Integrating the Healthcare Enterprise

IHE Radiology
Technical Framework Supplement

AI Result Assessment for Imaging (AIRA)

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 V23.0. 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 June 12, 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 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 a variety of DICOM Objects, which could either have individually referenceable AI Results, e.g., DICOM SR, or which do not have individually referenceable AI Results e.g., DICOM Secondary Capture. Therefore, the assessment is not limited to typical AI result objects. Non-AI result objects, e.g., Softcopy Presentations State objects 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: Do we need levels of rejection severity ? At the moment we do not have severities, the AI Result is rejected or not. We can envision rejection severity might be of interest to product developers, regulators and hospital QA processes, but is not particularly useful for imaging physicians.

Closed Issues

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.

3	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.
4	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. Added Requirements to Section 6.8.2.2.1 to indicate that these objects can only be assessed as a Single AI Result
5	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 Modifier 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. Use Document Modifier code (AIRA_26, 99IHE, «Assessment Process Outcome»)
6	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? Answer: Addressed in the use cases displayed in Figure 57.4.1.1-1

7	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. Answer: For now, a DICOM SR can only be verified by a human observer until a device observer is added as a Verifying Observer in the DICOM Standard.
8	Q: Shall this profile define a way how to encode assessment objects that are incomplete, e.g., because the assessment activity 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 tags like the Preliminary Flag could be used for this purpose. Answer: Preliminary and Completion Flag were added to the definition of Output AI Result Objects and the Assessment Status SR object. However, the usage of these attributes is left to the implementer

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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.

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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.

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*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.*

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Appendix A – Actors

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

165 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

170 ## Appendix B – Transactions

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

No new transactions and no definitions for existing transactions were modified.

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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	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 as defined in this glossary		

Volume 1 – Profiles

Domain-specific additions

None

Add new Section 57

57 AI Result Assessment for Imaging (AIRA) Profile

With the increasing number of regulatory cleared AI-based SaMD (Software as a Medical Device) 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 AIRA Profile specifies the structure and transactions for storage and communication of assessment of AI Results for different purposes, e.g., distribution of assessed AI results, post market surveillance, detection of data drift.

This profile does not define assessment criteria or operational processes required to ensure the quality of the AI results.

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

57.1 AIRA 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 57.1-1 shows the actors directly involved in the AIRA 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 57.3).

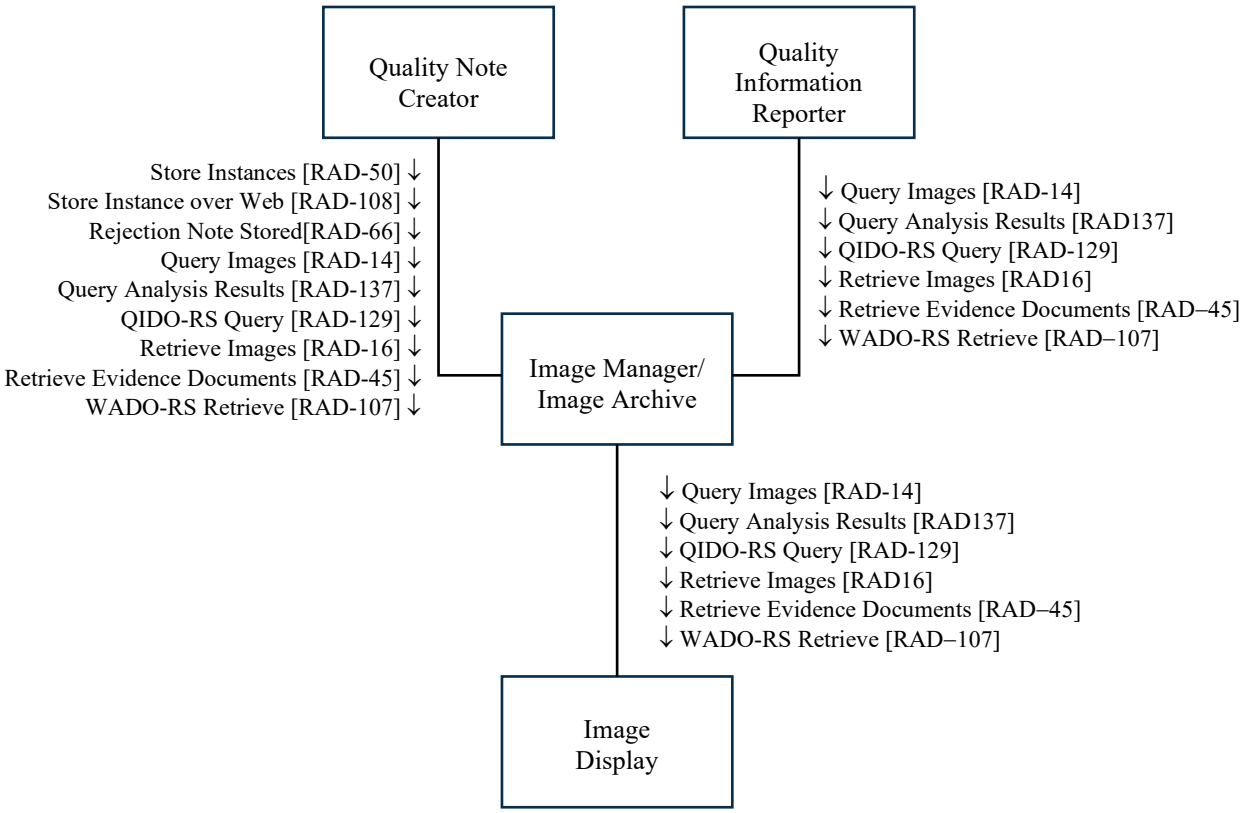


Figure 57.1-1: AIRA Actor Diagram

Table 57.1-1 lists the transactions for each actor directly involved in the AIRA 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 57.1-1: AIRA Profile - Actors and Transactions

Actors	Transactions	Initiator or Responder	Optionality	Reference
Quality Note Creator (See Sec. 57.1.1.1)	Store Instances [RAD-50]	Initiator	O	RAD TF-2: 4.50
	Store Instances over the Web [RAD-108] (Note 1)	Initiator	O	RAD TF-2: 4.108
	Rejection Note Stored [RAD-66]	Initiator	R	RAD TF-2: 4.66
	Query Images [RAD-14]	Initiator	O	RAD TF-2: 4.14
	Query Analysis Results [RAD-137]	Initiator	O	RAD TF-2: 4.137
	QIDO-RS Query [RAD-129] (Note 1)	Initiator	O	RAD TF-2: 4.129

Actors	Transactions	Initiator or Responder	Optionality	Reference
	Retrieve Images [RAD-16]	Initiator	O	RAD TF-2: 4.16
	Retrieve Evidence Documents [RAD-45]	Initiator	O	RAD TF-2: 4.45
	WADO-RS Retrieve [RAD-107] (Note 1)	Initiator	O	RAD TF-2: 4.107
Quality Information Reporter (See Sec. 57.1.1.2)	Query Images [RAD-14]	Initiator	O	RAD TF-2: 4.14
	Query Analysis Results [RAD-137]	Initiator	O	RAD TF-2: 4.137
	QIDO-RS Query [RAD-129] (Note 1)	Initiator	O	RAD TF-2: 4.129
	Retrieve Images [RAD-16]	Initiator	O	RAD TF-2: 4.16
	Retrieve Evidence Documents [RAD-45]	Initiator	O	RAD TF-2: 4.45
	WADO-RS Retrieve [RAD-107] (Note 1)	Initiator	O	RAD TF-2: 4.107
Image Manager/ Image Archive (See Sec. 57.1.1.3)	Store Instances [RAD-50]	Responder	R	RAD TF-2: 4.50
	Store Instances over the Web [RAD-108]	Responder	O	RAD TF-2: 4.108 RAD TF-1: 57.2.1
	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
	QIDO-RS Query [RAD-129]	Responder	O	RAD TF-2: 4.129 RAD TF-1: 57.2.1
	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	O	RAD TF-2: 4.107 RAD TF-1: 57.2.1
Image Display (See Sec. 57.1.1.4)	Query Images [RAD-14]	Initiator	O	RAD TF-2: 4.14
	Query Analysis Results [RAD-137]	Initiator	O	RAD TF-2: 4.137
	QIDO-RS Query [RAD-129] (Note 1)	Initiator	O	RAD TF-2: 4.129
	Retrieve Images [RAD-16]	Initiator	O	RAD TF-2: 4.16
	Retrieve Evidence Documents [RAD-45]	Initiator	O	RAD TF-2: 4.45
	WADO-RS Retrieve [RAD-107] (Note 1)	Initiator	O	RAD TF-2: 4.107

Note 1: Use of this transaction in a deployment requires an Image Manager / Image Archive that supports the RESTful Semantics Option. See Section 57.2.1.

57.1.1 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.

57.1.1.1 Quality Note Creator

Quality Note Creators record assessments of the validity of AI Results found in AI Result Objects and, depending on those assessments, may create new AI Result Objects and/or flag AI Result Objects as rejected. Assessments may be performed by either a human reviewer or an automated function or a combination of both. The term AI Result is used broadly here to refer to individual details being assessed and may not necessarily correspond to a discrete clinical finding. Some AI Result Objects contain a single AI Result, others contain multiple AI Results.

The Quality Note Creator shall create an Assessment Status Object for each assessment activity. An assessment activity involves one Verifying Observer recording the assessment of one or more AI Results in one or more AI Result Objects in a single study. The Assessment Status SR Object shall conform to the specification in RAD TF-3: 6.8.2.2 "AI Result Assessment data encoding".

The Quality Note Creator shall support storing Assessment Status SR Objects using at least one of the Store Instances over the Web [RAD-108] (RESTful) or Store Instances [RAD-50] (DIMSE) transactions, and it may support both.

The Quality Note Creator shall be able to reject Assessment Status Objects by using the Rejection Note Stored [RAD-66] transaction to store a KOS object with a Document Title of (113001, DCM, "Rejected for Quality Reasons") and a Document Title Modifier of (AIRA_26, 99IHE, "Assessment Process Outcome"), if it is a predecessor to a subsequent Assessment Activity.

The Quality Note Creator shall be able to reject AI Result Objects by using the Rejection Note Stored [RAD-66] transaction to store a KOS object with a Document Title of (113001, DCM, "Rejected for Quality Reasons") and a Document Title Modifier of (AIRA_26, 99IHE, "Assessment Process Outcome").

The Quality Note Creator shall be able to create replacement AI Result Objects as described in RAD TF-3: Section 6.8.2.1. For related concepts, see Section 57.4.1.

With two exceptions, the Quality Note Creator shall create a replacement AI Result Object for each assessed AI Result Object by removing any AI Results that were rejected or modified, including any corrected or new AI Results provide by the assessor, and retaining any other AI Results.

- The first exception is when all AI Results in the AI Result Object were rejected. No replacement AI Result Object is needed.
- The second exception is when no AI Results in the AI Result Object were rejected, modified, or added, and the AI Result Object SOP Class does not have a Verification Flag attribute.

The Quality Note Creator shall reject a given AI Result Object when a replacement AI Result Object is created for it, or when it is rejected in its entirety.

The Quality Note Creator shall support the different scenarios described in RAD TF-3: Table C-1 and Table C-2. These tables provide detailed information about the encoding and the dependency between the different objects created during an Assessment Activity depending on the Status of the individual AI Results.

The Quality Note Creator shall support corresponding query and retrieval transactions listed in Table 57.1-1 for each SOP Class they consume. The Quality Note Creator may support the RESTful version of the transaction, or the conventional DIMSE version of the transaction, or both.

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. This enables the Quality Note Creator to access Rejected Instances when retrieving AI Assessments performed by a previous Assessor.

- A Quality Note Creator 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 57.1.1.3.
- A Quality Note Creator 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 57.1.1.3.

57.1.1.2 Quality Information Reporter

Quality Information Reporters retrieve Output AI Result Objects and the Assessment Status Object (and potentially the Input AI Result Objects) 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 RAD TF-3: Table 6.8.2-1 “IODs for Encoding AI Results”.

The Quality Information Reporter shall support corresponding query and retrieval transactions listed in Table 57.1-1 for each SOP Class they consume. The Quality Information Reporter may support the RESTful version of the transaction, or the conventional DIMSE version of the transaction, or both.

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 57.1.1.3.
- 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 57.1.1.3.

57.1.1.3 Image Manager/Image Archive

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

Image Manager / Image Archive Actors shall support all the SOP Classes listed in RAD TF-3: 6.8.2 “Result Assessment Data Encoding”.

Instances referenced by the Quality Note Creator using a Rejection Note 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 Image Manager / Image Archive shall:

- support the DIMSE Semantics of [RAD-66] as a C-STORE SCU. See RAD TF-2: 4.66.4.1.2.1.
- be able to expose or hide rejected instances as specified in RAD TF-2: 4.66.4.1.3 and 4.66.4.1.3.1 (Expected Actions for Rejection Notes Stored for Quality Reasons). Briefly, this involves hiding the rejected instances in subsequent Query/Retrieve responses unless the client uses an AE Title specifically configured to provide access to hidden instances.

57.1.1.4 Image Display

The Image Display can be used to display an imaging study and 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 support query and retrieval of the imaging study, Output AI Result Objects and the Assessment Status Objects. Image Displays shall support corresponding query and retrieve transactions listed in Table 57.1-1 for each SOP Class they consume. The Image Displays may support the RESTful version of the transaction, or the conventional DIMSE version of the transaction, or both.

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”).

To prevent inadvertent use of rejected results in clinical workflow, the rejected result instances are sequestered by the Image Manager / Image Archive. Some Image Display users may need to review rejected results, for example as part of a QA process.

The Image Display shall be configurable to access an alternate AE Title (i.e., the "Expose Rejected Instances" Application Entity) or designated webservice endpoint provided by the Image Manager / Image Archive (see RAD TF-2: 4.66.4.1.3).

Note: The Expose Rejected Instances Application Entity/Webservice endpoint 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 Rejection Note instances or the Assessment Status Objects and then retrieve the result instances based on the contained references. The user might also query for the result instances directly and then retrieve selected results.

The Image Display shall be configurable to enable only specific users on the Image Display to access rejected instances.

57.2 AIRA Actor Options

Options that may be selected for each actor in this profile, if any, are listed in the Table 57.2-1. Dependencies between options, when applicable, are specified in notes.

Table 57.2-1: AIRA – Actors and Options

Actor	Option Name	Reference
Quality Note Creator	None	--
Quality Information Reporter	None	--
Image Manager/Image Archive	RESTFul Semantics	Section 57.2.1
Image Display	None	--

57.2.1 RESTFul Semantics Option

This option enables Image Manager/Image Archive Actors to use RESTFul message semantics to communicate with other actors in this profile

Image Manager/Image Archive Actors supporting this option shall serve as an Origin Server for the following transactions:

- Rejection Note Stored [RAD-66] – See RAD TF-2: 4.66.4.1.2.2 RESTful Semantics
  - The Image Manager / Image Archive shall be able to expose or hide rejected instances as specified in RAD TF-2: 4.66.4.1.3 and 4.66.4.1.3.2 (Expected Actions for Rejection Notes Stored for Quality Reasons). Briefly, this involves hiding the rejected instances in subsequent Query/Retrieve responses unless the client uses a webservice endpoint specifically configured to provide access to hidden instances.
- WADO-RS Retrieve [RAD-107]
- Store Instances of the Web [RAD-108]
- QIDO-RS Query [RAD-129]

- When responding to a QIDO-RS Query [RAD-129] transaction, the Image Manager / Image Archive shall additionally 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”).

The Image Manager/Image Archive shall enable configuration of a designated set of IP addresses allowed to initiate the query and retrieve request.

57.3 AIRA 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).

Section 57.5 describes some optional groupings that may be of interest for security considerations and Section 57.6 describes some optional groupings in other related profiles.

Table 57.3-1: AI Result Assessment For Imaging - Required Actor Groupings

AIRA Actor	Actor(s) to be grouped with	Reference	Content Bindings Reference
Quality Note Creator	ITI CT / Time Client	ITI TF-1: 7	--
Quality Information Reporter	None	--	--
Image Manager/Image Archive	None	--	--
Image Display	None	--	--

57.4 AIRA Overview

57.4.1 Concepts

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

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

- **AI Result:** Discrete outputs of an AI, e.g., a particular measurement or finding. The AI Assessment Activity operates on AI Results.
- **AI Result Object**: An instance of a supported IOD that contains one or more AI Results (see Section 57.4.1.1 “Encoding of AI Results using different IODs”).

57.4.1.1 Assessment Process and Outcome Encoding

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 reading the underlying study, it is essential to have a mechanism that allows those results to be assessed, and for the outcome of that assessment to be documented and communicated.

The assessment process involves individual AI Results being assessed against a reference standard. Often the reference standard will be the direct judgement of a human practitioner. Sometimes the reference standard will involve the judgement of a human practitioner applied indirectly by comparing the contents of their final report to the AI Results.

An assessment process can consist of one or more assessment activities. An assessment activity comprises assessing one or more Input AI Result Objects and potentially resulting in one or more Output AI Result objects. These Output AI Result Objects then can be used as input for a subsequent assessment activity.

For any given assessment process, multiple assessors (who may be human or machine) may be involved, but one assessor must be responsible for the outcome. The Verifying Observer is recorded as described in Section 57.1.1.1 and RAD TF-3: 6.8.2. When multiple assessment activities are performed in sequence on the same results, the Verifying Observer of the current assessment activity will replace the Verifying Observer of the preceding activity.

Possible outcomes of the assessment include the result being accepted unchanged, accepted with modification, or rejected. It is also possible that an assessment is inconclusive (i.e., the assessor is unable to assess), or that an assessment was not performed for some reason (i.e., the AI Result is unassessed), or that a new result (presumably missed by the AI) is added. Additionally, a result that is accepted, modified or added may be further assessed as being clinically relevant or being relevant for Q/A analysis (but not relevant for clinical purposes). See Figure 57.4.1.1-2 for the structure of this coding.

In the context of this profile AI Results that are either accepted, modified or added are referred to as confirmed AI Results. AI Results that have been rejected, unassessed or which the Assessor has been unable to assess are referred to as unconfirmed.

The encoding of the assessment outcome has three steps:

1. **Creation of Output AI Result Object(s):** These created objects will replace the assessed Input AI Result Object. These Output AI Result Objects use the same IOD as the Input AI Result Object but have a new SOP Instance UID. The Output AI Result Object will contain all AI Results that are confirmed.
2. **Creation of an Assessment Status Object:** This object is a DICOM Comprehensive SR with TID IHE_RADAIRA1 and provides detailed assessment information for each of the AI Results in the Output AI Result Object(s).
3. **Rejection of AI Result Objects:** a KOS instance with Document Title “Rejected for Quality Reasons” and a Document Title Modifier “Assessment Process Outcome” will be issued and sent to the Image Manager either to hide Input AI Result Objects or if due to a rejection by the Assessor entire objects must be rejected. The Image Manager/Image Archive will manage the access to this/these objects (i.e., hide or expose them as described in the Rejection Note Stored [RAD-66] transaction)

Unconfirmed AI Results will not be encoded in the Output AI Result Object(s); however, they will be referenced in the Assessment Status Object with their corresponding Status.

Some SOP Classes used for encoding AI Result Objects do not have individually referenceable AI Results (i.e., DICOM Secondary Capture, DICOM Encapsulated PDF or DICOM Parametric Maps). For these SOP Classes, the complete AI Result Object is considered a single AI Result and as such can only be assessed in its entirety. For details on these SOP classes refer to Section 57.4.1.2.

The example assessment scenario in Figure 57.4.1.1-1 shows relationships between various instances involved. The **Assessment Input** column shows AI Result Object instances that contain the AI Results being assessed. The **Assessment Output** Column shows instances that have been revised (either to remove rejected results, provide modified results, or encode newly created results). The **Accompanying Assessment Output** column shows the Assessment Status Object, and the KOS used to reject complete instances.

Five cases are depicted (shown as numbers in circles).

1. An input DICOM SR contains three AI Results, each identified by a unique Observation UID. During the Assessment Activity, one AI Result is rejected, one is accepted, one is modified, and a fourth result is added that the AI missed. The Output AI Result Object contains the two confirmed AI Results and the added result. The Assessment Status Object references the Observation UID of each individual AI Result and provides a status for each. Note that the Assessment Status Object references items in the Output AI Result Object for the confirmed results and references the item in the Input AI Result Object for the rejected result. The Original DICOM SR is rejected using a KOS object, since it is replaced by the Output AI Result Object.
2. An input DICOM SR contains only one accepted AI Result. During the assessment activity, the complete object is accepted. Although the AI Result is unchanged, an Output AI Result Object is created to update the Verification Flag (0040,A493) value to VERIFIED. Since an Output AI Result Object was created, the Original DICOM SR is rejected using the KOS object.
3. An input Secondary Capture contains multiple AI Results, but they are not individually referenceable. Therefore, the Secondary Capture object in its entirety is treated as a single AI Result. During the assessment activity, it is accepted. The Assessment Status Object references the SOP Instance UID of the Secondary Capture and assigns the accepted status. No Output AI Result Object or KOS is created.
4. An input DICOM SR contains multiple AI Results. During the assessment activity, they are all rejected. The Assessment Status Object references the Observation UID of each individual AI Result in the Input AI Result Object with a status of rejected. The Original DICOM SR is rejected using the KOS. No Output AI Result Object is created.
5. During the assessment activity, a new Segmentation object containing one segment is created. The Assessment Status Object references this segment and assigns a status of added.

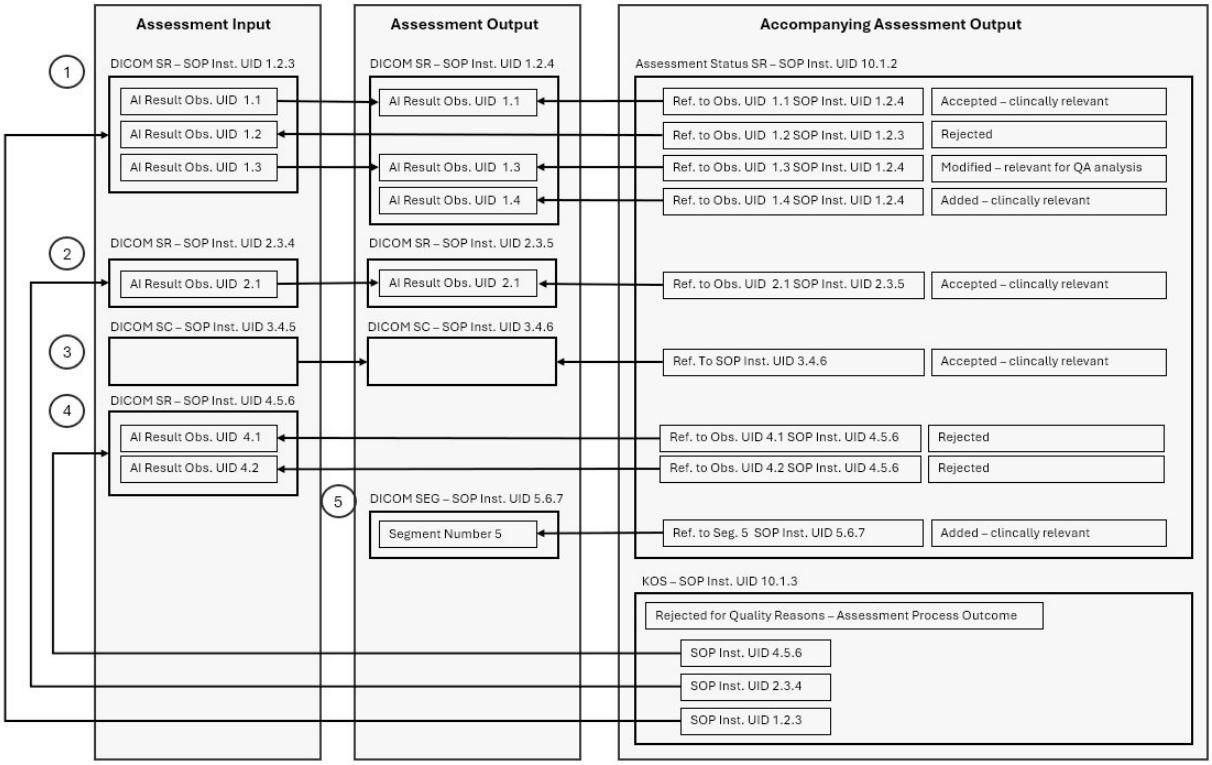


Figure 57.4.1.1-1: Assessment Process

The concepts for Assessment Status and Result Relevancy addressed by this profile are shown in Figure 57.4.1.1-2. See RAD TF-3: Table 4.3.2.3-1 for corresponding codes and definitions.

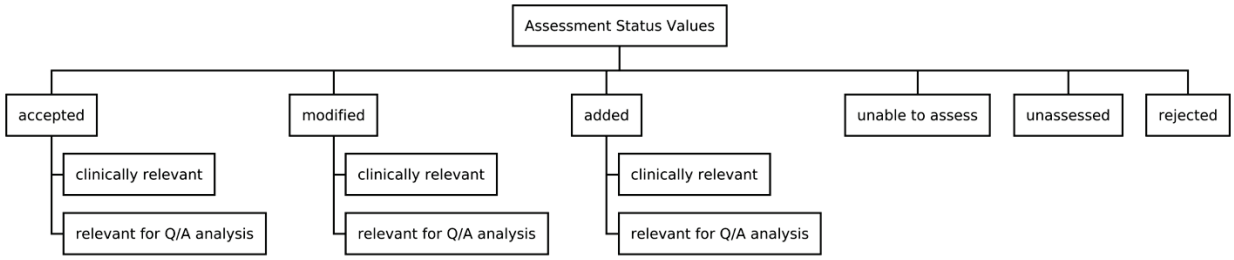


Figure 57.4.1.1-2: Assessment Status and Result Relevancy

Note: This profile does not define criteria for deciding whether results are “clinically relevant” or “relevant for Q/A analysis”.

57.4.1.2 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:

- Findings 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.

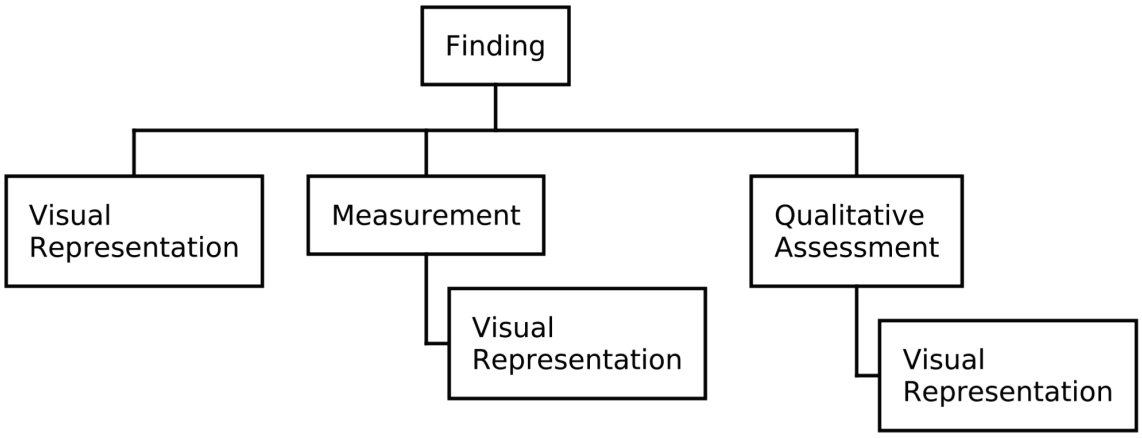


Figure 57.4.1.2-1: Finding Representation in DICOM SR

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 new template that was designed for this profile (see RAD TF-3: 6.8.2.2 “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 referenceable for acceptance/rejection.

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 referenceable 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.

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 assessed in total.

57.4.1.3 Controlling Access Concept for unassessed AI Results

Depending on the policy of an institution and/or legal issues, e.g., the requirements of the EU AI Act that only trained persons are allowed to use AI systems, it might be required to have access restrictions to unassessed AI Result objects.

How this can be achieved depends on the capabilities of the software being used and the processes/use cases, the internal access policies, and the infrastructure of the individual institution.

A possible solution might be that, in general, all unassessed AI Results are restricted from view by the PACS for those users/user groups outside the department where the images originated from, e.g., Radiology, Cardiology. One might debate that in emergency situations other personal shall also gain access to the AI Result Objects in the unassessed state. As mentioned earlier, this decision process is very specific for the individual organization.

Therefore, handling of this topic is out of scope for this profile.

57.4.1.4 Scenarios for the Assessment of AI Results

There are two base scenarios for 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 copied to the report, documenting only the accepted and modified 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 valid AI Results, i.e., 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.

57.4.1.4.1 AI supported report generation - Basic Assessment Process

Figure 57.4.1.4.1-1 “Basic Assessment Process” illustrates the workflow steps for all assessment scenarios. In the figure, the initial steps for the Image Manager / Image Archive obtaining the AI Results and associated images are not specified in the AIRA Profile.

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 the Image Manager by the Quality Note Creator. The assessment of the DICOM object content will be performed by the Quality Note Creator with the underlying concept as described in Section 57.4.1.1. 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, because of the assessment process, the initial AI Result Objects need to be updated, new AI Result Objects will be issued and stored replacing the initial AI Result Objects. In the best case, if all findings are accepted, the content of the existing AI Result Objects will be copied to new AI Result Objects that supersede the initial AI Result Objects.

Figure 57.4.1.4.1-1 illustrates the Basic Assessment Process; the processes for sending the imaging study and Input AI Result Objects to the Image Manager, and the combined process of image reading, report generation, and AI Result assessment are out of scope of the AIRA Profile.

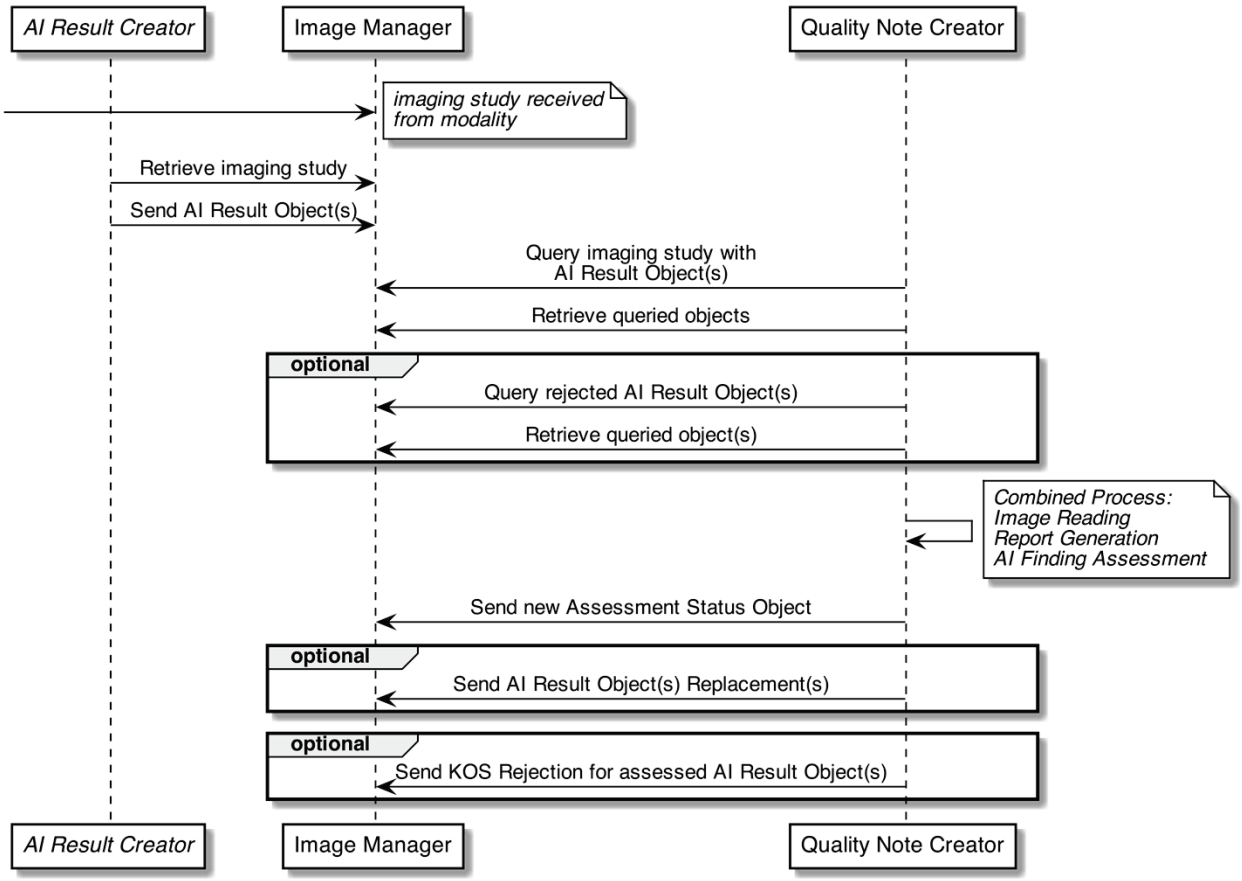


Figure 57.4.1.4.1-1: Basic Assessment Process

57.4.1.4.2 AI supported report generation - two step Quality Note Creator integration

There are two variants to integrate the Quality Note Creator 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 Result assessment activity. The

result of that process will then feed an activity performed automatically by another Quality Note Creator (see Figure 57.4.1.4.2-1 “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 Section 57.4.1.4.3 “AI supported report generation - Revision of a performed Validation Process”).

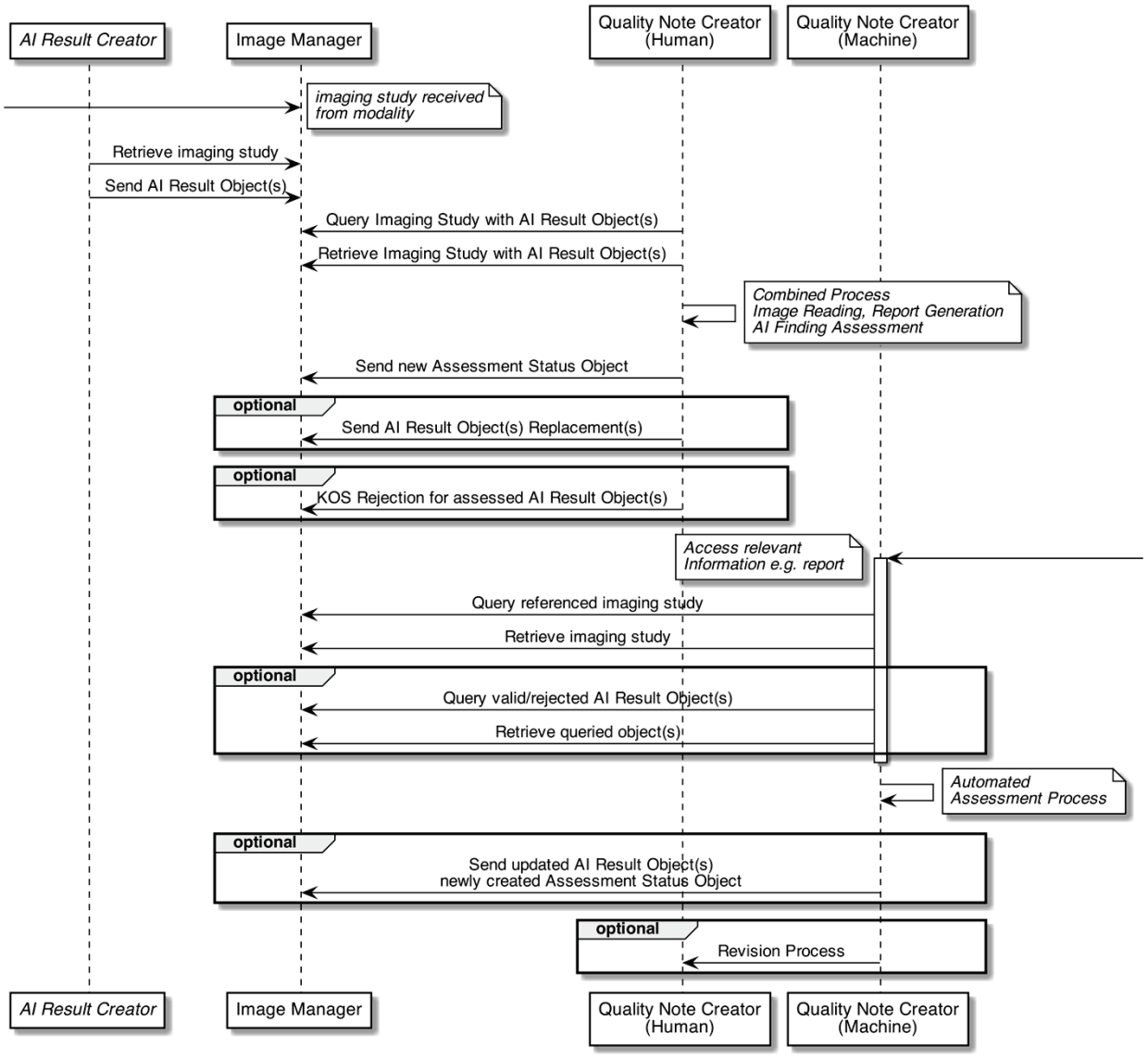


Figure 57.4.1.4.2-1: Two Step Quality Assessment - manual / automated

Variant B inverts the two Quality Note Creator steps by first running an automated activity, followed by a manual activity (see Figure 57.4.1.4.2-2 Two Step Quality Assessment - automated / manual). As a result, it might be that both, a new AI Result Object(s) and an

Assessment Status Object, will be written. In case the assessed AI Results are rejected, the corresponding AI Result Objects and Assessment Status Object must be hidden.

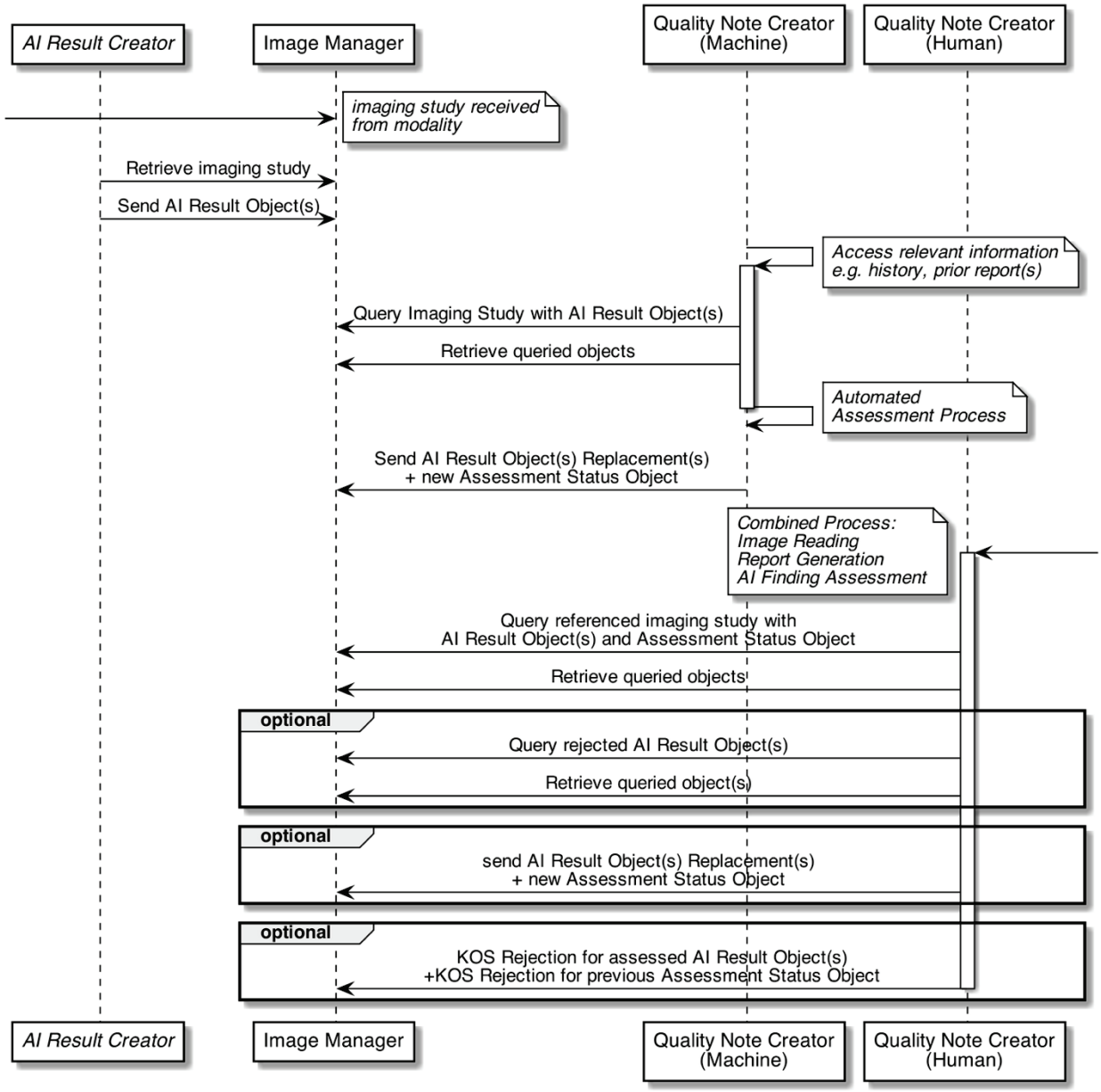


Figure 57.4.1.4.2-2: Two Step Quality Assessment - automated / manual

Both variants show that the Quality Note Creator must make use of other sources to perform its assigned tasks. However, the method the Quality Note Creator uses to access these sources is not specified by this profile.

The output of this Two Step Quality Assessment is Output AI Result Object(s) and either a new (some findings are accepted) or an updated (all findings are rejected) Assessment Status Object.

57.4.1.4.3 AI supported report generation - Revision of a performed Assessment

A previously performed assessment of AI results may be re-evaluated. In this case, 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 Output 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 57.4.1.4.3-1 “Revision of a performed Assessment Process”).

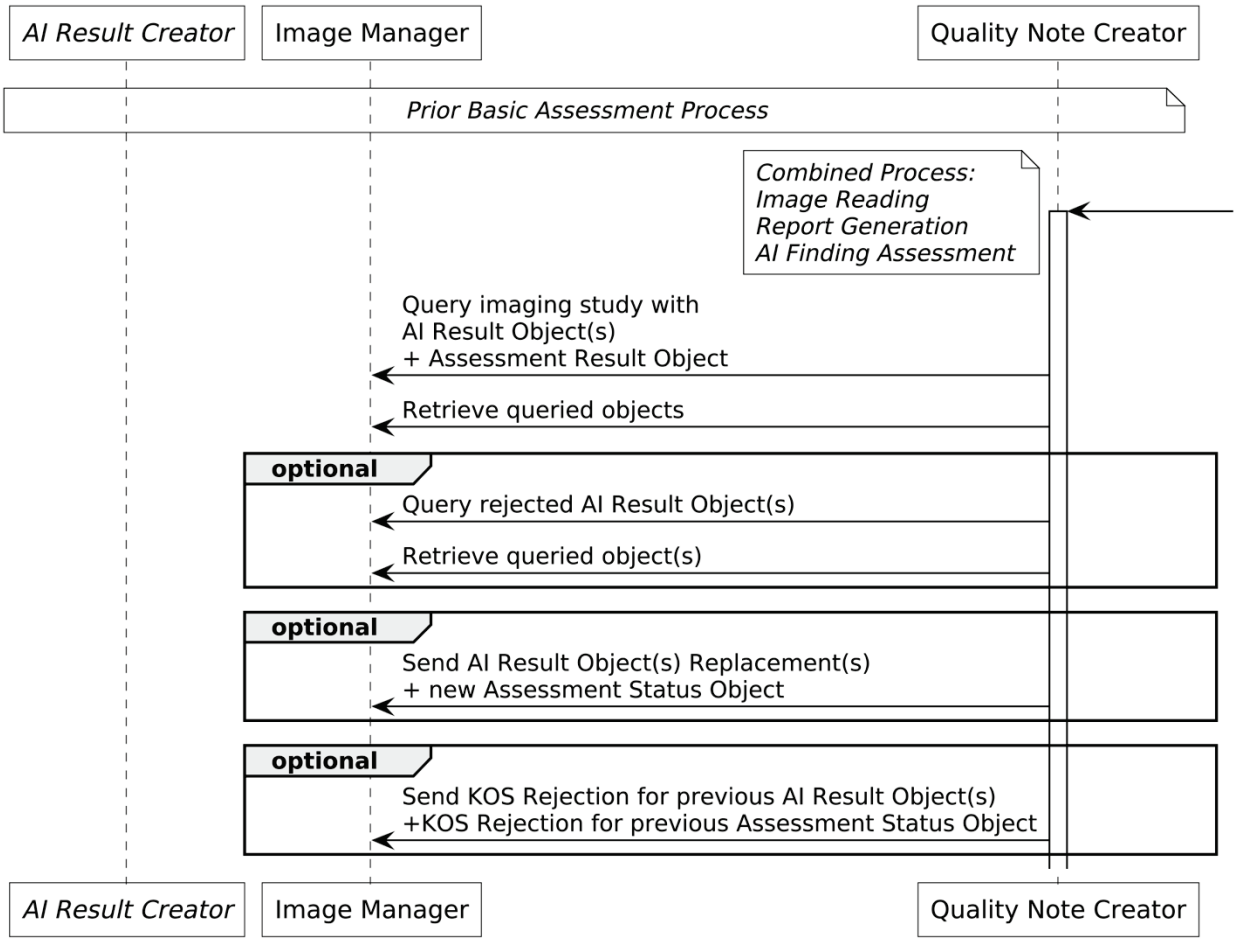


Figure 57.4.1.4.3-1: Revision of a performed Assessment

57.4.1.4.4 Parallel Activities during AI Result Assessment

The complete assessment of an AI Result Object might rely on the output of other activities that can start and finish at any time e.g.,:

- The AI Results in an AI Result Object can be examined by multiple activities. The Quality Note Creator always creates an Assessment Status Object as output from each activity.
- During most assessments, an Output AI Result Object is stored that replaces the existing AI Result Objects.

As these assessment activities 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 57.4.1.4.4-1 “Parallel AI Result Assessment Processes” envisions this.

This profile does not specify how to handle completing assessment results, e.g., they are created at the same time, or the assessments are in conflict.

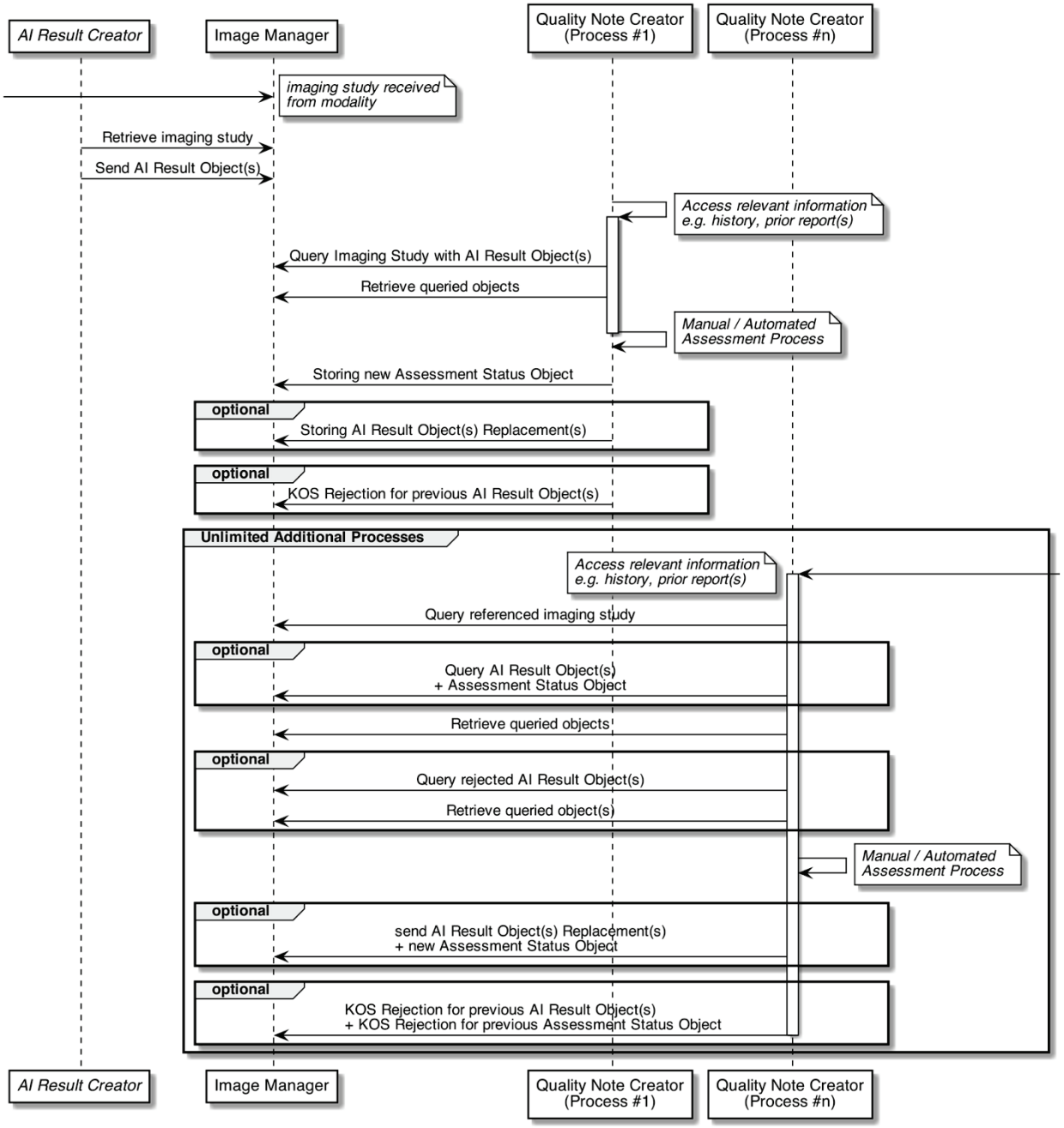


Figure 57.4.1.4.4-1: Parallel Processes during AI Result Assessment

57.4.1.5 Usage of Assessed AI Results

The use cases (Section 57.4.2.1) will often correlate with specific Assessment Status Values (see Figure 57.4.1.1-2).

AI Results assessed with the Assessment Status Values “accepted” or “modified” or “added” with the modifier “clinically relevant”” can be used for review processes for the purpose of

presenting only confirmed findings which might have an impact on the patient and/or the treatment. 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 Output AI Result Object(s).

The Assessment Status Values “accepted” or “modified” with the modifier “clinically relevant” only mark 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” or “modified” with the modifier “clinically relevant” alone will be of limited use for performance statistics.

For performance metrics results from the Assessment Status Value categories “accepted” or “modified” or “added” with the modifier “relevant for Q/A analysis” combined with “accepted” or “modified” or “added” with the modifier “clinically relevant” 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 “unable to assess”.

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 of the underlying acceptance 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 Output AI Result Object(s) and/or the Assessment Result Object to use them/it as input, generating an updated (corrected) version of the previous AI Result Object.

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

57.4.1.6 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 57.4.1.4 “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 for which object it will access and display.

57.4.1.7 Performance Metrics

Assessment of AI Results can be input into calculating performance metrics for AI algorithms. There are at least two factors to consider: patient safety/legal and process optimization.

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:

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

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

where:

Table 57.4.1.7-1: PCR and PIR Terms

Term	Definition
accepted findings	Sum of all findings assessed as "accepted"
incorrect findings	Sum of all findings assessed as "rejected", "modified" and "added"
corrected findings	Sum of all findings assessed as "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 term definitions (Table 57.4.1.7-2 "PPV and NPV Terms"), in principle, be calculated from the data provided by the output objects of this profile. The profile does not address the processes needed to provide gold standard quality for the assessment values.

Table 57.4.1.7-2: PPV and NPV Terms

Term	Definition (see Table 57.4.1.7-1)
true positives and / or true negative (See Note 1)	accepted and modified findings
false negatives	added findings
false positives	rejected findings

Note 1: The definition of "positive" and "negative" can differ with the metric that is addressed and needs to be determined individually.

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.

57.4.1.8 AI Performance Troubleshooting Support

This profile supports AI assessment either in the context of clinical usage or as the basic for the calculation of performance metrics.

The capabilities of the metrics which can be directly covered with the assessment output from this profile will not be sufficient to cover every monitoring aspect or troubleshooting of high rejections rates.

However, the data is sufficient to feed alarm metrics indicating whether something is not behaving as defined (see Section 57.4.1.7). Additionally, the assessment objects will give solid information about where to start to find the cause of the divergence.

There could be a variety of causes for this divergence:

- Image quality issues in the underlying images
- Algorithm use outside the intended use and parameters
- Data drift
- Potential gaps in user training or system integration

57.4.1.9 External Use of Assessments

Some applications of the assessment data captured by this profile include its collection, collation, review, and analysis in the context of vendor product monitoring and improvement, and post-market surveillance for regulatory purposes.

This could be served in part by aggregate assessment reports generated by the Quality Information Reporter on bulk performance metrics over time. Such reports conveniently address potential privacy issues by inherently removing patient-specific details in the process of aggregation.

That said, vendors (and regulators) may also have an interest in specific case assessment results to better understand where an algorithm is failing or otherwise performing sub-optimally. Access to such data would need to involve appropriate anonymization of the assessment objects and associated study data. After such anonymization, the study images and data that served as the input to an AI algorithm, the AI Result Objects generated by the AI algorithm, and Assessment Status Objects for those results might be provided to a vendor, regulator, or registry, but this is outside the current scope of this profile.

57.4.1.10 Addition of Unique Identifiers

For this profile to function properly, the availability of unique identifiers for the individual AI Results is essential. However, these unique identifiers are, according to the DICOM Standard, not mandatory for all supported AI Result Object IODs even if they include individually referenceable AI Results. Therefore, they may not be available in the instances created by the AI solution (Evidence Creator).

If these unique identifiers are not present, the profile treats the AI result Objects as a single AI Result. However, to leverage the full capabilities of the profile, it is recommended that Quality Note Creator can create new instances containing these unique identifiers and hide the AI Result Object originated from the Evidence Creator using IOCM mechanisms.

In the context of this profile the following two SOP Classes and their unique identifiers are impacted.

- DICOM Structured Reports. Observation UID (A040,A171)
- DICOM Presentation State Objects: Graphic Group ID (0070,0295) in either the Text Object Sequence (0070,0008) or in the Graphic Object Sequence (0070,0009)

Note that the requirements in Section 6.8.2.1 would be applicable to these newly corrected instances as well.

57.4.2 Use Cases

The AIRA 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.

57.4.2.1 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.

57.4.2.1.1 Assessment of AI Results during Reporting Use Case Description

During the reporting process, a radiologist or an automated system (Assessor) reviews 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/modified clinically relevant. However, not every AI finding or finding in the images will be assigned an Assessment Status Value (Figure 57.4.1.2-1) as some may not be relevant for the report, according to the Assessor. The underlying assessment concept is described in Section 57.4.1.1 Assessment Process and Outcome Encoding.

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

Note: It is also possible to create completely new DICOM objects during the Assessment Process (see Section 57.4.1.1)

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.

57.4.2.1.2 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 such as the EU AI Act, or for post market surveillance.

Because the assessment is for QA purposes, this use case differs from an assessment for reporting in that all of the AI Results in the study will be assessed and receive an Assessment Status Value (Figure 57.4.1.2.3-1).

57.4.2.1.3 Assessment of AI Results Use Case Process Flow

Figure 57.4.2.1.3-1 shows the process flow for the Use Case Assessment of AI Results covering both sub-use cases.

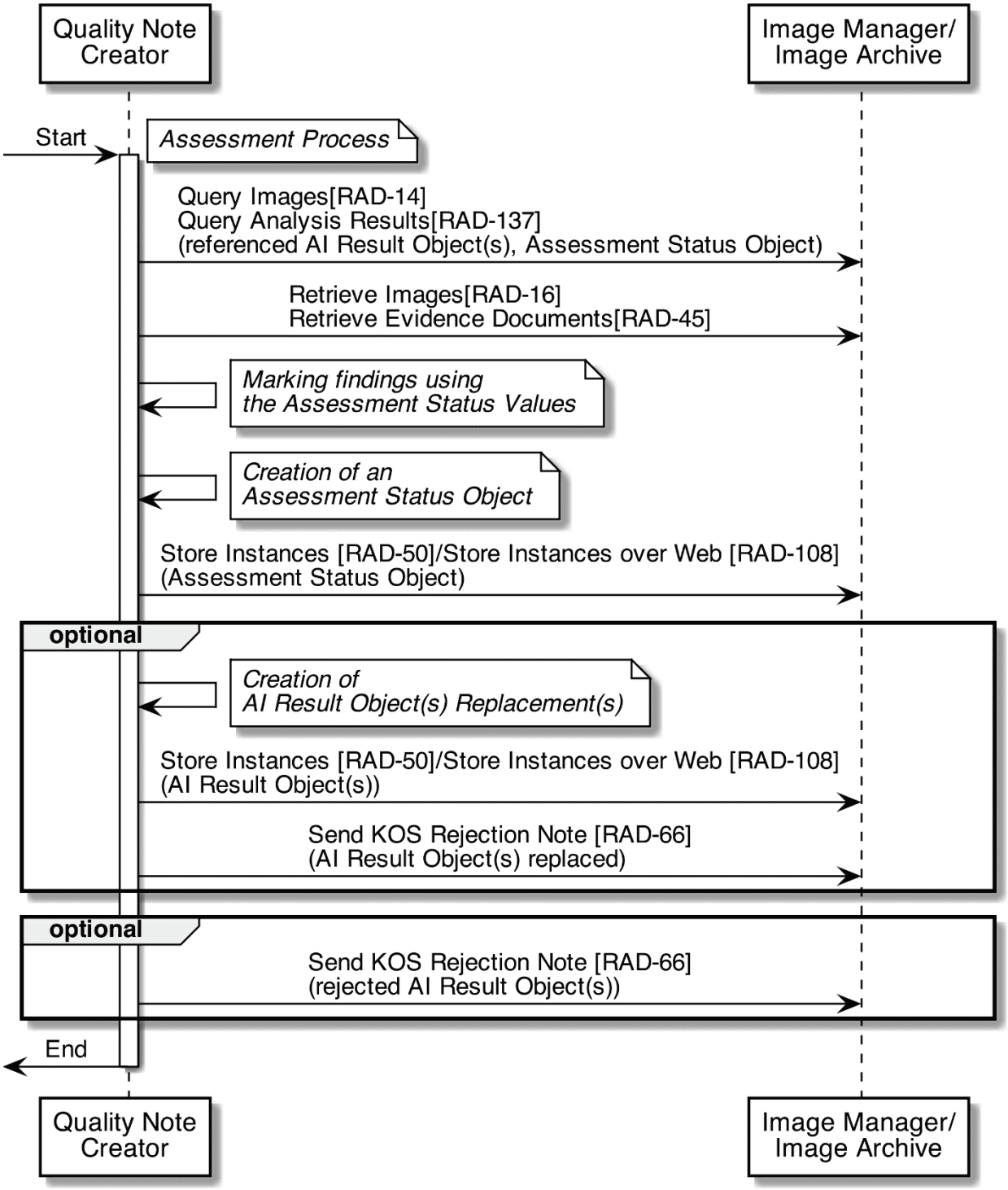


Figure 57.4.2.1.3-1: Assessment of AI Results

57.4.2.2 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.

57.4.2.2.1 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 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 Status Objects, the Image Display must identify the relevant AI Result Object(s) to be displayed.

57.4.2.2.2 Usage of Assessed AI Results for Clinical Review Process Flow

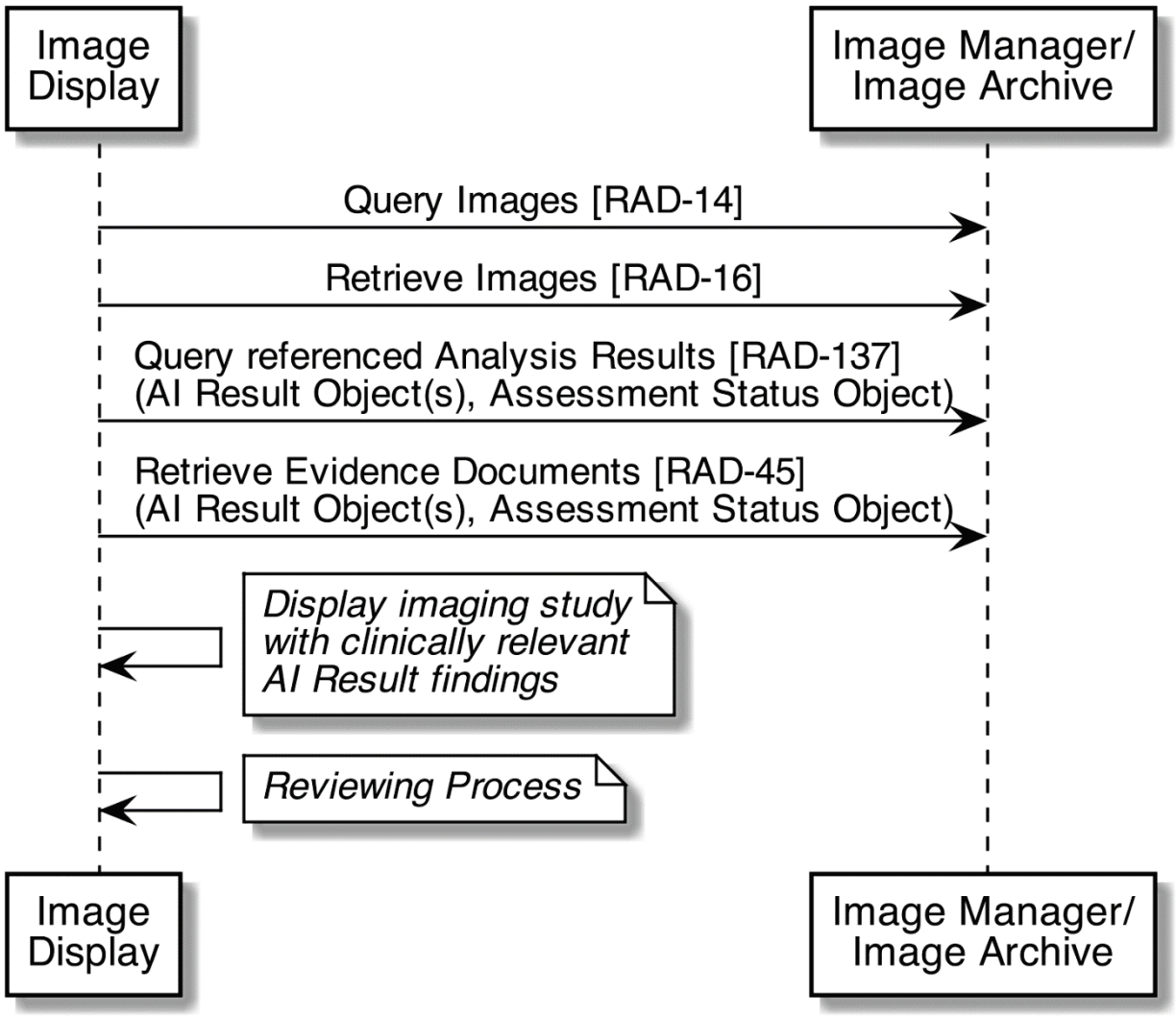


Figure 57.4.2.2.2-1: Usage of assessed AI Results for Clinical Review

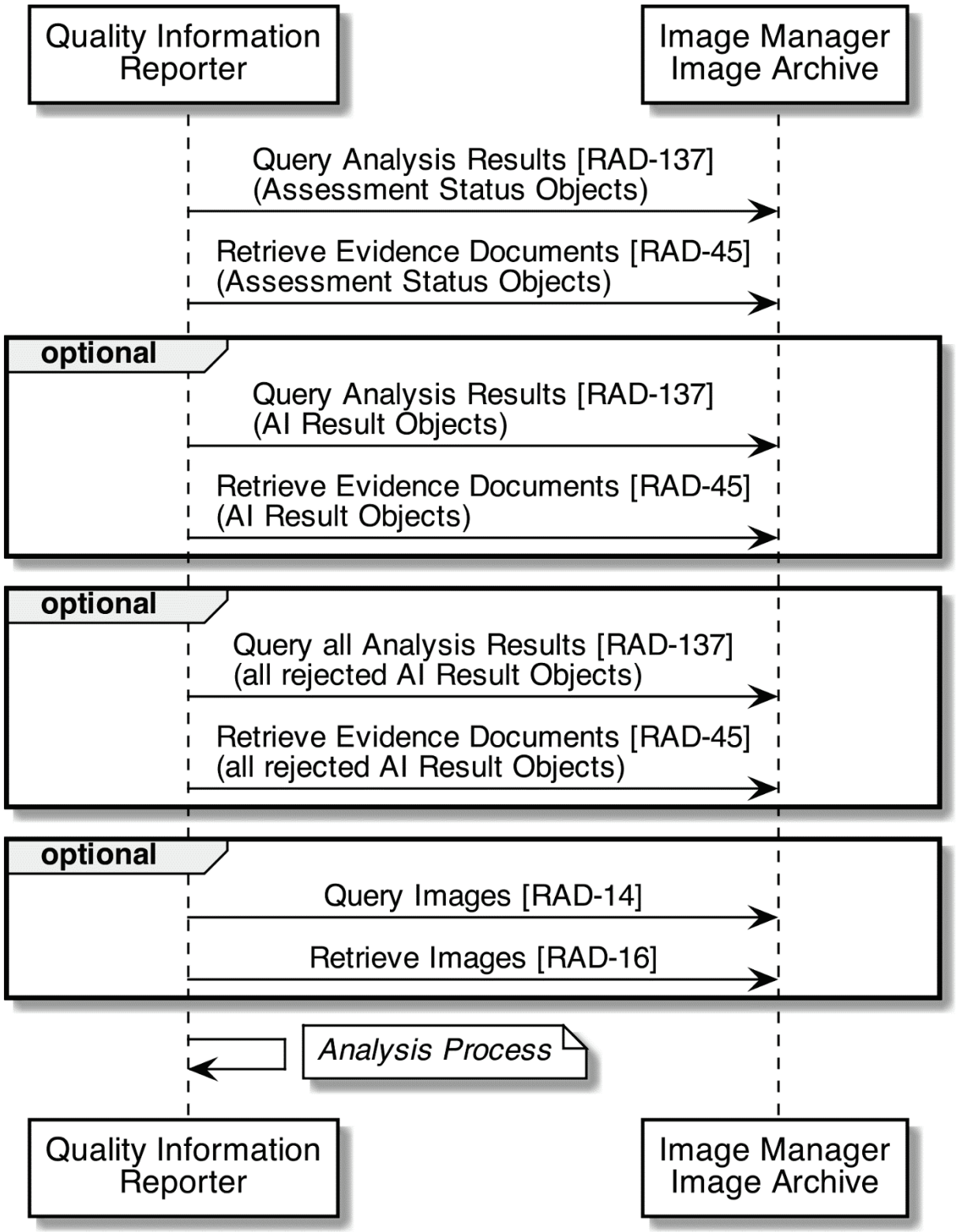
57.4.2.3 Use Case #3: Usage of Assessed AI Results for QA Analysis

57.4.2.3.1 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 Status 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 and the distribution of the output from this analysis, which are out of scope for this profile.

57.4.2.3.2 Usage of Assessed AI Results for QA Analysis Process Flow



825 **Figure 57.4.2.3.2-1: Usage of assessed AI Results for QA Analysis**

57.5 AIRA 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.

57.5.1 Security Considerations for Actors

This profile strongly recommends all AIRA 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 AIRA Profile does not add security considerations beyond those already established for the transfer and storage of clinical data in other profiles.

57.5.2 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 AIRA Profile to include appropriate PHI controls. Specifying such mechanisms and features is outside the scope of this profile.

57.6 AIRA Cross Profile Considerations

AI Results (AIR):

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

- The Quality Information Reporter can be grouped with a Watcher in the AIW-I Profile to communicate operational failures reported by the Task Performer (i.e., the Evidence Creator)

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

None

Volume 2 – Transactions

Update Section 4.14.2 as indicated below.

4.14 Query Images [RAD-14]

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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

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

885

Update Section 4.45.2 as indicated below

4.45 Retrieve Evidence Documents [RAD-45]

…

4.45.2 Actor Roles

890 **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	AIRA	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

Update Section 4.107 as indicated below

4.107 WADO-RS Retrieve [RAD-107]

…

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

None

Volume 3 – Content Modules

4 IHE Namespaces, Concept Domains and Vocabularies

4.3 IHE Radiology Format Codes and Vocabularies

Add Section 4.3.2.3 Codes for the AIRA Profile

4.3.2.3 Codes for the AIRA Profile

The following codes have been defined for the AIRA 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 AIRA Profile to Final Text.

Table 4.3.2.3-1: Codes for the AIRA Profile

Code	Coding Scheme	Code Meaning	Definition	Reference
IHE_RADAIRA1	99IHE	AI Assessment Result	This is a template identifier (TID) for a private SR template defined by the AIRA Profile for constructing an Assessment Status Object	RAD TF-3: 6.8.2.2.1
AIRA_21	99IHE	Input AI Result Object	AI Object that has been reviewed during the Assessment process	RAD TF-3: 6.8.2.1
AIRA_22	99IHE	Assessment Status Object	A DICOM Comprehensive SR that references each single AI result and captures the outcome of the assessment.	RAD TF-3: 6.8.2.1
AIRA_24	99IHE	Output AI Result Object	AI Result object after assessment Process containing confirmed AI results	RAD TF-3: 6.8.2.1
AIRA_26	99IHE	Assessment Process Outcome	A document containing the outcome of an assessment process. Used as a KOS Document Title Modifier	RAD TF-1: 57.1.1.1
AIRA_001	99IHE	Assessment Status Encoding	Root node for the Assessment Status Object	RAD TF-3: 6.8.2.2.1
AIRA_002	99IHE	Assessment Basis	The basis on which the outcome of the assessment was determined	RAD TF-3: 6.8.2.2.1
AIRA_003	99IHE	Result Assessment	Assessment of an individual Result	RAD TF-3: 6.8.2.2.1
AIRA_004	99IHE	Reference Type	The type of reference result that was assessed	RAD TF-3: 6.8.2.2.1

Code	Coding Scheme	Code Meaning	Definition	Reference
AIRA_005	99IHE	Referenced Instance	A referenced composite or image instance	RAD TF-3: 6.8.2.2.1
AIRA_006	99IHE	Assessment Status	The outcome of an assessment.	RAD TF-3: 6.8.2.2.1
AIRA_007	99IHE	Result Relevancy	An assessment of the relevancy of a result. E.g., whether it is clinically relevant or only relevant for Q/A analysis.	RAD TF-3: 6.8.2.2.1
AIRA_111	99IHE	Accepted	The assessment target is considered by the Assessor to be correct.	RAD TF-3: 6.8.2.2.1
AIRA_112	99IHE	Unassessed	The assessment target has not been assessed.	RAD TF-3: 6.8.2.2.1
AIRA_113	99IHE	Unable to Assess	After assessment it remains unclear whether the assessment target is correct or incorrect.	RAD TF-3: 6.8.2.2.1
AIRA_114	99IHE	Added	An AI Result has been added by the Assessor which has been missed by the AI.	RAD TF-3: 6.8.2.2.1
AIRA_115	99IHE	Rejected	The assessment target is considered by the Assessor to be incorrect.	RAD TF-3: 6.8.2.2.1
AIRA_116	99IHE	Modified	The assessment target has been modified by the Assessor to be correct.	RAD TF-3: 6.8.2.2.1
AIRA_121	99IHE	Clinically Relevant	The assessment target is considered by the Assessor to be clinically relevant. E.g., it was used in a report.	RAD TF-3: 6.8.2.2.1
AIRA_122	99IHE	Relevant for Q/A Analysis	The assessment target is not considered by the Assessor to be clinically relevant, but is correct and should be retained for Q/A analysis.	RAD TF-3: 6.8.2.2.1
AIRA_141	99IHE	Single Report Concordance	The assessment is based on an automated comparison of the input AI Result with the recorded output of a single human.	RAD TF-3: 6.8.2.2.1
AIRA_142	99IHE	Single Human Assessment	The assessment is based on review by a single human assessor.	RAD TF-3: 6.8.2.2.1
AIRA_143	99IHE	Multiple Human Assessments	The assessment is based on review by a multiple human assessor.	RAD TF-3: 6.8.2.2.1

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

970 # 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**
…		
QIDO-RS Query [RAD-129]	Query Information	Imaging Document Responder, Image Manager/Image Archive**, Image Display, Quality Note Creator, Quality Information Reporter**
…		

IHE Radiology Transaction	ATNA Trigger Event(s)	Actor(s) that shall be able to record audit event
Query Analysis Results [RAD-137]	Query Information	Image Display, Image Document Consumer, **Quality Information Reporter**

Add Section 6.8 Result Assessment Content Definitions

6.8 AI Result Assessment Content

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

6.8.1 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 IOD

DICOM PS3.3: A.35 Structured Report Document IOD

DICOM PS3.16: TID 1500 Measurement Report

DICOM PS3.3: A.45 Encapsulated PDF Document IOD

DICOM PS3.3: A.51 Segmentation IOD

DICOM PS3.3: A.75 Parametric Map IOD

6.8.2 AI Result Assessment Data Encoding

Persisting the results of an AI assessment process includes three steps (see RAD TF-1: 57.4.1.1):

1. Creation of Output AI Result Object(s) that include all confirmed findings. An Output AI result object is encoded using the same IOD as the Input AI Result Object.
2. Creation of Assessment Status Objects which contain the Status for each AI Result as well as some additional information.
3. Creation of KOS rejection notes for referencing all completely rejected instances and Input AI results for which Output AI Result Objects are created.

The 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 6.8.2-1 following TID 1500 for the assessment process and storing the Output AI Result Objects.

Table 6.8.2-1: 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 6.8.2-2 lists some of these SOP Classes. If the Quality Note Creator chooses to support any of them, requirements listed in Section 6.8.2.1 shall be fulfilled for the respective SOP Class.

Table 6.8.2-2: 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.

6.8.2.1 Output AI Result Objects

Quality Note Creators storing an AI Result Object updated during the assessment, shall use the same IOD as the one originally provided by the AI solution.

The Quality Note Creator shall copy contextual metadata (e.g., patient demographics, patient identifiers, study context, accession number) from the Input AI Result objects. Additionally, the information listed in Table 6.8.2.1-1 shall be populated in the Output AI objects:

Table 6.8.2.1-1: Attribute Requirements for Output AI Objects

Attribute	Tag	Option ality	Value	Comment
All IODs				
Manufacturer	(0008,0070)	R+	Copied from the Input AI Result object if present otherwise empty	In some IODs these attributes are Type 3 due

Attribute	Tag	Option ality	Value	Comment
Manufacturer's Model Name	(0008,0080)	R+	Copied from the Input AI Result object if present otherwise empty	to the usage of the General Equipment Module. This profile makes them Type 2
Software Versions	(0018,1020)	R+	Copied from the Input AI Result object if present otherwise empty	
Contributing Equipment Sequence	(0018,A001)	R+		An item for the Quality Note Creator shall be created in addition to existing ones
> Purpose of Reference Code Sequence	(0040,A170)	R	(109103,DCM, "Modifying Equipment")	
> Manufacturer	(0008,0070)	R	Manufacturer Name of the actor creating this object	
> Manufacturer's Model Name	(0008,0080)	R+	Manufacturer's Model Name of the actor creating this Object	
> Software Versions	(0018,1020)	R+	Software Version of the actor creating this object	
> Device UID	(0018,1002)	R+		
DICOM SR IODs				
Completion Flag	(0040,A491)	R	PARTIAL COMPLETE	
Verification Flag	(0040,A493)	R	VERIFIED UNVERIFIED	VERIFIED means that the object has been created during the assessment process of the AIRA Profile by a Human verifier. UNVERIFIED means that the object has been created during the assessment process of the AIRA Profile by a Device verifier
Verifying Observer Sequence	(0040,A703)	RC		Must be provided if Verification Flag = VERIFIED

Attribute	Tag	Option ality	Value	Comment
>Verifying Observer Name	(0040,A075)	RC		
>Verifying Observer Identification Code Sequence	(0040,A088)	O		Type 2 in DICOM therefore it at least needs to be present with zero length
>Verifying Organization	(0040,A027)	R		
>Verification DateTime	(0040,A030)	R		
Predecessor Document Sequence	(0040,A360)	R+	Reference to input AI Result Object(s) (i.e., prior to the assessment of these AI Results	Use (121360, DCM, ”Replaced Report”) in Purpose of Reference Code Sequence (0040,A170)
Referenced Instance Sequence	(0008,A170)	R+	Reference to the Assessment Status Object	Use (AIRA_22, 99IHE,”Assessment Status Object”) in Purpose of Reference Code Sequence (0040,A170)
DICOM RT Structure Set IOD				
Predecessor Structure Set Sequence	(3006,0018)	R+	Reference to input AI Result Object (i.e., prior to the assessment of these AI Results	Use (121360, DCM, ”Replaced Report”) in Purpose of Reference Code Sequence (0040,A170)
Referenced Instance Sequence	(0008,A170)	R+	Reference to the Assessment Status Object	Use (AIRA_22, 99IHE,”Assessment Status Object”) in Purpose of Reference Code Sequence (0040,A170)
DICOM Presentation State IODs				
Content Creator’s Name	(0070,0084)	R+		
Content Creator’s Identification Code Sequence	(0070,0086)	O		

Attribute	Tag	Option ality	Value	Comment
Referenced Instance Sequence (Note)	(0008,A170)	R+	Reference to the Assessment Status Object	Use (AIRA_22, 99IHE,"Assessment Status Object") in Purpose of Reference Code Sequence (0040,A170) (Note 1)
DICOM Segmentation IODs				
Content Creator's Name	(0070,0084)	R+		
Content Creator's Identification Code Sequence	(0070,0086)	O		
Referenced Instance Sequence	(0008,A170)	R+	Reference to input AI Result Object(s) (i.e., prior to the assessment of these AI Results	Use (AIRA_21, 99IHE, "Input AI Result Object") in Purpose of Reference Code Sequence (0040,A170)
			Reference to the Assessment Status Object	Use (AIRA_22, 99IHE,"Assessment Status Object") in Purpose of Reference Code Sequence (0040,A170)

Note: By adding these attributes the respective SOP Class will be a Standard extended SOP Class.

The Quality Note Creator shall create the Output AI Result objects in the same study as the Input AI Result objects.

For each assessment activity the Quality Note Creator shall create new Series for each AI Result Object Type.

Note: The requirements in DICOM for creating a new series apply.

Output AI Result Objects shall only include confirmed AI Results (accepted, added, and modified) by default. However, it shall be configurable to also add AI Results with a Status of unassessed or unable to assess to the Output AI Result Object.

If a study has 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 Output 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 Numbers are removed

When creating Output AI Result Objects, the unique identifiers of each AI result shall be maintained. Table 6.8.2.1-2 list the unique identifiers used throughout various IODs used for AI result encoding

Table 6.8.2.1-2: Unique Identifiers for AI Results in IODs with individually referenceable AI Results

IOD	Attribute/Concept Name
DICOM SR	Observation UID (0040,A171) (Note 1)
DICOM RTSS	Structure Set ROI Sequence (3006,0020)) > ROI Number (3006,0022)
DICOM Presentation State	Text Object Sequence (0070,0008) > Graphic Group ID (0070,0295
	Graphic Object Sequence (0070,0009) > Graphic Group ID (0070,0295)
DICOM Segmentation IOD	Segment Sequence (00062,0002) > Segment Number (0062,0004)

Note 1: Tracking UID will be not used as the Unique Identifier for AI Results in a DICOM SR. Tracking UID represents an entity than can span multiple studies or observations over a time period. As such it is not suited to uniquely identify an AI Result in a DICOM SR.

6.8.2.2 Assessment Status Object

An Assessment Status Object contains the results of an AI assessment process. An Assessment Status Object shall be encoded as an instance of the DICOM Comprehensive SR Storage SOP class using TID IHE_RADAIRA1 as the Root Template. It may include the Result Status for AI Results for multiple (dependent or independent) AI Result Objects in a study.

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 Input AI Result objects. Additionally, the information listed in Table 6.8.2.2-1 shall be provided:

Table 6.8.2.2-1: Attribute Requirements for the Assessment Status Object

Attribute	Tag	Option ality	Value	Comment
Manufacturer	(0008,0070)	R+	Manufacturer Name of the actor creating initial Assessment Status Object	

Attribute	Tag	Option ality	Value	Comment
Manufacturer's Model Name	(0008,0080)	R+	Manufacturer's Model Name of the actor creating initial Assessment Status Object	
Software Versions	(0018,1020)	R+	Manufacturer's Model Name of the actor creating initial Assessment Status Object	
Contributing Equipment Sequence	(0018,A001)	R+		An item shall be added when previous version is replaced.
> Purpose of Reference Code Sequence	(0040,A170)	R	(109102, DCM, "Processing Equipment")	
> Manufacturer	(0008,0070)	R	Manufacturer Name of the actor creating this object	
> Manufacturer's Model Name	(0008,0080)	R+	Manufacturer's Model Name of the actor creating this Object	
> Software Versions	(0018,1020)	R+	Software Version of the actor creating this object	
> Device UID	(0018,1002)	R+		
Preliminary Flag	(0040,A496)	O	PRELIMINARY FINAL	
Completion Flag	(0040,A491)	R	PARTIAL COMPLETE	
Verification Flag	(0040,A493)	R	VERIFIED UNVERIFIED	VERIFIED means that the object has been created during the assessment process of the AIRA Profile by a Human verifier. UNVERIFIED means that the object has been created during the assessment process of the AIRA Profile by a Device verifier
Verifying Observer Sequence	(0040,A703)	RC		Shall be provided if Verification Flag =VERIFIED

Attribute	Tag	Option ality	Value	Comment
>Verifying Observer Name	(0040,A075)	R		
>Verifying Observer Identification Code Sequence	(0040,A088)	O		Type 2 in DICOM therefore it at least needs to be present with zero length
>Verifying Organization	(0040,A027)	R		
>Verification DateTime	(0040,A030)	R		
Predecessor Document Sequence	(0040,A360)	RC	Reference to the Predecessor Assessment Status Object (if one exists)	Shall be provided when this Assessment Status Object replaces a predecessor object. Use (121360, DCM, ”Replaced Report”) in Purpose of Reference Code Sequence (0040,A170)
Referenced Instance Sequence	(0008,A170)	R+	Reference to input AI Result Object(s) (i.e., prior to the assessment of these AI Results)	Use (AIRA_21, 99IHE,“Input AI Result Object”) in Purpose of Reference Code Sequence (0040,A170)
		R+	References to AI Result Objects kept without changes	Use (AIRA_24, 99IHE,“Output AI Result Object”) in Purpose of Reference Code Sequence (0040,A170)
		R+	References to Output AI Result Object(s)	Use (AIRA_24, 99IHE,“Output AI Result Object”) in Purpose of Reference Code Sequence (0040,A170)

The Quality Note Creator shall create the Assessment Status Objects in the same study as the Input AI Result objects. For each assessment activity, the Quality Note Creator shall create new Series for the resulting Assessment Status Object.

Note: The requirements in DICOM for creating a new series apply.

6.8.2.2.1 TID IHE_RADAIRA1: AI Assessment Result

The Quality Note Creator shall encode the Assessment Status for the AI Results as defined in Table 6.8.2.2.1-1.

This TID is considered a "private" template, meaning it is specified by an organization other than DICOM, i.e., by IHE. 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_RADAIRA1.

Definitions for codes introduced by the AIRA Profile are found in Section 4.3.2.3.

Assessments are applied to individual AI Results within an AI Result Object whenever those results are individually referenceable (e.g., a referenced segment within a Segmentation Object). AI Result Objects that do not contain individually referenceable AI Results (e.g., Secondary Capture Objects, or DICOM SR instances where the AI Results do not have an Observation UID) shall be treated as a single AI Result, and therefore the Assessment Status shall apply to the complete AI Result Object.

Note: If an AI Result Object contains multiple individual results that are missing individual Unique Identifiers, Quality Note Creators can correct the instances prior to the Assessment Activity as described in RAD TF-1: 57.4.1.10.

Type: Non-Extensible

Order: Significant

Root: Yes

Table 6.8.2.2.1-1: TID IHE_RADAIRA1 - AI Assessment Result

	NL	Rel with Parent	VT		VM	Req Type	Condition	Value Set Constraint
1			CONTAINER	EV (AIRA_001, 99IHE, “Assessment Status Encoding”)	1	M		
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-n	M		
4	>	HAS OBS CONTEXT	CODE	EV (AIRA_002, 99IHE, “Assessment Basis”)	1	M		DCID IHERADAIRA4 “Assessment Basis”
5	>	CONTAINS	CONTAINER	EV (AIRA_003, 99IHE, “Result Assessment”)	1-n	M		
6	>>	CONTAINS	IMAGE	EV (AIRA_005, 99IHE, “AI Result Object”)	1	MC	XOR Row 7	
7	>>	CONTAINS	COMPOSITE	EV (AIRA_005, 99IHE, “AI Result Object”)	1	MC	XOR Row 6	
8	>>	CONTAINS	UIDREF	EV (AIR005, 99IHE, “Referenced Observation UID”)	1	U	XOR Row 9	Shall be the Observation UID (0040,A171) of the assessed content item in the referenced DICOM SR SOP Class

	NL	Rel with Parent	VT		VM	Req Type	Condition	Value Set Constraint
9	>>	CONTAINS	TEXT	EV (130489, DCM, "Referenced Region of Interest Identifier")	1	U	XOR Row 8	Shall be the ROI Number (3006,0022) of Structure Set ROI Sequence (3006,0020) of the referenced Instance of the RT Structure Set Storage SOP Class or Shall be the Graphic Group ID (0070,0295) of either the Text Object Sequence (0070,0008) or Graphic Object Sequence (0070,0009) of the Reference Instance of GSPS SOP Class
10	>>	CONTAINS	CODE	EV (AIRA_006, DCM, "Assessment Status"	1	M		BCID IHE_RADAIRA2, "Assessment Status"
11	>>>	HAS CONCEPT MOD	CODE	EV (AIRA_007, 99IHE, "Result Relevancy"	1	MC	IF Row 12 = (AIRA_111, 99IHE, "Accepted") or (AIRA_114, 99IHE, "Added") or (AIRA_116, 99IHE, "Modified")	BCID IHE_RADAIRA3 "Result Relevancy"

Content Item Descriptions

Row 3	The Observer Context describes the observer (human or device) that performed the result assessments in this object. When multiple observers are present it means that they collaborated in some fashion during the assessment activity.
Row 5	This container is included once for each assessed AI Result, including those with an Assessment Status (Row 10) of "rejected".
Row 6	If the AI Result is unconfirmed, reference the Input AI Result Object. If the AI Result is confirmed, reference the Output AI Result Object. For Segmentation instances, the Referenced Segment Number (0062,000B) of the IMAGE Value Type may be used to reference specific segments.
Row 7	If the AI Result is unconfirmed, reference the Input AI Result Object. If the AI Result is confirmed, reference the Output AI Result Object. For composite instances, a unique identifier may be provided to reference a specific AI Result in the referenced object (see rows 8 or 9). If this unique identifier is not provided, the AI Result Object will be assessed as a whole.

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

Table BCID IHE_RADAIRA2: Assessment Status

Coding Scheme Designator	Code Value	Code Meaning
99IHE	AIRA_111	Accepted
99IHE	AIRA_112	Unassessed
99IHE	AIRA_113	Unable to Assess
99IHE	AIRA_114	Added
99IHE	AIRA_115	Rejected
99IHE	AIRA_116	Modified

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

Table BCID IHE_RADAIRA3 Status Code Scope Modifier

Coding Scheme Designator	Code Value	Code Meaning
99IHE	AIRA_121	Clinically Relevant
99IHE	AIRA_122	Relevant for Q/A analysis

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

Table BCID IHE_RADAIRA4 "Assessment Basis"

Coding Scheme Designator	Code Value	Code Meaning
99IHE	AIRA_141	Single Report Concordance
99IHE	AIRA_142	Single Human Assessment
99IHE	AIRA_143	Multiple Human Assessments

Appendices to Volume 3

Add new Appendix C to Volume 3

Appendix C – AIRA Profile - Assessment Scenarios

Table C-1 describes the creation of the artefacts of the AI Result Assessment Process (Updated/ Replacement AI Result Objects, Assessment Status Objects, and Rejection Notes) for different scenarios depending on the Status of the individual AI Results.

Table C-1: Assessment Scenarios

Scenario (Note 1)	Status values for Individual AI Results (Note 2)	Output Object		Assessment Status Object AI Result Reference to	Create KOS to deprecate Input AI Result Object
		Create Replace-ment Instance	Include Individual AI Result		
Input AI Result Objects with one or more individually referenceable AI Results (with unique identifiers present) (Any IOD in Table C-2)	Rejected, Unassessed, Unable to Assess	Yes	No	Individual Result in Input AI Result Object	Yes
	Accepted, Added, Modified	Yes	Yes	Individual Result in Output AI Result Object	Yes
Input AI Result Objects without individually referenceable AI Results (Secondary Capture, Encapsulated PDF, or Parametric Maps)	Rejected, Unassessed, Unable to Assess	No	N/A	Input AI Result Object	Yes
	Accepted	No (Note 3)	N/A	Input AI Result Object	No
	Modified	Yes	N/A	Output AI Result Object	Yes
	Added	N/A	N/A	N/A	N/A
AI Result Objects as a whole have not been assessed	Unassessed	N/A	N/A	Input AI Result Object	Yes
Input AI Result Objects with multiple individually referenceable AI Results – all unique identifiers missing (SR and GSPS)	Rejected, Unable to Assess (all findings in the AI Result Object must rejected, are inconclusive)	No	No	Input AI Result Object	Yes
	Unassessed	Corresponds with "AI Result Objects as a whole have not been assessed" scenario above			
	Accepted, Modified	Yes	Yes	Output AI Result Object	yes

Scenario (Note 1)	Status values for Individual AI Results (Note 2)	Output Object		Assessment Status Object AI Result Reference to	Create KOS to deprecate Input AI Result Object
		Create Replace-ment Instance	Include Individual AI Result		
	Added	N/A	N/A	N/A	N/A
Addition of new AI Result Objects with individually referenceable AI Results (see Table C-2)	Added	Yes	Yes	Individual AI Results in Output AI Result Object	N/A

Note 1: This table shows the default configuration, in which status values of "Unassessed" and "Unable to Assess" are treated as unconfirmed AI Results. However, note that that depending on the configuration, these status values may also be treated as confirmed AI Results.

Note 2: "Individual AI results "also includes objects without individually referenceable AI Results, for which the AI Result Object is treated as a single AI Result.

Note 3: For Encapsulated PDF documents an Output AI Result Object shall be created, adding the Verification Flag and if the Verifying Observer is needed.

Table C-2 provides the Mapping between the unique identifiers for the supported AI Result Object IODs and the encoding in the Assessment Status Object.

Table C-2: AI Result Objects with individually referenceable AI Results – Unique Identifier Mapping (TID IHE_RADAIRA1)

IOD	AI Result Unique Identifier in Input AI Result Object	Result Reference Concept	Row in TID IHE_RADARAI1
SR	Observation UID (0040,A171)	(AIR005, 99IHE, Referenced Observation UID)	8
RTSS	Structure Set ROI Sequence (3006,0020)) > ROI Number (3006,0022)	(130489, DCM, Referenced Region of Interest Identifier)	9
GSPS	Text Object Sequence (0070,0008) > Graphic group ID (0070,0295) Graphic Object Sequence (0070,0009) > Graphic group ID (0070,0295)	(130489, DCM, Referenced Region of Interest Identifier)	9
SEG	Segment Sequence (0062,0002) > Segment Number (0062,0004)	Referenced Segment Number (0062,000B) of the IMAGE Value Type	6

Appendix D – AIRA Profile - Example AI Result Assessment Encodings

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

