

Integrating the Healthcare Enterprise



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**IHE Radiology
Technical Framework Supplement**

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**Imaging Object Change Management
(IOCM)**

15

Trial Implementation

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Foreword

25 This is a supplement to the IHE Radiology Technical Framework 12.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published on September 06, 2013 for trial implementation and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the Radiology Technical Framework. Comments are invited and may be submitted at http://www.ihe.net/Radiology_Public_Comments.

30 This supplement describes changes to the existing technical framework documents.

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

35 *Amend section X.X by the following:*

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

40 General information about IHE can be found at: www.ihe.net.

Information about the IHE Radiology domain can be found at: http://www.ihe.net/IHE_Domains.

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

The current version of the IHE Radiology Technical Framework can be found at: http://www.ihe.net/Technical_Frameworks.

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Introduction

In healthcare and Imaging centers, where images need to be shared among different systems, it is a common practice to distribute copies of imaging instances. At the same time, it is also common to modify studies or instances as follows:

- 165
- Correcting/updating demographics
 - Splitting/combining studies due to incorrect Modality Worklist item selection
 - Removing “bad” instances from circulation
 - Permanently deleting old imaging instances or entire studies as may be required by institutional record retention policies

170 The combination of needing to distribute copies of instances and needing to modify instances leads to copies which are inconsistent, which in turn creates the potential for confusion, error or loss of data.

This Supplement provides the support for the following three change management use cases:

- Data Retention Expiration.
- 175
- Correction or Rejection of Instances for Quality or Patient Safety Reasons.
 - Correction of Modality Worklist Selection.
 - This Supplement defines one new Actor: Change Requester. This actor can be grouped with existing actors in other profiles that have the ability to apply changes to existing imaging objects, in order to support imaging object change management.

180 Profile Abstract

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

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Open Issues and Questions

#	Issue/ (Answer)
2	Should a new instance contain a reference to the instance that it replaces? We could put the replacement relationship in the Referenced Image Sequence of the new instances. However, this Sequence is only available in the General Image module. That means only image objects can have this relationship defined. Therefore non-image

#	Issue/ (Answer)
	<p>objects such as GSPS will not have this relationship defined. It is important to note that it is still possible to replace a new GSPS object, for example, by deleting the existing one via a DICOM Key Object Selection Document (KOS) and then creating a new one. The only difference is that the new one will not have an explicit reference to the existing instance that it replaced.</p> <p>Committee Response: Yes. The reference would improve traceability which can be especially important in the data modification cases this Profile addresses.</p> <p>The current text includes this mechanism for images. A CP will be submitted to DICOM requesting a general attribute (e.g., Referenced Instance Sequence (0008, 114A) with a Purpose code that can be applied to all instances). See Section 4.74.4.1.2.</p>
3	<p>What “hiding behavior” is appropriate for instances that are rejected for quality reason?</p> <p>“Hiding Behavior” means that for instances that have been flagged with KOS for rejection, the Image Manager omits them from query results and refuses retrieval.</p> <p>Such hiding behavior is required for instances that are rejected due to patient safety reason.</p> <p>This specification proposes that for instances that are rejected for quality reasons, (inherited from MAWF) (but not for other reasons), there are two modes of behavior for both query and retrieve. The Image Manager / Archive must be able to support: (1) returning the KOS and the rejected instances, and (2) hiding the KOS and the rejected instances. However, there is no explicit mechanism defined in MAWF for how this should be done.</p> <p>Two possibilities were discussed:</p> <p>(1) Consumer AE Title driven server behavior, or</p> <p>(2) Server provides different AEs, one that returns all (correct and obsolete), one that returns only the latest view</p> <p>That means Image Manager / Archive has to support two AEs for Query and two AEs for Retrieve; one for administrative query/retrieve (i.e., return all), one for clinical query/retrieve (i.e., return latest, or hide rejected instances).</p> <p>Committee Response:</p> <ul style="list-style-type: none"> - Current text in MAWF only requires the IM to configure which mode to present, but does not specify a particular mechanism. - IOCM specifies the query/retrieve behavior is configurable based on the Called

#	Issue/ (Answer)
	<p>AE Title in the DICOM query/retrieve request</p> <ul style="list-style-type: none"> - Restriction of which mode to use is best handled by the IM, rather than always letting the consumer choose. Therefore the Profile specifies that the IM shall provide a configurable mechanism to control which systems have access to which behavior. No specific mechanism is defined though. See 4.66.4.1.3.1.
4	<p>What should be the behavior if the Image Manager supports MIMA? E.g., Can the rejected images due to quality reason allow to be sent.</p> <p>Committee Response:</p> <ul style="list-style-type: none"> - For images rejected due to quality reasons, these images should continue to be sent to the Receiving IM - For images rejected due to other reasons, these images should not be sent to the Receiving IM provided that they have not been sent prior to receiving the KOS
6	<p>Report related actors defined in SINR are currently excluded from this profile. Is this acceptable?</p> <p>Committee Response:</p> <p>Decision has been made to defer this to a future Supplement or Change Proposal, as we may want to address some of the larger issues, such as whether it still makes sense to have separate Image Manager and Report Manager actors.</p> <p>Affected actors: Report Creator, Report Manager, Report Repository, Enterprise Report Repository, Enterprise Report Repository Access</p>
7	<p>Is the recipient responsible for updating other instances that reference a deleted instance?</p> <p>Committee Response:</p> <p>No. It's too much to expect.</p> <p>For example, when an image is replaced a GSPS instance that references this image becomes useless because it references an image instance that is now gone/hidden.</p> <p>It would be challenging for a recipient to understand all the different SOP classes and all the possible reference attributes. The recipient would also need to judge if the reference is still valid to know if it <i>should</i> be updated.</p> <p>The creator of the objects that reference a deleted instance is encouraged (but not required) to maintain the referential integrity. IAN may be a useful tool for creators to be</p>

#	Issue/ (Answer)
	aware of deletions so they can make appropriate changes.
8	<p>Shall the use case Evidence Document Correction (X.3.5) be a named option?</p> <p>Committee Response:</p> <p>The Evidence Document Correction Use Case was removed because it is no longer mandatory for a Change Requester to support IAN (and take certain actions based on these notifications).</p>
9	<p>Would be it cleaner to use UPS rather than IAN to drive the DSS/OF behavior?</p> <p>In case of modality worklist selection correction, after the images are corrected, the Image Manager should update the DSS/OF so that DSS/OF can reset the procedure step back to Scheduled.</p> <p>Committee Response:</p> <p>The DICOM Unified Worklist and Procedure Step Service has not yet been incorporated into the IHE Profiles whereas IAN has. For now then, IAN is the best mechanism.</p>
10	<p>Would this profile be better as an option in SWF and PIR instead of a separate profile?</p> <p>The current profile uses grouping with the SWF and PIR for the required workflow related transactions. It may be difficult for the reader to understand the dependencies and what transactions are required.</p> <p>If this profile is an option in SWF and PIR, then it becomes more explicit which transactions are in scope.</p> <p>Committee Response:</p> <p>Decision has been made to keep IOCM as a separate Profile in order to increase its visibility as separate, but complementary, functionality to SWF and PIR.</p>
11	<p>How to differentiate between new original instances and replacement instances in the audit record?</p> <p>Committee Response:</p> <p>There does not appear to be a clear need to be able to distinguish between original and replacement instances for the purposes of audit logging.</p>
12	<p>For Table 4.74.4.1.2.1-1, should the Performed Procedure Step Start Date/Time of the replacement instances correspond to the time replacement instances are created, or should they be copied from the original instances?</p> <p>Committee Response:</p> <p>The replacement instances are still a result of the original Performed Procedure Step so</p>

#	Issue/ (Answer)
	they shall have the Start Date/Time of the original Performed Procedure Step.
13	<p>On the Rejection Note Stored transaction, for the Patient Safety Reason and Worklist Correction, the expected action stated that the Rejection Note itself should not be provided in query/retrieve or store. However, for the media export case, The Portable Media Creator is required to include the Rejection Note but not the rejected instances. Is it inconsistent behavior? For example, what if an Image Manager/Archive is also a Portable Media Creator?</p> <p>Committee Response:</p> <p>The required behavior can still be supported because the Image Manager / Archive can still keep the rejected note to itself so that it can be made available on the exported media.</p> <p>However, for the Data Retention Expired case, the expected action explicitly stated that the rejection note should be deleted, not just forbidden to be returned. Therefore the rejection note cannot be made available in the media.</p> <p>Furthermore, for all three use cases, the idea of making the rejection note available is to allow an Image Display which has obtained the prior copy of the study the ability to hide rejected instances if it receives the same study at a later time.</p> <p>So should IOCM be different from MAWF regarding the handling of the rejection note so that the KOS should still be available? This may make ‘dumb’ Image Displays unhappy if they receive a KOS with references to non-existing instances.</p>

Closed Issues

#	Issue/ (Answer)
1	<p>Is the Confirmation of Instances Availability option necessary? If yes, then should it be an option or should it be required?</p> <p>Response: Notification is a pro-active mechanism. Use case to notify the Requester could be accomplished with some other mechanisms (e.g., Requester could query at the instance level to find out if the receiving Image Manager / Archive has handled the object deletion / replacement properly). The second use case is for the receiving Image Manager / Archive to notify other systems about changes in the study. In fact, this second use case is a generalization of the first one in which one of the destinations is the Requester.</p> <p>Decided to make this transaction Required. Make sure the text handles one or more destinations.</p>

#	Issue/ (Answer)
	After public comment, we decided to remove the requirements of IAN completely except for the existing IAN requirement between IM/IA and DSS/OF that already exist in SWF.
2	<p>How do you find the latest information (i.e., ‘the Gold copy’)?</p> <p>Response: You can’t. Out of scope for this profile.</p> <p>In practice, there is not necessarily any authoritative reference for any instance.</p>
3	<p>Does MAWF change as a result of IOCM?</p> <p>Response: No. Leave MAWF as is. IOCM introduces no incompatibilities.</p>
4	<p>Inconsistency about content of IAN compared to Administrative Query and Clinical Query. i.e., IAN listed all instances (available and unavailable) but Administrative Query returns all while Clinical Query returns only available.</p> <p>Response: All available instances have status ‘available’. All obsolete instances have status ‘unavailable’. KOS with the four specific document titles defined in IOCM have status ‘unavailable’.</p>
5	<p>Should this profile discuss PIR across multiple enterprises?</p> <p>MIMA requires the forwarding of HL7 messages to multiple destinations (e.g., local IM/IA and enterprise IM/IA) which will trigger the external IM/IA to update the patient and procedure information, for example. In these cases, there is no requirement to create new instances and no requirement to push instances out to another IM/IA.</p> <p>Response: Call out that existing PIR use cases remain and as the preferred mechanisms. Add to Volume 1.</p>
6	<p>How does an item get back on the Worklist after it has been incorrectly selected?</p> <p>For the use case of Correction of Modality Worklist Selection, when the study is fixed to the correct MWL entry, new MPPS N-Create and N-Set will be sent for the corrected images. This allows the DSS/OF to update the scheduled procedure status of the correct MWL entry accordingly. However, since the incorrectly selected scheduled procedure has already been marked as ‘completed’, how does it get back on the worklist?</p> <p>Is it necessary to have an automated mechanism to reset the status of this scheduled procedure step in the DSS/OF? If yes, then how? The challenge is that according to DICOM, it is invalid to set another N-Set for the MPPS SOP Instance once its status is set to COMPLETED or DISCONTINUED. There does not seem to be any available mechanism that can reset a SPS status in the DSS/OF.</p> <p>Response: Use Keep the IAN notification to DSS/OF as a trigger for DSS/OF to re-open the wrong worklist item. (same as MAWF) (NOTE: This overlaps with open issue #9)</p>

#	Issue/ (Answer)
7	<p>Should the KOS be persisted?</p> <p>Response: Sometimes. The KOS should not be persisted for data retention use case because the KOS contains patient and procedure information. The KOS should be persisted for other rejection reasons. The KOS should only be accessible for the case of quality reasons, but not the case for patient safety or incorrect worklist selection.</p>
8	<p>Which destinations should the Image Manager send IAN to?</p> <p>Response: There is no publish-subscribe mechanism. IAN destinations are configurable as defined in the RAD-49, but how to configure the destinations is not defined in IHE. Also specific consumer behavior is out of scope, although there is some informative text defined in this profile in Volume 1 suggesting how to use IAN to correct evidence documents.</p> <p>No more requirements related to IAN besides the existing transaction between Image Manager / Archive and DSS/OF. So this question is not an issue anymore.</p>

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Volume 1 – Integration Profiles

1.7 History of Annual Changes

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

- 195 • Added the Imaging Object Change Management Profile which defines synchronization mechanisms for imaging objects between a Change Requester and an Image Manager/Image Archive and the subsequent access behavior of the rejected instances.

2.1 Dependencies among Integration Profiles

Add the following to Table 2-1

200

Integration Profile	Depends on	Dependency Type	Comments
<u>Imaging Object Change Management</u>	<u>Scheduled Workflow</u>	<u>Required for workflow management</u>	<u>Defines how Image Manager/Image Archive can obtain scheduled worklist in order to correct the modality worklist selection of the acquired instances.</u> <u>Support communication of procedure steps and storage commitment when Change Requester is grouped with Acquisition Modality, Image Manager/Image Archive or Evidence Creator.</u> <u>Support Image Manager to Image Manager change management if Multiple Patient Identity Resolution option is supported.</u>
	<u>Patient Information Reconciliation</u>	<u>Required for reconciliation workflow</u>	<u>Support the patient information reconciliation mechanisms for the actor that is grouped with the Change Requester.</u>

Add the following section to section 2.1, towards the end of the Integration Profiles Overview

2.1.28 Imaging Object Change Management Integration Profile

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

210

Add the following new actors to Section 2.3 Actor Descriptions in TF Vol. 1, following the alphabetical order.

2.3 Actors Descriptions

215 Change Requester – A system that communicates changes to an Image Manager / Archive, indicating that certain imaging instances should be deleted. In addition, it may also send new versions of these imaging instances containing corrected information.

220 *Add a new column in Table 2.3-1 with title IOCM.*
Add a new row in Table 2.3-1 with first column (Actor) as Change Requester.
Mark an X in the cell for IOCM: Change Requester.
Mark an X in the cell for IOCM:Display(ITI), IOCM:Image Display, IOCM:DSS/OF, IOCM:Image Manager/Archive, IOCM:Importer, IOCM:Portable Media Creator, IOCM:Report
225 *Reader, IOCM:Print Composer, IOCM:Portable Media Importer, IOCM:Imaging Document Source, IOCM:Imaging Document Consumer*

Add the new transaction 74 Replacement Instances Stored to TF Vol. 1, section 2.4 Transaction Descriptions. Update the transaction number accordingly.

230 *Update the name of transaction RAD-66 from the MAWF Trial Implementation Supplement. Changes to Section 2.4 from the MAWF TI supplement are shown in red font.*

2.4 Transaction Descriptions

235 66. ~~Image~~ Rejection Note Stored – Create and send a manifest referencing images that are rejected for quality or patient safety reasons, **rejected for incorrect modality worklist selection, or deleted due to data retention expiration.** The manifest can be used to hide or provide rejected images later in routine use, based on specific configuration.

74. Replacement Instances Stored – A Change Requester send new updated instances with corrected header information to an Image Manager/Image Archive.

240 *Add a new column in Table 2.4-1 with title IOCM*
Add a new row in Table 2.4-1 with first column (Transaction) as Replacement Instances Stored [RAD-74].
Mark an X in the cell for IOCM:Replacement Instances Stored [RAD-74].
Modify the name of the transaction RAD-66 to Rejection Note Stored.

245 *Mark an X in the cells for IOCM:Instance Availability Notification [RAD-49] and IOCM:Rejection Note Stored [RAD-66].*
Mark an X in the cells for IOCM:Distribute Imaging Information on Media[RAD-47], IOCM:Query Images[RAD-14], IOCM:Retrieve Images[RAD-16], IOCM:Query Key Image Notes[RAD-30], IOCM:Retrieve Key Image Notes[RAD-30], IOCM:Imported Objects

250 *Stored[RAD-61], IOCM:Provide and Register Imaging Document Set – MTOM/XOP [RAD-68], IOCM:WADO Retrieve [RAD-55], IOCM:Retrieve Imaging Document Set [RAD-69], IOCM:Retrieve Presentation States [RAD-17], IOCM:Retrieve Reports [RAD-27], IOCM:Retrieve Evidence Documents [RAD-45].*

255 *Add the following bullet to TF Vol. 1, section 2.5 Product Implementations*

2.5 Product Implementations

- The Importer Actor is generic in terms of not defining a specific transport mechanism for the Evidence Objects it imports. It may be necessary for the Importer to be grouped with additional Actors to support specific transport mechanisms. For example, to support
260 import from PDI Media, the Importer Actor must be grouped with the Portable Media Importer Actor.
- **The Change Requester is generic in terms of not defining a specific mechanism for obtaining the original instances that it requests changes to. It shall be grouped with at least one of the following actors in order to obtain the original instances:**
 - **Evidence Creator**
 - **Acquisition Modality**
 - **Image Manager/Image Archive**

270 *Modify TF Vol. 1, section 3 Scheduled Workflow (SWF) as defined in the Multiple Image Manager Archive (MIMA) Profile. The modified text new for IOCM is in red.*

3 Scheduled Workflow (SWF)

...

Table 3.2-1: Scheduled Workflow - Actors and Options

Actor	Option	Transaction	Vol. & Section
Image Manager/ Image Archive	Availability of PPS-Referenced Instances	<u>Instance Availability Notification [RAD-49]</u>	RAD TF-3:4.49
	PPS Exception Management	<u>Modality Procedure Step Completed [RAD-7]</u>	RAD TF-2:4.7
	Performed Work Status Update - Receive	<u>Performed Work Status Update [RAD-42] (as the Receiver)</u>	RAD TF-2:4.42
	<u>Multiple Identity Resolution (see section 3.2.1)</u>	<u>Procedure Scheduled [RAD-4]</u>	<u>RAD TF-2:4.4</u>
		<u>Modality Procedure Step In Progress [RAD-6]</u>	<u>RAD TF-2:4.6</u>
		<u>Modality Procedure Step Completed [RAD-7]</u>	<u>RAD TF-2:4.7</u>
		<u>Creator Procedure Step in Progress [RAD-20]</u>	<u>RAD TF-2:4.20</u>
		<u>Creator Procedure Step Completed [RAD-21]</u>	<u>RAD TF-2:4.21</u>
		<u>Procedure Updated [RAD-13]</u>	<u>RAD TF-2:4.13</u>
		<u>Image Manager Instances Stored [RAD-70]</u>	<u>RAD TF-3:4.70</u>
		<u>Image Manager Storage Commitment [RAD-71]</u>	<u>RAD TF-3:4.71</u>
		<u>Image Manager Instances Query [RAD-72]</u>	<u>RAD TF-3:4.72</u>
		<u>Image Manager Instances Retrieval [RAD-73]</u>	<u>RAD TF-3:4.73</u>
		<u>Modality Images Stored [RAD-8]</u>	<u>RAD TF-2:4.8</u>
		<u>Query Images [RAD-14]</u>	<u>RAD TF-2:4.14</u>
		<u>Retrieve Images [RAD-16]</u>	<u>RAD TF-2:4.16</u>
		<u>Creator Images Stored [RAD-18]</u>	<u>RAD TF-2:4.18</u>
<u>Rejection Note Stored [RAD-66] (see note 4)</u>	<u>RAD TF-3:4.66</u>		
<u>Replacement Instances Stored [RAD-74] (see note 5)</u>	<u>RAD TF-3:4.74</u>		

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

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

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

280 Note 4: An Image Manager/Archive claiming to support the Multiple Identity Resolution Option plus the Imaging Object Change Management Profile shall support the expected actions defined for the Rejection Note Stored [RAD-66] transaction. An Image Manager/Archive claiming to support the Multiple Identity Resolution Option plus the Imaging Object Change Management Profile as a Change Requester shall also support the message semantics defined for the Rejection Note Stored [RAD-66] transaction.

285 Note 5: An Image Manager/Archive claiming to support the Multiple Identity Resolution Option plus the Imaging Object Change Management Profile shall support the expected actions defined for the Replacement Instances Stored [RAD-74] transaction. An Image Manager/Archive claiming to support the Multiple Identity Resolution Option plus the Imaging Object Change Management Profile as a Change Requester shall also support the message semantics defined for the Replacement Instances Stored [RAD-74] transaction.

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

Add Section 28

295 **28 Imaging Object Change Management (IOCM)**

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

300 IHE Scheduled Workflow Profile defines an PPS Exception Management Option (RAD TF-1:3.3.4 and RAD TF-2:4.7.4.1.3.1) which specifies how to correct the incorrectly selected worklist entry after the Modality Performed Procedure Step In Progress transaction has been issued but before the Modality Performed Procedure Step Completed transaction is issued. This Imaging Object Change Management profile addresses the use case in which the incorrect modality worklist selection is detected after the Modality Performed Procedure Step Completed transaction is issued.

310 The required workflow steps for the DSS/OF and the actors grouped with Change Requester are specified in the Scheduled Workflow Profile.

28.1 Actors/ Transactions

315 Figures 28.1-1, 28.1-2 and 28.1-3 show the actors directly involved in the Imaging Object Change Management Integration Profile and the relevant transactions between them. Other actors that may be indirectly involved due to their participation in Scheduled Workflow, Consistent Presentation of Images, etc. are not necessarily shown.

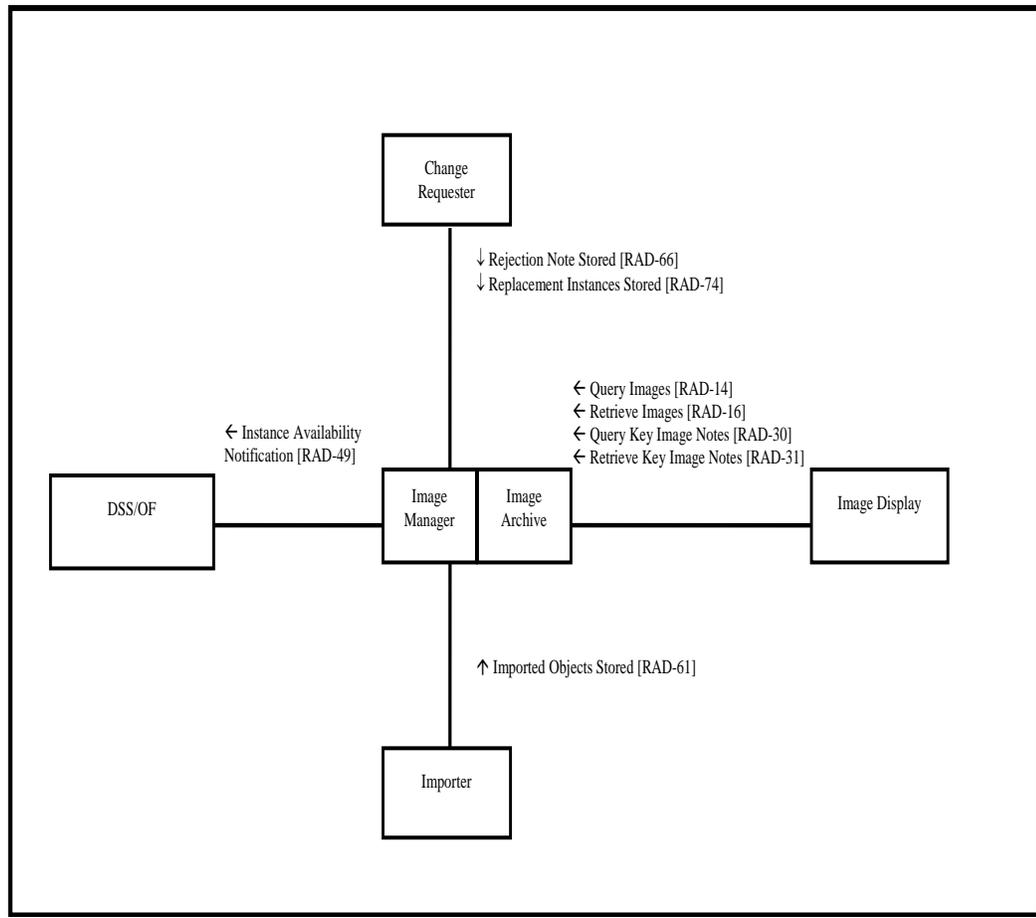


Figure 28.1-1: Imaging Object Change Management Actor Diagram related to SWF and IRWF

320

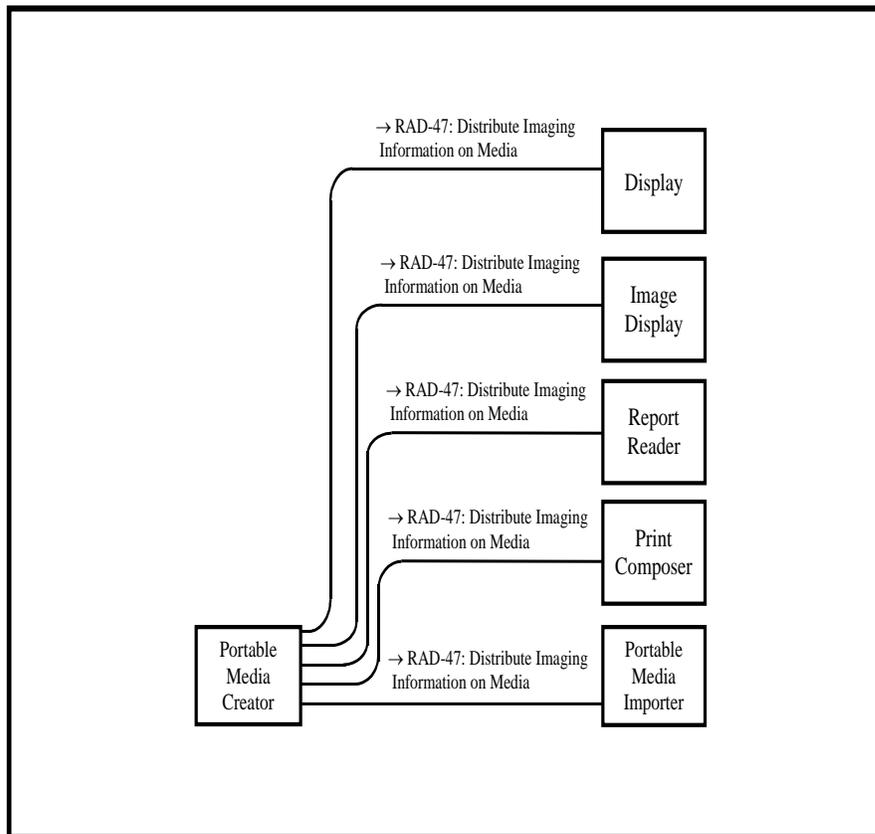


Figure 28.1-2: Imaging Object Change Management Actor Diagram related to PDI

325

If the Image Manager/Image Archive supporting IOCM is also grouped with an XDS-I.b Imaging Document Source then the Imaging Document Source shall support the IOCM functionality defined for the following transactions in Figure 28.1-3.

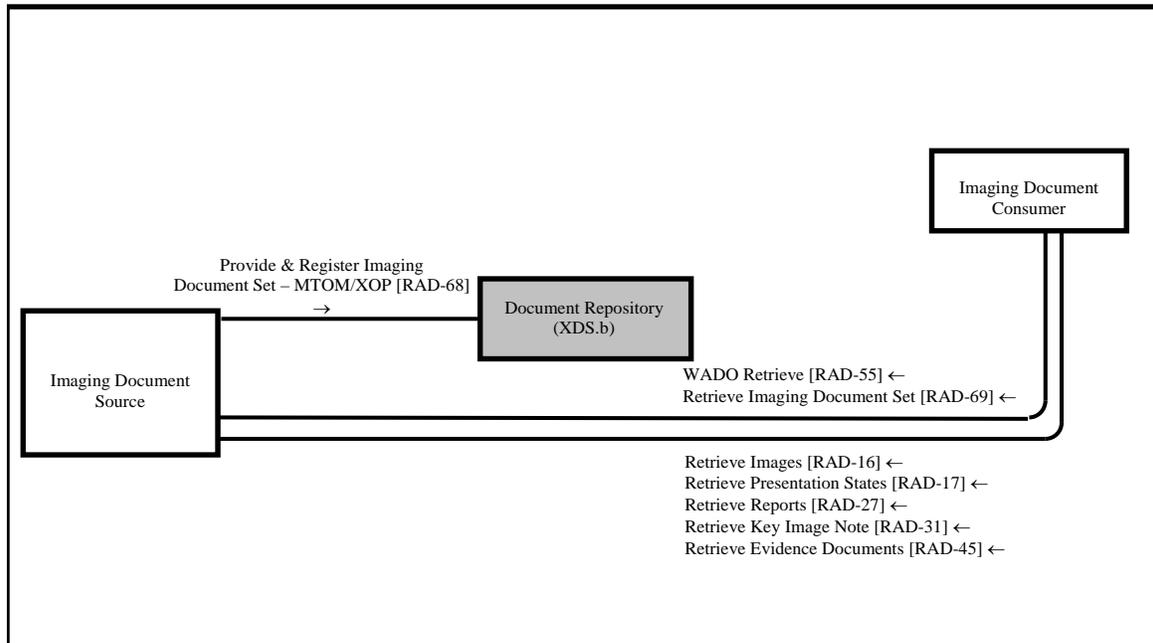


Figure 28.1-3: Imaging Object Change Management Actor Diagram related to XDS-I.b

330 Table 28.1-1 lists the transactions for each actor directly involved in the Imaging Object Change Management Profile. In order to claim support of this Integration Profile, an implementation must perform the required transactions (labeled “R”). Transactions labeled “O” are optional. A complete list of options defined by this Integration Profile and that implementations may choose to support is listed in Volume 1, Section 28.2.

335

Table 28.1-1: Imaging Object Change Management Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	Section in Vol. 2/3
Change Requester	Rejection Note Stored	R	4.66
	Replacement Instances Stored	R	4.74
Image Manager / Archive	Instance Availability Notification	R	4.49
	Rejection Note Stored	R	4.66
	Replacement Instances Stored	R	4.74
DSS/OF	Instance Availability Notification	R	4.49
Image Display	Query Images	R	4.14
	Retrieve Images	R	4.16
	Query Key Image Notes	R	4.30

Actors	Transactions	Optionality	Section in Vol. 2/3
	Retrieve Key Image Notes	R	4.31
	Distribute Imaging Information on Media	R	4.47 (Note 1)
Portable Media Creator	Distribute Imaging Information on Media	R	4.47
Display	Distribute Imaging Information on Media	R	4.47
Report Reader	Distribute Imaging Information on Media	R	4.47
Print Composer	Distribute Imaging Information on Media	R	4.47
Portable Media Importer	Distribute Imaging Information on Media	R	4.47
Importer	Imported Objects Stored	R	4.61
Imaging Document Source	Provide & Register Imaging Document Set – MTOM/XOP	R	4.68
	Retrieve Images	R	4.16
	Retrieve Presentation States	R	4.17
	Retrieve Reports	R	4.27
	Retrieve Key Image Note	R	4.31
	Retrieve Evidence Documents	R	4.45
	ADO Retrieve	R	4.55
	Retrieve Imaging Document Set	R	4.69
Imaging Document Consumer	Retrieve Images	R	4.16
	Retrieve Presentation States	R	4.17
	Retrieve Reports	R	4.27
	Retrieve Key Image Note	R	4.31
	Retrieve Evidence Documents	R	4.45
	WADO Retrieve	R	4.55
	Retrieve Imaging Document Set	R	4.69

Note 1: Distribute Imaging Information on Media transaction is required only if the Image Display actor supports the Portable Data for Imaging (PDI) Integration Profile.

340 28.2 Imaging Object Change Management Integration Profile Options

Options that may be selected for this Integration Profile are listed in the table 28.2-1 along with the Actors to which they apply. Dependencies between options when applicable are specified in notes.

Table 28.2-1: Imaging Object Change Management - Actors and Options

Actor	Options	Vol. & Section
Change Requester	<i>No option defined</i>	-

Actor	Options	Vol. & Section
Image Manager / Archive	<i>No option defined</i>	-
DSS/OF	<i>No option defined</i>	-
Image Display	<i>No option defined</i>	-
Portable Media Creator	<i>No option defined</i>	-
Display	<i>No option defined</i>	-
Report Reader	<i>No option defined</i>	-
Print Composer	<i>No option defined</i>	-
Portable Media Importer	<i>No option defined</i>	-
Importer	<i>No option defined</i>	-
Imaging Document Source	<i>No option defined</i>	-
Imaging Document Consumer	<i>No option defined</i>	-

345 **28.3 Imaging Object Change Management Integration Profile Actor Groupings and Profile Interactions**

Imaging Object Change Management builds upon the underlying Actor transactions defined in other Profiles. For this reason, certain IOCM Profile actors shall be grouped with actors from other Profiles as defined in Table 28.3-1.

350

Table 28.3-1: Imaging Object Change Management Integration Profile - Actors and Transactions

Integration Profile	Actor	Grouped With		Comments
		Profile	Actor	
Imaging Object Change Management	Change Requester (see note 1)	Scheduled Workflow	Acquisition Modality	Support communication of procedure steps and storage commitment when Change Requester is grouped with Acquisition Modality, Image Manager/Image Archive or Evidence Creator.
		Scheduled Workflow	Evidence Creator	
		Scheduled Workflow	Image Manager/Image Archive	Defines how Image Manager/Image Archive can obtain scheduled worklist in order to correct the modality worklist selection of the acquired instances.
	Image Manager/Image Archive	Scheduled Workflow	Image Manager/Image Archive	Support Image Manager to Image Manager change management

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Integration Profile	Actor	Grouped With		Comments
		Profile	Actor	
				if Multiple Patient Identity Resolution option is supported.
	Department System Scheduler/ Order Filler	Scheduled Workflow	Department System Scheduler/ Order Filler	VF defines how the Department System Scheduler/Order Filler provides scheduling information and receives updates from performed procedure steps and instance availability notification.
	Image Display	Scheduled Workflow	Image Display	VF defines message semantics for query-retrieval
	Change Requester (see note 1)	Patient Information Reconciliation	Acquisition Modality	R defines the patient information reconciliation mechanisms that shall be supported by these actors. IOCM shall not be used as an alternative mechanism for handling patient information reconciliation use cases.
		Patient Information Reconciliation	Image Manager/ Image Archive	
	Image Manager/ Image Archive	Patient Information Reconciliation	Image Manager/ Image Archive	
	Department System Scheduler/ Order Filler	Patient Information Reconciliation	Department System Scheduler/ Order Filler	
	Image Manager/ Image Archive	Import Reconciliation Workflow	Image Manager/ Image Archive	
	Department System Scheduler/ Order Filler	Import Reconciliation Workflow	Department System Scheduler/ Order Filler	IRWF defines the import reconciliation workflow mechanisms that shall be supported by these actors. IOCM specializes their behavior for handling change management use cases.
	Importer	Import Reconciliation Workflow	Importer	
	Portable Media Creator	Portable Data for Imaging	Portable Media Creator	
	Portable Media Importer	Portable Data for Imaging	Portable Media Importer	PDI defines the transactions that shall be supported by these actors to distribute imaging related information on interchange media. IOCM specializes their behavior for handling change
	Image Display	Portable Data for Imaging	Image Display	
	Report Reader	Portable Data for Imaging	Report Reader	
	Print Composer	Portable Data for	Print Composer	

Integration Profile	Actor	Grouped With		Comments
		Profile	Actor	
		Imaging		management use cases.
	Display (ITI TF)	Portable Data for Imaging	Display (ITI TF)	
	Imaging Document Source	Cross-Enterprise Document Sharing for Imaging	Imaging Document Source	XDS-I defines the transactions that shall be supported by these actors to share imaging information across enterprises. IOCM specializes their behavior for handling change management use cases.
	Imaging Document Consumer	Cross-Enterprise Document Sharing for Imaging	Imaging Document Consumer	

Note 1: At least one of the optional retrieve transactions is required to be supported. Refer to section 18.4 for additional requirements on the Imaging Document Consumer.

355 28.4 Imaging Object Change Management Process Flow

Imaging Object Change Management covers the following use cases:

- Data Retention Expiration
- Correction or Rejection of imaging instances for Quality Reasons
- Correction or Rejection of imaging instances for Patient Safety Reasons
- Correction of Modality Worklist Selection

360

The following use cases generally apply to all imaging objects as well as non-imaging objects including Grayscale Softcopy Presentation State (GSPS), Key Object Selection Document (KOS), Structured Report (SR), etc. although the examples may focus on the images themselves for simplicity.

365

The start and completion of creating Rejection Notes, and Replacement Instances if necessary, are reported as Procedure Steps In-Progress/Completed by the relevant IHE workflow actor that has been grouped with the Change Requester (either an Acquisition Modality or an Evidence Creator).

370

The Procedure Step transactions, Storage Commitment transaction, Query Modality Worklist transaction and the Query/ Retrieve Images transactions in the following diagrams are part of Radiology Scheduled Workflow as an example IHE Workflow Profile. They are not part of the Imaging Object Change Management Profile and are only included in the diagrams for illustration.

375

Note: There are existing profiles defined in the IHE Technical Framework that are also designed to manage changes in different aspects of imaging objects (e.g., Patient Information Reconciliation, Import Reconciliation Workflow, etc.) Vendors should continue to follow those integration profiles for their respective use cases.

28.4.1 Use Case: Data Retention Expiration

Instances may be deleted to comply with data retention policies.

- 380 • A local Image Manager / Archive, supporting the Multiple Identity Resolution option in IHE Scheduled Workflow Profile, stores instances to a centralized Image Manager / Archive for long term storage (IHE Supp MIMA RAD-70).
- Later, according to the data retention policy of the local Image Manager / Archive, selected studies are deleted internally.
- 385 • The local Image Manager / Archive has implemented the Change Requester actor of the IOCM Profile to communicate these changes to the centralized Image Manager / Archive.
- The local Image Manager / Archive, as an IOCM Change Requester, creates a Key Object Selection (KOS) instance with a Selection Document Title of “Data Retention Policy Expired” that lists the deleted instances, and sends this to the centralized Image Manager / Archive using the (RAD-66) transaction, followed by Storage Commitment (RAD-71).
- 390 • The centralized Image Manager / Archive receives the deletion requests and deletes the referenced studies accordingly.

The healthcare provider is responsible for drafting and implementing appropriate data retention policies (see 28.4).

395

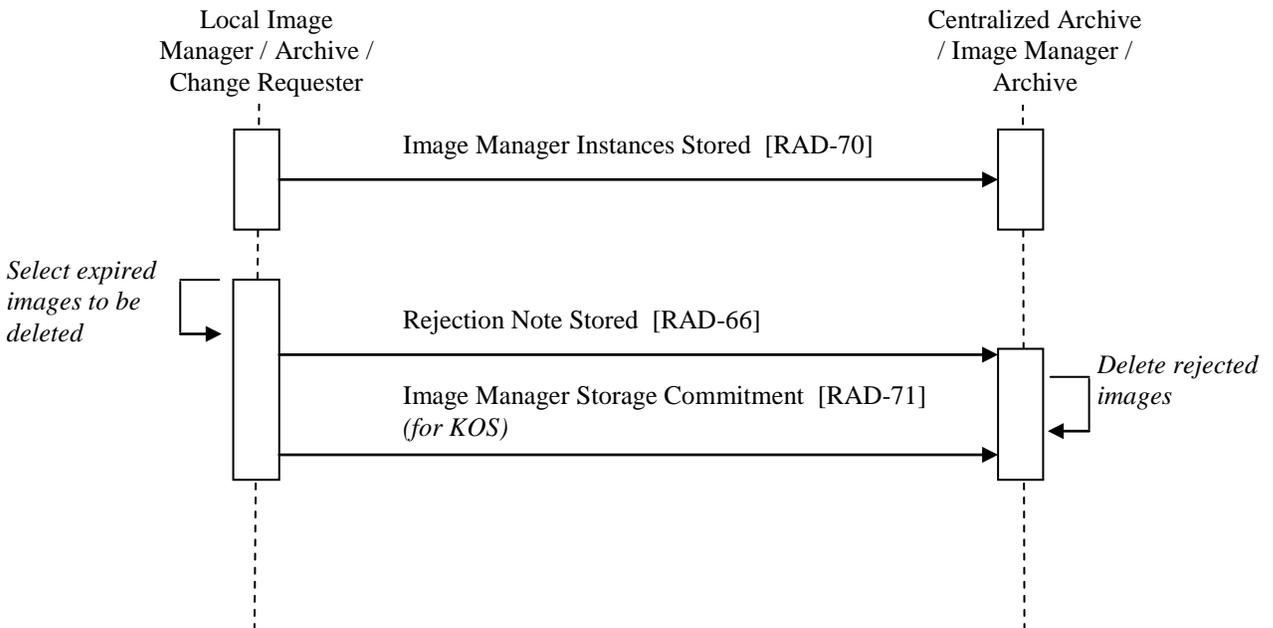


Figure 28.4.1-1: Process Flow for handling expired studies

400 **28.4.2 Use Case: Image Rejection for Quality Reasons**

Instances may be deleted for quality reasons. The Change Requester may be grouped with an Acquisition Modality actor, an Evidence Creator actor, or an Image Manager / Archive actor, depending on whether such QA happens on the modality, a separate workstation, or an image manager.

405 **Clinical aspect:** The Technologist or Radiologist decides that certain images are not useful for clinical use, e.g., due to patient motion. While correcting image acquisition context data on a Modality application, e.g., during quality control, the Technologist wants to mark these images as "rejected" so that other systems correctly handle the rejected images according to local policies. The procedure step has already been completed, and all images, including the rejected
 410 images, have been stored to the Image Manager / Archive.

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

415

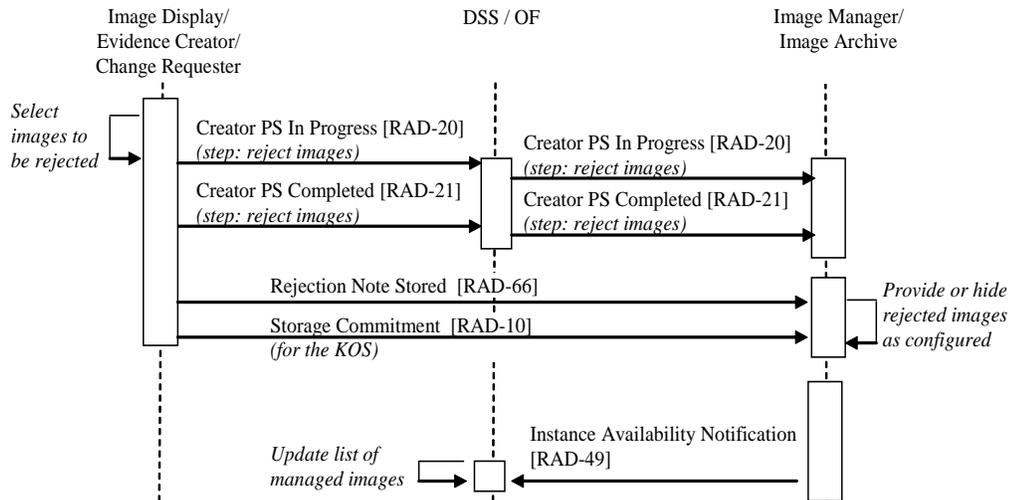


Figure 28.4.2-1: Process Flow for handling rejected images

420 **Technical aspect:** A user marks certain images of insufficient quality as "Rejected for Quality Reasons" and selects a reason. The Evidence Creator, as a Change Requester, creates a Key Object Selection (KOS) instance that references the rejected images with a Selection Document Title of "Rejected for Quality Reasons" and the reason. It creates a Creator PPS (RAD-20), sets it COMPLETED (including a reference to this KOS) and sends it to the DSS/OF (RAD-21). It also stores the KOS to the Image Manager / Archive (RAD-66), and then uses the Storage

425 Commitment (RAD-10) transaction. The Image Manager / Archive sends an Instance Available Notification (RAD-49) to the DSS/OF to confirm all the instances that remain available and those that are deleted.

The Image Manager / Archive can be configured to provide such rejected images or to hide them from subsequent query/ retrieve responses. An Image Display, when receiving a "Rejected for Quality Reasons" KOS, will display the images and / or KOS, or will hide both (RAD-16, per configuration).

430 **Variants:** Instead of an Evidence Creator being the Change Requester, an Image Manager is the Change Requester. The only difference will be that the Image Manager acting as the Change Requester does not have to create an MPPS referencing the Rejection Note or an MPPS
435 referencing the corrected images. In this case, the DSS/OF should monitor the IAN to maintain the complete list of instances.

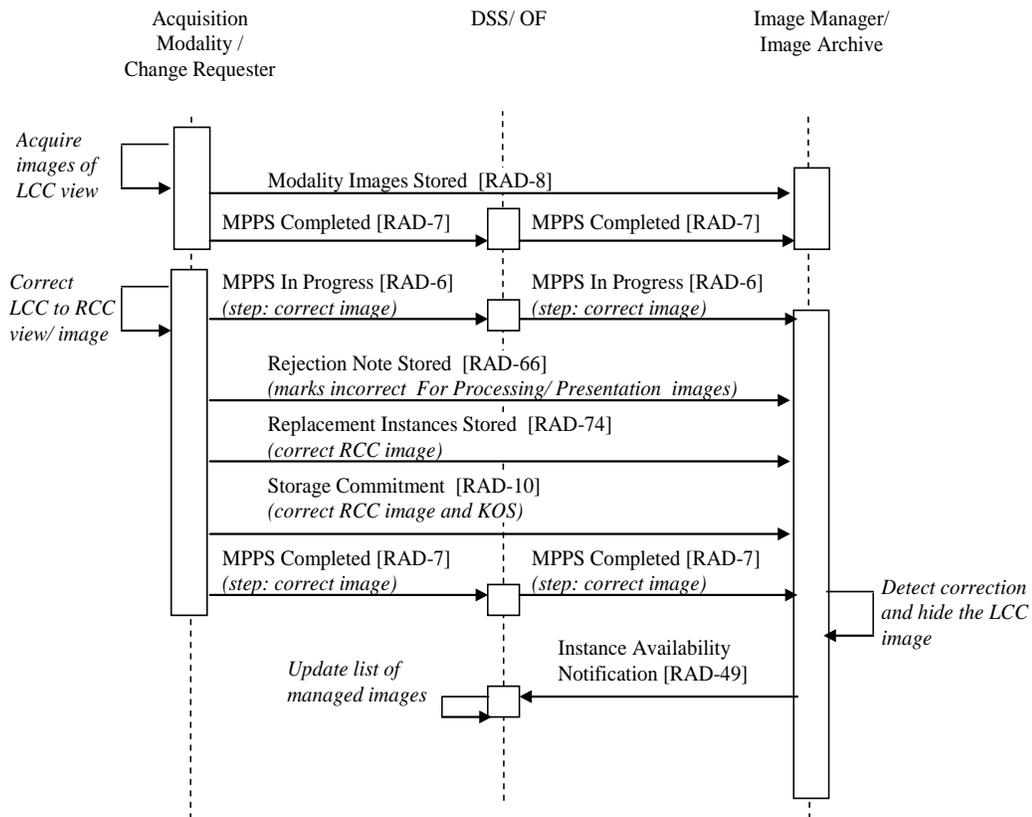
28.4.3 Use Case: Image Correction for Patient Safety Reasons

Instances may be corrected (deleted and replaced) for patient safety reasons. The Change Requester may be grouped with an Acquisition Modality actor, an Evidence Creator actor, or an
440 Image Manager/Archive, depending on whether such QA happens on the modality, a separate workstation, or an image manager.

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

445 The Technologist wants to correct this view information at the Acquisition Modality or at the nearby Quality Control Workstation (e.g., view code, view description, patient orientation, laterality) and "update" the images in the PACS. For correct interpretation and diagnosis, the Radiologist depends on a correct view labeling. Incorrectly labeled views may confuse CAD processing, and may also disturb proper display and navigation of images at a workstation. This
450 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.



455

Figure 28.4.3-1: Process Flow for correction of image labeling

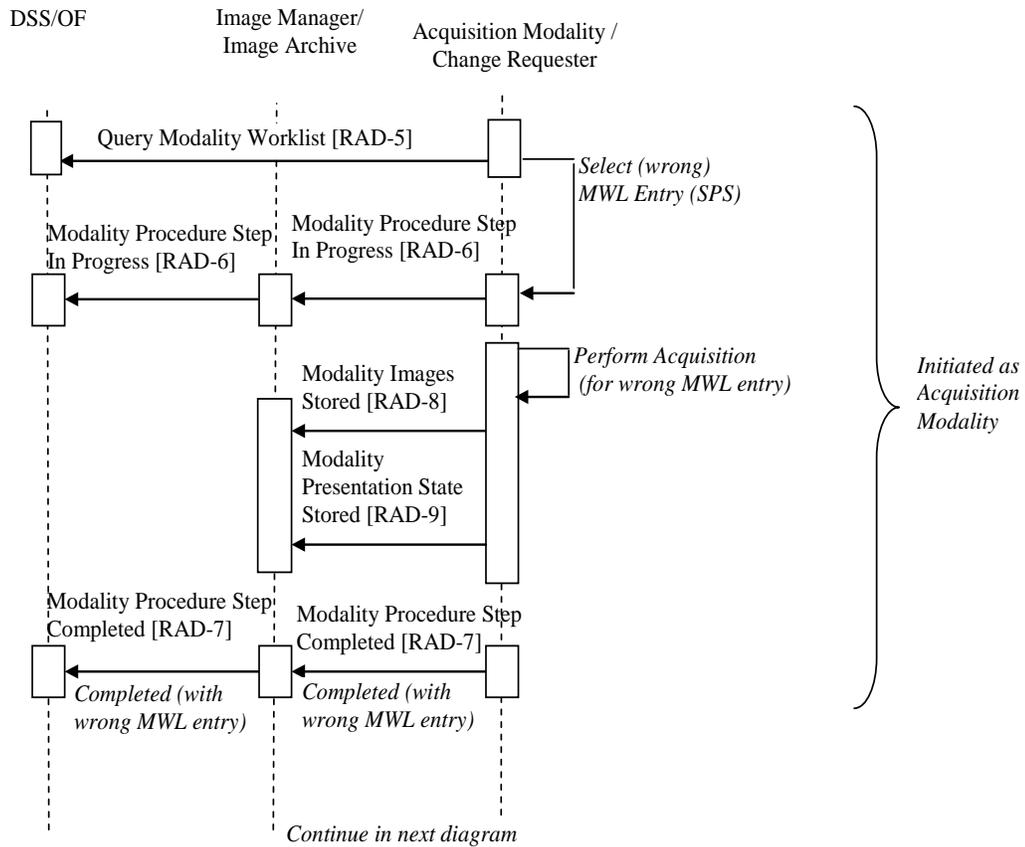
Technical aspect: The Acquisition Modality, as a Change Requester, creates and stores a Key Object Selection (KOS) with a Selection Document Title of “Rejected for Patient Safety Reasons” that lists the incorrect instances and sends this using Rejection Note Stored (RAD-66). It creates corrected images and stores them (RAD-74). It also creates a Modality PS (RAD-6), sets it COMPLETED (including references to both the corrected images and this KOS), and sends it to the DSS/OF (RAD-7). The Image Manager / Archive sends Instance Available Notification (RAD-49) to the DSS/OF to confirm all the instances that remain available and those that are deleted.

The Image Manager/Archive, as a consequence of receiving the KOS, hides the incorrect images from subsequent query/retrieve. An Image Display, when receiving a KOS with a Selection Document Title of “Rejected for Patient Safety Reasons”, does not display the KOS and its referenced images (RAD-16).

Variants: Instead of an Acquisition Modality being the Change Requester, an Image Manager is the Change Requester. The only difference will be that the Image Manager acting as the Change Requester does not have to create an MPPS referencing the Rejection Note or an MPPS referencing the corrected images. In this case, the DSS/OF should monitor the IAN to maintain the complete list of instances.

28.4.4 Use Case: Object Correction due to Modality Worklist Selection Error

475 **Clinical aspect:** A patient arrives at the hospital for a scheduled procedure. The Technologist selects a modality worklist entry for the procedure to be performed but mistakenly selects the wrong entry. The Technologist completes the acquisition step.



480 **Figure 28.4.4-1: Exception Management Workflow (Incorrect Worklist Entry Selected)**

Note: Storage Commitment (RAD-10) is not shown in the diagrams above only for simplification of the diagrams.

Later, the Technologist or Radiologist identifies that patient or order information is incorrect for the whole study. At this point there are two alternative scenarios that can follow:

- 485
1. The originally acquired images are relevant to the originally scheduled procedure for the correct patient.
 2. The originally acquired images are not relevant to the originally scheduled procedure for the correct patient.

490 Regardless of which scenario occurs, if additional images need to be acquired for the actual
 scheduled procedure for the correct patient, then acquisition of the new images shall be
 performed according to Scheduled Workflow.

495 The first scenario is illustrated in Figure 28.4.4-2., the Technologist determines that the acquired
 images are relevant to the actual scheduled procedure for the correct patient. In this case the
 Technologist matches the originally acquired images against the originally scheduled procedure
 for the correct patient using Quality Control tools provided by the Modality.

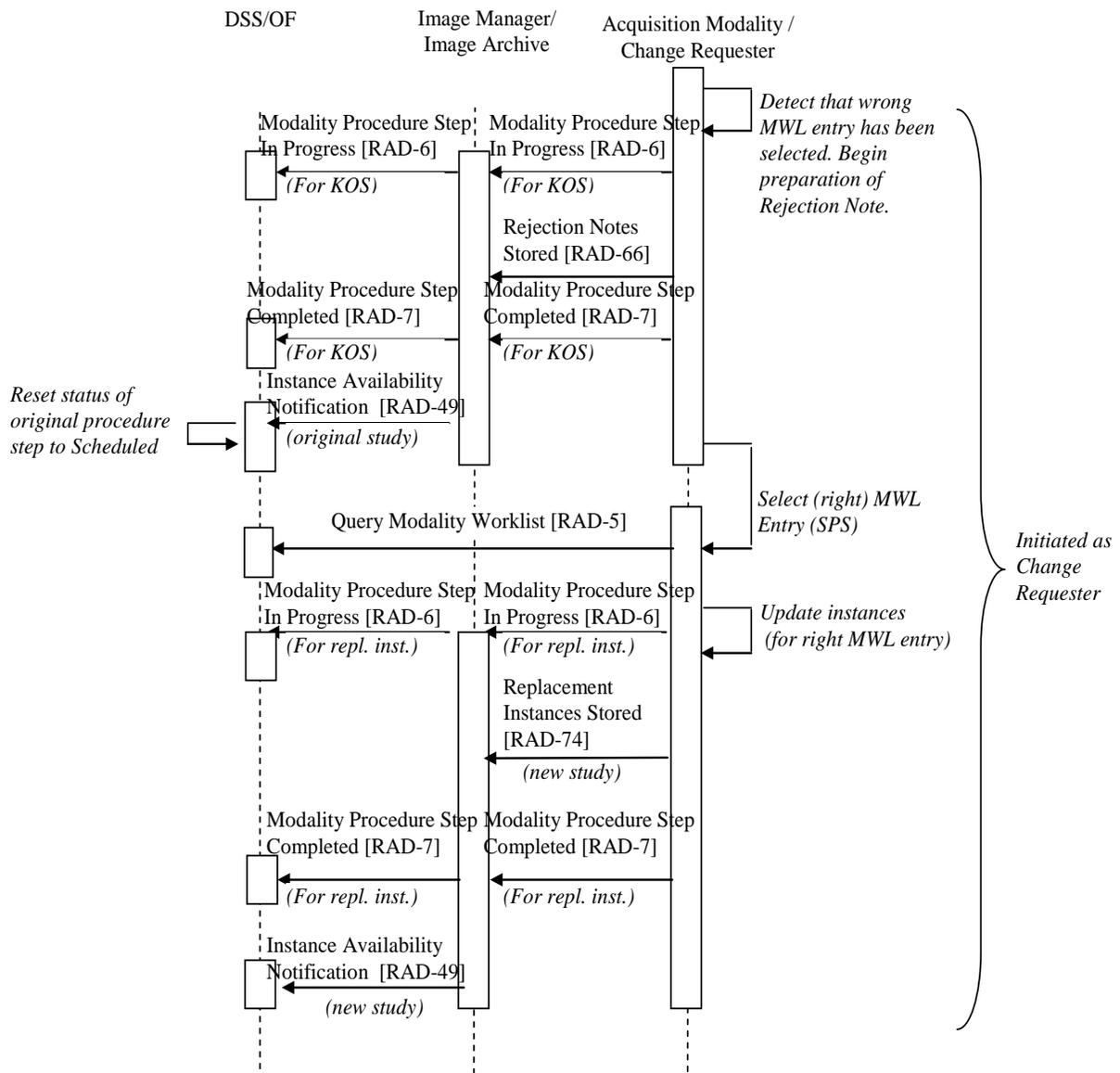


Figure 28.4.4-2: Acquired Images are Relevant to Correct Procedure

Note: Storage Commitment (RAD-10) is not shown in the diagrams above only for simplification of the diagrams.

500

The alternative scenario is that the Technologist determines that the originally acquired images are not relevant to the actual scheduled procedure for the correct patient. This could be handled in two different ways:

1. The originally acquired images are handled by the Technologist as an unscheduled case.
- 505 2. A new procedure is scheduled for the correct patient on the DSS/OF and the originally acquired images are updated to correspond to the new scheduled procedure obtained from the Modality Worklist.

Figure 28.4.4-3 illustrates the correction of the images as an unscheduled case.

510 The alternative approach of scheduling a new procedure on the DSS/OF is not illustrated here. It would follow the normal Scheduled Workflow sequencing with the exception that rather than acquiring new images, the originally acquired images would be updated to correspond to the new scheduled procedure obtained from the Modality Worklist.

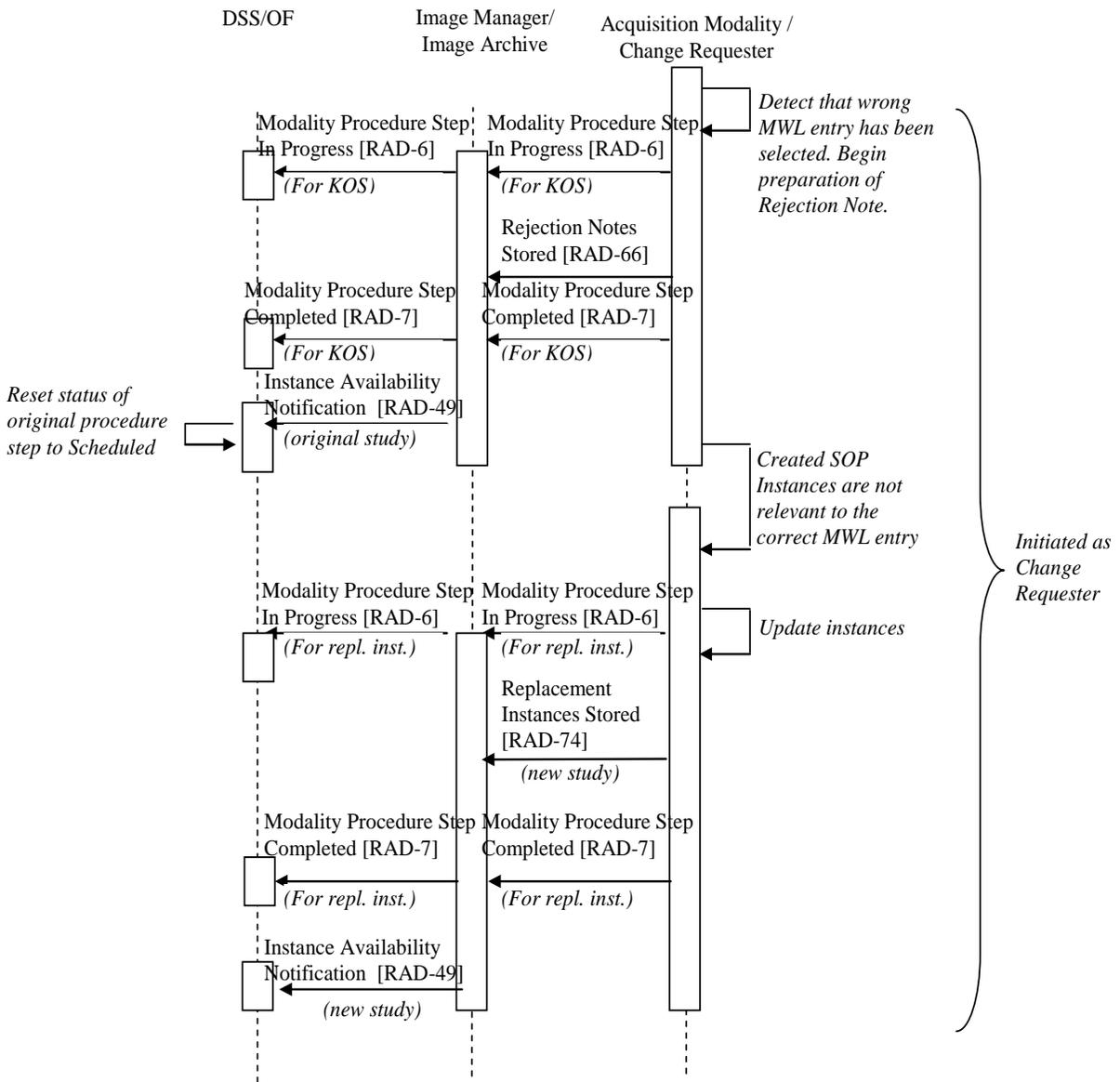


Figure 28.4.4-3: Acquired Images are Not Relevant to Correct Procedure and are Handled as an Unscheduled Case

515

Note: Storage Commitment (RAD-10) is not shown in the diagrams above only for simplification of the diagrams.

Technical aspect: The Acquisition Modality creates the originally acquired images with their headers set to the information from the incorrectly selected modality worklist entry. It creates a corresponding MPPS (RAD-6), completes and sends it (RAD-7), and stores the images to the Image Archive (RAD-8) (see Figure 28.4.4-1).

520

Later, the Technologist or the Radiologist detects the mistakes (see Figure 28.4.4-2). The Acquisition Modality, as a Change Requester, sends a Rejection Note (RAD-66) KOS which

525 contains references to the rejected SOP instances, the originally acquired images, to the Image
Manager. It also creates a MPPS (RAD-6) referencing this Rejection Note, completes the MPPS
with the reference to the KOS and sends it to the Image Manager / Archive and DSS/OF (RAD-
7). The Image Manager receives the Rejection Note and makes all the referenced SOP instances
530 unavailable. The Image Manager sends Instance Availability Notification (RAD-49) referencing
the rejected instances and the original procedure step to the DSS/OF. The DSS/OF resets the
status of the original procedure step.

The technical aspects then vary depending upon whether or not the originally acquired images
are relevant to the actual scheduled procedure for the correct patient.

535 If it is determined that the originally acquired images are relevant to the actual scheduled
procedure for the correct patient then the Acquisition Modality selects the correct modality
worklist entry (RAD-5) and updates the originally acquired images (while the study is still
available at the Acquisition Modality without re-acquisition) with the correct information. The
corrected images are assigned new SOP Instance UIDs so that they can be distinguished from the
originally acquired images which have already been exported. If the correct modality worklist
540 entry is not readily available, the Acquisition Modality queries the DSS/OF again, as illustrated
in Figure 28.4.4-2. In order to communicate the corrected images to other systems, the
Acquisition Modality, as a Change Requester, creates a new MPPS with the correct information
from the modality worklist (RAD-5). It then stores the new set of corrected images to the Image
Manager (RAD-74), and completes the MPPS and sends it (RAD-7). The Image Manager /
Archive confirms the status of the available corrected images by sending Instance Availability
545 Notification (RAD-49) to the DSS/OF.

Alternatively, if it is determined that the originally acquired images are not relevant to the actual
scheduled procedure for the correct patient then the Acquisition Modality either handles the
images as if they belong to an unscheduled procedure, or a new procedure for the acquired
images is entered on the DSS/OF. If treated as an unscheduled case as shown in Figure 28.4.4-3,
550 then there is no modality worklist entry to associate the originally acquired images with. The
images would thus require manual correction on the Acquisition Modality. The corrected images
are assigned new SOP Instance UIDs so that they can be distinguished from the originally
acquired images which have already been exported. In order to communicate the corrected
images to other systems, the Acquisition Modality, as a Change Requester, creates a new MPPS.
555 It then stores the new set of corrected images with manually corrected headers to the Image
Manager (RAD-74), completes the MPPS and sends it (RAD-7). The Image Manager / Archive
confirms the status of the available corrected images by sending Instance Availability
Notification (RAD-49) to the DSS/OF.

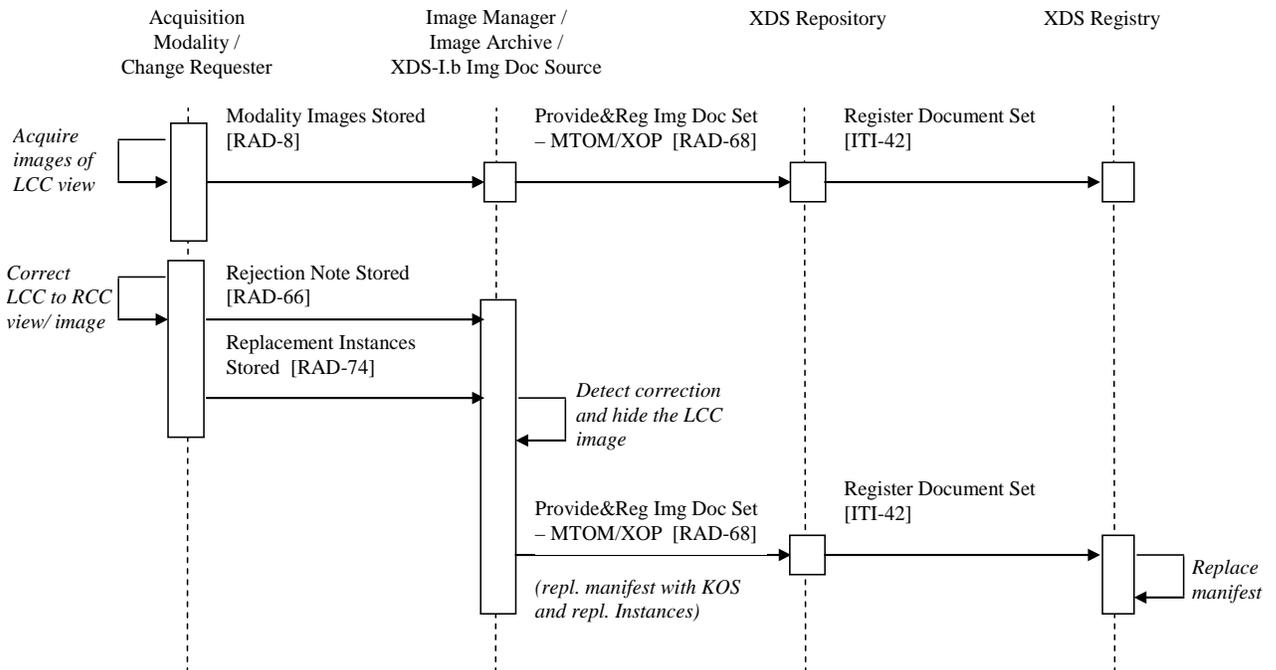
560 Instead of being handled as an unscheduled case, a new procedure could be scheduled on the
DSS/OF. In this case the technical aspects would follow the normal Scheduled Workflow
sequencing with the exception that, rather than acquiring new images, the originally acquired
images would be updated to correspond to the new scheduled procedure obtained from the
Modality Worklist.

565 Note: IHE Scheduled Workflow Profile defines an PPS Exception Management Option (RAD TF-1:3.3.4 and RAD TF-2:4.7.4.1.3.1) which specifies how to correct the incorrectly selected worklist entry after the Modality Performed Procedure Step In Progress transaction has been issued but before the Modality Performed Procedure Step Completed transaction is issued. Notice that there is no external component involved in this situation since the acquired images usually have not been shared prior to MPPS complete or discontinued.

570 **Variation:** Instead of an Acquisition Modality being the Change Requester, an Image Manager is the Change Requester. In this case, the Image Manager uses the received procedure information from Procedure Scheduled (RAD-4) and Procedure Updated (RAD-13) to choose the correct modality worklist, updates the images and creates a new set as described above. The Image Manager does not have to create an MPPS referencing the Rejection Note or an MPPS
575 referencing the corrected images. In this case, the DSS/OF should monitor the IAN to maintain the complete list of instances.

580 **Variation:** Instead of selecting an incorrect modality worklist entry, the Technologist forgets to complete the previous worklist entry before starting the new acquisition. The acquired images are incorrectly appended to an existing study of a different patient for a different procedure. As a result, the resulting study becomes partially incorrect. Only the incorrect images and/or presentation states are required to be corrected. In this case, when the DSS/OF receives the Instance Availability Notification, it updates the managed list of images for the procedure step but does not reset the status.

28.3.5 Image Correction of Exported Study



585 **Figure 28.4.5-1: Image Correction of Exported Study**

Note: The interaction between Acquisition Modality and Image Manager/Archive is a simplified version of Figure 28.4.3-1 for illustration purpose only.

590 This section shows how the synchronization mechanisms described in the previous use cases can be adapted to systems across the enterprise. Use Case: Image Correction for Patient Safety Reason (28.4.3) is used as an example for illustration.

595 The Acquisition Modality sends left breast cranial caudal view (LCC) images that are incorrectly labeled as right breast (RCC) view images to the Image Manager/Archive. The Image Manager/Archive is also acting as an XDS-I Imaging Document Source and publishes the manifest that references these incorrect images to the XDS Repository (RAD-68). The XDS Repository then registers the manifest to the XDS Registry (ITI-42).

600 Later, as described in 28.4.3, the Acquisition Modality corrects the study and sends a Rejection Note and Replacement Instances to the Image Manager / Archive (RAD-66, RAD-74). The Image Manager / Archive hides the incorrect images. Furthermore, the Image Manager/Archive acting as an XDS-I Imaging Document Source replaces the original submitted manifest that references the incorrect images by submitting a new replacement manifest that references the replacement instances. The replacement manifest also includes a reference to the KOS with a Selection Document Title of “Rejected for Patient Safety Reasons”.

605 Since the manifest no longer references the rejected instances, XDS Imaging Document Consumer that retrieves the replacement manifest will not be aware of the rejected instances. For an XDS Imaging Document Consumer that has already retrieved the original incorrect instances, the rejection note in the replacement manifest allows the consumer to hide the incorrect instances accordingly.

610 **Variant:** Instead of publishing a study using XDS-I.b, a Portable Media Creator exports the corrected study to an interchange media. The media includes the KOS with a Selection Document Title of “Rejected for Patient Safety Reasons” and the replacement instances.

28.5 Imaging Object Change Management Security Considerations

The section describes the policies for reducing risks after correction or rejection at the Change Requester.

615 Images that are marked as "rejected" for quality reasons (see 28.4.2) may or may not contain clinically relevant information. They may be useful in certain situations. Sites may decide to provide them regularly as part of a Study or may hide them at the Archive or at Workstations. IHE supports such policies by defining configurable behavior at the Image Manager/ Image Archive for storage and at the Image Display for presentation.

620 Incorrectly labeled images (see 28.4.3), e.g., containing a wrong patient orientation or laterality, may mislead image interpretation and thus may be harmful to a patient. For patient safety reasons, they are marked in order to not be used later; an Archive hides such images and does not provide them in IHE-defined query and retrieve transactions.

625 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.

630 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.

635 The correction and rejection mechanisms defined for IHE Imaging Object Change Management Integration Profile will only correctly work in a system environment where each system implements the corresponding Actors from this Integration Profile. In addition, the Image Manager/ Archive and Displays need to be configured in a way that meets the department or enterprise policies.

640 The correction and rejection mechanisms are capable of deleting or changing evidence of a performed procedure. That means a malicious user or system can use this mechanism to hide a mistake. Therefore the audit record should include information about who initiates the correction / rejection as well as the reason of the initiation. Traceability is also available using the Referenced Instance Sequence (see 4.74.4.1.2) in the header of the replacement instances.

645 Since any actor can group with the Change Requester, it is important for the Image Manager / Archive to validate the source and authority of the Change Requester before rejecting any referenced instances in the KOS. For example, the Image Manager / Archive can restrict rejection of instances referenced in the received KOS if and only if the KOS is sent from the same DICOM Application Entity as the original instances.

650

Volume 2 - Transactions

4.30 Query Key Image Notes

Replace 4.30.4.1.1 by the following text (same text extracted from MAWF):

4.30.4.1.1 Trigger Events

655 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. This text is extracted from MAWF with the additional text for IOCM in red.

660 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.

665 **The Image Archive participating in the Mammography Acquisition Workflow Integration Profile or Imaging Object Change Management 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

670 *Replace 4.31.4.1.2 by the following text. This text is extracted from MAWF with the additional text for IOCM in red.*

4.31.4.1.2 Message Semantics

675 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

680 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 or Imaging Object Change Management Integration Profile shall include or not include specific KOS instances that mark rejected images as defined in 4.66.4.1.3.

685 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.

690 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.

695 *Add a section 4.31.4.2.3.2:*

4.31.4.2.3.2 Presentation of rejected or incorrect images in Imaging Object Change Management

An Image Display participating in the Imaging Object Change Management Integration Profile may receive Key Image Notes.

700 **When an Image Display receives a Key Image Note with 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 shall be configurable as one of the following:**

- 705 • **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.**
- 710 • **When an Image Display receives a Key Image Note with the Key Object Selection (KOS) Document Title valued (113037, DCM, "Rejected for Patient Safety Reasons"), (113038, DCM, "Incorrect Modality Worklist Entry"), or (113039, DCM, "Data Retention Policy Expired"), it shall suppress the KOS and its referenced rejected instances from presentation.**

Volume 3 – Transactions (continued)

715 4.47 Distribute Imaging Information on Media

Add Section 4.47.4.1.2.1 after Message Semantics

4.47.4.1.2.1 Access to Rejected Instances

The contents of this section are required for Portable Media Creator actors in the Imaging Object Change Management Profile.

720 For Key Object Selection instances with one of the following Document Titles, the Portable Media Creator shall include the KOS instance on the media and exclude from the media all instances referenced by the KOS.

- (113001, DCM, “Rejected for Quality Reasons”)
- (113037, DCM, “Rejected for Patient Safety Reasons”)
- 725 • (113038, DCM, “Incorrect Modality Worklist Entry”)
- (113039, DCM, “Data Retention Policy Expired”)

Modified the following section with reference to IOCM

4.47.4.1.3.2 Image Display

730 The Image Display reads the DICOM image data from the media and provides the user with the ability to view all studies (that it supports) contained on the media. GSPS objects and Key Image Notes are read from the media and applied if the Consistent Presentation of Images and the Key Image Notes IHE Integration Profiles are supported. The Image Display actor may optionally be grouped with other actors that view other evidence objects.

735 **An Image Display actor in the Imaging Object Change Management Profile shall support presentation of rejected or corrected instances as defined in RAD IOCM 3:4.47.4.1.4.**

Modified the following section with reference to IOCM

4.47.4.1.3.3 Report Reader

740 The Report Reader reads the DICOM SR Reports from the media and may process them (based on the SR object classes it supports). At a minimum, it provides the user with the ability to view all reports per the DICOM SR SCP requirements.

A Report Reader actor in the Imaging Object Change Management Profile shall support presentation of rejected or corrected instances as defined in RAD IOCM 3:4.47.4.1.4.

745

Modified the following section with reference to IOCM

4.47.4.1.3.4 Portable Media Importer

The Portable Media Importer reads DICOM data from the media. Together with the actor with which it is grouped (see vol. 1), it shall be able to perform key attribute reconciliation.

750

Reconciliation may not be required in all cases (e.g., within the same importing institution/enterprise). Refer to Table 4.47.4-2 for key attributes to be reconciled. Import Reconciliation Workflow provides a workflow to reconcile key attributes (See Section RAD-TF 1:3.59). Note that the Referenced Study Sequence and Requested Attributes Sequence are removed for consistency with behavior of the unscheduled cases in SWF and PIR.

755

The grouped actors provide the capability of storing the supported DICOM objects to an Image Manager/ Image Archive (for image objects like Images, Presentation States, Key Image Notes, Evidence Documents), or to a Report Repository (for Diagnostic Reports).

Table 4.47.4-2: Media instances - Key attributes to be reconciled

Attribute from Media	Updating action
Patient Name	Replace with value from ADT (See note 1)
Patient ID	Replace with value from ADT (See note 1)
Patient's Birth Date	Replace with value from ADT (See note 1)
Patient's Sex	Replace with value from ADT (See note 1)
Study Instance UID	Remains unchanged
Series Instance UID	Remains unchanged
SOP Instance UID	Remains unchanged
Workflow-related Identifying Attributes (e.g., Order, Requested Procedure, Scheduled and Performed IDs and UIDs).	Values from such identifying attributes of media information <ul style="list-style-type: none"> • remain unchanged, • are replaced with a value from the local environment, or • are removed (zero length value). The exact method of reconciliation depends on the importing institution's procedures, and goes beyond the IHE scope.
Descriptive performed procedure information (this is information that pertains to the manner in which the information was created (e.g., acquisition context) or it may be payload of the instance (e.g., image structure, document content))	Remains unchanged (see Note 2)

760

Note 1: The manner in which the Portable Media Importer receives the ADT value is beyond the scope of this profile.

Note 2: Handling of Coded information is beyond the scope of this Integration Profile.

Add Section 4.47.4.1.3.4.1

4.47.4.1.3.4.1 Access to Rejected Instances

765 **The contents of this section are required for Portable Media Importer actors in the Imaging Object Change Management Profile.**

For Key Object Selection instances with one of the following Document Titles, the Portable Media Importer shall include the KOS instance on the media and exclude from the media all instances referenced by the KOS.

- 770
- **(113001, DCM, “Rejected for Quality Reasons”)**
 - **(113037, DCM, “Rejected for Patient Safety Reasons”)**
 - **(113038, DCM, “Incorrect Modality Worklist Entry”)**
 - **(113039, DCM, “Data Retention Policy Expired”)**

775 *Modified the following section with reference to IOCM*

4.47.4.1.3.5 Print Composer

The Print Composer reads the DICOM image data from the media and provides a means to print it.

780 **A Print Composer actor in the Imaging Object Change Management Profile shall support presentation of rejected or corrected instances as defined in RAD IOCM 3:4.47.4.1.4.**

Modified the following section with reference to IOCM

4.47.4.1.3.6 Display

785 The Display actor (defined in the IT Infrastructure TF) reads the web-viewable information from the media and displays it. Note that the web-viewable content will only be present if the Portable Media Creator involved supports the Web Content Option.

A Display actor in the Imaging Object Change Management Profile shall support presentation of rejected or corrected instances as defined in RAD IOCM 3:4.47.4.1.4.

790 *Add the following section*

4.47.4.1.4 Presentation of rejected or corrected instances in Imaging Object Change Management

795 An Image Display, Report Reader, Portable Media Importer, Print Composer or Display actor in the Imaging Object Change Management Integration Profile may receive Key Image Notes with the Key Object Selection (KOS) Document Title valued (113001, DCM, "Rejected for Quality Reasons"). It 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
- 800 • Present the rejected instances referenced in this KOS and this KOS itself
- Ignore this KOS and present the rejected instances

If it receives a Key Image Note with the Key Object Selection (KOS) Document Title valued (113037, DCM, "Rejected for Patient Safety Reasons"), (113038, DCM, "Incorrect Modality Worklist Entry"), or (113039, DCM, "Data Retention Policy Expired"), it shall suppress the
805 KOS and its referenced rejected instances from presentation.

4.49 Instance Availability Notification

Add a new section 4.49.4.1.2.1

4.49.4.1.2.1 Critical attributes in Imaging Object Change Management

810 The content of this section is required for Image Manager / Archives in the Imaging Object Change Management Integration Profile.

The Image Manager / Archive receives the Key Image Note with the Key Object Selection Document Title valued (113001, DCM, "Rejected for Quality Reasons"), (113037, DCM, "Rejected for Patient Safety Reasons"), (113038, DCM, "Incorrect Modality Worklist Entry") or (113039, DCM, "Data Retention Policy Expired"). According to the behavior configured (see
815 4.66.4.1.3), it shall send one of the following availability status values for all the rejected instances according to the received KOS:

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

820 It shall also send one of the following availability status values for all remaining instances in the same notification:

- "ONLINE", "NEARLINE" or "OFFLINE".

If the trigger event is receiving a Key Image Note with the Key Object Selection Document Title valued (113038, DCM, "Incorrect Modality Worklist Entry"), then the Image Manager / Archive
825 shall populate the Referenced SOP Instance UID in the Referenced Performed Procedure Step

Sequence with the corresponding MPPS Instance UID of the referenced rejected instances. For all other trigger events, the Image Manager / Archive shall populate the Referenced SOP Instance UID in the Referenced Performed Procedure Step Sequence with the corresponding MPPS Instance UID of the received instances.

830

Add the following new section.

4.49.4.1.3.1 Procedure Step Status Management in Imaging Object Change Management

835 The content of this section is required for DSS/OF in the Imaging Object Change Management Integration Profile.

If a completed procedure step has no more associated available instances, then the DSS/OF shall reset the status for this procedure step to Scheduled.

Modify 4.55, WADO Retrieve to define the behavior for an Image Manager/Archive that supports either MAWF or IOCM.

840 4.55 WADO Retrieve

Replace 4.55.4.1.3 with the following text:

4.55.4.1.3 Expected Actions

845 Upon reception of the WADO HTTP Request, the Imaging Document Source shall parse the request and if there are no errors, shall construct an HTTP Get Response with the requested DICOM instance content and return the response as specified by the DICOM WADO standard, with HTTP response code 200 (OK).

The Imaging Document Source shall return HTTP response code 406 (Not Acceptable), if it cannot serve the requested response MIME type(s) in parameter contentType and/or Accept Field.

850 The Imaging Document Source shall return HTTP response code 404 (Not Found) if it cannot locate the requested DICOM SOP Instance or cannot recognize the UID values specified in the received HTTP Request-URI.

855 The Imaging Document Source shall return HTTP response code 400 (Bad Request) if any required HTTP field or required WADO HTTP parameters are missing in the received HTTP Request-URI, or any other syntactic error is detected in the HTTP Request-URI (e.g., media type in contentType parameter conflicts with media types in Accept field).

The Imaging Document Source in the Imaging Object Change Management Integration Profile shall not return specific KOS instances with the Document Title valued (113001, DCM, “Rejected for Quality Reasons”), (113037, DCM, “Rejected for Patient Safety Reasons”), (113038, DCM, “Incorrect Modality Worklist Entry) or (113039, DCM, “Data Retention Policy Expired”). The Imaging Document Source shall return HTTP response

code 404 (Not Found) if the Imaging Document Consumer requested retrieval of such a KOS instance, or rejected DICOM SOP Instance(s) referenced in that KOS.

4.61 Imported Objects Stored

865 *Add Section 4.61.4.1.2.1 after Message Semantics*

4.61.4.1.2.1 Access to Rejected Instances

The contents of this section are required for Importer actors in the Imaging Object Change Management Profile.

870 For Key Object Selection instances with one of the following Document Titles, the Importer shall include the KOS instance on the media and exclude from the media all instances referenced by the KOS.

- (113001, DCM, “Rejected for Quality Reasons”)
- (113037, DCM, “Rejected for Patient Safety Reasons”)
- (113038, DCM,, “Incorrect Modality Worklist Entry”)
- 875 • (113039, DCM, “Data Retention Policy Expired”)

Modify 4.66 defined in MAWF to include new rejection reason and respective semantics. The following text is extracted from the MAWF Trial Implementation Supplement.

4.66 ~~Image~~-Rejection Note Stored

880 This section corresponds to Transaction RAD-66 of the IHE **Radiology** Technical Framework. Transaction RAD-66 is used by the Acquisition Modality, ~~and~~ Evidence Creator, **Image Manager/Image Archive and Change Requester** actors.

4.66.1 Scope

885 In this transaction, the Acquisition Modality, **Change Requester** or the Evidence Creator transmits a specific DICOM Key Object Selection (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, **or**
- 890 • **associated certain images to the correct modality worklist entry so that the original images are to be rejected for incorrect modality worklist selection reason, or**

Alternatively, a user or the Image Manager / Archive selects specific instances to be deleted due to data retention policy expiration, including a reason for deletion.

895

Add the new actor Change Requester

4.66.2 Use Case Roles

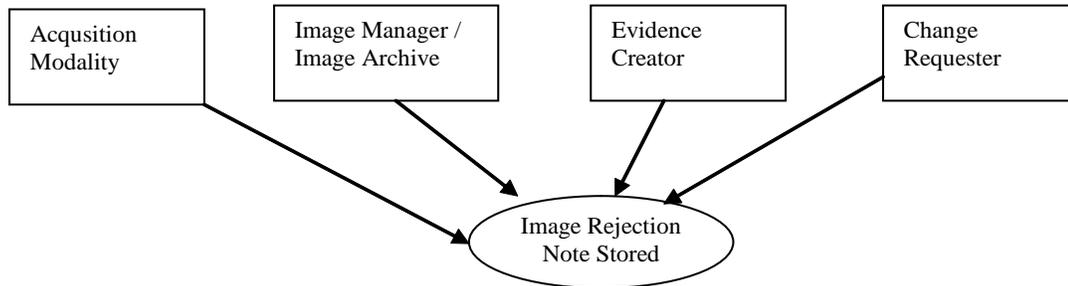


Fig. 4.66.2-1: Use Case Diagram

900 **Actor:** Acquisition Modality

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

Actor: Evidence Creator

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

Actor: Image Manager/ Image Archive

Role: Image Archive receives, processes and stores the 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 Rejection Note.

910 **Actor: Change Requester**

Role: Flags available instances that are (1) associated with an incorrect modality worklist entry, (2) expired for data retention policy or (3) rejected due to quality or patient safety reasons by creating a Rejection Note, and sending it to the Image Manager / Archive.

4.66.3 Referenced Standards

915 DICOM 2008~~9~~ PS 3.4: Key Object Selection Document Storage SOP Class

DICOM 2008~~9~~ PS 3.4: Storage SOP Class

DICOM 2009 PS 3.4: Query/Retrieve SOP Class

DICOM 2008~~9~~ PS 3.16: TID 2010, CID 7011

4.66.4 Interaction Diagram

920 Add the following diagram to Section 4.66.4. Change the transaction name from *Rejection Note Stored* to *Rejection Note Stored*.

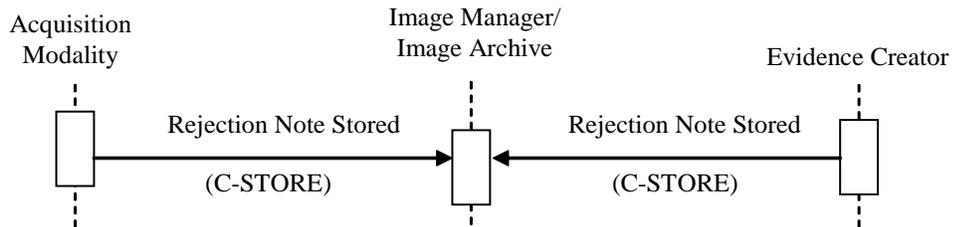


Figure 4.66.4-1 Interaction Diagram: Image Rejection Note Stored

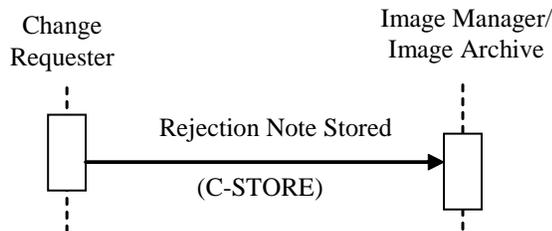


Figure 4.66.4-2: Interaction Diagram: Rejection Note Stored in IOCM

925

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

930

The following table summarizes Key Object Selection Document Titles usage in different profiles:

935

Table 4.66.4-1: Profile Supported Key Object Selection Document Title

KOS Document Title	MAWF	IOCM
<u>(113001, DCM, "Rejected for Quality Reasons")</u>	<u>X</u>	<u>X</u>
<u>(113037, DCM, "Rejected for Patient Safety Reasons")</u>	<u>X</u>	<u>X</u>
<u>(113038, DCM, "Incorrect Modality Worklist Entry")</u>		<u>X</u>
<u>(113039, DCM, "Data Retention Policy Expired")</u>		<u>X</u>

Modify the following messages in Section 4.66.4

4.66.4.1 Image Rejection Note Stored (for Quality Reasons)

940 4.66.4.1.1 Trigger Events

An operator at the Acquisition Modality, ~~or~~ the Evidence Creator or the Change Requester 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 ~~an~~ **Image Rejection Note** which the Acquisition Modality, ~~or~~ Evidence Creator or the Change Requester sends to the Image Manager / Image Archive.

4.66.4.1.2 Message Semantics

The Acquisition Modality, ~~or~~ Evidence Creator or Change Requester 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).
950 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.
- 955 • References to all rejected images.

4.66.4.1.2.1 Multiple Identity Resolution Option in Scheduled Workflow

The contents of this section are required for Change Requester actors grouped with Image Manager / Archive actors claiming the Imaging Object Change Management Profile that also support the Multiple Identity Resolution Option in the Scheduled Workflow Profile.

960 **The Image Manager / Archive shall meet the requirements defined in Appendix J: Multiple Identity Resolution Option. Specific to this transaction, it shall support:**

- **Cross-Referencing of Patient Identifiers (RAD TF-3: J.2.1)**
- **Configurable Mapping to Default Assigning Authorities (RAD TF-3: J.2.2)**
- **Message Semantics when Sending SOP Instances (Section J.2.4.1)**

965 4.66.4.1.3 Expected Actions

The Image Manager / 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.

- 970
- Regular use: For the Key Object Selection instance and all **imagesinstances** referenced therein, the **Image Manager / Image** Archive shall return SOP Instance UIDs in Query Responses and the instances in Patient, Study, Series, or Instance level retrievals.
 - Hide rejected **imagesinstances**: For the rejected instances referenced in the Key Object Selection, the **Image Manager / Image** Archive shall neither return SOP Instance UIDs
- 975
- in Query Responses nor return the **imagesinstances** in Patient, Study, Series, or Instance level retrievals.

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

980

<i>Add the following new section 4.66.4.1.3.1 and 4.66.4.1.3.2.</i>

4.66.4.1.3.1 Access to Rejected Instances

The contents of this section are required for Image Manager / Archive actors in the Imaging Object Change Management Profile.

- 985
- The Image Manager / Archive shall provide two Application Entities for each C-FIND service and each C-MOVE service; one AE associated with the Regular Use behavior, and one AE associated with the Hide Rejected Instances behavior (See 4.66.4.1.3).**

The Image Manager / Archive shall be configurable to restrict access to the “Regular Use” Application Entity to a limited set of calling AE Titles.

4.66.4.1.3.2 Multiple Identity Resolution Option in Scheduled Workflow

- 990
- The contents of this section are required for Image Manager / Archive actors claiming the Imaging Object Change Management Profile that also support the Multiple Identity Resolution Option in the Scheduled Workflow Profile.**

The Image Manager / Archive shall meet the requirements defined in Appendix J: Multiple Identity Resolution Option. Specific to this transaction, it shall support:

- 995
- **Cross-Referencing of Patient Identifiers (RAD TF-3: J.2.1)**
 - **Configurable Mapping to Default Assigning Authorities (RAD TF-3: J.2.2)**
 - **Expected Actions when Receiving SOP Instances (RAD TF-3: J.2.4.1)**

4.66.4.2 Image Rejection Note Stored (for Patient Safety Reasons)

4.66.4.2.1 Trigger Events

- 1000
- An operator at the Acquisition Modality, ~~or~~ the Evidence Creator **or the Change Requester** detects that certain just acquired images **or just created evidence documents** are incorrect. She

1005 corrects these images or evidence documents using the capability provided by the systems implementing these actors. Thereby, she generates an ~~Image~~ Rejection Note which the Acquisition Modality, ~~or~~ Evidence Creator or Change Requester sends to the Image Manager / Image Archive.

4.66.4.2.2 Message Semantics

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

- 1010
- ~~For Mammography images, t~~The user shall be able to store new, corrected images or evidence documents at the Acquisition Modality as defined in RAD TF-2:4.8.4.1.2.4 or at the Evidence Creator as defined in RAD TF-2:4.18.4.1.2.5.

~~For all other DICOM SOP Classes, IHE does not define a specific correction mechanism.~~

1015 The Acquisition Modality, ~~or~~ Evidence Creator or Change Requester shall create a new Key Object Selection instance in a new Series of the incorrect imagesinstances' 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:

- 1020
- 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 imagesinstances and derived instances (e.g., FOR PRESENTATION and FOR PROCESSING).

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

4.66.4.2.2.1 Multiple Identity Resolution Option in Scheduled Workflow

1025 The contents of this section are required for Change Requester actors grouped with Image Manager / Archive actors claiming the Imaging Object Change Management Profile that also support the Multiple Identity Resolution Option in the Scheduled Workflow Profile.

The Image Manager / Archive shall meet the requirements defined in Appendix J: Multiple Identity Resolution Option. Specific to this transaction, it shall support:

- 1030
- Cross-Referencing of Patient Identifiers (RAD TF-3: J.2.1)
 - Configurable Mapping to Default Assigning Authorities (RAD TF-3: J.2.2)
 - Message Semantics when Sending SOP Instances (Section J.2.4.1)

4.66.4.2.3 Expected Actions

1035 The **Image Manager / Image** Archive receives incorrect and corresponding corrected **imagesinstances**, 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 Manager / Image** Archive shall be triggered by this specific Key Object Selection to hide the incorrect **imagesinstances** and shall:

- 1040
- 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) or presentation state query/retrieve transaction (RAD-15, RAD-17).
 - 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.
- 1045

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).

1050 Note: 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).

4.66.4.2.3.1 Additional Requirements for Image Manager / Archive in IOCM

The Image Manager / Archive shall be triggered by this specific Key Object Selection to hide the incorrect instances as specified in 4.66.4.2.3 and it shall:

- Not accept subsequent occurrence of instances that have been hidden.

1055 4.66.4.2.3.1.1 Multiple Identity Resolution Option in Scheduled Workflow

The contents of this section are required for Image Manager / Archive actors claiming the Imaging Object Change Management Profile that also support the Multiple Identity Resolution Option in the Scheduled Workflow Profile.

The Image Manager / Archive shall:

- 1060
- Not provide the incorrect instances referenced in this KOS in responses to an instance query/retrieve transaction (RAD-72, RAD-73).
 - Not provide this KOS instance and the incorrect instances referenced in this KOS to store requests (RAD-70).

1065 In addition, the Image Manager / Archive shall meet the requirements defined in Appendix J: Multiple Identity Resolution Option. Specific to this transaction, it shall support:

- Cross-Referencing of Patient Identifiers (RAD TF-3: J.2.1)

- **Configurable Mapping to Default Assigning Authorities (RAD TF-3: J.2.2)**
- **Expected Actions when Receiving SOP Instances (RAD TF-3: J.2.4.1)**

1070 Add the following new sections in Section 4.66.4

4.66.4.3 Rejection Note Stored (for Incorrect Modality Worklist)

4.66.4.3.1 Trigger Events

1075 An operator at the Change Requester (grouped with an Acquisition Modality or Image Manager / Archive) detects that certain images just acquired and transmitted are associated with an incorrect modality worklist entry. She corrects the images to the correct modality worklist entry using the capability provided by the systems implementing these actors. Thereby, she generates a Rejection Note and sends it to the Image Manager / Archive.

4.66.4.3.2 Message Semantics

1080 The Change Requester shall enable a user to associate one or more objects in the study with the correct modality worklist entry. The Change Requester shall create a new Key Object Selection instance in a new Series of the study referencing the instances associated with the incorrect modality worklist entry. 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:

- 1085
- A Key Object Selection Document Title code of (113038, DCM, “Incorrect Modality Worklist Entry”).
 - References to all instances associated with the incorrect modality worklist entry.

4.66.4.3.2.1 Multiple Identity Resolution Option in Scheduled Workflow

1090 The contents of this section are required for Change Requester actors grouped with Image Manager / Archive actors claiming the Imaging Object Change Management Profile that also support the Multiple Identity Resolution Option in the Scheduled Workflow Profile.

The Image Manager / Archive shall meet the requirements defined in Appendix J: Multiple Identity Resolution Option. Specific to this transaction, it shall support:

- 1095
- Cross-Referencing of Patient Identifiers (RAD TF-3: J.2.1)
 - Configurable Mapping to Default Assigning Authorities (RAD TF-3: J.2.2)
 - Message Semantics when Sending SOP Instances (Section J.2.4.1)

4.66.4.3.3 Expected Actions

1100 The Image Manager / Archive receives incorrect instances and the corresponding corrected instances, as well as the Key Object Selection (KOS) instance with the Document Title values (113038, DCM, “Incorrect Modality Worklist Entry”). The Image Manager / Archive shall be triggered by this specific Key Object Selection instance to hide the incorrect instances and shall:

- Not provide this KOS instance in responses to Key Image Note query and retrieve requests (RAD-30, RAD-31).
- 1105 • Not provide the incorrect instances referenced in this KOS in responses to an image query/retrieve transaction (RAD-14, RAD-16) or presentation state query/retrieve transaction (RAD-15, RAD-17).
- Not accept subsequent occurrence of instances that have been hidden.
- 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.

1110 4.66.4.3.3.1 Multiple Identity Resolution Option in Scheduled Workflow Profile

The contents of this section are required for Image Manager / Archive actors claiming the Imaging Object Change Management Profile that also support the Multiple Identity Resolution Option in the Scheduled Workflow Profile.

The Image Manager / Archive shall:

- 1115 • Not provide the incorrect instances referenced in this KOS in responses to an instance query/retrieve transaction (RAD-72, RAD-73).
- Not provide this KOS instance and the incorrect instances referenced in this KOS to store requests (RAD-70).

1120 In addition, the Image Manager / Archive shall meet the requirements defined in Appendix J: Multiple Identity Resolution Option. Specific to this transaction, it shall support:

- Cross-Referencing of Patient Identifiers (RAD TF-3: J.2.1)
- Configurable Mapping to Default Assigning Authorities (RAD TF-3: J.2.2)
- Expected Actions when Receiving SOP Instances (RAD TF-3: J.2.4.1)

4.66.4.4 Rejection Note Stored (for Data Retention Expiry)

1125 4.66.4.4.1 Trigger Events

A manual or automatic procedure in the Change Requester (grouped with Image Manager / Archive) determines that certain instances exceed the required period of data retention and automatically deletes them locally. Based on configuration, the Change Requester communicates the expiry of instances to an external Image Manager / Archive (e.g., Centralized Archive).
1130 Thereby, it generates a Rejection Note and sends to the external Image Manager / Archive.

4.66.4.4.2 Message Semantics

1135 The Change Requester shall create a new Key Object Selection instance in a new Series for each study with the expired instances. 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 (113039, DCM, “Data Retention Policy Expired”).
 - References to all instances within the study that have exceeded the required data retention period.
- 1140

4.66.4.4.2.1 Multiple Identity Resolution Option in Scheduled Workflow

The contents of this section are required for Change Requester actors grouped with Image Manager / Archive actors claiming the Imaging Object Change Management Profile that also support the Multiple Identity Resolution Option in the Scheduled Workflow Profile.

1145 The Image Manager / Archive shall meet the requirements defined in Appendix J: Multiple Identity Resolution Option. Specific to this transaction, it shall support:

- Cross-Referencing of Patient Identifiers (RAD TF-3: J.2.1)
- Configurable Mapping to Default Assigning Authorities (RAD TF-3: J.2.2)
- Message Semantics when Sending SOP Instances (Section J.2.4.1)

1150 4.66.4.4.3 Expected Actions

The Image Manager / Archive receives the Key Object Selection (KOS) instance with the Document Title values (113039, DCM, “Data Retention Policy Expired”). The Image Manager / Archive shall be triggered by this specific Key Object Selection instance to delete the expired instances. The Image Manager / Archive shall also delete this specific Key Object Selection instance once it completes the deletion of the expired instances.

1155

If the Image Manager / Archive later receives the same expired instances that have been previously deleted due to the expiry of data retention period and not other reasons, then it shall receive the instances as defined in one of the corresponding instance stored transactions (RAD-8, RAD-9, RAD-18, RAD-19, RAD-29, RAD-43, RAD-61).

1160 4.66.4.4.3.1 Multiple Identity Resolution Option in Scheduled Workflow Profile

The contents of this section are required for Image Manager / Archive actors claiming the Imaging Object Change Management Profile that also support the Multiple Identity Resolution Option in the Scheduled Workflow Profile.

1165 In addition, the Image Manager / Archive shall meet the requirements defined in Appendix J: Multiple Identity Resolution Option. Specific to this transaction, it shall support:

- Cross-Referencing of Patient Identifiers (RAD TF-3: J.2.1)
- Configurable Mapping to Default Assigning Authorities (RAD TF-3: J.2.2)
- Expected Actions when Receiving SOP Instances (RAD TF-3: J.2.4.1)

1170 Add the following rows to the end of the table 5.1-2 in the Radiology Audit Trail Option to ITI-ATNA. This table is adopted from MAWF. The additional changes are highlighted in **red**.

<u>IHE Radiology Transaction</u>	<u>ATNA Trigger Event(s)</u>	<u>Actor(s) that shall be able to record audit event</u>
Image rRejection Note Stored [RAD-66]	<u>Instances-deleted</u>	<u>Sender: Acquisition Modality, Evidence Creator, Change Requester.</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>

1175 Modify 4.68 Provide and Register Imaging Document Set – MTOM/XOP to specify the behavior for an Imaging Document Source supporting MAWF or IOCM

4.68 Provide and Register Imaging Document Set – MTOM/XOP

Replace 4.68.4.1.3 Expected Actions with the following text:

4.68.4.1.3 Expected Actions

1180 The Document Repository Actor will receive this message and will process it according to the requirements specified in ITI TF-2: 3.41.4.1.3.

1185 **The Imaging Document Source in Imaging Object Change Management Integration Profile shall not include references in a manifest to DICOM KOS SOP instances with the Document Title valued (113001, DCM, “Rejected for Quality Reasons”), (113037, DCM, “Rejected for Patient Safety Reasons”), (113038, DCM, “Incorrect Modality Worklist Entry) or (113039, DCM, “Data Retention Policy Expired”) that mark rejected instances. The Imaging Document Source shall not include the rejected instance(s) that such a KOS references. If a previously submitted manifest includes references to rejected DICOM SOP Instances, then the Imaging Document Source shall submit an update to replace this**
1190 **manifest.**

Modify 4.69 Retrieve Imaging Document Set to specify the behavior for an Imaging Document Source supporting MAWF or IOCM

4.69 Retrieve Imaging Document Set

1195 *Replace 4.69.4.2.3 Expected Actions with the following text:*

4.69.4.2.3 Expected Actions

1200 An Imaging Document Source shall provide the document(s) indicated in the request. The Imaging Document Source shall return the document(s) or an error code in case the document could not be returned. The pixel data shall be encoded using one of the DICOM transfer syntaxes included in the Retrieve Imaging Document Set Request Message. If the Imaging Document Source cannot encode the pixel data using any of the provided transfer syntaxes then an error status shall be returned.

1205 If the Imaging Document Consumer specifies a transfer syntax field of 1.2.840.10008.1.2.4.94 (DICOM JPIP Referenced Transfer Syntax) or 1.2.840.10008.1.2.4.95 (DICOM JPIP Referenced Deflate Transfer Syntax), the following behavior is expected:

- If the DICOM Image Object(s) have a transfer syntax(es) that match the requested transfer syntax, the Retrieve Imaging Document Set Response shall include the DICOM Image Objects unchanged.
- If the DICOM Image Object(s) have a transfer syntax that differs from that of the request, the Retrieve Imaging Document Set Response shall include the DICOM image with the transfer syntax changed to the requested transfer syntax. In addition, the pixel data Attribute (7Fe0,0010 tag) will have been removed and replaced with a Pixel Data Provider URL (0028,7FE0 tag). The URL represents the JPIP request and will include the specific target information.
- Upon receipt of this Retrieve Imaging Document Set Response, the Imaging Document Consumer may request the pixel data from the pixel data provider using the supplied URL. Additional parameters required by the application may be appended to the URL when accessing the pixel data provider.

- 1220
- For example, a JPIP request for a 200 by 200 pixel rendition of the entire image can be constructed from the Pixel Data Provider URL as follows:
 - Pixel Data Provider URL (0028,7FE0) = <https://server.xxx/jpipserver.cgi?target=imgxyz.jp2>,
 - URL Generated by the application = <https://server.xxx/jpipserver.cgi?target=imgxyz.jp2&fsiz=200,200>

1225 The conditions of failure and possible error messages are given in the ebRS standard and detailed in ITI TF-2: 4.1.13 “Error Reporting”.

Add section 4.69.4.2.3.1

4.69.4.2.3.1 Access to Rejected Instances

1230 The contents of this section are required for Imaging Document Source and Imaging Document Consumer actors in the Imaging Object Change Management Profile.

For Key Object Selection instances with Document Titles (113001, DCM, “Rejected for Quality Reasons”), (113037, DCM, “Rejected for Patient Safety Reasons”), (113038, DCM, “Incorrect Modality Worklist Entry”), or (113038, DCM, “Data Retention Policy Expired”),

- 1235
- The Imaging Document Source shall not return the KOS instances that mark rejected instances.
 - The Imaging Document Source shall not return the rejected instances referenced by this specific KOS.

1240 When an Imaging Document Consumer receives a Key Image Note with Key Object Selection (KOS) Document Title valued (113001, DCM, "Rejected for Quality Reasons"), the Imaging Document Consumer shall support the three behaviors listed below. The behavior shall be configurable as one of the following:

- Suppress from presentation the rejected instances referenced in this KOS and this KOS itself
- 1245
- Present the rejected instances referenced in this KOS and this KOS itself
 - Ignore this KOS and present the rejected instances.

1250 When an Imaging Document Consumer receives a Key Image Note with the Key Object Selection (KOS) Document Title valued (113037, DCM, "Rejected for Patient Safety Reasons"), (113038, DCM, “Incorrect Modality Worklist Entry”), or (113039, DCM, “Data Retention Policy Expired”), it shall suppress the KOS and its referenced rejected instances from presentation.

Add section 4.74

4.74 Replacement Instances Stored

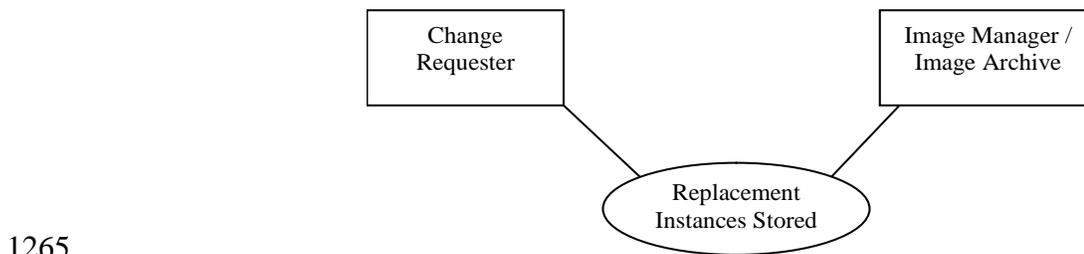
1255 This section corresponds to Transaction 74 of the IHE Radiology Technical Framework. Transaction 74 is used by the Change Requester and Image Manager / Archive actors.

4.74.1 Scope

1260 In the Replacement Instances Stored transaction, the Change Requester sends to the Image Manager / Archive new instances (images, presentation states, key image notes, etc.) that represent versions of existing instances that have been corrected in some way (e.g., corrected demographics, view information, or updated annotations).

Acquisition of additional SOP Instances, such as if correction of a Modality Worklist Selection requires additional SOP Instances to be acquired, is out of scope of this transaction, as this is covered by the Scheduled Workflow Profile.

4.74.2 Use Case Roles



Actor: Change Requester

Role: Transmit updated instances to Image Manager / Archive.

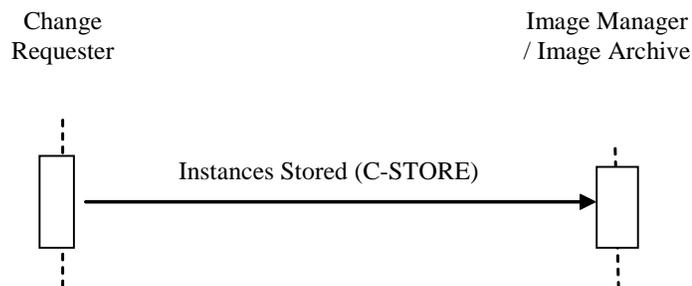
Actor: Image Manager / Archive

Role: Accept updated instances from Change Requester.

1270 4.74.3 Referenced Standard

DICOM 2009 PS 3.4: Storage Service Class.

4.74.4 Interaction Diagram



4.74.4.1 Instances Stored

1275 4.74.4.1.1 Trigger Events

The Change Requester has created new replacement instances and needs to send them to the Image Manager / Archive.

4.74.4.1.2 Message Semantics

1280 The Change Requester uses the DICOM C-STORE message to transfer the new instances. The Change Requester is the DICOM Storage SCU and the Image Manager / Archive is the DICOM Storage SCP.

A replacement instance created by the Change Requester shall:

- Have the same SOP Class as the replaced instance
- Belong to a new series
- 1285 • Set the header information according to the correct modality worklist entry if correction is the result of new modality worklist selection (see 4.74.4.1.2.1)
- Update the Critical Attributes as described in Table 4.74.4.1.2-1

Table 4.74.4.1.2-1: Critical Attributes for Replacement Instances

DICOM Attribute	DICOM Tag	Type	Description
Study Instance UID	(0020,000D)	R	Use Study Instance UID of the target study [IHE-1]
Series Instance UID	(0020,000E)	R	Generate new UID [IHE-2]
SOP Instance UID	(0008,0018)	R	Generate new UID [IHE-3]
Contributing Equipment Sequence	(0018,A001)	RC	Identification of the equipment that creates the replacement instances Required if the Change Requester is not the same as the original creator of the replaced instances.
> Purpose of Referenced Code Sequence	(0040,A170)	R	Describes the purpose for which the related equipment is being referenced. Use an appropriate code from Table 4.74.4.1.2-3
> Manufacturer	(0008,0070)	R	Manufacturer of the Change Requester
> Institution Name	(0008,0080)	R+	Institution where the Change Requester locates
> Station Name	(0008,1010)	R+	AE Title of the Change Requester
> Contribution DateTime	(0018,A002)	R+	The creation date and time of the replacement instances

1290 IHE-1: The new instances shall be associated with the study that they are targeted for. Therefore if the new instance replaces an existing instance within the same study, then the Study Instance UID shall remain the same. On the other hand, if the new instance is created due to correction of the modality worklist entry, then the Study Instance UID shall be the Study Instance UID associated with the correct modality worklist entry.

1295 IHE-2: New Series Instance UID means that the newly created instance will not reuse the existing series of the replaced instance.

IHE-3: New SOP Instance UID means that the instance is a new instance, not the same existing instance with updated header information. See Section 4.74.4.1.2.1 for details about replacement of SOP Instance UID.

Table 4.74.4.1.2-2: Codes for Contributing Equipment

Code Value	Code Scheme Designator	Code Meaning
DCM	109103	Modifying Equipment

1300

A Change Requester grouped with an Acquisition Modality shall also support the semantics defined in Modality Images Stored [RAD-8] and Modality Presentation State Stored [RAD-9].

A Change Requester grouped with an Evidence Creator shall also support the semantics defined in the Creator Images Stored [RAD-18] and Creator Presentation State Stored [RAD-19].

1305

A Change Requester grouped with an Image Manager/Archive that supports the Scheduled Workflow Multiple Identity Resolution Option, shall also support the semantics defined in Image Manager Instances Stored [RAD-70].

4.74.4.1.2.1 Correction of Scheduled Procedure Information

1310

Correction of scheduled procedure information in the corrected instances will be based on information from the modality worklist entry when the Change Requester is an Acquisition Modality. When a Change Requester is an Image Manager / Archive, it can get the same information from the Procedure Scheduled transaction (RAD-4). The following text will refer only to the modality worklist case. The use of RAD-4 information should be understood. Note that when using Table 4.74.4.1.2.1-1 and Tables defined in RAD TF-2: Appendix A.1, the Modality Worklist column refers to the correct Modality Worklist item, and the Image/Standalone IOD and MPPS IOD columns are for the replacement SOP Instances and their corresponding MPPS.

1315

During correction of scheduled procedure information, the Change Requester shall create new instances from the originally acquired instances which replace these original instances.

1320

Two alternative scenarios can follow, depending upon whether or not the acquired images are relevant to the actual scheduled procedure for the correct patient. Regardless, of which scenario occurs, if additional images need to be acquired for the actual scheduled procedure for the correct patient then this shall be done according to Scheduled Workflow.

1325

If it is determined that the originally acquired images are relevant to the actual scheduled procedure for the correct patient, or if a new scheduled procedure has been created on the DSS/OF for these images, then the patient and procedure attribute values can be taken from this scheduled information. The required mapping of attributes shall be as defined in RAD TF-2: Appendix A.1, unless the mapping rules are overridden by the attribute mapping defined in Table 4.74.4.1.2.1-1.

1330

Table 4.74.4.1.2.1-1: Critical Attributes Mapping Exception

DICOM attribute	Modality Worklist (return attribute values)	Filling values for:	
		Image/ Standalone IOD	MPPS IOD
Performed Protocol Code Sequence (0040,0260)	n.a.	Copy from the Original Instance or Original MPPS. The Performed Procedure Step for a corrected SOP Instance will still be that of the originally selected Modality Worklist item (and thus may not correspond to the correct one).	Copy from the Original Instance or Original MPPS. The Performed Procedure Step for a corrected SOP Instance will still be that of the originally selected Modality Worklist item (and thus may not correspond to the correct one).
Performed Procedure Step ID (0040,0253)	n.a.	Copy from the Original Instance or Original MPPS.	
Performed Procedure Step Start Date (0040,0244)	n.a.	Copy from the Original Instance or Original MPPS.	Copy from the Original Instance or Original MPPS.
Performed Procedure Step Start Time (0040,0245)	n.a.	Copy from the Original Instance or Original MPPS.	Copy from the Original Instance or Original MPPS.
Performed Procedure Step Description (0040,0254)	n.a.	Copy from the Original Instance or Original MPPS.	Copy from the Original Instance or Original MPPS.
Protocol Name (0018,1030)	n.a.	Copy from the Original Instance or Original MPPS.	Performed Series Sequence (0040,0340) Copy from the Original Instance or Original MPPS.

Alternatively, if the originally acquired images are not relevant to the actual scheduled procedure for the correct patient, and no new scheduled procedure has been created on the DSS/OF for these images, then the images could be manually corrected as for an unscheduled exam.

1335 **4.74.4.1.2.2 Maintenance of Instance Reference Integrity**

1340 Since SOP Instance UIDs are sometimes used as references in other related instances (e.g., Referenced Images Sequence in GSPS objects), if the Change Requester decided that these related instances remain valid and kept them, then the Change Requester shall ensure the consistency of SOP Instance references for all instances that were originally created by the same grouped Acquisition Modality or Evidence Creator. For example, if the Change Requester replaces the original object Image1 (SOP Instance UID 1.2.3) by replacement object Image2 (SOP Instance UID 1.2.3.1), then the Change Requester shall also correct existing GSPS object GSPS1 that has a reference to Image1 by replacing it with a new GSPS object GSPS2 that has the corrected reference to Image2, provided that GSPS1 was originally created by the same Change Requester.

1345

1350 The Image Manager / Archive is not required to maintain the referential integrity of the instances within a study. If the Image Manager / Archive receives instances for the same study from multiple sources, then it is possible that the referential integrity of some instances (e.g., GSPS object created by Evidence Creator) are broken upon receiving corrected instances from another source (e.g., Acquisition Modality).

4.74.4.1.2.3 Multiple Identity Resolution Option in Scheduled Workflow

The contents of this section are required for Change Requester actors grouped with Image Manager / Archive actors claiming the Imaging Object Change Management Profile that also support the Multiple Identity Resolution Option in the Scheduled Workflow Profile.

1355 The Image Manager / Archive shall meet the requirements defined in Appendix J: Multiple Identity Resolution Option. Specific to this transaction, it shall support:

- Cross-Referencing of Patient Identifiers (RAD TF-3: J.2.1)
- Configurable Mapping to Default Assigning Authorities (RAD TF-3: J.2.2)
- Message Semantics when Sending SOP Instances (Section J.2.4.1)

1360 4.74.4.1.3 Expected Actions

The Image Manager / Archive shall store the received DICOM objects such that they can be later retrieved (See 4.16 Retrieve Images) in a fashion meeting the requirements defined for a DICOM Level 2 Storage SCP (Refer to DICOM PS 3.4 B.4.1)

4.74.4.1.3.1 Multiple Identity Resolution Option in Scheduled Workflow

1365 The contents of this section are required for Image Manager / Archive actors claiming the Imaging Object Change Management Profile that also support the Multiple Identity Resolution Option in the Scheduled Workflow Profile.

The Image Manager / Archive shall meet the requirements defined in Appendix J: Multiple Identity Resolution Option. Specific to this transaction, it shall support:

- 1370
- Cross-Referencing of Patient Identifiers (RAD TF-3: J.2.1)
 - Configurable Mapping to Default Assigning Authorities (RAD TF-3: J.2.2)
 - Expected Actions when Receiving SOP Instances (RAD TF-3: J.2.4.1)

1375

4.74.5 Security Considerations

4.74.5.1 Security Audit Considerations

IHE Radiology Transaction	ATNA Trigger Event(s)	Actor(s) that shall be able to record audit event
Replacement Instances Stored [RAD-74]	Begin-storing-instances Instances-stored	Sender: Change Requester
	Instances-stored	Receiver: Image Manager / Archive.