Integrating the Healthcare Enterprise



IHE Radiology Technical Framework Supplement

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AI Results (AIR)

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Revision 1.2 – Trial Implementation

(Including 2022 AIR+ Extensions)

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

Foreword

This is a supplement to the IHE Radiology Technical Framework V20.0. Each supplement

30 undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published on July 6, 2022 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

35 Framework. Comments are invited and may be submitted at <u>http://www.ihe.net/Radiology_Public_Comments</u>.

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.

40 *Amend Section X.X by the following:*

Where the amendment adds text, make the added text **<u>bold underline</u>**. Where the amendment removes text, make the removed text **<u>bold strikethrough</u>**. 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.

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General information about IHE can be found at <u>IHE.net</u>.

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 <u>Profiles</u> and <u>IHE Process</u>.

50 The current version of the IHE Radiology Technical Framework can be found at <u>Radiology</u> <u>Technical Framework</u>.

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How to Read This Supplement

For an overview of the scope and goals, see Introduction to this Supplement (below), and Volume 3 Section 6.5.1.

For an overview of the participating actors and the transactions between them, see Volume 1 Section 49.1 and Section 49.4.2.

For key concepts that affect implementation and deployment and may be helpful in understanding the rest of the profile, see Volume 1 Section 49.4.1.

For the key technical requirements on encoding and displaying analysis results, see Volume 3 Section 6.5.3 and Volume 2 Section 4.136.4.1.3 respectively.

Introduction to This Supplement

This AI Results Profile addresses the capture, distribution, and display of medical imaging analysis results. The central use case involves results generated by artificial intelligence (AI Model) algorithms. Key considerations include:

• Interoperable Results:

The results need to be presented to radiologists in their reading environment. This depends on interoperability between result generation products and radiology reading workstation systems/software.

- Study Integrated Results:
- 220 Radiologists expect AI-generated results to be presented in the context of the study to which they apply and expect them to supplement (rather than replace) traditional image analysis results and thus a given study will be composed of acquired images, AI results, and traditional clinical data. The result objects defined in this profile are defined for the existing imaging data storage infrastructure.
- Effective Presentation:

Effective use of results hinges on presenting them in conjunction with the associated images during the busy process of reading the study.

- Convergence of Result Encoding:
- Many AI results are results that a human could otherwise have produced, and those human results may be used as training data for the AI. Analysis results might also be used by other AIs, e.g., in a GAN (generative adversarial network). AI and non-AI results need to be handled together. Convergent encoding of results facilitates this, as well as data pooling and sharing between sites.
 - Display Primitives:
- It is unrealistic to expect radiology displays to implement specific display capabilities for each of the myriad of algorithms being developed. To minimize implementation complexity for displays, and avoid needing different software for each new analysis result, compose analysis results from a reasonable set of primitives.
 - Result Trees:
- An increasingly large number of AI analyses are possible for any given study, generating an increasingly large number of results. To support effective navigation and display of studies with large numbers of AI Results, Result Tree objects encode relationships within the sets of instances, allowing Image Displays to support hierarchical navigation of sets of display primitives.
- 245 This profile will establish baseline data handling and presentation capabilities for an image display product to be "AI-Ready". Result generation products will be similarly motivated to

support these data formats so that their results can be compatible with a variety of displays and site workflows.

There are many other radiology applications of AI that are not about processing images. This profile is image-centric (i.e., processing imaging inputs).

While the profile will often refer specifically to radiologists, the profile is applicable to a variety of imaging clinicians and a variety of imaging specialties.

Depending on their validity and relevance, as determined by the imaging clinician, results (in whole or in part) may be incorporated into the diagnostic report and/or into the Electronic

255 Medical Record. This profile introduces no changes to current practices for encoding findings into reports and medical records.

AI Workflow for Imaging is addressed in a separate IHE Radiology profile.

Importantly, many questions and challenges that are interesting and worthwhile are out of scope, including, but not limited to:

- handling data flow from image acquisition to image analysis,
 - scheduling and managing AI analysis,
 - analyzing imaging data that is not images,
 - analyzing non-imaging data,
 - "interactive" use of AI
- capturing clinician confirmation/contradiction/adjustment feedback
 - conveying clinician feedback into algorithm monitoring and/or training
 - applying results to clinical processes other than imaging interpretation,
 - prioritizing reading worklists,
 - performing patient risk stratification,
 - submitting analysis results to the EMR for use outside radiology,
 - training and validating algorithms such as AI models,
 - tracking/communicating the training/provenance/validation of a model instance,
 - mapping primitives to/from FHIR Observation (https://www.hl7.org/fhir/observation.html)

275 Note: Out of scope does not mean products that conform to this profile are not permitted to address such needs, but rather that this profile does not address those questions or specify interoperable methods to meet those challenges.

This profile also does not address encoding results that lack machine-readable semantics (e.g., using Secondary Captures, or Softcopy Presentation States). Implementations that support such encodings as a fallback in addition to the methods required in this profile may refer to the IHE

280 Consistent Presentation of Images Profile for some guidance.

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Closed Issues

1.	Q. What is the scope of the profile?
	A: Results of image analysis that inform an imaging clinician during reading of the study
	This focus is a deliberate strategy to avoid scope creep. AI is a large space and there is much fun to be had.
2.	Q. How to capture confirmation/contradiction/adjustment of the result by a clinician?
	A: Out of Scope (but really important)
	Collecting such data may be critical to monitoring quality of results (particularly in the early stages) and to driving improvement of AI models through expert feedback. This was highlighted by both Luciano and Tessa.
	The mechanism would likely need to capture such accept/reject/(adjust) input during review and convey it to QA processes (similar model to dual-read discrepancy resolution?) and to the training environment for the AI model. The DICOM Verification Flag (0040,A493) is one possible recording mechanism.
	Consider addressing this in Phase II, and perhaps coordinating with AIW.
3.	Q. Should we include a Secondary Capture primitive?
	A. No
	The goal of the profile is raising the bar to be interoperable/scalable. Including it would undercut the interoperability and shut down use of AI results to drive workflow, provide clinical decision support, populate the patient records, be included in clinical databases, etc.
	Besides, anyone that wants to store/display Secondary Capture doesn't need a profile to help them do it.
	Counterpoint: Should we mention it as a "fall through" in the primitives section? Even if not part of the profile, a default "rendering" involves little/no integration cost for new algorithms, or for dumb displays generally. One might argue that algorithms will understand the nature of their results "best", although they won't be able to address the individual preferences of the radiologist and the "analog" result won't work with databases, clinical decision support, etc., etc., etc.

	-
4.	Q. Is it unreasonable for a display to support the full set of primitives?
	A. No. It's a bit of work, but it's what is needed
	Without a full set of primitives, we don't get effective interoperability. You can't really know which primitives the AI Models will need/use so if "some of them" are unsupported it is disruptive.
	That said, there is an open issue to have two specific sets with a large set of basic primitives and a small set of advanced primitives.
5.	Q. Should Surface Segmentations and RT Structure Sets be included as Named Options?
	A. No.
	RT Structure Sets are fairly complex and are out of our primary radiology interpretation scope.
	Surface Segmentations (mesh-based) are also fairly complex and are not yet widely used in this space. Most segmentations we imagine Evidence Creators doing is contour or voxel oriented.
	When interest emerges, these could be added as Named Options.
6.	Q. Specify use of existing STOW to store existing JSON (or binary) of SR now?
	A. Not now.
	Wait until DICOM WG-27 makes the transaction. When creating the IHE transaction, consider whether it should be specific to AI Results or general for Evidence documents.
7.	Q. Specify WADO-RS request to retrieve an SR, rendered into Sup219 representation?
	A. Not now.
	Wait until DICOM WG-27 makes the transaction.
8.	Q. Include "Report snippets"? (text rendering of a result for inclusion in a report)
	A. No.
	Out of scope for this profile. Might consider as part of a reporting profile that looks at the reporting process in more detail.

9.	Q. Make a new storage transaction for non-image instances?
	A. No.
	We have storage transactions for Images, Creator Images, Evidence Documents (just SR), Presentation States, Key Image Notes, Reports which should suffice.
10.	Q. Is there anything significant to be borrowed from IHE Evidence Documents?
	A. Not really.
	We have already borrowed the Store/Q/R transactions. Otherwise, it describes use of SWF and PPWF but we will likely be using AIW.
	It does make a requirement that the product DCS list all the SOP Classes supported, but that doesn't really seem to be an issue.
11.	Q. Should SR requirements describe each of the Enhanced, Comprehensive, and Comprehensive 3D IODs
	A: No. Just Comprehensive 3D.
	Since "lesser" SR IODs are all valid instances of "higher" IODs, Evidence Creators can simply label all their output as Comprehensive 3D. Since the Image Displays and Consumers should be prepared to handle 3D coordinates, they shouldn't mind and it removes a source of variability.
12.	Q. Should existing DICOM CAD SR templates be described in this supplement?
	A. No, not normatively.
	Section 49.6 "AIR Cross Profile Considerations" highlights the existing Mammo CAD and Chest CAD Profiles (although Chest CAD saw no uptake) that specify requirements on the mammo-specific and chest CAD-specific SR templates and associated display requirements. Interested Evidence Creators, Image Displays, and Image managers can support and claim those profiles.
	One could theoretically encode much of the content of those CAD IODs in TID 1500 and use them in this profile; however, that is not being specifically called out or analyzed here.
	If this profile is successful the committee could explore whether the benefits of harmonization/convergence would be worth the re-implementation costs.

13.	Q. Should Parametric Map support be an Option or required?	
	A. Required	
	Due to the prevalence of saliency maps and the likelihood of other parametric map- based results, it was felt that it should be part of the basic capabilities.	
	Also, if it were only an option, the likelihood of displays supporting it might go down and evidence creators that needed to use it would be unable to test their systems.	
14.	Q. Should probabilistic segmentations be stored as Segmentations or Parametric Maps?	
	A. Probabilistic Segmentations	
	Probabilistic Segmentations:	
	• are specifically designed to support such usage	
	• include metadata to describe segmentation semantics	
	• are well-suited to choosing a threshold then working with the segment	
	• have values that reflect confidence/applicability of a common statement	
	• can represent decimal probability values (as scaled integers)	
	• are part of the basic AIR Profile	
	Parametric Maps	
	• have values that "have a broader meaning"	
	• can represent floating point probability values	
	• but require advanced support by the display	
15.	Q. Should we help displays find summary/"entry points" into the collection of results?	
	A. Yes.	
	Deferred from the 2020 TI draft, work was approved for the 2022 cycle to add Result Trees which are included in this 2022 TI draft.	
	Result Trees encode hierarchical relationships within set of results. Image Displays can identify and retrieve these Trees and use them to support progressive disclosure and other navigation.	
	See in particular sections 49.2.1, 49.4.1.10, 4.136.4.1.3.9, and 6.5.3.9	

16.	Q. How should algorithms encode confidence in each result?
	A. Don't know.
	This is an area of ongoing research. Have highlighted the value in Appendix L and the underlying issue in 49.4.1.
17.	Q. Should we define encoding/display behavior for failed processing in more detail?
	A. No.
	Radiologists, and other interested systems and people, will be interested in tracking and perhaps doing exception handling when analysis fails; however, that is more appropriately addressed in workflow artifacts rather than encoding such details in the results themselves. If, for example, there is a need to create a persistent stored instance of completed UPS Workitems, that can be addressed separately.
	It is; however, useful to give guidance about encoding a finding that a sought feature, e.g., pneumothorax, was found to be absent when processing completed successfully. This is a valid clinical result and can also distinguish cases where nothing was found from cases where the algorithm was not run successfully.
18.	Q. Should we add informative/normative detail about preliminary/partial/verified/etc.?
	A. No.
	The states are mentioned briefly in Appendix L, but it is not clear what the best mechanism is for this. The Preliminary flag was introduced for a different purpose and there may be more nuance to what is needed here.
	Think through how image managers might expose/suppress unverified results, or how they might implement deletion/retention policies.

19.	Q. Should the algorithm description inside results include whether it is approved or for what?
	A. No.
	It is conceivable that displays might have different behavior depending on whether the algorithm is approved or not, or what the "approved paradigm of use" is" E.g., a result from an algorithm that has been approved for use in a "second reader" paradigm should not initially be presented to the radiologist.
	However, it is not clear what the full model is that should be encoded, and more importantly, it is unlikely this should be coded into the results themselves, rather than simply identifying the algorithm and leaving it to other out-of-band mechanisms to capture/communicate the current status of the identified algorithm.
20.	Q. Is "Rendering Intent" an appropriate flag to indicate results that are not intended for imaging clinician review?
	A: No. Not at this time.
	In principle, if an algorithm creates one SR that captures the actual finding(s) for the imaging clinician and another SR that is intended to drive worklist, it would be useful for the Evidence Creator to have a flag that could be set to allow the imaging clinician to suppress the worklist SR elements.
	This use case will be folded into future discussions about the organization of results, but will not be addressed in this first edition of the profile.
	Counterpoint: we should assume that each display implementation will analyze the entire content of the SR Tree for all the results and make its best guess if each is something the radiologist needs to see or not. The algorithm is probably unable to determine the purpose of the results it is creating.
21.	Q. Is the measurement group in TID 1500 sufficient for establishing relationships between related findings?
	A. For now, Yes.
	TID 1500 has good basic relationship linking mechanisms.
	To "organize" result sets is more complex and may need a separate mechanism like Root Results. Per Closed Issue 3, that has been factored out of this draft for more investigation.

22.	Q. Should we constrain pre-coord/post-coord of measurements or require displays to handle all conceivable variations?
	A. Don't constrain but provide guidance.
	Based on experience with Echo SR, unconstrained structure complexity and varying degrees of pre-coordination/post-coordination were a severe challenge for receiving systems and resulted in low interoperability.
	6.5.3.3 proposed use of either fully precoordinated codes with well-chosen code meaning text, or a "simple" post-coordinated structure. Neither is mandated, so evidence creators can handle greater complexity if needed. Some hope that highly complex cases will instead result in special purpose templates like has been done for other focused tasks such as TID 5300, or perhaps particular popular RadElement Sets.
	While an enumerated list of pre-coordinated codes may sound tedious, and require configuration to handle new codes, an advantage is that it is mechanical and unambiguous. The business logic is a fairly simple "if code=X, then semantics are Y" as opposed to trying to figure out how to parse all the different possible scenarios in the post-coordinated structure (including all the unexpected value combinations "wait, what does it mean to take that measurement in M-mode?"). People may reason it out but it's harder for software.
	Post-coordinated coding feels like it can avoid configuration by encoding the semantics of each post-code and combining, but the experience has not borne that out. Each new code value and each new post-coordinated concept has the potential to affect the meaning of the other post-coordinated concepts and values.
	Plan to monitor this issue during Trial Implementation and early Connectathons and potentially "iterate" the specification.
	If TIDs are created for specific RadElement Sets, should consider profiling 1500 so they are still valid instances of 1500 to minimize additional logic for displays. Might need collaboration between DICOM and IHE for such maintenance.
23.	Q. Do we need to address in detail the use of Patient Orientation and Spatial Locations Preserved in location display (per MAMMO Profile)?
	A. No.
	Too specific to the mammography use case of matching CAD output computed from For Processing versus display on For Presentation images - remain silent on this issue.
	The CXCAD Profile chose to skip it.

24.	Q. Should we permit other Linear/Area/Volume TIDs?
	A. No.
	TID 1500 and it's sub-templates are adequate. TIDs 1400 Linear Measurement, 1402 Volume Measurement, 1404 Numeric Meas, 1406 3D Linear Meas are not necessary.
25.	Q. How does a display know whether to display a polyline as a closed polygon?
	A. Per DICOM, the last point must be encoded the same as the first, otherwise it is an open polyline.
26.	Q. Is Contributing Equipment Sequence the best way to record algorithms?
	A. It's a good start.
	It has the advantage that it is present for all IODs and gives the display a uniform place to look for the information. Many deployment models involve the AI Models being separate from the Evidence Creator (which would appear in General Equipment) that packages their results.
	In terms of lower level TID elements, those can be encoded in SR, maintaining the correspondences described in Table 6.5.3.1-1
27.	Q. How are result primitives distinguished from other instances of the same type?
	A. References in Result Trees (if present)
	Parametric Maps and SRs generated as AI results look the same as Parametric Maps and SRs generated by, say, an MR scanner. A reference to those instances in a Result Tree effectively identifies them as part of a result set. One can also look at the equipment that created/contributed to the creation of the object.
	Beyond that, studies are the same Bag of Stuff that they have always been.
28.	Q. Should longitudinal analysis be described and/or explicitly supported?
	A. No requirements. The existing mechanisms should permit applications to get started.
	Tracking Identifier primitives (see 6.5.1) let an analysis package tag a current lesion assessment as being for the same lesion as a prior assessment. Result Trees can reference findings in prior studies. (Also note that some analysis packages will handle this internally in a data base after consuming AI Results rather than attempt to record it in the persistent object metadata.)
	Plan to initiate discussions in DICOM about "registration" of Tracking Identifiers.

29.	Q. Are the specified negative finding encodings acceptable?
	A. Require "Finding = X; Finding Absent = Y" for TI Profile conformance
	Negative findings obviously have clinical significance. They can also affect clinical pathways and automated treatment guidelines, triggers in templates, display filters and presentation, database structure and big-data queries.
	As described in 49.4.1.6 Negative and Partial Results, there are a variety of approaches to encoding negative (and positive) findings. But implementation variability reduces interoperability. Three encoding patterns include:
	A) Finding = X; Finding Absent = Y
	B) Finding = X; Finding = Y, Preceding Finding = Absent
	C) $X = Present; Y = Absent$
	The profile promotes convergence amongst conformance applications by requiring A) which follows the common positive convention and highlights positive and negative findings and hopefully makes implementation simpler for Displays. A risk of B) is that Y initially appears to be present and missing the second component doesn't miss a refinement but rather an inversion. A weakness of C) is that it makes it harder to scan for findings and separate them from other concept-value pairs.
	Need to keep monitoring this during trial implementation. May need to establish a code for Clinical Finding Indeterminate. May need to revert to a modifier that is a "Finding flag" to deal with classification findings, etc.
30.	Q. Should Result Tree be a new DICOM IOD (not just a new template)?
	A: Proceed with TID.
	Ultimately this will be a decision of DICOM WG-6.
	The client would query for SR objects in a study, then look at the TID value in the returned metadata (since many PACS do not support TID as a matching key, just a return key). Based on that the client would retrieve the Result Tree objects. Since the Display has to be ready to also handle results that aren't indexed in Result Trees, they will likely do a broad query to list everything in the study anyway.
	An IOD means fewer items in the initial query response since the PACS matches on SOP Class UID. However, some PACS reject new IODs until they are configured.
	Also, a new IOD would permit placing different constraints on the Content Item relationships without disrupting existing SR SOP Classes if we needed to do that.

31.	Q. Should details of AI execution/failure be recorded in the results?					
	A. No, not in Result objects. Address in AIW-I, not in the patient medical record.					
	It is true that during result presentation, Radiologists may want to be aware of, or able to check, details of the execution of AI(s) for the current study such as:					
	• whether an AI ran but failed (in whole or in part) and if so, why					
	• whether AI processing is still in progress (may choose to delay reading until it is)					
	• which AIs were/weren't triggered (based on execution rules/criteria)					
	AIW-I knows/tracks execution status and failures, and dept admin will also want to aggregate (across all studies) management/analysis. E.g., which exams are triggering for a given AI. An AIW-I actor should have an API for Image Displays and administrators to tap that information. It may be important to persist the information for both workflow and medicolegal reasons.					
	User expecting a Pneumonia AI result in a study can infer it ran by a positive/negative result. If it didn't run, their app could interact with the workflow system to find out. But don't put a message in a patient's X-ray study that the Acme Pneumonia app only works on CTs so it didn't run.					

32.	Q. Where/when/how should we address accept/reject of results by radiologist?
	A: Not here. Figure out workflow first. Then add encodings as appropriate.
	Accept/reject handling is new work, not a "presentation" feature. Consider proposing next cycle (important). There are questions about where/when/how this should be performed and where/how the acceptance/rejection should be recorded.
	Consider subtleties like approved/rejected (explicit), viewed/ignored (implicit), modified ("same" result, but adjusted), created (new result). May need comment fields to capture rationale, considerations, caveats, etc. Accepting for clinical use in report might be different than acceptance as a successful execution of the AI as part of validation/research/training.
	DICOM has "approval" objects that reference other objects and capture assertions or approvals about them. Acceptance/rejection could also be captured in a workflow log in AIW-I or SOLE. Rejection might also be implicit if the recorded findings of a radiologist contradict the AI results. New AI Result instances could also be created containing the original result and the radiologist's assessment of it.
	Policy questions include: Are rejected results expunged from the patient medical record or just sequestered (see MIMA)? Do we track what a radiologist had access to and what they viewed, or just what they explicitly interacted with? How much can we "burden" the radiologist interpretation workflow? What do we do when a Rad accepts two of the results inside a single SR instance but rejects the third? Even for current practice the rad doesn't use everything (but it all gets stored)
	These assessments will also drive performance monitoring and possibly re-training of the algorithm to improve its performance.
	See also AIR 49.4.1.8 Result Approval, Retention, & Feedback.
33.	Q. Should the Profile address results in specialized SR Templates, not just TID 1500?
	A: Stay silent as we are now. (No comments were received)
	Nodes in the Result Tree template can reference any SR, not just those based on TID 1500, and Observation UID can be populated in any SR. But since the content and structure of the specialized templates does not always conform to the encodings described in RAD TF-3 6.5, it may be difficult to standardize and express behavior requirements for Evidence Creators and Displays.
	I.e., the mechanisms will likely work but can't add specific display requirements for open ended SRs. Note that the simpler the element you point to the more likely the display can render it.
	Displays are welcome to support specialized templates.

34.	Q. What concepts should be supported for result Confidence/Certainty/Probability?
	A: Another item for important future work, potentially as extensions to AIR.
	Physicians frequently mention these concepts (in broad terms) as being important for filtering, triaging, and assessing results. However, the terms are not clearly defined. Regulatory concerns further complicate the situation, and will likely influence (or demand specificity from) the definitions.
	This is still an area of ongoing research. First the clinical community needs to figure out what they want to express, and achieve some harmonization of practice, then we can start work on encodings. Clear semantics/models for these terms are needed so that appropriate metadata can be specified.
	For now, anything encoded in objects is based on the creator's judgement/logic and that might differ from product to product. The clinical usage needs much more definition before we can tackle interoperable encodings and behaviors.
	Criticality is likely distinct from Severity (Patient vs. pathology?), e.g., a bad hangnail might be a high severity hangnail but low criticality to the patient's health.
	It has been observed that, for some users, a fine grain certainty value (e.g., score) is confusing to the user since it does not have well-defined meaning and the user interprets the value linearly and literally which is not accurate. One approach was to only show 'certain' and 'uncertain' instead. For now this is all implementation choice. The AI Model is free to provide whatever details it identified in the AI results.
	Notes:
	App L.1 mentions this concept (but no encoding or behavior)
	AIW-I has OBX-9 slot for unstructured/undefined value for this.
	DICOM has a code for EV (111012, DCM, "Certainty of Finding") used in several CAD templates. Additional codes would probably be needed.
	For "Severity", FHIR value set has 3 degrees from SNOMED (mild, moderate, severe); DICOM CID 3716 has 7 degrees, also from SNOMED. Thresholds/criteria are undefined and likely pathology-specific.
	Brian has a reference for some FDA wording

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35.	Q. Should direct consumption of Imaging AI Results by non-radiologists be addressed?			
	A: No direct discussion.			
	The Imaging Document Consumer means mechanisms exist, but doing this will be more about site permissions and policies rather than technical mechanisms.			
	Use Cases where, for example, uncurated AI results about stroke or pulmonary embolisms are passed directly to an interventionalist, bypassing the radiologist, are potentially risky, or against policy, so we should not directly discuss.			
	Most policies are expected to be that raw auto-interpretations will be curated by an expert of some form. And this is getting into workflow rather than data encoding.			
36.	Q. Should we discuss AI results that arrive after study has been reported?			
	A: Silent in profile.			
	This is probably more of a reporting workflow profile thing anyway.			
	Existing PACS already handle additional images added to a study. If the radiologist is currently reading the study, they might be alerted to these unread elements in the study. Since AIR results are all DICOM instances, that function might already trigger.			
	Filtered notifications (e.g., based on result significance or pathology/normal) could be sent to the radiologist or tech. If the report has already been delivered and read, radiologist might forward to the referring or use the addendum pathway, but this is getting into workflow.			
	The presence of a new result might be accompanied by the creation of a new Result Tree too, but basically, it's all just new content and the PACS may or may not alert that based on local policies and preferences.			

37.	Q. Should a Result Tree be allowed to reference another Result Tree?
	A: Prohibit.
	There might be complexities that we would need to work through. Some use cases can be handled by copying content from existing trees into new trees.
	• a "higher level" assessment is based on two "lower level" assessments that are already encoded with result trees. The new result tree could incorporate nodes from the lower level trees.
	• the same analysis is performed by three different vendor products that each create Result Trees. Another application determines the "majority" opinion and subsumes the three trees into a single composite tree.
	Note: a site that does multiple duplicative analysis has presumably worked out how to deal with discrepancies and how to database that. It will likely use the SRs directly not the Result tree to analyze. The Rad will use the Tree which will place the three results in context if they navigate down to them
	Depending on the situation, the earlier Result Tree objects could be deleted/deprecated.
	One could argue that including the lower level trees by reference would be more efficient, but the data volume is not large. Including by reference would add another method for creating loops which would need to be prohibited.
38.	Q. Do we need to clarify segmentation vs saliency?
	A: No problem really in our profile. No comments received.
	In AI, the word segmentation is sometimes used in a way that overlaps with saliency maps. Some recent research has also cast doubt on the usefulness of saliency maps.
39.	Q. Should Result Tree incorporate metadata for filtering/grouping results without having to retrieve the instances?
	A: No change. Keep it light. It's not a DICOMDIR
	Note: applications can retrieve just the root result and likely get many of the things they might filter/group on.
	Starting to include anatomy/severity/etc. in each node could be a slippery slope since filtering could be based on anything.
40.	TO DO:
	Monitor pre-coord vs post-coord coding patterns during Trial Implementation, RSNA Demo, and early Connectathons and potentially "iterate" the specification.

IHE Technical Frameworks General Introduction

The <u>IHE Technical Frameworks General Introduction</u> 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 Frameworks General Introduction Appendices

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

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

Appendix A – Actors

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

New (or modified) Actor Name	Definition
Image Display	A system that presents medical images and associated imaging data.

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

Existing Actor Name	Definition		
Evidence Creator	A system that creates evidence data such as images or measurements, through a process other than data acquisition.		
Image Manager / Image Archive	A system that stores and manages imaging data.		
Imaging Document Consumer	A system that makes use of imaging data.		

Complete List of Existing Actors Utilized in this Profile

Appendix B – Transactions

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

New (or modified) Transaction Name and Number	Definition	
Display Analysis Result [RAD-136]	Present one or more results of imaging analysis to a user.	
Query Analysis Results [RAD-137]	Query for a list of DICOM analysis results matching a filter.	

<u>Appendix D</u> – Glossary

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

New (or modified) Glossary Term	Definition
Imaging Analysis Result	A result produced by analyzing imaging data. The term encompasses results from classical image processing, machine learning and artificial intelligence, including traditional CADe and CADx as well as deep convolutional neural network.

Volume 1 – Profiles

Add new Section 49 for AIR Profile

335 49 AI Results (AIR) Profile

This AI Results Profile specifies how imaging analysis results can be reliably stored, retrieved, and displayed. The motivating use case involves results generated by artificial intelligence (AI Model) algorithms, although the profile applies equally to non-AI-based analysis. The profile will refer generally to "algorithms" and "analysis results" throughout.

340 This profile defines content for data encoding, transactions for moving that content around, and behaviors for basic handling of the content.

49.1 AIR 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.

345 IHE Transactions can be found in the Technical Frameworks General Introduction Appendix B. Both appendices are located at https://profiles.ihe.net/GeneralIntro/.

Figure 49.1-1 shows the actors directly involved in the AIR 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

350 grouping are shown in conjoined boxes (see Section 49.3).

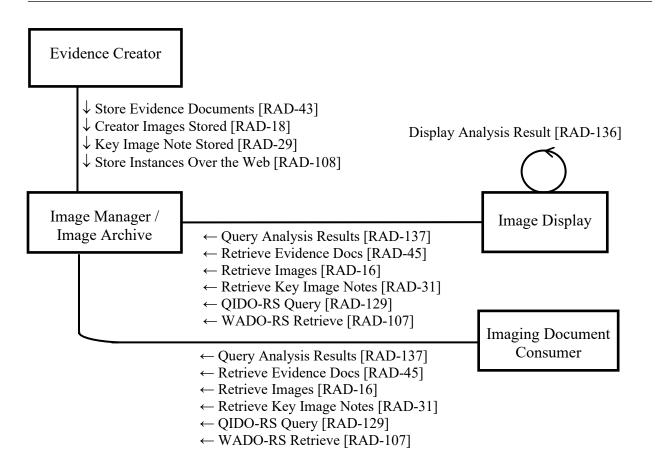


Figure 49.1-1: AIR Actor Diagram

Table 49.1-1 lists the transactions for each actor directly involved in the AIR Profile. To claim compliance with this profile, an actor shall support all required transactions (labeled "R") and may support the optional transactions (labeled "O").

Actors	Transactions	Initiator or Responder	Optionality	Reference
Evidence	Store Evidence Documents [RAD-43]	Initiator	O (See Sec. 49.1.1.1)	RAD TF-2: 4.43
Creator	Creator Images Stored [RAD-18]	Initiator	O (See Sec. 49.1.1.1)	RAD TF-2: 4.18
	Key Image Note Stored [RAD-29]	Initiator	O (See Sec. 49.1.1.1)	RAD TF-2: 4.29
	Store Instances Over the Web [RAD-108]	Initiator	O (See Sec. 49.1.1.1)	RAD TF-2: 4.108
Image	Store Evidence Documents [RAD-43]	Responder	R	RAD TF-2: 4.43
Manager/ Image	Query Analysis Results [RAD-137]	Responder	R	RAD TF-2: 4.137
Archive	Retrieve Evidence Documents [RAD-45]	Responder	R	RAD TF-2: 4.45
	Creator Images Stored [RAD-18]	Responder	R	RAD TF-2: 4.18

Table 49.1-1: AIR Profile - Actors and Transactions

Actors	Transactions	Initiator or Responder	Optionality	Reference
	Retrieve Images [RAD-16]	Responder	R	RAD TF-2: 4.16
	Key Image Note Stored [RAD-29]	Responder	R	RAD TF-2: 4.29
	Retrieve Key Image Notes [RAD-31]	Responder	R	RAD TF-2: 4.31
	QIDO-RS Query [RAD-129]	Responder	R	RAD TF-2: 4.129
	WADO-RS Retrieve [RAD-107]	Responder	R	RAD TF-2: 4.107
	Store Instances Over the Web [RAD-108]	Responder	R	RAD TF-2: 4.108
Image	Query Analysis Results [RAD-137]	Initiator	O (See Sec. 49.1.1.3)	RAD TF-2: 4.137
Display	Retrieve Evidence Documents [RAD-45]	Initiator	O (See Sec. 49.1.1.3)	RAD TF-2: 4.45
	Retrieve Images [RAD-16]	Initiator	O (See Sec. 49.1.1.3)	RAD TF-2: 4.16
	Retrieve Key Image Notes [RAD-31]	Initiator	O (See Sec. 49.1.1.3)	RAD TF-2: 4.31
	QIDO-RS Query [RAD-129]	Initiator	O (See Sec. 49.1.1.3)	RAD TF-2: 4.129
	WADO-RS Retrieve [RAD-107]	Initiator	O (See Sec. 49.1.1.3)	RAD TF-2: 4.107
	Display Analysis Result [RAD-136]	Initiator	R	RAD TF-2: 4.136
Imaging	Query Analysis Results [RAD-137]	Initiator	O (See Sec. 49.1.1.4)	RAD TF-2: 4.137
Document Consumer	Retrieve Evidence Documents [RAD-45]	Initiator	O (See Sec. 49.1.1.4)	RAD TF-2: 4.45
	Retrieve Images [RAD-16]	Initiator	O (See Sec. 49.1.1.4)	RAD TF-2: 4.16
	Retrieve Key Image Notes [RAD-31]	Initiator	O (See Sec. 49.1.1.3)	RAD TF-2: 4.31
	QIDO-RS Query [RAD-129]	Initiator	O (See Sec. 49.1.1.4)	RAD TF-2: 4.129
	WADO-RS Retrieve [RAD-107]	Initiator	O (See Sec. 49.1.1.4)	RAD TF-2: 4.107

49.1.1 Actor Descriptions and Actor Profile Requirements

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

49.1.1.1 Evidence Creator

Evidence Creators represent a source of results. The scope of this profile begins when the
Evidence Creator has created a result to store. Methods to manage the Evidence Creator or allow
it to obtain the inputs used in processing are not covered here. See the AI Workflow Profile for
details on one approach.

The actor may be implemented by an analysis or AI software package itself, or it may be a proxy, gateway, or partner system that encodes and transmits results on behalf of such software. The profile does not distinguish between analysis executed locally, in the cloud, hosted in

370 processing servers, or running in standalone workstations. For additional discussion, see Section 49.4.1.9 "AI Algorithm Deployment".

Evidence Creators shall encode their results using the Result Primitives described in Section 49.4.1.1.

Note: Evidence Creators are only required to support the Result Primitives needed to encode their results. This means they might not need to support all Result Primitives.

Evidence Creators shall support the SOP Class(es) corresponding to the Result Primitive(s) they support, as defined in RAD TF-3: 6.5 "Imaging Analysis Result Content".

Evidence Creators shall support a corresponding transaction listed in Table 49.1-1 for each primitive they produce. Evidence Creators may choose to support both the RESTful version of a transaction and the conventional DIMSE version of that transaction, or they may choose to support one or the other.

Result encoding is converged on the DICOM Comprehensive 3D SR IOD and the TID 1500 SR template.

Notes: 1. Since the Comprehensive 3D SR IOD is a superset of both the Comprehensive SR IOD and the Enhanced SR IOD, any content that an Evidence Creator might otherwise have created as an instance of the Comprehensive SR SOP Class or the Enhanced SR SOP Class can be safely relabeled as an instance of the Comprehensive 3D SR SOP Class.

2. This profile does not require the Evidence Creator to support TIDs other than the TIDs described in RAD TF-3: 6.5, and their included sub-templates. It is expected that many applications for which a specialized template exists (e.g., TID 4000 Mammography CAD, or TID 5300 Simplified Echo Procedure Report) will continue to use those specialized templates rather than follow this profile for general analysis results. Such support is outside the scope of this profile. Some related profiles are discussed in Section 49.6.

The Evidence Creator is responsible for appropriately populating the Patient-level and Studylevel attributes of the DICOM instances it creates. Since that information might come from the headers of the instances the Evidence Creator is processing or from the attributes in a processing workitem, as described in the AI Workflow for Imaging Profile, neither of those sources is

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49.1.1.2 Image Manager / Image Archive

specifically mandated in this profile.

Image Manager / Image Archive actors store analysis results for a study. Typically, the study will also contain modality and human-generated results (such as measurements or annotations).

400 Image Manager / Image Archives may include data caches or proxy systems in addition to the more typical PACS and VNA systems.

Image Manager / Image Archive actors shall support all the SOP Classes listed in RAD TF-3: 6.5.3 "Analysis Result Encodings".

49.1.1.3 Image Display

405 Image Displays present results, typically together with the other associated images and data relevant to a study.

Image Displays shall support the retrieval of all IODs described in RAD TF-3: 6.5.3. This means Image Displays are required to support a set of corresponding transactions listed in Table 49.1-1; however, Image Displays may choose to support both the RESTful version of a transaction and

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410 the conventional DIMSE version of that transaction, or they may choose to support one or the other.

Image Displays are required by [RAD-136] to support specific display capabilities for the IODs described in RAD TF-3: 6.5.3.

Display capabilities for SR are specifically focused on support of the Comprehensive 3D SR IOD and the TID 1500 SR Template.

- Notes: 1. The Comprehensive SR IOD and the Enhanced SR IOD are subsets of the Comprehensive 3D SR IOD, so an Image Display that has implemented support for the Comprehensive 3D SR IOD will have implemented all the capabilities to support the Comprehensive SR IOD and the Enhanced SR IOD; however, this profile does not require the Image Display to do so.
- 420 2. This profile does not require the Image Display to support TIDs other than the TIDs described in RAD TF-3: 6.5, and their included sub-templates. It is expected that many applications for which a specialized template exists (e.g., TID 4000 Mammography CAD, or TID 5200 Echocardiography SR) will continue to use those specialized templates rather than follow this profile for general analysis results. Image Displays should consider supporting additional TIDs as appropriate. Some related profiles are also discussed in Section 49.6.
- 425 3. Image Displays may, but are not required to, support other features and display capabilities for the IODs listed in RAD TF-3: 6.5.3. Such other features are not necessary for conformance to this profile.

Image Displays shall be able to identify Result Tree objects as described in RAD TF-1: 49.2.1 and be able to present Result Tree objects as defined in RAD TF-2: 4.136.4.1.3.9 "Display of Result Trees". I.e., Result Tree identification and display behaviors are required, not optional, for Image Displays

430 Image Displays.

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49.1.1.4 Imaging Document Consumer

Imaging Document Consumers make use of results in ways other than displaying them.

Imaging Document Consumers may include decision support systems, clinical databases, and report creators. An Evidence Creator might implement a grouped Imaging Document Consumer to access existing results as inputs.

Although this profile does not explicitly address adding results directly to an EMR, it is conceivable that a PACS or interface engine might implement an Imaging Document Consumer that selects, extracts, and transcodes results for insertion into an EMR using an unspecified mechanism.

- 440 Imaging Document Consumers shall support at least one of the Result Primitives described in RAD TF-3: 6.5.3.
 - Note: Imaging Document Consumers are only required to support Result Primitives needed to support the intended functionality of the Image Document Consumer system. This means they might not need to support all Result Primitives.
- 445 For each supported Result Primitive, Imaging Document Consumers shall support all the SOP Class(es) corresponding to the Result Primitive(s) they support, as defined in RAD TF-3: 6.5.3 "Analysis Result Encodings".
 - Note: This means, for example, that an Imaging Document Consumer that consumes volumetric segmentations will need to handle both segmentations encoded in the Segmentation SOP Class, and segmentations encoded as a set of contours in the Comprehensive 3D SR SOP Class.
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Imaging Document Consumers shall support corresponding query and retrieval transactions listed in Table 49.1-1 for each primitive they consume. Imaging Document Consumers may choose to support both the RESTful version of a transaction and the conventional DIMSE version of that transaction, or they may choose to support one or the other.

455 **49.2 AIR Actor Options**

Options that may be selected for each actor in this profile, if any, are listed in the Table 49.2-1. Dependencies between options, when applicable, are specified in notes.

Actor	Option Name	Reference
Evidence Creator	Result Tree Option	Section 49.2.1
Image Manager / Image Archive	No options defined	
Image Display	No options defined	
Imaging Document Consumer	Result Tree Option	Section 49.2.1

Table 49.2-1: AI Results – Actors and Options

49.2.1 Result Tree Option

460 This option involves encoding and storing information that describes hierarchical relationships amongst a set of related AI results (as a "Result Tree" object), and later applying that information to support effective handling of the AI results in a study, such as navigation of large sets of results by a reading radiologist.

Result Tree objects are identified by a Template Identifier (0040,DB00) value of

465 "IHERADAIR1" in the Content Template Sequence (0040,A504) in the header of the SR. The Query Analysis Results [RAD-137] transaction, by incorporating the matching and return key requirements of Query Evidence Documents [RAD-44], already requires Responders (Image Manager / Image Archive) and Initiators (Image Display and Imaging Document Consumer) to support Template Identifier (0040,DB00) as a return key. Using that, Initiators can locally filter the query responses received from the Responder.

Evidence Creators that claim the Result Tree Option shall be able to create Result Tree objects as defined in RAD TF-3: 6.5.3.9 "Result Trees".

475 Note: The Evidence Creator that creates the Result Tree may be the same Evidence Creator that created the result primitives that the Result Tree references. It is also possible that some Evidence Creators simply create result primitives (without supporting the Result Tree Option) and a subsequent Evidence Creator is responsible for determining an appropriate hierarchy for the primitives created by the earlier Evidence Creator and then creating an appropriate Result Tree object (see Section 49.4.2.4). A sophisticated Result Tree Evidence Creator might be able to compose Result Tree objects that span result primitives from multiple algorithms and/or from multiple vendors.

Imaging Document Consumers that claim the Result Tree Option shall be able to identify Result
 Tree objects and to process Result Tree objects; however, no specific required processing
 behaviors are defined.

49.3 AIR 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 <u>all</u>* of the requirements for the grouped actor (Column 2).

485 (Column 2).

Section 49.5 describes some optional groupings that may be of interest for security considerations and Section 49.6 describes some optional groupings in other related profiles.

AIR Actor	Actor(s) to be grouped with	Reference	Content Bindings Reference	
Evidence Creator	ITI CT / Time Client	<u>ITI TF-1: 7</u>		
Image Manager / Image Archive	None			
Image Display	None			
Imaging Document Consumer	None			

Table 49.3-1: AI Results - Required Actor Groupings

49.4 AIR Overview

490 **49.4.1 Concepts**

49.4.1.1 Result Primitives

It is unrealistic to expect radiology displays to implement specific display capabilities for each of the myriad of algorithms that have been developed and will continue to be developed. To make the implementation complexity for displays manageable, and to avoid needing different software for each new analysis result, this profile follows the direction get by DICOM WC 22 to

495 for each new analysis result, this profile follows the direction set by DICOM WG-23 to determine a reasonable, finite, set of primitive elements from which analysis results can be composed.

The primitives include things like measurements, qualitative findings, locations, and segmented regions. For a more complete description see RAD TF-3: 6.5.1.

- 500 Evidence Creator actors are required to render their results using the defined set of primitives encoded in specific DICOM SOP Classes (see RAD TF-3: 6.5.3 "Analysis Result Encodings") and Image Display actors are required to support basic presentation of those primitives (see RAD TF-2: 4.136.4.1 "Display Results").
- 505 Note: IHE profiles do not typically prohibit additional behaviors or functionality beyond that specified in the profile, for example, Evidence Creators that conform to this profile may have ways of encoding results in addition to those described in the profile.

49.4.1.2 Result Filtering and Navigation

Any given set of images (e.g., a CT Chest Study) may be analyzed by multiple algorithms evaluating multiple conditions and hence multiple, perhaps many, results may be generated. A central use case of this profile involves making these study results easily consumable by

radiologists, and other imaging clinicians, during the study interpretation process. Allowing radiologists to effectively filter and navigate results is likely to be a very important capability and challenge for Image Displays. It will be correspondingly important for Evidence Creators to make appropriate metadata available to the Image Displays (preferably using standard rather than private codes) and for Image Displays to help users to leverage that metadata.

This profile does require common metadata be populated by the Evidence Creators, does require support for common matching and return fields in the data query transactions, and does require certain baseline display capabilities in the Display Analysis Result [RAD-136] transaction, but otherwise leaves filtering and navigation capabilities up to the implementation.

520 For a further discussion of possible considerations, see RAD TF-1x: Appendix L, which describes a variety of filtering concepts that came up during profile development and discussions with radiologists.

49.4.1.3 Result Presentation

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This profile places a number of basic presentation requirements on the Image Display in the 525 Display Analysis Result [RAD-136] transaction.

Due to the variety of analysis results, details about how results and the associated images are presented is largely left to the implementation. Further, there is significant potential for display products to devise and provide display capabilities that present the results in ways that very effectively support the interpretation process. This profile is not intended to discourage such functions in any way.

Image Display implementations might consider some of the display capabilities described in the DICOM Volumetric Presentation States. In those objects, the Graphic Annotation Module includes Tracking UID (0062,0021) which can be used to reference an entity in a Segmentation or Structured Report instance to associate it with a Presentation State Graphic Annotation, and

535 the Volumetric Graphic Annotation Module includes Referenced Structured Context Sequence (0070,1903) which can be used to reference a node in a Structured Report instance to associate it with an Presentation State Graphic Annotation.

49.4.1.4 Codesets

While this profile does not mandate the use of particular codesets for most coded observations in
the results (beyond the structural codes required by the DICOM standard templates), agreeing
within the local site or organization on common codesets will be a key prerequisite of any
effective deployment of this profile. Conformance to Regional or National codesets would be a
forward-looking step that might yield benefits in the future when evaluating patients who have
been at multiple institutions, when applying national clinical guidelines, or when compiling
training datasets from diverse sources, etc.

Consistent use of common codes can facilitate many automatic, or semi-automatic, functions such as:

• Correlating current observations with prior observations

- Inserting findings into reports in dictation systems
- Using findings to drive decision support tools

Even more simply, consistent use of codes will make it far more practical to configure Image Displays to behave in sensible ways.

Finding Site

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When encoding values for the (363698007, SCT, "Finding Site") of an observation, a variety of recommended codesets may be found in DICOM PS3.16 Context Groups (CID Tables).

Anatomy codes are available that offer Creators a wide range of granularity, e.g., from finegrained to coarse-grained, codes exist for (36371001, SCT, "Left Sinus of Valsalva"), (81128002, SCT, "Sinus of Valsalva"), (8128003, SCT, "Aortic Root"), (54247002, SCT, "Ascending Aorta"), and (113262008, SCT, "Thoracic Aorta"). Maps of the hierarchical relationships between such codes are available that may be helpful to receiving systems.

Anatomic Region and Primary Anatomic Structure

Many of the same DICOM Context Groups apply when populating the Anatomic Region Sequence (0008,2218) and Primary Anatomic Structure Sequence (0008,2228). These, and Finding Site, will be particularly helpful when organizing results anatomically.

565 Qualitative Finding Concepts and Values

For the coded Concept of a Qualitative Evaluation, and for corresponding coded Values, the DICOM PS3.16 Context Groups again provide a starting set of codes.

The Reporting And Data Systems (RADS) vocabulary curated by the American College of Radiology provides organized sets of finding codes for a variety of evaluations including: BI-

570 RADS (Breast), C-RADS (CT Colonography), CAD-RADS (Coronary Artery Disease), LI-RADS (Liver), Lung-RADS (lung nodules), NI-RADS (Head & Neck), O-RADS (Ovarian-Adnexal), PI-RADS (Prostate), and TI-RADS (Thyroid).

The RadLex terms curated by the Radiological Society of North America (http://radlex.org) includes a variety of codes for clinical findings and imaging observations.

575 Another potential source of codes for measurements and qualitative findings are the Common Data Elements for Radiology (RDE), curated by RSNA and ACR (http://radelement.org).

Some RADELEMENT data elements and values may have equivalent concepts in terminologies such as SNOMED CT or LOINC, in which case the use of the latter is preferred in DICOM, due to their more widespread use in the EMR and the availability of mappings in the UMLS.

580 In Segmentations, sometimes the property being segmented is the anatomy, and sometimes it is something else that also needs an anatomical description, in which case the anatomy is coded separately. For the property being segmented, both a category and a type are specified, and the category determines whether the property type is anatomy, or not.

For example:

- Segmented Property Category Code (0062,0003) = (123037004, SCT, "Anatomical Structure")
 - Segmented Property Type Code (0062,000F) = (10200004, SCT, "Liver")

Compared to:

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- Segmented Property Category Code (0062,0003) = (49755003, SCT, "Morphologically Abnormal Structure")
- Segmented Property Type Code (0062,000F) = (50960005, SCT, "Hemorrhage")
- Anatomic Region Sequence (0008,2218) = (10200004, SCT, "Liver")

For further information, refer to PS3.16 CID 7150 Segmentation Property Categories.

Code Sources and Maintenance

595 DICOM codesets are largely constructed from SNOMED CT codes (that are free for use worldwide in the context of DICOM), LOINC codes (that are free for use worldwide), and DICOM codes (that are free for use worldwide).

Many of these codes are subject to maintenance and hence change over time as the terminology improves and evolves as well as errors being found and corrected. Accordingly, Evidence

- 600 Creators need to be aware that they should be using the most recent codes defined in the DICOM Standard, but also remain sensitive to the needs of the installed base of Image Displays and Image Consumers. Likewise, Image Displays and Image Consumers may want to support both old and new codes in order to function with new objects from new devices, old objects from old devices, and various combinations. The change from SNOMED RT style codes to SNOMED CT
- 605 style numeric identifiers has been particularly challenging in this respect, but also has significant benefits for harmonization and integration with other clinical systems like EMRs.

49.4.1.5 Confidence

Estimating and encoding the "confidence" that an AI model has in the result it produces, particularly in the medical context of a "finding", is an area of ongoing research.

- 610 As indicated in RAD TF-1x: Appendix L "Analysis Result Filtering and Navigation", confidence estimates are of significant interest to interpreting radiologists and might be very useful for the filtering and organization rules that radiologists might configure on their displays; for example, confidence thresholds might be used to determine whether a result is highlighted or not displayed at all.
- 615 Some AI Models may be able to generate quantitative estimates of confidence based on solid statistical modeling, others may be able to estimate rough relative confidence, and other Models may not be able to provide any indication of confidence at all.

For present/absent-type findings or staging/classification findings, a certainty score may be appropriate. For quantitative results, a 95% confidence interval for the result value might be more appropriate.

Note that the AI Model may have internal thresholds that control when it outputs a result at all, and those thresholds might be fixed as part of the regulatory process. Once a result is output, sites might also have locally controlled user thresholds for when a result is displayed, reported on, etc.

625 49.4.1.6 Negative and Partial Results

Many encoding descriptions in this profile describe "positive results", where an algorithm has detected or measured or located something. However, a "negative result", where an algorithm has reached a determination that something is not present, is also important clinical information and is expected to be encoded in analysis results.

630 This profile (see RAD TF-3:6.5.3.2) requires simple positive findings use the common conceptvalue pattern for a positive result:

(121071, DCM, "Finding") = (59282003, SCT, "Pulmonary embolism")

and corresponding negative findings use:

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(444436002, SCT, "Clinical finding not suspected") = (59282003, SCT, "Pulmonary embolism")

A negative result pattern introduced by DICOM TID 1350, but not adopted by this profile, is to attach a subordinate modifier (which makes it critical that the parsing system not overlook the modifier which reverses the sense of the modified concept):

(121071, DCM, "Finding") = (59282003, SCT, "Pulmonary embolism")

> (121052, DCM, "Presence of property") = (272519000, SCT, "Absent")

While some implementers might consider taking a finding value code, like the above pulmonary embolism code, and using it as a concept code with a paired value code of absent, SNOMED has indicated that is not appropriate.

Some coding systems are exploring the use of codes that *have* been defined as concepts that take a value, such as:

(RDE436, RADELEMENT, "Presence of pulmonary embolism") = (272519000, SCT, "Absent")

Methods of encoding negative findings is an area of ongoing investigation.

In addition to communicating useful clinical information, the presence of a negative result helps the radiologist differentiate the situation where nothing was found from the situation where the analysis was not performed.

Cases where the algorithm generated partial results that are in some sense valid, but processing did not fully complete, may decide whether or not it is appropriate to record those analysis results. DICOM CID 6402 includes a code for Partial Success, but this profile does not provide specific guidance on its use.

49.4.1.7 Analysis Results vs Workflow Status

information is recorded where.

While this profile addresses the encoding of analysis results, the planning and management of analysis processing tasks that generate those results is addressed by the AI Workflow for Imaging Profile. Since analysis results are one outcome of an analysis processing task, the distinction between results and task status can become blurred. It is useful to be clear about what

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Note: The terms used here are to illustrate concepts, not to propose a formalized model of results and status.

The previous section describes two cases where an analysis result is expected to be created:

- Positive result, where analysis processing completes successfully, and a positive finding or measurement is generated and encoded in a result object.
- Negative result, where analysis processing completes successfully, and a negative finding is generated and encoded in a result object.

Users may also have an interest in knowing about:

- Failed Processing, where analysis processing was run on a given dataset but was not able to complete successfully and stored no clinical results.
 - Unattempted Processing, where analysis processing was not run (or perhaps not even scheduled).
 - Partial Processing, where analysis processing was only partially completed and some clinical results may have been created.
- 675 This profile considers Failed Processing or Unattempted Processing information to be workflow status not clinical results, and thus is more appropriately addressed in workflow artifacts rather than encoding such details in the results themselves. Similarly, as described in the previous section, partial results might be encoded using this profile; however, details of the processing that was attempted and what challenges the processing encountered are better encoded in
- 680 workflow artifacts. The AIW-I Profile represents tasks, including their processing status, using DICOM UPS Workitem instances. UPS instances are not usually stored for very long beyond the completion of the task, (although conceivably a specification could be created to store them persistently), so capturing workitem status for analysis or communication to the radiologist or other user would depend on additional behaviors by systems such as a Watcher or Task Manager.

685 49.4.1.8 Result Approval, Retention, & Feedback

This profile is focused on the storage, retrieval, and display of analysis results in the image interpretation process. A full lifecycle management of results goes beyond the scope of this profile, but the associated questions and issues are important for implementations to consider.

Three specific aspects highlighted here are:

• Result approval, meaning policies and practices for the review and acceptance of results prior to them being made available for wider use. Policies might include requiring that

results be approved before they are made available to other clinicians and/or incorporated into the electronic medical record.

• Result retention, meaning policies and practices for what results are and are not persistently retained in the imaging record, and perhaps for how long. Policies might include deciding what results are deleted shortly after the study is reported, and which are kept for some period of time. Decision factors might include whether the result was viewed and/or referenced in the reporting process, whether the result was part of a billable activity, whether the result was above or below a threshold for confidence or severity, whether the result was the primary finding or subordinate data, or whether the result is covered by local medicolegal retention practices.

• Result feedback, meaning policies and practices for human experts to affirm, contradict, or modify results, to validate algorithms and/or provide improved training data for this or other algorithms. Policies may relate to localization of algorithms, local validation of algorithms, or wider area programs

While technical mechanisms to support each of the above would likely be helpful, it will be necessary to first establish the types of policies and practices needed and related details. Such information will be sought during trial implementation of this profile and may be the subject of future IHE work.

- 710 Result feedback is expected to be particularly important during the early years of the adoption of AI-based algorithms. It is worth noting that all of the result encodings described in RAD TF-3: 6.5.3 would also be appropriate for capturing results that have been generated or edited by a human, such as the radiologist. For example, when editing a contour, or adjusting a measurement, or reversing a finding, a new SR instance could be stored with the new values.
- 715 TID 1500 includes TID 1001 and TID 1002, where (121005, DCM, "Observer Type") can be set to (121006, DCM, "Person"), and details in TID 1003 can identify the specific person and their role in the organization. The new result can reference the original analysis result that was edited in the Predecessor Document Sequence (0040,A360).
- Beyond that, performing approval and feedback activities, or executing retention policies, are primarily workflow and higher-level data management functions that may be best addressed at the workflow layer above the basic result storage and display addressed by this profile. For comparison, image retention policies are generally not coded into the images themselves. Addressing these workflows, and perhaps generating audit messages associated with performing such tasks may be addressed in the AI Workflow of Imaging Profile.

725 49.4.1.9 Al Algorithm Deployment

Profile requirements about how results are encoded and submitted for storage are placed on the Evidence Creator, which represents the "hospital-facing" part of the system. The profile does not constrain how AI algorithms are integrated with the Evidence Creator or the analytic technology used by AI algorithms. Some products may choose to implement the AI algorithm and the

730 Evidence Creator features in the same software package. It is also possible that the Evidence Creator will be implemented by a platform product (such as an AI marketplace) and one or more

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AI algorithms are then integrated with that platform to avoid having to individually implement the result coding functions. Some implementations may progressively assemble components of an analysis result, culminating in data that is conformant with this AIR Profile and is stored by

735 the Evidence Creator as one or more instances. For an illustration of this concept, see Figure XXXX.1-1. "Example of Successive Refinement of JSON Payload to Complete SR" in DICOM Supplement 219 "JSON Representation of DICOM Structured Reports" available at <u>https://www.dicomstandard.org/supplements</u>.

Or to put it differently, it is permitted, but not required, that the Evidence Creator perform the analysis. The Evidence Creator may receive results from other software and be responsible for ensuring the result encoding conforms to this profile and for sending the results to the Image Manager / Image Archive.

On a related topic, some implementations may involve "interactive" AI Models in the sense that a user might choose "on the fly" to invoke one analysis or another based on what they observe in

- 745 the image, or a user might provide a needed seed point for a segmentation or select a particular region of an image for analysis, or perhaps there might be several iterative invocations of AI Models with user feedback in between. Regardless, it is expected that the generated results would be conformant with this profile and displayable by conformant Image Displays.
- In such scenarios, an Evidence Creator would potentially be integrated with the Image Display.
 750 Alternatively, the Image Display might be grouped with a Task Requester in the AI Workflow for Imaging Profile to have the analysis performed by an external Task Performer. In either case, this profile could potentially still be applied to encoding, storing, and being able to display the results generated, although such workflows or iterative result updates have not been analyzed here.
- 755 Interactive AI raises a number of interesting issues. Due to the possibility of bottlenecks in processing and data transfer, some AI may be implemented similar to post-processing labs where it is all done before reading starts. But as technology advances, more "on-the-fly" or interactive analysis may be possible, where the radiologist might request AI workup of a suspicious feature, perhaps to quantify its characteristics or to get a list of the most likely diagnostic findings.
- 760 Such issues (particularly relating to managing execution of AI Models) are out of scope of this profile. Implementers may also refer to Section 49.4.1.7 in the AI Workflow for Imaging Profile.

49.4.1.10 Result Trees

The use of multiple algorithms may produce very large collections of results for a given study. To provide Image Displays with information to help them organize and prioritize the result
"entries" listed/communicated to the operator at one time, this profile introduces a Result Tree object that conveys a basic hierarchy for a set of related results.

For example, a lung screening algorithm might produce a Result Tree object with a Lung-RADSTM score as the root result, supported by secondary results consisting of multiple detected nodule locations and assessments of the size, solidity, and margin of each detected nodule. A pneumonia algorithm might produce a Result Tree object that points to an SR finding of

"pneumonia present" as the root result and reference a separate saliency map instance as the next supporting layer.

An Image Display might initially present the roots of the two Result Trees (Lung-RADS = Category 3) and (Pneumonia present) and let the radiologist "drill down", rather than initially presenting 43 components consisting of location, size, solidity, margin, and Lung-RADS for

775 presenting 43 components consisting of location, size, solidity, margin, and Lung-RADS for each of 8 nodules, an overall Lung-RADS score, the pneumonia finding, and the pneumonia saliency map reference.

Result Trees are a means to help users navigate result sets. It is left to the system that creates a Result Tree to choose which result is most appropriate to present as the root result, and how to

- 780 organize the supporting results into a presentation hierarchy. Such choices may be driven by user preferences or local policies. The analysis presented in a Result Tree may be the result of an individual assessment package, or the analysis presented in the Result Tree may include results from multiple assessment components.
- Support for Result Trees is indicated with the Result Tree Option (see Section 49.2.1). Result
 Tree encoding is defined in RAD TF-3: 6.5 "Imaging Analysis Result Content", and associated
 display behaviors are defined in RAD TF-2: 4.136.4.1.3.9 "Display of Result Trees".

It is the nature of an imaging study that new analysis may be performed at any time, adding new results to the study. Correspondingly, new Result Trees may be created that incorporate references to those new results, or the new results may simply exist in the study alongside the

790 rest of the results that do not happen to be referenced by any Result Trees. Similarly, results may be "removed" using mechanisms such as Imaging Object Change Management (IOCM), in which case it might be advisable to remove or replace Result Trees that reference the removed result, but such behavior is up to the business logic of the associated products, potentially guided by site preferences and policies.

795 **49.4.2 Use Cases**

This profile is focused on handling Analysis Results that are generated from images and are applied in the context of "reading" the associated imaging study.

49.4.2.1 Use Case #1: Store, Retrieve & Display

49.4.2.1.1 Store, Retrieve & Display Use Case Description

800 Results are produced from the analysis of images by one or more Evidence Creators and are stored and later retrieved and displayed by an Image Display to support the interpretation of the associated imaging study.

As described in Section 49.4.1.9, the Evidence Creator is the "hospital-facing" facet of an algorithm.

805 An important characteristic of the Use Case is that the Image Display does not depend on specific knowledge of the algorithm or the details or internal structure of the result that the algorithm produces. This is intended to facilitate the use of a variety of image display products

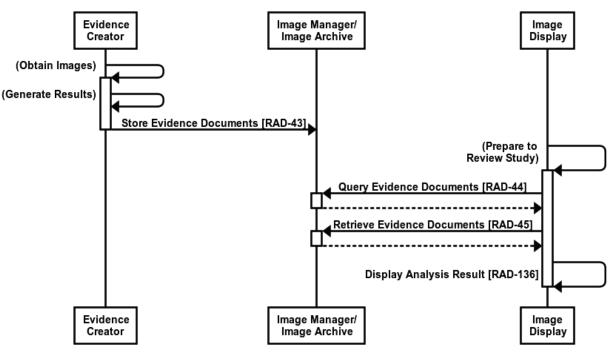
with a variety of products and architectures while minimizing the integration and customization overhead.

810 Although not shown, the use case expects there to be multiple Evidence Creators and a given study could easily have multiple results.

There is a possibility that some results may arrive after reading has been performed. Coordinating some kind of "Ready To Read" signal based on expected and received data and other aspects of reading workflow is outside the scope of this profile.

815 **49.4.2.1.2 Store, Retrieve & Display Process Flow**

Figure 49.4.2.1.2-1 shows storage and retrieval of SR instances using conventional DIMSE DICOM transactions. Alternatively, results could also, or instead, consist of image instances, and could be retrieved using RESTful DICOM transactions.





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Figure 49.4.2.1.2-1: Store, Retrieve & Display Process Flow in AIR Profile

The text in Figure 49.4.2.1.2-2 was used to generate the diagram in Figure 49.4.2.1.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

title Store, Retrieve, & Display participant Evidence\nCreator as EC participant Image Manager/nImage Archive as IM participant Image\nDisplay as ID EC->+EC: (Obtain Images) EC->+EC: (Generate Results) EC->-IM: Store Evidence Documents [RAD-43] ID->+ID: (Prepare to\nReview Study) ID->+IM: Query Evidence Documents [RAD-44] IM-->-ID: ID->+IM: Retrieve Evidence Documents [RAD-45] IM-->-ID: ID->-ID: \nDisplay Analysis Result [RAD-136]



825 **49.4.2.2 Use Case #2: Auxiliary Usage**

49.4.2.2.1 Auxiliary Usage Use Case Description

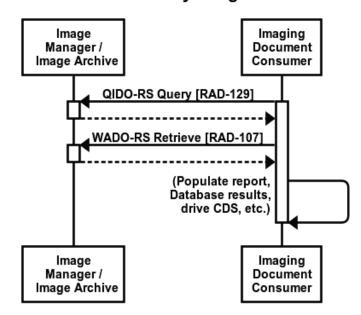
This use case highlights that non-display actors can make use of the same results used by the Image Displays in Use Case #1. Examples of Imaging Document Consumers include report creation systems that use result contents to populate fields in a draft imaging report, clinical

830 databases that extract measurements and support functions like comparing values for a given patient over time, and clinical decision support systems that use result contents as input values to drive their decision logic.

Such Imaging Document Consumers will benefit from the standardized representations, but would not be required to support display behaviors.

835 This use case also demonstrates query and retrieval using DICOMweb (RESTful DICOM transactions – QIDO-RS and WADO-RS); it could alternatively have used conventional DIMSE DICOM.

49.4.2.2.2 Auxiliary Usage Process Flow



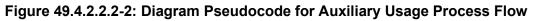
Auxiliary Usage

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Figure 49.4.2.2.2-1: Auxiliary Usage Process Flow in AIR Profile

The text in Figure 49.4.2.2.2-2 was used to generate the diagram in Figure 49.4.2.2.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

845	title Auxiliary Usage
	participant Image\nManager /\n Image Archive as IM participant Imaging\nDocument\nConsumer as IDC
	IDC->+IM: QIDO-RS Query [RAD-129] activate IDC IM>-IDC:
	IDC->IM: WADO-RS Retrieve [RAD-107] IM>-IDC:
	IDC->IDC: IDC->IDC: (Populate report,\nDatabase results,\ndrive CDS, etc.)
850	deactivate IDC



49.4.2.3 Use Case #3: Result Trees

49.4.2.3.1 Result Trees Use Case Description

This Use Case expands on the basic Store, Retrieve & Display Use Case (see Section 49.4.2.1) by introducing Result Trees. When large sets of results exist in a study (e.g., 40 or more primitives), presenting them to the radiologist interpreting the study has the potential to overwhelm the user and/or the reader's workflow. For example, presenting all 40 at once, or presenting them one by one in an arbitrary order, will likely be sub-optimal. The Result Tree encodes a hierarchical relationship between

860 primitives in a set. For example, the root of the tree could be an overall Lung-RADS assessment of the patient, with subordinate assessments for each nodule which in turn each have a segmentation, a margin assessment and an opacity result.

The Result Tree is created either by the algorithm that generated the set of results or some other application that understands the structure of the results.

865 The Image Display uses this hierarchy to offer navigation and display functions that allow a radiologist to progressively ingest/handle/work through large result sets.

For further discussion of this concept, see Section 49.4.1.10 Result Trees and Root Results.

The simple hierarchy facilitates useful navigation and display behaviors by the Image Display, without needing to modify those implementations to incorporate specific knowledge of each algorithm or the details or internal structure of the result that each algorithm produces.

While the results here are generated by AI-based algorithms, the mechanisms are applicable to any hierarchical instance set generated by a conventional or AI-based algorithm.

49.4.2.3.2 Result Trees Process Flow

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Figure 49.4.2.3.2-1 shows one Result Tree for each analysis and the Result Tree is created by the analysis algorithm itself. In this case, both of the Evidence Creators support the Result Tree Option. In the figure, the selected B results are SRs retrieved using [RAD-45]. Other retrieve transactions would be used as appropriate for other types of selected results.

It is also possible results might be created that are not referenced by a Result Tree. The Image Display would likely handle those based on configured site policies and/or user preferences.

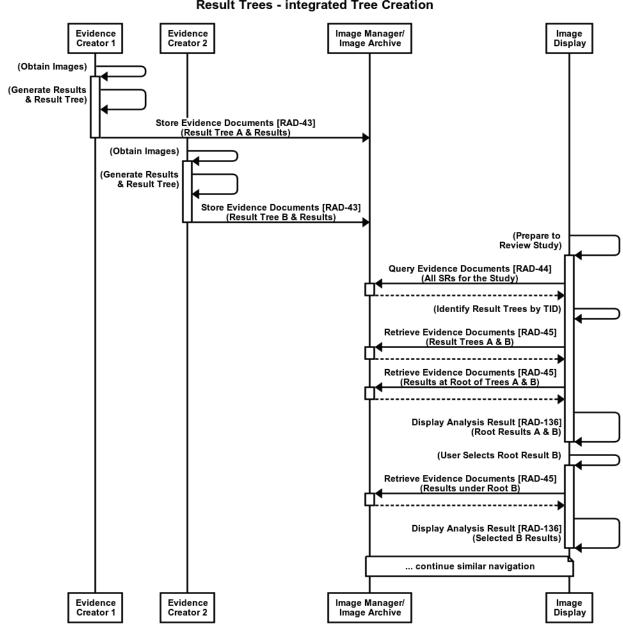






Figure 49.4.2.3.2-1: Result Trees Process Flow in AIR Profile

The text in Figure 49.4.2.3.2-2 was used to generate the diagram in Figure 49.4.2.3.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

title Result Trees - integrated Tree Creation participant Evidence\nCreator 1 as EC1 participant Evidence\nCreator 2 as EC2 participant Image Manager/nImage Archive as IM participant Image\nDisplay as ID EC1->+EC1: (Obtain Images) EC1->EC1: (Generate Results\n& Result Tree) EC1->-IM: Store Evidence Documents [RAD-43]\n(Result Tree A & Results) EC2->+EC2: (Obtain Images) EC2->EC2: (Generate Results\n& Result Tree) EC2->-IM: Store Evidence Documents [RAD-43]\n(Result Tree B & Results) ID->+ID: (Prepare to\nReview Study) ID->+IM: Query Evidence Documents [RAD-44]\n(All SRs for the Study) IM-->-ID: ID->ID: (Identify Result Trees by TID) ID->+IM: Retrieve Evidence Documents [RAD-45]\n(Result Trees A & B) IM-->-ID: ID->+IM: Retrieve Evidence Documents [RAD-45]\n(Results at Root of Trees A & B) IM-->-ID: ID->-ID: \nDisplay Analysis Result [RAD-136]\n(Root Results A & B) ID->+ID: (User Selects Root Result B) ID->+IM: Retrieve Evidence Documents [RAD-45]\n(Results under Root B) IM-->-ID: ID->-ID: \nDisplay Analysis Result [RAD-136]\n(Selected B Results) note over IM.ID: ... continue similar navigation

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Figure 49.4.2.3.2-2: Diagram Pseudocode for Result Trees Process Flow

Figure 49.4.2.3.2-3 shows a second variant where the two assessments are performed by the first two Evidence Creators and two Result Trees (one for each set of results) are created by a third Evidence Creator (which supports the Result Tree Option). Alternatively, the third Evidence Creator might create a single Result Tree spanning both analyses if that was appropriate. Also,

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Creator might create a single Result Tree spanning both analyses if that was appropriate. Also, the third Evidence Creator is shown retrieving results from the Image Manager; alternatively, the first two Evidence Creators could send their results directly to the third Evidence Creator which would store the results together with the Result Trees to the Image Manager when ready.

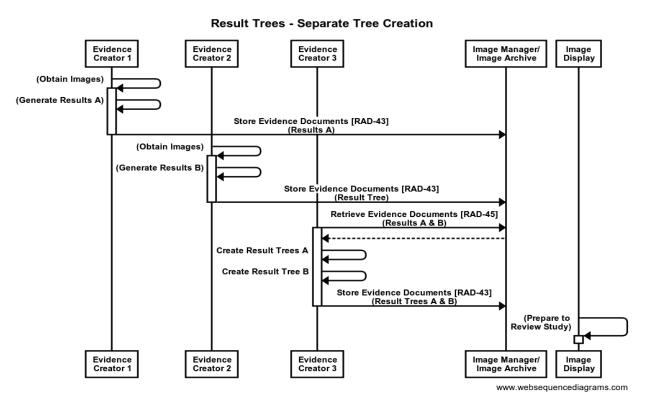


Figure 49.4.2.3.2-3: Result Trees Process Flow in AIR Profile

895 The text in Figure 49.4.2.3.2-4 was used to generate the diagram in Figure 49.4.2.3.2-3. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

title Result Trees - Separate Tree Creation
participant Evidence\nCreator 1 as EC1 participant Evidence\nCreator 2 as EC2 participant Evidence\nCreator 3 as EC3 participant Image Manager/nImage Archive as IM participant Image\nDisplay as ID
EC1->+EC1: (Obtain Images)
EC1->EC1: (Generate Results A) EC1->-IM: Store Evidence Documents [RAD-43]\n(Results A)
EC2->+EC2: (Obtain Images)
EC2->EC2: (Generate Results B)
EC2->-IM: Store Evidence Documents [RAD-43]\n(Result Tree)
EC3->IM: Retrieve Evidence Documents [RAD-45]\n(Results A & B) activate EC3 IM>EC3:
EC3->EC3: Create Result Tree A EC3->EC3: Create Result Tree B
EC3->-IM: Store Evidence Documents [RAD-43]\n(Result Trees A & B)
ID->+ID: (Prepare to\nReview Study)
note over IM,ID: continue as shown in Figure 49.4.2.3.2-1

Figure 49.4.2.3.2-4: Diagram Pseudocode for Result Trees Process Flow

49.5 AIR Security Considerations

900 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.

49.5.1 Security Considerations for Actors

This profile strongly recommends all actors group with an ITI <u>ATNA</u> Secure Application or Secure Node Actor using the <u>Radiology Audit Trail Option</u>.

The ATNA Profile requires actors to implement:

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

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

49.5.2 Security Considerations for Analysis Results

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

49.6 AIR Cross-Profile Considerations

Since the data created and exchanged in the AI Results Profile are encoded using common
 DICOM instances, many other Radiology profiles that manage content could be used in conjunction with the content of the AI Results Profile:

- Cross-Enterprise Document Sharing for Imaging (XDS-I) and/or Cross-Community Document Access for Imaging (XCA-I) could be used to exchange analysis results within and between enterprises
- Import Reconciliation Workflow (IRWF.b) and/or Import and Display of External Priors (IDEP) could be used to localize and manage the import of analysis results
 - Web-based Image Access (WIA) could be used to access analysis results using DICOMweb
 - Invoke Image Display (IID) could be used to launch viewing of analysis results
 - Portable Data for Imaging (PDI) could be used to distribute analysis results on portable media

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- Audit Trail and Node Authentication (ATNA) (with the Radiology Option) is recommended to secure the communication of, and record audit trails for, analysis results.
- 935
- Imaging Object Change Management (IOCM) could be used to manage changes and quality control of analysis results including deprecating distributed instances that have been disapproved or superseded by revised instances.
 - Standardized Operational Log of Events (SOLE) could be used to log processing events like the generation of image analysis results for operational analysis
- 940 Similarly, it would be sensible for Image Display systems to support the AI Results Profile together with other Profiles that include related display capabilities, such as:
 - Scheduled Workflow (SWF.b) to display the analysis results together with the images from the study
 - Mammography Image (MAMMO)
- Digital Breast Tomosynthesis (DBT)
 - NM Image (NMI)

Both the AI Results Profile and the Evidence Documents (ED) Profile make use of the [RAD-43], [RAD-44], and [RAD-45] transactions to store, query, and retrieve SR instances.

Both the AI Results Profile and the Web Image Access (WIA) Profile make use of the [RAD 129] and [RAD-107] transactions to query and retrieve DICOM instances using RESTful
 DICOMweb. The WIA Profile also documents using the ITI XDS and MHD Profiles to support
 backend functions, but that is not really relevant to the AI Results Profile.

The Mammography Image (MAMMO) Profile introduces requirements on the creation, exchange, and display of mammography images and DICOM SR objects containing CAD

- 955 results. While there are direct parallels between the latter and the results in this profile, the MAMMO Profile mandates the specialized SR template (TID 4000) and addresses many mammography-specific issues. Products that create and display mammography results are advised to conform to the MAMMO Profile. The situation is very similar for the Chest X-Ray CAD (CXCAD) Profile.
- 960 The Results Distribution (RD) Profile addresses the communication of imaging results, but in that context, "results" refers to diagnostic reports, so there is no direct interaction between the RD Profile and the AIR Profile.

AIW-I – AI Workflow for Imaging Profile

A Task Performer in AIW-I might be grouped with an Evidence Creator to assign and track completion of the processing performed by the Evidence Creator (or its constituent algorithms) as well as provide the Evidence Creator with information about how to access its input data and allow the Evidence Creator to communicate the list of instances it has created and where they have been stored. The tasks also facilitate controlling the parameters fed to the algorithm, recording execution status (for example, billing may depend on whether a given algorithm was
 run even if it didn't generate any results), and allowing systems (like Reporting Worklist
 Managers) to subscribe to notifications about AI processing that has been scheduled and/or completed.

RRR-WF - Radiology Remote Reading Workflow Profile

A Task Performer in RRR-WF might be grouped with an Image Display in a reading workstation to access a defined reporting task that identifies the study/instances to be reported and where they may be obtained. Since those instances may include the Analysis Results, this is one of the ways that the Image Display can become aware of the Analysis Results that it Query/Retrieves in this profile.

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Add new Appendix L.

980 Appendix L – Analysis Result Filtering and Navigation (Informative)

This Appendix describes example situations and possible behaviors that are potentially relevant to implementers of the AI Results (AIR) Profile. See RAD TF-1: 49.

As AI adoption increases, a given study may be subjected to many analyses, potentially from different vendors, leading to many AI-generated results.

- 985 Consider a chest CT that is acquired and evaluated by algorithms that produce a collection of results, including findings or observations about:
 - Cracked ribs,
 - Pneumothorax,
 - Pneumonia,
- 990 Scoliosis,

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- Aortic aneurysms,
- Coronary plaque, and
- Lung lesions

Further, some results may consist of multiple components; e.g.,

- A lung lesion result might include a finding that a lung nodule is present, a location for the nodule, a segmentation of its boundary, measurements of its dimensions and volume, an overall nodule classification as benign/suspicious/malignant/etc., a Key Object Selection indicating the image slice most representative of the nodule, etc.
 - A cracked rib result might include a finding on recency; is it recently cracked, or an older injury.
 - RadElement commonly groups multiple related elements into "element sets"

The software used to review imaging studies (studies which will now include all these analyses, both conventional and AI-based) will need to address the challenge of helping the radiologist be aware of the available information and review it as appropriate, while simultaneously avoiding

1005 the addition of extra time and tangible steps that are anathema in the imaging interpretation process.

Note: The display of individual result primitives is directly addressed by this profile in the form of baseline requirements in [RAD-136]. Specific result discovery or navigation behaviors by the Image Display are left to product design and not addressed by this profile; however, the profile indirectly addresses the related tasks of filtering and navigating the available results by trying to ensure sufficient relevant metadata is available in the result objects. A "zero-click interface" would certainly be appealing, but this profile does not attempt to design one.

The following "Hypothetical Behavior" sections are intended to facilitate discussion of possible use cases and mechanisms that would help imaging clinicians. If those discussions identify certain key metadata needed to support such mechanisms, that may result in Change Proposals with requirements, constraints, or recommendations for Evidence Creators or Image Displays. These hypothetical behaviors are not requirements in this profile.

L.1 Hypothetical Behavior: Result "Display Protocols"

One could imagine an Image Display allowing users to configure rules and behaviors that controlled what results were initially displayed and how they were presented. This is analogous to conventional hanging protocols which use rules to control what images are presented and how they are organized on the available displays.

A presumption in this display protocol discussion is that none of the results in the study would be inaccessible to the imaging clinician, rather some results would be automatically prioritized, arranged and presented, while others might require interactions by the imaging clinician to

1025 access. Based on experience in mammography CAD, where the rate of false positives presented a significant challenge, some forms of result filtering will be necessary to make the display of results usable when more than a few are present in a study.

Some conceivable factors that might be incorporated into rules might include:

- Whether the result is "normal" or "abnormal" (e.g., might not initially display results that are normal or unremarkable)
 - o Normal/abnormal may be treated as a continuum using a score or degree of severity
 - o Value ranges for normal/abnormal will sometimes be locally defined
- The algorithm "confidence", perhaps in terms of the sensitivity/specificity of the algorithm, or the positive/negative predictive value, or in terms of some generated metric (e.g., might not display results that do not exceed a certain threshold, and/or might highlight results with a particularly high confidence). Note that "confidence" is easier said than estimated. See RAD TF-1: 49.4.1.5.
 - The change or consistency of the current result when compared to prior results. (e.g., might highlight or display results that represent a change from the prior situation; a new lesion vs one that was previously present; a mass that has increased or decreased in size vs one that has not changed size)
- The criticality of an abnormal result (e.g., might display a result with high criticality, perhaps even if it was below the normal confidence threshold). The IHE Results Distribution Profile highlights the RADLEX codes for observation categories (from most to least severe, where the top 3 are differentiated by the rough time frame in which action should be taken):
 - RID49480[^]Category 1 Emergent Actionable Finding[^]RadLex
 - RID49481^Category 2 Urgent Actionable Finding^RadLex

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	 RID49482^Category 3 Noncritical Actionable Finding^RadLex
1050	 RID50261^Non-actionable^RadLex
	 RID13173^Normal^RadLex (synonym "Unremarkable")
	• Whether the result has been reviewed/verified/approved by a human (e.g., might display results a resident has "approved/verified/confirmed", perhaps even if it was below the normal confidence threshold).
1055	• The relationship between the type or anatomical location of the results and the indications, reason for study or anatomical focus of the imaging procedure (e.g., might suppress cardiac results that are normal when viewing a lung study but displayed them in a cardiac study, or might provide an organ-based summary of findings)
1060	• The algorithm make/model/version used (e.g., an imaging clinician might be evaluating a particular algorithm and want to see the results of that algorithm for all studies during the period of evaluation; or an imaging clinician might not have confidence in a particular algorithm and not want those results "cluttering" the display)
1065	• Whether the result is the root of a result tree (see the following Hypothetical Behavior: Result Trees, Layers of Detail) or a subordinate finding (e.g., might be configured to display the root result that pneumothorax is present or a lesion was detected, but suppress the segmentation result showing the lesion or pneumothorax location result unless requested).
1070	• Whether the algorithm completed successfully (e.g., algorithms that failed or only partially completed might still generate results useful for evaluating its performance, or simply knowing that it was run; results created with a failure status would not normally be displayed). Based on experience in mammography CAD, the following states might be considered:
	 Successfully processed
	 Partially processed; incomplete
1075	• Processing failed; unsupported data (e.g., wrong body part or modality)
	 Processing failed; modality model not validated
	 Processing failed; low confidence
	• The relative date/time of multiple results (e.g., current results might be presented next to prior results, and/or differentiated from a current result from re-processing a prior image)
1080	• Note that the date/time of the results reflects when they were created, as distinct from the date/time of the images from which the results were generated
	 Multiple findings might also be present in the study for the same Concept when different algorithms make a determination, say, on whether pneumonia is present, or the same algorithm is run with different parameters.

- 1085 The approval status of the algorithm (e.g., during normal clinical reading might not initially display the results of a research algorithm that is not yet FDA approved). The approval status of the algorithm might not be encoded directly in the result but rather the Algorithm Identification coded into the result might be used to consult a database or configuration table that records the status for each algorithm locally in use. 1090 The approved paradigm of the algorithm (e.g., might not initially display the results of an algorithm approved for use as a "second reader" since that would invalidate its intended mode of use, or). The type of reader (e.g., might not initially display some types of results to Emergency Room readers, or residents) 1095 The nature of the current review (e.g., might present the "worst" case of several • conflicting results when performing triage, while normal reading workflow might prioritize differently or might present both results). Known details about the patient (e.g., might not highlight a pneumothorax result for a • patient known to have chest tube in place unless the pneumothorax size exceeds a certain 1100 threshold) Relationships between results (e.g., for a primary finding that a tumor is present, the related results that show the segmented surface of the tumor, and the numerical measurements of the dimensions and volume might be displayed together, or the primary finding might be displayed with an indicator that there are secondary/supporting results 1105 that can also be displayed. In addition to direct references between results, relationships can also be inferred by results sharing the same Tracking Identifier, the same Finding Site, or the same Frame of Reference) Results that correspond to fields in the current report template (e.g., findings that will automatically "flow through" to populate elements of the report based on the current 1110 configuration would be displayed or highlighted to make sure the radiologist is fully aware. To a certain extent, the report template encodes a certain focus of interest. More specifically, a report template that is tuned to the needs of a particular specialist (cardiologist, pulmonologist, neurosurgeon, family doctor, etc.) may focus on findings relevant to their interests. A study of coronary artery calcification might not highlight an abdominal aortic aneurysm of less than 3cm. As more analysis is performed, the ratio of 1115 observations that do not appear in the report might exceed the observations that do.) Rules might also control how results are grouped or formatted on the display, for example grouping abnormal findings together, or grouping cardiac results separately from lung results, or
- 1120 An additional complexity is that a study might contain conflicting results. Consider a general chest X-Ray algorithm that evaluates 6 conditions, which determined that cracked ribs were absent, and another special purpose algorithm (which might be considered to be more sophisticated) which determined that two cracked ribs were present. What if the findings were

grouping results that came as a set from a particular algorithm.

reversed, with the more specialized model indicating no fractures and the less specialized model indicating fractures were present? Perhaps the result with the higher confidence would be displayed with an indication that conflicting results are present.

SR instances from different Evidence Creators will be in different series which may provide additional clues for the Image Display.

L.2 Hypothetical Behavior: Result Trees, Layers of Detail

- 1130 It seems likely that displays might leverage component hierarchy by first presenting a summary "root" result or key value to an imaging clinician and offer the ability to explore additional layers of detail as needed, for example allowing the imaging clinician to expose the segmentation that underlies a volume measurement. This exploration might be done to gain greater confidence in the root result, or to comprehend more details and nuances of the finding(s).
- 1135 In another example, a lung screening algorithm might record a LungRADSTM score as a root result, supported by secondary results consisting of multiple detected nodule locations and assessments of the size, solidity, and margin of each detected nodule. Another algorithm might record an SR finding of "pneumonia present" as a root result with a reference to a separate saliency map instance. An Image Display might then initially present the two root results
- 1140 (LungRADS = Category 3) and (Pneumonia present) and offer "drill down", rather than initially presenting 43 components consisting of location, size, solidity, margin, and LungRADS for each of 8 nodules, an overall LungRADS score, the pneumonia finding, and the pneumonia saliency map reference.

Result Trees (see RAD TF-3: 6.5.3.9) capture the hierarchy within a set of results. The results in a tree may have been generated together or may have been associated by the software that creates the Result Tree. If multiple applications were run on a study, each would likely generate its own result tree. More advanced logic or analysis software might prioritize all results for a given study.

As described in RAD TF-2: 4.136.4.1.3.9, a display can use a simple query filter to get the result 1150 trees in a study, the roots of which constitute a first-order set of "summary findings". The references in each of those result trees provide a logical next layer of detail. Ideally, some displays will develop much more sophisticated analysis and logic, or more advanced configurations, and more advanced navigation and display, while the result trees would provide a first simple step up from the flat list of findings.

1155 L.3 Hypothetical Behavior: Algorithm Rendering Intent

Mammography CAD allows the analysis algorithm to communicate recommendations about the behavior of the Image Display by flagging specific findings as having a Rendering Intent of either Presentation Required, or Presentation Optional. Evidence Creators could also encode an indication of the criticality of an abnormal result (see above) as a way to influence display behaviors.

Such an approach could make some display behaviors consistent for the same result across different displays. This supports some "centralization" of some display logic since it is configured/determined at the algorithm, rather than at each individual display. On the other hand, when there are many results, the problem remains of prioritizing/sequencing multiple algorithms all indicating presentation required.

In practical terms, the rendering intent of the algorithm is information that could be used by display logic, but would be unlikely to override the instructions of the user, and there is no obligation for displays to anything at all with it, so it is currently not a reliable mechanism for Evidence Creators.

1170 L.4 Hypothetical Behavior: Longitudinal Navigation

Longitudinal results (the same measurement or evaluation performed at several points in time) present another axis of result relationships commonly of interest to imaging clinicians. For example, the change in size of a given tumor or the stability of a stenosis grade for a given vessel may be of interest.

- 1175 Tracking Identifiers provide a mechanism for indicating that the subject of two or more measurements or evaluations is the same entity. An Evidence Creator creating a new measurement of a tumor might check prior measurements and if it can identify the same tumor, use that Tracking Identifier for the new measurements. Alternatively, a subsequent system might analyze a set of measurements to identify which are the same tumor (e.g., based on anatomical
- 1180 location) and create a new data object with the corresponding Tracking Identifiers updated to be the same.

Whether a set of longitudinal results are listed, graphed, scrolled through, or shown side-by-side, are design choices left to Image Display implementations.

RAD TF-2: 4.136.4.1.3.7 contains associated requirements for the display of Tracking
Identifiers. The value of Finding Site may also be useful to correlate findings or results from
different timepoints that may be related due to being at the same finding site. Note that finding
sites may describe anatomy, devices (stents, pins, biopsy clips, etc.), or, when associated with
Finding, a pathology.

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Volume 2 – Transactions

Add Section 4.136

4.136 Display Analysis Result [RAD-136]

1195 **4.136.1 Scope**

This transaction is used to present image analysis results to someone, such as a radiologist interpreting a study.

This transaction is not a typical IHE transaction between two devices; the primary focus is on the required behavior of the display rather than messaging between two actors. This can be thought of as an "informational transaction" between a display device and a user.

The specification is organized around a defined set of result data structures ("primitives") that may be encountered by the display, and the baseline display behaviors required for each. As with many IHE specifications, the display may have behaviors in addition to those required by this transaction.

1205 Methods for selecting the data to be displayed are outside the scope of this transaction.

4.136.2 Actor Roles

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

Role:	Display:			
	Presents results visually to a user, such as a radiologist.			
Actor(s):	The following actors may play the role of Display:			
	Image Display			

Table 4.136.2-1: Actor Roles

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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.

4.136.3 Referenced Standards

- DICOM <u>PS3.3: A.35.4</u> Key Object Selection Document IOD
- DICOM <u>PS3.3: A.35.13</u> Comprehensive 3D SR IOD
 - DICOM <u>PS3.16: TID 1500</u> Measurement Report
 - DICOM <u>PS3.3: A.51</u> Segmentation IOD

• DICOM <u>PS3.3: A.75</u> Parametric Map IOD

4.136.4 Messages

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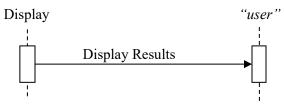


Figure 4.136.4-1: Interaction Diagram

4.136.4.1 Display Results

The Display presents the analysis results to the user.

The results being presented may or may not have been previously verified by a human and may or may not be accurate.

4.136.4.1.1 Trigger Events

A user or an automated function determines that one or more results should be presented.

4.136.4.1.2 Message Semantics

The results are encoded as described in RAD TF-3: 6.5.3.

- 1230 This transaction does not depend on how the instances that contain the encoded results are represented (DICOM binary, DICOM XML, DICOM JSON), or the messaging protocol by which the instances containing the encoded results were transferred to the Display. If the Display receives results by a profiled mechanism such as DICOM C-STORE, or DICOMweb WADO-RS, the messaging protocol is specified in that corresponding transaction. If results are accessed
- 1235 by being grouped with another actor such as an Image Manager / Image Archive or Evidence Creator, there is no messaging protocol involved.

4.136.4.1.3 Expected Actions (i.e., Display Requirements)

The behaviors in this section are specified as baseline capabilities. Displays may have additional or alternate capabilities that may be invoked or configured.

- 1240 Displays shall support the capabilities described in this section for result primitives (See RAD TF-3: 6.5.3) encoded in instances of the following:
 - Key Object Selection Document IOD
 - Comprehensive 3D SR IOD
 - Segmentation IOD
- Parametric Map IOD

4.136.4.1.3.1 General Result Display Requirements

The Display:

- shall make the user aware that results are available for display
- shall support multiple results collected together in one instance
 - e.g., multiple qualitative findings, measurements, locations, and/or regions in a single SR instance, multiple region segments in a single Segmentation instance, etc.
- shall support sets of results that are spread across multiple instances in one or more series in current and prior studies being reviewed by the user
- shall be able to display each result primitive (as defined in RAD TF-3: 6.5) in a complete, unambiguous, clinically useful manner without excessive user interaction
 - shall make clear the specific image/frame to which the result primitive applies
 - o this may involve toggling a GSPS-like overlay on/off
 - shall be able to superimpose each primitive on the appropriate underlying images in a manner appropriate to the primitive
- shall allow the user to control which result primitives are displayed on an individual basis (see RAD TF-1: 49.4.1.2 for some approaches and considerations)
 - that control shall include being able to select which, if any, locations, regions, measurements, and qualitative findings are displayed superimposed on images
 - that control shall include being able to resolve overlapping results (i.e., results where one could obscure the other when rendered together). The method is left to the implementation (e.g., allowing the user to cycle through them, choose between them, etc.).
 - shall make available for display the unique identifier, version, name, and manufacturer of the algorithm that generated each result
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- RAD TF-3: 6.5.3.1 describes the location(s) where this information is encoded
- shall make available for display the following information about each result
 - Content Date (0008,0023) and Content Time (0008,0033) of the primitive instance
- shall, if an image reference with concept of (121200, DCM, "Illustration of ROI") is associated with a primitive, make the user aware if it (unobtrusively) and be able to display that image.

If the Display is unable to present a result, it is up to the Display whether to notify the user, make a record in a log file, or fail silently.

Displays should note that instances of Segmentations and Parametric Maps both belong to the family of Enhanced Multiframe objects which make use of the mechanism that splits certain details between the Shared Functional Group Sequence (5200,9229) and the Per-frame

Functional Groups Sequence (5200,9230) depending on whether the values apply to specific frames or to all frames.

4.136.4.1.3.2 Display of Qualitative Findings

The Display shall be able to display qualitative findings.

- 1285 For qualitative findings that are associated with an image, location, or region, the Display:
 - shall be able to display qualitative findings in the context of the image with which they are associated
 - shall be able to display qualitative findings in the context of the locations or regions with which they are associated, when the latter is activated for superimposed display,
 - regardless of whether the location or region encodings are coordinate, contour, or pixel/voxel-based
 - shall be able to display not only the concept name of the qualitative findings but also any associated modifiers for the finding or enclosing Measurement Group including but not limited to Finding Site and Finding
- 1295 For qualitative findings that are not associated with an image, location, or region, the Display:
 - shall provide a method for discovering and displaying the qualitative findings; however, the specific presentation details are left to the discretion of the implementation of the Display.

4.136.4.1.3.3 Display of Measurements

- 1300 The Display:
 - shall be able to display measurements in the context of the image with which they are associated
 - shall be able to display measurements in the context of the locations or regions with which they are associated, when the latter is activated for superimposed display, regardless of whether the location or region encodings are coordinate, contour, or
 - pixel/voxel-based
 - shall be able to display not only the concept name of the qualitative findings but also any associated modifiers for the finding or enclosing Measurement Group including but not limited to Finding Site and Finding
- 1310 Displays should be prepared for a degree of variety in the measurement codes they receive and the patterns of pre-coordination and post-coordination used. See RAD TF-3: 6.5.3.3.

4.136.4.1.3.4 Display of Locations

The Display:

• shall be able to display point locations as a marker on the referenced image

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- shall be able to display line locations as graphics on the referenced image
 - shall be able to display the concept name of the location and any associated modifiers for the finding or enclosing Measurement Group including but not limited to Finding Site and Finding (e.g., "Lesion, Center")

The following capabilities are not required for conformance, but were described by domain users as potentially useful and may be worth consideration by implementers.

- may be able to display point locations as markers on images other than the referenced image which are in the same Frame of Reference
- may be able to present an MPR (Multi-Planar Reformat) view centered on a selected point location
- 1325 The form in which the location marks are displayed may influence user performance, and hence it may be necessary to display them in a manner prescribed by the vendor that generated the results, which is not encoded in the DICOM object. The form of the location mark rendering is not specified by this transaction.

4.136.4.1.3.5 Display of Regions

- 1330 The Display:
 - shall be able to display each region in a way that the user can see the boundary of the planar or volumetric region
 - shall be able to display each region as either:
 - \circ a shaded or wire frame volume if the Display supports 3D visualization, or
- 1335 a shaded region superimposed on the appropriate images, e.g., with the region colorcoded, or
 - o region contours superimposed on the appropriate images
 - shall be able, when superimposing regions that are encoded as Segmentation instances, to handle
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- different in-plane or cross-plane extent than the underlying images
 - different in-plane or cross-plane sampling rate (Pixel Spacing or Spacing Between Slices) than the underlying images
 - shall be able to display Segmentations that are either BINARY or FRACTIONAL (including fractional types of OCCUPANCY or PROBABILITY)
- shall be able to superimpose multiple selected regions
 - shall be able to display the associated region metadata, if available, including:
 - if encoded in an SR instance:

	 the concept name of the location and any associated modifiers for the finding or enclosing Measurement Group including, but not limited to,
1350	 (363698007, SCT, "Finding Site")
	 (121071, DCM, "Finding")
	 if encoded in a Segmentation instance:
	 Tracking ID (0062,0020)
	 Segment Number (0062,0004)
1355	 Segment Label (0062,0005)
	 Segment Description (0062,0006)
	 Segment Algorithm Type (0062,0008)
	 Segmented Property Category Code Sequence (0062,0003)
	 Segmented Property Type Code Sequence (0062,000F)
1360	 Anatomic Region Sequence (0008,2218)
	 Anatomic Region Modifier Sequence (0008,2220)
	• shall allow the user to toggle the display of each region on/off.
	The following capabilities are not required for conformance, but were described by domain users as potentially useful and may be worth consideration by implementers.
1365	• may be able to display a group of related regions in the same view
	• may be able to generate a volumetric view of the region(s) embedded in the images to which they apply
1370	• may be able to superimpose a region with a different orientation (e.g., Image Orientation (Patient)) than the underlying images (note that Creators may be configurable to produce segmentations that are aligned with the underlying data)
	• may be able to apply a Volumetric Presentation State, if present, to the rendering of the region.
	Note: An ROI that is encoded in an SR with a reference to a Segmentation may have information duplicated in the SR and

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Segmentation metadata, e.g., the same value for Finding Site in the SR as in Anatomic Region Sequence, or the same value in the Segmented Property Type Code Sequence as the Finding. In such cases the Display may omit the separate display of duplicate information.

4.136.4.1.3.6 Display of Parametric Maps

The Display:

• shall be able to display a parametric map alone as a color image

- shall be able to identify corresponding images from which a parametric map was derived, as identified in the Source Image Sequence (0008,2112) of the Derivation Image Sequence (0008,9124)
 - shall be able to display the meanings of the name-value pairs of the items of Quantity Definition Sequence (0040,9220), including but not limited to the value of (246205007, SCT, "Quantity")
 - shall be able to display the meaning of the units from Measurement Units Code Sequence (0040,08EA)
 - shall be able to display the values of LUT Label (0040,9210) and LUT Explanation (0028,3003) if Quantity Definition Sequence is absent or empty
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- shall be able to display a parametric map superimposed on appropriate underlying images in a manner that is functionally equivalent to the pipeline defined in DICOM <u>PS3.4</u> <u>Section N.2.4</u>.
 - shall allow the user to control blending parameters of the display
- shall support resampling of one or both datasets as part of the superimposition process (i.e., to handle cases where the extent, Pixel Spacing, and/or Spacing Between Slices differs)

The following capabilities are not required for conformance, but were described by domain users as potentially useful and may be worth consideration by implementers.

- may be able to perform spatial transformations to handle cases where the Parametric Map is not aligned to the axes of the underlying image
- may be able to use instances of DICOM Blending Softcopy Presentation State and/or DICOM Advanced Blending Presentation State and support more advanced blending capabilities such as references to the fused sets of images as well as compositing factors and pseudo-color palettes.
- 1405 Related functionality is also described in the Image Fusion (FUS) Profile.

4.136.4.1.3.7 Display of Tracking Identifiers

The Display:

- shall be able to show the Tracking Identifier for any given result
- shall be able to identify results that relate to the same entity, as indicated by sharing the same value for (112040, DCM, "Tracking Unique Identifier"), or within a single instance sharing the same value for (112039, DCM, "Tracking Identifier")
 - shall be able to associate results that are related to the same entity, e.g., by allowing the user to sequence through them, showing prior and current side-by-side, or listing them in chronological order

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The following capabilities are not required for conformance, but were described by domain users as potentially useful and may be worth consideration by implementers.

- may be able, when the same type of result is identified as relating to the same entity at two different timepoints, to calculate changes, for example the % increase, or the volume doubling time for a tumor
- Note: If such derived values are simply present as additional result primitives, having been pre-calculated by an Evidence Creator, then the Image Display will be able to display them, per the requirements above to display basic findings. The same is true for longitudinal assessments.

4.136.4.1.3.8 Display of Image References

- 1425 The Display:
 - shall be able to display the image(s) referenced by any result unless the SOP Class of the image is unsupported by the Display
 - shall be able to display the image(s) referenced by a Key Object Selection and shall be able to convey the Document Title and the (113012, DCM, "Key Object Description") content item, if present

4.136.4.1.3.9 Display of Result Trees

These display requirements relate to communicating the existence and content of Result Trees.

Display of Result Trees typically occurs in the course of presenting the content of a study for interpretation. The study may contain multiple Result Trees. The method for determining when to display Result Trees, or which Result Trees to display is not constrained.

For a selected Result Tree, the Display:

- shall be able to display the Concept Name and/or the Short Label of the node that is the Root Result of the Result Tree
- shall be able to display the primitive referenced by the node that is the Root Result of the Result Tree
- shall be able to indicate when Child Nodes are available for the node of a displayed result
- shall be able to display the Concept Names and/or the Short Labels of the Child Nodes when prompted by the user
- shall be able to display the primitives referenced by Child Nodes when prompted by the user

When presenting multiple peer results at the same layer, e.g., the volume and solidity assessment for each of a set of lung nodules, it is unconstrained whether they are presented together, e.g., in a table, or individually, e.g., as selected or in sequence. Implementations may want to offer multiple capabilities for use based on configuration and/or user interaction.

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- 1450 The following capabilities are not required for conformance, but were described by domain users as potentially useful and may be worth consideration by implementers.
 - may be able to prefetch (query and retrieve) instances in the Result Tree prior to the user selecting them
 - may be able to indicate to the user the number and type of supporting results available for a given displayed result
 - may be able to allow the user to select a specific supporting result for a displayed result

4.136.5 Protocol Requirements

N/A.

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4.136.6 Security Considerations

1460 This transaction involves presenting DICOM objects that typically constitute personal health information (PHI) to human observers who are typically clinicians. Typical access controls and audit trails in accordance with local policies would be appropriate.

4.136.6.1 Security Audit Considerations

The <u>Radiology Audit Trail Option</u> in the ITI Audit Trail and Node Authentication (ATNA) Profile defines audit requirements for IHE Radiology transactions. See RAD TF-3: 5.1.

4.136.6.2 Display Specific Security Considerations

Since this transaction involves the display of PHI, it may be reasonable for Image Displays to implement typical access controls for patient records, such as logins for users and role-based access policies.

1470 Since this transaction involves parsing datasets generated by other systems, it may be reasonable for Image Displays to implement basic digital hygiene, such as sanitizing datasets to avoid malicious executable scripts that might be executed by a browser-based viewer.

In RAD TF Volume 2: RAD-16 & 45 require no changes (already has Image Display, IM/IA, Imaging Document Consumer).

RAD-18 & RAD-43 require no changes (already have Image Display, IM/IA).

In the WIC TI Supplement, modify Table 4.108.2-1 as shown.

4.108 Store Instances Over the Web [RAD-108]

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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 Evidence Creator				
Role:	Receiver:				
	Receives objects from the Sender				
Actor(s):	The following actors may play the role of Receiver:				
	Image Manager/Archive				

Table 4.108.2-1: Actor Roles

1485 In the WIA TI Supplement, modify the Actor Roles table in both RAD-107 & RAD-129 as shown.

Table 4.(107 and 129).2-1: Actor Roles

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

In the WIA TI Supplement, add SCU keys to Table 4.129.4.1.2-4 as shown.

4.129.4.1.2 Message Semantics

1490

. . .

The Requester shall support all keys required for the SCU as defined in RAD TF-2: Table 4.14-1.

In addition, the Requester shall be capable of using the following attributes as matching key and return key:

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1500

• Issuer of Patient ID (0010,0021)

Note: Issuer of Patient ID is used in conjunction with Patient ID (0010,0010).

• Issuer of Accession Number Sequence (0008,0051)

Note: Issuer of Accession Number Sequence is used in conjunction with Accession Number (0008,0050). Issuer of Accession Number Sequence is useful when the Requester is dealing with multiple domains.

Note: For XDS-I Backend Option related requirements on accession number, see Table 4.129.4.1.3.1.

The Requester may implement one or more of the following sets of matching or return keys for the Query SCU:

Query Key Specifications	Type of objects		
RAD TF-2: Table 4.15-1	Presentation State Objects		
RAD TF-2: Table 4.26-1	DICOM Structured Report Objects		
RAD TF-2: Table 4.30-1	Key Image Notes		
<u>RAD TF-2: Table 4.44-1</u>	Evidence Document Objects		
RAD TF-2: Table 4.137-1	Analysis Result Objects		

Table 4.129.4.1.2-4: Additional SCU Query Keys

1505 In the WIA TI Supplement, add SCP keys to Table 4.129.4.1.3-1 as shown.

4.129.4.1.3 Expected Actions

•••

The Responder shall support all keys required for the SCP as defined in the sections referenced in Table 4.129.4.1.3-1:

1510

Table 4.129.4.1.3-1: SCP Query Keys

Query Key Specifications	Type of objects		
RAD TF-2: Table 4.14-1	Image Objects		
RAD TF-2: Table 4.15-1	Presentation State Objects		
RAD TF-2: Table 4.26-1	DICOM Structured Report Objects		
RAD TF-2: Table 4.30-1	Key Image Notes		
<u>RAD TF-2: Table 4.44-1</u>	Evidence Document Objects		
RAD TF-2: Table 4.137-1	Analysis Result Objects		

Add Section 4.137

4.137 Query Analysis Results [RAD-137]

4.137.1 Scope

1515 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:

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

Table 4.137.2-1: Actor Roles

1520

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.

4.137.3 Referenced Standards

DICOM <u>PS3.4: Annex C</u>: Query/Retrieve Service Class

1525 **4.137.4 Messages**

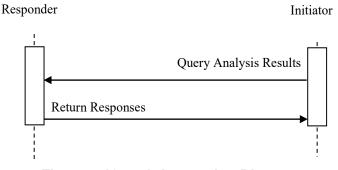


Figure 4.137.4-1: Interaction Diagram

4.137.4.1 Query Analysis Results

The Initiator provides a matching filter in a request for matching analysis results that are available on the Requester.

The Responder shall support handling such messages from more than one Initiator. The Initiator shall support making requests to more than one Responder.

4.137.4.1.1 Trigger Events

A user or an automated function on the Initiator needs information about analysis results available on the Responder.

Typically, the Initiator intends to subsequently retrieve appropriate matching instances.

4.137.4.1.2 Message Semantics

The message is a DICOM C-FIND request of the Query/Retrieve SOP Classes (Study Root – FIND and optionally Patient Root – FIND). The Initiator is the SCU, and the Responder is the SCP.

The Initiator shall send a C-FIND Request from the Study Root Query/Retrieve Information Model – FIND SOP Class or the Patient Root Query/Retrieve Information Model – FIND SOP Class to the Responder.

The Initiator uses one or more matching keys as filter criteria to obtain the list of matching entries in the Responder at the selected level (Patient & Study/Series/Instance).

In addition to the required and unique keys defined by the DICOM Standard, the IHE Radiology Technical Framework has defined matching and return keys to be supported by query SCUs and SCPs. The conventions for key usage are defined in RAD TF-2: 2.2.

The Initiator (SCU) and the Responder (SCP) shall support the following:

• keys identified as required in Table 4.14-1 (Query Images)

- keys identified as required in Table 4.44-1 (Query Evidence Documents)
- keys identified as required in Table 4.137-1 (Query Analysis Results)

Notes: 1. Some of the attributes listed below are indicated as being specific to particular types of instances and the SCP is not required to return those attributes for other types of instances. E.g., attributes under "Segmentation Specific – Instance Level" are only required to be returned for Segmentation instances.

2. The attributes in RAD TF-2: Table 4.44-1 specifically target SR instances, including the Template Identifier (0040,DB00) which will be useful for finding instances using TID 1500. Per DICOM, the value Template Identifier is a string of digits, without leading zeroes, and does not include the string "TID", so for TID 1500 it will be "1500".

Attribute Name	Тад	Query Key	Query Keys Matching		vs Return
		SCU	SCP	SCU	SCP
General Analysis Result Specific - Insta	ince Level				
Anatomic Region Sequence	(0008,2218)	0	0	R+	R+
>Anatomic Region Modifier Sequence	(0008,2220)	0	0	R+	R+
Primary Anatomic Structure Sequence	(0008,2228)	0	0	R+	R+
>Primary Anatomic Structure Modifier Sequence	(0008,2230)	0	0	R+	R+
Image Laterality	(0020,0062)	0	0	R+	R+
Image Type	(0008,0008)	0	0	0	R+
Series Description Code Sequence	(0008,103F)	0	0	0	R+
Contributing Equipment Sequence	(0018,A001)	0	0	0	R+
>Manufacturer	(0008,0070)	0	0	0	R+
>Manufacturer's Model Name	(0008,1090)	0	0	0	R+
>Software Versions	(0018,1020)	0	0	0	R+
>Device UID	(0018,1002)	0	0	0	R+
Segmentation Specific - Instance Level			·		
Segment Sequence	(0062,0002)	0	0	0	R+
>Segment Number	(0062,0004)	0	0	0	R+
>Segment Label	(0062,0005)	0	0	0	R+
>Segment Description	(0062,0006)	0	0	0	R+
>Segment Algorithm Type	(0062,0008)	0	0	0	R+
>Segmented Property Category Code Sequence	(0062,0003)	0	0	R+	R+
>Segmented Property Type Code Sequence	(0062,000F)	0	0	R+	R+
>Tracking ID	(0062,0020)	0	0	R+	R+
>Tracking UID	(0062,0021)	0	0	R+*	R+
Parametric Map Specific - Instance Lev	vel	•	•		•
Quantity Definition Sequence	(0040,9220)	0	0	0	R+

Table 4.137-1: Analysis Result Instance Specific Query Matching and Return Keys

1560 **4.137.4.1.3 Expected Actions**

The Responder shall accept and process the request. This involves parsing the matching key values provided by the Initiator, using those to determine matching analysis result instances, and composing response entries, containing the requested return keys, for return to the Initiator in the Return Responses message.

1565 **4.137.4.2 Return Responses**

The Responder sends matching entries back to the Initiator.

4.137.4.2.1 Trigger Events

The Responder receives a Query Analysis Results message.

4.137.4.2.2 Message Semantics

1570 The message is a DICOM C-FIND response of the Query/Retrieve SOP Classes (Study Root – FIND and optionally Patient Root – FIND). The Initiator is the SCU, and the Responder is the SCP.

4.137.5 Protocol Requirements

N/A.

1575 4.137.6 Security Considerations

The patient demographics and clinical record details returned in the response, and potentially matching details contained in the query, typically constitute personal health information.

4.137.6.1 Security Audit Considerations

This transaction is associated with a Query Information ATNA Trigger Event.

1580 The <u>Radiology Audit Trail Option</u> in the ITI Audit Trail and Node Authentication (ATNA) Profile defines audit requirements for IHE Radiology transactions. See RAD TF-3: 5.1.

In RAD TF Volume 2: Modify RAD-14 as shown (Add Image Document Consumer; already has Image Display, IM/IA)

1585 In 11 places in 4.14.4, replace Image Display with Initiator

In 9 places in 4.14.4, replace Image Archive or Image Manager or Image Manager/Archive with Responder

4.14 Query Images [RAD-14]

4.14.1 Scope

1590 The <u>InitiatorImage Display</u> queries the <u>ResponderImage Archive</u> for study, series and image instances for retrieval.

4.14.2 Actor Roles

Actor: Image Archive

Role: Responds to queries for Studies, Series, and Images.

1595 Actor: Image Display

Role: Issues Queries for Studies, Series, Images

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

Role:	<u>Initiator:</u>
	Issues queries for Studies, Series, Images
Actor(s):	The following actors may play the role of Initiator:
	Image Display
	Imaging Document Consumer
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

Table 4.14.2-1: Actor Roles

1600 <u>Transaction text specifies behavior for each role. The behavior of specific actors may also</u> <u>be specified when it goes beyond that of the general role.</u>

In RAD TF Volume 2: Modify RAD-44 as shown (Add Image Document Consumer; already has Image Display, IM/IA)

Since RAD-137 points the Image Document Consumer to RAD-44, it is better if IDC is formally mentioned.

1605

4.44 Query Evidence Documents [RAD-44]

4.44.1 Scope

This section describes the sequence of transactions required for the Image Display to quer<u>iesy the Image Archive</u> for instances of Evidence Documents.

1610 **4.44.2 Use Case Roles**

Actor: Image Display

Role: Query for Evidence Documents objects (generally in order to retrieve them).

Actor: Image Archive

Role: Respond to queries from the Image Display for Evidence Documents objects.

1615 <u>The roles in this transaction are defined in the following table and may be played by the actors shown here:</u>

Role:	<u>Initiator:</u>
	<u>Queries for Evidence Documents objects (generally in order to</u> <u>retrieve them)</u>
Actor(s):	The following actors may play the role of Initiator:
	Image Display
	Imaging Document Consumer
Role:	Responder:
	Returns Evidence Document entries matching the request
Actor(s):	The following actors may play the role of Responder:
	Image Manager / Image Archive

Table 4.44.2-1: Actor Roles

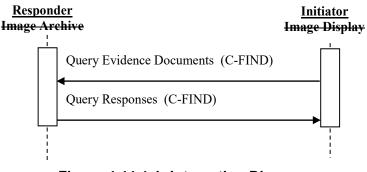
Transaction text specifies behavior for each role. The behavior of specific actors may also be specified when it goes beyond that of the general role.

1620

4.44.3 Referenced Standards

DICOM <u>PS3.4 Annex C</u>: Query/Retrieve Service Class

4.44.4 Messages



1625

Figure 4.44.4-1: Interaction Diagram

4.44.4.1 Query Evidence Documents

The Query (Study Root – FIND and optionally Patient Root – FIND) SOP Classes shall be supported. Refer to DICOM PS3.4: Query/Retrieve Service Class for detailed descriptive semantics.

1630 **4.44.4.1.1 Trigger Events**

Image Display The Requester needs to obtain information about Evidence Documents.

4.44.4.1.2 Message Semantics

The message semantics are defined by the DICOM Query/Retrieve SOP Classes.

The Initiator shall send aA C-FIND Request from the DICOM Study Root Query/Retrieve1635Information Model – FIND SOP Class or the DICOM Patient Root Query/Retrieve Information
Model – FIND SOP Class shall be sent from the Image Display to the ResponderImage
Archive.

The <u>InitiatorImage Display</u> uses one or more matching keys as filter criteria to obtain the list of matching entries in the <u>ResponderImage Archive</u> at the selected level (Patient & Study/Series/Instance)

1640 Study/Series/Instance).

In addition to the required and unique keys defined by the DICOM Standard, the IHE Radiology Technical Framework has defined matching and return keys to be supported by query SCUs and SCPs. The keys are defined in RAD TF-2: 4.14.4.1.2 and Table 4.14-1. The conventions for key usage are defined in RAD TF-2: 2.2. For the **InitiatorImage Display** (SCU) and the

1645 **<u>ResponderImage Archive</u>** (SCP) the additional Evidence Document Instances specific keys are defined in Table 4.44-1.

Attribute Name	Tag	Query Key	Query Keys Matching		Query Keys Return	
		SCU	SCP	SCU	SCP	
Evidence Document Instance Sp	pecific Level	-				
Content Date	(0008,0023)	0	0	0	R+	
Content Time	(0008,0033)	0	0	0	R+	
Referenced Request Sequence	(0040,A370)					
>Study Instance UID	(0020,000D)	0	0	R+*	R+	
>Accession Number	(0008,0050)	0	0	R+	R+	
>Requested Procedure ID	(0040,1001)	0	0	R+	R+	
>Requested Procedure Code Sequence	(0032,1064)					
>>Code Value	(0008,0100)	0	0	0	R+	
>>Coding Scheme Designator	(0008,0102)	0	0	0	R+	
>>Coding Scheme Version	(0008,0103)	0	0	0	R+	
>>Code Meaning	(0008,0104)	0	0	0	R+	
Content Template Sequence	(0040,A504)					
>Template Identifier	(0040,DB00)	0	0	R+	R+	
Concept Name Code Sequence	(0040,A043)					
>Code Value	(0008,0100)	0	0	R+*	R+	
>Coding Scheme Designator	(0008,0102)	0	0	R+*	R+	
>Coding Scheme Version	(0008,0103)	0	0	0	R+	
>Code Meaning	(0008,0104)	0	0	R+	R+	

Table 4.44-1: Evidence Document Instance	Specific Query Matching and Return Keys

4.44.4.1.3 Expected Actions

The <u>ResponderImage Archive</u> receives the C-FIND request, performs the matching on the provided keys and sends the list of matching records back to the <u>InitiatorImage Display</u> via C-FIND responses.

The <u>Initiator</u>Hmage Display is expected to use the Template ID to select Evidence Documents for retrieval that it supports.

4.44.4.1.3.1 Mammography Image Profile

1655 <u>InitiatorImage Display</u> and <u>ResponderImage Manager/Image Archive</u> actors supporting the Mammography Image Profile shall support the Mammography CAD SR SOP Class.

Volume 2x – Appendices

No new Volume 2x appendices

1660

Volume 3 – Content Modules

Add a new section as shown

4.3.2.2 Codes for the AIR Profile

1665 The following codes have been defined for the AIR Profile and extensions. 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 AIR Profile to Final Text.

Code	codeScheme	Code Meaning	Definition	Reference
IHERADAIR1	99IHE	Result Tree Template 1	This is a template identifier (TID) for a private SR template defined by the AIR Profile for constructing the root of a Result Tree.	RAD TF-3: 6.5.3.9.1
IHERADAIR2	99IHE	Result Tree Template 2	This is a template identifier (TID) for a private SR template defined by the AIR Profile for constructing a node in a Result Tree.	RAD TF-3: 6.5.3.9.2
AIR003	99IHE	Root Result	A result that is the root of a result tree.	RAD TF-3: 6.5.3.9.1
AIR004	99IHE	Child Node	A node in a tree that is a direct child of another (parent) node.	RAD TF-3: 6.5.3.9.2
AIR005	99IHE	Referenced Observation UID	The value of Observation UID for a specific Content Item in a Structured Report Instance.	
AIR032	99IHE	Qualitative Finding	A result that is a qualitative finding.	RAD TF-3: 6.5.3.2
AIR033	99IHE	Measurement	A result that is a measurement.	RAD TF-3: 6.5.3.3
AIR034	99IHE	Location	A result that is a spatial location. It may be a point or line.	RAD TF-3: 6.5.3.4
AIR035	99IHE	Region	A result that is a spatial region. It may be a planar or volumetric region.	RAD TF-3: 6.5.3.5
AIR036	99IHE	Parametric Map	A result that is a parametric map. This may be a saliency map which may have a subordinate image reference result on which it may be overlaid.	RAD TF-3: 6.5.3.6
AIR037	99IHE	Tracking Identifier	A result that is a tracking identifier.	RAD TF-3: 6.5.3.7

Table 4.3.2.2-1: AIR Codes

Code	codeScheme	Code Meaning	Definition	Reference
AIR038	99IHE	Image Reference	A result that is an image reference.	RAD TF-3: 6.5.3.8
AIR101	99IHE	Result Tree	A set of results organized as a tree to facilitate navigation of the set.	
AIR102	99IHE	Abdominal Aortic Aneurysm Assessment	An assessment of potential Abdominal Aortic Aneurysm(s)	
AIR103	99IHE	Breast Lesion Assessment	An assessment of potential Breast Lesion(s)	
AIR104	99IHE	Cardiomegaly Assessment	An assessment of potential Cardiomegaly	
AIR105	99IHE	Coronary Plaque Assessment	An assessment of potential Coronary Plaque	
AIR106	99IHE	COVID-19 Assessment	An assessment of potential COVID-19	
AIR107	99IHE	Endotracheal Tube Assessment	An assessment of potential Endotracheal Tube(s)	
AIR108	99IHE	Liver Lesion Assessment	An assessment of potential Liver Lesion(s)	
AIR109	99IHE	Pleural Effusion Assessment	An assessment of potential Pleural Effusion(s)	
AIR110	99IHE	Pneumonia Assessment	An assessment of potential Pneumonia	
AIR111	99IHE	Pneumothorax Assessment	An assessment of potential Pneumothorax	
AIR112	99IHE	Prostate Lesion Assessment	An assessment of potential Prostate Lesion(s)	
AIR113	99IHE	Pulmonary Embolism Assessment	An assessment of potential Pulmonary Embolism(s)	
AIR114	99IHE	Pulmonary Nodule Assessment	An assessment of potential Pulmonary Nodule(s)	
AIR115	99IHE	Rib Fracture Assessment	An assessment of potential Rib Fracture(s)	
AIR116	99IHE	Scoliosis Assessment	An assessment of potential Scoliosis	
AIR117	99IHE	Vertebra Assessment	An assessment of potential Vertebra issues	

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Note: If the templates are adopted by DICOM, the alphanumeric TID codes will be retired and DICOM numeric TIDs will be used instead.

Add the following rows to RAD TF-3: Table 5.1-2

5.1 ITI-20 Record Audit Event

Table 5.1-2: IHE Radiology	transactions and real	sulting ATNA	triaaer events

IHE Radiology Transaction	ATNA Trigger Event(s)	Actor(s) that shall be able to record audit event
Patient Registration [RAD-1]	Patient-record-event	
Display Analysis Result [RAD-136]	Study-used	Image Display
Query Analysis Results [RAD-137]	Query Information	Image Display
		Image Document Consumer

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Add the following new sections to RAD TF-3 Section 6 IHE Radiology Content Specifications.

6.5 Imaging Analysis Result Content

6.5.1 Scope

This IHE Radiology Content Specification defines standard encodings for the results of medical imaging data analysis. It is specifically intended to cover the output of artificial intelligence algorithms but can also address the results of more conventional analysis software and can also be used for human-generated results.

The specification abstracts imaging analysis results as being composed from a set of primitives. Creators of such results are required, in Section 6.5.3, to be able to encode each primitive using specified DICOM IODs. When the results of a given analysis involve multiple primitives, the primitives may be encoded individually in separate instances of the specified IOD, but in many cases it will make sense to encode multiple primitives together in the same instance; e.g., multiple related measurements in a single SR instance.

The set of primitives is comprised of the following:

Qualitative Findings

1690 This primitive is a coded concept name paired with a coded or text value. This structure is common in SR instances. A qualitative finding may or may not reference a specific location or region.

Algorithms might use this for results like flagging presence/absence of a particular finding, categorizing structures in an image, staging pathologies, etc.

- 1695 Examples of SR Concept-Value encoding include:
 - (121071, DCM, "Finding") = (36118008, SCT, "Pneumothorax")

- (373572006, SCT, "Clinical finding absent") = (23360400, SCT, "Pneumonia")
- (129715009, SCT, "Breast composition") = (129719003, SCT, "Extremely Dense")

See RAD TF-1: 49.4.1.4 for a discussion of codesets for concepts and values.

1700 Notes: 1. Whether "Score" findings are qualitative or measurements depends on the semantics. Scores that are rankings using discrete categorizations with specific criteria, like a BI-RADS Score, would be considered qualitative findings and use coded values, while scores that are numerical values on a continuum, like a pain score from 1-10, would be considered numerical measurement values, sometimes with no units.

2. Methods of encoding negative findings is an area of ongoing investigation. Additional guidance will be provided when it becomes available. See also RAD TF-1: 49.4.1.6.

Measurements

This primitive is a structure containing a coded concept paired with one or more numerical values and associated details like measurement units, etc. This structure is common in SR instances. A measurement may or may not be based on a specific location or region.

1710 Algorithms might use this for results like measured tumor sizes, blood flow rates, etc.

Examples include:

- (81827009, SCT, "Diameter") = "26.43","mm"; where (363698007, SCT, "Finding Site") = (54247002, SCT, "Ascending Aorta")
- 1715

1705

- (410668003, SCT, "Length") = "52", "mm"; where
 (121071, DCM, "Finding") = (27925004, SCT, "Nodule") and
 (363698007, SCT, "Finding Site") = (23451007, SCT, "Adrenal Gland")
 - (285285000, SCT, "Cobb Angle") = "18.4", "deg"; where
 (363698007, SCT, "Finding Site") = (122495006, SCT, "Thoracic spine")
- 1720 Note: Other details about the Cobb Angle measurement, like the specific vertebra selected to derive the Cobb Angle and whether the top or bottom surface was chosen, might be encoded as additional subordinate results.

Locations

This primitive is a spatial location, in the form of coordinates for a point or a line. The coordinates are typically expressed in an imaging coordinate system in the frame of reference of an imaging dataset. The coordinates may be within a single "slice" (2D) or within an imaged volume (3D).

1725 volume (3D).

Algorithms might use this for results like the location of a tumor or calcification, a spatial fiducial point, or the tip of a needle or tube.

Regions

The primitive is a planar or volumetric region of an imaging dataset.

1730 Algorithms might use this for results like classifying the type of tissue in different pixels/voxels, or defining the boundary of a particular organ, or encoding a bounding box showing the rough location or extent of an intracranial bleed, or encoding an arbitrary region within which a metric

like average density has been calculated. Semantically, a single region can consist of multiple discontiguous parts.

1735 Parametric Maps

This primitive is a set of 2D (or 3D) pixels (or voxels) that are image-like but the values encode a "parameter" such as a physical quantity or quantitative model parameter.

Algorithms might use this for results such as visual explanations (e.g., a "saliency map", showing which parts of a source image influenced the algorithms decision), or quantitative

- 1740 analysis (showing calculated values like brain perfusion, apparent diffusion coefficients (ADC), or the parameters of a dynamic contrast model.
 - Note: Tissue classifications may be more appropriately handled as segmentations. Similarly, a probabilistic classification (showing for each pixel the probability it contains malignant cells, or the probability the voxel is part of a hemorrhage) is best encoded as a segmentation, using the FRACTIONAL Segmentation Type.

1745 *Tracking Identifiers*

This primitive is an identification of a persistent entity in the form of a unique identifier.

Algorithms might use unique identifiers to designate the same lesion or tumor in a specific patient in each of a longitudinal set of studies over time. A display might use the corresponding human-readable identifier to communicate this to a user. Longitudinal analysis and evaluation of

1750 change are facilitated when the same Tracking Identifier is associated with other primitives like location coordinates, measurements, or qualitative findings (like tumor stage or therapeutic response).

Image References

This primitive is a reference to one or more image instances, in the form of an instance UID.When there is a need to be more specific for a multi-frame instance, the reference may include frame information.

Algorithms are also expected to commonly reference the "input" image that was analyzed; however, that is expected to be part of the result metadata, rather than the result "payload".

Note: The use of the word "image" in this section is intended to mean both a single-frame image IOD and a specific frame of a multi-frame image IOD.

Result Tree

1760

When a study contains multiple related primitives, a Result Tree may be used to encode a hierarchical relationship between the primitives.

This content is a directed acyclic graph that identifies one referenced result primitive as the root of the tree, and references other primitives as directly supporting the root. Further result primitives can be referenced below those supporting results, and so on.

The tree is intended to allow displays and other result consumers to be able to present a potentially large set of result primitives in a rational fashion without needing to understand the nature of all the potential sets of results that various algorithms could generate.

1770 The tree might be encoded by the software that created the set of results, or by another piece of software sophisticated enough to work out an appropriate hierarchy.

6.5.2 Referenced Standards

- DICOM <u>PS3.3: A.35.1</u> Basic Text SR IOD
- DICOM <u>PS3.3: A.35.4</u> Key Object Selection Document IOD
- DICOM <u>PS3.3: A.35.13</u> Comprehensive 3D SR IOD
 - DICOM <u>PS3.16: TID 1500</u> Measurement Report
 - DICOM <u>PS3.3: A.51</u> Segmentation IOD
 - DICOM <u>PS3.3: A.75</u> Parametric Map IOD

6.5.3 Analysis Result Encodings

1780 Creators of imaging analysis results shall be capable of encoding them as described in this section. The general requirements in Section 6.5.3.1 apply to the encoding of all of the primitives described in the subsequent sections.

The encodings make use of the following SOP Classes:

- Comprehensive 3D SR Storage (1.2.840.10008.5.1.4.1.1.88.34)
- Segmentation Storage (1.2.840.10008.5.1.4.1.1.66.4)
 - Parametric Map Storage (1.2.840.10008.5.1.4.1.1.30)
 - Key Object Selection Document Storage (1.2.840.10008.5.1.4.1.1.88.59)

The correspondence between Primitives and the IODs used for encoding is summarized in Table 6.5.3-1.

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Table 6.5.3-1: Primitives & Encoding IODs

	Ũ			
	SR IOD (TID 1500)	Segmentation IOD	Parametric Map IOD	Key Object Selection Document IOD
Qualitative Findings	Х			
Measurements	Х			
Locations	Х			
Regions	Х	х		
Tracking Identifiers	Х	х		
Parametric Maps			Х	
Image References	Х	Х	Х	Х

Notes: 1. For extensive specific guidance on topics such as encoding planar measurements and finding-related coordinates in SR, it is strongly recommended that readers refer to: Clunie, D., DICOM SR for communicating planar annotations, An Imaging Data Commons (IDC) White Paper, 2019 https://docs.google.com/document/d/1bR6m7foTCzofoZKeIRN5YreBrkjgMcBfNA7r9wXEGR4/edit?usp=sharing

6.5.3.1 General Result Encoding Requirements 1795

The Creator is expected to populate much of the contextual metadata (e.g., patient demographics, patient identifiers and issuers, study accession number, etc.) in the result instances based on those values in the medical imaging data being processed, and/or the UPS Workitem (if the Creator is being driven by the AI Workflow for Imaging Profile).

1800 Per DICOM, the attributes of the General Equipment Module describe the overall equipment that created the result instance (i.e., the Creator as a whole, not individual subcomponents or algorithms).

The Creator shall describe each algorithm that was used to generate the results in the Contributing Equipment Sequence (0018,A001). Multiple items may be included. The Creator shall encode the following details in the Contributing Equipment Sequence:

- Purpose of Reference Code Sequence (0040,A170) shall be (109102, DCM, "Processing Equipment")
- Manufacturer (0008,0070)
- Manufacturer's Model Name (0008,1090) ٠
- 1810 Software Versions (0018,1020) •
 - Device UID (0018,1002) •

Note: For algorithms that include a human operator, the identity of the user can be encoded in the Operators' Name (0008,1070) attribute or the Operator Identification Sequence (0008,1072).

Device UID is used to identify an instance of a contributing piece of software more specifically 1815 than a release version does, i.e., something akin to a serial number. Therefore, each time the algorithm is updated, a new Device UID value would be appropriate.

In SR instances, when an algorithm is identified in the SR Tree (typically in TID 4019 and/or TID 1004) it will also be identified in the Contributing Equipment Sequence (0018,A001). The content items, if present, shall contain the same value as the corresponding attribute shown in Table 6.5.3.1-1.

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Table 6.5.3.1-1: Corresponding Algorithm Identification Attributes and Content Items

Contributing	Device Observer	Algorithm Identification	Algorithm
Equipment	Content Item	Content Item	Identification
Sequence Attribute	(TID 1004)	(TID 4019)	Sequence Attribute
Manufacturer	(121014, DCM, "Device		Algorithm Source
(0008,0070)	Observer Manufacturer")		(0024,0202)

Contributing	Device Observer	Algorithm Identification	Algorithm
Equipment	Content Item	Content Item	Identification
Sequence Attribute	(TID 1004)	(TID 4019)	Sequence Attribute
Manufacturer's Model	(121015, DCM, "Device	(111001, DCM, "Algorithm	Algorithm Name
Name (0008,1090)	Observer Model Name")	Name")	(0066,0036)
Software Versions		(111003, DCM, "Algorithm	Algorithm Version
(0018,1020)		Version")	(0066,0031)
Device UID (0018,1002)	(121012, DCM, "Device Observer UID")		

In some non-SR instances, algorithms used for specific purposes are identified in a sequence that includes the Algorithm Identification Macro; for example, the Segmentation Algorithm Identification Sequence (0062,0007) in a Segmentation Image object or the Tracking Algorithm Identification Sequence (0066,0104) in an MR Tractography Results object.

The Author Observer Sequence (0040,A078) is not usually included in machine generated reports in which that information is the same as in the General Equipment Module (i.e., the authoring device is also the recording device).

DICOM SR Guidance

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- 1830 Content Date (0008,0023) and Content Time (0008,0033) are defined to be the date and time that the document content creation started. In the context of analysis results, these may be considered to be the date and time that the analysis that generated the result(s) started executing. They are distinct from the Instance Creation Date (0008,0012) and Instance Creation Time (0008,0013), if present which may be some time later.
- 1835 As an inherent part of the SR Content Tree encoding, each Content Item may have an Observation UID (0040,A171). Observation UIDs may be used to reference specific findings from another instance.

The Creator shall populate the Observation UID (0040,A171) of the corresponding Content Item for each primitive, i.e.:

- For Qualitative Findings, the corresponding finding Content Item (which may or may not have a Concept Name of (121071, DCM, "Finding"))
 - For Measurements, the corresponding NUM Content Item
 - For Locations, the corresponding SCOORD or SCOORD3D Content Item
 - For planar contour-based Regions, the corresponding SCOORD or SCOORD3D Content Item
 - For volumetric contour-based Regions, each of the corresponding SCOORD or SCOORD3D Content Items (using the same Observation UID, which represents the observation of the composite volume).

• For Tracking Identifiers, the corresponding Tracking Identifier or Tracking Unique Identifier Content Item. If both are present, populate the Observation UID of one, not both.

Notes: 1. A Tracking Unique Identifier uniquely identifies the entity that is the subject of an observation (e.g., this patient's aortic valve, or a specific lesion), while an Observation UID uniquely identifies the observation itself (e.g., a diameter measurement of that entity taken today at 2pm). So, a number of observations of the same entity will all have different Observation UIDs but the same Tracking Unique Identifier.

2. DICOM has published Supplement 219 (JSON Representation of DICOM Structured Reports) as a Frozen Draft for Trial Use and Comment. (https://www.dicomstandard.org/supplements). It specifies a simplified JSON representation of the content of a DICOM Structured Reporting instance. The intention is to allow developers to encode image-derived results, in particular, measurements and annotations that might be generated by artificial intelligence (AI), machine learning (ML) and quantitative imaging (QI). The approach is applicable to both export of AI/ML results and also to encoding of truth data for AI/ML training, testing, and validation. Implementers are encouraged to experiment with the encoding and provide feedback.

Frame of Reference (FoR) Guidance

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DICOM instances that encode spatial information typically include a Frame of Reference UID (0020,0052) that identifies the origin and coordinate system of coordinates in the instance (without specifically defining that origin and coordinate system). When two instances share the same Frame of Reference UID, coordinates in the two instances are nominally in the same coordinate space.

- Creators are strongly encouraged to use shared Frame of Reference UIDs whenever appropriate to avoid placing the burden on downstream systems of performing otherwise unnecessary registrations and transformations. Since the coordinate systems are typically patient-relative, any change of the patient position or use of a different device would result in a new Frame of Reference UID.
- 1875 Note: Some DICOM Image IODs (like CR images or Ultrasound images) do not necessarily contain a Frame of Reference UID. If DICOM Segmentation IODs are created for such images, the segmentation pixels are required by DICOM to correspond directly to the pixels of the segmented image. In that situation, the segmentation and the image are implicitly in the same Frame of Reference, and if the DICOM Segmentation IOD declares a Frame of Reference UID, the image may then be assumed to be in the same Frame of Reference.

6.5.3.2 Qualitative Findings

1880 Qualitative findings shall be encoded in an instance of the DICOM Comprehensive 3D SR SOP Class using <u>TID 1500</u> (Measurement Report) as the root template.

The value for Procedure Reported (121058, DCM, "Procedure reported") shall describe the imaging procedure analyzed, not the algorithm used.

Depending on whether the qualitative findings refer to a planar region of an image, a volume, or does not refer to any imaging, the root template will contain, respectively, <u>TID 1410</u> (Planar ROI Measurement and Qualitative Evaluations), <u>TID 1411</u> (Volumetric ROI Measurement and Qualitative Evaluations), or <u>TID 1501</u> (Measurement and Qualitative Evaluations). The CONTAINER for (C0034375, UMLS, "Qualitative Evaluations") in TID 1500 shall not be used, as those can be encoded in <u>TID 1501</u>.

1890 Notes: 1. A qualitative finding that refers to an entire image may be encoded using TID 1501 with an IMAGE reference without spatial coordinates. See also DICOM CP 1999.

2. TID 1411 supports encoding a simple ellipsoid Volume Surface, or a set of isocontours, that may be used to define a bounding region around an entity such as a tumor without precisely delineating its surface. In such cases a (130400, DCM, "Geometric purpose of region") = (75958009, SCT, "Bounded by") modifier is appropriate.

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3. Details about the patient condition that represent the context of other observations rather than being observations themselves are best encoded as Observation Context rather than analysis results.

Image references for qualitative evaluations in TID 1410 (Row 6 or 8) and 1411 (Row 6, 11, or 12) are mandated by DICOM for the ROIs that are the basis of the qualitative finding(s).

Image references, if any, for qualitative evaluations in TID 1501 are encoded in Rows 10b-10e.

1900 If multiple qualitative findings apply to the same entity (see Section 6.5.3.7 "Tracking Identifiers"), those findings may be encoded in a single invocation of TID 1501, TID 1410, or TID 1411.

A single SR instance may contain multiple invocations of multiple sub-templates (TID 1501, TID 1410, and TID 1411).

1905 Implementations shall encode simple negative findings using a negative finding concept. For example:

(373572006, SCT, "Clinical finding absent") = (23360400, SCT, "Pneumonia")

TID 1501, TID 1410, and TID 1411 are extensible, permitting (373572006, SCT, "Clinical finding absent") to be used in places where (121071, DCM, "Finding") appears. See also RAD TF-1:49.4.6 Negative and Partial Findings.

Implementations are encouraged to encode anatomical locations for qualitative findings using the Finding Site concept. This can be useful to help refine, organize and database the findings. For example:

(121071, DCM, "Finding") = (55584005, SCT, "Embolism")

(363698007, SCT, "Finding Site") = (39607008, SCT, "Lung")

While it is also possible to use

(121071, DCM, "Finding") = (59282003, SCT, "Pulmonary embolism"),

the Finding Site gives greater flexibility, such as,

(121071, DCM, "Finding") = (55584005, SCT, "Embolism")

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(363698007, SCT, "Finding Site") = (45653009, SCT, "Upper lobe of lung")

>(272741003, SCT, "Laterality") = (24028007, SCT, "Right")

or for an intracranial hemorrhage,

(121071, DCM, "Finding") = (50960005, SCT, "Hemorrhage")

(363698007, SCT, "Finding Site") = (78277001, SCT, "Temporal Lobe")

>(272741003, SCT, "Laterality") = (7771000, SCT, "Left")

See also the related discussion at the end of the following Section 6.5.3.3 "Measurements".

6.5.3.3 Measurements

Measurements shall be encoded in an instance of the DICOM Comprehensive 3D SR Storage SOP Class using <u>TID 1500</u> (Measurement Report) as the root template.

1930 Depending on whether the measurements reflect a planar region of an image, a volume, or are measurements that are not tied to a planar region or volume, the root template will contain, respectively, <u>TID 1410</u> (Planar ROI Measurement and Qualitative Evaluations), <u>TID 1411</u> (Volumetric ROI Measurement and Qualitative Evaluations), or <u>TID 1501</u> (Measurement and Qualitative Evaluations).

1935 Notes: 1. A measurement of an entire image may be encoded using TID 1501 with an IMAGE reference without spatial coordinates. See also DICOM CP 1999.

2. TID 1411 supports encoding a simple ellipsoid Volume Surface, which is often used to define a bounding region around an entity such as a tumor without precisely delineating its surface. In such cases a (130400, DCM, "Geometric purpose of region") = (75958009, SCT, "Bounded by") modifier is appropriate. An associated volume measurement would be expected to reflect the volume of the ellipsoid, not the volume of the tumor.

Image references for measurements in TID 1410 (in Row 6 or 8) and 1411 (in Row 6, 11, or 12) are mandated by DICOM for the ROIs that are the basis of the measurements.

Image references, if any, for measurements in TID 1501 are encoded in the invocation of TID 320 "Image or Spatial Coordinates" inside the invocation(s) of TID 300 "Measurement" used to encode the measurements inside TID 1501.

If multiple measurements apply to the same entity (see Section 6.5.3.7 "Tracking Identifiers"), they may be encoded in a single invocation of TID 1501, TID 1410, or TID 1411, i.e., in a single Measurement Group.

The anatomy, if relevant, is encoded in (363698007, SCT, "Finding Site"). See RAD TF-1: 49.4.1.4 for a discussion of codesets for Finding Site.

Note: TID 1501 (in TID 300), and TIDs 1410 and 1411 (in TID 1419), allow the (363698007, SCT, "Finding Site") to be encoded for each measurement, or if common, factored out to the Measurement Group level.

The finding to which a measurement pertains may be encoded in (121071, DCM, "Finding"), e.g., (86049000, SCT, "Neoplasm Primary") or (65818007, SCT, "Stent").

1955 Implementations are encouraged to follow the pattern of encoding the anatomical location in Finding Site, the "pathology" or device, if appropriate, in Finding, and the rest of the semantics into the Concept Name of the measurement. Some examples are shown in Table 6.5.3.3-1. This is particularly useful when multiple measurements or observations are made of the same structure.

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Table 6.5.3.3-1: Measurement Encoding Examples

Finding Site	Finding	Measurement Concept
(54247002, SCT, "Ascending Aorta")	n/a	(81827009, SCT, "Diameter")
(122495006, SCT, "Thoracic spine")	n/a	(285285000, SCT, "Cobb Angle")
(23451007, SCT, "Adrenal Gland")	(27925004, SCT, "Nodule")	(410668003, SCT, "Length")
(64033007, SCT, "Kidney")	(86049000, SCT, "Neoplasm Primary")	(118565006, SCT, "Volume")

Finding Site	Finding	Measurement Concept
(52433000, SCT, "Proximal Circumflex Coronary Artery")	(65818007, SCT, "Stent")	(410668003, SCT, "Length")

Applications may elect to use pre-coordinated codes, if available for specific findings, such as a measurement with a Concept Name of (18043-0, LN, "Left Ventricular Ejection Fraction by US"). Creators should be aware that receiving systems use codes to identify corresponding measurements to populate report fields, populate databases, or use values to drive clinical decision support. The difficulty for receiving systems increases when various Creators use different patterns of pre-coordination and post-coordination that mean the same thing, e.g.:

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- Finding Site = Adrenal Gland, Finding = Nodule, Measurement = Length
- Finding Site = Adrenal Gland, Measurement = Nodule Length
- Finding = Adrenal Gland Nodule, Measurement = Length
- Measurement = Adrenal Gland Nodule Length

The encoding pattern in Table 6.5.3.3-1 is just a recommendation. It is beyond the scope of this Content Specification to constrain all possible encodings. In future, templates that specialize TID 1500 and constrain the choice of codes, may be defined for specific use cases. DICOM PS3.16 already contains many application-specific templates.

1975 **6.5.3.4 Locations**

Point locations and line locations shall be encoded in an instance of the DICOM Comprehensive 3D SR Storage SOP Class using TID 1500 (Measurement Report) as the root template.

If the point location is a 2D point on a single image, the instance shall contain an SCOORD (111030, DCM, "Image Region") of Graphic Type POINT in TID 1501 (Measurement and Qualitative Evaluations).

If the point location is a 3D point, which may or may not be in the plane of a given image, the instance shall contain an SCOORD3D (111030, DCM, "Image Region") of Graphic Type POINT in TID 1501 (Measurement and Qualitative Evaluations). See DICOM CP 1999.

 If the line location is a sequence of 2D points on a single image, the instance shall contain an
 SCOORD (111030, DCM, "Image Region") of Graphic Type POLYLINE in TID 1501 (Measurement and Qualitative Evaluations).

If the line location is a sequence of 3D points in an image volume, the instance shall contain an SCOORD3D (111030, DCM, "Image Region") of Graphic Type POLYLINE in TID 1501 (Measurement and Qualitative Evaluations). See DICOM CP 1999.

1990 Image references for 2D point or line locations are mandated by DICOM in TID 1501 (in Row 10d).

Image references, if any, for 3D point or line locations in TID 1501 can be encoded in the Image Library of TID 1500 that is the parent of the TID 1501.

As described in DICOM, the Frame of Reference for the SCOORD location values is that of the mandatory referenced image (SELECTED FROM). The Frame of Reference for the SCOORD3D location values is encoded within the SCOORD3D content item data structure, and is generally expected to match the Frame of Reference of associated volume data. See the Frame of Reference Guidance in Section 6.5.3.1 for further details.

Locations may or may not be the basis for associated measurements or qualitative findings. If 2000 they are, the location will be encoded in conjunction with the associated measurement or qualitative finding. See Sections 6.5.3.2 and 6.5.3.3.

In addition to, or instead of, spatial coordinates, a location may be expressed in anatomical terms in the (363698007, SCT, "Finding Site") concept as described in Sections 6.5.3.2 and 6.5.3.3.

6.5.3.5 Regions

2005 Both planar regions and volumetric regions may use either contour-based encodings, or pixel/voxel-based encodings. Points and lines are encoded as locations, see Section 6.5.3.4.

Regions may or may not be the basis for associated measurements or qualitative findings. When associated with measurements, contour-based regions will be encoded in conjunction with the associated measurements or qualitative findings in a sub-template of <u>TID 1500</u>, and pixel/voxel-based regions will be referenced from the associated measurement or qualitative finding. See

2010 based regions will be referenced from the associated measurement or qualitative finding. Sections 6.5.3.2 and 6.5.3.3.

It is not necessary to create a region for measurements or qualitative findings of an entire image or series, since the contents of TID 1500 permit referencing the images directly.

Regions associated with an entity may define the surface of the entity, the entire internal volume of the entity, or may be a bounding box or ellipsoid that roughly encompasses the entity. Such semantics are encoded in (130400, DCM, "Geometric purpose of region") in <u>TID 1410</u> or <u>TID</u> <u>1411</u>.

Contour-based Regions

Contour-based regions shall be encoded as an instance of the DICOM Comprehensive 3D SR
 Storage SOP Class using TID 1500 (Measurement Report) as the root template. Planar regions are encoded in TID 1410 (Planar ROI Measurement and Qualitative Evaluations). Volumetric regions are encoded in TID 1411 (Volumetric ROI Measurement and Qualitative Evaluations).

If the contour-based planar or volumetric region is comprised of image-relative (2D) contour(s), the instance shall contain one or more SCOORD (111030, DCM, "Image Region") of Graphic Type POLYLINE, CIRCLE, or ELLIPSE.

If the contour-based planar or volumetric region is comprised of volume-relative (3D) contour(s), the instance shall contain one or more SCOORD3D (111030, DCM, "Image Region") of Graphic Type POLYGON, ELLIPSE, or ELLIPSOID.

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Note: As defined in DICOM, to represent a closed planar polygon using image-relative coordinates, a POLYLINE is encoded with the last vertex the same as the first vertex.

Image references for contour-based regions are mandated by DICOM in TID 1410 (in Row 6 or 8) and TID 1411 (in Row 6, 11, or 12).

Pixel/Voxel-based Regions

Pixel/voxel-based regions shall be encoded as instances of the DICOM Segmentation Storage
 SOP Class. One or more segments (multiple regions, or multiple segments of a single region) may be encoded in a single Segmentation instance. A single region shall not span multiple
 Segmentation instances.

Notes: 1. The DICOM Surface Segmentation Storage SOP Class is not used in this profile.

2040 2. Segmentation instances permit encodings that are binary (i.e., a single bit value defines whether a pixel/voxel is part of the region or not) or fractional (i.e., a scaled integer indicates either the percent probability the pixel/voxel is part of the region, or the fraction of the pixel/voxel that is part of the region).

3. Neither DICOM nor this profile supports label maps, in which a single encoded pixel represents an index into a map of labels for different segments. Instead it is expected that such information will be encoded with a separate bit plane per segment in a Segmentation instance.

4. Segmentation instances may be referenced in the relevant row of the corresponding template when qualitative findings or measurements are based on the pixel/voxel-based region. See Sections 6.5.3.2 and 6.5.3.3.

The Segmentation instances need not cover the same spatial extent nor be sampled at the same rate within plane (i.e., pixel spacing) or between planes (i.e., spacing between slices) as the images being segmented. For example, a Segmentation:

- might only encode frames that span the region of interest (e.g., a particular tumor) and not the entire volume of the images underlying the segmentation (e.g., the chest CT series)
 - might cover a smaller region within each frame, sufficient only to include the region of interest
- might have a Pixel Spacing or a Spacing Between Slices that is smaller (super-sampled) or larger (sub-sampled) compared to the original images

The extent and sampling of the Segmentation are encoded within the attributes of the instance.

The Creator that encodes Segmentations shall be capable of encoding them with the same orientation as the associated image.

2060 Note: This is required because image displays might not be capable of retrieving registration objects and/or perform such transformations. The Creator is not prohibited from encoding Segmentations in different orientations, as long as it can be configured to encode them with the same orientation.

Image references to images underlying Segmentations are recorded in the Source Image Sequence (0008,2112) in the Derivation Image Sequence (0008,9124) with a Purpose of

2065 Reference Code Sequence (0040,A170) value of (121322, DCM, "Source image for image processing operation") and a Derivation Code Sequence (0008,9215) value of (113076, DCM, "Segmentation").

6.5.3.6 Parametric Maps

Parametric Maps shall be encoded in an instance of the DICOM Parametric Map Storage SOP
 Class. For a given parametric map, the pixel values are either all floating point, all double, or all integer.

For Parametric Maps that represent saliency images for a finding (e.g., pneumothorax):

- the instance containing the finding shall reference both the Parametric Map instance, and the associated Image instance to which the finding pertains
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- the use of the (130401, DCM, "Visual explanation") concept in TIDs 1410, 1411, and 1501 for the reference to the Parametric Map is encouraged
- the Parametric Map instance shall use a value of (130404, DCM, "Saliency") for the Concept Name of (246205007, SCT, "Quantity") in the Quantity Definition Sequence (0040,9220)
- 2080 The Parametric Map instances need not cover the same spatial extent nor be sampled at the same rate within plane (i.e., pixel spacing) or between planes (i.e., spacing between slices) as the associated "underlying" images. For example, a Parametric Map:
 - might only encode frames corresponding to some of the associated images (or frames)
 - might cover a region that is smaller or larger than the associated images (or frames)
- might have a Pixel Spacing or a Spacing Between Slices that is smaller (super-sampled) or larger (sub-sampled) compared to the associated images

The extent and sampling of the Parametric Map are encoded within the attributes of the instance.

The Creator shall be capable of encoding the Parametric Map with the same orientation as the underlying image.

- 2090 For Parametric Maps that are intended to be available to overlay on an underlying image (e.g., the associated image from which the parametric map was derived), the Parametric Map shall use the Frame of Reference of the image on which it is intended to be overlaid. While the Creator is required to be able to encode the Parametric Map with the same orientation as the underlying image, it is permitted to have different pixel spacing, so the Image Display will not have to
- 2095 retrieve registration objects and perform transformations but may have to perform resampling. These requirements are intended to facilitate fused display by the Image Display without requiring sophisticated registration capabilities.

Image references to "underlying" images from which a parametric map was derived are encoded in the Source Image Sequence (0008,2112) of the Derivation Image Sequence (0008,9124) with

2100 a Purpose of Reference Code Sequence (0040,A170) value of (121322, DCM, "Source image for image processing operation"). If the parametric map is a saliency map, a Derivation Code Sequence (0008,9215) value of (130404, DCM, "Saliency") would be appropriate.

Blending Presentation State objects and Advanced Blending Presentation State objects may be created to encode fusion overlay parameters preferences, but the Creator should not assume that the Image Display supports those.

6.5.3.7 Tracking Identifiers

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Tracking Identifiers for persistent entities shall, if encoded in instances of DICOM SR Storage SOP Classes, use concept (112039, DCM, "Tracking Identifier") for human readable Tracking Identifiers and concept (112040, DCM, "Tracking Unique Identifier") for globally unique

2110 Tracking Identifiers (UIDs). Such Identifiers allow correlating multiple different observations of the same entity (such as an organ or lesion) when an algorithm is capable of making that determination.

If a measured entity is a known entity (e.g., it is a particular tracked lesion), <u>TID 4108</u> (Tracking Identifier) may be included in the invocation of TID 300 for the measurement and the Tracking
Identifier(s) of the measured entity encoded therein, or the tracking identifier concepts in TIDs 1501, 1411, and 1410 may be used to identify the entity that is the subject of the entire

Notes: 1. If there is a need to track specific observations (the diameter measurement recorded at 2:59pm on Aug 21 of lesion 45837459), each Content Item in the SR tree may have an Observation UID (and an Observation Datetime) associated with it as described in DICOM PS3.3 Table C.17-6.

2. TID is an abbreviation of Template ID in DICOM, not Tracking ID.

3. How Tracking Identifiers are assigned and correlated is not specified here. In some cases, an algorithm may assign them and may be able to inspect prior observations and determine the current entity is the same as the prior and thus it is appropriate to reuse the prior Tracking Identifier. In other cases, Tracking Identifier values may be provided to the algorithm by another system, e.g., as parameters in a workitem, or from an entity correlation service, or by reference to some external resource.

6.5.3.8 Image References

Measurement Group.

Image references that are subordinate to other results (e.g., references to images on which a measurement was taken, or references to the images that were processed to create a segmentation or parametric map) are discussed above in several sub-sections of Section 6.5.3.

Image references that comprise the result itself (for example identifying a relevant prior, or identifying an image that is most representative of an already identified finding) shall be encoded as an instance of the DICOM Key Object Selection Document Storage SOP Class.

Key Object Selection Documents communicate the purpose of the selection in the Document
 Title (i.e., the Concept Name of the root Container in <u>TID 2010</u>), with additional semantics optionally encoded in one or more (113011, DCM, "Document Title Modifier") values.

6.5.3.9 Result Trees

Result Trees shall be encoded in an instance of the DICOM Basic Text SR Storage SOP Class using TID IHERADAIR1 (Result Tree) as the root template.

2140 TID IHERADAIR1 (Result Tree) organizes result primitives by establishing one result as the root of the tree, and allowing each result to reference one or more subordinate results.

The Creator of the Result Tree is responsible for selecting the root result and organizing the nodes in the tree. While results that are direct children are usually those from which the parent result was derived or on which it depends, that is not required to be the case. The hierarchy is a way for the Creator to encode choices that can drive the display.

Ultimately, the tree suggests a pattern of progressive disclosure that is expected to be:

- helpful to a person trying to explore and understand a set of related results
- something a basic viewer can readily traverse and present

These TIDs are considered "private" templates, meaning they are specified by an organization other than DICOM. Accordingly, inside the Content Template Sequence (0040,A504), Mapping Resource (0008,0105) shall have a value of "99IHE" and Template Identifier (0040,DB00) shall have a value of "IHERADAIR1" or "IHERADAIR2" as appropriate.

Note: For TIDs defined by DICOM, the Template Identifier (0040,DB00) is a string of digits, without leading zeroes, and does not include the string "TID".

2155 6.5.3.9.1 TID IHERADAIR1 Result Tree

The Result Tree Template organizes results into a hierarchical tree. One result/finding is designated as the root/primary and may reference a set of other results/findings that are directly subordinate to, or elaborate on, the root result/finding. Referenced results, in turn, may each reference a set of other results.

2160 The tree shall be a directed acyclic graph. The tree shall not reference other trees (i.e., other instances based on TID IHERADAIR1). It is permitted for a given result to be referenced from multiple Result Trees or from multiple nodes in a single Result Tree.

The Template can only be instantiated at the root node and cannot be included in other Templates.

2165 The Template is not extensible; that is, no other Content Items may be added to this Template, or to the Templates that are included, recursively.

Type: Non-Extensible Order:Significant Root: Yes

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Table TID IHERADAIR1: Result Tree

	NL	Rel with Parent	VT	Concept Name	VM	Req Type	Condition	Value Set Constraint
1			CONTAINER	BCID newCID0 "Result Tree Titles"	1	М		Root node
2	>	HAS CONCEPT MOD	INCLUDE	D <u>TID 1204</u> "Language of Content Item and Descendants"	1	U		

	NL	Rel with Parent	VT	Concept Name	VM	Req Type	Condition	Value Set Constraint
3	>	HAS OBS CONTEXT	INCLUDE	D <u>TID 1002</u> "Observer Context"	1 - n	U		
4	>		INCLUDE	DTID IHERADAIR2 "Result Tree Node"	1	М		\$Concept = EV (AIR003, DCM, "Root Result")

Content Item Descriptions

Row 1	The Title may be displayed in selection lists and, as such, is expected to describe the nature of the content of the tree. Beyond newCID0, additional codes may be drawn from the RadElement Set codes at radelement.org. Private codes may also be used. Consider describing the type of assessment that generated the result set.
Row 3	The Observer Context describes the observer that determined the referenced instances comprise a Result Tree. This observer may or may not be the system that generated the instances referenced in the tree.

6.5.3.9.2 TID IHERADAIR2 Result Tree Node

The Tree Node Template references a Result in a Result Tree and optionally includes a subordinate layer of nodes. The referenced Result may have been encoded in one of several types of instance.

Table TID IHERADAIR2: Parameters

Parameter Name	Parameter Usage
\$Concept	Coded term or Context Group indicating the nature of the content referenced by the node. A value of (AIR003, DCM, "Root Result") shall only be used once in a Result Tree.

Type: Non-Extensible Order:Non-Significant Root: No

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Table TID IHERADAIR2: Result Tree Node

	NL	Rel with Parent	VT	Concept Name	VM	Req Type	Condition	Value Set Constraint
1		CONTAINS	TEXT	EV (125309, DCM, "Short Label")	1	М		
2		CONTAINS	CODE	EV (111056, DCM, "Rendering Intent")	1	U		D <u>CID 6034</u> "Intended Use of CAD Output"
3		CONTAINS	COMPOSITE	\$Concept	1	MC	IFF Rows 5 and 6 are absent	
4		CONTAINS	UIDREF	EV (AIR005, DCM, "Referenced Observation UID")	1	МС	IFF Row 3 is present	

	NL	Rel with Parent	VT	Concept Name	VM	Req Type	Condition	Value Set Constraint
5		CONTAINS	IMAGE	\$Concept	1	MC	IFF Rows 3 and 6 are absent	
6		CONTAINS	WAVEFORM	\$Concept	1	MC	IFF Rows 3 and 5 are absent	
7		CONTAINS	CONTAINER	EV (AIR004, DCM, "Child Node")	1-n	U		
8	>		INCLUDE	DTID IHERADAIR2 "Result Tree Node"	1	М		\$Concept = BCID newCID1 "Result Tree Nodes"

Content Item Descriptions

Row 1	This may be used by recipients, such as Image Displays, to help users identify the content referenced by the node, for example to facilitate browsing or selection by the user. Short Labels are not standardized and may omit details; thus, it is not recommended to use them for purposes such as automated matching or selection. Note: While some implementations may consider it helpful to incorporate clinical or other semantic content into the label text, the definitive representation of such information is the encoding in the node primitive itself and the label text should not be considered authoritative.
Row 2	The values in the CID only represent recommendations from the producer of the Content Item. Receiving devices may opt to display data marked "Not for Presentation" and not display data marked "Presentation Required" based on user interactions and/or configuration settings.
Row 3, 5, 6	Purpose of reference shall not be present.
Row 4	This row permits referencing a specific Content Item of interest within a Structured Report instance referenced in Row 3.
Row 5, 6	The Referenced Frame Number (0008,1160) attribute of the IMAGE Content Item permits referencing one or more frames in the referenced Image Instance when appropriate, for example when the Result Tree Node does not include all the frames in the image instance. Similarly, the Referenced Segment Number (0062,000B) attribute may be used when the Result Tree does not include all the segments in the segmentation instance

CID newcid0Result Tree Titles

This CID contains codes appropriate for the document title of Result Tree objects. This list is far from comprehensive and is intended to provide examples of scope and phrasing.

2185 **Type:** Extensible Version: yyyymmdd

Coding Scheme Designator	Code Value	Code Meaning	UMLS Concept Unique ID
99IHE	AIR101	Result Tree	
99IHE	AIR102	Abdominal Aortic Aneurysm Assessment	
99IHE	AIR103	Breast Lesion Assessment	

Table CID newcid0: Result Tree Titles

Coding Scheme Designator	Code Value	Code Meaning	UMLS Concept Unique ID
99IHE	AIR104	Cardiomegaly Assessment	
99IHE	AIR105	Coronary Plaque Assessment	
99IHE	AIR106	COVID-19 Assessment	
99IHE	AIR107	Endotracheal Tube Assessment	
99IHE	AIR108	Liver Lesion Assessment	
99IHE	AIR109	Pleural Effusion Assessment	
99IHE	AIR110	Pneumonia Assessment	
99IHE	AIR111	Pneumothorax Assessment	
99IHE	AIR112	Prostate Lesion Assessment	
99IHE	AIR113	Pulmonary Embolism Assessment	
99IHE	AIR114	Pulmonary Nodule Assessment	
99IHE	AIR115	Rib Fracture Assessment	
99IHE	AIR116	Scoliosis Assessment	
99IHE	AIR117	Vertebra Assessment	

CID newcid1Result Tree Nodes

Type:Extensible2190Version:yyymmdd

Table CID newcid1: Result Tree Nodes

Coding Scheme Designator	Code Value	Code Meaning	SNOMED- RT ID	UMLS Concept Unique ID
99IHE	AIR003	Root Result		
99IHE	AIR032	Qualitative Finding		
99IHE	AIR033	Measurement		
99IHE	AIR034	Location		
99IHE	AIR035	Region		
99IHE	AIR036	Parametric Map		
99IHE	AIR037	Tracking Identifier		
99IHE	AIR038	Image Reference		

Appendices to Volume 3

Add new Appendix A to Volume 3.

Appendix A – Example Analysis Result Encodings

2195 These examples were prepared in support of the AI Results (AIR) Profile. See Section 6.5.3 Imaging Analysis Result Content for the encoding specifications.

This appendix contains a limited set of illustrative examples. Additional examples may be available in IHE Connectathons or as part of the implementation materials associated with this profile which may be found via <u>Appendix G</u> of the IHE Technical Frameworks General Introduction and Shared Appendices.

A.1 Common Header Attributes

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The IODs used for Imaging Analysis Result Content (see Section 6.5.3) all include a number of common DICOM modules describing the Patient, Study, Series, etc. with which the analysis result is associated. Table A.1-1 provides an example of values for the attributes of such modules. Note that, depending on the specific IOD used, values such as SOP Class UID (0008,0016) and Modality (0008,0060) would differ and additional required attributes would be expected.

Attribute	Тад	Value
SOP Class UID	(0008,0016)	1.2.840.10008.5.1.4.1.1.88.34
SOP Instance UID	(0008,0018)	1.2.3.4.5.6.7.300
Study Date	(0008,0020)	20191029
Content Date	(0008,0023)	20191029
Study Time	(0008,0030)	154500
Content Time	(0008,0033)	155210
Accession Number	(0008,0050)	123456
Modality	(0008,0060)	SR
Manufacturer	(0008,0070)	Aperture Labs
Referring Physician's Name	(0008,0090)	Johnson^Cave^^Dr.^M.D.
Manufacturer's Model Name	(0008,1090)	AI Portal Platform
Patient's Name	(0010,0010)	Person^Chell^^^
Patient's ID	(0010,0020)	000001498
Issuer of Patient ID	(0010,0021)	Mercy Hospital

Table A.1-1: Common Imaging Analysis Result Header Example

Attribute	Тад	Value
Patient's Birth Date	(0010,0030)	19991109
Patient's Sex	(0010,0040)	F
Contributing Equipment Sequence	(0018,A001)	
>Purpose of Reference Code Sequence	(0040,A170)	(109102, DCM, "Processing Equipment")
>Manufacturer	(0008,0070)	Acme Algorithmics
>Manufacturer's Model Name	(0008,1090)	PneumoScan
>Software Versions	(0018,1020)	3.1.202006
>Device UID	(0018,1002)	1.2.8.7.6.5.78765234
Study Instance UID	(0020,000D)	1.2.3.4.5.6.7.100
Series Instance UID	(0020,000E)	1.2.3.4.5.6.7.2001
Study ID	(0020,0010)	345678
Series Number	(0020,0011)	3

A.2 Qualitative Finding

2210 As described in Section 6.5.3 Analysis Result Encodings, qualitative findings are encoded in DICOM SR objects using TID 1500 as the root template.

The example in Table A.2-1 represents the SR Content Tree inside the DICOM SR object. The header of the DICOM SR object would look like the example in Section A.1.

Notes: 1. The Image Library container is left empty since there is only a single source image which is considered to be reasonably well described by the imaging procedure.

2. The algorithm has also generated a saliency map image for the embolism finding. The saliency image is referenced in the Visual Explanation concept.

3. Although "Source Image" does not appear in TID 1501, node 1.8.3.5 in Table A.2-1 is based on Row 10b of TID 1501, which allows for an image reference with an ImagePurpose of which Source Image is a valid code.

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Table A.2-1: Qualitative Finding SR Content Example

Node	Code Meaning of Concept Name	Value	TID
1	Imaging Measurement Report		TID 1500
1.1	Language of Content Item and Descendants	(en-US, RFC5646, "American English")	TID 1204
1.2	Observer Type	(121007, DCM, "Device")	TID 1001 TID 1002
1.3	Device Observer UID	1.2.8.7.6.5.78765234	TID 1004
1.4	Device Observer Manufacturer	Acme Algorithmics	TID 1004

Node	Code Meaning of Concept Name	Value	TID
1.5	Device Observer Model Name	PneumoScan	TID 1004
1.6	Procedure Reported	(43778-0, LN, "Portable XR Chest AP supine")	TID 1500
1.7	Image Library		TID 1500
1.8	Imaging Measurements		TID 1500
1.8.1	Algorithm Name	PneumoScan	TID 1419
1.8.2	Algorithm Version	3.1.202006	TID 1419
1.8.3	Measurement Group		TID 1501
1.8.3.1	Tracking Identifier	Pneumo2394958	TID 1501
1.8.3.2	Tracking Unique Identifier	1.2.276.0.7230010.384756	TID 1501
1.8.3.3	Finding	(55584005, SCT, "Embolism")	TID 1501
1.8.3.3	Observation UID	1.2.3.4.5.6.7.8.21.0.1	SR IOD
1.8.3.4	Finding Site	(45653009, SCT, "Upper lobe of lung")	TID 1501
1.8.3.4.1	Laterality	(24028007, SCT, "Right")	TID 1501
1.8.3.5	Source Image	1.2.840.10008.5.1.4.1.1.1.1 (Digital X-Ray Image Storage – For Processing SOP Class) 1.2.3.4.5.6.7.8001 (SOP Instance of XR Chest AP Image)	TID 1501
1.8.3.6	Visual Explanation	1.2.840.10008.5.1.4.1.1.30 (Parametric Map Storage SOP Class) 1.2.3.4.5.6.7.9001 (SOP Instance of corresponding saliency map)	TID 1501

A.3 CT Chest Result Set

This is an example of a set of results generated by a variety of assessment algorithms operating on a CT Chest Study.

The example SR Content includes Observation UID (0040,A171) as required in RAD TF-3:
6.5.3.1. For simplicity, Observation UID is shown in the tables as a child node of the SR Content Item to which it applies, but is shown in italics with a "dash" for its sub-node number because it is actually an attribute in the representation of that Content Item as described in DICOM <u>PS3.3</u> <u>Section C.17.3</u>. Correspondingly, the TID value is shown as "SR IOD".

A.3.1 CT Chest Pneumothorax Assessment Result Set

2230 This is an example of a set of results generated by a pneumothorax assessment algorithm operating on a CT Chest Study.

The result set includes the Result Tree, the primary finding (pneumothorax is present) which has been designated as the root of the tree, and a contour-based volumetric segmentation representing the estimated extent of the pneumothorax.

2235 The primary finding and segmentation are shown here together in the same SR instance and their Observation UIDs are included in the Result Tree. Alternatively, the volumetric segmentation could have been encoded in a separate instance which could either have been DICOM Segmentation instance or an SR instance like that shown.

A.3.1.1 Result Tree

As described in Section 6.5.3 Analysis Result Encodings, Result Trees are encoded in DICOM SR objects using TID IHERADAIR1 as the root template.

The example in Table A.3.1.1-1 represents the SR Content Tree inside the DICOM SR object. The header of the DICOM SR object would look something like the example in Table A.1-1.

Node	Code Meaning of Concept Name	Value	TID
1	Pneumothorax Assessment		IHERADAIR1
1.1	Language of Content Item and Descendants	(en-US, RFC5646, "American English")	TID 1204
1.2	Observer Type	(121007, DCM, "Device")	TID 1001 TID 1002
1.3	Device Observer UID	1.2.8.7.6.5.787651234	TID 1004
1.4	Device Observer Manufacturer	Aperture Labs	TID 1004
1.5	Device Observer Model Name	AI 3D Pneumothorax	TID 1004
1.6	Short Label	"Pneumothorax Result"	IHERADAIR2
1.7	Root Result	COMPOSITE See A.3.3.2	IHERADAIR2
1.8	Referenced Observation UID	1.2.3.4.5.6.7.8.3121.0.1	IHERADAIR2
1.9	Child Node		IHERADAIR2
1.9.1	Short Label	"Pneumothorax Location"	IHERADAIR2
1.9.2	Region	COMPOSITE See A.3.3.2	IHERADAIR2
1.9.3	Referenced Observation UID	1.2.3.4.5.6.7.8.3121.0.2	IHERADAIR2

Table A.3.1.1-1: Result Tree SR Content Example

2245 A.3.1.2 Pneumothorax Result & Segmentation

As described in Section 6.5.3 Analysis Result Encodings, qualitative findings are encoded in DICOM SR objects using TID 1500 as the root template and contour-based segmentations may also be encoded in DICOM SR objects using TID 1500 as the root template.

The example in Table A.3.1.2-1 represents the SR Content Tree inside the DICOM SR object. The header of the DICOM SR object would look something like the example in Table A.1-1. The Tracking Identifiers in nodes 1.8.3.1 and 1.8.3.2 identify this specific occurrence of pneumothorax in this patient. Although this is the first encounter, the identifiers are included so that a subsequent detection that is able to determine that it is a subsequent encounter with the same occurrence of pneumothorax could indicate that by using the same identifiers. This could support, for example, size comparisons. If no identifiers are included in the first occurrence, there is nothing for the second occurrence to use. This is an example of using Tracking Identifiers to track a condition, rather than, for example, a region of tissue.

Node	Code Meaning of Concept Name	Value	TID
1	Imaging Measurement Report		TID 1500
1.1	Language of Content Item and Descendants	(en-US, RFC5646, "American English")	TID 1204
1.2	Observer Type	(121007, DCM, "Device")	TID 1001 TID 1002
1.3	Device Observer UID	1.2.8.7.6.5.78765234	TID 1004
1.4	Device Observer Manufacturer	Aperture Labs	TID 1004
1.5	Device Observer Model Name	AI 3D Pneumothorax	TID 1004
1.6	Procedure Reported	(29252-4, LN, " CT Chest WO contrast")	TID 1500
1.7	Image Library		TID 1500
1.8	Imaging Measurements		TID 1500
1.8.1	Algorithm Name	AI 3D Pneumothorax	TID 4019
1.8.2	Algorithm Version	1.5.8b	TID 4019
1.8.3	Measurement Group		TID 1501
1.8.3.1	Tracking Identifier	Pneumothorax2394958	TID 1501
1.8.3.2	Tracking Unique Identifier	1.2.276.0.7230010.384756	TID 1501
1.8.3.3	Finding	(36118008, SCT, "Pneumothorax")	TID 1501
1.8.3.3	Observation UID	1.2.3.4.5.6.7.8.3121.0.1	SR IOD
1.8.3.4	Finding Site	(39607008, SCT, "Lung")	TID 1501
1.8.3.4.1	Laterality	(7771000, SCT, "Left")	TID 1501
1.8.3.5	Geometric purpose of region	(111041, DCM, "Outline")	Extension
1.8.3.6	Image Region	SCOORD Contour a	TID 1501
1.8.3.6	Observation UID	1.2.3.4.5.6.7.8.3121.0.2	SR IOD
1.8.3.6.1		1.2.840.10008.5.1.4.1.1.2 (CT Image SOP Class) 1.2.3.4.5.6.7.8.3121.1.57 (CT SOP Instance a)	TID 1501
1.8.3.7	Image Region	SCOORD Contour b	TID 1501

Table A.3.1.2-1: Pneumothorax SR Content Example

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Node	Code Meaning of Concept Name	Value	TID
1.8.3.7	Observation UID	1.2.3.4.5.6.7.8.3121.0.2	SR IOD
1.8.3.7.1		1.2.840.10008.5.1.4.1.1.2 (CT Image SOP Class) 1.2.3.4.5.6.7.8.3121.1.58 (CT SOP Instance b)	TID 1501
1.8.3.etc.		more contours	

A.3.2 CT Chest Pneumonia Assessment Result Set

2260 This is an example of a set of results generated by a pneumonia assessment algorithm operating on a CT Chest Study.

The result set includes the Result Tree, the primary finding (pneumonia is absent) which has been designated as the root of the tree, a saliency map showing the image regions the AI associated with the pneumonia finding, and a "Projection" image with which the saliency map can be blended for presentation.

A.3.2.1 Result Tree

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As described in Section 6.5.3 Analysis Result Encodings, Result Trees are encoded in DICOM SR objects using TID IHERADAIR1 as the root template.

The example in Table A.3.2.1-1 represents the SR Content Tree inside the DICOM SR object. 2270 The header of the DICOM SR object would look something like the example in Table A.1-1.

Node	Code Meaning of Concept Name	Value	TID		
1	Pneumonia Assessment		IHERADAIR1		
1.1	Language of Content Item and Descendants	(en-US, RFC5646, "American English")	TID 1204		
1.2	Observer Type	(121007, DCM, "Device")	TID 1001 TID 1002		
1.3	Device Observer UID	1.2.8.7.6.5.787652341	TID 1004		
1.4	Device Observer Manufacturer	Acme Algorithmics	TID 1004		
1.5	Device Observer Model Name	PneumoScan CT	TID 1004		
1.6	Short Label	"Pneumonia Result"	IHERADAIR2		
1.7	Root Result	COMPOSITE See A.3.2.2	IHERADAIR2		
1.8	Referenced Observation UID	1.2.3.4.5.6.7.8.3221.0.1	IHERADAIR2		
1.9	Child Node		IHERADAIR2		
1.9.1	Short Label	"Saliency Map"	IHERADAIR2		
1.9.2	Parametric Map	IMAGE See A.3.2.3	IHERADAIR2		

Table A.3.2.1-1: Result Tree SR Content Example

Node	Code Meaning of Concept Name	Value	TID
1.9.3	Child Node		IHERADAIR2
1.9.3.1	Short Label	"Projection Image"	IHERADAIR2
1.9.3.2	Image Reference	IMAGE See A.3.2.4	IHERADAIR2

A.3.2.2 Pneumonia Result

As described in Section 6.5.3 Analysis Result Encodings, qualitative findings are encoded in DICOM SR objects using TID 1500 as the root template.

2275 The example in Table A.3.2.2-1 represents the SR Content Tree inside the DICOM SR object. The header of the DICOM SR object would look something like the example in Table A.1-1.

Node	Code Meaning of Concept Name	Value	TID
1	Imaging Measurement Report		TID 1500
1.1	Language of Content Item and Descendants	(en-US, RFC5646, "American English")	TID 1204
1.2	Observer Type	(121007, DCM, "Device")	TID 1001 TID 1002
1.3	Device Observer UID	1.2.8.7.6.5.787652341	TID 1004
1.4	Device Observer Manufacturer	Acme Algorithmics	TID 1004
1.5	Device Observer Model Name	PneumoScan CT	TID 1004
1.6	Procedure Reported	(29252-4, LN, " CT Chest WO contrast")	TID 1500
1.7	Image Library		TID 1500
1.8	Imaging Measurements		TID 1500
1.8.1	Algorithm Name	PneumoScan CT	TID 4019
1.8.2	Algorithm Version	3.1.202008	TID 4019
1.8.3	Measurement Group		TID 1501
1.8.3.1	(373572006, SCT, "Clinical finding absent")	(23360400, SCT, "Pneumonia")	TID 1501
1.8.3.1	Observation UID	1.2.3.4.5.6.7.8.3221.0.1	SR IOD
1.8.3.2	Finding Site	(39607008, SCT, "Lung")	TID 1501
1.8.3.2.1	Laterality	(51440002, SCT, "Bilateral")	TID 1501
1.8.3.3	Source Image	1.2.840.10008.5.1.4.1.1.2 (CT Image Storage SOP Class) 1.2.3.4.5.6.7.8.3121.1.1 1.2.3.4.5.6.7.8.3121.1.2	TID 1501
		etc.	

 Table A.3.2.2-1: Pneumonia Result SR Content Example

Node	Code Meaning of Concept Name	Value	TID
		(SOP Instances of CT Chest Images)	
1.8.3.4	Visual Explanation	1.2.840.10008.5.1.4.1.1.30 (Parametric Map Storage SOP Class) 1.2.3.4.5.6.7.8.3223.1.1 (SOP Instance of corresponding saliency map)	TID 1501

A.3.2.3 Saliency Image

As described in Section 6.5.3 Analysis Result Encodings, saliency images are encoded as an instance of the DICOM Parametric Map IOD.

The example in Table A.3.2.3-1 represents key header attributes of the Parametric Map instance. Common Header attributes would appear similar to that shown in Table A.1-1.

Attribute	Тад	Value
SOP Class UID	(0008,0016)	1.2.840.10008.5.1.4.1.1.30
SOP Instance UID	(0008,0018)	1.2.3.4.5.6.7.8.3223.1.1
Modality	(0008,0060)	СТ
Contributing Equipment Sequence	(0018,A001)	
>Purpose of Reference Code Sequence	(0040,A170)	(109102, DCM, "Processing Equipment")
>Manufacturer	(0008,0070)	Acme Algorithmics
>Manufacturer's Model Name	(0008,1090)	PneumoScan CT
>Software Versions	(0018,1020)	3.1.202006
>Device UID	(0018,1002)	1.2.8.7.6.5.78765234.1

 Table A.3.2.3-1: Saliency Image Header Example

A.3.2.4 "Projection" Image

- 2285 The "Projection" image is a planar view of the chest that corresponds spatially with the saliency image. It is available for blending with the saliency image to provide an anatomical reference for the saliency data. The projection image is derived from the transverse CT images, for example using a MIP algorithm, and is encoded as a DICOM CT Image object (which is used for transverse, coronal, sagittal and oblique images).
- 2290 The example in Table A.3.2.4-1 represents key header attributes of the CT Image instance. Common Header attributes would appear similar to that shown in Table A.1-1.

Attribute	Тад	Value	
SOP Class UID	(0008,0016)	1.2.840.10008.5.1.4.1.1.2	
SOP Instance UID	(0008,0018)	1.2.3.4.5.6.7.9.3241.1.1	
Modality	(0008,0060)	CT	
Contributing Equipment Sequence	(0018,A001)		
>Purpose of Reference Code Sequence	(0040,A170)	(109102, DCM, "Processing Equipment")	
>Manufacturer	(0008,0070)	Acme Algorithmics	
>Manufacturer's Model Name	(0008,1090)	PneumoScan CT	
>Software Versions	(0018,1020)	3.1.202006	
>Device UID	(0018,1002)	1.2.8.7.6.5.78765234.1	

Table A.3.2.4-1: Projection Image Header Example

A.3.3 CT Chest Lung Nodule Assessment Result Set

This example result set might be generated by a comprehensive lung nodule assessment algorithm.

The result set includes the Result Tree, the primary finding (overall Lung-RADSTM assessment) which has been designated as the root of the tree, and a set of nodule results, each consisting of a centroid location, an individual Lung-RADS nodule score, a segmentation, a calculated volume, a solidity assessment and a margin assessment.

- 2300 The nodule segmentations are shown here in individual Segmentation instances as they might be produced by an algorithm that segments a single nodule based on a seed location from a detection algorithm. Alternatively, the segmentations might have been in a single Segmentation instance with different Segment IDs used by the Result tree. Each nodule is represented by an individual SR which contains multiple observations for that nodule. The Root Result (an overall patient assessment) is shown in a segmentation SP as if it were generated by a third elserithm.
- 2305 patient assessment) is shown in a separate SR as if it were generated by a third algorithm.

A.3.3.1 Result Tree

As described in Section 6.5.3 Analysis Result Encodings, Result Trees are encoded in DICOM SR objects using TID IHERADAIR1 as the root template.

The example in Table A.3.3.1-1 represents the SR Content Tree inside the DICOM SR object. 2310 The header of the DICOM SR object would look like the example in Table A.1-1.

Node	Code Meaning of Concept Name	Value	TID
1	Pulmonary Nodule Assessment		IHERADAIR1
1.1	Language of Content Item and Descendants	(en-US, RFC5646, "American English")	TID 1204
1.2	Observer Type	(121007, DCM, "Device")	TID 1001 TID 1002
1.3	Device Observer UID	1.2.8.7.6.5.79765234x	TID 1004
1.4	Device Observer Manufacturer	Acme Algorithmics	TID 1004
1.5	Device Observer Model Name	Lung Sum	TID 1004
1.6	Root Result	COMPOSITE See A.3.3.2	IHERADAIR2
1.7	Referenced Observation UID	1.2.3.4.5.6.7.8.3321.0.1	IHERADAIR2
1.8	Short Label	"Overall Lung-RADS 4A"	IHERADAIR2
1.9	Child Node		IHERADAIR2
1.9.1	Qualitative Finding	COMPOSITE See A.3.3.3	IHERADAIR2
1.9.1.1	Referenced Observation UID	1.2.3.4.5.6.7.8.3331.1.1	IHERADAIR2
1.9.2	Short Label	"Nodule 1 Lung-RADS 3"	IHERADAIR2
1.9.3	Child Node		IHERADAIR2
1.9.3.1	Measurement	COMPOSITE See A.3.3.3	IHERADAIR2
1.9.3.1.1	Referenced Observation UID	1.2.3.4.5.6.7.8.3331.1.2	IHERADAIR2
1.9.3.2	Short Label	"Nodule 1 Density"	IHERADAIR2
1.9.4	Child Node		IHERADAIR2
1.9.4.1	Qualitative Finding	COMPOSITE See A.3.3.3	IHERADAIR2
1.9.4.1.1	Referenced Observation UID	1.2.3.4.5.6.7.8.3331.1.3	IHERADAIR2
1.9.4.2	Short Label	"Nodule 1 Margin"	IHERADAIR2
1.9.5	Child Node		IHERADAIR2
1.9.5.1	Qualitative Finding	COMPOSITE See A.3.3.3	IHERADAIR2
1.9.5.1.1	Referenced Observation UID	1.2.3.4.5.6.7.8.3331.1.4	IHERADAIR2
1.9.5.2	Short Label	"Nodule 1 Shape"	IHERADAIR2
1.9.6	Child Node		IHERADAIR2
1.9.6.1	Measurement	COMPOSITE See A.3.3.3	IHERADAIR2
1.9.6.1.1	Referenced Observation UID	1.2.3.4.5.6.7.8.3331.1.7	IHERADAIR2
1.9.6.2	Short Label	"Nodule 1 Diameter"	IHERADAIR2

 Table A.3.3.1-1: Result Tree SR Content Example

Node	Code Meaning of Concept Name	Value	TID
1.9.6.3	Child Node		IHERADAIR2
1.9.6.3.1	Measurement	COMPOSITE See A.3.3.3	IHERADAIR2
1.9.6.3.1.1	Referenced Observation UID	1.2.3.4.5.6.7.8.3331.1.5	IHERADAIR2
1.9.6.3.2	Short Label	"Nodule 1 Long Axis"	IHERADAIR2
1.9.6.4	Child Node		IHERADAIR2
1.9.6.4.1	Measurement	COMPOSITE See A.3.3.3	IHERADAIR2
1.9.6.4.1.1	Referenced Observation UID	1.2.3.4.5.6.7.8.3331.1.6	IHERADAIR2
1.9.6.4.2	Short Label	"Nodule 1 Short Axis"	IHERADAIR2
1.9.7	Child Node		IHERADAIR2
1.9.7.1	Measurement	COMPOSITE See A.3.3.3	IHERADAIR2
1.9.7.1.1	Referenced Observation UID	1.2.3.4.5.6.7.8.3331.2.1	IHERADAIR2
1.9.7.2	Short Label	"Nodule 1 Volume"	IHERADAIR2
1.9.7.3	Child Node		IHERADAIR2
1.9.7.3.1	Region	IMAGE See A.3.3.4	IHERADAIR2
1.9.7.3.1	Referenced Segment Number	1	SR IOD
1.9.7.3.2	Short Label	"Nodule 1 Segmentation"	IHERADAIR2
1.9.7.4	Child Node		IHERADAIR2
1.9.7.4.1	Location	COMPOSITE See A.3.3.3	IHERADAIR2
1.9.7.4.1.1	Referenced Observation UID	1.2.3.4.5.6.7.8.3331.3.1	IHERADAIR2
1.9.7.4.2	Short Label	"Nodule 1 Location"	IHERADAIR2
1.10	Child Node		
1.10.1	Qualitative Finding	COMPOSITE Similar to A.3.3.3	IHERADAIR2
1.10.1.1	Referenced Observation UID	1.2.3.4.5.6.7.8.3331.1.1	IHERADAIR2
1.10.2	Short Label	"Nodule 2 Lung-RADS 4A"	IHERADAIR2
1.10.3	Child Node		IHERADAIR2

Note: The above tree presents each nodule first as a Lung-RADS score, then its characteristics, and finally as a segmentation. Radiologists at a given site might prefer the tree be constructed with a different nesting to present nodules first as a segmentation region, then the characteristics and finally a proposed Lung-RADS score. The software that composes the Result Tree object might permit configuration to construct trees that match such local preferences.

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A.3.3.2 Lung-RADS Result

As described in Section 6.5.3 Analysis Result Encodings, qualitative findings are encoded in DICOM SR objects using TID 1500 as the root template.

The example in Table A.3.3.2-1 represents the SR Content Tree inside the DICOM SR object. The header of the DICOM SR object would look something like the example in Table A.1-1.

Node	Code Meaning of Concept Name	Value	TID
1	Imaging Measurement Report		TID 1500
1.1	Language of Content Item and Descendants	(en-US, RFC5646, "American English")	TID 1204
1.2	Observer Type	(121007, DCM, "Device")	TID 1001 TID 1002
1.3	Device Observer UID	1.2.8.7.6.5.7976523321	TID 1004
1.4	Device Observer Manufacturer	Acme Algorithmics	TID 1004
1.5	Device Observer Model Name	Lung CT Server	TID 1004
1.6	Procedure Reported	(29252-4, LN, "CT Chest WO contrast")	TID 1500
1.7	Image Library		TID 1500
1.8	Imaging Measurements		TID 1500
1.8.1	Algorithm Name	Lungfish	TID 4019
1.8.2	Algorithm Version	1.6	TID 4019
1.8.3	Measurement Group		TID 1501
1.8.3.1	Finding	(RID50139, RADLEX, "Lung-RADS 4A")	TID 1501
1.8.3.1	Observation UID	1.2.3.4.5.6.7.8.3321.0.1	SR IOD
1.8.3.2	Finding Site	(39607008, SCT, "Lung")	TID 1501
1.8.3.2.1	Laterality	(51440002, SCT, "Bilateral")	TID 1501
1.8.3.3	Source Image	1.2.840.10008.5.1.4.1.1.2 (CT Image Storage SOP Class) 1.2.3.4.5.6.7.8.322.1 1.2.3.4.5.6.7.8.322.2 etc. (SOP Instances of CT Chest Images)	TID 1501

Table A.3.3.2-1: Root Result SR Content Example

A.3.3.3 Nodule 1

As described in Section 6.5.3 Analysis Result Encodings, qualitative findings are encoded in DICOM SR objects using TID 1500 as the root template.

2325 The example in Table A.3.3.3-1 represents the SR Content Tree inside the DICOM SR object. The header of the DICOM SR object would look something like the example in Table A.1-1.

Node	Code Meaning of Concept Name	Value	TID
1	Imaging Measurement Report		TID 1500
1.1	Language of Content Item and Descendants	(en-US, RFC5646, "American English")	TID 1204
1.2	Observer Type	(121007, DCM, "Device")	TID 1001 TID 1002
1.3	Device Observer UID	1.2.8.7.6.5.7976523323	TID 1004
1.4	Device Observer Manufacturer	Acme Algorithmics	TID 1004
1.5	Device Observer Model Name	Nodule Server	TID 1004
1.6	Procedure Reported	(29252-4, LN, "CT Chest WO contrast")	TID 1500
1.7	Image Library		TID 1500
1.8	Imaging Measurements		TID 1500
1.8.1	Algorithm Name	Nodule Analyzer	TID 4019
1.8.2	Algorithm Version	5.234	TID 4019
1.8.3	Measurement Group		TID 1501
1.8.3.1	Tracking Identifier	Nodule 1	TID 1501
1.8.3.2	Tracking Unique Identifier	1.2.276.0.723001031.1	TID 1501
1.8.3.3	Finding	(27925004, SCT, "Nodule")	TID 1501
1.8.3.3	Observation UID	1.2.3.4.5.6.7.8.3331.0.1	SR IOD
1.8.3.4	Finding Site	(39607008, SCT, "Lung")	TID 1501
1.8.3.4.1	Laterality	(7771000, SCT, "Left")	TID 1501
1.8.3.5	Source Image	1.2.840.10008.5.1.4.1.1.2 (CT Image Storage SOP Class) 1.2.3.4.5.6.7.8.322.21 1.2.3.4.5.6.7.8.322.22 1.2.3.4.5.6.7.8.322.23 1.2.3.4.5.6.7.8.322.24 1.2.3.4.5.6.7.8.322.25 (SOP Instances of CT Chest Images)	TID 1501
1.8.3.6	(RID50134, RADLEX, "Lung-RADS Assessment")	(RID50138, RADLEX, "Lung-RADS 3")	TID 1501
1.8.3.6	Observation UID	1.2.3.4.5.6.7.8.3331.1.1	SR IOD
1.8.3.7	(111035, DCM, "Lesion Density")	(RID5741, RADLEX, "Solid")	TID 1501

 Table A.3.3.3-1: Nodule 1 SR Content Example

Node	Code Meaning of Concept Name	Value	TID
1.8.3.7	Observation UID	1.2.3.4.5.6.7.8.3331.1.2	SR IOD
1.8.3.8	(129737002, SCT, "Radiographic Lesion Margin Characteristics")	(82280004, SCT, "Smooth")	TID 1501
1.8.3.8	Observation UID	1.2.3.4.5.6.7.8.3331.1.3	SR IOD
1.8.3.9	(107644003, SCT, "Shape")	(42700002, SCT, "Round shape")	TID 1501
1.8.3.9	Observation UID	1.2.3.4.5.6.7.8.3331.1.4	SR IOD
1.8.3.10	(103339001, SCT, "Long Axis")	12.8 mm	TID 300
1.8.3.10	Observation UID	1.2.3.4.5.6.7.8.3331.1.5	SR IOD
1.8.3.10.1	Measurement Method	(126081, DCM, "RECIST 1.1")	TID 300
1.8.3.10.2	Source of Measurement	SCOORD POLYLINE with two coordinates	TID 320
1.8.3.10.2.1		IMAGE 1.2.3.4.5.6.7.8.322.23	TID 320
1.8.3.11	(103340004, SCT, "Short Axis")	9.2 mm	TID 300
1.8.3.11	Observation UID	1.2.3.4.5.6.7.8.3331.1.6	SR IOD
1.8.3.11.1	Measurement Method	(126081, DCM, "RECIST 1.1")	TID 300
1.8.3.11.2	Source of Measurement	SCOORD POLYLINE with two coordinates	TID 320
1.8.3.11.2.1		IMAGE 1.2.3.4.5.6.7.8.322.23	TID 320
1.8.3.12	(81827009, SCT, "Diameter")	11.5 mm	TID 300
1.8.3.12	Observation UID	1.2.3.4.5.6.7.8.3331.1.7	SR IOD
1.8.3.12.1	Derivation	(373098007, SRT, "Mean")	TID 300
1.8.4	Measurement Group		TID 1411
1.8.4.1	Tracking Identifier	Nodule 1	TID 1411
1.8.4.2	Tracking Unique Identifier	1.2.276.0.723001031.1	TID 1411
1.8.4.3	Geometric Purpose of Region	(111041, DCM, "Outline")	TID 1411
1.8.4.4	Referenced Segment	IMAGE	TID 1411
1.8.4.4	Referenced Segment Number	1	SR IOD
1.8.4.5	Source Image for Segmentation	1.2.840.10008.5.1.4.1.1.2 (CT Image Storage SOP Class) 1.2.3.4.5.6.7.8.322.21 1.2.3.4.5.6.7.8.322.22 1.2.3.4.5.6.7.8.322.23 1.2.3.4.5.6.7.8.322.24 1.2.3.4.5.6.7.8.322.25 (SOP Instances of CT Chest Images)	TID 1411
1.8.4.6	Finding	(27925004, SCT, "Nodule")	TID 1411

Node	Code Meaning of Concept Name	Value	TID
1.8.4.7	Finding Site	(39607008, SCT, "Lung")	TID 1419
1.8.4.7.1	Laterality	(7771000, SCT, "Left")	
1.8.4.8	(118565006, SCT, "Volume")	473 mm3	TID 1419
1.8.4.8	Observation UID	1.2.3.4.5.6.7.8.3331.2.1	SR IOD
1.8.5	Measurement Group		TID 1410
1.8.5.1	Tracking Identifier	Nodule 1	TID 1410
1.8.5.2	Tracking Unique Identifier	1.2.276.0.723001031.1	TID 1410
1.8.5.3	Geometric Purpose of Region	(111010, DCM, "Center")	TID 1410
1.8.5.4	Image Region	SCOORD Point	TID 1410
1.8.5.4	Observation UID	1.2.3.4.5.6.7.8.3331.3.1	SR IOD
1.8.5.4.1		1.2.840.10008.5.1.4.1.1.2 (CT Image SOP Class) 1.2.3.4.5.6.7.8.322.23 (CT SOP Instance a)	TID 1410

A.3.3.4 Segmentation 1

As described in Section 6.5.3 Analysis Result Encodings, volumetric segmentations may be encoded as an instance of the DICOM Segmentation IOD.

The example in Table A.3.3.4-1 represents key header attributes of the Segmentation instance. Common Header attributes would appear similar to that shown in Table A.1-1.

Тад	Value
J	Value
(0008,0016)	1.2.840.10008.5.1.4.1.1.66.4
(0008,0018)	1.2.3.4.5.6.7.8.3341.1.1
(0008,0060)	СТ
(0018,A001)	
(0040,A170)	(109102, DCM, "Processing Equipment")
(0008,0070)	Acme Algorithmics
(0008,1090)	Nodule Spotter
(0018,1020)	2.0.0.0.6
(0018,1002)	1.2.8.7.6.5.787653341.0
	(0008,0018) (0008,0060) (0018,A001) (0040,A170) (0008,0070) (0008,1090) (0018,1020)

 Table A.3.3.4-1: Segmentation Header Example

Attribute	Тад	Value
Segment Sequence	(0062,0002)	
>Segment Algorithm Name	(0062,0009)	Nodule Spotter
>Segmentation Algorithm Identification Sequence	(0062,0007)	
>>Algorithm Family Code Sequence	(0066,002F)	(123110, DCM, "Artificial Intelligence")
>>Algorithm Source	(0024,0202)	Acme Algorithmics
>>Algorithm Name	(0066,0036)	Nodule Spotter
>>Algorithm Version	(0066,0031)	2.0.0.0.6