

Integrating the Healthcare Enterprise



**IHE Radiology Technical Framework  
Supplement 2007-08**

**Mammography Acquisition Workflow  
(MAWF)**

**Trial Implementation Draft**

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## Foreword

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

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

This initiative has numerous sponsors and supporting organizations in different medical specialty domains and geographical regions. In North America, the primary sponsors are the Healthcare Information and Management Systems Society (HIMSS) and the Radiological Society of North America (RSNA). IHE Canada is sponsored by the Information Technology Association of Canada (ITAC) and Canada Health Infoway. IHE Europe (IHE-EUR) is supported by a large coalition of organizations including the ESR (European Society of Radiology), the Coordination Committee of the Radiological and Electromedical Industries (COCIR), Deutsche Röntgengesellschaft (DRG), the EuroPACS Association, Groupement pour la Modernisation du Système d'Information Hospitalier (GMSIH), Société Française de Radiologie (SFR), Società Italiana di Radiologia Medica (SIRM), the European Institute for health Records (EuroRec), and the European Society of Cardiology (ESC). In Japan IHE-J is sponsored by the Ministry of Economy, Trade, and Industry (METI); the Ministry of Health, Labor, and Welfare; and MEDIS-DC; cooperating organizations include the Japan Industries Association of Radiological Systems (JIRA), the Japan Association of Healthcare Information Systems Industry (JAHIS), Japan Radiological Society (JRS), Japan Society of Radiological Technology (JSRT), and the Japan Association of Medical Informatics (JAMI). Other organizations representing healthcare professionals are invited to join in the expansion of the IHE process across disciplinary and geographic boundaries.

The IHE Technical Frameworks for the various domains (IT Infrastructure, Cardiology, Laboratory, Radiology, etc.) defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of medical information to support optimal patient care. It is expanded annually, after a period of public review, and maintained regularly

through the identification and correction of errata. The current version for these Technical Frameworks may be found at [www.ihe.net/Technical\\_Framework](http://www.ihe.net/Technical_Framework).

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

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*These "boxed" instructions are used by the author to indicate to the Volume Editor how to integrate the relevant section(s) into the overall Technical Framework*

## Introduction

Workflow for digital X-ray image acquisition in Mammography often is performed at high pace, especially for screening exams. The image acquisition done is situation-specific, depending on the interaction with the patient and findings in the acquired images. For instance, frequently during an examination, views are added that result in images being added to a scheduled or potentially already "completed" procedure.

The Technologist at the Modality wants flexibility to convey procedure changes or certain clinically relevant changes in images from the Modality to the Archive and Information System. Optimal integration of acquisition steps into the overall workflow is critical, as examinations are not complete until the Radiologist is satisfied.

Despite technical means defined in the Scheduled Workflow and Mammography Image Profiles, variances in the way users and systems behave can lead to department inefficiencies, ambiguous data, special cases for automated billing, and less than optimal acquisition and reading environments.

This Supplement defines exception handling for acquiring Mammography FFDM images, based on the Scheduled Workflow Integration Profile. It also adds capabilities to Image Displays from the Mammography Image Integration Profile so that images from one examination are presented or accessible in a unified way.

Changes will affect the following Actors: Acquisition Modality, DSS/ Order Filler, Image Manager/ Image Archive, Image Display, Evidence Creator.

## Open Issues

- 1. While working on this Profile and finding technical solutions to its underlying use cases, the Technical Committee requested changes to the DICOM standard to realize needed Actor behavior. This includes one new attribute in MPPS and images, as well as code extensions to the Content Mapping Resource (see vol. 1, Appendix B). Corresponding Change Proposals to the DICOM Standards were submitted. This IHE Profile specification depends on these Change Proposals to be accepted and finalized. The IHE Radiology Technical Committee will stay in contact with the DICOM Committees and update this Profile as necessary based on the actions taken by DICOM.*

## Closed Issues

- 1. Should the Mammography Acquisition Workflow cover all Modalities used in Breast imaging?  
This Integration Profile focuses on FFDM Mammography Modalities and its specific workflow dynamics. Mammography image acquisition by other Modalities such as*

Ultrasound or MR, including multi-modality procedures, is assumed to be scheduled and managed by mechanisms described in the Scheduled Workflow Integration Profile.

2. The relationship between an Order and its procedures cannot be directly mapped into the billing process. There are too many elements external to the order (e.g. How/what insurance will pay) to create any connection between the technical charges/professional charges and what can be billed.
3. MPPS cannot be used for the Display of Images as the Image Display does not use MPPS. Information must be embedded in the Image Set.
4. Integration of Mammography Acquisition Workflow with the Reporting Workstation is out of scope.
5. *Order and Study scope: Is Accession Number used differently as compared to the current IHE use (see RAD TF-1: Appendix A)? When to open up a new Study? When and how to "link" Studies?*  
No specifics needed to satisfy the use cases. The regular IHE Procedure and Study model applies well to Mammography Acquisition Workflow.  
Currently, DICOM provides no general mechanism to link Studies at the Study level (including a reason for linking). However, the IHE/ DICOM data model enables actors to use internal logic to find the relations between studies.
6. *How to use/ convey Reason of Procedure? E.g. in case of conversions.*  
For Mammography, IHE defines a starter set of reason codes for requested procedures. A Modality currently cannot convey a "Reason for Performed Procedure", which is clinically relevant for remote reading. A corresponding CP was submitted to DICOM (2/6/08: Add Reason For Performed Procedure Code Sequence).
7. *Correcting DICOM clinical/ technical header data (i.e. not patient or procedure): How to convey the changes, especially a "delta"?*  
MPPS is not appropriate to convey such changes. Key Object Selection is appropriate, as it can list references to invalid instances and specify a context in the KOS title.
8. *Detecting BIRADS 0 cases and triggering additional activities: Is this part of Acquisition Workflow and which DICOM attribute can convey this?*  
The report status "BIRADS 0" will be established during the interpretation/ reporting process and will be part of a report. This Supplement does not define how reports trigger image acquisition.
9. *The impulse and use cases originate from IHE Mammography. Do these cases have more general relevance?*  
The Technical Committee decided that this Supplement will stay separate and not be packaged with other parts of the Radiology Technical Framework (e.g. as named options).

10. *Which information from workflow, view and Study/ Exam level should be used to enable Displays to present images in specific screen layouts?*  
This Supplement introduces common baseline coded values for procedures and reasons that can more precisely drive image hanging than textual descriptions, which are often used nowadays (e.g. procedure description). Display requirements from the Mammography Image Profile are extended slightly by certain triggers (see 4.16.4.2.2.5).
11. *Do we need to cover authorization of procedure/ order changes? The requirement for authorization itself is site specific.*  
This is done as part of the work on a "next generation SWF", and is not possible with HL7 v2.3.1.
12. *Room utilization and schedules - should this be part of Mammo workflow?*  
Maintaining schedules for resources may be done by the DSS/OF. IHE defines the following MWL query keys for a Modality (TF-2: 4.5-3): AE Title and Modality (required); Location and Performing Physician's name (optional).  
These mechanisms enable that use cases for recall and "finish exam in another room" can include such scheduling information. No additions needed.
13. *In the Conversion cases (see 23.3.1.2), should the Procedure Code Sequence in the MPPS COMPLETE that contains different Codes for Requested and Performed Procedure contain an additional Code designating that this is a "to-be-corrected" new Procedure information?*  
*For instance, Procedure Code Sequence would be {"Bilat. Dx Mammogram"; "to replace original procedure codes"} instead of {"Bilat. Dx Mammogram"}, as would be today?*  
Such an approach could help clarify race conditions theoretically. However, practical use and benefit of such an additional modifier is considered minimal beyond the triggers for exception handling based on Procedure and Protocol Codes that are defined in this Supplement.
14. *This Profile defines starter code sets for Procedures and Reasons for Procedures and requires actors to be configurable with regard to such code sets (see 23.4.1, 4.5.4.2.2.2). These code sets do not exist in DICOM or do not match easily to existing DICOM codes (e.g. CID 6061/ 6055). They are intended to provide a common basis for scheduling/ describing routine Mammo image acquisition and for related actor behavior. These code sets are extensible and adaptable by configuration. Is it acceptable that IHE defines new code values, or is it considered necessary that DICOM defines such codes?*  
IHE does not define required codes but re-uses DICOM-defined codes. A set of procedure codes is defined informatively which are planned to be used for MESA and Connectathon tests.

15. *Is the intent and use of the two dimensions for Reason for Requested Procedure and corresponding codes clearly described and useful (see 23.4.2)? Is it clear that IHE does not prescribe an order for such codes in the Code Sequence, i.e. a code of any dimension can occur at any position in the Sequence, and there can occur multiple different code values of one dimension (at any place in the Code Sequence)?*

IHE does not divide the code set for Reason for Requested Procedure into dimensions that describe specific aspects of such reasons: this is considered less helpful and may be misleading.

16. *This Profile has a section on deployment policies and risks of using configurable behavior of actors or mixed IHE/non-IHE system environments (see RAD TF-1: 23.4). Is this necessary or helpful?*

No comments or objections from Public Comment. Keep this section.

17. *Should the mechanisms described for rejected views (see 23.3.3.1) and view labeling corrections in images (see 23.3.3.2) be generalized and become an option for the Scheduled Workflow Integration Profile (which is required and maybe further specified for Mammography)? If yes,*

- *what are modality-specific relevant scenarios (incl. relevant attributes to be changed)?*
- *does it suffice to include the grouped Actor Evidence Creator/ Image Display ("workstation") in this option (instead of describing it for the Acquisition Modality as well)?*

A general "rejection for quality reasons" can be done with KIN today, except the configuration of an Image Display to show or hide the rejected images.

The view correction mechanism is specific for Mammography in a way that it requires that certain MG image attributes can be corrected. The hiding mechanism at IM/IA is a specific addition of behavior that does not fit the simple KIN storage of KOS objects. In conclusion, it does not seem feasible to generalize the whole rejection/ correction mechanism. However, due to the different IM/IA behavior resulting from receiving these specific rejection/ correction KOS, a new transaction is introduced.

Corrections from the workstation pose the risk of losing the acquisition context, i.e. it may not exactly be known from the images or MPPS what is incorrect (in contrast to correcting it at the Modality where the images were incorrectly labelled during acquisition). The originating Acquisition Modality is the more appropriate place for such corrections, whereas the Evidence Creator may be an additional system for "quality control" for which the user organization needs to defined clear processes of use.

18. *In the case of SIO views, some PACS will bring up images correctly while others will not. The Tech may want to permanently annotate the image with information such as "This is the Lateral Side" in order for the images to be viewed correctly. Such*

*comments are informative, give medical background, can be displayed, and do not drive image hanging.*

*Is it necessary to enable such comments, e.g. in Image Comments (0020,4000)?*

*The use cases did not necessitate to use such comments. Is everything considered?*

Such image comments are not used commonly, and are rather used as workarounds for certain environments or installations. IHE does not require such comment use.

19. *This Profile requires an Acquisition Modality to be able to create and store Key Image Notes (see. 23.1) in order to enable the Tech to reject images for quality reasons or to correct view labeling.*

*Is this essential for FFDM Modalities, or should KIN creation be optional?*

It is very valuable for users to be able to correct images at the modality during acquisition steps. Creating a Key Object Selection (KOS) instance at the Modality is not considered an undue burden for Modality implementers. Thus, IHE requires the Modality in MAWF to be able to create KOS for rejection/ correction.

20. *Beyond IHE requirements, the RIS may want to keep a patient's imaging history and use MPPS to prepare reporting or provide procedural/ billing functions, etc..*

*What does the RIS need to know about about changes in instances, e.g. laterality, invalid instances?*

There were no specific use cases or requirements proposed.

21. *What are the essential requirements for a PACS in case of value changes in DICOM objects (i.e. internal vs. external (interface) behaviour requirements)?*

*PACS should receive and apply all correcting information so that all subsequent query/ retrieve results provide correct and consistent data. This information should also be consistent with the RIS.*

*Readers may check sections 23.3.1, 23.3.3 and transaction sections 4.6, 4.8, 4.18, 4.20, 4.29, 4.49 (Message Semantics, Expected Actions) in order to determine if this is clearly and feasibly solved in the Supplement.*

Specific comments were obtained during Public Comment that led to changes in several places of the Supplement text.

22. *Are the requirements for Image Displays clear in terms of configurable presentation layouts depending on certain code values (see 4.16.4.2.2.5)?*

Specific comments were obtained during Public Comment that led to changes in several places of the Supplement text defining display requirements.

## GLOSSARY

*Add the following to the Glossary in RAD TF-1:*

**BIRADS 0:** The American College of Radiology defines an assessment system for Mammography image interpretation and reporting (Breast Imaging Reporting and Data System: BI-RADS). "Assessment 0" means that the Mammographic assessment is incomplete, and that additional images or prior studies are needed to finalize the assessment and report.

# Volume I – Integration Profiles

*This section describes the changes required in Volume I of the Technical Framework that result from including this Integration Profile.*

## History of Annual Changes

*Add the following bullet to the end of the bullet list in section 1.7*

- **Added the Mammography Acquisition Workflow Profile which defines how a Modality documents procedure and protocol changes . It defines how Modalities or Workstations reject images for quality reasons or correct view information in images. The Department System Scheduler and Image Archive will keep its internal information consistent with these changes.**

*Add the following section to Table 2-1 Integration Profiles Dependencies in section 2.1*

Integration Profile	Depends on	Dependency Type	Comments
<u>Mammography Acquisition Workflow</u>	<u>Scheduled Workflow</u>	<u>Required for workflow management</u>	<u>Defines how to convey changes of procedure and view information from the Acquisition Modality to Image Manager/ Image Archive and to the DSS/OF</u>
<u>Mammography Acquisition Workflow</u>	<u>Mammography Image</u>	<u>Required for Content creation and presentation</u>	<u>The main re-use benefit results from the creation and display of Mammography images.</u>

*Add the following section to the end of 2.1*

### 2.1.23 Mammography Acquisition Workflow Integration Profile

Mammography Acquisition Workflow describes mechanisms to handle situation-specific exceptions to routine image acquisition scenarios based on the IHE Radiology Scheduled Workflow Integration Profile. It defines how a Modality communicates ad-hoc procedure changes when supplemental images are taken or when the exam type changes. It defines interactions between Digital X-ray (FFDM) Modalities and systems managing departmental workflow when an examination is begun in one room and is finished in another room. It defines how corrections to view labels at the Modality are communicated to and used by an Image Archive.

*In Table 2.3-1, add a column with the heading “MAWF” at the end of the table.*

*Add “X” in this columns’ cells for these actors: Acquisition Modality, DSS/OF, Evidence Creator, Image Display, Image Manager/Archive.*

*Add the following transaction description in 2.3:*

**66. Image Rejection Note Stored – Create and send a manifest referencing images that are rejected for quality or patient safety reasons. The manifest can be used to hide or provide rejected images later in routine use, based on specific configuration.**

*Add to 2.5, at the end of the 2<sup>nd</sup> bullet list on p.39:*

- **The Evidence Creator in the Mammography Acquisition Workflow Integration Profile shall be grouped with an Image Display Actor. The grouped Actor queries, retrieves and presents Mammography images and lets an operator interactively reject images for quality reasons or correct view information in incorrectly labelled images.**

*In Table 2.4-1, add a column with the heading “MAWF” at the end of the table.*

*Add “X” in this columns’ cells for these transactions: Query Modality Worklist [RAD-5], Modality PS in Progress [RAD-6], Modality PS Completed [RAD-7], Modality Image Stored [RAD-8], Procedure Updated [RAD-13], Retrieve Images [RAD-16], Creator Images Stored [RAD-18], Creator PS In Progress [RAD-20], Creator PS Completed [RAD-21], Query Key Image Notes [RAD-30], Retrieve Key Image Notes [RAD-31], Instance Availability Notification [RAD-49], Image Rejection Note Stored [RAD-66].*

## 23 Mammography Acquisition Workflow Integration Profile

*This chapter 23 shall be added to Vol 1*

Workflow for digital X-ray image acquisition in Mammography (FFDM) often is performed at high pace, especially for screening exams, and depends on the interaction with the patient and findings in the acquired images. Workflow varies frequently at the Modality, and the Technologist needs to be able to convey changes in

- Performed procedures and steps: views are added, even for a "completed" acquisition step;
- Image labeling or image usage (rejection, quality issues, correction of image headers).

Despite the increased variability in the practice of FFDM Mammography image acquisition, IHE and DICOM workflow concepts and terms (see RAD TF-1: 3.3.1, 3.4.2, A.1) apply:

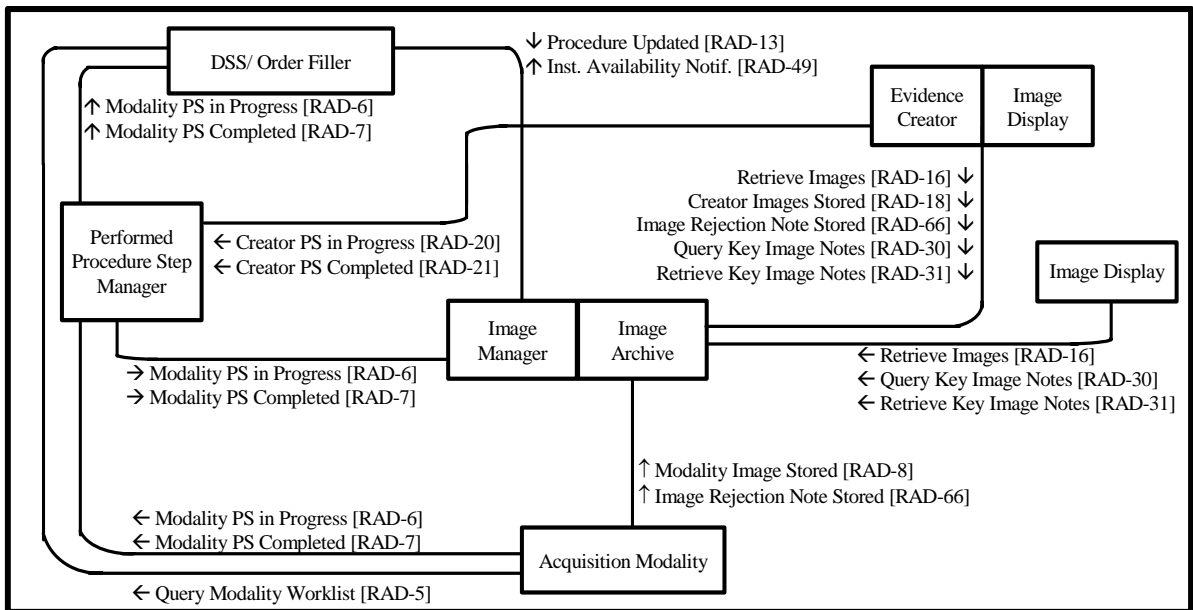
- A Referring Physician or the Mammography facility itself generates an *Order* that describes the imaging service to be performed for the patient, e.g. using CPT codes.
- The Mammography facility schedules one or more *Procedures* that add internal detail for performing the exam and fulfilling the order. A Procedure normally results in one report.
- According to the Procedure and scheduled acquisition *steps*, the Technologist at the Modality acquires images and finally "*completes*" the examination (steps).

As a limited set of procedures is performed at an FFDM Modality, it is possible to define a common set of codes and a common way for systems to use coded values to exchange what is scheduled for and what was performed at the Modality.

This Integration Profile focuses on the FFDM Mammography Modalities and their specific workflow dynamics. Breast image acquisition by other Modalities such as Ultrasound or MR, including multi-modality procedures is not described in this Profile and may be managed by mechanisms described in the Scheduled Workflow Integration Profile.

### 23.1 Actors/ Transactions

Figure 23.1-1 shows the actors involved in the Mammography Acquisition Workflow Integration Profile and the relevant transactions between them. This diagram does not show transactions from the Scheduled Workflow and Mammography Image Integration Profiles that are re-used and not extended by the Mammography Acquisition Workflow Integration Profile.



**Figure 23.1-1. Mammography Acquisition Workflow Actor Diagram**

Table 23.1-1 lists the transactions for each actor directly involved in the Mammography Acquisition Workflow Profile, i.e. transactions where this Profile adds requirements beyond simple re-use. In order to claim support of this Integration Profile, an implementation must perform the required transactions (labeled “R”) from this table **and** all required transactions for the same Actor defined in the Integration Profiles it depends on (Scheduled Workflow, Mammography Image: see RAD TF-1: Table 2-1). Transactions labeled “O” are optional.

**Table 23.1-1. Mammography Acquisition Workflow Integration Profile - Actors and Transactions**

Actors	Transactions	Optionality	Section in Vol. 2/ 3
Acquisition Modality	Query Modality Worklist [RAD-5]	R	4.5
	Modality PS in Progress [RAD-6] (Note 1)	R	4.6
	Modality PS Completed [RAD-7]	R	4.7
	Modality Image Stored [RAD-8]	R	4.8
	Image Rejection Note Stored [RAD-66]	R	4.66
DSS/ OF	Query Modality Worklist [RAD-5]	R	4.5
	Modality PS in Progress [RAD-6] (Note 1)	R	4.6
	Modality PS Completed [RAD-7]	R	4.7
	Procedure Updated [RAD-13]	R	4.13
	Instance Availability Notification [RAD-49]	R	4.49

Actors	Transactions	Optionality	Section in Vol. 2/ 3
Image Manager/ Image Archive	Modality Image Stored [RAD-8]	R	4.8
	Modality PS in Progress [RAD-6]	R	4.6
	Modality PS Completed [RAD-7]	R	4.7
	Procedure Updated [RAD-13]	R	4.13
	Image Rejection Note Stored [RAD-66]	R	4.66
	Instance Availability Notification [RAD-49]	R	4.49
Performed Procedure Step Manager	Modality PS in Progress [RAD-6]	R	4.6
	Modality PS Completed [RAD-7]	R	4.7
	Creator PS In Progress [RAD-20]	R	4.20
	Creator PS Completed [RAD-21]	R	4.21
Image Display	Retrieve Images [RAD-16]	R	4.16
	Query Key Image Notes [RAD-30]	R	4.30
	Retrieve Key Image Notes [RAD-31]	R	4.31
Image Display/ Evidence Creator	Retrieve Images [RAD-16]	R	4.16
	Query Key Image Notes [RAD-30]	R	4.30
	Retrieve Key Image Notes [RAD-31]	R	4.31
	Creator Images Stored [RAD-18]	R	4.18
	Image Rejection Note Stored [RAD-66]	R	4.66
	Creator PS In Progress [RAD-20] (Note 2)	R	4.20
	Creator PS Completed [RAD-21] (Note 2)	R	4.21

Note 1: Support of the Assisted Acquisition Protocol Setting (RAD TF-2: 4.6.4.1.2.4.2) is required in order to describe scheduled and performed procedure steps unambiguously by codes.

Note 2: To claim the Mammography Acquisition Workflow Integration Profile, the Evidence Creator shall support both Creator PS transactions RAD-20 and RAD-21.

## 23.2 Mammography Acquisition Workflow Integration Profile Options

Options that may be selected for this Integration Profile are listed in the table 23.2-1 along with the Actors to which they apply. Dependencies between options when applicable are specified in notes.

**Table 23.2-1. Mammography Acquisition Workflow Integration Profile - Actors and Options**

Actors	Options	Vol & Section
Acquisition Modality	<i>No options defined</i>	-
DSS/ OF	<i>No options defined</i>	-
Image Manager/ Image Archive	<i>No options defined</i>	-

Actors	Options	Vol & Section
Performed Procedure Step Manager	<i>No options defined</i>	-
Image Display	<i>No options defined</i>	-
Image Display/ Evidence Creator	<i>No options defined</i>	-

### 23.3 Mammography Acquisition Workflow Process Flow

Mammography Acquisition Workflow builds upon the routine image acquisition scenarios described in the IHE Radiology Scheduled Workflow Integration Profile (RAD TF-1: 3). However, depending on procedures and policies in a facility, there are situation-specific exceptions to be handled for Mammography image acquisition.

In Mammography practice, the term "order" may be used with meanings similar to both IHE concepts of "Order" and "Requested Procedure". This IHE Profile distinguishes "Order" and "Requested Procedure" unaltered as defined by RAD TF-1: 3.4.2 and A.1:

- **Order:** A request for imaging services to be performed on a patient. The Mammography facility receives this external request on paper, per telephone or digitally, and fulfills it by scheduling one or multiple Requested Procedures.
- **Requested Procedure:** Unit of work in the Mammography facility that results in a report. The Mammography facility may also generate Requested Procedures independently from an external imaging service request. A Requested Procedure is composed of one or multiple Scheduled and Performed Procedure Steps as smallest unit of work to be managed by an IHE Actor, e.g. describing the acquisition of Mammography Screening images.

Note that billing is enabled by capturing and transferring the relevant information such as procedural, technical or professional charges. The relationship between an Order and its Procedures cannot be directly mapped into the billing process. The billing calculations and functions vary widely and are not further analyzed or defined by this specification.

Use cases describe the clinical work and map it to technical aspects of system interoperability. For consistency in all use cases, the Departmental System Scheduler/ Order Filler (DSS/OF) is used as if it was grouped with the Performed Procedure Step Manager . The process flow diagrams which follow may intentionally omit transactions that are less relevant for a use case.

#### 23.3.1 Procedure Error or Modification

At the point of care, modifications to a scheduled procedure or procedure step may become necessary as a consequence of diagnostic actions or findings. The user at the point of care, e.g. at the Modality, may want to convey these modifications to the relevant systems (normally,

Information System and Archive) without going to another system, potentially in another room. Of course, the modifications described here could also be entered directly in an Information System or an Archive with specific system functions.

Use cases describing such workflow modifications deviate from "routine" image acquisition steps in the following ways:

- **Supplemental Views:** During a Procedure, additional views need to be taken to increase diagnostic accuracy *for this Procedure*. This means clarifying, extending or revising the diagnostic information of the same Procedure by adding views that were missing so far. The patient may still be present or may need to come back to the Mammography facility on the same day (otherwise, it is a recall - see below). Finally, one report will be created. Examples: Acquire additional views due to the presence of implants, due to large breasts, accessory breast tissue, or add magnification views in a breast area of suspicious calcifications.
- **Conversion:** *A Procedure is changed while the patient is present* in the facility or acquisition room. In agreement with a responsible clinician, the Technologist acquires views that are not part of the procedure. This normally results in corrections (e.g. scheduling a new procedure at the RIS), additional documentation of a rationale, authorization and/ or notifications back to referring physicians. Finally, one report will be created. Examples: During a screening mammogram, a lump is detected and additional views are taken so that finally, the procedure became a diagnostic mammogram. A unilateral diagnostic mammogram is converted to a bilateral diagnostic mammogram, or vice versa.
- **Screening Recall:** *A new procedure* is scheduled at the RIS for a *patient to come back* to the facility in order to clarify current findings by acquiring additional views (*diagnostic reasons*). The findings that need clarification were detected during interpretation and reporting of the original screening Procedure.

The new diagnostic Procedure may be scheduled for the same or another day, at the same or another Modality. It will result in a new Study and report (finally, two separate reports). Example: Suspicious microcalcifications are detected in a screening mammogram during reporting (patient has already left the institution). The patient is asked to return to the facility so that these findings can be further evaluated with additional diagnostic mammography (i.e., magnification views).

- **Screening Technical Recall:** *A new or additional procedure* is scheduled at the RIS for a *patient to come back* to the facility in order to improve image quality by acquiring additional views (*technical reasons*). The technical/ quality issues were detected during interpretation and reporting of a screening Procedure.

The new Procedure will result in a new Study and a report that addends the preceding screening Procedure's report (finally, one report and one report addendum). Note that in some facilities the Radiologist will not dictate a report until the additional images are obtained.

Example: A patient with dense breast tissue is requested to come back to the facility so that one view of inadequate quality from the screening procedure can be taken again with adapted modality acquisition settings.

Procedural changes at the Modality will be reflected in image headers and work status by coded values that enable automated processing and subsequent system behavior. The RIS uses this information to keep archived images consistent, to maintain a patient's imaging record, to document clinical rationales, to schedule subsequent exams including room utilization or to send status or order changes back to the Order Placer.

### 23.3.1.1 Supplemental Views: Implant views appended to a standard screening exam

**Clinical aspect:** A patient comes in for a scheduled standard screening exam. She has implants, which are detected by the Technologist at the Modality. The Tech completes the standard 4-view screening examination and also *completes the acquisition step*. At the same Modality, she then acquires the additional implant displacement images and completes the additional step. The Technologist wants to convey that additional images exist *for the same Procedure*.

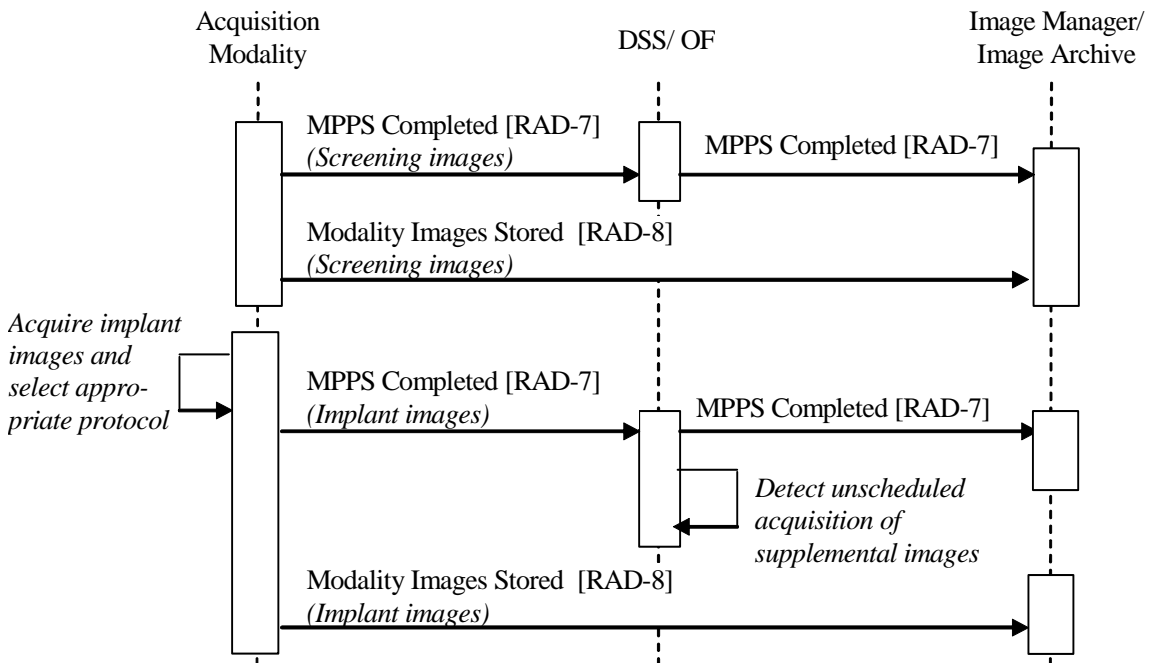


Figure 23.3-1. Process Flow for Supplemental Views

**Technical aspect:** The Acquisition Modality acquires the standard screening images, creates a corresponding MPPS (RAD-6), completes and sends it (RAD-7), and stores the images to the Image Archive (RAD-8). Later, the Modality appends implant images (Append Case RAD TF-2:

4.6.4.1.2.3.3) and values the Performed Protocol with implant acquisition codes in images and in a *new* MPPS (RAD-6) referencing the implant images (in addition to referencing the scheduling information from the screening procedure). The Modality completes this MPPS and sends it (RAD-7) to the DSS/OF that detects differences in what was scheduled (standard screening) and what was performed (standard screening and implant views) by comparing the scheduled and performed Protocol codes from the MPPS (RAD TF-2: 4.6.4.1.3.1). The Image Display is able to select presentation layouts based on coded values for Procedure and Protocol in images (RAD TF-2: 4.16.4.2.2.5).

Note: Unlike Scheduled Workflow, the Acquisition Modality in MAWF is required to support the Assisted Acquisition Protocol Setting Option (RAD TF-2: 4.6.4.1.2.4.2) to express the additional protocol used for the supplemental images of the same procedure. In addition, the Image Display is required to use Procedure, Reason and Protocol codes for selecting presentation layouts.

Variant: A facility that precisely documents procedures on the procedure level wants the Tech to change the Procedure Code from "Standard Screening" to "Screening with Implants".

Such a change in Procedure Codes will trigger behavior defined in the Conversion use cases: The DSS/OF will act upon the *Procedure* Code change and update archived instances, which is *not* expected when only Performed *Protocol* Codes change.

Variant: After having taken the first of the 4 screening views, and thus *before completing* the screening exam, the Tech detects the implants and just adds them with the correct Performed Protocol Code.

When completing the exam, *one* MPPS COMPLETE will be sent that references all 4 screening *and* the implant views (Modality-internal behavior that does not trigger specific behavior at the DSS/OF or Image Manager/ Image Archive).

### **23.3.1.2 Conversion: Convert unilateral to bilateral diagnostic exam**

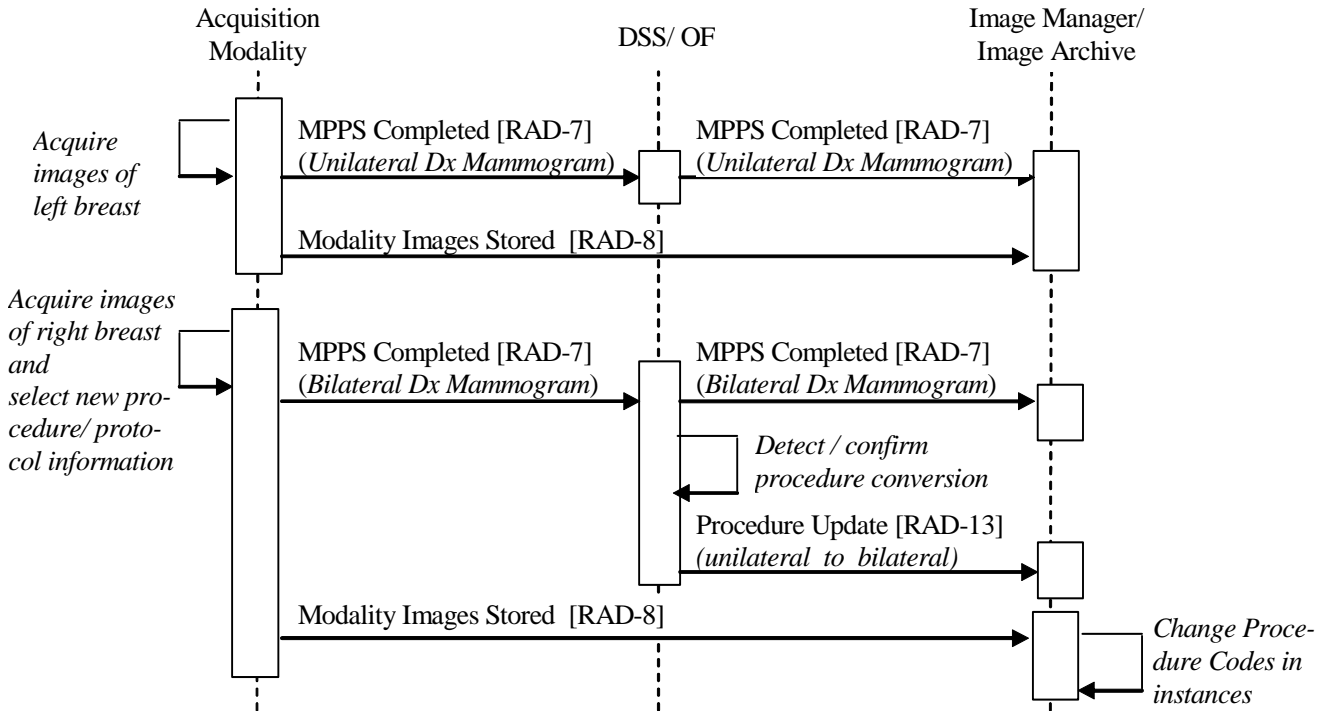
**Clinical aspect:** As a consequence of a previous screening exam, a patient is recalled for an Unilateral Diagnostic Mammogram. Diagnostic images are taken of the left breast (usually views other than MLO and CC). The *exam is completed* at the Modality.

While the patient is still present, the Radiologist again reviews the prior screening exam and decides that additional images of both breasts are needed. Therefore, the procedure should be converted to a Bilateral Diagnostic Mammography examination, and the Tech is asked by telephone (or other means of 2-way communication) to acquire the additional views of the right breast.

The Tech at the Modality enters the procedure change during the acquisition (scheduled unilateral to new bilateral diagnostic exam) and wants this information to be propagated to the RIS and PACS. She obtains the additional views, completes the exam and the images are archived as Bilateral Diagnostic Mammogram.

The Radiologist interprets the unilateral and bilateral diagnostic views and creates a report.

A clerk at the RIS notices the difference between the scheduled procedure and the additional information sent from the Modality after conversion. She replaces the original unilateral procedure with a bilateral diagnostic procedure, and may need to do/ confirm corresponding changes to archived images.



**Figure 23.3-2. Process Flow when converting a diagnostic procedure**

**Technical aspect:** The Acquisition Modality acquires images of one breast, creates a corresponding MPPS (RAD-6), sends it completed (RAD-7), and stores the images (RAD-8). Then the Modality acquires images of the *other* breast in one or more new Series of the same Study (Append Case RAD TF-2: 4.6.4.1.2.3.3). In order to inform downstream Actors about the conversion early, the Modality fills the most updated values for performed Protocol and Procedure codes in the MPPS and the new images (see RAD TF-2: 4.6.4.1.2.4.2, 4.8.4.1.2). The Modality creates a new MPPS (RAD-6) and sends it to the DSS/OF with status COMPLETED (RAD-7): it references the additional images and has a Procedure Code meaning "Bilateral Diagnostic Mammogram". The Modality stores the images of the other breast (RAD-8) to the Image Archive.

The DSS/OF receives an MPPS COMPLETED for the unilateral diagnostic Mammogram and another MPPS COMPLETED for the bilateral diagnostic Mammogram of the same diagnostic Study. The DSS/OF detects different codes for requested and performed Procedure in the 2<sup>nd</sup> MPPS, updates the Procedure Codes in the related worklist items, sends a Procedure Update message to the Image Manager (RAD-13), and may also notify the Order Placer (RAD-3).

The Image Manager receives the Procedure Update for this diagnostic Study from the DSS/OF (RAD-13) and, as the owner of the Procedure information, updates Procedure codes of this Study's instances.

The Image Display selects a presentation layout based on Procedure Codes and Performed Protocol Codes in the images (see RAD TF-2: 4.16.4.2.2.5).

Note: Unlike Scheduled Workflow, the Acquisition Modality in MAWF is required to support the Assisted Acquisition Protocol Setting Option (RAD TF-2: 4.6.4.1.2.4.2) and also to be able to use coded values for the Procedure and Reason codes. In addition, the DSS/OF is required to detect procedure changes and automatically send a Procedure Update to the Image Manager.

**Variant:** A patient comes in for a scheduled screening mammogram. After having acquired the first image, the Technologist discovers a lump. In agreement with a responsible clinician, the standard *screening exam is converted to a bilateral diagnostic exam*. The Technologist adds an extra image to the 4 standard screening images and sets the exam complete.

Conversion may change the reason for a procedure. DICOM provides no means to set a reason for *performed* Procedure analogous to Reason for Requested Procedure (see RAD TF-1: B.2.2).

**Variant:** While the Technologist acquires images for a unilateral diagnostic exam and *before setting the exam complete*, the Radiologist, who has reviewed patient history and a prior Study, requests additional views of the other breast, too. The Technologist converts to a bilateral diagnostic exam, adds the images and sets the exam complete.

This extends the Simple Acquisition, where *one* MPPS COMPLETE is sent. It will contain appropriate code values for procedure and protocol that describe the conversion.

Note: Normally, an examination that includes multiple Modalities is scheduled by separate procedures for each Modality. If a multi-Modality examination is scheduled by one single procedure with different Scheduled Procedure Steps for the Modalities, e.g. FFDM and Ultrasound, the change of procedure codes at the 1st Modality (FFDM) may affect the acquisition protocols at the 2nd Modality (Ultrasound). Then, procedure conversion or manual exception handling may need to be done at the DSS/OF.

### **23.3.1.3 Recall - the patient returns to the facility for a subsequent exam**

#### **23.3.1.3.1 Screening Recall for a Diagnostic Mammogram**

**Clinical aspect:** A patient gets a screening exam scheduled and performed and leaves the facility. Afterwards, the acquired images are interpreted and the detected findings are reported as status "BIRADS 0" (exam/ assesment incomplete).

The patient is recalled on the next day for additional images for diagnostic purposes, and a Unilateral Diagnostic Mammography exam is scheduled at the RIS in the facility. The institution considers this exam to be part of the original Order, but plans to generate a new report. The patient returns and images are acquired and stored to the PACS. Based on the BIRADS 0 report and the additional images, the exam is reported as an Unilateral Diagnostic Mammography exam as consequence to findings from a screening exam.

**Technical aspect:** The Reason for Requested Procedure Codes and Referenced Study Sequence in the image headers are used to "link" an original and a recall Study which are presented together by an Image Display.

The DSS/OF schedules the recall Procedure by creating a Modality Worklist item for a new Study of the same Order that caused the recall (same Accession Number). This Worklist item has a Reason for Requested Procedure code with the meaning "Recall for imaging findings" or "Recall for patient symptoms/ clinical findings", and references the Study that caused the recall in the Referenced Study Sequence (RAD TF-2: 4.5.4.2.2.2). The Acquisition Modality copies these values into the images it acquires. The Image Display uses the Reason code and the Study reference to present all images from both original and recall Studies in the same layout (RAD TF-2: 4.16.4.2.2.5).

### **23.3.1.3.2 Screening Technical Recall due to inadequate quality of views**

**Clinical aspect:** A patient has a screening exam scheduled and performed (MLO and CC view of each breast). The exam is completed and images are archived. The patient leaves the facility. Afterwards, the acquired images are interpreted and some views are detected to be technically inadequate. They need to be repeated. A report for the screening mammogram is created (BIRADS 0: assessment incomplete).

The patient is recalled for a later appointment for repeat views to the original exam. The recall procedure is scheduled at the RIS. The repeat views are acquired and images archived.

The additional images are interpreted and a separate report is created that references the previous BIRADS 0 report (no additional billing).

**Technical aspect:** This case corresponds to the screening recall case (23.3.1.3.1), except that the Modality Worklist item(s) scheduled for this new recall procedure (*new Study* for the same order) contains a Reason for Requested Procedure code meaning "Recall for technical reasons". The DSS/OF and Image Display use and interpret this code meaning for scheduling respectively presentation.

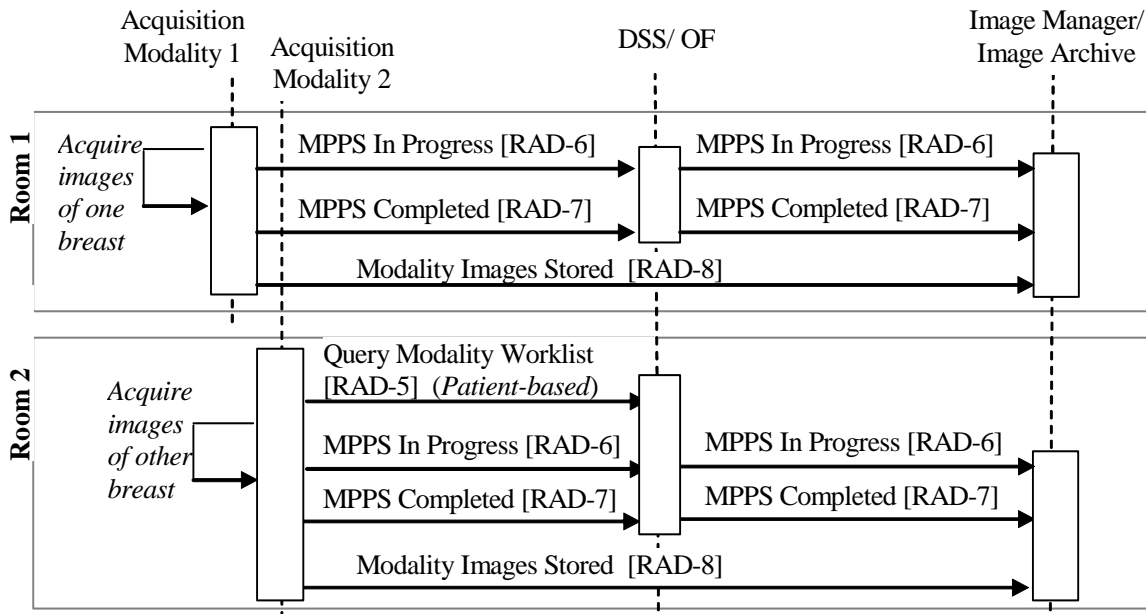
Variant: Some facilities schedule an additional Scheduled Procedure *Step* in the *same Study*, append images when the patient comes back, and finally create one report.

### **23.3.2 Finish an exam with supplemental views in another room**

The situation of finishing an exam in another room results from the decision to take supplemental images (see 23.3.1.1) or to convert a procedure (see 23.3.1.2).

**Clinical aspect:** A patient comes in for a follow-up exam on one breast. Images are taken. Since she is close to her yearly exam date, the Technologist wants the Radiologist to decide if supplemental images are to be taken. The Radiologist who is finishing a biopsy with another patient, checks the just acquired images some minutes later and calls for imaging of the other breast, too. The patient is waiting outside the acquisition room, which is occupied by the next

patient, so another machine in the room next door is used. The Technologist can see the original workitem on the Modality in the other room. She acquires the images and completes the exam.



**Figure 23.3-3. Process Flow for finishing an exam in another room, when the exam was completed and the procedure step is still available for the 2nd Modality**

**Technical aspect:** The critical issue with room changes is the availability of a Modality Worklist item in the 2<sup>nd</sup> room: This enables the Tech to efficiently acquire the supplemental images, similar to an Append Case, and avoids an unscheduled acquisition with manual reconciliation (see 4.6.4.1.2.3). Depending on how the DSS/OF manages worklist items *already used* for image acquisition in the 1<sup>st</sup> room, the original acquisition workitem can:

- Have a status MPPS IN PROGRESS, due to a technical or procedural error. This MPPS cannot be completed at the other Modality and needs manual intervention at the DSS/OF. The related workitem may or may not be available in the Modality Worklist.
- Have a status COMPLETED or DISCONTINUED and is *still available* in the Worklist. The 2<sup>nd</sup> Modality does a Patient-based Modality Worklist Query (RAD TF-2: 4.5.4.1.2.2.3) and is able to use workitems that were not originally scheduled for it (RAD TF-2: 4.5.4.2.3.1).
- Have a status COMPLETED or DISCONTINUED and is *not available* to be queried from the DSS/OF. It is necessary to schedule a new procedure step for the 2<sup>nd</sup> Modality at the DSS/OF.

The 2<sup>nd</sup> Modality will always create a new Series for the images it acquires. When the 1<sup>st</sup> Modality discontinues the original worklist item, the acquired images will always be stored to

the Archive (see RAD TF-2: 4.7.4.1.2), but the DSS/OF may require user interaction to resolve this DISCONTINUED case.

### 23.3.3 Correct or reject images at a Modality or Workstation

Quality assurance activities may be done on recently acquired images at

- the Modality that acquired the images (IHE Actor: Acquisition Modality)
- a separate Workstation that queried and retrieved the acquired images from an Image Manager/ Image Archive (grouped IHE Actors: Image Display/ Evidence Creator).

The following two examples for one Actor apply to the other Actor analogously. An organization should consider following certain policies to ensure consistent and correct use of modified images (see 23.4.2).

#### 23.3.3.1 Mark images as rejected for quality reasons

**Clinical aspect:** The Technologist or Radiologist decided 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 views as "rejected" so that other systems handle rejected images according to local policies. The procedure step has already *been completed*, and all images, including the rejected views, have been *stored* to the Archive.

Site policies may determine if rejected views will be presented to users on later retrieve or not, as they may be of clinical relevance or for quality control monitoring. The Archive gets all images as well as change information, and then applies internal rules to fulfill site policies.

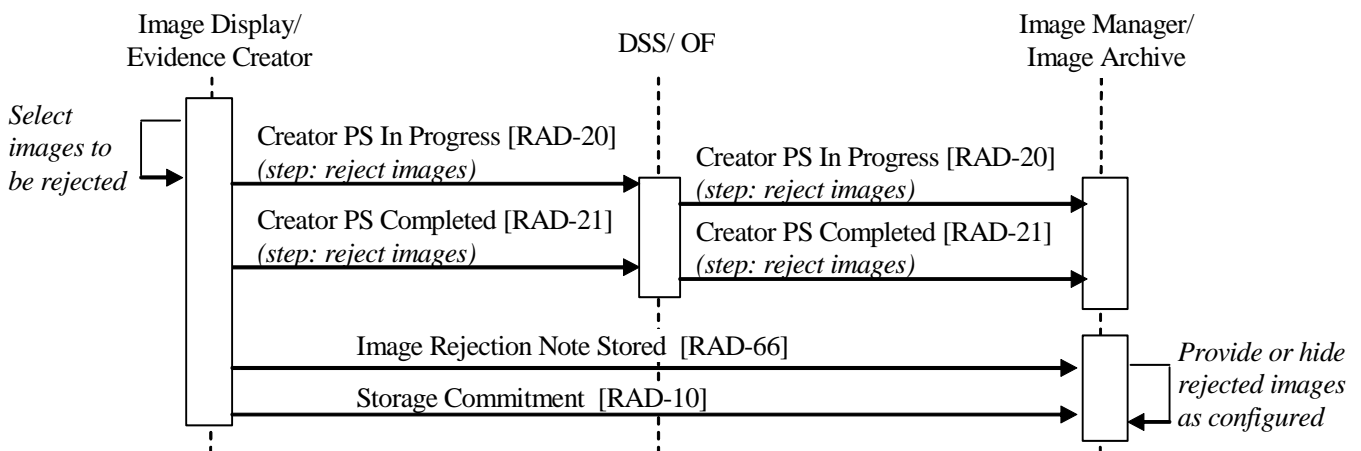


Figure 23.3-4. Process Flow for handling rejected images

**Technical aspect:** A user marks certain images of insufficient quality as "Rejected for Quality Reasons" and selects a reason. The Evidence Creator creates a Key Object Selection (KOS) instance that references the rejected images and contains the "rejection" title and 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 Archive (RAD-66), including a Storage Commit (RAD-10).

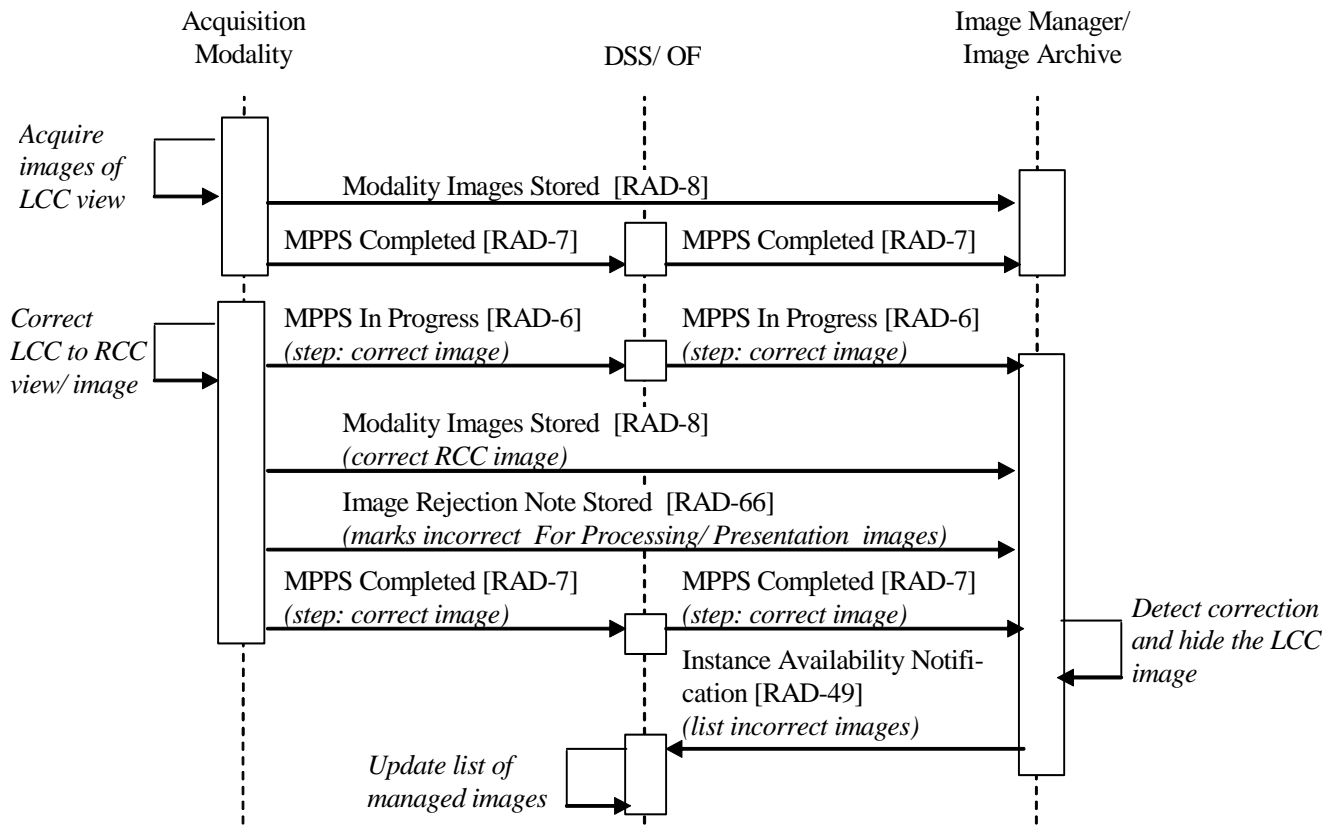
The Image Manager/ Archive can be configured to provide such rejected images or to hide them from subsequent query/ retrieve responses and is able to inform the DSS/OF of hidden instances (RAD-49). An Image Display, when receiving "quality rejection" KOS, will display the images and/ or KOS, or will hide both (RAD-16, per configuration).

### 23.3.3.2 View Corrections after Completed Image Acquisition

**Clinical aspect:** The Technologist takes a left breast cranial caudal view (LCC), and didn't realize that defaults were set for a right breast (RCC) view, thus the view is labelled incorrectly. The acquisition has been *set completed* and images were sent to the PACS.

The Tech 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, laterality) and "update" the images in the PACS. For correct interpretation and diagnosis, the Radiologist depends on a correct view labeling. Incorrectly labelled 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.



**Figure 23.3-5. Process Flow for correction of image labeling**

**Technical aspect:** The Acquisition Modality creates corrected images, including updated references between related FOR PRESENTATION and FOR PROCESSING images, and stores them (RAD-8). It creates and stores a Key Object Selection (KOS) that lists the incorrect instances by specifically marking them "Rejected for Patient Safety Reasons" (RAD-66). It also creates an MPPS (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 responses and is able to inform the DSS/OF of hidden instances (RAD-49). An Image Display, when receiving "patient safety rejection" KOS, does not display the images and KOS (RAD-16).

## 23.4 Implementation and Policy Considerations

This section describes fundamental aspects to be considered when deploying systems implementing Actors from the Mammography Acquisition Workflow Integration Profile on site.

### 23.4.1 Use of Codes (coded values) for Scheduling and Documentation

Coded values enable user guidance or increased automation by systems. Code values are defined by departments, sites or health enterprises, optimally based on a set of standards-based or common codes, e.g. CPT, LOINC. For Mammography Acquisition, codes are used:

- for scheduling and driving Modality behavior: codes for Requested Procedure, Reason for Requested Procedure and Scheduled Protocols enable selection of Modality settings and guidance for the Technologist;
- for documenting what was performed in images and workflow status. Codes for performed Procedure, Performed Protocols, Views, etc. enable Displays to present images in adequate screen layout, and enable Radiology staff to track performed work or compose charges.

A DSS/Order Filler will let a scheduling user select from a number of code values such that the Reason for Requested Procedure (0040,100A), the Requested Procedure<sup>1</sup> (0032,1064) and the Scheduled Protocols (0040,0008) in Modality Worklist items can be filled (see also: Assisted Acquisition Protocol Setting, RAD TF-2: 4.5.4.2.3 and 4.6.4.1.2.4.2).

A Mammography Modality will display and use the above listed codes from the Modality Worklist for default settings and for the images and workflow statuses it creates. It will also fill in automatically or let a user select values for Procedure Codes (0008,1032), Performed Protocol Codes (0040,0260), View Codes (0054,0220) and Image Laterality (0020,0062), by supporting the Assisted Acquisition Protocol Setting (RAD TF-2: 4.5.4.2.3 and 4.6.4.1.2.4.2).

An Image Display will be able to select a defined presentation layout based on these codes from images: Reason for Requested Procedure (0040,100A), Procedure Codes (0008,1032) and Performed Protocol Codes (0040,0260). Additional coded image values will be used for placing individual images on screen as defined in the Mammography Image Integration Profile (see RAD TF-2: 4.16.4.2).

It is important that a department or enterprise defines the code sets which are used by all of its systems in a common way, and that each relevant code set is available to each system with the same content. Each system needs to be configurable as to which code sets it uses. IHE Radiology does not (yet) define a mechanism how to distribute code sets commonly in organizations (e.g. see IHE Laboratory: Laboratory Code Set Distribution). For FFDM Acquisition Workflow, rather stable and limited code sets should suffice for workflow and display automation that may need less maintenance and synchronization effort.

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<sup>1</sup> each Requested Procedure is represented by a *single* code per DICOM

Different organizations will use codes differently, determined by local policies and way of working. There is no widely agreed relation or mapping between procedure, reason or protocol codes. For instance, if administrative staff at the DSS/OF schedules procedures coarsely, such a procedure either may be refined later by a Radiologist who adds Reason and Protocol codes, or the Technologist has freedom how to exactly perform the acquisition.

*Procedure* Codes convey the fundamental clinical question that led to the imaging service. The laterality of the Procedure is important information: if it is included in the Procedure code, e.g. "Diagnostic Mammography, left", then the laterality will always be known for the acquisition.

*Protocol* Codes define concrete tasks or steps for a Technologist to perform the acquisition.

The *Reason for Requested Procedure* Codes often determines

- at which Modality and how a procedure is performed (utilization, efficiency),
- rules for image transfer from the Modality to other systems, e.g. Archives or CAD systems,
- image presentation at the Display.

The Reason for Requested Procedure may be described by one or more codes. For instance, a scheduled procedure that is associated to regular screening and the patient reporting a recent nipple problem will be represented by the Reason Code Sequence {(R-42453, SRT, "Screening"), (F-8A09C, SRT, "Nipple problem")}.

The DSS/OF, Acquisition Modality and Image Display need to be configurable to use code sets in a flexible way. This Profile defines starter code sets (see RAD TF-2: 4.5.4.2.2.2):

- The informative code set for Procedures (RAD TF-2: Table 4.5-5) may be configured completely, partly or not at all at these Actors. It is planned to be used at Connectathons.
- The required code set for Reason for Procedure (RAD TF-2: Table 4.5-6) must be configured on these Actors in order to clearly indicate recall, screening and diagnostic procedures.

Note: Due to a lack of agreed Protocol codes, no starter code set is defined by IHE.

### **23.4.2 Policies for reducing risks after correction or rejection at a Modality**

Images that are marked as "rejected" for quality reasons (see 23.3.3.1) 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 labelled images (see 23.3.3.2), 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, TF-1: 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 Mammography Acquisition Workflow 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 meet the department or enterprise policies. For systems that are not covered by this Integration Profile, e.g. CAD systems, separate policies and methods need to be applied. For instance, after FOR PROCESSING images have been corrected due to corrections in FOR PRESENTATION images, they should be re-submitted for CAD processing (otherwise, CAD marks are incorrectly located).

## Appendix B: Topics for Standards Corrections or Supplements

### B.2 DICOM topics

<i>Add the following sections B.2.2, B.2.3, B.2.4 to the end of RAD TF-1: B.2</i>
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#### B.2.2 DICOM CP 881: Add a Reason for Performed Procedure to MPPS and images

When a procedure is converted at the Modality (see RAD TF-1: 23.3.1.2), the Reason for the Procedure may change, e.g. from screening to diagnostic. Such a reason is relevant for, e.g. remote reading, and needs to be documented at the Modality in the MPPS and Composite Instances. In analogy to the Reason for Requested Procedure Code Sequence, this requires addition of a Reason for *Performed* Procedure Code Sequence in MPPS messages and image IODs. Temporarily, an attribute tag of (gggg,eee1) is proposed to DICOM and used in this Supplement.

#### B.2.3 DICOM CP 885: Add a specific code for using KOS marking incorrect images

Incorrect archived images that are to be corrected or replaced by the Image Manager/ Image Archive are referenced in a Key Object Selection (KOS) instance (see RAD TF-1: 23.3.3.2). In order to distinguish this KOS instance from other KOS instances that were created by actions as defined in the Key Image Note Integration Profile and in order to trigger specific behavior by the Image Manager/ Image Archive, a specific KOS Title is needed. IHE proposes to add a code with the meaning "Rejected for Patient Safety Reasons" to the DICOM CID 7010 that marks the images as incorrect and potentially harmful for use.

Add the following new code to DICOM PS 3.16, CID 7010:

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
...		
DCM	113037	Rejected for Patient Safety Reasons

Add the following new row to DICOM PS 3.16, Annex D:

Code Value	Code Meaning	Definition
...		
113037	Rejected for Patient Safety Reasons	A list of objects that are incorrect and are potentially harmful for a patient when used routinely.

**B.2.4 DICOM CP 886: Add codes for Modifier and Reason for Requested Procedures in Mammography Acquisition Workflow**

Mammography Acquisition Workflow uses coded values for conveying certain details of the Reason for Requested Procedure in Worklists (see RAD TF-1: 23.4.1).

The recall scenarios depend on coded values for correct display of linked studies that are not yet defined in DICOM. Other optional codes are proposed to DICOM as well.

IHE proposes to add the following new codes to DICOM PS 3.16, CID 6061 (Breast Imaging Procedure Modifiers), which is included in CID 6051 (Breast Procedure Reason)

<b>Coding Scheme Designator (0008,0102)</b>	<b>Code Value (0008,0100)</b>	<b>Code Meaning (0008,0104)</b>
DCM	ZZZZA	Calibration
DCM	ZZZZB	Quality Control
DCM	ZZZZC	Localization
DCM	ZZZZD	Specimen
DCM	ZZZZE	Clip/ marker placement

IHE proposes to add the following new codes to DICOM PS 3.16, CID 6051 (Breast Procedure Reason):

<b>Coding Scheme Designator (0008,0102)</b>	<b>Code Value (0008,0100)</b>	<b>Code Meaning (0008,0104)</b>
DCM	ZZZZF	Recall for technical reasons
DCM	ZZZZG	Recall for imaging findings
DCM	ZZZZH	Recall for patient symptoms/ clinical findings
DCM	ZZZZI	Nipple discharge
DCM	ZZZZJ	Erythema
DCM	ZZZZK	Lymphadenopathy
DCM	ZZZZL	Malignancy, unknown primary

Add the following new rows to DICOM PS 3.16, Annex D:

<b>Code Value</b>	<b>Code Meaning</b>	<b>Definition</b>
ZZZZA	Calibration	Checking or adjusting an imaging device to ensure accurate measurements.
ZZZZB	Quality Control	Checking that images meet quality goals.

<b>Code Value</b>	<b>Code Meaning</b>	<b>Definition</b>
<i>ZZZZZC</i>	Localization	Determining the location or site of a finding or lesion.
<i>ZZZZZD</i>	Specimen	Collecting body tissue or liquid, potentially using imaging for guidance.
<i>ZZZZZE</i>	Clip/ marker placement	Marking a lesion by using imaging for guidance.
<i>ZZZZZF</i>	Recall for technical reasons	Patient returns for additional images to improve the quality of the current exam.
<i>ZZZZZG</i>	Recall for imaging findings	Patient returns for additional images to clarify findings from the current exam.
<i>ZZZZZH</i>	Recall for patient symptoms/ clinical findings	Patient returns for additional images to clarify symptoms or signs reported by the patient or a healthcare professional at the time of the current exam.
<i>ZZZZZI</i>	Nipple discharge	Discharge of unknown precise quality.
<i>ZZZZZJ</i>	Erythema	Reddening of the skin that may or may not be associated with inflammation.
<i>ZZZZZK</i>	Lymphadenopathy	The finding of Lymph nodes that are abnormal in size, consistency or number.
<i>ZZZZZL</i>	Malignancy, unknown primary	Signs of malignant tumor when no tumor has been found in a patient.

## Volume 2 - Transactions

*Editorial Note: In order to improve comprehensibility and readability of the Transaction text, some sections are included although they are not changed (but they provide relevant context).*

### 4.5 Query Modality Worklist

*Add to 4.5.3 - Referenced Standards the DICOM Code Set Resource:*

#### **DICOM 2008 PS 3.16: Content Mapping Resource**

*Replace text in sections to TF-2: 4.5.4.1.1*

#### 4.5.4.1 Query Scheduled MWL Message

This is the worklist query message sent to the Department System Scheduler/Order Filler.

##### 4.5.4.1.1 Trigger Events

The patient arrives at the Acquisition Modality for a procedure (scan/acquisition). **The Acquisition Modality may be a different device than was scheduled in the Scheduled Procedure Step (see 4.5.4.1.2.2.3), e.g. if the patient needs to be scanned in another room.**

The trigger event for an importation is a User that wants to perform a scheduled importation. The actual trigger for scheduling the importation is site specific, but may be triggered by such events as:

- Arrival of films as a result of a request for a scheduled consult.
- Patient with a scheduled procedure brings prior Evidence Objects on a PDI Media.
- Other communications not specified further by the IHE Technical Framework which result in the scheduling of a import.

*Add the following rows to TF-2: Table 4.5-3, including a new note:*

**Table 4.5-3. Return and Matching Keys For Modality Worklist**

Attribute Name	Tag	Query Keys Matching		Query Keys Return	
		SCU	SCP	SCU	SCP
...					
<b>Requested Procedure</b>					

Attribute Name	Tag	Query Keys Matching		Query Keys Return	
		SCU	SCP	SCU	SCP
...					
Referenced Study Sequence <u>[IHE-4][HHE-3]</u>	(0008,1110)				
>Referenced SOP Class UID	(0008,1150)	O	O	R+*	R
>Reference SOP Instance UID	(0008,1155)	O	O	R+*	R
<b><u>Reason for Requested Procedure Code Sequence</u></b>	<b><u>(0040,100A)</u></b>				<u>[IHE-5]</u>
> <u>Code Value</u>	<u>(0008,0100)</u>	<u>O</u>	<u>O</u>	<u>R+</u>	<u>R+</u>
> <u>Coding Scheme Version</u>	<u>(0008,0103)</u>	<u>O</u>	<u>O</u>	<u>O</u>	<u>O</u>
> <u>Coding Scheme Designator</u>	<u>(0008,0102)</u>	<u>O</u>	<u>O</u>	<u>R+</u>	<u>R+</u>
> <u>Code Meaning</u>	<u>(0008,0104)</u>	<u>O</u>	<u>O</u>	<u>R+</u>	<u>R+</u>

**(IHE-4): The DSS/OF participating in the Mammography Acquisition Workflow Integration Profile shall reference the originating Study in the Referenced Study Sequence in case of recall exams (see 4.5.4.2.2.2).**

**(IHE-5): These requirements for Reason For Requested Procedure Code Sequence apply to the DSS/OF and Acquisition Modality participating in the Mammography Acquisition Workflow Integration Profile only.**

*Add this section to TF-2: 4.5.4.1.2.2:*

#### **4.5.4.1.2.2.3 Patient Based Query for Mammography Acquisition Workflow**

**An Acquisition Modality participating in the Mammography Acquisition Workflow Integration Profile shall be able to do a Patient Based Query.**

**It shall be able to include the Reason for Requested Procedure Code Sequence (0040,100A) as a Query Return Key in the C-FIND Request.**

*Add section 4.5.4.1.3.1 to RAD TF-2:*

#### **4.5.4.1.3.1 Expected Actions for Mammography Acquisition Workflow**

**The Departmental System Scheduler/ Order Filler participating in the Mammography Acquisition Workflow Integration Profile shall accept the Reason for Requested Procedure Code Sequence (0040,100A) as a Query Return Key in the C-FIND Request and shall provide values as requested (see Table 4.5-3 and Table 4.5-6).**

#### **4.5.4.2 Receive Scheduled MWL Message**

This is the message that the Department System Scheduler sends to the modality as a reply containing DICOM Modality Worklist information.

##### **4.5.4.2.1 Trigger Events**

The Departmental System Scheduler/Order Filler had received a query for a MWL.

##### **4.5.4.2.2 Message Semantics**

C-FIND Response from the DICOM Modality Worklist SOP Class will be used for this message. Some of the attributes queried through the MWL SOP class originate with the Order Placer and ADT, while other attributes are managed internally by the Department System Scheduler/Order Filler. The DSS/Order Filler will determine the Requested Procedures needed to fulfill the Order, and decompose the Requested Procedures in Scheduled Procedure Steps, assigning proper Protocol Codes. The DSS/Order Filler shall support the definition of multiple Protocol Codes in a Scheduled Protocol Code Sequence contained in the Scheduled Procedure Steps for any Requested Procedure. Coded Values shall be used to specify ~~exactly~~ what actions are to be performed at the Acquisition Modality.

In addition to these Coded Values additional instructions for the technologist may be specified. It is recommended to use the Scheduled Procedure Step Description and the Requested Procedure Description attributes for these additional specific instructions.

Appendix B defines the origin and mappings of the attributes returned in a MWL query.

The details of the C-FIND Response from the DICOM MWL SOP Class are depicted in table 4.5-3 and appendix A. At the time images are being created/generated, these attributes will be stored into the DICOM image instance headers. The Acquisition Modality or Importer may need additional information; however this is beyond the scope of this document. Refer to RAD TF-1, Appendix A for a discussion of Accession Number and Procedure ID.

An Order may be cancelled after the corresponding Requested Procedure(s) and Scheduled Procedure Steps have been scheduled, and possibly even after a Performed Procedure Step has been started. In this case the Department System Scheduler/Order Filler shall remove the Scheduled Procedure Steps of the Order from its worklist, and the absence of these Scheduled Procedure Steps in the next C-FIND response to the Acquisition Modality or Importer will indicate that the procedure has been cancelled. In this way the technologist recognizes that the previously scheduled steps no longer need to be performed.

It is the responsibility of the Department System Scheduler/Order Filler to ensure that the patient and procedure information is current in the Modality Worklist response. The Department System Scheduler/Order Filler receives patient and procedure updates through Transactions RAD-2, RAD-3 and RAD-12.

Add a section 4.5.4.2.2.2

**4.5.4.2.2.2 Codes and References in Procedures (Mammography Acquisition Workflow)**

**This section defines requirements for the DSS/OF participating in the Mammography Acquisition Workflow Integration Profile regarding coded values (see RAD TF-1: 23.4.1).**

**The DSS/OF shall be able to fill in coded values from separate configurable code sets for Requested Procedure (0032, 1064), Reason for Requested Procedure (0040,100A) and Scheduled Protocols (0040,0008) into the Modality Worklist C-FIND response (i.e. Scheduled Procedure Steps). It shall support different coding schemes (0008,0102) for the different code sets and values.**

**The DSS/OF shall provide the means to select these codes using values provided in the order message RAD-2. It shall be able to use for procedure code selection the procedure laterality information that is included in an order (OBR-15) from the Order Placer as defined in RAD TF-2: Table 4.2-1 and Table B-1.**

*Note that per DICOM, each worklist response contains exactly one Procedure Code, whereas Code Sequences of Reason for Requested Procedure or Scheduled Protocol may contain zero, one or multiple codes. A DSS/OF implementation can be expected to guide the user to select meaningful code combinations, e.g. prevent from selecting a "screening" Procedure code and a Procedure Reason of "diagnostic".*

**The code set from Table 4.5-5 may be used or adapted as one of the possible configurable code sets used by the DSS/OF to fill the Requested Procedure Code Sequence (0032, 1064). The Acquisition Modality uses these codes to guide image acquisition or view selection (see RAD TF-2: 4.6.4.1.2) and to document the performed procedure (see RAD TF-2: A.1). The Image Display uses these codes for selecting presentation layouts (see RAD TF-2: 4.16.4.2.2.5).**

**Table 4.5-5: Codes for Procedures (informative)**

<b>Coding Scheme Designator (0008,0102)</b>	<b>Code Value (0008,0100)</b>	<b>Code Meaning (0008,0104)</b>
<b><u>99IHERADTF</u></b>	<b><u>MAWF0001</u></b>	<b><u>Screening Mammography, bilateral</u></b>
<b><u>99IHERADTF</u></b>	<b><u>MAWF0002</u></b>	<b><u>Screening Mammography, left</u></b>
<b><u>99IHERADTF</u></b>	<b><u>MAWF0003</u></b>	<b><u>Screening Mammography, right</u></b>
<b><u>99IHERADTF</u></b>	<b><u>MAWF0004</u></b>	<b><u>Diagnostic Mammography, bilateral</u></b>
<b><u>99IHERADTF</u></b>	<b><u>MAWF0005</u></b>	<b><u>Diagnostic Mammography, left</u></b>
<b><u>99IHERADTF</u></b>	<b><u>MAWF0006</u></b>	<b><u>Diagnostic Mammography, right</u></b>
<b><u>99IHERADTF</u></b>	<b><u>MAWF0007</u></b>	<b><u>Mammary Ductogram, Single Duct, left</u></b>
<b><u>99IHERADTF</u></b>	<b><u>MAWF0008</u></b>	<b><u>Mammary Ductogram, Single Duct, right</u></b>

<b>Coding Scheme Designator (0008,0102)</b>	<b>Code Value (0008,0100)</b>	<b>Code Meaning (0008,0104)</b>
<u>99IHERADTF</u>	<u>MAWF0009</u>	<u>Mammary Ductogram, Multiple Ducts, left</u>
<u>99IHERADTF</u>	<u>MAWF0010</u>	<u>Mammary Ductogram, Multiple Ducts, right</u>
<u>99IHERADTF</u>	<u>MAWF0011</u>	<u>Mammogram for marker placement, left</u>
<u>99IHERADTF</u>	<u>MAWF0012</u>	<u>Mammogram for marker placement, right</u>
<u>99IHERADTF</u>	<u>MAWF0013</u>	<u>Needle Localization, Image Guided, Mammography, left</u>
<u>99IHERADTF</u>	<u>MAWF0014</u>	<u>Needle Localization, Image Guided, Mammography, right</u>
<u>99IHERADTF</u>	<u>MAWF0015</u>	<u>Stereotactic Biopsy, Image Guidance, left</u>
<u>99IHERADTF</u>	<u>MAWF0016</u>	<u>Stereotactic Biopsy, Image Guidance, right</u>
<u>99IHERADTF</u>	<u>MAWF0017</u>	<u>Breast Specimen Mammography, left</u>
<u>99IHERADTF</u>	<u>MAWF0018</u>	<u>Breast Specimen Mammography, right</u>
<u>99IHERADTF</u>	<u>MAWF0019</u>	<u>Quality Control, Mammography</u>
<u>99IHERADTF</u>	<u>MAWF0020</u>	<u>Additional Mammography Views</u>

**The DSS/OF shall be able to fill one or more codes from Table 4.5-6 into the Reason for Requested Procedure Code Sequence (0040,100A) of the Modality Worklist Response. These values are necessary for recall cases (see RAD TF-1: 23.3.1.3) in order to**

- **guide image acquisitions, e.g. view settings, at the Acquisition Modality (RAD TF-2: 4.6.4.1.2),**
- **let the Image Display choose an appropriate presentation layout (RAD TF-2: 4.16.4.2.2.5).**

**In addition, the DSS/OF shall be configurable to extend the code set from Table 4-5.6.**

**In case of a recall Scheduled Procedure Step, the DSS/OF shall fill into the Modality Worklist Response:**

- **one appropriate recall code as defined in Table 4.5-6 below: either (MAWF0030, 99IHERADTF, "Recall for technical reasons") or (MAWF0031, 99IHERADTF, "Recall for imaging findings") or (MAWF0032, 99IHERADTF, "Recall for patient symptoms/ clinical findings");**
- **the Referenced Study Sequence (0008,1110) with one sequence item that contains**

- the Study Instance UID (0008,1155) from the Study for which the recall is being done
- the well-known UID 1.2.840.10008.3.1.2.3.1 (Detached Study Management) as the value of the Referenced SOP Class UID (0008,1150).

Table 4.5-6: Required Codes for Reasons for a Requested Procedure

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)	Definition
<u>99IHERADTF</u>	<u>MAWF003</u> <u>0</u>	<u>Recall for technical reasons</u>	<u>Patient returns for additional images to improve the quality of the current exam.</u>
<u>99IHERADTF</u>	<u>MAWF003</u> <u>1</u>	<u>Recall for imaging findings</u>	<u>Patient returns for additional images to clarify findings from the current exam.</u>
<u>99IHERADTF</u>	<u>MAWF003</u> <u>2</u>	<u>Recall for patient symptoms/ clinical findings</u>	<u>Patient returns for additional images to clarify symptoms or signs reported by the patient or a healthcare professional at the time of the current exam.</u>
<u>DCM</u>	<u>111416</u>	<u>Follow-up at short interval from prior study</u>	<u>The prior study recommended a follow-up breast imaging exam in 1 to 11 months (generally in 6 months).</u>
<u>SRT</u>	<u>R-42453</u>	<u>Screening</u>	<u>Indicates a regular screening exam.</u>
<u>SRT</u>	<u>R-408C3</u>	<u>Diagnostic</u>	<u>The exam is done in order to answer a specific diagnostic question.</u>
<u>SRT</u>	<u>A-04010</u>	<u>Implant</u>	<u>Indicates the existence of implant.</u>

Note: The codes from the coding scheme "99IHERADTF" are provisional. Their inclusion in the DICOM Standard is currently requested (see RAD TF-1: B.2.4).

**Furthermore, DICOM provides additional appropriate codes for configuring the Reason for Requested Procedure Codes at the DSS/OF: see DICOM Content Mapping Resource, Context Groups 6051 (Breast Procedure Reason), 6055 (Breast Clinical Finding or Indicated Problem) and 6061 (Breast Imaging Procedure Modifiers). These codes enable consistent use of common procedure reasons, e.g. by displaying the code meaning, but are**

**not expected to automatically drive system functions or workflow. Modalities will display the code meaning and use the codes to determine acquisition settings.**

**The DSS/OF shall be configurable for codes that can be filled into the Scheduled Protocol Code Sequence (0040,0008) of the Modality Worklist Response. For instance, such Protocol Codes may mean "standard screening", "magnification", "CAD".**

#### **4.5.4.2.3 Expected Actions**

The technologist checks for the existence of the Scheduled Procedure Steps, validates the displayed patient and procedure information, and checks the given instructions.

When an Acquisition Modality supports the ASSISTED ACQUISITION PROTOCOL SETTING option, it shall provide the means to use the protocol codes specified in the Scheduled Procedure Steps selected from the Modality Worklist (See ~~see~~ 4.6.4.1.2.4.2 Assisted Acquisition Protocols Setting Option).

For imports, the User checks for the existence of the Scheduled Procedure Steps, validates the selected Patient Demographics with the Patient demographics of the existing Evidence Objects or the hardcopy, and checks for special instructions given in the Scheduled Procedure Step Description on what Evidence Objects are to be imported (e.g. how many PDI Media or films are associated with the Scheduled Procedure Step). In addition, the Importer shall provide the means to use the protocol codes specified in the Scheduled Procedure Step selected from the Modality Worklist (See RAD TF-3: 4.59.4.1.2.3.3) Import Instruction Codes).

*Add the section 4.5.4.2.3.1*

#### **4.5.4.2.3.1 Expected Actions for Mammography Acquisition Workflow**

**An Acquisition Modality participating in the Mammography Acquisition Workflow Integration Profile shall be able to receive codes for Requested Procedures (e.g. those in Table 4.5-5), Reasons for Requested Procedure (including at a minimum those in Table 4.5-6) and Scheduled Protocols. It shall be configurable to use these codes for image acquisition and documentation of performed steps as defined by the ASSISTED ACQUISITION PROTOCOL SETTING (see 4.6.4.1.2.4.2).**

**The Acquisition Modality shall be able to acquire images using a MWL entry containing Scheduled Procedure Steps with a different AE Title (0040,0001), Station Name (0040,0010) or Location (0040,0011) than its own. This is necessary to more efficiently support the use of a Modality that is different from a scheduled device and room (see RAD TF-1: 23.3.2).**

## 4.6 Modality Procedure Step In Progress

*Replace the following paragraphs with this text:*

### 4.6.4.1 Procedure Step In Progress Message

#### 4.6.4.1.1 Trigger Event

Technologist begins procedure step from the Acquisition Modality ~~console~~.

#### 4.6.4.1.2 Message Semantics

The Acquisition Modality uses the Modality Performed Procedure Step SOP Class (N-CREATE Service) to inform the Performed Procedure Step Manager that a specific Procedure Step has been started and is in progress. In turn, the Performed Procedure Step Manager uses the N-CREATE service to forward the information to the Department System Scheduler/Order Filler Image Manager and Report Manager. The Performed Procedure Step Manager shall use the same Performed Procedure Step SOP Instance UID during this interchange. ~~The following aspects shall be taken into account during implementation of this step:~~

#### 4.6.4.1.2.1 Patient/Procedure/~~Scheduled~~ Procedure Step Information

The Acquisition Modality shall ensure that the Patient/Procedure/~~Scheduled~~ Procedure Step information it has is valid and current.

**The Acquisition Modality participating in the Mammography Acquisition Workflow Integration Profile may document a change in what was performed and thus shall support Assisted Acquisition Protocol Setting (4.6.4.1.2.4.2; see also 4.5.4.2.3) and fill in the most recent values for**

- **Procedure Code Sequence (0008,1032), see also 4.6.4.1.3.1**
- **Performed Protocol Code Sequence (0040,0260), Protocol Name (0018,1030) and Performed Procedure Step Description (0040,0254)**
- **Reason for Performed Procedure Code Sequence (gggg,eee1).**

*Note: The Reason for a Procedure may change when the Procedure is changed at the Modality. IHE requests DICOM to add a Reason for Performed Procedure Code Sequence to the MPPS, see RAD TF-1: B.2.2.*

#### 4.6.4.1.2.3.3 Append Case

*Replace the paragraphs below the figure "Append to a Normal Case" with this text:*

This is a case of 1-to-N relationship between SPS and PPS where first the PPS is generated in response to an SPS, as in the simple case. Other Performed Procedure Steps that have not been scheduled by additional SPSs are added sequentially at a later time, for instance

- due to unacceptable quality of certain images (“redo” certain images)
- because head MR images from a patient with severe headache that were just acquired are inconclusive, so that additional neck MR images are performed immediately (“add” certain images)
- **in digital Mammography, supplemental images to an already completed procedure step may be acquired on the same Modality, or on another Modality in another room (see RAD TF-1: 23.3).**

Note, that the scheduling of the additional procedure **step** would have resulted in two simple cases.

All Performed Procedure Steps shall refer back to the same Requested Procedure and to the original SPS. All Requested Procedure and Scheduled Procedure Step attributes shall be copied from the Scheduled Procedure Step Object to the Performed Procedure Step Relationship Module and the image Request Attribute Sequence (see **RAD TF-2: aAppendix A.1**).

#### 4.6.4.1.2.4 Protocol Handling

*Replace the text in 4.6.4.1.2.4 with the following text:*

The protocol (a specific combination of modality settings or a method) used in performing a procedure step shall be determined on the Acquisition Modality ~~at this time~~. **Protocol information is included in a Scheduled Procedure Step (SPS) being returned to an Acquisition Modality as part of a Modality Worklist (MWL) and in the Performed Procedure Step (PPS) from the Acquisition Modality to the PPS Manager. Most Modalities allow Manual Modality Setting (4.6.4.1.2.4.1), while the Assisted Acquisition Protocol Setting (4.6.4.1.2.4.2) adds functions beyond baseline Modality setting. Two cases/options are defined: Manual Modality Setting and Assisted Modality Setting. The first case is the one that is currently most commonly used while the second case introduces new functionality and is optional for the IHE Technical Framework.**

The Acquisition Modality shall not change the Requested Procedure Code (**0032,1064**) it obtains through the MWL. If the Requested Procedure Code is not correct or needs to be changed at the time the procedure is being performed, one of the following ~~two~~ methods shall be used:

- Department System Scheduler Method: The Procedure Information ~~shall be~~ corrected on the Department System Scheduler/Order Filler, and updated information shall be downloaded to the Acquisition Modality **in response to its next query**, ~~OR~~
- Acquisition Modality - **General** Method: The Acquisition Modality redefines Protocol Code(s) for the Procedure Steps it actually performs and **shall** sets the Procedure Code Sequence (0008,1032) to zero length;
- **Acquisition Modality - Mammography Acquisition Workflow Method: The Acquisition Modality participating in the Mammography Acquisition Workflow Integration Profile**

**shall be configurable to interpret, provide and redefine Procedure and Protocol Code(s) for the Procedure Steps it actually performs (see RAD TF-1: 23.3.1.2, 23.4.1, RAD TF-2: 4.5.4.2.2.2). It shall fill the corresponding code values into the Procedure Code Sequence (0008,1032) and Performed Protocol Code Sequence (0040,0260) as defined in the Assisted Acquisition Protocol Setting (4.6.4.1.2.4.2).**

**In case of procedure changes, the Acquisition Modality shall fill into the next MPPS to be sent one single Procedure Code (0008,1032) item that is different from the Scheduled Procedure Step's single Requested Procedure Code (0032,1064). Note that this overrides the recommendation from the Scheduled Workflow Integration Profile to leave the Procedure Code Sequence empty (see RAD TF-2: A.1) which is the trigger for manual exception handling at the DSS/OF.**

**The Scheduled Workflow Integration Profile specifies ~~The specification for~~ which methods are required or optional for its Acquisition Modality Actor in ~~is found in the Scheduled Workflow Integration Profile~~ (RAD TF-1: 3.3.4).**

*In 4.6.4.1.2.4.2, replace paragraphs or sentences as specifically marked.*

*Do NOT replace the complete 4.6.4.1.2.4.2. section, due to a parallel Change Proposal, which needs to be merged as well. The changes in the two texts do not overlap, so the order of applying the individual changes to the TF does not change the resulting text in the next TF version.*

#### **4.6.4.1.2.4.2 Assisted Acquisition Protocol Setting Option**

*This section is completely included in the Supplement in order to improve comprehensibility.*

When an Acquisition Modality Actor supports the ASSISTED ACQUISITION PROTOCOL SETTING option, it shall provide the means to use the protocol codes specified in the Scheduled Procedure Steps selected from the Modality Worklist.

According to the DICOM standard (PS 3.3): "A Protocol is a specification of actions prescribed by a Procedure Plan to perform a specific Procedure Step. A Scheduled Procedure Step contains only one Protocol that may be conveyed with one or more Protocol Codes. So, each Scheduled Procedure Step is performed according to a single Protocol which may be identified by one or more Protocol Codes." This option refines the semantics of the interpretation of Protocol Codes specifically in the case where more than one Protocol Code is present.

A Scheduled Procedure Step may contain a single Protocol Code, for example:

- A "Standard Chest X-ray" Protocol Code. This implies PA and Lateral views.

*Replace the 2<sup>nd</sup> bullet point with this text:*

- A ~~"Screening Mamography"~~ Protocol Code **"Standard Screening" for a bilateral Mammogram**. ~~This~~ implies RMLO and LMLO, RCC and LCC views.

A Scheduled Procedure Step may also contain multiple Protocol Codes in cases where more complex SPS requires several acquisition or image processing tasks be performed in a sequential manner, for example:

- An “MRI Acquisition” Protocol Code followed by an “MRA Acquisition” Protocol Code.
- A “CT Head without contrast” Protocol Code followed by a “CT with contrast” Protocol Code.
- A “CT Lumbar Spine” Protocol Code followed by a “Reformation of the discs” Protocol Code.
- A “CT Thorax” protocol Code followed by a “Recon with lung kernel” Protocol Code.

In this option, an Acquisition Modality shall process the protocol code sequence in each Scheduled Procedure Step (SPS) selected from the Modality Worklist and return the Performed Protocol Codes in the Performed Procedure Step (PPS). Department System Schedulers and Image Managers shall support the use of more than one Protocol Code in the Scheduled Protocol Code (SPC) Sequence. Modalities shall support either a single code or multiple codes in the SPC sequence. If a Department System Scheduler/Order Filler communicates with modalities that support only a single Protocol Code in the Scheduled Protocol Code Sequence, the procedure plan (mapping of order into requested procedures, scheduled procedure steps, and protocol codes) shall only use single protocol codes per SPS. The institution may decide to configure its Department System Scheduler to either schedule all Scheduled Procedure Step with a single code or to schedule Steps on modalities based on their capabilities and handling of multiple Procedure Codes.

The modality operator shall either accept the protocol proposed by the set of Protocol Codes or select one or more alternative protocol defined on the Modality. The operator shall not manually enter the attributes of the acquisition protocol as in the Manual Modality Setting. The Assisted Acquisition Protocol Setting Option simplifies the operator’s work on the modality and enables a better management of the protocols used in an imaging department. This option may provide benefits for charge posting.

When multiple Scheduled Protocol Codes are present in the SPC Sequence, each Scheduled Protocol Code shall be analyzed independently (i.e., not as a compound code). It follows that:

- The modality settings resulting from the simultaneous processing of the ordered set of Protocol Codes is semantically equivalent to the sequential processing of each Protocol Code independently. In other words, no additional semantics may be inferred from the simultaneous processing of multiple Protocol Codes in the sequence, and
- Protocol Codes shall be proposed to the operator in the order defined in the sequence. The Operator may choose to perform this sequence of Protocol Codes in a different order than scheduled, omit performing some of the protocol codes or include others.

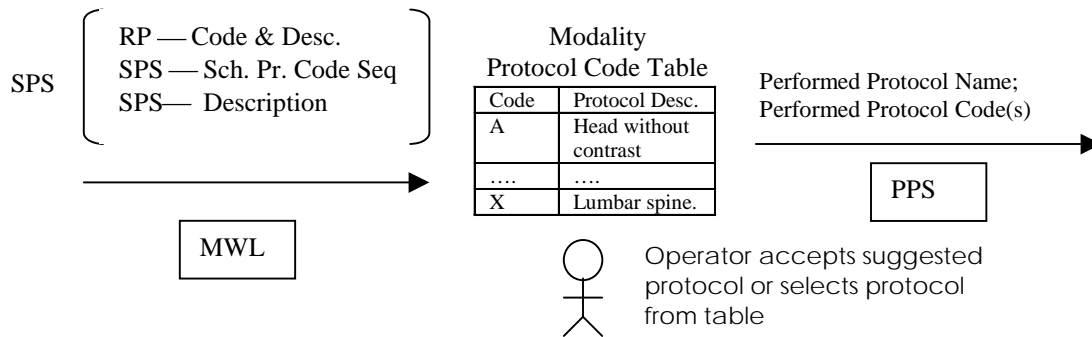
Whether the Scheduled Procedure Step includes one or several Protocol Codes, each Protocol Code shall be processed according to the Protocol Codes defined in the Modality Protocol Code Table.

- If a match is found, the modality settings defined in the Modality Protocol Code Table, shall be proposed to the operator. The operator may then choose to:
  - Accept the settings (i.e. modality acquisition parameters) proposed. In this case the Performed Protocol Code will take the value of the Scheduled Protocol Code.
  - Accept the settings (modality acquisition parameters) and refine them. (Local policy will determine what refinements are acceptable within a specific protocol code). In this case the Performed Protocol Code will take the value of the Scheduled Protocol Code.
  - Reject the settings proposed and manually select another protocol defined in the Modality Protocol Table. In this case the Performed Protocol Code will take the value of the manually selected Protocol Code (see recommendations in Tables A.1-1 to A.1-5 in Appendix A).
- If there is no identical Protocol Code defined in the Modality Protocol Table, the Acquisition Modality must alert the operator.

*Add a bullet point at the end:*

- **To enable accepting or rejecting protocol codes, an Acquisition Modality participating in the Mammography Acquisition Workflow Integration Profile shall be able to let an operator perform a procedure different than what was specified by the Requested Procedure Code (0032,1064). When this single code is changed, the Acquisition Modality shall fill it into Procedure Code Sequence (0008,1032) of the next MPPS to be sent.**

A Modality Protocol Table shall be configured on the Acquisition Modality. This table shall be synchronized with the Image Manager and the Department System Scheduler/Order Filler. A simple approach may be used to achieve such synchronization: if a requested Protocol Code is received, but not yet defined, the Acquisition Modality may provide a means to notify the operator that the Modality Protocol Table needs to be updated by creating the detailed acquisition settings corresponding to the new protocol Code.



When the ASSISTED ACQUISITION PROTOCOL SETTING option is supported by the Acquisition Modality actor, a value for the Performed Protocol Code Sequence shall be provided in addition to the Protocol Name. If multiple Protocol Codes have been selected and the corresponding acquisitions performed, the order of the Protocol Codes in the sequence shall reflect the order in which they were performed. This order may differ from the order in which they appeared in the Scheduled Protocol Code Sequence.

The ASSISTED ACQUISITION PROTOCOL SETTING option does not define a specific codification of acquisition protocols. The involved actors, Department System Scheduler, Acquisition Modality, Image Manager/Archive and Report Manager shall be configurable in order to support the codification scheme selected or defined by the healthcare enterprise.

*Add this paragraph at the end of 4.6.4.1.2.4.2:*

**An Acquisition Modality participating in the Mammography Acquisition Workflow Integration Profile shall be configurable to process all codes defined in 4.5.4.2.2.2:**

- **It shall be able to use the same sets of codes describing Procedures and Protocols as those used by the DSS/OF (see RAD TF-2: 4.5.4.2.2.2, Tables 4.5-5 and 4.5-6) for its acquisition settings as defined above in this section.**
- **For each item in the Reason for Requested Procedure Code Sequence (0040,100A), independent of its position in the sequence (a different order does not change the semantics of the Sequence), it shall be able to**
  - **Decide if this code can help select Modality settings for the acquisition, e.g. view settings;**
  - **Let an operator change the code and fill the changed code into the MPPS' Reason for Performed Procedure Code Sequence (gggg,eee1);**
  - **Copy the code into the MPPS' Reason for Performed Procedure Code Sequence (gggg,eee1) if it was not changed at the Acquisition Modality.**

*Note: The Reason for Performed Procedure Code Sequence is requested to be added by DICOM, see RAD TF-1: B.2.2.*

#### 4.6.4.1.3 Expected Actions

The Department System Scheduler/Order Filler, Report Manager and the Image Manager/Image Archive receive information from the Performed Procedure Step Manager and link it with the Requested Procedure and Scheduled Procedure Step. If the Requested Procedure ID is transmitted empty (Unscheduled Performed Procedure Step case), the Department System Scheduler/Order Filler and the Image Manager shall create an exception that must be manually resolved to link the Performed Procedure Step to the appropriate procedure.

*Add this new section 4.6.4.1.3.1:*

##### **4.6.4.1.3.1 Procedure and Protocol Changes at the Modality in Mammography Acquisition Workflow**

**An Acquisition Modality in the Mammography Acquisition Workflow Integration Profile may trigger a procedure change by sending an MPPS with Procedure Codes that differ from the corresponding code in the Scheduled Procedure Step.**

Note: The Reason for a Procedure may change when the Procedure is changed at the Modality. IHE requests DICOM to add a Reason for Performed Procedure Code Sequence (gggg.eee1) to the MPPS, see RAD TF-1: B.2.2.

**Therefore, the DSS/OF participating in the Mammography Acquisition Workflow Integration Profile shall process such differences between scheduled and performed Procedures in an MPPS by the following method: If it detects by comparing the Requested Procedure (0032,1064) and performed Procedure (0008,1032) Code Sequences that one or more items in these sequences do not match (order is irrelevant), then it shall immediately fill the most recent MPPS Procedure Code Sequence (0008,1032) values into**

- **the same attribute of all Procedure Steps with the same Requested Procedure ID (0040,1001) it internally manages, e.g. in worklists.**
- **the OBR-44 field of a new Procedure Update message (RAD-13) that in addition shall have the following field values (see 4.13.4.2):**
  - **OBR-18 contains the Accession Number (0008,0050) of this triggering MPPS**
  - **OBR-19 contains the Requested Procedure ID (0040,1001) of this triggering MPPS**
  - **ORC-1 is set to 'XO' and ORC-5 to 'SC'.**

**This message shall be sent to the Image Manager/ Image Archive to notify it of the procedure changes.**

**Note that the Scheduled Workflow Integration Profile recommends an empty Procedure Code Sequence (0008,1032) in MPPSes if the scheduled and performed procedure differ (see RAD TF-2: A.1) - this triggers an interactive exception mechanism. Thus, the DSS/OF in the Mammography Acquisition Workflow Profile, due to its dependency on SWF, is able to handle both empty and non-empty Procedure Code Sequences (by user interaction or by automatic Procedure Update to the Image Manager, respectively).**

**The DSS/OF may be able to compare values in the Scheduled Protocol Code Sequence (0040,0008) and the Performed Protocol Code Sequence (0040,0260) of the same Modality PPS it receives. IHE does not define a required behavior that results from Protocol changes.**

## 4.7 Modality Procedure Step Completed/Discontinued

### 4.7.4.1 Procedure Step Completed/Discontinued

#### 4.7.4.1.1 Trigger Event

Technologist completes procedure step from the Acquisition Modality console.

*Replace 4.7.4.1.2 with the following text*

#### 4.7.4.1.2 Message Semantics

The Acquisition Modality uses the Modality Performed Procedure Step SOP Class (N-SET service) to inform the Performed Procedure Step Manager that a specific Performed Procedure Step has been completed or discontinued. The Acquisition Modality may **have used** the MPPS N-SET service **beforehand** to send intermediate updates of the Performed Procedure Step information.

The final N-SET has either the MPPS status of "COMPLETED" or "DISCONTINUED". The Performed Procedure Step Manager sends corresponding N-SETs to the Department System Scheduler/Order Filler, Image Manager and Report Manager.

When an N-SET is issued with a "DISCONTINUED" status, one or more Series of Instances may be referenced, if images were created and sent. Those Instances shall be Stored and Storage Committed.

Along with other information, the Acquisition Modality shall transmit information about the protocol it used to produce the SOP instances to the recipients. See Protocol Handling in sec. 4.6.4.1.2.4 for detailed discussion of this issue.

Note: DICOM specifies that when attributes are allowed to be set by an N-SET, the value provided by the last N-SET overrides any value set by an earlier N-CREATE or N-SET.

**An Acquisition Modality participating in the Mammography Acquisition Workflow Integration Profile shall be able to convey procedure and protocol changes by filling in the most recent values for**

- **Procedure Code Sequence (0008,1032), Performed Procedure Step Description (0040,0254)**
- **Reason for Performed Procedure Code Sequence (gggg,eee1)**
- **Performed Protocol Code Sequence (0040,0260), Protocol Name (0018,1030).**

Note: The Reason for a Procedure may change when the Procedure is changed at the Modality. IHE requests DICOM to add a Reason for Performed Procedure Code Sequence to the MPPS, see RAD TF-1: B.2.2.

#### 4.7.4.1.3 Expected Actions

The Image Manager, Report Manager and Department System Scheduler/Order Filler receive information about the Performed Procedure Step being complete or discontinued. The Image Manager, Report Manager and Department System Scheduler are not required to act on intermediate N-SET messages with the MPPS Status "IN PROGRESS".

The Requested Procedure may be considered complete if all Performed Procedure Steps related to all Scheduled Procedure Steps have been completed (or properly discontinued). Additional new (unscheduled) Performed Steps may be performed at any time, even after the Requested Procedure has been assigned complete scanning status. See relationship between Scheduled and Performed Procedure Steps in sec. 4.6.4.1.2.3 for detailed discussion of this issue.

*Add this new subsection to 4.7.4.1.3:*

#### **4.7.4.1.3.3 Procedure and Protocol Changes at the Modality in Mammography Acquisition Workflow**

**In the Mammography Acquisition Workflow Integration Profile (MAWF), the Modality may send a performed Procedure Code in an MPPS that differs from the Requested Procedure Code in the Scheduled Procedure Step from the Modality Worklist. The DSS/OF participating in MAWF shall detect this procedure change and immediately update its worklists and the Image Manager/ Image Archive as described in 4.6.4.1.3.1.**

*Note that the Scheduled Workflow Integration Profile recommends an empty Procedure Code Sequence (0008,1032) in MPPSes if the scheduled and performed procedure differ (see RAD TF-2: A.1) - this triggers an interactive exception mechanism. Thus, the DSS/OF in the Mammography Acquisition Workflow Profile, due to its dependency on SWF, is able to handle both empty and non-empty Procedure Code Sequences (by user interaction or an automatic Procedure Update to the Image Manager, respectively).*

## 4.8 Modality Images Stored

*Replace section 4.8.4.1.2 with the following text:*

### 4.8.4.1.2 Message Semantics

The Acquisition Modality uses the DICOM C-STORE message to transfer the images. The Acquisition Modality is the DICOM Storage SCU and the Image Archive is the DICOM Storage SCP.

The technologist validates the available information for the patient and the Scheduled Procedure Step/Requested Procedure. It is a requirement that certain information be recorded in the image header. The details of the mapping to DICOM image instances are specified in appendix A. Effectively, this appendix strengthens the type definition of some DICOM attributes for the IHE Technical Framework.

**An Acquisition Modality participating in the Mammography Acquisition Workflow Integration Profile shall fill into the images the most updated values for Procedure Codes (0008,1032), Performed Procedure Step Description (0040,0254), Reason for Performed Procedure Codes (gggg,eee1), Performed Protocol Codes (0040,0260) (see also 4.6.4.1.2.4.2) and Protocol Name (0018,1030). This is necessary to convey ad hoc procedure changes as early as possible.**

**Note: The Reason for a Procedure may change at the FFDM Modality. IHE requests DICOM to add a Reason for Performed Procedure Code Sequence to Composite Instances, see RAD TF-1: B.2.2.**

*Add a section for defining correction of labeling of images:*

#### 4.8.4.1.2.4 View correction in Mammography images (MAWF)

**This section describes how already archived images with wrong view information are corrected later at the same Acquisition Modality that acquired these images. Transaction RAD-66 (see 4.66) defines that corrected images are referenced in MPPS and that incorrect images are referenced in a Key Object Selection instance.**

**The Acquisition Modality in the Mammography Acquisition Workflow Integration Profile shall provide an operator the capability to correct view information in Mammography images for the following values:**

- **View Code Sequence (0054,0220),**
- **View Modifier Code Sequence (0054,0222),**
- **Image Laterality (0020,0062),**
- **Performed Protocol Codes ((0040,0260), to ensure that view/ laterality can be corrected, if protocol codes contain them).**

**In order to keep an image's view information consistent, the Acquisition Modality shall correct all these values consistently and shall also update values for Patient Orientation (0020,0020) and the pixel matrix in the Image Pixel Module as necessary.**

**A corrected image to the incorrect image shall be created as a new instance of the same SOP Class as the incorrect image in a new Series of the same Study and shall**

- **Fill in new, corrected values for image attributes as described above.**
- **Correctly reference FOR PRESENTATION and FOR PROCESSING images:**
  - **If For Presentation and related For Processing images are corrected, then the references in the For Presentation images' Source Image Sequence (0008,2112) shall contain the references to the corrected For Processing images.**
  - **If only For Presentation images are corrected, then the references to the non-corrected For Processing images in Source Image Sequence (0008,2112) shall be removed from the corrected For Presentation images.**
- **Otherwise, copy all other values from the incorrect, original image.**

## 4.13 Procedure Update

*Editorial Note: A recent IHE RAD Change Proposal (RAD CP 135) adds explainig text to 4.13.1 on the issue of synchronizing code sets in order to enable the same sets of codes to be used consistently between DSS/OF, Modality, and Image Manager/ Archive:*

**"The organization operating the DSS/OF and the Image Manager/Image Archive is responsible for synchronizing Procedure and Protocol Codes between all the systems that use such codes. IHE does not yet define a common mechanism for code synchronization or access."**

*Add the following section 4.13.4.2.1 to Message Semantics:*

### 4.13.4.2.1 Propagate Procedure Changes by the Modality to the Image Manager/ Image Archive (Mammography Acquisition Workflow)

**In the Mammography Acquisition Workflow Integration Profile, the Acquisition Modality may trigger a procedure change by sending MPPS Procedure Codes that differ from the corresponding code in the Scheduled Procedure Step (see RAD TF-2: 4.6.4.1.2.4, 4.6.4.1.3.1).**

**The DSS/OF participating in the Mammography Acquisition Workflow Integration Profile shall process such differences as defined in RAD TF-2: 4.6.4.1.3.1. Then, it shall immediately create a new Procedure Update message and**

- **Copy from this triggering MPPS the values of Accession Number (0008,0050) into OBR-18, and the value of Requested Procedure ID (0040,1001) into OBR-19.**
- **Fill the most recent Procedure Code Sequence (0008,1032) values into its OBR-44 field,**
- **Set its ORC-1 to 'XO' and ORC-5 to 'SC'.**

**This message shall be sent to the Image Manager/ Image Archive to notify it of the procedure changes.**

## 4.14 Query Images

*Replace section 4.14.4.1.1 with the following text:*

### 4.14.4.1.1 Trigger Events

The user at the Image Display wishes to view selected images. **If the Image Display is grouped with another IHE Actor, e.g. an Evidence Creator, a system-internal trigger may occur.**

## 4.16 Retrieve Images

### 4.16.4.2 View Images

*Add the following section to 4.16:*

#### **4.16.4.2.2.5 Presentation of Mammography images based on Workflow information (Mammography Acquisition Workflow)**

**An Image Display participating in the Mammography Acquisition Workflow Integration Profile shall be able to display different procedures or additional views in specific presentation layouts, e.g. for conversion, recall or supplemental images. It shall be configurable to present Mammography images that were created in different workflow steps based on information from these image attributes:**

- **Procedure Code Sequence (0008,1932)**
- **Performed Protocol Code Sequence (0040,0260)**
- **Reason for Performed Procedure Code Sequence (gggg,eee1) .**  
**The Image Display shall be able to detect the recall-related codes, at least (MAWF0030, 99IHERADTF), (MAWF0031, 99IHERADTF), (MAWF0032, 99IHERADTF) as defined in Table 4.5-6, in this Code Sequence.**  
**If it has detected a recall-related code, it shall be able to present in one display layout both the current images and the images from the Study that caused the recall and that is referenced in the Referenced Study Sequence (0008,1110).**

**Note: The Reason for a Procedure may change at the FFDM Modality. IHE requests DICOM to add a Reason for Performed Procedure Code Sequence to Composite Instances, see RAD TF-1: B.2.2.**

## 4.18 Creator Images Stored

### 4.18.4.1 Images Stored

#### 4.18.4.1.1 Trigger Events

The Evidence Creator transfers images to the Image Archive sequentially within one or more DICOM associations, as the images become available or collectively.

Details about when it is appropriate to trigger the creation of a new Study/Series/Image Instance are described in section 4.8.4.1.1.1 “Study UIDs and Series UIDs”.

#### 4.18.4.1.2 Message Semantics

The Evidence Creator uses the DICOM C-STORE message to transfer the images. The Evidence Creator is the DICOM Storage SCU and the Image Archive is the DICOM Storage SCP.

Per the DICOM Standard, the Evidence Creator shall create a new series for its created images and not extend series containing source images.

The Evidence Creator derives images from source images, and the derived images may or may not have the same Image SOP Class as the source images.

The source images may include Performed Procedure Step relationship information. This information will include Scheduled Procedure Step information for the procedure performed at an Acquisition Modality. When present in the source images, the Evidence Creator shall extract appropriate Scheduled Procedure Step information and include it with PPS information produced by the Evidence Creator.

See Appendix A for rules on how to use the source image information in the derived image objects.

*Add a new section that defines how Mammo images (views) are corrected*

#### **4.18.4.1.2.5 View correction in Mammography images (MAWF)**

**The Evidence Creator in the Mammography Acquisition Workflow Integration Profile shall provide an operator the capability to correct view information in images. It shall perform corrections as defined for the Acquisition Modality in 4.8.4.1.2.4: the Evidence Creator shall show the same behavior as defined for the Acquisition Modality in this section.**

**In addition, the Evidence Creator shall add the following details about itself in the Contributing Equipment Sequence (0018,A001) of the new image:**

- **Purpose of Reference Code Sequence (0040,A170): contains an item having the code value (DCM, 109103, Modifying Equipment)**

- **Manufacturer (0008,0070)**
- **Manufacturer's Model Name (0008,1090)**
- **Software Versions (0018,1020)**
- **Institution Name (0008,0080)**
- **Contribution DateTime (0018,A002).**

**Note: Corrections by the Evidence Creator (normally a different system than the Modality that acquired the images) are specifically tracked in order to help clarify the change history. Private attributes created by the Modality may become inconsistent.**

## 4.30 Query Key Image Notes

*Replace 4.30.4.1.1. by the following text:*

### 4.30.4.1.1 Trigger Events

The user at the Image Display wishes to view Key Image Notes to use as a guide to find significant images. **An Image Display may query for Key Image Notes when a new patient is loaded in order to perform internal logic.**

*Replace 4.30.4.1.3 with the following text*

### 4.30.4.1.3 Expected Actions

The Image Archive receives the C-FIND request, performs the matching on the provided keys and sends the list of matching records back to the Image Display via C-FIND responses.

**The Image Archive participating in the Mammography Acquisition Workflow Integration Profile shall include or not include matching records related to specific KOS instances that mark rejected or corrected images as defined in 4.66.4.1.3 and 4.66.4.2.3.**

## 4.31 Retrieve Key Image Notes

*Replace 4.31.4.1.2 by the following text:*

### 4.31.4.1.2 Message Semantics

The message semantics are defined in the DICOM Query/Retrieve Service Class ~~section of the DICOM 2007 PS 3.4: Query/Retrieve Service Class~~. It is the responsibility of the Image Manager to assure that the patient and procedure information is current in the images and Key Image Note objects when they are retrieved from the Image Archive. It is the responsibility of the Imaging Document Source to assure that the patient and procedure information is current in the Key Image Note objects when they are retrieved from this Actor.

### 4.31.4.1.3 Expected Actions

The Image Archive or Imaging Document Source receives the C-MOVE request, establishes a DICOM association with the Image Display or Imaging Document Consumer, and uses the DICOM Key Image Note Storage SOP Class to transfer the requested Key Image Note objects.

**The Image Archive participating in the Mammography Acquisition Workflow Integration Profile shall include or not include specific KOS instances that mark rejected images as defined in 4.66.4.1.3.**

### 4.31.4.2 Render Key Image Notes

This transaction relates to the “Render Key Image Notes” event of the above interaction diagram. Key Image Notes cannot be rendered separately, but must be applied to images. Refer to ~~see~~ **RAD TF-2**: 4.16 for a description of the transaction used to retrieve images to which Key Image Notes may be applied.

The Image Display or Imaging Document Consumer is not required to, but may choose to, support retrieval and display of images from other studies than the one to which the Key Image Note belongs.

*Editorial: Add a period at the end of the preceding sentence.*

### 4.31.4.2.1 Trigger Events

The Image Display or Imaging Document Consumer receives Key Image Note instances from the Image Archive or Imaging Document Source.

#### 4.31.4.2.2 Invocation Semantics

This is a local invocation of functions resident within the Image Display or Imaging Document Consumer. The method used by the Image Display or Imaging Document Consumer to present images for viewing by the user flagged by the Key Image Notes is outside the scope of the IHE Technical Framework.

#### 4.31.4.2.3 Expected Actions

The Image Display or Imaging Document Consumer flags the images and renders the Key Image Note.

Note: It is recommended to use the just retrieved instance of the Key Image Note to ensure that the most recent patient data be displayed to reflect possible patient merge and patient update in the Image Manager/Image Archive or Imaging Document Source. This patient data may be inconsistent with patient data contained in a previously retrieved copy of the same Key Image Note instance.

*Add a section 4.31.4.2.3.1:*

#### **4.31.4.2.3.1 Presentation of rejected or incorrect images in Mammography Acquisition Workflow**

**An Image Display participating in the Mammography Acquisition Workflow Integration Profile may receive Key Image Notes with the Key Object Selection (KOS) Document Title valued (113001, DCM, "Rejected for Quality Reasons"). The Image Display shall support the three behaviors listed below. The behavior chosen shall be configurable as one of the following:**

- **Suppress from presentation the rejected instances referenced in this KOS and this KOS itself**
- **Present the rejected instances referenced in this KOS and this KOS itself**
- **Ignore this KOS and present the rejected instances.**

**If an Image Display receives a Key Image Note with the Key Object Selection (KOS) Document Title valued (113037, DCM, "Rejected for Patient Safety Reasons"), it shall suppress the KOS and its referenced rejected instances from presentation.**

Add the following text to Appendix A that clarifies the difference in mapping the critical integration value of the Requested Procedure Code to (Performed) Procedure Codes.

Replace the 1<sup>st</sup> paragraph in RAD TF-2: A.1 with the following text:

### A.1: Image Acquisition Integration-critical Attributes

The tables below describe requirements, recommendations or explanations on integration-critical attributes for image acquisition cases. They define which integration-critical attributes need to be equal (copied or generated locally), in order to correctly relate scheduled and performed procedure steps for the PPS cases described in 4.6.4.1.2.3.

**Note: These tables define the general mapping as used in the Scheduled Workflow Integration Profile (see RAD TF-1: 3). The Mammography Acquisition Workflow Integration Profile (see RAD TF-1: 23) uses the same mapping rules and behavior except for the mapping from Requested Procedure Code Sequence (0032,1064) to Procedure Code Sequence (0008,1032), where procedure changes may result in different performed procedure codes (see RAD TF-2: 4.6.4.1.2.4 and 4.7.4.1.2). For Mammography Acquisition Workflow, the Simple and Append Cases (Table A.1-1 and A.1-3) are most relevant and the other cases are much less relevant.**

Add text to the MAWF-relevant Table A.1-1 in the row for Procedure Code Sequence that explains the difference in handling Procedure Code and Protocol Codes in MAWF.

**Table A.1-1: Simple Case - required mapping of corresponding attributes**

In the simple normal case, a Procedure Step is performed

- exactly as scheduled, or
- different than scheduled, but without being rescheduled, e.g. due to a patient's allergic reaction to contrast media.
- 

DICOM attribute	Modality Worklist (return attribute values)	Filling values for:	
		Image/ Standalone IOD	MPPS IOD
Study Instance UID (0020,000D)	Source	Copy	Copy
Referenced Study Sequence (0008,1110)	Source	Copy	Copy
Accession number (0008,0050)	Source	Copy See (IHE-A.1.1)	Copy See (IHE-A.1.1)

DICOM attribute	Modality Worklist (return attribute values)	Filling values for:		
		Image/ Standalone IOD	MPPS IOD	
<b>Requested Procedure ID</b> (0040,1001)	Source	Request Attributes Sequence (0040,0275)	Copy	Copy
<b>Requested Procedure Description</b> (0032,1060)	Source		Copy Note: extended attribute	Copy
<b>Scheduled Procedure Step ID</b> (0040,0009)	Source		Copy	Copy
<b>Scheduled Procedure Step Description</b> (0040,0007)	Source		Copy	Copy
<b>Scheduled Protocol Code Sequence</b> (0040,0008)	Source		Copy	Copy
<b>Performed Protocol Code Sequence</b> (0040,0260)	n.a.	Equal (internally generated). Recommendation: Absent if the value is not known. Is non-empty if Assisted Protocol Setting option is supported (see 4.6.4.1.2.4).	Equal (internally generated). Shall be zero length if the value is not known, e.g. Assisted Protocol Setting not supported.	
<b>Study ID</b> (0020,0010)	n.a.	Equal (internally generated). Recommendation: use Requested Procedure ID.	Equal (internally generated). Recommendation: use Requested Procedure ID.	
<b>Performed Procedure Step ID</b> (0040,0253)	n.a.	Equal (internally generated). See (IHE-A.1.2)	Equal (internally generated).	
<b>Performed Procedure Step Start Date</b> (0040,0244)	n.a.	Equal (internally generated). Recommendation: use the same value for Study Date.	Equal (internally generated).	
<b>Performed Procedure Step Start Time</b> (0040,0245)	n.a.	Equal (internally generated). Recommendation: use the same value for Study Time.	Equal (internally generated).	
<b>Performed Procedure Step Description</b> (0040,0254)	n.a.	Equal (internally generated). Recommendation: use the same value for Study Description.	Equal (internally generated).	
<b>Requested Procedure Code Sequence</b> (0032,1064)	Value shall be used for Procedure Code Sequence as specified below.	n.a.	n.a.	
<b>Procedure Code Sequence</b> (0008,1032)	n.a.	Copy from: Requested Procedure Code Sequence (0032,1064). Recommendation: absent, if empty in MWL or performed acquisition is different to what was scheduled, <b>except in MAWF (see RAD TF-2: 4.6.4.1.2.4, 4.7.4.1.2).</b>	Copy from: Requested Procedure Code Sequence (0032,1064). Recommendation: empty, if empty in MWL or performed acquisition is different to what was scheduled, <b>except in MAWF (see RAD TF-2: 4.6.4.1.2.4, 4.7.4.1.2).</b>	

DICOM attribute	Modality Worklist (return attribute values)	Filling values for:		
		Image/ Standalone IOD	MPPS IOD	
<b>Referenced SOP Class UID</b> (0008,1150)	n.a.	<b>Referenced PPS Sequence</b> (IHE-A.1.3)	1.2.840.10008 .3.1.2.3.3	Equal (internally generated). See (IHE-A.1.4)
<b>Referenced SOP Instance UID</b> (0008,1155)	n.a.		Equal to SOP Instance of the associated MPPS (IHE-A.1.5).	Equal (internally generated). See (IHE-A.1.5)
<b>Protocol Name</b> (0018,1030)	n.a.	Recommendation: equal (internally generated)	<b>Performed Series Sequence</b> (0040,0340)	Equal (internally generated)

(IHE-A.1.1) A Zero Length Accession Number (One of the options proposed by DICOM PS3.4 Annex M) shall be created when no reliable value for this attribute is available. Reliable values are those that can be conveyed by means other than manual data entry such as a value received from the Order Filler via a Modality Worklist including an Accession Number or received through a bar code reader.

(IHE-A.1.2) Performed Procedure Step ID is generated by the modality arbitrarily and is not necessarily unique: Two different Performed Procedure Steps may share the same ID (e.g. may have been generated by different modalities). This ID may not enable a receiving system to reliably relate the PPS to the associated Requested Procedure and SPS. It is not reliable to assume that two PPSs with the same PPS ID value fulfill the same SPS/Requested Procedure, without checking the content of Scheduled Attributes Step Sequence.

(IHE-A.1.3) The Referenced Performed Procedure Step Sequence (0008,1111) that contains the PPS SOP Instance UID shall be included (per DICOM PS3.3 section C.7.3 strong recommendation, General Series Module Table, Note 1) when Acquisition Modality Actors support MPPS.

(IHE-A.1.4) In MPPS, SOP Class UID is sent in the Affected SOP Class UID (0000,0002) for the PPS N-Create message and in Requested SOP Class UID (0000,0003) for the PPS N-Set message. SOP Class UID (0008,0016) shall not be used.

(IHE-A.1.5) In MPPS, SOP Instance UID is sent in the Affected SOP Instance UID (0000,1000) of the PPS N-Create message and in Requested SOP Instance UID (0000,1001) for the PPS N-Set message. SOP Instance UID (0008,0018) shall not be used.

*Add text to the MAWF-relevant Table A.1-3 in the row for Procedure Code Sequence that explains the difference in handling Procedure Code and Protocol Codes in MAWF.*

**Table A.1-3: Append to a Simple/ Normal Case - required mapping of corresponding attributes**

Similar to the simple case, the first PPS is generated in response to an SPS. Other PPSes are added at a later time, for instance due to unacceptable quality of certain images.

DICOM attribute	Filling values for:			
	Original Image/ Standalone IOD	Append Image/ Standalone IOD	Append MPPS IOD	
<b>Study Instance UID</b> (0020,000D)	Equal (copied from MWL)	Equal (copied from MWL)	<b>Scheduled Step Attributes Sequence</b> (0040,0270)	Equal (copied from MWL)
<b>Referenced Study Sequence</b> (0008,1110)	Equal (copied from MWL)	Equal (copied from MWL)		Equal (copied from MWL)
<b>Accession number</b> (0008,0050)	Equal (copied from MWL). See (IHE-A.3.1).	Equal (copied from MWL). See (IHE-A.3.1).		Equal (copied from MWL). See (IHE-A.3.1).
<b>Requested Procedure ID</b> (0040,1001)	<b>Request Attributes Sequence</b> (0040,0275)	Equal (copied from MWL)		Equal (copied from MWL)
<b>Requested Procedure Description</b> (0032,1060)		Equal (copied from MWL)		Equal (copied from MWL)
<b>Scheduled Procedure Step ID</b> (0040,0009)		Equal (copied from MWL)		Equal (copied from MWL)
<b>Scheduled Procedure Step Description</b> (0040,0007)		Equal (copied from MWL)		Equal (copied from MWL)
<b>Scheduled Protocol Code Sequence</b> (0040,0008)		Equal (copied from MWL)	Equal (copied from MWL)	Equal (copied from MWL)
<b>Performed Protocol Code Sequence</b> (0040,0260)	Note: Values may not be relevant for the appended image and associated MPPS, e.g. due to adding images from an adjacent body region or from doing measurements.	Equal (internally generated). Recommendation: Absent if the value is not known. Is non-empty if Assisted Protocol Setting option is supported (see 4.6.4.1.2.4).	Equal (internally generated). Shall be zero length if the value is not known, e.g. Assisted Protocol Setting not supported.	
<b>Study ID</b> (0020,0010)	Equal (internally generated) Recommendation: use Requested Procedure ID.	Equal (internally generated) Recommendation: use Requested Procedure ID.	Equal (internally generated) Recommendation: use Requested Procedure ID.	
<b>Performed Procedure Step ID</b> (0040,0253)	Note: Values not relevant for the appended image and associated MPPS.	Equal (internally generated). See (IHE-A.3.2)	Equal (internally generated).	
<b>Performed Procedure Step</b>	Note: Values not relevant	Equal (internally	Equal (internally	

DICOM attribute	Filling values for:		
	Original Image/ Standalone IOD	Append Image/ Standalone IOD	Append MPPS IOD
<b>Start Date</b> (0040,0244)	for the appended image and associated MPPS.	generated). See (IHE-A.3.3)	generated).
<b>Performed Procedure Step Start Time</b> (0040,0245)	Note: Values not relevant for the appended image and associated MPPS.	Equal (internally generated). See (IHE-A.3.3)	Equal (internally generated).
<b>Performed Procedure Step Description</b> (0040,0254)	Note: Values not relevant for the appended image and associated MPPS.	Equal (internally generated). See (IHE-A.3.3)	Equal (internally generated).
<b>Requested Procedure Code Sequence</b> (0032,1064)	n.a.	n.a.	n.a.
<b>Procedure Code Sequence</b> (0008,1032)	Equal. Note: May be absent (see Table A.1-1)	Equal. If absent in original image, shall be absent here. Recommendation: absent, if performed acquisition is different from the original image's procedure, <b>except in MAWF (see RAD TF-2: 4.6.4.1.2.4, 4.7.4.1.2).</b>	Equal. If absent in original image, shall be empty. Recommendation: empty, if absent in the original/ appended image, <b>except in MAWF (see RAD TF-2: 4.6.4.1.2.4, 4.7.4.1.2).</b>
<b>Referenced SOP Class UID</b> (0008,1150)	<b>Referenced PPS Sequence</b> (0008,1111) (IHE-A.3.4) Note: Values not relevant for the appended image and associated MPPS.	<b>Referenced PPS Sequence</b> (0008,1111) (IHE-A.3.4) 1.2.840.10008.3.1.2.3.3 Equal to SOP Instance of the associated MPPS (IHE-A.3.6).	Equal (internally generated). See (IHE-A.3.5)
<b>Referenced SOP Instance UID</b> (0008,1155)			Equal (internally generated). See (IHE-A.3.6)
<b>Protocol Name</b> (0018,1030)	Note: Values not relevant for the appended image and associated MPPS.	Recommendation: equal (internally generated).	<b>Performed Series Sequence</b> (0040,0340) Equal (equally generated)

(IHE-A.3.1) A Zero Length Accession Number (One of the options proposed by DICOM PS3.4 Annex M) needs to be created when no reliable value for this attribute is available. Reliable values are those that can be conveyed by means other than manual data entry such as a value received from the Order Filler via a Modality Worklist including an Accession Number or received through a bar code reader.

(IHE-A.3.2) Performed Procedure Step ID is generated by the modality arbitrarily and is not necessarily unique: Two different Performed Procedure Steps may share the same ID (e.g. may have been generated by different modalities). This ID may not enable a receiving system to reliably relate the PPS to the associated Requested Procedure and SPS. It is not reliable to assume that two PPSs with the same PPS ID value fulfill the

same SPS/Requested Procedure, without checking the content of Scheduled Attributes Step Sequence.

- (IHE-A.3.3) In the Image IODs created in Append Case, the Study Date, Study Time and Study Description shall re-use the corresponding values from the original images to which they are appended.
- (IHE-A.3.4) The Referenced Performed Procedure Step Sequence (0008,1111) that contains the PPS SOP Instance UID shall be included (per DICOM PS3.3 section C.7.3 strong recommendation, General Series Module Table, Note 1) when Acquisition Modality Actors support MPPS.
- (IHE-A.3.5) In MPPS, SOP Class UID is sent in the Affected SOP Class UID (0000,0002) for the PPS N-Create message and in Requested SOP Class UID (0000,0003) for the PPS N-Set message. SOP Class UID (0008,0016) shall not be used.
- (IHE-A.3.6) In MPPS, SOP Instance UID is sent in the Affected SOP Instance UID (0000,1000) of the PPS N-Create message and in Requested SOP Instance UID (0000,1001) for the PPS N-Set message. SOP Instance UID (0008,0018) shall not be used.

If a PPS and related images is appended to a group case (see Rad TF-2, 4.6.4.1.2.3.3), e.g. for adding 3D post-processing evidence to a grouped MR head and neck exam, then the following conditions need to be considered for the appended images and MPPs, especially as compared to appending to a simple case:

- The Study Instance UID (0020,000D) in appended images and PPS shall have the same value as the Study Instance UID generated for the original grouped images.
- The Accession Number (0008,0050) shall be empty if the grouped SPS do not have the same Accession Number.
- The Referenced Study Sequence (0008,1110) in appended images shall have as many sequence items as there are different grouped Requested Procedures.
- The Request Attributes Sequence (0040,0275) in appended images shall have as many sequence items as there are grouped SPSes.
- The Scheduled Step Attributes Sequence (0040,0270) associated with the appended images shall have as many sequence items as there are grouped SPSes.
- Performed Protocol Code Sequence (0040,0260) will probably have different values than for the original grouped images.
- The Procedure Code Sequence (0008,1032) in appended images and the associated MPPS is recommended to contain as many items as there are different Procedure Codes in Requested Procedures if the system is able to ensure that what is acquired is what has been scheduled. It is recommended to be absent if the Procedure Code

Sequence is absent in MWL or the performed acquisition is different from what has been scheduled, **except in MAWF (see RAD TF-2: 4.6.4.1.2.4, 4.7.4.1.2).**

## Volume 3 - Transactions

### 4.49 Instance Availability Notification

*Replace 4.49.3 with the following text:*

#### 4.49.3 Referenced Standard

DICOM ~~2008 PS 3.4~~**Supplement 93, draft for letter ballot**: Instance Availability Notification

*Replace 4.49.4.1 with the following text:*

#### 4.49.4.1.1 Trigger Events

During image acquisition, an MPPS-capable Acquisition Modality creates a set of instances and stores them to an Image Manager/Image Archive. **During post-processing or quality control steps, an Evidence Creator creates one or multiple instances and stores them to an Image Manager/ Image Archive.** Alternatively as a part of importing Evidence Objects, an MPPS capable Importer imports instances and stores them to an Image Manager/Image Archive.

The Image Manager/Image Archive, after having received the last instance of the instance set referenced in the MPPS, shall send an Instance Availability Notification to the DSS/Order Filler that has also received the related MPPS. It may also decide to send the Instance Availability Notification to other instance managing actors in the workflow to inform them that all instances referenced in the related MPPS are available.

One Instance Availability Notification shall be sent for each MPPS that contains references to instances. MPPS without references to instances shall not trigger the sending of an Instance Availability Notification. This applies to all the MPPS cases described in transaction RAD-6 (Rad TF-2, 4.6: Simple Case, Unscheduled Case, Group Case, Append Case (Normal and Group Case), Abandoned Case) and in transaction RAD-7 (Rad TF-2, 4.7: MPPS DISCONTINUED, except the case of incorrect worklist entry selected, Rad TF 2, 4.7.4.1.3.1). **In addition, this applies to all cases of the Creator PPS transactions RAD-20 and RAD-21.** It also applies to the Import PPS cases described in transaction RAD TF-3: 4.59.4.1.2. 3- (Unscheduled Import and Unscheduled Import Cases) and the Import PPS Discontinued, RAD TF:3-4.60.4.1.2.2).

#### 4.49.4.1.2 Message Semantics

The end of the image acquisition **step** is indicated to the Department System Scheduler/Order Filler and Image Manager/ Image Archive by an MPPS message from the Acquisition Modality

referencing the DICOM instances that were created and are to be stored in the Image Manager/Image Archive. **The end of a post-processing or quality control step is indicated to the DSS/OF and Image Manager/ Image Archive by an MPPS message from the Evidence Creator referencing the DICOM instances that were created and are to be stored in the Image Manager/Image Archive.** The end of the DICOM object import is indicated to the Department System Scheduler/Order Filler and Image Manager/ Image Archive by an Import MPPS message from the Importer referencing the DICOM instances that were created and are to be stored in the Image Manager/Image Archive.

Note that the MPPS and Instance Availability Notification inform about different events. Thus, depending on the total volume of the images stored and characteristics of the local system environment, the MPPS may arrive considerably earlier at the DSS/OF than the Instance Availability Notification. The dependency of the IAN transaction on the MPPS Completed transaction may result in delayed notification to the DSS/OF of available instances, if the MPPS is not sent from the Acquisition Modality or Importer to the Image Manager/Image Archive in a timely fashion.

The Image Manager/Image Archive shall act as an Instance Notification SOP Class SCU and create an Instance Availability Notification SOP Class. It shall populate the Reference SOP Instance UID in the Referenced Performed Procedure Step Sequence. It shall include references to all instances that are referenced in the corresponding MPPS. The other attributes of the SOP Class are used as specified in DICOM Suppl. 93.

The Image Manager/Image Archive shall be able to send the Instance Availability Notification to multiple actors. The Image Manager/Image Archive shall send the Instance Availability Notification to the DSS/Order Filler and may be configured to also send it to other actors described in this transaction.

The DSS/Order Filler, Post-Processing Manager or the Report Manager shall understand that the receipt of this notification message implies that a complete set of instances is available at the Image Manager/Image Archive that is identified by the Retrieve AE Title attribute.

Due to transient error conditions (e.g. corrupted storage media, Query/Retrieve SCP not running) that may occur within the Image Manager/Image Archive, an actor may not be able to retrieve instances for which it has received availability notifications. If an actor is uncertain about the availability status of instances referenced by the Instance Availability Notification, it can use the Image Availability Query [RAD-11] to confirm the status as a supplementary method. Additionally, the Image Manager/Image Archive is assumed to be able to handle exceptions in instance storage or provision internally, based on local policy.

<i>Add a new section 4.49.4.1.2.1</i>
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#### **4.49.4.1.2.1 Availability status of rejected images in Mammography Acquisition Workflow**

**The Image Archive participating in the Mammography Acquisition Workflow Integration Profile receives the Key Image Note with the Key Object Selection Document Title valued (113001, DCM, "Rejected for Quality Reasons") or (113037, DCM, "Rejected for Patient Safety Reasons"), see RAD TF-2: B.2.3. According to the behavior configured (see 4.66.4.1.3) it shall send the following availability status:**

- **"UNAVAILABLE" when it is configured to hide rejected images.**
- **"ONLINE", "NEARLINE", "OFFLINE" when regular use of rejected instances is configured, depending on the actual availability of the individual instances.**

*Replace 4.49.4.1.3 with the following text:*

#### **4.49.4.1.3 Expected Actions**

The Department System Scheduler/Order Filler, Post-Processing Manager and Report Manager shall act as an Instance Notification SOP Class SCP. As a result of receiving the notification, the Department System Scheduler/Order Filler (or other actors) shall take appropriate action knowing that the referenced instances are available for further use in the workflow. Examples of such actions can be:

- The Department System Scheduler/Order Filler updates the procedure status internally, indicating that images for the procedure have been stored, **or are unavailable**.
- The Post-Processing Manager adds items to a corresponding worklist.
- The Report Manager adds items to a corresponding worklist.
- The Report Manager adds items to a list of relevant priors for use within Reporting.

*Add a new transaction RAD-66 to RAD TF-3 for storing the Key Object Selection instances that mark rejected/ incorrect images and that define certain IM/IA behavior beyond "storage only" (as defined in RAD-29):*

## 4.66 Image Rejection Note Stored

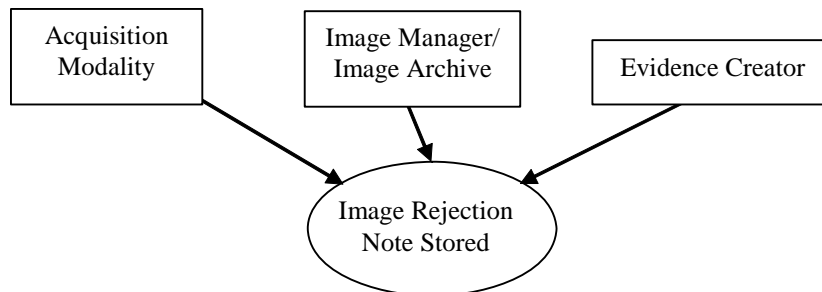
This section corresponds to Transaction RAD-66 of the IHE Technical Framework. Transaction RAD-66 is used by the Acquisition Modality and Evidence Creator actors.

### 4.66.1 Scope

In this transaction, the Acquisition Modality or the Evidence Creator transmit a specific DICOM Key Object Selection (Image Rejection Note) to the Image Manager/ Image Archive for marking referenced images as "rejected". Beforehand, a user will have:

- selected specific images to be rejected for quality reasons, including a reason for rejection, or
- corrected certain images so that the original incorrect images are to be rejected for patient safety reasons.

### 4.66.2 Use Case Roles



**Fig. 4.66-1 Use Case Diagram**

**Actor:** Acquisition Modality

**Role:** Flags acquired available images that are incorrect or rejected for quality reasons by creating an Image Rejection Note and sending it to the Image Manger/ Image Archive.

**Actor:** Evidence Creator

**Role:** Flags images that are incorrect or rejected for quality reasons by creating an Image Rejection Note and sending it to the Image Archive.

**Actor:** Image Manager/ Image Archive

**Role:** Image Archive accepts, processes and stores the Image Rejection Notes received from the Acquisition Modality or Evidence Creator. Image Manager/ Image Archive applies defined logic to the images that are referenced in the Image Rejection Note.

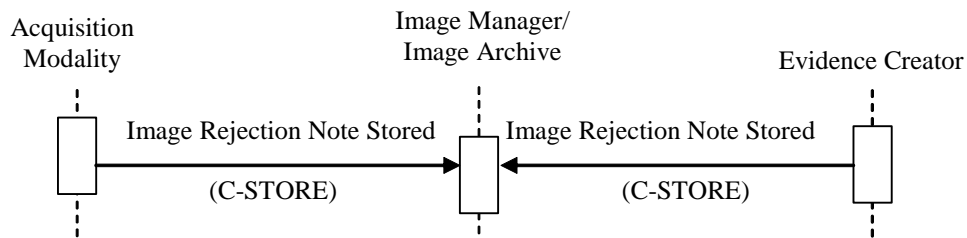
#### 4.66.3 Referenced Standards

DICOM 2008 PS 3.4: Key Object Selection Document Storage SOP Class

DICOM 2008 PS 3.4: Storage SOP Class

DICOM 2008 PS 3.16: TID 2010, CID 7011

#### 4.66.4 Interaction Diagram



**Fig. 4.66-2 Interaction Diagram: Image Rejection Note**

This transaction relates to the “DICOM C-STORE” event between the Acquisition Modality or the Evidence Creator and the Image Manager/ Image Archive in the above interaction diagram. The Acquisition Modality or the Evidence Creator is the DICOM Storage SCU and the Image Archive is the DICOM Storage SCP.

#### 4.66.4.1 Image Rejection Note Stored for Quality Reasons

##### 4.66.4.1.1 Trigger Events

An operator at the Acquisition Modality or the Evidence Creator detects that certain images just acquired are of insufficient quality. She marks these images using the capability provided by the systems implementing these actors. Thereby, she generates an Image Rejection Note which the Acquisition Modality or Evidence Creator sends to the Image Archive.

##### 4.66.4.1.2 Message Semantics

The Acquisition Modality or Evidence Creator shall create a new Key Object Selection instance in a new Series of the rejected images' Study. Integration-critical values shall be filled as defined in the Evidence Document Attribute Mapping (RAD TF-2: A.2). The instance shall be constructed as defined in DICOM PS 3.3 and 3.4, and shall have the following values in the DICOM template TID 2010:

- A Key Object Selection Document Title code of (113001, DCM, "Rejected for Quality Reasons").
- At least one Document Title Modifier code from DICOM Context Group 7011.
- References to all rejected images.

#### **4.66.4.1.3 Expected Actions**

The Image Archive receives the Key Object Selection with the Document Title valued (113001, DCM, "Rejected for Quality Reasons") and shall store it. The Image Manager/ Image Archive shall support the two behaviors listed below. The behavior chosen shall be configurable:

- Regular use: For the Key Object Selection instance and all images referenced therein, the Image Archive shall return SOP Instance UIDs in Query Responses and the instances in Patient, Study, Series, or Instance level retrievals.
- Hide rejected images: For the rejected instances referenced in the Key Object Selection, the Image Archive shall neither return SOP Instance UIDs in Query Responses nor return the images in Patient, Study, Series, or Instance level retrievals.

The Image Manager shall send an Instance Availability Notification (RAD-49) to the DSS/OF with the status "UNAVAILABLE".

#### **4.66.4.2 Image Rejection Note Stored for Patient Safety Reasons**

##### **4.66.4.2.1 Trigger Events**

An operator at the Acquisition Modality or the Evidence Creator detects that certain just acquired images are incorrect. She corrects these images using the capability provided by the systems implementing these actors. Thereby, she generates an Image Rejection Note which the Acquisition Modality or Evidence Creator sends to the Image Archive.

##### **4.66.4.2.2 Message Semantics**

The Acquisition Modality or the Evidence Creator shall be able to let a user correct one or more attributes in images that are displayed, depending on the image type:

- For Mammography images, the user shall be able to store new, corrected images at the Acquisition Modality as defined in 4.8.4.1.2.4 or at the Evidence Creator as defined in 4.18.4.1.2.5.
- For all other DICOM SOP Classes, IHE does not define a specific correction mechanism.

The Acquisition Modality or Evidence Creator shall create a new Key Object Selection instance in a new Series of the incorrect images' Study. Integration-critical values shall be filled as defined in the Evidence Document Attribute Mapping (RAD TF-2: A.2). The instance shall be constructed as defined in DICOM PS 3.3 and 3.4, and shall:

- have the Key Object Selection Document Title value (113037, DCM, "Rejected for Patient Safety Reasons") (new DICOM code to be requested, see RAD TF-1: B.2.3).
- reference all incorrect images (FOR PRESENTATION and FOR PROCESSING).

This Key Object Selection instance shall be stored to the Image Archive. It serves as a trigger to disallow routine use of these incorrect images that it references.

#### 4.66.4.2.3 Expected Actions

The Image Archive receives incorrect and corresponding corrected images, as well as the Key Object Selection (KOS) instance with the Document Title value (113037, DCM, "Rejected for Patient Safety Reasons") (new DICOM code to be requested, see RAD TF-1: B.2.3). The Image Archive shall be triggered by this specific Key Object Selection to hide the incorrect images and shall:

- Not provide this KOS instance in responses to Key Image Note query and retrieve requests (RAD-30, RAD-31).
- Not provide the incorrect instances referenced in this KOS in responses to an image query/ retrieve transaction (RAD-14, RAD-16).
- Instruct the Image Manager to send an Instance Availability Notification to the DSS/ OF that includes the unavailable instances (see RAD TF-3: 4.49.4.1.2.1), so that the DSS/ OF can track these changes.

Note that this hiding of incorrect instances is only triggered by a KOS with this specific title (in contrast to the general use of KOS as defined for Key Image Note, see RAD TF-1: 8).

*Add the following rows to the end of the table 5.1-2 in the Radiology Audit Trail Option to ITI-ATNA:*

<u>IHE Radiology Transaction</u>	<u>ATNA Trigger Event(s)</u>	<u>Actor(s) that shall be able to record audit event</u>
<u>Image rejection Note Stored [RAD-66]</u>	<u>Instances-deleted</u>	<u>Sender: Acquisition Modality, Evidence Creator.</u> <u>Note: The Actor rejecting/ correcting images must assume that the Image Archive may hide the images (similar to logical deletion).</u>
	<u>Instances-deleted</u>	<u>Receiver: Image Archive.</u> <u>Note: Although an Archive may be configured to provide rejected images, this may be changed any time by users. Thus, it is valuable to log this.</u>