

1. Proposed Work Item: AI Result Approval for Imaging (AIRAI)

Proposal Contributors: Marc Kämmerer, Antje Schroeder, Sebastian Penhouet, Daniel Kozimor, Andriamiharimamy Rajaonison, IHE Europe TF AIGI, Kevin O'Donnell

Work Item Editor: Antje Schroeder, supported by Steven Nichols, Marc Kämmerer

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Domain: Radiology

2. The Problem

Validation is critical to the success of AI in practice. Increasing numbers of AI models are available to generate radiological examination findings. Those findings must be validated by a user (and that validation recorded) to support a variety of processes:

- Hospital validation/acceptance testing of the AI model during deployment
- Radiologist validation of individual results during the reporting process
- Ongoing validation to detect drift or other performance changes as part of site reliability engineering or regulatory post-market surveillance processes (e.g. see EU AI-act chapter IX, Section 1)

A key challenge will be to avoid excessive complexity in the captured data, and the validation processes, particularly radiologist-driven validation given their existing time pressures.

Validation is the necessary basis for meeting the professional quality obligations of the radiology profession, and for establishing the trust of referring physicians in reports that incorporate AI.

3. Key Use Case

Use case 1: Validation capture and analysis

- a radiologist reviews a DICOM study and accepts/rejects the AI findings.
- Accepted results are incorporated into the report.
- The validation information is persisted in the PACS/ VNA for drift/performance analysis.
- Validation information and/or analysis is communicated to the vendor and/or regulator.

Use case 2: AI result revision/correction (Advanced)

- The radiologist encounters an incorrect AI result
- The radiologist revises/replaces the result; the correct information is used in the report.
- The corrected results are communicated to the AI solution for their analysis. They might also re-train, but that process is out of scope for this profile.

4. Standards & Systems

Systems in focus:

- Image Display/QA Workstation: Lets user review and/or validate AI results.
- Image Manager (PACS, VNA, Orchestrator...): Manages validation results (use case 1).
- AI Solution: Creates AI results and potential updates based on validation results (use case 2).

Standards: any object/ definition for the transmission/ storage of AI results e.g., IHE AIR+, concepts of IHE IOCM, DCM SR (TID 1500), SEG, KOS, SC, enc. PDF, GSPS.

5. Discussion

While the profile will not specify validation methods or required quality levels, it will be helpful to consider some possibilities as that may influence metadata and other design choices. E.g., explicit validation of individual findings by a radiologist, versus implicit validation by comparing the collection of findings in the final radiologist report to the available AI result findings and looking for correlations and contradictions. If a report is silent about pneumothorax and the AI was negative, is that sufficient for validation given the radiologist might have missed it? If a radiologist reports a second nodule that the AI did not find, how can that be captured?

Should the profile include the Report Creator to actively filter to prevent unvalidated findings from remaining in the report or being made available to other hospital information systems.

Q. Are validation results something that can be encoded as provenance information inside a finding object, or as an additional validation object that references the findings object. DICOM WG8 has agreed to be included in the discussions for this.