Integrating the Healthcare Enterprise

IHE Radiology
Technical Framework Supplement

Reject Analysis & Monitoring (RAM)

Revision 1.1 – Trial Implementation

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Please verify you have the most recent version of this document. See here for Trial Implementation and Final Text versions and here for Public Comment versions.

Foreword

This is a supplement to the IHE Radiology Technical Framework V22.0. 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 January 23, 2025 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.

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.

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.

General information about IHE can be found at IHE.net.

Information about the IHE Radiology domain can be found at IHE Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at Profiles and IHE Process

The current version of the Radiology Technical Framework can be found at Radiology Technical Framework.

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Introduction to this Supplement

This supplement adds a Reject Analysis & Monitoring Profile to record, distribute, and analyze information about images that have been rejected or otherwise flagged as having quality issues.

The profile standardizes storage, query, and retrieval of Rejection Notes and Quality Notes encoded as DICOM Key Object Selection (KOS) instances. It is intended to support capturing quality issues at the time of acquisition, and/or during subsequent QA and image reporting steps. The transactions involve sending QA information for a number of modality devices to a centralized location for management and processing in a manner similar to the IHE Radiation Exposure Monitoring Profile (REM), and the IHE Contrast Administration Monitoring Profile (CAM).

The profile also specifies Image Manager / Image Archive behaviors when the Rejection Note indicates the referenced images are non-diagnostic, to avoid visibility of rejected images in clinical workflow, referred to as "sequestration". The specification builds on similar behaviors described in the Image Object Change Management (IOCM) Profile. This is intended to facilitate removing non-diagnostic images from the clinical workflow but keeping them available for the quality improvement workflow.

To Do

1. Section 55.4.2.1 references CP-RAD-423 (Add Specificity to IOCM (unreject)) which was status “Assigned” at the time RAM was published for Trial Implementation. Revisit this CP as it is completed and update the profile text accordingly.
2. Table Z.1-1 and others contain codes with a coding scheme of “99IHE”. Ensure these codes are updated with DICOM or LOINC codes prior to RAM Final Text.

Closed Issues

1. For non-reject quality issues do we expand [RAD-66], use [RAD-29], or make new?
   A: Use [RAD-29] and [RAD-66]

   Add text to [RAD-66] and [RAD-29] to cover reject analysis as needed.
   Keep it easy for IM/IA (and modalities) to implement both IOCM and RAM.
2. Should we include KOS tagging of images as "good/OK"?
   A: No.

   While this would provide positive confirmation that a review of the images occurred and no issues were found, in practice it is unlikely to be done/used and it would generate a lot of instances/clutter. If there is a need to establish a "denominator" for rejection rates, a rough estimate can be established based on a survey/census of studies/images.
3. Should Storage Commitment of the Reject/Quality Notes be required on the Reporter?
   A: Yes.

For patient safety reasons, it is important to get confirmation from the Image Manager / Image Archive for Rejection Notes at least.

4. Is it OK to allow multiple modifier codes?
   A: Yes.

   TID 2010 Row 2 permits multiple modifier codes in general. Row 3 indicates that if Row 1 is "Rejected for Quality Reasons" or "Quality Issue", an implementation may optionally draw a code from CID 7011. Rows 2 and 3 are specifically not made mutually exclusive, so both may be used in the same instance.
   [RAD-66] refers to “at least one Document Title Modifier Code” and indicates that a profile invoking [RAD-66] may specify a different CID than 7011.
   [RAD-29] also refers specifically to “Document Title Modifier code(s)”

5. Should we incorporate Replacement Instances Stored [RAD-74] from IOCM?
   A: No.

   “Replacement” images, if acquired, are simply part of the study. We don’t have the same pattern of distributing, later rejecting, and then later still replacing.

6. Does RAM need to address Wrong Patient (IOCM Patient Safety)?
   A: Not directly.

   RAM defers to IOCM for handling this. The Quality Information Reporter is also advised to consider retrieving IOCM tags if it wants to include those process aspects of quality. Note that IOCM Safety case has to offer chance to make changes, not required to provide reason (broad or detailed), not permitted to provide alternate access to images

7. Should we encode Detailed reasons and have receiver roll-up instead of encoding Broad?
   A: No.

   One of the reasons for the Broad codes was to have something that would be readily comparable between sites since they might be inclined to specialize and extend their fine codes.

8. Do we need to discuss how to retract a rejection? A: No. Defer to IOCM.

   IOCM and specifically IHE RAD CP423 introduce the concept of rejected in error. When this is communicated to the SCP, they are expected to make a "best effort" to unreject/ retract, but it is not a guaranteed process. This Profile implicitly inherits this defined process and behavior by referencing IOCM. An example use case involves rejecting an image of an uncooperative patient then subsequently determining the initially rejected image is the best that is likely to be obtained and may prove adequate. It is also possible the "reject" button might be clicked mistakenly, perhaps instead of "quality issue" and it would be inappropriate to repeat the acquisition to remedy a user interface issue. Or the wrong image(s) might be selected when rejecting. If a tech has excessive quality

standards, the clinician might find and recall an image determined to be adequate and used in the report (meaning the image should follow normal medicolegal retention policies.

9. Should we reduce some (or all) of the Rejected for Quality Issue material from IOCM that is now addressed (in more detail) here?
   A: No.

   IOCM is Final Text, this will initially be TI.
   Might be tricky to migrate the sequestration into RAM if QI is not in IOCM.
   Comfortable with the overlap. No conflict. Leave as is. (we reuse RAD-66)

10. Should we drop Detailed Reasons in favor of comments
    A: No.

    For the creator, preconfigured codes or preconfigured comments are similar effort. For the information reporter, the codes will facilitate comparability and analysis. Will look for TI and deployment feedback.

11. Should we have a Rejection code for “Procedural image”?
    A: No.

    Procedural Image was defined as “Imaging under the direct guidance of a practitioner might result in images rejected as redundant, having limited clinical relevance after the procedure is completed. E.g., image-guided positioning of tubes.”
    It is not necessary or useful for procedural images to go into the reporting process, however rejection of the images is not an appropriate mechanism for keeping such images out of the reporting workflow.

12. Do we need to explain behavior for reading acquired “wrong worklist/patient” images?
    A: No.

    While many sites will have a policy to report images that were erroneously acquired on a given patient (after they are correctly re-identified), documenting such workflow behaviors is not part of the scope of this profile.

IHE Technical Frameworks General Introduction

The IHE Technical Frameworks General Introduction is shared by all of the IHE domain technical frameworks. Each technical framework volume contains links to this document where appropriate.

9 Copyright Licenses

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

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IHE Technical Frameworks General Introduction Appendices

The IHE Technical Framework General Introduction Appendices are components shared by all of the IHE domain technical frameworks. Each technical framework volume contains links to these documents where appropriate.

Appendix A – Actors

*Add the following **new or modified** actors to the IHE Technical Frameworks General Introduction Appendix A:*

New (or modified) Actor Name	Definition
Quality Note Creator	Flags medical data as having quality issues.
Quality Information Reporter	Consumes quality information and supports Quality Assurance analysis processes.

The table below lists *existing* actors that are utilized in this profile.

Complete List of Existing Actors Utilized in this Profile

Existing Actor Name	Definition
Image Manager / Image Archive	A system that stores and manages imaging data.
Image Display	A system that presents medical images and associated imaging data.

Appendix B – Transactions

*Add the following **new or modified** transactions to the IHE Technical Frameworks General Introduction Appendix B:*

New (or modified) Transaction Name and Number	Definition
Key Image Note Stored [RAD-29]	**Send a list of image references and the label or note applied to those images.** ~~**An Acquisition Modality or an Image Creator sends a Key Image Note to the Image Archive**~~
Rejection Note Stored [RAD-66]	~~**Create and s**~~Send a ~~**manifest referencing**~~**list of** image **references** **and the reason they are removed from clinical use**~~**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**~~.

Appendix D – Glossary

*Add the following **new or modified** glossary terms to the IHE Technical Frameworks General Introduction Appendix D:*

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New (or modified) Glossary Term	Definition
Reject Analysis	Analysis of sets of images that have been identified as non-diagnostic or having some quality issue. This typically includes compiling statistics and identifying underlying causes as part of a quality improvement program.

Volume 1 – Profiles

Add new Section 55

55 Reject Analysis & Monitoring (RAM) Profile

The RAM Profile centralizes recording of details when images are rejected or otherwise flagged as having quality issues and making those details available for subsequent analysis. Although named “Reject Analysis”, this profile also addresses quality issues that do not result in the image being rejected from clinical use.

Reject Analysis is an important part of a departmental quality system. Rejected images represent not just inefficient use of equipment, staff, and patients' time, but can also involve obstructed patient care and unnecessary exposure to radiation. Images that are not rejected but still have quality issues represent an opportunity to improve the quality of imaging and patient care.

The profile requires Image Manager / Image Archives to make rejected images invisible for query and retrieval unless special mechanisms are invoked, a behavior referred to as "sequestration". This is essentially the same behavior described in the Image Object Change Management (IOCM) Profile. This is intended to facilitate removing non-diagnostic images from the clinical workflow but keeping them available for the quality improvement workflow via a separate access mechanism.

While radiography has served as the driving use case, and some of the text specifically describes radiography, quality codes are provided for a variety of modalities, and the profile is intended to be broadly applicable.

While the profile ensures robust sets of rejection records are readily available to Quality Information Reporters, it does not mandate any specific reporting or analysis. Such choices are left to product designers and their customers. With the full details of rejections in hand, features to promote patient safety and healthcare quality should be easily provided.

55.1 RAM Actors, Transactions, and Content Modules

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A. IHE Transactions can be found in the Technical Frameworks General Introduction Appendix B. Both appendices are located at https://profiles.ihe.net/GeneralIntro/index.html.

Figure 55.1-1 shows the actors directly involved in the RAM Profile and the relevant transactions between them.

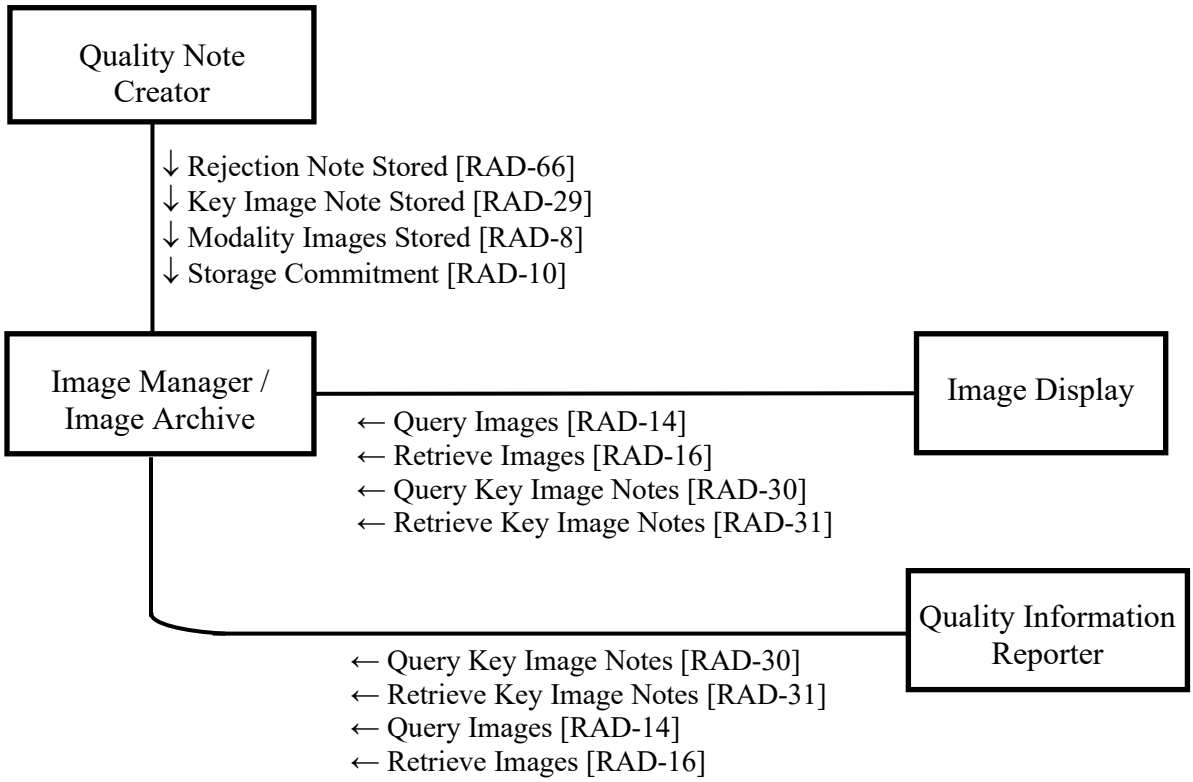

Figure 55.1-1: RAM Actor Diagram

Table 55.1-1 lists the transactions for each actor directly involved in the RAM Profile. To claim compliance with this profile, an actor shall support all required transactions (labeled "R") and may support the optional transactions (labeled "O").

Table 55.1-1: RAM Profile – Actors and Transactions

Actors	Transactions	Initiator or Responder	Optionality	Reference
Quality Note Creator	Rejection Note Stored [RAD-66]	Initiator	R	RAD TF-2: 4.66
	Key Image Note Stored [RAD-29]	Initiator	R	RAD TF-2: 4.29
	Modality Images Stored [RAD-8]	Initiator	R	RAD TF-2: 4.8
	Storage Commitment [RAD-10]	Initiator	R	RAD TF-2: 4.10
Quality Information Reporter	Query Key Image Notes [RAD-30]	Initiator	R	RAD TF-2: 4.30
	Retrieve Key Image Notes [RAD-31]	Initiator	R	RAD TF-2: 4.31
	Query Images [RAD-14]	Initiator	R	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	Initiator	R	RAD TF-2: 4.16
Image Manager / Image Archive	Rejection Note Stored [RAD-66]	Responder	R	RAD TF-2: 4.66
	Key Image Note Stored [RAD-29]	Responder	R	RAD TF-2: 4.29
	Modality Images Stored [RAD-8]	Responder	R	RAD TF-2: 4.8

Actors	Transactions	Initiator or Responder	Optionality	Reference
	Storage Commitment [RAD-10]	Responder	R	RAD TF-2: 4.10
	Query Key Image Notes [RAD-30]	Responder	R	RAD TF-2: 4.30
	Retrieve Key Image Notes [RAD-31]	Responder	R	RAD TF-2: 4.31
	Query Images [RAD-14]	Responder	R	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	Responder	R	RAD TF-2: 4.16
Image Display	Query Images [RAD-14]	Initiator	R	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	Initiator	R	RAD TF-2: 4.16
	Query Key Image Notes [RAD-30]	Initiator	R	RAD TF-2: 4.30
	Retrieve Key Image Notes [RAD-31]	Initiator	R	RAD TF-2: 4.31

55.1.1 Actor Descriptions and Actor Profile Requirements

Most requirements are documented in RAD TF-2 Transactions. This section documents any additional requirements on profile's actors.

55.1.1.1 Quality Note Creator

Quality Note Creators capture and distribute information about images that have been determined to be non-diagnostic (i.e., rejected) for some reason, or have been determined to have quality issues that may need to be tracked and addressed as part of an image quality program. Such information is encoded in DICOM Key Object Selection (KOS) instances.

Notes: 1. Workflow-oriented rejections, such as (113038, DCM, "Incorrect Modality Worklist Entry") are addressed by the Image Object Change Management (IOCM) Profile. A Quality Note Creator that supports the RAM Profile will often find it useful to support the IOCM Profile in parallel. See Section 55.6 RAM Cross-Profile Considerations.

2. Warm-up exposures, phantoms, and other non-patient images are identified by the Quality Control Subject (0010,0200) attribute and/or the Quality Control Image (0028,0300) attribute in the image header, not by modelling them as a quality defect using a KOS. Using those attributes, such images would be represented in neither the numerator nor the denominator of the quality analyses.

This profile does not distinguish between a Quality Note Creator that is driven by human assessment, or by AI (for example, flagging excessive noise or body part mismatch), or some combination of the two. The identity of the person and/or device responsible may be recorded in the quality note or rejection note by the Quality Note Creator.

Systems that might implement a Quality Note Creator include acquisition modalities, QA workstations, and reporting systems, to support recording quality issues identified at acquisition time, during a QA step, or during reporting, respectively.

The Quality Note Creator supports the Modality Images Stored [RAD-8] transaction in the 'Acquisition Modality' Role (RAD TF-2: 4.8.2) to store images.

When images should be removed from clinical use, the Quality Note Creator shall use Rejection Note Stored [RAD-66] to send a KOS instance with a Document Title value of (113001, DCM, "Rejected for Quality Reasons") that references the rejected images. This KOS instance is referred to as a Rejection Note. See RAD TF-2: 4.66.4.1

When a quality issue has been identified but the images should not be removed from clinical use, the Quality Note Creator shall use Key Image Note Stored [RAD-29] to send a KOS instance with a Document Title value of (113010, DCM, "Quality Issue") that references the relevant images. This KOS instance is referred to as a Quality Note. See RAD TF-2: 4.29.4.1.2.1.

When sending both the Rejection Note and the referenced images to an Image Manager / Image Archive, it is good practice, but not required, that the Rejection Note be sent first. This avoids the situation where the Image Manager / Image Archive receives images but is not yet aware that they are rejected, and might inappropriately make them available for retrieval or perform automatic forwarding or notifications.

The Quality Note Creator shall be configurable for how non-diagnostic images are handled (i.e., those referenced by a KOS with a Document Title of "Rejected for Quality Reasons") to avoid them being visible in the clinical process.

- In an environment with a RAM-conformant Image Manager / Image Archive, the Quality Note Creator may be configured to send non-diagnostic images to the Image Manager / Image Archive since it supports behavior to sequester such images (see Section 55.1.1.3).
- In other environments, the Quality Note Creator may be configured to send non-diagnostic images to a "Reject PACS" that is not part of the diagnostic reporting workflow but is accessible to the image quality program so the images can be reviewed to understand the nature and causes of the quality problems. The Quality Note Creator shall support configuration of an alternate destination for this purpose.
- The Quality Note Creator may also be configured to discard non-diagnostic images.

Note: Acquiring an additional diagnostic image to “replace” a non-diagnostic image is not uncommon. Re-using the SOP Instance UID value of the original non-diagnostic image as the SOP Instance UID of the re-acquired image is not permitted. It violates DICOM and has the potential to create a variety of problems.

The Quality Note Creator is responsible for delivery of KOS instances to the destinations despite intermittent connections (e.g., due to network trouble, or the destination being down).

The requirement for the Quality Note Creator to support Storage Commitment [RAD-10] applies after storing any instance, including both Key Object Selections and images.

Note: The Quality Note Creator may support configuration to not use the supported Storage Commitment based on local user practices.

The Quality Note Creator shall be capable of creating KOS instances for patient studies and for phantom/calibration studies.

Note: For phantom or calibration studies, it is expected that Quality Control Subject (0010,0200) will be present with a value of YES.

55.1.1.2 Quality Information Reporter

Quality Information Reporters retrieve rejection and quality information (KOS instances) and are expected to support some sort of review process and/or present some form of report to the user based on that information.

The format, contents, and analysis of such reports are part of the product design and are not defined by the IHE. Examples include generating a daily or weekly breakdown of rejections, or detailed review of individual rejection cases. See Section 55.4.1.3 Analysis & Reporting.

In terms of root cause analysis, as noted in Section 55.1.1.1, most Reason Codes represent observable issues in the images. The underlying cause of the issue may or may not be known when the issue is observed. Possible causes of which the technologist is aware might or might not be included in the Key Object Description.

The identity of the acquisition device, and the identity of the technologist performing the acquisition, are potential sources of quality issues and thus are key data elements to include in the quality analysis. These and other relevant details may be available to the Quality Information Reporter in the headers of the images referenced in the KOS instances. The attributes of the General Equipment Module in the images will reflect the acquisition device. When the Rejection Note or Quality Note is created on a QC workstation, the PACS, or during reporting, the attributes of the General Equipment Module in the KOS instances will reflect that device, not the acquisition device.

Having accurate information in the image headers about the technologist will typically depend on the technologist making the acquisition device aware when the technologist changes. This is not always the case in some sites. An information reporter might obtain this information from other sources, such as interacting or integrating with the RIS to access details about who completed the study, but no standard interface is currently available to achieve this.

It will often be useful for a system that implements the Quality Information Reporter Actor to also implement the Image Display Actor to include review of the images in the analysis process. The system might also choose to implement a “Reject PACS” as described in Section 55.1.1.3.

An information reporter may also choose to retrieve and analyze some of the KOS instances created by the Image Object Change Management (IOCM) Profile, if such instances are present on the Image Manager / Image Archive. KOS with a title of (113037, DCM, "Rejected for Patient Safety Reasons") or (113038, DCM, “Incorrect Modality Worklist Entry”) would potentially be relevant. KOS with a title of (113039, DCM, “Data Retention Policy Expired”) would likely not be of interest.

55.1.1.3 Image Manager / Image Archive

Image Manager / Image Archives store and manage rejection information (KOS instances and images) as part of the imaging record.

Images referenced by the Quality Note Creator using a KOS instance with a Document Title of "Quality Issue" are considered to be diagnostic and are handled by the Image Manager / Image Archive the same as if they were not flagged. The Image Manager / Image Archive receives such Quality Notes via Key Image Note Stored [RAD-29].

Images referenced by the Quality Note Creator using KOS with a Document Title of "Rejected for Quality Reasons" are considered non-diagnostic and should not be visible in the clinical process. The Image Manager / Image Archive receives such Rejection Notes via Rejection Note

Stored [RAD-66]. The sequestration behaviors that the Image Manager / Image Archive is required to support are described in RAD TF-2: 4.66.4.1.3. Briefly, this involves hiding the rejected instances in subsequent Query/Retrieve responses unless the client uses special mechanisms to bypass this behavior.

As an adjunct to the Image Manager / Image Archive described here, Section 55.1.1.1 and 55.1.1.4 refer to a “Reject PACS” which is a system outside the clinical workflow that may be used to manage non-clinical images. The Reject PACS is not included as a formal actor in this profile since it has no special behavior requirements. It is an alternate deployment pattern that may be considered.

55.1.1.4 Image Display

Image Displays, when used for reject analysis, display images referenced in Rejection Notes and Quality Notes to help reviewers better understand the nature of the quality issue and possibly help determine the root cause.

To prevent inadvertent use of rejected images in clinical workflow, the rejected images are sequestered by the Image Manager / Image Archive or moved to a different location than the clinical archive. The Image Display is expected to handle both of these storage patterns through the use of alternate AE Titles.

The Image Display shall be configurable to access an alternate AE Title. That AE Title may be the “Expose Rejected Instances” Application Entity provided by the Image Manager / Image Archive (see RAD TF-2: 4.66.4.1.3) or it may be the AE Title of the "Reject PACS" (see Section 55.1.1.1).

Note: The Expose Rejected Instances Application Entity bypasses sequestering behavior. It provides access to all available instances, both those that have been rejected and those that have not been rejected.

The user of the Image Display might query and retrieve the KOS instances and then retrieve the image instances based on the references in the KOS. The user might also query for the image instances directly and then retrieve selected images.

55.2 RAM Actor Options

Options that may be selected for each actor in this profile, if any, are listed in the Table 55.2-1. Dependencies between options, when applicable, are specified in notes.

Table 55.2-1: Reject Analysis & Monitoring – Actors and Options

Actor	Option Name	Reference
Quality Note Creator	*No options defined*	--
Quality Information Reporter	*No options defined*	--
Image Manager / Image Archive	*No options defined*	--
Image Display	*No options defined*	--

55.3 RAM Required Actor Groupings

An actor from this profile (Column 1) shall implement all of the required transactions and/or content modules in this profile ***in addition to all*** of the requirements for the grouped actor (Column 2) (Column 3 in alternative 2).

Section 55.5 describes some optional groupings that may be of interest for security considerations and Section 55.6 describes some optional groupings in other related profiles.

Table 55.3-1: Reject Analysis & Monitoring – Required Actor Groupings

RAM Actor	Actor(s) to be grouped with	Reference
Quality Note Creator	ITI Consistent Time (CT) / Time Client	ITI TF-1: 7.1
	Radiation Exposure Monitoring (REM) / Acquisition Modality (See Note 1)	RAD TF-1: 22.1
Quality Information Reporter	None	--
Image Manager / Image Archive	None	--
Image Display	None	--

Note 1: This grouping is only required if the Quality Note Creator is an acquisition modality that uses X-rays.

55.4 RAM Overview

55.4.1 Concepts

55.4.1.1 Rejection Notes and Quality Notes

A **Rejection Note** is a way of maintaining a record of the rejection of DICOM images. It is encoded as an instance of a DICOM Key Object Selection (KOS) object. The KOS captures a list of image instances and associated metadata about the rejection of those instances (e.g., the reason that the instances have been rejected). A Rejection Note can be distinguished from other KOS instances by the document title of the TID 2010 container, which is (113001, DCM, "Rejected for Quality Reasons").

The presence of a Rejection Note may result in the Image Manager/Image Archive sequestering the referenced images so those are not used clinically. See Section 55.1.1.3 for more details. It is not uncommon for rejected images to be retained for medicolegal reasons as well as quality review.

A **Quality Note** is a way of maintaining a record of quality issues identified in DICOM images. Quality issues differ from rejections in that the images are still considered diagnostic and are included in the clinical workflow. It is also encoded as an instance of a DICOM KOS object. A Quality Note can be distinguished from other KOS instances by the document title of the TID 2010 container, which is (113010, DCM, "Quality Issue").

Both Rejection Notes and Quality Notes include one or more Document Title Modifier codes to describe the reason the images were labelled as being rejected or having a quality issue. Many

reason codes, for example (111212, DCM, "Over exposed") could be appropriately used in either a Rejection Note (indicating that the over-exposure is sufficiently severe that the image is non-diagnostic) or a Quality Note (indicating that the image is diagnostic but the degree of over-exposure is undesirable/sub-optimal and ideally would be avoided in the future). A given image might be referenced by one or more Rejection Notes and one or more Quality Notes, indicating that multiple issues were observed, some of which would not have otherwise resulted in the image being rejected, but due to other issues, it was.

Since the KOS instances are persistently stored by the Image Manager/Image Archive in the corresponding Study folders, they are available for querying, retrieval, and analysis as part of record keeping and in support of quality control processes.

55.4.1.2 Codesets

For sites to analyze reject and quality records and use them to drive QA processes, it is critical to use standard codesets in a consistent fashion for imaging procedure codes and quality reasons.

This profile does not mandate the use of particular codesets, so agreeing within the local site or organization on common codesets will be a prerequisite for effective deployment of this profile.

Sections under Section 55.1.1.1 provide recommended quality codesets.

Note: Sites that prefer a synonymous meaning that still matches the definition for the code can configure systems to use the synonym without degrading their interoperability by using an entirely different code.

55.4.1.3 Analysis & Reporting

The motivation for analysis and reporting of rejection and quality notes is to maintain and/or improve the quality of imaging services. The goals include minimizing risks and physical impact on patients, and lowering procedure costs.

Quality notes may indicate issues that made it harder or slower for the imaging clinician to interpret the image, may have resulted in a slower or less complete exam, or may have used higher than desired radiation. In the case of rejection notes, imaging may have needed to be repeated, negatively impacting the timeliness of care, the efficiency of the department, the comfort of the patient, and potentially introducing additional radiation risks. Or if imaging was not repeated, there was an absence of potentially important diagnostic information.

Reject rates that are too high may indicate inefficient workflows and, depending on the imaging modality, unnecessary radiation exposure to the patient. Too few rejected images or identified quality issues may indicate a lack of quality control and the fact that suboptimal images are being sent to the radiologist for interpretation.

A key benefit of the profile is that both rejection and quality data is centrally aggregated for issues identified at all conformant modality devices, and for issues identified at acquisition, during QA or during review.

It is expected that site quality programs will involve monthly review by stakeholders such as the lead technologists, physicists, and department administrators.

The profile is intended to facilitate, but does not mandate, the ability of a Quality Information Reporter to do things like:

- tabulate the frequency of each quality issue and reason for rejection, overall and organized by individual modality device/room, operator/technologist, work shift, location (inpatient/outpatient/ER/OR/portable/ortho/etc.), protocol/procedure type, and facility (if the review spans multiple sites).
- assist in identifying trends through interactive plots and summary statistics, for example month to month, year to year, before/after a quality program intervention, or score relative to an established target.

  Note: The Quality Information Reporter likely maintains past statistics, so it would typically always query for the latest month of Rejection Notes and Quality Notes rather than retrieving an entire year's worth.

- drill down analysis by procedure, location, device, technologist, etc., displaying associated images and metadata and assisting the determination of the root cause of a given quality issue or rejection.
- facilitate access to the images when necessary to better understand a specific issue.
- support random sampling of "good" (i.e., unflagged) images for a given procedure, device, technologist, or shift to assess whether the initial QA phase is sufficiently sensitive.
- break out notes created by the imaging clinicians during interpretation as indicating issues that made it past initial QA.
- potentially identify rejections or quality issues that are being "overcalled" (i.e., flagging images that are within the established acceptable quality range as having an issue, perhaps out of a desire to always produce "textbook images")
- enable detailed analysis of protocol parameters and system use. Examples in radiography include exposure index (EI) analysis, automatic exposure control (AEC) performance, and image processing parameter optimization. Additional information for radiography is available in [Little, K et al, AAPM task group report 305: Guidance for standardization of vendor-neutral reject analysis in radiography, J of Applied Clinical Medical Physics, 2023, https://doi.org/10.1002/acm2.13938].

The analysis is intended to help guide remediation steps to avoid the rejection or quality issues in the future.

- targeted technologist education. For example, if knee images are not coming out well due to poor positioning, a tech or group of techs might be given training on positioning techniques, potentially using the Rejection Note tagged images as teaching aids. Subsequent reporting might indicate the success/impact of the remediation.
- device service. For example, certain artifacts might indicate equipment that is degraded and in need of repair or re-calibration.
- revise or clarify policies, procedures, and protocols

- Radiologists can be assisted in determining how changes in techniques and protocols impact diagnostic ability.

Data will generally be continuously collected for all imaging procedures. Periodic process improvement and data analysis would focus on local variations attributable to x-ray equipment, operators, procedures, and ordering physicians. The RAM Profile does not define purpose of analysis, analytical methods, and other usage.

55.4.1.4 Problem Rate Denominators

Quality systems are often driven by the rate of occurrence of particular problems. To assess that, it is necessary to determine the denominator of the tracked performance metric, i.e., once one has determined that a certain number of images were over-exposed, the denominator (the total number of relevant images acquired over the same period) is needed to determine a percentage rate.

Note: Some analysis makes the sometimes-practical assumption that that the denominator, i.e., imaging volume, is relatively stable over time. In such cases, the denominator "cancels out" and it is possible to work with the numerator. E.g., consider the number of instances of "wrong body part" per week rather than the rate.

Creating quality notes for all images, i.e., for "good" images too, would enumerate the denominator but would potentially "clutter" the studies, and computationally would likely not be the most efficient way to compute the denominator. Some possible alternatives include:

- For ionizing radiation modalities (which often have the most active quality programs), query/retrieve RDSR instances over the period in question
  - This provides technologist, device, and procedure type (if known), for each exposure as well as total number of radiographic frames.
  - It is expected that some Quality Information Reporters may already be grouped with a Dose Information Reporter from the IHE Radiation Exposure Monitoring (REM) Profile.
- Query the Image Manager / Image Archive for images of the given modality type over the period in question.
  - To get subtotal denominators for each technologist, device, procedure type, etc., it would likely be necessary to retrieve an image from each series of interest (e.g., for the previous week) which would be additional work for the Quality Information Reporter.
- Monitor Modality Performed Procedure Step (MPPS) messages
  - As with the query approach, subtotal denominators may require retrieving sample images.
- Subscribe to Instance Availability Notification [RAD-49] transactions from the Image Manager / Image Archive.

- As with the query approach, subtotal denominators may require retrieving sample images.

- Group the Quality Information Reporter with the Image Manager / Image Archive to inspect the database directly.
- Group the Quality Information Reporter with the Order Filler (RIS) to inspect information it may have on the number of images for orders marked complete by the technologist.
- Consider asking the Quality Note Creator to create an additional KOS for every series which would include the total number of acquisitions, the technologist, the device and procedure.

55.4.2 Use Cases

55.4.2.1 Use Case #1: Rejection

The Reject Case involves rejecting an image (non-diagnostic) and storing rejection information for later quality management use.

55.4.2.1.1 Rejection Case Description

Typically, acquired images are checked for quality at the time of acquisition, or shortly thereafter as part of a QA step. An image that is determined to be non-diagnostic is "rejected" and is not sent for interpretation. Acquisition of a "repeat" image may take place to obtain a diagnostic quality image and allow the imaging workflow to proceed.

Notes: 1. Quality issues that do not prevent the image from being interpreted are discussed in Section 55.4.2.2 Use Case 2.

2. In current practice, if the image is checked but no quality issues are observed, the workflow proceeds as normal and there is no record of the review.

Image rejection most commonly occurs at the modality. Rejection can also occur during image interpretation. An image marked as a quality issue (see Use Case 2) by the technologist might later be judged non-diagnostic and rejected by the radiologist. More specifically, this may occur when the tech observes an artifact that they are unable to avoid so they tag the quality issue and leave it to the radiologist to decide if it is usable. Note that this can result in two KOS quality statements for the same image, which the Quality Information Reporter should be prepared to handle.

In other cases, particularly for modalities that do not involve ionizing radiation, the technologist might observe a quality issue that can be improved so they retake the image and the original is Rejected to keep it out of the flow.

While rejected images should not be used clinically, it is highly desirable to retain the images for review during the quality management process, since inspection of the image can be very helpful in understanding the characteristics and cause of the quality failure. It is also possible that review determines the rejected image was usable or that it would have been possible to process the image to make it usable. Such findings can lead to process improvements. Examining the images

can also help distinguish between a repeated acquisition that was needed to replace the original, or to supplement the original (e.g., the anatomy was too large to fit in a single image). Some reject-repeats are due to technologist misjudgments, while others are unavoidable (e.g., patient motion, or the patient forgot about jewelry they were wearing when asked).

"Unrejection" (where a rejection is reversed, and the rejected image is intended to be returned to clinical use) is not discussed here. For a discussion of how this is handled, see IHE CP-RAD-423 for a description of the process in the context of the IOCM Profile.

55.4.2.1.2 Rejection Case Process Flow

Figure 55.4.2.1.2-1 shows a Quality Note Creator grouped with the Acquisition Modality. Alternatively, the Acquisition Modality could send the acquired images to a Quality Note Creator in a separate QA workstation.

Radiation dose information associated with the acquired images is shown being stored by the Quality Note Creator and retrieved by the Quality Information Reporter for use in the Quality Review Process; however, that analysis is optional (and would not exist for modalities like MR and ultrasound).

Alternatively, there could be a Quality Note Creator on a workstation between the Modality and the Image Manager / Image Archive, or on the Image Manager / Image Archive itself, or on the radiology reading workstation.

Note that when the Quality Information Reporter retrieves the rejected images referenced in the Rejection Note for use in the Quality Review Process, it uses the mechanism to bypass the Sequestration behavior of the Image Manager / Image Archive (see RAD TF-2: 4.66.4.1.3.1) which would be hiding the rejected images from normal use.

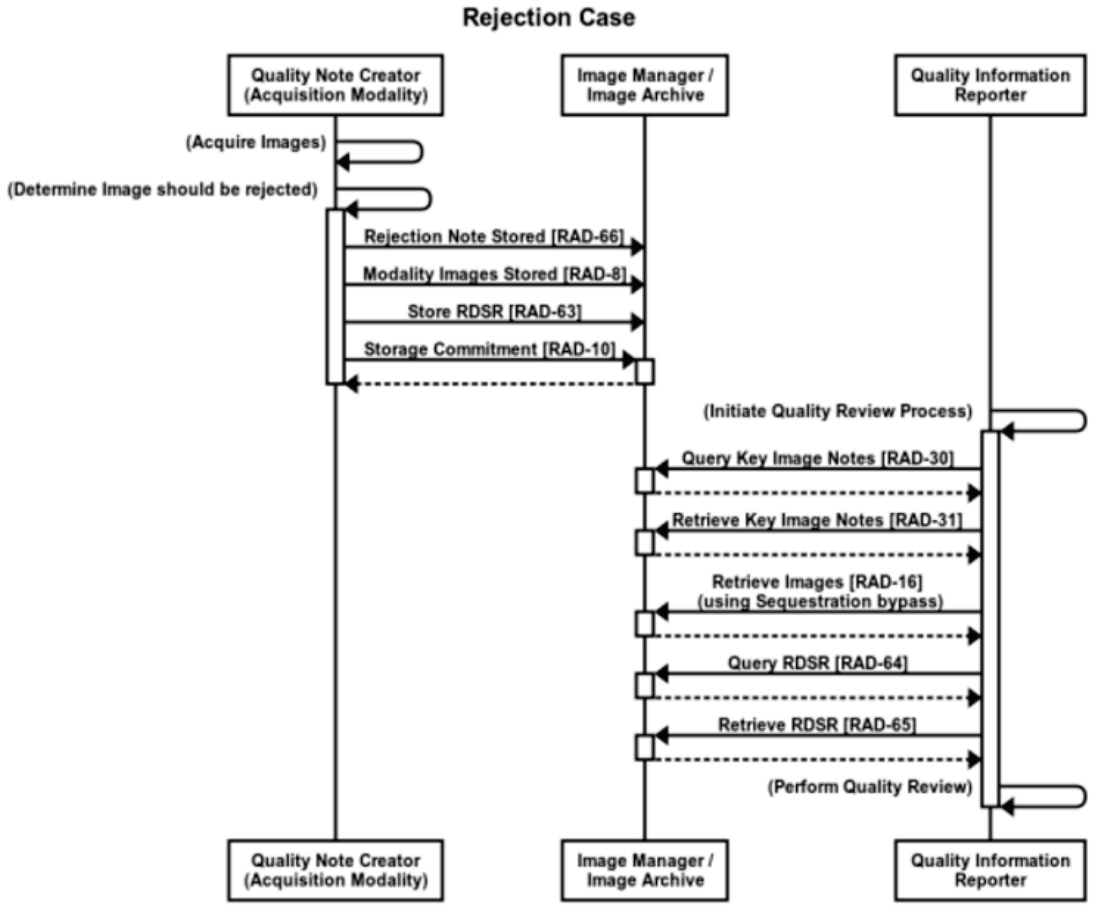

Figure 55.4.2.1.2-1: Rejection Process Flow

640 The text in Figure 55.4.2.1.2-2 was used to generate the diagram in Figure 55.4.2.1.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.


```
title Rejection Case

participant Quality Note Creator\n(Acquisition Modality) as QR
participant Image Manager /\nImage Archive as IMIA
participant Quality Information\nReporter as QA

QR->QR: (Acquire Images)
QR->+QR: (Determine Image should be rejected)
QR->IMIA: Rejection Note Stored [RAD-66]
QR->IMIA: Modality Images Stored [RAD-8]
QR->IMIA: Store RDSR [RAD-63]
QR->+IMIA: Storage Commitment [RAD-10]
IMIA-->-QR:
deactivate QR

QA->+QA: (Initiate Quality Review Process)
QA->IMIA: Query Key Image Notes [RAD-30]
activate IMIA
IMIA-->-QA:
QA->IMIA: Retrieve Key Image Notes [RAD-31]
activate IMIA
IMIA-->-QA:
QA->IMIA: Retrieve Images [RAD-16]\n (using Sequestration bypass)
activate IMIA
IMIA-->-QA:
QA->IMIA: Query RDSR [RAD-64]
activate IMIA
IMIA-->-QA:
QA->IMIA: Retrieve RDSR [RAD-65]
activate IMIA
IMIA-->-QA:
QA->-QA: (Perform Quality Review)
```

Figure 55.4.2.1.2-2: Diagram Pseudocode for Rejection Process Flow

55.4.2.2 Use Case #2: Quality Issue

The Quality Issue Case involves labelling an image as having a quality issue and storing that information for later quality management use.

Note: Non-diagnostic (rejected) images are discussed in Section 55.4.2.1 Use Case 1.

55.4.2.2.1 Quality Issue Description

Images found to have quality issues are sub-optimal, but still considered to be diagnostic and proceed through the clinical workflow as usual.

The diagram here shows the image being labelled during a post-acquisition quality assessment step on a QA workstation. The study would typically be "completed" in the RIS by the QA tech after the QA review is complete.

Note: If there were no quality issues, the QA Workstation would forward the images to the Image Manager /Image Archive without creating a Quality Note.

Additionally, quality labels might be applied by a reviewer at the Acquisition Modality, the Image Manager / Image Archive, or by the imaging clinician during image interpretation. Some issues noted by the reading clinician might include positioning, cropping, and exposure factors, etc.

The diagram shows the images being sent from the Acquisition Modality to the QA Workstation. Alternatively, the images might be sent directly from the Acquisition Modality to the Image Manager / Image Archive and they QA Workstation views the new images there before creating and storing Quality Notes as appropriate.

Quality Notes created at later steps would be stored similarly and also be made available as feedback to the techs and be analyzed during periodic quality reviews. Also not shown here is the possibility that the imaging clinician might consult the quality tags applied to the images during the QA step, or the possibility that an image is both rejected and found to have lesser quality issues.

55.4.2.2.2 Quality Issue Process Flow

Figure 55.4.2.2.2-1 shows a Quality Note Creator grouped with the Acquisition Modality. Alternatively, the Acquisition Modality could send the acquired images to a Quality Note Creator in a separate QA workstation.

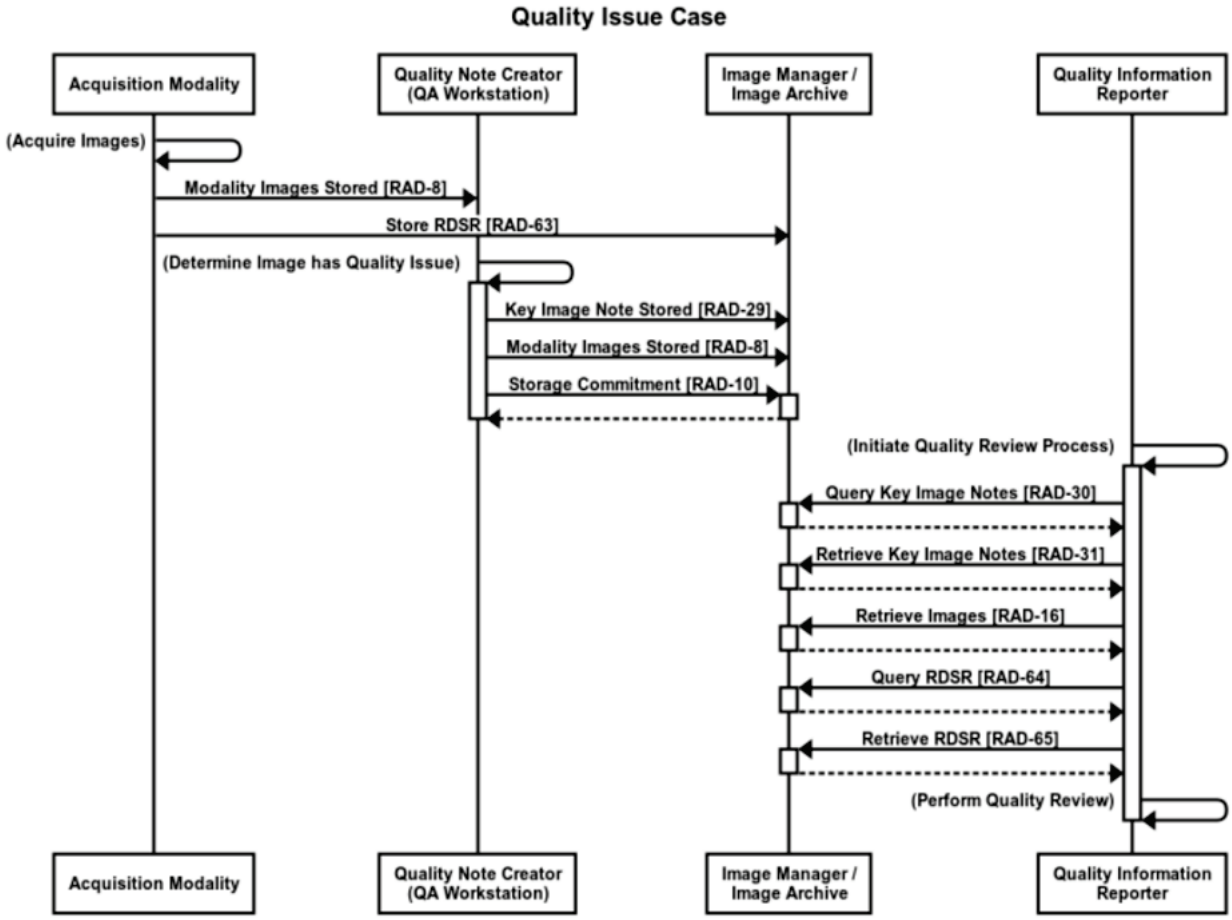

Figure 55.4.2.2.2-1: Quality Issue Process Flow

The text in Figure 55.4.2.2.2-2 was used to generate the diagram in Figure 55.4.2.2.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

```
title Quality Issue Case

participant Acquisition Modality as AM
participant Quality Note Creator\n(QA Workstation) as QR
participant Image Manager /\nImage Archive as IMIA
participant Quality Information\nReporter as QA

AM->AM: (Acquire Images)
AM->QR: Modality Images Stored [RAD-8]
AM->IMIA: Store RDSR [RAD-63]
QR->+QR: (Determine Image has Quality Issue)
QR->IMIA: Key Image Note Stored [RAD-29]
QR->IMIA: Modality Images Stored [RAD-8]
QR->+IMIA: Storage Commitment [RAD-10]
IMIA-->-QR:
deactivate QR

QA->+QA: (Initiate Quality Review Process)
QA->IMIA: Query Key Image Notes [RAD-30]
activate IMIA
IMIA-->-QA:
QA->IMIA: Retrieve Key Image Notes [RAD-31]
activate IMIA
IMIA-->-QA:
QA->IMIA: Retrieve Images [RAD-16]
activate IMIA
IMIA-->-QA:
QA->IMIA: Query RDSR [RAD-64]
activate IMIA
IMIA-->-QA:
QA->IMIA: Retrieve RDSR [RAD-65]
activate IMIA
IMIA-->-QA:
QA->-QA: (Perform Quality Review)
```

Figure 55.4.2.2.2-2: Diagram Pseudocode for Quality Issue Process Flow

55.5 RAM Security Considerations

KOS instances contain PHI such as patient demographics. The security considerations are similar to those for images. It may also be appropriate to log the creation, query, and transfer of KOS instances using the Record Audit Event [ITI-20] transaction defined in the IHE ITI Audit Trail and Note Authentication (ATNA) Profile.

Since rejection notes can result in clinical images going unreviewed and potentially being deleted, security considerations should include determining which operators and systems are able to submit rejection notes. It may also be prudent for Image Manager / Image Archives to retain rejected images at least until local quality review has been completed.

Quality Note Creators and Quality Information Reporters are typically connected to the same data networks as imaging modality systems and should follow similar data protection practices, such as implementing the Authenticate Node [ITI-19] transaction in ATNA to enable secure connections.

55.6 RAM Cross-Profile Considerations

Since the data created and exchanged in the Reject Analysis & Monitoring Profile are encoded using common DICOM SR instances, many other Radiology profiles that manage content could be used in conjunction with the content of the RAM Profile:

- **Cross-Enterprise Document Sharing for Imaging (XDS-I.b)** and/or **Cross-Community Document Access for Imaging (XCA-I)** could be used to exchange quality information within and between enterprises.
- **Import Reconciliation Workflow (IRWF.b)** and/or **Import and Display of External Priors (IDEP)** could be used to localize and manage the import of quality information.
- **Portable Data for Imaging (PDI**) could be used to distribute quality information on portable media.
- **Audit Trail and Node Authentication (ATNA)** (with the Radiology Audit Trail Option) is recommended to secure the communication of, and record audit trails for, quality information.
- **SWF.b – Scheduled Workflow.b** - An Image Manager / Image Archive in SWF.b that also supports Reject Analysis and Monitoring is expected to reconcile the KOS instances along with the rest of the instances in a patient's study.

  Note: SWF.b addresses reconciliation driven by HL7 v2.5 messages. Reconciliation driven by HL7 v.2.3 messages is handled in the Patient Information Reconciliation (PIR) Profile which is used in concert with the original SWF Profile.

- **IOCM – Image Object Change Management** - A Change Requester in IOCM could be grouped with a Quality Note Creator in RAM to handle both image quality issues and other workflow and patient safety issues.
  An Image Manager / Image Archive in IOCM could be grouped with an Image Manager / Image Archive in RAM to support awareness and sequestration of rejected images while making them available to quality review processes. The internal logic of the two profile behaviors is very similar.

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Modify Section 4.10.2 as shown

4.10 Storage Commitment [RAD-10]

…

Table 4.10.2-1 Actor Roles

Role:	**Requester:** Requests a storage commitment from the Responder for DICOM objects previously transmitted.
Actor(s):	The following actors may play the role of Requester: Acquisition Modality Evidence Creator Importer Workitem Performer **Quality Note Creator**
Role:	**Responder:** Assumes responsibility for reliable storage, retrieval, and validity of the referenced DICOM objects.
Actor(s):	The following actors may play the role of Responder: Imager Manager/Archive Report Manager Report Repository

…

Modify Section 4.16.2 as shown

Note: This edit assumes changes in CP-RAD-545 "Refactor RAD-16 Actor Roles for Reuse"

4.16 Retrieve Images [RAD-16]

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4.16.2 Actor Roles

Table 4.16.2-1: Actor Roles

Role:	**Requester:** Submit retrieve requests for DICOM images
Actor(s):	The following actors may play the role of Requester: Imaging Display Imaging Document Consumer **Quality Information Reporter**
Role:	**Responder:** Return the requested DICOM images
Actor(s):	The following actors may play the role of Responder: Image Manager / Image Archive Imaging Document Source

…

740 *Modify Section 4.29.2 as shown*

4.29 Key Image Note Stored [RAD-29]

…

Table 4.29.2-1: Actor Roles

Role:	**Sender:** Flags significant images by creating a Key Object Selection instance and sending it to the Receiver.

Actor(s):	The following actors may play the role of Sender: Acquisition Modality Evidence Creator **Quality Note Creator**
Role:	**Receiver:** Receives and stores Key Object Selection instances.
Actor(s):	The following actors may play the role of Receiver: Imager Manager / Image Archive

Modify Section 4.29.4.1 as shown to add profile-specific semantics and tidy up terms

4.29.4.1 Key Image Note Stored Message

4.29.4.1.1 Trigger Events

The Sender determines that DICOM instances need to have particular labels applied and a corresponding Key Image Note stored.

4.29.4.1.2 Message Semantics

The message is a DICOM C-STORE of a Key Object Selection instance. The Sender is the SCU. The Receiver is the SCP.

The Sender shall create a new Key Object Selection ~~**Storage**~~ instance in a new Series of the referenced images' Study. Integration-critical values shall be filled as defined in the Evidence Document Attribute Mapping (RAD TF-2x: Appendix A.2). The instance shall be constructed as defined in DICOM PS3.3 and PS3.4.

The value of the Key Object Selection Document Title code and the Document Title Modifier code(s) may be constrained by the Profile invoking this transaction.

Key Object Selection **instances**~~**Documents**~~ that reference multi-frame images shall populate the Referenced Frame Number (0008,1160) in each applicable occurrence of the Referenced SOP Sequence (0008,1199) in the Key Object Selection **instance**~~**Document**~~, unless the Key Object Selection **instance**~~**Document**~~applies to all the frames in the image.

4.29.4.1.2.1 RAM Quality Notes

Quality Note Creators that claim support of the Reject Analysis & Monitoring (RAM) Profile shall conform to the requirements in this section.

Note: Key Object Selection instances that convey quality information about non-rejected instances are referred to as Quality Notes and are conveyed using this Key Image Note Stored [RAD-29] transaction. Key Object Selection instances that convey quality information about rejected instances are referred to as Rejection Notes and are conveyed using Rejection Note Stored [RAD-66].

Each Key Object Selection instance shall include one Broad Reason code value in the Document Title Modifier. If multiple Broad Reason codes apply to the same image(s), or if there are both Rejection issues and Quality issues for the same image(s), then the Quality Note Creator shall create multiple KOS.

Additional Detailed Reason code values that fall under the Broad Reason code may be included in the Document Title Modifier if known. Reason codes are further constrained in RAD TF 2x: Appendix Z.

The method for selecting appropriate Document Title Modifiers (see RAD TF 2x: Appendix Z) is not constrained. For example, the Quality Note Creator might allow configuration of a short list of common Broad Reason codes for an operator to select from and then display Detailed Reason codes based on the Broad Reason Code.

Broad Reason codes predominantly represent observable issues in the images. The underlying cause of the issue may or may not be known when the issue is observed. A few Detailed Codes describe a cause for an observed issue and may be included if the cause is known. The Key Object Description content item may be used to record a text description of any suspected causes, or known causes, for which codes are not available. Determination or confirmation of the cause is left until later analysis.

The Quality Note Creator shall be capable of recording a free text comment in the Key Object Description (Row 7 of DICOM PS3.16 TID 2010). This might be used to record potential causes (known or suspected) for the quality issue, or perhaps relevant factors, e.g., that the urgency of a stroke case meant that position optimization was intentionally skipped to obtain an image more quickly.

The Quality Note Creator may record the identity of the person and/or device responsible for the Rejection/Quality Note in the Observer Context (Row 6 of TID 2010).

The Sender shall populate the attributes in the Contributing Equipment Sequence (0018,A001) in the Key Object Selection, to the extent that these attributes are populated in the top-level dataset of the referenced image instance, as shown in Table 4.29.4.1.2.1-1.

Table 4.29.4.1.2.1-1: KOS Corresponding Attributes

DICOM attribute	Referenced Image	Key Object Selection (Contributing Equipment Sequence)
Purpose of Reference Code Sequence (0040,A170)	n.a.	(109101, DCM, "Acquisition Equipment")
Manufacturer (0008,0070)	Source	Copy
Manufacturer's Model Name (0008,1090)	Source	Copy
Software Versions (0018,1020)	Source	Copy
Device Serial Number (0018,1000)	Source	Copy

DICOM attribute	Referenced Image	Key Object Selection (Contributing Equipment Sequence)
Station Name (0008,1010)	**Source**	**Copy**
Date of Last Calibration (0018,1200)	**Source**	**Copy**
Operators' Name (0008,1070)	**Source**	**Copy**
Operator Identification Sequence (0008,1072)	**Source**	**Copy**

Note: This is intended to support the Quality Information Reporter doing basic analysis from the content of the KOS, without having to retrieve the referenced images unless needed for visual analysis.

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4.29.4.1.3 Expected Actions

The Receiver will store the received Key Image Note **instances**~~**objects**~~.

…

Modify Table 4.30.2-1 as shown.

805 *Note: This edit assumes changes in CP-RAD-546 "Refactor RAD-30 and 31 for Reuse"*

4.30 Query Key Image Notes [RAD-30]

…

4.30.2 Actor Roles

Table 4.30.2-1: Actor Roles

Role:	**Requester:** Query for Key Image Notes together with the referenced image data
Actor(s):	The following actors may play the role of Requester: Image Display **Quality Information Reporter**
Role:	**Manager:** Respond to queries for Key Image Notes matching the specified filter.
Actor(s):	The following actors may play the role of Manager: Image Manager / Image Archive

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Modify Table 4.31.2-1 as shown.

Note: This edit assumes changes in CP-RAD-546 "Refactor RAD-30 and 31 for Reuse"

4.31 Retrieve Key Image Notes [RAD-31]

…

4.31.2 Actor Roles

Table 4.31.2-1: Actor Roles

Role:	**Requester:** Submit retrieve requests for Key Image Notes
Actor(s):	The following actors may play the role of Requester: Imaging Display Imaging Document Consumer **Quality Information Reporter**
Role:	**Manager:** Return the requested Key Image Notes
Actor(s):	The following actors may play the role of Responder: Image Manager / Image Archive Imaging Document Source

Modify Table 4.66.2-1 as shown

4.66 Rejection Note Stored [RAD-66]

…

Table 4.~~29~~66.2-1: Actor Roles

Role:	**Sender:** Flags ~~**significant**~~**rejected** images by creating a ~~**Key Object Selection instance**~~**Rejection Note** and sending it to the Receiver.

Actor(s):	The following actors may play the role of Sender: Acquisition Modality Evidence Creator **Change Requester** **Quality Note Creator**
Role:	**Receiver:** Receives and stores ~~**Key Object Selection instances**~~**the Rejection Notes, and applies them by removing or sequestering the referenced images**.
Actor(s):	The following actors may play the role of Receiver: Image Manager/ Image Archive

Modify Table 4.66.4-1 as shown

Table 4.66.4-1: Key Object Selection Document Title Usage by Profile

KOS Document Title	IOCM	RAM	Section
(113001, DCM, "Rejected for Quality Reasons")	X	**X**	4.66.4.1
(113037, DCM, "Rejected for Patient Safety Reasons")	X		4.66.4.2
(113038, DCM, "Incorrect Modality Worklist Entry")	X		4.66.4.3
(113039, DCM, "Data Retention Policy Expired")	X		4.66.4.4

Modify Section 4.66.4.1 as shown to add profile-specific semantics

4.66.4.1 Rejection Note Stored (for Quality Reasons)

4.66.4.1.1 Trigger Events

An operator at the Sender determines that certain images are of insufficient quality, requiring that they be rejected.

4.66.4.1.2 Message Semantics

The message is a DICOM C-STORE of a Key Object Selection instance. The Sender is the SCU. The Receiver is the SCP.

The Sender 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-2x: Appendix A.2). The instance shall be constructed as defined in DICOM PS3.3 and 3.4, and shall have:

- A Key Object Selection Document Title code of (113001, DCM, "Rejected for Quality Reasons").
- At least one Document Title Modifier code. Unless otherwise specified by the profile invoking this transaction, the code(s) shall be drawn from DICOM Context Group 7011.
- References to all rejected instances are specified as Content Items with value type of COMPOSITE, IMAGE or WAVEFORM in the Content Sequence (0040,A730).

This Key Object Selection instance shall be stored to the Receiver. It serves as a trigger to disallow routine use of these rejected instances that it references.

4.66.4.1.2.1 RAM Rejection Notes

Quality Note Creators that claim support of the Reject Analysis & Monitoring Profile shall conform to the requirements for Quality Notes in RAD TF-2: 4.29.4.1.2.1 RAM Quality Notes.

Notes: 1. Key Object Selection instances that convey quality information about rejected instances are referred to as Rejection Notes and are conveyed using this Rejection Note Stored [RAD-66] transaction. Key Object Selection instances that convey quality information about non-rejected instances are referred to as Quality Notes and are conveyed using Key Image Note Stored [RAD-29].

2. The Profile requirements in RAD TF-2: 4.29.4.1.2.1 override the use of CID 7011 as described in Section 4.66.4.1.2.

4.66.4.1.3 Expected Actions

The Receiver receives the Key Object Selection instance and shall store it. The Receiver shall support the two behaviors listed below. The behavior chosen shall be configurable.

- **Expose Rejected Instances**: For the Key Object Selection instance and all instances referenced therein, the Receiver shall return SOP Instance UIDs in Query Responses and the instances in Patient, Study, Series, or Instance level retrievals.
- **Hide Rejected Instances**: For the rejected instances referenced in the Key Object Selection, the Receiver shall neither return SOP Instance UIDs in Query Responses nor return the instances in Patient, Study, Series, or Instance level retrievals. If the request includes optional Additional Query/Retrieve Attributes defined in Table 4.66.4.1.3-1, then the returned value(s) of the requested attributes shall reflect the absence of hidden rejected instances.

Table 4.66.4.1.3-1: Additional Query/Retrieve Attributes

…

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Add Appendix Z as shown

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Appendix Z: Reject Analysis Coding (Normative)

This appendix defines the usage of broad and detailed codes for describing the basis of images being rejected or flagged for quality issues according to the Reject Analysis and Monitoring (RAM) Profile (see RAD TF-1: 55.1.1.1). These codes supplant the use of DICOM PS3.16 CID 7011.

Broad Reason codes are provided in Table Z.1-1. Detailed Reason codes are provided in Table Z.1-2 and in subsequent modality-specific tables.

Implementations are permitted to introduce local Detailed Reason codes if there is a needed concept that is not covered here. Implementations are expected to use the Broad Reason codes listed here to maintain data consistency and comparability within and across sites.

Z.1 Non-modality-specific Reason Codes

This section contains a table for broad reason codes, and a table for detailed reason codes that are generally applicable across most modalities. The subsequent sections include detailed reason codes that are modality-specific.

The Detailed Codes column indicates some detailed reason codes that might logically be associated with the given broad reason codes but is not intended to be normative.

Table Z.1-1: Broad Reason Codes

Coding Scheme	Code Value	Code Meaning	Notes	Detailed Codes
DCM	111213	No image	The image pixels do not appear to contain patient data. Causes might include an unexposed or faulty plate, or a faulty reconstruction or processing algorithm.	Incomplete acquisition Wrong detector use
99IHE	RAM001	Wrong body part	The anatomy in the image does not match the anatomy indicated in the order. Note: ensure the image metadata correctly describes the imaged anatomy. Local policies may call for such images to be read, so they will not be rejected and removed from the workflow. If the ordered anatomy is partially present, use code (111209, DCM, “Wrong patient positioning”) instead.	
DCM	111209	Wrong patient positioning	The appearance of the image indicates the patient was not prepared and/or positioned as required for the procedure. E.g., weightbearing vs. non-weight bearing, upright vs. supine vs prone vs left-decubitus, shoulder rotated in the wrong direction, inadequate inhalation.	Incomplete anatomic coverage Known object

Coding Scheme	Code Value	Code Meaning	Notes	Detailed Codes
99IHE	RAM002	Wrong view	The view acquired by the equipment is not correct. E.g., posterior-anterior view vs anterior-posterior, incorrect tube angulation	
99IHE	RAM003	Wrong protocol	The protocol used to acquire the image is not correct.	Wrong grid use Wrong coil use Phase wrap
99IHE	RAM004	Wrong contrast media	The timing, distribution, and/or presence of contrast media in the image is not correct. Causes might include failure of the injector, extravasation at the injection site, or incorrect injection settings.	Visible extravasation
DCM	111210	Motion blur	Image blur due to relative motion between the anatomy of interest and the imaging equipment during acquisition which has been inadequately compensated for.	Voluntary motion Involuntary motion
DCM	111207	Image artifact(s)	Signals are present that do not faithfully reproduce actual anatomic structures because of distortion, addition, or deletion of information.	Known object Inverse pinhole artifact Detector defect Grid artifact(s) Beam hardening artifact(s) Shadowing artifact Electromagnetic interference artifact(s) Uneven fat saturation artifact(s) Geometric distortion
99IHE	RAM005	High noise	The pixel noise in the image is undesirably high. Causes might include poor technique parameters, non-optimized image processing, or patient characteristics.	
99IHE	RAM006	Poor image contrast	The dynamic range of the pixels (sometimes referred to as contrast) in the image is too narrow or is shifted. Causes might include poor technique parameters such as mAs or kV or nonoptimized image processing. If the problem is related to contrast media use code (RAM004, 99IHE, “Wrong contrast media”) instead.	Pixel clipping Under exposed Over exposed Excessive attenuation Insufficient counts
99IHE	RAM007	Mislabeled Image	The metadata, such as the view, anatomy, patient positioning, do not correspond to the image. This also applies to the wrong marker being placed in the image (e.g., an L marker, when right was imaged and ordered).	

Coding Scheme	Code Value	Code Meaning	Notes	Detailed Codes
99IHE	RAM008	Redundant image	The image largely duplicates the content of other images, and thus provides no additional clinical information. Site policy might reject such images to "declutter" the reading workflow. Others might keep them available to the radiologist but flag the redundancy for quality improvement.	Procedural image

Notes: 1. The above 99IHE codes are provided for use in RAM Trial Implementation. They will be replaced with DICOM and/or LOINC codes in Final Text.

2. Identifying wrong patient issues is addressed by the IHE Image Object Change Management (IOCM) Profile.

Table Z.1-2: Non-modality-specific Detailed Reason Codes

Coding Scheme	Code Value	Code Meaning	Notes
99IHE	RAM009	Incomplete acquisition	Images and/or data is missing due premature termination of the acquisition process. Causes might include equipment issues such as power failure; unexpected detector disconnection; mechanical failure, or software failure. Causes might also include operator error or patient issues.
99IHE	RAM010	Incomplete anatomic coverage	The required anatomy is not fully visualized in the image (i.e., "cut off"). Causes might include anatomy obscured by collimation; detector-tube alignment; orthopedic fixation device not visible.
99IHE	RAM011	Known object	Required anatomy is obscured by known objects (or resulting image artifacts) E.g., patient buttons, jewelry, oxygen line, positioning device, improperly placed shield.
99IHE	RAM012	Detector defect	Missing pixels or lines caused by dead elements in an imaging detector
99IHE	RAM013	Pixel clipping	Multiple image pixels whose true value appears to have been truncated at the maximum value. Causes might include oversaturation of the detector, or issues in image reconstruction or processing.
99IHE	RAM014	Voluntary motion	Patient did not comply with motion or breathing instructions
99IHE	RAM015	Involuntary motion	Patient condition prevented compliance with motion or breathing instructions. Causes might include spasms, cough, language barrier, or other inability to understand or follow instructions.

Z.2 Radiography

The codes in Table Z.2-1 supplement those in Section Z.1 to address quality issues specific to radiography images.

900 **Table Z.2-1: Detailed Radiography Reason Codes**

Coding Scheme	Code Value	Code Meaning	Notes
DCM	111211	Under exposed	Inadequate number of quanta reached the detector during exposure. Reasons for under exposed images include low kVp, low mAs product, excess Source Image Distance. Under exposed images have inadequate signal and higher noise in the areas of interest. Causes might also include failure of AEC (Automatic Exposure Control)
DCM	111212	Over exposed	An excess number of quanta reached the detector during exposure. Reasons for over exposed images include high kVp, high mAs product, short Source Image Distance. Over exposed images have high signal and lower noise in the areas of interest. Over exposed area may demonstrate lack of contrast from over saturation of the detector. Causes might also include failure of AEC (Automatic Exposure Control)
DCM	111208	Grid artifact(s)	Feature(s) arising from the acquisition unit's anti-scatter grid mechanism. For two-dimensional systems, such features include those of mechanically damaged or incorrectly positioned grids. For moving or Bucky grids, artifacts may result from intentional grid motion that is inadequate in duration or velocity uniformity. E.g., wrong SID (Source-to-Image Distance)
99IHE	RAM017	Wrong grid use	The use (or nonuse) of an x-ray scatter grid is not correct.
99IHE	RAM018	Wrong detector use	The x-ray detector usage is incorrect. E.g., no detector selected; incorrect detector selected; bucky not pushed in far enough to initialize detector
99IHE	RAM019	Inverse pinhole artifact	A bright spot or high-intensity area, likely caused by a small, unintentional, obstruction that partially blocks the X-ray beam.

Z.3 Mammography

The codes in Table Z.3-1 supplement those in Section Z.1 to address quality issues specific to mammography and breast tomosynthesis images.

Table Z.3-1: Detailed Mammography Reason Codes

Coding Scheme	Code Value	Code Meaning	Notes
DCM	111211	Under exposed	Inadequate number of quanta reached the detector during exposure. Under exposed images have inadequate signal and higher noise in the areas of interest. Reasons for under exposed images include low kVp, low mAs product, excess Source Image Distance, or failure of AEC (Automatic Exposure Control).
DCM	111212	Over exposed	An excess number of quanta reached the detector during exposure. Over exposed images have high signal and lower noise in the areas of interest. Over exposed area may demonstrate lack of contrast from over saturation of the detector. Reasons for over exposed images include high kVp, high mAs product, short Source Image Distance, or failure of AEC (Automatic Exposure Control).
DCM	111208	Grid artifact(s)	Feature(s) arising from the acquisition unit's anti-scatter grid mechanism. For two-dimensional systems, such features include those of mechanically damaged or incorrectly positioned grids. For moving or Bucky grids, artifacts may result from intentional grid motion that is inadequate in duration or velocity uniformity. E.g., wrong SID (Source-to-Image Distance).
99IHE	RAM017	Wrong grid use	The use (or nonuse) of an x-ray scatter grid is not correct.
99IHE	RAM018	Wrong detector use	The x-ray detector usage is incorrect. E.g., no detector selected; incorrect detector selected; bucky not pushed in far enough to initialize detector.

Z.4 CT

The codes in Table Z.4-1 supplement those in Section Z.1 to address quality issues specific to CT images.

Table Z.4-1: Detailed CT Reason Codes

Coding Scheme	Code Value	Code Meaning	Notes
RADLEX	RID11327	Beam hardening artifact(s)	Streaks, bands, or darkening near dense structures, such as bone or metal implants.

Z.5 MR

The codes in Table Z.5-1 supplement those in Section Z.1 to address quality issues specific to MR images.

Table Z.5-1: Detailed MR Reason Codes

Coding Scheme	Code Value	Code Meaning	Notes
99IHE	RAM030	Electromagnetic interference artifact(s)	Zipper or herringbone patterns, or random noise characteristic of electromagnetic interference.
99IHE	RAM031	Uneven fat saturation artifact(s)	Patches or streaks where fat appears brighter due to uneven saturation by the pre-pulse. Causes might include issues with the magnetic field, patient motion, or scan parameters.
RADLEX	RID11395	Phase wraparound	Superposition of anatomy outside the field of view on anatomy inside the field of view.
99IHE	RAM033	Wrong coil use	Noise, artifacts, and degraded image quality from incorrect use of coils, e.g., activating all the coils in a long spine coil when scanning a short patient
99IHE	RAM034	Geometric distortion	Warping or misshaping of some or all of the imaged anatomy.

Z.6 Ultrasound

The codes in Table Z.6-1 supplement those in Section Z.1 to address quality issues specific to ultrasound images.

Table Z.6-1: Detailed Ultrasound Reason Codes

Coding Scheme	Code Value	Code Meaning	Notes
99IHE	RAM025	Electromagnetic interference artifact(s)	Banding, noise, ghosting or distortion characteristic of electromagnetic interference.
99IHE	RAM026	Excessive attenuation	Inadequate image signal due to attenuation by tissues between the transducer and the anatomy of interest.
99IHE	RAM027	Shadowing artifact	A form of excessive attenuation due to the anatomy of interest being behind a dense structure such as bone or metal in the acquired view.

Z.7 Nuclear Medicine

The codes in Table Z.7-1 supplement those in Section Z.1 to address quality issues specific to nuclear medicine images.

Table Z.7-1: Detailed Nuclear Medicine Reason Codes

Coding Scheme	Code Value	Code Meaning	Notes
RADLEX	RID11320	Activity at injection site	The radiopharmaceutical appears to have been injected into tissues.
99IHE	RAM029	Insufficient counts	The number of acquired counts is below the threshold normally required to create a good image.

