Integrating the Healthcare Enterprise

IHE Radiology
Technical Framework Supplement

AI Result Assessment for Imaging (AIRAI)

For review and comment only.

DO NOT implement this public comment version.

Revision 1.0 – Draft for Public Comment

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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 February 27, 2025 for Public Comment. Comments are invited and can be submitted at https://www.ihe.net/Radiology_Public_Comments. In order to be considered in development of the Trial Implementation version of the supplement, comments must be received by March 26, 2025.

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 https://profiles.ihe.net/RAD.

CONTENTS

Introduction to this Supplement

This profile, AI Result Assessment for Imaging, addresses the need to document and communicate the results from an assessment process that rates the individual results of AI solutions. There are two central use cases for which the output objects of the profile will provide information for

- the assessment of AI findings for the purpose of only distributing the clinically relevant results as they are referenced in a written report
- the assessment of AI findings for the purpose of computing metrics, e.g., alarm metrics showing the number of rejected findings over time, contribution of data for statistical analysis, e.g., positive predictive value.

The profile encompasses human as well as machine assessment.

The assessment result objects are defined for most structured DICOM objects, e.g., DICOM SR and unstructured DICOM objects, e.g., DICOM SC alike. Therefore, the assessment is not limited to typical ai result objects. Non-ai result objects, e.g., softcopy presentations states can also be processed.

However, the assessment process itself is not defined by this profile. Therefore, e.g., the process for ensuring the correctness of the ratings is out of scope. Without additional processes established the usage of the assessment results for re-training AI models is limited.

Open Issues and Questions

1	Q: How do we record assessments of different measurements when there are multiple in a parametric map instance? A: Only assess the entire instance. If necessary to distinguish different measurements, split into multiple instances.
2	Q: What are the requirements on data to be assessed? (E.g., SR nodes must have Observation UIDs) And how should those requirements be specified? Currently the Evidence Creator is not part of this profile. However certain requirements for the different AI Result Objects apply for the presence of unique identifiers in order to be suitable for the assessment processes described in this profile.

3	Q: Do we want to use a specific Rejection Code for rejected AI Result objects (which would trigger updates to [RAD-66] or do we want to re-use behavior defined for the (113001, DCM, “Rejected for Quality Reasons”) Document Title with Rejected for Quality Reason (111219,DCM,”Inappropriate image processing”) Document Title in KOS. Current profile text re-uses (113001, DCM, “Rejected for Quality Reasons”), since at this point we don’t see conflicting or additional requirements for the AI assessment process.
4	Q: Do we need levels of rejection severity (patient safety vs not great)?
5	Q: What happens next to instances which have multiple findings, some of which are rejected? E.g., are they rewritten to remove rejected findings? Are they kept with the findings tagged rejected? Rejecting an object due to all findings being rejected is obviously to be solved by IOCM using KOS rejection for Quality Reasons or Patient Safety. But what happens if not all findings of an object are rejected. In that case the existing object should simply be updated with a new version of that AI Result Object leaving the possibility for non-administrative users to gain access to the history of that object. How shall we solve this problem? IOCM with an update request instead of rejection request? Relying on Document Titles?
6	Q: Should we add devices as Verifying Observer (in DICOM)? Automated assessment of findings based on AI analysis of radiological reports could create an assessment as AI as the Verifying Observer.
7	Q: Shall this profile define a way how to encode assessment objects that are incomplete, e.g., because the assessment process was interrupted. This could be useful if the Quality Note Creator wanted to save the current, incomplete state of the assessment for the purpose of allowing the assessor to continue the assessment where it was left off instead of starting from scratch again. For example, certain attributes like the Preliminary Flag could be used for this purpose.

Closed Issues

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1	Report Creator out of scope.
2	Q: Is it ok that the name of the verifying human or machine will be used for any finding referenced within that newly created object - regardless of the previous observer. Rational behind: The verifying human/ machine is responsible for any finding referenced within the newly created object. A: Yes, maybe not today but in the future, when AI systems are more mature and it becomes legally accepted.

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.

*Update the following appendices to the General Introduction as indicated below. Note that these are **not** appendices to this domain's Technical Framework (TF-1, TF-2, TF-3 or TF-4) but rather, they are appendices to the IHE Technical Frameworks General Introduction located here.*

Appendix A – Actors

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

No new or modified actors.

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
Quality Note Creator	Flags medical data as having quality issues
Quality Information Reporter	Consumes quality information and supports Quality Assurance analysis processes.
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** transaction definitions to the IHE Technical Frameworks General Introduction Appendix B:*

No new transactions or modified transaction definitions.

Appendix D – Glossary

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

New (or modified) Glossary Term	Definition	Synonyms	Acronym/ Abbreviation
AI Result	Smallest unit that can be assessed (depending on the AI algorithm/ solution this can be a complete object, a clinical finding (e.g., a lung nodule) or an observation on a clinical finding (e.g., the longest diameter of a specific lung nodule)		
AI Result Object	Object format of an AI Result, e.g., DICOM SR, SEG, KOS, SC, encapsulated PDF, GSPS		
Assessor	Human or machine that assesses AI Result Objects		
Assessment Status Object	DICOM Structured Report containing the assessment status for each AI Result		
Finding	Part of an AI Result Object consisting of 1 or multiple observations.		
Observation	Smallest unit describing parts or an entire finding, e.g., long axis, short axis, volume		

Volume 1 – Profiles

Domain-specific additions

None

Add new Section X

X AI Result Assessment for Imaging (AIRAI) Profile

With the increasing number of regulatory cleared AI-based SaMD products available, validation of the results produced by AI becomes critical to the success of AI in clinical practice (e.g., deployment of valid findings, for acceptance testing during deployment, post market surveillance).

The AIRAI Profile specifies the structure as well as the transactions for storage and communication of results derived from the process of assessing AI Results for different purposes, e.g., report deployment, post market surveillance, detection of data drift.

This profile does not define processes required to ensure the quality of the validation results.

The AIRAI Profile addresses AI Results encoded in DICOM objects only.

X.1 AIRAI 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 X.1-1 shows the actors directly involved in the AIRAI Profile and the relevant transactions between them. If needed for context, other actors that may be indirectly involved due to their participation in other related profiles are shown in dotted lines. Actors which have a required grouping (if any), are shown in conjoined boxes (see Section X.3).

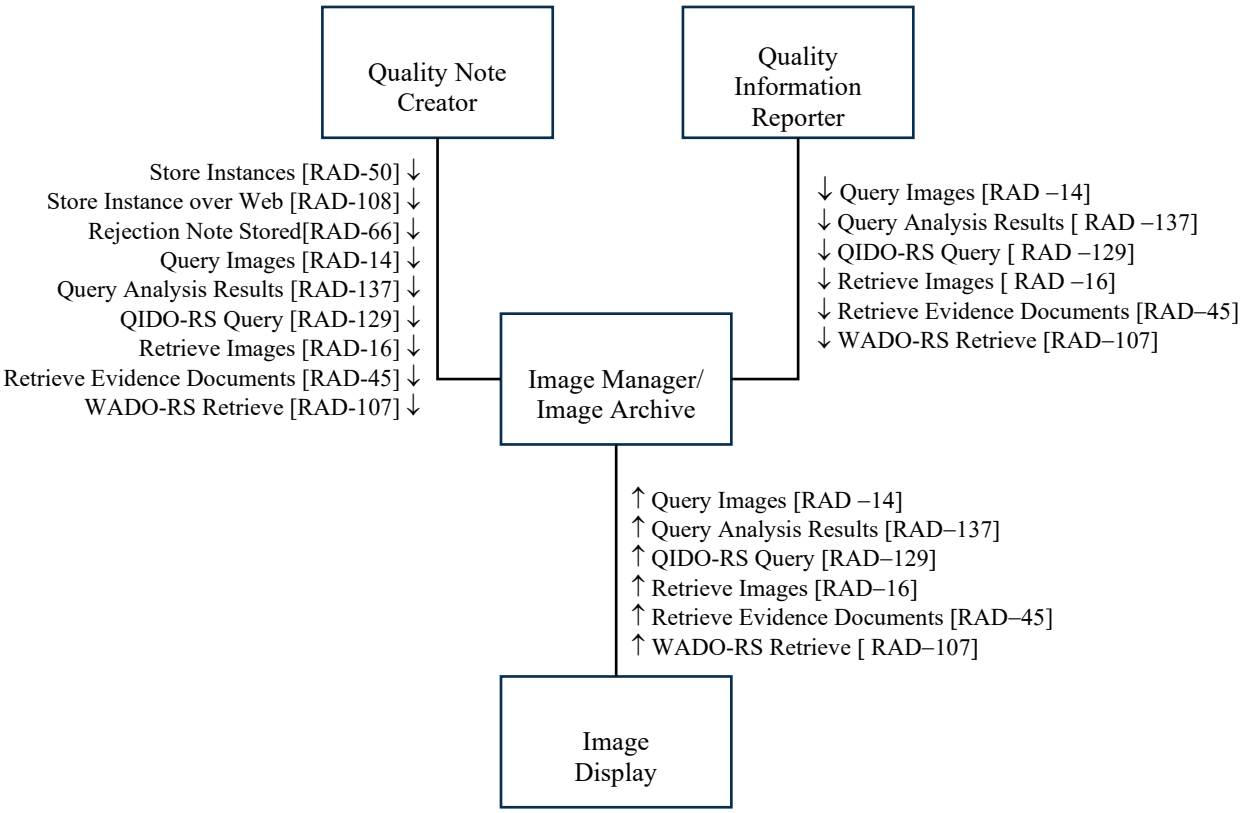

Figure X.1-1: AIRAI Actor Diagram

Table X.1-1 lists the transactions for each actor directly involved in the AIRAI 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 X.1-1: AIRAI Profile - Actors and Transactions

Actors	Transactions	Initiator or Responder	Optionality	Reference
Quality Note Creator	Store Instances [RAD-50]	Initiator	O (Note 1)	RAD TF-2: 4.50
	Store Instances over the Web [RAD-108]	Initiator	O (Note 1)	RAD TF-2: 4.108
	Rejection Note Stored [RAD-66]	Initiator	R	RAD TF-2: 4.66 RAD TF-1: X.1.1.1
	Query Images [RAD-14]	Initiator	O (Note 2)	RAD TF-2: 4.14
	Query Analysis Results [RAD-137]	Initiator	O (Note 2)	RAD TF-2: 4.137 (Note 2)
	QIDO-RS Query [RAD-129]	Initiator	O (Note 2)	RAD TF-2: 4.129 RAD TF-1: X.1.1.1

Actors	Transactions	Initiator or Responder	Optionality	Reference
	Retrieve Images [RAD-16]	Initiator	O (Note 3)	RAD TF-2: 4.16
	Retrieve Evidence Documents [RAD-45]	Initiator	O (Note 3)	RAD TF-2: 4.45
	WADO-RS Retrieve [RAD-107]	Initiator	O (Note 3)	RAD TF-2: 4.107
Quality Information Reporter	Query Images [RAD-14]	Initiator	O (Note 2)	RAD TF-2: 4.14
	Query Analysis Results [RAD-137]	Initiator	O (Note 2)	RAD TF-2: 4.137 (Note 4)
	QIDO-RS Query [RAD-129]	Initiator	O (Note 2)	RAD TF-2: 4.129 RAD TF-1: X.1.1.2
	Retrieve Images [RAD-16]	Initiator	O (Note 3)	RAD TF-2: 4.16
	Retrieve Evidence Documents [RAD-45]	Initiator	O (Note 3)	RAD TF-2: 4.45
	WADO-RS Retrieve [RAD-107]	Initiator	O (Note 3)	RAD TF-2: 4.107
Image Manager/ Image Archive	Store Instances [RAD-50]	Responder	R	RAD TF-2: 4.50
	Store Instances over the Web [RAD-108]	Responder	R	RAD TF-2: 4.108
	Rejection Note Stored [RAD-66]	Responder	R	RAD TF-2: 4.66
	Query Images [RAD-14]	Responder	R	RAD TF-2: 4.14
	Query Analysis Results [RAD-137]	Responder	R	RAD TF-2: 4.137 (Note 2)
	QIDO-RS Query [RAD-129]	Responder	R	RAD TF-2: 4.129 RAD TF-1: X.1.1.3
	Retrieve Images [RAD-16]	Responder	R	RAD TF-2: 4.16
	Retrieve Evidence Documents [RAD-45]	Responder	R	RAD TF-2: 4.45
	WADO-RS Retrieve [RAD-107]	Responder	R	RAD TF-2: 4.107
Image Display	Query Images [RAD-14]	Initiator	O (Note 2)	RAD TF-2: 4.14
	Query Analysis Results [RAD-137]	Initiator	O (Note 2)	RAD TF-2: 4.137 (Note 4)
	QIDO-RS Query [RAD-129]	Initiator	O (Note 2)	RAD TF-2: 4.129
	Retrieve Images [RAD-16]	Initiator	O (Note 3)	RAD TF-2: 4.16
	Retrieve Evidence Documents [RAD-45]	Initiator	O (Note 3)	RAD TF-2: 4.45
	WADO-RS Retrieve [RAD-107]	Initiator	O (Note 3)	RAD TF-2: 4.107

Note 1: The Quality Note Creator shall support either Store Instances [RAD-50] or Store Instances over the Web [RAD-108] (RESTful semantics). The Quality Note Creator may support both semantics.

Note 2: The actor shall support either Query Images [RAD-14] and Query Analysis Results [RAD-137] (DIMSE semantics), or QIDO-RS Query [RAD-129] (RESTful semantics). The actor may support both semantics.

Note 3: The actor shall support either Retrieve Images [RAD-16] and Retrieve Evidence Documents [RAD-45] (DIMSE semantics), or WADO-RS Query [RAD-107] (RESTful semantics). The actor may support both semantics.

Note 4: The Query Analysis Results [RAD-137] transaction is found in the AI Results Trial Implementation Supplement.

A product implementation using this profile may group actors from this profile with actors from a workflow or transport profile to be functional. The grouping of the content module described in this profile to specific actors is described in more detail in Required Actor Groupings in Section X.4 or in Cross Profile Considerations in Section X.6.

X.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.

X.1.1.1 Quality Note Creator

Quality Note Creators are used to review AI Result Object(s) and assess their validity. Assessment can either be performed by a human reviewer or through an automated function or the combination of both.

This assessment process can result in the creation of updated AI Result Objects (see Section X.4.1), which can contain accepted, added, unreviewed AI results and AI Results with unknown Status. Rejected AI Results will be removed from these objects.

Furthermore, an Assessment Status SR object will be created containing the details of each finding that is not rejected like the status of each finding and the observer.

AI Result Objects that cannot be updated (e.g., Secondary Capture Images or Encapsulated PDF documents) can only be rejected as a whole and therefore will be deprecated.

Quality Note Creator shall support creation of updated AI Objects and Assessment Status SR objects as defined in RAD TF-3: 6.x.2 "AI Result Assessment data encoding".

Quality Note Creator shall support deprecation of instances using transaction [RAD-66] Rejection Note Stored using a KOS Document Title of (113001, DCM, "Rejected for Quality Reasons"). See RAD TF-2: 4.66.4.1.

Instances to be deprecated shall include:

- Original AI result objects
- AI result objects that cannot be updated (e.g., Secondary Capture Images) and contain invalid content
- Structured AI result objects that do not contain any valid AI Results.

If the Quality Note Creator supports the QIDO-RS Query [RAD-129] transaction, it shall additionally support the SCU Query Matching and Return Keys as defined in the Query Analysis Results [RAD-137] transaction (see RAD TF-2: 4.137.4.1.2 “Message Semantics”).

Quality Note Creators shall be able to query and retrieve hidden rejected instances as described in RAD TF-2: 4.66.4.1.3: Expected Actions using AE title to Expose Rejected Instances, when retrieving AI Assessment data from a previous Assessor.

X.1.1.2 Quality Information Reporter

Quality Information Reporters retrieve updated AI objects as well as the Assessment Status SR object (and potentially the original ones) to do Q/A analysis based on the information provided in these objects.

The Quality Information Reporter shall support retrieval and analysis of at least DICOM Comprehensive SR Storage SOP Class (1.2.840.10008.5.1.4.1.1.88.33) for the Assessment Status Object, and, depending on the Q/A analysis the Quality Information Reporter wants to perform, at least one of the AI Result Object types listed in Table RAD TF-3: Table 6.x.2-1 “IODs for Encoding AI Results”.

If the Quality Information Reporter supports the QIDO-RS Query [RAD-129] transaction, it shall additionally support the SCU Query Matching and Return Keys as defined in the Query Analysis Results [RAD-137] transaction (see RAD TF-2: 4.137.4.1.2 “Message Semantics”).

The Quality Information Reporter shall be able to query and retrieve hidden rejected instances:

- A Quality Information Reporter that supports Query Images [RAD-14] (DIMSE semantics), shall be able to query the AE Title on the Image Manager/Image Archive that exposes rejected instances. See Section X.1.1.3 and RAD TF-2: 4.66.4.1.3.
- A Quality Information Reporter that supports QIDO-RS Query [RAD-107] (RESTful semantics), shall be able to query the QIDO-RS endpoint on the Image Manager/Image Archive that exposes rejected instances. See Section X.1.1.3.

X.1.1.3 Image Manager/Image Archive

The Image Manager/Image Archive is responsible for managing the Imaging study, the associated original AI Result Object, the update AI Result Objects, the Assessment Status SR object and rejected AI Result Objects.

Image Manager / Image Archive Actors shall support all the SOP Classes listed in RAD TF-3: 6.x.2 “Result Assessment Data Encoding”.

The Image Manager/Image Archive shall support Query Matching and Return Keys as defined in the Query Analysis Results [RAD-137] transaction (see RAD TF-2: 4.137.4.1.2 “Message Semantics”) for the QIDO-RS Query [RAD-129] transaction.

The Image Manager/Image Archive shall be configurable to expose rejected instances as a Responder to a [RAD-14] and [RAD-129] query:

- Shall provide two AE Titles for [RAD-14] to hide or expose rejected instances as specified in RAD TF-2: 4.16.4.1.3.
- Shall provide two webservice endpoints for [RAD-129] to hide or expose rejected instances. The Image Manger/Image Archive shall support the behavior to Expose Rejected Instances and Hide Rejected Instances as specified in RAD TF-2: 4.66.4.1.3.

The Image Manager/Image Archive shall provide access to rejected hidden instances as described in RAD TF-2: 4.66.4.1.3:

- in response to a [RAD-14] query (DIMSE semantics) using a designated AE title to Expose Rejected Instances.
- in response to a [RAD-129] query (RESTful semantics) using a designated webservice endpoint to Expose Rejected Instances

The Image Manager/Image Archive shall be configurable to restrict access to a limited set of query Initiators:

- a designated set of calling AE Titles initiating a [RAD-14] query, and
- a designated set of IP addresses initiating a [RAD-129] query

X.1.1.4 Image Display

The Image Display can be used to display an imaging study and non-rejected AI Results. This actor may choose to only display a subset of AI Results based on their individual assessment status upon user request and/or the user's role or configuration.

The Image Display shall retrieve the imaging study, updated AI Result Objects and the Assessment Status SR Object.

If the Image Display supports the QIDO-RS Query [RAD-129] transaction, it shall additionally support the SCU Query Matching and Return Keys as defined in the Query Analysis Results [RAD-137] transaction (see RAD TF-2: 4.137.4.1.2 "Message Semantics").

Upon user request and the user's role, the Image Display shall be able to query and retrieve hidden rejected instances as described in RAD TF-2: 4.66.4.1.3: Expected Actions using AE title to Expose Rejected Instances. The Image Display shall be able to query and retrieve hidden rejected issues. This ability is expected to be configurable to be limited to specific users on the Image Display, based on their role and the specific request.

X.2 AIRAI Actor Options

Options that may be selected for each actor in this profile, if any, are listed in the Table X.2-1. Dependencies between options, when applicable, are specified in notes.

Table X.2-1: AIRAI – Actors and Options

Actor	Option Name	Reference
Quality Note Creator	None	--

Actor	Option Name	Reference
Quality Information Reporter	None	--
Image Manager/Image Archive	None	--
Image Display	None	--

X.4 AIRAI Overview

X.4.1 Concepts

This section describes some of the basic concepts underlying the Assessment of AI Results.

Throughout this section and the AIRAI Profile, the following definitions apply:

- **Original AI Result Object(s):** These are the result objects as created by the AI solution. This term is used to refer to any supported IOD that can contain AI results (see Section X.4.1.1 “Encoding of AI Results using different IODs”).
- **Updated AI Result Object(s):** These are newly created instances (e.g., having a new SOP Instance UID) of the same IOD as the Original AI Result Object containing the updated (assessed) AI findings.

X.4.1.1 Encoding of AI Results using different IODs

DICOM Structured Reports (SR) using TID 1500

DICOM SRs allow encoding of AI/Result/finding information as structured data at different levels of granularity:

- Finding with multiple measurements and/or qualitative assessments (e.g., a finding of a lung lesion with diameter and volume measurements and a margin assessment).
- The finding itself, any measurement or qualitative assessment can be associated with a visual representation (location, segmented region, or some other geometric primitive).
- Each finding can be associated with a tracking identifier, which can be used to track this finding over time.
- It is possible to reference a Segment of a Segmentation Object using the Referenced Segment Number (0062,000B) attribute of the IMAGE Value Type encoding as the visual representation of a finding.

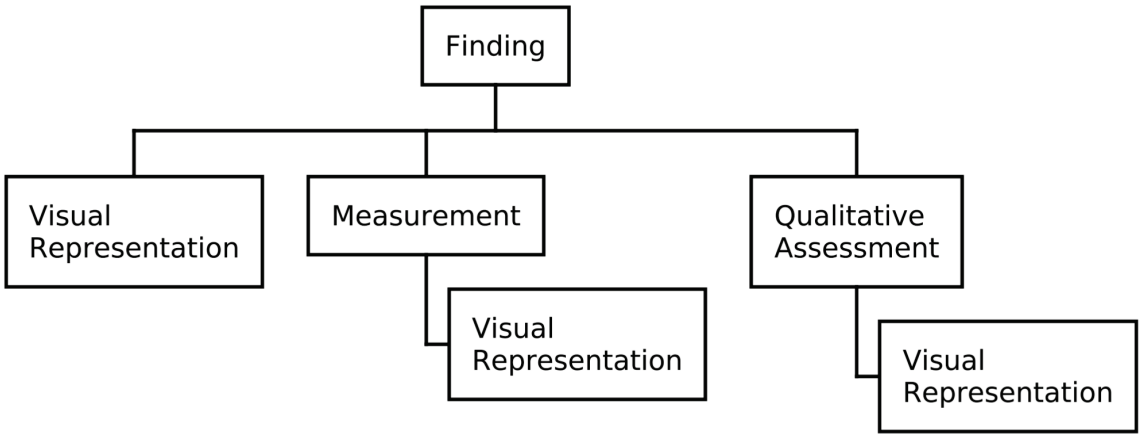

Figure X.4.1.1-1: Finding Representation in DICOM SR

Validation of the information in the SR can occur on any of the above-mentioned levels, e.g., the finding could be a false positive and as such be rejected. The visual representation could be inaccurate, or the measurement or qualitative assessment could be incorrect, but the finding itself is valid.

DICOM SRs can be marked as unverified or verified (including information of the verifying observer) and provide a means to document predecessors.

The results of the assessment (accepted, rejected, modified, etc.) of the content can be defined on all content levels, from the entire object down to the Observation level. The assessment result will be captured in an additional new SR Object using a for this profile designed new template (see RAD TF-3: 6.x.2.2 “Assessment Status Object)”.

DICOM Encapsulated PDF Documents

DICOM encapsulated PDF provides AI Results in report form (text with potentially graphics or tables embedded).

The report object itself can only be accepted or rejected in total.

DICOM Segmentation Objects

DICOM Segmentation Objects are enhanced multi-frame objects, which represent a classification of pixels in one or more referenced images. Each identified structure is associated with a unique Segment number, as Segment Label and potentially Tracking Identifiers.

Segments can be referenced from a DICOM SR encoded in TID 1500 using the Referenced Segment Number (0062,000B) of the IMAGE Value Type.

It is possible to accept or reject Segments independent of each other.

DICOM Grayscale Presentation States

Presentation States specify information for the presentation/display of images. This includes overlays, graphical and textual annotations, which could represent AI findings.

Each annotation can be stored as an item in the graphical Annotation Sequence and as such is individually accessible for acceptance/rejection.

Items in the Graphical Annotation sequence may be associated with a Tracking Identifier.

DICOM Secondary Capture Image Objects

Secondary Capture Images could either be used to burn the finding information directly into the images, or they could represent screen shots of result screens. The individual findings visible in these images are not individually accessible and as such, the Secondary Capture objects can only be accepted or rejected in total.

DICOM RT Structure Sets

RT Structure Sets provide a means to store segmented patient structures and related data. Each Patient Structure is stored in a uniquely identified ROI which is associated with uniquely identifiable Observation. Therefore, each ROI can be accepted/rejected individually.

Additionally, RTSS Objects provide a means to specify predecessors and also can have an Assessment Status.

DICOM Parametric Maps

Parametric Maps are multi-frame images containing values that encode “parameters” such as physical quantities. A Parametric Map Instance allows encoding for multiple measurements in one Instance. However, for the purpose of this profile it is expected that one instance only contains one measurement and, as such, can only be accepted or rejected in total.

X.4.1.2 Base Scenarios for the Assessment of AI Results

Applying AI to radiological workflows produces all different sorts of results. As not all of them are correct or in concordance with the physician responsible for the reading of the underlying study it is essential to have a mechanism that allows to document and communicate the outcome of the physician's validation process.

As an underlying principle for the validation processes as covered by this profile: Per assessment process there can only be one assessor who is responsible (= verifying observer). However, as assessment processes can be serialized which might consequently lead to the revision of already assessed AI Result Object(s) it is possible that the Assessment Status Object for a new AI Result Object might contain individual AI Results verified by different Observers. Nevertheless, the verifying observer for the new AI Result Object(s) as well as for the Assessment Status Object can only be one party.

There are two base scenarios for applying the assessment of AI results:

- Scenario 1 - Clinical Usage

  During the written report creation process, the radiologist and/ or an automated process marks the findings that will be taken in the report, documenting only the accepted AI findings as well as additional findings which have not been covered by the AI system in the initial result objects in new AI Result Objects. These objects will be distributed to

other clinicians for enabling them to see the study images with, e.g., the correct and accepted findings only.

- Scenario 2 - Performance Monitoring

  In the evaluation phase before deploying an AI system, as well as for monitoring the performance after the deployment, the evaluation results must be assessed. All incorrect findings (false negative, false positive, wrong outlines etc.) must be documented. Any other finding will automatically be regarded as accepted. The outcome of this process must be persisted in a way that it can be distributed to other systems responsible for the analysis of these results.

These two scenarios build the foundation for the use case dependent integration in real world workflows.

X.4.1.2.1 Real World Workflow Integration Concepts

X.4.1.2.1.1 AI supported report generation - Basic Assessment Process

Figure X.4.1.2.1-1 “Basic Assessment Process” illustrates the base scenario for all assessment scenarios.

The two main actors are the Image Manager and the Quality Note Creator. Existing DICOM objects (AI Result Objects, imaging study objects) will be retrieved from or sent to the Image Manager by the Quality Note Creator. The assessment of the DICOM object content will be performed by the Quality Note Creator. For this assessment, usually only the images and the valid AI Result Objects will be queried by the Quality Node Creator. However, on some occasions, e.g., all AI Result Objects have been rejected before, it might be that the Quality Note Creator also needs to query the rejected AI Result Objects. If, as a result of the assessment process, the initial AI Result Objects need to be updated, new AI Result Objects will be issued and stored updating the initial AI Result Objects. In the best case, if all findings are accepted the content of s the existing AI Result Objects will be written to new AI Result Objects that update the initial AI Result Objects.

AI Result Objects written in the course of this profile workflow will only contain non-rejected findings. If due to a rejection by the Assessor the entire object must be rejected, a KOS instance with Document Title “Rejected for Quality Reasons” and Rejected for Quality Reason “Inappropriate image processing” will be issued and sent to the Image Manager which will manage the access to this/these objects (i.e., hide or expose them as described in the Rejection Notes Stored [RAD-66] transaction).

For this profile, the processes sending the original AI Result Objects to the Image Manager, sending the imaging study to the Image Manager, and the combined process of image reading, report generation, and AI Finding assessment are out of scope.

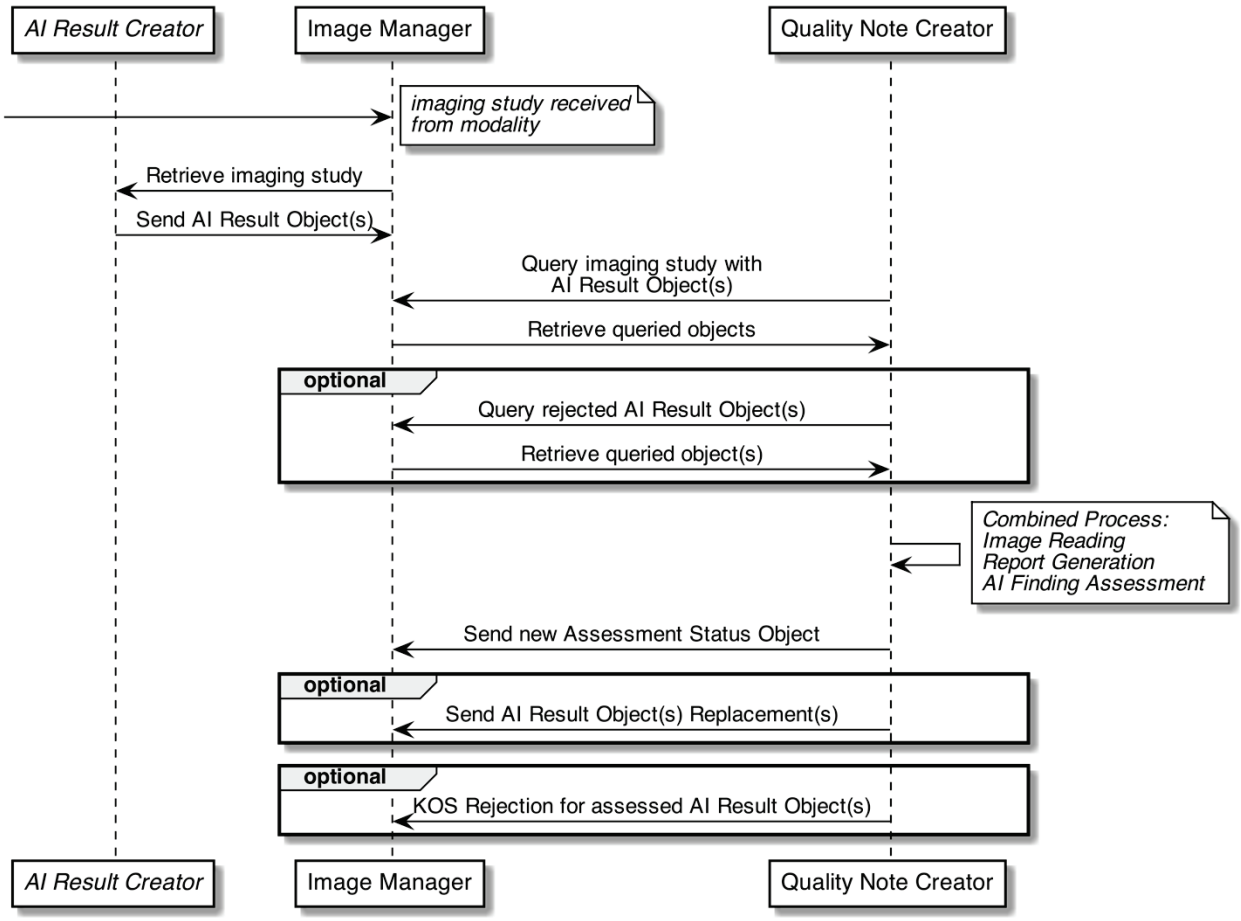

Figure X.4.1.2.1.1-1: Basic Assessment Process

X.4.1.2.1.2 AI supported report generation - two step Quality Note Creator integration

This concept regards two variants of the integration of Quality Note Creators in the AI-supported reporting workflow:

Variant A uses the Quality Note Creator (Human) in a user-centered way, leaving the user going through a combined image reading, report generating and AI finding validating process. The result of that process will then feed a process performed automatically by another Quality Note Creator (see Figure X.4.1.2.1.1-1 “Two Step Quality Assessment - manual / automated”). As a result of this assessment, it might be necessary to start a revision process for a synopsis of the results from both processes (see AI supported report generation - Revision of a performed Validation Process).

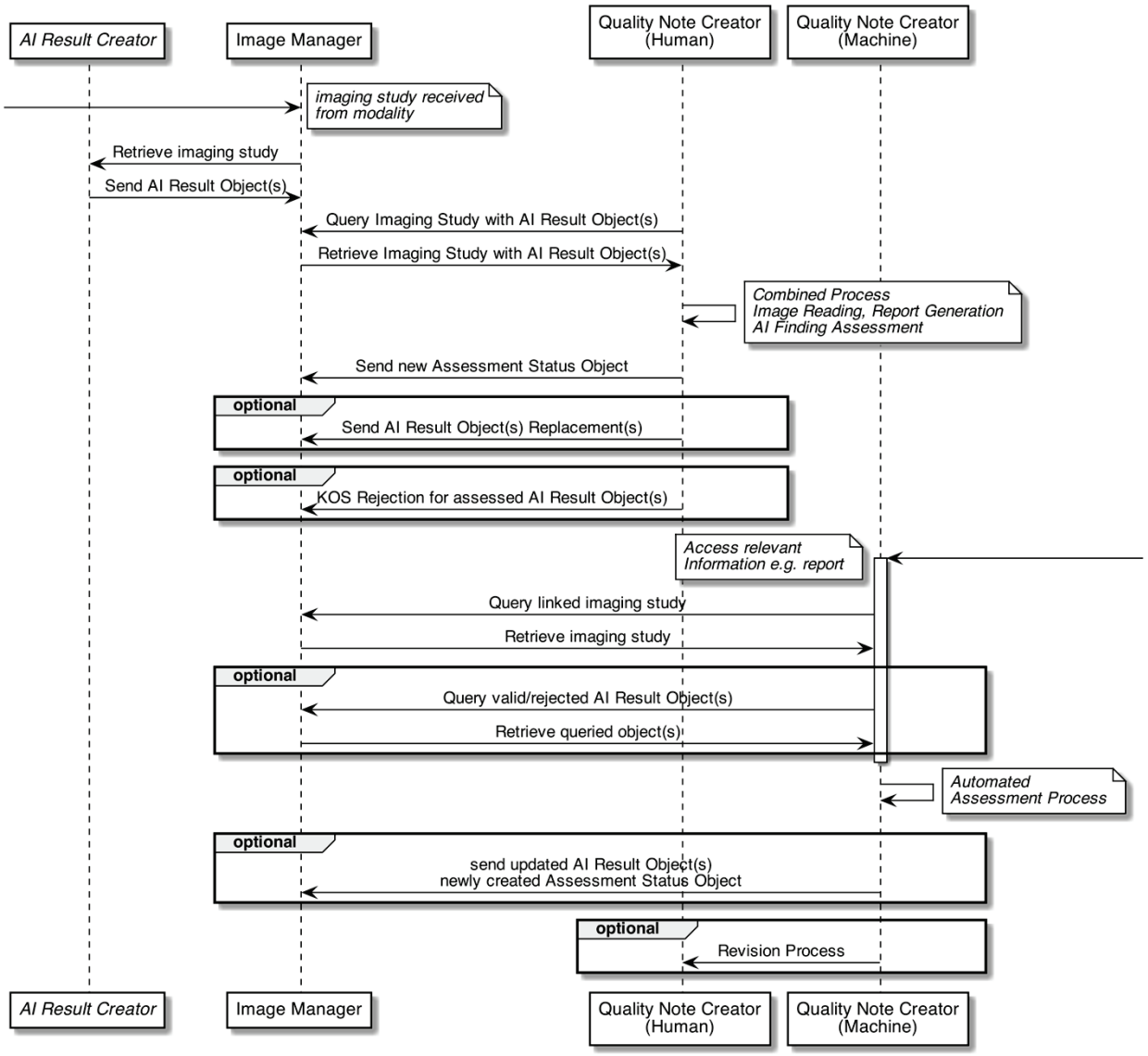

Figure X.4.1.2.1.2-1: Two Step Quality Assessment - manual / automated

Variant B inverses the two Quality Note Creator steps by first running an automated process, followed by a manual process (see Figure X.4.1.2.1.2-2 Two Step Quality Assessment - automated / manual). As a result, it might be that a new AI Result Object(s) together with an Assessment Status Object will be written. In case the assessed AI Results are rejected, the corresponding objects must be revoked.

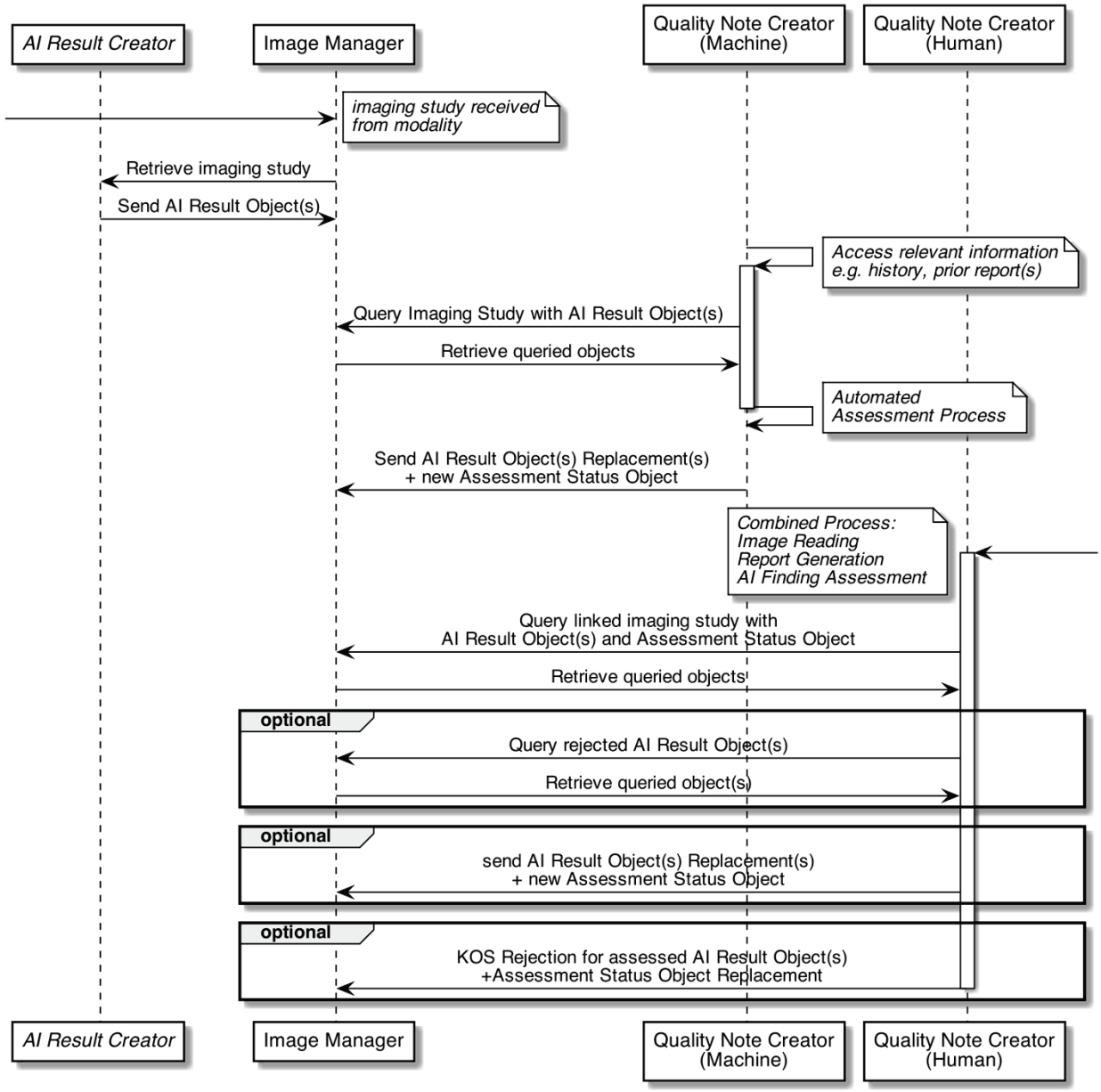

Figure X.4.1.2.1.2-2 Two Step Quality Assessment - automated / manual

Both variants show that the Quality Note Creator must make use of other sources to perform its assigned tasks. However, the access to these sources is not covered by this profile. The output of this Two Step Quality Assessment is updated AI Result Object(s) and either a new (some findings are accepted) or an updated (all findings are rejected) Assessment Status Object.

X.4.1.2.1.3 AI supported report generation - Revision of a performed Assessment

This concept regards the process when already-performed validation of AI Results will be re-evaluated. Therefore, the Quality Note Creator accesses the Imaging Study, the AI Result

Object(s) and the latest Assessment Status Object. Optionally it may be necessary for the Quality Note Creator to also query for rejected AI Result Objects. The revision process will result in either updated AI Result Object(s) with a new Assessment Object or, in case of a complete rejection of the previous evaluation, the rejection (KOS) of the previously created AI Result Object(s) and an updated Assessment Status Object (see Figure X.4.1.2.1.3-1 “Revision of a performed Assessment Process”).

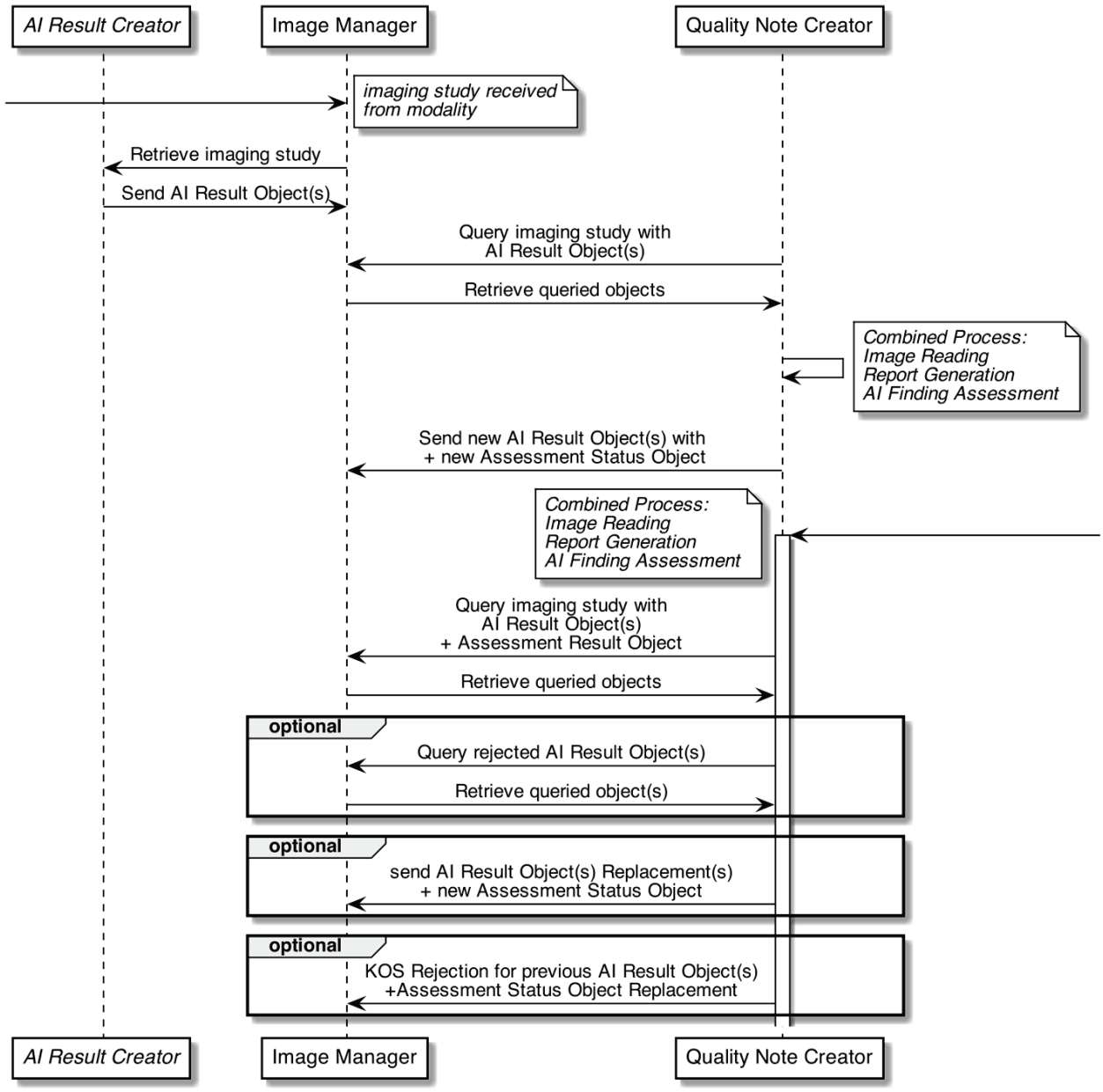

Figure X.4.1.2.1.3-1: Revision of a performed Assessment

X.4.1.2.1.4 Parallel AI findings assessment processes

The assessment of an AI Result Object is a coherent process which might rely on the output of other processes that can start and finish at any time. The output from each Quality Note Creator process is always a new Assessment Status Object. In addition, in most cases AI Result Object(s) are stored updating the existing the AI Result Objects. For the edge case of rejecting AI Result Objects, a rejection object (KOS) will be sent. As these assessment processes are not linked in time, a new or an updated Assessment Status Object can only refer to the objects available at the time the validation process started.

Therefore, an AI Result Object can represent a consensus of several review processes being a superset of several independent review processes of assessed AI Results. Figure X.4.1.2.1.4-1 “Parallel AI Findings Assessment Processes” envisions this.

It is not in the scope of this profile how the situation must be handled if assessment results are competing, e.g., they are created at the same time.

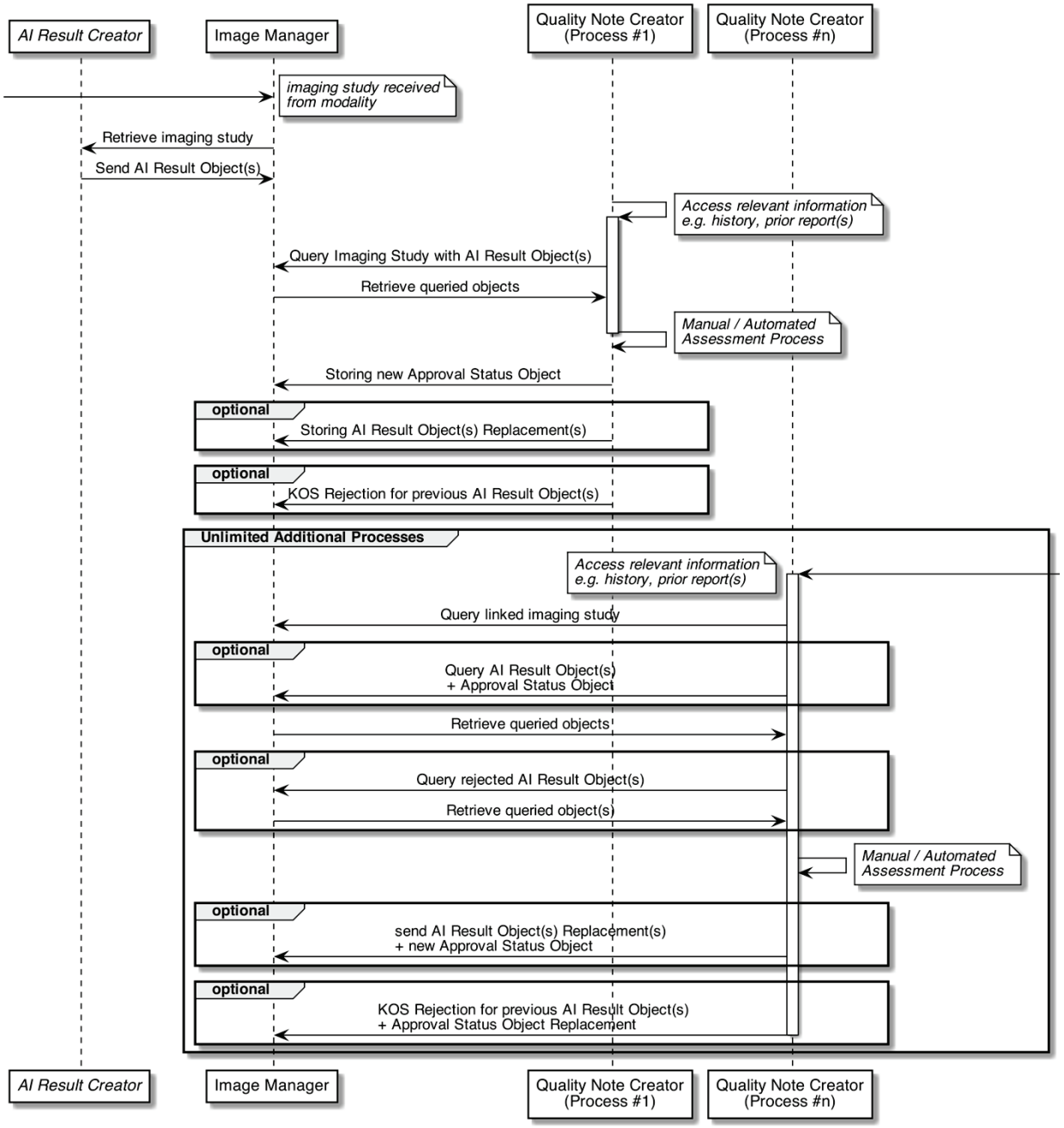

Figure X.4.1.2.1.4-1: Parallel AI Findings Assessment Processes

X.4.1.3 Assessment Process Concept

The assessment process uses a two-fold approach. The original AI Result Object(s) will be replaced by updated versions (keeping the initial IOD) containing only the AI Results with the status as defined in Table X.4.1.3-1 Validation Status Values below. Additionally, an Assessment Status Object (DICOM Comprehensive SR with TID IHE_RADAIRAI1) will be

created providing the detailed status information (see Table X.4.1.3-1) for each of the AI Results in the updated AI Result Object(s).

Rejected AI Results will not be encoded in the Update AI Result Object(s); however, they will be referenced in the Assessment Status Object with a Status of "rejected".

All other status will be encoded within the Assessment Status Object. The values and their modifiers are shown in Figure X.4.1.3-1.

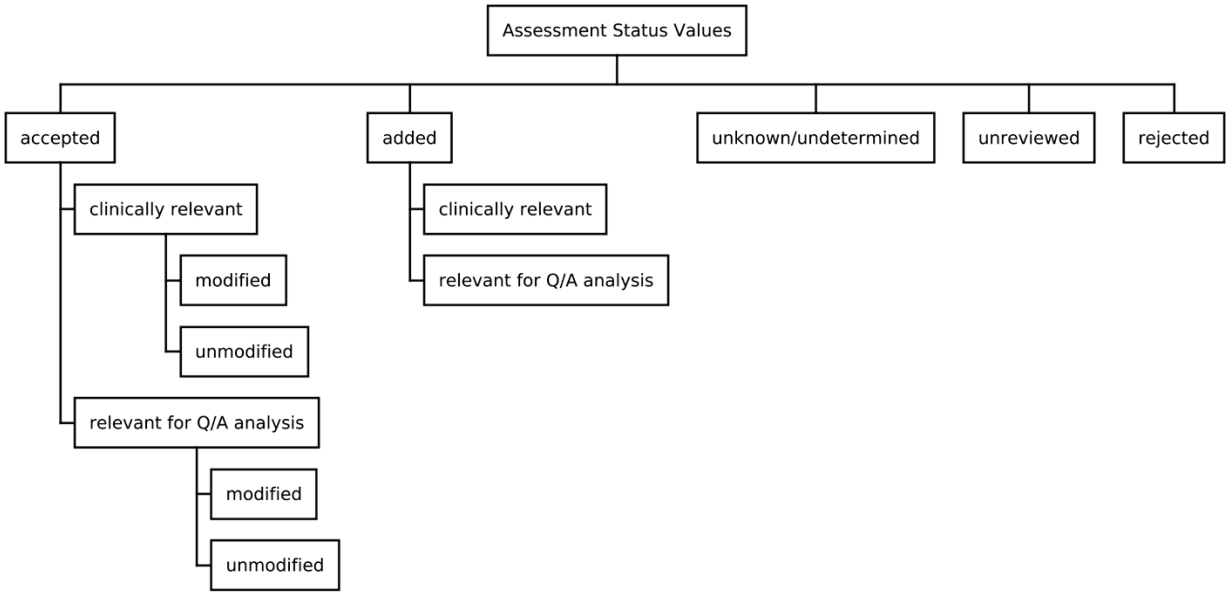

Figure X.4.1.3-1: Assessment Status Values

The meaning of the values and modifiers from Figure X.4.1.3-1 "Assessment Status Values" are explained in Table X.4.1.3-1 "Assessment Status Values Meaning".

Table X.4.1.3-1: Assessment Status Values Meaning

Status/Status Modifier	Meaning
Status	
accepted	The AI Result is considered correct by the Assessor.
added	An AI Result has been added by the Assessor which has been missed by the AI.
unknown/undetermined	After evaluation it remains unclear if the AI Result is correct or incorrect.
unreviewed	The AI Result has not been evaluated.
rejected	The AI Result has been rejected by the Assessor.
Status Modifier	
modified	The AI Result assessment is valid after some modifications have been applied.
unmodified	The AI Result assessment is valid as is without any modification.
clinically relevant	The AI Result is considered clinically relevant, e.g., it is used in a report.
relevant for Q/A analysis	The AI result is correct but will only be used for Q/A analysis and not in the context of clinical reporting.

X.4.1.4 Usage of assessed AI Results

The use cases (Section X.4.2.1) will often correlate with particular Assessment Status Values (Table X.4.1.3-1 “Assessment Status Values”).

AI Results “Accepted/ added clinically relevant modified / unmodified” can be used for review processes for the purpose of presenting only accepted findings which are clinically relevant enough to be mentioned in the written report. Findings marked as such are typically used in a review scenario where the study will be reviewed by a different physician than the one who created the initial written report and the resulting updated AI Result Object(s). The modifiers “modified” or “unmodified” are simply stating that the representation of the finding has been modified compared to the initial representation of that finding. This distinction has no impact regarding the usage for a review process. However, it becomes relevant for the Quality Assessment use cases where the findings are used for computing metrics.

The Assessment Status Values “accepted clinically relevant modified / unmodified” only marks AI Results which are clinically relevant enough to be mentioned in the written report. This implies that there are also other results which might be correct but not marked as such. Therefore, findings from the categories “accepted clinically relevant modified / unmodified” alone will be of limited use for performance statistics.

For performance metrics results from the Assessment Status Value categories “accepted / added relevant for Q/A analysis with/without modified / unmodified” combined with “accepted / added clinically relevant modified / unmodified are of interest, e.g., for quality monitoring over time.

The usage for performance metrics requires that all incorrect results are documented (rejected, missed, modified) and all other results must either automatically become accepted, or they must be assessed with “unknown/undetermined” or “unreviewed”.

Having all the findings assessed, the outcome can be used for different statistical evaluations, e.g., post market surveillance, data drift or other quality assurance purposes.

Independent from the underlying accepted criteria, the AI Results can be used for reprocessing purposes. Some AI solutions generate reports, e.g., DICOM Encapsulated PDF, DICOM SC, or text to be copied into the clinical report, based on the findings that were made by the algorithm. These AI solutions can retrieve the updated AI Result Object(s) and/or the Assessment Result Object to use them/it as input, generating an updated (corrected) version of the previous unstructured result object.

In all these contexts it is essential that the unique identifiers of each accepted AI Result are kept in sync between the original AI Result Object(s) and the updated AI Result Object(s).

X.4.1.5 Access to Assessed AI Results

Depending on the use case, the actors Image Display, Quality Note Creator and Quality Information Reporter must have access to different subsets of the stored AI Results and Assessment Status Objects.

For any use case based on Scenario 1 - Clinical Usage (Section X.4.1.2 “Base Scenarios for the Assessment of AI Results”), the Image Display must be granted access to the latest non-rejected object(s) as well as to the referenced imaging study.

However, for use cases that encompass the revision of previously assessed AI Results, it might become necessary for the Image Display to access any accepted and rejected object.

For use cases based on the base scenario “Performance Monitoring”, it might be enough for the Quality Information Reporter to access the Assessment Status Objects only for basic analysis. For more advanced analysis, it is inevitable that the actor must be granted access to any version of the AI Result Objects as well as to the existing Assessment Status Objects.

As these access requirements are so use case-dependent, the rejection processes must take care of it. Therefore, using KOS instances for rejecting AI Result Objects with the Document Title (113001, DCM, “Rejected for Quality Reasons”) enables the Image Manager/Image Archive to expose rejected documents, when it is configured to do so.

In essence, the access to the different versions of AI Results and Assessment Status Objects is completely dependent on the specific use case and its variants. Therefore, the Image Display must be responsible which object it will access and display.

X.4.1.6 Performance Metrics

There are at least two sides to be considered, the patient's safety/legal side and the process optimization side.

For patient safety and legal reasons, the performance of an AI solution must be monitored. Therefore, the prevalence of correct results (PCR) over time and prevalence of incorrect results (PIR) over time are a solid base for alarm metrics.

They are defined as follows:

$$PCR = accepted\ findings \div (accepted\ findings + corrected\ findings)$$

$$PIR = incorrect\ findings \div (accepted\ findings + corrected\ findings)$$

The classes are defined in Table X.4.1.6-1 Class Definition of AI Finding Assessment.

Table X.4.1.6-1: Class Definition of AI Finding Assessment

Class	Definition
accepted findings	Sum of all findings assessed as "accepted clinically relevant unmodified", "accepted relevant for Q/A analysis unmodified"
incorrect findings	Sum of all findings assessed as "rejected", "added clinically relevant", "added relevant for Q/A analysis", "accepted clinically relevant modified", "accepted relevant for Q/A analysis modified"
corrected findings	Sum of all findings assessed as "accepted clinically relevant modified", "accepted relevant for Q/A analysis modified"

Also, other performance indicators, e.g., Positive Predictive Value (PPV), Negative Predictive Value (NPV)

$$PPV = number\ of\ true\ positives \div (number\ of\ true\ positives + number\ of\ false\ negatives)$$

$$NPV = number\ of\ false\ positives \div (number\ of\ true\ positives + number\ of\ false\ positives)$$

can, according to the profile output assessment classes (Table X.4.1.6-2 "Available AI Finding Assessment Classes<), in principle, be calculated from the data provided by the output objects of this profile. However, the profile does not address the needed processes to provide the gold standard quality of the assessment values.

Table X.4.1.6-2: Available AI Finding Assessment Classes

Class	Definition
accepted findings	true positives and / or true negative
added findings	false negatives
rejected findings	false positives

For process optimization monitoring, there are a variety of metrics that are useful, depending on the purpose/use case of the monitoring.

However, for most of them additional data is required, e.g., for the Enhanced Detection Rate (EDR) which is defined as follows:

$$EDR = findings\ human \div additional\ AI\ findings$$

Consequently, the output objects of this profile can only contribute parts of the needed data that must be acquired through other processes which are out of scope for this profile.

X.4.1.7 Assessment Process Responsibility

The principle of an assessment process is that there can be only one Assessor starting it and being responsible for the creation of updated AI Result Objects. Following this principle results in a few scenarios, that implementers need to address:

- the Verifying Observer of an AI Result Object can either be a human or a machine (Assessor)
- depending on the workflow chain it is possible that a machine Verifying Observer overwrites the human Verifying Observer in the latest created AI Result Object
- the Verifying Observer of any individual AI Finding might be overwritten by the current (latest) Verifying Observer.

X.4.2 Use Cases

The AIRAI Profile focuses on

- assessment of AI Results and the storage of the objects resulting from the assessment process
- using the assessed AI Results either in a clinical context or for quality assurance

which is reflected by the following use cases.

X.4.2.1 Use Case #1: Assessment of AI Results

This use case covers two sub-use cases, the assessment during a reporting process for clinical review and the assessment for quality assurance purposes.

X.4.2.1.1 Assessment of AI Results during Reporting Use Case Description

During the reporting process, a radiologist or an automated system reviews (Assessor) an imaging study including AI Result Objects. While reviewing the images the Assessor selects some AI Results to be captured in the report. These findings will be marked as accepted clinically relevant (modified / unmodified). However not every AI finding or finding in the images will be assigned an Assessment Status Value (Figure X.4.1.3-1) as these are not relevant for the report, according to the Assessor.

Additionally, the Assessor may also add findings missed by the AI, modify or reject some. The non-rejected findings will be stored in new AI Result Object(s) using the same IOD as the original. Additionally, the Assessment Result Values are written into a new Assessment Result Object.

If specific AI Results were available in multiple AI Result Object(s) (e.g., if a measurement in a DICOM SR is associated with a segmented structure in a DICOM Segmentation objects), the Quality Note Creator ensures that all affected objects are updated, and referential integrity is maintained across all AI Result Objects.

To enable the Image Manager to replace the existing AI Result Object(s) with the newly created versions, a DICOM Key Object Selection Document will be written by the Quality Note Creator. This KOS document will also cover the rejection of entire AI Result Object(s) without replacement, e.g., when all findings of a structured AI Result Object are rejected, when a finding within an unstructured object is rejected, or if the Assessor deems a structured object invalid even if only one finding is rejected.

Upon receiving this KOS instance, the Image Manager revokes the referenced object(s). They will be superseded by the newly created AI Result Objects, if they have been issued and stored.

X.4.2.1.2 Assessment of AI Results for QA Purposes Use Case Description

The Assessor assesses the AI Results in the context of the imaging study. This validation happens for quality assurance purposes, e.g., for regulatory requirements as the EU AI Act or for post market surveillance.

The difference to the sub-use case Assessment of AI Results during Reporting is that any of the AI Results in the study will be assessed and receive an Assessment Status Value (Figure X.4.1.3-1).

Following the marking of the findings process AI Result Objects as well as KOS objects for rejected objects are created as described in the previous sub-use case (Section X.4.2.1.1).

X.4.2.1.3 Assessment of AI Results Use Case Process Flow

Figure X.4.2.1.3-1 shows the process flow for the Use Case Assessment of AI Results covering both sub-use cases.

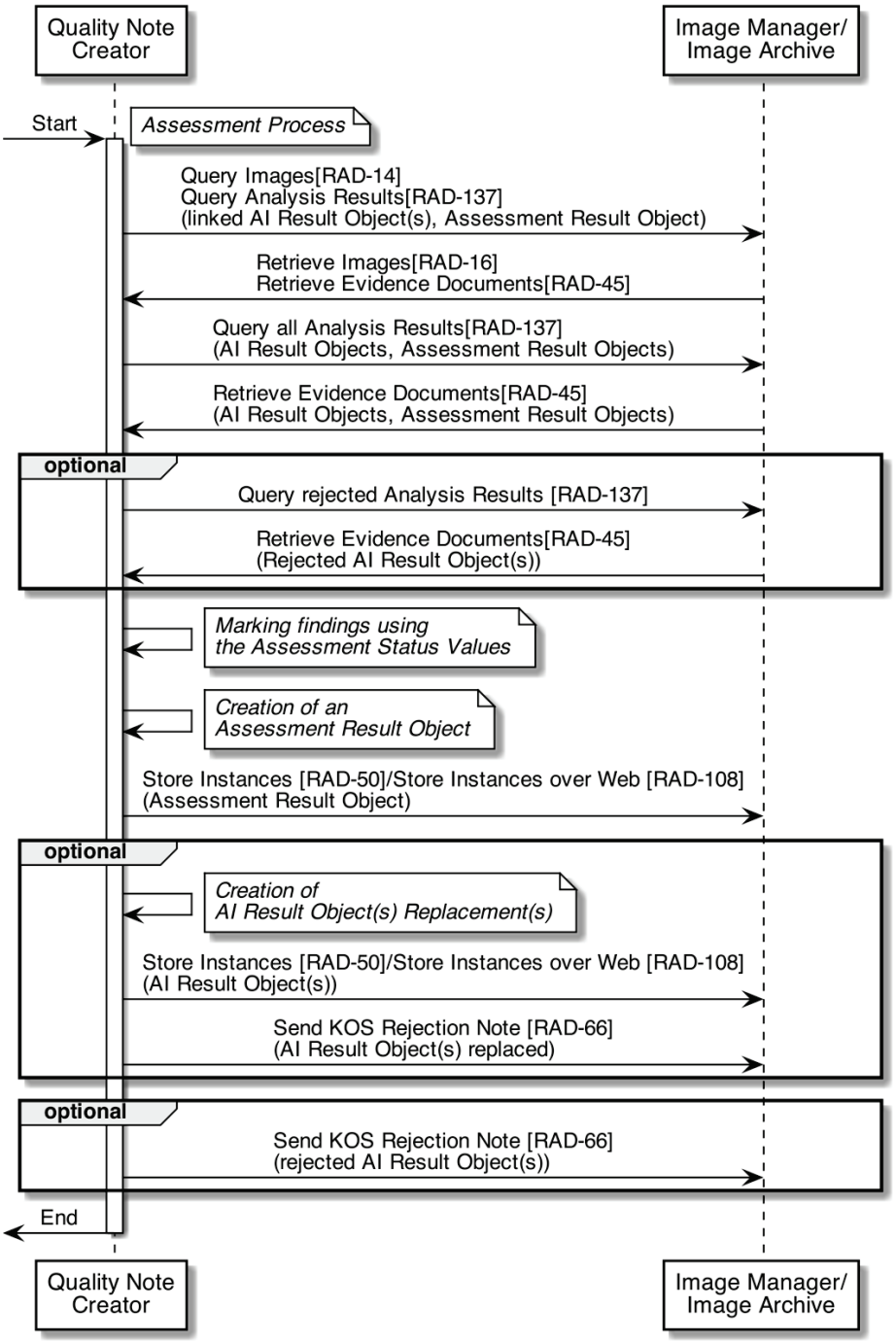

Figure X.4.2.1.3-1: Assessment of AI Results

X.4.2.2 Use Case #2: Usage of assessed AI Results for Clinical Review

This use case describes how assessed AI Results are used for subsequent clinical reviews.

X.4.2.2.1 Usage of assessed AI Results for Clinical Review Description

After the final written report has been created for an imaging study another clinician wants to review the study. This could be the referring physician who ordered the study, or it could be a radiologist when opening the study as a prior during the reporting process of a follow-up study.

In any case, it is in the interest of the physician reviewing the study to be presented by default with the AI Results that have been recognized as clinically relevant, in concordance with the written report.

After the retrieval of the study including all AI Result Object(s) and the Assessment Result Objects, the Image Display must identify the relevant AI Result Object(s) to be displayed.

X.4.2.2.2 Usage of assessed AI Results for Clinical Review Process Flow

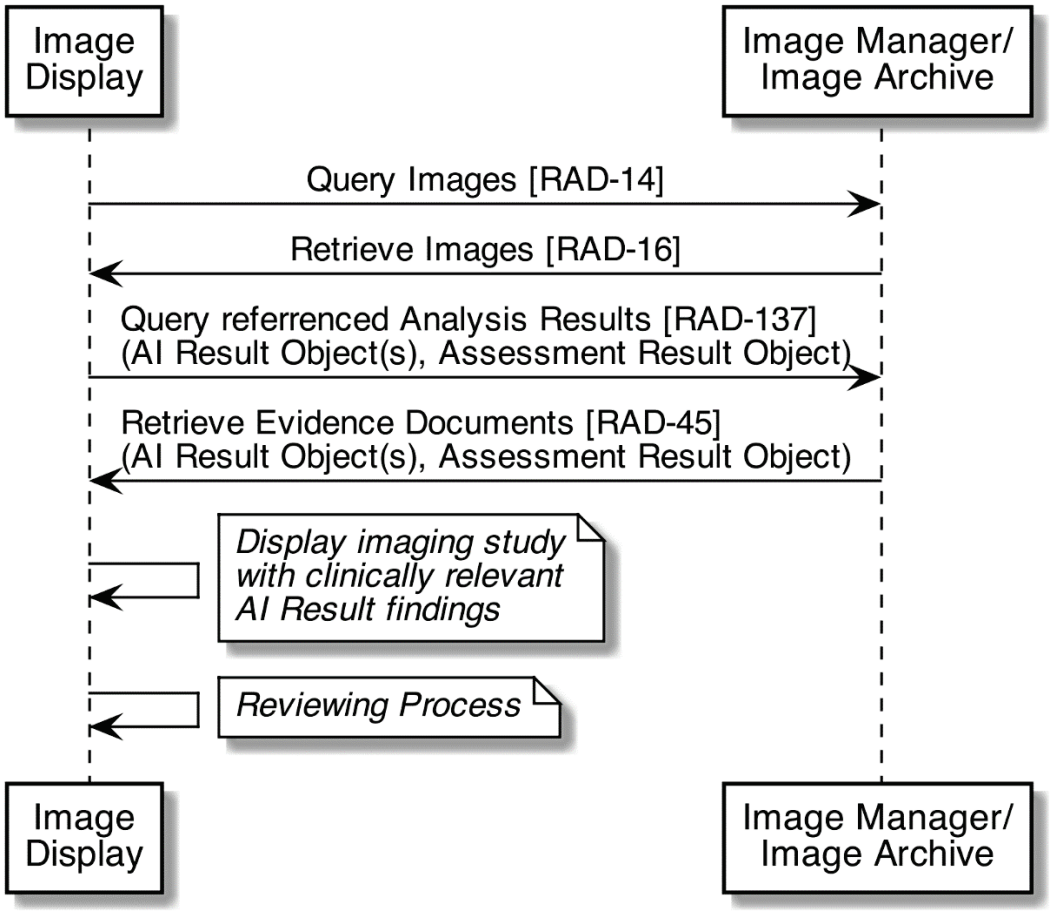

Figure X.4.2.2.2-1: Usage of assessed AI Results for Clinical Review

X.4.2.3: Use Case #3: Usage of assessed AI Results for QA Analysis

X.4.2.3.1 Usage of assessed AI Results for QA Analysis Description

For Quality Assurance (QA) the Quality Information Reporter needs all available AI Result Objects as well as all available Assessment Result Objects of an Imaging Study. Depending on the intended Analysis it might optionally be necessary to also retrieve the rejected AI Result Objects and/or the objects of the Imaging Study.

The retrieval of the objects is followed by the analysis process, which is out of scope for this profile as is the distribution of the output from this analysis.

X.4.2.3.2 Usage of assessed AI Results for QA Analysis Process Flow

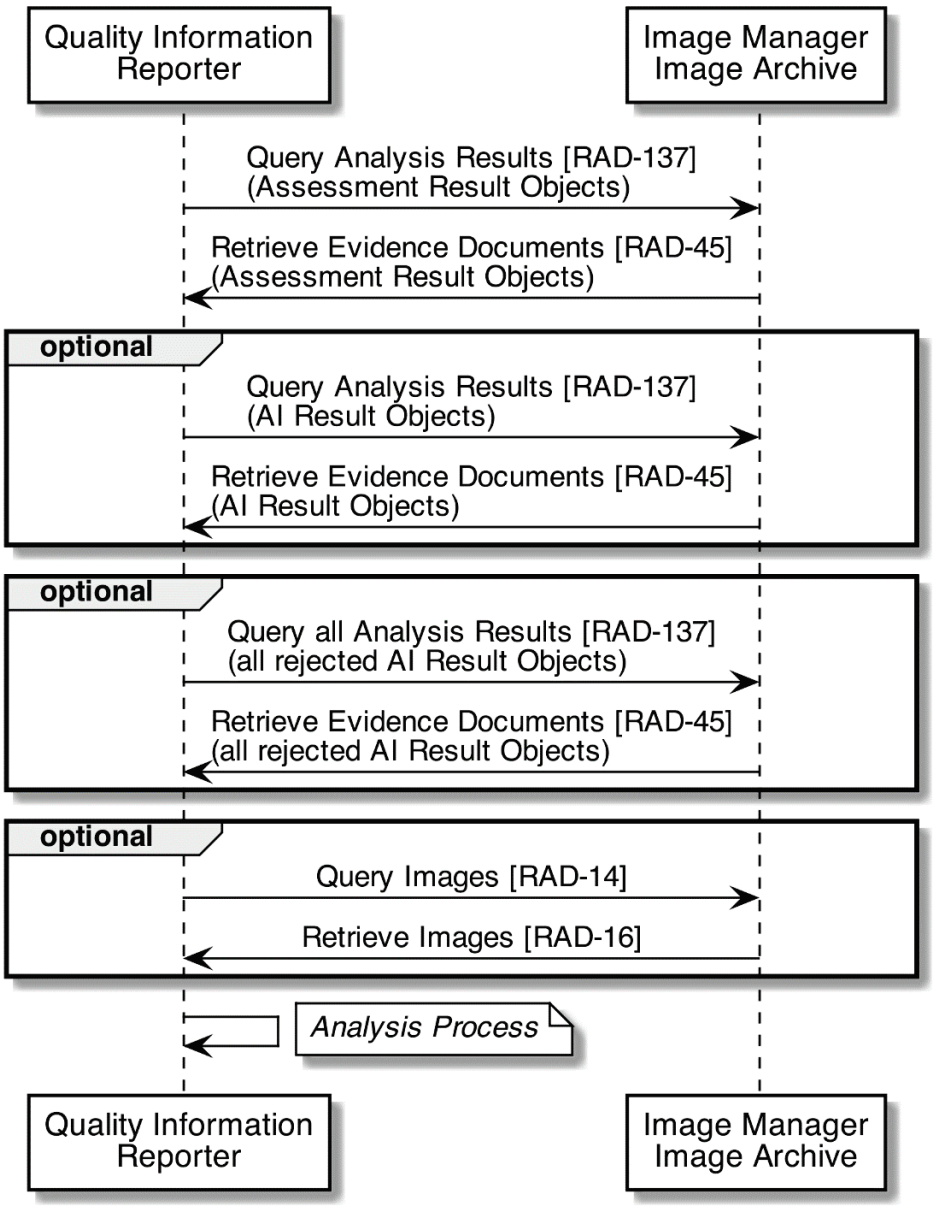

Figure X.4.2.3.2-1: Usage of assessed AI Results for QA Analysis

X.5 AIRAI Security Considerations

Refer to RAD TF-1x: Appendix F "Security Environment Considerations".

Protected Healthcare Information (PHI) is present in the DICOM instances being stored, retrieved, processed, and displayed.

X.5.1 Security Considerations for Actors

This profile strongly recommends all AIRAI actors be grouped with an ITI Audit Trail and Node Authentication (ATNA) Secure Application or Secure Node Actor using the Radiology Audit Trail Option.

The ATNA Profile requires actors to implement:

- Record Audit Event [ITI-20] transaction which would record when and where analysis results are distributed and displayed.
- Authenticate Node [ITI-19] transaction to further ensure the integrity of transactions via node authentication and communication encryption.

The AIRAI Profile does not add security considerations beyond those already established for the transfer and storage of clinical data in other profiles.

X.5.2 Security Considerations for Assessment Results

Assessment Result instances as defined in this profile contain personal demographic information and clinical information. It is appropriate for products implementing the AIRAI Results Profile to include appropriate PHI controls. Specifying such mechanisms and features is outside the scope of this profile.

X.6 AIRAI Cross Profile Considerations

AI Results (AIR):

- Quality Note Creator can be grouped with Evidence Creator in AIR following the encoding rules for updated AI result objects
- Quality Note Creators can be grouped with an Image Display in the AIR Profile to get access the imaging study and support standardized display of AI findings during the assessment process
- Image Display can be grouped with AIR Image Display to allow standardized display of AI findings.

AI Workflow for Imaging (AIW-I):

- AIW-I provides the workflow to generate the AI Results that will be assessed in this profile
- The Quality Note Creator can be grouped with a Task Performer in AIW-I to perform the AI assessment as a scheduled work item

Image Object Change Management (IOCM):

- Image Display/Quality Note Creator can be grouped with Change Requester in IOCM to manage different versions of updated AI Result Objects and Assessment Status SR objects which are results of subsequent review processes or which result from the consolidation of multiple parallel review activities.

Integrated Reporting Applications (IRA):

- Quality Note Creator can be grouped with an Evidence Creator in IRA to use accepted findings in the reporting process.

Appendices to Volume 1

N/A

Volume 2 – Transactions

Update Section 4.14.2 as indicated below.

4.14 Query Images [RAD-14]

730 …

4.14.2 Actor Roles

The roles in this transaction are defined in the following table and may be played by the actors shown here:

Table 4.14.2-1: Actor Roles

Role:	**Initiator:** Issues queries for Studies, Series, Images
Actor(s):	The following actors may play the role of Initiator: Image Display **Quality Note Creator** **Quality Information Reporter**
Role:	**Responder:** Responds to queries for Studies, Series, and Images
Actor(s):	The following actors may play the role of Responder: Image Manager / Image Archive

735

Update Section 4.16.2 as indicated below.

4.16 Retrieve Images [RAD-16]

…

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 Evidence Creator **Quality Note Creator** **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

Update Section 4.45.2 as indicated below

4.45 Retrieve Evidence Documents [RAD-45]

…

4.45.2 Actor Roles

Table 4.45.2-1: Actor Roles

Role:	**Requester:** Requests and receives Evidence Documents
Actor(s):	The following actors may play the role of Requester: Imaging Display Imaging Document Consumer **Quality Note Creator** **Quality Information Reporter**

Role:	**Responder:** Sends requested Evidence Documents
Actor(s):	The following actors may play the role of Responder: Image Manager / Image Archive Imaging Document Source

Update Section 4.50.2

4.50 Store Instances [RAD-50]

…

4.50.2 Actor Roles

Table 4.50.2-1: Actor Roles

Role:	**Sender:** Sends DICOM instances.
Actor(s):	The following actors may play the role of Sender: Export Selector **Quality Note Creator**
Role:	**Responder:** Receives and stores DICOM instances.
Actor(s):	The following actors may play the role of Receiver: Export Manager **Image Manager / Image Archive**

Update Section 4.66 as indicated below

4.66 Rejection Note Stored [RAD-66]

…

4.66.2 Actor Roles

Table 4.66.2-1: Actor Roles

Role:	**Sender:** Flags ~~**significant**~~ **rejected** ~~**images**~~ **instances** 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** **Image Display**
Role:	**Receiver:** Receives and stores ~~**Key Object Selection instances**~~ **the Rejection Notes and applies them by removing or sequestering the referenced** ~~**images**~~ **instances**.
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	AIRAI	Section
(113001, DCM, "Rejected for Quality Reasons")	X	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

765

Update Section 4.107 as indicated below

4.107 WADO-RS Retrieve [RAD-107]

…

770 **4.107.2 Actor Roles**

The Roles in this transaction are defined in the following table and may be played by the actors shown here:

Table 4.107.2-1: Actor Roles

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

Transaction text specifies behavior for each Role. The behavior of specific actors may also be specified when it goes beyond that of the general role.

Update Section 4.108 as indicated below

4.108 Store Instances over the Web [RAD-108]

…

4.108.2 Actor Roles

The Roles in this transaction are defined in the following table and may be played by the actors shown here:

Table 4.108.2-1: Actor Roles

Role:	**Sender**: Creates and sends well-formed DICOM composite objects
Actor(s):	The following actors may play the role of Sender:

	Image Capturer Lightweight Modality **Quality Note Creator**
Role:	**Receiver**: Receives objects from the Sender
Actor(s):	The following actors may play the role of Receiver: Image Manager **/ Image Archive**

Transaction text specifies behavior for each Role. The behavior of specific actors may also be specified when it goes beyond that of the general Role.

Update Section 4.129 as indicated below

4.129 QIDO-RS Query [RAD-129]

…

4.129.2 Actor Roles

The Roles for this transaction are defined in the following table and may be played by the actors shown here:

Table 4.129.2-1: Actor Roles

Role:	**Requester:** Queries for study metadata
Actor(s):	The following actors may play the role of Requester: Imaging Document Consumer **Image Display** **Quality Note Creator** **Quality Information Reporter**
Role:	**Responder:** Returns metadata for matching query results
Actor(s):	The following actors may play the role of Responder: Imaging Document Responder **Image Manager / Image Archive**

Transaction text specifies behavior for each Role. The behavior of specific actors may also be specified when it goes beyond that of the general Role.

Update Section 4.137 as indicated below. Please note that [RAD-137] is added in the AIR Profile, which is currently in Trial Implementation

4.137 Query Analysis Results [RAD-137]

This transaction is used to query for image analysis results.

4.137.2 Actor Roles

The roles in this transaction are defined in the following table and may be played by the actors shown here:

Table 4.137.2-1: Actor Roles

Role:	**Initiator:** Queries for analysis result objects.
Actor(s):	The following actors may play the role of Initiator: Image Display Image Document Consumer **Quality Note Creator** **Quality Information Reporter**
Role:	**Responder:** Returns analysis result entries matching the request.
Actor(s):	The following actors may play the role of Initiator: Image Manager / Image Archive

Transaction text specifies behavior for each role. The behavior of specific actors may also be specified when it goes beyond that of the general role.

Appendices to Volume 2

N/A

815

Volume 3 – Content Modules

4 IHE Namespaces, Concept Domains and Vocabularies

4.3 IHE Radiology Format Codes and Vocabularies

Add to Section 4.3.2.x Coder for the AIRAI Profile

4.3.2.x Codes for the AIRAI Profile

The following codes have been defined for the AIRAI Profile. They are shown here as part of the IHE coding system and should be used for Trial Implementation. IHE Radiology intends to migrate these codes, and the templates they are used in, to the DICOM Standard prior to advancing the AIRAI Profile to Final Text

Table 4.3.2.x-1: Codes for the AIRAI Profile

Code	Coding Scheme	Code Meaning	Definition	Reference
IHE_RADAIRAI1	99IHE	AI Validation Result Root	This is a template identifier (TID) for a private SR template defined by the AIRAI Profile for constructing the root of an Assessment Status Object	RAD TF-3: 6.x.2.2.1
AIRAI_21	99IHE	Original AI Result Object	AI Object that has been reviewed during the Assessment process	RAD TF-3: 6.x.2.1
AIRAI_22	99IHE	Assessment Status Object	DICOM Comprehensive SR containing Status Information about each single AI result	RAD TF-3: 6.x.2.1
AIRAI_24	99IHE	Assessed AI Result Object	Updated AI Result object after assessment Process	RAD TF-3: 6.x.2.1
AIRAI_25	99IHE	Replaced Assessment Status Object	An Assessment Status Object that is replacing a predecessor	RAD TF-3: 6.x.2.1
AIRAI_001	99IHE	Assessment Status Object	Root node for the Assessment Status Object	RAD TF-3: 6.x.2.2.1
AIRAI_002	99IHE	Assessment Basis	Concept Name defining how the Assessment was performed	RAD TF-3: 6.x.2.2.1
AIRAI_003	99IHE	Result Assessment	Container for the status of each individual AI Result	RAD TF-3: 6.x.2.2.1
AIRAI_004	99IHE	Result Type	Concept name for the Result Type	RAD TF-3: 6.x.2.2.1
AIRAI_005	99IHE	Referenced Instance	Concept Name for the Reference into a composite or image instance	RAD TF-3: 6.x.2.2.1

Code	Coding Scheme	Code Meaning	Definition	Reference
AIRAI_006	99IHE	Result Status Assessment	Concept name for the actual status of an AI Result	RAD TF-3: 6.x.2.2.1
AIRAI_007	99IHE	Assessment Scope	Concept name describing the scope of the Assessment (clinically relevant or relevant for Q/A Analysis)	RAD TF-3: 6.x.2.2.1
AIRAI_008	99IHE	Modification Scope	Concept name describing whether an AI Result was accepted modified or unmodified	RAD TF-3: 6.x.2.2.1
AIRAI_101	99IHE	Referenced Annotation	Indicates that the assessed AI Results is an annotation in a DICOM Presentation State	RAD TF-3: 6.x.2.2.1
AIRAI_103	99IHE	Referenced Document	Indicates that the assessed AI Result is encoded as a DICOM Encapsulated PDF	RAD TF-3: 6.x.2.2.1
AIRAI_104	99IHE	Referenced Parametric Map	Indicates that the assessed AI Result is encoded as a DICOM Parametric Map	RAD TF-3: 6.x.2.2.1
AIRAI_105	99IHE	Referenced Observation	Indicates that the assessed AI Result is encoded as a DICOM SR	RAD TF-3: 6.x.2.2.1
AIRAI_111	99IHE	accepted	The AI Result is accepted	RAD TF-3: 6.x.2.2.1
AIRAI_112	99IHE	unreviewed	The AI Result is unreviewed	RAD TF-3: 6.x.2.2.1
AIRAI_113	99IHE	unknown/undetermined	The Status of the AI Result is unknown	RAD TF-3: 6.x.2.2.1
AIRAI_114	99IHE	added	The AI Result is added	RAD TF-3: 6.x.2.2.1
AIRAI_115	99IHE	rejected	The AI Result is rejected	RAD TF-3: 6.x.2.2.1
AIRAI_121	99IHE	Clinically relevant	The AI Result has been deemed clinically relevant	RAD TF-3: 6.x.2.2.1
AIRAI_122	99IHE	Relevant for Q/A analysis	The AI Result is a valid finding but is not clinically relevant	RAD TF-3: 6.x.2.2.1
AIRAI_131	99IHE	modified	The AI Result was modified prior to acceptance	RAD TF-3: 6.x.2.2.1
AIRAI_132	99IHE	unmodified	The AI result was accepted as is	RAD TF-3: 6.x.2.2.1
AIRAI_141	99IHE	Single Report Concordance	Assessment Status Object is created initially by a human assessor followed by an automated assessment	RAD TF-3: 6.x.2.2.1
AIRAI_142	99IHE	Single Human Assessor	Validation Status Object is based on the assessment of a single human assessor	RAD TF-3: 6.x.2.2.1

Code	Coding Scheme	Code Meaning	Definition	Reference
AIRAI_143	99IHE	Multiple Human Assessments	Validation Status Object is based on the assessment of a multiple human assessors	RAD TF-3: 6.x.2.2.1

Update Section 5.1 Record Audit Event to update the following Audit Event

5.1 ITI-20 Record Audit Event

Table 5.1-2: IHE Radiology transactions and resulting ATNA trigger events

IHE Radiology Transaction	ATNA Trigger Event(s)	Actor(s) that shall be able to record audit event
…		
Query Images [RAD-14]	Query Information	Image Display**,** **Quality Information Reporter, Quality Note Creator**
Retrieve Images [RAD-16]	Study-used	Image Display, Image Document Consumer**,** **Quality Information Reporter, Quality Note Creator**
…		
Store Instances [RAD-50]	Begin-storing-instances	Export Selector**, Quality Note Creator**
	Instances-Stored	Export Manager**, Image Manager/Image Archive**
…		
Retrieve Evidence Documents [RAD-45]	Study-used	Image Display**, Quality Information Reporter, Quality Note Creator**
…		
Rejection Note Stored [RAD-66]	Instances-deleted	Sender: Acquisition Modality, Evidence Creator, Change Requester, **Quality Note Creator.** Note: The actor rejecting/correcting images must assume that the Image Archive may hide the images (similar to logical deletion)
…		
WADO-RS Retrieve [RAD-107]	Instances-Stored	Imaging Document Source**,** Image Manager/Image Archive,
	Study Used	Imaging Document Consumer, Image Display, **Quality Note Creator, Quality Information Reporter**
Store Instances over the Web [RAD-108]	Begin-storing-instances	Sender: Image Capturer, Lightweight Modality, Evidence Creator, **Quality Note Creator**

IHE Radiology Transaction	ATNA Trigger Event(s)	Actor(s) that shall be able to record audit event
…		
QIDO-RS Query [RAD-129]	Query Information	Imaging Document Responder, Image Manager/Image Archive**, Image Display, Quality Note Creator, Quality Information Reporter**
…		
Query Analysis Results [RAD-137]	Query Information	Image Display, Image Document Consumer**, Quality Information Reporter**

Add Section 6.6 Result Assessment Content Definitions

6.x AI Result Assessment content definitions

This IHE Radiology Content Specification defines encoding rules for the results of an AI assessment step.

6.x.1 Reference Standards

DICOM PS3.3: A.8 Secondary Capture Image IODs

- DICOM PS3.3: A.19 RT Structure Set IOD
- DICOM PS3.3: A.33 Softcopy Presentation State IODs
- DICOM PS3.3: A.35 Structured Report Document IODs
- DICOM PS3.16: TID 1500 Measurement Report
- DICOM PS3.3: A.45 Encapsulated PDF IODs
- DICOM PS3.51: Segmentation IOD
- DICOM PS3.75: Parametric Map IOD

6.x.2 AI Result Assessment data encoding

Persisting the results of an AI assessment process includes two steps:

- Creation of updated AI Result Objects, that includes all non-rejected findings (see RAD TF-1: X.4.1.3). This updated AI result object is encoded the same as the source AI Result.
- Creation of an Assessment Status SR object, which lists the Status for each finding as well as some additional information.

Quality Note Creator shall support the DICOM Comprehensive SR Storage SOP Class (1.2.840.10008.5.1.4.1.1.88.33) for encoding the Assessment Status Object.

In addition, the Quality Note Creator shall support at least one of the DICOM SR SOP Classes listed in Table 6.x.2-1 following TID1500 for the assessment process and storing the updated AI Result Objects.

Table 6.x.2-1: IODs for encoding AI results

DICOM SOP Class Name	SOP Class UID
DICOM Enhanced SR Storage	1.2.840.10008.5.1.4.1.1.88.22
DICOM Comprehensive SR Storage	1.2.840.10008.5.1.4.1.1.88.33
DICOM Comprehensive 3D SR Storage	1.2.840.10008.5.1.4.1.1.88.34

DICOM supports other SOP Classes, that can carry AI results. Quality Note Creators may be able to handle them as well. Table 6.x.2-2 lists some of these SOP Classes. If the Quality Note Creator choses to support any of them, Requirements listed in Section 6.x.2.1 shall be fulfilled for the respective SOP Class.

Table 6.x.2-2: IODs for encoding AI results

DICOM SOP Class Name	SOP Class UID
DICOM Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7
DICOM RT Structure Set Storage	1.2.840.10008.5.1.4.1.1.481.3
DICOM Grayscale Softcopy Presentation State Storage	1.2.840.10008.5.1.4.1.1.11.1
DICOM Encapsulated PDF Storage	1.2.840.10008.5.1.4.1.1.104.1
DICOM Segmentation Storage	1.2.840.10008.5.1.4.1.1.66.4
DICOM Parametric Maps	1.2.840.10008.5.1.4.1.1.30

The following two subsections address content definitions for instances produced in the above two steps.

6.x.2.1 Updated AI Result Objects

Quality Note Creators storing assessed AI results, shall use the same IOD as the one originally provided by the AI solution.

The Quality Note Creator is expected to copy contextual metadata (e.g., patient demographics, patient identifiers, study context, accession number) from the original AI Result objects. Additionally, the information listed in Table 6.x.2.1-1 shall be provided:

Table 6.x.2.1-1: Attribute Requirements for updated AI objects

Attribute	Tag	Value	Comment
All IODs			
Manufacturer	(0008,0070)	Copied from the Original AI Result object	
Manufacturer's Model Name	(0008,0080)	Copied from the Original AI Result object	
Software Versions	(0018,1020)	Copied from the Original AI Result object	
Contributing Equipment Sequence	(0018,A001)		An item for the Quality Note Creator shall be created in addition to existing ones
> Purpose of Reference Code Sequence	(0040,A170)	(109102,DCM, "Processing Equipment"	
> Manufacturer	(0008,0070)	Manufacturer Name of the actor creating this object	
> Manufacturer's Model Name	(0008,0080)	Manufacturer's Model Name of the actor creating this Object	
> Software Versions	(0018,1020)	Software Version of the actor creating this object	
> Device UID	(0018,1002)		
DICOM SR IODs			
Verification Flag	(0040,A493)	VERIFIED UNVERIFIED	VERIFIED means that the object has been created during the assessment process of the AIRAI Profile by a Human verifier. UNVERIFIED means that the object has been created during the assessment process of the AIRAI Profile by a Device verifier
Verifying Observer Sequence	(0040,A703)		Must be provided if Verification Flag = VERIFIED
>Verifying Observer Name	(0040, A075)		
>Verifying Observer Identification Code Sequence	(0040, A088)		Type 2 in DICOM
>Verifying Organization	(0040, A027)		
>Verification DateTime	(0040, A030)		
Predecessor Document Sequence	(0040, A360)	Reference to the original AI Result Object	Use (AIRAI_21, 99IHE, "Original AI Result Object") in Purpose of Reference Code Sequence (0040, A170)

Attribute	Tag	Value	Comment
Referenced Instance Sequence	(0008,A170)	Reference to the Assessment Status SR	Use (AIRAI_22, 99IHE,"Assessment Status Object") in Purpose of Reference Code Sequence (0040,A170)
DICOM RT Structure Set IOD			
Predecessor Structure Set Sequence	(3006,0018)	Reference to RTSS for Original AI results	Use (AIRAI_21, 99IHE, "Original AI Result Object") in Purpose of Reference Code Sequence (0040, A170)
Referenced Instance Sequence	(0008,A170)	Reference to the Assessment Status SR	Use (AIRAI_22, 99IHE,"Assessment Status Object") in Purpose of Reference Code Sequence (0040,A170)
DICOM Presentation IODs			
Referenced Instance Sequence	(0008,A170)	Reference to the Assessment Status SR	Use (AIRAI_22, 99IHE,"Assessment Status Object") in Purpose of Reference Code Sequence (0040,A170) (Note 1)
DICOM Segmentation IODs			
Referenced Instance Sequence	(0008,A170)	Reference to the original AI Result Object	Use (AIRAI_21, 99IHE, "Original AI Result Object") in Purpose of Reference Code Sequence (0040, A170)
Referenced Instance Sequence	(0008,A170)	Reference to the Assessment Status SR	Use (AIRAI_22, 99IHE,"Assessment Status Object") in Purpose of Reference Code Sequence (0040,A170)

Note 1: By adding the Referenced Instance Sequence this will be a Standard extended SOP Class.

In case that for a study there are multiple AI Result Objects representing the same findings (e.g., Contour Segmentations referenced from a DICOM SR content tree), the Quality Note Creator shall ensure that all AI Result objects are updated according to the validation results and that referential integrity between different updated AI Result Objects is maintained, e.g.:

- References into completely rejected objects are removed
- References into rejected RTSS Observations are removed
- References into rejected Segment Labels are removed

6.x.2.2 Assessment Status Object

Assessment Status Objects shall be encoded as an instance of the DICOM Comprehensive SR Storage SOP class using TID IHE_RADAIRAI1 as the Root Template. The Assessment Status Object provides the results of an AI assessment process. It may include the Result Status for AI Results for multiple (dependent or independent) AI Result Objects in the study.

Each Assessment Status object shall only contain one Observer Context Content Item. This means if two different observers assess the same AI Result object(s), a separate Assessment Status object is created for each observer.

The Quality Note Creator of the Assessment Status object is expected to copy contextual metadata (e.g., patient demographics, patient identifiers, study context, accession number) from the original AI Result objects. Additionally, the information listed in Table 6.x.2.2-1 shall be provided:

Table 6.x.2.2-1: Attribute Requirements for the Assessment Status Object

Attribute	Tag	Value	Comment
Manufacturer	(0008,0070)	Manufacturer Name of the actor creating initial Assessment Status Object	
Manufacturer's Model Name	(0008,0080)	Manufacturer's Model Name of the actor creating initial Assessment Status Object	
Software Versions	(0018,1020)	Manufacturer's Model Name of the actor creating initial Assessment Status Object	
Contributing Equipment Sequence	(0018,A001)		An item shall be added when previous version is replaced.
> Purpose of Reference Code Sequence	(0040,A170)	(109102, DCM, "Processing Equipment"	
> Manufacturer	(0008,0070)	Manufacturer Name of the actor creating this object	
> Manufacturer's Model Name	(0008,0080)	Manufacturer's Model Name of the actor creating this Object	
> Software Versions	(0018,1020)	Software Version of the actor creating this object	
> Device UID	(0018,1002)		
Verification Flag	(0040,A493)	VERIFIED UNVERIFIED	
Verifying Observer Sequence	(0040,A703)		Shall be provided if Verification Flag =VERIFIED
>Verifying Observer Name	(0040,A075)		
>Verifying Observer Identification Code Sequence	(0040,A088)		Type 2 in DICOM
>Verifying Organization	(0040,A027)		
>Verification DateTime	(0040,A030)		

Attribute	Tag	Value	Comment
Predecessor Document Sequence	(0040,A360)	Reference a Predecessor Approval Status Object (if one exists)	Shall be provided when a previous version is replaced. Use (AIRAI_25, 99IHE,"Replaced Assessment Status Object") in Purpose of Reference Code Sequence (0040,A170)
Referenced Instance Sequence	(0008,A170)	Reference to the updates AI Result Object(s) and/or References to AI Result Objects accepted completely	Use (AIRAI_24, 99IHE,"Assessed AI Result Object") in Purpose of Reference Code Sequence (0040,A170)
Referenced Instance Sequence	(0008,A170)	Reference to Original AI Result Object(s)	Use (AIRAI_21, 99IHE,"Original AI Result Object") in Purpose of Reference Code Sequence (0040, A170)

6.x.2.2.1 TID IHE_RADAIRAI1: AI Validation Result Root

The Quality Note Creator shall encode the Assessment Status for the AI results as defined in Table 6.x.2.2.1-1.

This TIDs is considered "private" templates, meaning they are specified by an organization other than DICOM. Accordingly, inside the Content Template Sequence (0040,A504), Mapping Resource (0008,0105) shall have a value of "99IHE" and Template Identifier (0040,DB00) shall have a value of IHE_RADAIRAI1.

Type: Extensible

Order:Significant

Root: Yes

Table 6.x.2.2.1-1: TID IHE_RADAIRAI1 - Another AI Validation Result Root

	NL	Rel with Parent	VT	Concept Name	VM	Req Type	Condition	Value Set Constraint
1			CONTAINER	EV (AIRAI_001, 99IHE, "Assessment Status Object"	1	M		Root node
2	>	HAS CONCEPT MOD	INCLUDE	DTID 1204 "Language of Content Item and Descendants"	1	U		
3	>	HAS OBS CONTEXT	INCLUDE	DTID 1002 "Observer Context"	1	M		

	NL	Rel with Parent	VT	Concept Name	VM	Req Type	Condition	Value Set Constraint
4	>	HAS OBS CONTEXT	CODE	EV (AIRAI_002, 99IHE, “Assessment Basis”)	1	M		DCID IHERADAIRAI6 Assessment Basis
5	>	CONTAINS	CONTAINER	EV (AIRAI_003, 99IHE, “Result Assessment”)	1-n	M		
6	>>	CONTAINS	CODE	EV (AIRAI_004, 99IHE, “Result Type”)	1	M		DCID IHERADAIRAI3 Reference Codes for Result Type
7	>>	CONTAINS	COMPOSITE	EV (AIRAI_005, 99IHE, “Referenced Instance)	1	MC	IFF Row 6 = (AIRAI_105, 99IHE, "Referenced Observation") or (AIRAI_101, 99IHE, "Referenced Annotation") or (13048, DCM, "Region in Space") or (AIRIA_103, 99IHE, "Referenced Document")	
8	>>	CONTAINS	UIDREF	EV (AIR005, 99IHE, “Referenced Observation UID”)	1	MC	If single AI Results are assessed and IFF Row 6 = AIRAI_105, 99IHE, "Referenced Observation")	
9	>>	CONTAINS	TEXT	EV (130489, DCM, ‘Referenced Region of Interest Identifier”)	1	MC	If single AI Results are assessed and IFF Row 6 = (13048, DCM, "Region in Space")	
10	>>	CONTAINS	UIDREF	EV (112040, DCM, Tracking Unique Identifier)	1	MC	If single AI Results are assessed and IFF Row 6 =	

	NL	Rel with Parent	VT	Concept Name	VM	Req Type	Condition	Value Set Constraint
							(AIRAI_101, 99IHE, "Referenced Annotation") Or IFF Row 6= ((AIRAI_105, 99IHE, "Referenced Observation") and Row 8 is absent)	
11	>>	CONTAINS	IMAGE	EV (AIRAI_005, 99IHE, “Referenced Instance”)	1	MC	IFF Row 6 = (121200, DCM, "Visual Explanation") or (121191, DCM, "Referenced Segment") or (AIRAI_104, 99IHE, "Referenced Parametric Map")	
12	>>	CONTAINS	CODE	EV (AIRAI_006, DCM, “Result Assessment Status”	1	M		BCID IHERADAIRAI3, “Assessment Status”
13	>>>	HAS CONCEPT MOD	CODE	EV (AIRAI_007, 99IHE, “Assessment Scope”	1	MC	IF Row 12 = (AIRIA_111, 99IHE, “Accepted”) or (AIRIA_114, 99IHE, “Added”	BCID IHE_RADAIRIA 4 “Status Code Scope Modifier”
14	>>>	HAS CONCEPT MOD	CODE	EV (AIRAI_008, 99IHE, “Modification Scope”	1	MC	IF Row 12 = (AIRAI_111, 99IHE, “Accepted”)	BCID IHE_RADAIRIA 5 “Status Code Modification Modifier”

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Content Item Descriptions

Row 3	The Observer Context describes the observer (human or device) that performed the assessment of the AI Results referenced in this object.
Row 7,11	Either one of these rows must be provided. For composite instances like DICOM SR, GSPS, RTSS or encapsulated PDF row 7 must be used For image instances like Secondary Capture Images, Segmentation Objects or parametric maps row 11 must be used
Row 7	For composite instances a unique identifier may be provided to reference a concrete AI Result in the referenced object (see rows 8-10). If this unique identifier is not provided the AI Result Object will be rejected as a whole
Row 8	For DICOM SR Instances the Referenced Observation Concept is used to reference the value of the Observation UID (0040,A171)Attribute for the AI Result in the DICOM SR
Row 9	For RTSS instances the Region in Space Concept is used to reference the value of RT ROI Observation Sequence (3006,0080) > Observation Number (3006,0082) attribute in the RTSS Object
Row 10	For GSPS instances the Referenced Annotation Concept is used to reference the value of the Text Object Sequence (0070,0008) > Tracking ID (0062,0020) > Tracking UID (0062,0021) or Graphic Object Sequence (0070,0009) > Tracking ID (0062,0020) > Tracking UID (0062,0021) of the AI Result in the GSPS object or for SR Instances which do not provide Observation UID (0040,A171) but contain the content item "112040, DCM, Tracking Unique Identifier"
Row 11	For image instances only for Segmentation objects referencing of individual AI Results is possible by providing the Referenced Segment Number (0062,000B) of the IMAGE Value Type. If the Segment Number is not available of for all other AI Result Objects only complete objects can be rejected.

Type: **Extensible**
Version: **yyyymmdd**

Table BCID IHE_RADAIRAI2 Reference Codes for Result Type

Coding Scheme Designator	Code Value	Code Meaning
99IHE	AIRAI_105	Referenced Observation
99IHE	AIRAI_101	Referenced Annotation
DCM	130488	Region in Space
99IHE	AIRAI_103	Referenced Document
DCM	121200	Visual Explanation
DCM	121191	Referenced Segment
99IHE	AIRAI_104	Referenced Parametric Map

910 **Type:** **Non-Extensible**
Version: **yyyymmdd**

Table BCID IHE_RADAIRAI3: Assessment Status

Coding Scheme Designator	Code Value	Code Meaning (Note 1)
99IHE	AIRAI_111	accepted
99IHE	AIRAI_112	unreviewed
99IHE	AIRAI_113	unknown/undetermined
99IHE	AIRAI_114	added
99IHE	AIRAI_115	rejected

Note 1: See Section X.4.1.3 for an explanation of the Code Meaning

Type: **Non-Extensible**
Version: **yyyymmdd**

Table BCID IHE_RADAIRAI4 "Status Code Scope Modifier"

Coding Scheme Designator	Code Value	Code Meaning
99IHE	AIRAI_121	clinically relevant
99IHE	AIRAI_122	relevant for Q/A analysis

Type: **Non-Extensible**
Version: **yyyymmdd**

Table BCID IHE_RADAIRAI5 "Status Code Modification Modifier"

Coding Scheme Designator	Code Value	Code Meaning
99IHE	AIRAI_131	modified
99IHE	AIRAI_132	unmodified

Type: **Non-Extensible**
Version: **yyyymmdd**

Table BCID IHE_RADAIRAI6 "Assessment Basis"

Coding Scheme Designator	Code Value	Code Meaning
99IHE	AIRAI_141	Single Report Concordance
99IHE	AIRAI_142	Single Human Assessor
99IHE	AIRAI_143	Multiple Human Assessments

Appendices to Volume 3

Appendix X – AIRAI Profile Examples

Examples for the AIRAI Profile are found in Google Drive in this folder.

