in the imported data and report progress/status of the importation process. The Profile complements the Scheduled

Workflow Profile by using the existing workflow mechanisms for notification and storage of
770 imported Evidence Objects.

> **NOTE:** *As of June 2012, IHE introduced an updated Import Reconciliation Profile (IRWF.b) for Trial Implementation. In addition to the original use cases, several new use cases are addressed, and the underlying mechanisms are improved. The IRWF Profile documented in this section has been deprecated by the Radiology Domain and is now replaced by the IRWF.b. When that*
775 *supplement becomes Final Text, the contents of Section 21 will be removed. In the interim, new implementations should be based on IRWF.b, found at https://profiles.ihe.net/RAD.*

2.3.20 Radiation Exposure Monitoring (REM)

The Radiation Exposure Monitoring Integration Profile specifies communications between
systems generating reports of irradiation events (generally acquisition modalities and
780 workstations) and systems which receive, store, or process those reports (generally local dose
information management systems and/or national/regional dose registries). It defines how
DICOM SR objects for CT and projection X-ray dose objects are created, stored, queried,
retrieved, de-identified, and may be processed and displayed.

2.3.21 Mammography Acquisition Workflow (MAWF) - RETIRED

785 This section was previously reserved for the Mammography Acquisition Workflow Profile
(MAWF). That profile was retired in 2024.

2.3.22 MR Diffusion Imaging (DIFF)

MR Diffusion Imaging is a Trial Implementation Profile.

2.3.23 CT/MR Perfusion Imaging with Contrast (PERF)

790 *CT/MR Perfusion Imaging with Contrast* is a Trial Implementation Profile.

2.3.24 Basic Image Review (BIR)

The Basic Image Review Profile defines baseline functions and user interface relevant to simple
review of DICOM images, and which attributes should be used to implement those capabilities.

The Basic Image Review Profile is designed to provide sufficient display functionality to allow
795 adequate review of images for the purpose of clinical decision-making by ordering physicians. It
does not address application or modality specific requirements, such as may be needed for
primary interpretation of mammography by radiologists, or primary interpretation of nuclear
medicine image, which are addressed by other profiles.

2.3.25 Chest X-Ray CAD Display (CXCAD) - RETIRED

800 This section was previously reserved for the Chest X-Ray CAD Display Profile (CXCAD). That
profile was retired in 2024.

2.3.26 Imaging Object Change Management (IOCM)

The Imaging Object Change Management Integration Profile (IOCM) specifies how one actor communicates local changes applied on existing imaging objects to other actors that manage copies of the modified imaging objects in their own local systems. The supported changes include (1) object rejection due to quality or patient safety reasons, (2) correction of incorrect modality worklist entry selection, and (3) expiration of objects due to data retention requirements. It defines how changes are captured and how to communicate these changes.

2.3.27 Cross-Community Access for Imaging (XCA-I)

The Cross-Community Access for Imaging (XCA-I) Integration Profile specifies actors and transactions to query and retrieve patient-relevant medical imaging data being held by other communities.

Within a community, a group of facilities/enterprises shares clinical information via an established mechanism such as XDS-I (in which case the community can be referred to as an XDS Affinity Domain). This profile addresses sharing between such communities.

The XCA-I Profile extends the IT Infrastructure XCA Profile. XCA provides access to Diagnostic reports and Imaging Manifests. XCA-I provides access to the imaging objects referenced in the Manifests. The reader of XCA-I is expected to have read and understood the XCA Profile, including the meaning of terms such as Community, homeCommunityId, etc.

2.3.28 Post-Acquisition Workflow (PAWF)

Post-Acquisition Workflow is a Trial Implementation Profile.

2.3.29 Cross-Enterprise Document Reliable Interchange of Images (XDR-I)

Cross-Enterprise Document Reliable Interchange of Images is a Trial Implementation Profile.

2.3.30 Stereotactic Mammography Image (SMI) - RETIRED

This section was previously reserved for the Stereotactic Mammography Image Profile (SMI). That profile was retired in 2024.

2.3.31 Management of Radiology Report Templates (MRRT)

The MRRT Profile concerns the use of imaging report templates to create diagnostic imaging reports. This profile distinguishes between *report authoring templates*, which are templates used by radiologists to guide the creation of a clinical imaging report, and *report instance templates*, which describe technical constraints on the structure and content of imaging report instances, such as the constraints described in and XML schema or the HL7 Clinical Document Architecture. This profile applies to the former, *report authoring templates,* and describes methods for the formatting of imaging report templates and the management of their transport between template libraries and report creation systems. Specifically, this profile describes an enhanced feature set for report authoring templates, delineates how such templates from a

vendor-agnostic template library could be used immediately by a reporting system, and provides a format for migration of templates between reporting systems.

840 2.3.32 Scheduled Workflow.b (SWF.b)

The Scheduled Workflow.b (SWF.b) Profile establishes the continuity and integrity of basic departmental imaging data. It maintains the consistency of patient and ordering information as well as providing the scheduling and imaging acquisition procedure steps. This profile makes it possible to determine whether images and other evidence objects associated with a particular
845 performed procedure step have been stored (archived) and are available to enable subsequent workflow steps, such as reporting. It may also provide central coordination of the completion of processing and reporting steps as well as notification of appointments to the Order Placer

2.3.33 Invoke Image Display (IID)

Invoke Image Display is a Trial Implementation Profile.

850 2.3.34 Mobile access to Health Document for Imaging (MHD-I) – DEPRECATED

This section was previously reserved for the Mobile access to Health Documents for Imaging (MHD-I) Profile. That profile was deprecated in 2017 and replaced with the Web-based Image Access (WIA) Profile.

2.3.35 Digital Breast Tomosynthesis (DBT)

855 The Digital Breast Tomosynthesis (DBT) Profile specifies the creation, exchange and use of DBT images. It defines basic display capabilities that Image Displays are expected to provide, especially simultaneous review of DBT, conventional 2D mammography images (FFDM), and breast projection X-Ray images.

The Digital Breast Tomosynthesis Profile is designed to provide faithful storage and retrieval of
860 DBT images. Furthermore, sufficient display functionality to allow adequate review of current and prior studies consisting of DBT, conventional 2D mammography, and/or breast projection X-Ray images is defined. The support for CAD is out of the scope for this profile.

2.3.36 Web-based Image Capture (WIC)

The Web-based Image Capture (WIC) Profile provides a simple, lightweight, mobile-friendly
865 mechanism to encode and send captured images, videos and evidence documents from the mobile device to the Image Manager so that these objects can be easily integrated into the rest of the imaging workflow.

2.3.37 Clinical Decision Support – Order Appropriateness Tracking (CDS-OAT)

Clinical Decision Support – Order Appropriateness Tracking is a Trial Implementation Profile.

870 ### 2.3.38 Radiation Exposure Monitoring – Nuclear Medicine (REM-NM)

The Radiation Exposure Monitoring (REM-NM) Profile specifies communications between systems generating reports of radiopharmaceutical administration events (generally laboratory or dose creator/injector systems) and systems which receive, store, or process those reports (generally nuclear medicine modalities, local dose information management systems and/or
875 national/regional dose registries). It defines how DICOM nuclear medicine dose SR objects are created, stored, queried, retrieved, de-identified, read, and may be processed and displayed

2.3.39 Cross-Enterprise Remote Read Workflow Definition (XRR-WD)

Cross-Enterprise Remote Read Workflow Definition is a Trial Implementation Profile.

2.3.40 Web-based Image Access (WIA)

880 Web-based Image Access (WIA) Profile defines methods for image sharing and interactive viewing of imaging studies using RESTful services such as WADO-RS and QIDO-RS.

2.3.41 Standardized Operational Log of Events (SOLE)

Standardized Operational Log of Events is a Trial Implementation Profile.

2.3.42 Management of Acquisition Protocols (MAP)

885 *Management of Acquisition Protocols* is a Trial Implementation Profile.

2.3.43 Results Distribution (RD)

Results Distribution is a Trial Implementation Profile.

2.3.44 Radiology Remote Reporting Workflow (RRR-WF)

Radiology Remote Reading Workflow is a Trial Implementation Profile.

890 ### 2.3.45 Encounter-based Imaging Workflow (EBIW)

Encounter-based Imaging Workflow is a Trial Implementation Profile.

2.3.46 Import and Display of External Priors (IDEP)

Import and Display of External Priors is a Trial Implementation Profile.

2.3.47 AI Results (AIR)

895 *AI Results* is a Trial Implementation Profile.

2.3.48 AI Workflow for Imaging (AIW-I)

AI Workflow for Imaging is a Trial Implementation Profile.

2.3.49 Contrast Administration Management (CAM)

Contrast Administration Management is a Trial Implementation Profile.

900 ### 2.3.50 Interactive Multimedia Report (IMR)

Interactive Multimedia Report is a Trial Implementation Profile.

2.3.51 Intentionally left blank

2.3.52 Prioritization of Worklists for Reporting (POWR)

Prioritization of Worklists for Reporting is a Trial Implementation Profile.

905 ## 2.4 Product Implementations

As described in detail in the *IHE Technical Frameworks General Introduction*, an implementer chooses specific profiles, actors, and options to implement for their product. To comply with an actor in an IHE profile, a system must perform all the required transactions for that actor in that profile.

910 To communicate the conformance of a product offering with IHE profiles, implementers provide an IHE Integration Statement describing which IHE integration profiles, IHE actors and options are incorporated.

Further discussion about integration statements and a sample form can be found in Appendix F to the *IHE Technical Frameworks General Introduction*. To make consumers aware of the

915 product integration statement, enter it in the IHE Product Registry (http://product-registry.ihe.net/).

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:

920 • The Image Archive in any Radiology profile shall be grouped with the Image Manager, and the Image Manager shall be grouped with the Image Archive.

• The Image Manager participating in Scheduled Workflow or Reporting 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

925 configuration.

• The Department System Scheduler/Order Filler participating in any of the following profiles, Scheduled Workflow, Patient Information Reconciliation, Charge Posting, Presentation of Grouped Procedures, Import Reconciliation Workflow, or Reporting Workflow, shall be grouped with a Performed Procedure Step Manager. The grouped

930 Performed Procedure Step Manager shall be capable of being disabled via configuration.

• The Print Composer in any Radiology profile shall be grouped with an Image Manager, an Acquisition Modality, an Image Display or an Evidence Creator.

- The Evidence Creator participating in Post-Processing Workflow shall be grouped with an Image Display from one or more Radiology profiles.

935
- An actor in a Radiology profile that is grouped with a Secure Node or Secure Application of the ITI Audit Trail and Node Authentication Integration Profile (ITI TF-1: 9) shall support the applicable Radiology events and semantics defined in RAD TF-3: 5.1.

- The Post-Processing Manager in the Post-Processing Workflow Profile shall be grouped with either an Image Manager or a Department System Scheduler.

940
- The Portable Media Importer in the Portable Data for Imaging Profile shall be grouped with at least one of the following actors from one or more Radiology profiles in order to perform import of the supported evidence objects and/or Diagnostic Reports:

  - Evidence Creator (Evidence Documents)

  - Acquisition Modality (Images, Key Image Notes, Evidence Documents)

945
  - Image Manager/Image Archive (Images, Presentation States, Key Image Notes, Evidence Documents)

  - Report Creator (Diagnostic Reports)

  - Report Manager (Diagnostic Reports)

  - Report Repository (Diagnostic Reports)

950
  - Importer

- The Imaging Document Consumer shall be grouped with an ITI XDS.b Document Consumer, thereby supporting the Document Consumer's transactions for querying a Document Registry and retrieving from a Document Repository as defined in the ITI XDS.b Profile.

955
- The Importer in the Import Reconciliation Workflow Profile is generic in terms of not defining a specific transport mechanism for the Evidence Objects it imports. It may be necessary for the Importer to be grouped with additional actors to support specific transport mechanisms. For example, to support import from PDI Media, the Importer must be grouped with the Portable Media Importer.

960
- The Change Requester is generic in terms of not defining a specific mechanism for obtaining the original instances that it requests changes to. It shall be grouped with at least one of the following actors in order to obtain the original instances:

  - Evidence Creator

  - Acquisition Modality

965
  - Image Manager/Image Archive

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.

970 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. On the other hand, the Report Submission Transaction must be supported even by an implementation that groups the Report Creator and the Report Manager.

975 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.

980 The following examples describe which actor's typical systems might be expected to support. This is not intended to be a requirement, but rather to provide some examples to aid understanding.

- A modality system, such as an MRI scanner and console or Ultrasound system might typically include an Acquisition Modality and a Print Composer.

985
- An imaging workstation, such as a post-processing workstation or advanced review station might typically include an Image Display, an Evidence Creator, and a Print Composer.

- A HIS registration and order entry system might typically include the ADT Patient Registration and an Order Placer.

990
- A departmental RIS system might typically include a Department System Scheduler, an Order Filler, a Performed Procedure Step Manager, a Report Manager, and a Report Reader.

- An Ultrasound system that generates echo report measurements would likely include an Acquisition Modality that supports both the Scheduled Workflow Profiles and the
995   Evidence Documents Profile.

When an implementation has an actor supporting multiple integration profiles, the actor is required to support logical cross-behaviors/ transactions. For example, if an Evidence Creator supports the Post-Processing Workflow and Evidence Documents Profiles, then the actor must generate PPS messages when creating evidence documents. If an Image Display supports the
1000 Simple Image and Numeric Reports and Consistent Presentation of Images Profiles, then the actor must make use of any GSPS referenced by the Simple Image and Numeric Report when rendering the relevant images.

If an implementation supports the Consistent Presentation of Images Integration Profile with both an Image Display and a Print Composer, both actors shall support calibration against the
1005 Grayscale Softcopy Display Function, in a consistent manner across both actors. In addition, the

combined actors must perform the image data manipulations necessary to match the presentation of the Hardcopy with the Softcopy presentations.

1010   If an implementation includes a Print Composer in combination with an Image Manager, Acquisition Modality, or Evidence Creator (and not an Image Display), then it is recommended but not required that the Print Composer calibrate its display system. In addition, the Print Composer must be able to perform the image data manipulations specified by the Grayscale Softcopy Presentation State that is related to the image.

3   Scheduled Workflow (SWF)

The ***Scheduled Workflow Integration Profile*** establishes the continuity and integrity of basic
1015   departmental imaging data. It specifies a number of transactions that maintain the consistency of
patient and ordering information as well as providing the scheduling and imaging acquisition
procedure steps. This profile also makes it possible to determine whether images and other
evidence objects associated with a particular performed procedure step have been stored
(archived) and are available to enable subsequent workflow steps, such as reporting. It may also
1020   provide central coordination of the completion of processing and reporting steps as well as
notification of appointments to the Order Placer.

3.1 Actors/Transactions

Figure 3.1-1 diagrams the actors involved with this profile and the transactions between actors. .

1025
Note: In an attempt to simplify Figure 3.1-1, not all of the "optional" transactions listed in Table 3.1-1 are shown in the diagram.
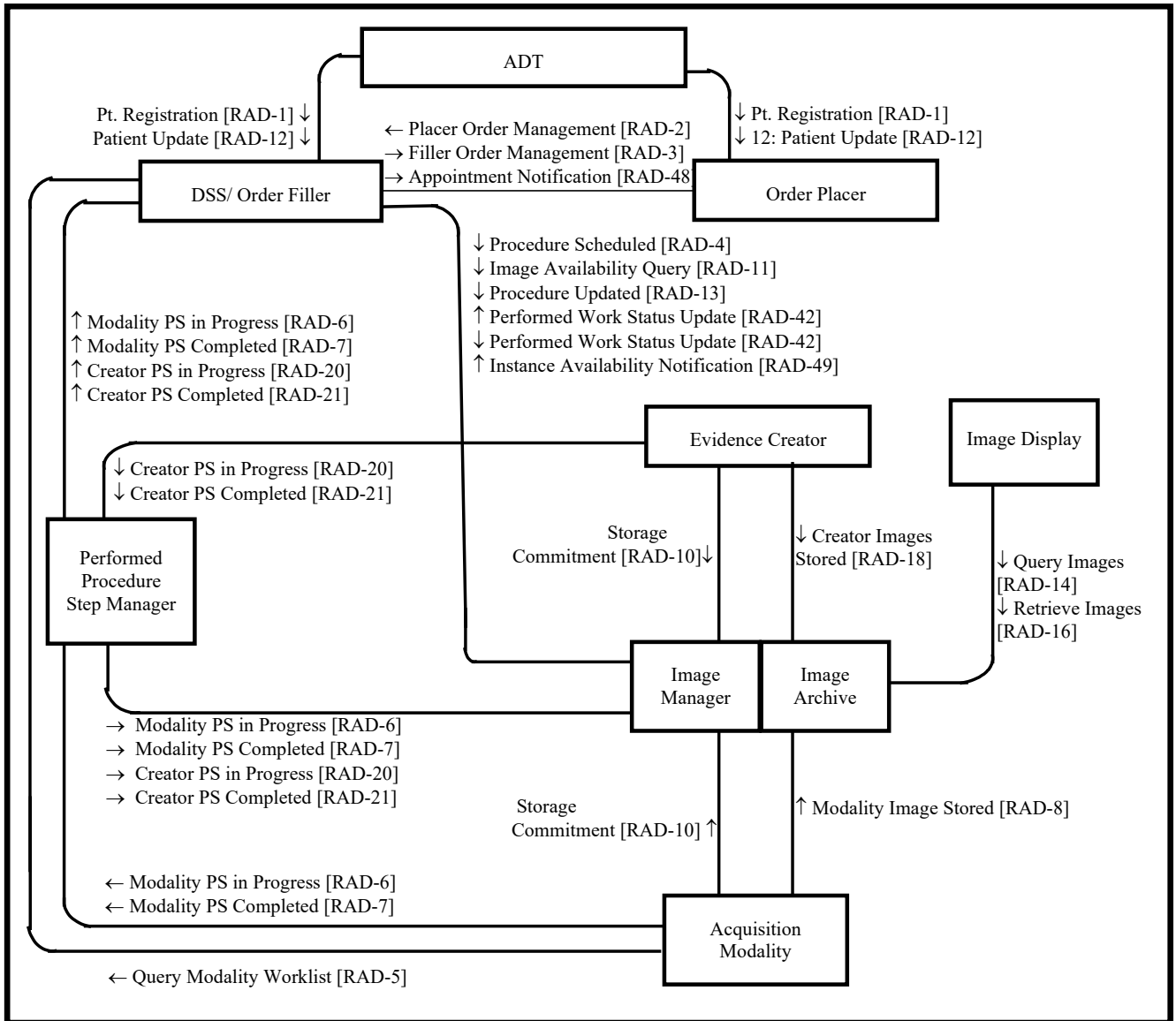
Figure 3.1-1: Scheduled Workflow Diagram

1030
Table 3.1-1 lists the transactions for each actor directly involved in the Scheduled 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 3.2.

Table 3.1-1: Scheduled Workflow - Actors and Transactions

Actors	Transactions	Optionality	TF Reference
ADT Patient Registration	Patient Registration [RAD-1] (Note 2)	R	RAD TF-2: 4.1
	Patient Update [RAD-12] (Note 2)	R	RAD TF-2: 4.12
Order Placer	Patient Registration [RAD-1] (Note 2)	R	RAD TF-2: 4.1
	Patient Update [RAD-12] (Note 2)	R	RAD TF-2: 4.12
	Placer Order Management [RAD-2] (Note 2)	R	RAD TF-2: 4.2
	Filler Order Management [RAD-3] (Note 2)	R	RAD TF-2: 4.3
	Appointment Notification [RAD-48]	O	RAD TF-2: 4.48
Department System Scheduler/ Order Filler	Patient Registration [RAD-1] (Note 2)	R	RAD TF-2: 4.1
	Patient Update [RAD-12] (Note 2)	R	RAD TF-2: 4.12
	Placer Order Management [RAD-2] (Note 2)	R	RAD TF-2: 4.2
	Filler Order Management [RAD-3] (Note 2)	R	RAD TF-2: 4.3
	Procedure Scheduled [RAD-4] (Note 2)	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: 4.6
	Modality Procedure Step Completed [RAD-7]	R	RAD TF-2: 4.7
	Images Availability Query [RAD-11]	O	RAD TF-2: 4.11
	Procedure Updated [RAD-13] (Note 2)	R	RAD TF-2: 4.13
	Creator Procedure Step in Progress [RAD-20]	R	RAD TF-2: 4.20
	Creator Procedure Step Completed [RAD-21]	R	RAD TF-2: 4.21
	Performed Work Status Update [RAD-42] (as the Receiver, see Note 1))	O	RAD TF-2: 4.42
	Appointment Notification [RAD-48]	O	RAD TF-2: 4.48
	Instance Availability Notification [RAD-49]	O	RAD TF-2: 4.49
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 Stored [RAD-8]	R	RAD TF-2: 4.8
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
	Procedure Scheduled [RAD-4] (Note 2)	R	RAD TF-2: 4.4

Actors	Transactions	Optionality	TF Reference
Image Manager/ Image Archive	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 Stored [RAD-8]	R	RAD TF-2: 4.8
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
	Images Availability Query [RAD-11]	R	RAD TF-2: 4.11
	Procedure Updated [RAD-13] (Note 2)	R	RAD TF-2: 4.13
	Query Images [RAD-14]	R	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	R	RAD TF-2: 4.16
	Creator Images Stored [RAD-18]	R	RAD TF-2: 4.18
	Creator Procedure Step in Progress [RAD-20]	R	RAD TF-2: 4.20
	Creator Procedure Step Completed [RAD-21]	R	RAD TF-2: 4.21
	Performed Work Status Update [RAD-42] (as the Receiver, see Note 1)	O	RAD TF-2: 4.42
	Instance Availability Notification [RAD-49]	O	RAD TF-2: 4.49
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
	Creator Procedure Step in Progress [RAD-20]	R	RAD TF-2: 4.20
	Creator Procedure Step Completed [RAD-21]	R	RAD TF-2: 4.21
Image Display	Query Images [RAD-14]	R	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	R	RAD TF-2: 4.16
Evidence Creator	Creator Images Stored [RAD-18]	R	RAD TF-2: 4.18
	Creator Procedure Step in Progress [RAD-20]	O	RAD TF-2: 4.20
	Creator Procedure Step Completed [RAD-21]	O	RAD TF-2: 4.21
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10

1035

Note 1: The Department System Scheduler or the Image Manger may optionally choose to be receivers of Performed Work Status Update transactions in order to monitor the status of work in workflows that are managed by other systems (see RAD TF-2: 4.42).

Note 2: The actor shall implement the HL7 v2.3.1 Message Semantics for this transaction.

Refer to Table 2-1 for other profiles that may be pre-requisites for this profile.

3.2 Scheduled Workflow Integration Profile Options

1040 Options that may be selected for this Integration Profile are listed in the Table 3.2-1 along with the actors to which they apply. Dependencies between options when applicable are specified in notes.

Table 3.2-1: Scheduled Workflow - Actors and Options

Actor	Option	TF Reference
ADT Patient Registration	*No options defined*	--
Order Placer	Departmental Appointment Notification	RAD TF-2: 4.48
	No options defined	--
DSS/Order Filler	Image Availability	RAD TF-2: 4.11
	Departmental Appointment Notification	RAD TF-2: 4.48
	PPS Exception Management	RAD TF-2: 4.7
	Performed Work Status Update - Receive	RAD TF-2: 4.42
	Availability of PPS-Referenced Instances	RAD TF-2: 4.49
Acquisition Modality	Patient Based Worklist Query (Note 1)	RAD TF-2: 4.5
	Broad Worklist Query (Note 1)	RAD TF-2: 4.5
	Assisted Acquisition Protocol Setting	RAD TF-2: 4.6
	PPS Exception Management	RAD TF-2: 4.7
	Modality Group Case (Note 2)	RAD TF-2:.4.6
	Billing and Material Management	RAD TF-2: 4.7
Image Manager/ Image Archive	Availability of PPS-Referenced Instances	RAD TF-2: 4.49
	PPS Exception Management	RAD TF-2: 4.7
	Performed Work Status Update - Receive	RAD TF-2: 4.42
Image Display	*No options defined*	--
Performed Procedure Step Manager	*No options defined*	--
Evidence Creator	Creator Performed Procedure Step	RAD TF-2: 4.20 RAD TF-2: 4.21
	PPS Exception Management (Note 3)	RAD TF-2: 4.21

Note 1: At least one of these two options is required. Both may be supported.

1045 Note 2: When a modality claims support for the Modality Group Case Option, it is required to support all three grouping scenarios described in RAD TF-2: 4.6.4.1.2.3.4.

Note 3: An Evidence Creator claiming the PPS Exception Management Option shall also support the Creator Performed Procedure Step Option.

1050 The Evidence Creator, 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 RAD TF-1x: Appendix D).

3.2.1 HL7 v2.5.1 Option

The HL7 v2.5.1 Option has been retired. Relevant systems may instead support Scheduled
Workflow.b. See RAD TF-1: 34.

3.3 Scheduled Workflow Process Flow

This section describes the process and information flow of patient care as it is defined in the
Radiology Technical Framework under "normal" circumstances. It covers transactions [RAD-1]
through [RAD-12] and transaction [RAD-23], which reflect a typical patient encounter from
registration/admission through the performance of an ordered procedure. See RAD TF-1x:
Appendix C for an overview of the information exchange between the Department System
Scheduler/Order Filler and Image Manager.

To support the Scheduled Workflow Profile, an actor that claims support of other content
profiles (Consistent Presentation of Images, Key Image Notes or Evidence Documents) is
required to support the relevant storage, query and retrieve transactions and manage creation of
those objects in the same way images are supported. The following diagrams will mostly show
the management of images.

3.3.1 Administrative and Procedure Performance Process Flow

This case covers both inpatient and outpatient procedures. The patient may be new or known to
the current healthcare facility. The following sequence of steps describes the typical process flow
when a request is made to perform an imaging procedure on a patient.
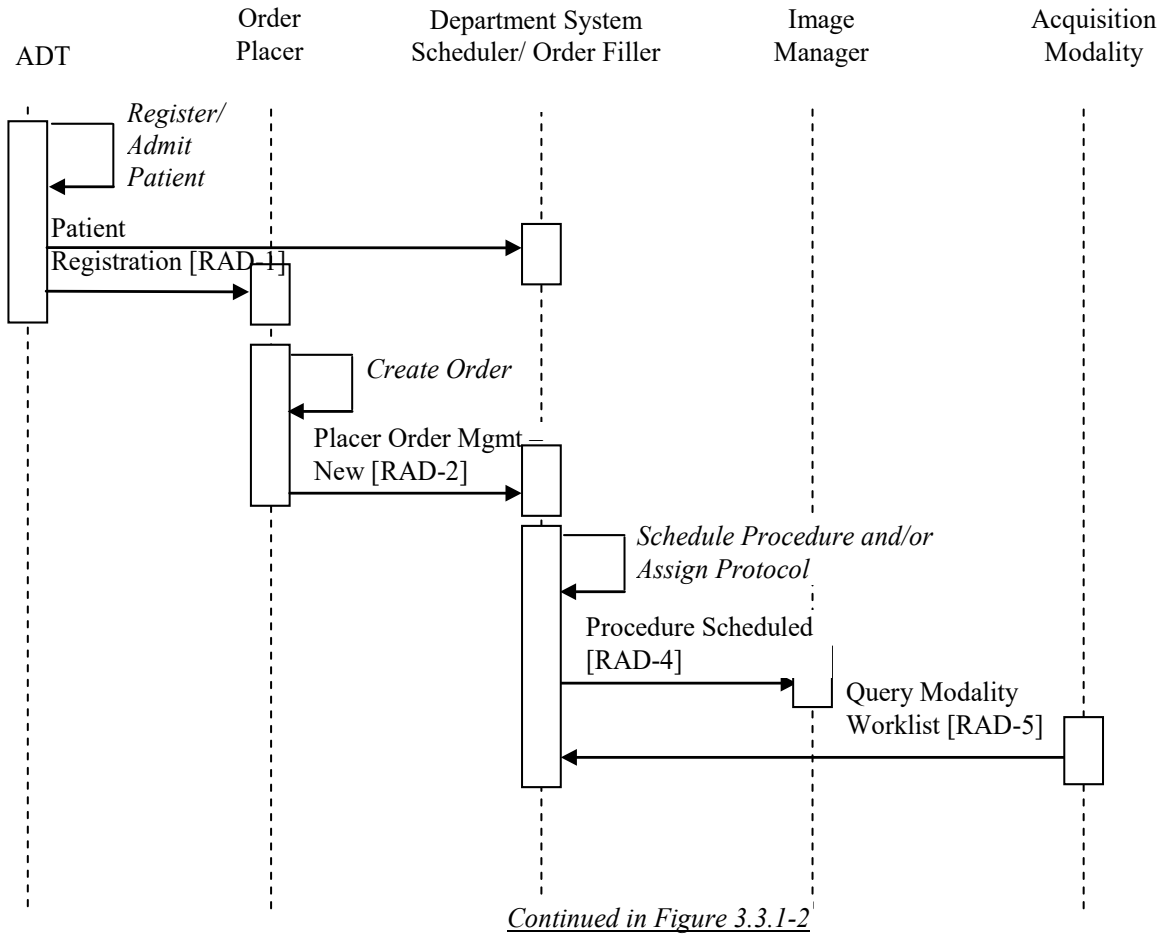
Figure 3.3.1-1: Administrative Process Flow
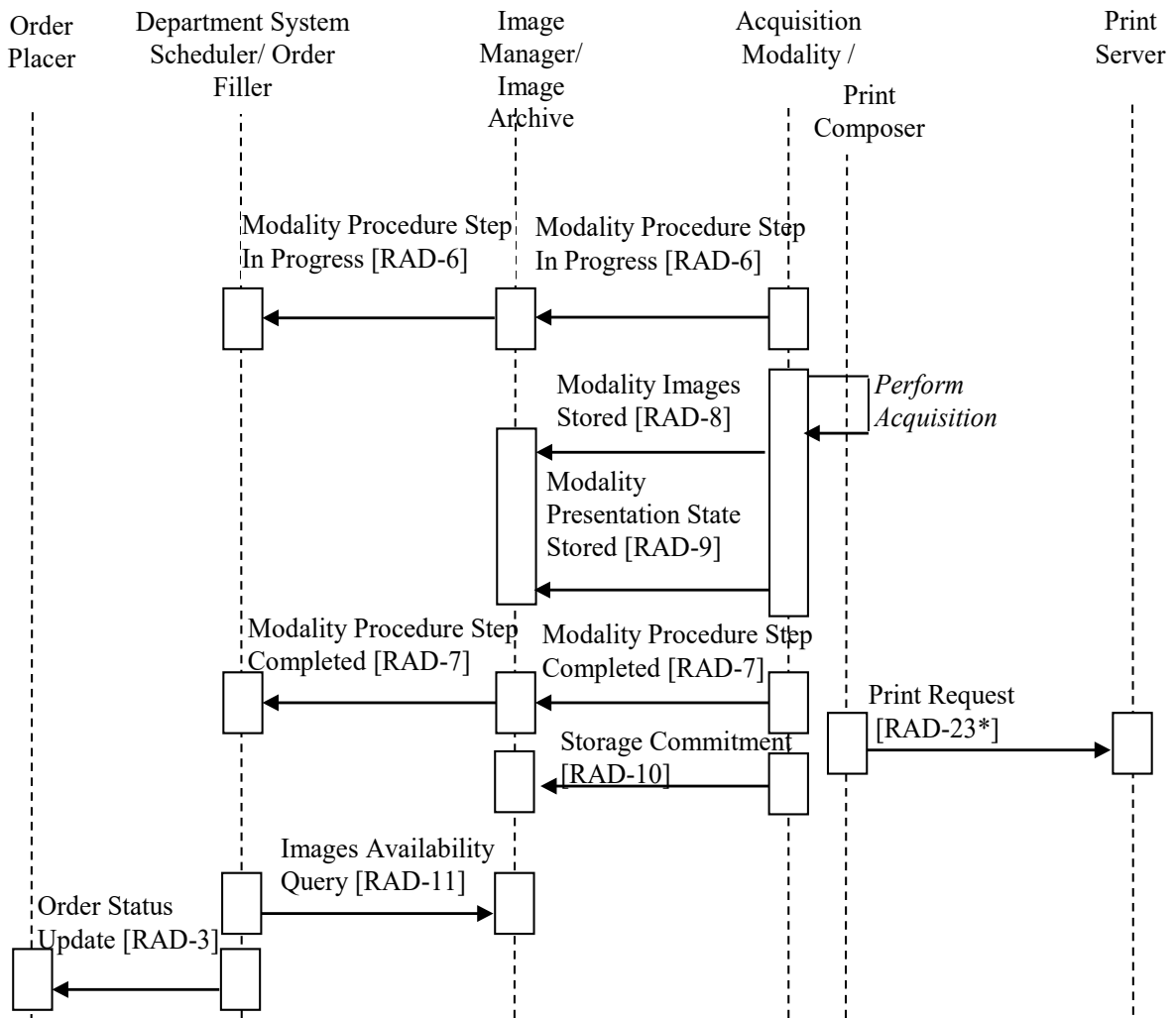
Figure 3.3.1-2: Procedure Performance Process Flow

Note: The Print Request [RAD-23] transaction is not a part of this profile; it is displayed for illustration purposes only.

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

- The Print Composer is grouped with an Acquisition Modality but is shown separately in the diagram to distinguish the different transactions.

- *Schedule Procedure*: The Department System associates the order with a number of 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 grouped into Scheduled Procedure Steps based on the timing and ordering. Scheduled Procedure Steps are scheduled, i.e., assigned a time slot and performing resource (modality).

- *Protocol Assigned*: The radiologist determines the protocol (i.e., settings and conditions to be used in performing the Scheduled Procedure Steps); in particular, the ordered list of codes identifying the protocol for each of the steps. This may happen prior to, simultaneous with, or subsequent to the *Schedule Procedure* process step.

- The diagram above shows one particular sequencing of the Modality Procedure Step Completed [RAD-7] transaction. This transaction may occur at any point following the creation of an image and/or Presentation State (GSPS) objects. This means it can occur before images and/or GSPS are stored, after storage, after printing (as in this example), or even after storage commitment. The Radiology Technical Framework does not specify the timing of this transaction in relation to other transactions.

- The diagram above shows the managed creation of images. The equivalent flow applies to other Evidence Documents that the actor supports.

3.3.2 Patient Update Flow

This case covers the situation where patient information updates are introduced into the system at the various stages of the normal process flow. Such updates will cause additional transactions to occur to assure synchronization of information between interested actors. Only the affected parts of the normal flow diagram are presented below. All subsequent process steps will progress according to the normal flow diagram.

3.3.2.1 Patient Update before Procedure Scheduling

If patient information is changed before the corresponding procedure(s) are scheduled by the Department System Scheduler/Order Filler, the Patient Registration steps are altered as presented in the Figures 3.3.2.1-1 and 3.3.2.1-2.
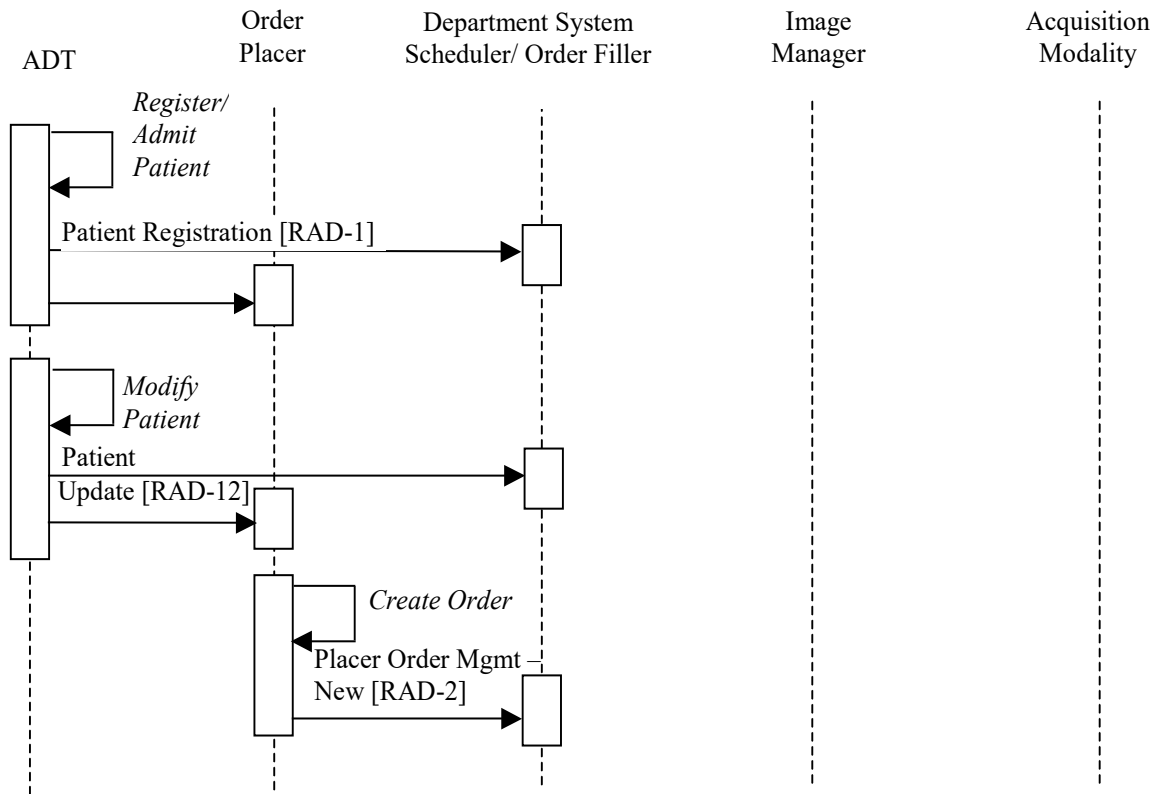
1110

Figure 3.3.2.1-1: Patient Update before Order Entry
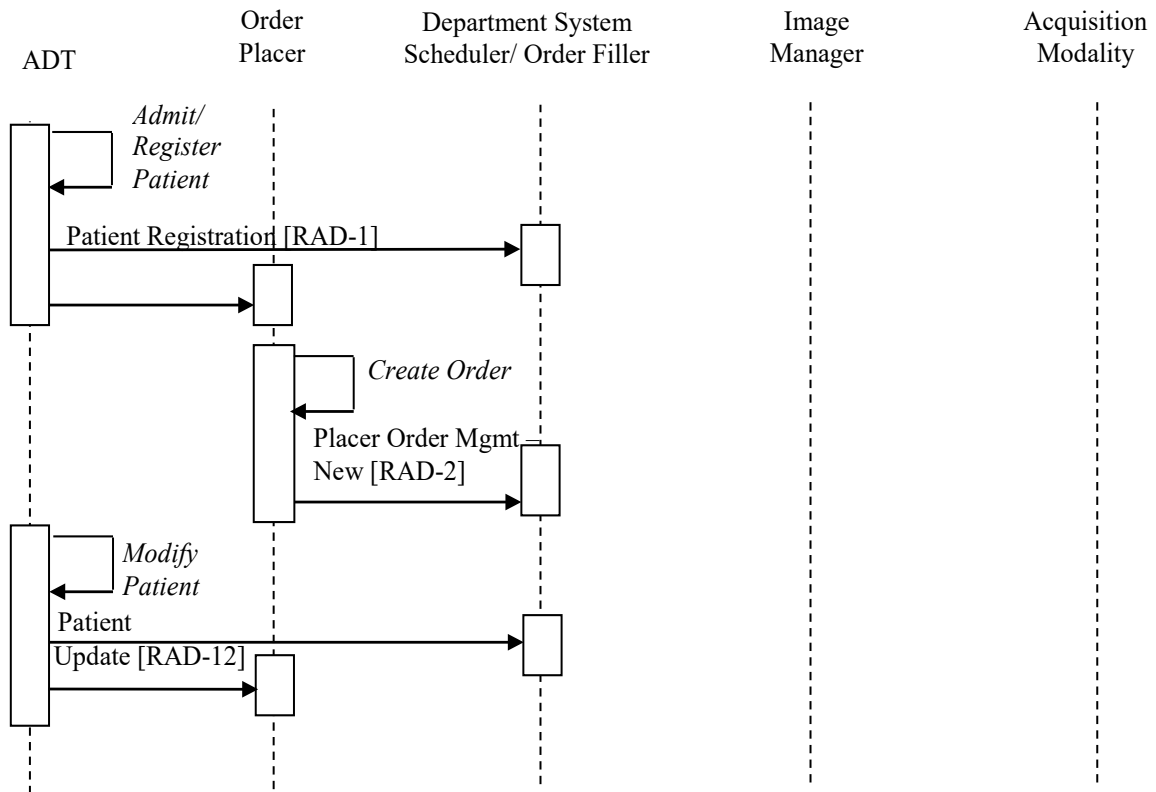
Figure 3.3.2.1-2: Patient Update after Order Entry

The *Modify Patient* process includes changing inpatient demographics, merging two patient records and moving the information from one patient record to another.

3.3.2.2 Patient Update after Procedure Scheduling

If patient information is changed after procedure(s) are scheduled by the Order Filler, the Patient Update transactions are altered as follows:
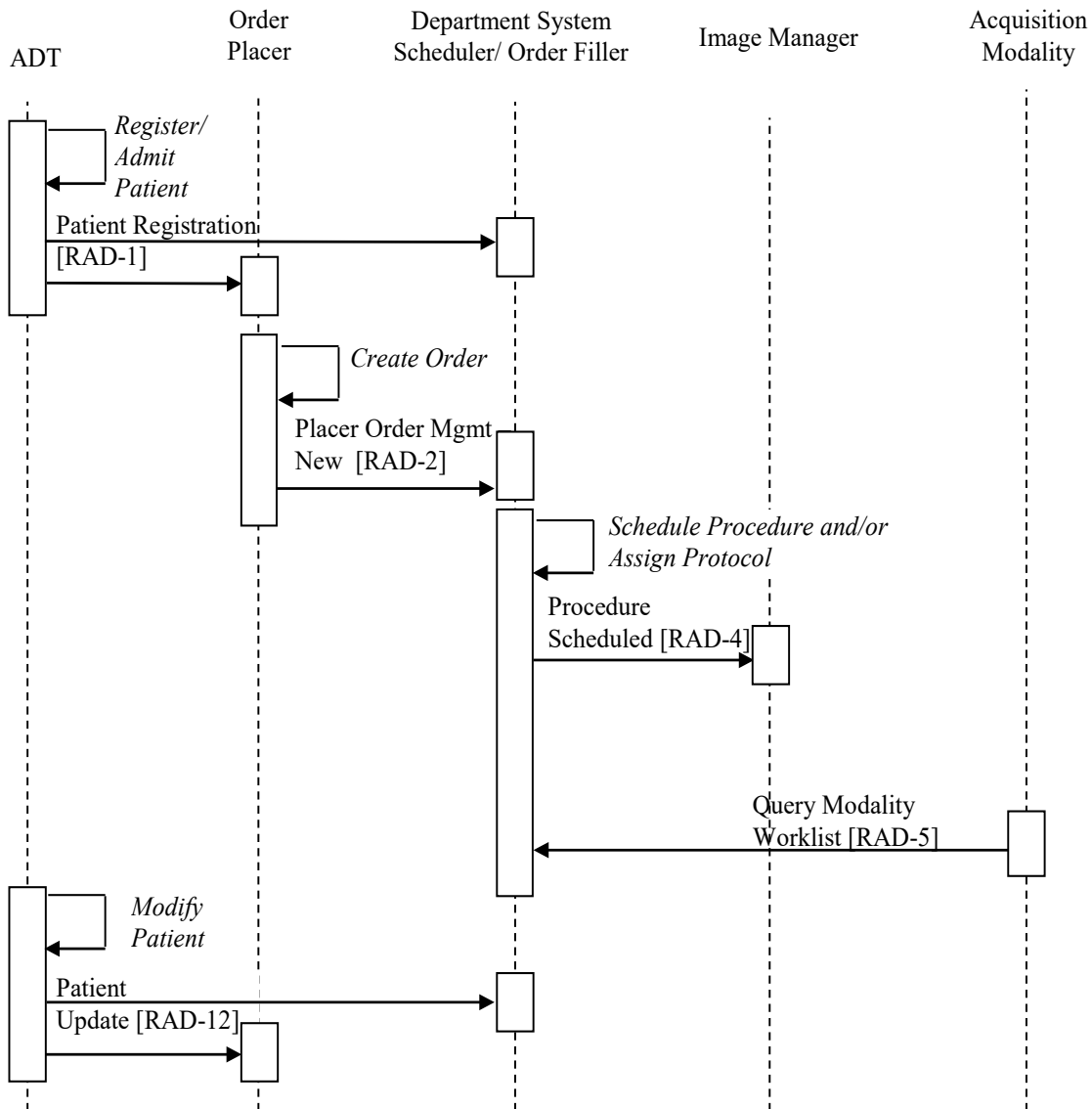
Figure 3.3.2.2-1: Patient Update after Procedure Scheduling

Note that in the Patient Information Reconciliation (PIR) Profile, the Image Manager will also be notified and will have additional responsibility when Patient updates occur.

3.3.3 Order Change Flow

This case covers the situation when the Order Placer or the Department System Scheduler/Order Filler has to change order information or cancel/discontinue an order. When an order information change is necessary, for HL7 v2.3.1, the Radiology Technical Framework requires the initiating actor to cancel the order and generate the new one using the new information. Figures 3.3.3-1 and 3.3.3-2 depict examples of order cancellation/re-ordering flow initiated by the Order Placer and the Department System Scheduler/Order Filler, respectively. Note that one should consider

1130 these transactions as being performed between the process flow fragments depicted in Figures 3.3.1-1 and 3.3.1-2 to ensure synchronization of information between interested actors.
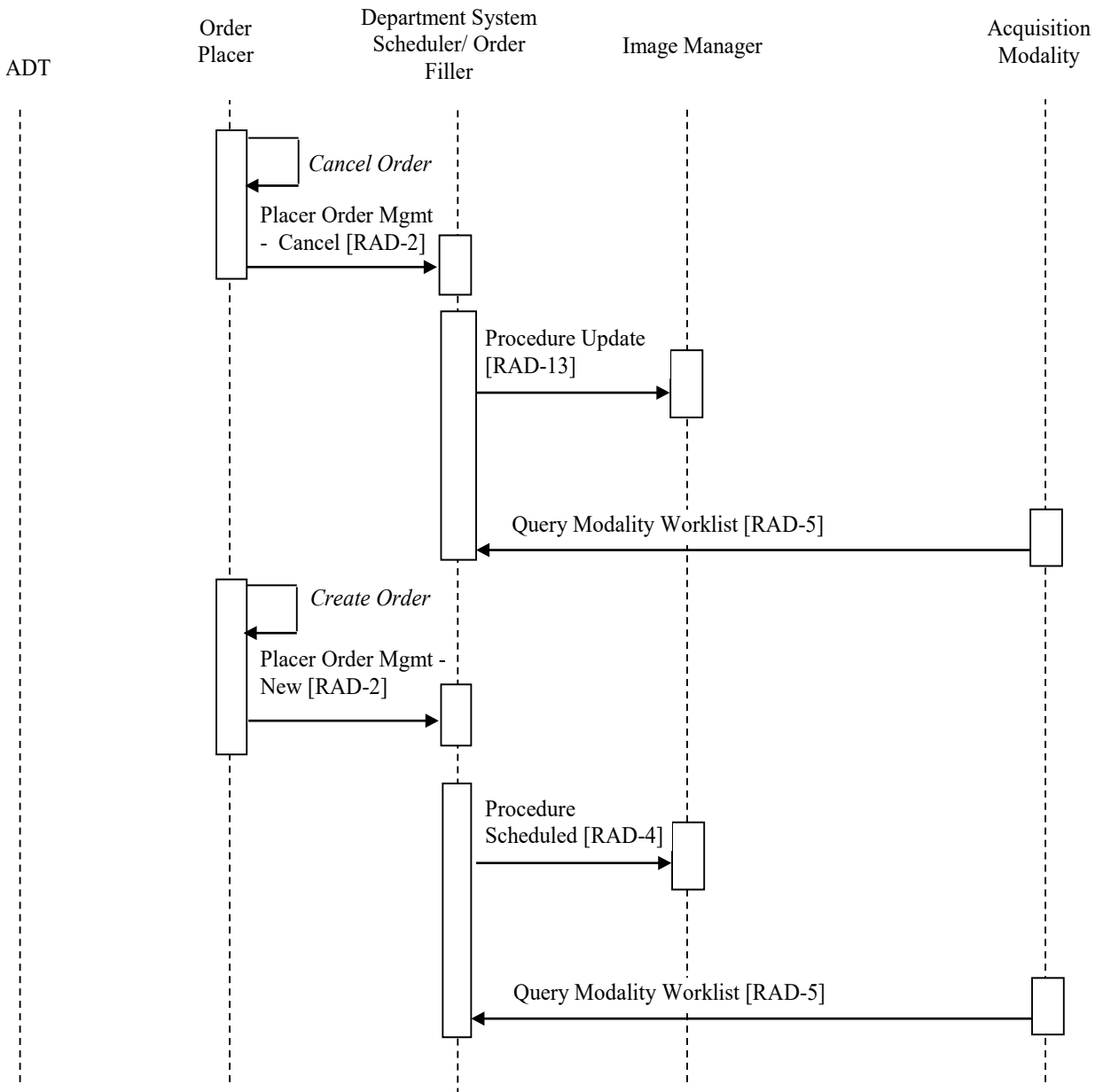
Figure 3.3.3-1: Order Replacement by the Order Placer

Department System Scheduler/Order Filler may cancel an order received from the Order Placer
1135 and place the new order as a replacement, as shown in the Figure 3.3.3-2.
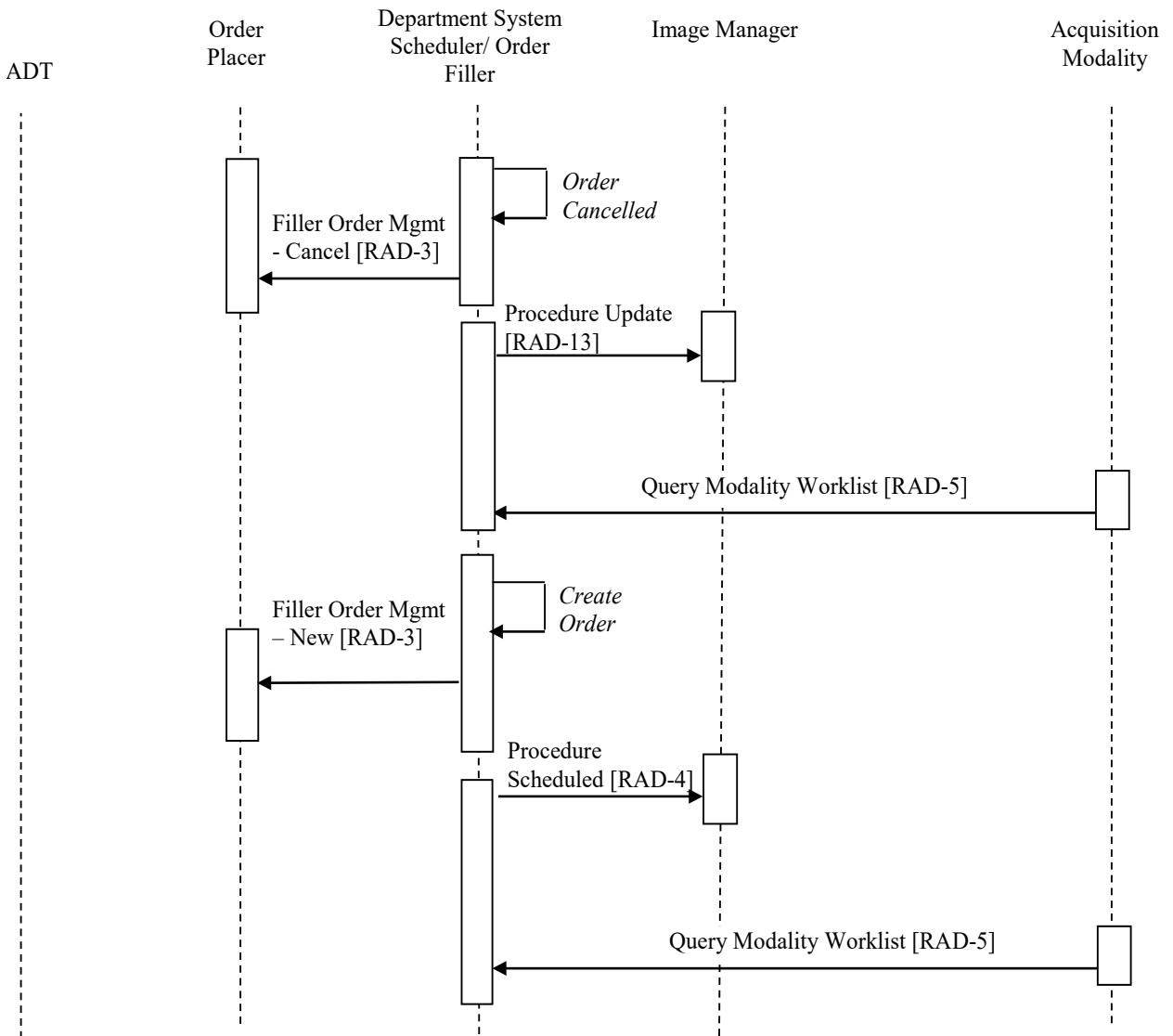
Figure 3.3.3-2: Order Replacement by the Department System Scheduler/Order Filler

The Department System Scheduler/Order Filler may also generate a new order on its own as a means of handling the unidentified patient case discussed in Section 4.2. The process flow in such a situation corresponds to the ordering sequence in Figure 3.3.3-2, without the preceding Order Cancel transaction.

1140

Note: The Radiology Technical Framework does not support notification of the modality of the order discontinuation after the Modality Procedure Step In Progress message has been generated by the Acquisition Modality, i.e., the current procedure step will be completed even though the order could be discontinued.

1145

3.3.4 Exception Management Workflow

This case addresses the need to manage errors at the modality. The types of exceptions covered by this case are as follows:

- Selection of the incorrect Scheduled Procedure Step from the Modality Worklist.

- The need to handle the consequences of having performed a procedure step other than the scheduled one.

Some of these exception cases are addressed using required functionality for IHE actors in the Scheduled Workflow Profile and are described first in this section. Other exception cases are listed separately in this section and this Exception Management Workflow is supported by the PPS Exception Management Option or other options in the Scheduled Workflow Integration Profile. The following numbered items list exception cases that shall be supported by the actors listed in each item.

In the course of the scheduled workflow, such exceptions may occur at different times:

1. Before the Modality Procedure Step in Progress transaction is issued, the Operator/Radiologist changes the order on the Department System Scheduler which then provides the Modality Worklist as defined by the Scheduled Workflow Integration Profile (see the Order Change flow described in Section 3.3.3). This will ensure that the most recent Worklist Information is used by the Modality. This case does not require the PPS Exception Management Option. The Acquisition Modality shall be able to process new worklist information that results from this order change; when or how the modality re-queries the Department System Scheduler is not specified by this framework.

2. After the Modality Procedure Step in Progress transaction has been issued, but before the Modality Procedure Step Completed transaction is issued, the Operator/Radiologist may discontinue the PPS. In this case any images that may have been acquired are part of the discontinued PPS and they shall be Storage Committed. This case is supported by Abandoned case (see RAD TF-2: 4.6.4.1.2.3.5) of the Scheduled Workflow Integration Profile. See the end of this section for discussion of this case and PPS Exception Management Option.

3. After the Modality Procedure Step Completed transaction has been issued, the Operator/Radiologist may notice or become aware that an incorrect worklist entry selection was made. Whether this occurs before the Requested Procedure is read or afterwards, the modality is not responsible for performing the necessary corrections. Rather the Image Manager and the Department Scheduler Actors must make such corrections (see RAD TF-2: 4.7.4.1.3.1). The Image Manager and the Order Filler may also offer a correction capability to recover the erroneous instances. IHE does not provide a mechanism to automatically propagate this correction between the Image Manager/Image Archive and the Department System Scheduler/Order Filler.

These next cases are optional for Acquisition Modalities and deal with using a different protocol at the modality as was scheduled by the Department System Scheduler/ Order Filler.

1185   1. **After** the Modality Procedure Step in Progress transaction has been issued, but before the Modality Procedure Step Completed transaction is issued, the Operator/Radiologist may decide to modify the "in progress" Performed Procedure Step from what was intended by the Requested Procedure and Scheduled Procedure Step selected. In the Scheduled Workflow Integration Profile, the Acquisition Modality notifies the PPS Manager (and in

1190   turn the Image Manager and the Department System Scheduler) by returning a Procedure Code Sequence of zero length. In addition, if the Assisted Acquisition Protocol Setting Option is supported by the Acquisition Modality, it can indicate this change by returning a Performed Protocol Code Sequence different from the Scheduled Protocol Code Sequence (see Figure 3.3.4-1 below).

1195   2. **Before** the Modality Procedure Step in Progress transaction is issued, the Operator/Radiologist decides to proceed without changing the order on the Department System Scheduler/Order Filler by performing one or more Procedure Steps different than scheduled by the Modality Worklist entry as defined by the Scheduled Workflow Integration Profile. Its handling at the Acquisition Modality may be facilitated by the

1200   Assisted Acquisition Protocol Setting Option.
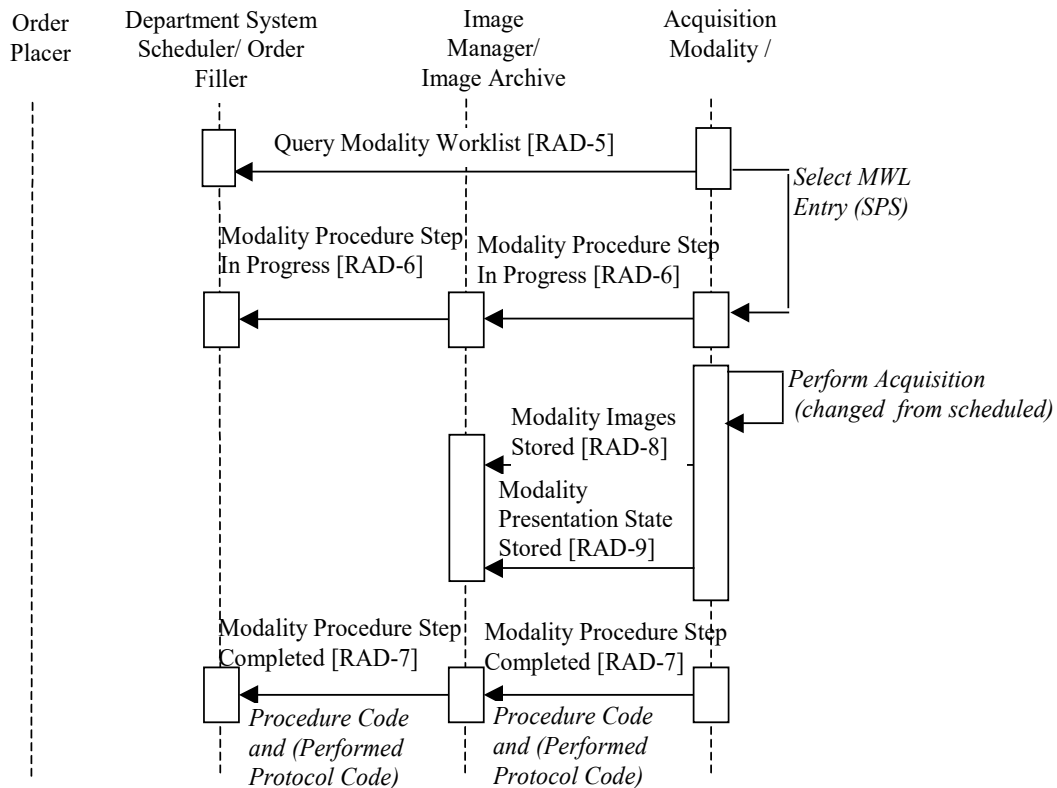
Figure 3.3.4-1: Exception Management Workflow (Changed from Scheduled on Modality)

The last case in this section describes how the PPS Exception Management Option may be utilized in the Scheduled Workflow Integration Profile. This feature is optional for the Acquisition Modality, Department System Scheduler and Image Manager Actors.

1. After the Modality Procedure Step In Progress transaction has been issued, the Operator/Radiologist may realize that the wrong SPS has been selected (incorrect patient or incorrect Requested Procedure/Order for the same patient). In this case some of the acquired images or other evidence objects may already have been stored to the Image Manager/Image Archive (with or without storage commitment confirmed). With the PPS Exception Management Option of the Scheduled Workflow Integration Profile, the Acquisition Modality notifies the PPS Manager (and in turn the Image Manager and the Department System Scheduler/Order Filler) of the error so that these systems take appropriate action (see RAD TF-2: 4.7.4.1.3.1 and Figure 3.3.4-2 below).

   IHE does not define how the modality may dispose of and/or correct the images or other evidence objects. Each implementation shall decide if it is useful to support the storage of the corrected images or other evidence objects, when clinically meaningful. However, if they do, new *Modality Procedure Step in Progress/Completed* and Storage Commitment transactions shall be used.
   In this case, the PPS Exception Management Option of the Scheduled Workflow Integration Profile provides further functionality. The Modality notifies the PPS Manager (and in turn the Image Manager and the Department System Scheduler) of the reason for the discontinuation so that these systems may take the appropriate actions (see Figure 3.3.4-3 below).
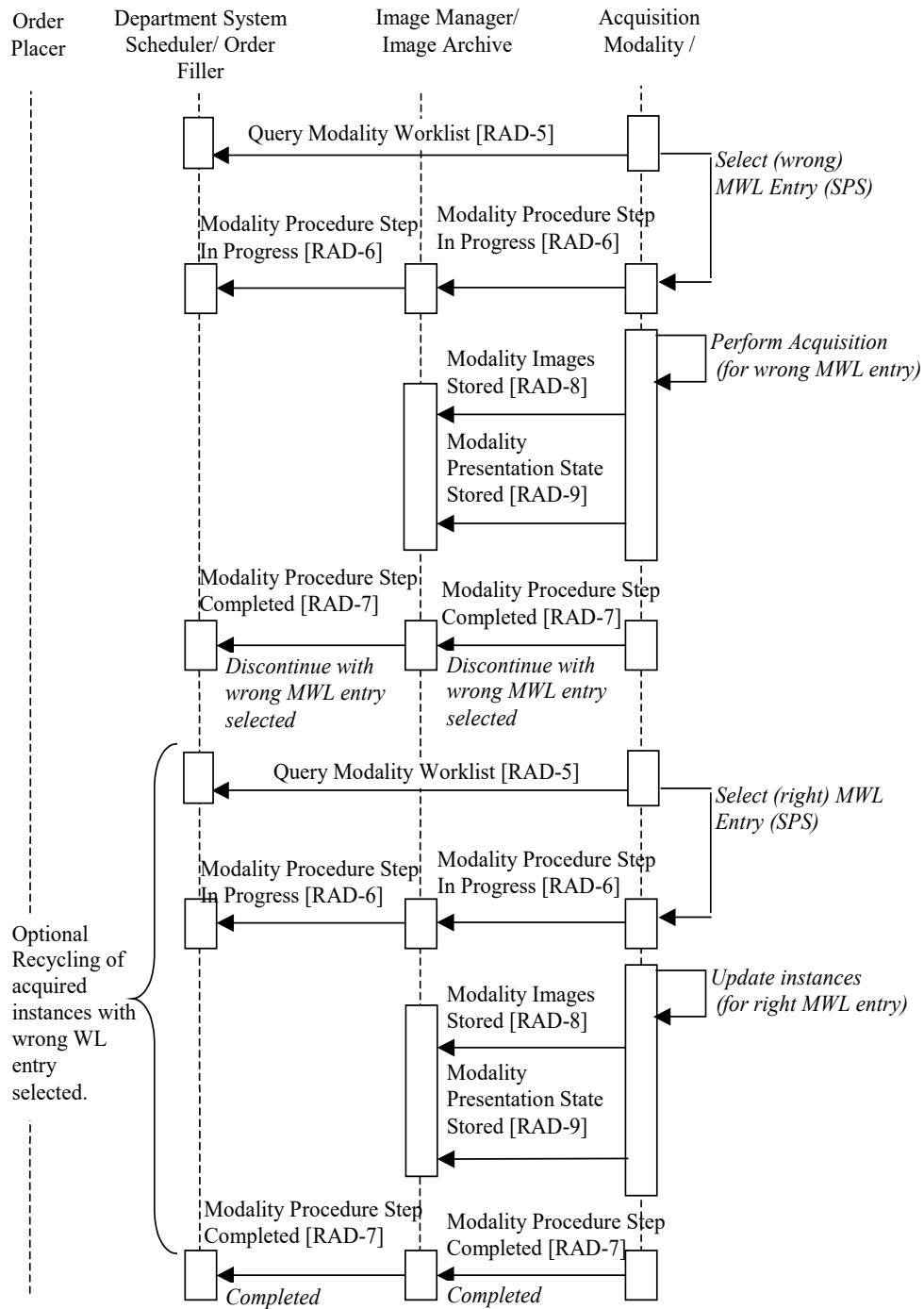
Figure 3.3.4-2: Exception Management Workflow (Wrong Worklist Entry Selected)
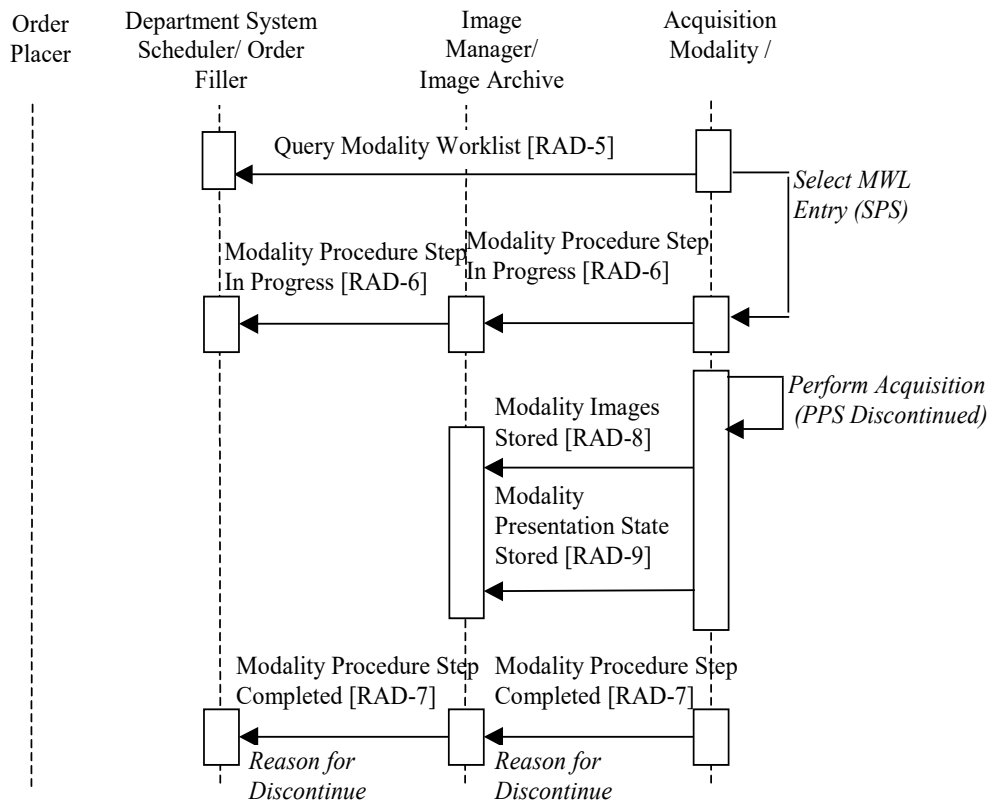
1230   **Figure 3.3.4-3: Exception Management Workflow (Discontinued with a Reason)**

3.3.5 Implicit Post-Processing

This case addresses image post-processing tasks performed as an implicit part of the Scheduled Workflow.

In general, post-processing tasks scheduled and managed explicitly using post processing
1235 worklists are addressed by the Post-Processing Workflow Integration Profile (see Section 12 for further details on that profile). However, at some sites, post-processing tasks performed on the acquisition system or adjacent workstations are implied by the information in the acquisition worklist. In such cases, the post-processing is managed by the technician simply carrying out the steps following acquisition.

1240 Technicians may be instructed that certain post-processing should always be performed for certain acquisitions, or alternatively, different protocol codes may be provided in the acquisition worklist to indicate intended post-processing. In either case, no worklist is used on the post-processing Evidence Creator.

In the case of this "implicit post-processing workflow", the Evidence Creator may obtain source
1245 images and other evidence objects necessary for post-processing by receiving them from the Acquisition Modality (either pulled or pushed via some non-IHE defined mechanism) or by being grouped with an Image Display (giving the system query/retrieve capabilities). Based on

the information contained in the images, the Evidence Creator can send status messages and store its results according to the IHE transactions as shown in the following use cases.

1250 The following sequence of steps describes the typical process flow when the Evidence Creator receives the images from an Acquisition Modality via some non-IHE means.
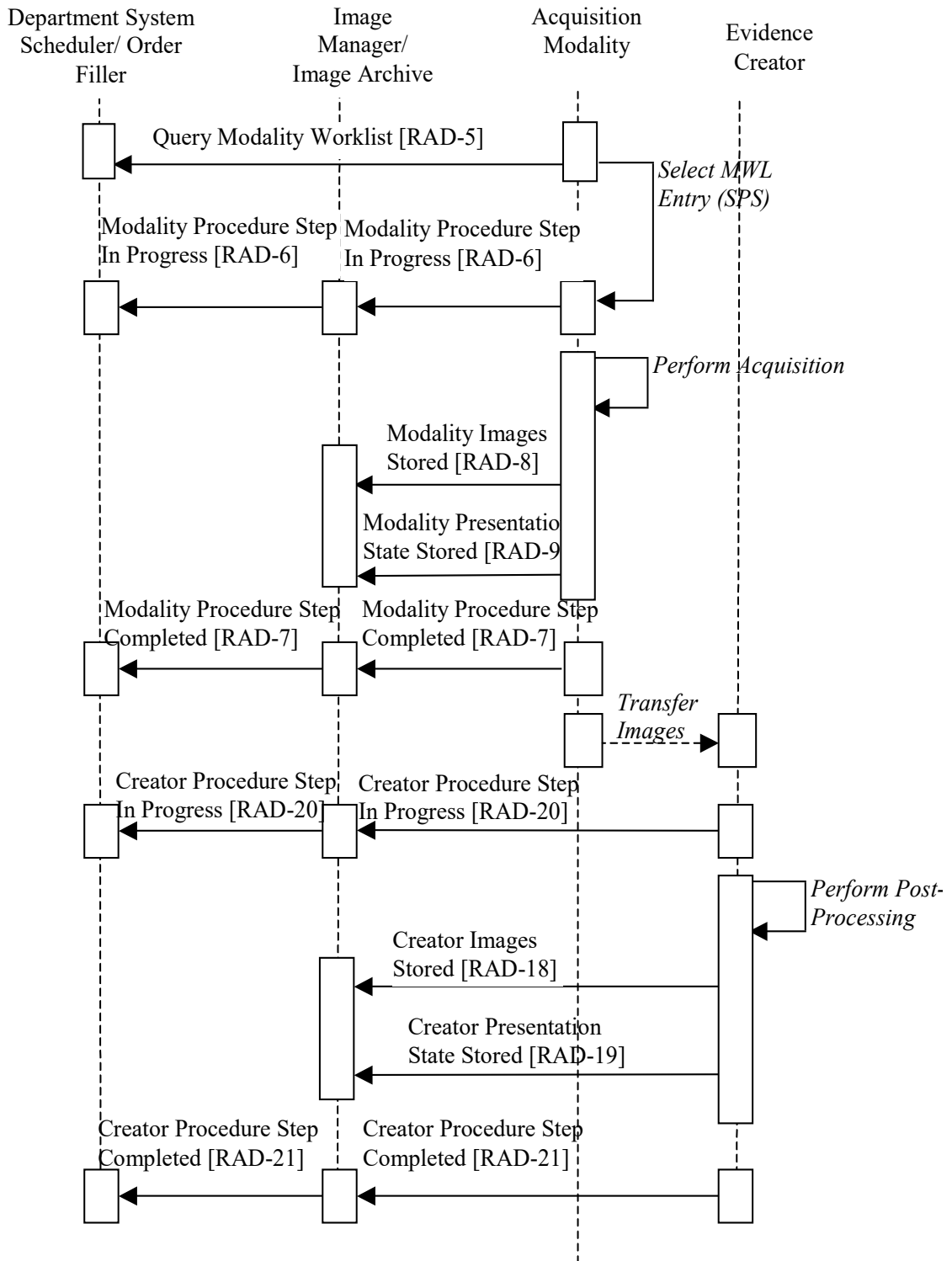
Figure 3.3.5-1: Post-processing in Scheduled Workflow

Note 1: The Modality Presentation State Stored [RAD-9] and Creator Presentation State Stored [RAD-19] transactions are not a part of this profile; they are displayed for illustration purposes only.

Note 2: When the Acquisition Modality performs implicit post-processing, it reports performed procedure step progress using [RAD-6] and [RAD-7] rather than [RAD-20] and [RAD-21]. The post-processing result instances may be referenced in the same [RAD-7] acquisition PPS as the acquired images, or may be referenced in one or more separate [RAD-7] PPS messages.

The following should be noted in relation to the Post-Processing process flow in Scheduled Workflow as described above:

- The images for post-processing are transferred from the Acquisition Modality to the Evidence Creator by means that are out of scope of the Radiology Technical Framework.

- *Perform Post-Processing*: The Evidence Creator uses the source images and/or other evidence objects it receives from the Acquisition Modality to perform post-processing tasks and generate new set(s) of images and/or other evidence documents. It uses information from the source images to populate the newly created objects and the Creator Performed Procedure Step Messages.

The following sequence of steps describes the typical process flow when Evidence Creator is grouped with Image Display.

Figure 3.3.5-2: Post-processing in Scheduled Workflow (performed on Evidence Creator)

Note 1: The Modality Presentation State Stored [RAD-9] and Creator Presentation State Stored [RAD-19] transactions are not a part of this profile; they are displayed for illustration purposes only.

1275　　Note 2: When the Acquisition Modality performs implicit post-processing, it reports performed procedure step progress using [RAD-6] and [RAD-7] rather than [RAD-20] and [RAD-21]. The post-processing result instances may be referenced in the same [RAD-7] acquisition PPS as the acquired images, or may be referenced in one or more separate [RAD-7] PPS messages.

The following should be noted in relation to the Post-Processing process flow on the independent
1280　workstation:

- The Evidence Creator is grouped with the Image Display and the images for post-processing are retrieved from the Image Archive where the Acquisition Modality has transferred them.

- *Perform Post-Processing*: The Evidence Creator uses the source images and/or other
1285　evidence objects it receives from the Image Archive to perform post-processing tasks and generate new set(s) of images and/or other evidence documents. It uses information from the source images to populate the newly created objects and the Creator Performed Procedure Step Messages.

3.3.6　Departmental Appointment Booking

1290　This case addresses the use of the Departmental Appointment Notification Option by the Order Placer and Order Filler Actors.

Order Fillers that support this option shall have ability to be configured so that the Appointment Notification transaction is not sent when connected to an Order Placer that does not support the Departmental Appointment Notification Option.

1295　In the IHE Scheduled Workflow Integration Profile, the scheduling needed to perform an Order is managed by the Departmental System Scheduler/Order Filler. The Order Placer may request along with an Order a preferred date and time for this Order, but it is the Order Filler that sets, updates and possibly cancels the appointment(s) for examinations. When a new Order is placed by the Order Placer or the Order Filler, an Appointment Notification (New Bookings) is sent to
1300　the Order Placer. This Appointment Notification (New Bookings) may include several appointments bookings in case some of the Scheduled Procedure Steps require separate appointments. Equally, one or more Scheduled Procedure Steps may be scheduled during the same appointment booking.

If any changes to some of these appointments are made by the Order Filler, it issues an
1305　Appointment Notification (Reschedule Bookings) to inform the Order Placer of the change. If that appointment is cancelled by the Order Filler, it issues an Appointment Notification (Cancel Bookings) to the Order Placer.

This Departmental Appointment Notification Option allows the Order Placer to remain aware of any scheduling changes that may be made by the Order Filler, but not to request an appointment
1310　change. For such a change, it may be necessary to use means not defined in this Integration Profile (e.g., a phone call to the person entering orders on the Order Filler) that an appointment booking has to be changed.
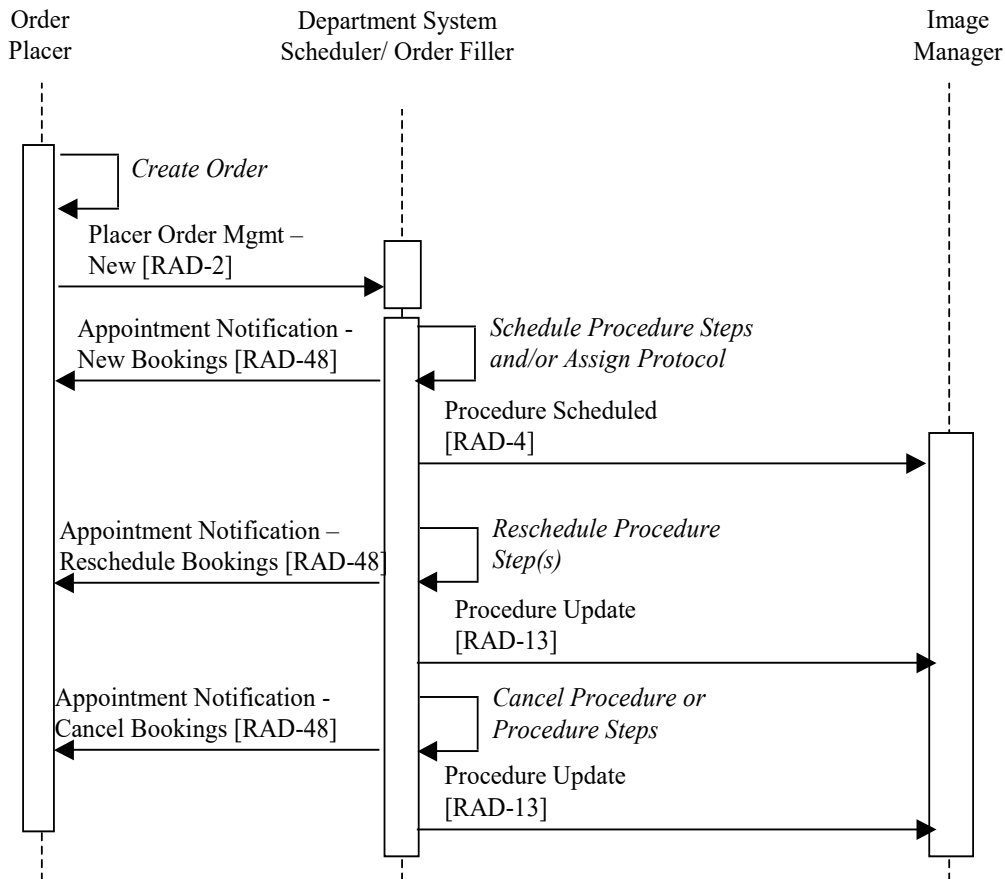
Figure 3.3.6-1: Departmental Appointment Bookings Process Flow

3.4 Data Model for Scheduled Workflow

This section defines the integrated data model adopted by the Radiology Technical Framework for the HL7 messages and the DICOM Information Object Definitions (IODs). The Entity Relationship (ER) diagram represents the integration of proper subsets of HL7 v2.3.1 and the DICOM Model of the Real World with minor extensions as noted in Section 3.4.1 and described in RAD TF-1x: Appendix B.

3.4.1 Model of the Real World

Figure 3.4-1 depicts the model of the real world within scope of the Scheduled Workflow Profile. This model provides an overview of the high-level integration of the DICOM and HL7 models. This integrated model differs from the DICOM Model of the Real World (refer to DICOM PS3.3) in the following respects:

- The Service Episode, Procedure Plan and Procedure Type entities have been excluded and are outside the scope of the Radiology Technical Framework

- The relationship between the Visit and Imaging Service Request has been excluded and is outside the scope of the Radiology Technical Framework.

1330
- The HL7 Placer Order and Filler Order entities have been inserted into the DICOM hierarchy between the Patient entity and Imaging Service Request entity. IHE requires that a single Placer Order shall correspond to one and only one Filler Order.

- The DICOM Imaging Service Request Entity is equated with the HL7 Filler Order entity. In this relationship, IHE provides clarification of the use of the Accession Number -
1335
DICOM attribute (0008,0050); see RAD TF-1x: Appendix A for further discussion.
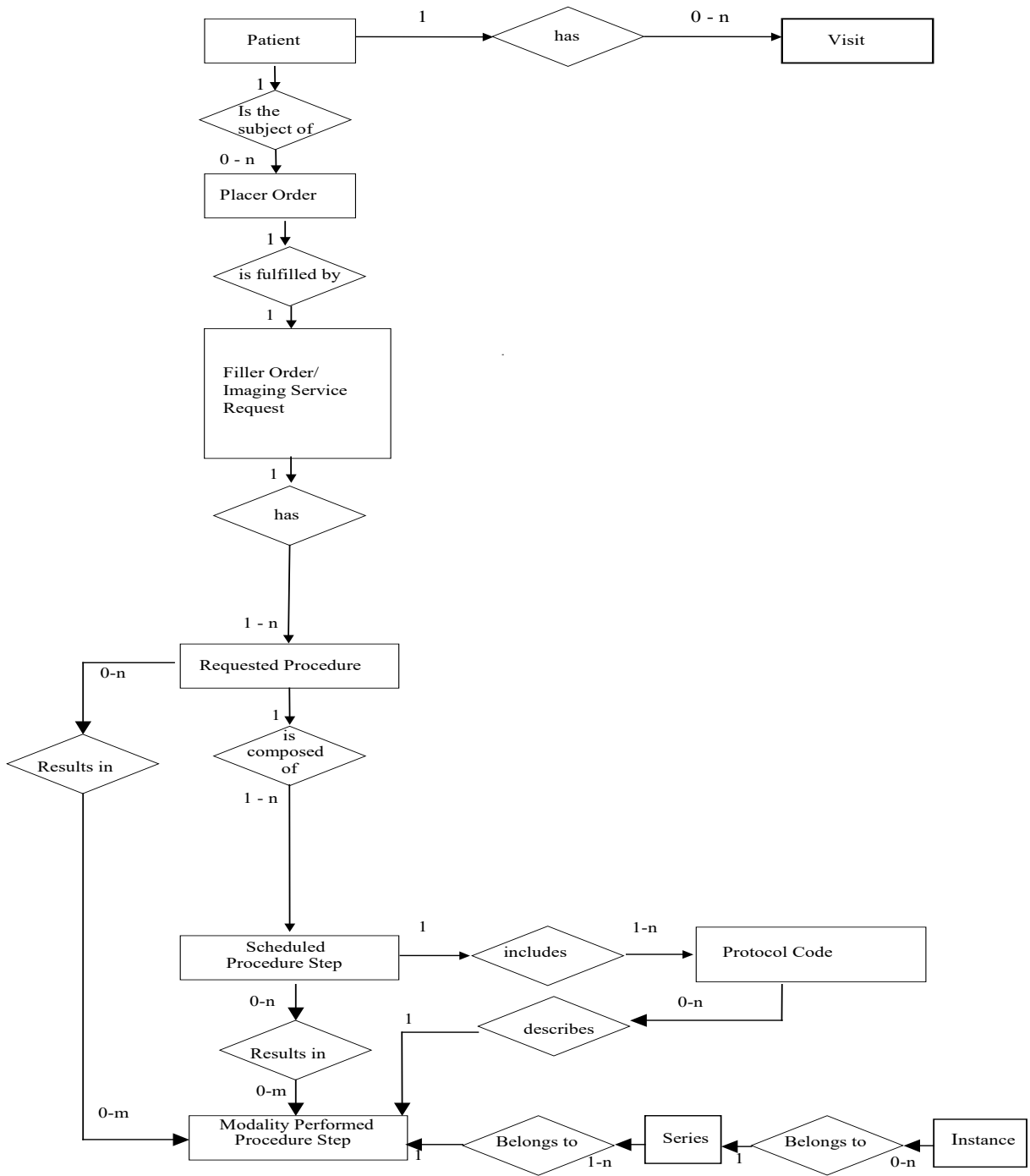
Figure 3.4-1: Real World Model for Scheduled Workflow

1340 ## 3.4.2 Scheduled Workflow Concepts in Practice

The IHE "Real World" model for Scheduled Workflow described above offers three major levels of control that can be used to customize a broad range of specific workflow situations:

- **Order**: A request for an Imaging Service

- **Requested Procedure**: Unit of work resulting in one report with associated codified, 1345 billable acts.

- **Scheduled and Performed Procedure Step**: the smallest unit of work in the workflow that is scheduled (work to do) and/or performed (work done).

The Order Filler/Department System Scheduler uses the Universal Service ID in each order that it receives to determine what specific Requested Procedures are needed, and for each Requested 1350 Procedure the Procedure Steps that need to be scheduled.

A departmental Procedure Plan may be used in the Order Filler to predefine for each one of the types of Orders that may be requested from the imaging department (generally defined in the Order Placer) the breakdown in Requested Procedure (with a specific procedure code) and for each Requested Procedure Code, the breakdown in Scheduled Procedure Steps.

1355 For an illustration of mapping between transactions [RAD-2], [RAD-3], [RAD-5], [RAD-6] and [RAD-7], see the IHE white paper "Code Mapping in IHE Radiology Profiles", https://www.ihe.net/uploadedFiles/Documents/Radiology/IHE_RAD_White-Paper_Codes.pdf.

The figure below defines an example of the breakdown of a "rule out pulmonary embolism" Order.
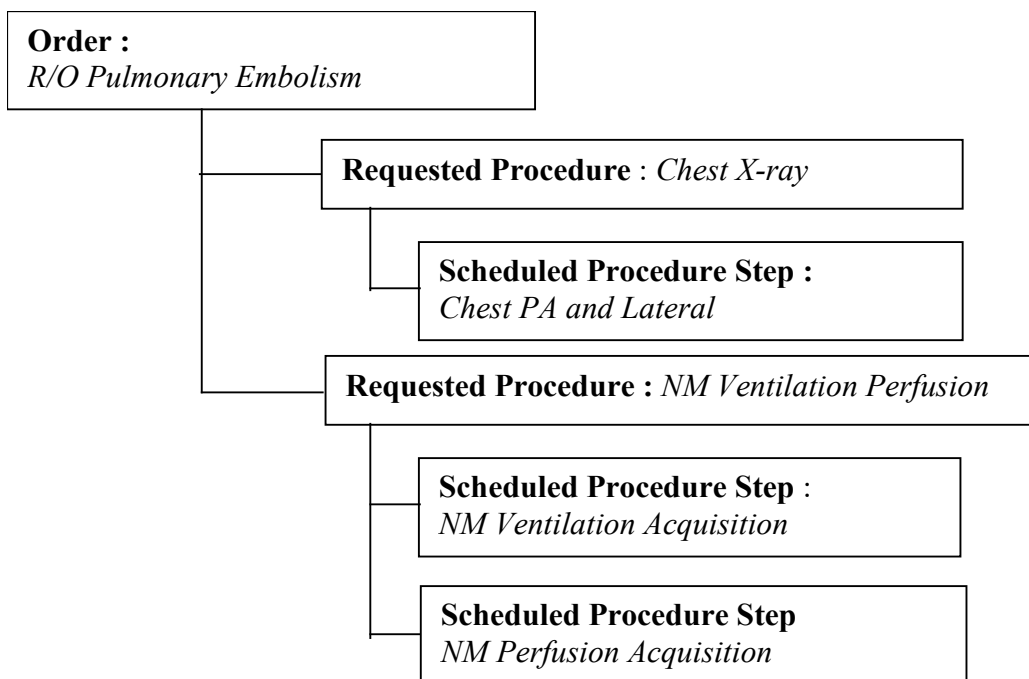
1360

In this Procedure Plan, for this specific Order, two Requested Procedures are defined. The Chest X-ray that will be read and reported by a different radiologist than the NM Ventilation-Perfusion, hence two different Requested Procedures. The NM Ventilation Perfusion Procedure has been scheduled as two different Scheduled Procedure Steps, to account for the fact that the patient will
1365 have the two NM acquisitions performed at a different time, thus allowing for patient preparation between the two examinations. This is the way this institution has decided to handle this Order. Another Institution may choose to require the same radiologist to read both the X-ray and the NM images. In that case it would define in its Procedure plan for the same Order to have a single Requested Procedure with three Scheduled Procedure Steps.

1370 Many Orders processed in a Radiology Department would have a simpler breakdown such as this Chest X-ray example.

Order :
Chest X-ray

Requested Procedure : *Chest X-ray*

Scheduled Procedure Step :
Chest PA and Lateral
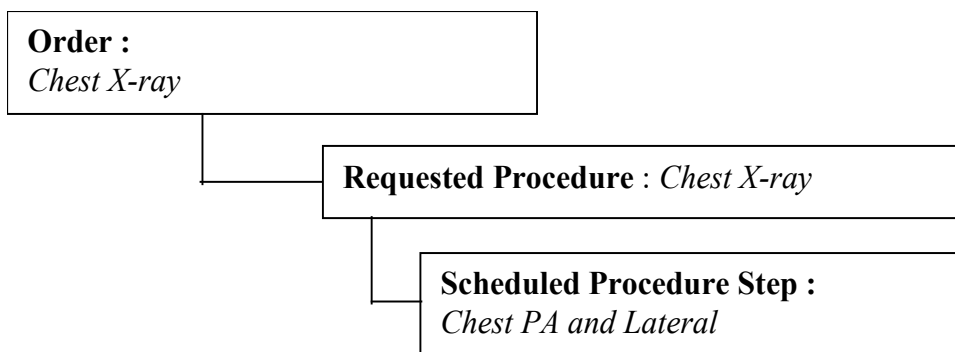
It should be noted that the three level Order breakdown has been defined in the IHE Scheduled Workflow so that any type of Orders, from the simple case to the more complex cases may be
1375 handled by the same workflow concepts, thus providing a general approach that can be easily customized by each imaging department in the definition of its Procedure Plan.

In the IHE Scheduled Workflow, the **Accession Number identifies the Order**. The requested Procedure ID distinguishes among Requested Procedures when an Order requires multiple Procedures. IHE sets a common meaning for these two terms to provide clinicians with a
1380 consistent and non-ambiguous access across different vendor products (RIS, PACS and Modalities).

3.4.2.1 Tracking Performed Procedure Steps

Scheduled Workflow not only addresses the breakdown of Orders into Requested Procedures and Scheduled Steps but also allows tracking the Procedure Steps that have actually been
1385 performed. The Performed Procedure Steps may or may not correspond to the Scheduled Procedure Steps. This provides the flexibility needed to adjust on the Modality if the actual acquisition differs from what was scheduled.

Note: MPPS Complete [RAD-7] reflects the completion of a Modality Performed Procedure Step. As explained in the previous example, depending on the Requested Procedure that has been requested in the Order, it is the role of
1390 the Department System Scheduler/Order Filler to create the corresponding SPS and set the rules to process the MPPS completion transaction [RAD-7] when received, and therefore to trigger any Order Update with the [RAD-3] transaction. The number of MPPS received by the Department System Scheduler/Order Filler may not match the number of MPPS transactions expected by the Department System Scheduler/Order Filler. Management of

1395

this case is a local configuration task of the Department System Scheduler/Order Filler and is not intended to be specified in this profile.

Using the Pulmonary Embolism example above, one may decide to follow the Order breakdown as defined in the procedure Plan.

```
Order :
R/O Pulmonary Embolism

    └── Requested Procedure : Chest X-ray

            └── Scheduled Procedure Step :        Performed Procedure Step :
                Chest PA and Lateral                 Chest PA and Lateral

    └── Requested Procedure : NM Ventilation Perfusion

            └── Scheduled Procedure Step :        Performed Procedure Step :
                NM Ventilation Acquisition           NM Ventilation Acquisition

            └── Scheduled Procedure Step          Performed Procedure Step
                NM Perfusion Acquisition             NM Perfusion Acquisition
```
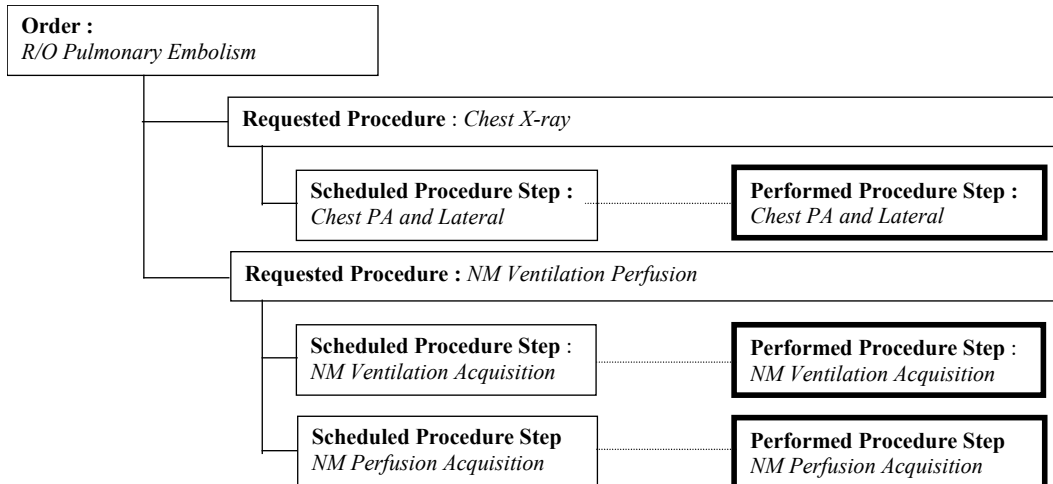
1400 The Chest X-ray Requested Procedure would contain the series of images associated with the Chest PA and Lateral Performed Procedure and the NM Ventilation Perfusion would contain both the series for the ventilation and the series of images for the perfusion. From this example one can see how the Requested Procedure forms the "folder" where the radiologists find the images to be read resulting from the Scheduled Procedures Steps.

1405 Using the Pulmonary Embolism example above, one may decide that following the Chest X-ray, it is not necessary to perform the NM Perfusion Ventilation.

```
Order :
R/O Pulmonary Embolism

    └── Requested Procedure : Chest X-ray

            └── Scheduled Procedure Step :        Performed Procedure Step :
                Chest PA and Lateral                 Chest PA and Lateral

    └── Requested Procedure : NM Ventilation Perfusion

            └── Scheduled Procedure Step :        Performed Procedure Step :
                NM Ventilation Acquisition           NM Ventilation Acquisition   (cancelled)

            └── Scheduled Procedure Step          Performed Procedure Step
                NM Perfusion Acquisition             NM Perfusion Acquisition     (cancelled)
```
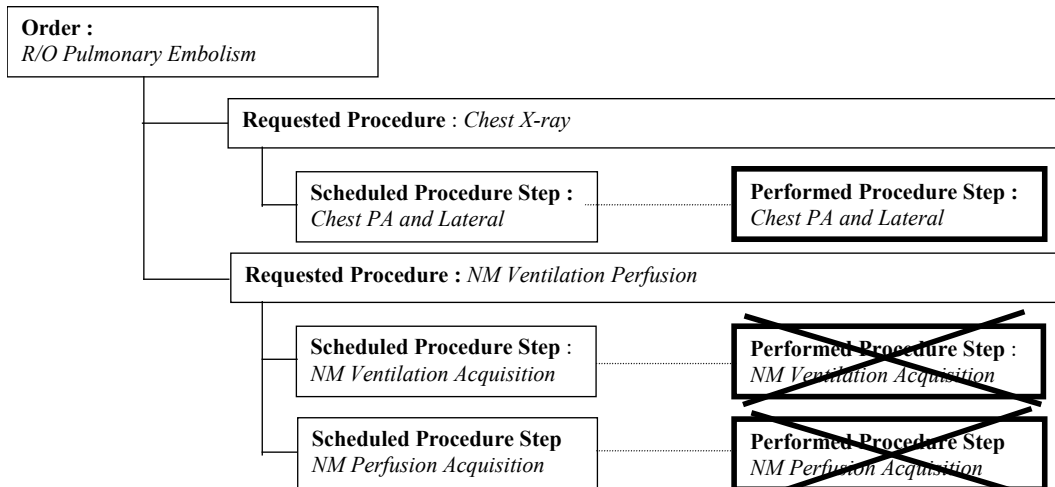
In this later case, the Nuclear Scheduled Procedure Steps will be cancelled. Only the Chest X-ray Requested Procedure will "contain" the Image corresponding to the Chest PA and lateral Chest X-ray.

1410   To illustrate further the capabilities of the IHE Scheduled Workflow Profile, let's look at a Chest/Abdomen/Pelvis Order that a radiology department chooses to break down into a Chest Requested Procedure and an Abdomen/Pelvis Requested Procedure in order to take advantage of the subspecialties of its radiologists. Some hospitals also may want to produce separate reports to align with the charging policies.
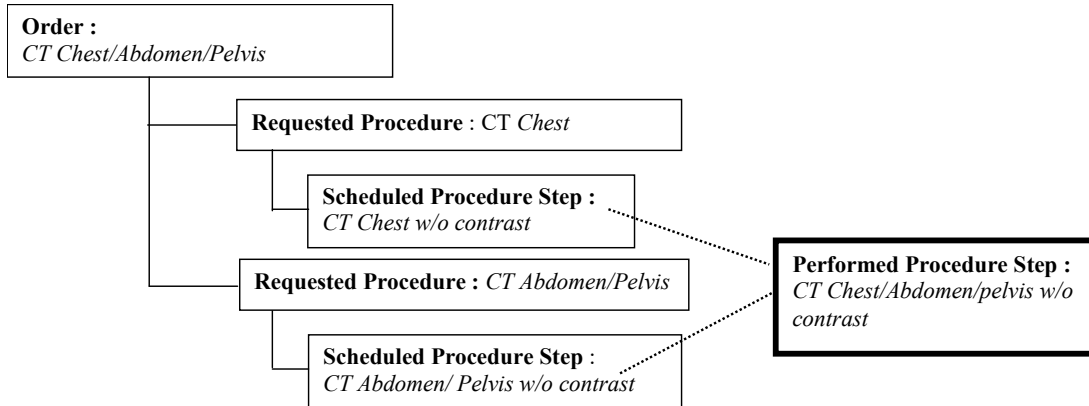
1415

In this example, a single Performed Procedure Step has been performed in response to two Scheduled Procedure Steps. IHE refers to this as a Group Case (see RAD TF-2: 4.6). At the time of reading, the same series of images produced by this Performed Procedure Step would be read once in the context of the CT Chest Requested Procedure and again in the context of the

1420   Abdomen/Pelvis Requested Procedure.

3.4.2.2 Extending the Scheduled Workflow Concepts to Include Post-Processing Tasks

The workflow concepts (as described in Section 3.4.2.1 above) may be extended to include other Scheduled Procedure Steps, such as those used to describe post-processing tasks.

1425   Some of the Scheduled Procedure Steps may be Image Post-Processing related. These Scheduled Procedure Steps would result in Post-Processing Performed Procedure Steps. This is illustrated by the following example of an MR Brain with a Functional Analysis Post-Processing.
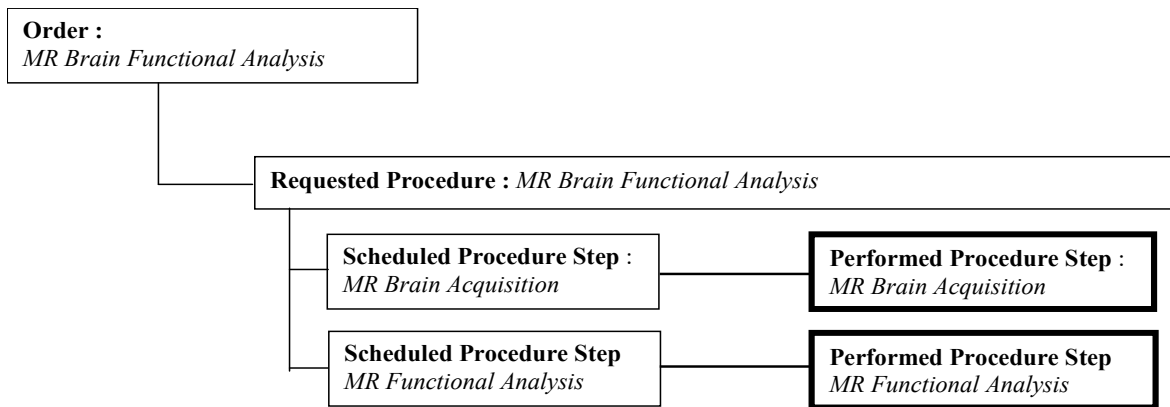
1430 In the above example, two different Scheduled Procedure Steps have been defined for the Requested Procedure. This reflects the fact that in this radiology department, the functional analysis post-processing is not performed by the MR Technologist, but by the Radiologist and therefore needs to be independently scheduled on an independent workstation. Another department may well choose to have the Technologist perform the post-processing immediately after the MR acquisition (either on the MR itself or on a co-located workstation). In that case the

1435 Requested Procedure would include a single Scheduled Procedure Step that includes both the acquisition and the post-processing task.

This Section does not provide an exhaustive description of all the workflow cases supported by the IHE Scheduled Workflow Profile, nor does it describe the Workflow enabled by other IHE Integration Profiles such as the Presentation of Grouped Procedures, Post-Processing Workflow

1440 and Reporting Workflow.

3.4.3 Scheduled Workflow Information Model

The Scheduled Workflow Model is represented in this section as an Entity Relationship (ER) diagram. The Scheduled Workflow Model is based on the DICOM and HL7 standards. The keys relating the entities and the unique keys of each entity are defined and the cardinality of the

1445 entities is indicated.

An example of the conventions used to specify an entity's relationships is presented in Figure 3.4-2.

Entity Name
Foreign Key (FK) relating this entity to previous - The FK is shown to clarify the ER diagram and not intended to represent a relational model.
Unique Key (U) for this entity. There are cases where Unique keys that are identical within the scope of this document have different contextual meanings, as defined in this document. The "+" symbol indicates two attributes must be combined to guarantee uniqueness.

1450 **Figure 3.4-2: Example of the Entity Relationship Diagram**

Figures 3.4-3 and 3.4-4 present the overview of the IHE Information Model. Mappings between specific HL7 Elements and DICOM Attributes are identified in RAD TF-2x: Appendix B.
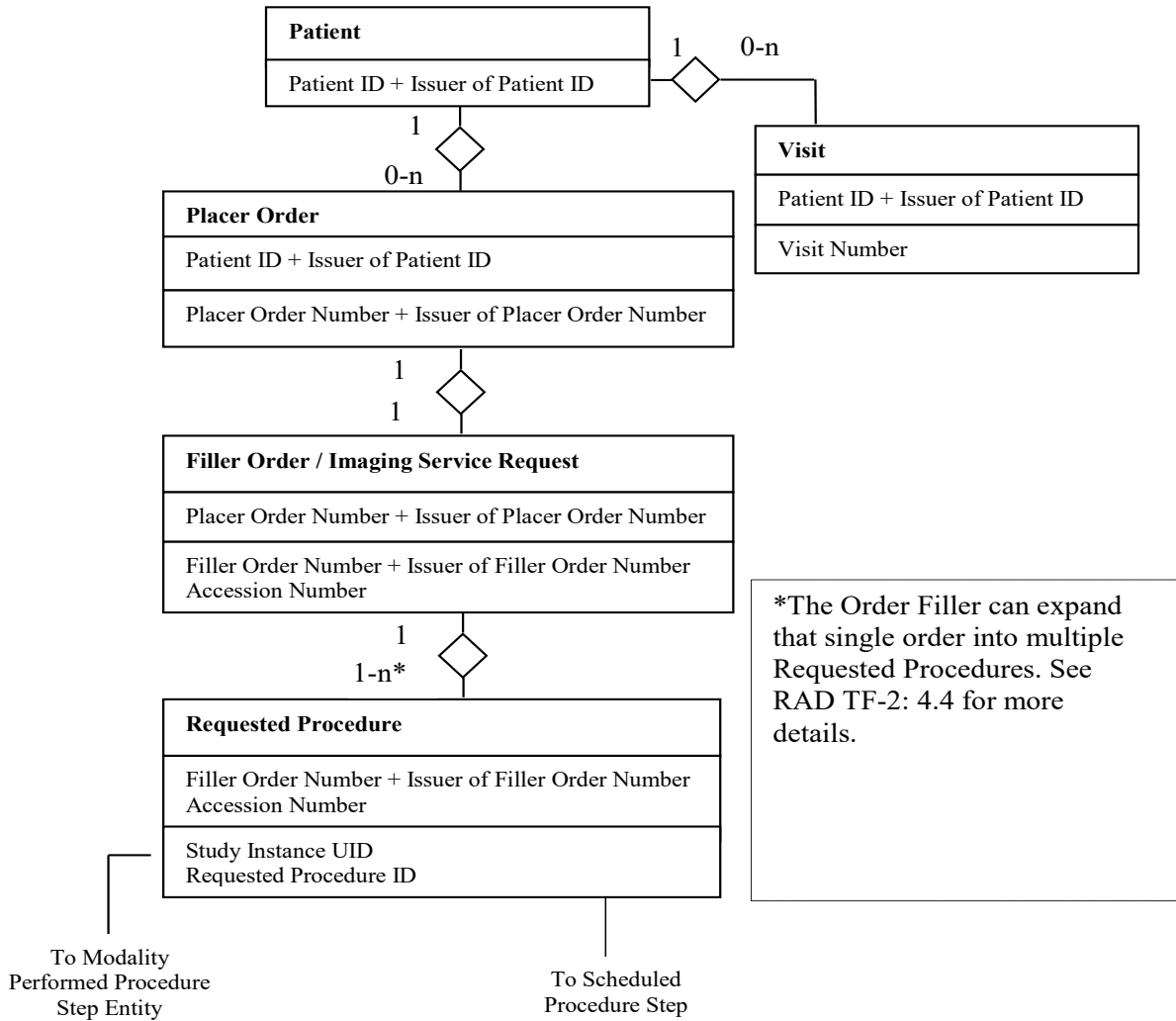
1455

Figure 3.4-3: Schedule Workflow Information Model

From Requested Procedure Step

```
                                                    1
                                                    ◇
                                                  1-n
                    ┌─────────────────────────────────────┐
                    │ **Scheduled Procedure Step**         │
                    ├─────────────────────────────────────┤
                    │ Requested Procedure ID               │
                    │ Study Instance UID                   │
                    ├─────────────────────────────────────┤
                    │ Scheduled Procedure Step ID          │
                    └─────────────────────────────────────┘
                                      0-n**
                                       ◇
        0-n**                        0-m**
          ◇             ┌─────────────────────────────────────┐
                        │ **Modality Performed Procedure Step**│
        0-m**           ├─────────────────────────────────────┤
                        │ Scheduled Procedure Step ID          │
                        │ Study Instance UID                   │
                        ├─────────────────────────────────────┤
                        │ Performed Procedure Step UID***      │
                        │ Affected SOP Instance UID            │
                        └─────────────────────────────────────┘
                                       1
                                       ◇
                                      1-n
  ┌─────────────────────────────┐
  │ **See RAD TF-2: 4.6 for a   │    ┌─────────────────────────────────┐
  │ thorough description of the │    │ **Series**                       │
  │ cardinality relationship    │    ├─────────────────────────────────┤
  │ options of Modality         │    │ Performed Procedure Step UID***  │
  │ Performed Procedure Step.   │    ├─────────────────────────────────┤
  │                             │    │ Series Instance UID              │
  │ ***The Performed Procedure  │    └─────────────────────────────────┘
  │ Step UID is present as the  │                 1
  │ Affected SOP Instance UID.  │                 ◇
  └─────────────────────────────┘               0-n
                                    ┌─────────────────────────────────┐
                                    │ **DICOM Instance**               │
                                    ├─────────────────────────────────┤
                                    │ Series Instance UID              │
                                    ├─────────────────────────────────┤
                                    │ SOP Instance UID                 │
                                    └─────────────────────────────────┘
```

1460

Figure 3.4-4: Schedule Workflow Information Model, continued

4 Patient Information Reconciliation (PIR)

The *Patient Information Reconciliation Integration Profile* extends the *Scheduled Workflow and the Reporting Workflow Integration Profile* by offering the means to match images, diagnostic reports, and other evidence objects acquired for a misidentified or unidentified patient (for example, during a trauma case) with the patient's record. In the example of the trauma case, this integration profile allows subsequent reconciliation of the patient record with images that are acquired (either without a prior registration or under a generic registration) before the patient's identity can be determined. Thus, images can be acquired and interpreted immediately and later, when the patient's official registration and order information is entered into the ADT, Order Placer and Order Filler Systems, this information is matched with the acquired image set and reports, greatly simplifying these exception handling situations. In addition, this Integration Profile allows the Image Manager and Report Manager to receive patient update messages to maintain consistency of the patient information. The Image Manager and Report Manager do not receive those transactions in the Scheduled Workflow Integration Profile.

4.1 Actors/Transactions

Figure 4.1-1 diagrams the actors involved with this profile and the transactions between actors. The shaded actors are NOT actually included in this profile but are included to show the other endpoint of transactions that ARE part of the profile (e.g., Query Reporting Worklist, Query/ Retrieve Reports and Query/ Retrieve Images). As a result, the shaded actors are not listed in Table 4.1-1.

1480
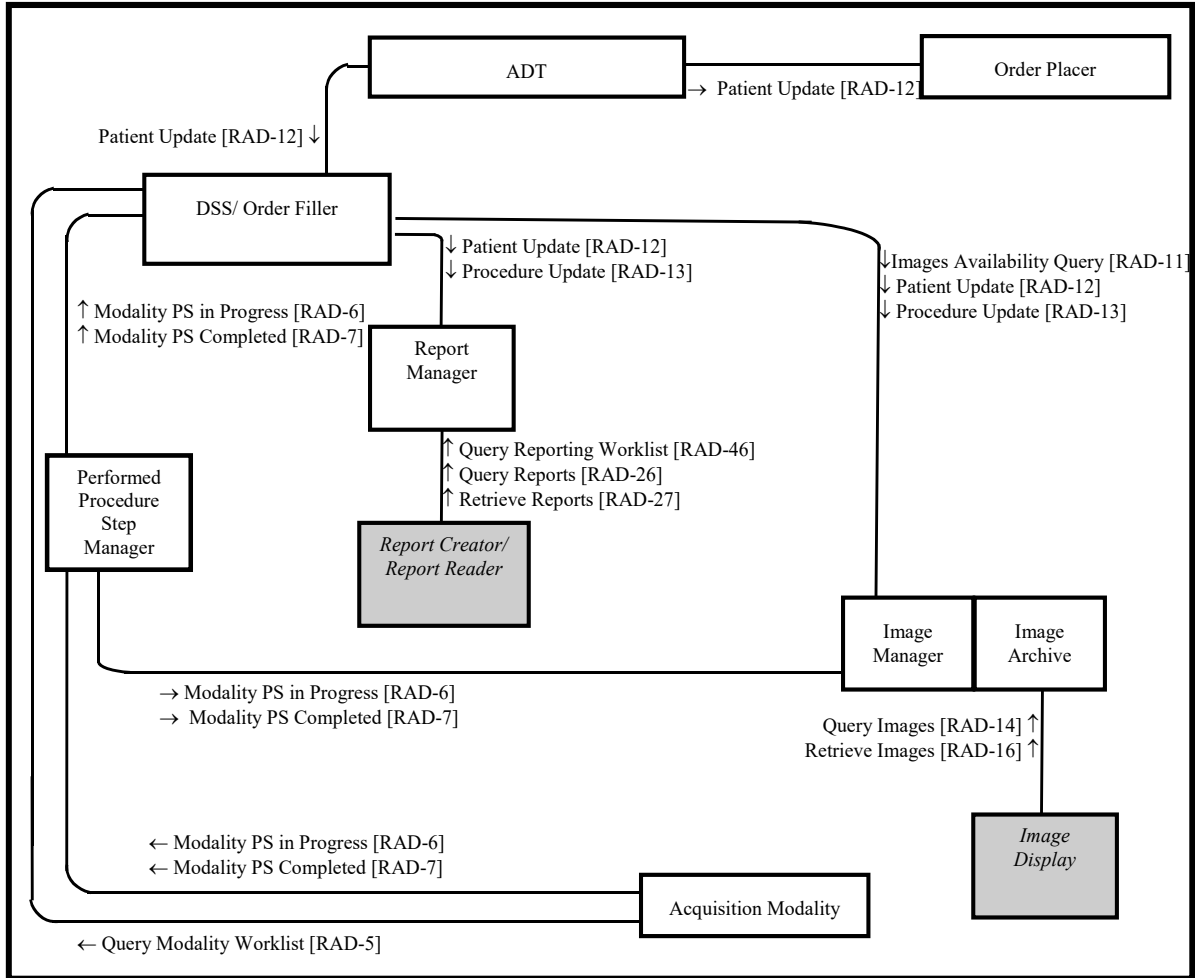
Figure 4.1-1: Patient Information Reconciliation Diagram

1485

Table 4.1-1 lists the transactions for each actor directly involved in the Patient Information Reconciliation 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 4.2.

Table 4.1-1: Patient Information Reconciliation - Actors and Transactions

Actors	Transactions	Optionality	TF Reference
ADT Patient Registration	Patient Update [RAD-12] (Note 1)	R	RAD TF-2: 4.12
Order Placer	Patient Update [RAD-12] (Note 1)	R	RAD TF-2: 4.12
Department System Scheduler/ Order Filler	Patient Update [RAD-12] (Note 1)	R	RAD TF-2: 4.12
	Procedure Update [RAD-13] (Note 1)	R	RAD TF-2: 4.13
	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
	Images Availability Query [RAD-11]	O	RAD TF-2: 4.11
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
Image Manager/ Image Archive	Patient Update [RAD-12] (Note 1)	R	RAD TF-2: 4.12
	Procedure Update [RAD-13] (Note 1)	R	RAD TF-2: 4.13
	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
	Query Images [RAD-14]	R	RAD TF-2: 4.16
	Retrieve Images [RAD-16]	R	RAD TF-2: 4.16
	Images Availability Query [RAD-11]	R	RAD TF-2: 4.11
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
Report Manager (optionally grouped with a Report Repository)	Patient Update [RAD-12] (Note 1)	R	RAD TF-2: 4.12
	Procedure Update [RAD-13] (Note 1)	R	RAD TF-2: 4.13
	Query Report [RAD-26]	R	RAD TF-2: 4.26
	Retrieve Reports [RAD-27]	R	RAD TF-2: 4.27
	Query Reporting Worklist [RAD-46]	R	RAD TF-2: 4.46

Note 1: The actor shall implement the HL7 v2.3.1 Message Semantics for this transaction.

Refer to Table 2-1 for other profiles that may be pre-requisites for this profile.

Note that this is an enhancing profile. Actors must perform reconciliation for all other profiles they support.

Where the actor entry in the table refers to another *integration profile* (e.g., *Scheduled Workflow*), all required transactions in the referenced profile for that actor must be implemented.
1500   Some of these transactions in the referenced integration profile (for example the Department System Scheduler responsibilities in the Patient Update transaction) are extended as specified in Volume 2 and Volume 3.

To support the Patient Information Reconciliation Profile, an actor that claims support of other content profiles (Consistent Presentation of Images, Key Image Notes, Simple Image & Numeric
1505   Reports or Evidence Documents) is required to support reconciliation of the relevant Evidence Objects. The following diagrams will mostly show the management/ reconciliation of images.

The Report Manager must update existing workitems based on the patient information update but since the report content is not modified the rest of the reporting workflow is not affected. In other words, no additional reporting workitems will be scheduled or cancelled because of this update.
1510   The report status is also not affected e.g., a verified report in which the patient information has been updated remains verified. This profile does not require notification of other actors about the patient update.

In case of DICOM SR, the patient information might be included in the content sequence. The update of the patient information in the report header might result in inconsistent header
1515   information with the report content. The patient information update shall not create a new SR SOP instance, according to DICOM SR SOP Class behavior as described in DICOM PS3.4 Annex O.

4.2 Patient Information Reconciliation Integration Profile Options

Options that may be selected for this Integration Profile are listed in the Table 4.2-1 along with
1520   the actors to which they apply.

Table 4.2-1: Patient Information Reconciliation – Actors and Options

Actor	Options	TF Reference
ADT Patient Registration	*No options defined*	-
Order Placer	*No options defined*	-
DSS/Order Filler	*No options defined*	-
Acquisition Modality	*No options defined*	-
Image Manager/ Image Archive	*No options defined*	-
Performed Procedure Step Manager	*No options defined*	-
Report Manager	*No options defined*	-

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4.2.1 HL7 v2.5.1 Option

The HL7 v2.5.1 Option has been retired. Relevant systems may instead support Scheduled
Workflow.b. See Section 34.

4.3 Unidentified Patient Image Acquisition and Reconciliation

This section describes the general process flow related to the handling of procedures for
unidentified patients. The transactions covered are Patient Registration [RAD-1], Placer Order
Management [RAD-2], Procedure Scheduled [RAD-4], Query Modality Worklist [RAD-5],
Modality Procedure Step In Progress [RAD-6], Modality Procedure Step
Completed/Discontinued [RAD-7], Patient Update [RAD-12], and Procedure Update [RAD-13].

The Unidentified Patient case covers the trauma case or emergency room patient when a
patient's condition requires that a procedure be conducted immediately. This is done before
proper patient registration, ordering and/or scheduling of the procedure are performed (due to the
lack of either information or time or other deviation from the normal process flow). In this case
patient/study information must be later reconciled and properly updated at the ADT, Order
Placer, Department System Scheduler/Order Filler, Image Manager and Report Manager. There
are several examples of information flow in this case. These examples are described in use cases
(see Sections 4.4.1 – 4.4.5 for details):

- Case 1: Unidentified Patient registered at ADT and ordered at Order Placer.

- Case 2: Unidentified Patient registered at ADT and ordered at Department System
  Scheduler/Order Filler.

- Case 3: Unidentified Patient registered at ADT but acquisition completed at Modality
  prior to order.

The Radiology Technical Framework also supports cases when registration or temporary
registration of a patient by ADT is not applicable or desired, for example:

- Emergency Department patient can be identified but, due to time or system availability
  constraints the procedure must be performed before proper order entry and scheduling
  may occur.

- Patient ID, though valid, has never been propagated to all actors due to communication
  failures, or the wrong patient record was used in ordering/scheduling.

- Patient ID, though valid, has been mistyped at the modality.

- Patient cannot be registered at the ADT by the time of the procedure. The patient presents
  to the Order Filler (Imaging Department) and the order is placed and performed in the
  department.

The following additional use cases are identified (see Sections 4.4.4 and 4.4.5):

- Case 4: Unidentified Patient assigned temporary Departmental ID and scheduled at
  Department System Scheduler/Order Filler.

- Case 5: Image Acquisition completed without scheduling at Department System Scheduler/Order Filler.

Cases 4 and 5 require patient reconciliation on the department level. In the case of procedures performed on the unidentified patient in multiple departments (e.g., Radiology and Laboratory), this will require reconciliation of patient information in multiple locations.

The Radiology Technical Framework also recognizes that the following 4-step case of handling unidentified patients may be utilized in certain installations:

1. The patient is delivered to the department, where a temporary departmental Patient ID and/or name are assigned.

2. The order is then entered by the Department System Scheduler/Order Filler and with this Patient ID and/or name, and the procedure is performed on the Acquisition Modality.

3. The Department System Scheduler/Order Filler sends a new order transaction to the Order Placer. This departmental Patient ID is shared by the Image Manager, Department System Scheduler/Order Filler and Order Placer. However, this departmental Patient ID is not known to the ADT.

4. After resolution of the patient identity, the ADT registers/admits the patient with the correct Patient ID and sends a message to the Order Placer and Department System Scheduler/Order Filler. Each system locally merges the new record with the existing one identified by the departmental Patient ID.

Because this case requires reconciliation at multiple points throughout the enterprise, IHE does not recommend this workflow.

4.3.1 Patient Information Reconciliation during Image Acquisition

This section describes the general process flow related to the handling of procedures for image acquisition ongoing during patient reconciliation. The transactions covered are Patient Registration [RAD-1], Placer Order Management [RAD-2], Procedure Scheduled [RAD-4], Query Modality Worklist [RAD-5], Modality Procedure Step In Progress [RAD-6], Modality Procedure Step Completed/Discontinued [RAD-7], Patient Update [RAD-12], Procedure Update [RAD-13], Query Images [RAD-14], Query Presentation States [RAD-15], Retrieve Images [RAD-16] and Retrieve Presentation States [RAD-17].

When a Patient Update occurs, in addition to the information exchange between the ADT, Order Placer and Department System Scheduler/Order Filler, Patient Update information is also sent to the Image Manager. Even after a Patient Update has occurred images coming from the Modality may continue to use the original Patient Information, so on-going Patient update with incoming images from the modality may be necessary. It is the responsibility of the Image Manager to ensure that the patient information is updated in the images, Grayscale Softcopy Presentation States and other Evidence Objects when they are retrieved from the Image Archive. This example is described in Case 6 (see Section 4.4.6).

4.4 Use Cases

The following sections describe the Unidentified Patient use cases. For the purpose of simplification, the following transactions were omitted from the corresponding diagrams:

- Modality Performed Procedure Step In Progress [RAD-6]

1600

- Modality Images Stored [RAD-8]

- Modality Presentation State Stored [RAD-9]

- Storage Commitment [RAD-10]

These transactions may occur within the time frame of the diagram, but their content does not affect each of the use cases.

1605 ### 4.4.1 Case 1: Unidentified Patient Registered at ADT and Ordered at the Order Placer

The ADT is a single point of patient reconciliation in the enterprise. Process flow requires that any unidentified patient be assigned a permanent Patient ID and a temporary name (e.g., "John Doe"). All subsequent transactions follow the normal flow (see Section 3.1) including order 1610 entry and procedure scheduling. 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 Department System Scheduler/Order Filler about corresponding changes. The ADT sends a Patient Update message 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 1615 Manager and the Report Manager.
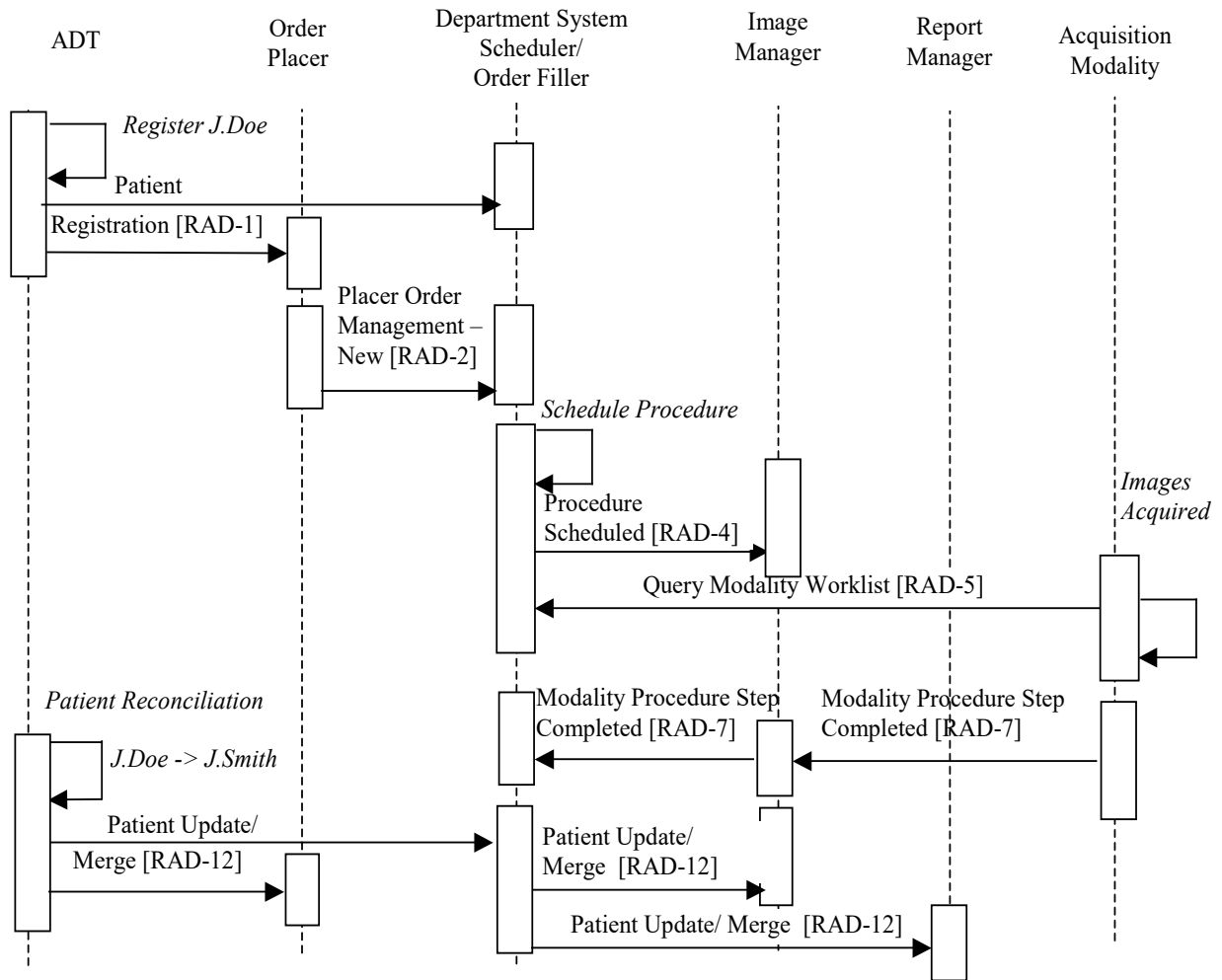
Figure 4.4-1: Unidentified Patient – Case 1

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.

- If a permanent Patient ID was assigned, then the ADT may only send a Patient Update [RAD-12] transaction with proper information.

Note that the Performed Procedure Step Manager is not shown on the Process Flow diagrams and is presumed to be grouped with the Image Manager. 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.

4.4.2 Case 2: Unidentified Patient Registered at ADT and Ordered at Department System Scheduler/Order Filler

1630   This case is based on Case 1. However, in this situation the order for a procedure is generated by the Department System Scheduler/Order Filler and submitted to the Order Placer. Procedures are scheduled normally and image acquisition uses modality worklist. When the patient information is reconciled, the ADT sends the Patient Update messages to both the Order Placer and Department System Scheduler/Order Filler. The Department System Scheduler/Order Filler

1635   sends the Patient Update message to the Image Manager and the Report Manager.
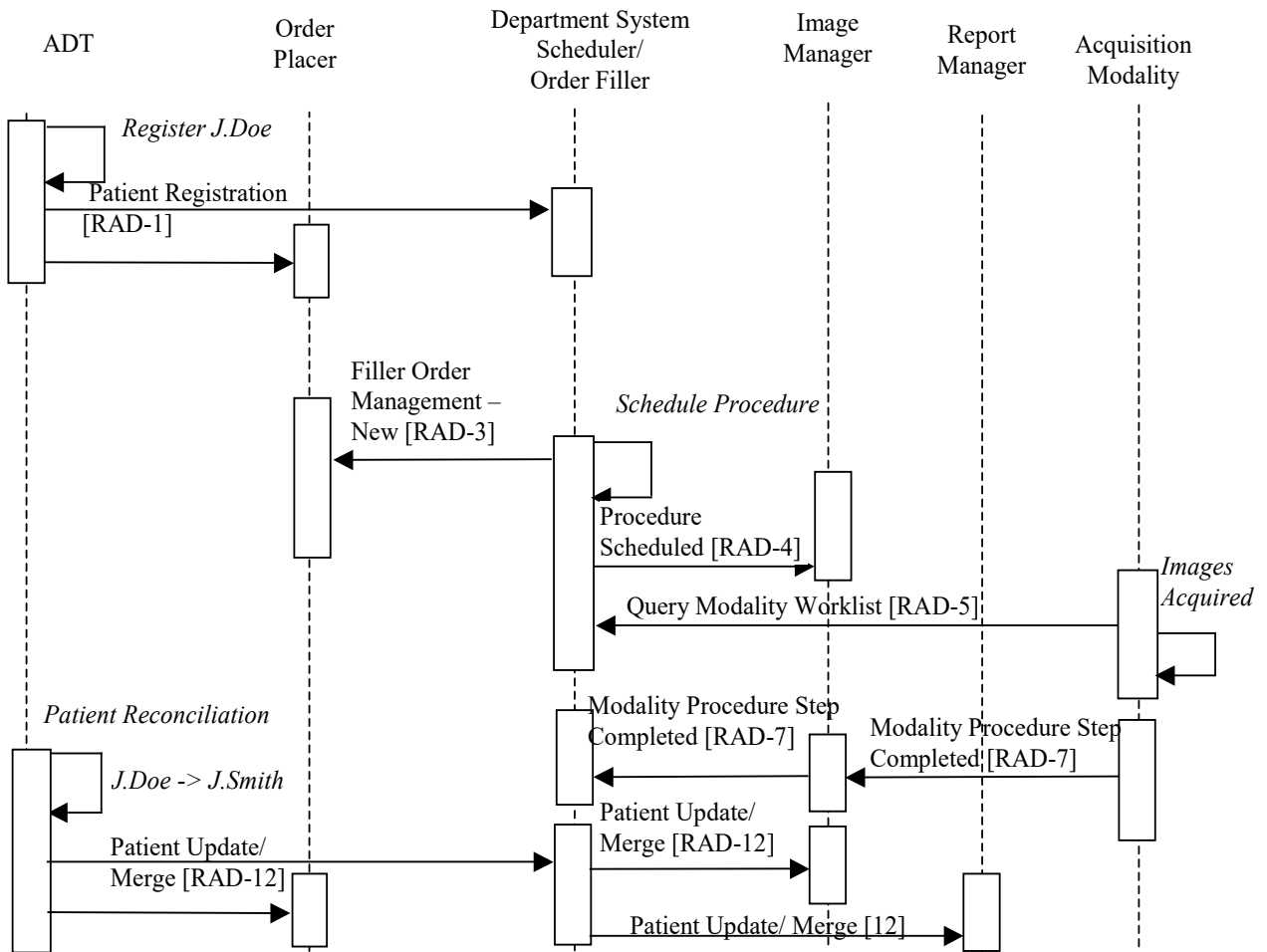
Figure 4.4-2: Unidentified Patient – Case 2

76

1640   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 registration and merge transactions.

1645

- If a permanent Patient ID was assigned, then the ADT may only send a Patient Update transaction with proper information.

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

4.4.3 Case 3: Unidentified Patient Registered at ADT but Completed at Modality Prior to Order

1650   As in Cases 1 and 2, this uses a permanent Patient ID generated by the ADT. However, no order entry or scheduling takes place before the Acquisition Modality performs the procedure. A permanent Patient ID and a temporary name are manually entered at the Acquisition Modality (typically, from a card) and conveyed to the Department System Scheduler/Order Filler and the Image Manager by the Acquisition Modality. Subsequently, the Department System

1655   Scheduler/Order Filler generates and submits an order to the Order Placer. When the patient information is reconciled, the ADT sends the Patient Update messages to both the Order Placer and the Department System Scheduler/Order Filler. The Department System Scheduler/Order Filler sends a Patient Update message to the Image Manager and the Report Manager.
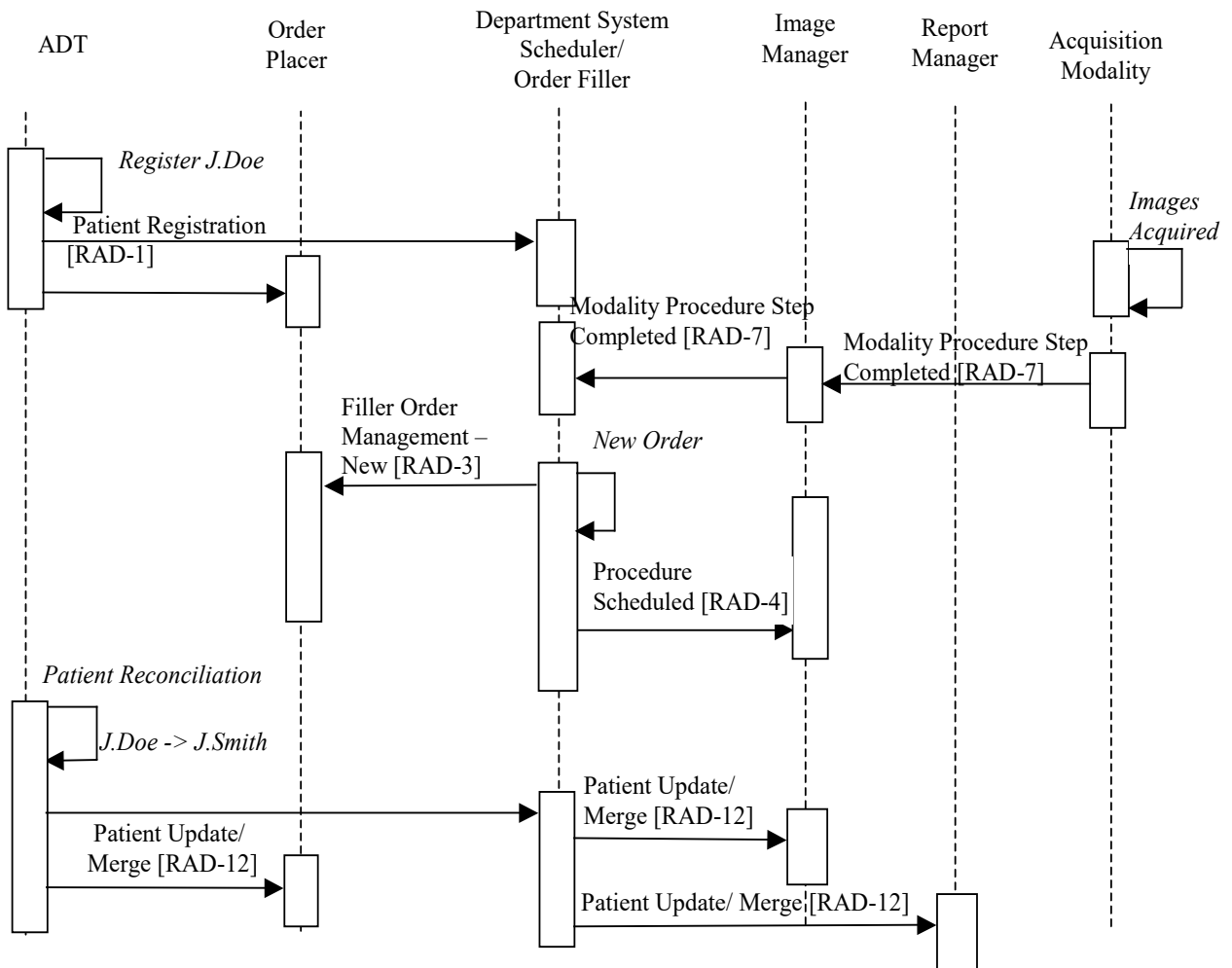
Figure 4.4-3: Unidentified Patient – Case 3

Significant Transactions:

- On receiving a Modality Procedure Step Completed [RAD-7], the Department System Scheduler/Order Filler recognizes it as an unscheduled case.

- The Department System Scheduler/Order Filler sends a Filler Order Management (New Order) [RAD-3] transaction to the Order Placer.

- Using the information from the Procedure Step Completed transaction and the placed order, the DSS/Order Filler creates a new Requested Procedure record and sends a Procedure Scheduled transaction to the Image Manager.

- To reconcile the patient information, the ADT may register a new patient and merge the temporary patient with the correct patient and send both registration and merge transactions.

- If a permanent Patient ID was assigned, then the ADT may only send a Patient Update transaction with proper information.

1675   • The DSS/Order Filler sends a Patient Update transaction to the Image Manager.

4.4.4 Case 4: Unidentified Patient Assigned Temporary Departmental ID and Scheduled at DSS/Order Filler

In this case, no valid Patient ID is available to the Department System Scheduler/Order Filler. It assigns a temporary Patient ID and a temporary name and schedules the required procedure.

1680   Note: The Department System Scheduler/Order Filler must ensure that the assigned temporary Patient ID is unique within its scope.

The temporary Patient ID is conveyed to the Image Manager. When patient information becomes known, the ADT sends new patient information to both the Order Placer and the Department System Scheduler/Order Filler. The Department System Scheduler/Order Filler reconciles
1685   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 and the Report Manager. At the same time, the Department System Scheduler/Order Filler generates and submits an order to the Order Placer using a permanent Patient ID.

1690

Figure 4.4-4: Unidentified Patient– Case 4

Significant Transactions:

- Patient information is reconciled internally by the Department System Scheduler/Order Filler using the Patient Registration from ADT.

1695
- The Department System Scheduler/Order Filler sends the Patient Update [RAD-12] transaction to the Image Manager.

- The Department System Scheduler/Order Filler sends the Filler Order Management (New Order) [RAD-3] transaction to the Order Placer.

4.4.5 Case 5: Image Acquisition Completed Without Scheduling at Department System Scheduler/Order Filler

1700

In this case, no valid Patient ID is available to the Department System Scheduler/Order Filler and no scheduling is done before the procedure is performed. A temporary ID and name are entered by the technologist at the Modality and conveyed to the Department System Scheduler/Order Filler and to the Image Manager. The Patient ID and name are selected by the technologist

1705 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.

Upon receiving the Modality Procedure Step Completed message, the DSS/Order Filler and Image Manager recognize an unscheduled case based on the content of the message (absent or

1710 empty Referenced Study Sequence, see RAD TF-2x: Appendix A). When patient information becomes known, the ADT sends the new patient information to both the Order Placer and Department System Scheduler/Order Filler. The Department System Scheduler/Order Filler performs a merge of the permanent patient record with the temporary one and sends a Patient Update to the Image Manager and the Report Manager. At the same time, Department System

1715 Scheduler/Order Filler generates and submits an order to the Order Placer using a valid Patient ID.

Figure 4.4-5: Unidentified Patient – Case 5

1720 Significant Transactions:

- On receiving a Procedure Step Completed transaction, the Department System Scheduler/Order Filler recognizes it as an unscheduled case.

- Patient information is reconciled internally by the Department System Scheduler/Order Filler using the Patient Registration from the ADT.

1725
- The Department System Scheduler/Order Filler sends a Patient Update (Merge) transaction to the Image Manager and to the Report Manager.

- The Department System Scheduler/Order Filler sends a Filler Order Management (New Order) [RAD-3] transaction to the Order Placer.

1730
- Using the information from the Procedure Step Completed transaction and placed order, the Department System Scheduler/Order Filler creates a new Requested Procedure record and sends a Procedure Scheduled [RAD-4] transaction to the Image Manager and Report Manager.

4.4.6 Case 6: Patient Information Reconciliation During Image Acquisition

1735 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 continue updating the patient information from items retrieved from the Image Archive.

Significant Transactions:

1740
- The Modality may continue to send information using the original patient information even after the patient update has occurred.

- The Image Manager must continue reconciling Patient Information even after the Patient Update transaction has been completed.

Only partial transactions are shown. Other transactions are performed according to the profile
1745 requirements.

Figure 4.4-6: Patient Information Reconciliation during Image Acquisition

5   Consistent Presentation of Images (CPI)

1750

The *Consistent Presentation of Images Integration Profile* specifies a number of transactions that maintain the consistency of presentation for grayscale images. The presentation of images depends upon the contrast/brightness and the spatial and graphical operations applied, such as user annotations, shutters, flip/rotate, display area selection, and zoom. The spatial and graphical operations are defined in the Grayscale Softcopy Presentation State. For the consistency of the perceived pixel intensity a standard contrast curve, the Grayscale Standard Display Function, has been defined against which different types of display and hardcopy output devices are calibrated. This profile is intended to establish consistency between any combination of softcopy and hardcopy displays. In order to guarantee both grayscale contrast/brightness consistency and spatial/ graphical consistency in presentation of images, it is required that both the Grayscale Standard Display Function and the Grayscale Softcopy Presentation State are supported.

1755

1760

Note that this Integration Profiles applies only to grayscale images, and is not applicable for color images.

The Scheduled Workflow Profile or Post-Processing Profile, when combined with this profile, allows the process of creating, storing and accessing Presentation States to be managed using worklist to provide the relevant patient and procedure details, and using performed procedure steps to provide status information.

1765

5.1 Actors/Transactions

Figure 5.1-1 diagrams the actors involved with this profile and the transactions between actors.
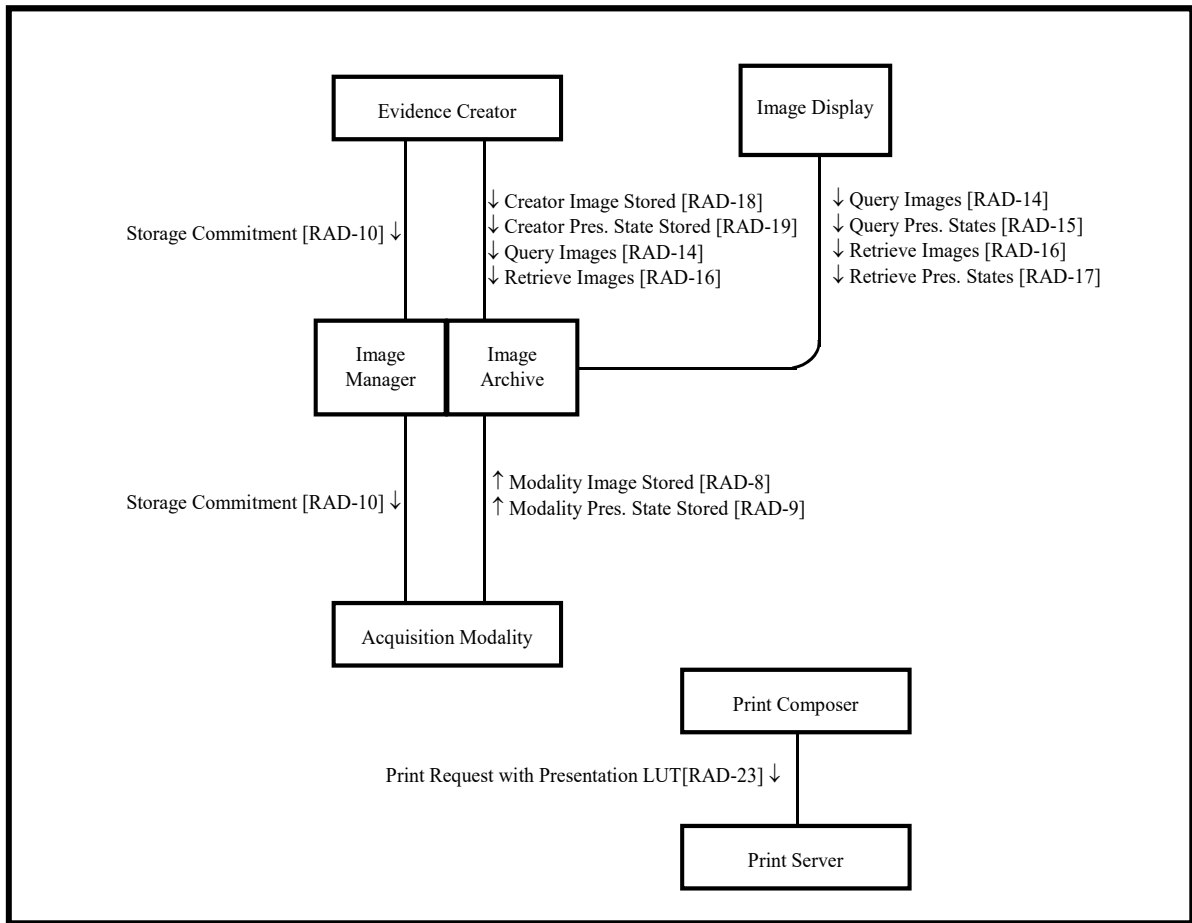
Figure 5.1-1: Consistent Presentation of Images Diagram

Table 5.1-1 lists the transactions for each actor directly involved in the Consistent Presentation of Images 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. For a complete list of options defined by this Integration Profile and that implementations may choose to support are listed in Section 5.2.

Table 5.1-1: Consistent Presentation of Images - Actors and Transactions

Actors	Transactions	Optionality	TF Reference
Acquisition Modality	Modality Images Stored [RAD-8]	R	RAD TF-2: 4.8
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
	Modality Presentation State Stored [RAD-9]	R	RAD TF-2: 4.9
Image Manager/ Image Archive	Modality Images Stored [RAD-8]	R	RAD TF-2: 4.8
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
	Query Images [RAD-14]	R	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	R	RAD TF-2: 4.16
	Creator Images Stored [RAD-18]	R	RAD TF-2: 4.18

Actors	Transactions	Optionality	TF Reference
	Modality Presentation State Stored [RAD-9]	R	RAD TF-2: 4.9
	Query Presentation States [RAD-15]	R	RAD TF-2: 4.15
	Retrieve Presentation States [RAD-17]	R	RAD TF-2: 4.17
	Creator Presentation State Stored [RAD-19]	R	RAD TF-2: 4.19
Image Display	Query Images [RAD-14]	R	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	R	RAD TF-2: 4.16
	Query Presentation States [RAD-15]	R	RAD TF-2: 4.15
	Retrieve Presentation States [RAD-17]	R	RAD TF-2: 4.17
Evidence Creator	Creator Images Stored [RAD-18]	O	RAD TF-2: 4.18
	Creator Presentation State Stored [RAD-19]	R	RAD TF-2: 4.19
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
	Query Images [RAD-14]	O	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	O	RAD TF-2: 4.16
Print Composer	Print Request with Presentation LUT [RAD-23]	R	RAD TF-2: 4.23
Print Server	Print Request with Presentation LUT [RAD-23]	R	RAD TF-2: 4.23

Note: Refer to Table 2-1 for other profiles that may be pre-requisites for this profile.

5.2 Consistent Presentation of Images Integration Profile Options

1780 Options that may be selected for this Integration Profile are listed in the Table 5.2-1 along with the actors to which they apply. Dependencies between options when applicable are specified in notes.

Table 5.2-1: Consistent Presentation of Images – Actors and Options

Actor	Options	TF Reference
Acquisition Modality	*No options defined*	-
Image Manager/ Image Archive	*No options defined*	-
Image Display	*No options defined*	-
Evidence Creator	*No options defined*	-
Print Composer	User Specifiable Lighting Condition	RAD TF-2: 4.23.4.2.4
Print Server	*No options defined*	-

5.3 Consistent Presentation of Images Process Flow

1785 This section describes the typical process flow related to viewing images with Grayscale Softcopy Presentation States and performing image post-processing that may generate new images and/or Grayscale Softcopy Presentation States. The transactions covered are [RAD-14] through [RAD-22].

Consistent Presentation of Images is an integration feature that provides access to images with
1790   their full-fidelity content as they were acquired or created. Such access is available either:

- Internally to the source imaging department;

- Between imaging departments (e.g., Cardiology and Radiology); or

- Throughout the Healthcare Enterprise to other departments or care providers other than
  an imaging department (e.g., Surgery, Neurology, Oncology).

1795   Consistent Presentation of Images enables advanced review as well as simple or sophisticated
post-processing of images along with related objects (such as Grayscale Softcopy Presentation
States, or Structured Reports) in a variety of clinical scenarios. Examples include the following:

- Based on patient identifying information, a clinician wishes to look for imaging studies
  performed on this patient. The clinician may access one or more series of images, related
1800   to a recent examination;

- A reading physician performing a primary or secondary read wishes to retain viewing
  parameters including clinical annotations;

- A clinician reviewing a report that references key images wishes to review those images;

- A technologist about to perform an imaging examination wishes to retrieve a prior
1805   imaging examination to ensure consistent patient positioning;

- A reading physician interpreting a study wishes to perform a comparison with images
  acquired in a prior study. The physician also needs to review the images as they were
  presented when a prior diagnosis was prepared; and

- A surgeon creates a 3D volume analysis of an image set to plan surgery on a patient.

1810   The appearance of grayscale images displayed on different types of softcopy display devices or
printed by different types of hardcopy output devices has often been inconsistent. To address this
problem and achieve consistent presentation of grayscale images the DICOM Standard defines:

- A standard curve, the Grayscale Standard Display Function, against which different types
  of display and hardcopy output devices should be calibrated;

1815   - Basic Print Management with Presentation Look Up Table, for controlling the consistent
  appearance of preformatted images on printed output;

- Grayscale Softcopy Presentation State, an object for storing and communicating the
  parameters that describe how an image or set of images shall be displayed. A Grayscale
  Softcopy Presentation State object contains references to the images it applies to, and the
1820   transformations (grayscale transformations, shutter transformations, image annotation,
  spatial transformations, and display area annotation) that shall be applied when the
  images are presented on a softcopy display.

The typical use of these capabilities is depicted in Figure 5.3-1.
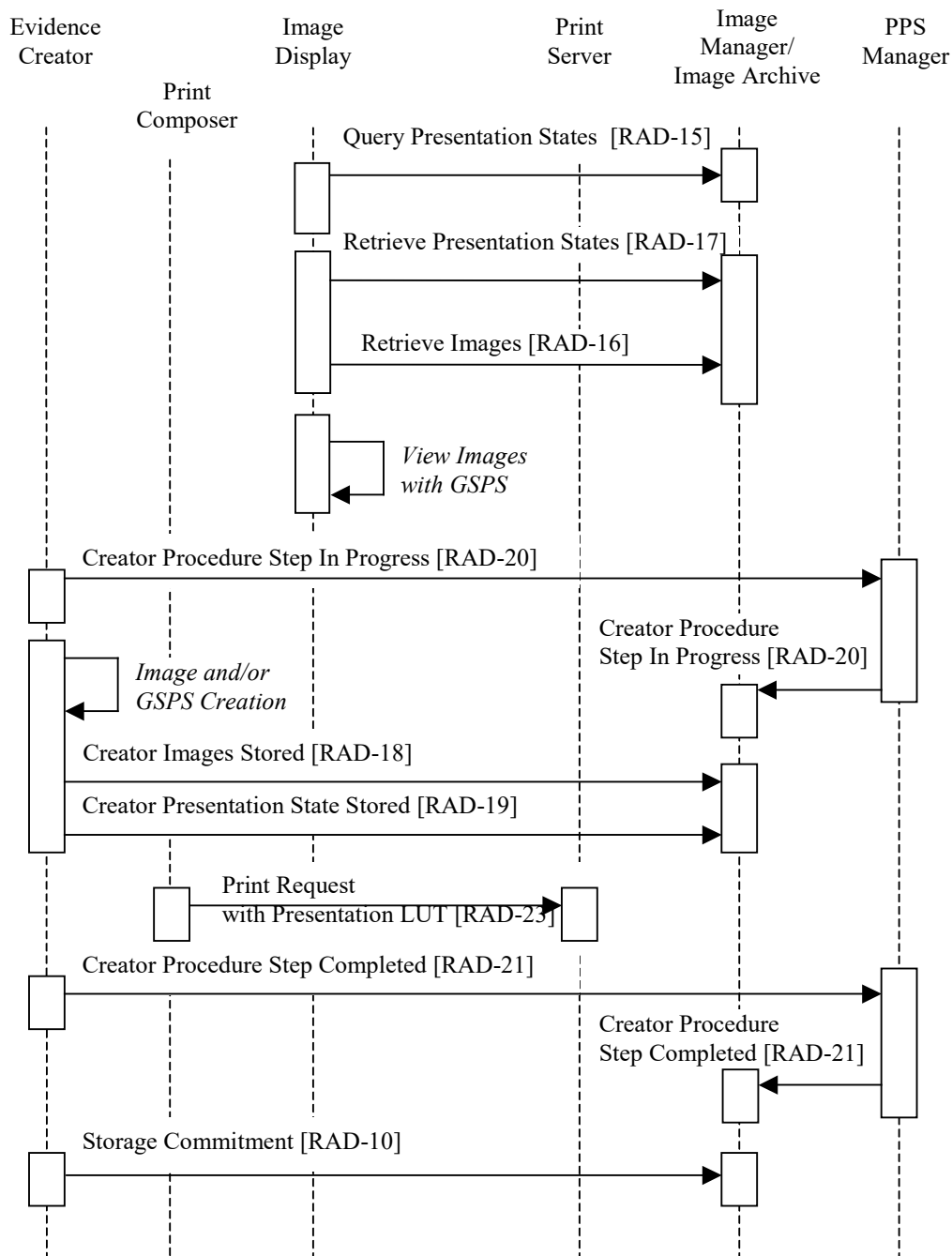
Figure 5.3-1: Consistent Presentation of Images Process Flow

The following shall be taken into account in relation to the presented example of the Consistent Presentation of Images Process Flow:

- The Evidence Creator shall be grouped with an Image Display but is shown separately in the diagram above to distinguish the transactions;

1830
- In this example, the Print Composer is grouped with the Evidence Creator, but may be grouped with other actors that have access to images;

- The diagram above includes Procedure Step transactions which are not part of this profile, but are defined the associated workflow profile. The diagram shows one particular sequencing of the Procedure Step Completed transaction. This transaction may
1835
occur at any point after image and/or Presentation State (GSPS) creation. This means it can occur before images and/or GSPS are stored, after storage, after printing as in this example, or even after storage commitment. The Radiology Technical Framework does not specify the timing of this transaction in relation to other transactions.

1840 # 6   Presentation of Grouped Procedures (PGP)

The *Presentation of Grouped Procedures Integration Profile (PGP)* addresses what is sometimes referred to as the linked studies problem: viewing image subsets resulting from a single acquisition with each image subset related to a different requested procedure (e.g., CT chest, abdomen and pelvis). It provides a mechanism for facilitating workflow when viewing
1845 images and reporting on individual requested procedures that an operator has grouped (often for the sake of acquisition efficiency and patient comfort). A single acquired image set is produced, but the combined use of the scheduled workflow transactions and the consistent presentation of images allows separate viewing and interpretation of the image subsets related to each of the requested procedures.

1850 ## 6.1   Actors/Transactions

Figure 6.1-1 diagrams the actors involved with this profile and the transactions between actors.

Figure 6.1-1: Presentation of Grouped Procedures Diagram

Table 6.1-1 lists the required transactions for each actor directly involved in the Presentation of
1855 Grouped Procedures (PGP) 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 and that implementations may choose to support is listed in Section 6.2.

Table 6.1-1: Presentation of Grouped Procedures - Actors and Transactions

Actors	Transactions	Optionality	TF Reference
Department System Scheduler/ Order Filler	Modality Procedure Step In Progress [RAD-6] (Note 1)	R	RAD TF-2: 4.6
	Modality Procedure Step Completed [RAD-7]	R	RAD TF-2: 4.7
Acquisition Modality	Modality Procedure Step In Progress [RAD-6] Note 1)	R	RAD TF-2: 4.6
	Modality Procedure Step Completed [RAD-7]	R	RAD TF-2: 4.7
	Modality Presentation State Stored [RAD-9]	R	RAD TF-2: 4.9
Image Manager/ Image Archive	Modality Procedure Step In Progress [RAD-6] (See Note 1)	R	RAD TF-2: 4.6
	Modality Procedure Step Completed [RAD-7]	R	RAD TF-2: 4.7
	Modality Presentation State Stored [RAD-9]	R	RAD TF-2: 4.9
Performed Procedure Step Manager	Modality Procedure Step In Progress [RAD-6] (See Note 1)	R	RAD TF-2: 4.6
	Modality Procedure Step Completed [RAD-7]	R	RAD TF-2: 4.7

1860 Refer to Table 2-1 for other profiles that may be pre-requisites for this profile.

Note 1: This transaction has an extension that is required by this actor in this profile. This detailed definition of this extension is in RAD TF-2: 4.6.4.1.2.3.6.

1865 Note 2: The use of the integration capabilities offered by the Presentation of Grouped Procedures (PGP) Integration Profile (enabled by the Modality Procedure Step In Progress/Completed and the Modality Presentation State Stored) requires an Image Display to be integrated with other workflow-aware actors. Such actors may be an Image Manager/Archive or Department System Scheduler/Order Filler. A stand-alone Image Display cannot directly benefit from the PGP Integration Profile capabilities. However, if the stand-alone Image Display supports the Consistent Presentation of Images (CPI) Integration Profile, it may benefit from the Presentation States generated by the Acquisition Modality implementing the PGP Integration Profile.

6.2 Presentation of Grouped Procedures Integration Profile Options

1870

Options that may be selected for this Integration Profile are listed in the Table 6.2-1 along with the actors to which they apply.

Table 6.2-1: Presentation of Grouped Procedures – Actors and Options

Actor	Options	TF Reference
Acquisition Modality	*No options defined*	--
Department System Scheduler/Order Filler	*No options defined*	--
Image Manager/Image Archive	*No options defined*	--
Performed Procedure Step Manager	*No options defined*	--

6.3 Presentation of Group Procedures Process Flow

1875   Presentation of Grouped Procedures (PGP) provides a mechanism for facilitating viewing images and reporting on individual Requested Procedures that have been fulfilled by a single Performed Procedure Step acquisition. The transactions covered are [RAD-5] through [RAD-10].

The following use case defines the PGP transaction flow:

1880
- When a number of Scheduled Procedure Steps, each corresponding to a different Requested Procedure, are grouped by a technologist and result in the acquisition of images forming a single Performed Procedure Step, the Presentation of these Grouped Procedures can be facilitated by the combined use of Grayscale Softcopy Presentation States and associated Performed Procedure Steps as defined below.

1885
- This also applies to Evidence Creators that retrieve images resulting from grouped procedures on the Acquisition Modality and for which presentation states may be defined specifically associated with one or more of the Requested Procedures.

- For each of the Requested Procedures, the operator may create one or more Grayscale Softcopy Presentation States in order to define the corresponding viewing parameters applicable to a subset of images related to the Requested Procedure. These Grayscale
1890   Softcopy Presentation States shall be associated with a specific Performed Procedure Step related to the Requested Procedure.

The following example illustrates the PGP flow:

- In this illustration, the grouping of chest, abdomen and pelvis Requested Procedures would result in one PPS related to the acquired images on a spiral CT scanner. Then the
1895   operator would select the chest subset of the acquired images, choose the appropriate window width/window level for the chest images and produce a GSPS recording the chest presentation state. A Procedure Step Completed transaction related to this chest view would then be sent to the Image Manager and to the Department System Scheduler/Order Filler. Likewise, for the abdomen and the pelvis, thus resulting in four
1900   PPS, one for the images of the three grouped procedures and three PPS each related to the presentation states. Finally, the images and GSPSs are stored in the Image Archive and Storage Commitment is performed.

- A reading physician may use the GSPSs (associated with the Requested Procedure indicated in the PPS transaction) created by the technologist to facilitate viewing and
1905   interpreting the CT chest images separately from the CT abdomen images. This will facilitate interpretation as well as reviewing the relevant subset of prior images.

The following sequence of steps describes the typical process flow involved in Presentation of Grouped Procedures:
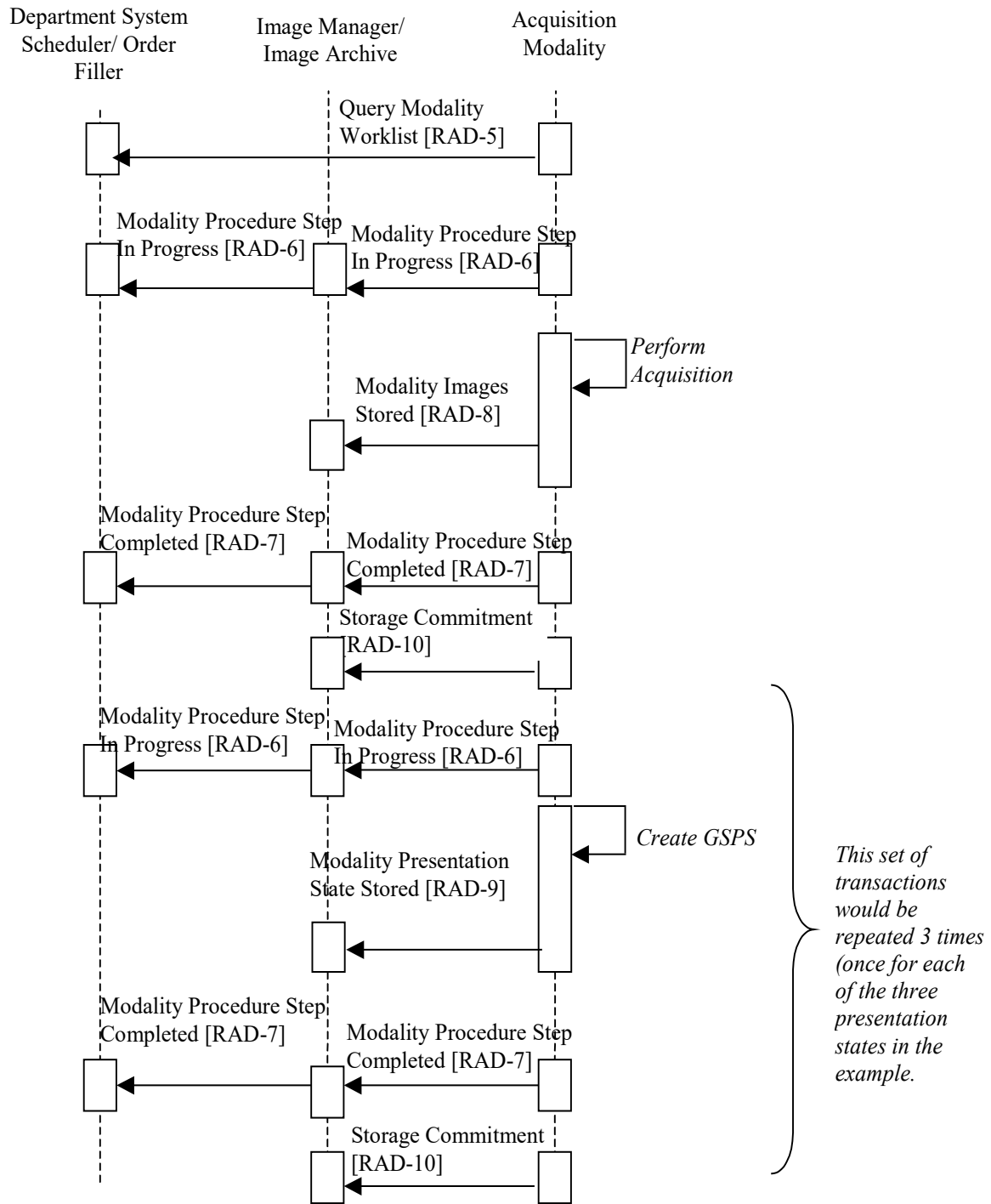
1910 **Figure 6.3-1: Presentation of Grouped Procedures Process Flow**

7 Access to Radiology Information (ARI)

The *Access to Radiology Information Integration Profile* specifies a number of query transactions providing access to radiology information, including images and related reports, in a DICOM format as they were acquired or created. Such access is useful both to the radiology
1915 department and to other departments such as pathology, surgery and oncology. Non-radiology information (such as lab reports) may also be accessed if made available in DICOM format.

7.1 Actors/Transactions

Figure 7.1-1 diagrams the actors involved with this profile and the transactions between actors. The italicized transactions represent a "generic" set of query/ retrieve transactions. The specific
1920 transactions required are dependent on which specific content profile(s) are supported by the Image Display and Image Manager/ Image Archive Actors.
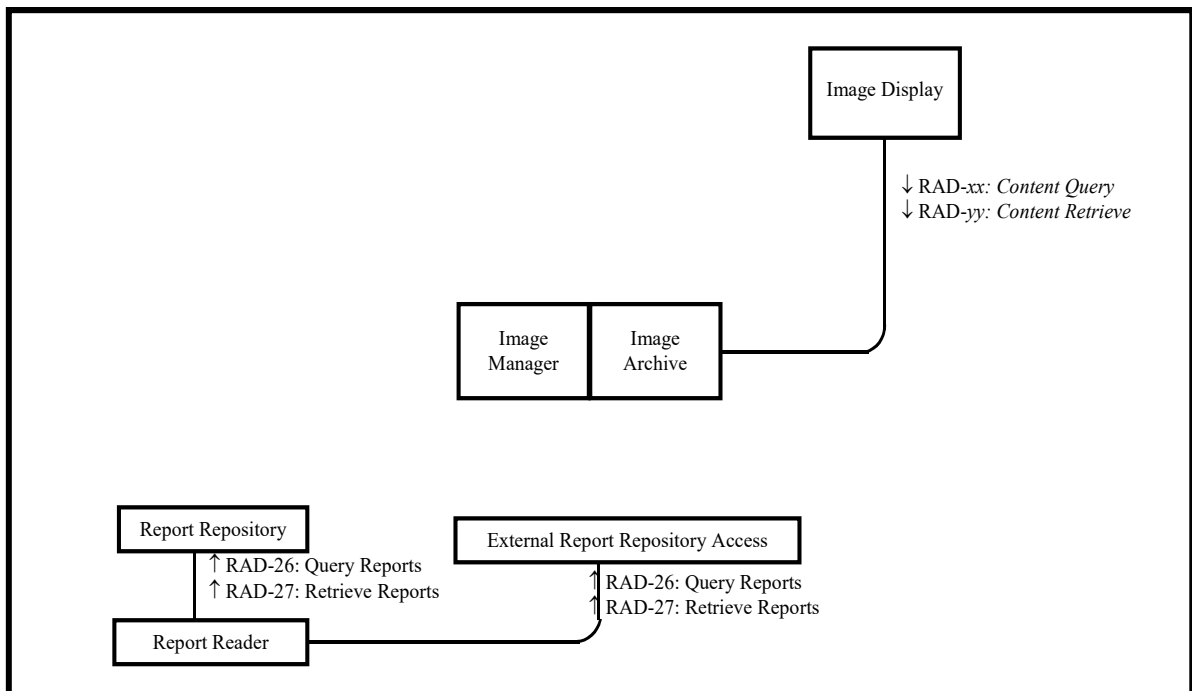
Figure 7.1-1: Access to Radiology Information Diagram

1925

Table 7.1-1 lists the transactions for each actor directly involved in the Access to Radiology Information Integration Profile. In order to claim support of this Integration Profile, an implementation must perform the required transactions (labeled "R"). A complete list of options defined by this Integration Profile and that implementations may choose to support is listed in
1930   Section 7.2.

Table 7.1-1: Access to Radiology Information - Actors and Transactions

Actors	Transactions	Optionality	TF Reference
Report Reader	Query Reports [RAD-26]	R	RAD TF-2: 4.26
	Retrieve Reports [RAD-27]	R	RAD TF-2: 4.27
Report Repository	Query Reports [RAD-26]	R	RAD TF-2: 4.26
	Retrieve Reports [RAD-27]	R	RAD TF-2: 4.27
External Report Repository Access	Query Reports [RAD-26]	R	RAD TF-2: 4.26
	Retrieve Reports [RAD-27]	R	RAD TF-2: 4.27
Image Display	Required transactions depend on the Content Profiles supported		
Image Manager/ Image Archive	Required transactions depend on the Content Profiles supported		

Note: Refer to Table 2-1 for other profiles that may be pre-requisites for this profile.

The Image Display and Image Manager/ Archive Actors are required to support the Query/Retrieve transactions for each dependent Content Profile they support. They must support
1935   at least one Content Profile, for example the Mammography Image Profile, the NM Image Profile and others.

7.2 Access to Radiology Information Integration Profile Options

Options that may be selected for this Integration Profile are listed in the Table 7.2-1 along with the actors to which they apply. Dependencies between options when applicable are specified in
1940   notes.

Table 7.2-1: Access to Radiology Information - Actors and Options

Actor	Options	TF Reference
Image Display	Multiple Sources	RAD TF-1: 7.3.1
Image Manager/Image Archive	No options defined	-
Report Reader	Multiple Sources	RAD TF-1: 7.3.1
Report Repository	No options defined	-
External Report Repository Access	No options defined	-

7.3 Multiple Sources Option

This option requires Image Displays and Report Readers to support query and retrieve from multiple information sources in order for a user to gain access to distributed radiology information.

Image Displays, in particular, are typically closely associated with, and draw information from, a single Image Manager/Image Archive. An Image Display that implements this option supports a user that desires to view information consolidated from multiple sources (e.g., ultrasound mini-PACS, cardiology PACS, and radiology PACS).

Querying multiple sources also provides an opportunity for an Image Display to access objects stored in a "legacy" archive that has been replaced by, and is possibly having its information migrated to, a new Image Manager/Image Archive.

7.3.1 Requirements for the Multiple Sources Option

In order to claim support for this profile option, an Image Display shall be able to query and retrieve from multiple Image Manager/Image Archives.

In order to claim support for this profile option, a Report Reader shall be able to query and retrieve from multiple Report Repositories.

There is no requirement as to whether the multiple queries or retrieves are done concurrently or sequentially.

Image Displays and Report Readers shall have the ability to be configured to access multiple Image Manager/Image Archives and Report Repositories (respectively).

Image Managers and Report Managers shall also support the Patient Information Reconciliation integration profile in order to ensure that the information gathered from them is as accurate as possible. Since having actors in different ADT (patient identifier) domains could result in unpredictable query results, this option assumes that all actors are members of the same ADT domain (i.e., it can be assumed that a given patient identifier uniquely refers to a single patient).

An Image Display or Report Reader supporting this profile option may be configured to initially query only its local information source; however, it shall be possible to query multiple sources with a single user request.

When an Image Display and Report Reader are combined, a single user request shall suffice to trigger a query of multiple sources for both images (and anything else stored in an Image Manager/Image Archive) and reports.

If communication with an information source fails, an Image Display or Report Reader shall provide the information it received from the other sources. In addition, the Image Display and Report Reader shall inform the user that they are viewing potentially incomplete results.

When an Image Display or Report Reader performs a study-level or series-level query to multiple sources and finds the study/series referenced in multiple places, the study/series is either duplicated or the study/series is split across the systems. When the user requests a retrieval of the study/series an Image Display and Report Reader shall collate the information, determine if the

1980   information is actually duplicated or split, and present to the user a consolidated view of results. The consolidated view of results may be shown and updated either as responses are received or when the final response has been received from the last responding information source.

A participating Image Display or Report Reader shall manage duplicate instances in a manner that avoids redundant retrieval.

1985 ## 8 Key Image Note (KIN)

The *Key Image Note Integration Profile* specifies transactions that allow a user to mark one or more images in a study as significant by attaching to them a note managed together with the study. This note includes a title stating the purpose of marking the images and, optionally, a user comment field. Physicians may attach Key Image Notes to images for a variety of purposes:
1990   referring physician access, teaching files selection, consultation with other departments, and image quality issues, etc.

It should be noted that while Key Image Notes meet the definition of Evidence Documents, they are a special case that is dealt with separately in this Profile for historical reasons. Refer to the Evidence Documents Profile (Section 14) for a description of general evidence document
1995   handling.

The process of creating and using Key Image Notes can be managed by worklists that provide patient/ procedure details and by performed procedure steps that report status information (e.g., see Integration Profiles on Scheduled Workflow, Post-Processing Workflow, Reporting Workflow).

2000 ### 8.1 Actors/Transactions

Figure 8.1-1 diagrams the actors involved with this profile and the transactions between actors.
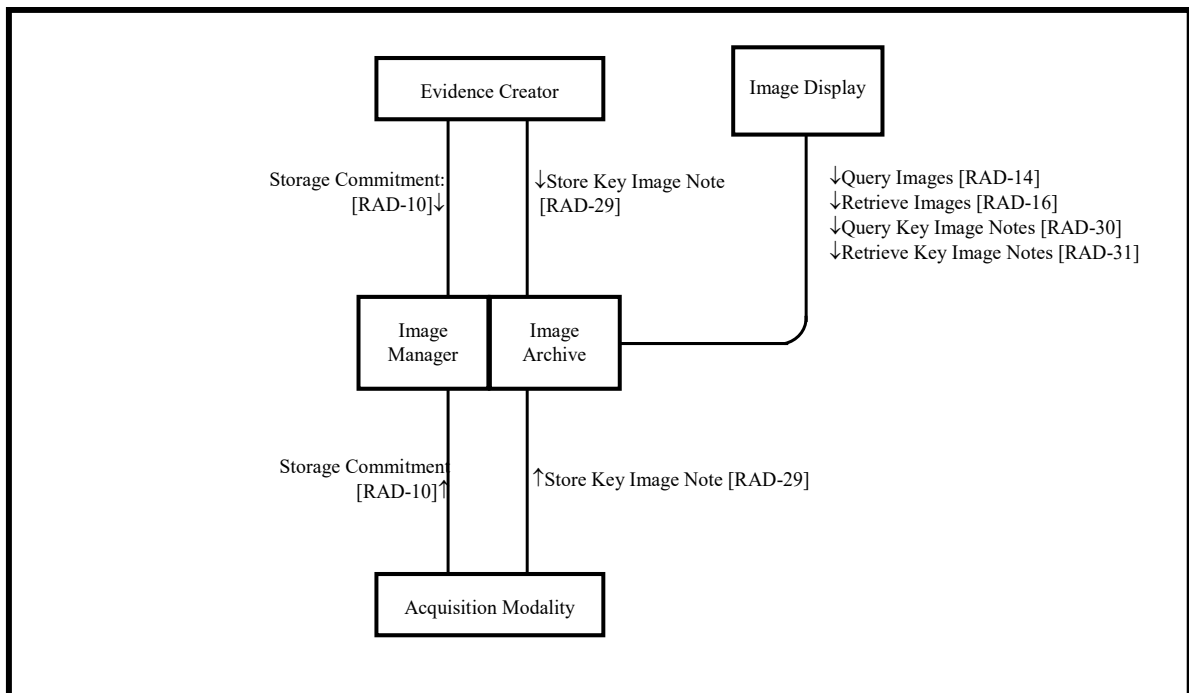
Figure 8.1-1: Key Image Note Diagram
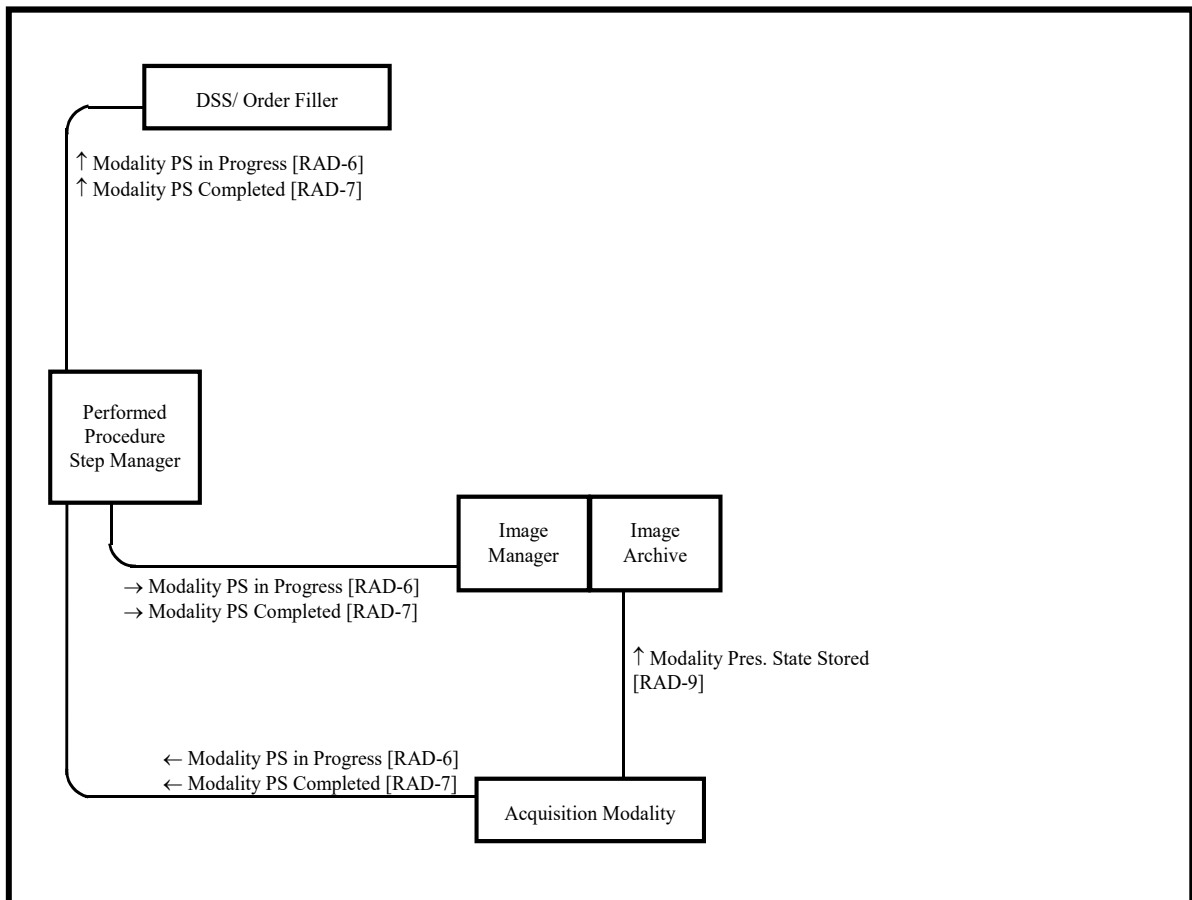
2005 Table 8.1-1 lists the transactions for each actor directly involved in the Key Image Notes Integration Profile. In order to claim support of this Integration Profile, an implementation must perform the required transactions (labeled "R"). Transactions labeled "O" are optional. A complete list of options defined by this Integration Profile and that implementations may choose to support is listed in Section 8.2.

2010 **Table 8.1-1: Key Image Note Integration Profile - Actors and Transactions**

Actors	Transactions	Optionality	TF Reference
Acquisition Modality	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
	Key Image Note Stored [RAD-29]	R	RAD TF-2: 4.29
Evidence Creator	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
	Key Image Note Stored [RAD-29]	R	RAD TF-2: 4.29
Image Manager/Image Archive Image Archive	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
	Query Images [RAD-14]	R	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	R	RAD TF-2: 4.16
	Key Image Note Stored [RAD-29]	R	RAD TF-2: 4.29
	Query Key Image Notes [RAD-30]	R	RAD TF-2: 4.30
	Retrieve Key Image Notes [RAD-31]	R	RAD TF-2: 4.31
Image Display	Query Images [RAD-14]	R	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	R	RAD TF-2: 4.16
	Query Key Image Notes [RAD-30]	R	RAD TF-2: 4.30
	Retrieve Key Image Note [RAD-31]	R	RAD TF-2: 4.31

Refer to Table 2-1 for other profiles that may be pre-requisites for this profile.

8.2 Key Image Notes Integration Profile Options

Options that may be selected for this Integration Profile are listed in the Table 8.2-1 along with the actors to which they apply. Dependencies between options when applicable are specified in
2015 notes.

Table 8.2-1: Key Image Notes - Actors and Options

Actor	Options	TF Reference
Acquisition Modality	*No options defined*	-
Evidence Creator	*No options defined*	-
Image Manager/ Image Archive	*No options defined*	-
Image Display	*No options defined*	-

8.3 Key Image Note Pattern

The Key Image Note allows a user to mark one or more images in a study as significant by attaching to them one or more notes managed together with the study. Each note includes a title stating the purpose of marking the images and a user comment. Physicians may attach Key Image Notes to images for a variety of purposes: referring physician access, teaching files selection, consultation with other departments, and image quality issues, etc. The list of titles used to describe why the images are being marked is defined by DICOM and is contained in DICOM PS3.16 CID 7010 (Key Object Selection Document Title).

A single Key Image Note may reference several images within a study. Multiple Key Image Notes may reference the same image.

When a Key Image Note refers to an image, it may also include a reference to a specific Presentation State for the image thus ensuring that the Key Image Note includes significant information about the image presentation state (window width/window level, flip, zoom, rotate, graphical and textual annotations as defined in the Consistent Presentation of Images Integration Profile). This information may be used by the Image Display that supports both the Key Image Notes and Consistent Presentation of Images Integration Profiles.

The content pattern of a Key Image Note is shown in Figure 8.3-1 and shall use the DICOM Key Object Selection Document SOP Class definition. The marked images of a study are those referenced by a Key Object Selection Document that belong to the same study as the Key Object Selection Document.

IHE does not require Evidence Creator Actors producing Key Image Notes to support the ability to reference images outside of the study. However, if they chose to do so, the inclusion of the Identical Documents Sequence is required per the DICOM Standard.

IHE requires Image Display Actors receiving Key Image Notes to display the fact that images referenced by the Key Object Selection Document belonging to the same study are flagged. It is beyond the scope of IHE to specify the means used to show this fact. Although Image Display recipients of Key Image Notes are required, per the DICOM Standard, to accept the Key Object Selection Documents with references outside the study, they are not required but may choose to support retrieval and display of the images from other studies outside of the one to which the Key Image Note belongs.
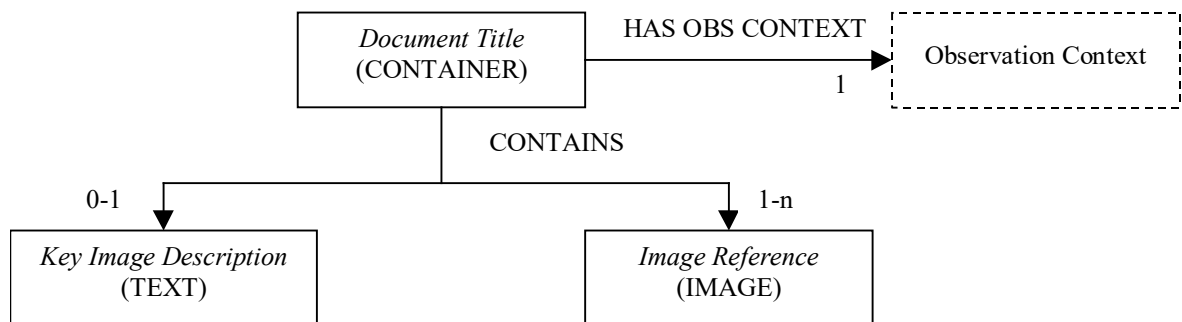
Figure 8.3-1: Key Image Note Pattern

9 Simple Image and Numeric Report (SINR)

2050   The **Simple Image and Numeric Report Integration Profile** facilitates the growing use of digital dictation, voice recognition, and specialized reporting packages, by separating the functions of reporting into discrete s for creation, management, storage and viewing. Separating these functions while defining transactions to exchange the reports between them enables a vendor to include one or more of these functions in an actual system.

2055   Reports exchanged have a simple structure attractive to many imaging departments: a title, an observation context, and one or more sections, each with a heading, observation context, text, image references, and optionally coded measurements. Some elements can also be coded to facilitate computer searches. Such reports can be input to the formal diagnostic report, thus avoiding re-entry of information.

2060   The process of creating imaging reports can be managed by worklists that provide patient/ procedure details and by performed procedure steps that report status information (e.g., see the Reporting Workflow Integration Profile).

9.1 Actors/Transactions

Figure 9.1-1 diagrams the actors involved with this profile and the transactions between actors.

2065

Figure 9.1-1: Simple Image and Numeric Report Diagram

2070 Table 9.1-1 lists the transactions for each actor directly involved in the Simple Image and Numeric Report 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 and that implementations may choose to support is listed in Section 9.2.

Table 9.1-1: Simple Image and Numeric Report - Actors and Transactions

Actors	Transactions	Optionality	TF Reference
Report Creator	Report Submission [RAD-24]	R	RAD TF-2: 4.24
Report Manager	Report Submission [RAD-24]	R	RAD TF-2: 4.24
	Report Issuing [RAD-25]	R	RAD TF-2: 4.25
	Query Reports [RAD-26]	R	RAD TF-2: 4.26
	Retrieve Reports [RAD-27]	R	RAD TF-2: 4.27
	Structured Report Export [RAD-28]	O	RAD TF-2: 4.28
Report Reader	Query Reports [RAD-26]	R	RAD TF-2: 4.26
	Retrieve Reports [RAD-27]	R	RAD TF-2: 4.27
Report Repository	Report Issuing [RAD-25]	R	RAD TF-2: 4.25
	Query Reports [RAD-26]	R	RAD TF-2: 4.26
	Retrieve Reports [RAD-27]	R	RAD TF-2: 4.27
External Report Repository Access	Query Reports [RAD-26]	R	RAD TF-2: 4.26
	Retrieve Reports [RAD-27]	R	RAD TF-2: 4.27
Enterprise Report Repository	Structured Report Export [RAD-28]	R	RAD TF-2: 4.28

2075 Refer to Table 2-1 for other profiles that may be pre-requisites for this profile.

9.2 Simple Image and Numeric Report Integration Profile Options

Options that may be selected for this Integration Profile are listed in the Table 9.2-1 along with the actors to which they apply. Dependencies between options when applicable are specified in notes.

2080 **Table 9.2-1: Simple Image and Numeric Report - Actors and Options**

Actor	Options	TF Reference
Enterprise Report Repository	*No options defined*	-
External Report Repository Access	*No options defined*	-
Report Creator	Enhanced SR	RAD TF-2: 4.24.4.1.2
Report Manager	*No options defined*	-
Report Reader	Enhanced SR	RAD TF-2: 4.27.4.2.2
Report Repository	*No options defined*	-

The Report Creator, Report Manager and Report Repository 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 RAD TF-1x: Appendix D).

2085 9.3 Diagnostic Report Process Flow

This section describes the typical process flow related to diagnostic reporting. The transactions covered are [RAD-24] through [RAD-27].

In the initial stage of diagnostic reporting, a reading physician records the diagnosis by generating a draft DICOM Structured Report object, which is submitted to the Report Manager.
2090 Once a report is sent to the Report Manager, the Report Creator relinquishes control of the report to the Report Manager.

There are other documents which are sometimes referred to as "reports" and may be encoded using DICOM SR (for example, procedure reports, CAD results and echocardiography measurement reports) however such documents do not follow the same kind of verification and
2095 distribution process described in this profile. These other documents serve different purposes and are instead addressed in the Evidence Documents Profile.

Reports are processed and modified by the Report Manager. This involves adding and changing report data as well as verifying draft reports. In all cases, any change in the report content by the Report Manager leads to the creation of a new DICOM Structured Report object. At any time,
2100 the Report Manager can transmit reports to the Report Repository for external access, but at a minimum the final report must be sent to the Report Repository. A Report Creator can effectively amend a report by submitting a new SR SOP Instance.

The Report Repository provides permanent storage of DICOM Structured Reports. It also allows reports to be queried and retrieved throughout the enterprise by Report Readers. A Report
2105 Reader provides a user interface to view DICOM Structured Reports that it retrieves from the Report Repository or External Report Repository Access.

The External Report Repository Access is a gateway to obtain other enterprise department reports, such as Laboratory and Pathology, from within the Imaging department. DICOM Structured Reports are queried and retrieved by a Report Reader from the External Report
2110 Repository Access.

The Enterprise Report Repository receives diagnostic reports in HL7 format.

The Simple Image Report and Simple Image and Numeric Reports are required minimally to have the functionality defined in DICOM PS3.16 TID 2000. Creators may introduce increased complexity as long as it conforms to the SOP class. The templates referenced in the Technical
2115 Framework are included in DICOM PS3.16.
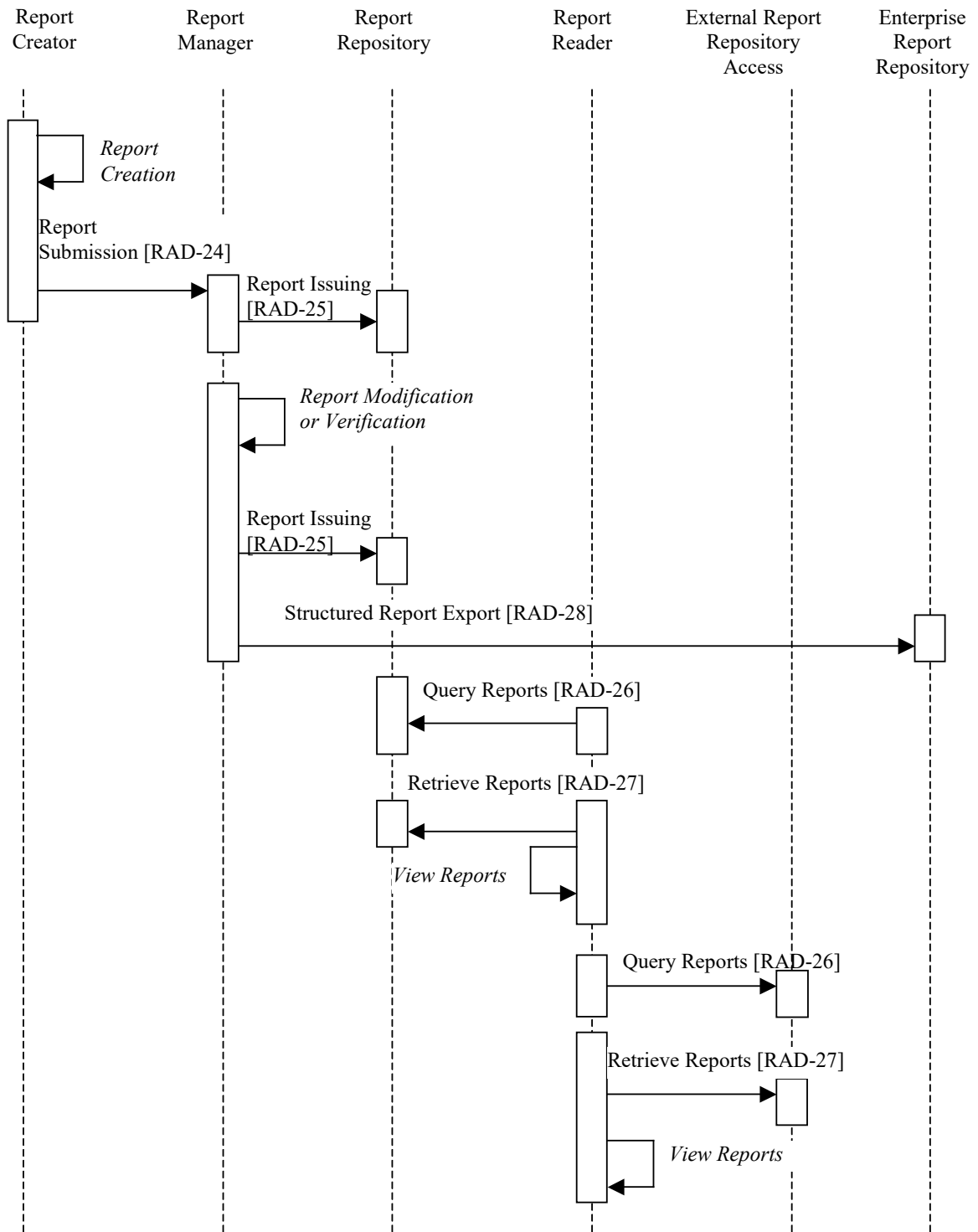
Figure 9.3-1: Diagnostic Reporting Process Flow

9.4 Diagnostic Reporting Use Cases

2120 DICOM Structured Reports offer the capability to encode arbitrarily structured diagnostic report data. The Radiology Technical Framework stipulates that the reporting actors need to support several use cases and their specific content patterns, which are detailed in the following sections.

The diagrams in the following sections define the report content pattern and utilize the following conventions:

2125
- Each rectangle is a single Content Item.
- Italic text in a rectangle denotes a generic grouping of Concept Names to be used for the Content Item. These must be configurable in the reporting actors.
- Uppercase text in a rectangle denotes the Content Item Value Type.
- Text following the Content Item Value Type specifies the possible Content Item
2130 Value(s), if known (only used for Observation Context).
- Text on lines defines the relationship between Content Items.
- Numbers on lines define the cardinality of descendent Content Items.

9.4.1 Simple Image Report

The Simple Image Report allows documents with multiple sections (with headings) containing
2135 report text and references to relevant images. Some text items of these documents may also be related to specific images. This allows a reading physician to identify one or more images from which their conclusions were inferred. This content pattern is shown in Figure 9.4-1 and shall use the DICOM Basic Text SR Information Object Definition and Basic Image Diagnostic Report Template (DICOM PS3.16 TID 2000).

2140   Note: TID 2000 has other requirements not shown in the diagram.
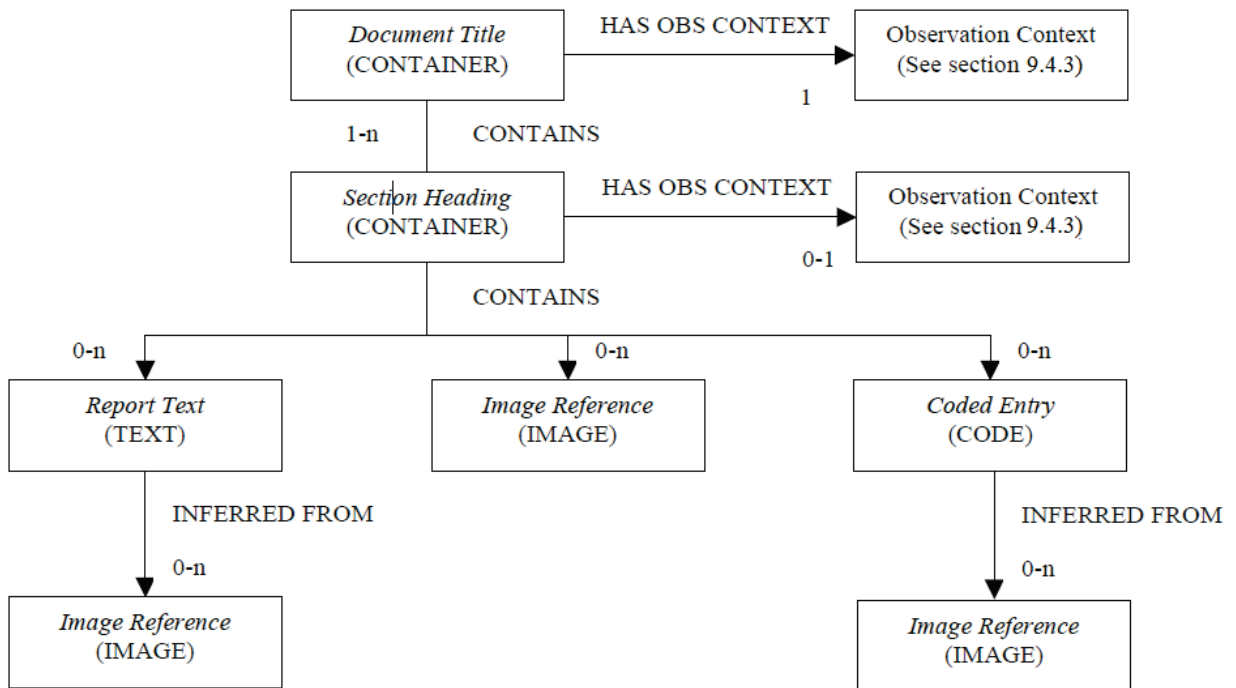
Figure 9.4-1: Simple Image Report Pattern

9.4.2 Simple Image and Numeric Report

The Simple Image and Numeric Report is similar to the Simple Image Report described in Section 9.3.1 but allows the addition of numeric values. This enables a diagnosis to include measurements and other numeric values. Like the Simple Image Report, particular text values can be encoded to signify that they are inferred from specific images or numeric values. This content pattern is shown in Figure 9.4-2 and shall use the DICOM Enhanced SR Information Object Definition and Basic Image Diagnostic Report Template (DICOM PS3.16 TID 2000).

2145

2150 Note: TID 2000 has other requirements not shown in the diagram.
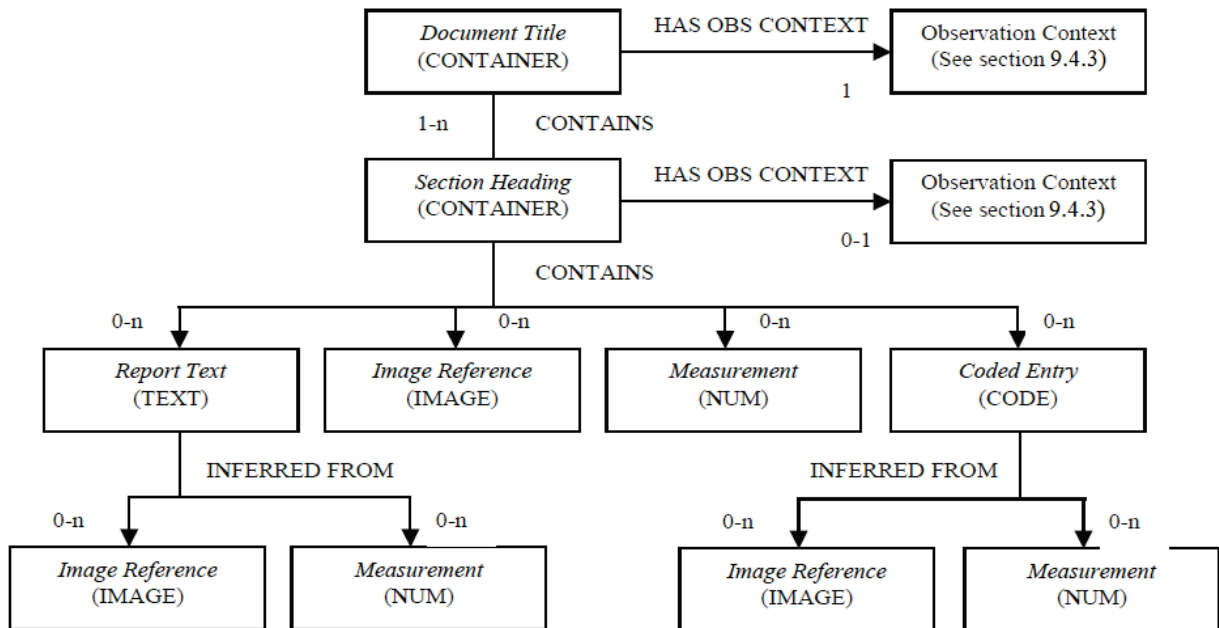
Figure 9.4-2: Simple Image and Numeric Report Pattern

9.4.3 Observation Context

2155 Encoding of the Observation Context for Simple Image Report and Simple Image and Numeric Report shall follow the definition in DICOM PS3.16 TID 1001.

Observation context content items may be descended from the root content item, and may be superseded by subsequent observation contexts at the section level. Therefore, the observation context may change throughout the report. This capability allows one report to include, for 2160 example, observations on a mother and fetus, observations by multiple observers, or observations from multiple studies.

10 Basic Security (SEC) - DEPRECATED

This profile has been superseded by the Radiology Audit Trail Option in ITI Audit Trail and Node Authentication Profile (ITI TF-1: 9.2.2) and RAD TF-3: 5.1 for a detailed description of the Radiology Audit Trail Option).

11 Charge Posting (CHG)

The *Charge Posting Integration Profile* specifies information exchange from the Department System Scheduler/Order Filler to the Charge Processor about charges associated with particular procedures, as well as communication about patient demographics, accounts, insurance, and guarantors between ADT Patient Registration and Charge Processor. The Charge Posted transaction contains some information to generate a claim. Currently, these interfaces contain fixed field formatted or HL7-like data. The goal of including this in the Radiology Technical Framework is to standardize interface between clinical systems and the Charge Processors. Additionally, the Charge Posted transaction reduces the need of the billing system to have knowledge of the radiology internals. The result is that the Charge Processor will receive more complete, timely and accurate data.

The Department System Scheduler/Order Filler indicates to the Charge Processor that procedures are available for Technical and/or Professional billing. The Charge Posted [RAD-35] transaction may occur at various times in the workflow. Regulations and site operating procedures determine when a procedure is eligible for Charge Posting. Often, the events are different for technical and professional charges.

Technical charges are typically eligible at procedure completion.

Professional charges are typically eligible at result verification.

Events that may trigger charges are Procedure Ordered, Procedure Scheduled, Procedure Completed, Result Dictated, Result Transcribed, and Result Verified.

11.1 Actors/Transactions
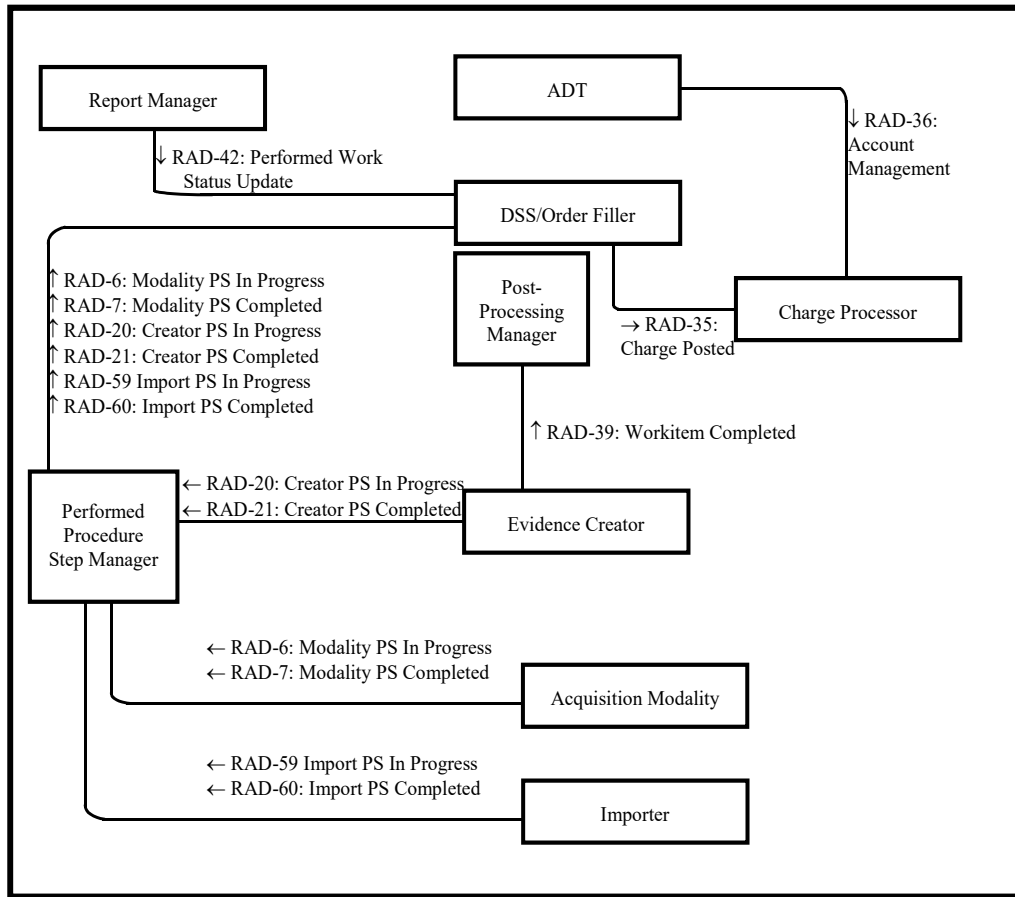
2190

Figure 11.1-1: Charge Posting Transaction Diagram

Table 11.1-1 lists the transactions for each actor directly involved in the Charge Posting 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 and that implementations may choose to support is

2195 listed in Section 11.2.

Table 11.1-1: Charge Posting – Actors and Transactions

Actors	Transactions	Optionality	TF Reference
ADT Patient Registration	Account Management [RAD-36]	R	RAD TF-2: 4.36
Department System Scheduler/ Order Filler/Performed Procedure Step Manager (Note 3)	Charge Posted [RAD-35] (Note 5)	R	RAD TF-2: 4.35
	Modality Procedure Step In Progress [RAD-6]	R	RAD TF-2: 4.6
	Modality Procedure Step Completed [RAD-7] (Note 2)	R	RAD TF-2: 4.7

Actors	Transactions	Optionality	TF Reference
	Creator PS In Progress [RAD-20]	R	RAD TF-2: 4.20
	Creator PS Completed [RAD-21]	R	RAD TF-2: 4.21
	Performed Work Status Update [RAD-42]	R	RAD TF-2: 4.42
	Import Procedure Step In Progress [RAD-59]	R	RAD TF-2: 4.59
	Import Procedure Step Completed [RAD-60] (Note 4)	R	RAD TF-2: 4.60
Acquisition Modality	Modality Procedure Step In Progress [RAD-6] (Note 1)	R	RAD TF-2: 4.6
	Modality Procedure Step Completed [RAD-7]	R	RAD TF-2: 4.7
Report Manager	Performed Work Status Update [RAD-42]	R	RAD TF-2: 4.42
Evidence Creator	Creator PS In Progress [RAD-20]	R	RAD TF-2: 4.20
	Creator PS Completed [RAD-21]	R	RAD TF-2: 4.21
Post-Processing Manager (Note 3)	Workitem Completed [RAD-39]	R	RAD TF-2: 4.39
Charge Processor	Charge Posted [RAD-35] (Note 5)	R	RAD TF-2: 4.35
	Account Management [RAD-36]	R	RAD TF-2: 4.36
Importer	Import Procedure Step In Progress [RAD-59]	R	RAD TF-2: 4.59
	Import Procedure Step Completed [RAD-60] (Note 4)	R	RAD TF-2: 4.60

Refer to Table 2-1 for other profiles that may be pre-requisites for this profile.

Note 1: An Acquisition Modality that claims the Charge Posting Profile shall support the Assisted Protocol Setting Option (see RAD TF-2: 4.6.4.1.2.4.2).

Note 2: In the transaction, the DSS/Order Filler shall use the Billing and Material Management information supplied by the Acquisition Modality (see RAD TF-2: 4.7.4.1.3.2) or the Importer (see RAD TF-2: 4.60.4.1.3.2 and RAD TF-2: 4.60.4.1.3.2)

Note 3: The Post-Processing Manager participates in this profile only if the Post Processing Workflow Integration Profile is one of the pre-requisite profiles supported. In this case, the Post-Processing Manager shall be grouped with the DSS/ Order Filler.

Note 4: To claim the Charge Posting Profile, the Importer shall support the Billing and Material Management Option (see RAD TF-2: 4.60.4.1.2.3).

Note 5: The DSS/Order Filler and Charge Processor shall support the HL7v2.3.1 semantics for [RAD-35]. (See RAD TF-2: 4.35.4.1.2).

11.2 Charge Posting Integration Profile Options

Options that may be selected for this Integration Profile are listed in the Table 11.2-1 along with the actors to which they apply. Dependencies between options when applicable are specified in notes.

Table 11.2-1: Charge Posting – Actors and Options

Actor	Options	TF Reference
ADT Patient Registration	*No options defined*	-
Department System Scheduler / Order Filler	*No options defined*	-
Acquisition Modality	PPS Exception Management	RAD TF-2: 4.7
	Modality Group Case	RAD TF-2: 4.6
	Billing and Material Management	RAD TF-2: 4.7.1.2.3
Performed Procedure Step Manager	*No options defined*	-
Evidence Creator (Note 1)	*No options defined*	-
Report Manager	*No options defined*	-
Charge Processor	*No options defined*	-
Importer	Billing and Material Management	RAD TF-2: 4.60.4.1.2.3

Note 1: The Billing and Materials Management Option may in some cases also apply to an Evidence Creator in Charge Posting. However, it is at this time not specified.

11.3 Charge Posting Process Flow
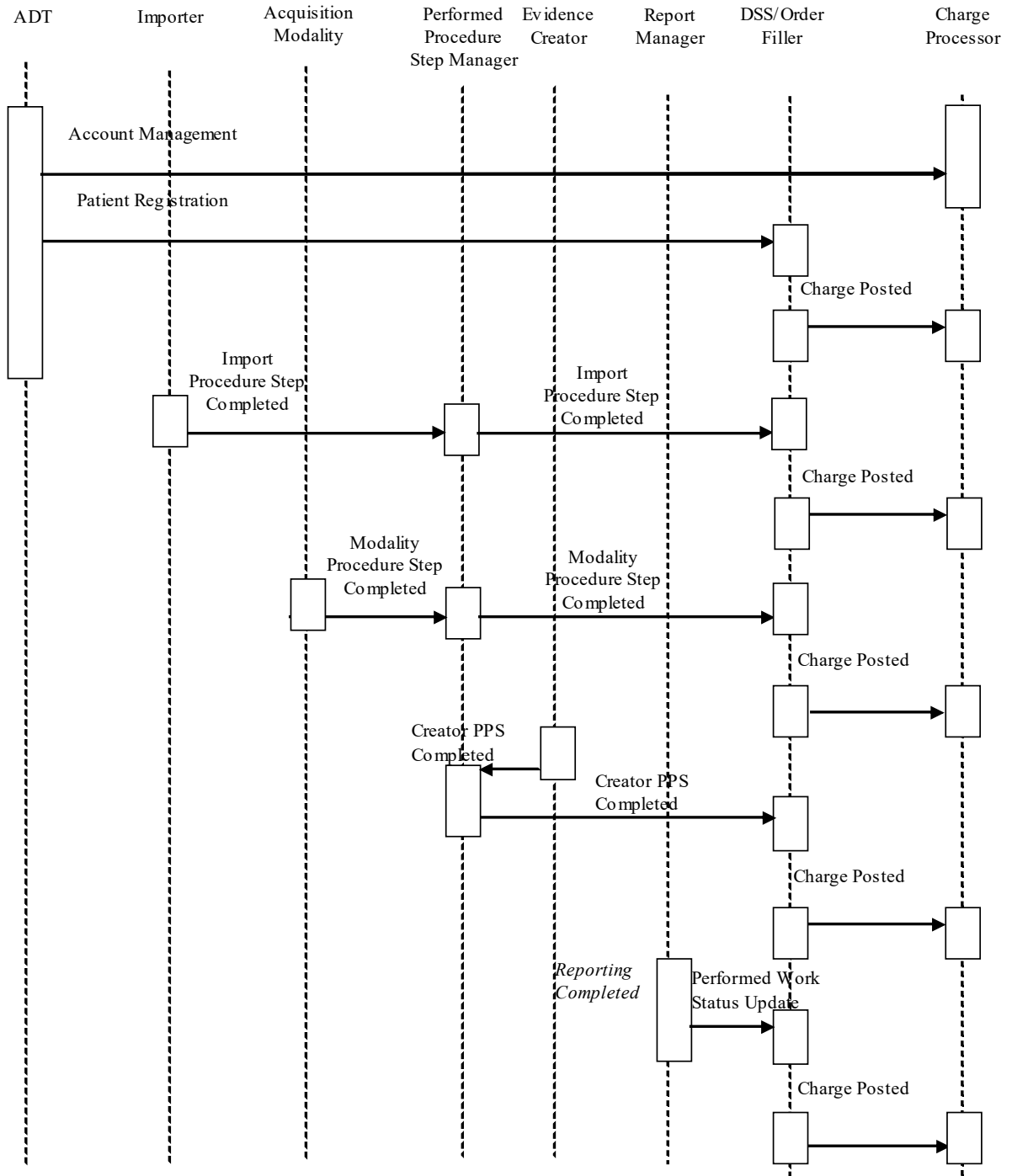
Figure 11.3-1: Charge Posting Process Flow

2220 Events that may trigger a Charge Posted transaction are Procedure Ordered, Procedure Scheduled, Procedure Completed, Result Dictated, Result Transcribed, and Result Verified.

11.3.1 Use Cases

This section describes the potential use cases relating to the charge posting functionality. It is the responsibility of the Department System Scheduler/Order Filler to ensure that the billing 2225 information is sent to the Charge Processor. The Department System Scheduler/Order Filler forwards the data that is required by the Charge Processor to generate the claim.

The Charge Processor shall accept the Charge Posted transaction information. Interpretation and subsequent billing processes by the Charge Processor are beyond the scope of this profile.

Below are listed the typical use cases:

2230 • A Department System Scheduler/Order Filler makes technical charges available for posting when the modality has completed the procedure.

• A Department System Scheduler/Order Filler makes professional charges available for posting at time of report verification.

• A site makes both technical and professional charges available at time of result 2235 verification.

• A site may have a single charge that comprises both the technical and professional components.

11.3.2 Technical Billing

Technical charges are based on the procedure and often include typical materials usage. These 2240 are one or more charges that are included in the Charge Posted transaction. The Charge Posted transaction message can be sent immediately when the Department System Scheduler/Order Filler receives confirmation that the procedure is completed. Additionally, a site may wish to send information on materials used during a procedure to the Charge Processor for inclusion with the technical charges.

2245 Note that it may be site policy to verify from the Image Manager that the images have been stored. This is dependent on the business rules established for that site.

11.3.3 Professional Billing

Professional charges are based on the reading physician providing the results for the procedure. These are one or more charges that are included in the Charge Posted transaction. The 2250 Professional Billing Charge Posted transaction can be sent any time after the Department System Scheduler/Order Filler receives confirmation from the Report Manager that the report has been completed and verified. This may be done by grouping the Report Manager with Department System Scheduler.

Note that IHE specifies a non-country specific procedure coding scheme.

2255 The Charge Posted transaction defines the below sources of information:

- Patient Order Information

  - Scheduling and Requested Procedure

  - Scheduling and Scheduled Procedure Step

- Modality Performed Procedure Step

2260
  - Status Information - Completed / Discontinued

  - Protocol Code

  - Consumables

- Optionally, additional manual input or processing by the Department System Scheduler/Order Filler

11.4 Data Model for Charge Posting

2265

The data model adopted by the Radiology Technical Framework for the HL7 messages used in the Charge Posting Profile is based on a subset of HL7 v2.3.1 as described is Section 11.3.1.

11.4.1 Model of the Real World

Figure 11.4-1 depicts the model of the real world within scope of the Charge Posting Profile.
2270 This model corresponds to the approach suggested in the HL7 standard, in particular:

- Financial data related to the patient are accumulated as properties of accounts. A patient may have more than one active (open) account at a time.

- One account may contain financial data pertaining to more than one Visit. A visit, however, cannot span multiple accounts.

2275
- There may be multiple Billable Procedures performed and multiple charges posted as a result of one visit. There may be one charge posted for multiple procedures and one procedure to be charged in multiple charge postings, for example, for Technical and Professional charges.

- Requested Procedures may be Billable Procedures. One Requested Procedure may
2280 correspond to more than one Billable Procedure.

```
                   ┌─────────────┐
                   │   Patient   │
                   └─────────────┘
                     1 │
                     ◇ Has ◇
                  0 - n │
                   ┌─────────────┐
                   │   Account   │
                   └─────────────┘
                       1 │
                   ◇ Encompasses ◇
                   1 - n │
                   ┌─────────────┐
                   │    Visit    │
                   └─────────────┘
                       1 │
                     ◇ has ◇

                   1 - n │
   ┌──────────────────┐           ◇ Is a ◇        ┌──────────────────────┐
   │ Billable Procedure│◄─────────         ◄───────│ Requested Procedure  │
   └──────────────────┘       0-n        1        └──────────────────────┘
        1-n │
      ◇ is composed of ◇
      1 - m │
   ┌──────────────────┐
   │ Procedure Charge │
   └──────────────────┘
```
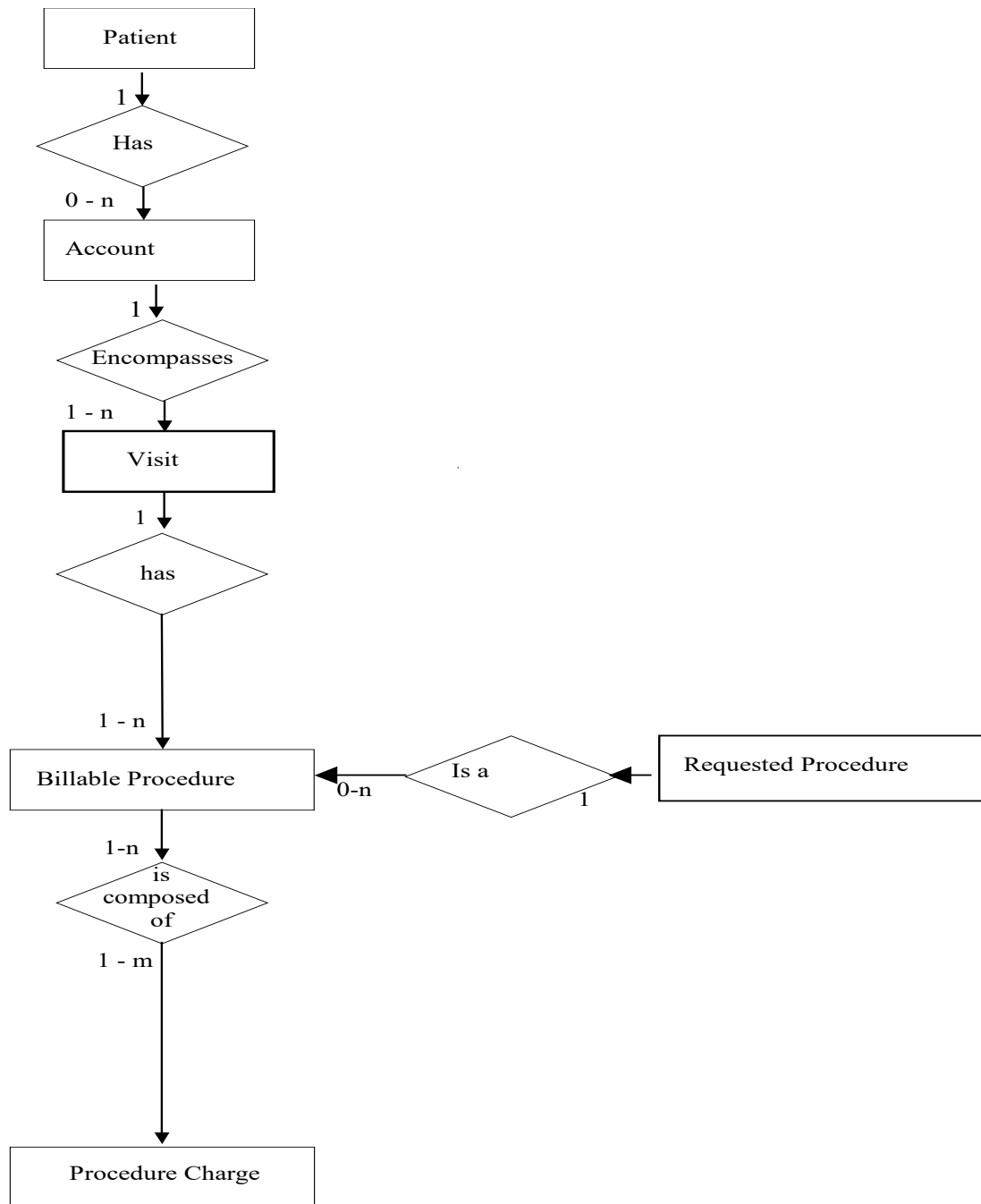
Figure 11.4-1: Model of the Real World for Charge Posting

12 Post-Processing Workflow (PWF)

IMPORTANT NOTE: *As of June 2012, IHE introduced a new Trial Implementation Profile: Post-Acquisition Workflow (PAWF). The use cases addressed are largely the same as PWF, but the underlying mechanisms are improved. The PWF Profile documented in this section has been deprecated by the Radiology Domain and is now replaced by PAWF. When the PAWF Profile becomes Final Text, the contents of this section will be removed. In the interim, new implementations should be based on PAWF, found at* **http://www.ihe.net/Technical_Frameworks/#radiology**

The Post-Processing Workflow Integration Profile addresses the need to schedule and track the status of the typical post-processing workflow steps, such as Computer Aided Detection or Image Processing. Worklists for each of these tasks are generated and can be queried, workitems can be selected and the resulting status returned from the system performing the work to the system managing the work. Typically, the workitems will involve the creation of objects such as images and evidence documents. The created images and evidence documents contain the necessary references for maintaining continuity of order information.

The Post-Processing Workflow Integration Profile is a continuation of the Scheduled Workflow Integration Profile.

12.1 Actors/Transactions

Figure 12.1-1 shows the actors directly involved in the Post-Processing Workflow Integration Profile and the relevant transactions between them. The italicized transactions represent a "generic" set of query/ retrieve transactions. The specific transactions required are dependent on which specific content profile(s) are supported by the Image Display and Image Manager/ Image Archive Actors.
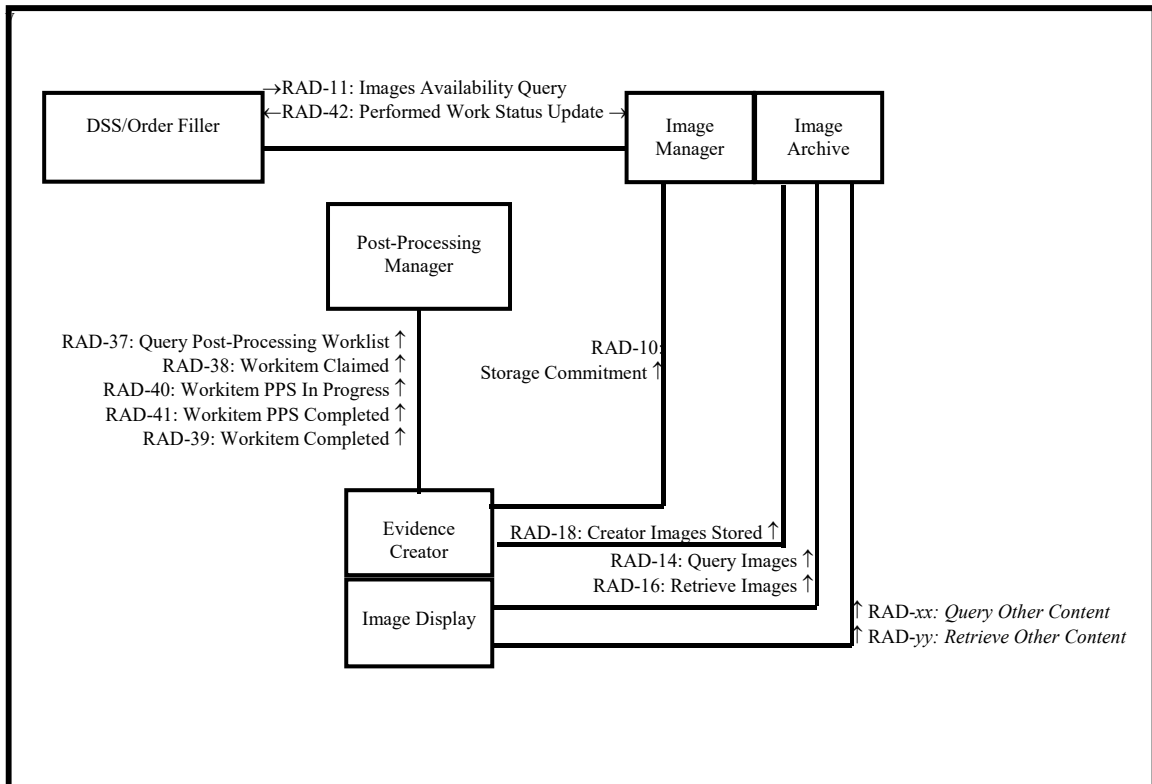
Figure 12.1-1: Post-Processing Workflow Actor Diagram

2310   Table 12.1-1 lists the transactions for each actor directly involved in the Post-Processing
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 and that implementations may choose
to support is listed in Section 12.2.

2315   **Table 12.1-1: Post-Processing Integration Profile - Actors and Transactions**

Actors	Transactions	Optionality	TF Reference
Department System Scheduler/ Order Filler	Images Availability Query [RAD-11]	R	RAD TF-2: 4.11
	Performed Work Status Update (Send) [RAD-42]	R	RAD TF-2: 4.42
Image Manager/ Image Archive	Images Availability Query [RAD-11]	R	RAD TF-2: 4.11
	Query Images [RAD-14]	O	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	O	RAD TF-2: 4.16
	Creator Images Stored [RAD-18]	O	RAD TF-2: 4.18
	Storage Commitment [RAD-10]	O	RAD TF-2: 4.10
	Performed Work Status Update (Send) [RAD-42]	R	RAD TF-2: 4.42
	Query Images [RAD-14]	O	RAD TF-2: 4.14

Actors	Transactions	Optionality	TF Reference
Evidence Creator/Image Display	Retrieve Images [RAD-16]	O	RAD TF-2: 4.16
	Creator Images Stored [RAD-18]	O	RAD TF-2: 4.18
	Storage Commitment [RAD-10]	O	RAD TF-2: 4.10
	Query Post-Processing Worklist [RAD-37]	R	RAD TF-2: 4.37
	Workitem Claimed [RAD-38]	R	RAD TF-2: 4.38
	Workitem PPS In Progress [RAD-40]	R	RAD TF-2: 4.40
	Workitem PPS Completed [RAD-41]	R	RAD TF-2: 4.41
	Workitem Completed [RAD-39]	R	RAD TF-2: 4.39
Post-Processing Manager	Query Post-Processing Worklist [RAD-37]	R	RAD TF-2: 4.37
	Workitem Claimed [RAD-38]	R	RAD TF-2: 4.38
	Workitem PPS In Progress [RAD-40]	R	RAD TF-2: 4.40
	Workitem PPS Completed [RAD-41]	R	RAD TF-2: 4.41
	Workitem Completed [RAD-39]	R	RAD TF-2: 4.39

Note: Refer to Table 2-1 for other profiles that may be pre-requisites for this profile.

Table 12.1-1 represents the case where the Evidence Creator and Image Display are performing post-processing on image objects and therefore the relevant storage, query, retrieve and storage commit transactions are listed.

The Evidence Creator, Image Display and Image Manager Actors may also support the Consistent Presentation of Images or Key Image Note Profiles. In that case, the Evidence Creator is expected to create GSPS and Key Image Note objects as part of its scheduled workitems. The Image Display and Image Manager Actors would be expected to store, commit, query, retrieve and display those objects as described in the relevant profiles.

The scenarios shown in the following flow diagrams happen not to include GSPS or Key Image Note related transactions. Those transactions would typically be sequenced in the same location as the corresponding image object related transactions.

12.2 Post-Processing Workflow Integration Profile Options

Options that may be selected for this Integration Profile are listed in the table below along with the actors to which they apply.

Table 12.2-1: Post-Processing Integration Profile – Actors and Options

Actors	Option	TF Reference
Department System Scheduler/Order Filler	*No options defined*	-
Image Manager/Image Archive	*No options defined*	-
Image Display	*No options defined*	-
Evidence Creator/Image Display	*No options defined*	-
Post-Processing Manager	*No options defined*	-

12.3 Implementation Issues

12.3.1 Actor Grouping Clarification

This profile is designed with the following implementation scenarios in mind:

Scenario 1:

The Post-Processing Manager is grouped with the Image Manager in System A. The DSS in System B needs status information. In this case:

System A claims support of the Post-Processing Workflow Profile as the Post-Processing Manager and Image Manager Actors.

System B claims support of the Scheduled Workflow Profile as the DSS and implements the optional Performed Work Status Update transaction.

Scenario 2:

The Post-Processing Manager is grouped with the DSS in System A. The Image Manager in System B is not interested in status information. In this case:

System A claims support of the Post-Processing Workflow Profile as the Post-Processing Manager and DSS Actors.

System B claims support of the Scheduled Workflow Profile as the Image Manager.

Scenario 3:

The Post-Processing Manager is grouped with the DSS in System A. The Image Manager in System B needs status information. In this case:

System A claims support of the Post-Processing Workflow Profile as the Post-Processing Manager and DSS Actors.

System B claims support of the Scheduled Workflow Profile as the Image Manager and implements the optional Performed Work Status Update transaction.

Scenario 4:

A Post-Processing Manager is grouped with the DSS in System A. Another Post-Processing Manager is grouped with the Image Manager in System B. In this case:

System A claims support of the Post-Processing Workflow Profile as the Post-Processing Manager and DSS Actors.

System B claims support of the Post-Processing Workflow Profile as the Post-Processing Manager and Image Manager Actors.

This leaves the site with the decision of how to reconcile control of the post-processing workflow. There are two approaches.

Any system implementing the Post-Processing Manager shall be able to disable this functionality through configuration.

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In the first approach, the site selects one of the two systems to be the Post-Processing Manager for the Post-Processing workflow by configuring the other to disable its workflow management functionality.

2370 In the second approach, the site may configure one Post-Processing Manager to start Post-Processing worklists for one set of procedure codes and configure the second Post-Processing Manager to start Post-Processing worklists for a complementary set of procedure codes. Making sure that the procedure code sets are non-overlapping and complementary is a configuration responsibility of the site.

12.3.2 Input Availability

2375 In case of being grouped with the Image Manager, the Post-Processing Manager will have some internal logic to determine when images available are sufficient for the Post-Processing workflow to begin. In some cases, it may not be necessary for a post-processing to be performed. Generally, these decisions are based on the procedure code of the requested procedure.

2380 In case of being grouped with the Department System Scheduler, the Post-Processing Manager uses the Image Availability transaction to know when images are available in the Image Archive for query. The image set needed for the Post-Processing workitem might or might not include all the instances the Post-Processing Manager has been notified about via previous MPPS or/and GP-PPS messages related to a requested procedure. Based on the received information and its internal logic the Post-Processing Manager decides which data the Post-Processing workitem 2385 input consists of.

Generally, the Post-Processing Manager will create a workitem in the Post-Processing worklist when the required images are available, although it may create the workitem before that with an empty or incomplete Input Information Sequence and the Input Availability Flag set to PARTIAL, until the images are available in the Image Archive.

2390 The Post-Processing Manager and Post-Processing Client (Evidence Creator) must be prepared to handle workitems with PARTIAL image availability in a stable fashion.

The Post-Processing Client may elect not to present workitems with PARTIAL status to the user for selection until their status later changes to COMPLETE. If the Post-Processing Client chooses to let the user select and start work on those items, then the Post-Processing Client is 2395 responsible for monitoring the post-processing worklist and make sure the user/application receives the full data when it is available.

Similarly, the Post-Processing Manager may choose to leave workitems with PARTIAL status out of provided worklists until the status is COMPLETE. If the Post-Processing Manager decides to provide PARTIAL workitems in the worklists, then it may be expected to check image 2400 availability and provide updated post-processing worklist replies to queries from the Post-Processing Client for workitems the client claims.

12.3.3 Evidence Creators in Scheduled Workflow vs. Post-Processing Workflow

An Evidence Creator that supports the Post-Processing Workflow Profile shall use mechanisms defined in this profile, i.e., General Purpose Performed Procedure Step, for all post-processing tasks including unscheduled tasks.

Evidence Creators that only support the Scheduled Workflow Profile may continue to use the Modality Performed Procedure Step transactions to communicate tasks performed as described in the Scheduled Workflow Profile.

12.4 Post-Processing Process Flow

The following are some possible post-processing use cases.

12.4.1 Computer Aided Detection Use Case

A modality procedure (e.g., a mammography screening exam or a lung CT) is to be acquired and CAD processing is to be performed on the images. The images and CAD processing results will be interpreted together on a review workstation by the reading physician.

The specific actors in this case are Acquisition Modality (digital mammography or CT acquisition system), Evidence Creator/Image Display (CAD processing system), Department System Scheduler, Image Manager/Image Archive, Post-Processing Manager, and Image Display (review workstation).

The Post-Processing Manager is grouped with either the Department System Scheduler or Image Manager and is responsible for providing work to the Evidence Creator. The DICOM Standard services used are Storage of Images (Digital Mammography X-ray or CT), Query/Retrieve, General Purpose Worklist, and Storage of Structured Reports (e.g., Mammography CAD or Chest CAD).

When MPPS Complete has been received and the acquired images are available on the Image Archive, the Post-Processing Manager would add a CAD workitem to the worklist. The CAD processing system would query the worklist, claim the workitem and based on the contained references, retrieve the images from the Image Manager and perform the scheduled CAD processing, reporting the status back to the Post-Processing Manager (including references to result objects created). The generated Evidence documents (CAD processing results) are stored as DICOM Structured Reports (e.g., Mammography CAD or Chest CAD).

The Evidence Document includes references to the images that were analyzed (typically for mammography screening, the MLO and CC views of the left and right breasts), a summary of the algorithms that were executed, including algorithm identification, whether they succeeded or failed, and the findings detected by the algorithms. For example, CAD processing for mammography or lung studies may include identification of the locations of things like suspected densities (masses) and micro-calcifications on the images.

Although in this case, the Evidence Creator does not actually create images, just an Evidence Document object (e.g., a CAD object), it is also possible that if the images were enhanced during processing (e.g., a filtered image), new versions of the image might also be stored to the Image

2440   Manager. At the end, the Post-Processing Manager is notified with a GP-SPS update that the scheduled step is complete.

The images and evidence documents are then available for retrieval by the Image Display on a Review/Reporting system where they can be reviewed by a reading physician and a proper diagnostic report generated. In this way, the profile complements the Simple Image and Numeric
2445   Report Profile.

12.4.2 3D Reconstruction Use Case

A modality procedure (e.g., a standard CT lumbar spine exam) is to be acquired and reconstructed and the results sent to a 3D post-processing application where Multi-Planar Reconstruction (MPR) is performed to get coronal images of the lumbar spine. The originally
2450   created axial images and the new coronal images are interpreted together, either at the modality or on a review station.

The specific actors in this case are the Acquisition Modality (e.g., a CT system), Image Display/Evidence Creator (3D workstation), Department System Scheduler, Image Manager/Image Archive, Post-Processing Manager, and Image Display (review workstation).

2455   The Post-Processing Manager is grouped with either the Department System Scheduler or Image Manager and is responsible for providing work to the Evidence Creator. The DICOM Standard services used are Storage of Images (CT), Query/Retrieve, and General Purpose Worklist.

When MPPS Complete has been received and the acquired images are available on the Image Archive, the Post-Processing Manager would add a post-processing workitem (GP-SPS) to the
2460   worklist. The 3D-processing system would query the worklist, claim the workitem and based on the contained references, retrieve the images from the Image Manager and perform the scheduled MPR processing, reporting the status back to the Post-Processing Manager (including references to result objects created). The MPR result images are stored as DICOM Images (CT). At the end, the Post-Processing Manager is notified with a GP-SPS update that the scheduled step is
2465   complete.

The images are then available for retrieval by the Image Display on a review/reporting system.

12.4.3 Post-Processing Process Flow Diagrams

The following scenario illustrates a case where an image processing task is performed on acquired images and then a subsequent CAD step is performed on the processed images. The
2470   Transaction Summary is depicted for two scenarios:

- The Post-Processing Manager is grouped with the Department System Scheduler
- The Post-Processing Manager is grouped with the Image Manager

The Performed Work Status Update (Started) message must be sent sometime after the Workitem Claimed transaction but at the latest, when the first GP-PPS In Progress is received. In
2475   this scenario it is shown right after the Workitem Claimed. Also, it is conceivable that in some scenarios, the processing workstation has loaded potentially useful studies/images prior to claiming the workitem or maybe even before getting the worklist.
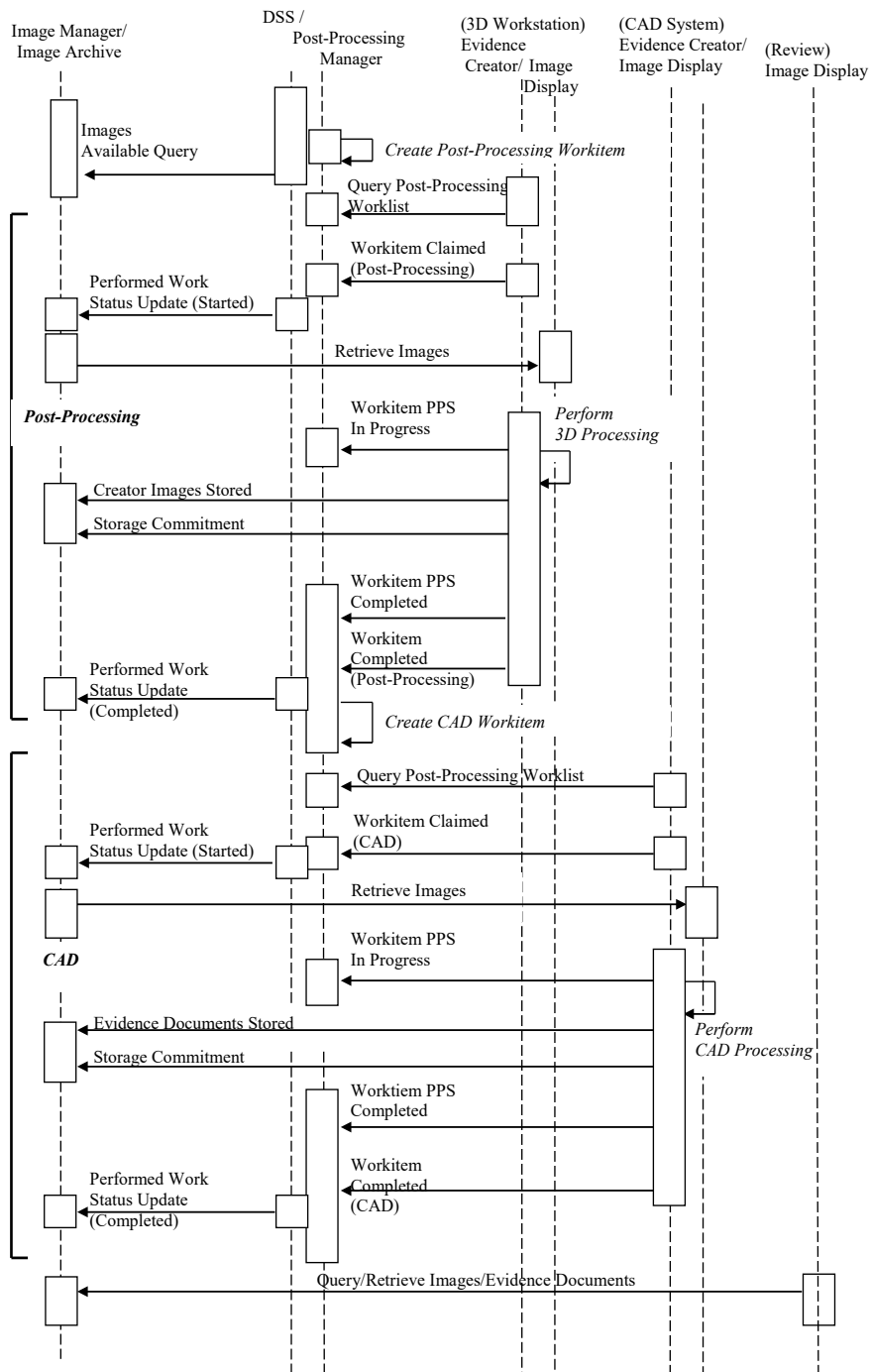
Figure 12.4-1: Post-Processing Manager Grouped with Department System Scheduler
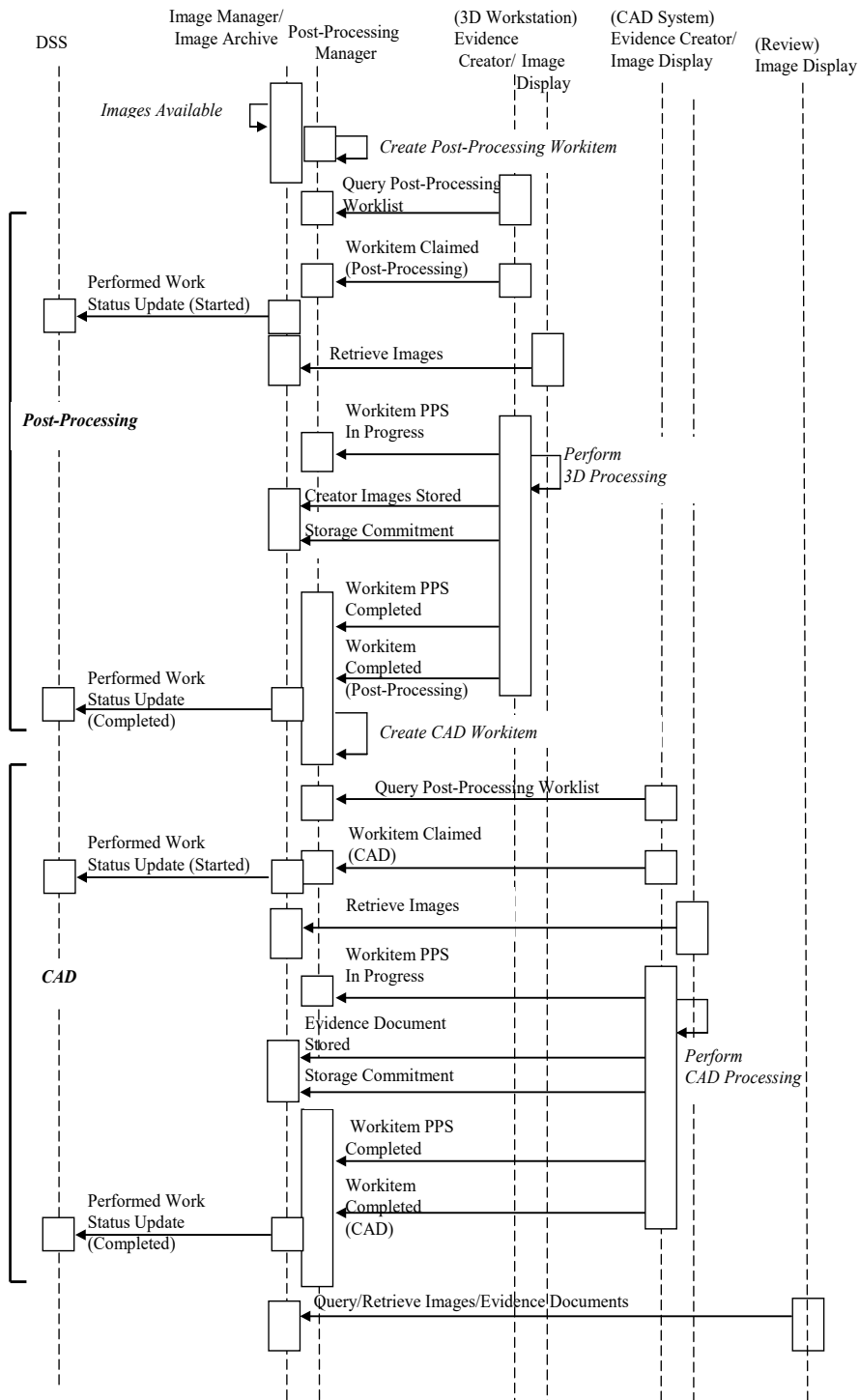
2480

Figure 12.4-2: Post-Processing Manager Grouped with Image Manager

13 Reporting Workflow (RWF)

The Reporting Workflow Profile addresses the need to schedule and track the status of the various reporting tasks. Reporting tasks include interpretation, dictation, transcription, verification, comparison, revision, and coding. Workitems for each of these tasks are generated and can be queried from worklists. Workitems can be claimed. The resulting intermediate and final statuses can be returned from the system performing the work to the system managing the work. The system managing the work also makes the status available for other interested systems in the enterprise.

The output of the Reporting Workflow Profile is defined to be information encoded as DICOM SR objects. The details for creation, storage, query/ retrieve and encoding are described by the Simple Image and Numeric Report (SINR) Profile (see RAD TF-1: 9).

The Reporting Workflow Integration Profile is a continuation of the Scheduled Workflow Integration Profile.

13.1 Actors/Transactions

Figure 13.1-1 shows the actors directly involved in the Reporting Workflow Integration Profile and the relevant transactions between them. Other actors that may be indirectly involved due to their participation in the Scheduled Workflow, etc. are not necessarily shown. Image Display can participate in this profile if it is grouped with a Report Creator.
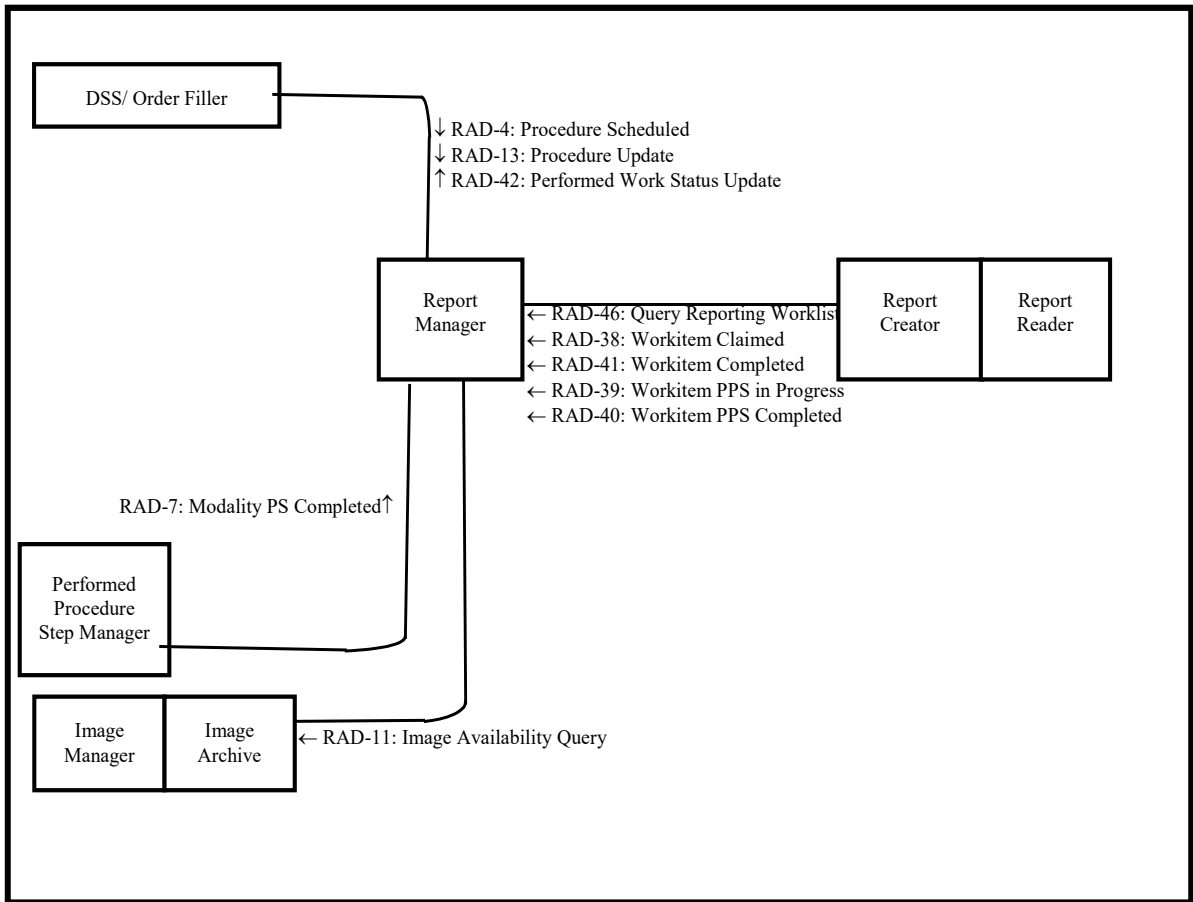
Figure 13.1-1: Reporting Workflow Actor Diagram

Table 13.1-1 lists the transactions for each actor directly involved in the Reporting Workflow
Integration Profile. In order to claim support of this Integration Profile, an implementation must
2505 perform the required transactions (labeled "R"). Transactions labeled "O" are optional. A
complete list of options defined by this Integration Profile and that implementations may choose
to support is listed in Section 13.2.

Table 13.1-1: Reporting Workflow Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	TF Reference
Department System Scheduler/ Order Filler	Procedure Scheduled [RAD-4] (Note 1)	R	RAD TF-2: 4.4
	Procedure Update [RAD-13] (Note 1)	R	RAD TF-2: 4.13
	Performed Work Status Update (Receive) [RAD-42]	R	RAD TF-2: 4.42
Image Manager/ Image Archive	Images Availability Query [RAD-11]	R	RAD TF-2: 4.11
	Query Images [RAD-14]	R	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	R	RAD TF-2: 4.16

Actors	Transactions	Optionality	TF Reference
Report Creator (Report Reader)	Query Reporting Worklist [RAD-46]	R	RAD TF-2: 4.46
	Workitem Claimed [RAD-38]	R	RAD TF-2: 4.38
	Workitem PPS In Progress [RAD-39]	R	RAD TF-2: 4.39
	Workitem PPS Completed [RAD-40]	R	RAD TF-2: 4.40
	Workitem Completed [RAD-41]	R	RAD TF-2: 4.41
Report Manager	Procedure Scheduled [RAD-4] (Note 1)	R	RAD TF-2: 4.4
	Images Availability Query [RAD-11]	R	RAD TF-2: 4.11
	Procedure Update [RAD-13] (Note 1)	R	RAD TF-2: 4.13
	Query Reporting Worklist [RAD-46]	R	RAD TF-2: 4.46
	Workitem Claimed [RAD-38]	R	RAD TF-2: 4.38
	Workitem PPS In Progress [RAD-39]	R	RAD TF-2: 4.39
	Workitem PPS Completed [RAD-40]	R	RAD TF-2: 4.40
	Workitem Completed [RAD-41]	R	RAD TF-2: 4.41
	Performed Work Status Update (send) [RAD-42]	R	RAD TF-2: 4.42
	Modality Performed Procedure Step Completed [RAD-7]	R	RAD TF-2: 4.7
Performed Procedure Step Manager	Modality Performed Procedure Step Completed [RAD-7]	R	RAD TF-2: 4.7

Note 1: The actor shall implement the HL7 v2.3.1 Message Semantics for this transaction.

Refer to Table 2-1 for other profiles that may be pre-requisites for this profile.

13.1.1 Actor Grouping Clarification

Any system implementing the Report Manager will have some internal logic to determine when images stored on the Image Manager are sufficient for the reporting workflow to begin. In some cases, it may not be necessary for a report to be generated. Generally, these decisions are based on the procedure code of the requested procedure.

This profile is currently designed with the following grouping scenarios in mind:

Scenario 1:

The Report Manager is grouped with the Image Manager in System A. The DSS in System B needs status information. In this case:

System A claims support of the Reporting Workflow Profile as the Report Manager and Image Manager Actors.

System B claims support of the Scheduled Workflow Profile as the DSS and implements the optional Performed Work Status Update transaction.

Scenario 2:

The Report Manager is grouped with the DSS in System A. The Image Manager in System B needs status information. In this case:

System A claims support of the Reporting Workflow Profile as the Report Manager and DSS Actors.

System B claims support of the Scheduled Workflow Profile as the Image Manager.

Scenario 3:

A Report Manager is implemented on a system A and is grouped with neither the DSS nor the Image Manager. The DSS in system B needs status information. The Image Manager in System C might or might not need the status information. In this case:

System A claims support of the Reporting Workflow Profile as the Report Manager.

System B claims support of the Scheduled Workflow Profile as the DSS and implements the Performed Work Status Update transaction.

System C claims support of the Scheduled Workflow Profile as the Image Manager and may implement the optional Performed Work Status Update transaction if the needed.

13.1.2 Input Availability

The Report Manager uses the Images Availability Query transaction to know when images are available in the Image Archive for query. The image set relevant for the reporting workflow might or might not include all the instances the Report Manager has been notified about via previous MPPS or/and GP-PPS messages related to a requested procedure. Based on the received information and its internal logic the Report Manager decides which data the reporting workitem input consists of.

Generally, the Reporting Manager will create a workitem in the reporting worklist when the required images are available, although it may create the workitem before that with an incomplete Input Information Sequence and the Input Availability Flag set to PARTIAL. The Reporting Manager and Report Creator must be able to handle workitems with PARTIAL image availability in a stable way. The Report Creator may not display workitems with PARTIAL status to the user for selection until their status later changes to COMPLETE. If the Report Creator allows the user to select and start work on items with partially available input, then the Report Creator is responsible for monitoring the reporting worklist and make sure the user receives the full data when it is available.

Similarly, the Report Manager may choose to leave workitems with PARTIAL status out of the provided worklist until the status is COMPLETE. If the Report Manager provides workitems with partially available input data in the worklist, then a later check of the image availability and update of the workitem in the worklist may be expected even for workitems that have been already claimed.

13.2 Reporting Workflow Integration Profile Options

Options that may be selected for this Integration Profile are listed in the Table 13.2-1 along with the actors to which they apply. Dependencies between options when applicable are specified in notes.

Table 13.2-1: Reporting Workflow - Actors and Options

Actor	Options	TF Reference
Department System Scheduler / Order Filler	HL7 v2.5.1	RAD TF-1: 13.2.1 RAD TF-2: 4.4.1.2.2 RAD TF-2: 4.13.4.2
Image Manager/ Image Archive	*No options defined*	-
Report Creator	*No options defined*	-
Report Manager	HL7 v2.5.1	RAD TF-1: 13.2.1 RAD TF-2: 4.4.1.2.2 RAD TF-2: 4.13.4.2
Report Reader	*No options defined*	-
Performed Procedure Step Manager	*No options defined*	-

13.2.1 HL7 v2.5.1 Option

The HL7 v2.5.1 Option requires actors to support HL7 v2.5.1 in addition to HL7 v2.3.1 in the transactions referenced in Table 13.2-1. The actor shall permit configuration for each system that it communicates with using the referenced transactions whether HL7 v2.3.1 or HL7 v2.5.1 is used. It is possible that the actor may receive HL7 v2.3.1 messages and send HL7 v2.5.1 messages or vice versa.

- A Department System Scheduler / Order Filler that supports the HL7 v2.5.1 Option shall support the HL7 v2.5.1 Message Semantics for [RAD-4] and [RAD-13] in RAD TF-2: 4.4.1.2.2 and RAD TF-2: 4.13.4.2.

- A Report Manager that supports the HL7 v2.5.1 Option shall support the HL7 v2.5.1 Message Semantics for [RAD-4] and [RAD-13] in RAD TF-2: 4.4.1.2.2 and RAD TF-2: 4.13.4.2.

The specifications in the HL7 v2.5.1 Option maintain semantic equivalency with HL7 v2.3.1 implementations and the field correspondences are summarized in RAD TF-2x: Appendix N.

13.3 Reporting Tasks

The process of report creation is considered to be composed of multiple tasks. The following individual tasks have been identified:

- Interpretation - the physician accesses the acquired images, reviews them and typically generates either a draft report or dictation.

- Interpretation and Dictation - the physician generates an audio file of dictated observations that will make up the diagnostic report's content.

- Transcription - the transcriptionist accesses the physician's dictated report and generates the transcribed text report.

- Verification - the physician accesses the transcribed or draft report, confirms the text content accuracy and generates the verified report.

2590
- Review - the physician accesses the report, reviews the content and may generate either an agreement or disagreement.

- Comparison - the physician accesses two verified reports, reviews the content, and generates either a difference report or confirmation of similarity.

- Coding - the coder accesses a draft or verified report, and assigns codes.

2595   Note: Verification is considered to be different from a signature, although it may trigger a signature. A signature has policies attached to it. It is not part of this Reporting Workflow profile.

In the report creation process, actors such as the report creator perform relevant workitems obtained by querying the relevant worklist.

2600   Depending on the capabilities of the system containing the Report Creator and the permissions of the user, it may be possible to carry out several steps at once. For example, a speech recognition workstation may support interpretation, dictation and transcription all at once, and a senior physician may have authority to immediately verify the resulting report. In other situations or implementations, it may be necessary to perform the steps separately. The types and sequence of tasks may vary from site to site. A sequential process made up of an interpretation/dictation, a
2605   transcription, and a verification task is very common, but this can vary between institutions.

The logic of determining what tasks to schedule and when to schedule them is the responsibility of the Report Manager and is not defined by IHE. Typically, this logic will involve completion of pre-requisite tasks and/or availability of needed input objects. Much of the needed information is available in the PPS transactions from the Report Creators, Image Managers and other actors,
2610   in the Image Availability transaction to the Image Manager, and in reports stored to the Report Manager.

The logic of presenting a relevant list of workitems to the user is the responsibility of the Report Creator and is only partially defined by IHE in the Query Reporting Worklist transaction. Typically, this will involve filtering the available workitems based on the Scheduled Workitem
2615   Code (to find particular types of tasks), the Scheduled Human Performer (to find work for a particular person), the Scheduled Station Name (to find work for a particular workstation), Patient Name (to find work for a particular patient), Accession Number (to find work for a particular order), or Procedure Step Status (to find work in a particular state).

A number of common workitem codes are listed in RAD TF-2: 4.46 - Query Reporting Worklist.
2620   Systems may allow sites to configure additional codes that reflect their local workflow practices and can be used by the Report Creators to filter workitems.

As the Report Creator completes tasks, it reports performed workitem codes to the Report Manager. This is particularly important when the Report Creator performs additional tasks as it enables the Report Manager to modify the workflow. Further robustness and flexibility is
2625   provided by allowing the Report Creator to identify and suggest subsequent workitem codes in the General Purpose Performed Procedure Step Results Module, giving the Report Manager additional input to the logic it uses to select subsequent workflow steps in an adaptive manner.

The following diagram (Figure 13.3-1, parts 1 & 2) gives an example of a full Reporting Workflow from scheduling of the initial Interpretation/Dictation task, to the final release of the verified report. Prior to the start of this, images and evidence documents would have been stored to the Image Manager and PPS transactions containing references to those objects sent to the Report Manager.

In this example, the Report Manager is grouped with neither the DSS nor the Image Manager, and the DSS is acting as the Performed Procedure Step Manager.

In the figure(s) below, there are parenthetic notations associated with most of the Query Reporting Worklist and Workitem PPS In-Progress/ Completed transactions. These notes indicate the Scheduled or Performed Workitem Codes associated with those transactions. For a complete set of codes, refer to RAD TF-2: Table 4.46-4.
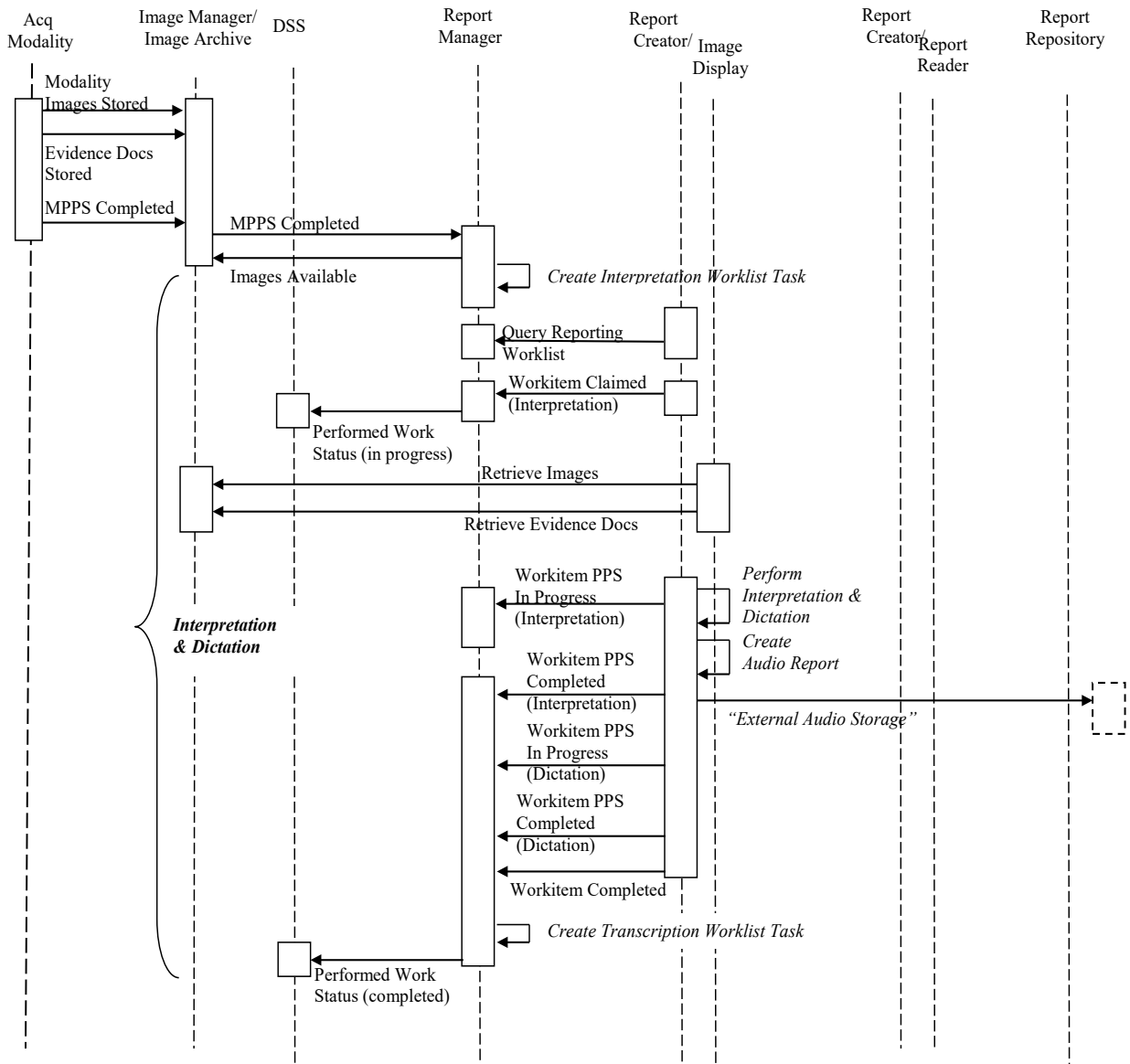
2640

Figure 13.3-1 (part 1): Reporting Workflow Overall Sequence
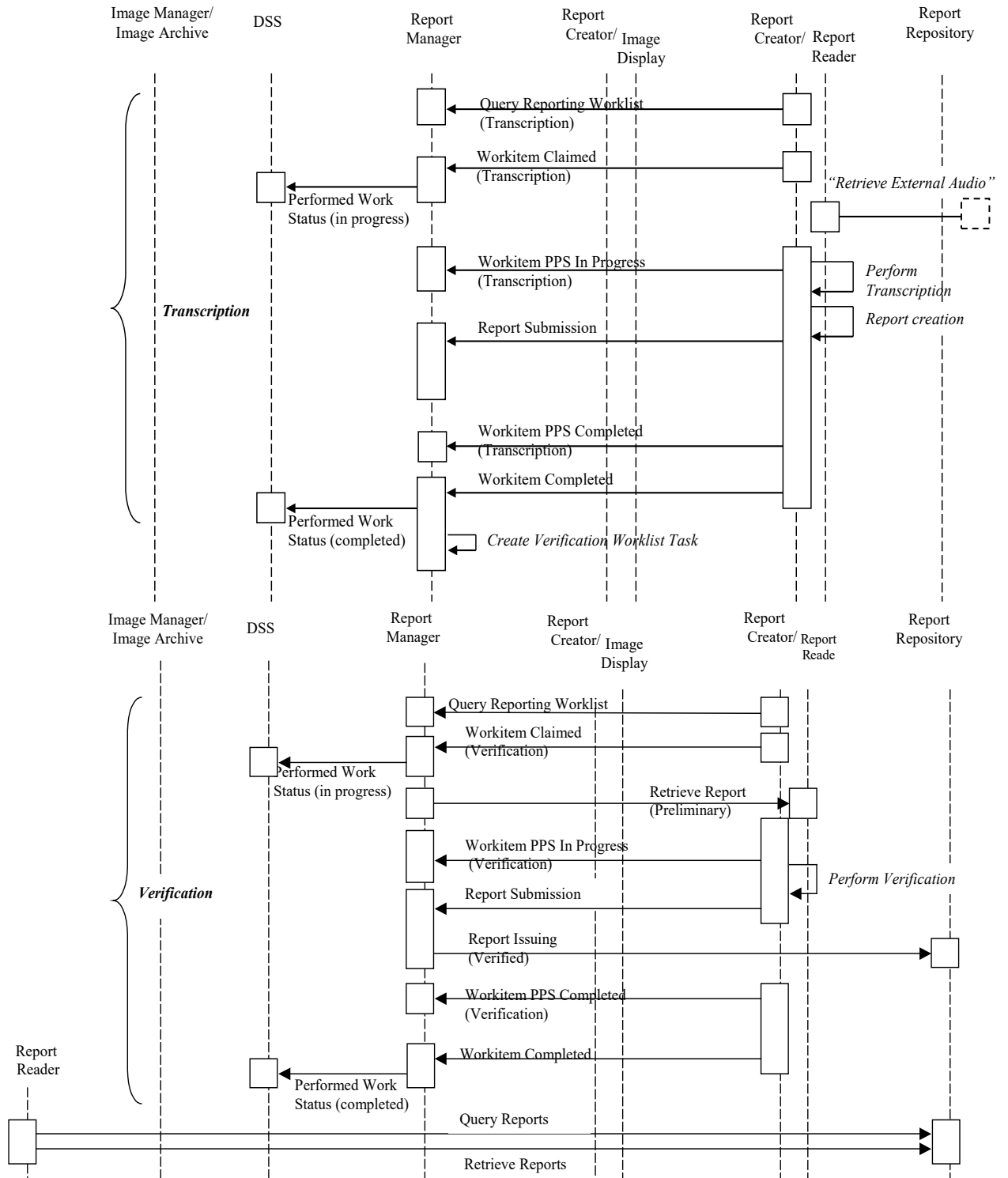
Figure 13.3-1 (part 2): Reporting Workflow Overall Sequence

2645 ## 13.4 Diagnostic Reporting Use Cases

This section describes diagnostic reporting creation uses cases. Each use case is a combination of one or many reporting tasks. These use cases do not cover all reporting use cases. However, their feasibility is demonstrated.

13.4.1 Use case 1: Predefined Report

2650 The primary user is the reading physician. When interpreting a study, the user chooses a report from a list of pre-configured draft reports and can edit the report's content in order to customize it. This use case covers the situation where the user can use a predefined/ canned report (which is frequently the case when the results are normal), and has permission to verify the report.

This use case finally results in:

2655
- multiple Performed Procedure Steps for each of the performed workitems Interpretation, Transcription and Report Verification, each having a corresponding code value in the Performed Workitem Code Sequence;

- a report which has been verified and is referenced in the output results status message;

- removing the workitem from the worklist, after the workitem status was set to completed.

2660 The basic flow is illustrated in Figure 13.4-1
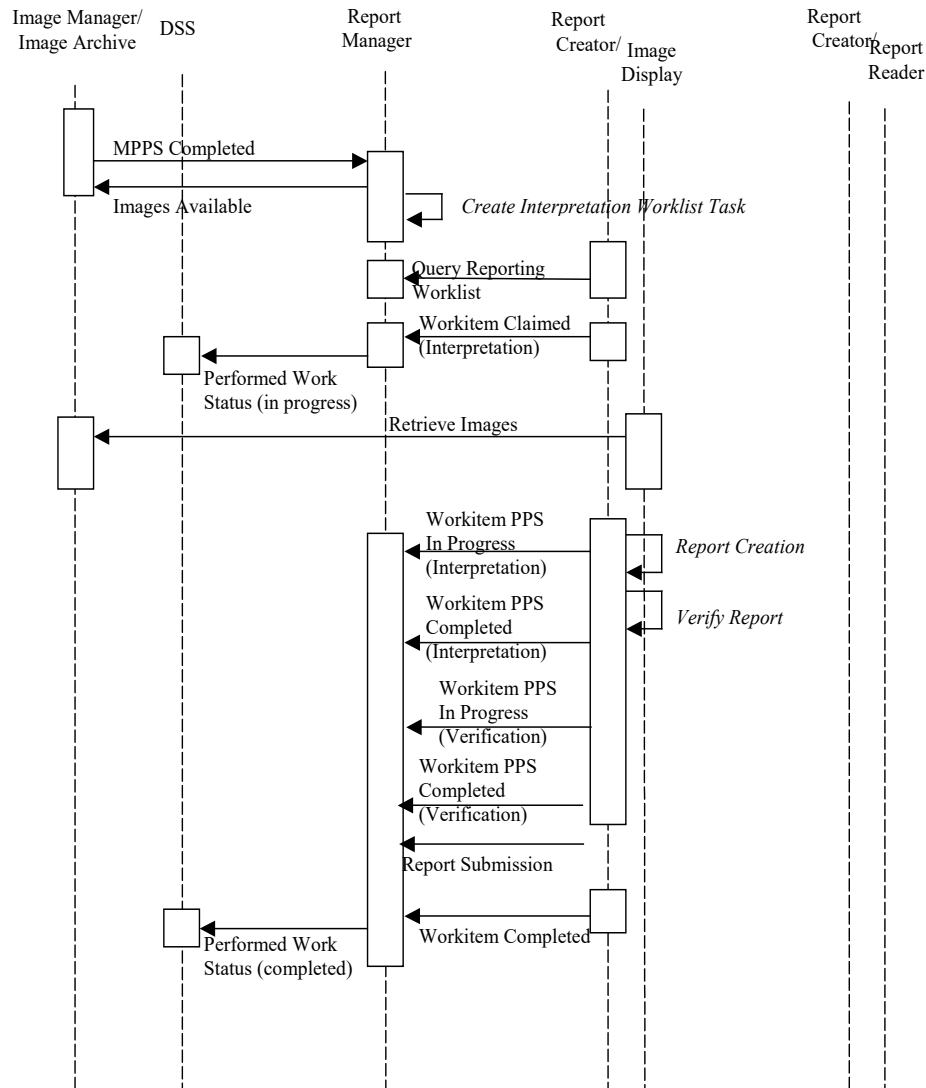
Figure 13.4-1 Use Case 1: Predefined Report

13.4.2 Use case 2: Workitem Deferred

The primary user can be the reading physician, the transcriptionist, or the verifying physician.
2665   This use case takes place when the user starts to work on the workitem and decides not to complete it.

At the end of this use case the workitem status is set to scheduled and the workitem remains in the worklist.

The basic flow is illustrated in Figure 13.4-2 (optional transactions denoted by dotted lines).

2670   Transactions Workitem PPS In Progress and Workitem PPS Completed are optional since some implementations may let the user skip before sending these transactions
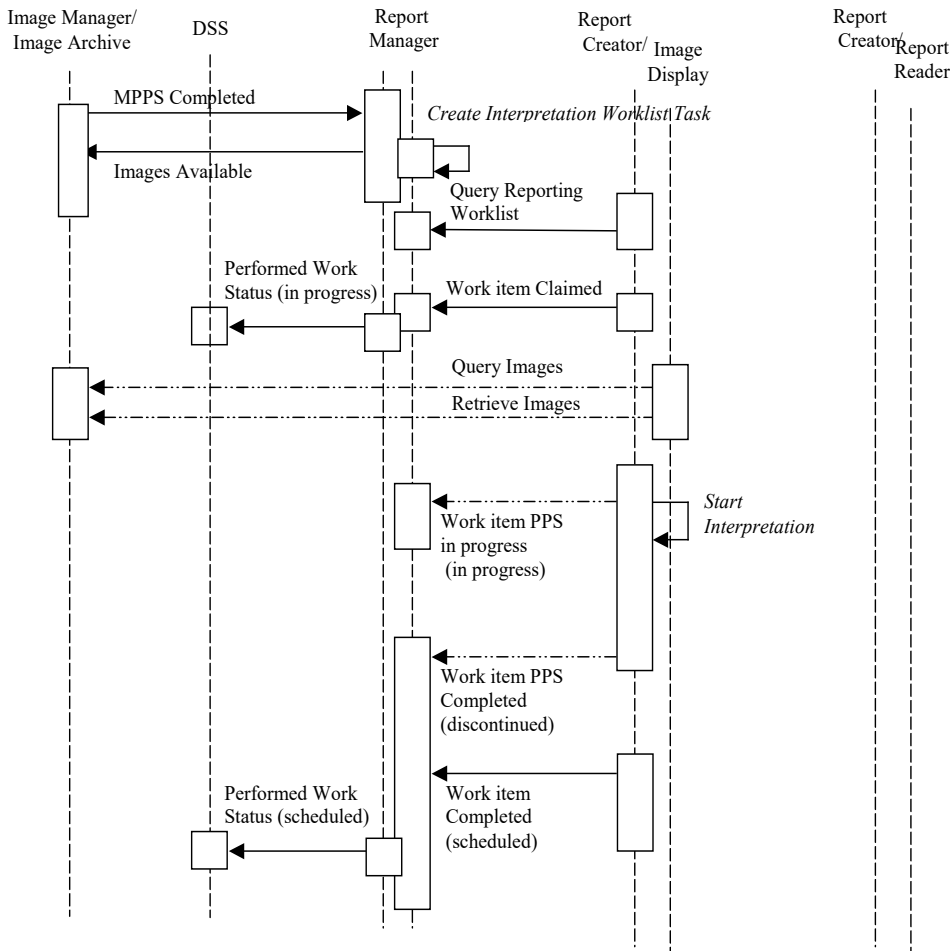
Figure 13.4-2 Use Case 2: Workitem Deferred

13.4.3 Use case 3: Direct Report Creation

2675   The primary user is the reading physician. This use case takes place when the user creates the report's content. The user may define a template or choose a template from pre-defined ones to fill in. The major difference between this use case and the "Predefined Report" use case (Section 13.4.1) is that in this use case, the user is expected to have to perform more "customization/ tailoring" of the report content (i.e., in contrast to the 'canned report' nature of the Predefined

2680   Report case).

At the end of this use case the workitem status is set to completed, the workitem is removed from the worklist, a report is generated, the output results status message references the generated report, the suggested subsequent workitem is set to Report Verification and the multiple Performed workitem code sequences include Interpretation and Transcription.

2685   The basic flow is illustrated in Figure 13.4-3.

This use case has an extension when the user has verification permission. In this case the generated report is verified, and the multiple Performed workitem code sequences include Interpretation, Transcription and Report Verification.
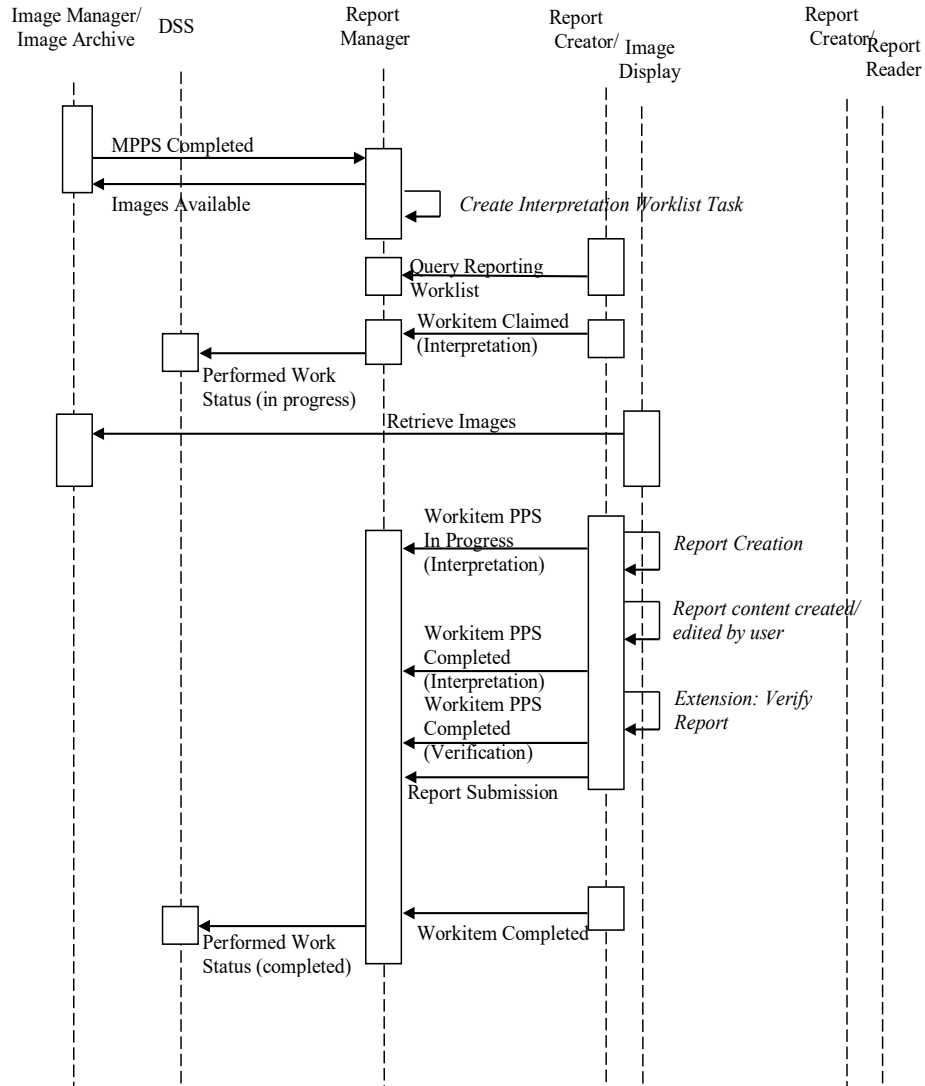
2690
Figure 13.4-3 Use Case 3: Direct Report Creation

13.4.4 Use case 4: Interpretation and Dictation

The primary user is the reading physician. This use case takes place when the user dictates the interpretation.

This use case finally results in:

2695
- multiple Performed Procedure Steps for each of the performed workitems Interpretation and Dictation, each having a corresponding code value in the Performed Workitem Code Sequence;

138

- an output results status message, referencing the generated audio file and suggesting its Transcription as subsequent workitem;

2700

- removing the workitem from the worklist, after the workitem status was set to completed.

The basic flow is illustrated in Figure 13.4-4 (optional transactions denoted by dotted lines).

Note: It is beyond the scope of the Radiology Technical Framework to define the "External Audio Storage" transaction shown in this figure.

2705 This use case has two variations. The first variation is when a voice recognition system is available at the Report Creator. In this case a report is generated, the output results reference the generated report, the suggested subsequent workitem is set to Report Verification, and two Performed Procedure Steps are created each having a Performed Workitem Code Sequence value of Interpretation or Transcription respectively. The second variation takes place when a voice recognition system is available at the Report Creator and the user has verification permission. In

2710 this case the generated report is verified, and three Performed Procedure Steps are created each having a Performed Workitem Code Sequence value of Interpretation, Transcription or Report Verification respectively.
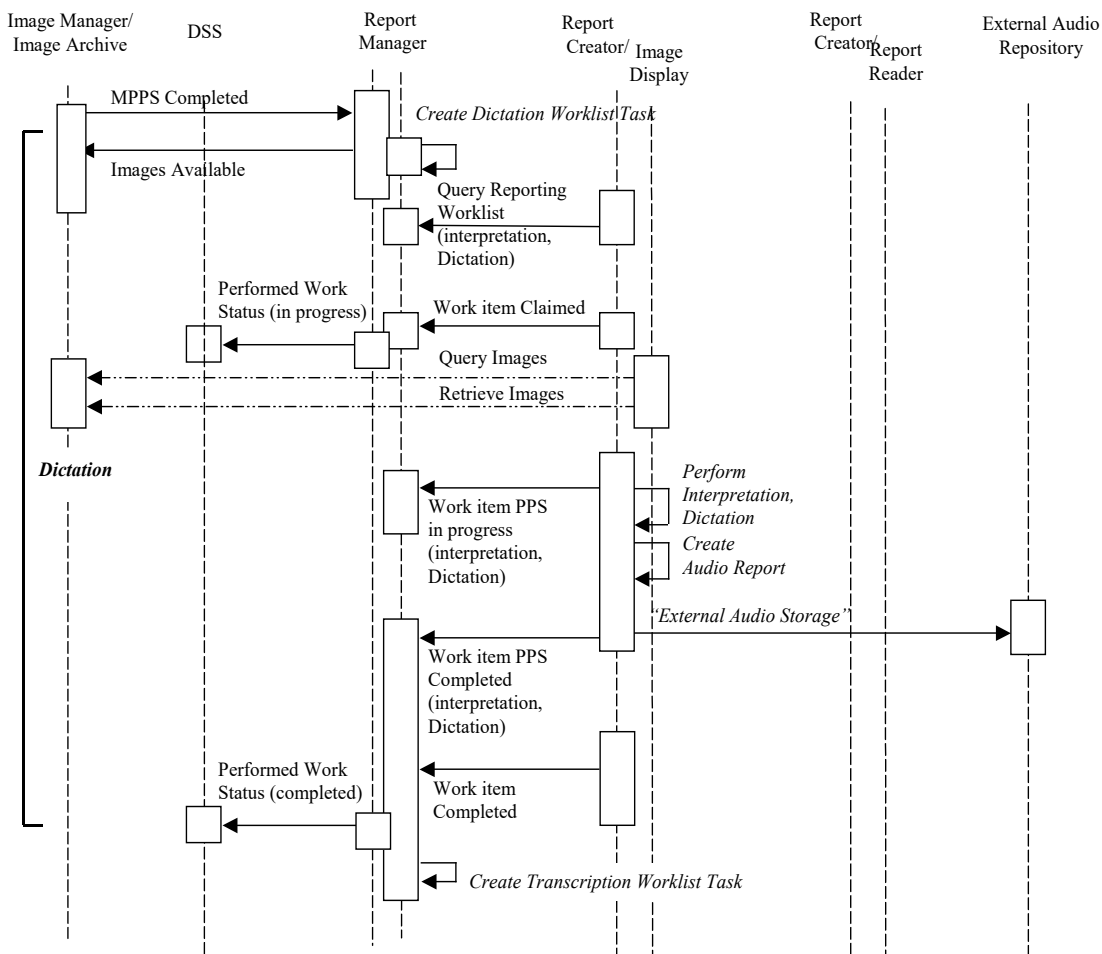
Figure 13.4-4 Use Case 4: Interpretation and Dictation

2715 ## 13.4.5 Use case 5: Transcription

The primary user is the transcriptionist. This use case can start when an audio file is available, and takes place when the transcriptionist transcribes the audio content into a transcribed report.

This use case finally results in:

2720
- a Performed Procedure Step for Transcription, having a corresponding code value in its Performed Workitem Code Sequence;

- an output results status message, referencing the generated report and suggesting its Verification as subsequent workitem;

- removing the workitem from the worklist, after the workitem status was set to completed.

The basic flow is illustrated in Figure 13.4-5.

2725
    Note: It is beyond the scope of the Radiology Technical Framework to define the "Retrieve External Audio" transaction shown in this figure.
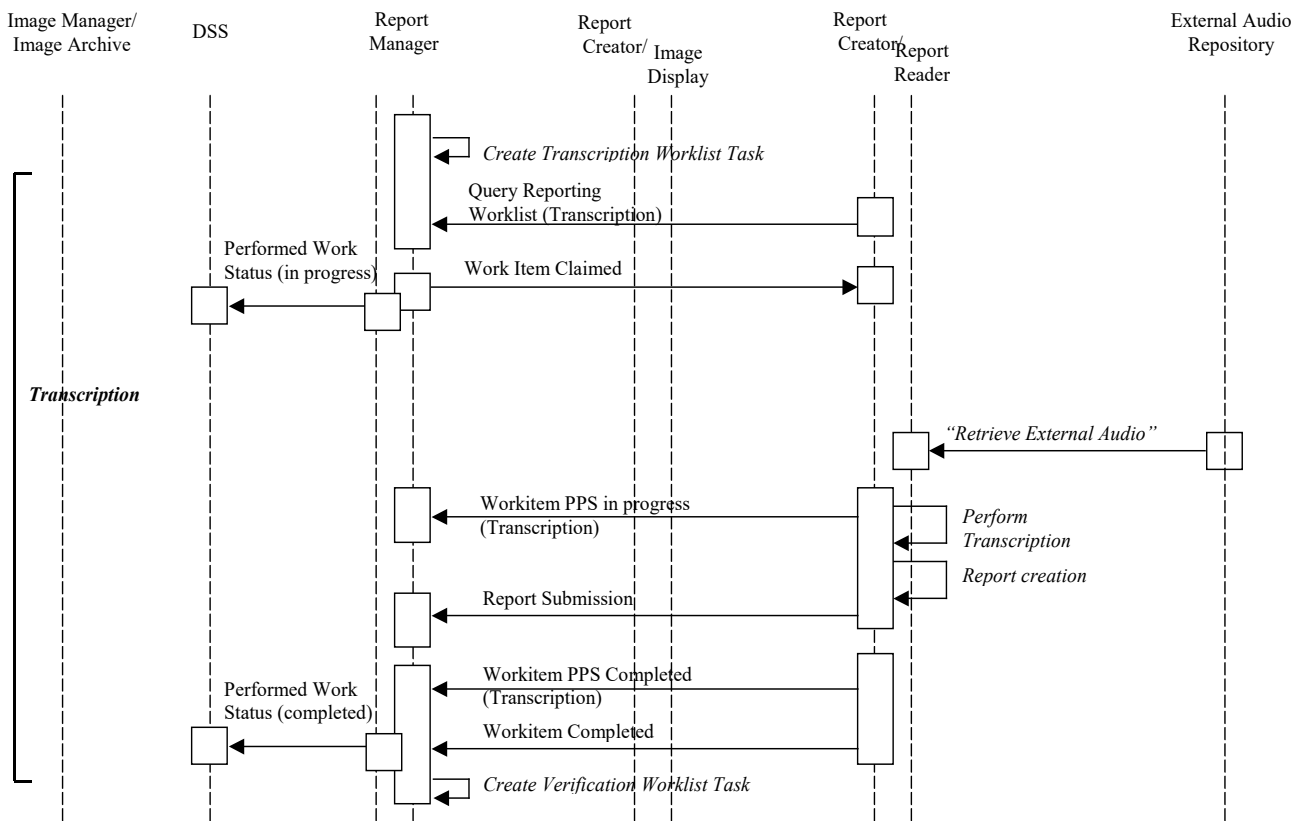
Figure 13.4-5 Use Case 5: Transcription

13.4.6 Use case 6: Partial completion

2730 The primary user is the reading physician.

This use case happens when the user begins the task and then decides that this task cannot be completed at this moment. The reason can be that more input is necessary to perform this task such as additional image acquisition, post- processing (3D) or that the actual data is of bad quality and new acquisition is required. This may require a new scheduling and a new workitem when interpretation would be possible again

2735

At the end of this use case the workitem status is set to discontinued, and the workitem is removed from the worklist.

The Report Creator may decide whether sending partial results to the Report Manager (via the Workitem PPS transactions) is useful.

2740 The basic flow is illustrated in Figure 13.4-6 (optional transactions denoted by dotted lines).

Preferably the Report Manager would need to know about the reason for discontinuation. However, this is not possible actually with the DICOM GP PPS transaction. It will be included later when this becomes possible.
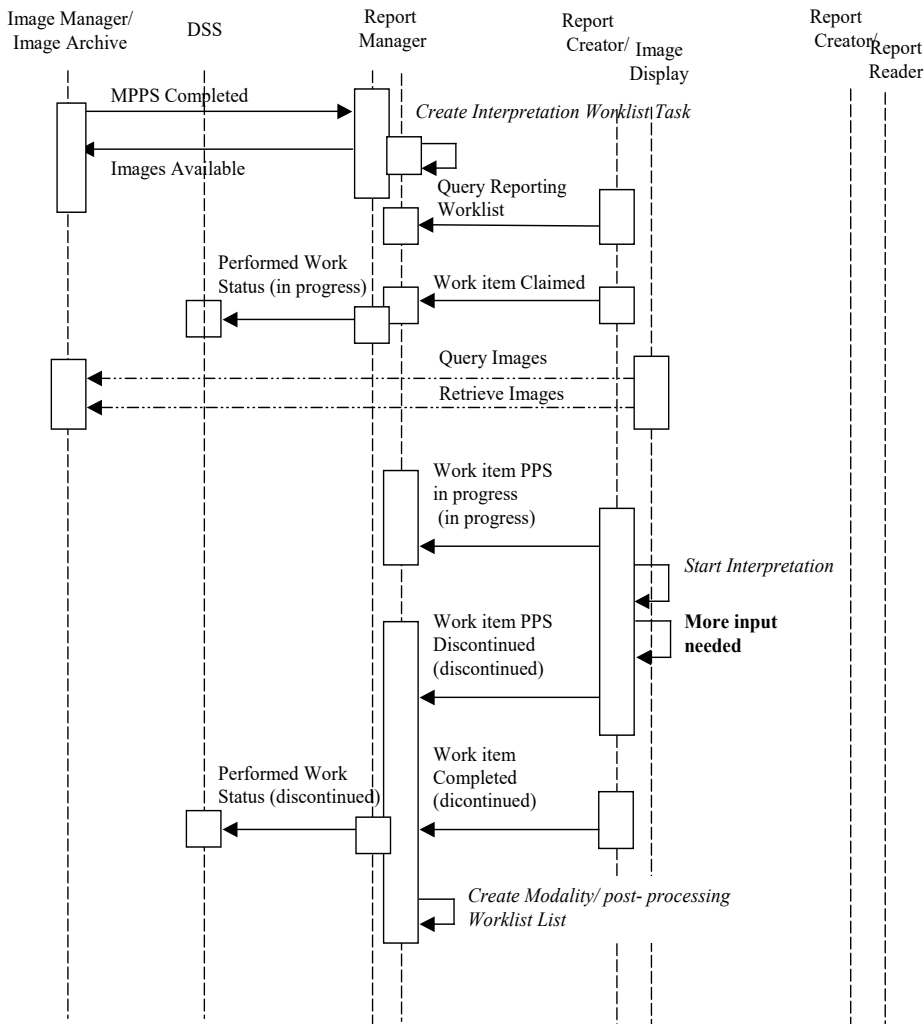
2745 **Figure 13.4-6 Use Case 6: Partial Completion**

13.4.7 Use case 7: Verification

The primary user is the verifying physician.

This use case can start when a non-verified report needs verification. Verification is a confirmation of the correctness of the report's content. It is NOT a legal signature. For DICOM
2750 SR instances, verification results in setting the Verification Flag value to "VERIFIED".

This use case finally results in:

- a Performed Procedure Step for Report Verification, having a corresponding code value in its Performed Workitem Code Sequence;

- an output results status message, referencing the verified report;

2755 - removing the workitem from the worklist, after the workitem status was set to completed.

The basic flow is illustrated in Figure 13.4-7.
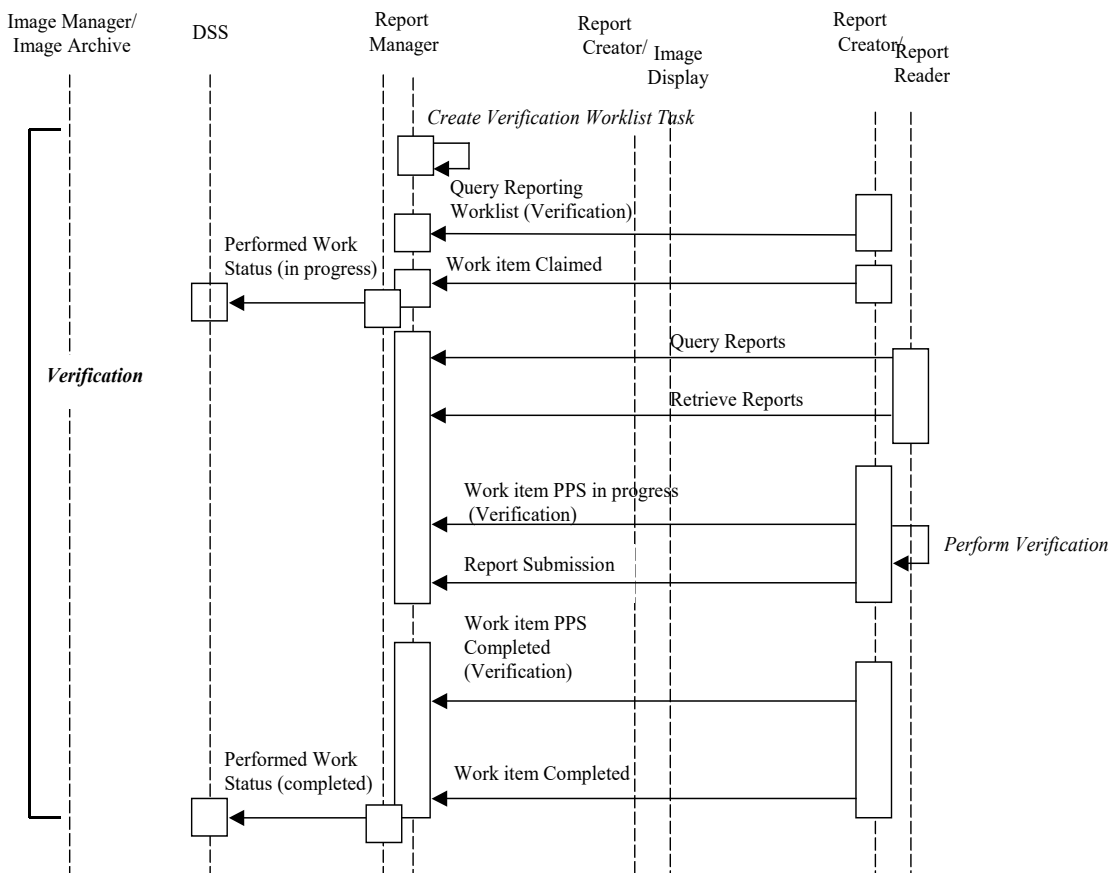
Figure 13.4-7 Use Case 7: Verification

2760 This use case has an extension when the user needs to correct the report's content by dictation. In this case the report is not verified, the output results reference the unverified report and the audio file, the Performed workitem code sequence includes Report Verification, and the suggested subsequent workitem set to Transcription.

13.4.8 Use case 8: Double reading

The primary user is the reading physician.

2765 This use case takes place when two report objects are needed for the same requested procedure.

The Report Manager generates two reporting workitems. Each workitem is processed separately according to use cases 1 to 7. Once both verified reports are generated, they are compared according to the comparison use case.

13.4.9 Use case 9: Comparison

2770 The primary user is the reading physician

This use case takes place when there are two verified reports for the same requested procedure to be compared.

At the end of this use case, the user finds the reports either similar or different. In the case of a disagreement, a discrepancy report is generated.

2775 The basic flow is illustrated in Figure 13.4-8. This flow assumes that the reports being compared have been submitted to the Report Manager.
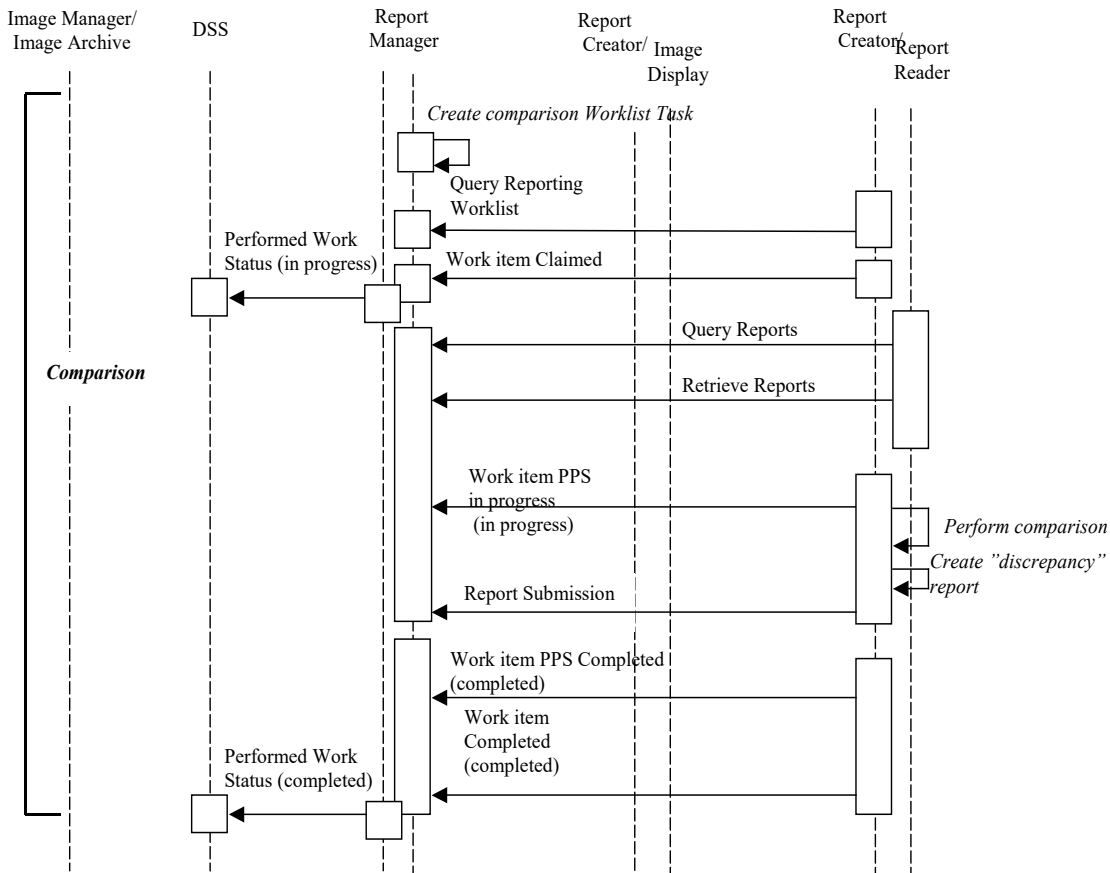
Figure 13.4-8 Use Case 9: Comparison

13.4.10   Use case 10: Review

2780   The primary user is the reading physician. This use case takes place when the user needs to review the report's content already verified by another physician. For example, this can happen when a physician returns from vacation and must review the work done on his behalf by a colleague. In this case, the Report Manager would schedule Review workitems either based on a request from the user, the administrator, or automatically based on department policy and the
2785   user being marked as "back".

Another scenario is in an "educational setting" where a 'student' is given a list of reports done by a more senior colleague to review with the purpose of learning from it.

13.4.11   Use case 11: Over Read

The primary user is the reading physician. This is often done for the purposes of quality
2790   assurance on the reading process.

In this use case the Report Manager generates two reporting workitems for the same requested procedure intended to be performed sequentially. The first verified report is used as input into second reporting workitem. Each workitem is processed separately according to use cases 1 to 7.

2795

At the end of this use case, the user performing the "over read" either agrees or disagrees with the original report's content. In the case of an agreement, an additional 'Verifying Observer Sequence' is added to the original report object. In the case of a disagreement, a discrepancy report is generated.

14 Evidence Documents (ED)

2800 The Evidence Documents Profile allows detailed non-image information, such as measurements, CAD results, procedure logs, etc. to be made available as input to the process of generating a diagnostic report either as additional evidence for the reporting physician or in some cases for selected items in the Evidence Document to be included in the diagnostic report.

The process of creating and using Evidence Documents can be managed by worklists that provide patient/ procedure details and by performed procedure steps that report status
2805 information (e.g., see Integration Profiles on Scheduled Workflow, Post-Processing Workflow, Reporting Workflow).

Evidence Documents represent one of the inputs to the reporting process described in the Reporting Workflow Profile and may provide details which get included in diagnostic reports described in the Simple Image & Numeric Reports Profile.

2810 It should be noted that while Key Image Notes meet the definition of Evidence Documents, they are a special case which is dealt with separately in the Key Image Notes Profile for historical reasons.

14.1 Actors/Transactions

Figure 14.1-1 shows the actors directly involved in the Evidence Documents Integration Profile
2815 and the relevant transactions between them. Other actors that may be indirectly involved due to their participation in Scheduled Workflow, etc. are not necessarily shown.
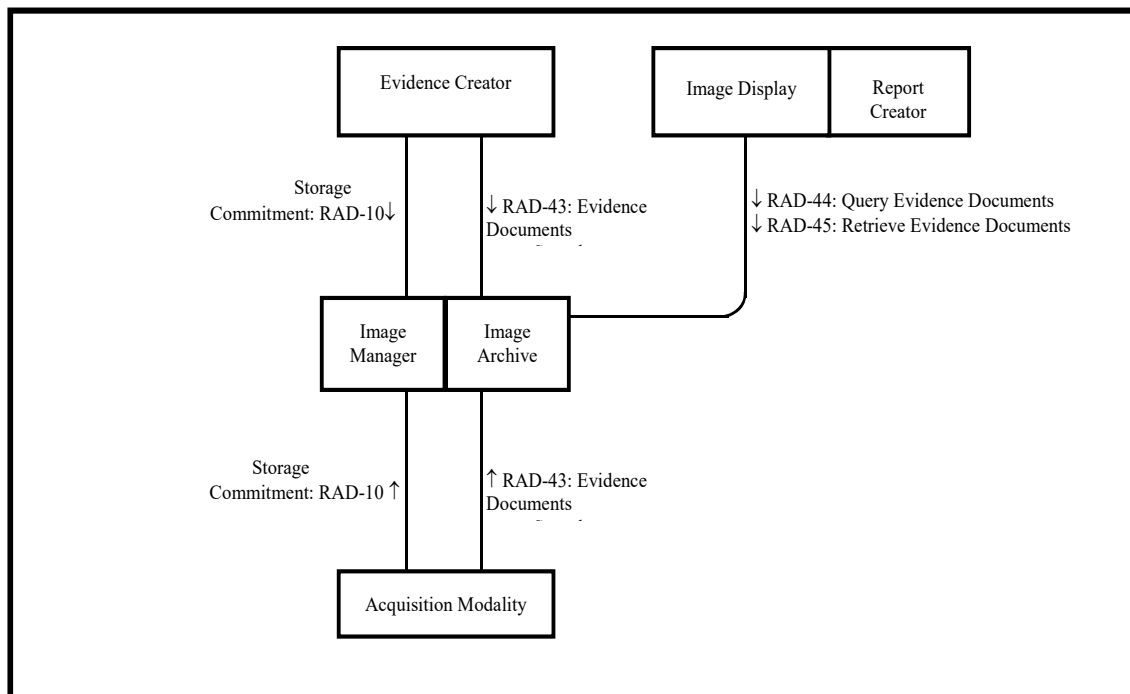
Figure 14.1-1: Evidence Documents Actor Diagram

2820 Table 14.1-1 lists the transactions for each actor directly involved in the Evidence Documents 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 and that implementations may choose to support is listed in Section 14.2.

Table 14.1-1: Evidence Document Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	TF Reference
Evidence Creator	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
	Evidence Documents Stored [RAD-43]	R	RAD TF-2: 4.43
Acquisition Modality	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
	Evidence Documents Stored [RAD-43]	R	RAD TF-2: 4.43
Image Manager/ Image Archive	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
	Evidence Documents Stored [RAD-43]	R	RAD TF-2: 4.43
	Query Evidence Documents [RAD-44]	R	RAD TF-2: 4.44
	Retrieve Evidence Documents [RAD-45]	R	RAD TF-2: 4.45
Image Display (Report Creator)	Query Evidence Documents [RAD-44]	R	RAD TF-2: 4.44
	Retrieve Evidence Documents [RAD-45]	R	RAD TF-2: 4.45

2825 Note: Refer to Table 2-1 for other profiles that may be pre-requisites for this profile.

If a Report Creator wishes to participate in this profile, it does not have to support any transactions directly, however it is required to be grouped with an Image Display in order to be able to Query/Retrieve the Evidence documents, and the Report Creator is expected to be able to transfer some contents of the retrieved document into the report it creates.

2830 14.2 Evidence Documents Integration Profile Options

Options that may be selected for this integration profile are listed in the Table 14.2-1 along with the actors to which they apply. Dependencies between options when applicable are specified in notes.

Table 14.2-1: Evidence Documents - Actors and Options

Actor	Options	TF Reference
Evidence Creator	*No options defined*	- -
Acquisition Modality	*No options defined*	- -
Image Manager/ Image Archive	*No options defined*	- -
	No options defined	- -
Image Display (Report Creator)	*No options defined*	- -
	No options defined	- -

2835

The Evidence Creator, Acquisition Modality and Image Manager/ Image Archive will likely support a variety of DICOM SOP Classes. Each DICOM SOP Class that is supported by the actor shall be listed in the product's DICOM Conformance Statement. The IHE Integration Statement (see RAD TF-1x: Appendix D) shall reference the DICOM Conformance Statement but does not repeat the list of DICOM SOP Classes that are considered to contain Evidence Documents. Examples of DICOM SOP Classes that may contain evidence are listed in RAD TF-2: 4.43, Table 4.43-1 and Table 4.43-2.

14.3 Evidence Document Process Flow

Evidence Documents belong to the family of Evidence Objects that also includes Images, Presentation States, and Key Image Notes. These are objects generated as a result of performing procedure steps on systems in a clinical department.

The start and completion of creating Evidence Documents is reported in the Scheduled Workflow Profile by the Evidence Creator using Creator Procedure Step In-Progress/Completed transactions, or by the Acquisition Modality using the Modality Procedure Step In-Progress/Completed; and in the Post-Processing Workflow by the Evidence Creator using the Workitem Procedure Step In-Progress/Completed transactions.

As with other Evidence Objects, Evidence Documents are usually created by the system operator, and used by the reading physician in the process of creating a Diagnostic Report, either by reviewing or interpreting the Evidence Document contents, or by copying selected parts into the Report. Evidence Documents represent the uninterpreted information that is primarily managed and used inside an imaging department, although distribution outside the imaging department is not precluded. In contrast, the diagnostic reports described in the Simple Image and Numeric Reports Profile represent the interpreted information which is the primary output of the imaging department and are available for wide distribution.

Due to the difference between the way the Evidence Creator reports status in the Scheduled Workflow Profile (using a Creator Procedure Step transaction to the Performed Procedure Step Manager) and the way the Evidence Creator reports status in the Post-Processing Workflow Profile (using a Workitem PPS transaction to the Post-Processing Workflow Manager), two examples of the process flow will be shown below.

The scheduling part of the workflow that would typically precede the part of the workflow in the following diagram can be seen in RAD TF-1: Figure 3.2-1 (Administrative Process Flow) in the Scheduled Workflow Profile.
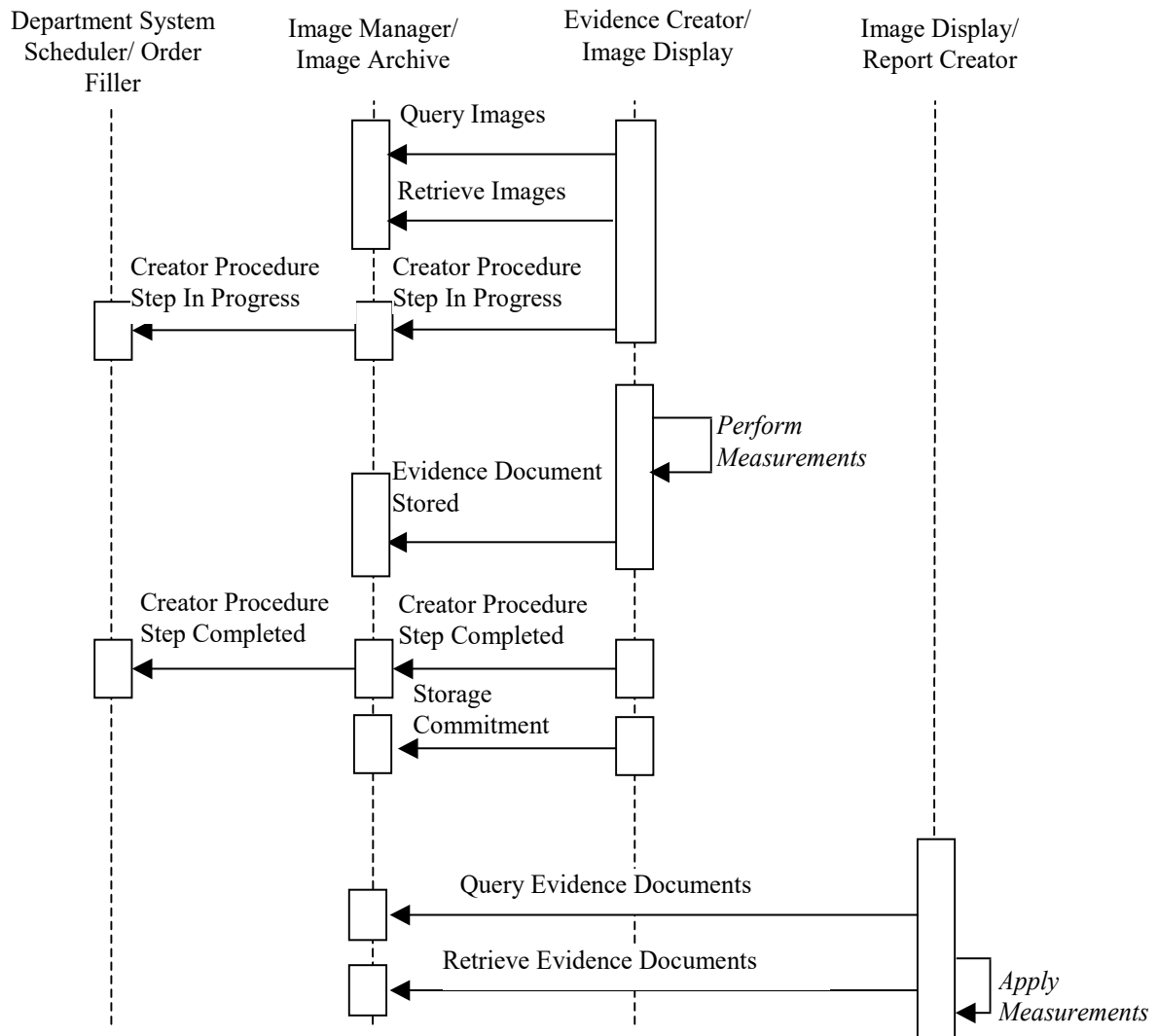
Figure 14.3-1: Evidence Document Management In Scheduled Workflow

2870   Note that the Procedure Step transactions and the Query/ Retrieve Images transactions in the above diagram are not part of the Evidence Documents Profile.

The scheduling part of the workflow that would typically precede the part of the workflow in the following diagram can be seen in RAD TF-1: Figure 12.3-1. (Post-Processing Manager Grouped with Department System Scheduler) in the Post-Processing Workflow Profile.
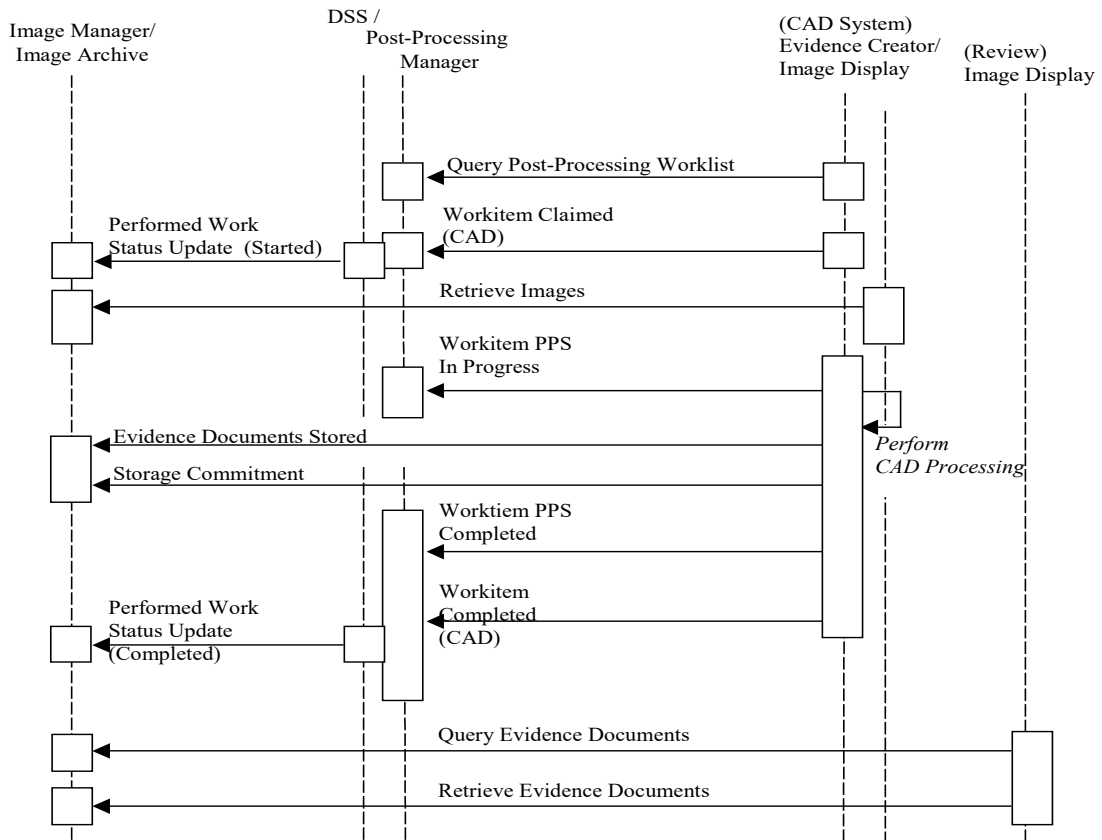
2875

Figure 14.3-2: Evidence Document Management In Post-Processing Workflow

Note that the Worklist and Workitem transactions in the above diagram are not part of the Evidence Documents Profile.

15 Portable Data for Imaging Integration Profile (PDI)

2880 The **Portable Data for Imaging Integration Profile** specifies actors and transactions that provide for the interchange of imaging-related information on interchange media. The intent of this profile is to provide reliable interchange of image data and diagnostic reports for import, display or print by a receiving actor.

This profile addresses identification of the media content's source and the patient (where 2885 appropriate), reconciliation of data during import, and the structure of the media contents.

The central elements of the profile are:

- Reliable interchange of imaging-related information based on the DICOM standard

- A Web Content Option which provides guidelines for including web-viewable content on media. The Web Content Option addresses the case of media containing both DICOM-2890 encoded objects and objects in XHTML or JPEG derived from these DICOM-encoded objects.

- A Basic Viewer Option, which requires that there be at least one viewer present on the media that implements the Basic Image Review (BIR) Profile.

- DVD and USB Media Options

2895   15.1 Actors/ Transactions

Figure 15.1-1 diagrams the actors directly involved in this profile and the transactions between actors.
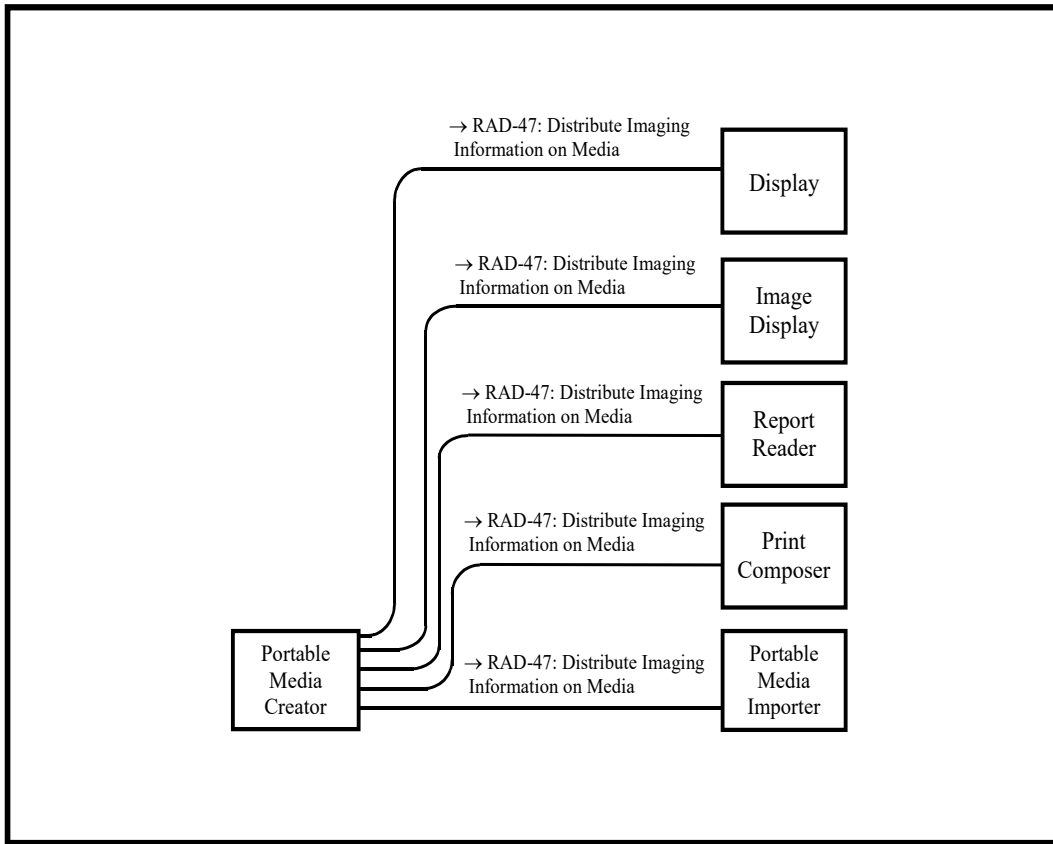
Figure 15.1-1: Portable Data for Imaging Diagram

2900 Table 15.1-1 lists the transactions for each actor directly involved in the Portable Data for Imaging Profile. In order to claim support of this integration profile, an implementation shall perform the required transactions (labeled "R"). Transactions labeled "O" are optional. A complete list of options defined by this integration profile is listed in Section 15.2. Note that one of a number of actors must be grouped with Portable Media Importer as described in RAD TF-1:
2905 2.5.

Table 15.1-1: Portable Data for Imaging Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	TF Reference
Portable Media Creator	Distribute Imaging Information on Media [RAD-47]	R	RAD TF-2: 4.47
Portable Media Importer	Distribute Imaging Information on Media [RAD-47]	R	RAD TF-2: 4.47
Image Display	Distribute Imaging Information on Media [RAD-47]	R	RAD TF-2: 4.47
Report Reader	Distribute Imaging Information on Media [RAD-47]	R	RAD TF-2: 4.47
Print Composer	Distribute Imaging Information on Media [RAD-47]	R	RAD TF-2: 4.47

Actors	Transactions	Optionality	TF Reference
Display (ITI TF)	Distribute Imaging Information on Media [RAD-47]	R	RAD TF-2: 4.47

15.2 Portable Data for Imaging Integration Profile Options

Options that may be selected for this integration profile are listed in Table 15.2-1 along with the actors to which they apply. Dependencies between options when applicable are specified in notes.

2910

Table 15.2-1: Portable Data for Imaging - Actors and Options

Actor	Options	TF Reference
Portable Media Creator	Web Content	RAD TF-1: 15.4.2 RAD TF-2: 4.47.4.1.2
	Basic Viewer	RAD TF-1: 15.5 RAD TF-2: 4.47.4.1.2.2.3.1 RAD TF-2: 4.47.4.1.2.2.4
	DVD Media	RAD TF-1: 15.4.4 RAD TF-2: 4.47.4.1.4.1
	USB Media	RAD TF-1: 15.4.4 RAD TF-2: 4.47.4.1.4.2
Portable Media Importer	DVD Media	RAD TF-1: 15.4.4 RAD TF-2: 4.47.4.1.4.1
	USB Media	RAD TF-1: 15.4.4 RAD TF-2: 4.47.4.1.4.2
Image Display	DVD Media	RAD TF-1: 15.4.4 RAD TF-2: 4.47.4.1.4.1
	USB Media	RAD TF-1: 15.4.4 RAD TF-2: 4.47.4.1.4.2
Report Reader	DVD Media	RAD TF-1: 15.4.4 RAD TF-2: 4.47.4.1.4.1
	USB Media	RAD TF-1: 15.4.4 RAD TF-2: 4.47.4.1.4.2
Print Composer	DVD Media	RAD TF-1: 15.4.4 RAD TF-2: 4.47.4.1.4.1
	USB Media	RAD TF-1: 15.4.4 RAD TF-2: 4.47.4.1.4.2
Display	*No options defined*	-

15.3 Portable Data for Imaging Process Flow

This section describes the typical process flow related to the use of Interchange Media. The transaction covered is Distribute Imaging Information on Media [RAD-47].

2915 The following steps can be identified in this process flow:

- The source actor (Portable Media Creator) writes a group of image dataset(s) and/or the associated diagnostic report(s) onto a piece of interchange media. It is presumed that the Portable Media Creator has access to the data from a grouped actor, or another source outside the scope of IHE.

2920
- The media is physically transported to a destination where the imaging-related information contained on the media will be used.

2925
- The Portable Media Importer reads DICOM objects (images, presentation states, key image notes, evidence documents and reports) on the media and imports them into the local information space. The Portable Media Importer reconciles the data as needed (e.g., to change the recorded Patient ID to the local Patient ID). If some classes of DICOM objects are present on the media and cannot be imported, the Portable Media Importer notifies the operator of the studies and series affected and makes clear that they are not supported by the importing application.

2930
- The Image Display (which may be included on the media by a Portable Media Creator), Report Reader, Display or Print Composer reads the objects it supports and renders them depending on the receiver's needs.

The potential usage scenarios of the data are described in the use cases below.

15.3.1 Use Cases

2935
This profile is not intended to provide an archival solution. The matter of whether or not CD, DVD or USB media are suitably robust for long-term archive is not addressed by IHE.

Use Case 1 - Patient/Referring Physician Viewing: Diagnostic and therapeutic imaging data, such as images and reports, is received on media potentially serving multiple use cases. The patient or the referring physician can view the data, either with a viewer application residing on the same media, or previously installed on their own equipment (either of which may be an Image Display implementing the Basic Image Review Profile), or using a web browser. For security and privacy reasons, media given to a patient would not contain data of other patients. Refer to Section 15.5 for additional security considerations.

2940

Use Case 2 - Healthcare Enterprise Interchange: One or more patients' data, such as images, reports or complete studies, is received on media to enable a diagnostic or therapeutic care process. Media data are imported at a different site, generally for the purpose of a "second read import" or "reference import".

2945

2950
- Second Read Import: Media data is imported to the Image Manager/Archive to be read/over read. In order to avoid data conflicts, key patient/study attributes may need to be reconciled with existing local data. Images and related presentation states can be sent to a Print Composer to be printed.

- Reference Import: Media data is imported to the Image Manager/Archive and/or Report Repository to become part of the patient history. It may be used as "relevant prior" data for future reads. In order to avoid data conflicts, key patient/study attributes may need to be reconciled with existing local data.

2955   **Use Case 3 - Operating Room Viewing:** Media data is used to enable diagnostic or therapeutic processes in environments without a reliable network connection. The volume of data can be very large and may contain image data, post-processing results and reports. In the operating room, the surgical staff receives the media and reads its contents using advanced viewing capabilities, which may include manipulating or processing images.

2960   ## 15.3.2 Process Flow Description

The use cases can be specified in terms of three media-related activities:

- Media Export
- Media Viewing
- Media Import

2965   **A) Media Export (All Use Cases):**

The Portable Media Creator assembles the media content (DICOM and optionally web-viewable content) and writes it to the physical medium.

The following sequence of activities will be performed during media creation:

- Export of DICOM data (FSC activity).

2970   - Optionally, export of web-viewable data, which involves deriving easily accessible informative data from the DICOM data (Web Content Option).

- Optionally, inclusion of one or more viewers, one or more of which may conform to the Basic Image Review Profile (Basic Viewer Option).

- Optionally, inclusion of additional content.

2975   **B) Media Viewing:**

B1) Web (Use Case 1) (care providers, other users and patients without DICOM viewing equipment or software or media created with the Basic Viewer Option):

Any web-viewable media content is received and displayed by a Display, which exists as a generally available resource (i.e., web browser). Note that the Portable Media Creator
2980   cannot rely on the presence of web-viewable content on all media since it will be included only on media created using the Web Content Option).

B2) DICOM (Use Case 1 and 3) (users with DICOM viewing equipment or software):

The DICOM portion of the media content is displayed using specialized applications pre-existing in the reading environment or included on the media itself. The variety of
2985   DICOM objects that an Image Display and/or Report Reader can process is indicated by its support of the corresponding content profiles. The Print Composer sends images from the media to a Print Server for printing.

C) Media Import (Use Case 2):

The "Media Import" activity is accomplished by a Portable Media Importer and deals exclusively with the DICOM portion of the media content. The Portable Media Importer is grouped with one or more content actors (Evidence Creator, Report Creator, etc.), depending on the type of media content to be imported. The grouped actor provides storage capability for the media data accessed by the Portable Media Importer.

The Portable Media Importer accesses all DICOM instances referenced by the DICOMDIR file and enables the user to select a media patient dataset to be imported.

- The Portable Media Importer obtains local data that is known to be accurate within the importing institution/enterprise and reconciles "key attributes" of patient and study information (when required). A method for performing these steps is documented in the Import Reconciliation Workflow Profile (see Section 21). Refer to RAD TF-2: 4.47.4.1.3 for the list of "key attributes" and the related reconciliation actions to be performed.

  Note: The Portable Media Importer may for example be grouped with an Evidence Creator to allow the storage of its diagnostic and therapeutic imaging content to an Image Manager/Image Archive, or grouped with a Report Creator to store reports on a Report Repository. This enables use of the content for subsequent "relevant prior" data for future reads. A grouping with an Acquisition Modality could also be used to allow subsequent "reads/over reads". In the case of a Portable Media Importer grouped with the Print Composer, the imported content (images and presentation states) can be sent to the Print Server to be printed.

Figure 15.3.2-1 shows an example flow of events covering the use cases described in the previous sections.
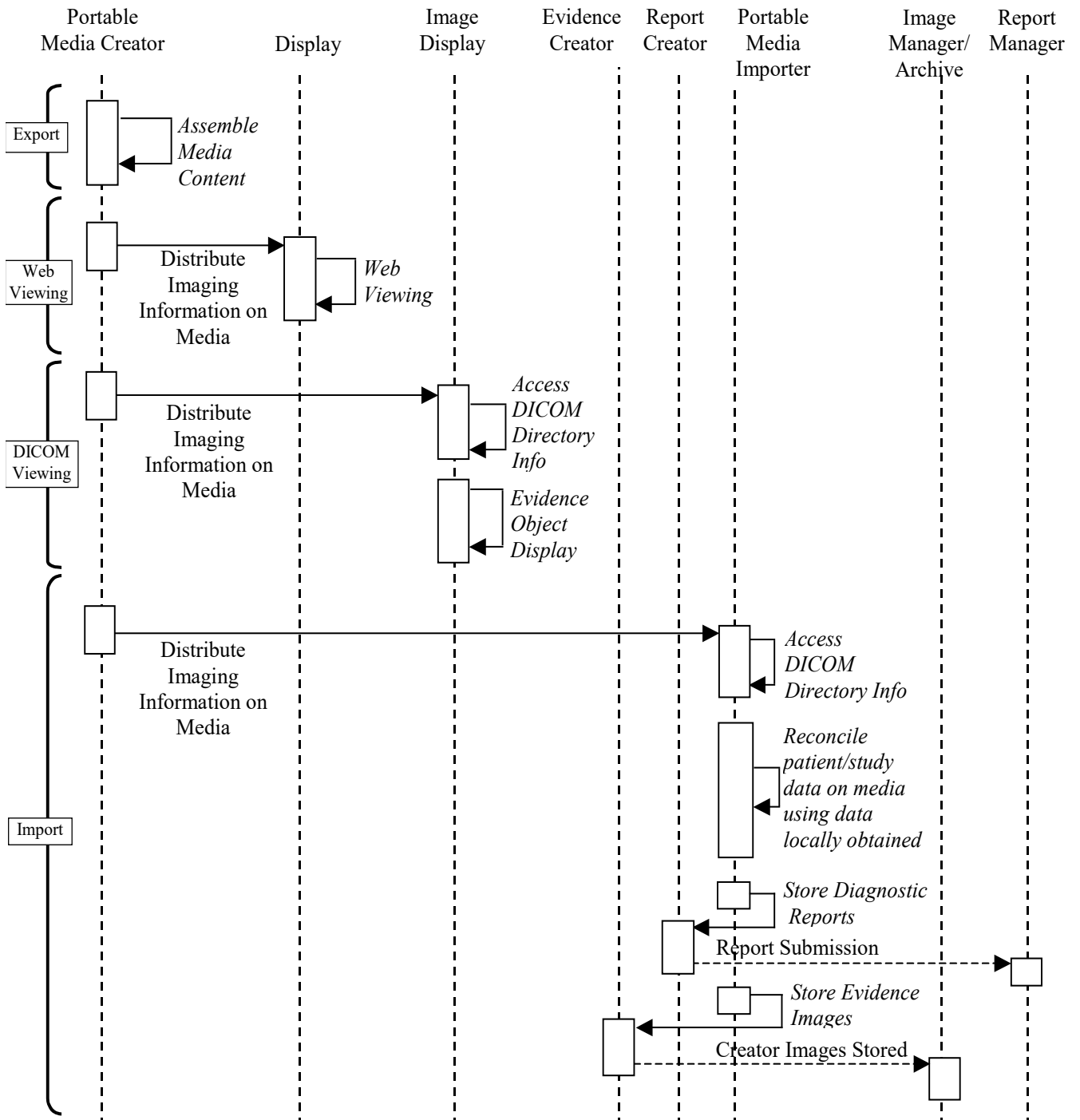
3010

Figure 15.3.2-1: Portable Data for Imaging Process Flow

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15.4 Media Content

3015 The requirements on media content are intended to promote the reliable transfer of imaging data, including diagnostic reports, and to allow for the viewing of images and reports on general purpose computers.

The intent is that the media content be a "complete set of images of diagnostic quality" (a quote from a statement on the matter by the American Medical Association Expert Panel on Medical Imaging).

3020 The media content can be accessed via two "entry points" on the media: the DICOMDIR file for DICOM imaging information and optionally the INDEX.HTM file for web-viewable content. Created media are required to contain DICOM data and may optionally include web-viewable data derived from it. This web-viewable data, if present, shall faithfully preserve the clinical intent of the original DICOM information.

15.4.1 DICOM Content

3025 The DICOM data shall be created by using the DICOM Media Storage Application Profile appropriate for the content as defined in the Distribute Imaging Information on Media transaction and depending on the Options supported by the Portable Media Creator. The DICOMDIR file shall reference all DICOM files stored on the media.

3030 DICOM files shall not be placed in the root directory, but no constraints are placed on the name of directory that contains them.

15.4.2 Web Content Option

Portable Media Creators implementing the Web Content Option may also include web-viewable data on the media.

3035 The web-viewable data shall be derived from the DICOM information as XHTML files and referenced JPEG images. The XHTML entry page (INDEX.HTM) shall allow access to all of this data. This enables end-users to access relevant media content using a generally available web browser. The INDEX.HTM file shall be placed in the root directory.

3040 Note that the web-viewable data specified in this integration profile reflects the full set of the exported DICOM data or a subset considered at the time of creation to faithfully represent the patient's clinical condition. For example, if a DICOM Structured Report references only Key Images and a larger DICOM dataset, the web-viewable data derived from it may selectively include the report in XHTML format and only JPEG images derived from the DICOM Key Images.

15.4.3 Other Content

3045 Viewing applications (for example a DICOM Media Viewer) may optionally be included on the media. Such viewers may conform to the Basic Image Review (BIR) Profile (Basic Viewer Option). Such viewers may have launch links included in the HTML.

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3050 Additional data (e.g., a diagnostic report in non-DICOM format) may be also included on the media. Since the format of any such data is not specified by this profile, such data shall be placed in a separate directory on the media. If such data is referenced in the INDEX.HTM file, it shall be clearly indicated that this content was not generated in conformance with the IHE Radiology Technical Framework, and its reliable import has not been addressed.

15.4.4 Media Type (CD, DVD and USB)

3055 The baseline media type is CD with uncompressed images.

DVD Media Option and USB Media Option are defined for support of compressed images (using JPEG lossy and lossless and JPEG 2000 reversible and irreversible) on DVD and USB media respectively.

3060 Compressed images on CD, such as are commonly used for cardiac angiography and for cine ultrasound, are supported through the use of the DVD Media Option, which allows for CD as a media type that can be read by DVD drives.

15.5 Basic Viewer Option

A Portable Media Creator that claims the Basic Viewer Option shall be able to include a viewer on the media. That viewer shall support the display requirements of the Retrieve Images [RAD-16] of the Basic Image Review Profile as an Image Display. The viewer is not required to support the Query Images [RAD-14] transaction.

3065

Additional requirements beyond the Basic Image Review Profile are required by the Basic Viewer Option. They are appropriate for the Physician Viewing use case in Section 15.3.1, particularly when the receiving user has no pre-existing relationship with the sender, is unfamiliar with any viewer included on the media, has no pre-installed local Image Display, and has little control over a relatively basic hardware and software environment. The requirements for the support of SOP Instances on the Media are specified in Rad TF-2: 4.16.4.1.3.3.1.1.

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15.5.1 Platform Hardware and Software Requirements

The Basic Viewer Option requires that the Image Display included on the media works under normal user privileges and does not require software installation. Specifically, the Image Display application shall be executable from the PDI media on a system equipped with the following minimum characteristics:

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- graphics hardware and a single monitor of 1024x768 resolution in 24 bit RGB color

- a mouse or other pointing device with a single button

3080 - a drive that supports reading media on which the viewer is provided

- a consumer-grade printer

- without requiring installation of, or permission to install, applications, frameworks (such as Java or .NET), libraries (such as DLLs or ActiveX controls), device or graphics drivers or software other than those shipped with the basic operating system

159

3085   • without requiring the presence of a network connection (for download of software,
        licensing or registration or exchange of any other information whether via the Internet or
        local area network)

These requirements are not intended to discourage the presence of applications that support
multiple platforms, either in a single application or through the presence of multiple applications.
3090   Nor are they intended to endorse the suitability of any hardware or software platform for this
purpose, only to recognize what is realistic to maximize the probability that a user will be able to
use the viewer on the media.

If a pre-installed framework is present, the application may use it to improve performance.

Similarly, accelerated graphics performance, more memory and more processors or cores can be
3095   used if available, but the application is required to be able to work without them.

The application is required to take advantage of the size of the primary monitor; i.e., if the
display is larger than the minimum 1024x768 requirement, then the large size should be used,
rather than displaying a fixed 1024x768 size window.

The application shall tolerate the presence of multiple monitors of different resolutions, though it
3100   is not required to be able to make use of multiple monitors.

It is recommended, though not required, that the application be usable with both portrait and
landscape monitors in addition to both grayscale and color monitors.

The option does not require that the application provides a means of calibration (to the DICOM
GSDF as required in the CPI Profile), but does not preclude providing such a capability from
3105   within the application, or providing, or taking advantage of, an external means of calibration.

The option requires the application to support single-button pointing devices, but does not
preclude it from taking advantage of multiple buttons, if present, including a middle scroll wheel.
If a middle scroll wheel is present, then it is required to be supported by the application at least
for the purpose of scrolling between multiple slices of cross-sectional images.

3110   The ability to display reports present on the media shall not depend on any additional pre-
installed software beyond any capabilities present in the operating system requirements (such as
a PDF viewer or specific fonts).

15.5.2 Security and Persistence Requirements

The Basic Viewer Option does not require that the Image Display included on the media support
3115   the IHE ITI ATNA Profile, but it is not precluded from doing so.

The Basic Viewer Option requires that the Image Display automatically launches if permitted by
the operating system, site configuration, and not disabled by the user.

If the Web Content Option is also supported, then the INDEX.HTM file shall contain a link that
executes the viewer (see RAD TF-2: 4.47.4.1.2.2.2).

3120   The Basic Viewer Option requires that the on-board Image Display application shall execute all the required functions without requiring write access to local persistent storage (e.g., the C: drive), but it is not precluded from using the local store if accessible.

15.5.3 Disclaimer Limitations

The Basic Viewer Option requires that the Image Display application shall not present the user
3125   with a disclaimer, notice, or any other form of display (whether on the screen, physical media or packaging) to the effect that either:

- the images on the media are not for diagnostic or clinical use, or

- that the application itself is not for diagnostic or clinical use.

Nor shall the application require that the user agree to any such conditions before proceeding to
3130   use the application.

It is however permitted to present a disclaimer that the provider of the media and the application on the media have no control over the display hardware or state of display calibration or any other aspect of the viewing environment, and that this alone may affect the suitability of the displayed images for diagnostic use.

3135   This requirement is present because the ordering physicians or radiologists who receive the media may indeed be making decisions about the patient's management, that this constitutes clinical or diagnostic use even though it may not be the intent to perform the primary radiological interpretation, and that it is inappropriate and unsafe to provide either degraded images or an application that degrades them for display.

3140   It is recommended, though not required, that the application also not irritate the user with notices with respect to whether or not the user has the patient's permission to view the images, nor require that the user agree to any terms or conditions or license as a pre-requisite for viewing the patient's images.

The suitability of any viewer that complies with the Basic Image Review Profile for clinical or
3145   diagnostic use may be subject to local regulation or policy, which is beyond the scope of IHE to define.

15.5.4 Usability Requirements

The application shall automatically run when the media is inserted unless the configuration of the machine has been specifically set up to prevent it (or the user holds the SHIFT key down when
3150   inserting the media). I.e., there shall be an AUTORUN.INF file present in the root directory that executes the viewer.

The Basic Viewer Option requires that it shall be possible to manually start the Image Display application by clicking on a file in the root directory named VIEWER.BAT or VIEWER.EXE.

If the media contains multiple viewers, the initially launched application shall allow the user to
3155   select which viewer to use.

When the application starts:

- it shall provide the user with the option of immediately terminating (e.g., to allow a pre-installed already executing viewer to be used instead)

3160

- it shall provide immediate feedback to the user when it is invoked, e.g., through a dialog box or splash screen or appropriate cursor change when they double-click the application icon

- it shall terminate with a clear and unambiguous error message to the user if the hardware or software requirements of the platform are insufficient to execute

3165

- it shall provide a display or listing of the media contents (patients, studies and series) to the user automatically, without requiring any further user-initiated action, since the goal is to be able to view the contents of the media (not images from other sources)

Only one instance of the application shall be executing at any one time, and the application shall be robust in the face of attempts by the user to execute multiple copies (e.g., if they double-click the application icon multiple times in frustration whilst waiting for the first invocation to actually

3170 run).

The user shall have the ability to close the application using the ordinary window decoration icon for this purpose, typically an iconic "X" in the top right of the window.

The application shall be "closable" even if the media has been physically removed.

The viewer may close if the media is physically removed. If the viewer does not terminate, there

3175 is no requirement that the contents of new media that is inserted be read.

Closing and reopening additional studies on the media is addressed in the Basic Image Review Profile requirements, which require the user to be able to select any series from any study for display and to change what is selected.

For all activities that take more than five seconds to complete, including startup and reading of

3180 images from the media, some indication of the relative progress towards completion is required.

A manual for the use of the viewer in PDF form shall be accessible on the media in the root directory and named "VIEWER.PDF", though there is no requirement that a PDF reader be supplied and it is not included in the minimum platform requirements.

15.6 PDI Cross Profile Considerations

3185 **15.6.1 ITI Cross-Enterprise Document Media Interchange (XDM)**

A Portable Media Creator in PDI might be grouped with a Portable Media Creator in the XDM Profile (ITI TF-1: 16) to enable it to include DICOM instances on the same media as XDM content (see RAD TF-2: 4.47.4.1.2.2.3). To link the DICOM instances with the XDM metadata, a KOS instance should be used. This instance can be e.g., provided by an existing XDS-I

3190 infrastructure.

A Portable Media Importer in PDI might be grouped with a Portable Media Importer in the XDM Profile to process the combined PDI / XDM media, e.g., for the use in an XDS-I infrastructure (see RAD TF-2: 4.47.4.1.3.4).

15.7 Security and Privacy Aspects

3195 Portable Media Creator Actors shall make a reasonable effort to ensure that no malicious software (viruses, etc.) is present on created media.

The automatic launch of applications from media poses a risk that malicious software could be started. Despite these risks, many recipients prefer the convenience of auto-run. It is the site's or operating system's responsibility to suppress auto-run if required

3200 Furthermore, if a DICOM media viewer is present, security issues at the receiving actor are minimized by:

- working under normal (restricted) user privileges and not requiring the user to work with administrator or root privileges and

- not needing software installed on the computer where the media is used.

3205 Audit trails to track export/import/viewing activities are addressed in the Record Audit Event [ITI-20] (ITI TF-2: 3.20) and in RAD TF-3: 5.1. Portable Media Creator and media reading actors that claim support of the Audit Trail and Node Authentication Integration Profile shall generate such audit trail events.

Encryption of data and other access controls to media content are not addressed in this profile.
3210 Media created using this profile should be considered to be unlocked information (e.g., like paper records). Such media should be handled according to appropriate site policies (e.g., do not give a patient a disk containing data from other patients, do not leave disks where they can be taken by unauthorized persons, etc.).

For many Use Cases it is not appropriate to place data from multiple patients on a single volume
3215 of media for security and privacy reasons.

It is not good practice to include on media, either in the physical label, in the DICOMDIR or DICOM instances, the Web Content or any other content, such sensitive information as the patient's address, telephone number or national identifier (such as a US Social Security Number), which might be used for unauthorized purposes such as identity theft or fraud. Though
3220 it is not a requirement of this profile to require the Portable Media Creator to remove any such information from any DICOM instances received prior to encoding on media, it is strongly recommended.

16 NM Image Integration Profile

3225 The NM Image Profile specifies how NM Images are to be stored by Acquisition Modalities and Evidence Creator workstations and how Image Displays should retrieve and make use of them.

It defines the basic display capabilities Image Displays are expected to provide, (such as might be sufficient for a referring physician) but does not address advanced review features.

The profile defines how result screens, both static and dynamic, such as those created by NM
3230 Cardiac Processing Packages, should be stored using DICOM objects that can be displayed on general purpose Image Display systems.

The profile does not address advanced processing functions typically found on dedicated NM workstations.

The NM Image Profile can be enhanced by combining it with workflow profiles such as
3235 Scheduled Workflow, Post-Processing Workflow and Reporting Workflow which address how to schedule, manage and report the status of the steps in which NM Image objects are created.

16.1 Actors/ Transactions

Figure 16.1-1 shows the actors directly involved in the NM Image Integration Profile and the relevant transactions between them. Other actors that may be indirectly involved due to their
3240 participation in the Scheduled Workflow Profile, the Post-Processing Workflow Profile, etc. are not necessarily shown.
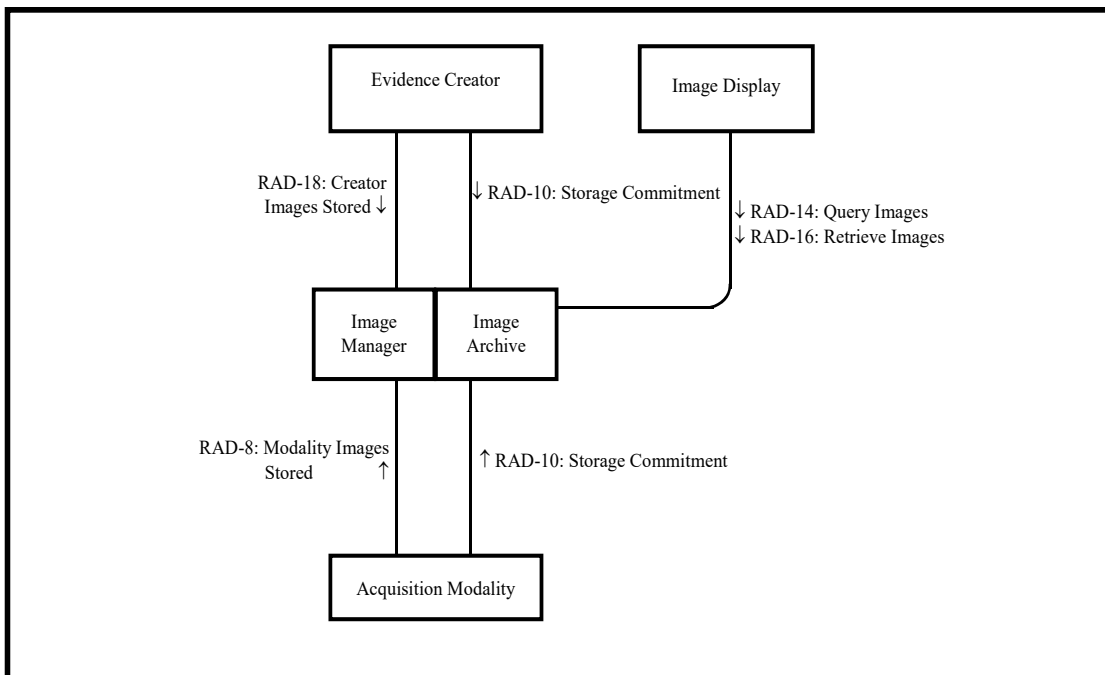
Figure 16.1-1: NM Image Actor Diagram

3245 Table 16.1-1 lists the transactions for each actor directly involved in the NM Image 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 named options defined by this integration profile and that implementations may choose to support is listed below in Section 16.2.

Table 16.1-1: NM Image Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	TF Reference
Acquisition Modality	Modality Images Stored [RAD-8]	R	RAD TF-2: 4.8
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
Evidence Creator	Creator Images Stored [RAD-18]	R	RAD TF-2: 4.18
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
Image Manager/Archive	Modality Images Stored [RAD-8]	R	RAD TF-2: 4.8
	Creator Images Stored [RAD-18]	R	RAD TF-2: 4.18
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
	Query Images [RAD-14]	R	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	R	RAD TF-2: 4.16
Image Display	Query Images [RAD-14]	R	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	R	RAD TF-2: 4.16

3250

To participate as an evidence creator in Nuclear Medicine, the system must create derivative data from original NM modality image data. Examples of such derivative data include:

a) Reconstruction, reorientation, filtering, or other processing of NM data, with output of NM modality image objects.

3255 b) Quantization of NM data, with the display and storage of result screens as SC or MFSC image objects.

c) Registration between an NM data set and another data set.

For all NM modality objects created, the evidence creator must meet the requirements of an acquisition modality with respect to encoding, storage, and inclusion of required DICOM tags, as 3260 noted in RAD TF-2: 4.8.4.1.2.2.

If the system creates SC or MFSC objects, the evidence creator is encouraged to support the Result Screen Export Option, and conform to the requirements of this option for any stored result screens.

16.2 NM Image Integration Profile Options

3265 Options that may be selected for this integration profile are listed in the Table 16.2-1 along with the actors to which they apply. Dependencies between options when applicable are specified in notes.

Table 16.2-1: NM Image - Actors and Options

Actor	Options	TF Reference
Acquisition Modality	*No options defined*	--
Evidence Creator	Result Screen Export Cardiac NM Presentation State Cardiac NM Presentation State	RAD TF-1: 16.2.3 RAD TF-1: 16.2.5
Image Manager / Image Archive	Result Screen Export Cardiac NM Presentation State	RAD TF-1: 16.2.3 RAD TF-1: 16.2.5
Image Display	MPR General NM (Note 1) Cardiac NM (Note 1) Result Screen Export Cardiac NM Presentation State	RAD TF-1: 16.2.4 RAD TF-1: 16.2.2 RAD TF-1: 16.2.1 RAD TF-1: 16.2.3 RAD TF-1: 16.2.5

Note 1: Image Display actors shall support the General NM Option, the Cardiac NM Option or both.

16.2.1 Cardiac NM Option

This option involves the Image Display presenting nuclear medicine cardiac images in a standardized layout based on the American College of Cardiology (ACC) NM Cardiac Display for stress and rest tomographic myocardial perfusion.

See RAD TF-2: 4.16.4.2.2.3.7 for normative requirements.

16.2.2 General NM Option

This option involves the Image Display presenting whole body imaging and other non-cardiac NM interpretations, such as oncology, neurology, or bone imaging.

See RAD TF-2: 4.16.4.2.2.3.6 for normative requirements.

16.2.3 Result Screen Export Option

This option involves the Evidence Creator storing the Result Screen of a clinical analysis (which may include static or dynamic images, graphics or text) for display by the Image Display.

See RAD TF-2: 4.18.4.1.2.4 for normative requirements on the Evidence Creator for encoding Result Screens.

See RAD TF-2: 4.16.4.2.2.4 for normative requirements on the Image Display for displaying Result Screens.

The Image Manager/Image Archive shall support storage and retrieval of the DICOM Secondary Capture and Multiframe Secondary Capture SOP Classes.

16.2.4 MPR Option

This option involves the Image Display supporting the General NM Option to provide multi-planar reconstruction (MPR) functionality to reconstruct non-cardiac SPECT (RECON TOMO) images into planes other than the original acquisition.

See RAD TF-2: 4.16.4.2.2.3.6 for normative requirements.

16.2.5 Cardiac NM Presentation State Option

This option allows users to set the window level for cardiac data, store it as a Grayscale Softcopy Presentation State, and provide it for display. This functionality is achieved by grouping NMI actors with relevant actors from the Consistent Presentation of Images (CPI) Profile (Section 1:5):

- Evidence Creators that support this option shall be grouped with an Evidence Creator in the Consistent Presentation of Images Profile and shall be able to create and store GSPS objects for the Nuclear Medicine Image Storage SOP Class.

- Image Displays that support this option shall be grouped with an Image Display in the Consistent Presentation of Images Profile and shall be able to query, retrieve and render GSPS objects for the Nuclear Medicine Image Storage SOP Class.

- Image Manager/Image Archives that support this option shall be grouped with an Image Manager/Image Archive in the Consistent Presentation of Images Profile which enables storage and retrieval of the Grayscale Softcopy Presentation State objects.

16.3 NM Image Process Flow
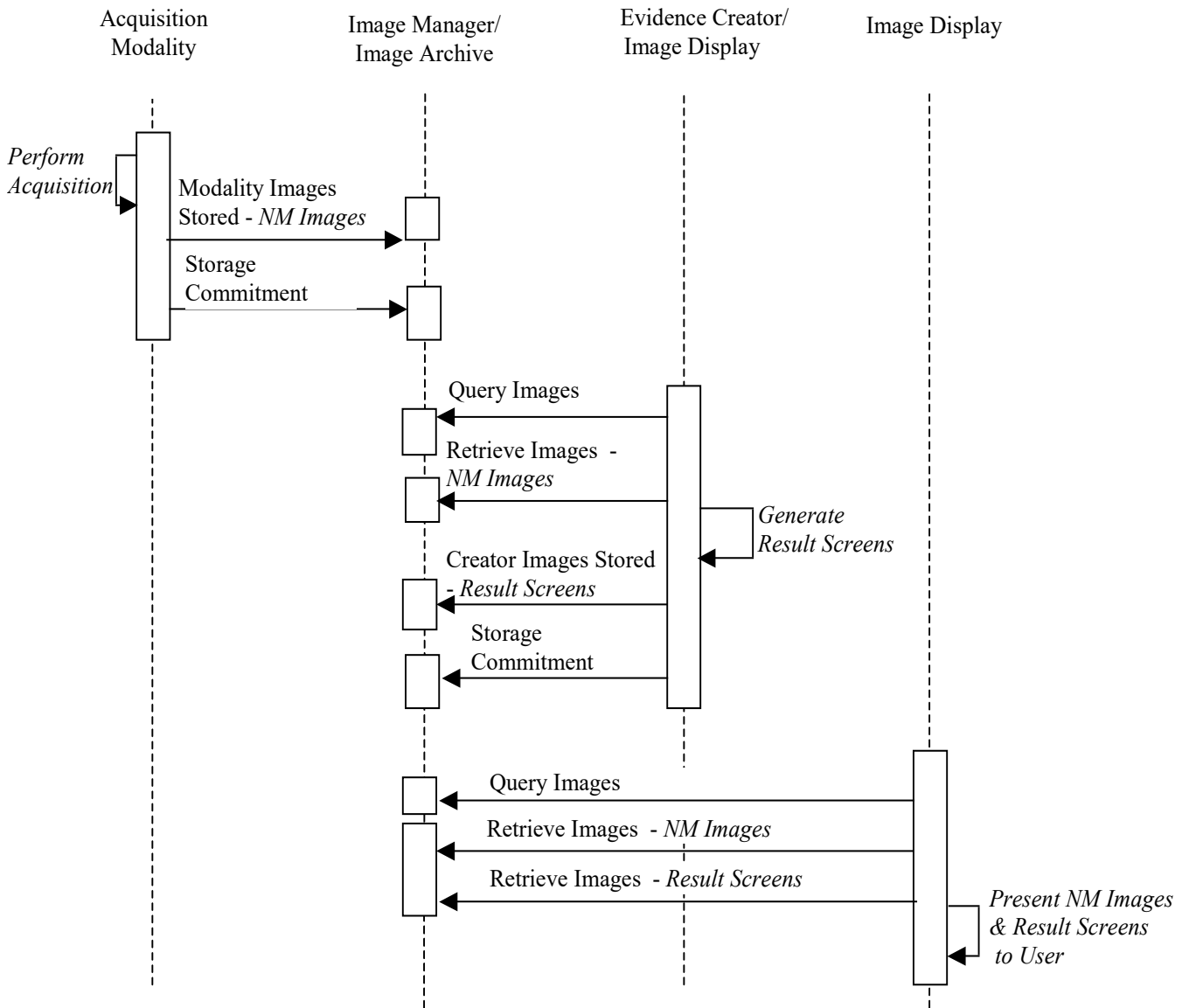
Figure 16.3-1: NM Image Process Flow

3310   The process of creating, storing and using NM Image content can be managed in much the same way as other image content using the Scheduled Workflow and Post-Processing Workflow Profiles. Examples of NM Workflow and Guidelines for carrying it out using the two mentioned Workflow Profiles can be found in RAD TF-1x: Appendix E: Nuclear Medicine.

17 Teaching File and Clinical Trial Export (TCE)

3315 This profile defines a means of selecting the relevant images, key image notes, reports, evidence documents and presentation states on the Export Selector (which would typically be grouped with an Acquisition Modality, Image Display, Evidence Creator or Report Creator), a means to enter additional information at that time, a means of transfer to an Export Manager whose behavior is defined, and a means of transfer to a Receiver whose behavior is not defined (but

3320 which might be a teaching file authoring or distribution system, clinical trial image management system, or a publication authoring system or might be grouped with an Image Manager/Archive or Portable Media Creator).

17.1 Actors/Transactions

Figure 17.1-1 shows the actors directly involved in the Teaching File and Clinical Trial Export

3325 Integration Profile and the relevant transactions between them. Other actors that may be indirectly involved due to their participation in Key Image Note, Consistent Presentation of Images, Evidence Document, Simple Image and Numeric Report and Portable Data for Imaging Profiles, etc. are not shown.
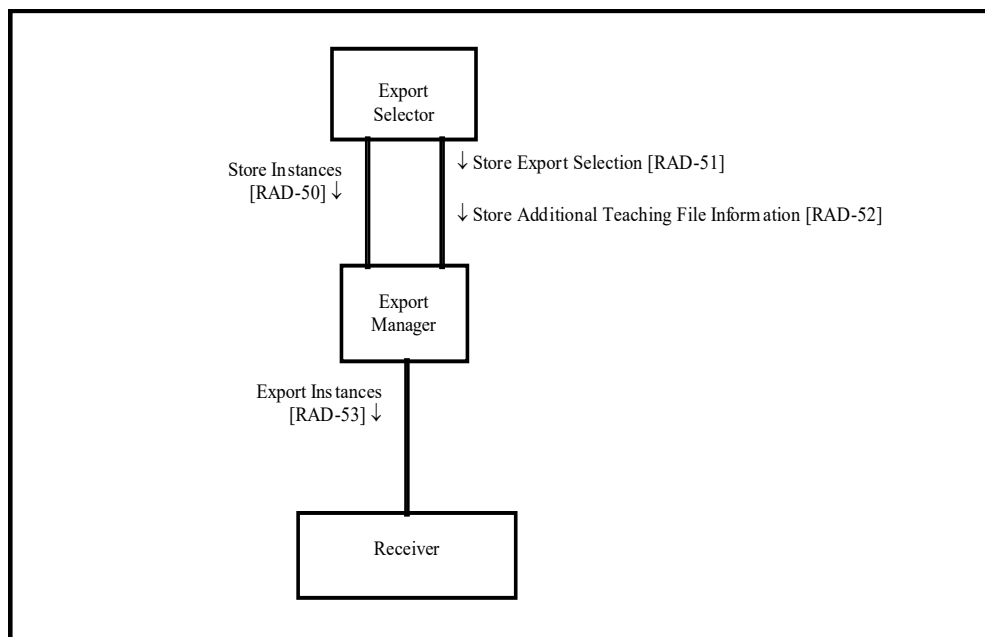
3330

Figure 17.1-1: Teaching File and Clinical Trial Export Actor Diagram

Table 17.1-1 lists the transactions for each actor directly involved in the Teaching File and Clinical Trial Export Profile. In order to claim support of this integration profile, an implementation must perform the required transactions (labeled "R"). Transactions labeled "O"

3335 are optional. A complete list of options defined by this integration profile and that implementations may choose to support is listed in Section 17.2.

Table 17.1-1: Teaching File and Clinical Trial Export Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	TF Reference
Export Selector	Store Instances [RAD-50]	R (see Note)	RAD TF-2: 4.50
	Store Export Selection [RAD-51]	R	RAD TF-2: 4.51
	Store Additional Teaching File Information [RAD-52]	O	RAD TF-2: 4.52
Export Manager	Store Instances [RAD-50]	R (see Note)	RAD TF-2: 4.50
	Store Export Selection [RAD-51]	R	RAD TF-2: 4.51
	Store Additional Teaching File Information [RAD-52]	R	RAD TF-2: 4.52
	Export Instances [RAD-53]	R	RAD TF-2: 4.53
Receiver	Export Instances [RAD-53]	R	RAD TF-2: 4.53

3340

Note: If the Export Manager is grouped with an Image Manager/Archive, there is no need for Store Instances [RAD-50] transactions between the Export Selector and the Export Manager as long as the instances are already available to the Export Manager.

17.2 Teaching File and Clinical Trial Export Integration Profile Options

3345 Options that may be selected for this integration profile are listed in the Table 17.2-1 along with the actors to which they apply. Dependencies between options when applicable are specified in notes.

Table 17.2-1: Teaching File and Clinical Trial Export - Actors and Options

Actor	Options	TF Reference
Export Selector	Additional Teaching File Information	RAD TF-1: 17.2.3 RAD TF-2: 4.52
	Delay for Reason	RAD TF-1: 17.2.4 RAD TF-2: 4.51.4.1.5
Export Manager	De-identify Pixel Data	RAD TF-1: 17.2.1 RAD TF-2: 4.51.4.1.4.4
	Remap Identifiers	RAD TF-1: 17.2.2 RAD TF-2: 4.51.4.1.4.3
	Additional Teaching File Information	RAD TF-1: 17.2.3 RAD TF-2: 4.52
	Delay for Reason	RAD TF-1: 17.2.4 RAD TF-2: 4.51.4.1.5
Receiver	Additional Teaching File Information	RAD TF-1: 17.2.3 RAD TF-2: 4.53

17.2.1 De-identify Pixel Data Option

In the default case, the Export Manager is responsible for de-identifying instances by removing
3350 the necessary DICOM attributes or replacing them with alternative identification values

(pseudonymization), without invalidating the IOD. This operation would normally be fully automated, usually according to some pre-configured set of rules.

If identification is burned in to the pixel data; however, as is commonly the case with Ultrasound and Secondary Capture images, it is difficult to remove this automatically. Accordingly, a human operator would use an appropriate user interface to "black out" offending areas of text.

This named option requires that the capability to remove the offending information be present, and that images shall not be forwarded as de-identified and pseudonymized until it has been confirmed that burned in identification is no longer present.

The option does not specify constraints on how this capability might be implemented, either in terms of workflow, such as providing an internally managed work list for operators or user interface features, such as the size, shape and number of graphic operations needed for editing the pixels.

17.2.2 Remap Identifiers Option

For teaching file applications, it is rarely necessary to exercise much control over the identifiers that are generated and used to replace the patient identifiers. As long as valid and globally unique UIDs are generated, and other identifiers are replaced with values that do not invalidate the IOD, they may be sequential or arbitrary or random.

For clinical trial applications this may be sufficient as long as the receiving site is informed of the new arbitrary identifiers and to which trial subject they correspond through some out of band mechanism, such as a data transmittal form.

However, clinical trial workflow is greatly enhanced if the subject enrollment list is used to remap the patient's actual identifiers to the trial subject identifiers, and additional clinical trial attributes are inserted into the header. Provision of such a capability is the "Remap Identifiers Option".

Further, in some protocols, the list of expected studies and their mapping to pre-defined time points is known in advance, and the remapping capability could take advantage of this knowledge, if available.

This named option requires that such a remapping capability be present.

The option does not specify constraints on how this capability might be implemented, either in terms of configuration, such as providing a user interface or preloading capability for the subject enrollment list or remapping table, or sophistication, such as providing rule-driven generation of UID and text values at either the patient or the study level.

This option does require that at minimum specific attributes be added or remapped; see the description of the Store Export Selection [RAD-51] transaction in RAD TF-2: 4.51.4.1.4.3.

17.2.3 Additional Teaching File Information Option

The manifest of instances to be exported (the Export Selection) consists of references only, with no additional information. To allow for the user of the Export Selector to not only flag instances

for export, but also to add additional information such as text and codes, a named option is specified that provides for the support of a specific transaction Store Additional Teaching File Information [RAD-52]. This allows additional information to be encoded in one or more Structured Report instances that may be stored and included in the set of instances to be exported. The Store Export Selection [RAD-51] Key Object Selection document references the Additional Teaching File Information SR instances. Once pseudonymized, this information is exported using the Export Instances [RAD-53] transaction just like any other instance.

17.2.4 Delay for Reason Option

Images may have been selected for teaching before the final pathological diagnosis or other information is known, yet may need to be de-identified before transfer to the authoring system, after which additional material cannot be linked. Since such information may be important to the integrity of the teaching file, this option defines a mechanism for the Export Manager to delay export until the system has received the specified information, and then to forward both to the Receiver.

17.3 Implementation Issues

This profile is designed with the following implementation scenarios in mind:

Scenario 1:

The Export Manager is grouped with an Image Manager/Archive. In this case, there is no need for Store Instances [RAD-50] transactions between the Export Selector and the Export Manager, as long as the instances are already available to the Export Manager.

Scenario 2:

The Export Manager is not grouped with an Image Manager/Archive. In this case, Store Instances [RAD-50] transactions between the Export Selector and the Export Manager are used to make the instances available to the Export Manager.

Scenario 3:

The Receiver is grouped with a Portable Media Creator and claims support of the Portable Data for Imaging Profile. In this case the instances and manifest received are recorded to media.

Scenario 4:

The Export Manager is grouped with the Image Manager/Archive in System A. The Receiver is grouped with an Image Manager/Archive in System B. In this case, the exported instances and manifest are made available in System B.

17.4 Teaching File and Clinical Trial Export Integration Profile Process Flow

3420

This section describes the typical process flow related to the selection, pseudonymization and export of images, key image notes, reports, evidence documents and presentation states during the creation of a teaching file or for a clinical trial.

The transactions covered are [RAD-50] through [RAD-53].

3425 In general, the process flow is as follows.

On an Export Selector, the user selects images, key image notes, reports, evidence documents and presentation states, either as individual instances or as entire series or studies, that are relevant for a Teaching File or a Clinical Trial or some other purpose (such as use in a publication).

3430 The Export Selector is possibly grouped with an Image Display, an Acquisition Modality, an Evidence Creator and/or a Report Creator. When grouped with an appropriate actor participating in the appropriate Profile, the device may also be capable of displaying or importing Portable Media (PDI Profile), query and retrieval of Reports (SINR Profile), Evidence Documents (ED Profile), query and retrieval of Key Image Notes (KIN Profile), and/or Presentation States (CPI
3435 Profile).

The user selection results in the creation of a manifest, listing what was selected for export. This document is the Export Selection.

Optionally, the user may enter additional information during selection as text or with simple structure and codes, which is encoded and sent separately from the manifest.

3440 The instances are transferred to the Export Manager, unless the Export Manager is grouped with an Image Manager/Archive and the instances are known to already reside there (by static configuration or recollection of the application entity from which the images were received).

The additional information, if any, and the manifest, are transferred to the Export Manager.

The Export Manager is capable of replacing patient identifiers with pseudonymous identifiers,
3445 possibly according to some pre-registered mapping scheme or arbitrarily, and optionally providing manual editing of the pixel data to perform de-identification, and optionally delaying the export until further information (e.g., the histopathology report) is available.

The Export Manager transfers the pseudonymized instances and manifest to a Receiver, whose further behavior is not defined (except to the extent that the Receiver may be grouped with an
3450 Image Manager/Archive or Portable Media Creator).
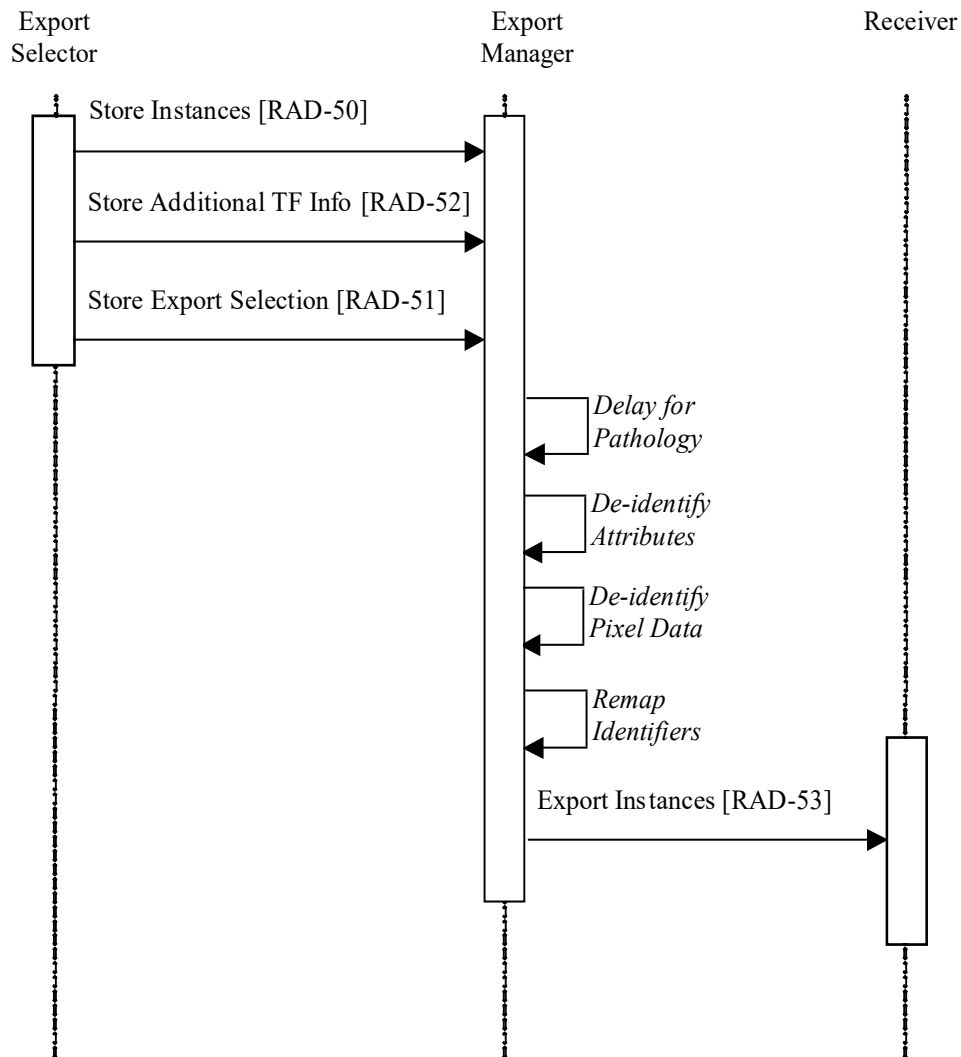
Figure 17.4.1-1: Basic Process Flow in Teaching File and Clinical Trial Export Profile

Note 1: In Figure 17.4.1-1, the sequence of the [RAD-50], [RAD-51] and [RAD-52] transactions is not specified; these transactions may overlap or occur in any order.

3455 Note 2: In Figure 17.4.1-1, the [RAD-50] transaction may be omitted if the Export Manager is grouped with the Image Manager/Archive.

The following use cases are not intended to be exhaustive nor in any way to constrain the manner in which the profile is implemented. Rather they illustrate a range of scenarios from simple to complex that may be satisfied with the same actors and transactions. To provide context, in some 3460 use cases, behavior is described that is outside the scope of this profile. Further, they serve to illustrate the differences and similarities between workflows for teaching files and clinical trials.

17.4.1 Teaching File Use Cases

The teaching file is a vital tool in medical education. Traditionally assembled from collections of film, teaching files now need to be constructed from digital images. Digital media enables

3465   broader dissemination of the content both within and outside the enterprise, often as federated collections that share a common query mechanism.

Teaching file case authors need access to images and related information, which usually reside in the Image Archive/Manager and are viewed on an Image Display. Cases may also be identified on the Acquisition Modality. Relevant images, series or studies are often identified whilst the
3470   author is engaged in other tasks such interpretation; hence need to be flagged for later authoring.

Enterprises frequently restrict access to information containing a patient's identity on systems on which teaching files are typically authored; hence the images and related information may need to be de-identified before transfer to the authoring system. Distribution of teaching files beyond an institution always involves de-identification.

3475   ### 17.4.1.1 Use Case 1 – Images Selected for Teaching File During Reporting, Review or Acquisition

User Actions:

A radiologist is performing diagnostic reporting of possibly many studies for different patients during the course of the day. Alternatively, the radiologist is consulting on a study received from
3480   a referral patient on CD, or the radiologist is performing an image-guided biopsy on an acquisition device.

Images from a particular patient are noted to be of special interest and potentially suitable for teaching. The radiologist selects several relevant images from the current and prior studies to be de-identified and saved to his teaching file collection. The selection may entail entire series or
3485   studies, such as when later 3D reconstruction or multi-modality fusion may be required. No additional information is entered at this time since the radiologist is busy.

Sometime later, the radiologist will access his teaching file collection and use a teaching file authoring program on his personal computer to create a multi-media teaching file. The manner in which the teaching file is authored and distributed is beyond the scope of this profile.

3490   The transfer to the radiologist's teaching file collection may take place either over the network or on media (the latter case might be applicable if the radiologist is a locum or from an outside facility or if the clinical and teaching networks are not connected).

Implementation:

The radiologist is viewing images on an Image Display grouped with an Export Selector. The
3495   Image Display is also participating in the Portable Data for Imaging Profile in the case of the review of the referral CD, or the radiologist is working on an Acquisition Modality grouped with an Export Selector.

The Export Selector allows one or more images from current and prior studies to be selected, and then to be "exported for teaching".

3500   The Export Selector may be preconfigured to know that the images are already stored on an Image Manager/Archive with which the Export Manager is grouped; in such a case no Store

Instances [RAD-50] transactions are required. In the media case, Store Instances [RAD-50] transactions would be required.

The user action triggers a Store Export Selection [RAD-51] transaction to the Export Manager.

3505 The manifest is encoded as a Key Object Selection document with a Document Title of "For Teaching File Export". When entire series or studies have been selected, the manifest will enumerate all the instances from all the selected series and studies.

There may be multiple different teaching file "folders" to which the case might be added. To allow the user to identify which teaching file the images are intended for, a free text field or a 3510 pre-configured pull-down list is provided, which is encoded as the disposition in the text value of the Key Object Selection document.

No additional content was entered at the time of selection, so no Store Additional Teaching File Information [RAD-52] transaction is sent.

If the Export Manager is not grouped with an Image Manager/Archive that already has the 3515 images, upon receiving the images via the Store Instances [RAD-50] transaction, the Export Manager stores them internally.

When the Export Manager receives the Store Export Selection [RAD-51] transaction, and all the images referenced therein are available, the collection is queued for pseudonymization and export.

3520 The Export Manager automatically removes all patient identification from the image attributes as well as other text and private attributes (according to a pre-configured set of rules), checks to be sure that the SOP Class of the image is not one likely to contain burned-in identification in the pixel data, and inserts new dummy patient identification and other text attributes so as not to invalidate compliance of the instance with the IOD. Note that the extent of de-identification is 3525 configurable, and if de-identification is to be performed in the teaching file authoring system later, may not be performed by the Export Manager at all. This may be the case when the patient's identity is required by teaching file authoring system to allow the user to search for other clinical and historical information.

If the Export Manager supports the De-identify Pixel Data Option, any of the images likely to 3530 contain burned in identification information in the pixel data are placed on an internal work list for a human operator to check and if necessary edit the pixel data to remove the burned in identification, before the images are forwarded to the Receiver.

The Export Manager then sends the pseudonymized DICOM images and an updated Key Object Selection document containing the manifest referencing the new identifiers and UIDs to the 3535 appropriate Receiver using an Export Instances [RAD-53] transaction.

The Receiver may be the enterprise's central teaching file authoring system. Upon receiving the images and the manifest, it extracts the identity of the radiologist who created the manifest from the Person Observer Identifying Attribute template encoded within the Key Object Selection document. It uses this identity, or the disposition information, to route the case to that user's 3540 folder of pending cases for authoring. The Receiver could be grouped with a Portable Media

Creator, in which case the images and manifest could be burned to an IHE PDI CD. Note that the behavior of the Receiver is described only to illustrate the use case, and is beyond the scope of this profile.

17.4.1.2 Use Case 2 – Complete Teaching File Authoring During Reporting with Multiple Instance Types and Multiple Export Targets

3545

User Actions:

A radiologist is performing diagnostic reporting. Images from a particular patient are noted to be of special interest and potentially suitable for teaching. In addition to having the clinical report for the current case that has just been created, the radiologist has also queried for prior reports,
3550 extracted a surgical pathology report from an external report repository, and had evidence documents previously created by a quantitative analysis package running on the acquisition device. The radiologist selects several relevant images from the current and prior studies, saves presentation states containing the appropriate windows and annotations of interesting lesions, as well as several evidence documents and the surgical pathology report, and decides to create a
3555 teaching file.

The workstation then prompts the radiologist to enter additional information according to a pre-defined template of headings and plain text sections, including history, organ system, anatomy, findings, differential diagnosis and final diagnosis. The radiologist uses the workstation's text editing capability to cut and paste from the various reports into the template, as well as selecting
3560 organ system, anatomy and diagnoses from pick-lists of codes.

Upon completion, the user instructs the workstation to release the case, which is then made available throughout the enterprise on the PACS and electronic medical record systems with a pseudonymous identification in the departmental teaching collection folder, as well as via the web both inside and outside the enterprise.

3565 **Implementation:**

The radiologist is viewing images on an Image Display grouped with an Export Selector, as well as an Evidence Creator, Report Creator and Report Reader. It participates in the Evidence Document and Simple Image and Numeric Report Profiles and hence has access to Evidence Documents and Reports, as well as an External Report Repository. It is also participating in the
3570 Consistent Presentation of Images Profile hence supports the creation and retrieval of Presentation States. The Export Selector supports the Additional Teaching File Information Option.

The Export Selector allows one or more images, reports, evidence documents or presentation states from current and prior studies to be selected, and then to be "exported for teaching",
3575 together with the additional information.

The user action triggers Store Instances [RAD-50] transactions, Store Additional Teaching File Information [RAD-52] transactions and multiple Store Export Selection [RAD-51] transactions to the Export Manager (one for each Receiver).

3580   The manifest is encoded as a Key Object Selection document. The additional information is encoded as a Structured Report according to a pre-defined template.

The Export Manager de-identifies and re-identifies the image, reports, evidence documents, presentation states and additional information with pseudonymous values as in Use Case 1.

The Export Manager then sends the pseudonymized DICOM instances, the pseudonymized additional information, and an updated Key Object Selection document containing the manifest
3585   referencing the new identifiers and UIDs to the appropriate Receivers using Export Instances [RAD-53] transactions.

The multiple Receivers in this use case include the Image Managers and Archives for the clinical PACS and the Electronic Medical Record Systems, as well as a Receiver that is the enterprise's own web-based teaching file distribution system, and another Receiver that is a portal to a central
3590   repository of teaching files operated by the parent academic institution.

17.4.1.3 Use Case 3 – Images Selected for Teaching File During Reporting with Delayed Export Awaiting Pathology

User Actions:

A radiologist is performing diagnostic reporting. Images from a particular patient are noted to be
3595   of special interest and potentially suitable for teaching. The radiologist selects several relevant images from the current study to be de-identified and saved to his teaching file collection.

However, the teaching file case cannot be authored until the pathology report is available. Accordingly, during selection the radiologist chooses the "delay for histopathology report" modifier to the "export for teaching" action.

3600   **Implementation:**

The implementation proceeds as in Use Case 1.

The Key Object Selection document, in addition to having a Document Title that indicates that the case is for teaching file export, also has a coded Concept Modifier indicating "Delay for histopathology report".

3605   When the Export Manager receives the Store Export Selection [RAD-51] transaction, and all the images referenced therein are available, the collection is queued. However, since the Export Manager supports the Delay for Reason Option, pre-configured rules within the Export Manager triggered by the "Delay for Reason" modifier indicate that the device should wait until it receives a (relevant) histopathology report for the patient, before de-identifying and pseudonymizing the
3610   images and the histopathology report and forwarding them to the Receiver.

The manner in which the Export Manager receives the histopathology report is undefined and outside the scope of this profile, but it must be re-encoded in a DICOM Structured Report (perhaps as plain text) for export to the Receiver, and a reference to it included in a revised manifest.

3615 **17.4.2 Clinical Trial Use Cases**

Clinical trials have similar needs to teaching files, in that images and related information need to be selected for export to other systems, and other organizations in the case of multi-center trials. During export, images need to be de-identified and trial-specific identifiers inserted in accordance with local or national policy and the rules of the trial protocol.

3620 The following use cases serve to illustrate the differences and similarities between workflows for teaching files and clinical trials.

17.4.2.1 Use Case 4 – Series or Studies Selected for Clinical Trial from Referring User's Workstation or Acquisition Modality

User Actions:

3625 A patient enrolled in a multi-center clinical trial undergoes an examination, the images of which require review by a central facility. Though the patient has given their informed consent to release their identification (PHI) to the central facility, site policy dictates that the images be de-identified first regardless. The managers of the trial supply replacement identifiers to be used.

3630 A technologist, nurse or physician participating in the trial uses a referring user's workstation on the PACS to select the relevant studies, or selected series from the study, for export to the central facility.

Alternatively, the technologist performing a study uses the acquisition device to select the relevant study, or selected series from the study, for export to the central facility.

Implementation:

3635 In this case, the user is viewing images on an Image Display or Acquisition Modality grouped with an Export Selector. The Export Selector allows images, series and studies to be selected, and then to be "exported for clinical trial".

The user action triggers the Export Selector to send images and an Export Selection to the Export Manager as in Use Case 1, except that the Document Title of the Key Object Selection document
3640 specifies "For Clinical Trial Export" instead of "For Teaching File Export", and there is no Additional Teaching File Information transaction.

There may be multiple trials in progress, and a single patient may be a participant in more than one trial; hence, to allow the user to identify which clinical trial the images are intended for, a free text field or a pre-configured pull down list is provided, which is encoded as the disposition
3645 in the text value of the Key Object Selection document.

The Export Manager de-identifies and re-identifies the image, reports, evidence documents, presentation states and additional information with pseudonymous values as in Use Case 1, except that the Export Manager supports the Remap Identifiers Option. In order to pseudonymize the images with the trial-specific identifiers, both as replacements for the conventional patient
3650 identification attributes and to populate the clinical trial specific attributes, the Export Manager contains a pre-configured mapping of Patient to Subject identifiers (usually referred to as a

subject enrollment list). The Export Manager inserts replacement patient identification and clinical trials attributes obtained from its mapping table.

3655 The Export Manager then sends the pseudonymized DICOM images and an updated manifest to a Receiver as in Use Case 1. Which Receiver to send to may be pre-configured or may vary depending on the disposition text value of the manifest.

The Receiver may be the system responsible for transferring the images to the central review facility. For privacy and security considerations, typically it will use a secure Internet channel, such as a VPN, TLS (SSL) or SSH tunnel. The security mechanism is beyond the scope of this 3660 profile.

Or, the Receiver could be grouped with a Portable Media Creator, as described in Use Case 1, in which case CDs would be burned and mailed to the central review facility.

This use case is distinguished from the teaching file use cases in that:

- Selection is usually at the study or series level, and rarely at the image level
3665 - A mapping to pre-defined replacement identifiers is defined in the Export Manager
- The Export Manager also inserts clinical trial specific attributes
- A means of routing the images to the appropriate trial is required

In other respects, this use case is fundamentally the same as Use Case 1.

17.4.3 Research Collection Use Cases

3670 The selection of instances or entire studies for research purposes shares many similarities with use cases for teaching files and clinical trials. The studies generally remain in circulation for clinical use, as well as being "copied" into separate "folders" in the clinical Image Manager/Archive or copied to a separate research Image Manager/Archive. De-identification may not be required for local research collections, but for those maintained centrally (outside the 3675 enterprise), remapping of identifiers to predefined pseudonyms is often required.

A specific Document Title of "For Research Collection Export" is provided for such use cases, which are otherwise no different from the foregoing teaching file and clinical trial use cases in terms of user actions, actors or sequencing of transactions.

17.4.4 Publication Authoring Use Cases

3680 The selection of instances for use in a publication shares many similarities with use cases for teaching files. De-identification of the DICOM Header and the pixel data is required. The disposition for these use cases should reference the target author of the selected instances. A specific Document Title of "For Publication Export" (TCE008) is provided for such use cases, which are otherwise no different from the foregoing teaching use cases in terms of user actions, 3685 actors or sequencing of transactions. This use case is supported by the process flow shown in Figure 17.4.1-1.

18 Cross-Enterprise Document Sharing for Imaging (XDS-I.b) Integration Profile

IMPORTANT NOTE: *The Cross-Enterprise Document Sharing for Imaging (XDS-I) Integration Profile (originally found here) has been deprecated and is replaced by a functionally equivalent profile called Cross-Enterprise Document Sharing for Imaging (XDS-I.b), which is described in the remainder of this section.*

The Cross-Enterprise Document Sharing (XDS.b) Profile in the IHE IT Infrastructure Domain provides a solution for sharing (publishing, finding and retrieving) documents across a group of affiliated enterprises. The XDS for Imaging (XDS-I.b) Profile, defined here, extends and specializes the mechanisms defined by XDS.b to support imaging "documents", specifically including the following:

- Imaging studies that include images acquired on a broad range of different modalities, as well as evidence documents (e.g., post-processing measurements/analysis outcome), and presentation states.

- Diagnostic reports resulting from the interpretation of one or more related imaging studies provided in a ready-for-display form

- A selection of diagnostically significant images associated with the report content.

These document types along with the actor capabilities required to share them are defined by this profile.

Since the XDS for Imaging (XDS-I.b) Profile depends on and extends the IT Infrastructure XDS.b Profile including the use of terms defined in XDS.b (e.g., XDS Affinity Domain, submission set, etc.) the reader of XDS-I.b is expected to have read and understood the XDS Profile (ITI TF-1: 10). The XDS-I.b specification does not repeat requirements and text for the XDS-defined actors Document Repository, Document Registry, and Document Consumer, and does not place any new requirements on these actors.

Both the XDS.b and XDS for Imaging (XDS-I.b) Integration Profiles are not intended to address all cross-enterprise EHR communication needs. Many scenarios may require the use of other IHE Integration Profiles, such as Patient Identifier Cross-Referencing (PIX), Audit Trail and Node Authentication (ATNA), Enterprise User Authentication (EUA), Cross-Enterprise User Authentication (XUA) and Retrieve Information for Display (RID). Other scenarios may be only partially supported, while still others may require future IHE Integration Profiles, which will be defined by IHE as soon as the necessary base standards are available. Specifically:

1. The operation of any XDS Affinity Domain will require that a proper security model be put in place. It is expected that a range of security models should be possible. Although the XDS-I.b Integration Profile is not intended to include nor require any specific security model, it is required that XDS-I.b implementers shall group XDS-I.b actors with actors from the IHE Audit Trail and Node Authentication and will need an Access Control capability that operates in such a cross-enterprise environment. New IHE Integration Profiles have been identified as candidates (e.g., Public Key Infrastructure, Access

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Control, etc.). There is a discussion of XDS-I.b security considerations in RAD TF-1x: Appendix H.

2. XDS and XDS-I.b do not address transactions for the management or configuration of an XDS Affinity Domain. For example, the configuration of network addresses or the definition of what type of clinical information is to be shared is specifically left up to the policies established by the XDS Affinity Domain.

3. XDS and XDS-I.b do not specifically address the patient information reconciliation process necessary between the XDS Affinity Domain and any other local patient identity domains that Document Sources and Document Consumers may be members of. For a discussion of some of these issues see RAD TF-1x: Appendix G.

4. XDS and XDS-I.b do not directly address the rendering and display of the documents retrieved by the Document and Imaging Document Consumers. Users wishing to achieve a well-defined level of display/ rendering capability simply need to request systems that combine the XDS-I.b Imaging Document Consumer with an Image Display from the appropriate profile (e.g., Mammography Image, NM Image, Basic Image Review, etc.).

18.1 Actors/ Transactions

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A. IHE Transactions can be found in the Technical Frameworks General Introduction Appendix B. Both appendices are located at https://profiles.ihe.net/GeneralIntro/index.html.

Figure 18.1-1 shows the actors directly involved in this profile and the transactions between actors. The shaded XDS actors are NOT actually included in this profile but are included to show the other endpoint of transactions that ARE part of the profile (e.g., the Document Repository that is the endpoint for the Provide and Register Imaging Document Set – MTOM/XOP transaction). As a result, the shaded actors are not listed in Table 18.1-1. Actors which have required grouping (if any), are shown in conjoined boxes (see Section 18.1.2). The XDS-I.b Profile does not place any additional requirements on any of these actors above and beyond what is required of them by the ITI XDS.b Profile.
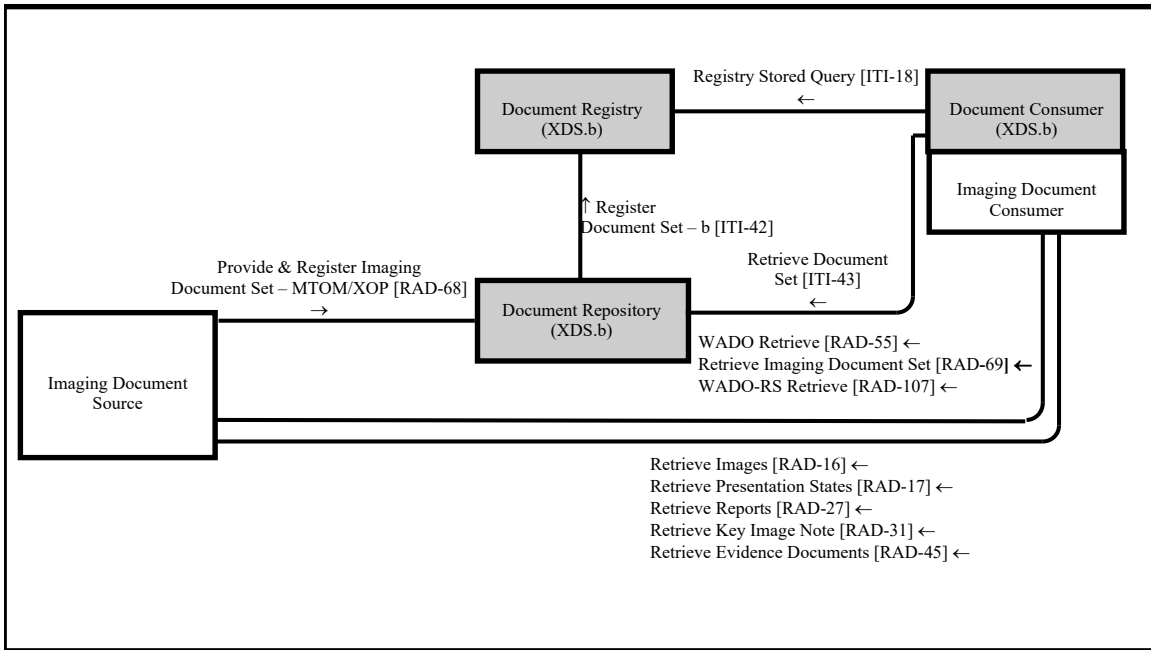
3755 **Figure 18.1-1: Cross-Enterprise Document Sharing for Imaging Diagram**

Table 18.1-1 lists the transactions for each actor directly involved in the Cross-Enterprise Document Sharing for Imaging (XDS-I.b) Profile. In order to claim support of this integration profile, an implementation shall perform the required transactions (labeled "R"). Transactions labeled "O" are optional. A complete list of options defined by this integration profile is listed in 3760 Section 18.2.

Table 18.1-1: Cross-enterprise Document Sharing for Imaging Integration Profile - Actors and Transactions

Actors	Transactions	Initiator or Responder	Optionality	TF Reference
Imaging Document Consumer	Retrieve Images [RAD-16]	Initiator	O (Note 1)	RAD TF-2: 4.16
	Retrieve Presentation States [RAD-17]	Initiator	O	RAD TF-2: 4.17
	Retrieve Reports [RAD-27]	Initiator	O (Note 1)	RAD TF-2: 4.27
	Retrieve Key Image Note [RAD-31]	Initiator	O	RAD TF-2: 4.31
	Retrieve Evidence Documents [RAD-45]	Initiator	O (Note 1)	RAD TF-2: 4.45
	WADO Retrieve [RAD-55]	Initiator	O (Note 1)	RAD TF-2: 4.55
	Retrieve Imaging Document Set [RAD-69]	Initiator	O (Note 1)	RAD TF-2: 4.69
	WADO-RS Retrieve [RAD-107]	Initiator	O (Note 4)	RAD TF-2: 107
Imaging Document Source	Provide and Register Imaging Document Set – MTOM/XOP [RAD-68]	Initiator	R	RAD TF-2: 4.68
	Retrieve Images [RAD-16]	Responder	O (Note 3)	RAD TF-2: 4.16
	Retrieve Presentation States [RAD-17]	Responder	O (Note 3)	RAD TF-2: 4.17
	Retrieve Reports [RAD-27]	Responder	O (Note 3)	RAD TF-2: 4.27
	Retrieve Key Image Note [RAD-31],	Responder	O (Note 3)	RAD TF-2: 4.31
	Retrieve Evidence Documents [RAD-45]	Responder	O (Note 3)	RAD TF-2: 4.45
	WADO Retrieve [RAD-55]	Responder	O (Note 3)	RAD TF-2: 4.55
	Retrieve Imaging Document Set [RAD-69]	Responder	O (Note 3)	RAD TF-2: 4.69
	WADO-RS Retrieve [RAD-107]	Responder	O (Note 4)	RAD TF-2: 107

Note 1: At least one of these retrieve transactions is required to be supported. See Section 18.1.1.2.

Note 2: Intentionally left blank.

Note 3: These transactions are required if the Imaging Document Source supports the 'Set of DICOM Instances' Option

18.2 Integration Profile Options

Options that may be selected for this integration profile are listed in Table 18.2-1 along with the actors to which they apply. Dependencies between options when applicable are specified in notes.

Table 18.2-1: Cross-enterprise Document Sharing for Imaging - Actors and Options

Actor	Options	TF Reference
Imaging Document Source	Set of DICOM Instances (Note 1)	RAD TF-1: 18.2.1
	PDF Report (Note 1)	RAD TF-1: 18.2.2
	CDA Wrapped Text Report (Note 1)	RAD TF-1: 18.2.3
	CDA Imaging Report with Structured Headings (Note 1)	RAD TF-1: 18.2.4
	Remove Imaging Document	RAD TF-1: 18.2.5
	Reference ID	RAD TF-1: 18.2.6
	DICOM Retrieve by WADO-RS	RAD TF-1:18.2.7

Actor	Options	TF Reference
Imaging Document Consumer	DICOM Retrieve by WADO-RS	RAD TF-1:18.2.7

Note 1: At least one of these four options is required. See Section 18.1.1.1.

18.2.1 Set of DICOM Instances Option

18.2.2 PDF Report Option

This option enables an Imaging Document Source to publish a PDF imaging report to an XDS infrastructure.

An Imaging Document Source that supports this option shall use the Provide and Register Imaging Document Set – MTOM/XOP [RAD-68] transaction to create an imaging report in PDF Format and submit that document to an XDS Document Repository. See RAD TF-2: 4.68.4.1.2.2.

The published report may contain embedded images or pre-computed links that reference images in a non-DICOM format. The Imaging Document Source is required to ensure that image references in the report are valid links.

18.2.3 CDA Wrapped Text Report Option

This option enables an Imaging Document Source to publish a CDA imaging report to an XDS infrastructure.

An Imaging Document Source that supports this option shall use the Provide and Register Imaging Document Set – MTOM/XOP [RAD-68] transaction to create a CDA R2 document containing an imaging report with Structured Headings and submit that document to an XDS Document Repository. See RAD TF-2: 4.68.4.1.2.2.

18.2.4 CDA Imaging Report with Structured Headings Option

This option enables an Imaging Document Source to publish a CDA imaging report to an XDS infrastructure.

An Imaging Document Source that supports this option shall use the Provide and Register Imaging Document Set – MTOM/XOP [RAD-68] transaction to create a CDA R2 document containing an imaging report with Structured Headings and submit that document to an XDS Document Repository. See RAD TF-2: 4.68.4.1.2.2.

18.2.5 Remove Imaging Document Option

This option uses the ITI Remove Metadata and Documents (RMD) Profile to enable the Imaging Document Source to remove published imaging documents (e.g., imaging manifest and reports) from a Document Repository and related metadata from the Document Registry. Use of this option depends upon an Imaging Document Source participating in an environment with an RMD Document Registry and Document Repository.

An Imaging Document Source shall be grouped with an RMD Document Administrator that supports the Remote Registry Option and the Remote Repository Option. See Section 18.1.2.

3805 When the Imaging Document Source determines that a report is to be deleted, the grouped Document Administrator shall remove the metadata of the report from the Document Registry using the Remove Metadata [ITI-62] transaction, and remove the report from the Document Repository using the Remove Documents [ITI-86] transaction.

3810 When the Imaging Document Source determines that all referenced objects in a manifest are to be deleted (i.e., imaging study has been deleted), the grouped Document Administrator shall remove the metadata of the manifest from the Document Registry using the Remove Metadata [ITI-62] transaction, and remove the manifest from the Document Repository using the Remove Documents [ITI-86] transaction.

3815 Note 1: This option is not used when the Imaging Document Source determines that a manifest is to be replaced (i.e., some but not all referenced objects in the manifest have been deleted, or referenced objects have been added). In this case, the Imaging Document Source submits a new manifest that references the remaining objects. This new manifest will replace the existing manifest in accordance with the RPLC (replace) Document Relationship as defined in RAD TF-2: 4.68.4.1.2.1.

3820 Note 2: For an Imaging Document Source that is grouped with an Image Manager that supports the Imaging Object Change Management Profile, when the Imaging Document Source deletes a study that has been published with a manifest, it may choose to either:

- Use the Remove Imaging Document Option to remove the study manifest metadata from the Document Registry and the Manifest from the Document Repository, or

3825 - Create a corresponding Rejection Note for the deleted study and replace the published manifest with a new manifest which contains only the Rejection Note.

The Imaging Document Source may choose either method depending on the integration need.

18.2.6 Reference ID Option

This option requires the Imaging Document Source to include Accession Number and Study Instance UID in the Document Sharing Metadata when submitting an imaging document (e.g., 3830 imaging manifest or report) to the Document Repository.

An Imaging Document Source that supports this option shall include the Accession Number and its assigning authority in the referencedIdList attribute of the DocumentEntry metadata submitted to the XDS.b Document Registry for the imaging document as described in RAD TF-2: Table 4.68.4.1.2.3-1, if the Accession Number is known.

3835 An Imaging Document Source that supports this option shall include the Study Instance UID of the imaging study in the referencedIdList attribute of the DocumentEntry metadata submitted to the XDS.b Document Registry for the imaging document as described in RAD TF-2: Table 4.68.4.1.2.3-1, if the Study Instance UID is known.

Use of this option depends upon an Imaging Document Source participating in an environment 3840 with an XDS.b Document Registry that supports the Reference ID Option. XDS.b Document Registries supporting the Reference ID Option (ITI TF-1: 10.2.6) store the values in the referencedIdList attribute. When the Reference ID Option is not supported by the Document Registry, then the values in referencedIdList are handled according to the rules outlined in ITI

3845 TF-3: 4.2.3.1.6 "Extra Metadata Elements". Note that support for the Reference ID Option by the XDS.b Document Registry is necessary to enable the Document Consumer to perform a successful FindDocumentsByReferenceId Stored Query in the Registry Stored Query [ITI-18] transaction.

18.2.7 DICOM Retrieve by WADO-RS Option

3850 This option enables a RESTful retrieve of a set of DICOM instances referenced in a DICOM manifest.

An Imaging Document Source that supports this option shall:

- include in the DICOM manifest a value for Retrieve URL (0008,1190) to enable the referenced instances to be retrieved. See RAD TF-2: 4.68.4.1.2.1.1.

- support the WADO-RS Retrieve [RAD-107] transaction as a responder.

3855 An Imaging Document Consumer that supports this option shall be able to use WADO-RS Retrieve [RAD-107] transaction as an initiator to retrieve DICOM instances from an Imaging Document Source. The Imaging Document Consumer shall support at least the 'Get Instances Request' Message in [RAD-107]. See RAD TF-2: 4.107.4.1.

18.3 Image Information Sharing Process Flow

3860 The sharing of imaging related information among different health professionals and facilities, even across administrative and geographic boundaries can lead to a large variety of information flows. Typical imaging information sets used in healthcare settings are well known, but the challenge is to distill the "exchange" scenarios to drive the sharing of imaging information across enterprises distributed over a community, region or nation.

18.3.1 Overview of Imaging Information Sharing Use Cases

3865 The following use case scenarios express the core imaging information sharing common to most clinical settings. They cover:

1. **Routine imaging referral**. The referring physician in his office requests that a patient have an examination done at an imaging facility. The physician expects to have electronic access to the imaging report and to the images if needed after the examination has been performed on his patient. This use case is further analyzed in this profile.

2. **Course of Treatment Consult**. An emergency physician orders an imaging examination for a patient at his hospital. After reviewing the preliminary report, the ER physician decides to consult a surgical specialist at the regional hospital for advice on a course of action. For this, the surgical specialist accesses the images and preliminary report and reviews them in order to propose, on the phone, a course of action for the patient. This use case is further analyzed in this profile.

3. **Clinical Consult**. A general practitioner performs a routine imaging referral, reviews the shared imaging report and chooses to send the patient for evaluation by a specialist (e.g., an oncologist). The specialist needs access to the imaging report and full image set

produced at the imaging facility where the patient had been sent by his general practitioner to perform the examination. This use case is further analyzed in this profile.

4. **General imaging record access**. A patient relocates or decides to change her physician. The new physician needs to retrieve relevant information from the patient record, review its content, including recent labs and imaging studies. A similar situation occurs when a patient is admitted for an emergency and timely access to the patient's past information is required, including prior imaging studies. This use case is further analyzed in this profile.

This profile describes the information sharing transactions for care-delivering systems to publish a patient's imaging diagnostic documents (EHR-CR) for sharing across enterprises as longitudinal patient care records (EHR-LR). The policies or administrative details regarding the sharing of imaging information are for the most part not explicitly discussed so as not to obscure clinical needs. Administrative variations between countries and regions are expected, and can be added or modified without losing the clinical information-sharing context.

Since the focus is on the sharing and access to patients imaging records rather than the entire workflow in which such information sharing takes place, other activities are described as though they are being done by telephone, paper mail, fax, etc. In an integrated electronic environment these other activities may be more automated, but those details are separate from the records access/sharing and are to be addressed by separate integration profiles.

18.3.2 Assumptions

The imaging information needs to be shared between multiple care delivery organizations (information sources and consumers), each (typically) with its own RIS and PACS. The point of service ("POS") for physicians may be supported by a variety of systems: hospital EMR, physician practice system, PACS viewers, EHR web application, etc.

The concept of sharing information across enterprises that have agreed to join in such a health information network is based on basic design principles that can be summarized in the following points:

1. A group of healthcare enterprises have agreed to work together using a common set of policies and to share a common infrastructure of repositories and a registry for an affinity domain.

2. Information sources (e.g., EHR, lab system, PACS) select the "documents" they wish to share.

3. Documents may include any information in an agreed format (e.g., a PDF document, a DICOM manifest, etc.). Documents are stored in multiple document repositories.

4. Shared documents are registered with a central service called a document registry that tracks only indexing information and the location from which documents may be retrieved.

5. Information consumers may query this well-defined unique/singular indexing service (document registry) to find the document index information for any patient and the location from which documents may be retrieved (document repositories).

3920   6. Information sources remain the owner of the documents shared in repositories and, thereby, remain responsible for replacing or deprecating its documents if necessary.

In each one of the use cases, it is assumed that the people and the information systems that participate in a single "Affinity Domain" have agreed upon mechanisms to address:

- Governance: operational structure, data stewardship, etc.

3925
- Privacy: consent management and data masking controls

- Security: Authorization and authentication, network security, audit trails, etc.

- Normalized patient ID schemes: MPI (Master Patient Index), unique information IDs, etc.

- Coded Vocabularies used for registry information

18.3.3 Use cases

3930 **18.3.3.1 Routine Imaging Referral Use Case**

This scenario describes imaging information sharing in a typical patient referral and reporting use case where:

- An examination is performed upon the request of a referring physician:

3935
- The referring physician accesses the regional health information network and reviews the report along with the key images and may optionally access the full image set that made the study.

This scenario is characterized by all the information being provided for sharing at one time, as a single logical unit, when the imaging study is completed by the radiology enterprise (i.e., a single "document submission set").

3940 **18.3.3.1.1   Process Flow**

Figure 18.3.3-1 highlights the people and systems participating in this regional health information network, including:

- *Physician Office*: A referring physician working out of a private office with a physician practice system for access to information

3945
- *RIS/PACS Enterprise A*: A radiology enterprise with modality equipment and a RIS/PACS to manage report and imaging information: Radiology Enterprise A

- *RIS/PACS Enterprise B*: Another radiology enterprise with a RIS/PACS to manage report and imaging information: Radiology Enterprise B

- *Document Registry*: A document registry that serves as the information index for the regional health information network

3950

In the process flow description, steps that pertain to information sharing are shown in bold (and numbered). In contrast, the steps that do not pertain to the focus of information sharing are

shown in italic (and not numbered). These steps are expressed to ensure a more complete context.

3955   Figure 18.3.3-2 shows the transaction diagram for this process flow.

Exam is ordered

The Referring Physician orders the examination and the patient goes to the Imaging Department: Radiology Enterprise A.

3960   This is well-understood workflow that may be executed using any combination of paper, faxes, telephone, and electronic communications. It may or may not be addressed using the IHE Scheduled Workflow Integration Profile.

Although this step is part of the use case, it is peripheral to the specific steps for sharing of imaging of information.

3965   **Step 1: Obtain Relevant Prior Imaging Information**

- The PACS at Radiology Enterprise A, where the acquisition and reporting are performed, does a query of the Document Registry to identify relevant prior images and reports. It should be noted that the determination of what is relevant is the responsibility of the consumer and not the registry.

3970   - The PACS at Radiology Enterprise A retrieves prior imaging information from a repository in another radiology enterprise within the regional health network: Radiology Enterprise B, in preparation for study acquisition and subsequent reporting
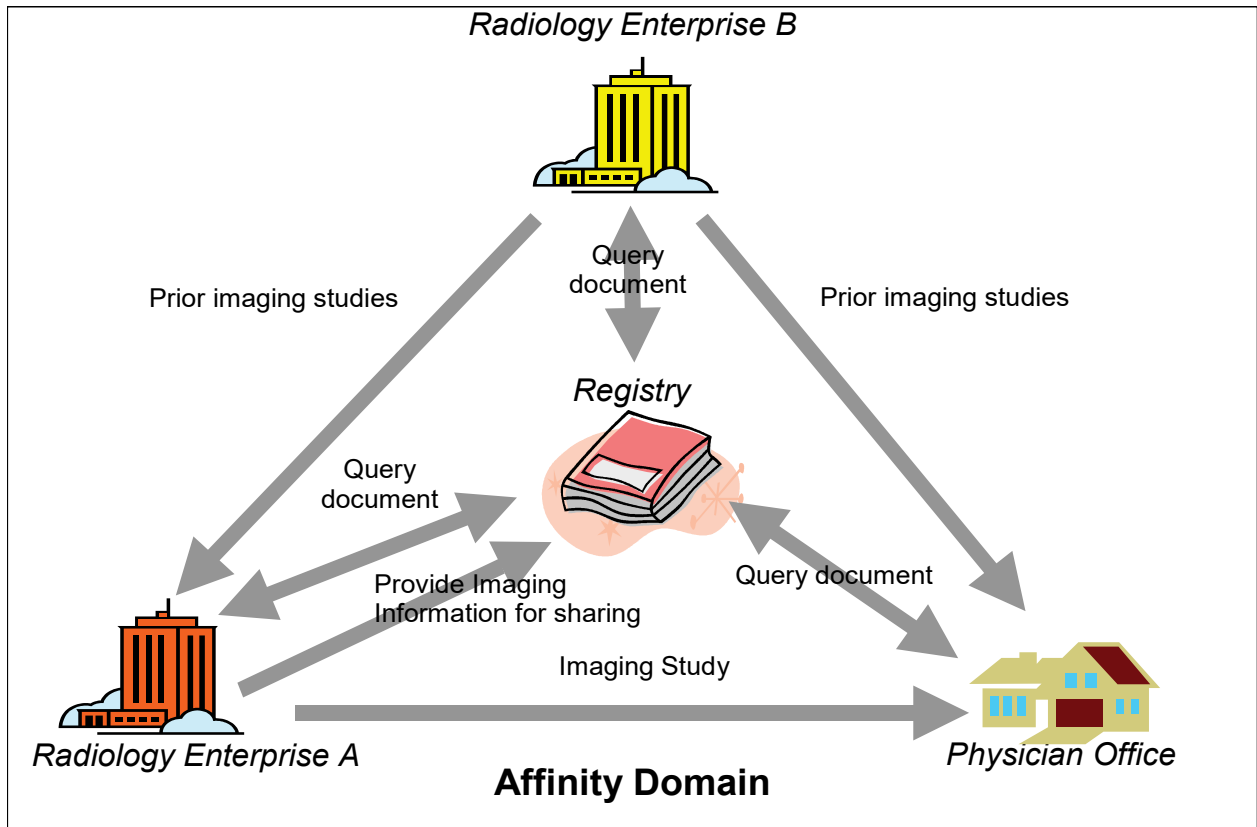
Figure 18.3.3-1: Data Flow within the Regional Health Network for a Routine Imaging Referral

Exam is Acquired and Reported

Images are sent from the modality to the PACS. This is well-understood workflow described in the SWF Profile.

The study is reported. This is well understood workflow that is managed by systems within Radiology Enterprise A,

Step 2: Share Imaging Information within the Regional Health Network (Affinity Domain)

- The PACS at Radiology Enterprise A, serving as an "Imaging Document Source", provides imaging information to the document repository, which may include:

  - Acquired DICOM images

  - Final report encoded as DICOM Structured Report

  - Key Image Notes and annotations, encoded as DICOM Key Object Selections and Grayscale Presentation States respectively.

- The document repository then registers metadata for these documents in the registry.

Step 3: Obtain and Display Study Results

- A physician practice system in the Physician's office, serving as a document consumer, queries the Document Registry in the regional health network. This query may be triggered by the patient's next appointment, a call from the patient to the physician's secretary, an electronic notification that the examination's result is available (using the IHE ITI Notification for Document Availability Profile), etc.

3995

- The physician practice system presents a list of imaging information available for the patient

- The referring physician selects the study results and relevant prior studies and reports

4000

- The physician practice system in the Physician's office, serving as an Imaging Document Consumer, retrieves the selected documents from the RIS/PACS Document Repositories in the regional health network and displays them to the referring physician.

Referring Physician reviews the results

The Referring Physician reviews the results of the examination: the report and images from the RIS/PACS in Radiology Enterprise A, and the results of prior examinations: reports and images

4005   from the RIS/PACS in Radiology Enterprise B
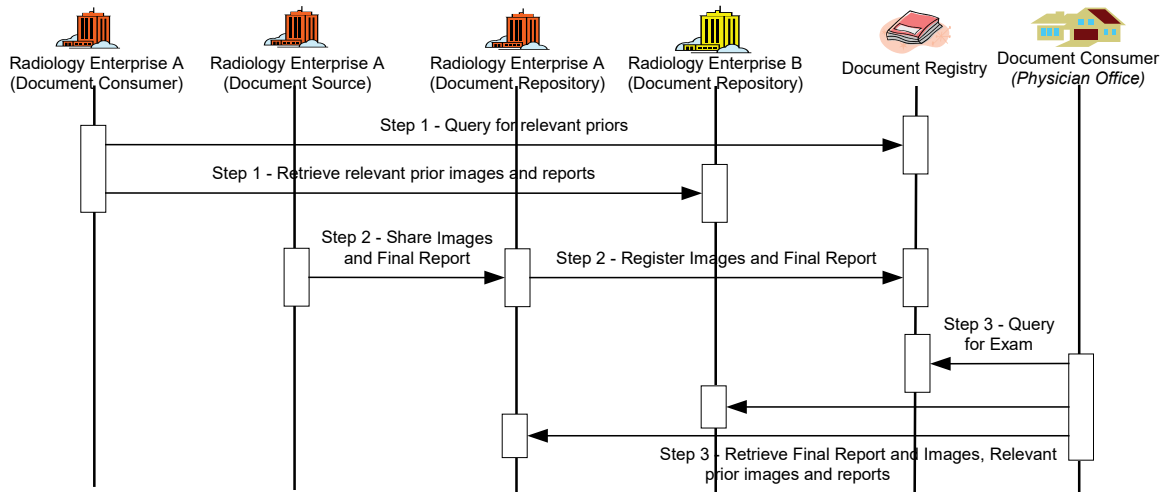
Figure 18.3.3-2: Process Flow – Routine Imaging Referral Use Case

18.3.3.2 Course of Treatment Consult Use Case

4010   This scenario is a variation on the routine imaging referral use case in that an addendum is generated after completion of the final report. As such, this scenario is characterized by information being provided for sharing at two separate times while ensuring that the initial information is supplemented by the addendum report.

The use of addendum reports is commonly encountered in a course of treatment consultation where:

4015

- An ER physician orders an exam, and the study is acquired in the affiliated radiology department.

- A department radiologist creates and shares a report as well as identifies key images and annotations.

4020
- A remotely located surgical specialist, at the request of the ER physician, reviews the report along with key images and the full study, and provides a consult to the ER physician (this use case does not constrain the method for communicating the results of the consult, e.g., phone, fax, etc.).

- The radiologist identifies additional information and completes an addendum to the initial report.

4025 Note that the scenario where the radiologist seeks an opinion from a more senior radiologist is similar to this use case.

18.3.3.2.1 Process Flow

The process flow description and steps are as for the routine imaging referral, but with the following variations (shown in bold):

4030 *Exam is ordered*

Step 1: Obtain Relevant Prior Imaging Information

Exam Acquisition and Reporting

Step 2: Share Imaging Information within the Regional Health Network (Affinity Domain)

4035
- The PACS at Enterprise A, serving as an "Imaging Document Source", provides imaging information to the document repository, which may include:

  - Acquired DICOM images

  - Final Report encoded as DICOM Structured Report

  - Key image notes and annotations, encoded as DICOM Key Object Selections and Grayscale Presentation States respectively.

4040
- The document repository then registers metadata for these documents in the registry

Step 3: Obtain and Display Study Results

ER Physician reviews the results

Step 4: Share Addendum to Report within the Regional Health Network (Affinity Domain)

4045
- Sometime later on, the radiologist creates an addendum to the initial report. This addendum is transcribed into the RIS at Enterprise A and signed off by the radiologist. This addendum must now supplement the initial report.

- The RIS at Enterprise A performs a document query of the document registry for the first submission set.

4050
- The RIS at Enterprise A, serving as a "Imaging Document Source", provides the addendum for sharing to the document registry including the content of the first submission set and declaring the new document as an addendum to the initial report.

Figure 18.3.3-3 shows the transaction diagram for this process flow.
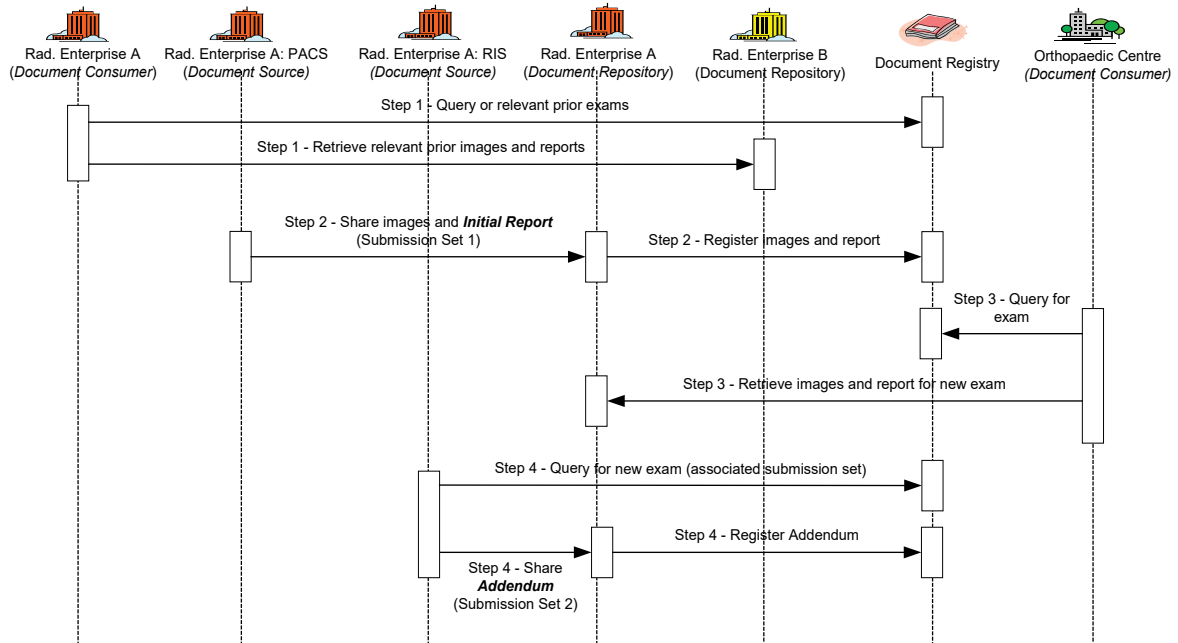
4055 **Figure 18.3.3-3: Process Flow – Course of Treatment Consult Use Case**

18.3.3.3 Clinical Consult Use Case

This scenario is an extension of the routine imaging referral use case in that a consult report is generated based from the original imaging exam and radiologist report. As such, this scenario is characterized by information being provided for sharing at <u>two separate times by two separate</u>
4060 <u>source systems</u>.

The reports shared in this use case are based on the same initial imaging exam. However, the reports are generated by different people and registered by different systems.

The generation of consult reports is commonly encountered in cancer treatment. As such, the following clinical consult use case is used to describe the scenario:

4065
- A general practitioner performs a routine imaging referral (as per Use Case 1).

- In reviewing the imaging exam report from the radiologist, the practitioner chooses to send the patient to an oncologist for a consultation.

- The oncologist, located at a Cancer Center, reviews the report along with key images, the full study, and past imaging information records for the patient

4070
- The oncologist generates an additional report that is made available to the general practitioner

- The general practitioner reviews the oncologists report and takes appropriate treatment action

18.3.3.3.1   Process Flow

4075   Figure 18.3.3-4 highlights the people and systems participating in this regional health information network. These are the same as for the routine imaging referral but with one additional participant:

- *Physician Office*

- *RIS/PACS Enterprise A*

4080
- *RIS/PACS Enterprise B*

- *Document Registry*

- *Oncologist*: An oncologist working out of a cancer center: Cancer Center. This center has an Electronic Health Record (EHR) application that serves as the POS application for reviewing imaging information within the regional health network. The EHR application

4085   has DICOM Viewing capabilities.
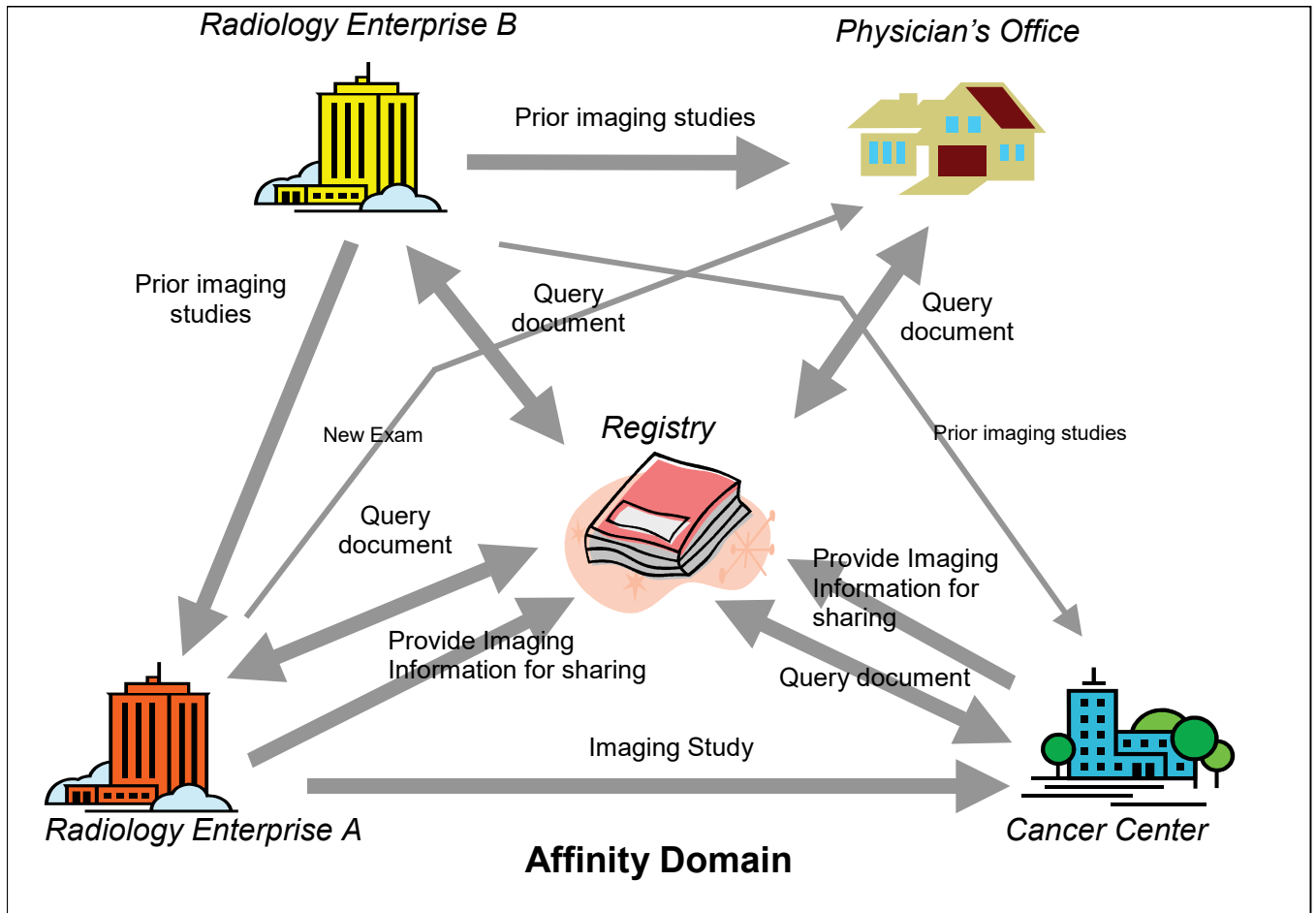
Figure 18.3.3-4: Data Flow within the Regional Health Network for a Clinical Consult

4090 The process flow description and steps are as for the routine imaging referral, but with certain variations. The variations that pertain to information sharing are shown in bold (and numbered). In contrast, the variations that do not pertain to the focus of information sharing are shown in italic (and not numbered).

Exam is ordered

Step 1: Obtain Relevant Prior Imaging Information

4095 *Exam Acquisition and Reporting*

Step 2: Share Imaging Information within the Regional Health Network (Affinity Domain)

Step 3: Obtain and Display Study Results (General Practitioner)

- This is identical to Step 3 in the routine imaging referral use case

- Based on the radiology report, the general practitioner determines that a consult with an
4100 oncologist is required

Step 4: Obtain and Display Study Results (Oncologist)

4105

- The EHR application in the oncologist's office, serving as a document consumer, queries the document registry in the regional health network. This query is triggered by a consult request from the general practitioner via paper, fax, phone, and/or electronic notification. The EHR application presents a list of imaging information available for the patient, including the most recent exam completed at Radiology Enterprise A

- The oncologist selects the exam reported by the radiologist as well as a number of relevant prior exams

4110

- The EHR application in the oncologist's office, serving as an Imaging Document Consumer, retrieves the documents selected from the RIS/PACS document repositories in the regional health network and displays them to the oncologist

- The oncologist reviews the images using image manipulation tools such as window level, zoom, pan, invert, measurement, etc. The oncologist may also apply 3D rendering such as multi-planar reformatting

4115 *Oncologist Generates Consult Report*

- The oncologist reviews the results of the examination along with prior exams

- The oncologist generates a consult report

Step 5: Share Consult Report within the Regional Health Network (Affinity Domain)

4120

- The EHR application in the oncologist's office, serving as an "Imaging Document Source", provides the consult report to the document registry for sharing. This has reference to the original imaging exam, which was used during the consult.

Figure 18.3.3-5 shows the transaction diagram for this process flow.
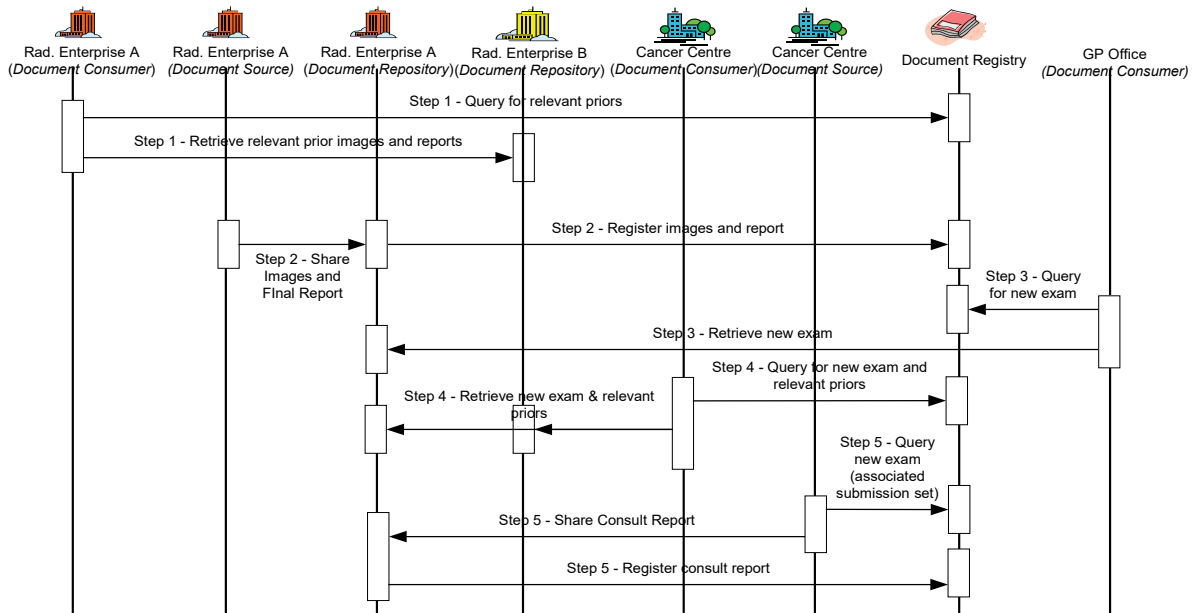
4125
Figure 18.3.3-5: Process Flow – Clinical Consult Use Case

18.3.4 Queries

As presented in the use cases, human or machine users may query the Registry to identify documents that they may retrieve in a subsequent step. The type of query attributes may vary between users or query scenarios, depending on the intent of the query. For instance, human
4130 users often wish to query specifically, restricting the search by several query attributes and values.

The following query attributes are relevant (but not exhaustive):

- Patient Identity – The patient is expected to be identified by Patient ID

- Exam Identity – The physician is looking for a specific exam. The attributes used to
4135 identify the exam may include one or more of the following:

  - Date

  - Modality

  - Body part/anatomical region

  - Document type – images, diagnosis, progress report, preliminary report, etc.

4140 - Author – in the case of reports, the physician may well identify the report by its author i.e., the radiologist and / or specialist

The metadata in the query response needs to be sufficient to allow the system consumer to parse the response and identify relevant priors. Relevant metadata includes (but is not limited to):

- Exam date

4145
- Modality
- Body part/anatomical region
- Procedure code

18.4 Intentionally left blank

18.5 Patient Information Reconciliation

4150   These considerations can be found in RAD TF-1x: Appendix G.

18.6 Security Considerations

All XDS-I.b actors are grouped with either a Secure Node or Secure Application from the ITI
ATNA Profile; see Section 18.1.2. This grouping is required to provide the capability for
security auditing, for establishing a trust relationship between systems exchanging information,
4155   and to enable secure data exchange. Some care sites may use alternate mechanisms for providing
equivalent security.

Other security considerations can be found in RAD TF-1x: Appendix H.

19 Mammography Image Integration Profile

4160 The Mammography Image Profile specifies how DICOM Mammography images and evidence objects are created, exchanged and used. It describes how Acquisition Modalities transfer Full Field Digital Mammography (FFDM) Images, how CAD systems act as Evidence Creators, and how Image Displays should retrieve and make use of images and CAD results. It defines the basic display capabilities Image Displays are expected to provide, and which attributes should be used to implement those capabilities.

4165 Managing the process of creating, storing and using Mammography Image content is similar to workflow for other image content (e.g., see Scheduled Workflow and Post-Processing Workflow Profiles).

The Mammography Image Profile is designed to provide faithful and complete storage and retrieval of Mammography data and sufficient display functionality to allow adequate review of

4170 current and prior images and CAD results for the purpose of primary interpretation by radiologists. It should also be sufficient for secondary review for referring physicians. It does not address the use of other modalities appropriate for breast imaging such as MR or US.

19.1 Actors/ Transactions

Figure 19.1-1 shows the actors directly involved in the Mammography Image Integration Profile

4175 and the relevant transactions between them.
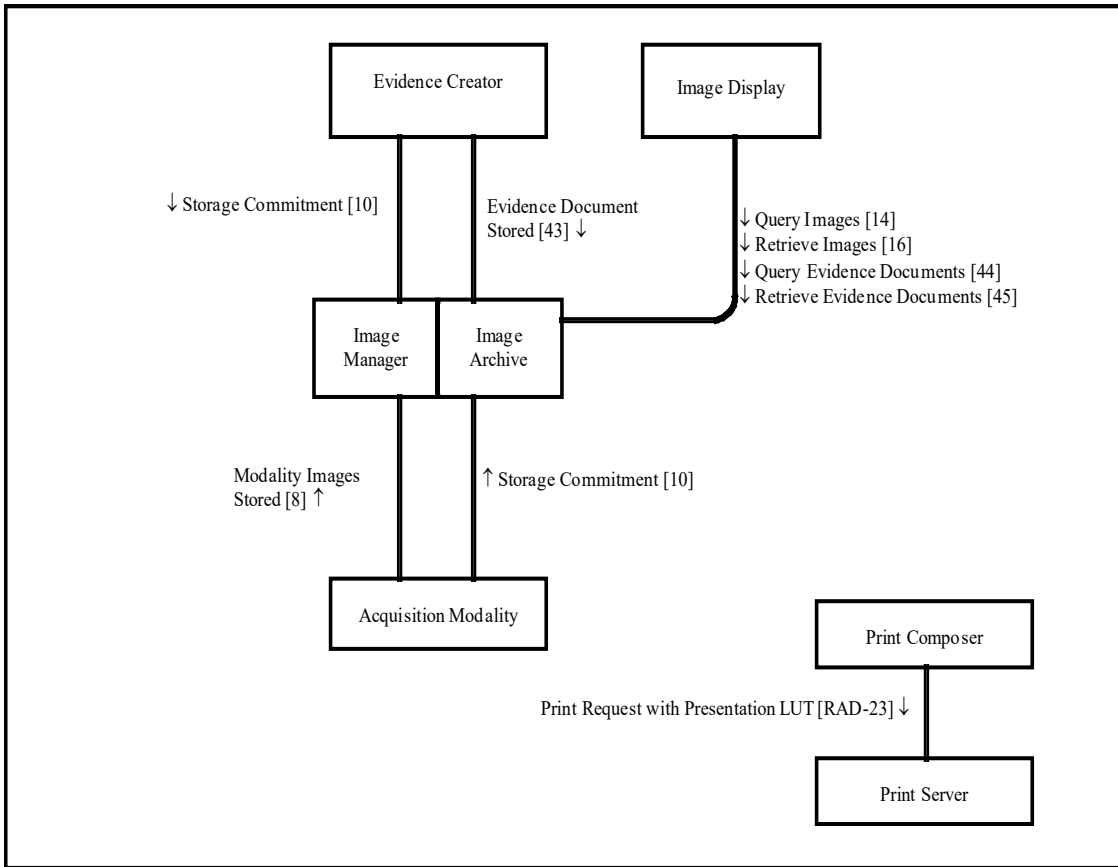
Figure 19.1-1: Mammography Image Profile Actor Diagram

Table 19.1-1 lists the transactions for each actor directly involved in the Mammography Image
4180 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 and that implementations may choose to support is
listed in Section 19.2.

Table 19.1-1: Mammography Image Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	TF Reference
Acquisition Modality	Modality Images Stored [RAD-8]	R	RAD TF-2: 4.8
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
Evidence Creator	Evidence Document Stored [RAD-43]	R	RAD TF-2: 4.43
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
Image Manager/Archive	Modality Images Stored [RAD-8]	R	RAD TF-2: 4.8
	Evidence Document Stored [RAD-43]	R	RAD TF-2: 4.43
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
	Query Images [RAD-14]	R	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	R	RAD TF-2: 4.16

Actors	Transactions	Optionality	TF Reference
	Query Evidence Documents [RAD-44]	R	RAD TF-2: 4.44
	Retrieve Evidence Documents [RAD-45]	R	RAD TF-2: 4.45
Image Display	Query Images [RAD-14]	R	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	R	RAD TF-2: 4.16
	Query Evidence Documents [RAD-44]	R	RAD TF-2: 4.44
	Retrieve Evidence Documents [RAD-45]	R	RAD TF-2: 4.45
Print Composer	Print Request with Presentation LUT [RAD-23]	R	RAD TF-2: 4.23
Print Server	Print Request with Presentation LUT [RAD-23]	R	RAD TF-2: 4.23

4185

19.2 Mammography Image Integration Profile Options

Options that may be selected for this integration profile are listed in the Table 19.2-1 along with the actors to which they apply. Dependencies between options when applicable are specified in notes.

4190

Table 19.2-1: Evidence Documents - Actors and Options

Actor	Options	TF Reference
Acquisition Modality	Partial View	RAD TF-2: 4.8.4.1.2.3.1
Image Archive/Manager	*No options defined*	--
Image Display	Partial View	RAD TF-2: 4.16.4.2.2.1.1.7

19.3 Mammography Image Profile Process Flow
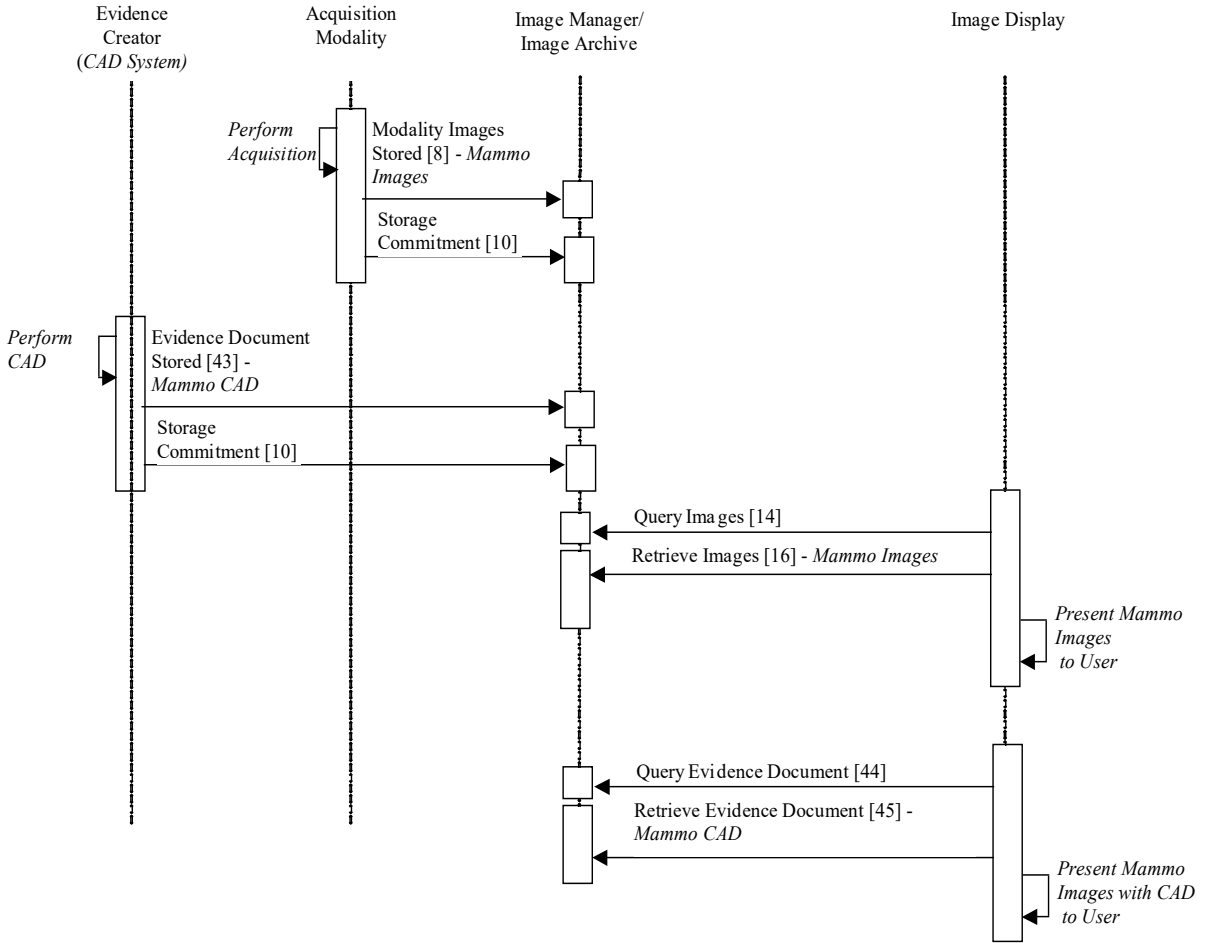
Figure 19.3-1: Basic Process Flow in Mammography Image Profile

4195 The workflow between the Acquisition Modality and the Evidence Creator that is the CAD device is currently outside the scope of IHE to define.

20 Image Fusion (FUS)

Image Fusion is a Trial Implementation Profile.

21 Import Reconciliation Workflow (IRWF)

4200

IMPORTANT NOTE: *As of June 2012, IHE introduced an updated Import Reconciliation Profile (IRWF.b) for Trial Implementation. In addition to the original use cases, several new use cases are addressed, and the underlying mechanisms are improved. The IRWF Profile documented in this section has been deprecated by the Radiology Domain and is now replaced*

4205

by the IRWF.b. When that supplement becomes Final Text, the contents of this section will be removed. In the interim, new implementations should be based on IRWF.b, found at https://profiles.ihe.net/RAD/.

The Import Reconciliation Workflow Integration Profile (IRWF) specifies both the data and workflow requirements for importing existing Evidence Objects and importing Hardcopy from

4210

an external Enterprise. Worklists and Patient Demographics Query are provided as mechanisms to provide local patient and procedure information to be used in the process of reconciling the imported patient/procedure information. Procedure Step Completed messages enable subsequent workflow steps to occur based on the importation of the Evidence Objects.

Reconciling critical patient demographics (e.g., Patient Name, Patient ID) and order/procedure

4215

Information (e.g., Accession Number) is an important part of the importation process since the local Enterprise will typically have different identifiers (for patient, orders, etc.) from the Enterprise that created the Evidence Objects or Hardcopy being imported.

When the attribute values must be changed, this Profile provides a mechanism to preserve a copy of the original values inside the imported DICOM Composite Objects.

4220

This profile also makes it possible to determine whether images, reports and other evidence objects associated with a particular import have been stored (archived) and are available to subsequent workflow steps, such as post-processing and reporting.

21.1 Actors/Transactions

Figure 21.1-1 diagrams the actors involved with this profile and the transactions between them.
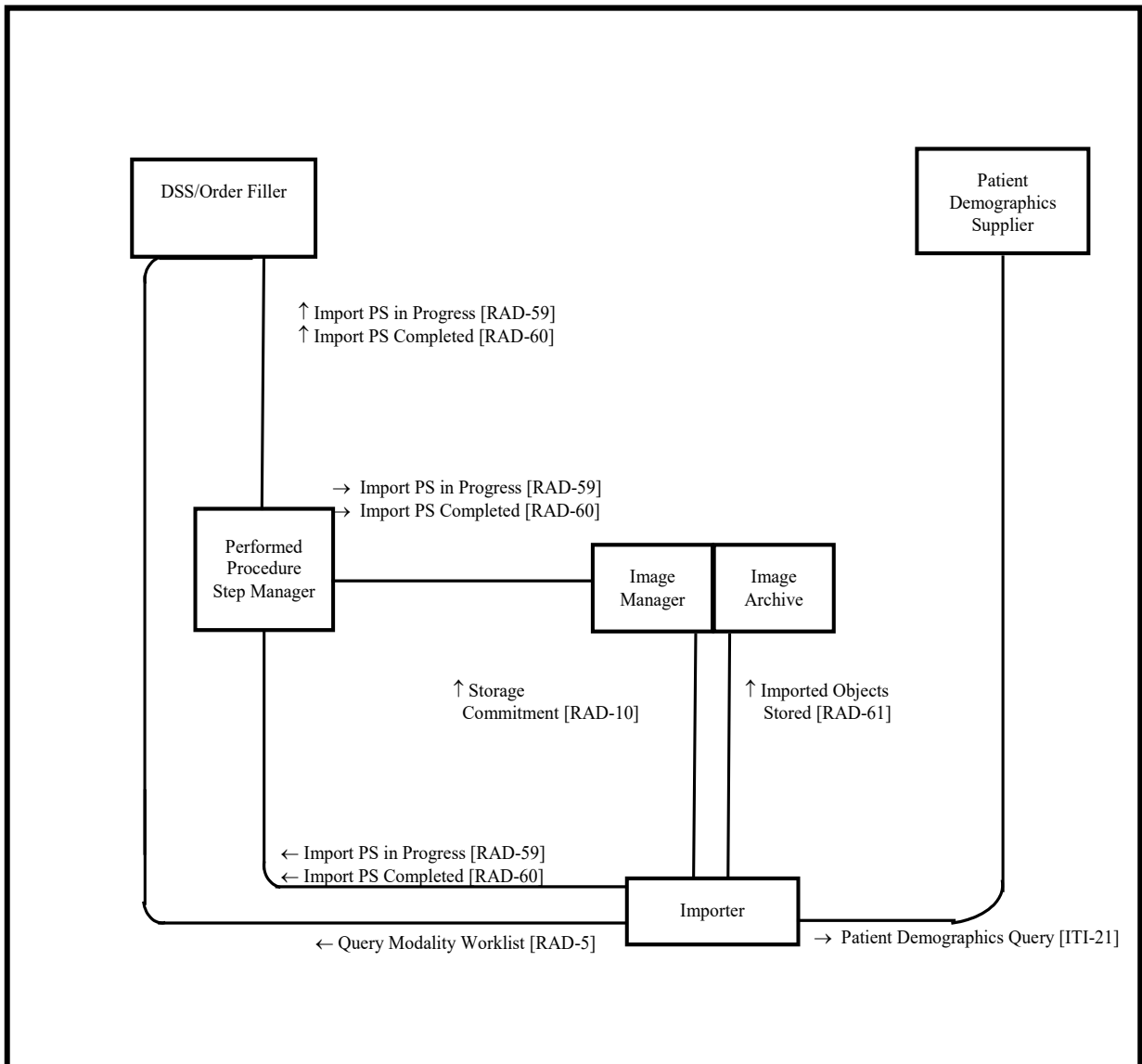
4225

Figure 21.1-1: Import Reconciliation Workflow Diagram

Table 21.1-1 lists the transactions for each actor directly involved in the Import Reconciliation Workflow Integration Profile. In order to claim support of this integration profile, Import Reconciliation Actors present in the Scheduled Workflow Profile must also support Scheduled 4230 Workflow and 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 21.2.

Table 21.1-1: Import Reconciliation Workflow Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	TF Reference
Department System Scheduler/ Order Filler	Query Modality Worklist [RAD-5]	R	RAD TF-2: 4.5
	Import Procedure Step In Progress [RAD-59]	R	RAD TF-2: 4.59
	Import Procedure Step Completed [RAD-60]	R	RAD TF-2: 4.60
Patient Demographics Supplier	Patient Demographics Query [ITI-21]	R	ITI TF-2: 3.21
Importer	Query Modality Worklist [RAD-5] (Note 1)	O	RAD TF-2: 4.5
	Patient Demographics Query [ITI-21] (Note 1)	O	ITI TF-2: 3.21
	Import Procedure Step In Progress [RAD-59]	R	RAD TF-2: 4.59
	Import Procedure Step Completed [RAD-60]	R	RAD TF-2: 4.60
	Imported Objects Stored [RAD-61]	R	RAD TF-2: 4.61
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
Image Manager/ Image Archive	Import Procedure Step In Progress [RAD-59]	R	RAD TF-2: 4.59
	Import Procedure Step Completed [RAD-60]	R	RAD TF-2: 4.60
	Imported Objects Stored [RAD-61]	R	RAD TF-2: 4.61
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
Performed Procedure Step Manager	Import Procedure Step In Progress [RAD-59]	R	RAD TF-2: 4.59
	Import Procedure Step Completed [RAD-60]	R	RAD TF-2: 4.60

4235
Note 1: The Importer shall support at least one of the Query Modality Worklist or Patient Demographics Query transactions.

Refer to Table 2-1 for other profiles that may be pre-requisites for this profile

21.2 Import Reconciliation Workflow Integration Profile Options

4240
Options that may be selected for this integration profile are listed in the Table 21.2-1 along with the actors to which they apply. Dependencies between options, when applicable, are specified in notes.

Table 21.2-1: Import Reconciliation Workflow - Actors and Options

Actor	Option	TF Reference
Department System Scheduler/ Order Filler	*No options defined*	-
Importer	Scheduled Import (Note 1)	RAD TF-1: 21.2.1
	Unscheduled Import (Note 1)	RAD TF-1: 21.2.2
	Billing and Material Management	RAD TF-2: 4.60
Image Manager/ Image Archive	*No options defined*	-
Performed Procedure Step Manager	*No options defined*	-

Note 1: The Importer shall support at least one of the Scheduled Import or Unscheduled Import Options.

The Importer 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 in the DICOM Conformance Statement.

21.2.1 Scheduled Import Option

Importers claiming the Scheduled Import Option are required to support the Query Modality Worklist transaction (see RAD TF-2: 4.5) to obtain import worklists and use the patient and procedure information provided to reconcile the imported data.

For further details of this option, refer to RAD TF-2: 4.59.4.1.2.3.1.

21.2.2 Unscheduled Import Option

Importers claiming the Unscheduled Import Option are required to support the Patient Demographics Query [ITI-21] transaction (ITI TF-2: 3.21) to obtain patient demographics for reconciling the imported data.

For further details of this option, refer to RAD TF-2: 4.59.4.1.2.3.2.

Note that the identifiers provided by the ITI Patient Demographic Supplier Actor are expected to be consistent with those that would be obtained using SWF transactions. This is necessary to ensure the synchronization of the Patient Demographics from both sources.

21.3 Integration Workflow Process Flow

This section describes the workflow related to importing DICOM data or importing hardcopy created external to the Enterprise. Import Reconciliation Workflow uses many transactions from Scheduled Workflow (see RAD TF-1: 3 or 34). In most cases there are no changes in these transactions. See RAD TF-1x: Appendix C for an overview of the information exchange between the Department System Scheduler/Order Filler and Image Manager.

Once the desired information has been imported into the local Enterprise it is up to the local institution to determine the retention policies for physical media associated with the import (e.g., films, CDs, DVDs) and the imported data itself.

21.3.1 Import Process Flow

This section describes the typical process flow for managed importation. This profile only applies to data from patients that have been registered and assumes that the patient demographics information is known and available to the local system and user. If the Patient is not registered, the data is imported and needs to be reconciled by other mechanisms such as PIR.

21.3.1.1 Use Cases

The primary use cases for importing radiology information are:

1. External Acquisition or Read: An institution has referred the patient to an external facility for acquisition, or for reading. The institution receives the acquired study on media from the external facility and imports it to the local archive.

2. External Priors: The institution receives media containing prior images and/or reports for a current patient. The data is imported to the local archive and associated with the patient's record so they can be referred to as priors during the reading of the current study.

3. Patient Referral: The institution receives media containing a patient's radiological history associated with a referral or patient transfer. The data is imported to the local archive and associated with the patient's record.

The importation may be managed in two different ways:

1. Scheduled Import: The institution schedules the import task on an importation worklist which provides the local demographics and local procedure information.

2. Unscheduled Import: The institution does not electronically schedule the import task and instead relies on the Importer to obtain local demographics from a Demographics Supplier.

In either case it is a prerequisite that the patient has been registered so that locally correct demographic information for the patients is available. Importation of "locally unknown" patients followed by Patient Information Reconciliation is not covered by this integration profile.

Importation could be performed piecewise on a physician's workstation, or batched at a central location.

The data may arrive at the institution by a variety of transport mechanisms including hardcopy (films, prints), media (CDs, DVDs) or simple network transfer. This profile does not dictate a particular transport mechanism.

For any import, there may exist information in addition to the media, which will be taken into account by the importing enterprise but its usage is not specified by IHE. This information may be available electronically, written or orally. Main examples for such information are:

- Administrative information like checklists, importation rules, workflow codes or billing items.

- Clinical information like lab reports, discharge summaries, ECGs, potentially as PDI web data.

Note that the person importing the Evidence Objects or Hardcopy can be assumed to have the most comprehensive and complete information available for the importing task. In case of exceptions, the import may need to be aborted (see RAD TF-2: 4.60.4.1.2.2 for Exception Management).

After the importation is done and the imported evidence objects are available through the Image Manager/ Image Archive (which may be indicated by an Instance Availability Notification), the enterprise may schedule subsequent steps like reading or reporting.

21.3.1.2 Scheduled Import Process Flow

4315   An enterprise internally schedules an import, e.g., associated with an external acquisition or read. There may be other scheduling items, which are not within the scope of the Technical Framework, but will be taken into account by the Enterprise:

- For external referrals, patient and order information needs to be conveyed to the external Enterprise.

4320
- Clinical information may be received in addition to the DICOM information, e.g., electronic referrals, Lab Reports, Clinical Summaries, or PDI web information.

- The importation of data is typically a scheduled event separate from how the data is used (images to be reported, historical data to be used in-conjunction with a current procedure, etc.).

4325
- The importation scheduling information may include instructions, e.g., which studies, series or images are to be imported.

The following steps can be identified in the scheduled process flow:

- Using Scheduled Workflow, the relevant study data to be imported is available in the scheduled procedure step. Note that the Patient Registration and Procedure Ordering all
4330   use the Scheduled Workflow Profile (see Sections 3.3.1, 3.3.2, and 3.3.3).

- Depending on the type of media to be imported, the procedure step can be scheduled to the appropriate Importing device (e.g., Film Scanner, PDI Workstation).

- The SCHEDULED IMPORT Option is used to import the evidence objects and reconcile the patient and procedure data (e.g., to change the recorded Patient ID to the local Patient
4335   ID) using the Modality Worklist Query. The resultant DICOM objects are stored in the PACS.

- Errors and exceptions during import are handled by using Exception Management described in RAD TF-2: 4.60.4.1.2.2.

- Subsequent steps may be

4340
- performed, such as implicit post-processing (see Section 3.3.5);

- scheduled for a Post-Processing or Reporting Workflow, probably involving the Availability Notification Option.

This process flow requires that the Patient be registered and that procedure step(s) be scheduled for the importation. Associated Patient Registration Scheduling, and subsequent Availability or
4345   Notification transactions are part of the Scheduled Workflow (see Section 3 or Section 34). The following sequence of steps describes the typical process flow for the scheduled import of patient data.
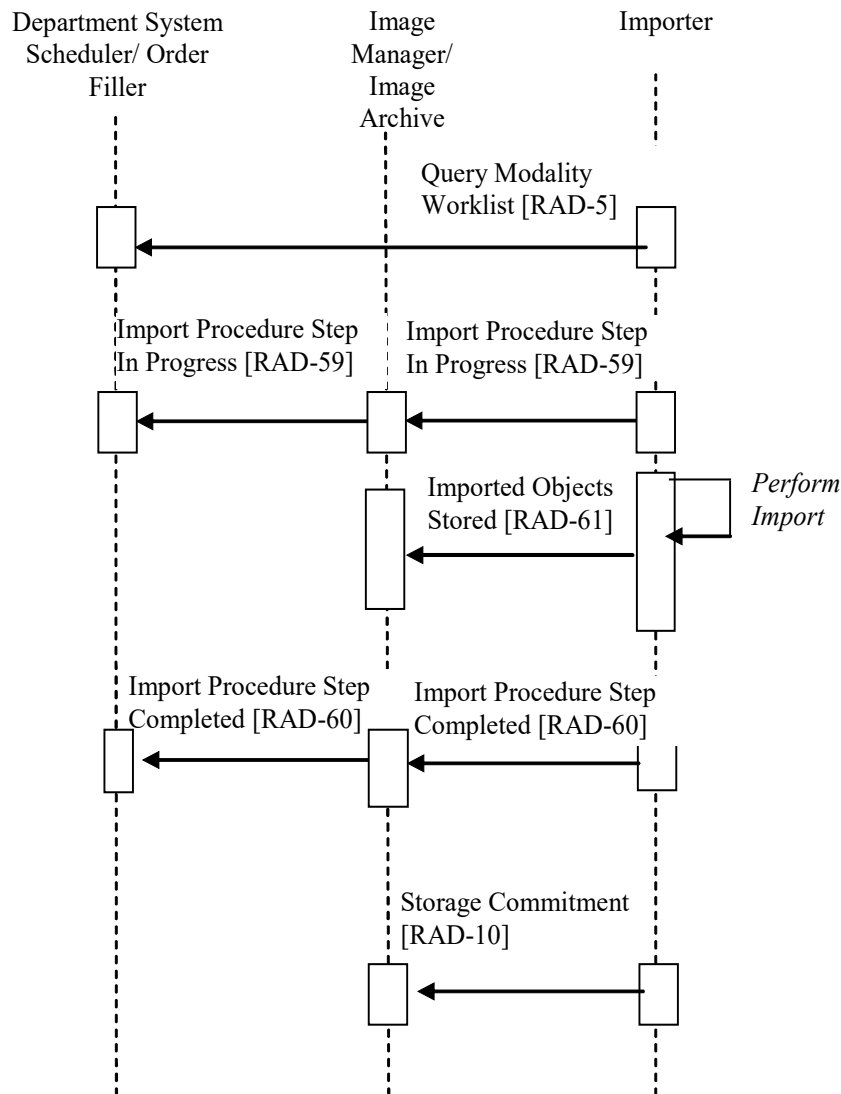
Figure 21.3.1-1: Scheduled Import Reconciliation Workflow Process Flow

4350 **21.3.1.2.1   Scheduled Import Data Reconciliation**

Importation requires that some of the Patient/Procedure information be treated differently than prescribed in Scheduled Workflow.

The Study UID provided by the Modality Worklist shall be ignored and the reconciliation rules shall be followed. As part of the import process, the Importer reconciles the patient data as
4355   needed (e.g., to change the recorded Patient ID to the local Patient ID). See RAD TF-2x: Appendix A.5 for a full list of the reconciliation requirements. The original DICOM object identifiers must be maintained in the imported DICOM Composite Objects. The policies of the importing enterprise will determine

- if demographics from the Import Data can be used (e.g., Birth Date, Patient Sex)

4360　　　• whether or how enterprise-specific codes in the imported data are coerced or ignored

21.3.1.3 Unscheduled Import Process Flow

An enterprise has received evidence objects for import that are not part of an order or scheduled procedure in one of its information systems, e.g., relevant priors prior to a consultation. There is no scheduled procedure to trigger the importation. The actual task of importation may be a
4365　batched process that does not schedule individual importations.

- Aside from the physical media (e.g., films, CDs), there may be clinical information in addition to the DICOM data in electronic, written or oral format, such as referral letters. The incorporation of this information into the Enterprise is out of scope for the Import Reconciliation Workflow Profile.

4370　The following steps can be identified in this process flow:

- The User does the import at an appropriate device (e.g., a film scanner is used to digitize films, a workstation with PDI capabilities is used to import PDI media).

- The UNSCHEDULED IMPORT Option is used to retrieve the Patient Demographics information, import the Evidence Objects and to reconcile the patient data (e.g., to
4375　change the recorded Patient ID to the local Patient ID) using the Patient Demographics Query. The resultant DICOM objects are stored in the PACS.

- Errors and exceptions during import are handled by using Exception Management described in RAD TF-2: 4.60.1.2.2.

- The Evidence Objects are available from the PACS and may be used in subsequent
4380　scheduled or unscheduled steps, or at a later time.

This process flow requires that the Patient be registered. Associated Patient Registration, and subsequent Availability or Notification transactions are part of the Scheduled Workflow (see Section 3 or Section 34). The following sequence of steps describes the typical process flow for the unscheduled import of patient data.

　　　　Copyright © 2024: IHE International, Inc.
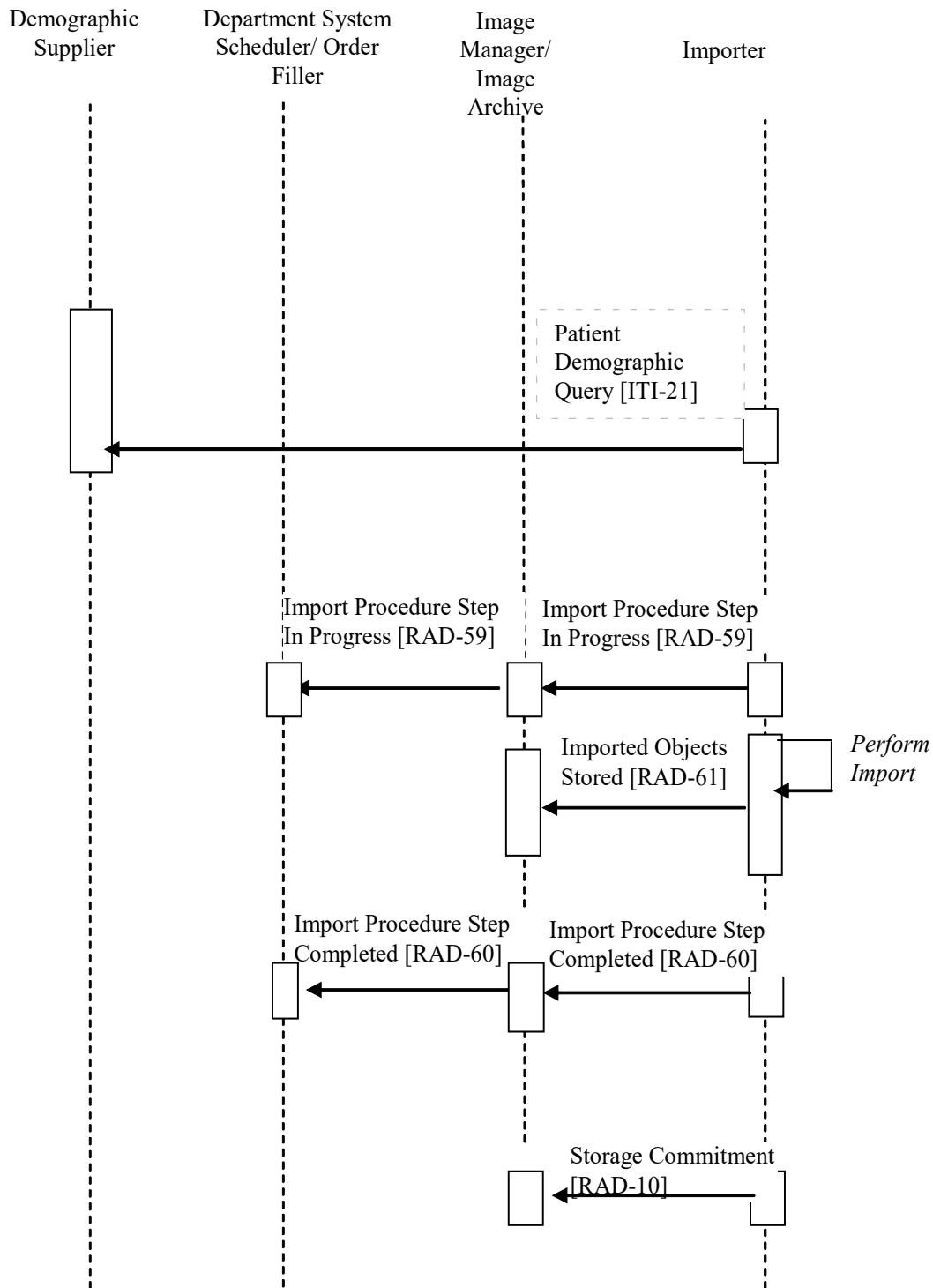
Figure 21.3.1-2: Unscheduled Import Reconciliation Workflow Process Flow

4385

21.3.1.3.1 Unscheduled Import Data Reconciliation

As part of the import process, the Importer reconciles the patient data as needed (e.g., to change the recorded Patient ID to the local Patient ID). The original DICOM object identifiers must be maintained in the imported DICOM Composite Objects in order to maintain the relationship of the Images within the Study (see RAD TF-2x: Appendix A.5).

The policies of the importing enterprise will determine

- whether demographics from the Import Data can be used (e.g., Birth Dates, Patient Sex)

- whether or how enterprise-specific codes in the imported data are coerced or ignored

21.3.2 Import Exception Management Workflow

Exception management Workflow is required for Import Reconciliation Workflow. This case addresses the need to manage errors generated through the Import Reconciliation Workflow such as:

- Selection of the incorrect Scheduled Procedure Step from the Modality Worklist

- Selection of the incorrect Patient Demographics from the Patient Demographics List

- The inability to support the DICOM Composite Objects to be imported

- Equipment Failure

- Bad media

Some of these exception cases are addressed using required functionality for IHE actors in the Import Reconciliation Workflow and Scheduled Workflow Profiles, while others make use of the IMPORT PPS EXCEPTION MANAGEMENT (see RAD TF-2: 4.60.4.1.2.2). The following numbered items list exception cases that shall be supported by the actors listed in each item.

22 Radiation Exposure Monitoring (REM) Integration Profile

4410 This integration profile specifies how details of radiation exposure resulting from imaging procedures are exchanged among the imaging systems, local dose information management systems and cross-institutional systems such as dose registries. The data flow in the profile is intended to facilitate recording individual procedure dose information, collecting dose data related to specific patients, and performing population analysis.

4415 Use of the relevant DICOM objects (CT Dose SR, Projection X-Ray Dose SR) is clarified and constrained.

The Profile focuses on conveying the details of individual irradiation events. A proper radiation exposure management program at an imaging facility would involve a medical physicist and define such things as local policies, local reporting requirements, annual reviews, etc. Although this Profile is intended to facilitate such activities, it does not define such policies, reports or

4420 processing, or in itself constitute a radiation exposure management program.

The Profile addresses dose reporting for imaging procedures performed on CT and projection X-ray systems, including mammography. It does not address procedures such as nuclear medicine, radiotherapy, or implanted seeds. Administration of radiopharmaceuticals for nuclear medicine procedures (PET, general NM including planar imaging, SPECT, as well as non-imaging

4425 procedures) is addressed in the REM-NM Profile (see Section 40).

The Profile is intended to support quality assurance (QA) of the technical process (was the dose appropriate for the procedure performed). It is less suited to QA of the ordering process (was the procedure ordered/scheduled appropriate for the indications (appropriateness criteria)), or QA of the operational process (were any differences between the procedure scheduled and the

4430 procedure performed justified by the situation/equipment/patient and appropriately approved).

Background

In the vast majority of medical procedures involving radiation, the potential benefit to the patients' health far outweighs the potential risk, but the trade-off should not be overlooked, and technological mechanisms can facilitate a conscious evaluation of that trade-off.

4435 Estimating radiation dose delivered to patients for medical purposes can facilitate a number of important activities:

- For facilities exposing patients to radiation, monitoring such exposures can help ensure their policies, procedures and protocols are adequate and being followed appropriately.

4440
- For imaging physicians, monitoring such exposures can assist them in determining how changes in techniques and protocols impact radiation dose as well as image quality. This will enable them to maintain patient doses As Low As Reasonably Achievable (ALARA).

- For patients' physicians, overall data provided from monitoring such exposures can help them determine (in consultation with the imaging physician) if the benefit from the

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215

4445   diagnostic information provided by an individual examination (or additional examinations) outweigh any small risk that may be associated with the imaging exam.

- For medical physicists, having such post-procedure information available for individual patients may help them make essential patient-specific dose estimates for pregnant patients or patients exhibiting skin erythema as a result of long fluoroscopy examinations.

4450
- For professional societies and regulatory agencies, a collection of exposure data can be useful when setting or reviewing radiation dose related guidelines and regulations. Many such groups have expressed a desire to establish standards of practice or dose reference levels based on a quantitative understanding of current practice, however they have found it prohibitively difficult to collect such data.

4455
- For physicists and physicians, this kind of data can be vital to answering some of the fundamental scientific questions that remain and developing a more detailed understanding of the health impacts of radiation exposure and how it should be measured and managed.

4460 However, it is important to understand the technical and practical limitations of such dose monitoring and the reasons why the monitored values may not accurately provide the radiation dose administered to the patient:

- The values provided by this tool are not "measurements" but only calculated estimates.

- For computed tomography, "CTDI" is a dose estimate to a standard plastic phantom. Plastic is not human tissue. Therefore, CTDI should not be represented as the dose
4465   received by the patient.

- For planar or projection imaging, the recorded values may be exposure, skin dose or some other value that may not be patient's body or organ dose.

- It is inappropriate and inaccurate to add up dose estimates received by different parts of the body into a single cumulative value.

4470 Despite such limitations, interest in monitoring radiation dose estimates is clearly expressed in such documents as the European directive Euratom 97/43 and the American College of Radiology Dose Whitepaper [1]. DICOM, with advice from the IEC, AAPM, ACR, NCRP and others, developed DICOM Dose objects appropriate for radiation dose monitoring

4475 By profiling automated methods of distribution, dose information can be collected and evaluated without imposing a significant administrative burden on staff otherwise occupied with caring for patients.

22.1 Actors/ Transactions

Figure 22.1-1 shows the actors directly involved in the Radiation Exposure Monitoring Integration Profile and the relevant transactions between them. Other actors that may be
4480 indirectly involved due to their participation in other relevant transactions are not necessarily shown.
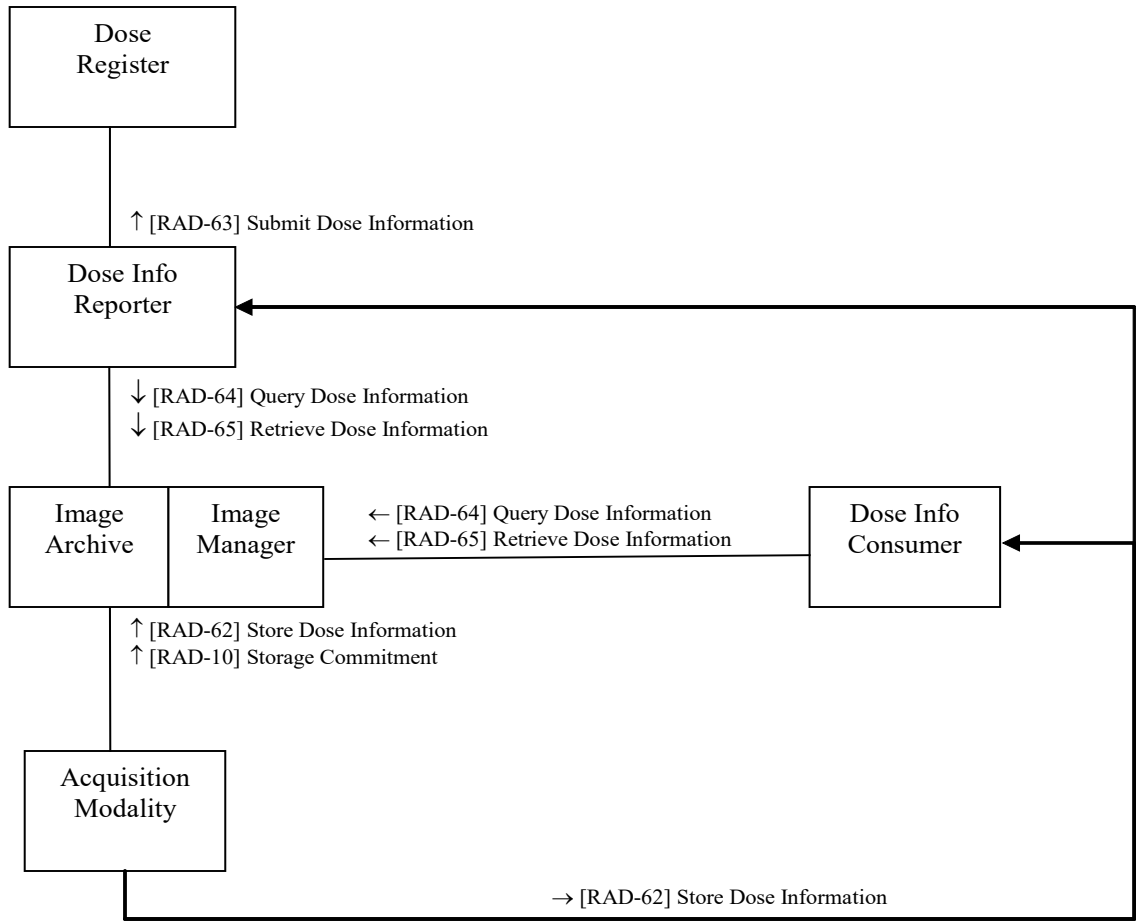
Figure 22.1-1: Radiation Exposure Monitoring - Actor Diagram

Table 22.1-1 lists the transactions for each actor directly involved in the Radiation Exposure
Monitoring 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 and that implementations may choose
to support is listed in Section 22.2.

4485

Table 22.1-1: Radiation Exposure Monitoring – Actors and Transactions

Actors	Transactions	Optionality	TF Reference
Acquisition Modality	Store Dose Information [RAD-62]	R	RAD TF-2: 4.62
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
Image Manager/Archive	Store Dose Information [RAD-62]	R	RAD TF-2: 4.62
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
	Query Dose Information [RAD-64]	R	RAD TF-2: 4.64
	Retrieve Dose Information [RAD-65]	R	RAD TF-2: 4.65

Actors	Transactions	Optionality	TF Reference
Dose Information Reporter	Query Dose Information [RAD-64]	R	RAD TF-2: 4.64
	Retrieve Dose Information [RAD-65]	R	RAD TF-2: 4.65
	Submit Dose Information [RAD-63]	R	RAD TF-2: 4.63
	Store Dose Information [RAD-62]	R	RAD TF-2: 4.62
Dose Information Consumer	Query Dose Information [RAD-64]	R	RAD TF-2: 4.64
	Retrieve Dose Information [RAD-65]	R	RAD TF-2: 4.65
	Store Dose Information [RAD-62]	R	RAD TF-2: 4.62
Dose Registry	Submit Dose Information [RAD-63	R	RAD TF-2: 4.63

4490

An Acquisition Modality in this profile might not necessarily generate the irradiation itself. An Acquisition Modality may generate Dose objects on behalf of an irradiating modality system based on irradiation details obtained by manual input and/or some proprietary method, as long as it can do so completely and correctly.

4495 Actors are encouraged to describe in their DICOM Conformance Statement additional details of how they implement specific DICOM-based transactions (e.g., the time frame in which an Acquisition Modality is able to store a Dose object relative to the completion of the irradiation event).

22.2 Radiation Exposure Monitoring Integration Profile Options

4500 Options that may be selected for this integration profile are listed in the Table 22.2-1 along with the actors to which they apply. Dependencies between options when applicable are specified in notes.

Table 22.2-1: Radiation Exposure Monitoring – Actors and Options

Actor	Options	TF Reference
Acquisition Modality	*No options defined*	- -
Image Manager/Archive	*No options defined*	- -
Dose Information Reporter	*No options defined*	- -
Dose Information Consumer	*No options defined*	- -
Dose Registry	*No options defined*	- -

22.3 Radiation Exposure Monitoring Process Flow

4505 This Profile addresses the flow of dose information from the source, through the organization and beyond. It does not mandate, but is intended to facilitate the ability to do things like:

- view the estimated dose a patient (or particular organs) received for a certain exam

- determine if the estimated dose for a given procedure, system or physician regularly exceeds some reference level, policy trigger or is otherwise an "outlier" requiring further investigation

- compute the population "dose summary" for a specific exam in a certain hospital or region

- compute the population "dose summary" for a certain pathology or indication

- compare exam-specific "dose summaries" against other sites/regions, against local policy targets or against standards of practice

Note: To summarize dose for a specific exam type or pathology, the Dose Information Reporter needs to know such details for each dose object. IHE has required that such information be provided in the dose objects as coded values so they will be machine readable. If consistent codes are present in the dose objects, they can simply be sorted or mapped by a lookup table (see RAD TF-1x: Appendix I.1.1 Code Set Management). Alternatively, a Dose Information Reporter might be grouped with a DSS/Order Filler so such details could be obtained for each Accession #. In either case, a critical task for sites wishing to do such analysis is to choose a set of codes for exam types and pathologies and to distribute and use them consistently across their systems.

22.3.1 General Case

Typically, irradiation events occur on X-ray based imaging modalities, which record them in Dose objects that are part of the same study as the images and stored to the Image Manager/Archive.

In many organizations, a Dose Information Reporter will collect Dose objects covering a particular period (e.g., today, this week or last month), analyze them, compare to site policy and generate summary reports.

All, or a sampled subset of the Dose objects might be submitted to a National Registry to facilitate composing population statistics and other research. Such Dose objects will generally undergo a configurable de-identification process prior to submission.
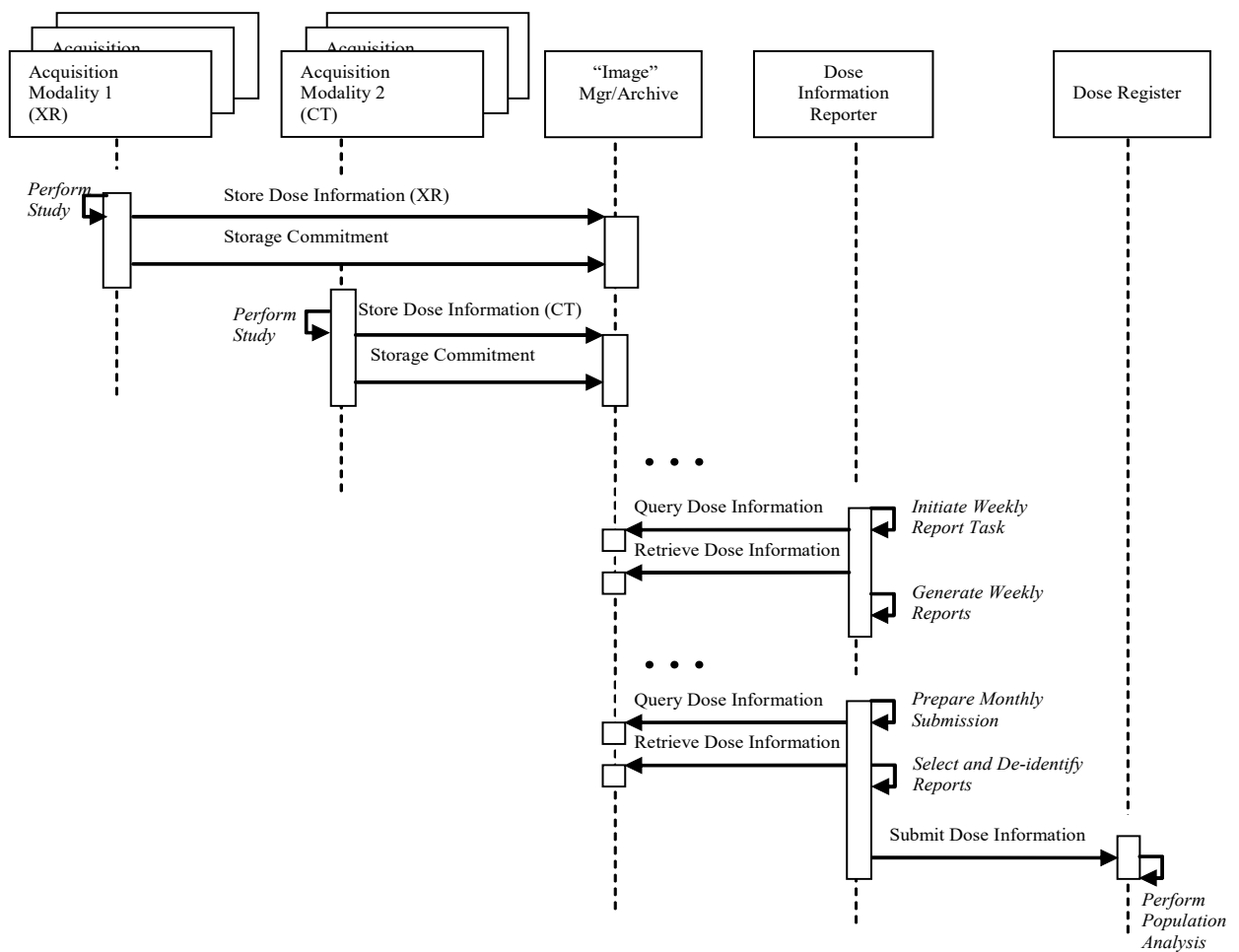
4535   **Figure 22.3-1: Radiation Exposure Monitoring – General Case**

22.3.2 Real-World Use Cases

To provide additional context for the General Case process flow, the following use cases describe real-world applications of the dose information.

22.3.2.1 Use Case: Department QA (Process Control)

4540   Data will generally be continuously collected and evaluated on all procedures. Process control and data analysis would focus on local variations attributable to x-ray equipment, operators, procedures and ordering physicians. For example:

> As part of the departmental quality improvement program, the hospital's medical physicist accesses the Dose Information Reporter to carry out his bi-monthly assessment of radiation
4545   dose. For a selected set of procedures, the dose-area product of each x-ray procedure is evaluated for each room. No significant variation of the average is found over the last 6 months. Another report compares average dose for different performing radiologists over

several interventional procedures, and a third report compares performing technologists for CT and radiographic exams.

4550   It becomes clear that for a certain interventional procedure a newly arrived radiologist tends to generate 2 to 3 times the dose-area product of his colleagues, whose averages are in a narrow cluster well below the newcomer. While the dose-area product sub-total in fluoroscopy is similar among the radiologists (and is consistent with the average fluoroscopy time of the report), there is a significant discrepancy in dose-area product for the acquisition

4555   sub-total. The number of acquired images (higher than the departmental average) also corroborates this.

The medical physicist writes a memo to the department chair, who raises the issue at the weekly radiologist meeting. Upon discussion, it becomes clear the radiologist uses a supplementary acquisition which his colleagues do not. After more discussion, the

4560   radiologists agree that the acquisition, although moderately useful, probably does not bring any information that would not be picked up in the rest of the exam, and it is agreed it should not be done. The medical physicist reviews the situation a month later, and is reassured that the results show all radiologists now have similar dose-area product for that procedure.

Hospitals generally have policies relating to patient radiation dose, often benchmarking

4565   performance estimates against published reference levels. Policies (and reference levels) are often broken down by procedure, patient age group, and perhaps weight group, or gender.

Analysis tools can help sites monitor whether policies are being followed, and measure progress toward improvement targets. While image quality generally sets the low side limit on dose (too low and the images are unacceptable to the radiologists), QA programs can be an effective way

4570   to counter dose creep, establish upper trigger levels and encourage lower values.

22.3.2.2 Use Case: Patient Impact Evaluation

A few days after a CT exam is carried out for a young female patient, the referring physician identifies the patient as pregnant (which was not known at the time of the scan). The referring physician requests an evaluation of the risk to the fetus from the radiologist who read the exam.

4575   The radiologist requests a hospital medical physicist to provide an estimate of the radiation dose received by the uterus in the course of the CT exam.

The medical physicist retrieves the images and dose data for the study in question, and determines with the help of the radiologist which series encompass the uterus. Knowing which series are of interest, the medical physicist is then able to leverage the dose indicators and weight

4580   of the patient contained in the dose and image objects to estimate the total dose to the uterus.

How the information is recorded and distributed will vary, but in this particular hospital, the dose estimate is then provided to the clinical coordinator of the department, who enters it in the RIS, appending a statement to the report (which had already been signed off), and demoting the status of the study to "pending signature". Before signing off the report, the radiologist completes the

4585   addendum with her estimate of the risk to the fetus given the dose measurement, and communicates this result by phone to the referring physician, who also receives the written addendum electronically signed by the radiologist a few days later.

Important analysis details include time/date of scans, body area irradiated, exposure values.

22.3.2.3 Use Case: Population Dose and Dose Indicators

4590 Organizations wishing to assess Population Dose and Dose Indicators will often set up a Dose Registry. A sampling of dose estimates with reasonable accuracy are collected from a number of clinical sites, often for specific targeted procedures. It is not necessary that every procedure performed be collected; a representative sample of procedures is sufficient. That being said, it may be easier for a dose registry to discard a portion of the procedures submitted than to try and 4595 get each submitting site to follow the same regimen for selecting procedures to submit.

Note that conversion of estimated dose values to patient or population risk involves complex scientific questions. Streamlining the collection of additional, more detailed data can only help.

For further discussion, see RAD TF-1x: Appendix I – Deployment of Dose Registries.

22.3.2.4 Use Case: Dose Reference Levels

4600 Quantitative Dose Guidelines are often distributed in the form of Dose Reference Levels for typical procedures for groups of patients of different characteristics (e.g., a target dose level to stay below for adult head studies).

Such guidelines are often the logical result of analyzing Population Dose or other data mining performed by a professional society or regulatory body.

4605 ### 22.3.2.5 Use Case: Site Benchmarking

Imaging facilities may find it useful to compare their dose profile by modality, exam type, and pathology to other facilities of the same type, facilities in the same region, and to the nation as a whole. A national radiation dose registry might provide facilities submitting data with reports comparing them to regional and national benchmarks.

4610 ### 22.3.2.6 Use Case: Population Epidemiology

To analyze certain population epidemiology questions, e.g., the occupational hazards of being a radiologist, one has patients with a known disease and would like to use the patients' radiation history to estimate the likelihood of radiogenic etiology. Requirements include access to a complete radiation history of each such patient. Because of long latent periods, data must be 4615 archived in a manner that makes it both physically readable and dosimetrically intelligible years, or decades, after it is written.

22.3.2.7 Use Case: Clinical Trials

The radiation dose can be an important component of a clinical trial. For example, a trial of a proposed low-dose CT lung screening procedure would benefit from being able to collect dose 4620 data to balance against the resulting detection rates for a proper trade-off analysis. Co-submission of image and Dose objects could facilitate this.

22.3.2.8 Use Case: Procedure Operational Awareness (Quasi-realtime)

Some regulations already require that $K_{a,r}$ be displayed on fluoroscopy systems within sight of the primary operator. This permits the operator to factor radiation effects into the continuous clinical benefit-risk analysis occurring during any procedure (keeping in mind that $K_{a,r}$ is not the same as cumulative skin dose). Such direct display can be handled by the modality and has no need of the transactions provided by this profile.

22.3.2.9 Use Case: Clinical Management

Dose estimates and dose estimate maps can facilitate planning for subsequent procedures (such as deciding how much time to allow for tissue to heal, or deciding what direction to image from to avoid damaged tissues). Particularly for interventional fluoroscopy, the dose distribution delivered by each procedure should be part of the patients' medical record.

22.3.2.10 Use Case: Longitudinal Patient Dose Record

The lifetime radiation dose received by a patient can be stored and retrieved from a longitudinal record, whether it is stored as part of the entire patient history, or as a separate entity. This may in future form a vital source of information for clinical decision-making with respect to the appropriateness and risk of an additional procedure, as well as remediation in the event of an unfortunate outcome. As methods evolve for estimating effective dose to radio-sensitive tissues and quantifying cancer risk, these can be retrospectively applied to stored dose information. This use case is distinct from registry use cases, since the goal is to track the individual, rather than population, dose. It is distinct from the Clinical Management use case, since it spans a longer term, multiple episodes of care and multiple sites.

This use case necessarily requires support of acquisition and collation of dose information from multiple acquisition sites, since a patient may be provided healthcare at many sites over their entire life time.

22.3.3 Example REM Profile Deployments

These examples are intended to illustrate a few ways the Radiation Exposure Monitoring Profile might be deployed inside a hospital or clinic. It is not intended to be normative, or to show all possible deployments. Further practical examples related to the use of a Registry appear in RAD TF-1x: Appendix I.

22.3.3.1 A Hospital Scenario

The Radiology PACS would perhaps implement the Image Manager/Archive in this profile and also the PIR, SWF Profiles.

The RIS might implement the Dose Information Reporter in this profile and be grouped with a DSS/Order Filler supporting the SWF and PIR Profiles.

A Dose Mapping Workstation might implement both the Dose Information Consumer (to obtain Dose objects) and the Evidence Creator (to submit new ones).

4660   Perhaps Cardiology has a separate PACS which also implements an Image Manager/Archive for the cardiology modalities. The Dose Information Reporter (in the Radiology RIS) could query both Archives and manage dose for the hospital in one place.

22.3.3.2 An Imaging Clinic Scenario

Many imaging clinics will have a PACS and could follow a similar layout to the Hospital above.

Alternatively, a PACS-less clinic which decides they do not need long term archiving or reconciliation of the Dose objects might not have an Image Manager/Archive.

4665   The Office Management System or a standalone workstation could implement the Dose Information Reporter, and takes advantage of its ability to receive Dose objects directly from the local modalities.

22.3.3.3 A Longitudinal Patient Record Scenario

4670   Multiple sites, including hospitals and imaging clinics, implement Acquisition Modalities and/or Image Manager/Archives that provide information in response to queries from a local Dose Information Reporter.

The local Dose Information Reporter transmits identifiable (as opposed to de-identified) dose information to a remote Dose Register nominated by the patient to act as their lifetime repository of longitudinal dose information. Each local site may use different forms of the patient's name
4675   and different domains for patient identifier, and accordingly the Dose Information Reporter should include multiple identifiers for different domains, and/or regional or national identifiers, if known, and the Dose Register may need to be grouped with a PIX Manager or similar mechanism to resolve identities. See also the issues raised in the Multiple Image Manager/Archive (MIMA) Trial Implementation supplement.

4680   If the remote Dose Register is grouped with its own Dose Information Reporter, then given the appropriate authorization by the patient, another local site with a Dose Consumer may access the information to make clinical decisions.

Additionally, if remote Dose Register and/or Dose Information Reporter is also capable of modeling effective dose using organ segmentation information, it may want to receive and store
4685   the images reconstructed from the irradiation events described in the dose objects, and hence to be grouped with a remote Image Manager/Archive Actor.

22.4 Radiation Exposure Monitoring Profile Security Considerations

Dose Objects have the same security considerations as images.

Security and Privacy policies may require the de-identification of some or all of the PHI details
4690   prior to the submission or use of Dose Objects (see RAD TF-2: 4.63.4.1.2.1). De-identification behavior may need to vary by destination due to differences in PHI exposure risk and the need to retain some details, such as approximate patient age or weight, when performing Radiation Dose analysis.

22.5 Cross-Profile Considerations

4695 Several synergies and interactions of the Radiation Exposure Monitoring Profile with other profiles are specifically called out here.

22.5.1 Radiology Profiles

22.5.1.1 Portable Data for Imaging (PDI)

4700 The Dose objects from this profile may be included on PDI media, either along with the rest of the study data to provide a "complete package", or on their own as a way of conveying Dose objects to a patient, another organization or a dose registry.

22.5.1.2 Patient Identification Reconciliation (PIR)

An Image Manager/Archive which also implements the Patient Identification Reconciliation Profile is expected to reconcile the Dose objects along with the rest of the DICOM objects in a
4705 patients' study. This is highly desirable.

22.5.1.3 Teaching Files and Clinical Trials Export (TCE)

As DICOM objects, the Dose objects can be referenced in a TCE manifest and processed along with other objects from a study. This could allow submitting dose details in clinical trials where such information is relevant, or including dose details in a teaching file, perhaps one specifically
4710 addressing protocol dose and the effects on image quality.

22.5.1.4 REM for Nuclear Medicine (REM-NM)

REM for Nuclear Medicine is closely related to REM. Actors supporting REM may consider also supporting REM-NM (see RAD TF-1: 40).

22.5.2 ITI Profiles

4715 #### 22.5.2.1 Patient Identity Cross-referencing (PIX)

The PIX Profile could clearly be useful if there is a need to collate patient dose records across multiple Patient ID Domains. It could also be useful if a single Dose Information Reporter is querying multiple Image Manager/Archives in different Patient ID Domains.

22.5.2.2 Cross-Enterprise Document Sharing (XD*)

4720 Since Dose objects are normal DICOM SR objects, the collection of XDS Profiles (XDS, XDS-I, XDR, XDM, etc.) can be used to distribute or access dose records across multiple sites.

22.5.2.3 Consistent Time (CT)

Consistent Time is particularly useful if a gantry and reader are trying to compose a Dose object by synchronizing study details based on timestamps.

4725 **22.5.2.4 Audit Trail and Node Authentication (ATNA)**

Audit events relevant to the transactions of the REM Profile are identified in RAD TF-3: Table 5.1-2 in the Radiology Audit Trail Option.

23 Mammography Acquisition Workflow (MAWF) - RETIRED

4730 This section was previously reserved for the Mammography Acquisition Workflow Profile (MAWF). That profile was retired in 2024 and is no longer maintained by IHE Radiology. The MAWF Trial Implementation Supplement is now in the Radiology Archives.

Note: Functionality to reject images for quality or patient safety reasons is addressed in the IOCM profile and can be used instead for these use cases. See Section 28.

24 MR Diffusion Imaging (DIFF)

4735 MR Diffusion Imaging is a Trial Implementation Profile.

25 CT/MR Perfusion Imaging with Contrast (PERF)

CT/MR Perfusion is a Trial Implementation Profile.

26 Basic Image Review (BIR)

4740 The Basic Image Review Profile defines baseline functions and user interface relevant to simple review of DICOM images, and which attributes should be used to implement those capabilities.

The Basic Image Review Profile is designed to provide sufficient display functionality to allow adequate review of images for the purpose of clinical decision-making by ordering physicians. It does not address application or modality specific requirements, such as may be needed for 4745 primary interpretation of mammography by radiologists, or primary interpretation of nuclear medicine image, which are addressed by other profiles.

The Basic Image Review Profile is intended to provide for:

- display of grayscale and color images from any modality, including cross-sectional modalities like CT, MR and PET, projection radiography modalities like CR, DX, XA 4750 and XRF, as well as ultrasound and nuclear medicine, though it is not limited to any particular modality

- basic grayscale or color rendering of the images as encoded (i.e., without additional image processing like pseudo-coloring, multi-planar reconstruction, volume or surface rendering, or multi-modality fusion)

4755 - visual navigation of the available series of single and multi-frame images through the use of thumbnails

- side-by-side comparison of at least two sets of images, whether they be multi-frame images, series from the same study, or different studies, with synchronized scrolling, panning and zooming in the case of cross-sectional modalities

4760 - annotation of laterality, orientation as well as spatial localization of cross-sectional images for anatomic reference

- annotation of demographics, management and basic technique information to provide for safe identification and usage

4765
- simple measurements of linear distance and angle as used by clinicians for change detection and treatment planning
- cine capability to allow review of multi-frame images that involve cardiac motion (e.g., cardiac US, XA, CT or MR)

26.1 Actors/ Transactions

4770 Figure 26.1-1 shows the actors directly involved in the Basic Image Review Integration Profile and the relevant transactions between them.
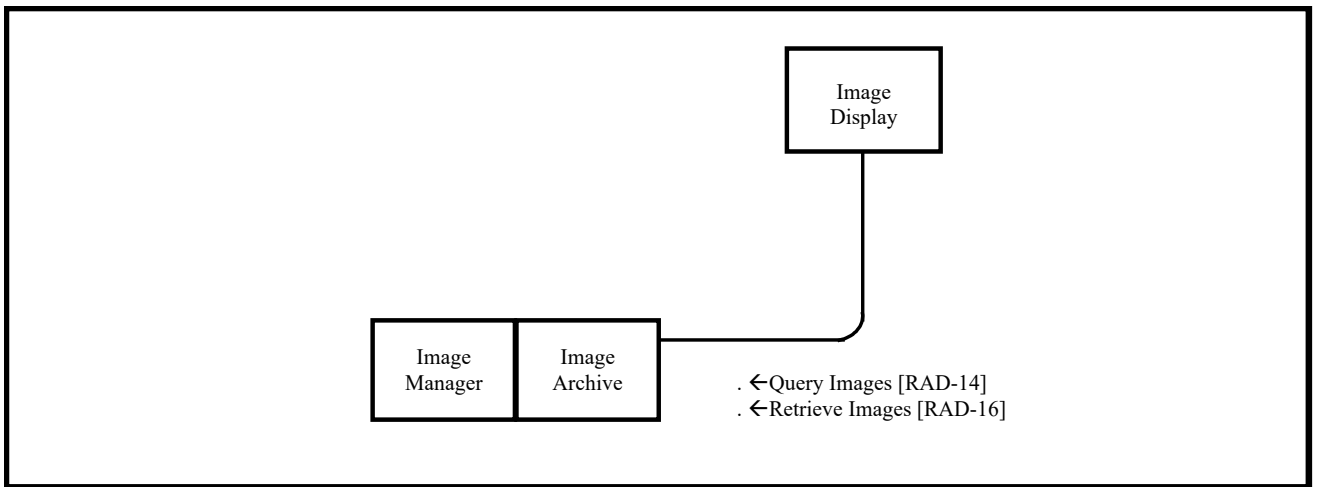
Figure 26.1-1: Basic Image Review Actor Diagram

Table 26.1-1 lists the transactions for each actor directly involved in the BIR Profile. To claim compliance with this profile, an actor shall support all required transactions (labeled "R") and 4775 may support the optional transactions (labeled "O").

Table 26.1-1: Basic Image Review Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	TF Reference
Image Manager / Image Archive	Query Images [RAD-14]	R	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	R	RAD TF-2: 4.16
Image Display	Query Images [RAD-14]	R	RAD TF-2: 4.14
	Retrieve Images [RAD-16] (See Note)	R	RAD TF-2: 4.16

Note: When an Image Display is grouped with a Portable Media Importer, no network activity is required, [RAD-14] is not required, and only the display requirements (in RAD TF-2: 4.16.4.2.25) of the Retrieve Images [RAD-16] transaction are applicable. This is the case, for example, for the Portable Media Creator in the PDI Profile that 4780 supports the Basic Viewer Option and includes a Basic Image Review Image Display on the PDI media.

26.2 Basic Image Review Integration Profile Options

Options that may be selected for each actor in this profile, if any are listed in the Table 26.2-1. Dependencies between options when applicable are specified in notes.

Table 26.2-1: Basic Image Review - Actors and Options

Actor	Options	TF Reference
Image Manager / Image Archive	*No options defined*	- -
Image Display	*No options defined*	- -

4785

26.3 Basic Image Review Process Flow
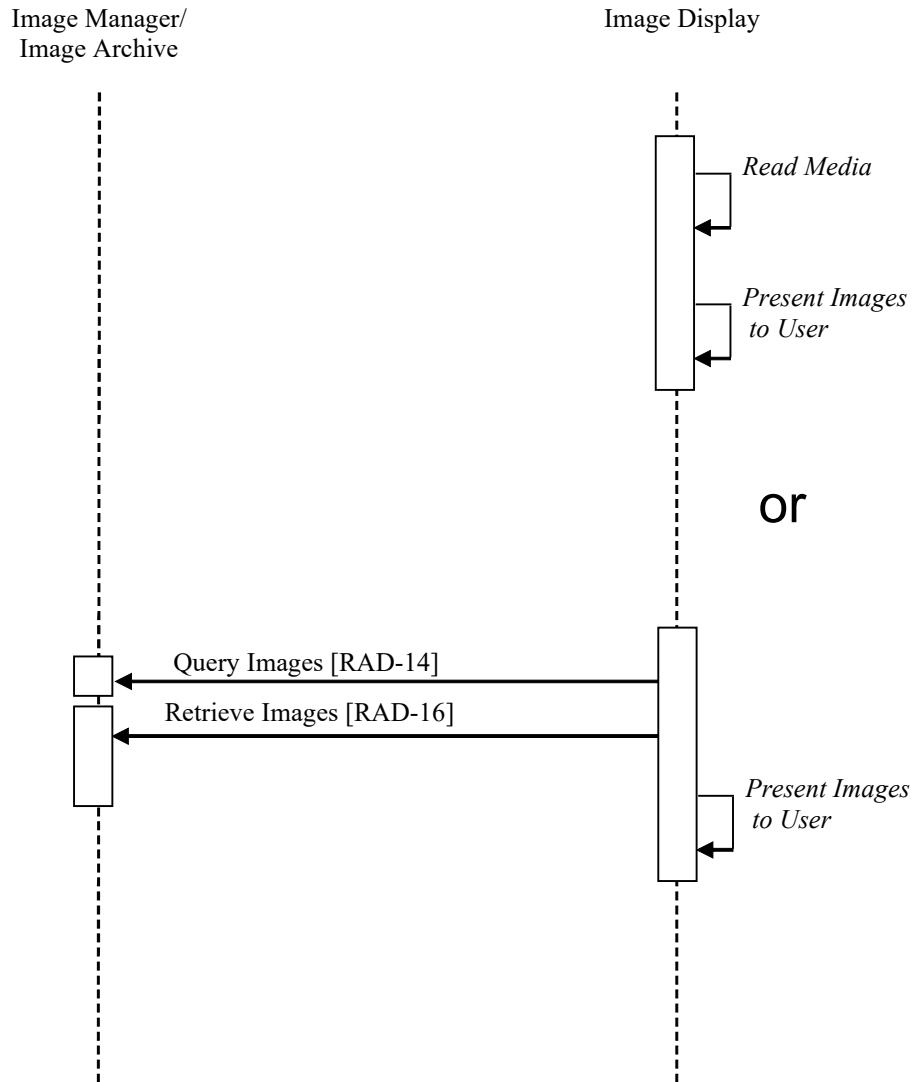
Figure 26.3-1: Basic Process Flow in Basic Image Review Profile

27 Chest X-Ray CAD Display (CXCAD) - RETIRED

4790   This section was previously reserved for the Chest X-Ray CAD Display Profile (CXCAD). That profile was retired in 2024 and is no longer maintained by IHE Radiology. The CXCAD Trial Implementation Supplement is now in the [Radiology Archives](#).

28 Imaging Object Change Management (IOCM)

4795 The Imaging Object Change Management Integration Profile (IOCM) specifies how one actor communicates local changes applied on existing imaging objects to other actors that manage copies of the modified imaging objects in their own local systems. The supported changes include (1) object rejection due to quality or patient safety reasons, (2) correction of incorrect modality worklist entry selection, and (3) expiration of objects due to data retention requirements. It defines how changes are captured and how to communicate these changes.

4800 IHE Scheduled Workflow Profile defines an PPS Exception Management Option (RAD TF-1: 3.3.4 and RAD TF-2: 4.7.4.1.3.1) which specifies how to correct the incorrectly selected worklist entry after the Modality Performed Procedure Step In Progress transaction has been issued but before the Modality Performed Procedure Step Completed transaction is issued. This Imaging Object Change Management Profile addresses the use case in which the incorrect modality
4805 worklist selection is detected after the Modality Performed Procedure Step Completed transaction is issued.

The required workflow steps for the DSS/OF and the actors grouped with Change Requester are specified in the Scheduled Workflow Profile.

28.1 Actors/ Transactions

4810 Figures 28.1-1 shows the actors directly involved in the Imaging Object Change Management Integration Profile and the relevant transactions between them. Other actors that may be indirectly involved due to their participation in Scheduled Workflow, Consistent Presentation of Images, etc. are not necessarily shown.
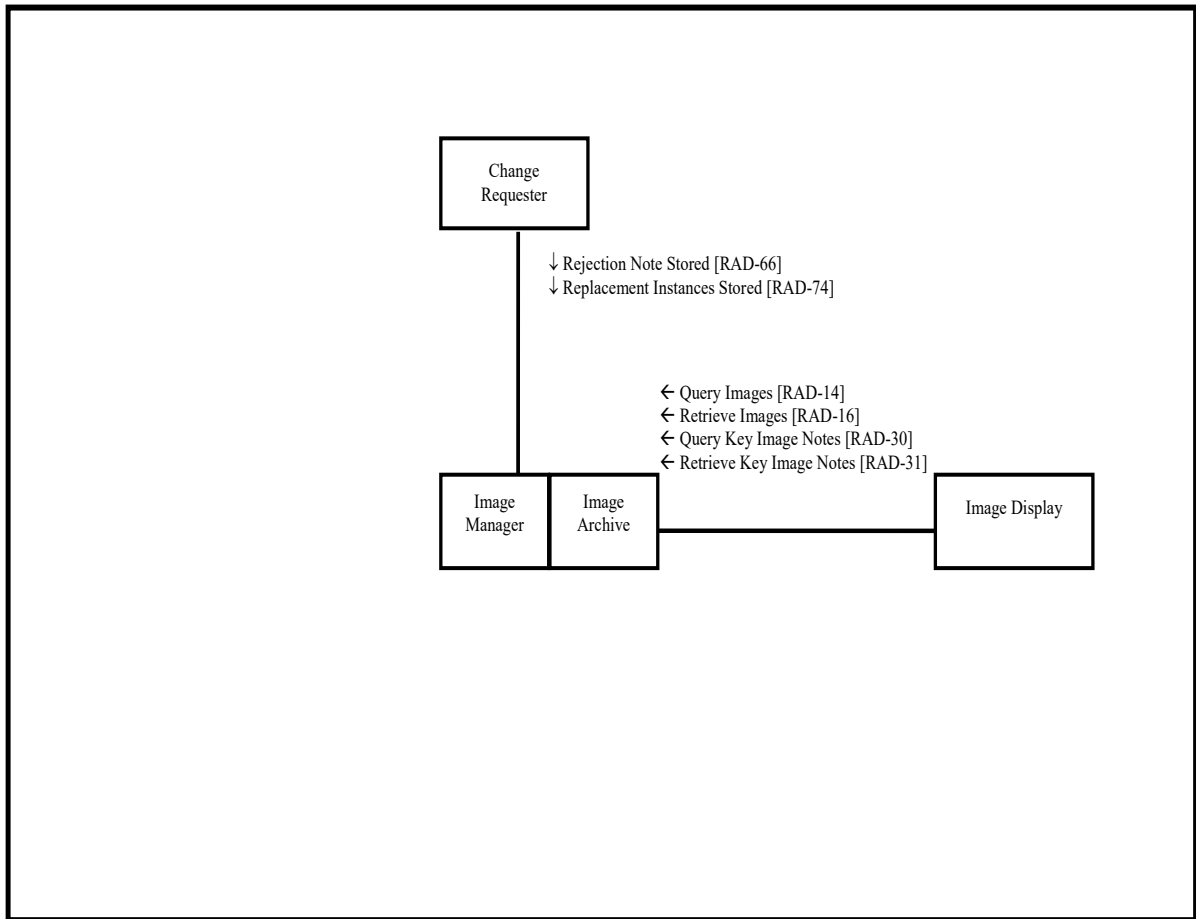
4815   **Figure 28.1-1: Imaging Object Change Management Actor Diagram related to SWF**

Table 28.1-1 lists the transactions for each actor directly involved in the Imaging Object Change Management 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 and that implementations may choose
4820   to support is listed in Section 28.2.

Table 28.1-1: Imaging Object Change Management Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	TF Reference
Change Requester	Rejection Note Stored [RAD-66]	R	RAD TF-2: 4.66
	Replacement Instances Stored [RAD-74]	R	RAD TF-2: 4.74
Image Manager / Archive	Rejection Note Stored [RAD-66]	R	RAD TF-2: 4.66
	Replacement Instances Stored [RAD-74]	R	RAD TF-2: 4.74
Image Display	Query Images [RAD-14]	R	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	R	RAD TF-2: 4.16
	Query Key Image Notes [RAD-30]	R	RAD TF-2: 4.30

Actors	Transactions	Optionality	TF Reference
	Retrieve Key Image Notes [RAD-31]	R	RAD TF-2: 4.31

28.2 Imaging Object Change Management Integration Profile Options

4825 Options that may be selected for this integration profile are listed in the Table 28.2-1 along with the actors to which they apply. Dependencies between options when applicable are specified in notes.

Table 28.2-1: Imaging Object Change Management - Actors and Options

Actor	Options	TF Reference
Change Requester	*No option defined*	-
Image Manager / Archive	*No option defined*	-
Image Display	*No option defined*	-

28.3 Imaging Object Change Management Integration Profile Actor Groupings and Profile Interactions

4830 Imaging Object Change Management builds upon the underlying actor transactions defined in other Profiles. For this reason, certain IOCM Profile actors shall be grouped with actors from other Profiles as defined in Table 28.3-1.

Table 28.3-1: Imaging Object Change Management Integration Profile - Actors and Transactions

Integration Profile	Actor	Grouped With		Comments
		Profile	Actor	
Imaging Object Change Management	Change Requester (see Note 1)	Scheduled Workflow	Acquisition Modality	Support communication of procedure steps and storage commitment when Change Requester is grouped with Acquisition Modality, Image Manager/Image Archive or Evidence Creator.
		Scheduled Workflow	Evidence Creator	
		Scheduled Workflow	Image Manager/ Image Archive	Defines how Image Manager/Image Archive can obtain scheduled worklist in order to correct the modality worklist selection of the acquired instances.

Integration Profile	Actor	Grouped With		Comments
		Profile	Actor	
	Image Manager/ Image Archive	Scheduled Workflow	Image Manager/ Image Archive	Support Image Manager to Image Manager change management if Multiple Patient Identity Resolution Option is supported.
	Image Display	Scheduled Workflow	Image Display	SWF defines message semantics for query-retrieval
	Change Requester (see Note 1)	Patient Information Reconciliation	Acquisition Modality	PIR defines the patient information reconciliation mechanisms that shall be supported by these actors. IOCM shall not be used as an alternative mechanism for handling patient information reconciliation use cases.
		Patient Information Reconciliation	Image Manager/ Image Archive	
	Image Manager/ Image Archive	Patient Information Reconciliation	Image Manager/ Image Archive	

4835 Note 1: At least one of the optional retrieve transactions is required to be supported. Refer to RAD TF-1: 18.4 for additional requirements on the Imaging Document Consumer.

28.4 Imaging Object Change Management Process Flow

Imaging Object Change Management covers the following use cases:

- Data Retention Expiration

4840
- Correction or Rejection of imaging instances for Quality Reasons

- Correction or Rejection of imaging instances for Patient Safety Reasons

- Correction of Modality Worklist Selection

The following use cases generally apply to all imaging objects as well as non-imaging objects including Grayscale Softcopy Presentation State (GSPS), Key Object Selection Document

4845 (KOS), Structured Report (SR), etc. although the examples may focus on the images themselves for simplicity.

The start and completion of creating Rejection Notes, and Replacement Instances if necessary, are reported as Procedure Steps In-Progress/Completed by the relevant IHE workflow actor that has been grouped with the Change Requester (either an Acquisition Modality or an Evidence

4850 Creator).

The Procedure Step transactions, Storage Commitment transaction, Query Modality Worklist transaction and the Query/ Retrieve Images transactions in the following diagrams are part of

Radiology Scheduled Workflow as an example IHE Workflow Profile. They are not part of the Imaging Object Change Management Profile and are only included in the diagrams for
4855   illustration.

>   Note: There are existing profiles defined in the Radiology Technical Framework that are also designed to manage changes in different aspects of imaging objects (e.g., Patient Information Reconciliation, Import Reconciliation Workflow, etc.) Vendors should continue to follow those integration profiles for their respective use cases.

28.4.1 Use Case: Data Retention Expiration

4860   Instances may be deleted to comply with data retention policies.

- A local Image Manager / Archive, supporting the Multiple Identity Resolution Option in IHE Scheduled Workflow Profile, stores instances to a centralized Image Manager / Archive for long term storage using the Image Manager Instances Stored [RAD-70] transaction (currently in the IHE RAD Multiple Image Manager Archive (MIMA) Trial
4865   Implementation Supplement).

- Later, according to the data retention policy of the local Image Manager / Archive, selected studies are deleted internally.

- The local Image Manager / Archive has implemented the Change Requester of the IOCM Profile to communicate these changes to the centralized Image Manager / Archive.

4870   - The local Image Manager / Archive, as an IOCM Change Requester, creates a Key Object Selection (KOS) instance with a Selection Document Title of "Data Retention Policy Expired" that lists the deleted instances, and sends this to the centralized Image Manager / Archive using the Rejection Notes Stored [RAD-66] transaction, followed by the Image Manager Storage Commitment [RAD-71] transaction (in the MIMA
4875   Supplement).

- The centralized Image Manager / Archive receives the deletion requests and deletes the referenced studies accordingly.

The healthcare provider is responsible for drafting and implementing appropriate data retention policies (see Section 28.4).
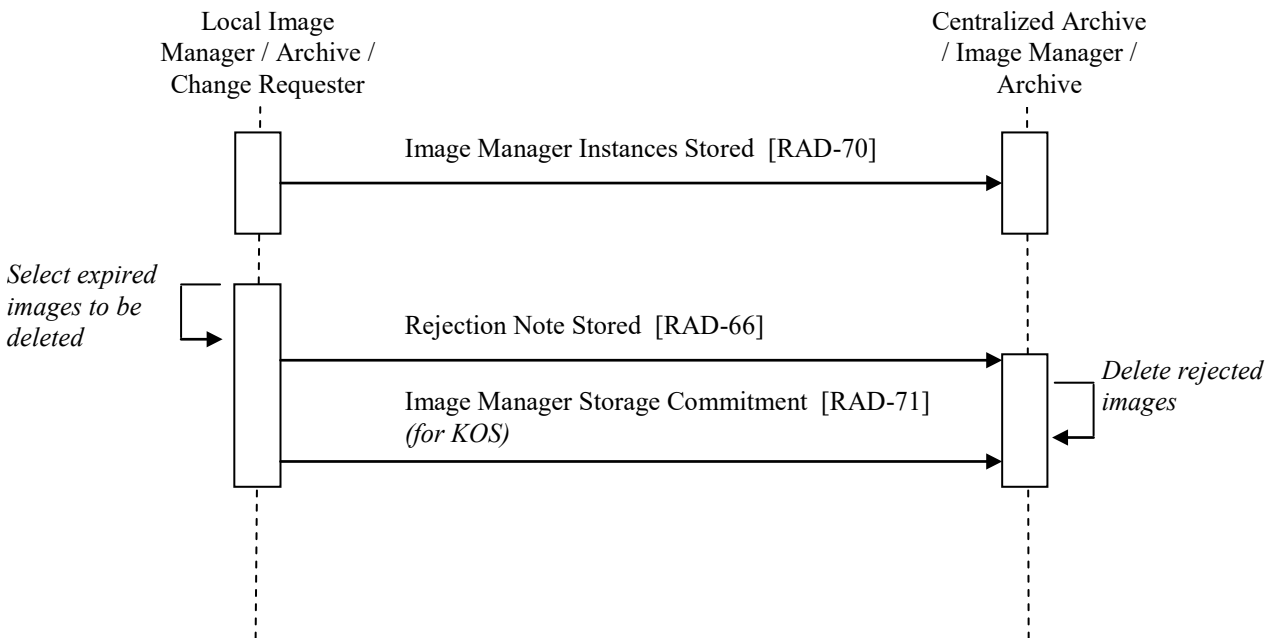
4880

Figure 28.4.1-1: Process Flow for handling expired studies

28.4.2 Use Case: Image Rejection for Quality Reasons

Instances may be deleted for quality reasons. The Change Requester may be grouped with an Acquisition Modality, an Evidence Creator, or an Image Manager / Archive, depending on
4885 whether such QA happens on the modality, a separate workstation, or an image manager.

Clinical aspect: The Technologist or Radiologist decides that certain images are not useful for clinical use, e.g., due to patient motion. While correcting image acquisition context data on a Modality application, e.g., during quality control, the Technologist wants to mark these images as "rejected" so that other systems correctly handle the rejected images according to local
4890 policies. The procedure step has already been completed, and all images, including the rejected images, have been stored to the Image Manager / Archive.

Site policies may determine if rejected images will be presented to users on later retrieval or not, as they may be of clinical relevance or for quality control monitoring. The Image Manager / Archive gets all images as well as change information, and then applies internal rules to fulfill
4895 site policies.
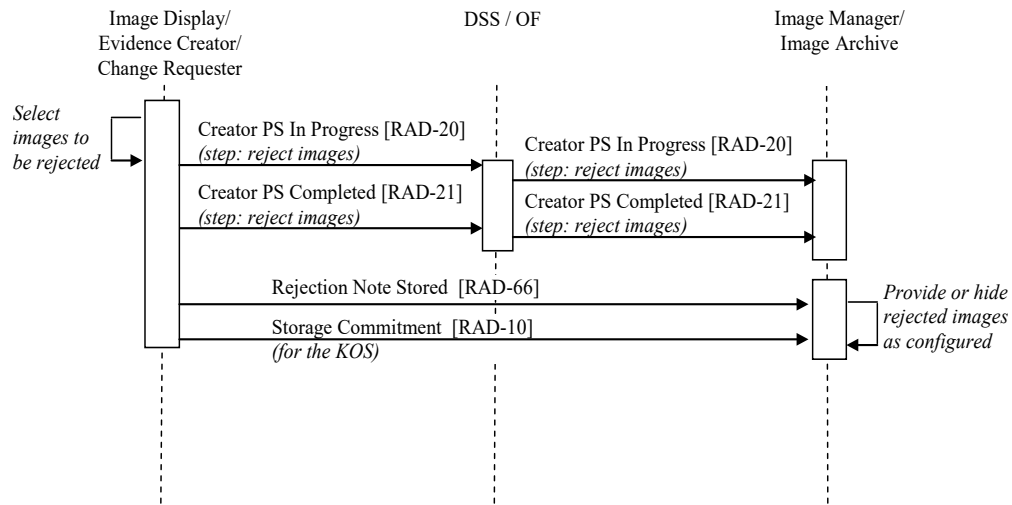
Figure 28.4.2-1: Process Flow for handling rejected images

Technical aspect: A user marks certain images of insufficient quality as "Rejected for Quality Reasons" and selects a reason. The Evidence Creator, as a Change Requester, creates a Key Object Selection (KOS) instance that references the rejected images with a Selection Document Title of "Rejected for Quality Reasons" and the reason. It creates a Creator PPS [RAD-20], sets it COMPLETED (including a reference to this KOS) and sends it to the DSS/OF [RAD-21]. It also stores the KOS to the Image Manager / Archive [RAD-66], and then uses the Storage Commitment [RAD-10] transaction.

The Image Manager / Archive can be configured to provide such rejected images or to hide them from subsequent query/ retrieve responses. An Image Display, when receiving a "Rejected for Quality Reasons" KOS, will display the images and / or KOS, or will hide both ([RAD-16], per configuration).

Variant: Instead of an Evidence Creator being the Change Requester, an Image Manager is the Change Requester. The only difference will be that the Image Manager acting as the Change Requester does not have to create an MPPS referencing the Rejection Note or an MPPS referencing the corrected images.

28.4.3 Use Case: Image Correction for Patient Safety Reasons

Instances may be corrected (deleted and replaced) for patient safety reasons. The Change Requester may be grouped with an Acquisition Modality, an Evidence Creator, or an Image Manager/Archive, depending on whether such QA happens on the modality, a separate workstation, or an image manager.

Clinical aspect: The Technologist takes a left breast cranial caudal view (LCC), and didn't realize that the defaults were set for a right breast (RCC) view, thus the view is labeled incorrectly. The acquisition has been set completed and images were sent to the PACS.

The Technologist wants to correct this view information at the Acquisition Modality or at the nearby Quality Control Workstation (e.g., view code, view description, patient orientation,

4925 laterality) and "update" the images in the PACS. For correct interpretation and diagnosis, the Radiologist depends on a correct view labeling. Incorrectly labeled views may confuse CAD processing, and may also disturb proper display and navigation of images at a workstation. This is a patient safety issue; the incorrect image does not provide additional clinical information but may be harmful, so it is not to be used any more.

The RIS may be notified about such changes, e.g., for logging or informing a user.
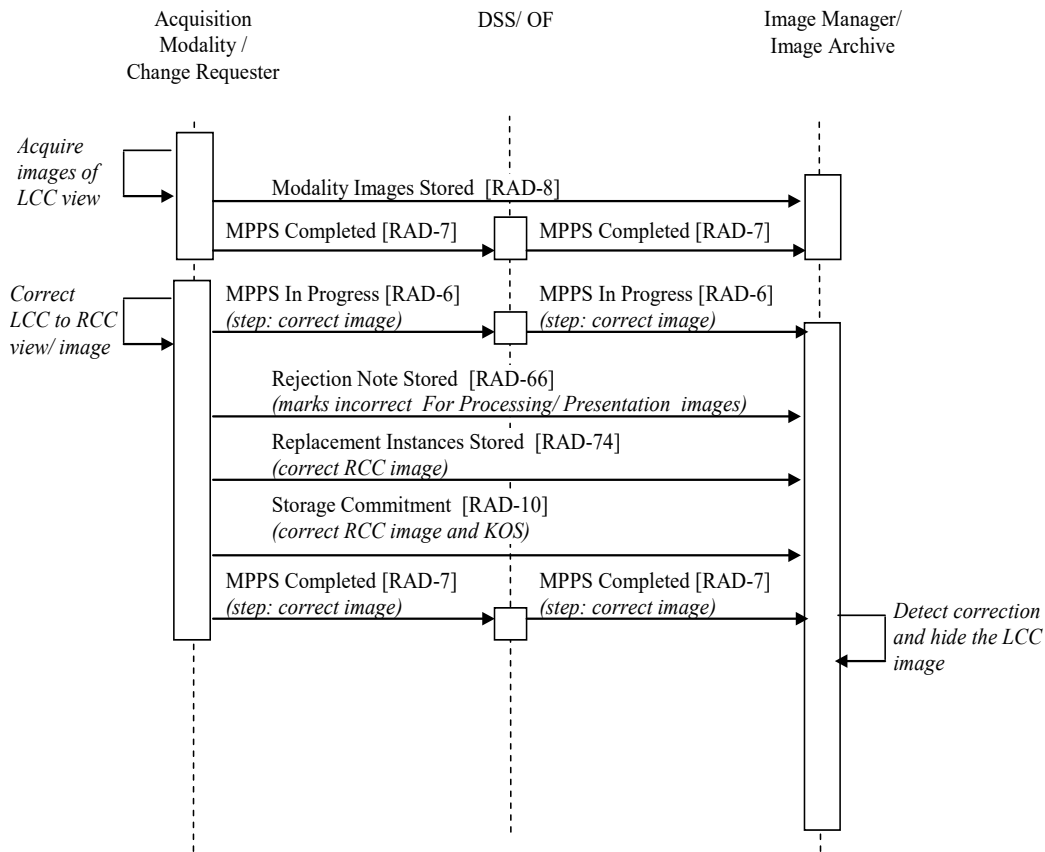
4930

Figure 28.4.3-1: Process Flow for correction of image labeling

Technical aspect: The Acquisition Modality, as a Change Requester, creates and stores a Key Object Selection (KOS) with a Selection Document Title of "Rejected for Patient Safety Reasons" that lists the incorrect instances and sends this using Rejection Note Stored [RAD-66].
4935 It creates corrected images and stores them [RAD-74]. It also creates a Modality PS [RAD-6], sets it COMPLETED (including references to both the corrected images and this KOS), and sends it to the DSS/OF [RAD-7].

The Image Manager/Archive, as a consequence of receiving the KOS, hides the incorrect images from subsequent query/retrieve. An Image Display, when receiving a KOS with a Selection
4940 Document Title of "Rejected for Patient Safety Reasons", does not display the KOS and its referenced images [RAD-16].

Variant: Instead of an Acquisition Modality being the Change Requester, an Image Manager is the Change Requester. The only difference will be that the Image Manager acting as the Change Requester does not have to create an MPPS referencing the Rejection Note or an MPPS referencing the corrected images.

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28.4.4 Use Case: Object Correction due to Modality Worklist Selection Error

Clinical aspect: A patient arrives at the hospital for a scheduled procedure. The Technologist selects a modality worklist entry for the procedure to be performed but mistakenly selects the wrong entry. The Technologist completes the acquisition step.

4950
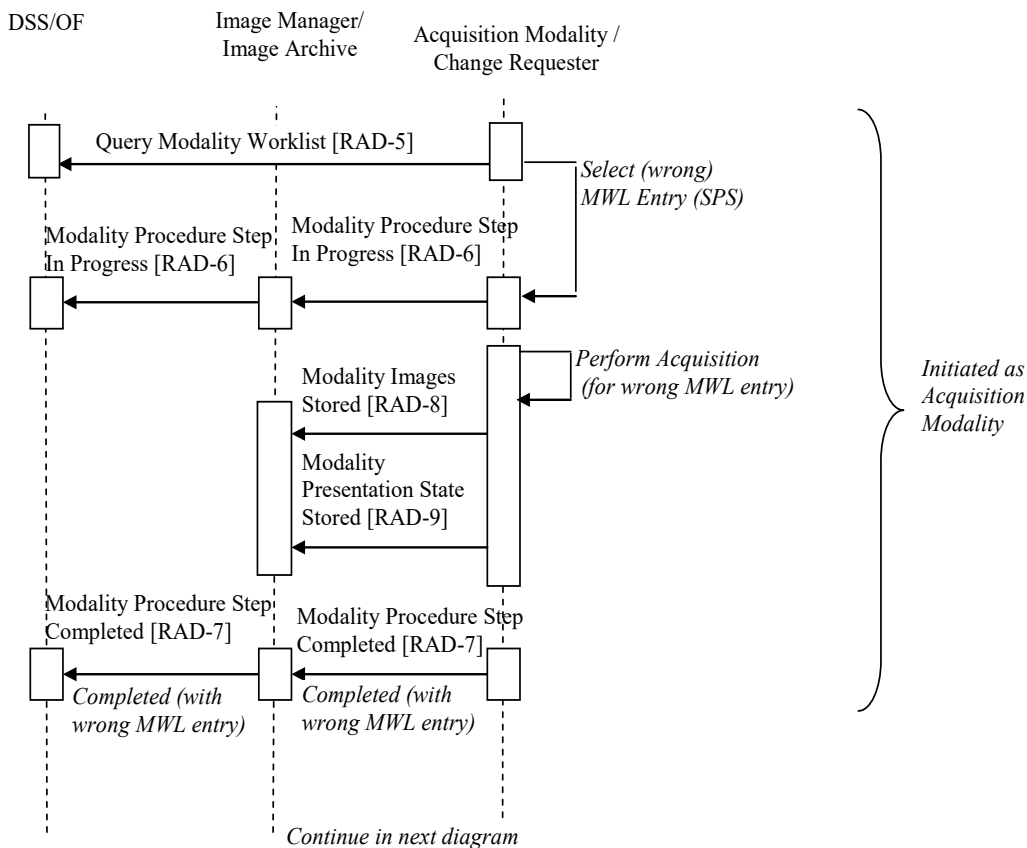
Figure 28.4.4-1: Exception Management Workflow (Incorrect Worklist Entry Selected)

Note: Storage Commitment [RAD-10] is not shown in the diagrams above only for simplification of the diagrams.

Later, the Technologist or Radiologist identifies that patient or order information is incorrect for the whole study. At this point there are two alternative scenarios that can follow:

4955

1. The originally acquired images are relevant to the originally scheduled procedure for the correct patient.

2. The originally acquired images are not relevant to the originally scheduled procedure for the correct patient.

4960   Regardless of which scenario occurs, if additional images need to be acquired for the actual scheduled procedure for the correct patient, then acquisition of the new images shall be performed according to Scheduled Workflow.

The first scenario is illustrated in Figure 28.4.4-2; the Technologist determines that the acquired images are relevant to the actual scheduled procedure for the correct patient. In this case the
4965   Technologist matches the originally acquired images against the originally scheduled procedure for the correct patient using Quality Control tools provided by the Modality.
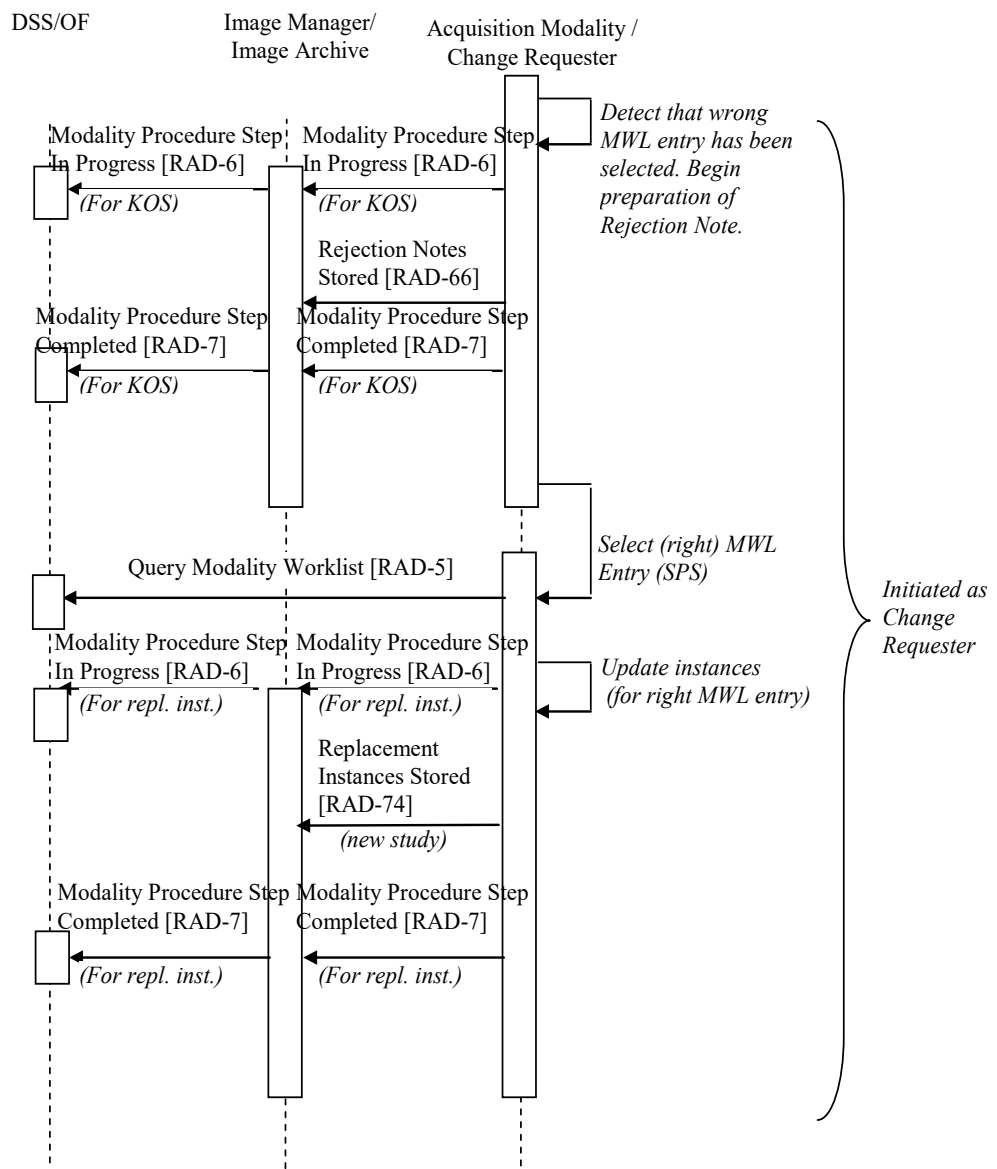
Figure 28.4.4-2: Acquired Images are Relevant to Correct Procedure

4970   Note: Storage Commitment [RAD-10] is not shown in the diagrams above only for simplification of the diagrams.

The alternative scenario is that the Technologist determines that the originally acquired images are not relevant to the actual scheduled procedure for the correct patient. This could be handled in two different ways:

1. The originally acquired images are handled by the Technologist as an unscheduled case.

4975
2. A new procedure is scheduled for the correct patient on the DSS/OF and the originally acquired images are updated to correspond to the new scheduled procedure obtained from the Modality Worklist.

Figure 28.4.4-3 illustrates the correction of the images as an unscheduled case.

The alternative approach of scheduling a new procedure on the DSS/OF is not illustrated here. It
4980   would follow the normal Scheduled Workflow sequencing with the exception that rather than acquiring new images, the originally acquired images would be updated to correspond to the new scheduled procedure obtained from the Modality Worklist.
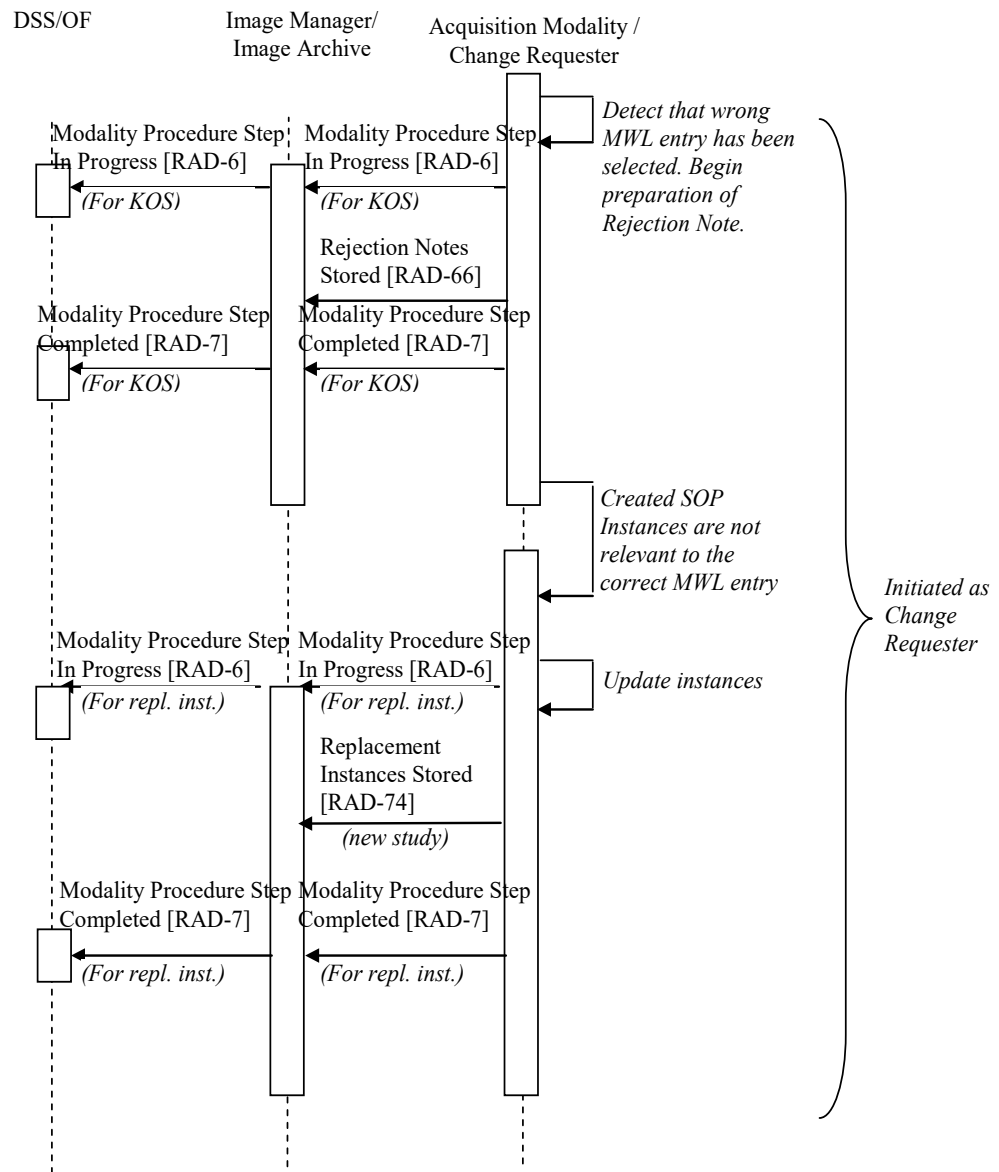
Figure 28.4.4-3: Acquired Images are Not Relevant to Correct Procedure and are Handled as an Unscheduled Case

4985

Note: Storage Commitment [RAD-10] is not shown in the diagrams above only for simplification of the diagrams.

Technical aspect: The Acquisition Modality creates the originally acquired images with their headers set to the information from the incorrectly selected modality worklist entry. It creates a corresponding MPPS [RAD-6], completes and sends it [RAD-7], and stores the images to the

4990 Image Archive [RAD-8] (see Figure 28.4.4-1).

Later, the Technologist or the Radiologist detects the mistakes (see Figure 28.4.4-2). The Acquisition Modality, as a Change Requester, sends a Rejection Note [RAD-66] KOS which contains references to the rejected SOP instances, the originally acquired images, to the Image

4995 Manager. It also creates a MPPS [RAD-6] referencing this Rejection Note, completes the MPPS with the reference to the KOS and sends it to the Image Manager / Archive and DSS/OF [RAD-7]. The Image Manager receives the Rejection Note and makes all the referenced SOP instances unavailable.

The technical aspects then vary depending upon whether or not the originally acquired images are relevant to the actual scheduled procedure for the correct patient.

5000 If it is determined that the originally acquired images are relevant to the actual scheduled procedure for the correct patient then the Acquisition Modality selects the correct modality worklist entry [RAD-5] and updates the originally acquired images (while the study is still available at the Acquisition Modality without re-acquisition) with the correct information. The corrected images are assigned new SOP Instance UIDs so that they can be distinguished from the
5005 originally acquired images which have already been exported. If the correct modality worklist entry is not readily available, the Acquisition Modality queries the DSS/OF again, as illustrated in Figure 28.4.4-2. In order to communicate the corrected images to other systems, the Acquisition Modality, as a Change Requester, creates a new MPPS with the correct information from the modality worklist [RAD-5]. It then stores the new set of corrected images to the Image
5010 Manager [RAD-74], and completes the MPPS and sends it [RAD-7].

Alternatively, if it is determined that the originally acquired images are not relevant to the actual scheduled procedure for the correct patient then the Acquisition Modality either handles the images as if they belong to an unscheduled procedure, or a new procedure for the acquired images is entered on the DSS/OF. If treated as an unscheduled case as shown in Figure 28.4.4-3,
5015 then there is no modality worklist entry to associate the originally acquired images with. The images would thus require manual correction on the Acquisition Modality. The corrected images are assigned new SOP Instance UIDs so that they can be distinguished from the originally acquired images which have already been exported. In order to communicate the corrected images to other systems, the Acquisition Modality, as a Change Requester, creates a new MPPS.
5020 It then stores the new set of corrected images with manually corrected headers to the Image Manager [RAD-74], completes the MPPS and sends it [RAD-7].

Instead of being handled as an unscheduled case, a new procedure could be scheduled on the DSS/OF. In this case the technical aspects would follow the normal Scheduled Workflow sequencing with the exception that, rather than acquiring new images, the originally acquired
5025 images would be updated to correspond to the new scheduled procedure obtained from the Modality Worklist.

> Note: IHE Scheduled Workflow Profile defines an PPS Exception Management Option (see Section 3.3.4 and RAD TF-2: 4.7.4.1.3.1) which specifies how to correct the incorrectly selected worklist entry after the Modality Performed Procedure Step In Progress transaction has been issued but before the Modality Performed Procedure Step Completed transaction is issued. Notice that there is no external component involved in this situation since
5030 the acquired images usually have not been shared prior to MPPS complete or discontinued.

Variant: Instead of an Acquisition Modality being the Change Requester, an Image Manager is the Change Requester. In this case, the Image Manager uses the received procedure information from Procedure Scheduled [RAD-4] and Procedure Updated [RAD-13] to choose the correct
5035 modality worklist, updates the images and creates a new set as described above. The Image

Manager does not have to create an MPPS referencing the Rejection Note or an MPPS referencing the corrected images.

Variant: Instead of selecting an incorrect modality worklist entry, the Technologist forgets to complete the previous worklist entry before starting the new acquisition. The acquired images are incorrectly appended to an existing study of a different patient for a different procedure. As a result, the resulting study becomes partially incorrect. Only the incorrect images and/or presentation states are required to be corrected.

28.5 Imaging Object Change Management Security Considerations

The section describes the policies for reducing risks after correction or rejection at the Change Requester.

Images that are marked as "rejected" for quality reasons (see Section 28.4.2) may or may not contain clinically relevant information. They may be useful in certain situations. Sites may decide to provide them regularly as part of a Study or may hide them at the Archive or at Workstations. IHE supports such policies by defining configurable behavior at the Image Manager/ Image Archive for storage and at the Image Display for presentation.

Incorrectly labeled images (see Section 28.4.3), e.g., containing a wrong patient orientation or laterality, may mislead image interpretation and thus may be harmful to a patient. For patient safety reasons, they are marked in order to not be used later; an Archive hides such images and does not provide them in IHE-defined query and retrieve transactions.

IHE defines a Key Object Selection document with a special title code as a specific trigger to the Image Manager for hiding incorrect instances (different from general Key Image Note use specified in Section 8).

Note that a central correction mechanism at the Image Manager/ Image Archive decreases the risk for harmful or misleading use of rejected or incorrect images, such images are not included in regular query results or retrieve transactions, and their presentation does not depend on local configuration of individual workstations.

Rarely, race conditions may result from information in archived images that is not yet corrected, e.g., due to latencies from asynchronous messaging. In this case, Image Displays may receive and present inconsistent, incomplete or wrong information.

The correction and rejection mechanisms defined for IHE Imaging Object Change Management Integration Profile will only correctly work in a system environment where each system implements the corresponding actors from this integration profile. In addition, the Image Manager/ Archive and Displays need to be configured in a way that meets the department or enterprise policies.

The correction and rejection mechanisms are capable of deleting or changing evidence of a performed procedure. That means a malicious user or system can use this mechanism to hide a mistake. Therefore, the audit record should include information about who initiates the correction / rejection as well as the reason of the initiation. Traceability is also available using

the Referenced Instance Sequence (see RAD TF-2: 4.74.4.1.2) in the header of the replacement
instances.

Since any actor can group with the Change Requester, it is important for the Image Manager /
Archive to validate the source and authority of the Change Requester before rejecting any
referenced instances in the KOS. For example, the Image Manager / Archive can restrict
rejection of instances referenced in the received KOS if and only if the KOS is sent from the
same DICOM Application Entity as the original instances.

29 Cross-Community Access for Imaging (XCA-I)

The Cross-Community Access for Imaging (XCA-I) Integration Profile specifies actors and transactions to query and retrieve a patient's medical imaging data being held by other communities.

Within a community, a group of facilities/enterprises shares clinical information via an established mechanism such as XDS-I (in which case the community can be referred to as an XDS Affinity Domain). This profile addresses sharing between such communities.

The XCA-I Profile extends the IT Infrastructure Cross-Community Access (XCA) Profile. XCA provides access to diagnostic reports and Imaging Manifests. XCA-I provides access to the imaging objects referenced in the Manifests. The reader of XCA-I is expected to have read and understood the XCA Profile, including the meaning of terms such as Community, homeCommunityId, etc.

29.1 Actors/ Transactions

Figure 29.1-1 shows the actors defined in the Cross-Community Access for Imaging (XCA-I) Profile and the transactions between them.

The shaded actors are NOT included in this profile but are shown to illustrate the full set of actors that play a role in the full XCA-I interactions (see Section 29.3.3.2). As a result, the shaded actors are not listed in Table 29.1-1. XCA-I actors which have a required grouping are shown in conjoined boxes (see Section 29.3.3).

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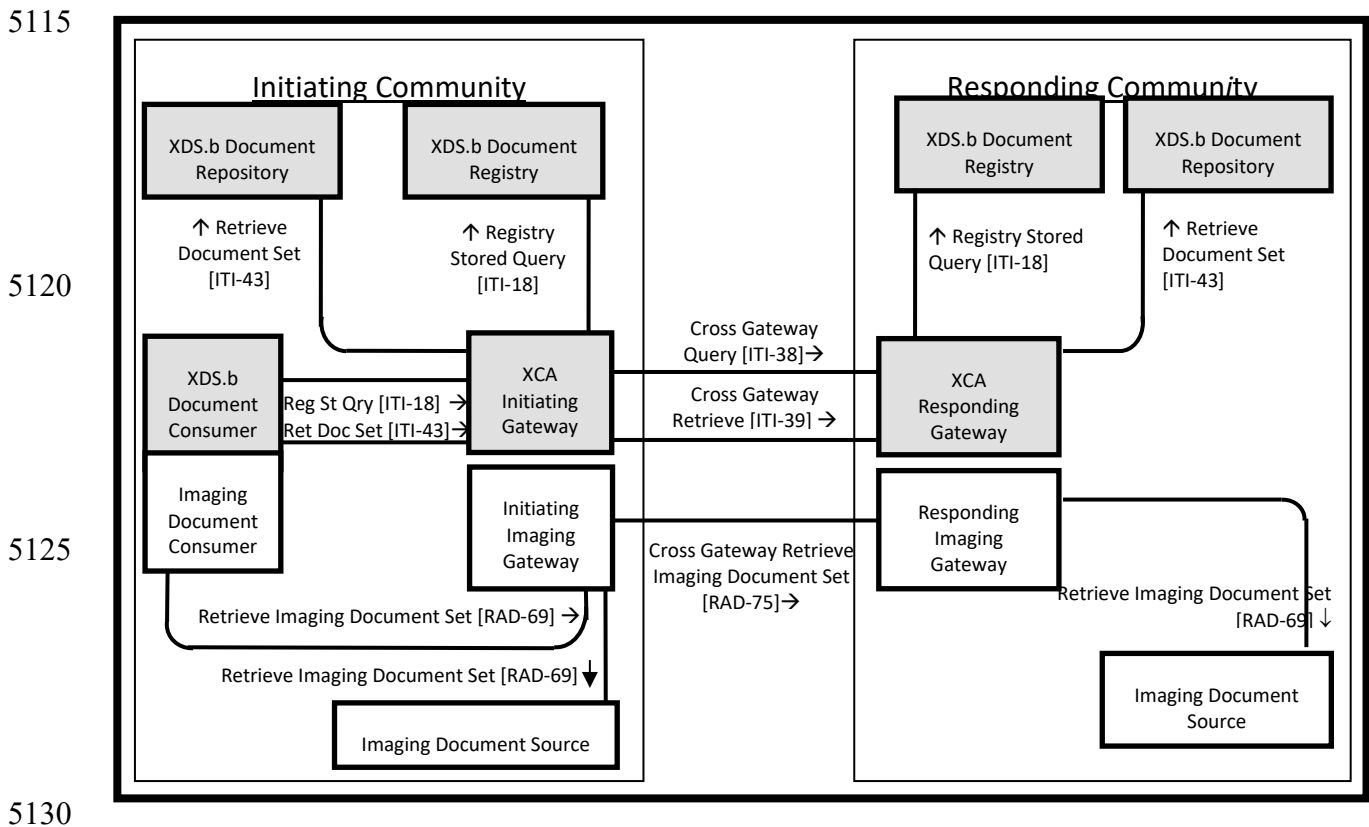
Figure 29.1-1: Cross-Community Access for Imaging Actor Diagram

Table 29.1-1 lists the transactions for each actor directly involved in the XCA-I Profile. To claim support of this Profile, an implementation must perform the required transactions (labeled "R"). Transactions labeled "O" are optional. A complete list of options defined by this integration
5135 profile and that implementations may choose to support is listed in Section 29.2.

Table 29.1-1: Cross-Community Access for Imaging Integration Profile - Actors and Transactions

Actors	Transactions	Initiator or Responder	Optionality	TF Reference
Imaging Document Consumer	Retrieve Imaging Document Set [RAD-69]	Initiator	R	RAD TF-2: 4.69
Imaging Document Source	Retrieve Imaging Document Set [RAD-69]	Responder	R	RAD TF-2: 4.69
Initiating Imaging Gateway	Retrieve Imaging Document Set [RAD-69]	Initiator and Responder	R	RAD TF-2: 4.69
	Cross Gateway Retrieve Imaging Document Set [RAD-75]	Initiator	R	RAD TF-2: 4.75
Responding Imaging Gateway	Cross Gateway Retrieve Imaging Document Set [RAD-75]	Responder	R	RAD TF-2: 4.75
	Retrieve Imaging Document Set [RAD-69]	Initiator	R	RAD TF-2: 4.69

29.1.1 Actor Descriptions and Actor Profile Requirements

5140 Most requirements are documented in RAD TF-2 Transactions. This section documents any additional requirements on profile's actors.

29.1.1.1 Initiating Imaging Gateway

The Initiating Imaging Gateway shall be part of a community that supports XDS-I.b.

The Responding Imaging Gateway shall support the use of Asynchronous Web Services Methods ([ITI TF-2: Appendix V.5](#)) for the [RAD-75] transaction.

5145 ### 29.1.1.2 Responding Imaging Gateway

The Responding Imaging Gateway shall be part of a community that supports XDS-I.b.

The Initiating Imaging Gateway is required to support Asynchronous Web Services Exchange for the [RAD-69] transaction.

29.2 XCA-I Profile Options

5150 Options that may be selected for this integration profile are listed in the Table 29.2-1 along with the Actors to which they apply. Dependencies between options when applicable are specified in notes.

Table 29.2-1: Cross-Community Access for Imaging - Actors and Options

Actor	Options	TF Reference
Imaging Document Consumer	Asynchronous Web Services	RAD TF-2: 4.69.4.3
Initiating Imaging Gateway	Asynchronous Web Services	RAD TF-2: 4.75.4.2 RAD TF-2: 4.69.4.3
Responding Imaging Gateway	*No options defined*	-
Imaging Document Source	Asynchronous Web Services	RAD TF-2: 4.69.4.3

29.3 XCA-I Process Flow

5155 The XCA-I Profile addresses sharing image data sets between communities.

29.3.1 Use Case – Image set sharing between communities

Assume a geographically dispersed region, such as Southeast Wisconsin, with several healthcare communities (or XDS Affinity Domains). One community provides image sharing services for Greater Milwaukee region and one for Kenosha region.

5160 • In each community, a Health Information Exchange Service Provider (HIE-SP) provides:

- • an XDS Infrastructure (an XDS Registry and an XDS Repository) for sharing reports and image manifests.

- an Affinity Domain with a common patient identifier and common coded terminology for managing the sharing of images.

5165
- In each community, Diagnostic Imaging Service Providers provide access to locally stored images through transactions defined by the XDS-I.b Integration Profile.

- Two communities agree to share patient records for urgent care using transactions defined in XCA-I.

5170 A patient X, who receives her primary care in Kenosha, frequently travels to the Greater Milwaukee region for business. While visiting Milwaukee, patient X is admitted to the Milwaukee University Hospital (MUH) for urgent care. The attending physician places an imaging procedure order.

The local PACS, acting as an XDS-I.b Imaging Document Consumer, performs an automated query for relevant priors within the Greater Milwaukee region and to the Kenosha region through 5175 an XDS.b Stored Query transaction to the local HIE-SP's Initiating Gateway.

The Initiating Gateway in Greater Milwaukee queries both the local Document Registry and the Responding Gateway for Kenosha. Relevant priors are located in Kenosha and in the South Milwaukee Diagnostic Imaging Center. The South Milwaukee Diagnostic Imaging Center shares images using XDS-I.b as part of the Greater Milwaukee region.

5180 The MUH PACS, acting as an XDS-I.b Imaging Document Consumer, directly accesses images from the South Milwaukee Diagnostic Imaging Center via their XDS I.b Imaging Document Source.

Images from the Kenosha region are retrieved through the Greater Milwaukee HIE-SP's XCA-I Initiating Imaging Gateway, retrieving the images from the Kenosha HIE-SP's XCA-I 5185 Responding Imaging Gateway. The Kenosha HIE-SP XCA-I Responding Imaging Gateway, in turn, retrieves the images from Imaging Document Source imaging repositories in the Kenosha region.

29.3.2 Detailed Interactions

Figure 29.3.2-1 presents a high level view of the interactions between actors when both initiating 5190 and responding communities are XDS-I.b Affinity Domains. Details on each interaction follow the figure.
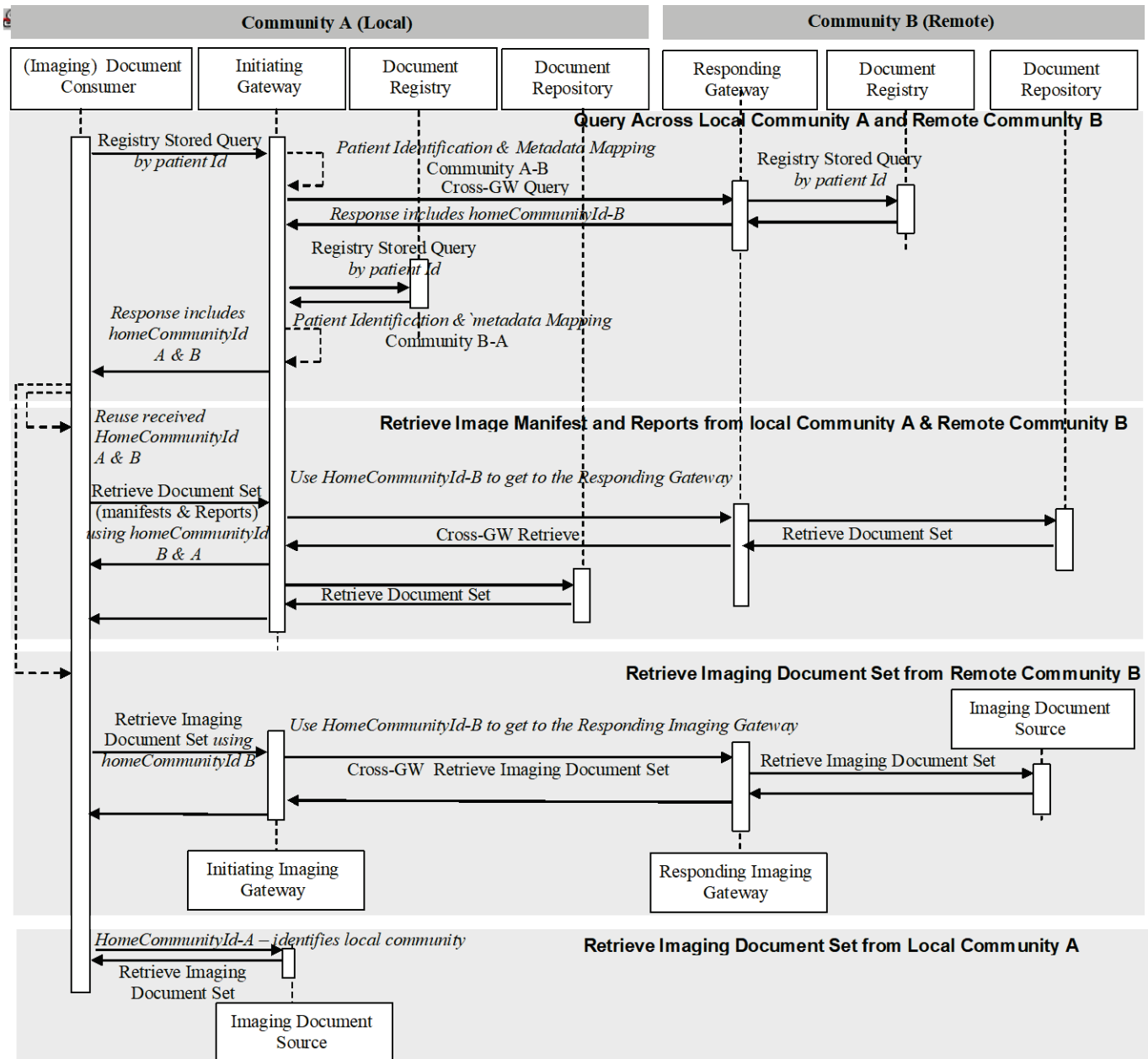
Figure 29.3.2-1: XCA-I Detailed Interactions

5195

<u>XCA Interactions to query for and retrieve Imaging Manifests for a patient</u>

XCA Query across Local Community A and Remote Community B:

    Document Consumer *wants to find Imaging Manifests for a patient -*

5200
- The Document Consumer initiates a Registry Stored Query [ITI-18] to the Initiating Gateway. The query contains the Local Affinity Domain patient id, discovered by PIX, PDQ, or some other means.

Initiating Gateway *processes Registry Stored Query by patient id request –*

- The Initiating Gateway sends a Registry Stored Query [ITI-18] to its local Document Registry.

5205
- The Initiating Gateway sends a Cross Gateway Query [ITI-38] to each Responding Gateway it is configured to contact, using the Patient ID as known in the remote community. In this example there is one Responding Gateway, but there may be more than one.

Responding Gateway *processes Cross Gateway Query [ITI-38] by patient id –*

5210
- The Responding Gateway initiates a Registry Stored Query [ITI-18] to the local Document Registry. The Responding Gateway updates the response from the Document Registry to ensure that the homeCommunityId is specified on every applicable element. This updated response is sent to the Initiating Gateway as the response to the Cross Gateway Query [ITI-38].

5215 **Initiating Gateway** *processes the query responses –*

- The Initiating Gateway collects the responses from its local Document Registry and from all Responding Gateways it contacted. For each response it verifies that the homeCommunityId is present in each appropriate element.

- Once all responses are received the Initiating Gateway consolidates them into one
5220 Registry Stored Query response to the Document Consumer.

Document Consumer *receives Registry Stored Query by patient id response –*

- The Document Consumer receives the results of the query from the Initiating Gateway and must account for three unique aspects of the response; namely that

  a) the homeCommunityId attribute will be specified,

5225
  b) the Document Consumer may not be able to map the repositoryUniqueId value directly to a Document Repository located in a remote community,

  c) the Document Consumer may not be able to understand the terminology used in the response. For example, if the local and remote community have different Requested Procedure vocabularies, then the Initiating Gateway's response to the Document
5230 Consumer's request will contain coding/vocabulary from the remote community.

XCA Retrieve from local Community A & Remote Community B:

Document Consumer *wants to retrieve the Imaging Manifest and reports for the patient –*

- The Document Consumer sends Retrieve Document Set [ITI-43] transaction to the Initiating Gateway including values it received in the query response

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251

5235   a) the document uniqueID

        b) the repository uniqueID

        c) the homeCommunityID(s)

Initiating Gateway *processes Retrieve Document Set [ITI-43] –*

5240
- If a homeCommunityId represents the local community, the Initiating Gateway will initiate a Retrieve Document Set [ITI-43] to the local Document Repository for Imaging Manifest documents.

- The Initiating Gateway uses homeCommunityID(s) to determines which Responding Gateway(s) to retrieve from and initiates a Cross Gateway Retrieve [ITI-39] request to the Responding Gateway(s) for Imaging Manifest documents.

5245   **Responding Gateway** *processes Cross Gateway Retrieve –*

- The Responding Gateway initiates a Retrieve Document Set [ITI-43] transaction to its local Document Repository for Imaging Manifest documents. If the Cross Gateway Retrieve requests multiple documents with different repositoryUniqueIds, the Responding Gateway will contact multiple Document Repositories in its community,
5250   consolidate the responses, and send them to the Initiating Gateway.

Initiating Gateway consolidates the results from its local Document Repository and from the Responding Gateway(s) and sends a Retrieve Document Set Response to the Document Consumer.

The Document Consumer now has Imaging Manifests for the patient from its local Community
5255   A and Remote Community B.

XCA-I Interactions to retrieve images for a patient

XCA-I Retrieve Image Set from Remote Community B and Local Community A :

Imaging Document Consumer *wants to retrieve the studies referenced in the Imaging*
5260   *Manifests:*

- The Imaging Document Consumer initiates a Retrieve Imaging Document Set [RAD-69] to the Initiating Imaging Gateway. The request includes values from the retrieved Imaging Manifests:

    a) the repositoryUniqueIds identifying the Imaging Document Sources,

5265   b) the documentUniqueIds identifying the imaging documents (DICOM SOP Instance UIDs) within the Imaging Document Source,

    c) list of one or more DICOM transfer syntax UIDs,

    d) Study Instance UIDs,

    e) Series Instance UIDs

5270   f) The homeCommunityId(s) identifying the Responding Imaging Gateway.

Initiating Imaging Gateway *processes Retrieve Imaging Document Set [RAD-69] –*

- The Initiating Imaging Gateway uses repositoryUniqueId and homeCommunityId values to determine where to retrieve from. The Initiating Imaging Gateway may have to initiate a Retrieve Imaging Document Set [RAD-69] request to its local Imaging Document
5275   Source(s) or an Cross Gateway Retrieve Imaging Document Set [RAD-75] requests to a Responding Imaging Gateway.

> Note: When an Imaging Document Consumer recognizes that the homeCommunityId in a query response is its local community, it may initiate a Retrieve Imaging Document Set [RAD-69] directly to the Imaging Document Source(s) in its local community, rather than retrieving local studies via the Initiating Imaging Gateway.

5280 **Responding Imaging Gateway** *processes Cross Gateway Retrieve Imaging Document Set –*

- The Responding Imaging Gateway processes the Cross Gateway Retrieve Imaging Document Set request by initiating a Retrieve Imaging Document Set [RAD-69] transaction to the Imaging Document Source identified by the repositoryUniqueId within the request. If the Cross Gateway Retrieve Imaging Document Set requests multiple
5285   documents with different repositoryUniqueIds, the Responding Imaging Gateway will contact multiple Imaging Document Sources and consolidate the responses.

Initiating Imaging Gateway sends a Retrieve Imaging Document Set Response to the Imaging Document Consumer.

29.3.3 XCA-I Required Actor Groupings

5290   An actor from this profile (Column 1) shall implement all of the required transactions and/or content modules in this profile *in addition to all* of the requirements for the grouped actor (Column 2).

Table 29.3.3-1: XCA-I - Required Actor Groupings

XCA-I Actor	Actor(s) to be grouped with	Reference
Imaging Document Consumer	ITI XDS.b / Document Consumer	ITI TF-1: 10.1
	ITI CT / Time Client	ITI TF-1: 7.1
	ITI ATNA / Secure Node or Secure Application	ITI TF-1: 9.1
Imaging Document Source	ITI ATNA / Secure Node or Secure Application	ITI TF-1: 9.1
	ITI CT / Time Client	ITI TF-1: 7.1
Initiating Imaging Gateway	ITI ATNA / Secure Node or Secure Application	ITI TF-1: 9.1
	ITI CT / Time Client	ITI TF-1: 7.1
Responding Imaging Gateway	ITI ATNA / Secure Node or Secure Application	ITI TF-1: 9.1
	ITI CT / Time Client	ITI TF-1: 7.1

29.3.4 Cross-Profile Considerations

5295 The XCA-I Profile requires that the Initiating and Responding Imaging Gateways are used in conjunction with the XCA Initiating and Responding Gateways and will be part of communities that support XDS-I.b.

XCA-I initiating and responding communities use the XDS-I.b and XDS.b integration profiles for enabling Imaging Document Set behavior.

5300 Note: The XCA-I Profile does not explicitly group the XCA-I Initiating Imaging Gateway and XCA Initiating Gateway pair and the XCA-I Responding Imaging Gateway and XCA Responding Gateway pair.

The implementer may also consider grouping other actors as needed. For example, an Image Document Source may choose to group with an IRWF Importer for importing images.

29.4 XCA-I Security Considerations

5305 ### 29.4.1 XCA Risk Assessment

The risk analysis for XCA enumerates assets, threats, and mitigations. The complete risk data is stored and maintained in a central location. The complete risk data is stored and available from IHE[1].

The risks associated with the data content and protocols of [RAD-69] and [RAD-75] are a subset
5310 of those identified for the transactions in the ITI XCA Profile.

29.4.2 Requirements/Recommendations

The following mitigations shall be implemented by all XCA-I actors. These mitigations moderate all high impact risks.

M1: All actors in XCA-I shall be grouped with an ATNA Secure Node or Secure Application
5315 Actor and a CT Time Client Actor.

M2: An Imaging Document Source shall include a SHA1 hash of the image document content in the Document metadata of the [RAD-69] response. The Imaging Document Consumer shall have the ability to verify the SHA1 hash of the image document with the SHA1 hash in the metadata.

M3: Imaging Document Consumer implementations shall handle overloading through excessive
5320 volume of response data by discontinuing the read on the socket and closing it. The Initiating and Responding Imaging Gateways shall respond to disconnection by discontinuing processing of responses.

M6: The Responding Imaging Gateway shall return either zero documents with no further information or XDSUnknownPatientId in response to queries of unknown patient identifiers,
5325 depending on local policy. This applies to patient identifiers that are properly formatted or improperly formatted. By not using an error code indicating that the identifier is ill formatted, you are able to reduce the ability of applications to fish for data.

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[1] The risk analysis data may be found online: XCARiskAnalysis.xls

The following mitigations address the risk of a document being maliciously changed. This mitigation is optional.

5330   **M5**: Documents may be digitally signed using the ITI Digital Signature (DSG) Profile

The following mitigations are transferred to the vendors, XDS Affinity Domains, and enterprises.

T1: Backup systems for registry metadata, repository documents, and gateway configuration are
5335   recommended.

T2: All implementations are recommended to ensure that all received data is propagated appropriately (i.e., without corruption and complete results) or an error is presented.

T3: Network protection services are recommended to be sufficient to guard against denial of service attacks on all service interfaces.

5340   **T4**: A process that reviews audit records and acts on inappropriate actions is recommended.

T5: It is recommended that service interfaces be implemented with a good design to guard against corruption and denial of service attacks

29.4.3 Policy Choices

Security and privacy policy choices will not be addressed by this profile. Each community may
5345   have different security and privacy policies. The profile has been designed with this fact in mind and an understanding of enough variety of policies so that any reasonable policy can be implemented without violating the profile.

30 Post-Acquisition Workflow (PAWF)

Post-Acquisition Workflow is a Trial Implementation Profile.

5350   ## 31 Cross-Enterprise Document Reliable Interchange of Images (XDR-I)

Cross-Enterprise Document Reliable Interchange of Images is a Trial Implementation Profile.

32 Stereotactic Mammography Image (SMI) - RETIRED

This section was previously reserved for the Stereotactic Mammography Image Profile (SMI).
5355   That profile was retired in 2024 and is no longer maintained by IHE Radiology. The SMI Trial Implementation Supplement is now in the Radiology Archives.

33 Management of Radiology Report Templates (MRRT)

The MRRT Profile concerns the use of imaging report templates to create diagnostic imaging reports. This profile distinguishes between *report authoring templates*, which are templates used
5360   by radiologists to guide the creation of a clinical imaging report, and *report instance templates*,

which describe technical constraints on the structure and content of imaging report instances, such as the constraints described in and XML schema or the HL7 Clinical Document Architecture. This profile applies to the former, *report authoring templates,* and describes methods for the formatting of imaging report templates and the management of their transport
5365   between template libraries and report creation systems. Specifically, this profile describes an enhanced feature set for report authoring templates, delineates how such templates from a vendor-agnostic template library could be used immediately by a reporting system, and provides a format for migration of templates between reporting systems.

33.1 MRRT Actors, Transactions, and Content Modules

5370   This section defines the actors, transactions, and content modules in the MRRT Profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A.

Figure 33.1-1 shows the actors directly involved in the MRRT Profile and the relevant transactions between them. If needed for context, other actors that may be indirectly involved due to their participation in other related profiles are shown in dotted lines. Actors that have a
5375   mandatory grouping are shown in conjoined boxes.
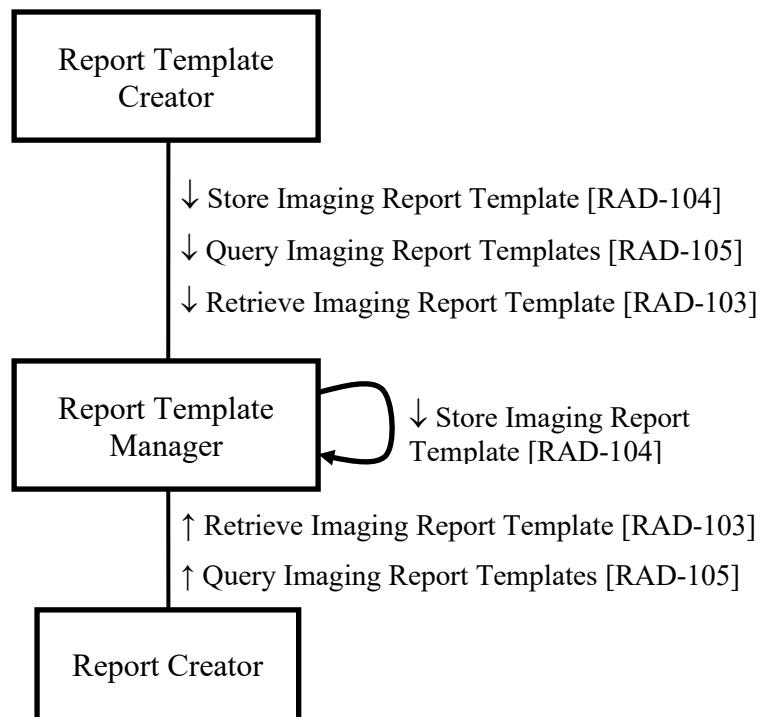
Figure 33.1-1: MRRT Actor Diagram

5380   Table 33.1-1 lists the transactions for each actor directly involved in the MRRT Profile. To claim compliance with this profile, an actor shall support all required transactions (labeled "R") and may support the optional transactions (labeled "O").

Table 33.1-1: MRRT - Actors and Transactions

Actors	Transactions	Initiator or Responder	Optionality	Reference
Report Template Manager	Retrieve Imaging Report Template [RAD-103]	Responder	R	RAD TF-2: 4.103
	Store Imaging Report Template [RAD-104]	Initiator or Responder	R	RAD TF-2: 4.104
	Query Imaging Report Templates [RAD-105]	Responder	R	RAD TF-2: 4.105
Report Creator	Retrieve Imaging Report Template [RAD-103]	Initiator	R	RAD TF-2: 4.103
	Query Imaging Report Templates [RAD-105]	Initiator	O	RAD TF-2: 4.105
Report Template Creator	Store Imaging Report Template [RAD-104]	Initiator	R	RAD TF-2: 4.104
	Retrieve Imaging Report Template [RAD-103]	Initiator	O	RAD TF-2: 4.103
	Query Imaging Report Templates [RAD-105]	Initiator	O	RAD TF-2: 4.105

5385

Table 33.1-2 lists the content module(s) defined in the MRRT Profile. To claim support with this profile, an actor shall support all required content modules (labeled "R") and may support optional content modules (labeled "O").

Table 33.1-2 MRRT – Actors and Content Modules

Actors	Content Modules	Optionality	Reference
Report Template Manager	MRRT Report Template Structure	R	RAD TF-3: 6.6
Report Creator	MRRT Report Template Structure	R	RAD TF-3: 6.6
Report Template Creator	MRRT Report Template Structure	R	RAD TF-3: 6.6

5390   ### 33.1.1 Actor Descriptions and Actor Profile Requirements

33.1.1.1 Report Template Manager

The Report Template Manager shall support Store Imaging Report Template [RAD-104] as both the Sender and Receiver.

33.2 MRRT Actor Options

5395   Options that may be selected for each actor in the MRRT Profile, if any, are listed in Table 33.2-1. Dependencies between options when applicable are specified in notes.

Table 33.2-1: Management of Radiology Report Templates - Actors and Options

Actor	Option Name	Reference
Report Template Manager	*No options defined*	-
Report Creator	*No options defined*	-
Report Template Creator	*No options defined*	-

33.3 MRRT Required Actor Groupings

None.

33.4 MRRT Overview

33.4.1 Concepts

A template is a document with a preset structure, used as a starting point for a Report Creator, so that the structure does not have to be recreated each time it is used. A template describes how a Report Creator should interact with a user to create a report instance.

For example, a radiologist may use a speech recognition system to create a narrative report describing the interpretation of a diagnostic imaging study. The speech recognition system assists the radiologist in applying templates during the reporting process. The radiologist also may edit the text of the report using that system.

The Management of Radiology Report Template White Paper provides more detail on how radiologists typically employ imaging report templates.

33.4.2 Use Cases

33.4.2.1 Use Case #1: New Template Storage

33.4.2.1.1 New Template Storage Use Case Description

A radiologist may need a template to help create a report for a specific study. If such a template is not available in an accessible template library, the radiologist may use a Report Template Creator to create, then edit, a template that serves the need. That template is stored in a Report Template Manager where it is available for later retrieval by a Report Creator. In some cases, a single application may serve as both Report Template Creator and Report Template Manager. In other cases, the Report Template Creator may be a separate application.

5420 **33.4.2.1.2 New Template Storage Process Flow**
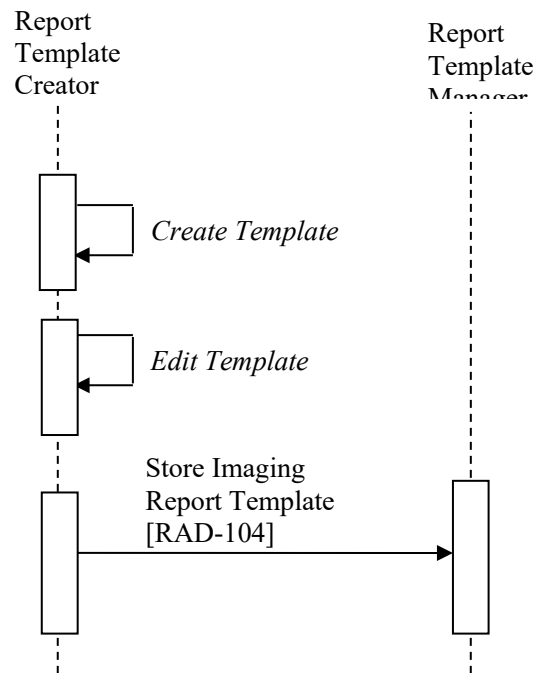
Figure 33.4.2.1.2-1: New Template Storage Process Flow in MRRT Profile

33.4.2.2 Use Case #2: Template Import

33.4.2.2.1 Template Import Use Case Description

5425 A radiologist may need a template to help create a report for a specific study. The Report Creator queries for and retrieves an appropriate template or templates from the Report Template Manager, either based on the users request or an automated algorithm. In some cases, a single application may serve as both Report Template Manager and Report Creator, but in other cases the Report Template Manager may be maintained by a radiology practice, a reporting vendor, or 5430 a professional group. After selecting the template, the user creates a report based on the template.

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33.4.2.2.2 Template Import Process Flow
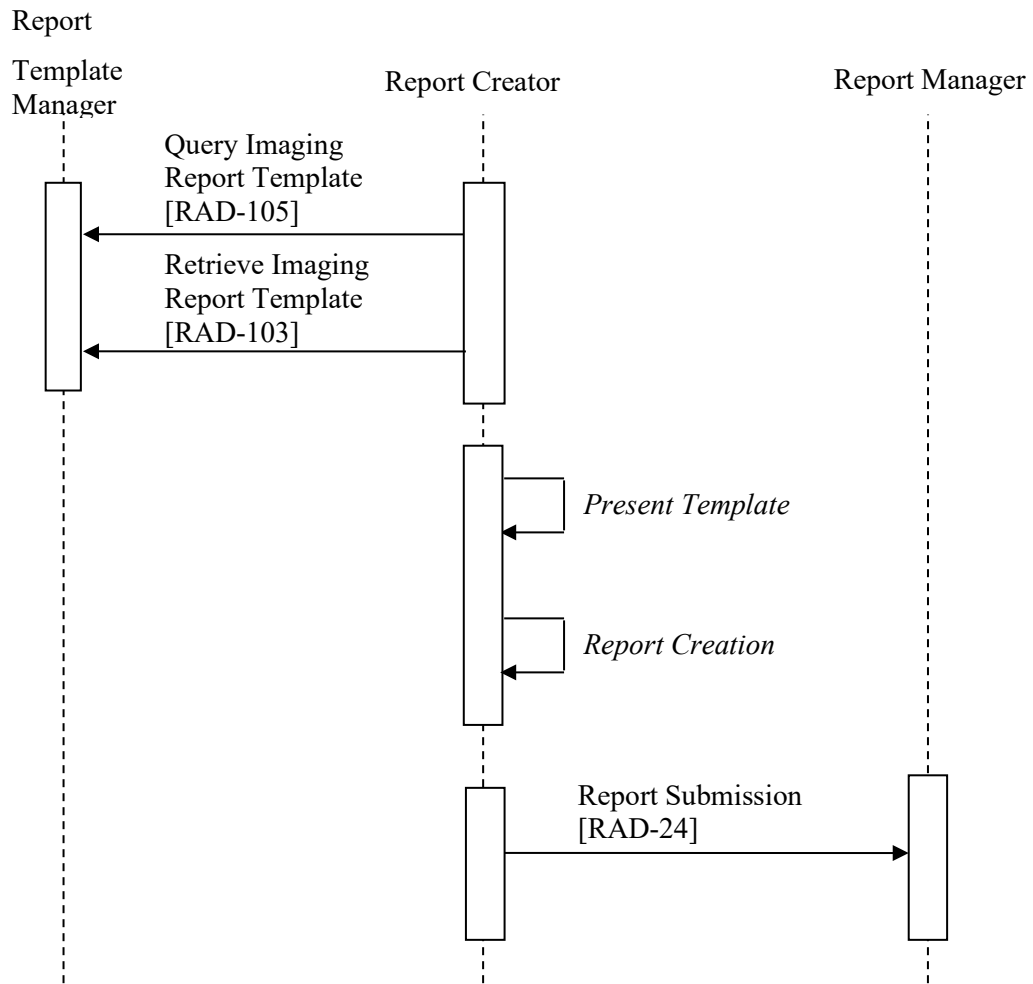
Figure 33.4.2.2.2-1: Template Import Process Flow in MRRT Profile

Note: The Report Submission [RAD-24] transaction is not part of the MRRT Profile. It is shown to provide context.

33.4.2.3 Use Case #3: Template Migration

33.4.2.3.1 Template Migration Use Case Description

If a radiology practice elects to change reporting vendors, the practice will need to transmit its templates from their current Report Template Manager to a new Report Template Manager. They would use the Store Imaging Report Template transaction to migrate the templates from their old Report Template Manager to the new Report Template Manager. This eliminates the need for custom programming to reverse-engineer the template format of the prior vendor.

33.4.2.3.2 Template Migration Process Flow
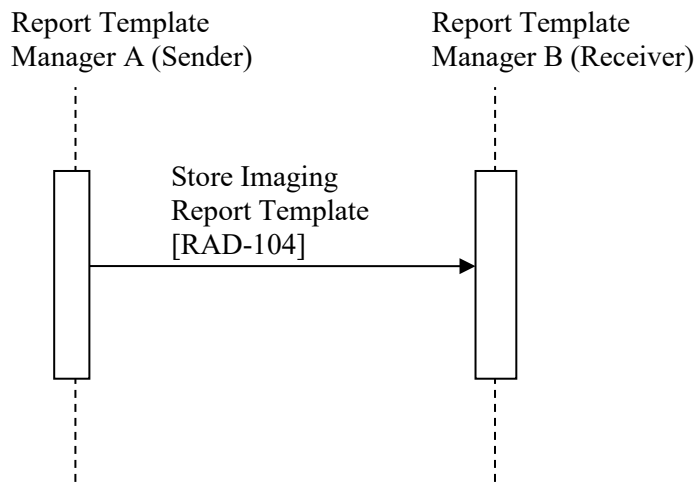
Figure 33.4.2.3.2-1: Template Migration Process Flow in MRRT Profile

5445 ### 33.4.2.4 Use Case #4: Build Template

33.4.2.4.1 Build Template Description

Similar to Use Case #1, a radiologist may need a template to help create a report for a specific study. The radiologist may use a Report Template Creator to create, then edit, a template that serves the need. However, this template utilizes common pieces from other templates. That

5450 template is stored in a Report Template Manager where it is available for later retrieval by a Report Creator.

33.4.2.4.2 Template Import Process Flow
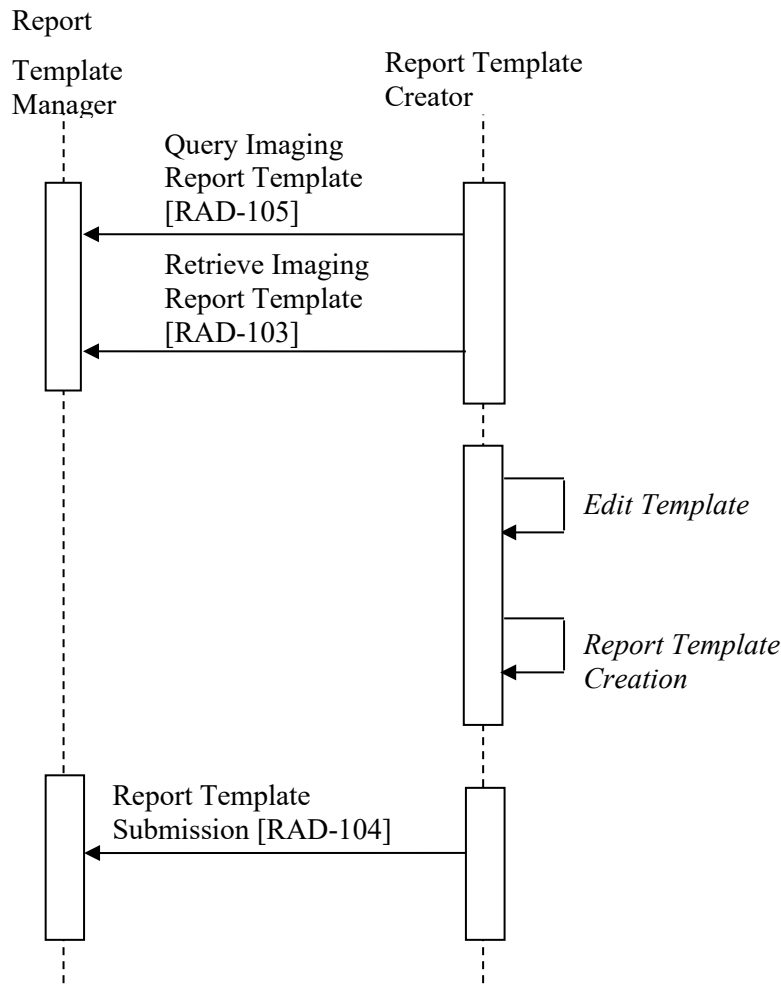
Figure 33.4.2.4.2-1: Build Template Process Flow in MRRT Profile

5455 ## 33.4.2.5 Use Case #5: Manage Template

33.4.2.5.1 Manage Template Description

A radiologist has decided that a particular template should be retired, due to replacement to a new template. The radiologist may use a Report Template Creator to edit a template that changes the metadata. That template is stored in a Report Template Manager where it available for later
5460 retrieval by a Report Creator.

33.4.2.5.2 Manage Template Process Flow
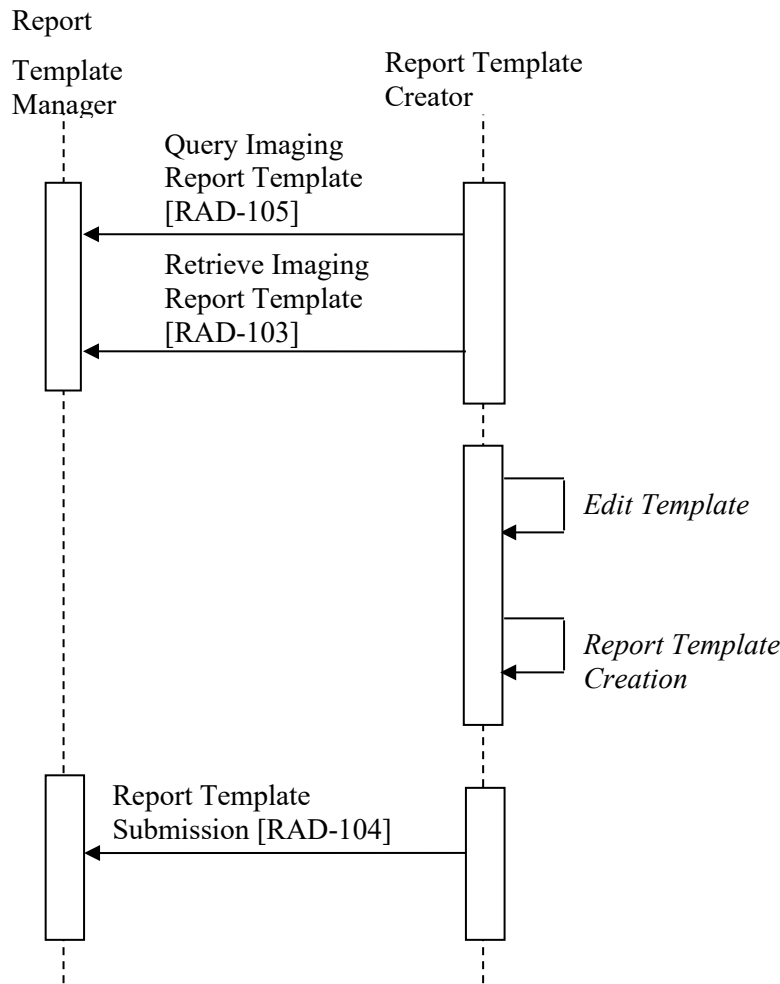
Figure 33.4.2.5.2-1: Manage Template Process Flow in MRRT Profile

33.5 MRRT Security Considerations

5465   None.

33.6 MRRT Cross Profile Considerations

SINR - Simple Image and Numeric Report. A Report Creator in SINR might be grouped with a Report Template Manager in the MRRT Profile, yielding a unified reporting application that manages its own templates.

5470   The transactions outlined here generally will occur before the transactions described in SINR and shown in RAD TF-1: Figure 9.3-1.

34 Scheduled Workflow.b (SWF.b)

The ***Scheduled Workflow.b Integration Profile*** establishes the continuity and integrity of basic departmental imaging data. It maintains the consistency of patient and ordering information as well as providing the scheduling and imaging acquisition procedure steps. This profile makes it possible to determine whether images and other evidence objects associated with a particular performed procedure step have been stored (archived) and are available to enable subsequent workflow steps, such as reporting. It may also provide central coordination of the completion of processing and reporting steps as well as notification of appointments to the Order Placer.

This profile also offers the means to match images, diagnostic reports, and other evidence objects acquired for a misidentified or unidentified patient (for example, during a trauma case) with the patient's record. In the example of the trauma case, this Profile allows subsequent reconciliation of the patient record with images that are acquired (either without a prior registration or under a generic registration) before the patient's identity can be determined. Thus, images can be acquired and interpreted immediately and later, when the patient's official registration and order information is entered into the ADT, Order Placer and Order Filler Systems, this information is matched with the acquired image set and reports, greatly simplifying these exception handling situations.

34.1 SWF.b Actors/Transactions

This section defines the actors and transactions in this profile. General definitions of actors are given in the IHE Technical Frameworks General Introduction Appendix A.

Figure 34.1-1 shows the actors directly involved in the SWF.b Profile and the relevant transactions between them. If needed for context, other actors that may be indirectly involved due to their participation in other related profiles are shown in dotted lines. Actors which have a mandatory grouping are shown in conjoined boxes.

Note: In an attempt to simplify Figure 34.1-1, not all of the "optional" transactions listed in Table 34.1-1 are shown in the diagram.
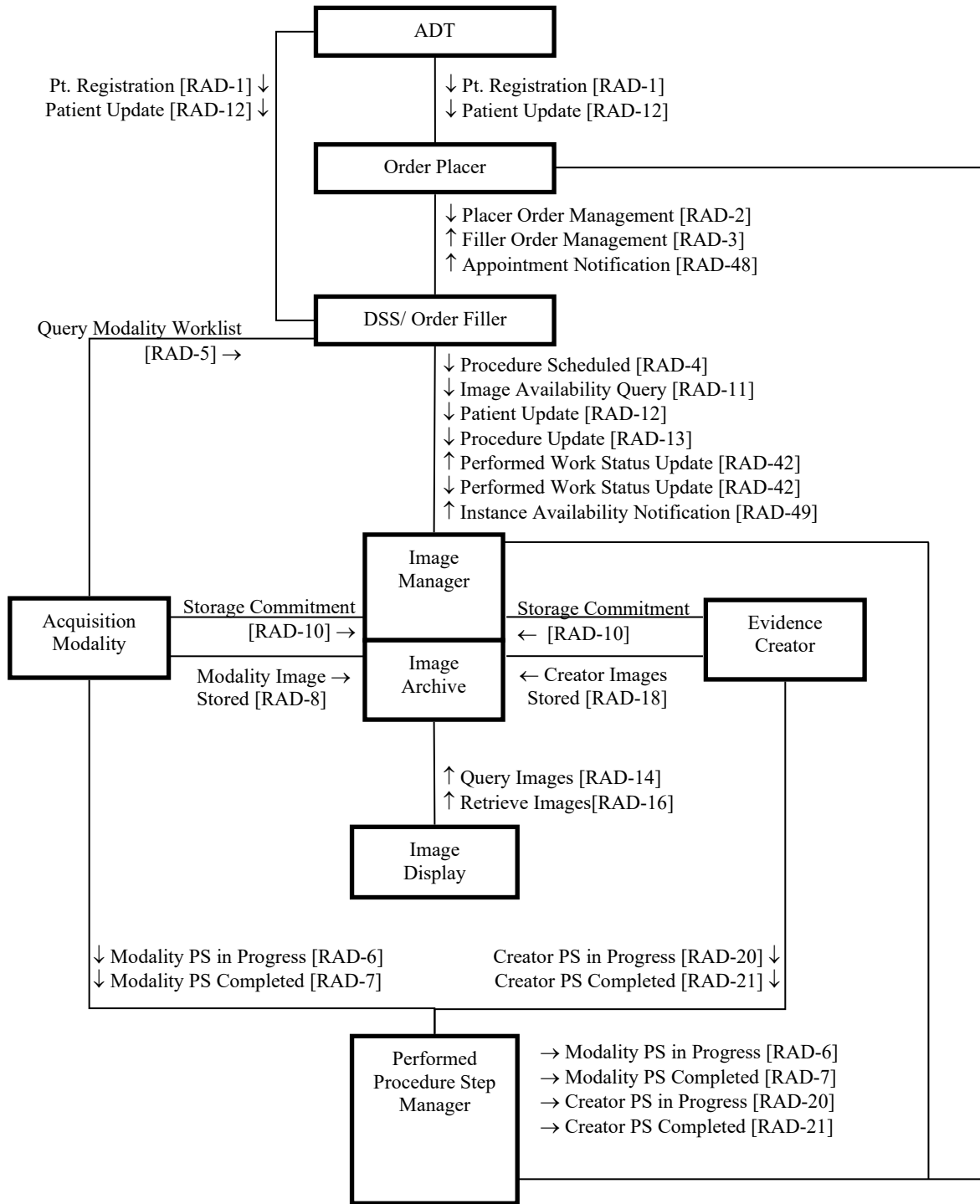
Figure 34.1-1: Scheduled Workflow.b Actor Diagram

5500

Table 34.1-1 lists the transactions for each actor directly involved in the Scheduled Workflow.b Profile. To claim compliance with this profile, an actor shall support all required transactions (labeled "R") and may support the optional transactions (labeled "O").

Table 34.1-1: SWF.b Profile - Actors and Transactions

Actors	Transactions	Optionality	TF Reference
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
	Appointment Notification [RAD-48]	O	RAD TF-2: 4.48
Department System Scheduler/ Order Filler	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
	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: 4.6
	Modality Procedure Step Completed [RAD-7]	R	RAD TF-2: 4.7
	Images Availability Query [RAD-11]	O	RAD TF-2: 4.11
	Procedure Update [RAD-13]	R	RAD TF-2: 4.13
	Creator Procedure Step in Progress [RAD-20]	R	RAD TF-2: 4.20
	Creator Procedure Step Completed [RAD-21]	R	RAD TF-2: 4.21
	Performed Work Status Update [RAD-42] (as the Receiver, see Note 1))	O	RAD TF-2: 4.42
	Appointment Notification [RAD-48]	O	RAD TF-2: 4.48
	Instance Availability Notification [RAD-49]	O	RAD TF-2: 4.49
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 Stored [RAD-8]	R	RAD TF-2: 4.8
	Storage Commitment [RAD-10]	R	RAD 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
	Modality Images Stored [RAD-8]	R	RAD TF-2: 4.8
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
	Images Availability Query [RAD-11]	R	RAD TF-2: 4.11
	Patient Update [RAD-12]	R	RAD TF-2: 4.12

Actors	Transactions	Optionality	TF Reference
	Procedure Update [RAD-13]	R	RAD TF-2: 4.13
	Query Images [RAD-14]	R	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	R	RAD TF-2: 4.16
	Creator Images Stored [RAD-18]	R	RAD TF-2: 4.18
	Creator Procedure Step in Progress [RAD-20]	R	RAD TF-2: 4.20
	Creator Procedure Step Completed [RAD-21]	R	RAD TF-2: 4.21
	Performed Work Status Update [RAD-42] (as the Receiver, see Note 1)	O	RAD TF-2: 4.42
	Instance Availability Notification [RAD-49]	O	RAD TF-2: 4.49
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
	Creator Procedure Step in Progress [RAD-20]	R	RAD TF-2: 4.20
	Creator Procedure Step Completed [RAD-21]	R	RAD TF-2: 4.21
Image Display	Query Images [RAD-14]	R	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	R	RAD TF-2: 4.16
Evidence Creator	Creator Images Stored [RAD-18]	R	RAD TF-2: 4.18
	Creator Procedure Step in Progress [RAD-20]	O	RAD TF-2: 4.20
	Creator Procedure Step Completed [RAD-21]	O	RAD TF-2: 4.21
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10

Note 1: The Department System Scheduler or the Image Manger may optionally choose to be receivers of Performed Work Status Update transactions in order to monitor the status of work in workflows that are managed by other systems (see RAD TF-2: 4.42).

34.1.1 Actor Descriptions and Actor Profile Requirements

Most requirements are documented in Transactions (Volume 2). This section documents any additional requirements on the profile's actors.

34.1.1.1 ADT Patient Registration

In each of the transactions assigned in Table 34.1-1, the ADT Patient Registration shall implement the HL7 v2.5.1 Message Semantics when such semantics are defined.

Note: The HL7 v2.5.1 message semantics maintain semantic equivalency with the HL7 v2.3.1 message semantics and the field correspondences are summarized in RAD TF-2x: Appendix N.

34.1.1.2 Order Placer

In each of the transactions assigned in Table 34.1-1, the Order Placer shall implement the HL7 v2.5.1 Message Semantics when such semantics are defined.

Note: The HL7 v2.5.1 message semantics maintain semantic equivalency with the HL7 v2.3.1 message semantics and the field correspondences are summarized in RAD TF-2x: Appendix N.

34.1.1.3 Order Filler

In each of the transactions assigned in Table 34.1-1, the Order Filler shall implement the HL7 v2.5.1 Message Semantics when such semantics are defined.

5525

> Note: The HL7 v2.5.1 message semantics maintain semantic equivalency with the HL7 v2.3.1 message semantics and the field correspondences are summarized in RAD TF-2x: Appendix N.

34.1.1.4 Image Manager/Image Archive

In each of the transactions assigned in Table 34.1-1, the Image Manager/Image Archive shall implement the HL7 v2.5.1 Message Semantics when such semantics are defined.

5530

> Note: The HL7 v2.5.1 message semantics maintain semantic equivalency with the HL7 v2.3.1 message semantics and the field correspondences are summarized in RAD TF-2x: Appendix N.

34.1.1.5 Performed Procedure Step Manager

The Performed Procedure Step Manager (which is grouped with both Order Fillers and Image Manager/Image Archives) shall be capable of being disabled via configuration. This avoids having two active PPS Managers creating confusion or forwarding loops.

5535

34.2 SWF.b Actor Options

Options that may be selected for each actor in this profile, if any, are listed in Table 34.2-1. Dependencies between options when applicable are specified in notes.

Table 34.2-1: Scheduled Workflow.b - Actors and Options

Actor	Option Name	TF Reference
ADT Patient Registration	*No options defined*	-
Order Placer	Departmental Appointment Notification	RAD TF-1: 34.2.1 RAD TF-1: 34.4.2.7 RAD TF-2: 4.48
DSS/Order Filler	Image Availability	RAD TF-1: 34.2.2 RAD TF-2: 4.11
	Departmental Appointment Notification	RAD TF-1: 34.2.1 RAD TF-1: 34.4.2.7 RAD TF-2: 4.48
	PPS Exception Management	RAD TF-1: 34.2.3 RAD TF-2: 4.7.4.1.2.2 RAD TF-2: 4.7.4.1.3.1 RAD TF-2: 4.21.4.1.2.1
	Performed Work Status Update - Receive	RAD TF-1: 34.2.9 RAD TF-2: 4.42
	Availability of PPS-Referenced Instances	RAD TF-1: 34.2.8 RAD TF-2: 4.49
	Billing and Material Management	RAD TF-1: 34.2.6 RAD TF-2: 4.7.4.1.3.2

Actor	Option Name	TF Reference
	Enterprise Identity	RAD TF-1: 34.2.10 RAD TF-2: 4.4.1.2.9 RAD TF-2: 4.5.4.1.2.3
Acquisition Modality	Patient Based Worklist Query (Note 1)	RAD TF-2: 4.5
	Broad Worklist Query (Note 1)	RAD TF-2: 4.5
	Assisted Acquisition Protocol Setting	RAD TF-1: 34.2.5 RAD TF-2: 4.5.4.2.3 RAD TF-2: 4.6.4.1.2.4 RAD TF-2x: A.1
	PPS Exception Management	RAD TF-1: 34.2.3 RAD TF-2: 4.7.4.1.2.2 RAD TF-2: 4.7.4.1.3.1 RAD TF-2: 4.7.4.1.2.2
	Modality Group Case	RAD TF-1: 34.2.4 RAD TF-2: 4.6
	Billing and Material Management	RAD TF-1: 34.2.6 RAD TF-2: 4.7.4.1.2.3
	Enterprise Identity	RAD TF-1: 34.2.10 RAD TF-2: 4.5.4.1.2.3 RAD TF-2: 4.6.4.1.2.5 RAD TF-2: 4.8.4.1.2.5
Image Manager/ Image Archive	Availability of PPS-Referenced Instances	RAD TF-1: 34.2.8 RAD TF-2: 4.49
	PPS Exception Management	RAD TF-1: 34.2.3 RAD TF-2: 4.7.4.1.2.2 RAD TF-2: 4.7.4.1.3.1 RAD TF-2: 4.21.4.1.2.1
	Performed Work Status Update - Receive	RAD TF-1: 34.2.9 RAD TF-2: 4.42
	Enterprise Identity Option	RAD TF-1: 34.2.10 RAD TF-2: 4.4.1.2.9 RAD TF-2: 4.6.4.1.2.5 RAD TF-2: 4.8.4.1.2.5 RAD TF-2: 4.18.4.1.2.6 RAD TF-2: 4.20.4.1.2.5
Image Display	Enterprise Identity	RAD TF-2: 4.14.4.1.2
Performed Procedure Step Manager	*No options defined*	-
Evidence Creator	Creator Performed Procedure Step	RAD TF-1: 34.2.7 RAD TF-2: 4.20 RAD TF-2: 4.21
	PPS Exception Management Option (Note 2)	RAD TF-1: 34.2.3 RAD TF-2: 4.21.4.1.2.1

Actor	Option Name	TF Reference
	Enterprise Identity Option	RAD TF-1: 34.2.10 RAD TF-2: 4.18.4.1.2.6 RAD TF-2: 4.20.4.1.2.4

Note 1: At least one of these two options is required. Both may be supported.

Note 2: An Evidence Creator claiming the PPS Exception Management Option shall also support the Creator Performed Procedure Step Option.

The Evidence Creator, 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 RAD TF-1x: Appendix D).

34.2.1 Departmental Appointment Notification Option

This option involves the Order Filler notifying the Order Placer when imaging procedures are newly scheduled, rescheduled or canceled on the Order Filler.

Order Fillers and Order Placers that claim this option shall support the Appointment Notification [RAD-48] transaction and the use case and process flow described in Section 34.4.2.7.

Order Fillers that claim this option shall have ability to be configured so that the Appointment Notification transaction is not sent when connected to an Order Placer that does not support the Departmental Appointment Notification Option.

34.2.2 Image Availability Option

This option involves the Order Filler checking on the availability of images generated during acquisitions.

Order Fillers Actors that claim this option shall support the Images Availability Query [RAD-11] transaction.

34.2.3 PPS Exception Management Option

This option involves using PPS message features to communicate and handle advanced exception cases.

Acquisition Modalities, Evidence Creators, Image Managers and Order Fillers that claim this option shall support the use case and process flow described in Section 34.4.2.5.

34.2.4 Modality Group Case Option

This option involves the Acquisition Modality combining multiple Scheduled Procedure Steps and performing them in a procedure described by a single Performed Procedure Step.

Acquisition Modality Actors that claim this option shall support all three grouping scenarios described in RAD TF-2: 4.6.4.1.2.3.4.

34.2.5 Assisted Acquisition Protocol Setting Option

5570 This option involves the Acquisition Modality using procedure codes provided in the modality worklist to automatically assist the operator in selecting and setting the acquisition protocol.

See RAD TF-2: 4.6.4.1.2.4.2 for more details.

34.2.6 Billing and Material Management Option

This option involves using PPS message features to communicate details related to billing and materials consumed during the procedure from the Acquisition Modality to the Order Filler.

5575 See RAD TF-2: 4.7.4.1.2.3 for more details.

34.2.7 Creator Performed Procedure Step Option

This option involves the Evidence Creator using PPS messages to keep the PPS Manager informed about steps performed on the Evidence Creator.

5580 Evidence Creator Actors that claim this option shall support the Creator Procedure Step in Progress [RAD-20] transaction and the Creator Procedure Step Completed [RAD-21] transaction.

34.2.8 Availability of PPS-Referenced Instances Option

This option involves Image Manager/Archives notifying relevant actors of the availability status of newly stored DICOM objects.

5585 Image Manager/Archive Actors and Order Filler Actors that claim this option shall support the Instance Availability Notification [RAD-49] transaction.

34.2.9 Performed Work Status Update – Receive Option

This option involves Order Fillers and Image Mangers monitoring the status of work in workflows that are managed by other systems.

5590 Image Manager/Archive Actors and Order Filler Actors that claim this option shall support the Performed Work Status Update [RAD-42] transaction as an SCP (to receive such updates).

Other profiles such as Charge Posting (CHG), Post-Processing Workflow (PWF) and Reporting Workflow (RWF) require actors such as the Order Filler, Post-Processing Manager and Report Manager to support the transactions as an SCU (to send such updates).

5595 ### 34.2.10 Enterprise Identity Option

The Enterprise Identity Option enhances the communication among the Evidence Creator, Acquisition Modality, DSS/Order Filler, Image Display and Image Manager/Image Archive with the inclusion and/or coercion of unique qualifiers for Institution, Patient ID and Accession Number. Additionally, the attributes for Other Patient IDs are included, if provided by the
5600 DSS/Order Filler.

Including the Issuer of Patient ID attribute to identify the Patient ID Registration Domain enables the Acquisition Modality to provide images for export with a uniquely qualified patient identifier.

5605 Including the Issuer of Accession Number Sequence provides unique issuer identity of the Accession Number when multiple Accession Number Issuers may be part of the same enterprise, for example, when a Cardio-Vascular Information System and a Radiology Information System both exist and provide images to a common enterprise PACS.

Including the Institution Name, Institution Code Sequence and Institution Address provides enterprise identification information that is useful to recipients beyond the enterprise.

5610 A DSS/Order Filler supporting the Enterprise Identity Option shall handle such information as specified in:

- Procedure Scheduled [RAD-4]   See RAD TF-2: 4.4.4.1.2.9
- Query Modality Worklist [RAD-5]   See RAD TF-2: 4.5.4.1.2.3
- Modality Procedure Step In Progress [RAD-6] See RAD TF-2: 4.6.4.1.2.5
5615 - Creator Procedure Step In Progress [RAD-20] See RAD TF-2: 4.20.4.1.2.4

An Acquisition Modality supporting the Enterprise Identity Option shall handle such information as specified in:

- Query Modality Worklist [RAD-5]   See RAD TF-2: 4.5.4.1.2.3
5620 - Modality Procedure Step In Progress [RAD-6] See RAD TF-2: 4.6.4.1.2.5
- Modality Images Stored [RAD-8]   See RAD TF-2: 4.8.4.1.2.8

An Evidence Creator supporting the Enterprise Identity Option shall handle such information as specified in:

5625 - Creator Images Stored [RAD-18]   See RAD TF-2: 4.18.4.1.2.6
- Creator Procedure Step in Progress [RAD-20] See RAD TF-2: 4.20.4.1.2.4

An Image Manager/Image Archive supporting the Enterprise Identity Option shall handle such information and coerce, if needed, the appropriate information as specified in:

5630 - Procedure Scheduled [RAD-4]   See RAD TF-2: 4.4.4.1.2.9
- Modality Images Stored [RAD-8]   See RAD TF-2: 4.8.4.1.3.2
- Creator Images Stored [RAD-18]   See RAD TF-2: 4.18.4.1.3.2

An Image Display and an Image Manager/Image Archive supporting the Enterprise Identity
5635   Option shall handle such information in their queries, as specified in:

- Query Images [RAD-14]   See RAD TF-2: 4.14.4.1.2

34.3 SWF.b Required Actor Groupings

An actor from this profile (Column 1) shall implement all of the required transactions and/or
content modules in this profile in addition to all of the transactions required for the grouped actor
5640   Column 2).

Section 34.5 may describe some optional groupings that may be of interest for security
considerations and Section 34.6 describes some optional groupings in other related profiles.

Table 34.3-1: Scheduled Workflow.b - Required Actor Groupings

SWF.b Actor	Actor to be grouped with	Reference
ADT Patient Registration	None	--
Order Placer	None	--
DSS/Order Filler	SWF.b / Performed Procedure Step Manager	RAD TF-1: 34.1
Acquisition Modality	None	--
Image Manager	SWF.b / Image Archive	RAD TF-1: 34.1
	SWF.b / Performed Procedure Step Manager	RAD TF-1: 34.1
Image Archive	SWF.b / Image Manager	RAD TF-1: 34.1
Image Display	None	--
Performed Procedure Step Manager	None	--
Evidence Creator	None	--

34.4 SWF.b Overview

5645   The primary features of the Scheduled Workflow.b Profile are:

- Patient management

- Order management

- Bridging HL7 orders into DICOM worklists

- Acquisition of DICOM data with proper structure and identifiers

5650   - Handling routine exceptions (such as emergency procedures that are performed before
  they are formally ordered, or procedures where the identity of the patient is unknown or
  mis-selected)

273

34.4.1 Concepts

5655 This section defines the integrated data model adopted by the IHE Technical Framework for the HL7 messages and the DICOM Information Object Definitions (IODs). The Entity Relationship (ER) diagram represents the integration of proper subsets of HL7 v2.5.1 and the DICOM Model of the Real World with minor extensions as noted in the following section and described in RAD TF-1x: Appendix B.

34.4.1.1 Model of the Real World

5660 Figure 34.4.1.1-1 depicts the model of the real world within scope of the Scheduled Workflow.b Profile. This model provides an overview of the high-level integration of the DICOM and HL7 models. This integrated model differs from the DICOM Model of the Real World (refer to DICOM PS3.3) in the following respects:

5665 - The Service Episode, Procedure Plan and Procedure Type entities have been excluded and are outside the scope of the IHE Technical Framework

- The relationship between the Visit and Imaging Service Request has been excluded and is outside the scope of the IHE Technical Framework.

5670 - The HL7 Placer Order and Filler Order entities have been inserted into the DICOM hierarchy between the Patient entity and Imaging Service Request entity. IHE requires that a single Placer Order shall correspond to one and only one Filler Order.

- The DICOM Imaging Service Request Entity is equated with the HL7 Filler Order entity. In this relationship, IHE provides clarification of the use of the Accession Number - DICOM attribute (0008,0050); see RAD TF-1x: Appendix A for further discussion.
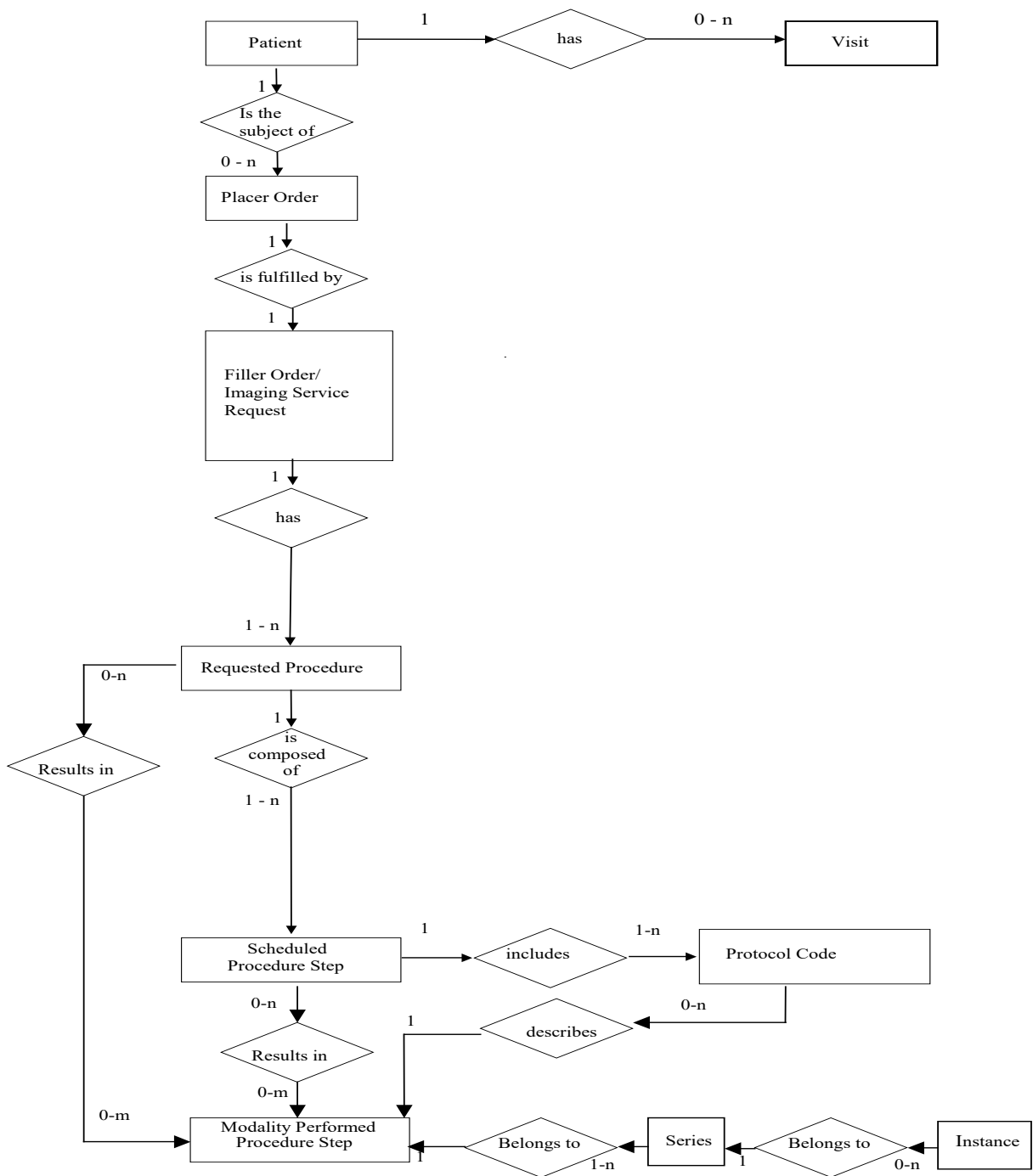
5675   **Figure 34.4.1.1-1: Real World Model for Scheduled Workflow**

34.4.1.2 Scheduled Workflow Concepts in Practice

The IHE "Real World" model for Scheduled Workflow described above offers three major levels of control that can be used to customize a broad range of specific workflow situations:

Order: A request for an Imaging Service

5680   **Requested Procedure**: Unit of work resulting in one report with associated codified, billable acts.

Scheduled and Performed Procedure Step: the smallest unit of work in the workflow that is scheduled (work to do) and/or performed (work done).

The Order Filler/Department System Scheduler uses the Universal Service ID in each order that 5685   it receives to determine what specific Requested Procedures are needed, and for each Requested Procedure the Procedure Steps that need to be scheduled.

A departmental Procedure Plan may be used in the Order Filler to predefine for each one of the types of Orders that may be requested from the imaging department (generally defined in the Order Placer) the breakdown in Requested Procedure (with a specific procedure code) and for 5690   each Requested Procedure Code, the breakdown in Scheduled Procedure Steps.

For an illustration of mapping between transactions [RAD-2], [RAD-3], [RAD-5], [RAD-6] and [RAD-7], see the IHE white paper "Code Mapping in IHE Radiology Profiles", https://www.ihe.net/uploadedFiles/Documents/Radiology/IHE_RAD_White-Paper_Codes.pdf

The figure below defines an example of the breakdown of a "rule out pulmonary embolism" 5695   Order.

```
Order :
R/O Pulmonary Embolism
    │
    ├──── Requested Procedure : Chest X-ray
    │         │
    │         └──── Scheduled Procedure Step :
    │               Chest PA and Lateral
    │
    └──── Requested Procedure : NM Ventilation Perfusion
              │
              ├──── Scheduled Procedure Step :
              │     NM Ventilation Acquisition
              │
              └──── Scheduled Procedure Step
                    NM Perfusion Acquisition
```

In this Procedure Plan, for this specific Order, two Requested Procedures are defined. The Chest X-ray that will be read and reported by a different radiologist than the NM Ventilation-Perfusion, hence two different Requested Procedures. The NM Ventilation Perfusion Procedure has been 5700   scheduled as two different Scheduled Procedure Steps, to account for the fact that the patient will have the two NM acquisitions performed at a different time, thus allowing for patient preparation

between the two examinations. This is the way this institution has decided to handle this Order. Another Institution may choose to require the same radiologist to read both the X-ray and the NM images. In that case it would define in its Procedure plan for the same Order to have a single

5705   Requested Procedure with three Scheduled Procedure Steps.

Many Orders processed in a Radiology Department would have a simpler breakdown such as this Chest X-ray example.

Order :
Chest X-ray

Requested Procedure : *Chest X-ray*

Scheduled Procedure Step :
Chest PA and Lateral

It should be noted that the three level Order breakdown has been defined in Scheduled

5710   Workflow.b so that any type of Orders, from the simple case to the more complex cases may be handled by the same workflow concepts, thus providing a general approach that can be easily customized by each imaging department in the definition of its Procedure Plan.

In Scheduled Workflow.b, the **Accession Number identifies the Order**. The requested Procedure ID distinguishes among Requested Procedures when an Order requires multiple

5715   Procedures. IHE sets a common meaning for these two terms to provide clinicians with a consistent and non-ambiguous access across different vendor products (RIS, PACS and Modalities).

34.4.1.2.1 Tracking Performed Procedure Steps

Scheduled Workflow.b not only addresses the breakdown of Orders into Requested Procedures

5720   and Scheduled Procedure Steps but also allows tracking the Procedure Steps that have actually been performed. The Performed Procedure Steps may or may not correspond to the Scheduled Procedure Steps. This provides the flexibility needed to adjust on the Modality if the actual acquisition differs from what was scheduled.

> Note: MPPS Complete [RAD-7] reflects the completion of a Modality Performed Procedure Step. As explained in the
5725   > previous example, depending on the Requested Procedure that has been requested in the Order, it is the role of
> the Department System Scheduler/Order Filler to create the corresponding SPS and set the rules to process the
> MPPS completion transaction [RAD-7] when received, and therefore to trigger any Order Update with the
> [RAD-3] transaction. The number of MPPS received by the Department System Scheduler/Order Filler may not
> match the number of MPPS transactions expected by the Department System Scheduler/Order Filler.
5730   > Management of this case is a local configuration task of the Department System Scheduler/Order Filler and is not
> intended to be specified in this profile.

Using the Pulmonary Embolism example above, one may decide to follow the Order breakdown as defined in the procedure Plan.

```
┌─────────────────────────┐
│ Order :                 │
│ R/O Pulmonary Embolism  │
└─────────────────────────┘
    │   ┌──────────────────────────────────────────────────────────┐
    ├───│ Requested Procedure : Chest X-ray                        │
    │   └──────────────────────────────────────────────────────────┘
    │      ┌──────────────────────────────┐   ┌──────────────────────────────┐
    │      │ Scheduled Procedure Step :   │...│ Performed Procedure Step :   │
    │      │ Chest PA and Lateral         │   │ Chest PA and Lateral         │
    │      └──────────────────────────────┘   └──────────────────────────────┘
    │   ┌──────────────────────────────────────────────────────────┐
    └───│ Requested Procedure : NM Ventilation Perfusion           │
        └──────────────────────────────────────────────────────────┘
           ┌──────────────────────────────┐   ┌──────────────────────────────┐
           │ Scheduled Procedure Step :   │...│ Performed Procedure Step :   │
           │ NM Ventilation Acquisition   │   │ NM Ventilation Acquisition   │
           └──────────────────────────────┘   └──────────────────────────────┘
           ┌──────────────────────────────┐   ┌──────────────────────────────┐
           │ Scheduled Procedure Step     │...│ Performed Procedure Step     │
           │ NM Perfusion Acquisition     │   │ NM Perfusion Acquisition     │
           └──────────────────────────────┘   └──────────────────────────────┘
```
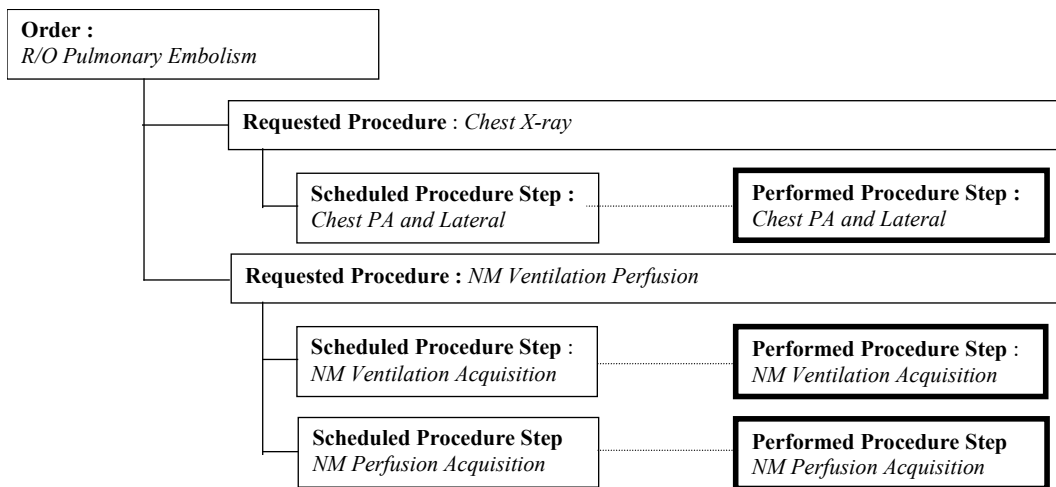
5735

The Chest X-ray Requested Procedure would contain the series of images associated with the Chest PA and Lateral Performed Procedure and the NM Ventilation Perfusion would contain both the series for the ventilation and the series of images for the perfusion. From this example one can see how the Requested Procedure forms the "folder" where the radiologists find the images to be read resulting from the Scheduled Procedures Steps.

5740

Using the Pulmonary Embolism example above, one may decide that following the Chest X-ray, it is not necessary to perform the NM Perfusion Ventilation.

```
┌─────────────────────────┐
│ Order :                 │
│ R/O Pulmonary Embolism  │
└─────────────────────────┘
    │   ┌──────────────────────────────────────────────────────────┐
    ├───│ Requested Procedure : Chest X-ray                        │
    │   └──────────────────────────────────────────────────────────┘
    │      ┌──────────────────────────────┐   ┌──────────────────────────────┐
    │      │ Scheduled Procedure Step :   │...│ Performed Procedure Step :   │
    │      │ Chest PA and Lateral         │   │ Chest PA and Lateral         │
    │      └──────────────────────────────┘   └──────────────────────────────┘
    │   ┌──────────────────────────────────────────────────────────┐
    └───│ Requested Procedure : NM Ventilation Perfusion           │
        └──────────────────────────────────────────────────────────┘
           ┌──────────────────────────────┐   ┌──────────────────────────────┐
           │ Scheduled Procedure Step :   │...│ ╳ Performed Procedure Step : ╳│
           │ NM Ventilation Acquisition   │   │ ╳ NM Ventilation Acquisition ╳│
           └──────────────────────────────┘   └──────────────────────────────┘
           ┌──────────────────────────────┐   ┌──────────────────────────────┐
           │ Scheduled Procedure Step     │...│ ╳ Performed Procedure Step   ╳│
           │ NM Perfusion Acquisition     │   │ ╳ NM Perfusion Acquisition   ╳│
           └──────────────────────────────┘   └──────────────────────────────┘
```
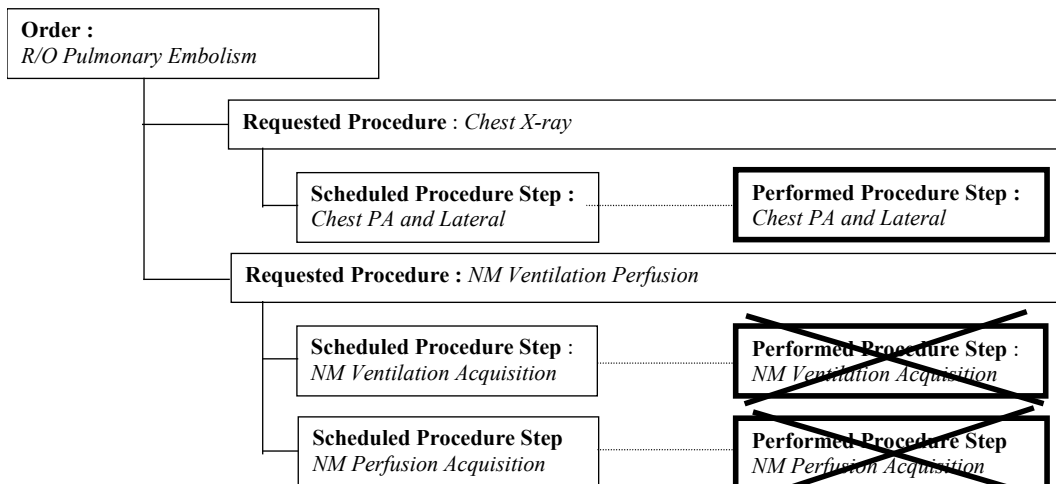
In this later case, the Nuclear Scheduled Procedure Steps will be cancelled. Only the Chest X-ray Requested Procedure will "contain" the Image corresponding to the Chest PA and lateral Chest X-ray.

5745

To illustrate further the capabilities of Scheduled Workflow.b, let's look at a Chest/Abdomen/Pelvis Order that a radiology department chooses to break down into a Chest Requested Procedure and an Abdomen/Pelvis Requested Procedure in order to take advantage of

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5750   the subspecialties of its radiologists. Some hospitals also may want to produce separate reports to align with the charging policies.
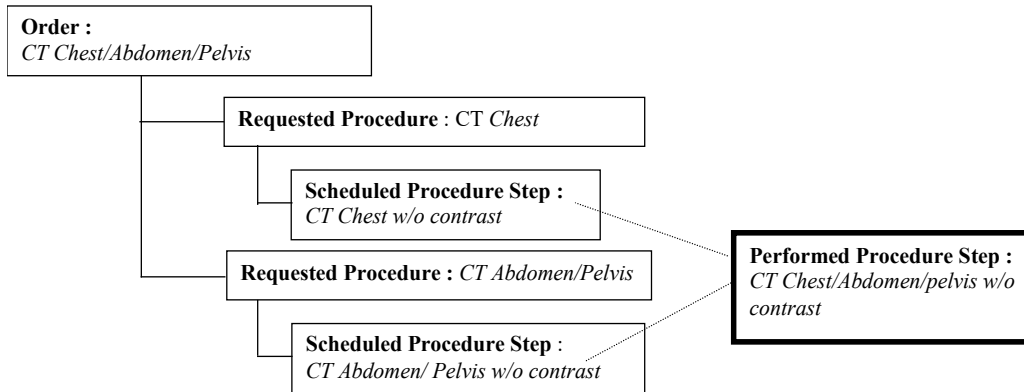
In this example, a single Performed Procedure Step has been performed in response to two
5755   Scheduled Procedure Steps. IHE refers to this as a Group Case (see RAD TF-2: 4.6). At the time of reading, the same series of images produced by this Performed Procedure Step would be read once in the context of the CT Chest Requested Procedure and again in the context of the Abdomen/Pelvis Requested Procedure.

34.4.1.2.2 Extending the Scheduled Workflow Concepts to Include Post-
5760   ### Processing Tasks

The workflow concepts described above may be extended to include other Scheduled Procedure Steps, such as those used to describe post-processing tasks.

Some of the Scheduled Procedure Steps may be Image Post-Processing related. These Scheduled Procedure Steps would result in Post-Processing Performed Procedure Steps. This is illustrated
5765   by the following example of an MR Brain with a Functional Analysis Post-Processing.

In the above example, two different Scheduled Procedure Steps have been defined for the Requested Procedure. This reflects the fact that in this radiology department, the functional analysis post-processing is not performed by the MR Technologist, but by the Radiologist and
5770   therefore needs to be independently scheduled on an independent workstation. Another

---

department may well choose to have the Technologist perform the post-processing immediately after the MR acquisition (either on the MR itself or on a co-located workstation). In that case the Requested Procedure would include a single Scheduled Procedure Step that includes both the acquisition and the post-processing task.

5775   This Section does not provide an exhaustive description of all the workflow cases supported by the Scheduled Workflow.b Profile, nor does it describe the Workflow enabled by other IHE Integration Profiles such as the Presentation of Grouped Procedures, Post-Processing Workflow and Reporting Workflow.

34.4.1.3 Scheduled Workflow Information Model

5780   The Scheduled Workflow Model is represented in this section as an Entity Relationship (ER) diagram. The Scheduled Workflow Model is based on the DICOM and HL7 standards. The keys relating the entities and the unique keys of each entity are defined and the cardinality of the entities is indicated.

An example of the conventions used to specify an entity's relationships is presented in Figure
5785   34.4.1.3-1.

Entity Name
Foreign Key (FK) relating this entity to previous - The FK is shown to clarify the ER diagram and not intended to represent a relational model.
Unique Key (U) for this entity. There are cases where Unique keys that are identical within the scope of this document have different contextual meanings, as defined in this document. The "+" symbol indicates two attributes must be combined to guarantee uniqueness.
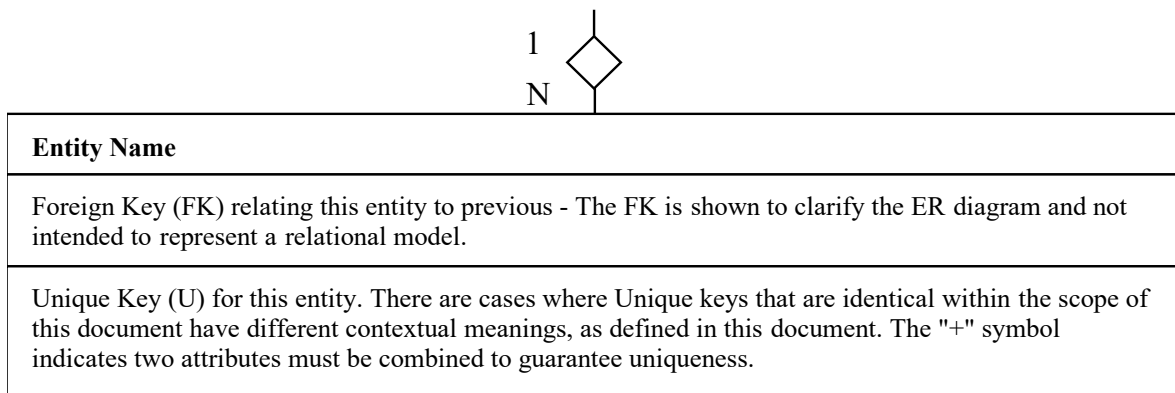
Figure 34.4.1.3-1: Example of the Entity Relationship Diagram

Figures 34.4.1.3-2 and 34.4.1.3-3 present the overview of the IHE Information Model. Mappings between specific HL7 Elements and DICOM Attributes are identified in RAD TF-2x: Appendix
5790   B.
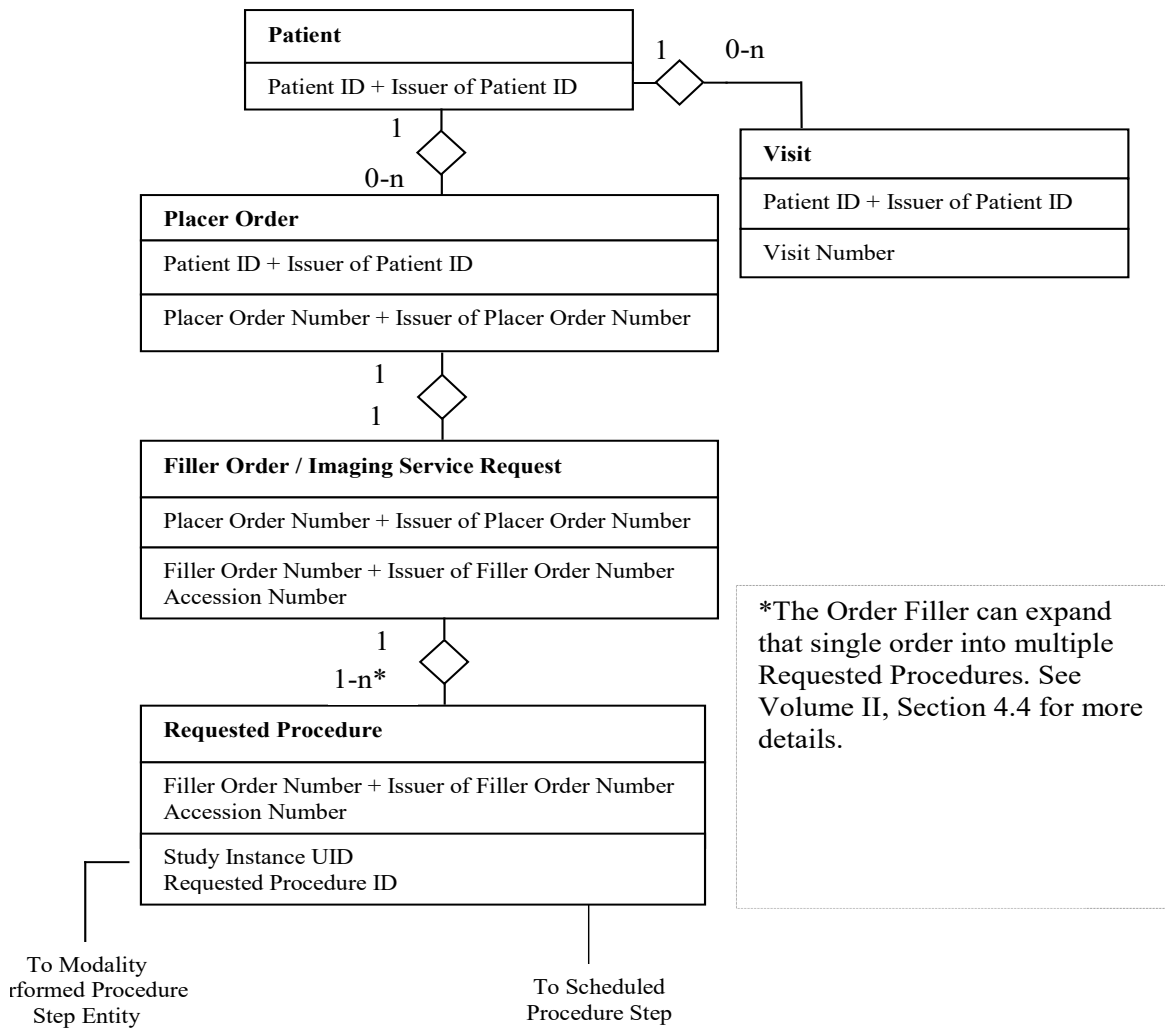
Figure 34.4.1.3-2: Schedule Workflow Information Model

From Requested Procedure Step

Scheduled Procedure Step

Requested Procedure ID
Study Instance UID

Scheduled Procedure Step ID

Modality Performed Procedure Step

Scheduled Procedure Step ID
Study Instance UID

Performed Procedure Step UID***
Affected SOP Instance UID

Series

Performed Procedure Step UID***

Series Instance UID

DICOM Instance

Series Instance UID

SOP Instance UID

**See Volume II, Section 4.6 for a thorough description of the cardinality relationship options of Modality Performed Procedure Step.

***The Performed Procedure Step UID is present as the Affected SOP Instance UID.

5795 **Figure 34.4.1.3-3: Schedule Workflow Information Model, continued**

34.4.2 Use Cases

This section first describes the process and information flow of patient care as it is defined in the IHE Technical Framework under "normal" circumstances, reflecting a typical patient encounter

5800 from registration/admission through the performance of an ordered procedure. Next a number of workflow variations (patient update, order change, exception management, implicit post-processing and departmental appointment notification) are described and finally, a variety of use cases related to handling unidentified patients.

5805 The unidentified patient cases cover trauma cases or emergency room patients when a patient's condition requires that a procedure be conducted immediately. This may need to be done before steps like proper patient registration, ordering and/or scheduling of the procedure are performed (due to the lack of either information or time or other deviation from the normal process flow). In this case patient/study information must be later reconciled and properly updated at the ADT, Order Placer, Department System Scheduler/Order Filler, and Image Manager. There are several examples of information flow in this case shown in Uses Cases #7-13.

5810 The ADT may utilize a Master Patient Index (MPI) to resolve the patient information to the correct Patient ID.

The IHE Radiology Technical Framework also supports cases when registration or temporary registration of a patient by ADT is not applicable or desired, for example:

5815
- Emergency Department patient can be identified but, due to time or system availability constraints the procedure must be performed before proper order entry and scheduling may occur.

- Patient ID, though valid, has never been propagated to all actors due to communication failures, or the wrong patient record was used in ordering/scheduling.

- Patient ID, though valid, has been mistyped at the modality.

5820
- Patient cannot be registered at the ADT by the time of the procedure. The patient presents to the Order Filler (Imaging Department) and the order is placed and performed in the department.

Patient reconciliation may also be initiated on the department level. In the case of procedures performed on the unidentified patient in multiple departments (e.g., Radiology and Laboratory), 5825 this will require reconciliation of patient information in multiple locations.

See RAD TF-1x: Appendix C for an overview of the information exchange between the Department System Scheduler/Order Filler and Image Manager.

To support the Scheduled Workflow.b Profile, an actor that claims support of other content profiles (Consistent Presentation of Images, Key Image Notes or Evidence Documents) is 5830 required to support the relevant storage, query and retrieve transactions and manage creation and reconciliation of those objects in the same way images are supported. The following diagrams will mostly show the management of images.

In case of DICOM SR, the patient information might be included in the content sequence. The update of the patient information in the report header might result in inconsistent header 5835 information with the report content. The patient information update shall not create a new SR SOP instance, according to DICOM SR SOP Class behavior as described in DICOM PS3.4 Annex O.

In the Unidentified Patient use cases, for the purpose of simplification, the following transactions were generally omitted from the corresponding diagrams:

5840
- Modality Performed Procedure Step In Progress [RAD-6]

- Modality Images Stored [RAD-8]

- Modality Presentation State Stored [RAD-9]

- Storage Commitment [RAD-10]

These transactions may occur within the time frame of the diagram, but their content does not
5845 affect each of the use cases.

34.4.2.1 Use Case #1: Simple

34.4.2.1.1 Simple Use Case Description

The most typical ("normal") case involves a radiology procedure being ordered, scheduled and performed for a registered patient.

5850 The administrative steps involve a patient being registered, an order being placed for the registered patient, and the order being scheduled. The procedure is then performed, with imaging data being produced and status messages communicated to interested systems.

This case covers both inpatient and outpatient procedures. The patient may be new or known to the current healthcare facility.

5855 **34.4.2.1.2 Simple Process Flow**
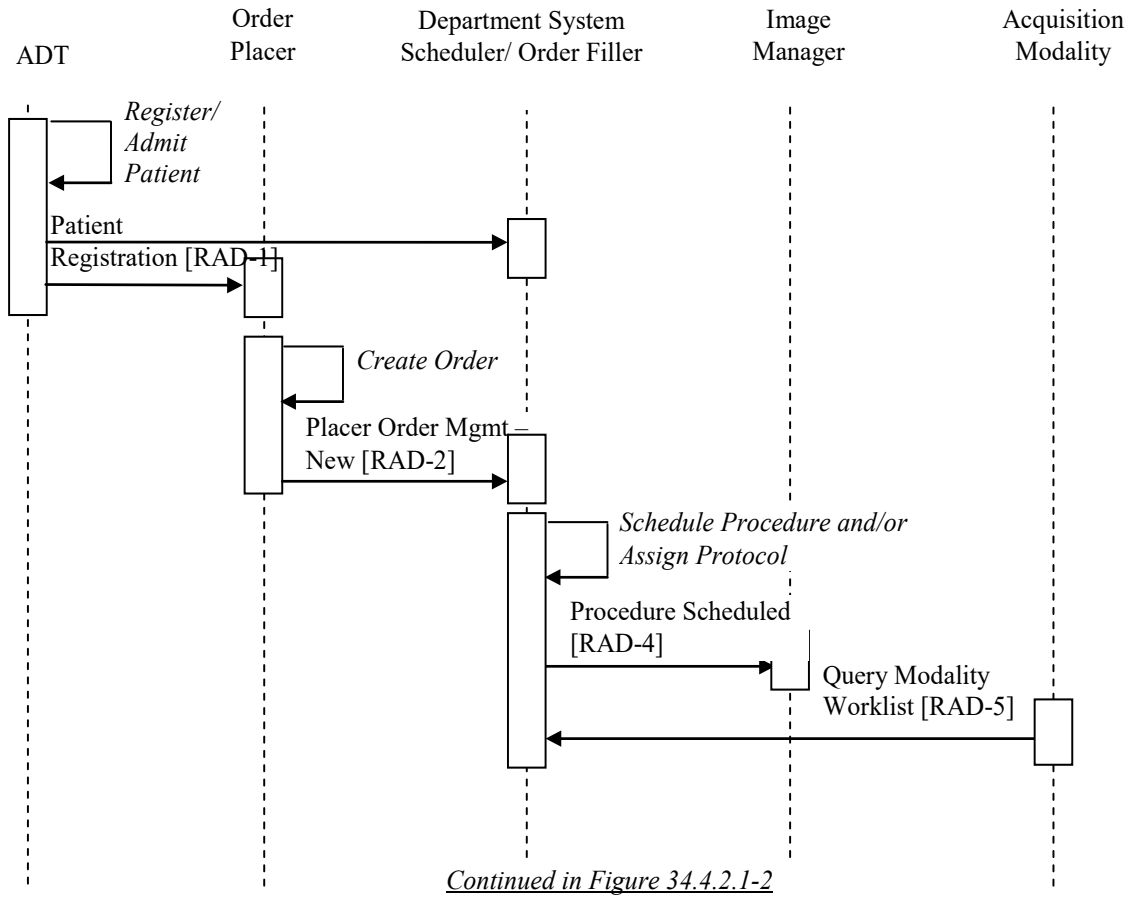
Figure 34.4.2.1.2-1: Administrative Process Flow in SWF.b
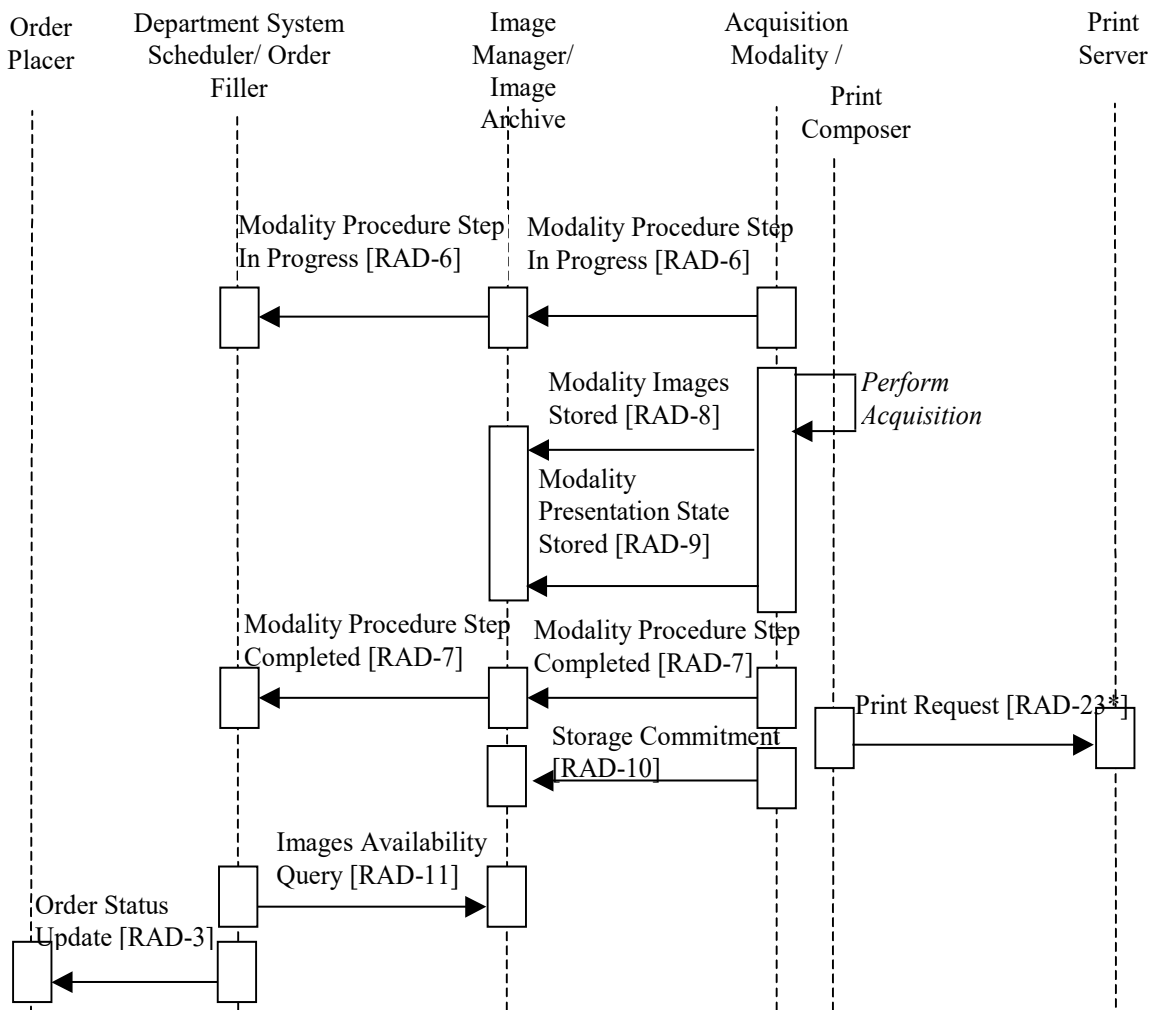
Figure 34.4.2.1.2-2: Procedure Performance Process Flow in SWF.b

5860   Note: The Print Request [RAD-23] transaction is not a part of this profile; it is displayed for illustration purposes only.

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

- The Print Composer is grouped with an Acquisition Modality but is shown separately in
5865   the diagram to distinguish the different transactions.

- *Schedule Procedure*: The Department System associates the order with a number of
     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 grouped into Scheduled Procedure Steps based on the timing and
5870   ordering. Scheduled Procedure Steps are scheduled, i.e., assigned a time slot and
     performing resource (modality).

- *Protocol Assigned*: The radiologist determines the protocol (i.e., settings and conditions to be used in performing the Scheduled Procedure Steps); in particular, the ordered list of codes identifying the protocol for each of the steps. This may happen prior to, simultaneous with, or subsequent to the *Schedule Procedure* process step.

5875

- The diagram above shows one particular sequencing of the Modality Procedure Step Completed [RAD-7] transaction. This transaction may occur at any point following the creation of an image and/or Presentation State (GSPS) objects. This means it can occur before images and/or GSPS are stored, after storage, after printing (as in this example), or even after storage commitment. The IHE Technical Framework does not specify the timing of this transaction in relation to other transactions.

5880

- The diagram above shows the managed creation of images. The equivalent flow applies to other Evidence Documents that the actor supports.

34.4.2.2 Use Case #2: Patient Update

5885 This case covers the situation where patient information updates are introduced into the system at various stages of the normal process flow.

34.4.2.2.1 Patient Update Use Case Description

Such updates will cause additional transactions to occur to assure synchronization of information between interested actors. Only the affected parts of the normal flow diagram are presented
5890 below. All subsequent process steps will progress according to the normal flow diagram.

Three subcases are shown based on when the patient update is initiated:

- After the patient is registered but before the order is entered

- After the order is entered but before the procedure is scheduled

- After the procedure is scheduled

5895 The *Modify Patient* process includes changing inpatient demographics, merging two patient records and moving the information from one patient record to another.

34.4.2.2.2 Patient Update Process Flow
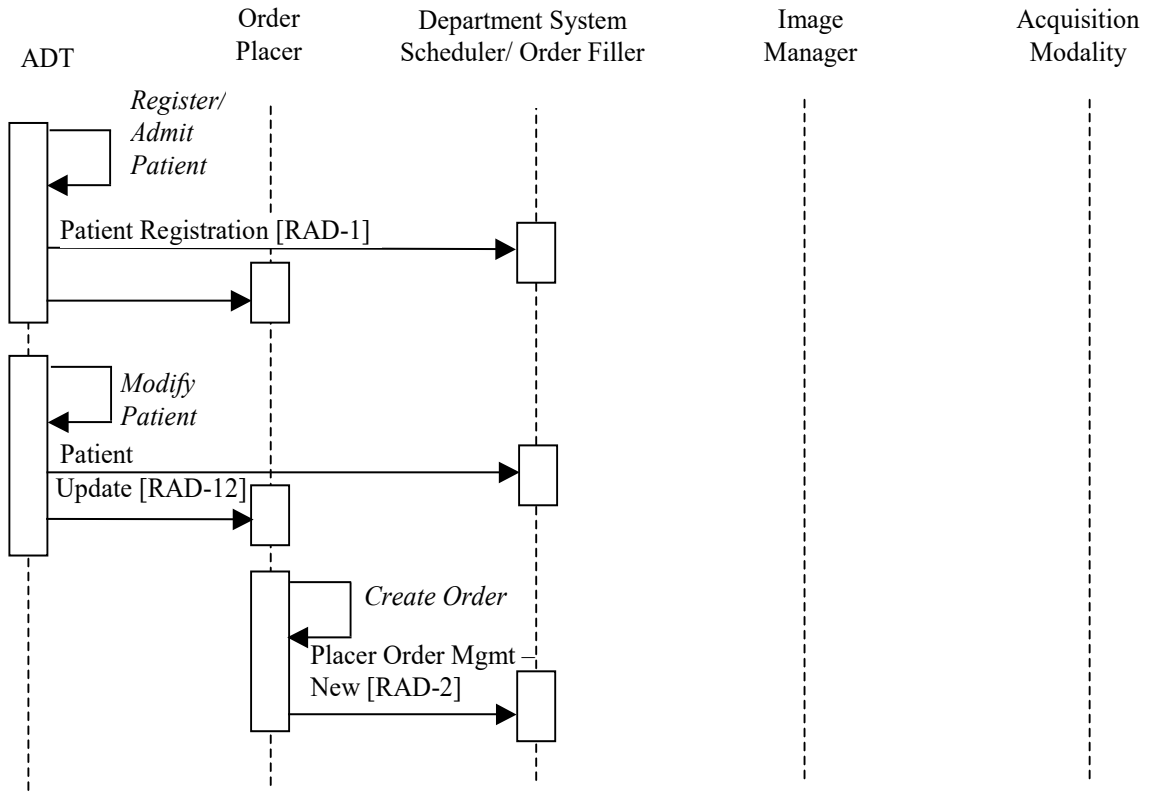
Figure 34.4.2.2.2-1: Patient Update before Order Entry in SWF.b
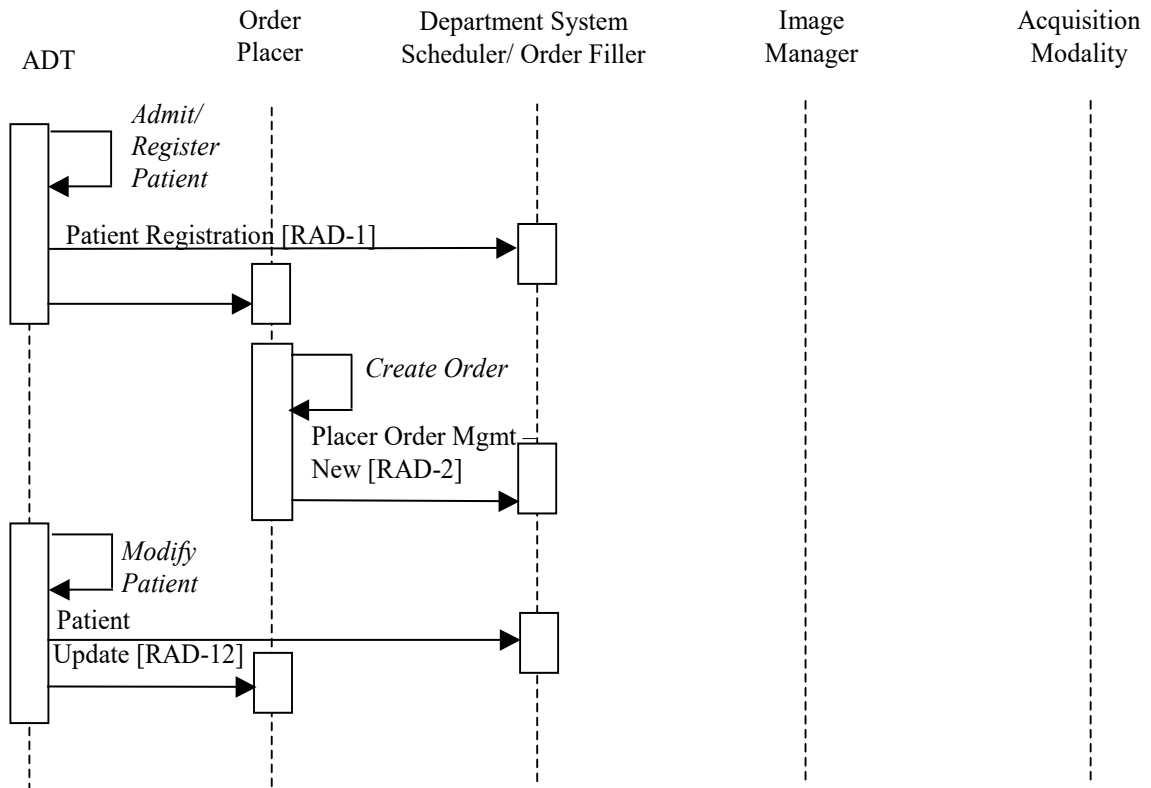
Figure 34.4.2.2.2-2: Patient Update after Order Entry in SWF.b
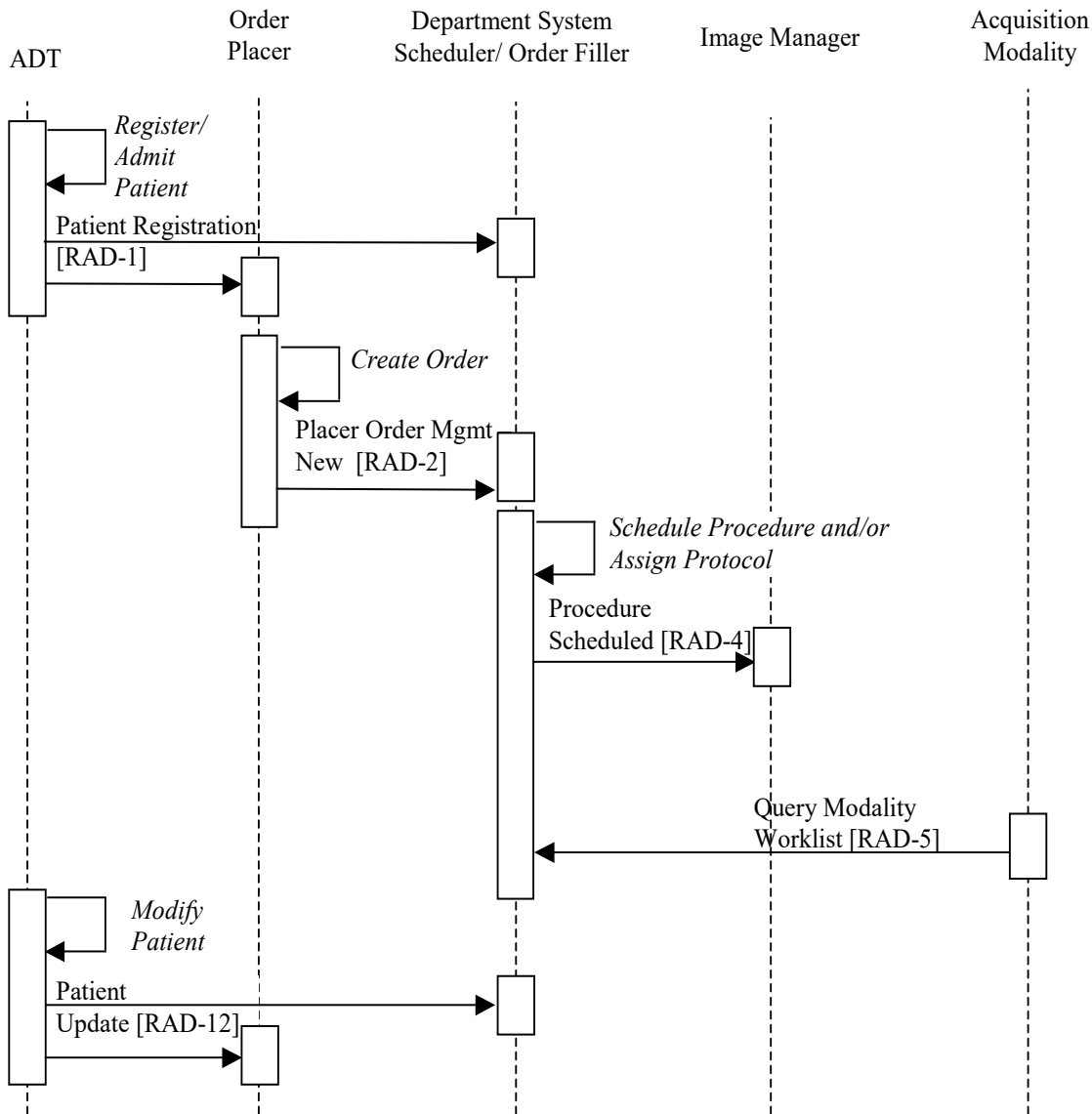
Figure 34.4.2.2.2-3: Patient Update after Procedure Scheduling in SWF.b

Note that in later use cases the Image Manager will also be notified and will have additional
5905 responsibility when patient updates occur.

34.4.2.3 Use Case #3: Order Change

This case covers the situation when the Order Placer or the Department System Scheduler/Order
Filler has to change order information or cancel/discontinue an order.

34.4.2.3.1 Order Change Use Case Description

5910 When an order information change is necessary, the IHE Technical Framework allows for the
initiating actor to change the order in a single message with the new information. Figures

34.4.2.3.2-1 and 34.4.2.3.2-2 depict examples of order change flow initiated by the Order Placer and the Department System Scheduler/Order Filler respectively. Note that one should consider these transactions as being performed between the process flow fragments depicted in the Figures 34.4.2.1-1 and 34.4.2.1-2 to ensure synchronization of information between interested actors.

5915

Such updates will cause additional transactions to occur to assure synchronization of information between interested actors. Only the affected parts of the normal flow diagram are presented below. All subsequent process steps will progress according to the normal flow diagram.

5920   Three subcases are shown based on when the patient update is initiated:

- After the patient is registered but before the order is entered

- After the order is entered but before the procedure is scheduled

- After the procedure is scheduled

The *Modify Patient* process includes changing inpatient demographics, merging two patient records and moving the information from one patient record to another.

5925

34.4.2.3.2 Order Change Process Flow
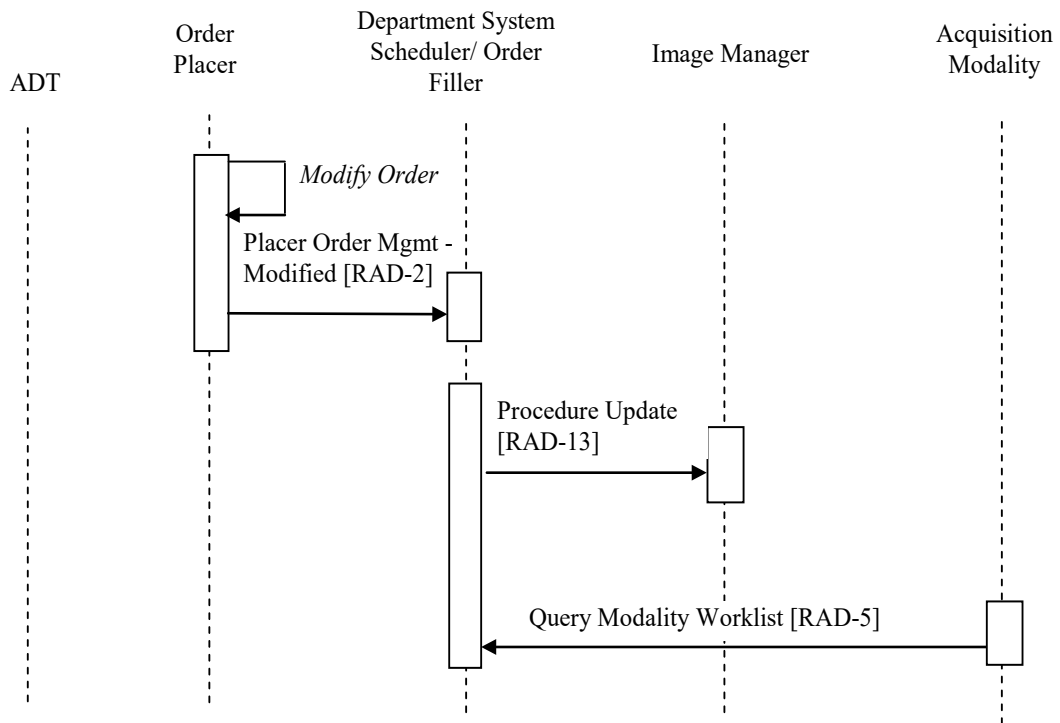
Figure 34.4.2.3.2-1: Order Modified by the Order Placer

Department System Scheduler/Order Filler may modify an order originally received from the Order Placer, as shown in Figure 34.4.2.3.2-2.

5930
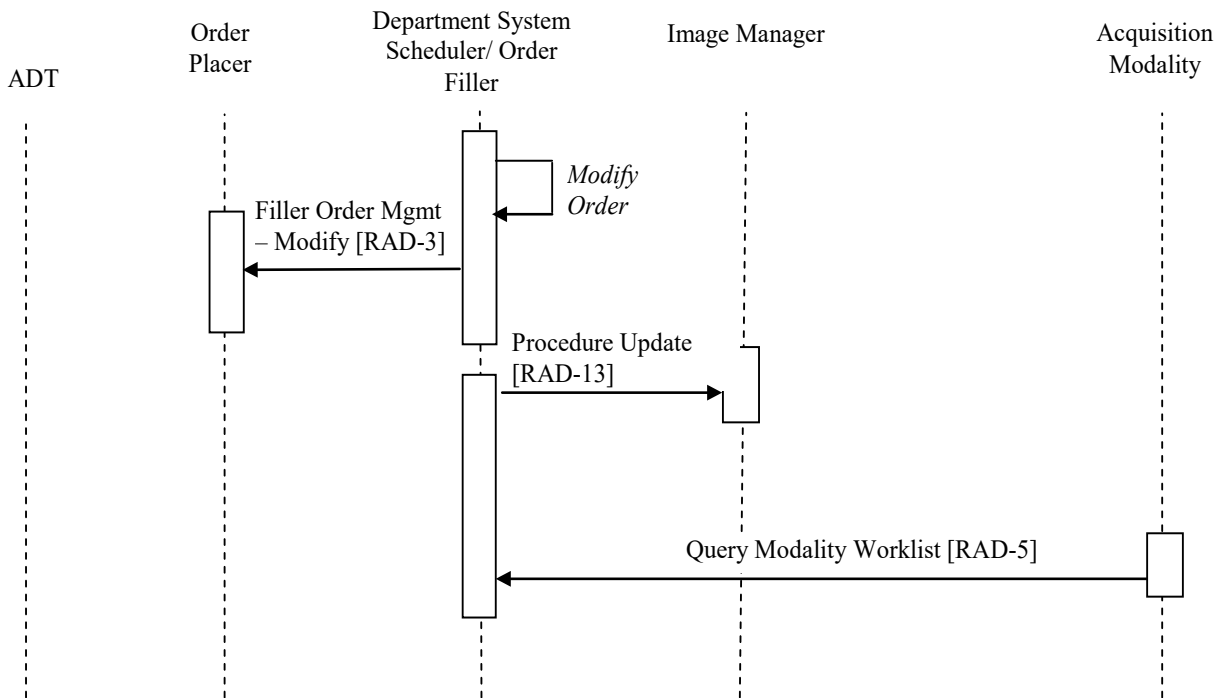
Figure 34.4.2.3.2-2: Order Modified by the Department System Scheduler/Order Filler

The Order Placer may not change an order that has already been started, i.e., one for which Order Filler has transmitted an "In-Progress" status. However, if the Order Filler receives the change order message after it has sent the Status Update message (for example, in a case of a race condition between two messages), Order Filler will accept the change order and perform Procedure Update [RAD-13] to notify Image Manager.

The Order Filler may not change a scheduled procedure step that has already been started, i.e., one for which the Acquisition Modality has transmitted an "In-Progress" status. The IHE Technical Framework does not support notification to the modality of the Scheduled Procedure Step discontinuation or change after the Modality Procedure Step In Progress message has been generated by the Acquisition Modality, i.e., the current procedure step will be completed even though the order could be changed or discontinued.

34.4.2.4 Use Case #4: Exception Management Without Reason Codes

This case addresses the need to manage errors at the modality (but without providing coded reasons for the exception).

34.4.2.4.1 Exception Management Without Reason Codes Use Case Description

The types of exceptions covered by this case are as follows:

- Selection of the incorrect Scheduled Procedure Step from the Modality Worklist.

5950   • Handling the consequences of having performed a procedure step other than the
             scheduled one.

The following numbered items list exception cases that shall be supported by the actors listed in
each item.

In the course of the scheduled workflow, such exceptions may occur at different times:

5955   1. Before the Modality Procedure Step in Progress transaction is issued, the
            Operator/Radiologist changes the order on the Department System Scheduler which then
            provides the Modality Worklist as defined by the Scheduled Workflow.b Profile (see the
            Order Change flow described in Section 34.4.2.3). This will ensure that the most recent
            Worklist Information is used by the Modality. The Acquisition Modality shall be able to
5960   process new worklist information that results from this order change; when or how the
            modality re-queries the Department System Scheduler is not specified by this framework.

         2. After the Modality Procedure Step in Progress transaction has been issued, but before the
            Modality Procedure Step Completed transaction is issued, the Operator/Radiologist may
            discontinue the PPS. In this case any images that may have been acquired are part of the
5965   discontinued PPS and they shall be Storage Committed. This case is supported by
            Abandoned case (see RAD TF-2: 4.6.4.1.2.3.5) of the Scheduled Workflow.b Profile.
            (See Section 34.4.2.5 for a description of Discontinuation with Reason.)

         3. After the Modality Procedure Step Completed transaction has been issued, the
            Operator/Radiologist may notice or become aware that an incorrect worklist entry
5970   selection was made. Whether this occurs before the Requested Procedure is read or
            afterwards, the modality is not responsible for performing the necessary corrections.
            Rather the Image Manager and the Department System Scheduler/Order Filler must make
            such corrections (see RAD TF-2: 4.7.4.1.3.1). The Image Manager and the Order Filler
            may also offer a correction capability to recover the erroneous instances. IHE does not
5975   provide a mechanism to propagate automatically this correction between the Image
            Manager/Image Archive and the Department System Scheduler/Order Filler.

Acquisition Modalities are recommended, but not required, to support the following two cases to
deal with using a different protocol at the modality as was scheduled by the Department System
Scheduler/ Order Filler.

5980   1. **After** the Modality Procedure Step in Progress transaction has been issued, but before the
            Modality Procedure Step Completed transaction is issued, the Operator/Radiologist may
            decide to modify the "in progress" Performed Procedure Step from what was intended by
            the Requested Procedure and Scheduled Procedure Step selected. In the Scheduled
            Workflow.b Profile, the Acquisition Modality notifies the PPS Manager (and in turn the
5985   Image Manager and the Department System Scheduler) by returning a Procedure Code
            Sequence of zero length. In addition, if the Assisted Acquisition Protocol Setting Option
            is supported by the Acquisition Modality, it can indicate this change by returning a
            Performed Protocol Code Sequence different from the Scheduled Protocol Code
            Sequence (see Figure 34.4.2.4.2-1 below).

5990   2. **Before** the Modality Procedure Step in Progress transaction is issued, the Operator/Radiologist decides to proceed without changing the order on the Department System Scheduler/Order Filler by performing one or more Procedure Steps different than scheduled by the Modality Worklist entry as defined by the Scheduled Workflow.b Profile. Its handling at the Acquisition Modality may be facilitated by the Assisted

5995   Acquisition Protocol Setting Option.

34.4.2.4.2 Basic Exception Management Process Flow
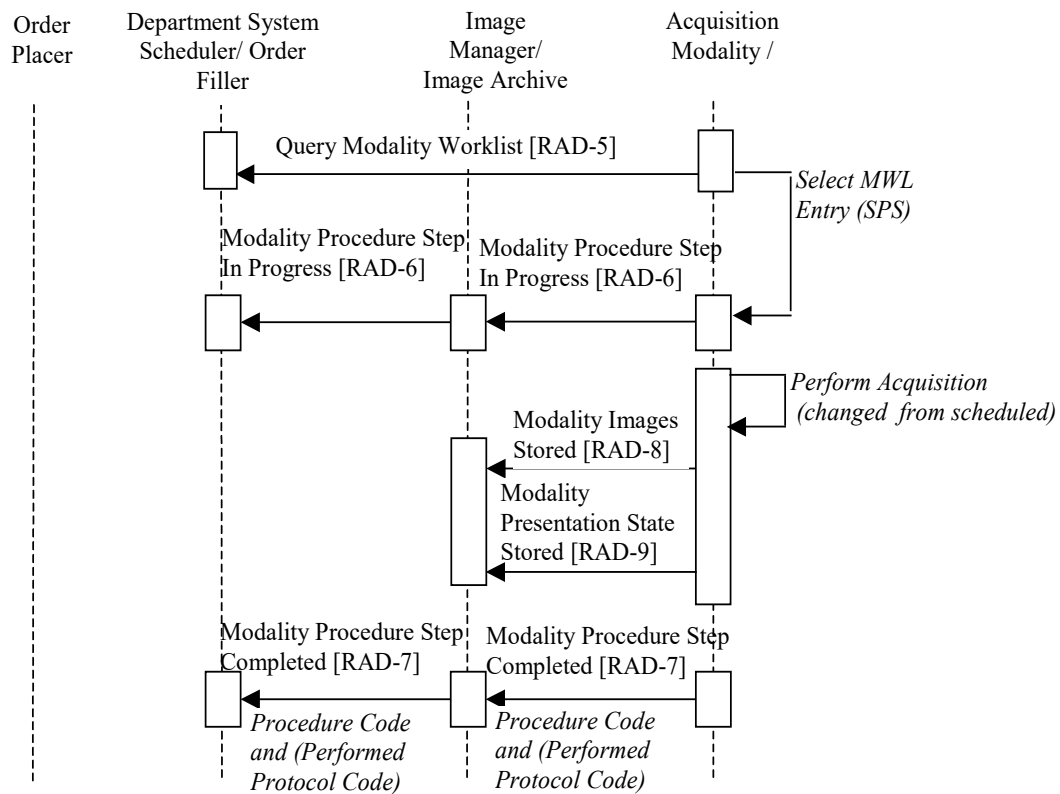
Figure 34.4.2.4.2-1: Exception Management Workflow (Changed from Scheduled on Modality)

34.4.2.5 Use Case #5: Exception Management with Reason Codes

34.4.2.5.1 Exception Management with Reason Codes Use Case Description

These additional use cases include providing coded reasons for the exception and are only required for systems claiming support of the PPS Exception Management Option (see Section 34.2.3).

6005

   1. After the Modality Procedure Step In Progress transaction has been issued, the Operator/Radiologist may realize that the wrong SPS has been selected (incorrect patient

6010   or incorrect Requested Procedure/Order for the same patient). In this case some of the acquired images or other evidence objects may already have been stored to the Image Manager/Image Archive (with or without storage commitment confirmed). The Acquisition Modality notifies the PPS Manager (and in turn, the Image Manager and the Department System Scheduler/Order Filler) of the error using the Reason Codes as described in RAD TF-2: 4.7.4.1.2.2 so that these systems take appropriate action as described in RAD TF-2: 4.7.4.1.3.1 (see Figure 34.4.2.6.2-1 below).

6015   IHE does not define how the modality may dispose of and/or correct the images or other evidence objects. Each implementation may decide if it is useful to support the storage of the corrected images or other evidence objects, when clinically meaningful. However, if they do, new *Modality Procedure Step in Progress/Completed* and Storage Commitment transactions shall be used.

6020   2. As in sub-case 2 of Exception Management Without Reason Codes, after the Modality Procedure Step in Progress transaction has been issued, but before the Modality Procedure Step Completed transaction is issued, the Operator/Radiologist may discontinue the PPS. In addition to the Exception Management Without Reason Codes behavior, the Modality also notifies the PPS Manager (and in turn the Image Manager
6025   and the Department System Scheduler) of the reason for the discontinuation using the Reason Codes as described in RAD TF-2: 4.7.4.1.2.2 so that these systems may take the appropriate actions (see Figure 34.4.2.6.2-2 below).

34.4.2.5.2 Exception Management with Reason Codes Process Flow
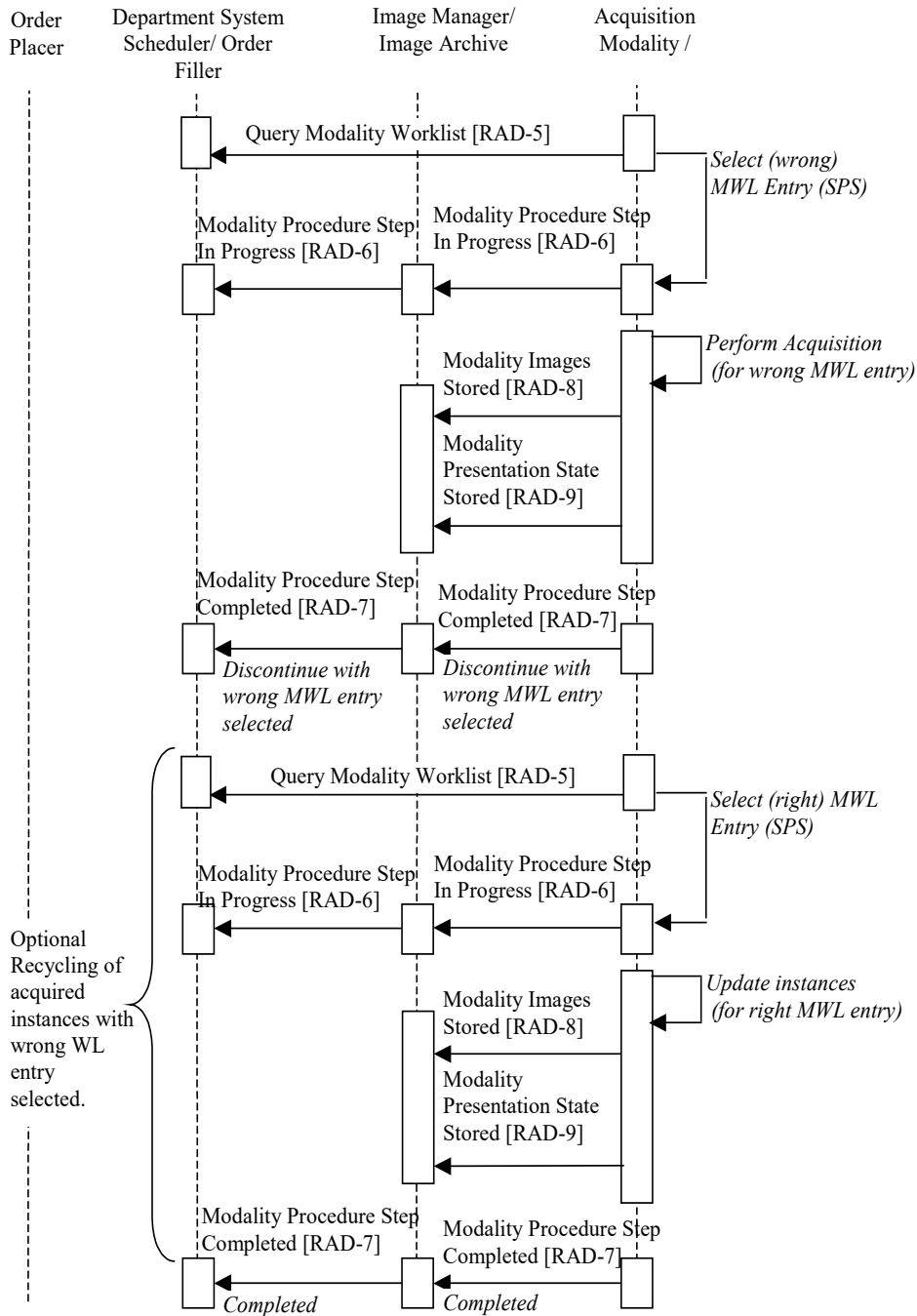
Figure 34.4.2.5.2-1: Exception Management Workflow (Wrong Worklist Entry Selected)
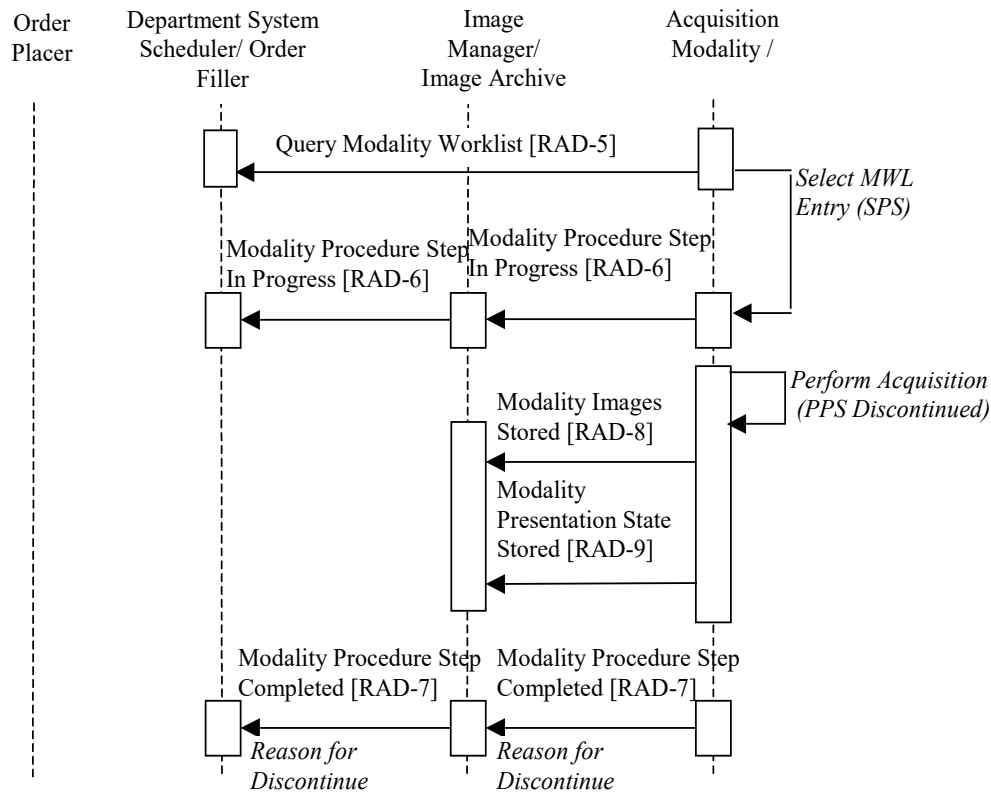
Figure 34.4.2.5.2-2: Exception Management Workflow (Discontinued with a Reason)

34.4.2.6 Use Case #6: Implicit Post-Processing

This case addresses image post-processing tasks performed as an implicit part of the scheduled workflow.

34.4.2.6.1 Implicit Post-Processing Use Case Description

In general, post-processing tasks scheduled and managed explicitly using post processing worklists are addressed by the Post-Processing Workflow Profile (see RAD TF-1: 12 for further details on that profile). However, at some sites, post-processing tasks performed on the acquisition system or adjacent workstations are implied by the information in the acquisition worklist. In such cases, the post-processing is managed by the technician simply carrying out the steps following acquisition.

Technicians may be instructed that certain post-processing should always be performed for certain acquisitions, or alternatively, different protocol codes may be provided in the acquisition worklist to indicate intended post-processing. In either case, no worklist is used on the post-processing Evidence Creator.

In the case of this "implicit post-processing workflow", the Evidence Creator may obtain source images and other evidence objects necessary for post-processing by receiving them from the Acquisition Modality (either pulled or pushed via some non-IHE defined mechanism) or by

6050   being grouped with an Image Display (giving the system query/retrieve capabilities). Based on the information contained in the images, the Evidence Creator can send status messages and store its results according to the IHE transactions as shown in the following use cases.

34.4.2.6.2 Implicit Post-Processing Process Flow

The following sequence of steps describes the typical process flow when the Evidence Creator
6055   receives the images from an Acquisition Modality via some non-IHE means.
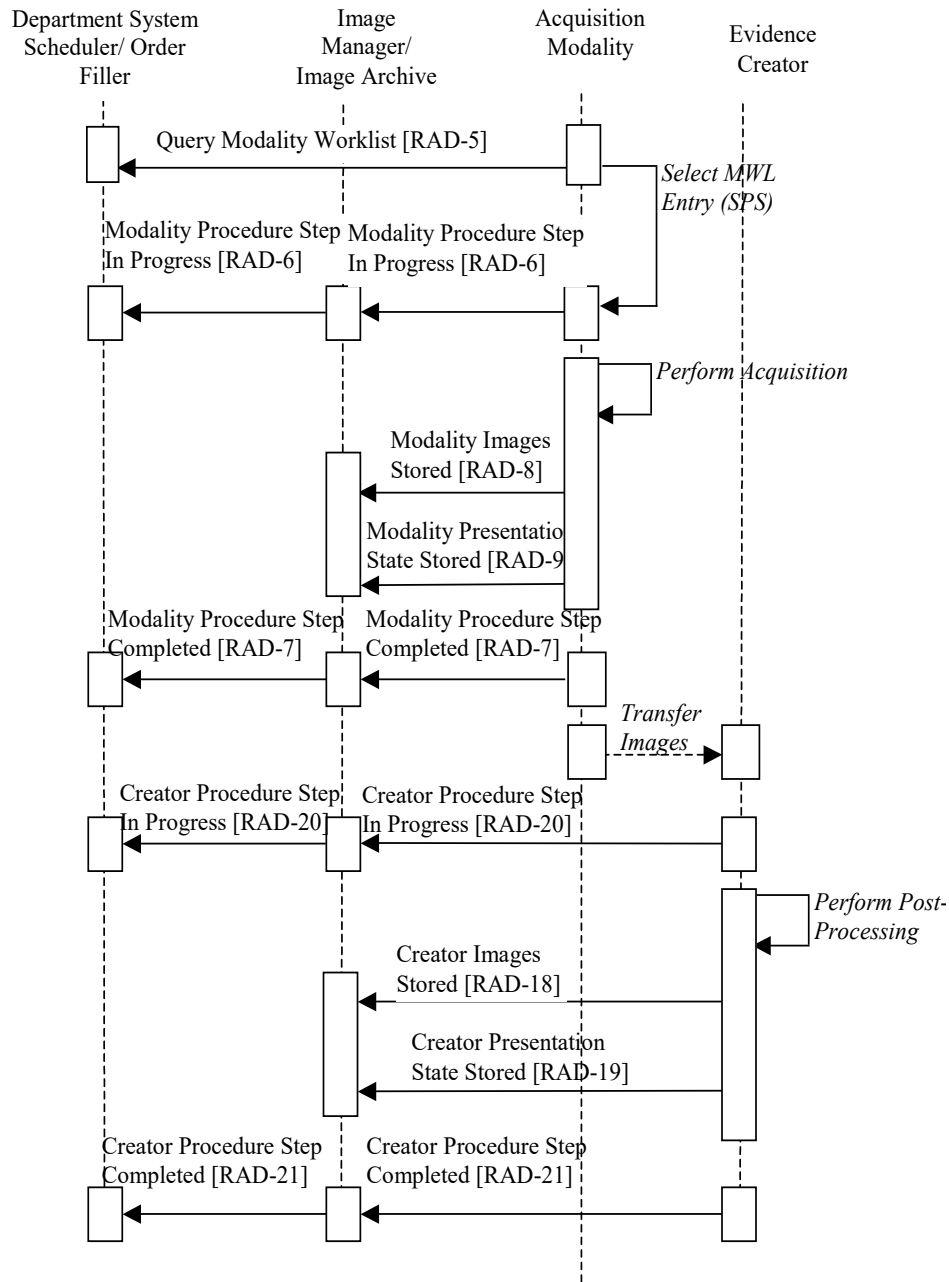
Figure 34.4.2.6.2-1: Post-processing in Scheduled Workflow.b

Note 1: The Modality Presentation State Stored [RAD-9] and Creator Presentation State Stored [RAD-19] transactions are not a part of this profile; they are displayed for illustration purposes only.

6060   Note 2: When the Acquisition Modality performs implicit post-processing, it reports performed procedure step progress using [RAD-6] and [RAD-7] rather than [RAD-20] and [RAD-21]. The post-processing result instances may be referenced in the same [RAD-7] acquisition PPS as the acquired images, or may be referenced in one or more separate [RAD-7] PPS messages.

The following should be noted in relation to the Post-Processing process flow in Scheduled
6065   Workflow.b as described above:

- The images for post-processing are transferred from the Acquisition Modality to the Evidence Creator by means that are out of scope of the IHE Technical Framework.

- *Perform Post-Processing*: The Evidence Creator uses the source images and/or other evidence objects it receives from the Acquisition Modality to perform post-processing
6070   tasks and generate new set(s) of images and/or other evidence documents. It uses information from the source images to populate the newly created objects and the Creator Performed Procedure Step Messages.

The following sequence of steps describes the typical process flow when Evidence Creator is grouped with Image Display.
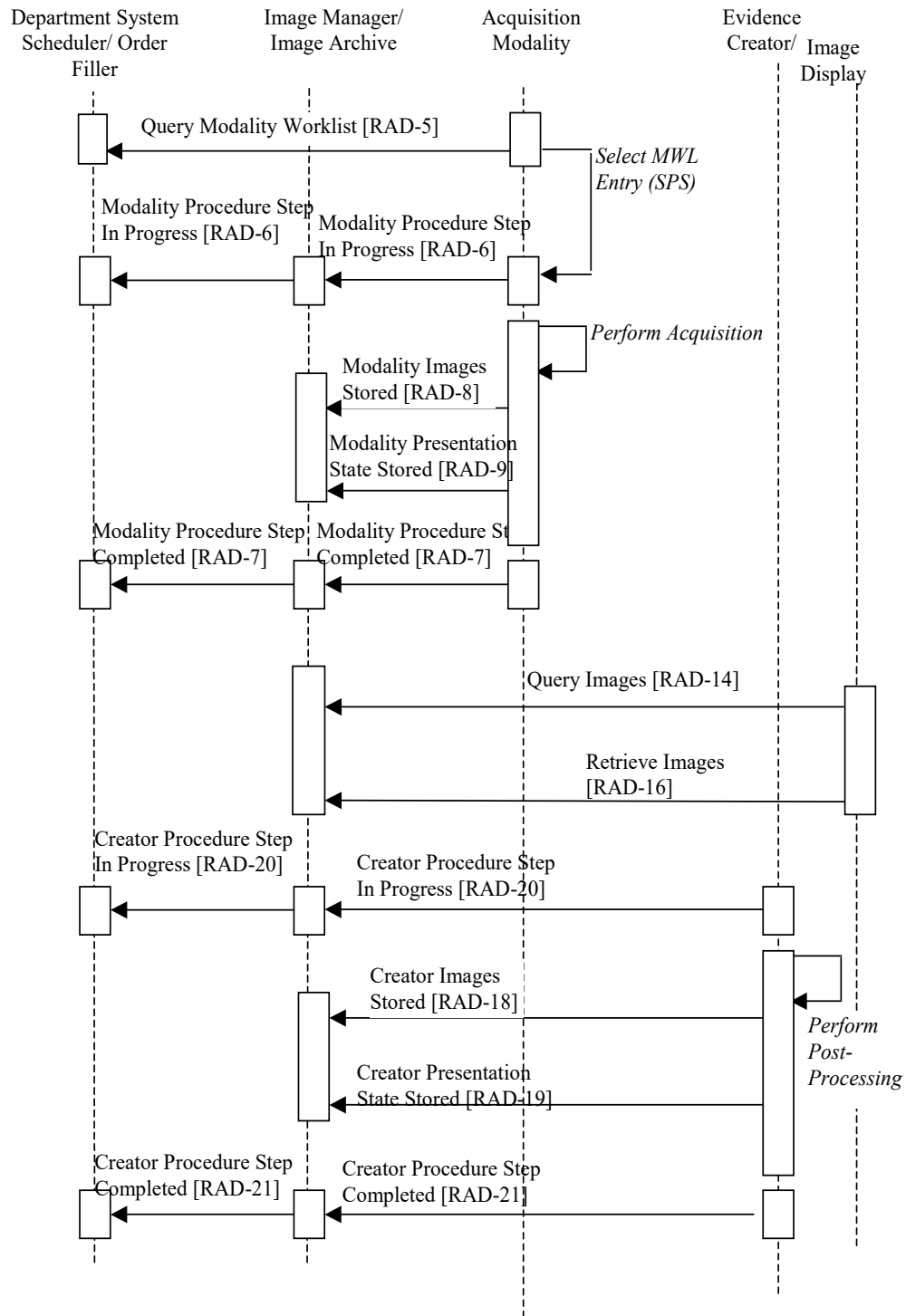
6075

Figure 34.4.2.6.2-2: Post-processing in Scheduled Workflow.b (performed on Evidence Creator)

Note 1: The Modality Presentation State Stored [RAD-9] and Creator Presentation State Stored [RAD-19] transactions are not a part of this profile; they are displayed for illustration purposes only.

6080   Note 2: When the Acquisition Modality performs implicit post-processing, it reports performed procedure step progress
           using [RAD-6] and [RAD-7] rather than [RAD-20] and [RAD-21]. The post-processing result instances may be
           referenced in the same [RAD-7] acquisition PPS as the acquired images, or may be referenced in one or more
   separate [RAD-7] PPS messages.

The following should be noted in relation to the Post-Processing process flow on the independent
6085   workstation:

- The Evidence Creator is grouped with the Image Display and the images for post-processing are retrieved from the Image Archive where the Acquisition Modality has transferred them.

6090   - *Perform Post-Processing*: The Evidence Creator uses the source images and/or other evidence objects it receives from the Image Archive to perform post-processing tasks and generate new set(s) of images and/or other evidence documents. It uses information from the source images to populate the newly created objects and the Creator Performed Procedure Step Messages.

34.4.2.7 Use Case #7: Departmental Appointment Booking

6095   This case addresses the use of the Departmental Appointment Notification Option by the Order
Placer and Order Filler Actors.

34.4.2.7.1 Departmental Appointment Booking Use Case Description

In the Scheduled Workflow.b Profile, the scheduling needed to perform an Order is managed by
the Departmental System Scheduler/Order Filler. The Order Placer may request along with an
6100   Order a preferred date and time for this Order, but it is the Order Filler that sets, updates and
possibly cancels the appointment(s) for examinations. When a new Order is placed by the Order
Placer or the Order Filler, an Appointment Notification (New Bookings) is sent to the Order
Placer. This Appointment Notification (New Bookings) may include several appointments
bookings in case some of the Scheduled Procedure Steps require separate appointments. Equally,
6105   one or more Scheduled Procedure Steps may be scheduled during the same appointment
booking.

If any changes to some of these appointments are made by the Order Filler, it issues an
Appointment Notification (Reschedule Bookings) to inform the Order Placer of the change. If
that appointment is cancelled by the Order Filler, it issues an Appointment Notification (Cancel
6110   Bookings) to the Order Placer.

Although the Order Placer is kept aware of any scheduling changes that may be made by the
Order Filler, no mechanism is defined in SWF.b to request an appointment change. For such a
change, a phone call to the person entering orders on the Order Filler could be used.

34.4.2.7.2 Departmental Appointment Booking Process Flow
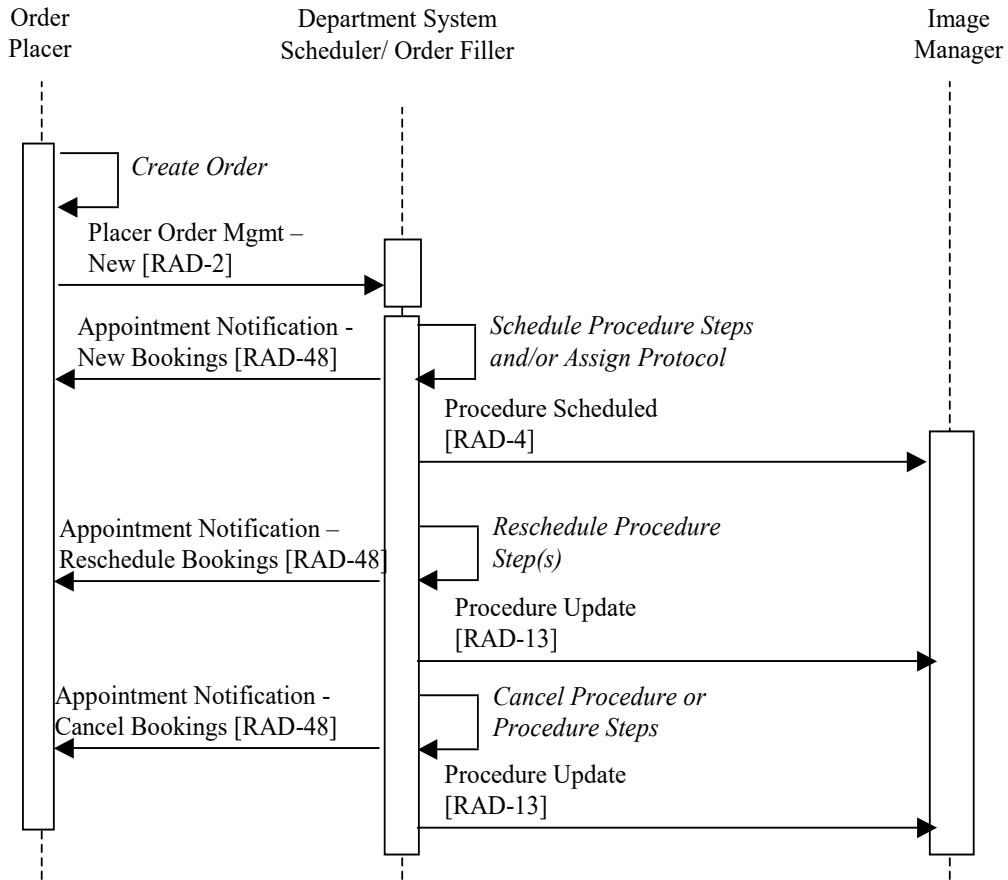
Figure 34.4.2.7.2-1: Departmental Appointment Booking Process Flow

34.4.2.8 Use Case #8: Unidentified Patient Registered at ADT and Ordered at the Order Placer

34.4.2.8.1 Unidentified Patient Registered at ADT and Ordered at the Order Placer Use Case Description

In this case, the Unidentified Patient has been registered at the ADT and the procedure Ordered at the Order Placer.

The ADT is a single point of patient reconciliation in the enterprise. Process flow requires that any unidentified patient be assigned a permanent Patient ID and a temporary name (e.g., "John Doe"). All subsequent transactions follow the normal flow (see Section 34.4.2.1) including order entry and procedure scheduling. 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 Department System Scheduler/Order Filler about corresponding changes. The ADT sends a Patient Update message to both the Order Placer and Department System Scheduler/Order Filler. The

6130   Department System Scheduler/Order Filler sends the Patient Update message to the Image
        Manager and the Report Manager.

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]
6135   and Patient Update [RAD-12] (Merge) transactions.

- If a permanent Patient ID was assigned, then the ADT may only send a Patient Update
  [RAD-12] transaction with proper information.

Note that the Performed Procedure Step Manager is not shown on the Process Flow diagrams
and is presumed to be grouped with the Image Manager. It may be grouped with the Department
6140   System Scheduler/Order Filler with corresponding changes in the flow of PPS related
        transactions between the Image Manager and Department System Scheduler/Order Filler.

34.4.2.8.2 Unidentified Patient Registered at ADT and Ordered at the Order Placer Process Flow
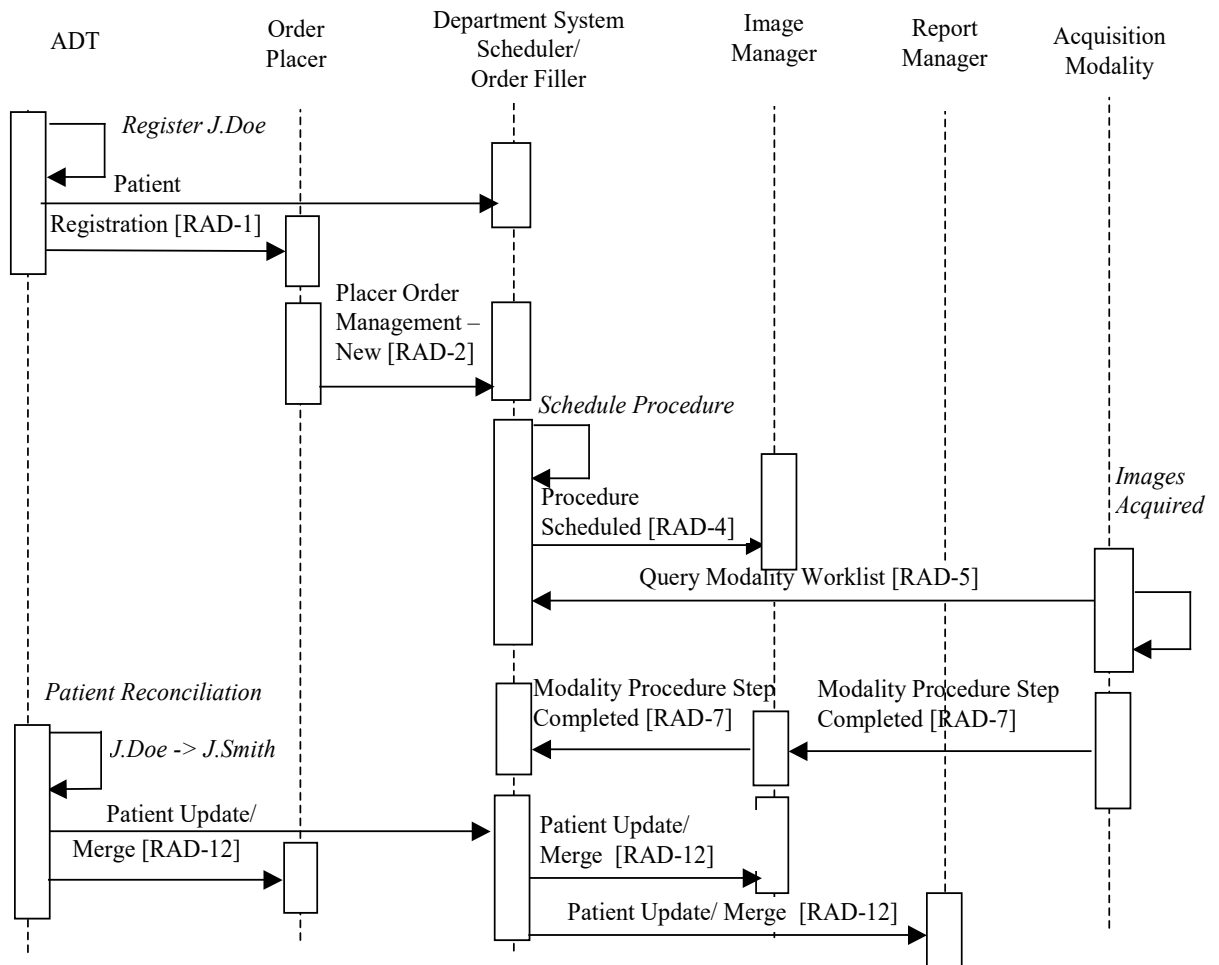
6145

Figure 34.4.2.8.2-1: Unidentified Patient – Placer Order

34.4.2.9 Use Case #9: Unidentified Patient Registered at ADT and Ordered at Department System Scheduler/Order Filler

6150 **34.4.2.9.1 Unidentified Patient Registered at ADT and Ordered at Department System Scheduler/Order Filler Use Case Description**

This case is based on Use Case 7. However, in this situation the order for a procedure is generated by the Department System Scheduler/Order Filler and submitted to the Order Placer. Procedures are scheduled normally and image acquisition uses modality worklist. When the
6155 patient information is reconciled, 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 and the Report Manager.

Significant Transactions:

6160
- To reconcile the patient information, the ADT may register a new patient and merge the temporary patient with the correct patient and send both registration and merge transactions.

- If a permanent Patient ID was assigned, then the ADT may only send a Patient Update transaction with proper information.

6165
- A Filler Order Management (New Order) [RAD-3] transaction is sent from Department System Scheduler/Order Filler to the Order Placer.

34.4.2.9.2 Unidentified Patient Registered at ADT and Ordered at Department System Scheduler/Order Filler Process Flow
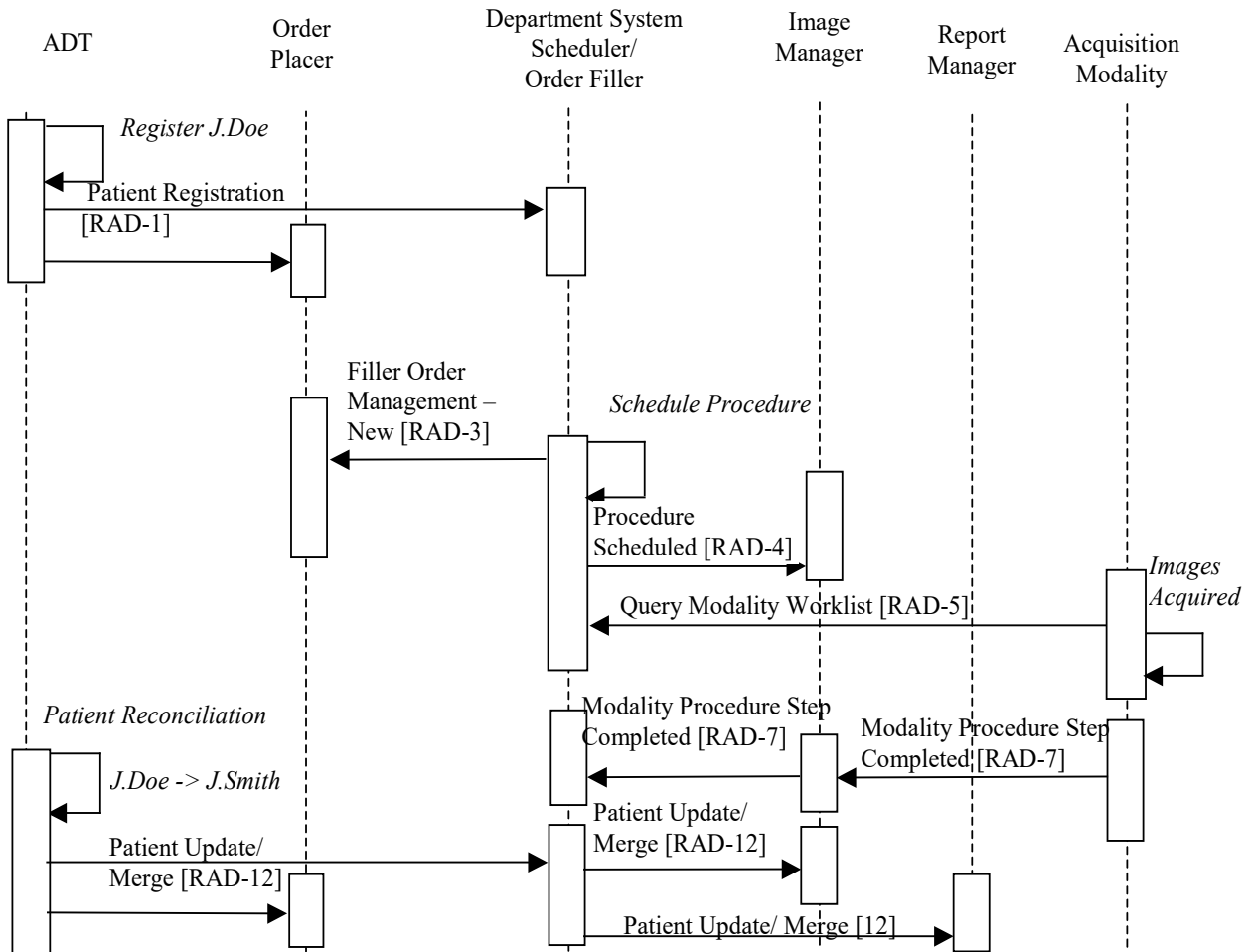
Figure 34.4.2.9.2-1: Unidentified Patient – Filler Order

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34.4.2.10 Use Case #10: Unidentified Patient Registered at ADT but Completed at Modality Prior to Order

34.4.2.10.1 Unidentified Patient Registered at ADT but Completed at Modality Prior to Order Use Case Description

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As in Use Cases 8 and 9, this uses a permanent Patient ID generated by the ADT. However, no order entry or scheduling takes place before the Acquisition Modality performs the procedure. A permanent Patient ID and a temporary name are manually entered at the Acquisition Modality (typically, from a card) and conveyed to the Department System Scheduler/Order Filler and the

6180 Image Manager by the Acquisition Modality. Subsequently, the Department System Scheduler/Order Filler generates and submits an order to the Order Placer. When the patient information is reconciled, the ADT sends the Patient Update messages to both the Order Placer and the Department System Scheduler/Order Filler. The Department System Scheduler/Order Filler sends a Patient Update message to the Image Manager and the Report Manager.

6185 Significant Transactions:

- On receiving a Modality Procedure Step Completed [RAD-7], the Department System Scheduler/Order Filler recognizes it as an unscheduled case.

- The Department System Scheduler/Order Filler sends a Filler Order Management (New Order) [RAD-3] transaction to the Order Placer.

6190

- Using the information from the Procedure Step Completed transaction and the placed order, the DSS/Order Filler creates a new Requested Procedure record and sends a Procedure Scheduled transaction to the Image Manager.

- To reconcile the patient information, the ADT may register a new patient and merge the temporary patient with the correct patient and send both registration and merge

6195 transactions.

- If a permanent Patient ID was assigned, then the ADT may only send a Patient Update transaction with proper information.

- The DSS/Order Filler sends a Patient Update transaction to the Image Manager.

34.4.2.10.2 Unidentified Patient Registered at ADT but Completed at Modality
6200   **Prior to Order Process Flow**
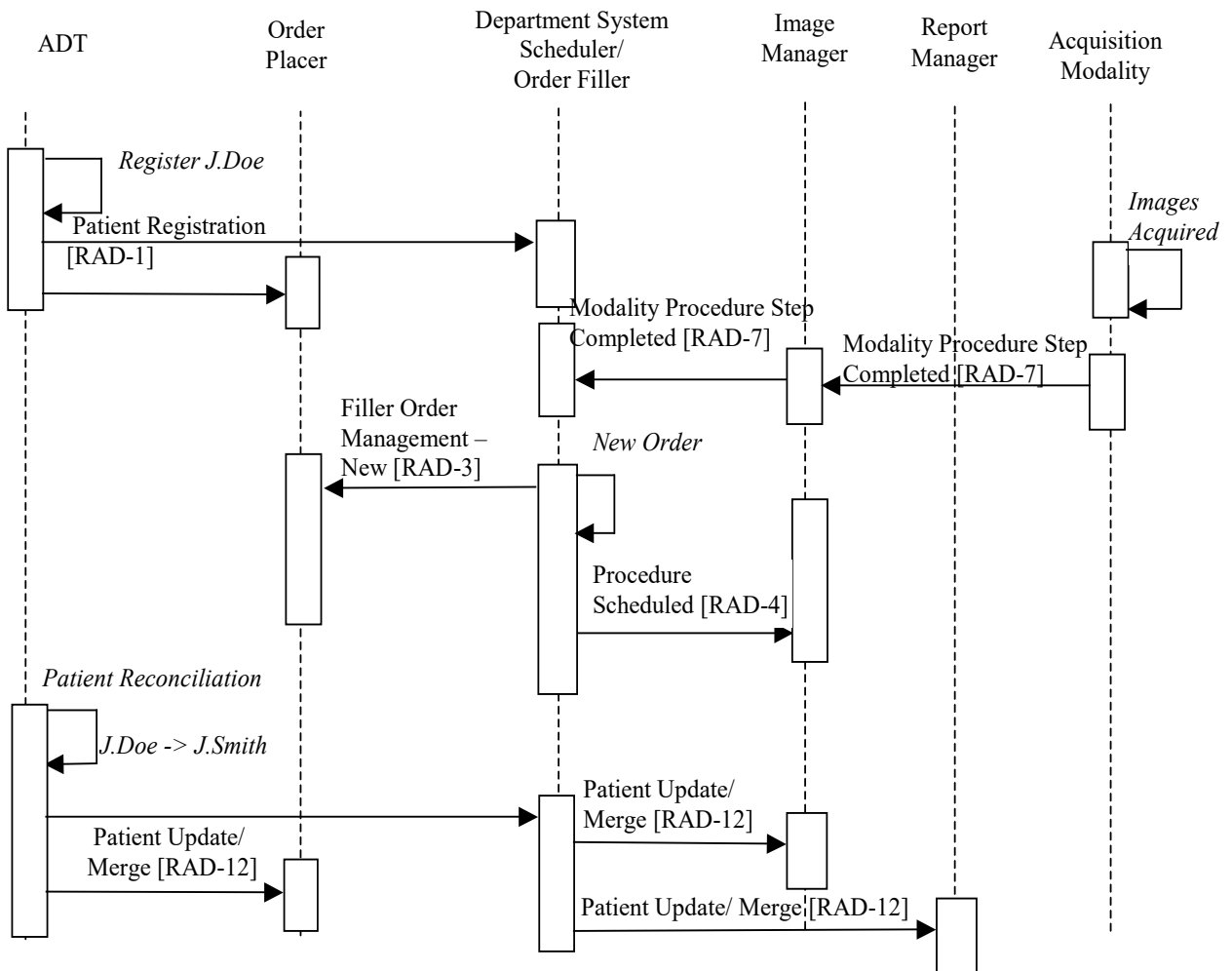
Figure 34.4.2.10.2-1: Unidentified Patient– Unscheduled

34.4.2.11 Use Case #11: Unidentified Patient Assigned Temporary Departmental ID and Scheduled at DSS/Order Filler

6205   **34.4.2.11.1 Unidentified Patient Assigned Temporary Departmental ID and Scheduled at DSS/Order Filler Use Case Description**

In this case, no valid Patient ID is available to the Department System Scheduler/Order Filler. It assigns a temporary Patient ID and a temporary name and schedules the required procedure.

> Note: The Department System Scheduler/Order Filler must ensure that the assigned temporary Patient ID is unique
6210   within its scope.

The temporary Patient ID is conveyed to the Image Manager. When patient information becomes known, the ADT sends new patient information to both the Order Placer and the Department

System Scheduler/Order Filler. The Department System Scheduler/Order Filler 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 and the Report Manager. At the same time, the Department System Scheduler/Order Filler generates and submits an order to the Order Placer using a permanent Patient ID.

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] transaction to the Image Manager.

- The Department System Scheduler/Order Filler sends the Filler Order Management (New Order) [RAD-3] transaction to the Order Placer.

The IHE Technical Framework also recognizes that the following 4-step case of handling unidentified patients may be utilized in certain installations:

1. The patient is delivered to the department, where a temporary departmental Patient ID and/or name are assigned.

2. The order is then entered by the Department System Scheduler/Order Filler and with this Patient ID and/or name, and the procedure is performed on the Acquisition Modality.

3. The Department System Scheduler/Order Filler sends a new order transaction to the Order Placer. This departmental Patient ID is shared by the Image Manager, Department System Scheduler/Order Filler and Order Placer. However, this departmental Patient ID is not known to the ADT.

4. After resolution of the patient identity, the ADT registers/admits the patient with the correct Patient ID and sends a message to the Order Placer and Department System Scheduler/Order Filler. Each system locally merges the new record with the existing one identified by the departmental Patient ID.

Because this case requires reconciliation at multiple points throughout the enterprise, IHE does not recommend this workflow.

34.4.2.11.2 Unidentified Patient Assigned Temporary Departmental ID and Scheduled at DSS/Order Filler Process Flow
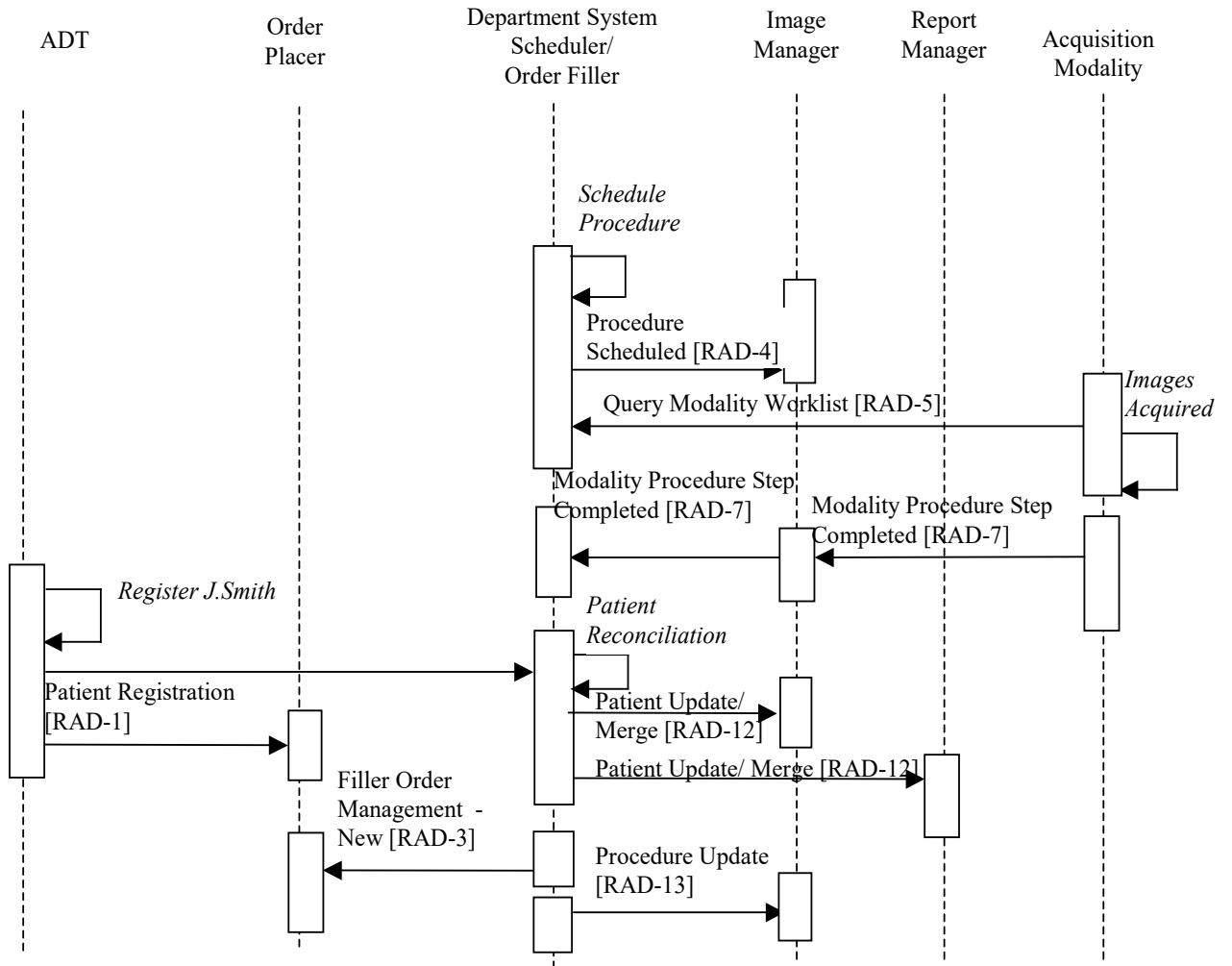
6245   **Figure 34.4.2.11.2-1: Unidentified Patient– Scheduled Temp ID**

34.4.2.12 Use Case #12: Image Acquisition Completed Without Scheduling at Department System Scheduler/Order Filler

34.4.2.12.1 Image Acquisition Completed Without Scheduling at Department System Scheduler/Order Filler Use Case Description

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In this case, no valid Patient ID is available to the Department System Scheduler/Order Filler and no scheduling is done before the procedure is performed. A temporary ID and name are entered by the technologist at the Modality and conveyed to the Department System Scheduler/Order Filler and to the Image Manager. The Patient ID and name are selected by the technologist

6255

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.

Upon receiving the Modality Procedure Step Completed message, the DSS/Order Filler and Image Manager recognize an unscheduled case based on the content of the message (absent or

6260

empty Referenced Study Sequence, see RAD TF-2x: Appendix A). When patient information becomes known, the ADT sends the new patient information to both the Order Placer and Department System Scheduler/Order Filler. The Department System Scheduler/Order Filler performs a merge of the permanent patient record with the temporary one and sends a Patient Update to the Image Manager and the Report Manager. At the same time, Department System

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Scheduler/Order Filler generates and submits an order to the Order Placer using a valid Patient ID.

Significant Transactions:

- On receiving a Procedure Step Completed transaction, the Department System Scheduler/Order Filler recognizes it as an unscheduled case.

6270

- 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 to the Image Manager and to the Report Manager.

- The Department System Scheduler/Order Filler sends a Filler Order Management (New

6275

Order) [RAD-3] transaction to the Order Placer.

- Using the information from the Procedure Step Completed transaction and placed order, the Department System Scheduler/Order Filler creates a new Requested Procedure record and sends a Procedure Scheduled [RAD-4] transaction to the Image Manager and Report Manager.

6280 **34.4.2.12.2 Image Acquisition Completed Without Scheduling at Department System Scheduler/Order Filler Process Flow**

Figure 34.4.2.12.2-1: Unidentified Patient – Unscheduled Temp ID

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34.4.2.13 Use Case #13: Patient Information Reconciliation During Image Acquisition

34.4.2.13.1 Patient Information Reconciliation During Image Acquisition Use Case Description

6290 This section describes the process flow related to the handling of image acquisition ongoing during patient reconciliation.

When a Patient Update occurs, in addition to the information exchange between the ADT, Order Placer and Department System Scheduler/Order Filler, Patient Update information is also sent to the Image Manager. Even after a Patient Update has occurred images coming from the Modality
6295 may continue to use the original Patient Information, so on-going Patient update with incoming images from the modality may be necessary. It is the responsibility of the Image Manager to ensure that the patient information is updated in the images, Grayscale Softcopy Presentation States and other Evidence Objects when they are retrieved from the Image Archive.

Updates may need to occur after the initial Patient Registration and Order Placement has
6300 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 continue updating the patient information from items retrieved from the Image Archive.

Significant Transactions:

6305 • The Modality may continue to send information using the original patient information even after the patient update has occurred.

• The Image Manager must continue reconciling Patient Information even after the Patient Update transaction has been completed.

• Only partial transactions are shown. Other transactions are performed according to the
6310 profile requirements.

34.4.2.13.2 Patient Information Reconciliation During Image Acquisition Process Flow

Figure 34.4.2.13.2-1: Reconciliation During Acquisition

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34.5 SWF.b Security Considerations

Refer to RAD TF-1x: Appendix F Security Environment Considerations.

34.6 SWF.b Cross Profile Considerations

6320 **SWF – Scheduled Workflow**
Systems which may be deployed in environments transitioning from HL7 v2.3.1 to HL7 v2.5.1 may find it useful to support both the SWF.b Profile and the original Scheduled Workflow Profile (RAD TF-1: 3). Specifically, it would be useful to be able to configure for each system it communicates with using the referenced transactions whether HL7 v2.3.1 or HL7 v2.5.1 is used.
6325 In such a scenario, the actor might need to be able to receive HL7 v2.3.1 messages and send HL7 v2.5.1 messages or vice versa.

35 Invoke Image Display (IID)

Invoke Image Display is a Trial Implementation Profile.

36 Intentionally left blank

6330 This section was previously reserved for the Mobile access to Health Documents for Imaging (MHD-I) Profile. That profile was deprecated in 2017 and replaced with the Web-based Image Access (WIA) Profile.

37 Digital Breast Tomosynthesis (DBT)

6335 The Digital Breast Tomosynthesis (DBT) Profile specifies the creation, exchange and use of DBT images. It defines basic display capabilities that Image Displays are expected to provide, especially simultaneous review of DBT and conventional 2D mammography images (FFDM).

The Digital Breast Tomosynthesis Profile is designed to provide faithful storage and retrieval of DBT images. Furthermore, sufficient display functionality to allow adequate review of current
6340 and prior studies consisting of DBT and/or conventional 2D mammography images is defined. The support for CAD is out of the scope for this profile.

37.1 DBT Actors, Transactions, and Content Modules

This section defines the actors, transactions, and/or content modules in this profile.

Figure 37.1-1 shows the actors directly involved in the Digital Breast Tomosynthesis Profile and
6345 the relevant transactions between them. If needed for context, other actors that may be indirectly involved due to their participation in other related profiles are shown in dotted lines. Actors which have a mandatory grouping are shown in conjoined boxes.
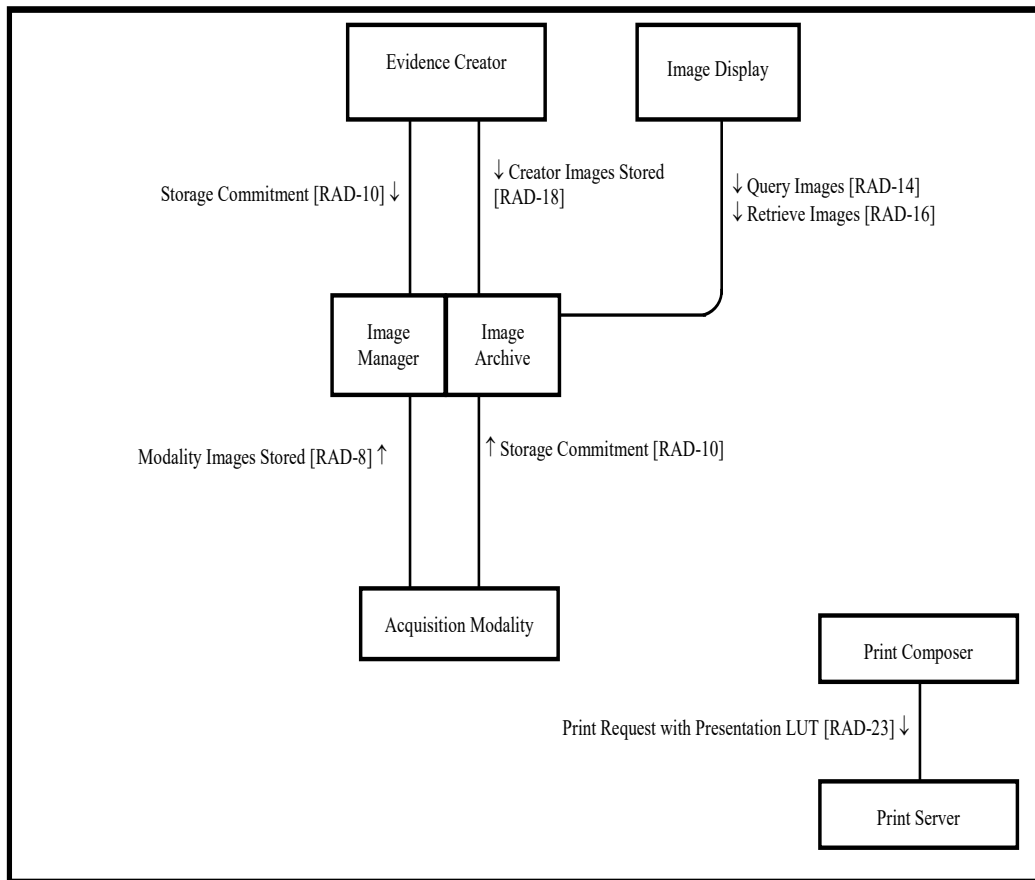

Figure 37.1-1: DBT Actor Diagram

6350 Table 37.1-1 lists the transactions for each actor directly involved in the Digital Breast Tomosynthesis Profile. To claim compliance with this profile, an actor shall support all required transactions (labeled "R") and may support the optional transactions (labeled "O").

Table 37.1-1: DBT Profile - Actors and Transactions

Actors	Transactions	Optionality	TF Reference
Acquisition Modality	Modality Images Stored [RAD-8]	R	RAD TF-2: 4.8
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
Evidence Creator	Creator Images Stored [RAD-18]	R	RAD TF-2: 4.18
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
Image Manager/Archive	Modality Images Stored [RAD-8]	R	RAD TF-2: 4.8
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
	Query Images [RAD-14]	R	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	R	RAD TF-2: 4.16
	Creator Images Stored [RAD-18]	R	RAD TF-2: 4.18
Image Display	Query Images [RAD-14]	R	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	R	RAD TF-2: 4.16
Print Composer	Print Request with Presentation LUT [RAD-23]	R	RAD TF-2: 4.23
Print Server	Print Request with Presentation LUT [RAD-23]	R	RAD TF-2: 4.23

6355 37.1.1 Actor Descriptions and Actor Profile Requirements

Most requirements are documented in Transactions (Volume 2). This section documents any additional requirements on this profile's actors.

37.1.1.1 Acquisition Modality

The Acquisition Modality acquires breast projection X-Ray images and generates tomosynthesis 6360 images. Storage of the breast projection X-Ray images for tomosynthesis is optional.

The Acquisition Modality can optionally acquire conventional 2D mammography images or generate a 2D image mathematically from tomosynthesis data. Creation and storage of conventional 2D mammography images is facilitated by grouping the Acquisition Modality in the DBT Profile with an Acquisition Modality from the Mammography Image Profile (see 6365 Section 19).

In order to generate and store additional derived tomosynthesis reconstructions (e.g., slabs), the Acquisition Modality can be grouped with an Evidence Creator.

37.1.1.2 Image Manager/Archive

The Image Manager/Archive receives breast tomosynthesis images, conventional 2D 6370 mammography images, 2D images generated mathematically from tomosynthesis data, and

optionally breast projection X-Ray images for tomosynthesis from the Acquisition Modality or an Evidence Creator, responds to query requests, and stores requested image data to an Image Display.

37.1.1.3 Image Display

6375 The Image Display retrieves breast tomosynthesis images as well as 2D images generated mathematically from tomosynthesis data and/or conventional 2D mammography images from the current and prior exams and displays them. The Image Display can be grouped with an Evidence Creator in order generate derived tomosynthesis reconstructions (e.g., slabs).

37.1.1.4 Evidence Creator

6380 The Evidence Creator generates derived tomosynthesis reconstructions (e.g., slabs). The Evidence Creator can be grouped with the Acquisition Modality or the Image Display in order to access the images. If the Evidence Creator is a stand-alone system, the workflow to get access to the images is out of scope for this profile. The Evidence Creator uses the Creator Images Stored [RAD-18] transaction to store these reconstructions (see RAD TF-2: 4.18.4.1.2.5).

6385 ### 37.1.1.5 Print Composer

Print Composers assemble film sheets of the selected key images and send print requests to a Print Server. A Print Composer can be grouped with an Image Display in order to get access to the key images. If the Print Composer is a stand-alone system, the workflow to get access to the key images is out of scope for this profile.

6390 ### 37.1.1.6 Print Server

The Print Server processes the print requests from a Print Composer.

37.2 DBT Actor Options

Table 37.2-1: DBT - Actors and Options

Actor	Option Name	TF Reference
Acquisition Modality	Partial View	RAD TF-1: 37.2.2
	For Presentation Breast Projection X-Ray Images	RAD TF-1:3 7.2.3
	For Processing Breast Projection X-Ray Images	RAD TF-1: 37.2.4
	Media Creation	RAD TF-1: 37.2.6
Evidence Creator	*No options defined*	--
Image Manager/Archive	Key Images	RAD TF-1: 37.2.1
	For Presentation Breast Projection X-Ray Images	RAD TF-1:3 7.2.3
	For Processing Breast Projection X-Ray Images	RAD TF-1: 37.2.4
	User Annotation	RAD TF-1: 37.2.5
Image Display	Key Images	RAD TF-1: 37.2.1

Actor	Option Name	TF Reference
	Partial View	RAD TF-1: 37.2.2
	For Presentation Breast Projection X-Ray Images	RAD TF-1: 37.2.3
	User Annotation	RAD TF-1: 37.2.5
	Media Creation	RAD TF-1: 37.2.6
Print Composer	*No options defined*	--
Print Server	*No options defined*	--

37.2.1 Key Images Option

6395 The Key Images Option enables users to mark key images or frames of a breast tomosynthesis image by attaching a Key Image Note and provide them for display. The functionality is defined in the Key Image Note Profile (RAD TF-1:8); therefore, this functionality is achieved by grouping with relevant actors from the Key Image Note Profile:

6400
- Image Displays that support creation of Key Image Notes shall be grouped with an Evidence Creator in the Key Image Note Profile and shall be able to create and store Key Image Notes for one or more of the SOP classes in RAD TF-2: Table 4.16.4.1.3.7-1.

- Image Displays that support rendering of Key Image Notes shall be grouped with an Image Display in the Key Image Note Profile and shall be able to query, retrieve and render Key Image Notes for one or more of the SOP classes in RAD TF-2: Table 6405 4.16.4.1.3.7-1.

- Image Manager/Archives that support storage and retrieval of Key Image Notes shall be grouped with an Image Manager/Archive in the Key Image Note Profile to enable storage/retrieval of the Key Object Selection Document.

37.2.2 Partial View Option

6410 The Partial View Option addresses the creation and display of mosaic images.

It defines additional attributes which the Acquisition Modality includes in the image headers in order to indicate whether an image is part of a mosaic and which part of the set the image represents as defined in RAD TF-2: 4.8.4.1.2.7.1 Partial View Option.

Furthermore, it defines how Image Displays make use of this information to annotate the images 6415 in the viewport as defined in RAD TF-2: 4.16.4.2.2.1.3.7 Partial View Option.

37.2.3 For Presentation Breast Projection X-Ray Images Option

The For Presentation Breast Projection X-Ray Images Option addresses the creation, retrieval and display of breast projection X-Ray images acquired for the purpose of tomosynthesis to identify the source of image quality issues, such as patient motion.

6420   Acquisition Modalities and Image Manager/Archives that support this option shall implement the requirements for creation and storage of breast projection X-Ray images as defined in RAD TF-2: 4.8.4.1.2.7.2 Breast Projection X-Ray Images Option.

Image Displays that support this option shall implement the requirements for retrieval and display of breast projection X-Ray images as defined in RAD TF 2: 4.16.4.2.2.1.3.10.

6425   37.2.4 For Processing Breast Projection X-Ray Images Option

The For Processing Breast Projection X-Ray Images Option addresses the creation and retrieval of breast projection X-Ray images acquired for the purpose of tomosynthesis in order to create retrospective reconstructions of tomosynthesis slices from projection images.

6430   Acquisition Modalities and Image Manager/Archives that support this option shall implement the requirements for creation and storage of breast projection X-Ray images as defined in RAD TF-2: 4.8.4.1.2.7.2 Breast Projection X-Ray Images Option.

37.2.5 User Annotation Option

The User Annotation Option allows users to perform annotation on key images or frames of a breast tomosynthesis image, store it as a Grayscale Softcopy Presentation State, and provide it
6435   for display. The functionality is defined in the Consistent Presentation of Images Profile (RAD TF-1:5); therefore, this functionality is achieved by grouping with relevant actors from the Consistent Presentation of Images Profile:

- Image Displays that support creation of Grayscale Softcopy Presentation State objects shall be grouped with an Evidence Creator in the Consistent Presentation of Images
6440   Profile and shall be able to create and store GSPS objects for one or more of the SOP Classes in RAD TF-2: Table 4.16.4.1.3.7-1.

- Image Displays that support rendering of Grayscale Softcopy Presentation State objects shall be grouped with an Image Display in the Consistent Presentation of Images Profile and shall be able to query, retrieve and render GSPS objects for one or more of the SOP
6445   Classes in RAD TF-2: Table 4.16.4.1.3.7-1.

- Image Manager/Archives that support storage and retrieval of Grayscale Softcopy Presentation State objects shall be grouped with an Image Manager/Archive in the Consistent Presentation of Images Profile to enable storage/retrieval of the Grayscale Softcopy Presentation State objects.

6450   37.2.6 Media Creation Option

The Media Creation Option allows users to export breast tomosynthesis studies to external media. The functionality is defined in the Portable Data for Imaging Profile (see RAD TF-1: 15); therefore, this functionality is achieved by grouping with relevant actors from the Portable Data for Imaging Profile:

6455   - Acquisition Modalities or Image Displays that support creation of external media shall be grouped with a Portable Media Creator in the Portable Data for Imaging Profile.

- The Portable Media Creator shall be capable of encoding on the media all of the SOP Classes that are required to be supported by the Digital Breast Tomosynthesis Profile (which are defined in the Modality Images Stored and Retrieve Images transactions).

6460
- If the Key Images Option is also supported, the Portable Media Creator shall be capable of encoding on the media instances of the Key Object Selection Document Storage SOP Class.

- If the User Annotation Option is also supported, the Portable Media Creator shall be capable of encoding on the media instances of the Grayscale Softcopy Presentation State
6465 Storage SOP Class.

If a viewer is added to the media in addition to the breast tomosynthesis study, the viewer shall fulfill the Image Display requirements defined in RAD TF-2: 4.16.4.2.2.1.3.11.

37.3 DBT Required Actor Groupings

6470 An actor from this profile (Column 1) shall implement all of the required transactions and/or content modules in this profile in addition to all of the transactions required for the grouped actor (Column 2).

If this is a content profile, and actors from this profile are grouped with actors from a workflow or transport profile, the Content Bindings reference column references any specifications for mapping data from the content module into data elements from the workflow or transport
6475 transactions.

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

Section 37.5 describes some optional groupings that may be of interest for security
6480 considerations and Section 37.6 describes some optional groupings in other related profiles.

Table 37.3-1: DBT - Required Actor Groupings

DBT Actor	Actor to be grouped with	Reference	Content Bindings Reference
Image Manager/Archive	Mammography Image / Image Manager/Archive	RAD TF-1: 19.1	--
Image Display	Mammography Image / Image Display	RAD TF-1: 19.1	--
Acquisition Modality (see Note 1)	Mammography Image / Acquisition Modality	RAD TF-1: 19.1	--

Note 1: Acquisition Modalities that generate conventional 2D mammography images shall be grouped with an Acquisition Modality in the Mammography Image Profile.

37.4 DBT Overview

6485 The Digital Breast Tomosynthesis (DBT) Profile specifies the creation, exchange and use of DBT images. It defines basic display capabilities that Image Displays are expected to provide, especially simultaneous review of DBT and conventional 2D mammography images (FFDM).

The Digital Breast Tomosynthesis Profile is designed to provide faithful storage and retrieval of DBT images. Furthermore, sufficient display functionality to allow adequate review of current
6490 and prior studies consisting of DBT and/or conventional 2D mammography images is defined. The support for CAD is out of the scope for this profile.

37.4.1 Concepts

The Mammography Image Profile provides functionality for faithful storage, retrieval and display of conventional 2D mammography images and associated CAD results. The DBT Profile
6495 extends this functionality to support breast tomosynthesis images and images derived from them.

37.4.2 Use Cases

37.4.2.1 Use Case #1: DBT Screening

This use case addresses the basic mammography screening workflow, which includes creation, storage and retrieval of breast tomosynthesis images and optionally conventional 2D
6500 mammography images.

37.4.2.1.1 DBT Screening Use Case Description

This use case encompasses a group of scenarios which vary in the number and type of images that are created at the modality and whether a current study only or a current and a prior are reviewed. Each study, current or prior can include one or multiple views of each breast, where
6505 one view may contain a set of:

- Tomosynthesis slices
- Tomosynthesis projection images
- Tomosynthesis slabs
- Conventional 2D mammography images
6510 - Generated 2D images derived from tomosynthesis data

During the review of a study the radiologist can utilize the available display options, such as contrast adjustments, image sizing changes, etc.

The goal for this use case is to support fast reading of the data, which includes:

- Instantaneous scrolling through slices
6515 - Instantaneous switching between images (different views, different image types, prior images)

- Instantaneous switching to the next case.

37.4.2.1.2 DBT Screening Process Flow
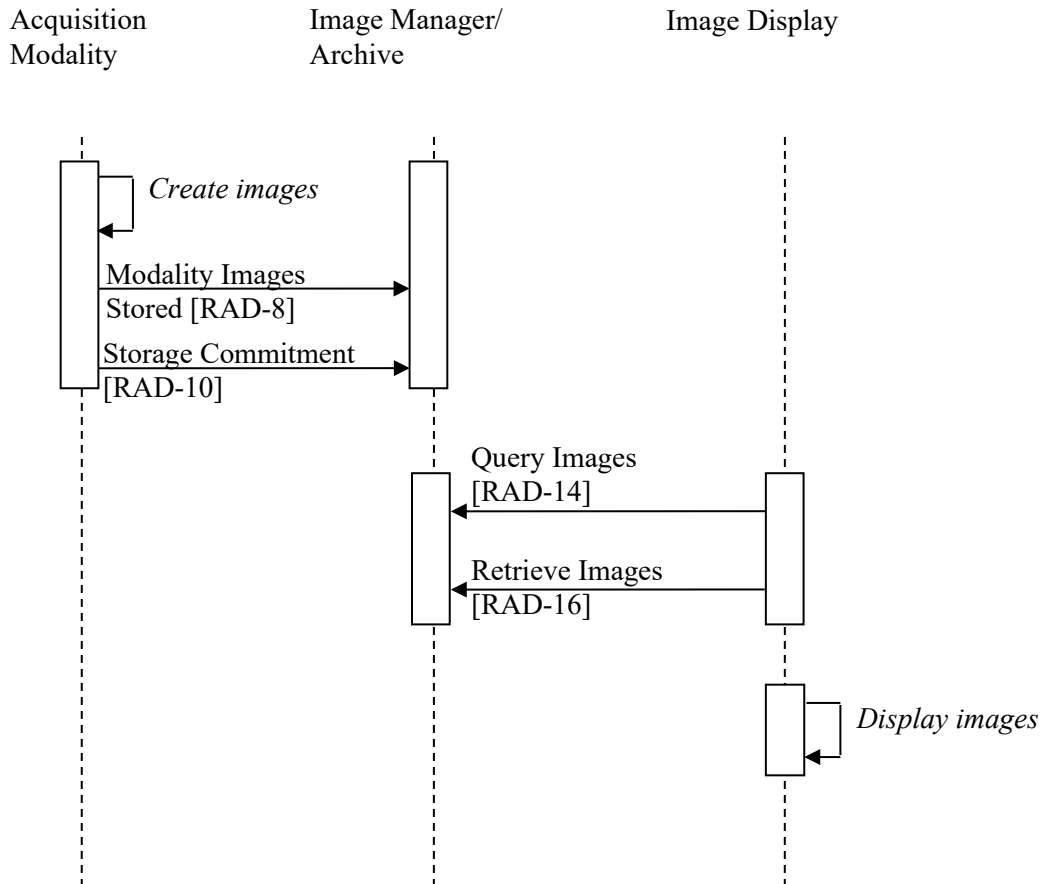
Figure 37.4.2.1.2-1: Process Flow in DBT Screening Use Case

37.4.2.2 Use Case #2: Additional reconstructions

During review of a study, the radiologist requests another DBT image (reconstruction). This may result in a complete volume or a sub-volume of the acquired DBT data.

37.4.2.2.1 Additional Reconstructions Use Case Description

While reviewing the study, the radiologist identifies the need for additional DBT images using different reconstruction parameters. This can be triggered by the lesion type, by the character of the breast tissue (e.g., fatty or dense), any other clinical information (medication, hormone status), or just by the image impression of the first DBT image. Using the functionality of their workstation the radiologist creates the additional DBT image(s) (e.g., using a different slice

6530   thickness for reconstruction) either covering the complete volume or a sub-volume. The additional images are stored in the PACS.

37.4.2.2.2 Additional Reconstructions Process Flow
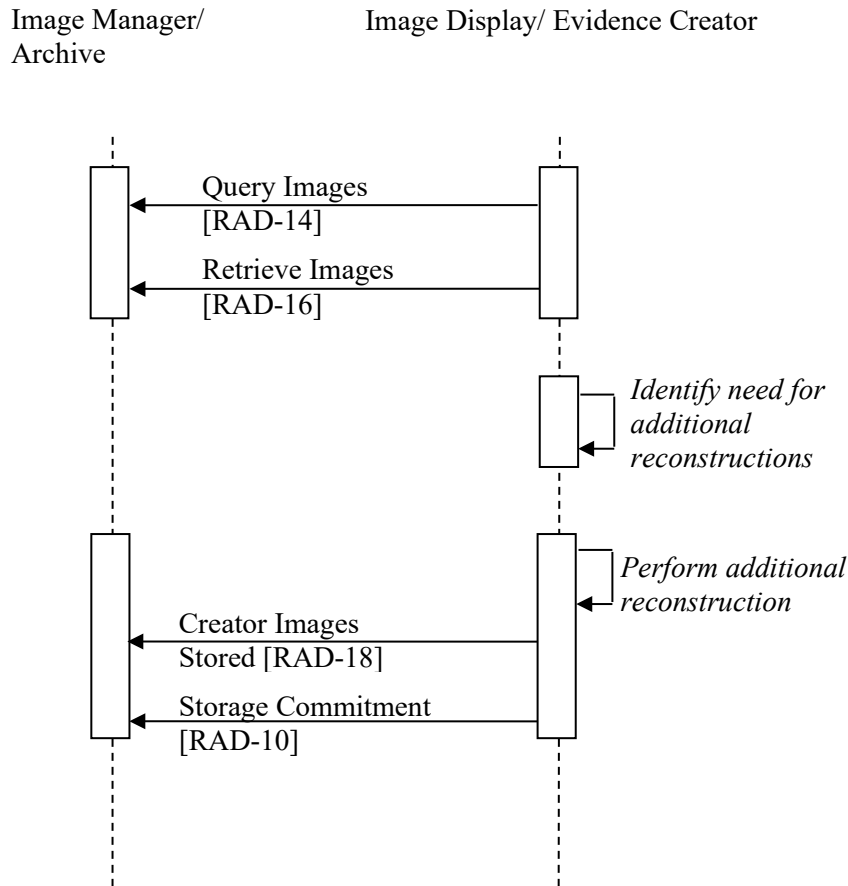
Figure 37.4.2.2.2-1: Process Flow in Additional Reconstructions Use Case

6535 ### 37.4.2.3 Use Case #3: DBT in Diagnostic Mammography

This use case describes acquisition and display of additional DBT images for diagnostic purposes based on the findings in the screening exam.

37.4.2.3.1 DBT in Diagnostic Mammography Use Case Description

Based on findings (e.g., suspected mass, asymmetry) in a conventional 2D mammography or
6540   DBT screening study or a palpable finding in the patient, a DBT diagnostic study may be ordered. Exaggerated, rolled, 90-degree (LM, ML) and/or spot compression views are acquired using DBT acquisition or combination 2D/DBT acquisition.

The diagnostic study may contain one or more diagnostic views of a single breast or both breasts, each of which may include a set of:

6545
- Tomosynthesis slices
- Tomosynthesis projection images
- Tomosynthesis slabs
- Conventional 2D mammography images
- Generated 2D images derived from tomosynthesis data

6550 During the review of a study the radiologist can utilize the available display options, such as contrast adjustments, image sizing changes, etc.

37.4.2.3.2 DBT in Diagnostic Mammography Process Flow
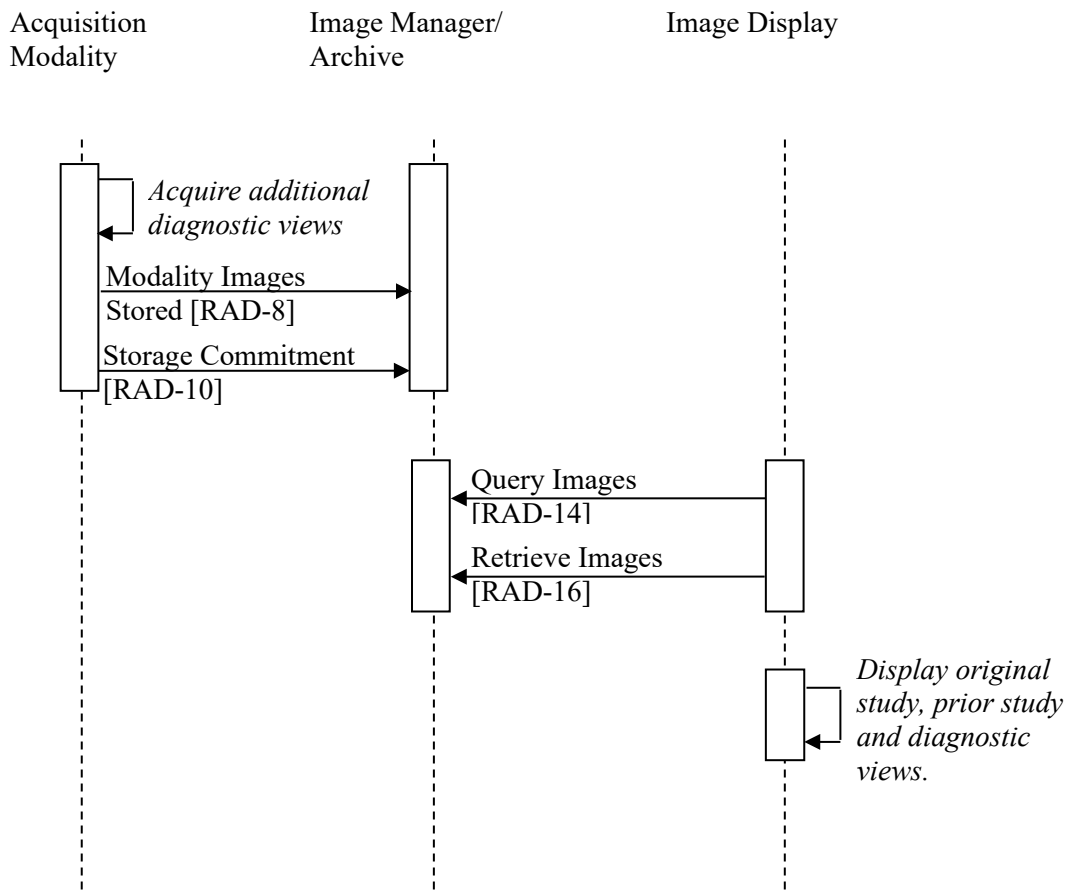
Figure 37.4.2.3.2-1: Process Flow in DBT for Diagnostic Mammography Use Case

6555 **37.4.2.4 Use Case #4: Key Images in DBT Screening**

This use case addresses flagging of key images or frames in the DBT image for further review (e.g., by the referring physician or when asking for a second opinion).

37.4.2.4.1 Key Images in DBT Screening Use Case Description

6560 Due to the size of the DBT image, it is helpful to flag key frames for subsequent reviews (e.g., for a second opinion, for a referring physician or even when reviewed as a prior) in order to find relevant frames faster and not miss key frames while scrolling rapidly.

While reviewing a screening exam, the radiologist identifies a lesion that she/he would like a second opinion on. She/he flags the frame which best represents the finding for a secondary review by a colleague. She/he stores the information about the key frame in the Key Image Note 6565 and sends it to the PACS.

The second reader retrieves the images and the Key Image Note on the workstation and opens them. By selecting the Key Image Note, the relevant frame is displayed right away for review. Starting from the flagged images she/he reviews surrounding frames and provides feedback to the other radiologist.

6570 **37.4.2.4.2. Key Images in DBT Screening Process Flow**
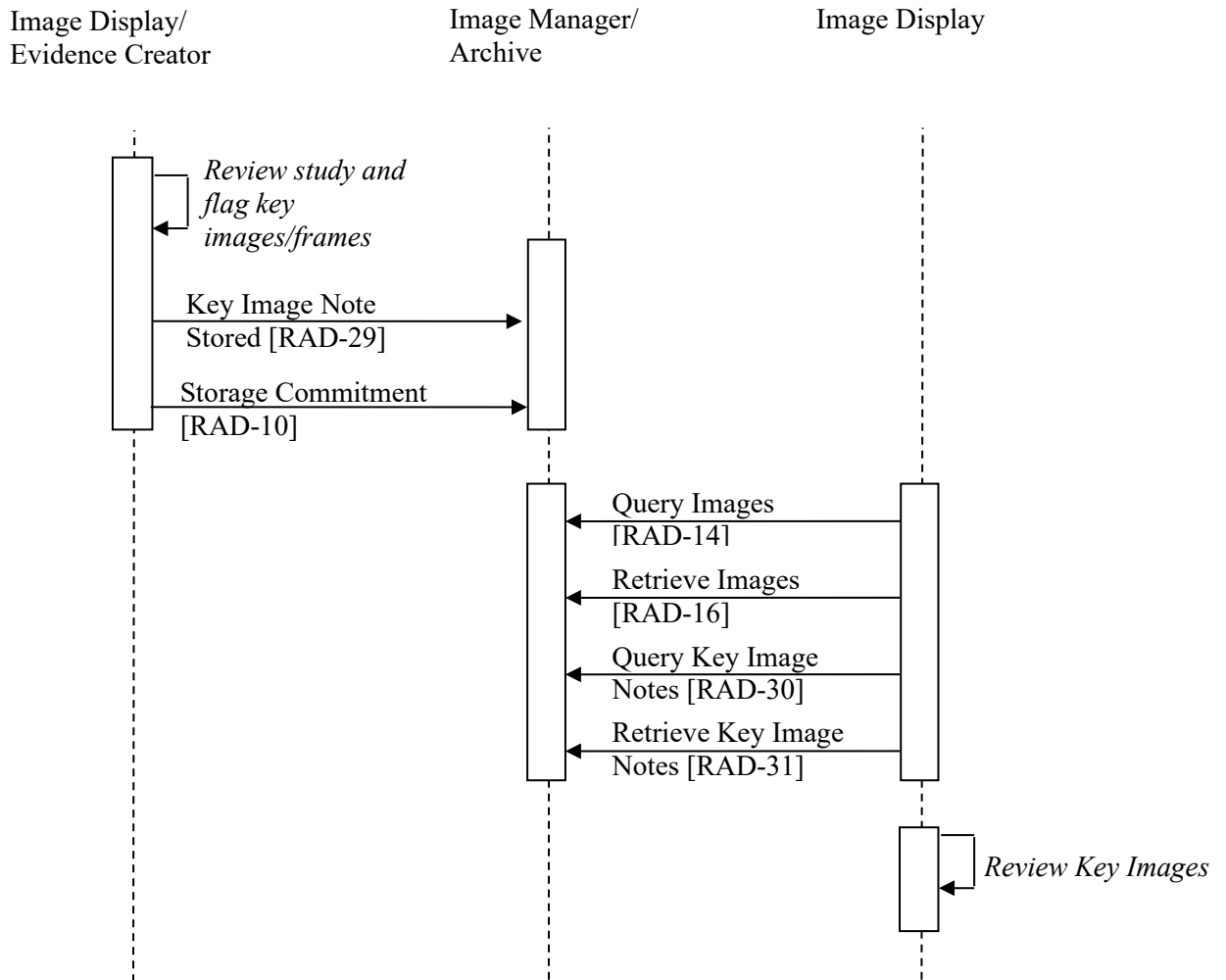
Figure 37.4.2.4.2-1: Process Flow in Key Images in DBT Screening Use Case

37.4.2.5 Use Case #5: User annotation in DBT studies

This use case addresses how to store user annotations on DBT images and make them available
6575 for review at a later point in time.

37.4.2.5.1 User annotation in DBT studies Use Case Description

While reviewing a DBT image, the radiologist identifies a lesion that she/he would like a second
opinion on. She/he marks the region on the relevant frame for review by a colleague. She/he

stores the user annotation information in a Grayscale Softcopy Presentation State object and
6580 sends it to the PACS.

The second reader retrieves the images and the Grayscale Softcopy Presentation State object on
the workstation and opens them. By selecting the user annotation, the annotated frame is
displayed right away for review showing the marks of the initial reader also applying any zoom
and window/level settings stored in the Grayscale Softcopy Presentation State object.

6585 **37.4.2.5.2 User annotation in DBT studies Process Flow**
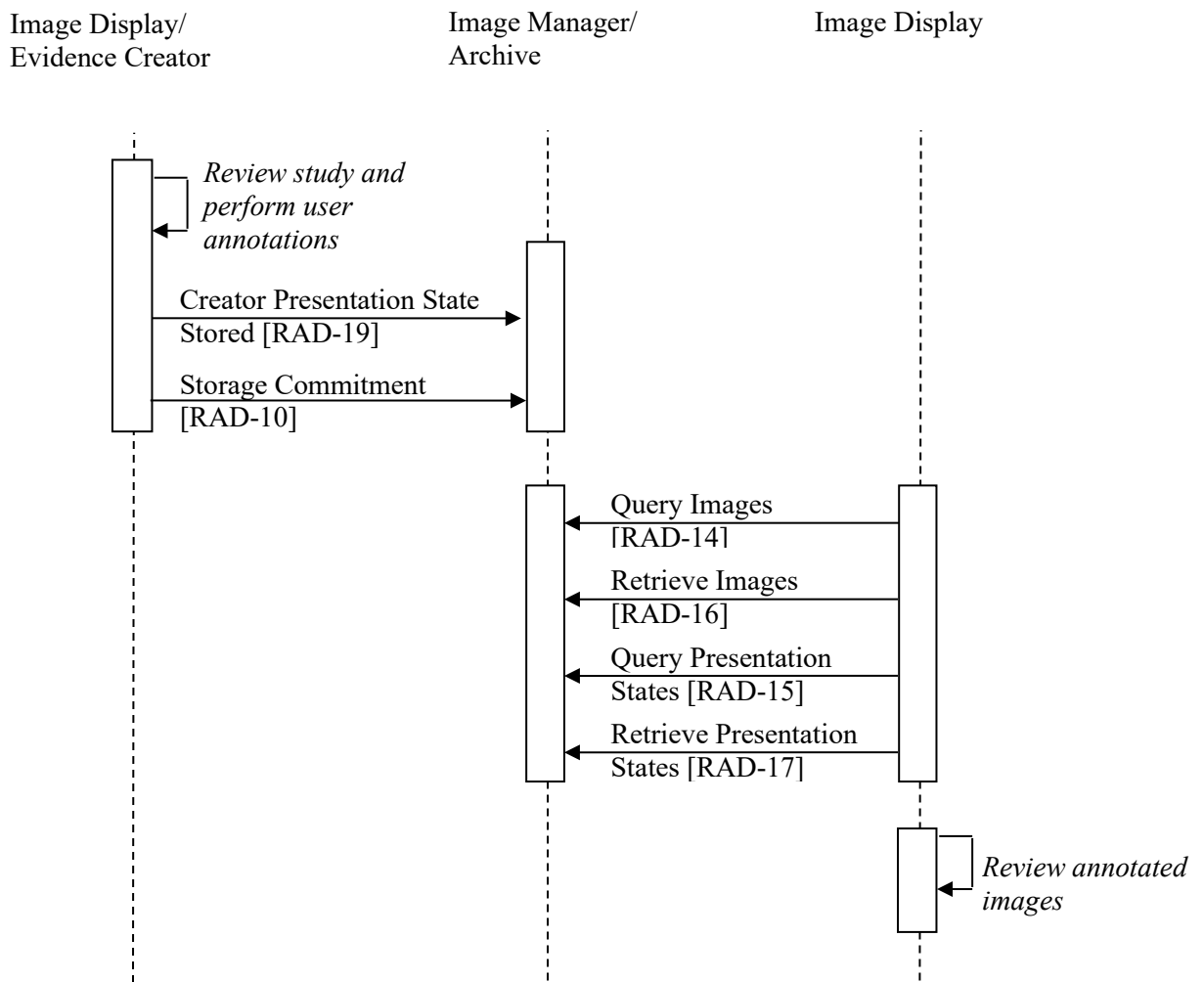
Figure 37.4.2.5.2-1: Process Flow in User Annotation in DBT studies Use Case

37.4.2.6 Use Case #6: Printing of selected DBT Frames

This use case addresses printing of selected frames from a DBT study.

6590 **37.4.2.6.1 Printing of selected DBT Frames Use Case Description**

During reviewing a DBT study, the clinician selects particular frames (with or without annotation) and wants to format them for printing. Options for printing are either in True Size or in Same Size.

37.4.2.6.2 Printing of selected DBT Frames Process Flow
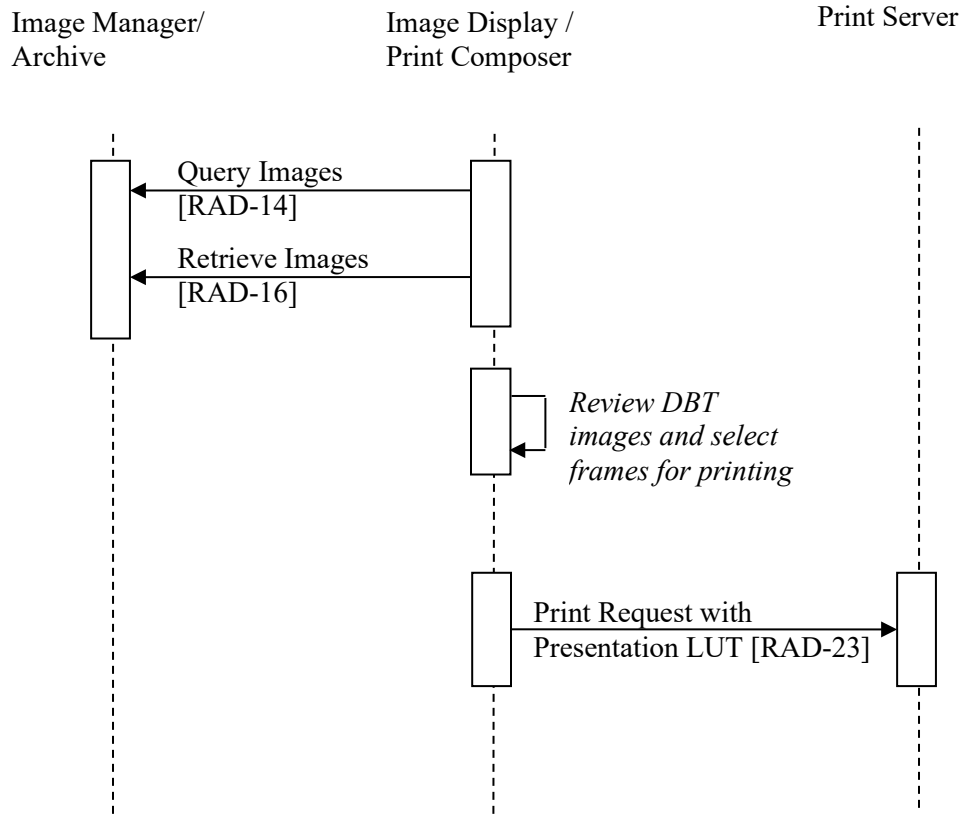
6595

Figure 37.4.2.6.2-1: Process Flow in Printing of Selected DBT Frames Use Case

37.4.2.7 Use Case #7: Additional reconstructions based on Projection Images

This use case addresses the workflow to generate additional tomosynthesis reconstructions based on breast projection X-Ray images for tomosynthesis, for systems supporting both Breast 6600 Projection X-Ray Images Options.

37.4.2.7.1 Additional reconstructions based on Projection Images Description

The radiologist reviews the tomosynthesis images at a workstation and detects technical problems with the reconstruction. Therefore she/he loads the source breast projection X-Ray images (For Presentation) and reviews them. She/he decides that the problem could be solved by

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6605   using different reconstruction parameters. The Evidence Creator which is grouped with the Image Display performs the additional reconstruction, provides the images for display and stores them to the Image Manager/Archive.

37.4.2.7.2 Additional reconstructions based on Projection Images Process Flow
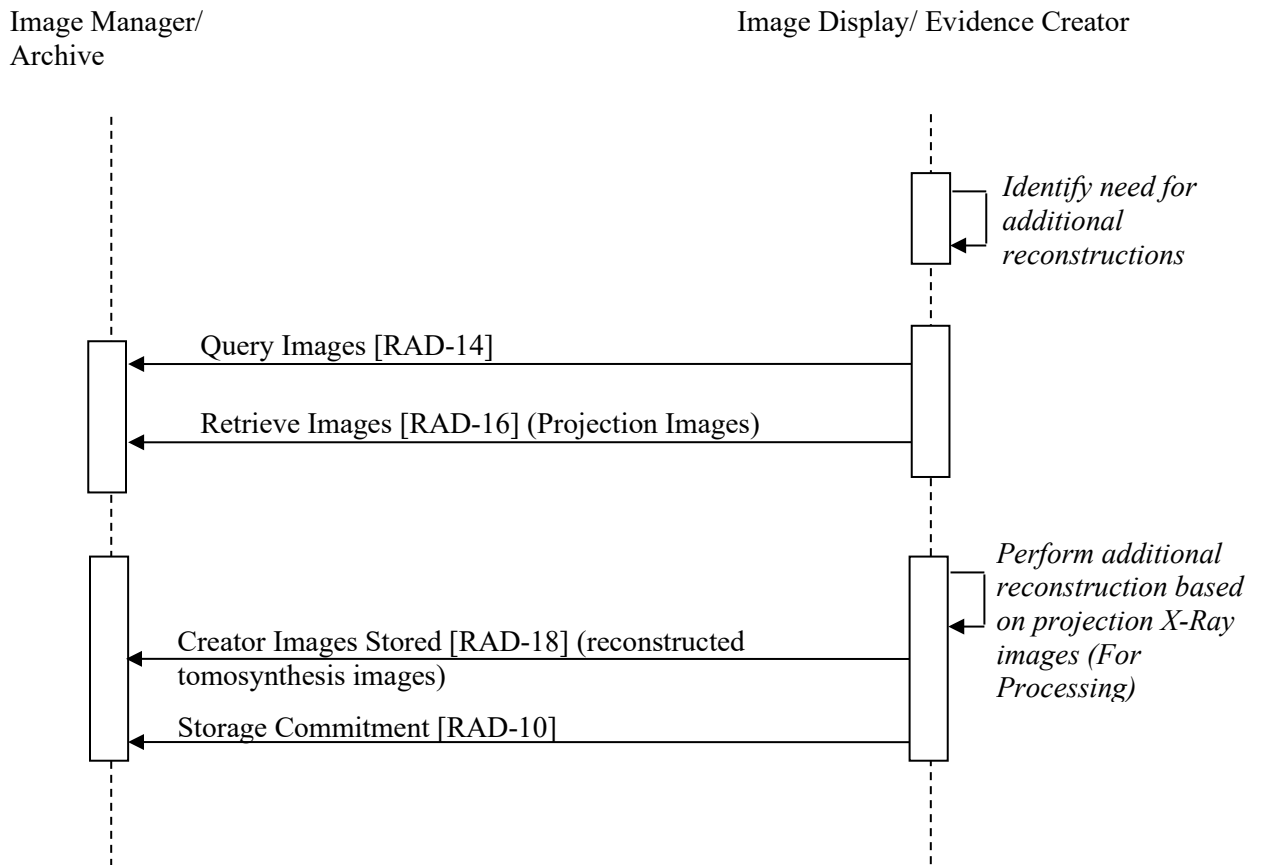
6610   **Figure 37.4.2.7.2-1: Process Flow in Additional Reconstructions based on Projection Images Use Case**

37.4.2.8 Use Case #8: Review of Projection Images

This use addresses reviewing the breast projection X-Ray images for tomosynthesis in addition to the tomosynthesis reconstructions and the conventional 2D mammography images for systems
6615   supporting the For Presentation Breast Projection X-Ray Images Option.

37.4.2.8.1 Review of Projection Images Use Case Description

The radiologist reviews the breast tomosynthesis images at a workstation and detects some problems with the images. Therefore she/he loads the source breast projection X-Ray images (For Presentation) and reviews them for diagnostic purposes or to check for quality issues such as patient motion.

6620

37.4.2.8.2 Review of Projection Images Use Case Process Flow
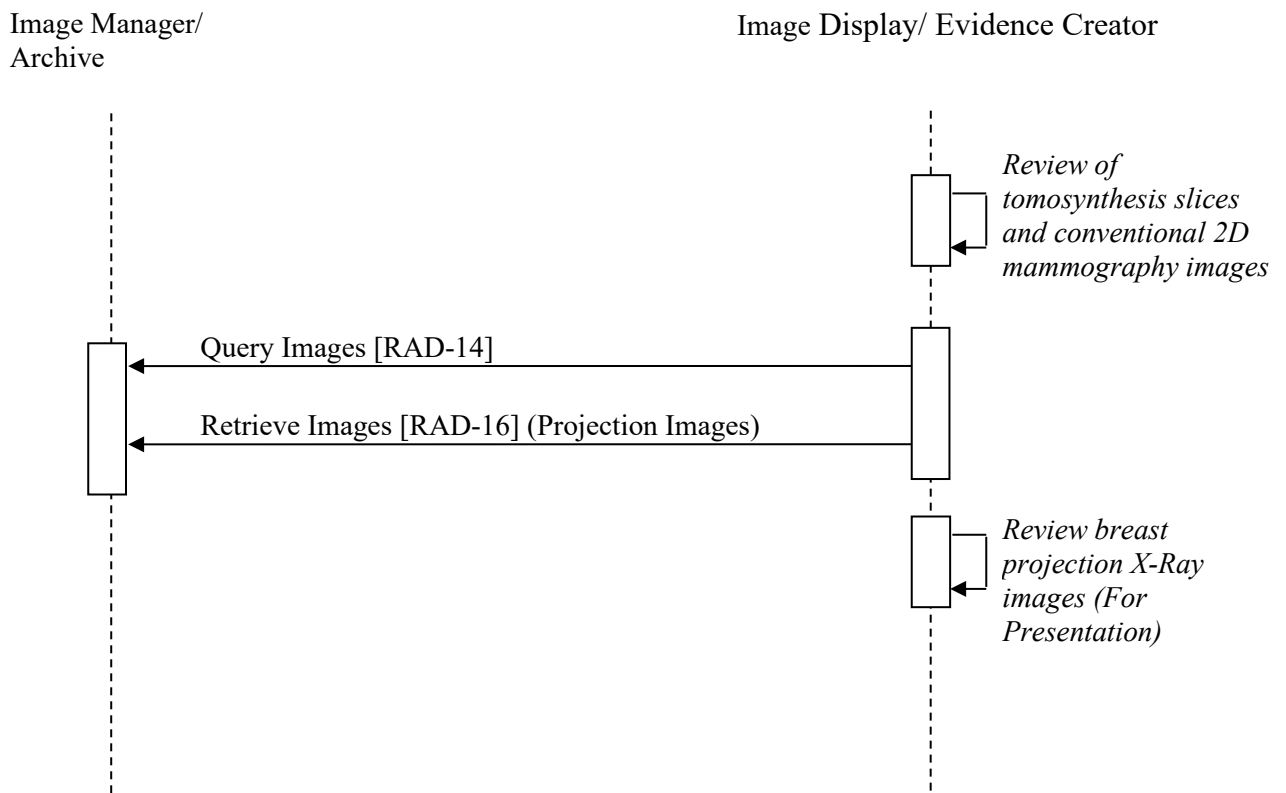
Figure 37.4.2.8.2-1: Process Flow in Review of Projection Images Use Case

37.5 DBT Security Considerations

6625   N/A

37.6 DBT Cross Profile Considerations

SWF – Scheduled Workflow

6630 The main focus of the Digital Breast Tomosynthesis Profile is to define creation and review of digital breast tomosynthesis studies including DBT images, conventional 2D mammography images, and breast projection X-Ray images. The scheduling workflow is addressed in the Scheduled Workflow Profile.

BIR - Basic Image Review

6635 The Basic Image Review Profile clearly states that specialty viewing (like Mammography) is outside the scope of that profile. Therefore, review of DBT images in the BIR Profile is confined to partial (display – only) support. Specific viewer requirements are addressed in Section 37.2.6.

38 Web-based Image Capture (WIC)

There is an increasing use of mobile devices such as smartphones or tablets for image capture or viewing in healthcare. For example, a clinician can use a tablet to launch an image viewer via the EMR. The camera on the mobile device can capture high quality still images and videos.

6640 However, there is no standard way for these devices to upload captured images or evidence documents directly to the Image Manager.

The Web-based Image Capture (WIC) Profile provides a simple, lightweight, mobile-friendly mechanism to encode and send captured images, videos and evidence documents from the mobile device to the Image Manager so that these objects can be easily integrated into the rest of

6645 the imaging workflow.

38.1 WIC Actors, Transactions, and Content Modules

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

6650 Figure 38.1-1 shows the actors directly involved in the WIC Profile and the relevant transactions between them. If needed for context, other actors that may be indirectly involved due to their participation in other related profiles are shown in dotted lines. Actors which have a mandatory grouping are shown in conjoined boxes.
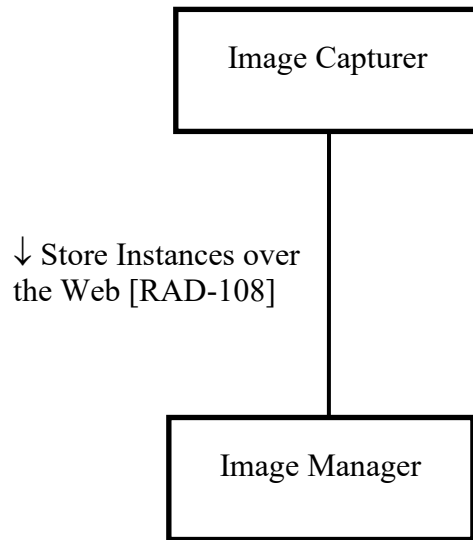
6655

Figure 38.1-1: WIC Actor Diagram

Table 38.1-1 lists the transactions for each actor directly involved in the WIC Profile. To claim compliance with this profile, an actor shall support all required transactions (labeled "R") and may support the optional transactions (labeled "O").

6660 **Table 38.1-1: WIC Profile - Actors and Transactions**

Actors	Transactions	Initiator or Responder	Optionality	TF Reference
Image Capturer	Store Instances over the Web [RAD-108]	Responder	R	RAD TF-2: 4.108.1
Image Manager	Store Instances over the Web [RAD-108]	Initiator	R	RAD TF-2: 4.108.1

38.1.1 Actor Descriptions and Actor Profile Requirements

Most requirements are documented in Transactions (Volume 2 and 3). This section documents any additional requirements on this profile's actors.

6665 ### 38.1.1.1 Image Manager

The Image Manager shall support JPEG, MPEG4, DICOM Instance and Evidence Document Storage.

38.2 WIC Actor Options

Options that may be selected for each actor in this profile, if any, are listed in the Table 38.2-1.
6670 Dependencies between options when applicable are specified in notes.

Table 38.2-1: WIC - Actors and Options

Actor	Option Name	TF Reference
Image Capturer (Note 1)	JPEG Storage	Section 38.2.1
	MPEG4 Storage	Section 38.2.2
	Evidence Document Storage	Section 38.2.3
	DICOM Instance Storage	Section 38.2.4
	PNG Storage	Section 38.2.5
Image Manager (Note 2)	PNG Storage	Section 38.2.5

Note 1: The Image Capturer shall support at least one option.

Note 2: The Image Manager is required to support JPEG, MPEG4, DICOM Instance and Evidence Document Storage.

38.2.1 JPEG Storage Option

The Image Capturer captures still images in baseline JPEG format (i.e., DICOM Transfer Syntax 1.2.840.10008.1.2.4.50) and stores to the Image Manager using the DICOM PS3.18 metadata and bulk data. See RAD TF-2: 4.108.4.1.2.3.1.

38.2.2 MPEG4 Storage Option

The Image Capturer captures video stream encoded in AVC/H.264 format using a MP4 container and stores to the Image Manager using the DICOM PS3.18 metadata and bulk data. See RAD TF-2: 4.108.4.1.2.4.1.

38.2.3 Evidence Document Storage Option

The Image Capturer supports creation of DICOM instances using DICOM Native XML Format or JSON Metadata format for evidence documents such as GSPS, SR, KOS, and DICOM Encapsulated PDF/CDA. See RAD TF-2: 4.108.4.1.2.5.

38.2.4 DICOM Instance Storage Option

The Image Capturer supports creation or transmissions of DICOM instances encoded in DICOM binary format. See RAD TF-2: 4.108.4.1.2.6.

38.2.5 PNG Storage Option

The Image Capturer supports creation of images in lossless PNG format. See RAD TF-2: 4.108.4.1.2.3.2.

The Image Manager supports storing images in lossless PNG format and conversion of PNG images to an appropriate standard uncompressed or lossless (reversible) compressed Transfer Syntax. See RAD TF-2: 4.108.4.1.3.1.

38.3 WIC Required Actor Groupings

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

6700   Section 38.5 describes some optional groupings that may be of interest for security considerations and Section 38.6 describes some optional groupings in other related profiles.

Table 38.3-1: WIC - Required Actor Groupings

WIC Actor	Actor to be grouped with	TF Reference
Image Capturer	None	--
Image Manager	None	--

38.4 WIC Overview

6705   38.4.1 Concepts

The Web-based Image Capture Profile enables an imaging-enabled client application running on a wide variety of devices (ranging from workstation to lightweight mobile devices) to transmit DICOM instances to the server using HTTP(S).

6710   Instead of creating a DICOM PS3.10 binary instance, WIC supports DICOM PS3.18 which defines the Native DICOM Model in XML and a DICOM JSON Object Model. This enables non-traditional imaging clients (such as the clients might be used in wound care department, dermatology, etc.) to create proper DICOM instances using common tools like XML and JSON.

38.4.2 Use Cases

38.4.2.1 Use Case #1: Image Upload to a New Study

6715   38.4.2.1.1 Image Upload to a New Study Use Case Description

Clinical Use Case: A nurse in the wound care department sees patients in the ward. She photographs the wounds to track the healing process. She uses one of the department's photo cameras, a departmental tablet or her mobile phone to take a series of pictures of a patient. She immediately imports the images in the imaging system under the correct patient name and adds
6720   an appropriate report note in the patient chart.

This use case is addressed by the Lightweight Modality in the Encounter-Based Imaging Workflow (EBIW) Profile. EBIW incorporates the Store Instances over the Web [RAD-108] transaction defined by WIC for RESTful storage of images.

38.4.2.2 Use Case #2: Image Upload to an Existing Study

6725 **38.4.2.2.1 Image Upload to an Existing Study Use Case Description**

Clinical Use Case: A radiologist uses a tablet to retrieve a study from the central repository. While viewing the study, she identifies certain key images and adds some markup indicating the region of interest. Finally, she creates a report. When she saves the changes, the application sends the markups, key objects and reports to the central repository for persistent storage.

6730 **Technical Use Case 1:** The Imaging Document Consumer retrieves and views a study from the Imaging Document Source using the Web-based Image Access (WIA) Profile. The Imaging Document Consumer, grouped with the Image Capturer, creates new evidence documents (e.g., Key Image Notes, screen captures as Secondary Capture, etc.) using the same patient and study context. The Image Capturer then uploads the created evidence documents to the Image
6735 Manager.

38.4.2.2.2 Image Upload to an Existing Study Process Flow
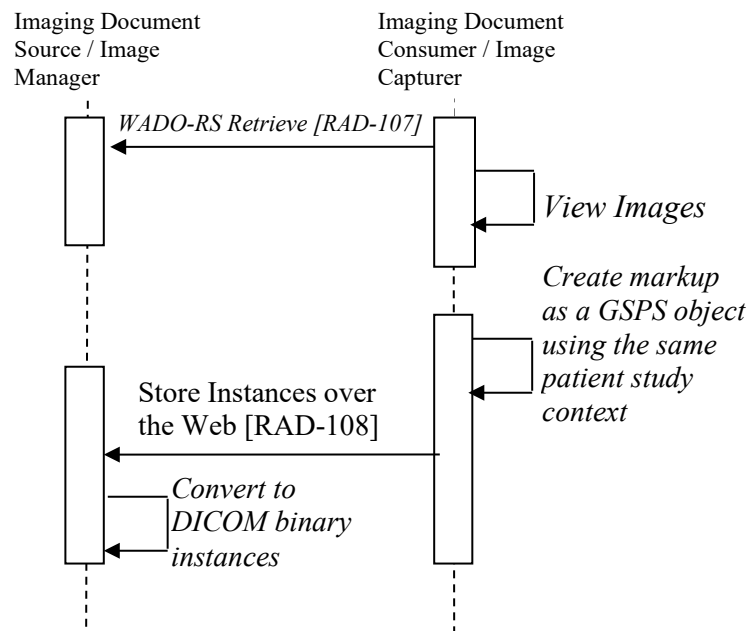
Figure 38.4.2.2.2-1: Image Upload to an Existing Study Process Flow in WIC Profile

Technical Use Case 2: Similarly, using the Invoke Image Display (IID) Profile, an EMR, as an
6740 Image Display Invoker, launches an Image Display to view a patient's study. Using the markup tools and key image tools provided by the Image Display, the user creates new markups and tag certain images as key images. The IID Image Display, grouped with the Image Capturer, stores the markup and key images in the same patient and study context to the Image Manager using DICOM JSON Object Model. The Image Manager receives the instances and converts them into

6745   DICOM binary format. Another Image Display (not part of this profile), which is a traditional
        PACS workstation, retrieves the study and presents the markup as well as key images.
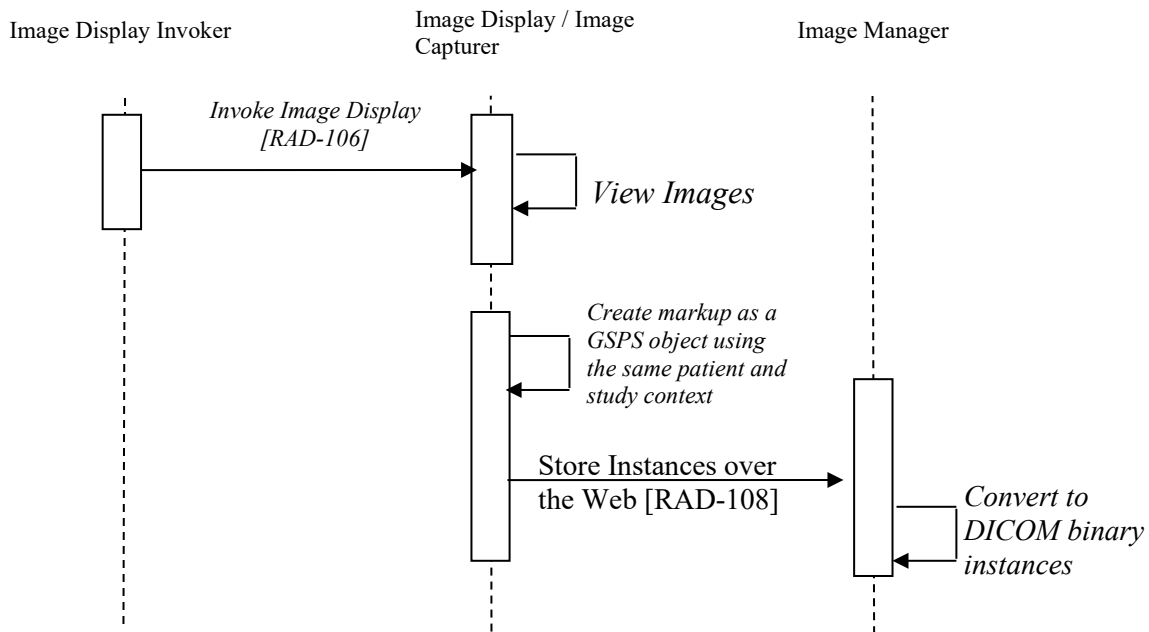
Figure 38.4.2.2.2-2: Image Upload to an Existing Study Process Flow in WIC Profile

38.5 WIC Security Considerations

6750   The WIC Profile has similar considerations to other IHE profiles that are based on HTTP or
        REST. See ITI TF-2: Appendix Z.8 for recommendations for secure transportation,
        authentication, authorization, and securing patient identifiers in URLs. Implementers are
        encouraged to review that section for applicability to their product environment.

        Since the Image Capturer may be running on a mobile device that can easily be lost, it is
6755   important to consider how much information should be retained in the mobile device. This
        includes patient demographics as well as the images, videos or reports. Likewise, since that
        mobile device may be running outside of the hospital's private network, it is important to ensure
        that the communication between the Image Capturer and the Image Manager is secure.

        The ITI Audit Trail and Node Authentication (ATNA) Profile specifies encryption to provide
6760   secure data transport, and ATNA audit messages can ensure audit trails for private health
        information are captured.

        It is recommended that the Image Manager be grouped with the ATNA Secure Node or Secure
        Application.
        • The Image Manager may want to restrict which devices are authorized to upload images.
6765   ATNA provides certificate-based node authentication.

- The Image Manager may want to record audit messages for the transactions performed. It is not expected that the Image Capturer will record audit messages.

The Image Manager may want to restrict which users are authorized to upload images. The ITI Internet User Authorization (IUA) Profile provides OAuth-based user authorization.

38.6 WIC Cross Profile Considerations

IID – Invoke Image Display

An Image Capturer might be grouped with an Image Display in the Invoke Image Display Profile to create and store evidence documents back to the associated Image Manager based on images being viewed and their associated patient and study context.

XDS-I.b – Cross-Enterprise Document Sharing for Imaging

An Image Capturer might be grouped with an XDS-I.b Imaging Document Consumer to create and store new objects back to the Image Manager based on study objects it is viewing.

An Image Manager might be grouped with an XDS-I.b Imaging Document Source to receive objects sent from an Image Capturer and publish a new manifest.

WIA – Web-based Image Access

An Image Capturer might be grouped with an WIA Imaging Document Consumer to create and store new objects back to the Image Manager based on study objects it is viewing.

An Image Manager might be grouped with an WIA Imaging Document Source to receive objects sent from an Image Capturer.

ITI PDQm – Patient Demographics Query for Mobile

An Image Capturer might be grouped with a PDQm Patient Demographics Consumer to retrieve reliable patient demographics from the Patient Demographics Supplier.

39 Clinical Decision Support – Order Appropriateness Tracking (CDS-OAT)

Clinical Decision Support – Order Appropriateness Tracking is a Trial Implementation Profile.

40 Radiation Exposure Monitoring – Nuclear Medicine (REM-NM)

The REM-NM Profile specifies communications between systems generating reports of radiopharmaceutical administration events (generally laboratory or dose creator/injector systems) and systems which receive, store, or process those reports (generally nuclear medicine modalities, local dose information management systems and/or national/regional dose registries). It defines how DICOM nuclear medicine dose SR objects are created, stored, queried, retrieved, de-identified, read, and may be processed and displayed.

40.1 REM-NM Actors, Transactions, and Content Modules

6800   This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A at http://www.ihe.net/Technical_Frameworks.

Figure 40.1-1 shows the actors directly involved in the REM-NM Profile and the relevant transactions between them. If needed for context, other actors that may be indirectly involved
6805   due to their participation in other related profiles are shown in dotted lines. Actors which have a mandatory grouping are shown in conjoined boxes.
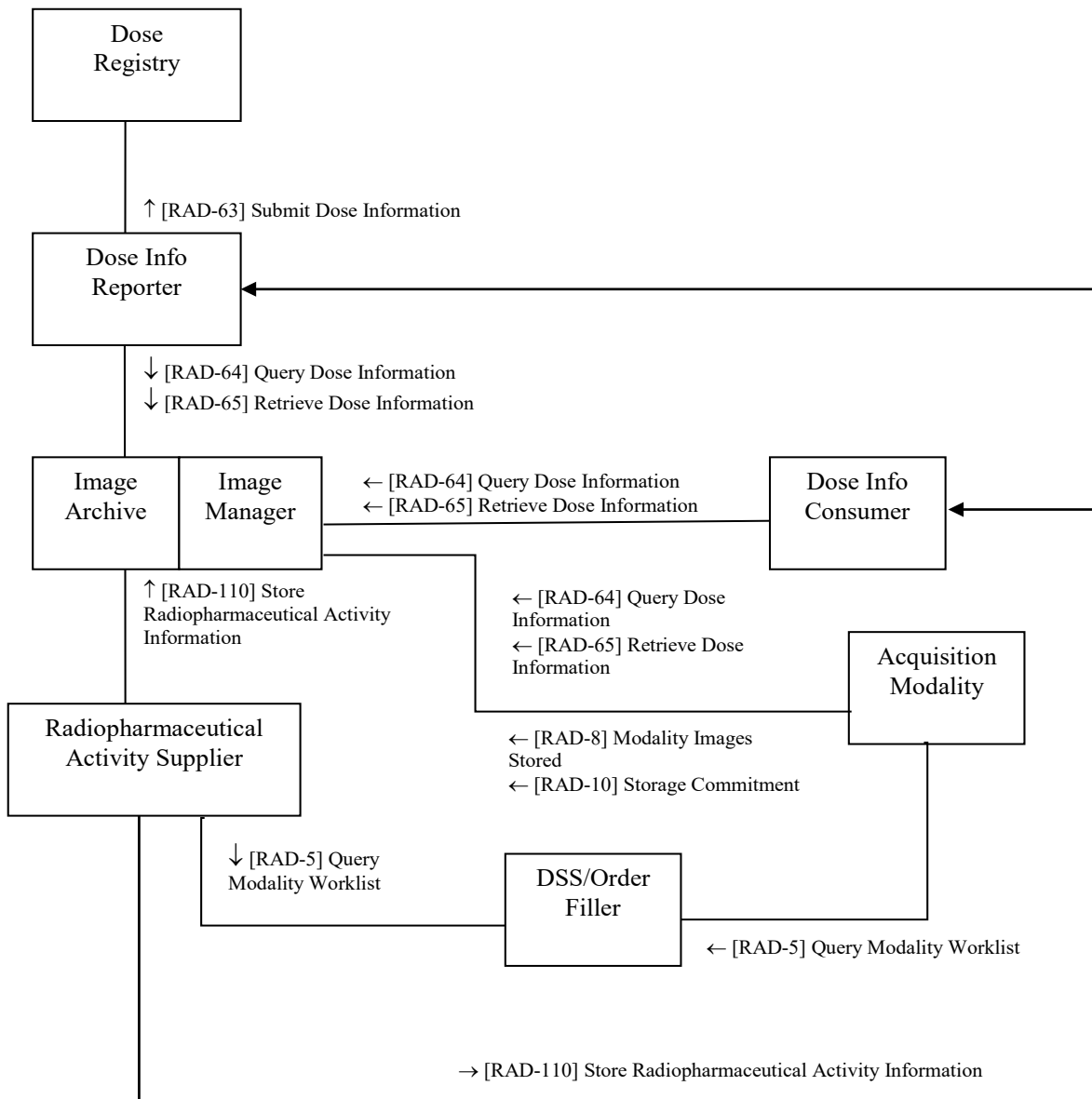

Figure 40.1-1: REM-NM Actor Diagram

6810   Table 40.1-1 lists the transactions for each actor directly involved in the REM-NM Profile. To claim compliance with this profile, an actor shall support all required transactions (labeled "R") and may support the optional transactions (labeled "O").

Table 40.1-1: REM-NM Profile - Actors and Transactions

Actors	Transactions	Initiator or Responder	Optionality	Reference
Radiopharmaceutical Activity Supplier	Query Modality Worklist [RAD-5]	Initiator	R	RAD TF-2: 4.5
	Store Radiopharmaceutical Activity Information [RAD-110]	Initiator	R	RAD TF-2: 4.110
Acquisition Modality	Query Modality Worklist [RAD-5]	Initiator	R	RAD TF-2: 4.5
	Modality Images Stored [RAD-8]	Initiator	R	RAD TF-2: 4.8
	Storage Commitment [RAD-10]	Initiator	R	RAD TF-2: 4.10
	Query Dose Information [RAD-64]	Initiator	R	RAD TF-2: 4.64
	Retrieve Dose Information [RAD-65]	Initiator	R	RAD TF-2: 4.65
Image Manager / Archive	Modality Images Stored [RAD-8]	Responder	R	RAD TF-2: 4.8
	Storage Commitment [RAD-10]	Responder	R	RAD TF-2: 4.10
	Query Dose Information [RAD-64]	Responder	R	RAD TF-2: 4.64
	Retrieve Dose Information [RAD-65]	Responder	R	RAD TF-2: 4.65
	Store Radiopharmaceutical Activity Information [RAD-110]	Responder	R	RAD TF-2: 4.110
Dose Information Reporter	Submit Dose Information [RAD-63]	Initiator	R	RAD TF-2: 4.63
	Query Dose Information [RAD-64]	Initiator	R	RAD TF-2: 4.64
	Retrieve Dose Information [RAD-65]	Initiator	R	RAD TF-2: 4.65
	Store Radiopharmaceutical Activity Information [RAD-110]	Responder	R	RAD TF-2: 4.110
Dose Information Consumer	Query Dose Information [RAD-64]	Initiator	R	RAD TF-2: 4.64
	Retrieve Dose Information [RAD-65]	Initiator	R	RAD TF-2: 4.65
	Store Radiopharmaceutical Activity Information [RAD-110]	Responder	R	RAD TF-2: 4.110
Dose Registry	Submit Dose Information [RAD-63]	Responder	R	RAD TF-2: 4.63
DSS/Order Filler	Query Modality Worklist [RAD-5]	Responder	R	RAD TF-2: 4.5

6815   A Radiopharmaceutical Activity Supplier may generate Dose objects on behalf of another system based on administration details obtained by manual input and/or some proprietary method, as long as it can do so completely and correctly.

Actors are encouraged to describe in their DICOM Conformance Statement additional details of how they implement specific DICOM-based transactions (e.g., the time frame in which a

6820   Radiopharmaceutical Activity Supplier is able to store a Dose object relative to the completion of the irradiation event).

40.1.1 Actor Descriptions and Actor Profile Requirements

Most requirements are documented in Transactions (Volumes 2 and 3) and National Extensions (Volume 4). This section documents any additional requirements on profile's actors.

40.1.1.1 Acquisition Modality

Images created for a given study by the Acquisition Modality shall have the same Study Instance UID as the associated Dose Reports (Radiopharmaceutical and X-Ray). Thus the Acquisition Modality in REM-NM is required to be grouped with both an SWF.b Acquisition Modality and an REM Acquisition Modality (if applicable). See Table 40.3-1: REM-NM Required Actor Groupings and Section 40.4.1 Concepts.

The Acquisition Modality shall record Radiopharmaceutical Administered Activity Information, if present the RRDSR, into each created image instance in the associated study. See RAD TF-2: 4.8.4.1.2.10.

40.1.1.2 Image Manager / Archive

Some Use Cases require that the Dose Report be accessible to the Acquisition Modality in a timely manner. Therefore, the Image Manager/Archive shall make the Dose Report available for retrieval during the conduct of the acquisition; i.e., it shall not sequester it until the acquisition procedure is complete.

40.2 REM-NM Actor Options

Options that may be selected for each actor in this profile, if any, are listed in the Table 40.2-1. Dependencies between options when applicable are specified in notes.

Table 40.2-1: REM for Nuclear Medicine - Actors and Options

Actor	Option Name	Reference
Radiopharmaceutical Activity Supplier (Note 1)	Patient Based Worklist	RAD TF-2: 4.5.4.1.2
	Radiopharmaceutical Activity Supplier Worklist Query	RAD TF-2: 4.5.4.1.2
Acquisition Modality (Note 1)	Patient Based Worklist	RAD TF-2: 4.5.4.1.2
	Broad Worklist Query	RAD TF-2: 4.5.4.1.2
Image Manager/Archive	*No options defined*	--
Dose Information Reporter	*No options defined*	--
Dose Information Consumer	*No options defined*	--
Dose Registry	*No options defined*	--
DSS/Order Filler	*No options defined*	--

Note 1: The actor shall support at least one of the two options. Both may be supported.

40.3 REM-NM Required Actor Groupings

6845 An actor from this profile (Column 1) shall implement all of the required transactions and/or content modules in this profile *in addition to* all of the transactions required for the grouped actor (Column 2).

Section 40.5 describes some optional groupings that may be of interest for security considerations and Section 40.6 describes some optional groupings in other related profiles.

6850

Table 40.3-1: REM-NM - Required Actor Groupings

REM-NM Actor	Actor to be grouped with	Reference	Content Bindings Reference
Radiopharmaceutical Activity Supplier	ITI CT / Time Client	ITI TF-1: 7.1	--
Acquisition Modality	ITI CT / Time Client	ITI TF-1: 7.1	--
	REM / Acquisition Modality (See Note 1)	RAD TF-1: 22.1	
	SWF.b / Acquisition Modality	RAD TF-1: 34.1	--
Image Manager / Archive	None	--	--
Dose Information Reporter	None	--	--
Dose Information Consumer	None	--	--
Dose Registry	None	--	--
DSS/Order Filler	SWF.b / DSS/Order Filler	RAD TF-1: 34.1	--

Note 1: Required if the Acquisition Modality is a hybrid PET/CT or SPECT/CT.

40.4 REM-NM Overview

40.4.1 Concepts

There are three main concepts.

6855 1. The Acquisition Modality is not the creator of the Dose Report (RRDSR). Instead, it is a consumer of this report.

2. There are use cases that do not involve an imaging procedure at all.

3. In some cases that do involve an imaging procedure, the Dose Report may not be available to the Acquisition Modality until some time after the imaging procedure has
6860 started.

40.4.2 Use Cases

40.4.2.1 Use Case #1: Non-Imaging Procedure

In the simplest case, there is an injection with no imaging.

40.4.2.1.1 Non-Imaging Procedure Use Case Description

6865 A patient is scheduled for a Nuclear Medicine procedure that does not involve imaging (e.g., for measurement with a thyroid uptake probe).

The Radiopharmaceutical Activity Supplier, typically a Hot Lab management system, an infusion system, or a radioisotope generator queries the DSS/Order Filler for a Worklist entry to get the patient demographics, order and procedure details for the current patient.

6870 The Radiopharmaceutical is prepared and administered to the patient.

Administration may be done manually or using an automated device such as an automatic injector. A variety of routes of administration are possible (e.g., oral, by inhalation, intravenous, etc.).

The Radiopharmaceutical Activity Supplier records the amount of activity that was administered
6875 to the patient, generating a new Radiopharmaceutical Administration Event UID. Some systems may derive the administered activity by measuring the dose container before (pre-administration assay) and after (residual assay) and taking the difference. Some generators measure the administered activity directly. Other details may include the volume of administered activity, extravasation, etc.

6880 Upon completion of the radiopharmaceutical administration, the Radiopharmaceutical Activity Supplier stores the completed Radiopharmaceutical Radiation Dose Structured Report (RRDSR) to the Image Manager/Archive where it will be available as a persistent record. From there, Dose Information Consumers and Dose Information Reporters may access the report, for example to generate analysis reports or drive dashboards. (See Section 22.3.2 for more examples of dose
6885 report analysis as described for REM).

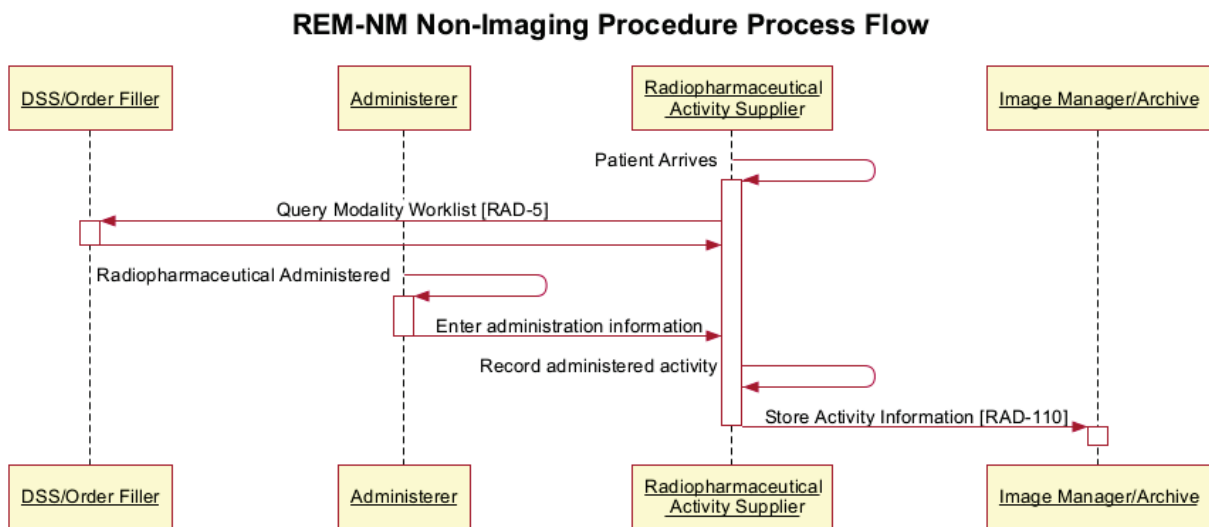### 40.4.2.1.2 Non-Imaging Procedure Process Flow

Figure 40.4.2.1.2-1: Non-Imaging Procedure Process Flow in REM-NM Profile

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343

The text in Figure 40.4.2.1.2-2 was used to generate the diagram in Figure 40.4.2.1.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

```
title REM-NM Non-Imaging Procedure Process Flow
Participant DSS/Order Filler as OF
Participant Administerer as Injector
Participant Radiopharmaceutical\n Activity Supplier as RAS
Participant Image Manager/Archive as IM

RAS->RAS: Patient Arrives
Activate RAS

RAS->+OF: Query Modality Worklist [RAD-5]
OF->-RAS:
Injector->+Injector: Radiopharmaceutical Administered
Injector->-RAS: Enter administration information

RAS->RAS: Record administered activity
RAS->+IM: Store Activity Information [RAD-110]

Deactivate RAS
```

Figure 40.4.2.1.2-2: Diagram Pseudocode for Non-Imaging Procedure Process Flow

40.4.2.2 Use Case #2: General Imaging Procedure

In the most common imaging procedures a single radiopharmaceutical is administered on one occasion to a patient for imaging purposes.

40.4.2.2.1 General Imaging Procedure Use Case Description

A patient is scheduled for a standard Nuclear Medicine imaging procedure.

The Radiopharmaceutical Activity Supplier Actor, typically a Hot Lab management system, an infusion system, or a radioisotope generator queries the DSS/Order Filler for a Worklist entry to get the patient demographics, order and procedure details for the current patient.

The Radiopharmaceutical is prepared and administered to the patient.

Administration may be done manually or using an automated device such as an automatic injector. A variety of routes of administration are possible (e.g., oral, by inhalation, intravenous, etc.).

The Radiopharmaceutical Activity Supplier records the amount of activity that was administered to the patient, generating a new Radiopharmaceutical Administration Event UID. Some systems may derive the administered activity by measuring the dose container before (pre-administration

6910 assay) and after (residual assay) and taking the difference. Some generators measure the administered activity directly. Other details may include the volume of administered activity, extravasation, etc.

Upon completion of the radiopharmaceutical administration, the Radiopharmaceutical Activity Supplier stores the completed Radiopharmaceutical Radiation Dose Structured Report (RRDSR) to the Image Manager/Archive where it will be available as a persistent record. From there, Dose Information Consumers and Dose Information Reporters may access the report, for example to
6915 generate analysis reports or drive dashboards. (See Section 22.3.2 for more examples of dose report analysis as described for REM.)

After an amount of time (determined by clinical protocols outside of this profile; typically 30 to 90 minutes for PET, and up to more than 24 hours for some NM cases) the patient is taken to the Acquisition Modality. As part of preparation for performing the imaging procedure, the
6920 Acquisition Modality locates the RRDSR by querying the Image Manager/Archive and retrieves the RRDSR(s) for the study. The images created by the Acquisition Modality and the RRDSR will contain the same Study Instance UID since both the Acquisition Modality and the Radiopharmaceutical Activity Supplier obtain the Study Instance UID from the Worklist. Imaging data is acquired, and the Acquisition Modality uses the administered activity
6925 information from the Dose Report to do decay correction. The Acquisition Modality also includes in the encoded images information about the radionuclide, radiopharmaceutical and administered activity obtained from the Dose Report.

The Acquisition Modality does not forward the retrieved Dose Report to the Image Manager/Archive when storing the resulting images.

6930 A valid alternative product implementation would be for the Acquisition Modality to be grouped with a Radiopharmaceutical Activity Supplier to support scenarios in which there is no separate Radiopharmaceutical Activity Supplier.

40.4.2.2.2 General Imaging Procedure Process Flow

REM-NM General Imaging Procedure Process Flow
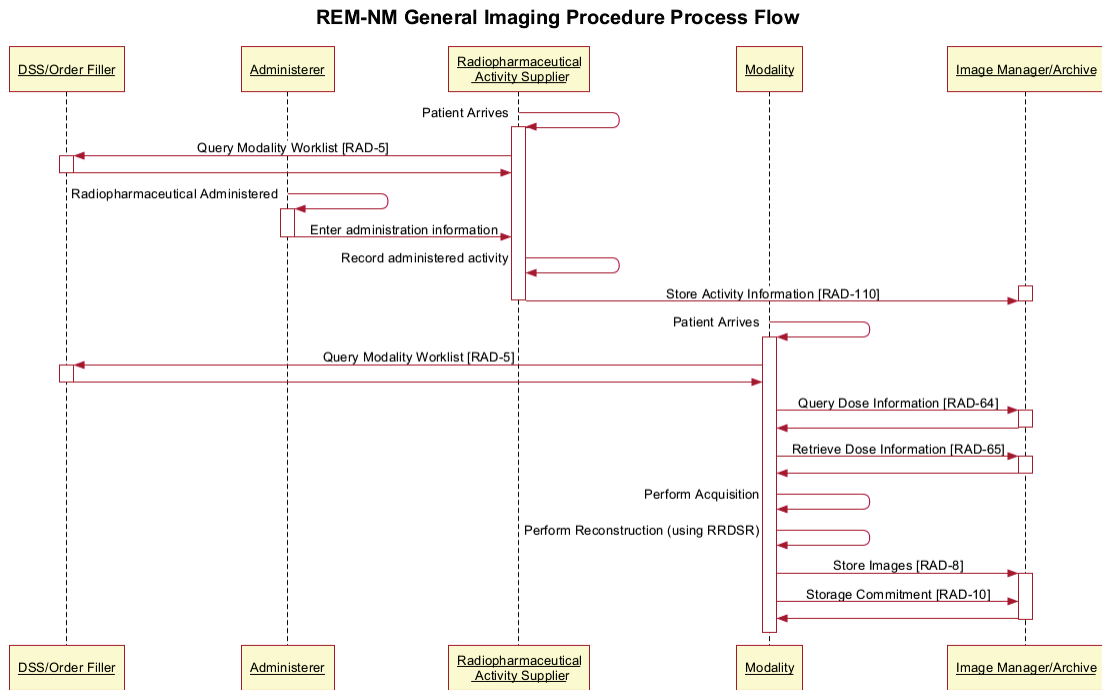
Figure 40.4.2.2-1: General Imaging Procedure Process Flow in REM-NM Profile

The text in Figure 40.4.2.2-2 was used to generate the diagram in Figure 40.4.2.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

```
title REM-NM General Imaging Procedure Process Flow
Participant DSS/Order Filler as OF
Participant Administerer as Injector
Participant Radiopharmaceutical\n Activity Supplier as RAS
Participant Modality
Participant Image Manager/Archive as IM

RAS->RAS: Patient Arrives
Activate RAS

RAS->+OF: Query Modality Worklist [RAD-5]
OF->-RAS:
Injector->+Injector:Radiopharmaceutical Administered
Injector->-RAS: Enter administration information

RAS->RAS: Record administered activity
RAS->+IM: Store Activity Information [RAD-110]



Deactivate IM

Deactivate RAS

Modality->Modality: Patient Arrives
Activate Modality
Modality->+OF: Query Modality Worklist [RAD-5]
OF->-Modality:
Modality->+IM: Query Dose Information [RAD-64]
IM->-Modality:
Modality->+IM: Retrieve Dose Information [RAD-65]
IM->-Modality:

Modality->Modality: Perform Acquisition
Modality->Modality: Perform Reconstruction (using RRDSR)
Modality->+IM: Store Images [RAD-8]
Modality->IM: Storage Commitment [RAD-10]
IM->-Modality:
```

6940

Figure 40.4.2.2-2: Diagram Pseudocode for General Imaging Procedure Process Flow

40.4.2.3 Use Case #3: Simultaneous Administration and Imaging

This use case is very similar to Use Case #2, with one exception. In this use case a radiopharmaceutical is administered to a patient during the imaging process. This means the
6945   Dose Report is not available until some time after the acquisition setup has been completed. The Acquisition Modality will need to accommodate this case by allowing lookup of the Dose Report when it is actually needed, after the traditional scan setup.
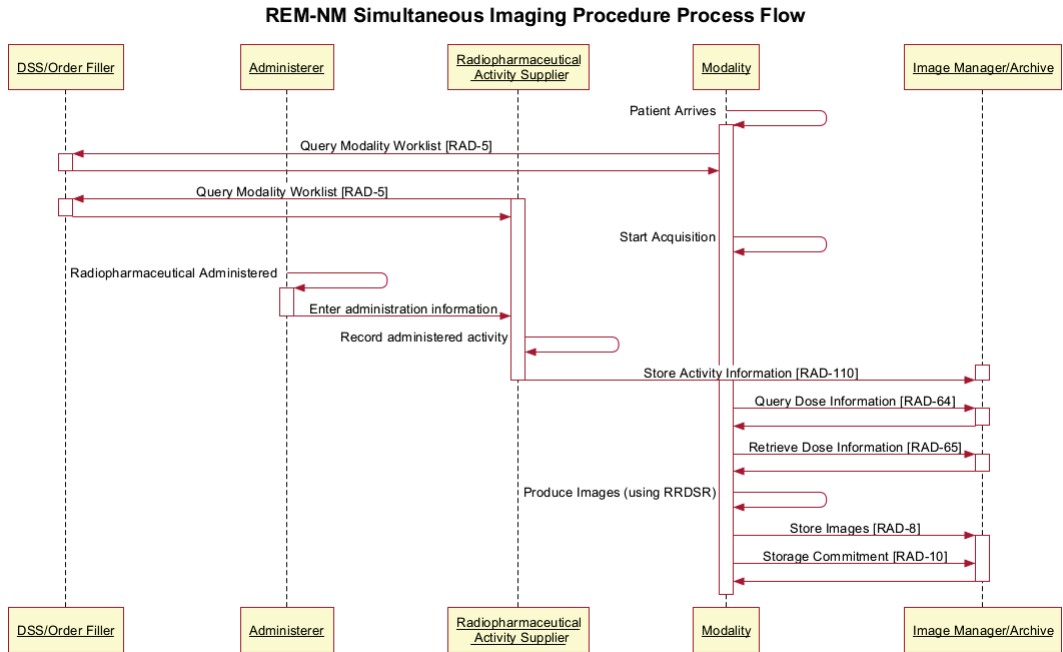
40.4.2.3.1 Simultaneous Administration and Imaging Use Case Description

A patient is scheduled for a standard Nuclear Medicine imaging procedure.

6950   The Radiopharmaceutical Activity Supplier Actor, typically a Hot Lab management system, an infusion system, or a radioisotope generator queries the DSS/Order Filler for a Worklist entry to get the patient demographics, order and procedure details for the current patient.

The Radiopharmaceutical is prepared.

6955   At some point, the patient is also taken to the Modality. The Acquisition Modality queries the Order Filler for a Worklist Entry for the imaging procedure.

The Modality begins the data acquisition procedure, and the radiopharmaceutical is administered to the patient at approximately the same time (the order in which these events occur may depend on the exact procedure and radiopharmaceutical being used).

6960   Administration may be done manually or using an automated device such as an automatic injector. A variety of routes of administration are possible (e.g., oral, by inhalation, intravenous, etc.).

The Radiopharmaceutical Activity Supplier records the amount of activity that was administered to the patient, generating a new Radiopharmaceutical Administration Event UID. Some systems may derive the administered activity by measuring the dose container before (pre-administration assay) and after (residual assay) and taking the difference. Some generators measure the administered activity directly. Other details may include the volume of administered activity, extravasation, etc.

6965

Upon completion of the radiopharmaceutical administration, the Radiopharmaceutical Activity Supplier stores the completed Radiopharmaceutical Radiation Dose Structured Report (RRDSR) to the Image Manager/Archive where it will be available as a persistent record. From there, Dose Information Consumers and Dose Information Reporters may access the report, for example to generate analysis reports or drive dashboards. (See RAD Section 22.3.2 for more examples of dose report analysis as described for REM.)

6970

The Acquisition Modality allows enough time for the RRDSR to be created and stored. The Acquisition Modality locates the RRDSR by querying the Image Manager/Archive and retrieves the RRDSR(s) for the study. The Acquisition Modality uses the administered activity information from the Dose Report to do decay correction. The Acquisition Modality also includes in the encoded images information about the radionuclide, radiopharmaceutical and administered activity obtained from the Dose Report. The images created by the Acquisition Modality and the RRDSR will contain the same Study Instance UID since both the Acquisition Modality and the Radiopharmaceutical Activity Supplier obtain the Study Instance UID from the Worklist.

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The Acquisition Modality does not forward the Dose Report to the Image Manager/Archive when storing the resulting images.

6985   A valid alternative product implementation would be for the Acquisition Modality to be grouped with a Radiopharmaceutical Activity Supplier to support scenarios in which there is no separate Radiopharmaceutical Activity Supplier, or if the Modality needs to report more dose information in a new Dose Report.

40.4.2.3.2 Simultaneous Administration and Imaging Process Flow

REM-NM Simultaneous Imaging Procedure Process Flow

6990

Figure 40.4.2.3.2-1: Simultaneous Administration and Imaging Process Flow in REM-NM Profile

6995 The text in Figure 40.4.2.3.2-2 was used to generate the diagram in Figure 40.4.2.3.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.
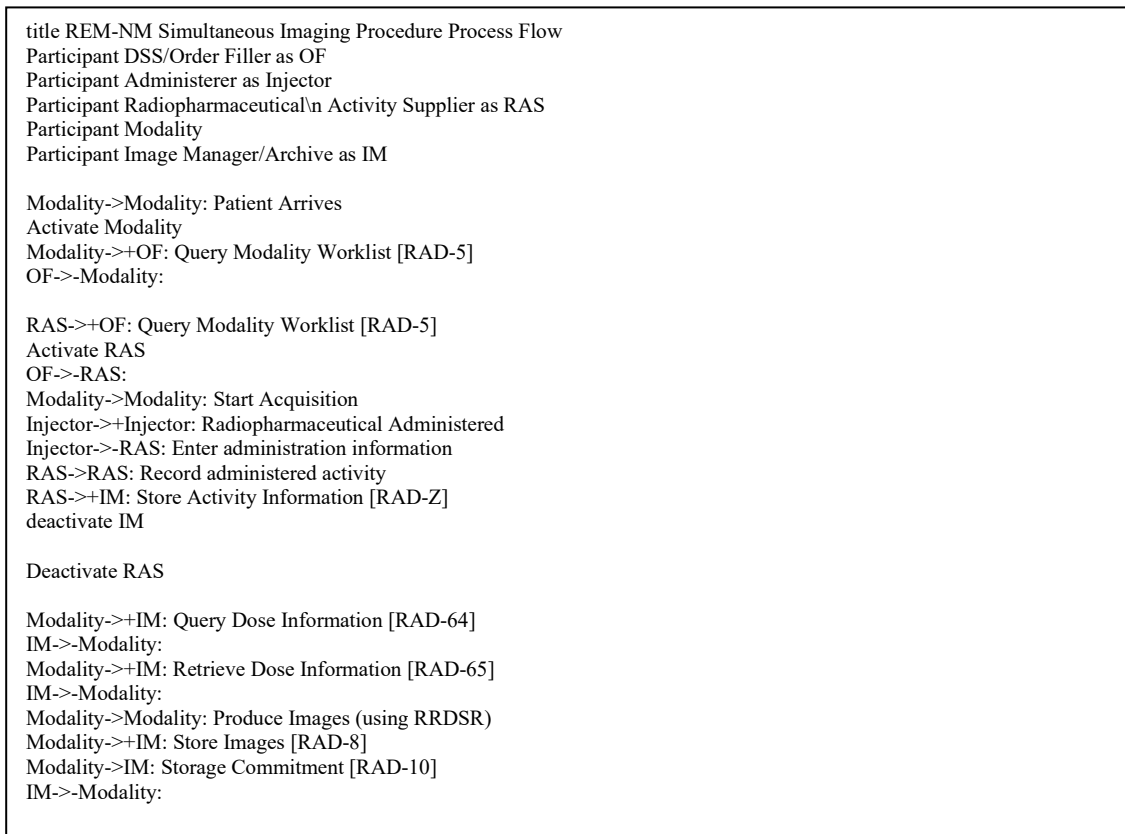
```
title REM-NM Simultaneous Imaging Procedure Process Flow
Participant DSS/Order Filler as OF
Participant Administerer as Injector
Participant Radiopharmaceutical\n Activity Supplier as RAS
Participant Modality
Participant Image Manager/Archive as IM

Modality->Modality: Patient Arrives
Activate Modality
Modality->+OF: Query Modality Worklist [RAD-5]
OF->-Modality:

RAS->+OF: Query Modality Worklist [RAD-5]
Activate RAS
OF->-RAS:
Modality->Modality: Start Acquisition
Injector->+Injector: Radiopharmaceutical Administered
Injector->-RAS: Enter administration information
RAS->RAS: Record administered activity
RAS->+IM: Store Activity Information [RAD-Z]
deactivate IM

Deactivate RAS

Modality->+IM: Query Dose Information [RAD-64]
IM->-Modality:
Modality->+IM: Retrieve Dose Information [RAD-65]
IM->-Modality:
Modality->Modality: Produce Images (using RRDSR)
Modality->+IM: Store Images [RAD-8]
Modality->IM: Storage Commitment [RAD-10]
IM->-Modality:
```

Figure 40.4.2.3.2-2: Diagram Pseudocode for Simultaneous Imaging Procedure Process Flow

40.4.2.4 Use Case #4: Dose Information Reporter Pull-based Workflow

7000 Two alternative methods for distributing the dose information to the Dose Information Reporter (and on to the Registry) are presented in Use Case #4 and #5.

The Dose Information Reporter processes Dose Reports that were created by the Radiopharmaceutical Activity Supplier. In this Use Case, the Dose Information Reporter retrieves the Dose Reports from the Image Manager/Archive.

7005 **40.4.2.4.1 Dose Information Reporter Pull-based Workflow Use Case Description**

This Use Case begins when the Dose Report is stored on the Image Manager/Archive by the Radiopharmaceutical Activity Supplier.

The Dose Information Reporter periodically collects Dose Reports to be submitted to a Dose Registry. The Dose Reports are obtained by querying the Image Manager/Archive. Selected
7010 reports are de-identified by the Dose Information Reporter and then submitted to the Dose Registry. The analysis performed by the Dose Registry (e.g., population analysis) is beyond the scope of this profile.

7015 The Dose Information Reporter may also generate weekly or monthly departmental reports summarizing the departmental activity. The Dose Information Reporter periodically collects relevant Dose Reports by querying the Image Manage/Archive. Information from these Dose Reports is summarized in a departmental report document. The content of these summary reports is beyond the scope of this profile, and may be site dependent.

40.4.2.4.2 Dose Information Reporter Pull-based Process Flow
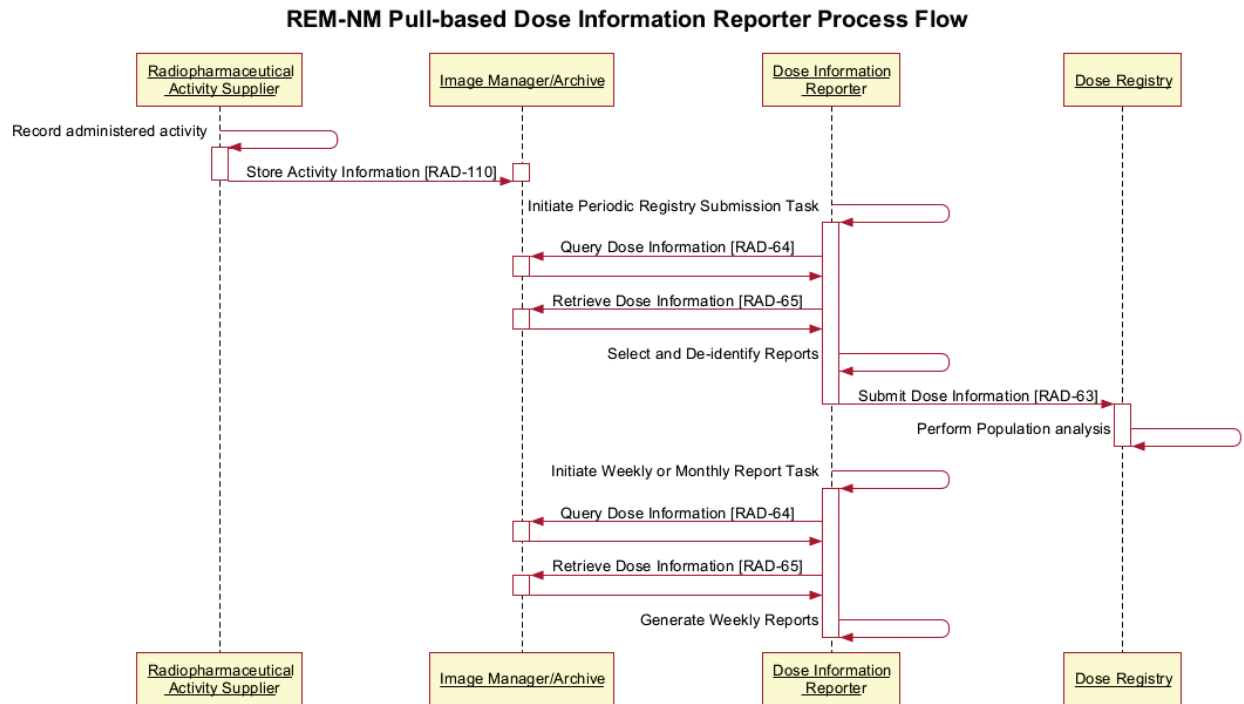
7020 **Figure 40.4.2.4.2-1: Pull-based Dose Information Reporter Process Flow in REM-NM Profile**

The text in Figure 40.4.2.4.2-2 was used to generate the diagram in Figure 40.4.2.4.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

```
title REM-NM Pull-based Dose Information Reporter Process Flow
Participant Radiopharmaceutical\n Activity Supplier as RAS
Participant Image Manager/Archive as IM
Participant Dose Information\n Reporter as Reporter
Participant Dose Registry as Dose Register
RAS->RAS: Record administered activity
Activate RAS
RAS->+IM: Store Activity Information [RAD-110]

Deactivate IM
Deactivate RAS

Reporter->+Reporter : Initiate Periodic Registry Submission Task
Reporter->+IM: Query Dose Information [RAD-64]
IM->-Reporter:
Reporter->+IM: Retrieve Dose Information [RAD-65]
IM->-Reporter:
Reporter->Reporter: Select and De-identify Reports
Reporter->+Dose Register: Submit Dose Information [RAD-63]
Deactivate Reporter
Dose Register->-Dose Register: Perform Population analysis

Reporter->+Reporter : Initiate Weekly or Monthly Report Task
Reporter->+IM: Query Dose Information [RAD-64]
IM->-Reporter:
Reporter->+IM: Retrieve Dose Information [RAD-65]
IM->-Reporter:
Reporter->-Reporter : Generate Weekly Reports
```

7025   **Figure 40.4.2.4.2-2: Diagram Pseudocode for Pull-based Dose information Reporter Process Flow**

40.4.2.5 Use Case #5: Dose Information Reporter Push-based Workflow

The Dose Information Reporter processes Dose Reports that were created by the Radiopharmaceutical Activity Supplier. In this Use Case, the Dose Information Reporter
7030   receives the Dose Reports pushed directly from the Radiopharmaceutical Activity Supplier.

40.4.2.5.1 Dose Information Reporter Push-based Workflow Use Case Description

This Use Case begins when the Dose Report is stored on the Dose Information Reporter by the Radiopharmaceutical Activity Supplier.

The Dose Information Reporter periodically selects Dose Reports that it has received, to be
7035   submitted to a Dose Registry. Selected reports are de-identified by the Dose Information Reporter and then submitted to the Dose Registry. The analysis performed by the Dose Registry (e.g., population analysis) is beyond the scope of this profile.
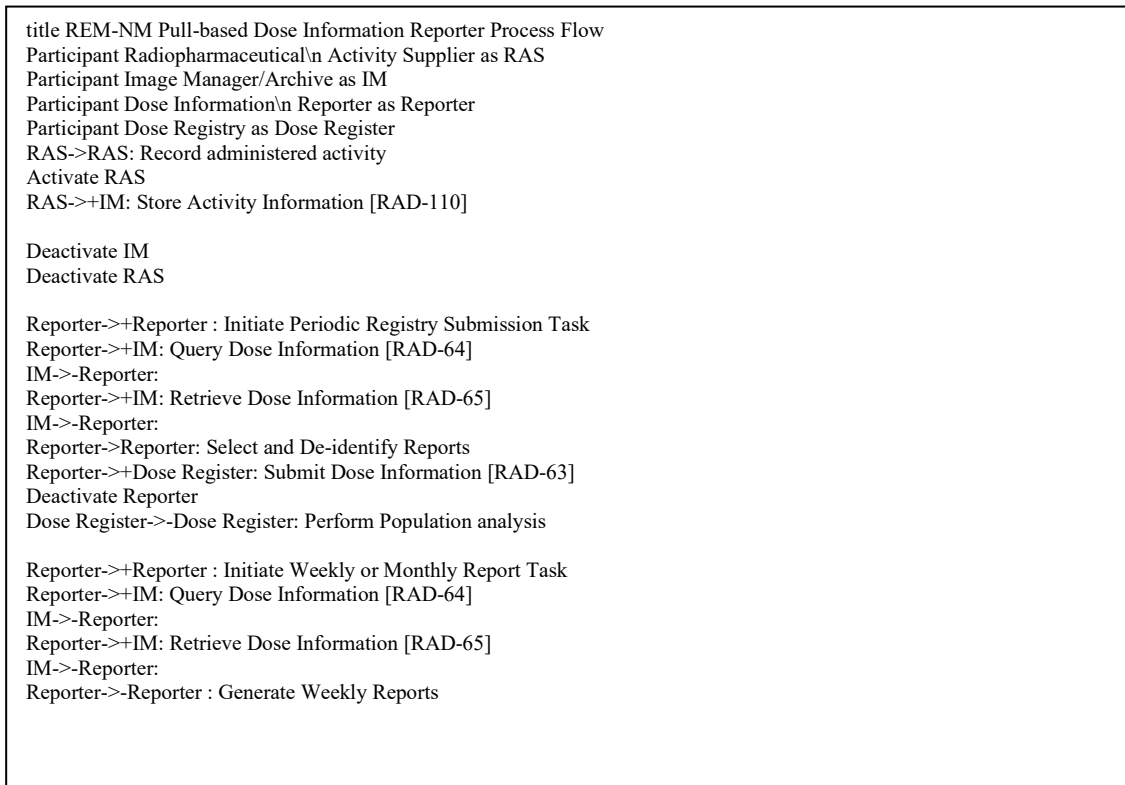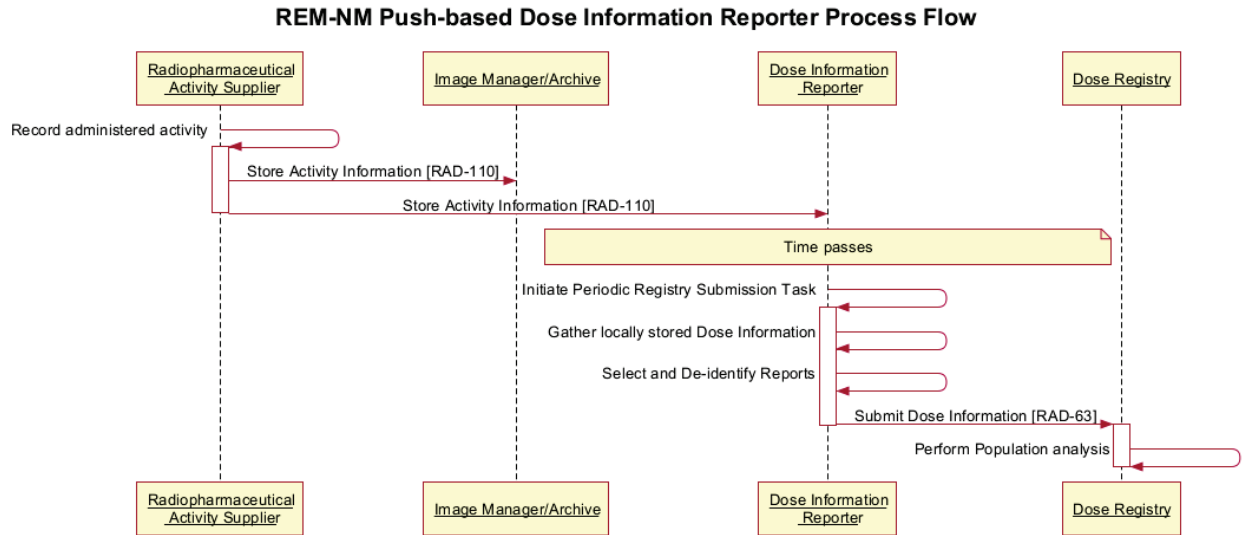
The Dose Information Reporter may also generate weekly or monthly departmental reports summarizing the departmental activity based on the Dose Reports that it has received. The Dose
7040   Information Reporter periodically selects relevant Dose Reports for processing. Information

from these Dose Reports is summarized in a departmental report document. The content of these summary reports is beyond the scope of this profile, and may be site dependent.

40.4.2.5.2 Dose Information Reporter Push-based Process Flow

7045 **Figure 40.4.2.5.2-1: Push-based Dose Information Reporter Process Flow in REM-NM Profile**

The text in Figure 40.4.2.5.2-2 was used to generate the diagram in Figure 40.4.2.5.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

```
title REM-NM Push-based Dose Information Reporter Process Flow
Participant Radiopharmaceutical\n Activity Supplier as RAS
Participant Image Manager/Archive as IM
Participant Dose Information\n Reporter as Reporter
Participant Dose Registry as Dose Register
RAS->RAS: Record administered activity
Activate RAS
RAS->IM: Store Activity Information [RAD-110]

IM->-:
RAS->Reporter: Store Activity Information [RAD-110]
Deactivate RAS
Note over Reporter: Time passes

Reporter->+Reporter : Initiate Periodic Registry Submission Task
Reporter->Reporter: Gather locally stored Dose Information
Reporter->Reporter: Select and De-identify Reports
Reporter->+Dose Register: Submit Dose Information [RAD-63]
Deactivate Reporter
Dose Register->-Dose Register: Perform Population analysis
```

7050   **Figure 40.4.2.5.2-2: Diagram Pseudocode for Push-based Dose Information Reporter Process Flow**

40.5 REM-NM Security Considerations

Dose Objects have the same security considerations as images.

7055   Security and Privacy policies may require the de-identification of some or all of the PHI details prior to the submission or use of Dose Objects (see RAD TF-2: 4.63.4.1.2.1). De-identification behavior may need to vary by destination due to differences in PHI exposure risk and the need to retain some details, such as approximate patient age or weight, when performing Radiation Dose analysis.

40.6 REM-NM Cross Profile Considerations

7060   Several synergies and interactions of the REM-NM Profile with other profiles are specifically called out here.

40.6.1 Radiology Profiles

40.6.1.1 Portable Data for Imaging (PDI)

The Dose objects from this profile may be included on PDI media, either along with the rest of
7065   the study data to provide a "complete package", or on their own as a way of conveying Dose objects to a patient, another organization or a dose registry.

40.6.1.2 Teaching Files and Clinical Trials Export (TCE)

As DICOM objects, the Dose objects can be referenced in a TCE manifest and processed along with other objects from a study. This could allow submitting dose details in clinical trials where such information is relevant, or including dose details in a teaching file, perhaps one specifically addressing protocol dose and the effects on image quality.

40.6.1.3 Radiation Exposure Monitoring (REM)

Radiation Exposure Monitoring is closely related to REM-NM. Actors supporting REM-NM may consider also supporting REM (see Section 22).

40.6.2 IT Infrastructure Profiles

40.6.2.1 Cross-Enterprise Document Sharing (XD*)

Since Dose objects are normal DICOM SR objects, the collection of XDS Profiles (XDS, XDS-I, XDR, XDM, etc.) can be used to distribute or access dose records across multiple sites.

40.6.2.2 Audit Trail and Node Authentication (ATNA)

Audit events relevant to the transactions of the REM-NM Profile are identified in RAD TF-3: Table 5.1-2 in the Radiology Audit Trail Option.

41 Cross-Enterprise Remote Read Workflow Definition (XRR-WD)

Cross-Enterprise Remote Read Workflow Definition is a Trial Implementation Profile.

42 Web-based Image Access (WIA)

Web-based Image Access (WIA) Profile defines methods for image sharing and interactive viewing of imaging studies using RESTful services such as WADO-RS and QIDO-RS.

A consumer, such as an enterprise viewer, can retrieve metadata about studies from a PACS, VNA, etc. and then it can retrieve the images and display to the user, all using RESTful services.

WIA can be used independently or combined with other profiles such as the IT Infrastructure domain's Mobile access to Health Document (MHD) Profile. When combined with MHD, it allows the MHD Document Consumer to locate and access imaging studies using document metadata.

42.1 WIA Actors, Transactions, and Content Modules

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

7100 Figure 42.1-1 shows the actors directly involved in the WIA Profile and the relevant transactions between them. If needed for context, other actors that may be indirectly involved due to their participation in other related profiles are shown in dotted lines. Actors which have a mandatory grouping are shown in conjoined boxes.
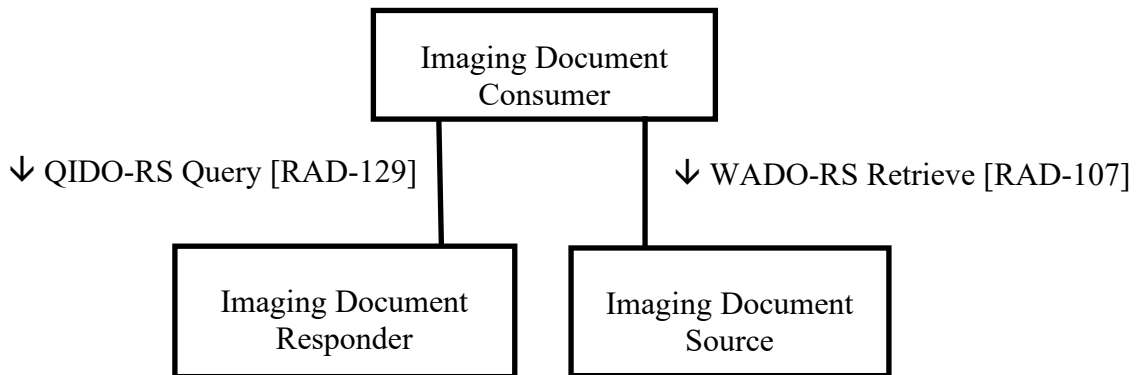

Figure 42.1-1: WIA Actor Diagram

7105 Table 42.1-1 lists the transactions for each actor directly involved in the WIA Profile. To claim compliance with this profile, an actor shall support all required transactions (labeled "R") and may support the optional transactions (labeled "O").

Table 42.1-1: WIA-RS Profile - Actors and Transactions

Actors	Transactions	Initiator or Responder	Optionality	TF Reference
Imaging Document Consumer	WADO-RS Retrieve [RAD-107]	Initiator	R	RAD TF-2: 4.107
	QIDO-RS Query [RAD-129]	Initiator	R	RAD TF-2: 4.129
Imaging Document Responder	QIDO-RS Query [RAD-129]	Responder	R	RAD TF-2: 4.129
Imaging Document Source	WADO-RS Retrieve [RAD-107]	Responder	R	RAD TF-2: 4.107

7110 ## 42.1.1 WIA Actor Descriptions and Actor Profile Requirements

Most requirements are documented in Transactions (Volumes 2) and Content Modules (Volume 3). This section documents any additional requirements on WIA actors.

42.1.1.1 Imaging Document Consumer

The Imaging Document Consumer requests imaging study metadata from an Imaging Document
7115 Responder using the QIDO-RS Query [RAD-129] transaction. Using these results, the Imaging

Document Consumer determines which images are needed for their application. The Imaging Document Consumer can issue a WADO-RS Retrieve [RAD-107] transaction to the Imaging Document Source to either retrieve detailed metadata or the objects.

42.1.1.2 Imaging Document Responder

The Imaging Document Responder receives a QIDO-RS Query [RAD-129] transaction request from the Imaging Document Consumer and returns matching imaging study metadata. This includes a URL that can be used by the Imaging Document Consumer to retrieve the detailed metadata or objects from the Imaging Document Source using the WADO-RS Retrieve [RAD-107] transaction.

42.1.1.3 Imaging Document Source

The Imaging Document Source receives a WADO-RS Retrieve [RAD-107] transaction request from an Imaging Document Consumer to retrieve the detailed metadata or objects.

42.2 WIA Actor Options

Options that may be selected for each actor, if any, are listed in the Table 42.2-1. Dependencies between options when applicable are specified in notes.

Table 42.2-1: Web-based Image Access - Actors and Options

Actor	Option Name	TF Reference
Imaging Document Consumer	XDS-I Backend	Section 42.2.1
	MHD Document Consumer Integration	Section 42.2.2
Imaging Document Responder	XDS-I Backend	Section 42.2.1
Imaging Document Source	XDS-I Backend	Section 42.2.1

42.2.1 XDS-I Backend Option

The XDS-I Backend Option accesses imaging studies within an XDS-I infrastructure.

An **Imaging Document Consumer** can select the appropriate endpoint for the desired behavior.

An Imaging Document Consumer shall:
- Support the requirements defined in RAD TF-2: 4.129.4.1.2.1.

An **Imaging Document Responder** can find imaging manifests from an XDS-I environment and generate the corresponding imaging study metadata query response. By implementing this option, the Imaging Document Responder can support interactive viewing in an XDS-I environment (see Use Case #4 in Section 42.4.2.4).

An Imaging Document Responder shall:
- Be grouped with an XDS.b Document Consumer.

- Support the requirements defined in RAD TF-2: 4.129.4.1.3.1.

7145 • Provide a separate endpoint that services a QIDO-RS query supporting the XDS-I Backend Option behavior.
Note: This profile does not specify how endpoints are communicated to the Imaging Document Consumer.

An **Imaging Document Source** can retrieve imaging studies from an XDS-I Imaging Document
7150 Source and return the imaging studies to the Imaging Document Consumer. By implementing this option, the Imaging Document Source can support interactive viewing in an XDS-I environment (see Use Case #4 in Section 42.4.2.4).

An Imaging Document Source shall:
• Be grouped with an XDS-I.b Imaging Document Consumer.

7155 42.2.2 MHD Document Consumer Integration Option

The MHD Document Consumer Integration Option enables an Imaging Document Consumer to follow imaging study document references found in MHD responses to retrieve the study without retrieving the XDS-I Imaging Manifest.

An Imaging Document Consumer can then access the referenced imaging studies using the
7160 retrieved document references (see Use Case #3 in Section 42.4.2.3).

The Imaging Document Consumer shall be grouped with an MHD Document Consumer.

The grouped MHD Document Consumer will find a document reference for an XDS-I Imaging Manifest in the Find Document References [ITI-67] response. In that document reference, a `DocumentReference.context.related.identifier.value` may be present with an Accession
7165 Number or a Study Instance UID needed to execute the QIDO-RS Query [RAD-129] request. If not present, the MHD Document Consumer shall retrieve the XDS-I Imaging Manifest using the Retrieve Document [ITI-68] transaction to locate these values.

Note: For more information on identifier coding, see ITI TF-2: Appendix Z Section 9.1.2 - XDS CXi mapped to FHIR Identifier Type.

7170 42.3 WIA Required Actor Groupings

An actor from this profile (Column 1) shall implement all required transactions for the grouped actor (Column 3) in Table 42.3-1.

Section 42.5 describes some optional groupings that may be of interest for security considerations and Section 42.6 describes some optional groupings in other related profiles.

7175 **Table 42.3-1: Web-based Image Access - Required Actor Groupings**

WIA Actor	Grouping Condition	Actor(s) to be grouped with	TF Reference
Imaging Document Consumer	MHD Document Consumer Integration Option	ITI MHD / Document Consumer	ITI TF-1: 33

WIA Actor	Grouping Condition	Actor(s) to be grouped with	TF Reference
Imaging Document Responder	XDS-I Backend Option	ITI XDS.b / Document Consumer	ITI TF-1:
Imaging Document Source	XDS-I Backend Option	XDS-I.b / Imaging Document Consumer	RAD TF-1: 18

42.4 WIA Overview

42.4.1 Concepts

42.4.1.1 Image sharing infrastructures

7180   WIA enables retrieval of imaging studies shared within an enterprise and across enterprises using RESTful services. WIA can be used with different image sharing infrastructures, including but not limited to XDS / XDS-I and DICOM / DICOMweb.

The Imaging Document Responder returns imaging study metadata in response to query requests. The source of the imaging study metadata is not constrained, and several models are
7185   possible. The Imaging Document Responder can find imaging study metadata from sources such as:

- Image Manager/Image Archive: The Imaging Document Responder can have direct access to the Image Manager/Image Archive, or it can communicate with one or more Image Managers/Image Archives via standard mechanism such as the Query Images
7190   [RAD-14] transaction.

- XDS Document Registry: When WIA Imaging Document Responder is grouped with an XDS Document Consumer, the Imaging Document Responder can transform the query submitted by the Imaging Document Consumer into the corresponding Registry Stored Query [ITI-18] transaction as well as translate the response back.

7195   As a result, the Imaging Document Consumer can find imaging studies from an Imaging Document Responder using a consistent mechanism, regardless of whether the imaging study is published to an XDS or non-XDS environment.

Similarly, the Imaging Document Source returns imaging studies in response to retrieve requests. The source of the imaging studies is not constrained, and several models are possible. The
7200   Imaging Document Source can retrieve imaging studies from sources such as:

- Image Manager/Image Archive: The Imaging Document Source can have direct access to the Image Manager/Image Archive, or it can communicate with one or more Image Managers/Image Archives via standard mechanism such as the Retrieve Images [RAD-16] transaction.

7205   •   XDS-I Imaging Document Source: The Imaging Document Source can have direct access to the XDS-I Imaging Document Source, or it can communicate with one or more XDS-I Imaging Document Sources via retrieval mechanisms defined in XDS-I.

As a result, the Imaging Document Consumer can retrieve imaging studies from an Imaging Document Source using a consistent mechanism, regardless of whether the imaging study is
7210   published to an XDS-I or non-XDS-I environment.

42.4.1.2 Imaging Reports

WIA focuses on retrieving imaging studies using RESTful services. Retrieving other imaging study related documents, such as radiology reports, may be done using the ITI MHD Profile, XDS Profile, or other means.

7215   WIA can be used independently or combined with MHD. When combined with MHD, an MHD Document Consumer can be grouped with a WIA Imaging Document Consumer enabling the MHD Document Consumer to interact with imaging studies. For details, see Section 42.2.2.

42.4.1.3 QIDO-RS and WADO-RS URL

When the Imaging Document Responder returns a QIDO-RS response, the Retrieve URL
7220   (0008,1190) specifies the WADO-RS URL that the Imaging Document Consumer can use for subsequent retrieval. The WADO-RS URL is expected to be a base WADO-RS URL (i.e., without any sub-resources or parameters) that enables the Imaging Document Consumer to retrieve the content. The Imaging Document Consumer may want to modify the WADO-RS URL. For example, it may modify the URL to retrieve a rendered object instead of the DICOM
7225   object itself, provided the Imaging Document Source supports the optional rendering transaction.

42.4.2 Use Cases

42.4.2.1 Use Case #1: Image Study Sharing

42.4.2.1.1 Image Study Sharing Use Case Description

A radiologist, using a mobile or desktop device, has been asked to have a quick review of some
7230   images of a patient. In her EMR client, she looks up the patient details. She would like to discover what studies are available for her patient within and across the enterprises. The Imaging Document Consumer embedded in the EMR client queries the Imaging Document Responder for her patient using the patient's identifier provided by the EMR client. The Imaging Document Responder returns a response with multiple entries, one per matching study. She then selects one
7235   study; her device retrieves the instances via WADO-RS and renders them for display.

Examples for QIDO-RS and WADO-RS are in WIA_Profile_Examples.docx. See https://drive.google.com/drive/folders/1GGwVV6cFzFiYlZT4YZg7loBs6sXEGGM0.

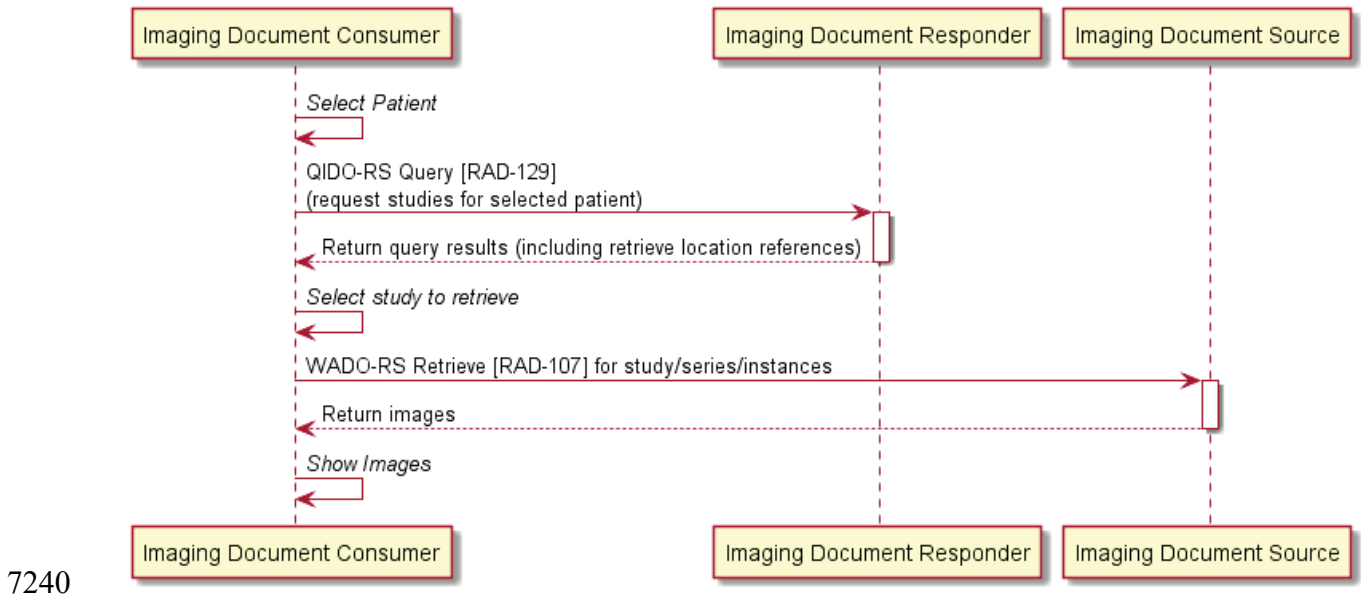## 42.4.2.1.2 Image Study Sharing Process Flow

7240

Figure 42.4.2.1.2-1: Image Study Sharing Diagram

The text in Figure 42.4.2.1.2-2 was used to generate the diagram in Figure 42.4.2.1.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

7245

```
@startuml
'title Image Study Sharing

participant "Imaging Document Consumer" as IDC
participant "Imaging Document Responder" as IDR
participant "Imaging Document Source" as IDS

IDC->IDC: //Select Patient//
IDC->IDR: QIDO-RS Query [RAD-129]\n(request studies for selected patient)
activate IDR
IDR-->IDC: Return query results (including retrieve location references)
deactivate IDR

IDC->IDC: //Select study to retrieve//

IDC->IDS: WADO-RS Retrieve [RAD-107] for study/series/instances
activate IDS
IDS-->IDC: Return images
deactivate IDS

IDC->IDC: //Show Images//
@enduml
```

**Figure 42.4.2.1.2-2: Imaging Study Sharing Diagram Pseudocode**

42.4.2.2 Use Case #2: Interactive Viewing

42.4.2.2.1 Interactive Viewing Use Case Description

A radiologist, using a mobile or desktop device, has been asked to have a quick review of some images of a patient. In his EMR client, he looks up the patient details. He would like to discover what studies are available for his patient.

The Imaging Document Consumer embedded in the EMR client queries the Imaging Document Responder for his patient using the patient's identifier provided by the EMR client. To view the study, the viewer uses QIDO-RS to query for additional image metadata in order to determine which objects to retrieve for the initial view. In some cases, the viewer also uses WADO-RS to retrieve full object metadata for advanced image viewing. Once the viewer determines what images to retrieve based on the metadata, it uses WADO-RS to retrieve initial set of images/frames and display them. Then based on user interactions, additional images/frames are retrieved and displayed accordingly.

42.4.2.2.2 Interactive Viewing Process Flow
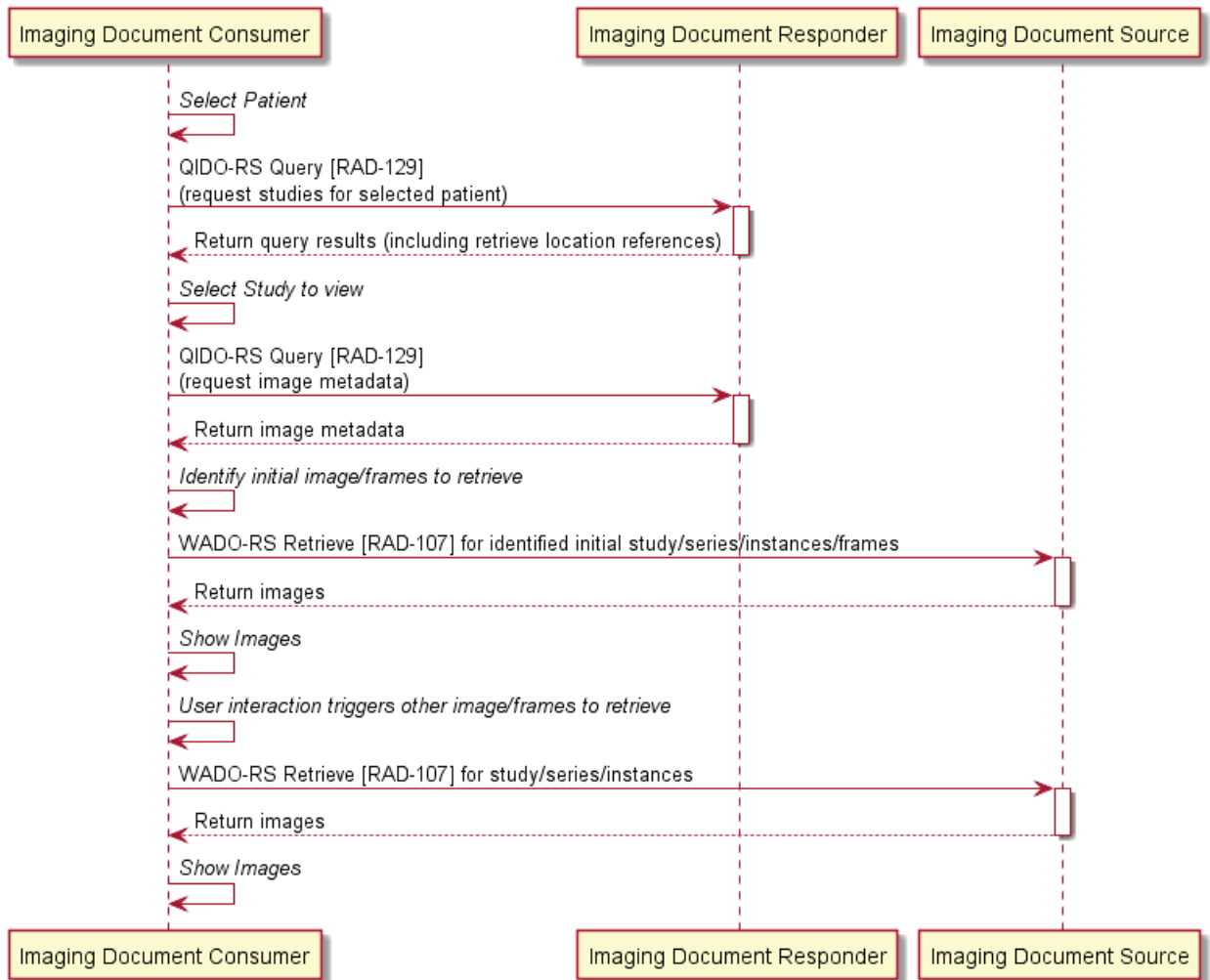
7285

Figure 42.4.2.2.2-1: Interactive Viewing Diagram

The text in Figure 42.4.2.2.2-2 was used to generate the diagram in Figure 42.4.2.2.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

```
@startuml
'title Interactive Viewing

participant "Imaging Document Consumer" as IDC
participant "Imaging Document Responder" as IDR
participant "Imaging Document Source" as IDS

IDC->IDC: //Select Patient//
IDC->IDR: QIDO-RS Query [RAD-129]\n(request studies for selected patient)
activate IDR
IDR-->IDC: Return query results (including retrieve location references)
deactivate IDR

IDC->IDC: //Select Study to view//
IDC->IDR: QIDO-RS Query [RAD-129]\n(request image metadata)
activate IDR
IDR-->IDC: Return image metadata
deactivate IDR

IDC->IDC: //Identify initial image/frames to retrieve//
IDC->IDS: WADO-RS Retrieve [RAD-107] for identified initial
study/series/instances/frames
activate IDS
IDS-->IDC: Return images
deactivate IDS
IDC->IDC: //Show Images//

IDC->IDC: //User interaction triggers other image/frames to retrieve//
IDC->IDS: WADO-RS Retrieve [RAD-107] for study/series/instances
activate IDS
IDS-->IDC: Return images
deactivate IDS

IDC->IDC: //Show Images//
@enduml
```

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Figure 42.4.2.2.2-2: Interactive Viewing Diagram Pseudocode

42.4.2.3 Use Case #3: MHD Document Consumer accessing Imaging Study

42.4.2.3.1 MHD Document Consumer accessing Imaging Study Use Case Description

A radiologist, using a mobile or desktop device, has been asked to have a quick review of some clinical documents of a patient. In her EMR client, she looks up the patient details to discover what documents are available for her patient. The Imaging Document Consumer embedded in the EMR client queries the Imaging Document Responder for her patient using the patient's identifier and discovers several document references, some of them corresponding to imaging studies (e.g., XDS-I Imaging Manifests). She then selects one of the imaging study references which trigger her device to query for additional imaging study metadata that includes the retrieve

location references. With this information, her device is able to retrieve the instances via WADO-RS and render them for display.

In this use case, the report has no embedded links to the relevant images. In other cases, if the report includes embedded links to relevant images, then the viewer can execute those links (may

7340   be WADO-RS or may be proprietary) to retrieve the images.

42.4.2.3.2 MHD Document Consumer Accessing Imaging Study Process Flow
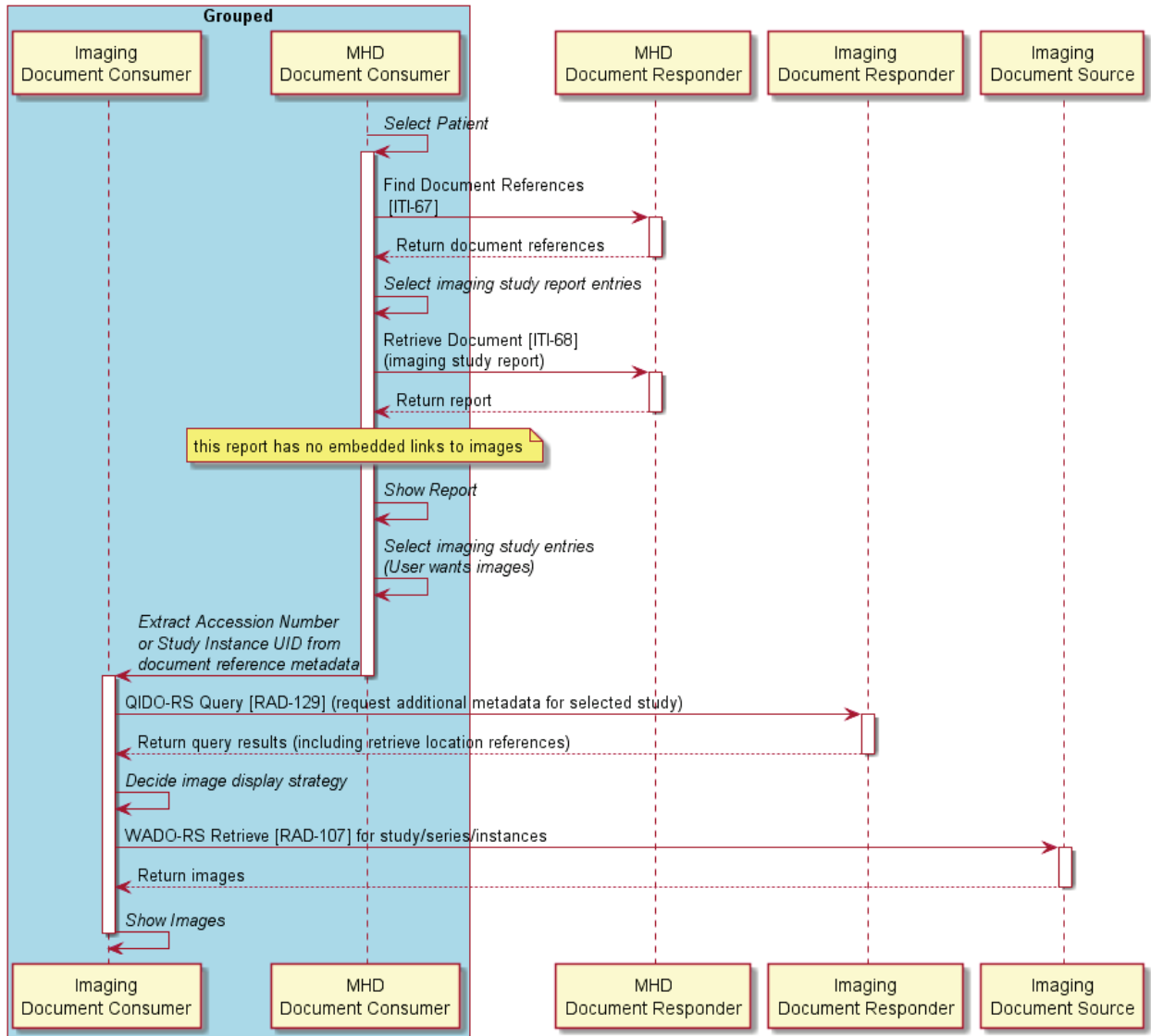

Figure 42.4.2.3.2-1: MHD Document Consumer Accessing Imaging Study Diagram

7345   The text in Figure 42.4.2.3.2-2 was used to generate the diagram in Figure 42.4.2.3.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

```
@startuml
'title MHD Document Consumer accessing imaging study

box "Grouped" #LightBlue
participant "Imaging\nDocument Consumer" as IDC
participant "MHD\nDocument Consumer" as MDC
end box

participant "MHD\nDocument Responder" as MDR
participant "Imaging\nDocument Responder" as IDR
participant "Imaging\nDocument Source" as IDS

MDC->MDC: //Select Patient//

activate MDC
MDC->MDR: Find Document References\n [ITI-67]
activate MDR
MDR-->MDC: Return document references
deactivate MDR

MDC->MDC: //Select imaging study report entries//

MDC->MDR: Retrieve Document [ITI-68]\n(imaging study report)
activate MDR
MDR-->MDC: Return report
deactivate MDR

note over MDC: this report has no embedded links to images
MDC->MDC: //Show Report//

MDC->MDC: //Select imaging study entries//\n//(User wants images)//
MDC->IDC: //Extract Accession Number//\n//or Study Instance UID
from//\n//document reference metadata//
deactivate MDC

activate IDC
IDC->IDR: QIDO-RS Query [RAD-129] (request additional metadata for selected
study)
activate IDR
IDR-->IDC: Return query results (including retrieve location references)
deactivate IDR

IDC->IDC: //Decide image display strategy//

IDC->IDS: WADO-RS Retrieve [RAD-107] for study/series/instances
activate IDS
IDS-->IDC: Return images
deactivate IDS

IDC->IDC: //Show Images//
deactivate IDC
@enduml
```

Figure 42.4.2.3.2-2: MHD Document Consumer Accessing Imaging Study Pseudocode

7400 **42.4.2.4 Use Case #4: Interactive Viewing in XDS-I environment**

42.4.2.4.1 Interactive Viewing in XDS-I environment Use Case Description

A radiologist, using a mobile or desktop device, has been asked to have a quick review of some clinical documents of a patient. In his EMR client, he looks up the patient details and discovers what imaging studies are available for his patient. The Imaging Document Consumer embedded
7405 in the EMR client queries the Imaging Document Responder for his patient using the patient's identifier provided by the EMR client. The Imagining Document Responder queries the XDS environment for imaging manifest, composes the results, and returns them to the client. He then selects one or more imaging studies and starts interactive viewing as defined in Use Case #2.

In order to support this use case, the Imaging Document Responder is required to support the
7410 XDS-I Backend Option. This allows the Imaging Document Responder to access the XDS environment to query for the imaging study metadata and process the XDS-I Imaging Manifest used in the workflow.

> Note: In some cases, the Imaging Document Responder may retrieve the XDS-I Imaging Manifest and/or DICOM header to obtain the necessary information to respond to the query.

7415 The Imaging Document Source may optionally implement the XDS-I Backend Option. This grouping with the optional XDS-I Imaging Document Consumer allows the Imaging Document Source to retrieve imaging studies from an XDS-I Imaging Document Source.

Alternatively, the Imaging Document Source may be grouped with an XDS-I Imaging Document Source (not shown in the diagram). As a result, the Imaging Document Source has direct access
7420 to the imaging studies without relying on the grouped XDS-I Imaging Document Consumer to retrieve the studies.

42.4.2.4.2 Interactive Viewing in XDS-I environment Process Flow
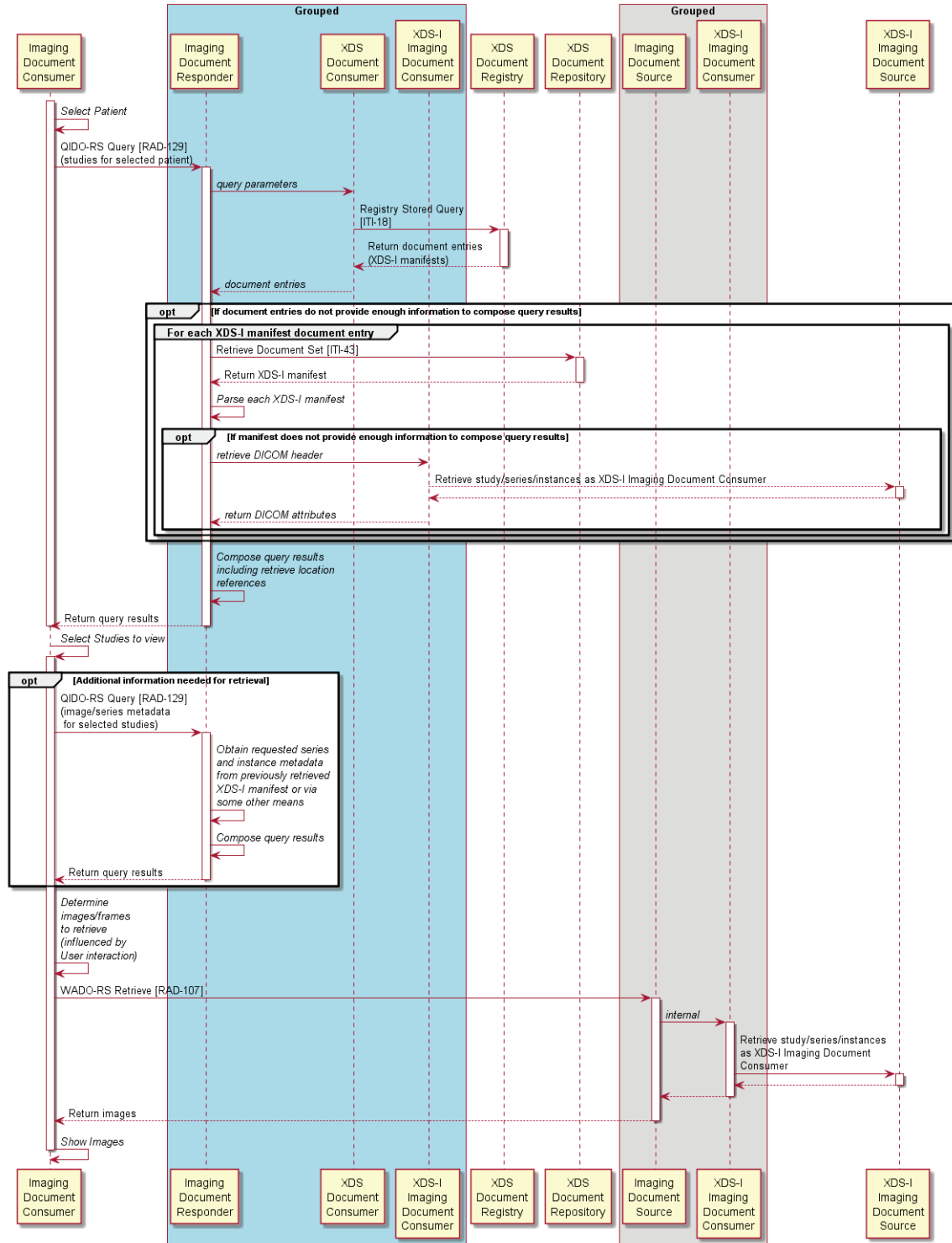
Figure 42.4.2.4.2-1: Interactive Viewing with XDS-I Imaging Doc Source Diagram

The text in Figure 42.4.2.4.2-2 was used to generate the diagram in Figure 42.4.2.4.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

```
@startuml

'title Interactive Viewing in XDS-I environment with Grouped Imaging Document
Source

participant "Imaging\nDocument\nConsumer" as IDC

box "Grouped" #LightBlue
participant "Imaging\nDocument\nResponder" as IDR
participant "XDS\nDocument\nConsumer" as DCon
participant "XDS-I\nImaging\nDocument\nConsumer" as XIDC0
end box

participant "XDS\nDocument\nRegistry" as DReg
participant "XDS\nDocument\nRepository" as DRepo

box "Grouped"
participant "Imaging\nDocument\nSource" as IDS
participant "XDS-I\nImaging\nDocument\nConsumer" as XIDC
end box

participant "XDS-I\nImaging\nDocument\nSource" as XIDS

activate IDC
IDC->IDC: //Select Patient//
IDC->IDR: QIDO-RS Query [RAD-129]\n(studies for selected patient)
activate IDR
IDR->DCon: //query parameters//
DCon->DReg: Registry Stored Query\n[ITI-18]
activate DReg
DReg-->DCon: Return document entries\n(XDS-I manifests)
deactivate DReg
DCon-->IDR: //document entries//

opt If document entries do not provide enough information to compose query
results
group For each XDS-I manifest document entry
IDR->DRepo: Retrieve Document Set [ITI-43]
activate DRepo
DRepo-->IDR: Return XDS-I manifest
deactivate DRepo
IDR->IDR: //Parse each XDS-I manifest//

opt If manifest does not provide enough information to compose query results
IDR->XIDC0: //retrieve DICOM header//
XIDC0-->XIDS: Retrieve study/series/instances as XDS-I Imaging Document
Consumer
activate XIDS
XIDS-->XIDC0
deactivate XIDS
XIDC0-->IDR: //return DICOM attributes//
end
end
end
```

```
7485    IDR->IDR: //Compose query results//\n//including retrieve
        location//\n//references//
        IDR-->IDC: Return query results
        deactivate IDR
        deactivate IDC

7490

        IDC->IDC: //Select Studies to view//
        activate IDC
        opt Additional information needed for retrieval
        IDC->IDR: QIDO-RS Query [RAD-129]\n(image/series metadata\n for selected
7495    studies)
        activate IDR
        IDR->IDR: //Obtain requested series//\n//and instance metadata//\n//from
        previously retrieved//\n//XDS-I manifest or via//\n//some other means//
        IDR->IDR: //Compose query results//
7500    IDR-->IDC: Return query results
        deactivate IDR
        end

        IDC->IDC: //Determine//\n//images/frames//\n//to retrieve//\n//(influenced
7505    by//\n//User interaction)//
        IDC->IDS: WADO-RS Retrieve [RAD-107]
        activate IDS
        IDS->XIDC: //internal//
        activate XIDC
7510    XIDC->XIDS: Retrieve study/series/instances\nas XDS-I Imaging
        Document\nConsumer
        activate XIDS
        XIDS-->XIDC:
        deactivate XIDS
7515    XIDC-->IDS:
        deactivate XIDC
        IDS-->IDC: Return images
        deactivate IDS

7520    IDC->IDC: //Show Images//
        deactivate IDC

        @enduml
```

Figure 42.4.2.4.2-2: Interactive Viewing with XDS-I Imaging Doc Source Pseudocode

42.5 WIA Security Considerations

The WIA Profile has similar security considerations to other IHE profiles that are based on HTTP or REST. See ITI TF-2: Appendix Z.8 for recommendations for secure transportation, authentication, authorization, and securing patient identifiers in URLs. Implementers are encouraged to review that section for applicability to their product environment.

When WIA actors are grouped with XDS actors to access XDS-I infrastructure, all the XDS security requirements apply. See ITI TF-1: 10.7 for details.

Implementers may also consider implementing Cross-Origin Resource Sharing (CORS) (https://www.w3.org/TR/cors/) support to allow browser-based clients to retrieve information from distributed sources (for example, queries are performed on server A, and instances are downloaded from server B).

Deployments should consider whether or not:

- The Imaging Document Consumer performs user authentication to access patient data.

- The Imaging Document Responder and Imaging Document Source use credentials or tokens supplied by the Imaging Document Consumer in the QIDO-RS Query and WADO-RS Retrieve transactions

- The Imaging Document Consumer, Imaging Document Responder or the Imaging Document Source (or all) records access in an audit log.

This profile does not define how the Imaging Document Consumer supplies credentials to the Imaging Document Responder or Imaging Document Source in order to provide the user with a seamless "single sign on" experience. The HTTP GET URL transaction allows for a range of authentication mechanisms including HTTP basic authentication (over a secure connection to protect the cleartext credentials), digest authentication, client certificate-based authentication, provision of a SAML assertion in an authentication header, or other mechanisms that are suitable for stateless atomic transaction.

The user authentication and authorization methods are outside the scope of the WIA Profile. Implementers should consider the use of the IHE ITI Profiles Enterprise User Authentication (EUA) and Internet User Authorization (IUA) in their implementations.

Implementations should also consider how availability and integrity will be protected including intentional attacks such as a maliciously crafted query that interfere with service availability.

Both the WADO-RS and QIDO-RS transactions may include in their response a URL which specifies where the corresponding objects can be retrieved. In the absence of protection, such as TLS, a malicious attacker may intercept the response and rewrite these URL's to a location of suspect origin. An Imaging Document Consumer should verify that any received URL is valid and corresponds to a known secure location.

42.6 WIA Cross Profile Considerations

42.6.1 XDS.b – Cross-Enterprise Document Sharing

An Imaging Document Responder that implements the XDS-I Backend Option will be grouped XDS Document Consumer to locate imaging manifest in an XDS environment (see Section 42.4.2.4: Use Case #4).

If an Imaging Document Consumer wants to retrieve documents other than imaging manifests, it may be grouped with an XDS Document Consumer to access clinical documents published in an XDS environment.

42.6.2 XDS-I.b – Cross-Enterprise Document Sharing for Imaging

7570 An Imaging Document Source that implements the XDS-I Backend Option will be grouped with an XDS-I Imaging Document Consumer to satisfy a WADO-RS Retrieve [RAD-107] request for the retrieval of object or metadata from an XDS-I.b Imaging Document Source (see Section 42.4.2.4: Use Case #4).

An Imaging Document Responder may be grouped with an XDS-I.b Imaging Document Consumer to satisfy a QIDO-RS Query [RAD-129] request for additional metadata from an 7575 XDS-I.b Imaging Document Source. (see Section 42.4.2.4: Use Case #4.)

42.6.3 PIX or PIXv3 or PIXm – Patient Identifier Cross-Referencing

An Imaging Document Consumer that supports the XDS-I Backend Option is recommended to be grouped with a Patient Identifier Cross-Reference Consumer to identify the affinity domain patient id before issuing the QIDO-RS Query [RAD-129] transaction.

7580 ### 42.6.4 PDQ or PDQv3 or PDQm – Patient Demographics Query

An Imaging Document Consumer that supports the XDS-I Backend Option is recommended to be grouped with a Patient Demographics Consumer to identify the affinity domain patient id before issuing the QIDO-RS Query [RAD-129] transaction.

7585 ## 43 Standardized Operational Log of Events (SOLE)

Standardized Operational Log of Events is a Trial Implementation Profile.

44 Management of Acquisition Protocols (MAP)

Management of Acquisition Protocols is a Trial Implementation Profile.

45 Results Distribution (RD)

7590 Results Distribution is a Trial Implementation Profile.

46 Radiology Remote Reporting Workflow (RRR-WF)

Radiology Remote Reading Workflow is a Trial Implementation Profile.

47 Encounter-based Imaging Workflow (EBIW)

Encounter-based Imaging Workflow is a Trial Implementation Profile.

7595 ## 48 Import and Display of External Priors (IDEP)

Import and Display of External Priors is a Trial Implementation Profile.

49 AI Results (AIR)

AI Results is a Trial Implementation Profile.

50 AI Workflow for Imaging (AIW-I)

7600   AI Workflow for Imaging is a Trial Implementation Profile.

51 Contrast Administration Management (CAM)

Contrast Administration Management is a Trial Implementation Profile.

52 Interactive Multimedia Reporting (IMR)

Interactive Multimedia Reporting is a Trial Implementation Profile.

7605   ## 53 Intentionally left blank

54 Prioritization of Worklists for Reporting (POWR)

Prioritization of Worklists for Reporting is a Trial Implementation Profile.