TU-A-134-1 Tuesday 8:00AM - 8:55AM Room: 134

1. Buying Imaging Equipment for Interoperability and Compliance: Beyond DICOM
2. Informatics for the Acceptance Testing of Imaging Equipment

For patient service, safety and regulatory compliance, the quality control of image and image information needs to extend beyond the scanner console to encompass the entire imaging chain. Imaging physicists are often the ultimate quality control professionals and technology experts that are responsible for equipment selection and testing. To aid in these tasks, this session is designed to provide the clinical physicist with practical awareness and tools for equipment selection and acceptance testing that promotes interoperability throughout the imaging chain, protecting image and information quality for smooth clinical operation and patient safety.

MAYO CLINIC

Buying Imaging Equipment for Interoperability and Compliance

Beyond DICOM

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Traditional Medical Physics Responsibility

I. Evaluation and selection of new equipment — This Talk

II. Contracting for new equipment/systems

III. Acceptance Testing and Quality Control Measurements and Reporting — Next Talk

IV. Patient Safety/Dosimetry

V. Clinical optimization/Innovation

Equipment Evaluation and Selection

- Radiologist Assessment of clinical utility
- Usability (technologist or radiologist interface)
- Physics Assessment (image quality/patient safety)
- Financials (business needs)
- Workflow/Dataflow
- Support
- Interoperability
- Security/Compliance

Connectivity Review

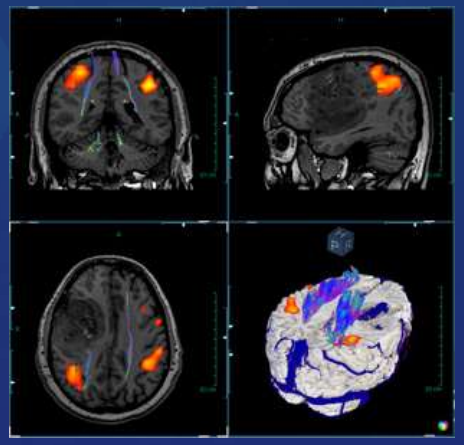
Aligning reality of stakeholder expectation with technical solutions before you buy.

The work of radiology is accomplished by a team

Radiologist

Technologist

Engineering



Vendor

Physicist

Administrator

IT/ PACS Administrator

Pictures from Toshiba, Invivo, Nordic Neurolabs and Volcano promortional material

Connectivity Review

SCOPE:

For the evaluation or purchase of any new and unique (of a substantively different product or software version) **image creator or modifier** that will integrate with the electronic environment

Relevant to both
ACQUISITION MODALITIES and POST-PROCESSING SOFTWARE

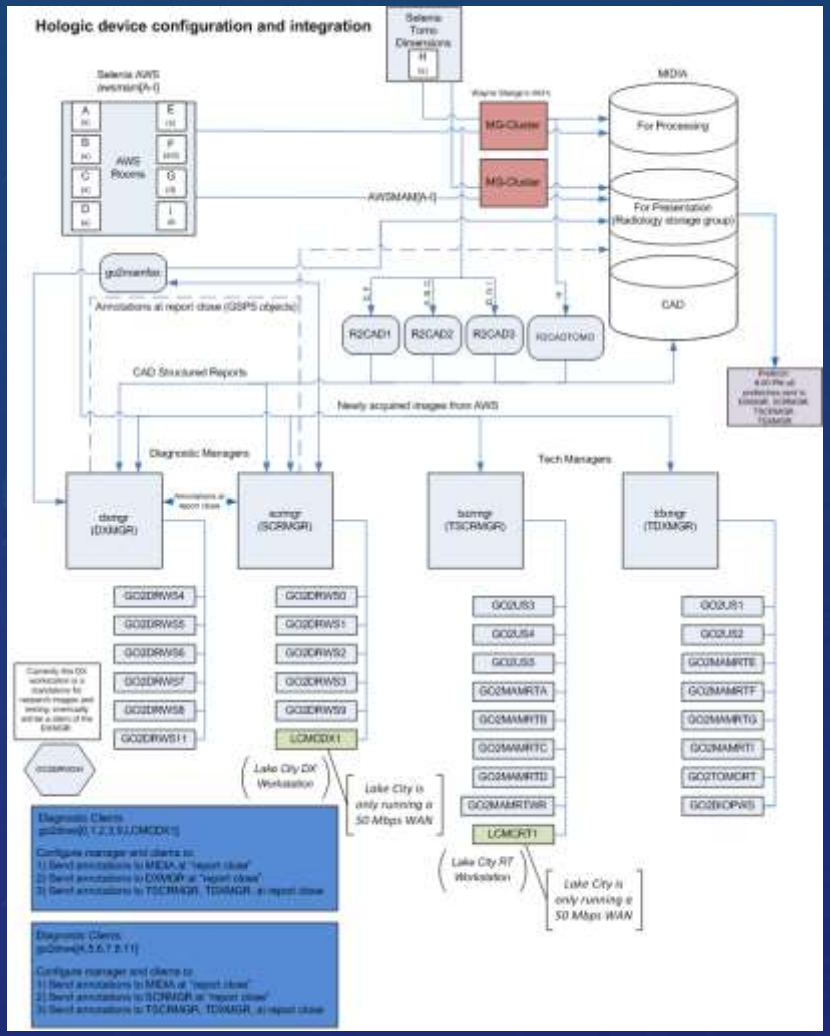
Connectivity Review

A. Workflow/Dataflow
B. Support
C. Interoperability
D. Security/Compliance

A. Workflow/DataFlow:

How is it used and what data flow is triggered?

Electronic Environment Workflow	Breast Imaging Workflow
Exam Order Entry in RIMS - (MSS, Orders or Manual) - Exam may be Generic	Exam must be a specific orderable in MSS
Patient Arrives in Scanner area-Patient Arrived in RIMS	Patient arrives GO 2, entered in PCIL, Arrived in RIMS
Technologist	
Tech scans RIMS room utilization	Beginning of exam
Tech refreshes DICOM Modality Worklist on scanner and select patient	Patient selected off of worklist via bar code
Tech replaces order and adds additional exams if needed. Tech enters initials and executes a saves in RIMS. Tech does not complete exam at this time	Tech replaces, modifies, adds additional images as needed. Tech selects appropriate work procedures and completes in RIMS,
Tech acquires images per protocol	Routine imaging is aquired per MQSA, 2 or 4 view mammogram. If the patient is returning for a diagnostic based on findings from a screening exam, the technologist will view the annotations on the tech Hologic tech workstation, applied by the radiologist for specific site location
Images are manually sent to PACS.	Upon acceptance (QA process) of the images on Hologic, the images are automatically sent to MIDIA, and all Hologic managers
Tech completes PenRad entry, clicks "done go to schedule"	
Tech scans RIMS room utilizaton	End of exam
Tech scanns patient questionnaire	At end of exam the patietn questionnaire is scanned with a document scanner and sent to the Hologic workstation. This is not arcived anywhere, and is duplicate information that is in PenRad.
Multiple exams during single visit: Exam Splitting. A) Tech select body part as defined by protocol B) Tech scans all contiguous body parts C) After processing, tech uses study split to assign correct acc#	If additional imaging is needed on the same patient (we only do one body part) Hologic will match the images up even if performed in a separate room.
Post Processing Recons required? A) If Yes, Tech programs scanner to process images and send to PACS and XX (post processing workstation) If No, skip this step	Routine post processing in not reqired. If there is an error on the exam, miss labveled or an image needs to be deleted etc, the tech notifies the QA desk, The QA person initiates a RIMS web form to get the exam deleted in MIDIA, QA person deletes exam from all Hologic managers. When RIMS notifies the exam has been removed, the tech resends the appropriate images to all Hologic managers and MIDIA.
Tech signs onto PACS workstation and finds patient on Unverified XXX worklist	na in Breast Imaging
Zero Image workflow – If exam exists with out images, and all images are sent to one accession number, the tech must verify zero image exams prior to verifying exams with images	images would be present
Did the exam profile correctly? A) Is it unspecified? Is it a "Generic" order? If Unspecified, contact RSC on call to merge exam B) Is it a "Generic" order? If Generic order, go to RIMS and replace the order to the correct exam	na in Breast Imaging
Perform QA on the exam: GSPS - Gray Scale Presentation State If the technologist makes any changing to the images, e.g., window levels, magnification, measurement, annotation, the tech will save the images using save a presentations state prior to Verifying the image in PACS	na in Breast Imaging
Tech marks the exam VERIFIED in PACS a) Exam is auto-completed in RIMS b) Images are sent to QREADS for early view	No PACS, a.) exam completed at the time it was performed b.) Images are sent to Qreads after final report or sent to early view EEDS
Radiologist	
Images are viewed on GE PACS and dicated using XX	Images are viewed on Hologic workstations
R2 CAD is selected	Radiologist views CAD marks
Annotations are added	Images on patients with a "finding" are annotated by the radiologist (Annotation button).The radiologist sends the images to all managers (click Pie button)
Report created in PenRad	Radiologst creates report by clicking on specific options as well as typing and voice recognition in Dragon. Letter code is added and appropriate letter is sent to patient (Secured Mayo Printing)
Report is Finalized in RIMS or WB by the Radiologist. GE status updated to Completed (status 90).	Report is finalized in PenRad and automatically sent on to RIMS. If the exam was not completed by the tech, the PenRad report will send an error message to the PenRad mail box. The PenRad administrators will view the mail box, comlete in RIMS and resend (password in PenRad) the exam to RIMS. Other report errors are managed by transcription interacting with the radiologist. Transcriptionins opens exam for radiologist (back to Exam List), radiologist corrects, transcription sends final report to RIMS.
Images are archived to MIDIA at finalization	Images were archived (MIDIA) at time of acquisition (Acceptance button from Hologic), become available in Qreads after report finalizaton



B. Support

Sample of Support related questions:

A. Is it a strategically aligned purchase?

Is this an enterprise convergence application?

supporting many different vendors for the same type of system makes support harder

B. Clinical Use? FDA Approval? Replacing existing system?
C. Installation plan? Who, What, Where, When?
D. Business Associate Agreement?
E. Do images need to be saved?
F. Interacts with the RIS?
G. Reported on by Radiologists
H. Hardware Break/fix SLA?
I. Application Break/fix SLA

C. Interoperability Assessment

Resources:

- DICOM Conformance Statement
- IHE integration Statement
- Sample Images
- Vendor Implementation Notes/Manuals
- Site Specific Interoperability Questionnaire

And/or

- On-site trial

DICOM Conformance Statement (DCS)

A document standard that provides:

- Description of how an application entity implements the DICOM standard
- Describes this in a standard format which facilitates comparison

Despite these documents being a standard form for describing a standard, there can be variation in how useful or readable a DCS is.

DICOM Conformance Statement

Limitations:

"The integration of any device into a system of interconnected devices goes beyond the scope of the DICOM 3.0 standard and this conformance statement when interoperability is desired. The responsibility for analyzing the applications requirements and developing a solution that integrates the Agfa equipment with other vendors' systems is the user's responsibility and should not be underestimated.

In some circumstances it might be necessary to perform a validation to make sure that functional interoperability between the Agfa equipment and non-Agfa devices works as expected. The user should ensure that any non-Agfa provider accepts responsibility for any validation required for their connection with the Agfa equipment." *from Agfa DICOM Conformance Statement*

Integrating the Healthcare Enterprise (IHE)

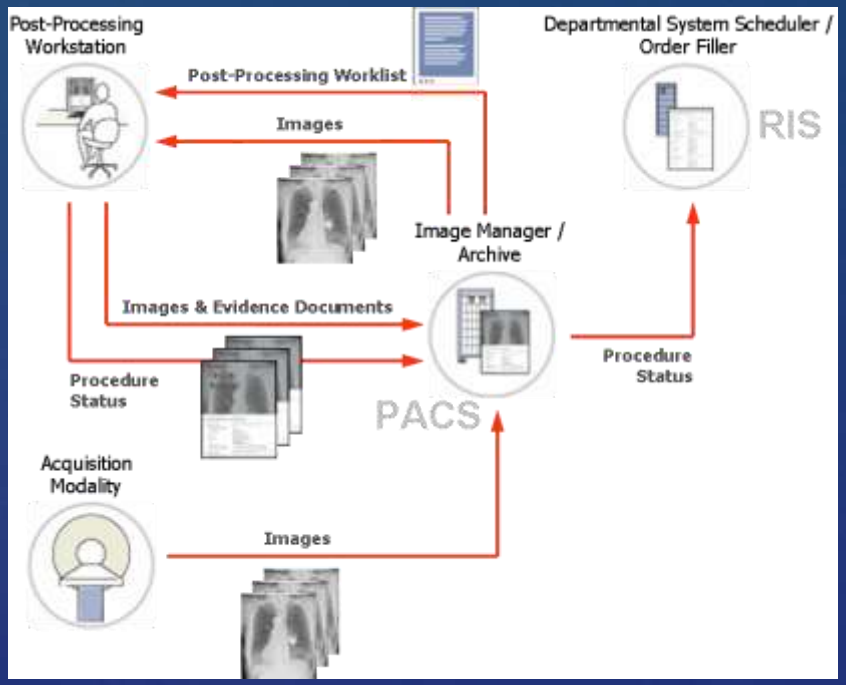
IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical need in support of optimal patient care.

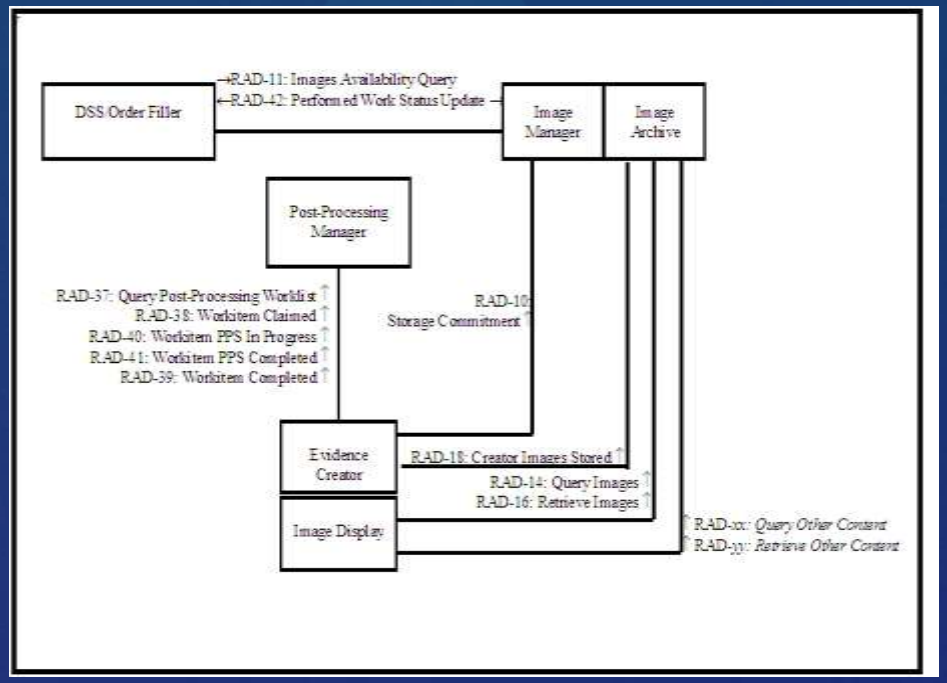
IHE integration profiles describe a workflow and agents in that workflow. For example, the Post-Processing Workflow provides worklists, status and result tracking for post-acquisition tasks, such as Computer-Aided Detection or Image Processing

Has the equipment or software been validated for all of the relevant integration profiles?

IHE Integration Profile

EXAMPLE: Post-Processing Workflow





Limitations of utility:

1) Your workflow matches the IHE workflow
2) Every other system in the profile has also been validated for its role

Interoperability Questionnaire

Other questions for vendors that might not be identifiable in the DICOM DCS or IHE profiles.

What matters to your practice?

Where have you been burned?

Sample Concerns:

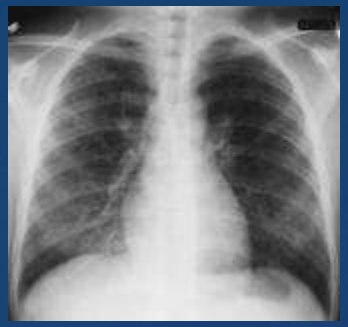
- Does the system utilize wireless connections?
  - What is its function (between subparts of system or between the unit and institutional electronic environment?
  - Encryption?
  - Can wired and wireless be used simultaneously?
- Does it use lossy compression or is that an option? What compression options are available?
- Do image transfers happened in background or foreground?

Interoperability Questionnaire

Sample Concerns, continued:

- When DICOM data elements or image data are modified what of the following are changed? Study , series, or instance UID.
- How are DICOM associations managed when transmitting images?
- How are temporarily-unavailable (off-line) DICOM Store destinations managed?
- Do image transfers from the modality or the workstation occur in the foreground or in the background
- If post-processing software, is hardware provided? Video card? Display?

Sample Images



1. Assign them to a test order and put it into your electronic environment
2. Use a tool kit to assess conformance with the DICOM standard
   - From David Clunie
   - DICOM Viewer/Validator Software

On-site Trial

Try before you buy

Sample images

- Are not fed by your ordering or information systems.
- Do not allow variation in workflow operations on the modality

It is not possible to trial every system .

Sometimes vendors can provide modality emulators.

D. Security and Compliance

Take a look at the

ACR–AAPM–SIIM PRACTICE GUIDELINE FOR ELECTRONIC MEDICAL INFORMATION PRIVACY AND SECURITY

Know the regulations with Electronic Protected Health Information (ePHI)

- **HIPAA**
- **HITECH**

D. Security and Compliance

HIPAA/HITECH in a nutshell :

Security Rule:

- Ensure the confidentiality, integrity, and availability of all e-PHI they create, receive, maintain or transmit
- Identify and protect against reasonably anticipated threats to the security or integrity of the information
- Protect against reasonably anticipated, impermissible uses or disclosures;
- Ensure compliance by their workforce

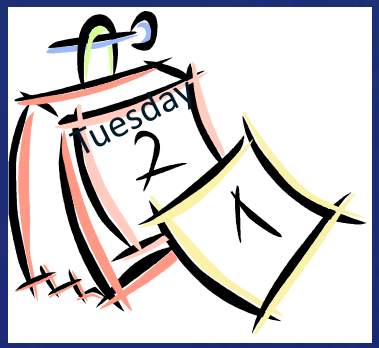
Vendor provisions for HIPAA/HITECH

Reality Radiology Workflow

D. Security and Compliance

Concern for any device connected to a network architecture:

- Maintainable OS
- Uses an antivirus or are otherwise protected from malware and viruses, i.e vendors must provide a robust and regular maintenance plan.
- May need to be protected from pushing unvalidated patches to imaging equipment



Know your network/information security policies!

D. Security and Compliance

Cracking the Neanderthal Code

Our closest cousin's DNA may unravel secrets of evolution

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June 13, 2013

Patients Put at Risk By Computer Viruses

By CHRISTOPHER WEAVER

The Food and Drug Administration is warning makers of heart monitors, mammogram machines and myriad other medical devices that their gear is at risk of being infected with computer viruses that can endanger patients.

Connectivity Review- Summary

Pull together all the information discussed to make sure it's self-consistent and do-able.

Involve major stakeholders to get their perspective

A. Workflow/Dataflow
B. Support
C. Interoperability
D. Security/Compliance

Summary

A connectivity review provides forethought to implementation.

Two Uses for the review:

1. Are we buying the right system ? Can it do what we expect it to do?

And/or

2. For the purchase that is coming
   - What is it going to take to make it work?
   - Assess issues and estimate effort and allocate resources before we have patients waiting.

Summary

Role for physicists:

As a technical advisor to imaging equipment purchases, physicists have an interest in making sure the questions in a connectivity review are addressed and they may be integral in getting many aspects addressed.