

# **Integrating the Healthcare Enterprise**

# IHE Radiology: Mammography User's Handbook

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**Note:** This is the first edition of the IHE Radiology: Mammography User's Handbook. New editions will be available at *IHE.net* and will include examples of more contractual RFP language, more Profiles (for Radiology, IT Infrastructure, Cardiology, and Laboratory domains), and scenarios for workstations and basic PACS installations.

The Handbook is intended to meet the needs of the IHE user community. Feedback on the contents or suggested additions is welcome on the IHE Forum page at *forums.rsna.org*.

# **Executive Summary**

This handbook has been developed by the IHE Mammography Committee and the IHE Radiology Technical and Planning Committees expressly for those who are considering the purchase and implementation of digital mammography equipment. The intention of this handbook is to make the purchasing and implementation process easier and more successful. Three chapters are currently included herein. Chapter 1 is focused on the purchase and integration of full field digital mammography modalities. Chapter 2 addresses the requirements for successful deployment of a mammography diagnostic review workstation. Chapter 3 offers details on integrating a mammography film printer. Also included in this handbook are a Glossary and a sample RFP (request for purchase) together with a series of appendixes to provide more details on the planning and purchasing process of digital mammography equipment. This handbook exists as part of the IHE Radiology User's Handbook. These documents are available online at http://www.ihe.net/Resources/handbook.cfm.

In each chapter you will find sections describing the planning and purchasing process of digital mammography equipment. Details are given as to how to select the appropriate IHE integration profiles to make the new equipment integrate seamlessly and become fully functional in an IHE conforming enterprise. Details as to how to put together RFPs, how to interpret vendor responses to your RFPs and how to select the right product for your goals and environment are explained.

Each chapter also goes over the configuration and implementation process of digital mammography equipment. Possible workflow scenarios are explained. Details on how to test the main profile requirements that may apply to each piece of equipment are provided together with information on potential installation and legacy issues.

Last but not least, this handbook goes over all relevant profiles that may be necessary for your new equipment and the benefits your enterprise will experience by adopting such profiles. Implementation of the listed profiles for each type of digital mammography equipment will assure optimal function of the equipment in the heterogeneous environments that exist essentially in all facilities.

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# Introduction

# What is IHE?

Integrating the Healthcare Enterprise (IHE) is an initiative whose goal is to make all necessary information about any given patient readily available to a care provider in order to ensure optimal medical care to the patient. This initiative is driven by care providers (including ACC, HIMSS and RSNA) and vendors. IHE defines *Integration Profiles* that use established IT standards to integrate systems from multiple vendors for effective interoperability and efficient workflow in day-to-day work scenarios of health professionals (users), using information from patients' records.

This handbook helps you to understand, choose and select IHE integration capabilities for products you purchase or upgrade so that the systems will better support your clinical needs. It targets users that

- 1. Make decisions on purchasing or maintaining health IT systems (e.g. CIO, Radiologist, Physician),
- 2. Install and administer these systems in an institution (e.g. IT/ Physician administrators).

# What is an Integration Profile?

An *IHE Integration Profile* describes precisely how to solve given real-world clinical problems through functional system components, called *IHE Actors*. These are based on standards such as Digital Imaging and Communication in Medicine (DICOM) and Health Level 7 (HL7). Integration Profiles do not create standards; rather they clearly, carefully define how Actors use established standards unambiguously in order to be interoperable and work together, e.g. how to acquire and display digital mammography images.

#### How do you obtain products with IHE Integration Profiles?

You specify IHE capabilities as requirements on the information systems (such as PACS, RIS, acquisition modalities, and review workstations) you are purchasing or upgrading. Simply state in the RFP which IHE Actors and Integration Profiles you need.

#### What is the business case for implementing Integration Profiles?

Integration Profiles give clear definitions, based on widely accepted standards, of how systems fit together. Integration via IHE reduces integration costs at the start, makes future acquisitions easier, and provides valuable functionality. The alternative—building site-specific interfaces—is more expensive and requires maintaining these custom interfaces for the systems' lifetime.

#### What other benefits does IHE provide?

IHE makes it practical for healthcare providers to use advanced information technology to improve the quality and efficiency of care. By ensuring the integrity of medical information, IHE enhances patient safety. By reducing the time spent in solving data problems such as lost and mismatched studies, IHE allows efficient use of staff time. By providing healthcare providers comprehensive patient information, IHE enables betterinformed medical decisions.

#### What should you do next?

Learn about the IHE Integration Profiles available for Radiology and other parts of the Enterprise and consider how they meet your organization's goals. Read this IHE Radiology: Mammography User's Handbook to learn how to require these capabilities in an RFP and how to implement them in your setting. These resources and more are available at <u>www.ihe.net</u>.

# How to Use this Handbook

**Each main chapter in this Handbook presents a typical scenario** for augmenting your integration by acquiring and deploying new or upgraded IHE-capable systems like modalities, archives (PACS) or a radiology information system (RIS).

Each scenario includes advice for those selecting and purchasing new systems:

- Mapping your departmental goals to IHE features (X.1.1, X.1.2)
- Writing RFPs to obtain the desired IHE system functions including sample RFP text (X.1.3)
- Identifying and evaluating relevant products (X.1.4, X.1.5)

And advice for the technical staff who will handle the installation and configuration of the new systems (Sections X.2.1 to X.2.4):

- Workflow changes that maximize the benefit of the IHE-integrated systems (X.2.1)
- Installation testing to confirm that IHE capabilities are functioning properly (X.2.2)
- Issues to consider when installing and configuring IHE-capable systems (X.2.3)
- Including "legacy" systems in your integration activities (X.2.4).

The scenarios assume familiarity with and ability to locate certain documents and information. **The appendices provide tutorials** for those needing further background. You may wish to read appendices first if you are interested in methodology and general aspects of integration. For instance, if you want to know what the IHE specifications (Technical Frameworks) contain, where to find them and how to find out which parts are relevant for you, Appendix B will answer your questions. The Glossary (section V) will provide definitions of terms that may be unfamiliar to the new user.

This Handbook provides direction on how to make use of the tools developed by the IHE initiative to deploy radiology systems that exchange information effectively and based on standards, to meet critical clinical needs. It does not attempt to take account of the many other factors that determine the efficiency and suitability of an application for clinical use. The tools provided by IHE are thus only part—albeit an essential one—of the full set of resources required to select, purchase, deploy and upgrade IHE systems.

# Glossary

*Actor* [IHE]: The functional unit in IHE. It is a system or application that is responsible for creating, managing, storing and communicating certain information. Each Actor supports a specific set of IHE transactions to communicate with other Actors. A vendor product may include one or more Actors.

*Broker*: A device or application that addresses legacy issues by interfacing between the rest of the world and a system that does not comply with a particular specification. Messages to and/or from the system are instead sent to the broker, which translates between the required specification and what the system can understand.

*Connectathon* [IHE]: An annual event where participating vendors test their implementations of IHE Actors with other vendors in a supervised environment.

*Digital Imaging and Communication in Medicine (DICOM):* The established standard for the exchange of digital information between medical imaging equipment and other systems.

DICOM service: See Service Class.

*Domain* [IHE]: A working group in IHE that addresses a particular clinical area—e.g., Radiology, Cardiology, Laboratory or IT Infrastructure. Each domain publishes a Technical Framework (TF).

*Health Level 7 (HL7):* The established standard for the exchange, management and integration of data that support clinical patient care and the management, delivery and evaluation of healthcare services.

*Image Manager/Image Archive*: A pair of IHE Actors that described the capabilities of a system that provides safe, long-term storage and management of medical images and other evidence objects and supplies availability information for those objects to other information systems. PACS is the common product category description for such a system.

*Integrating the Healthcare Enterprise (IHE)*: An initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information.

*Integration Profile* [IHE]: A precise description of how standards are to be implemented to address a specific clinical integration need. Each Profile includes definitions of the clinical use case, the clinical information and workflow involved and the set of Actors that address that need. Integration Profiles reference the fully detailed integration specifications defined in the IHE Technical Framework in a form that is convenient to use in requests for proposals (RFPs) and product descriptions.

*Integration Statement* [IHE]: A document prepared and published by a vendor to describe the IHE Integration Profiles, Actors and options supported by a specific version of a product.

Interface engine: See Broker

*Lost study*: A study that has been deleted or cannot be located (often due to having been incorrectly indexed because of errors or mismatches in demographics or tracking information).

*PACS (Picture Archiving and Communication System)*: A system for storage, management and distribution of medical images and related information. The integration capabilities of such a system are described generically in the IHE Technical Frameworks as the Image Manager/Image Archive actor pair.

# Profile [IHE]: See Integration Profile

*Registration System*: The system used for patient registration under normal workflow; usually the owner/source of patient demographics (PID).

*Service Class* [DICOM]: A function, such as storage or printing, specified by DICOM and implemented by a device, which may provide or use the service.

*Service Class Provider (SCP)* [DICOM]: A system or application that provides a DICOM Service (often viewed as the "server" of a service).

*Service Class User (SCU)* [DICOM]: A system or application that uses a DICOM Service (often viewed as the "client" of a service).

*Supplement* [IHE]: A proposed addition to the Technical Framework (TF). After public comment, review, trial implementation and testing, it is generally merged into the TF.

*Technical Framework (TF)* [IHE]: The document that defines Integration Profiles, the problems and use cases they address, and the Actors involved. It provides detailed implementation instructions for each Actor (primarily used as a guide for vendors).

*Transaction* [IHE]: An exchange of information between Actors. For each Transaction, the TF describes how to use an established standard (such as HL7, DICOM or W3C) to exchange information.

*Worklist*: A list of work items, such as image acquisitions, to be performed. Generally, it is retrieved electronically and contains details about the task, such as patient name and identification (ID) number, Accession Number, and relevant input data. May or may not dictate a specific schedule or piece of equipment.

# Additional Abbreviations

 $AE \ Title \ [DICOM] = Application-Entity \ Title$  $AN \ [DICOM] = Accession \ Number$  $CAD = Computer-Aided \ Detection$  $CPI \ [IHE] = Consistent \ Presentation \ of \ Images$  $DCS = DICOM \ Conformance \ Statement$  $FFDM = Full \ Field \ Digital \ Mammography$  $HIS = Hospital \ Information \ System$  $IT = Information \ Technology$  $MPPS \ [DICOM] = Modality \ Performed \ Procedure \ Step$  $MQSA = Mammography \ Quality \ Standards \ Act \ of \ 1992$  $MWL \ [DICOM] = Modality \ Worklist$  $PACS = \ Picture \ Archiving \ and \ Communication \ System$  $PID = \ Patient \ demographics$ 

*PIR* [IHE] = Patient Information Reconciliation

- *RFI* = Request for Information (customer requests product information from vendors)
- RFP = Request for Proposals (customer requests product, company, technical or other information from vendors for a bidding process)

*RIS* = Radiology Information System

SOP [DICOM] = Service Object Pair (definition of an Information Object and its functions)

*SWF* [IHE] = Scheduled Workflow

# **1** Integration of a Digital Mammography Modality

This chapter describes how to integrate a full field digital mammography acquisition modality (FFDM) into a mammography imaging practice in order to be able to acquire, store, retrieve and print digital mammography images. It focuses on devices that create DICOM Digital Mammography X-Ray images using a digital detector (DR) or computed radiography (CR). Specifics for film digitizers are not covered—IHE considers film digitizers under the role of a digital mammography modality and they should follow the same rules.

When buying and installing a new digital mammography modality, consideration should be made to the systems and capabilities already in place in the health enterprise and how the new modality will interact within the pre-existing environment. Choosing a modality with IHE integration capabilities can provide many benefits and maximize the capacity of the new modality to function optimally in an IHE compliant environment.

An exemplary IT environment to acquire and use digital mammography images is shown in the diagram below. For the digital mammography modality, IHE defines what image information needs to be created in order to enable further use of the images by diagnostic review workstations or printers. IHE also defines how the modality stores the images to PACS, as a necessary first step to using digital mammography images in your institution.

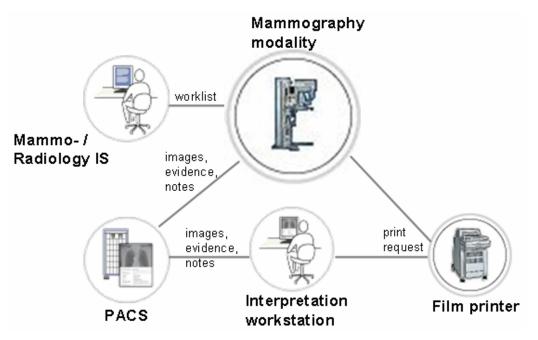


Figure 1. Environment for integrating a digital mammography modality

# 1.1 The Planning and Purchasing Process of a Digital Mammography Modality

Intended for administrators and radiologists who make purchasing decisions, this section walks you through the different IHE profiles that may apply to a digital mammography modality and helps you select the IHE integration profiles that will address your

organizational goals. This section will also show you how to clearly state IHE requirements in a request for proposals (RFP) and how to interpret vendor responses.

It is not always possible to address all goals by making a single IHE-related equipment purchase. Achieving the full benefit of an IHE integration profile requires that the systems interacting with the modality, such as RIS and PACS, also play their roles as defined in the corresponding profiles. Appendix A provides a general discussion of sequencing requirements and planning individual purchases as part of a long-term plan.

To track progress toward organizational goals and determine return on investment, a well-defined set of performance metrics is needed—see Appendix I.

Having clear organizational goals is important for defining the requirements for equipment acquisition. Each IHE integration profile is designed to meet a specific set of organizational goals. Below is a list of the IHE integration profiles that may apply to a digital mammography modality and the contributions that each relevant integration profile makes in supporting a range of institutional goals.

# **1.1.1** Selecting IHE Integration Profiles for the Digital Mammography Modality

Specifying integration requirements for the digital mammography modality you are purchasing is a simple matter of selecting which IHE integration profiles (work scenarios) and which associated IHE actors (system functions) you want supported by the modality. Note that some IHE integration profiles include options that provide additional functionality you may also decide to select.

The following table gives an overview of the IHE integration profiles that may apply to the digital mammography modalities you may already have or plan to purchase or upgrade, including subsequent integration steps. Note that all of your connected systems in your health enterprise need to participate in the relevant IHE integration profiles to achieve the full benefit. Further details on these IHE integration profiles are provided in the following sections.

IHE Integration Profile	<b>Proposed</b> <b>Integration Step</b> (1= essential), (2-4= additional)	Mammo Modality	Review Workstation	PACS	Mammo- / Radiology IS	Film Printer
Mammography Image	1	Х	Х	Х		Х
Scheduled Workflow	2	X	Х	Х	Х	
Portable Data for Imaging	3	X	Х	Х		
Key Image Note and / or	4		Х	Х		
Consistent Presen- tation of Images	4		Х	Х		

**Table 1.** Systems and IHE integration profiles relevant to a digital mammography modality in your institution

# 1.1.1.1 IHE Mammography Image Profile (MAMMO)

The IHE Mammography Image Profile as applied to the digital mammography modality ensures that the acquired digital mammography images contain all relevant information that is necessary for further image processing, application of CAD, storage, review and printing. This profile is absolutely necessary for generating correct digital mammography image content to ensure optimal presentation of images at a mammography review workstation. In addition, you may want to choose the *Partial View Option* of this integration profile for added benefit when image tiling may apply. In case the breast is larger than the detector, it enables the digital mammography modality to mark images as covering the breast tissue entirely or partially and in the correct order.

Requesting support for the MAMMO profile by the digital mammography modality will provide the following benefits to your healthcare enterprise:

- Reduce Errors and Enhance Patient Care
  - Ensuring proper, consistent creation of patient and technical information
  - Ensures that the acquired images contain the necessary data for identifying patient and technology, and that further image processing and review is correct and meaningful, mainly by:

- Scaling of the image so that images from the same patient, acquired on different detectors can be displayed at the same size or printed in true size
- Storing contrast information at the modality so that contrast adjustments do not degrade the quality of displayed images
- Clear definition of breast tissue and background air so that if contrast adjustments are made during interpretation of the images, the background blackness will be maintained for optimal viewing of the structure of the breast.
- Improve Image Quality
  - Improves image display and printing by including relevant data in images
  - Ensures that all technique acquisition parameters are available for review
  - Ensures that the images can be oriented, justified and sized correctly for proper and expeditious interpretation
  - Ensures that presentation images can be used in a consistent manner on different mammography review workstations

# 1.1.1.2 IHE Scheduled Workflow Profile (SWF)

The IHE Scheduled Workflow Profile is the cornerstone of IHE integration for the acquisition process. It establishes a seamless flow of information that supports efficient patient care in a typical imaging encounter and maintains the consistency of patient information from patient registration through ordering, scheduling, image acquisition, storage and viewing. At the modality, it is used to request patient demographic data automatically, send messages about the progress of the examination back to the RIS and to send images to the PACS.

The Scheduled Workflow Profile ensures that patient demographics, order and procedural information are correct and consistent. It allows images to be available for review in a timely fashion. Modality operators use the Modality Worklist to query and retrieve the relevant patient demographics and scheduled procedure information from the RIS.

Requesting support for the SWF profile by the digital mammography modality will provide the following benefits to your organization:

- Reduce Errors and Enhance Patient Care
  - Prevents manual data entry errors and stale data at the modality console by downloading current patient and study information from the RIS
  - Prevents delays in patient care by transmitting images and completion status electronically
  - Prevents lost or "broken"<sup>1</sup> studies—modality stores studies with accurate patient and procedure information for current or prior studies

<sup>&</sup>lt;sup>1</sup> A "broken" study occurs when there is a mismatch between key demographic or tracking information between the patient record, the order and the images.

- Improve Exam Throughput
  - Saves manual search or data entry time by using *worklists* to download patient and study details and using accurate data for archiving
  - Saves time wasted manually confirming image transfer to PACS—the modality automatically confirms PACS receipt of images
  - Reduces delays in the review/reporting process—the modality specifically reports exams in progress and completed exams to the RIS, allowing faster initial and final reads
  - Prevents time wasted by manually fixing demographics for emergency or Jane Doe studies—PACS updates its studies based on patient identifying data feeds from the RIS or Mammography IS
- Improve Billing Process
  - Recovers lost revenue for additional procedures performed that are not entered into the RIS—the modality updates the RIS with procedures actually performed
  - Prevents payer claim rejection of reported procedures not matching the order—the modality reports procedures actually performed and flags when they differ so they can be reconciled
- Reduce Operational Costs
  - Prevents extra head count with the efficiencies and improvements in throughput described above

# **1.1.1.3** IHE Portable Data for Imaging Profile (PDI)

The IHE Portable Data for Imaging Profile enables creating DICOM-compliant image CDs on the modality.

Requesting support for the PDI profile by the digital mammography modality will provide the following benefits to your organization:

- Reduce Operational Costs
  - Reduces unnecessary films for surgery, referrals to other sites or referring physicians—the modality creates digital image CDs to be sent to other image consumers

#### **1.1.2** Selecting IHE Integration Actors on the Digital Mammography Modality

Each IHE integration profile contains several *actors*. Frequently, partial benefits can be achieved by implementing a subset of a profile's actors, such an acquisition modality alone, even though not all of the integration functions described in the profile are available. (See Appendix A for planning individual purchases as part of a long-term plan).

The <u>Acquisition Modality Actor</u> is the key role played by a modality device: it creates images, and stores them to PACS that afterwards can make them available for viewing or CAD processing.

Additional IHE actors a modality device can perform include:

- <u>Print Composer Actor</u>: sends print requests to DICOM printers (for image distribution to "non-digital" users)
- <u>Image Display Actor</u>: retrieves and displays images from PACS, e.g., prior mammograms
- <u>Media Creator Actor</u>: creates CDs with imaging data
- <u>Media Importer Actor</u>: imports image data from CDs into your digital mammography modality.

The following table summarizes the IHE actors that enable essential digital mammography modality functions (key actors) and additional/advanced functions for specific work scenarios. You may choose to request actors and profiles step-wise in your RFP, depending on your existing IT environment and integration approach (see Appendix A).

IHE Integration Profile	Key IHE Actor	Additional IHE Actor
Mammography Image	Acquisition Modality	Image Display, Print Composer, Evidence Creator
Scheduled Workflow	Acquisition Modality	Image Display
Portable Data for Imaging	Portable Media Creator	Portable Media Importer, Image Display, Report Reader

Table 2. Key and additional IHE actors for a digital mammography modality

# 1.1.3 Specifying Integration Requirements in an RFP

Requiring IHE support in your RFP in order to meet your goals as shown above is achieved by stating which IHE integration profiles and which IHE actors the digital mammography modality should support. Sample statements to specify the IHE integration profiles and actors relevant to a digital mammography modality are:

- "The system shall support the IHE Mammography Image and the SWF Integration Profile as the Acquisition Modality Actor."
- "The system shall support the IHE Portable Data for Imaging Integration Profile (PDI) as the Media Creator Actor."

Note that a subset of IHE Profiles and Actors (see 1.1.1) may suffice as a first step (e.g. Acquisition Modality), depending on how many other IHE-capable systems already exist in your institution that the new system can connect to. For instance, if there is no Information System or PACS to connect to initially, you do not need to require the Scheduled Workflow Integration Profile in the RFP. Nevertheless, it may be valuable to you to burn CDs and thus require the Media Creator Actor in PDI for the product to be purchased.

# **1.1.4 Identifying Suitable Products**

While you may choose to proceed directly to sending your RFP to a broad group of potential vendors, find out which vendors have products with relevant IHE integration capabilities by referring to public sources. For a description of these sources, see Appendix D.

# **1.1.5** Reading Integration Statements from Vendors

Vendors may respond to your RFP by providing an IHE integration statement. These documents are also available for many products at *www.ihe.net/Resources/ihe\_integration\_statements.cfm*.

An integration statement is a direct statement of which IHE profiles, actors and options are supported by a particular product from a particular vendor (see Appendix E).

# **1.2 The Configuration and Implementation Process of a Digital Mammography Modality**

The following sections are intended for the implementation team. They cover important clinical and IT considerations when deploying a digital mammography modality with IHE capabilities, including dealing with "legacy" issues when connecting the modality to other systems that do not support IHE profiles.

# **1.2.1** Considering Changes to Your Workflow

IHE profiles are designed to implement digital imaging in a streamlined clinical workflow. For instance, they eliminate the need to enter patient information at the modality, searching for lost film folders or reconciling cases in the unmatched study folder on the PACS. They also allow images to be immediately available for viewing. To gain the full benefit of these changes, there are several tasks that need to be performed in the correct manner.

# **1.2.2** Confirming That It Works

The following sections provide guidance on how to confirm that the modality is operating according to each IHE profile implemented. Each section provides elements for testing an individual profile as it relates to the modality. Often, there are other ways than those described herein to confirm the data and the transactions—see Appendix H.

It can be challenging to determine whether or not the modality actor is following an IHE integration profile. If we take the Mammography Image Profile as an example, verifying that the modality includes a particular set of data in the acquired images may not be possible but through the lack of functionality at the review workstation, such as data mentioned in 1.2.2.6. On the other hand, the lack of functionality at the review workstation may not indicate a problem with the modality, but a lack of feature set at the workstation itself or another system in your workflow such as the image manager (a.k.a. archive) or evidence creator (a.k.a. CAD). This section provides information on the functional expectations for the images generated by the digital mammography modality. Your ability to detect or troubleshoot issues will likely be dependent upon the feature set of your modalities and the support of your vendor.

#### **1.2.2.1** Transmission of Images

Most modalities give an indication through their user interface of the images and studies they have successfully transmitted to other store destination devices such as PACS, CAD, etc. They can also verify that the same number of images contained within the study acquired at the modality is stored on the store destination device. Querying and retrieving the study from the image manager can provide another indication that the images were successfully stored.

Note that with the digital mammography modality "For Presentation Images" are stored to PACS, whereas "For Processing" images may be sent to a CAD system. When storing both "For Processing" and "For Presentation" images, the number of images stored in PACS for a study should be double the acquired images. However, when verifying images received on a workstation, this may or may not be the case if the workstation has a preference for one data type over another for the same image. Nevertheless, the result of a query will contain information of "For Processing" images.

If the modality is connected to a CAD system, the modality can transfer the images to the CAD system, which in turn automatically forwards CAD results to the review workstation. It is assumed that CAD systems automatically receive acquired images from the modality in a way that currently is not defined by IHE.

# **1.2.2.2 Image Data Types and References**

The digital mammography modality shall be capable of sending images in both raw data format (a.k.a. "For Processing" images) for use by CAD systems, and in a display ready format (a.k.a. "For Presentation" images) for image display purposes. Depending upon your local requirements, there may be exceptions to this typical data configuration. If you are uncertain as to what data formats are sent to which devices, check with your modality's manufacturer on how this is accomplished.

Note: Image display systems are not required to process or even display "For Processing" images. Images that appear "washed-out", cannot be displayed, or cannot be sent to image display systems at all, are likely to be "For Processing" images sent to image displays that do not have the support to process the data as the digital mammography modality manufacturer intended or may not be able to appropriately prioritize display of "For Presentation" images rather than "For Processing" images.

Since CAD marks generated from "For Processing" images (usually the case) are expected to be presented along with the displayable, "For Presentation" images, the two different data types referring to the same original "For Processing" image must be correlated. Therefore, the "For Presentation" images are required to reference the "For Processing" images by populating the Source Image Sequence (0008,2112) attribute.

To determine whether or not data is correlated correctly, cross reference the source identifier in the CAD results with that in the "For Presentation" image. For those with troubleshooting tools within their applications, the source identifier attribute is the SOP Instance UID (0008,1155) within the Source Image Sequence (0008,2112). Otherwise, you may have to engage the assistance of your image display system, CAD, PACS and modality vendors to verify reference unique identifiers (UIDs).

#### **1.2.2.3** Patient, Study, and Image Information in Images

The IHE Mammography Image Profile extends requirements in DICOM to more fully identify the patient and exam information. The following information must be provided by the digital mammography modality:

- Patient information: patient's name, patient ID, patient's age, birth date
- Study, series and image information: acquisition date, acquisition time, operator's name, compression force, body part thickness, positioner primary angle
- Equipment information: manufacturer, institution name, institution address, manufacturer's model name, device serial number, detector ID, software versions

• X-Ray acquisition dose information: kVp, exposure, exposure time, filter material, anode target material, relative x-ray exposure, entrance dose and organ dose in mGy.

By viewing such information on other systems, such as an image manager or review workstation you can check if these attributes have been provided by the digital mammography modality.

Note: if a system's application does not provide access to view one of the following fields, examining the DICOM conformance statements of your digital mammography modality should confirm whether or not the modality provides this information.

# **1.2.2.4 Changes to Patient Information**

Patient name changes should not be made on the modality. The RIS is the primary information source and is capable of managing name updates, as long as the modality does not introduce additional unexpected changes. To ensure correct patient information, the Modality Worklist should be re-queried just before starting a new exam in case patient or order details have changed. The modality operator should verify that the right patient is selected for each examination.

In unscheduled cases, patient names and identification (ID) numbers may be unknown. As these are required to commence the procedure, they will need to be selected from a predefined list of temporary patient names and IDs and entered at the modality. In such unscheduled cases, the *accession number*, a key identifier for the imaging order, must be left blank. Later, when the correct patient ID, name and accession number are known, the RIS and PACS will reconcile the image information with the correct values.

# 1.2.2.5 Air Gap Suppression

A digital mammography modality needs to indicate the parts of the digital detector that are not covered by tissue, i.e. air gap. This ensures that, when changing contrast adjustments to an image, the air gap area of the image remains black while the rest of the breast tissue contrast is changing. A mammography digital modality detects the breast tissue and chooses to either

a) replace non-breast image data areas with a specific "pixel padding value", or

b) provide a "pixel padding value range" that defines non-breast image data.

Check the modality's DICOM conformance statement to determine which method is supported: pixel padding (DICOM attribute 0028,0120) or a range of non-breast tissue pixel values (DICOM attributes 0028,0120 and 0028,x121).

# **1.2.2.6 Image Presentation and Hanging Information in Images**

A digital mammography modality shall provide a certain set of image attributes that enables image displays to consistently hang images across different viewing applications. Image displays may then use a combination of study, series and image information to improve upon the basic presentation and orientation of images. The digital mammography modality is required to supply the following attributes for placement and image orientation used in hanging images:

- Patient orientation (0020,0020)
- Image laterality (0020,0062)
- View code sequence (0054,0220)
- View code modifier sequence (0054,0222), when present.

Verify that the digital mammography modality populates correctly and sends the above attributes through either its DICOM conformance statement, troubleshooting tools provided with the application, or by working with the manufacturer to verify DICOM header content.

# **1.2.2.7** Measurements and Image Size

In order to be able to determine the true physical image size on a display system the digital mammography modality shall encode correctly the *imager pixel spacing* (0018,1164) and *estimated radiographic magnification factor* (0018,1114). Verify that these parameters are included in the image header, by referencing the modality's DICOM conformance statement, using troubleshooting tools provided with the modality, or by asking the vendor to verify that the proper data is sent.

# 1.2.2.8 Partial View—Optional Indicator for Breast Tissue Coverage of Images

If your digital mammography modality claims support for the Partial View Option, it will always indicate whether or not the image represents the entire breast, or is part of a set of images representing the entire breast. If a partial view, it will also indicate the relative position of the image to other possible images within the set. To troubleshoot support for this feature,

- 1) verify that the modality claims support for this option through its IHE Integration Statement, or
- 2) use troubleshooting tools provided with the application or check with the modality manufacturer to verify that the image header contains values for these attributes: partial view (0028,1350), partial view code sequence (0028,1352).

# **1.2.2.9** Storage Commitment

Storage commitment is a service that passes responsibility for the image from the modality to the image manager. It can also be used to confirm that the CAD system has received images sent from the modality. Find out from your modality vendor what functions and user interfaces are available to confirm that an image has been successfully committed to another device.

1. Find out if the modality prevents or warns you on trying to delete images prior to the image archive claiming possession of the images. *(Storage Commitment)*. Note that in this case, it may be safer to ask your vendor first and to use specific test images. Verify that the images on the modality cannot be deleted because they have not been permanently stored through the PACS system.

2. Attempt to delete the images from the modality after the image archive claims possession of the images. *(Storage Commitment)*. Verify that the images on the modality can be deleted because they have been permanently stored through the PACS system.

# 1.2.2.10 Scheduled Workflow—Receiving Worklists and Completing Acquisition Steps

If you want to test workflow functions on your modality (i.e. support for the Acquisition Modality in the Scheduled Workflow Integration Profile), please refer to chapter 1.2.2.1 in the IHE Radiology User's Handbook.

# **1.2.3** Considering Installation Issues

Even with IHE, installation is not truly "plug & play". Some thought must be given to the workflow and dataflow of mammography images and CAD results. In addition, systems are not self-configuring and they must be configured properly to communicate with other devices. This section provides tips on typical considerations and actions necessary for installation and system communications of a digital mammography modality.

# **1.2.3.1** Define and Understand your Workflow and Dataflow

Due to variability in system features among acquisition modalities, PACS, and review workstations, there is not one model of data and workflow that fits all situations. Typically, mammography diagnostic review workstations are specialty workstations that may or may not be tightly integrated with your modality or PACS. Careful consideration must be given as to how images and CAD results are routed through your system—this normally needs product-specific configuration. The following questions may help in planning your dataflow:

- 1. What type of data is needed in my system, and by what devices? The digital mammography modality can send both "For Processing" and "For Presentation" images. Typically, CAD operates on "For Processing" images and generates a *mammography CAD structured report*. Review workstations generally display "For Presentation" images and CAD results, although some may also support displaying "For Processing" images, too. Determine the source and destination of each type of data needed for your system devices.
- 2. Do I want to archive "For Processing" images in my PACS, as well as "For Presentation" images? For basic operation, archiving only the "For Presentation" images is adequate for most facilities. However, a site may have additional reasons to store the "For Processing" images in addition to storing the "For Presentation" images. Examples of some reasons include a specialty review workstation that offers additional processing features that operate only on "For Processing" images. This usually only occurs when the acquisition modality vendor and review workstation vendor are of the same manufacturer. Additionally, by archiving "For Processing" images, CAD results can be regenerated from the archived data, although storing the CAD structured reports is more efficient and practical. When archiving "For Processing" images, it is

important to note that both review workstation and CAD systems may change their processing algorithm over time. It may be viewed as a benefit or liability to reprocess archived images with a different algorithm.

- 3. Do I want to archive CAD results in my PACS? Some facilities prefer to not archive CAD results, while others feel strongly about preserving the results. Some workstations may need to retrieve CAD results from PACS in order for these to be displayed. If CAD results are to be archived, make sure that your Image Manager supports the DICOM mammography CAD structured report. Not all do.
- 4. How will images get to the mammography diagnostic review workstation(s)? There are a variety of ways that images can get to image displays. Images can be sent directly from the modality, retrieved from the image manager, or be sent from an image manager that has store and forward capabilities. If your image manager does not have store and forward capabilities, for workflow efficiency, the acquisition modality will likely need to send images to at least 3 destinations: the image manager, the review workstation(s), and CAD system.
- 5. How will images get to my CAD system(s)? Images are typically sent directly from the acquisition modality to the CAD system. For sites that want to archive "For Processing" images and have the ability to store and forward images from the image manager, the image manager may be the source of "For Processing" images for the CAD system.
- 6. How will CAD results get to the review workstation? Mammography CAD structured reports will most likely follow the same destination routing as images. Either the CAD results will be sent directly to review workstation(s), sent directly to the image manager (if archiving), and/or sent to an image manager that has the ability to forward the results to the review workstation(s).
- 7. Make sure that you consider the total number of acquisition modalities, review workstations, and mammography CAD systems in context of all desired data routing. Review study volume along with data routing requirements to ensure that you have adequate bandwidth and proper network design to handle the volume of traffic generated by your workflow design.

# **1.2.3.2** Getting Devices to Communicate

First, you should be aware of the capabilities, licensing and configuration requirements for the devices within your system. Experience has shown that even devices that PACS Administrators believe to be "promiscuous" (able to receive data from any device), may have to be configured specially to handle digital mammography images and objects.

# **1.2.3.2.1** Integrating the Digital Mammography Modality with the Image Manager

If you have a PACS and want the digital mammography modality to store its images on to the PACS, the following installation steps need to be considered.

1. The digital mammography modality will need to know the AE title, internet protocol (IP) address, and port for the DICOM storage service class provider (SCP) of the image manager. The person installing the interface will also need to understand if only "For Presentation" images, "For Processing" images, or both image types are to be archived by the image manager. Check with your PACS

vendor on whether or not adding or replacing a modality requires an updated license.

- 2. The acquisition modality will need to know the AE title, IP address, and port of the DICOM Storage Commitment Service of the image manager. Many times, these settings are the same for the Store service, but this can not be assumed.
- 3. The image manager will need to know the AE title, IP address and port of the digital mammography modality's Store service class user (SCU). Some image managers that are "promiscuous" may not require this information, but it is good practice not to assume.
- 4. The image manager will also need to know the AE title, IP address, and port of the digital mammography modality's Storage Commitment SCU.

# **1.2.3.2.2** Integrating the Digital Mammography Modality with CAD Systems

If the digital mammography modality is forwarding images on to the CAD system the following configuration steps become relevant.

- 1. The modality will need to know the AE title, IP address, and port of the CAD system, and whether or not it is to send "For Processing" or "For Presentation" images. Note: it is typical to send "For Processing" images to CAD systems.
- 2. The CAD system will need to know the AE title and IP address of the digital mammography modality's Store service class user (SCU). Some CAD systems that are "promiscuous" may not require this information, but it is good practice not to assume. Very often CAD systems deploy licensing schemes. Check with your CAD system vendor on whether or not installing a new modality or replacing an existing modality requires an updated license for your CAD system.
- 3. If the CAD system supports the DICOM Storage Commitment service, the digital mammography modality will need to know the AE title, IP address, and port of this service on the CAD. The CAD will also need to know the DICOM Storage Commitment information form the modality (AE title, IP address, and port).

# 1.2.3.2.3 Integrating the Digital Mammography Modality with Review Workstations

The following configuration steps may apply if your digital mammography modality needs to send acquired images to the mammography diagnostic review workstation(s) directly, mainly in case you do not have or cannot use a PACS.

- 1. The digital mammography modality will need to know the AE title, IP address, and port of each review workstation, and whether or not it is to send "For Processing" or "For Presentation" images. Note: it is typical to send "For Presentation" images to a review workstation, especially when the acquisition modality vendor and review workstation vendor are different manufacturers.
- 2. The review workstation system will need to know the AE title and IP address of the digital mammography modality's Store service class user (SCU). Some image

displays that are "promiscuous" may not require this information, but it is good practice not to assume.

#### **1.2.3.2.4** Integrating the Digital Mammography Modality with Printers

The digital mammography modality that is acting as the IHE Actor "Print Composer" will need to know the AE title, IP address, and port for the DICOM Printer service class provider (SCP) of the printer (a.k.a. Print Server). This information needs to be shared with the printer vendor so the printer can be configured. At the digital mammography modality (Print Composer), configure the printer properties supported for the specific printer, such as medium type, minimum and maximum density, film orientation, film size ID, magnification type, trim, configuration information and polarity. Note that the Presentation LUT Shape value of "LIN OD" allows the acquisition modality (Print Composer) to have greater control over the optical density of the printed film, and to take what action is necessary to result in consistency of appearance for the anticipated viewing conditions.

- 1. Print the "For Presentation" images from the digital mammography modality application (Print Request with Presentation Look-Up Table). Verify that film images are identical to original post-processed images. See DICOM 2003 PS 3.4: Presentation LUT Class for a full list of print attributes.
- 2. You may also verify the following for the digital mammography modality:
  - a. True size printing: the pixels of a single view are printed so that distance measurements made optically on the printed film are approximately equivalent to those made on a film-screen mammography exposure. The attributes *imager pixel spacing* (0018, 1164) and *requested image size* (2020,0030) are to be used, without correcting the *imager pixel spacing* by *estimated radiographic magnification factor* (0018,1114).
  - b. Justifying the images: the chest wall will be printed as close to the edge of the film as the Print Server is capable. Note that this function may be printer dependent.
  - c. The digital mammography modality is able to send the Maximum Density attribute (2010,0130).
  - d. The digital mammography modality is able to burn into the pixel a set of clinical, institution, technical and view annotations as defined in the Transaction Print Request with Presentation LUT in the IHE Radiology Technical Framework, vol.2, 4.23.4.8.
  - e. Burning in a ruler, caliper or other form of distance scale into the pixel data.
  - f. Transmitting a pixel data bit depth of 12 bits to the Print Server.
  - g. Burning a VOI LUT transformation (linear, sigmoid or tabular) into the pixel data.
- 3. For the printer, you may perform these tests to verify their Print Server capabilities:

- a. True size printing (see above) with a precision of a maximum 2% error in linear distance.
- b. Printing with a border between the chest wall edge of the digital mammography image and the physical edge of the film no greater than 5mm.
- c. Applying the *maximum density* attribute (2010,0130) in the request, and printing with a maximum optical density no less than 3.5.
- d. Receiving a pixel data bit depth of 12 bits.
- e. Using a Presentation LUT Shape value of "IDENTITY" and "LIN OD" and the Presentation LUT Sequence (2050,0010).

# 1.2.3.2.5 Additional Integration beyond the IHE Mammography Profile

Although not necessarily part of the IHE Mammography Image Profile, consider what other IHE profiles and services the digital mamography modality supports. Refer to the IHE Radiology User Handbook for assistance on installing other IHE profiles, especially chapters on modality and PACS integration.

Typically, the acquisition modality will have an AE title and IP address for each DICOM service class user (SCU), and an AE title, IP address, and port for every DICOM service class provider (SCP). Common services supported by modalities include: Modality Worklist (SCU), Modality Performed Procedure Step (SCU), Print (SCU), and Query/Retrieve (SCU).

# **1.2.4 Identifying and Addressing "Legacy" Problems**

IHE integration profiles are built assuming that all relevant systems support these profiles. If some systems do not support the profiles you have selected but do support the standards the profile is built on, some benefit is still possible. If you have deficient systems, consider how to work around the deficiencies in the short term and when you plan to replace or upgrade those systems.

If your digital mammography modality is from the early days of FFDM image acquisition, the images created will most probably not conform to the requirements IHE describes in the IHE Mammography Image Profile. You may need to check with the modality's vendor if or how correct values can be created. IHE does not describe how to migrate or convert such "old" data.

# **1.2.4.1** Connecting the Modality to a non-IHE PACS

It is necessary that your non-IHE PACS can receive, store and provide DICOM Digital Mammography X-Ray Image IODs. If your digital mammography modality is connected to a CAD system, it is necessary that the PACS also support DICOM Mammography CAD SR objects. In order to get this information, request a DICOM Conformance Statement (DCS) from your PACS vendor for the current product release installed at your site (see Appendix F).

The essential DICOM services for enabling correct use and updates of patient and procedure data is described in the IHE Radiology User's Handbook in section 1.2.4.1.1.

# **1.2.4.2** Connecting the Modality to a non-IHE RIS

If you want your new digital mammography modality to receive Modality Worklist and participate in your department's workflow, the IHE Radiology User's Handbook section 1.2.4.2.1 describes the essential steps to take. Again, you need to check your RIS' DICOM Conformance Statement (see also Appendix F).

# 2 Integration of a Diagnostic Review Workstation for Mammography Reading and Reporting

This chapter describes how to integrate a diagnostic review workstation into a digital mammography environment for reading and reporting on mammography studies. It focuses on how a review workstation may play the display role for digital mammography images from any mammography modality vendor so that the review workstation does not become specific and limited to a single acquisition modality vendor.

When considering the purchase of a diagnostic review workstation for mammography, which serves for soft-copy interpretation and reporting, it is important to ensure that the review workstation will be able to communicate with any pre-existing PACS and with all of the installed digital mammography modalities. Also, critical to a sound decision is the knowledge that the diagnostic review workstation will be able to correctly display any digital mammography image with accompanying annotations and CAD marks for proper interpretation.

The IT environment that incorporates a diagnostic review workstation for reading of digital mammography images and CAD results is shown in the diagram below. For the IHE-capable review workstation, it is critical that modality, PACS and printer it communicates with also support the IHE mammography requirements. In subsequent steps, additional IHE requirements may be fulfilled by these systems that support consistent use of data, broad mammography imaging information access and result/ report creation and usage.

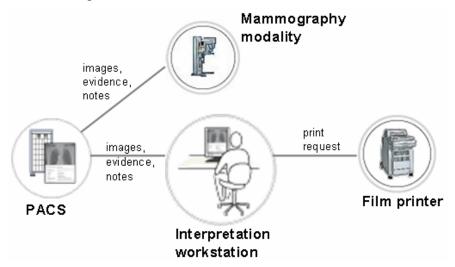


Figure 2. System environment for integrating a Mammography workstation

# 2.1 The Planning and Purchasing Process of a Mammography Review Workstation

Intended for administrators and radiologists who make purchasing decisions, this section walks you through the different IHE profiles that may apply to a mammography diagnostic review workstation and helps you select the IHE integration profiles that will address your organizational goals. This section will also show you how to clearly state

IHE requirements in a request for proposals (RFP) and how to interpret vendor responses when purchasing a mammography diagnostic review workstation.

It is not always possible to address all goals by making a single IHE-related equipment purchase. Achieving the full benefit of an IHE integration profile requires that the systems interacting with the mammography diagnostic review workstation, such as PACS and printers, also play their roles as defined in the corresponding profiles. Appendix A provides a general discussion of sequencing requirements and planning individual purchases as part of a long-term plan.

To track progress toward organizational goals and determine return on investment, a well-defined set of performance metrics is needed—see Appendix I.

Having clear organizational goals is important for defining the requirements for equipment acquisition. Each IHE integration profile is designed to meet a specific set of organizational goals. Below is a list of the IHE integration profiles that may apply to a diagnostic review workstation intended to be used for mammography image review and the contributions that each relevant integration profile makes in supporting a range of institutional goals.

Note that the review workstation largely benefits from being connected to a PACS that communicates procedure and patient data with a Mammography or Radiology Information System by using the IHE Scheduled Workflow Profile. This is critical for a seamless flow of information that supports the consistency of patient information in images from prior and current exams, as well as reliable data access in a filmless Mammography department.

# 2.1.1 Selecting IHE Integration Profiles for a Mammography Diagnostic Review Workstation

Specifying integration requirements for the mammography diagnostic review workstation you are purchasing is a simple matter of selecting which IHE integration profiles (work scenarios) and which associated IHE actors (system functions) you want supported by the review workstation. Note that some IHE integration profiles include options that provide additional functionality you may also decide to select. For further information, see Appendix B.

The following table gives an overview of the IHE integration profiles that may apply to a mammography diagnostic review workstation you may already have or plan to purchase/upgrade, including subsequent integration steps. Note that all of your connected systems in your health enterprise need to participate in the relevant IHE integration profiles to achieve the full benefit. Further details on these IHE integration profiles are described in the following sections.

IHE Integration Profile	<b>Proposed</b> <b>Integration Step</b> (1= essential), (2-4= additional)	Mammo Modality	<b>Review</b> Workstation	PACS	Mammo- / Radiology IS	Film Printer
Mammography Image	1	Х	X	Х		Х
Scheduled Workflow	2	X	X	Х	X	
Portable Data for Imaging	3	Х	X	Х		
Access to Radiology Information	3		X	Х		
Key Image Note and / or	4		X	Х		
Consistent Presen- tation of Images	4		X	Х		
Evidence Documents	4		X	Х		

**Table 3.** Systems and IHE Integration Profiles relevant for a Mammography workstation in your institution

# 2.1.1.1 IHE Mammography Image Profile (MAMMO)

The IHE Mammography Image Profile as applied to the mammography diagnostic review workstation assures the correct display of digital mammography images from any digital mammography modality claiming conformance to the same profile. This profile is absolutely necessary to allow the display of digital mammography images from different vendors in a similar way as it was previously done with analog mammography.

The IHE Mammography Image Profile ensures proper image orientation, justification, contrast display and image sizing. This profile dictates provisions leading to the accurate display of CAD mark and the display of all relevant technical and identification information on image base. The profile also requires that the displays used for mage interpretation are correctly calibrated for optimal image review.

The IHE Mammography Image Profile requires that a mammography diagnostic review workstation be able to display mammography images in several standard ways: *fit to viewport, true size, same size* and *view actual pixels*. The *fit to viewport* display is intended to allow up to eight images to be displayed simultaneously on the display pair, primarily for temporal comparison. *True size* display is useful for percutaneous biopsy,

surgical planning or size comparison to prior films. *Same size* display allows easy comparison of digital mammography images acquired at different resolutions or using different detector sizes. *View actual pixels* display allows for display of all captured data or "full resolution," which is especially useful when evaluating micro-calcifications or subtle masses.

The IHE Mammography Image Profile, however, does not define hanging protocols or how images of different matrices should be sized relative to each other. In addition, you may want to choose the *Partial View Option* of this integration profile for added benefit when image tiling may apply. In case the breast is larger than the detector, it enables the review workstation to appropriately use image information for marking and displaying a set of images in which each image partially covers the breast tissue in the correct order.

Requesting support for the MAMMO profile by the mammography diagnostic review workstation will provide the following benefits to your healthcare enterprise:

- Reduce Errors and Enhance Patient Care
  - Ensures that images are oriented and marked correctly to avoid inadvertent interpretation errors that are due to improper hanging of an image.
  - Ensures that the skin line is detected so that if contrast adjustments are performed for interpretation of the mammogram at the review workstation, the background blackness will be maintained; without this, the background will become lighter as the window width and window level are raised resulting in difficult image interpretation.
  - Allows for scaling of the image on the review workstation so that images from the same patient, performed at different times on different detectors can be displayed at the same size or even true size. This allows for evaluation of developing densities and allows the radiologist to evaluate for a change in size of known lesions during temporal comparison with prior digital images or even film mammograms.
  - Ensures display of all relevant clinical and technical information. For instance, acquisition dates can be used to display current and prior studies in a meaningful order or technique factors may be used for image quality troubleshooting.
  - Ensures that original image presentation and consequent contrast adjustments performed at the review workstation follow the acquisition modality intent. Without this, image presentation and contrast adjustments made at the review workstation may degrade the quality of the displayed image.
- Increase Throughput
  - Reduces time to read the images. Images will be displayed on the screen oriented so that the important area is automatically displayed and with the correct orientation and sizing.

- Improve Image Quality
  - Improves image display and printing by including relevant data in images
  - Ensures that all technique acquisition parameters are available for review
  - Ensures that the images can be oriented, justified and sized correctly for proper and expeditious interpretation
  - Ensures that presentation images can be used in a consistent manner on different mammography diagnostic review workstations
  - Automatically uses contrast display settings created at the acquisition modality
  - Keeps background brightness unchanged while adjusting the breast tissue contrast keeping background air suppressed.
- Reduce Operational Cost
  - Largely eliminates film printing, management and storage costs because the review workstation displays images for soft-copy review, both from the institution's PACS or by exchanging Imaging CDs with referring physicians or surgeons.

#### 2.1.1.2 IHE Portable Data for Imaging Profile (PDI)

The IHE Portable Data for Imaging Profile enables creating correct DICOM image CDs on the modality.

Requesting support for the PDI profile by the digital mammography modality will provide the following benefits to your organization:

- Reduce Operational Costs
  - Reduces unnecessary films for surgery, referrals to other sites or referring physicians—the review workstation creates digital image CDs to be sent to other image consumers.
- Increase Throughput
  - Prevents time scanning film priors from other sites—the review workstation supports the import of studies on CD. Reading time may also be decreased significantly be not having to deal with a mixed environment where film and digital images are required to be viewed together.
- Improve Data Availability and Accessibility
  - Improves access to data from other sites—the workstation can import patient and diagnostic information on CD from other institutions and clinics
  - Improves data access by other care providers (e.g. referring physicians, second-opinion radiologists)—the workstation exports patient and diagnostic information on CD.

# 2.1.1.3 IHE Access to Radiology Information Profile (ARI)

The IHE Access to Radiology Information Profile makes images and reports available to users at other networked workstations (e.g., for surgeons or referring physicians). This profile specifies a number of query transactions providing access to radiology information, including images and related reports, in a DICOM format as they were acquired or created. Such access is useful both to the radiology department and to other departments such as pathology, surgery and oncology.

Requesting support for the ARI profile by the mammography diagnostic review workstation will provide the following benefits to your organization:

- Improve Data Availability and Accessibility
  - Improves access around the hospital—the workstation can query/retrieve DICOM imaging data.

# 2.1.1.4 IHE Key Image Notes Profile (KIN)

The IHE Key Image Note Profile enables the radiologist to attach simple notes to mammography images during image review. Such notes allow the radiologist to flag one or more images in a study as significant by attaching to them a note managed together with the study. This note includes a title stating the purpose of marking the images and, optionally, a user comment field. Radiologists may attach key image notes to images for a variety of purposes: referring physician access, teaching files selection, consultation with other departments, and image quality issues, etc.

Requesting support for the KIN profile by the mammography diagnostic review workstation will provide the following benefits to your organization:

- Improve Communication
  - Reports poor technique or patient motion and other acquisition issues—the technologist can create digital "sticky notes" on the modality for the radiologist to see on the review workstation (communication tool)
- Improve Organization of Data
  - The radiologist can flag data for different purpose using 'sticky notes" for all users to sort through at a latter time (i.e. teaching files)

#### 2.1.1.5 IHE Evidence Documents (ED):

The IHE Evidence Document Profile enables display of CAD results on the mammography diagnostic review workstation.

Requesting support for the ED profile by the mammography diagnostic review workstation will provide the following benefits to your organization:

- Increase Throughput
  - Reduces radiologist time spent accessing multiple workstations to review images and CAD marks—the review workstation allows the review of CAD results together with the corresponding images.
- Improve Data Availability and Accessibility

• Prevents incomplete clinical data because the review workstation can display images and CAD results simultaneously.

# 2.1.2 Selecting IHE Integration Actors on the Mammography Diagnostic Review Workstation

Each IHE integration profile contains several *actors*. Frequently, partial benefits can be achieved when your systems implement integration profiles partly (a subset of a profile's actors, such as image display) and not all of the IHE functions are available (see Appendix A for planning individual purchases as part of a long-term plan).

The *Image Display Actor* is the key role played by a mammography diagnostic review workstation in order to retrieve and display images from PACS.

Additional IHE actors a mammography diagnostic review workstaiton can implement include:

- <u>Print Composer Actor</u>: sends print requests to DICOM printers (for image distribution to "non-digital" users)
- <u>Media Creator Actor</u> to create CDs with imaging data
- <u>Media Importer Actor</u> to import imaging data from CDs into your Mammography Workstation
- Evidence Creator Actor to create and store measurements, especially CAD
- <u>Report Reader Actor</u> to retrieve and display diagnostic reports.

The following table summarizes the IHE actors that enable essential review workstation functions (key actors) and additional/advanced functions for specific work scenarios. You may choose to request actors and profiles step-wise in your RFP, depending on your existing IT environment and integration approach (see Appendix A and B).

IHE Integration Profile	Key IHE Actor	Additional IHE Actor
Mammography Image	Image Display	Print Composer, Evidence Creator
Portable Data for Imaging	Image Display	Portable Media Creator, Portable Media Importer, Report Reader
Access to Radiology Information	Image Display	Report Reader
Key Image Note and / or Consistent Presen- tation of Images	Image Display	Evidence Creator
Evidence Documents	Image Display	Evidence Creator

**Table 4.** Key and additional IHE actors for a digital mammography modality

# 2.1.3 Putting Integration Requirements in Your RFP

Requiring IHE support in your RFP in order to meet your goals as shown above is achieved by stating which IHE work scenarios (integration profiles and options) and which system functions (IHE actor/roles) the mammography diagnostic review workstaiton should support. Sample statements to specify the IHE integration profiles and actors relevant to a review workstation are:

- The mammography diagnostic review workstation shall support the following integration profiles as the **Image Display Actor**: IHE Mammography Image Profile, IHE Access to Radiology Information Profile, IHE Key Image Notes Profile, and IHE Evidence Documents Profile."
- "The mammography diagnostic review workstation shall support the following integration profiles as the **Evidence Creator Actor**: IHE Mammography Image Profile, IHE Key Image Notes Profile, and IHE Evidence Documents Profile."

Note that a subset of IHE Profiles and Actors may suffice as a first step depending on how many other IHE-capable systems already exist in your institution that the new system can connect to. For instance, if there is no PACS to connect to initially, you do not need to require the Access to Radiology Information Profile in the RFP. Nevertheless, it may be valuable to you to burn CDs and thus require the Media Creator Actor in PDI for the product to be purchased.

## 2.1.4 Identifying Suitable Products

While you may choose to proceed directly to sending your RFP to a broad group of potential vendors, find out which vendors have products with relevant IHE integration capabilities by referring to public sources. For a description of these sources, see Appendix D.

## 2.1.5 Reading Integration Statements from Vendors

Vendors may respond to your RFP by providing an IHE integration statement. These documents are also available for many products at *www.ihe.net/Resources/ihe\_integration\_statements.cfm*.

An integration statement is a direct statement of which IHE profiles, actors and options are supported by a particular product from a particular vendor (see Appendix E).

## 2.2 The Configuration and Implementation Process of a Mammography Diagnostic Review Workstation

The following sections are intended for the implementation team. They discuss important clinical and IT considerations when deploying a mammography diagnostic review workstation with IHE capabilities, including how to approach "legacy" issues when connecting the review workstation to other systems that do not support IHE integration profiles.

## 2.2.1 Considering Changes to Your Workflow

IHE integration profiles are designed to implement digital imaging in a streamlined clinical workflow. For instance, they eliminate the need to enter patient information at the modality, searching for lost film folders or reconciling cases that are marked as unmatched studies by the RIS or PACS. They also allow images to be immediately available for viewing and combine CAD results with the digital mammography images automatically. To gain the full benefit of these changes, there are several tasks that need to be performed in the correct manner.

# 2.2.2 Confirming That It Works

The following sections provide guidance on how to confirm that the mammography diagnostic review workstation is operating according to each IHE profile implemented. Each section provides elements for testing an individual profile as it relates to the review workstation. Often, there are other ways than those described herein to confirm the data and transactions—see Appendix H.

Sometimes it may be challenging to determine whether or not the mammography diagnostic review workstation follows an IHE integration profile. If we take the IHE Mammography Image Profile as an example, verifying that the appropriate image scaling takes place on the review workstation really depends on the type of information generated and stored in the images by the acquisition modality. Incomplete or inaccurate information generated at the acquisition modality will perpetuate to the review workstation and will make the workstation appear that it does not comply with the profile,

while the problem is generated further up the chain. Similarly, a non-IHE compliant PACS may have altered certain key information in an mammography image prior to routing it to the review workstation. Similarly, image query and retrieve functionality may differ between a workstation and a PACS. Such action may result to the review workstation not being able to display that image together with the corresponding CAD marks.

In general, the lack of functionality and features at the digital mammography modality or another system in your workflow such as the image manager (a.k.a. archive) or evidence creator (a.k.a. CAD) may impede on evaluating how well the mammography diagnostic review workstation implements the IHE integration profiles. This section provides information on the functional expectations for the review workstation. Your ability to detect or troubleshoot issues will likely be dependent upon the feature set and DICOM implementation of your other integrated systems and the support of your corresponding vendors.

## 2.2.2.1 IHE Mammography Image Profile (MAMMO)

The IHE Mammography Image Profile describes requirements, so that the mammography diagnostic review workstation is capable to display the digital mammography images in a similar way to that of the analog mammography environment. The user can decide on the layout of the different acquired views, i.e. CC and MLO views. Current and prior sets of digital mammography images can be displayed on the review workstation simultaneously. In addition, CAD marks are be displayed together with the corresponding digital images.

To test this functionality, you can load a number of current and prior digital mammography studies and CAD marks for some of the studies and test the following functions (more details regarding this are given in the following subsections):

- The radiologist is able to specify image hanging protocols that fit their reading preferences
- The image hanging protocols allow the combination of current and prior studies
- The mammography diagnostic review workstation is able to display CAD marks on top of the corresponding images.

Furthermore, since different acquisition modalities may use various types of digital detector technologies, images will have different matrix sizes and inherent resolution. To be able to easily compare structures within the breasts from images that originate on different detector technologies, the review workstation is required to display digital mammography images at a specified number of sizing modes like, same size and true size. Such functionality ensures improvements in the reading workflow for the radiologist by reducing the number of steps necessary to compare the images despite their differences in resolution or matrix size.

To test this functionality you first need to evaluate the appropriate information stored in the image header by the digital mammography modality either by analyzing the images or by looking into the vendor's conformance statement and then evaluate the image sizing on the workstation displays. More details regarding this test are given in the following subsections.

The IHE Mammography Image Profile also makes provisions for the accurate image presentation and printing of digital mammography images to the way the digital mammography modality (the image creator) intended. At the same time, the profile defines a well prescribed set of information to be displayed by the review workstation. In order to test the accuracy of image presentation and printing by the review workstation, knowledge of the corresponding presentation information stored into the image headers is needed together with the experience of the vendors themselves in this matter.

To test this functionality you can load a set of studies on the review workstation and make sure that the following functions work:

- Appearance of the digital mammography images is accurate in the displayed gray levels
- Application of window level and window width is smooth and does not suddently wash out the displayed information
- Changing the window level and window width does not change the background of the image (providing that the acquisition modality detected the sin line)
- Patient, study, image and radiographic technique information is displayed according to the defined requirements.

The following subsections will go into more detail as to what to expect when evaluating the different requirements of the IHE Mammography Image Profile.

# 2.2.2.1.1 Air Gap Suppression

The digital mammography modality that conforms to the IHE Mammography Image Profile is required to detect the breast skin line and separate the detector area that is covered by air from that covered by breast tissue. The acquisition modality detects the breast tissue and chooses to either

- a) replace non-breast image data areas with a specific "pixel padding value", or
- b) provide a "pixel padding value range" that defines non-breast image data.

Check the modality's DICOM conformance statement or examine the image header to determine which method is supported: pixel padding (DICOM attribute 0028,0120) or a range of non-breast tissue pixel values (DICOM attributes 0028,0120 and 0028,x121).

The mammography diagnostic review workstation is expected to work with both above methods of air gap suppression. When the pixel padding information exists in the header of the displayed images, changing contrast adjustments of an image on the review workstation should force the air gap area of the image to remain black while the rest of the breast tissue contrast is changing. If the air gap does not remain black during contrast adjustments, then the review workstation does not support this function of the profile providing that the pixel padding information is present in the image header.

# 2.2.2.1.2 Screen Layout and Hanging of Images

General purpose review workstations have traditionally presented images as acquired, centered in the viewport, and many times in the order in which they were acquired. The review workstations that support hanging protocols may use a combination of study and series information to improve upon the basic presentation. These methods do not, however, provide enough consideration to support the common practice of hanging chest walls back to back with deterministic placement of left and right breasts. The IHE Mammography Image Profile does not require specific hanging protocols, but it does require certain image values to be provided by the acquisition modalities and used by the mammography diagnostic review workstations for consistent hanging among vendors.

The digital mammography modality is required to supply the following attributes that must be used by the review workstation to determine the proper placement and image orientation used in hanging images:

- Patient orientation (0020,0020)
- Image laterality (0020,0062)
- View code sequence (0054,0220)
- View code modifier sequence (0054,0222), when present.

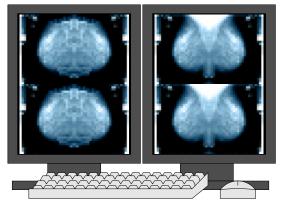
If images are not placed and oriented as expected on the mammography diagnostic review workstation, verify that the review workstation supports the IHE Mammography Image Profile and does take the above attributes into consideration upon presentation. If the review workstation claims support for this profile, verify that the digital mammography modality is correctly populating and sending the above attributes through either its DICOM conformance statement, troubleshooting tools provided with the application, or by working with the manufacturer to verify DICOM header content. Work with the review workstation vendor to verify that hanging protocols are programmed correctly per your expectations.

If the review workstation does not claim support for the IHE Mammography Image Profile, confirm with the manufacturer that at least the laterality, patient orientation, and view code parameters are considered by the hanging protocols algorithm. Check with the review workstation manufacturer to make sure that hanging protocols are programmed correctly for the user logged in.

For the purposes of testing the ability to create and use predefined hanging protocols on the mammography diagnostic review workstation, the following scenarios are defined.

- 1. Eight images consisting of four standard screening views, right and left CC and MLO, in current and prior examinations, are displayed on two portrait monitors in two rows of four columns such that
  - the prior views are on the top row and the current views are on the bottom row,
  - the right and left CCs are displayed in the left two columns with the chest walls back to back,
  - the right and left MLOs are displayed in the right two columns with the chest walls back to back, and

• The images of the right breast are displayed on the left and the left breast on the right (so-called "ventral" viewing, i.e., as if standing in front of the patient).



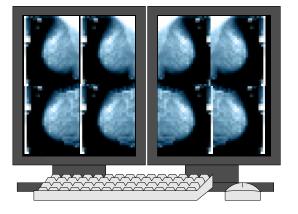
RCC (prior)	LCC (prior)	RMLO (prior)	LMLO (prior)
RCC (current)	LCC (current)	RMLO (current)	LMLO (current)

- 2. The same images as in scenario 1, except that
  - The images of the right breast are displayed on the right and the left breast on the left (so-called "dorsal" viewing, i.e., as if standing behind the patient).



LCC (prior)	RCC (prior)	LMLO (prior)	RMLO (prior)
LCC (current)	RCC (current)	LMLO (current)	RMLO (current)

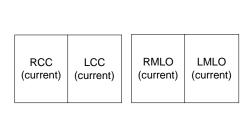
- 3. The same images as in scenario 1, except that
  - the current images of the left and right breast are displayed with chest walls back to back in the center two columns, and
  - the corresponding prior images are displayed in the first and last (outer) two columns, oriented in the same direction as the corresponding current images (nipples outwards)



RMLO (prior)	RMLO (current)	LMLO (current)	LMLO (prior)
RCC (prior)	RCC (current)	LCC (current)	LCC (prior)

- 4. Four images consisting of four standard screening views, right and left CC and MLO, in a single examination, are displayed on two portrait monitors in one row of four columns such that
  - the right and left CCs are displayed in the left two columns with the chest walls back to back,
  - the right and left MLOs are displayed in the right two columns with the chest walls back to back, and
  - the images of the right breast are displayed on the left and the left breast on the right.



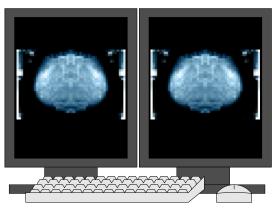


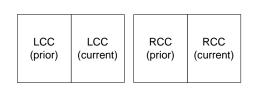
- 5. Four images consisting of two standard screening views, right and left CC, in current and prior examinations, are displayed on two portrait monitors in one row of four columns such that
  - the right and left CCs of the current exam are displayed in the left two columns with the chest walls back to back,
  - the right and left CCs of the current exam are displayed in the right two columns with the chest walls back to back, and
  - the images of the right breast are displayed on the left and the left breast on the right.



LCC RCC	LCC	RCC
(current) (current)	(prior)	(prior)

- 6. Four images consisting of two standard screening views, right and left CC, in current and prior examinations, are displayed on two portrait monitors in one row of four columns such that
  - the right CCs of the current and prior exam are displayed in the left two columns with the chest walls back to back,
  - the left CCs of the current and prior exam are displayed in the right two columns with the chest walls back to back, and
  - the images of the prior exam are displayed on the left and the current exam on the right.





## 2.2.2.1.3 Measurements and Image Size

The true physical size of a feature in a digital mammography image that was acquired according to the IHE Mammography Image Profile can be determined by the values of *imager pixel spacing* (0018,1164) divided by the *estimated radiographic magnification factor* (0018,1114). These two parameters should be used by the mammography diagnostic review workstation for making measurements and image resizing of digital mammography images.

Review workstations following the IHE Mammography Image Profile are able to display digital mammography images in "true size" mode on the display—same physical size as

screen-film mammography, as well as display the digital mammography images in the same relative size, even if these images are produced by different detector technologies with different inherent resolution or matrix size. When troubleshooting, verify that these two parameters are included in the header of the images, by referencing the digital mammography modality's DICOM conformance statement, using troubleshooting tools provided with both the acquisition modality and review workstation, or by working with each vendor to verify that the proper data is sent and used in sizing and measurement calculations.

To test this portion of the IHE Mammography Image Profile you can use images generated by detectors with different physical size (i.e.  $18x24 \text{ cm}^2$  and  $24x30 \text{ cm}^2$ ) and similar or different pixel resolution.

- Acquire images of the same physical object on a small and a large format detector. Display the two images back to back and switch to the "true size" display mode on the mammography diagnostic review workstation. The object in the two images should appear to be of equal size.
- Use a physical ruler to measure the object on the display—the object size as measured with the physical ruler on the display should be approximately the same size when you measure the object physically.
- Use the measurement tools on the review workstation to measure the object on the display while in "true size" mode—the object size as measured with the software measuring tools on the display should be approximately the same size when you measure the object physically.
- Now switch to the "same size" display mode using the previous images on the review workstation. The object in the two images should still appear to be of equal size, although they may appear to be larger or smaller compared to the physical size of the object.
- Use the measurement tools on the review workstation to measure the object on the display while in "same size" mode—the object size as measured with the software measuring tools on the display should be approximately the same size when you measure the object physically.

Note: some review workstations may use the DICOM attribute *pixel spacing* (0028,0030) to calculate sizing and measurements. Pixel spacing is not the correct parameter to use for image measurement and sizing calculations on a mammography diagnostic review workstation. The IHE Mammography Image Profile requires that all measurements on digital mammography images are done according to the *imager pixel spacing* (0018,1164) divided by the *estimated radiographic magnification factor* (0018,1114).

The mammography diagnostic review workstation shall also provide to the user the ability to display the digital mammography images in "view actual pixel" mode, which allows the user to see each image pixel captured by the digital detector as a single pixel on the display. Since a typical digital mammography image may be larger than what the display is able to fit at one time in this mode, the review workstation shall provide navigation tools, such as a pan tool, to allow the user to view all parts of the image.

#### 2.2.2.1.4 Image Presentation and Contrast Adjustments

The digital mammography modalities may intent to store multiple image presentations looks—into the header of the image so that the user will have the opportunity to review the digital mammography images with different looks. The mammography diagnostic review workstation will then be able to allow the user to select among the available image presentations within the images. Each image presentation will be displayed correctly and any changes to the window width and window center performed by the user will be interpreted correctly by the review workstation.

The IHE Mammography Image Profile specifically defines that the mammography diagnostic review workstation is able to apply all the transformations specified by the *VOI LUT sequence* (0028,3010) or the *window width* (0028,1051), *window center* (0028,1050) and *VOI LUT function* (0028,1056) attributes as selected by the user from the available choices. The review workstation can support both *sigmoid* and *linear* VOI LUT functions for window operations.

When checking the performance of the review workstation regarding the original image presentation or any further contrast adjustments made by the user, you should be aware of the following:

- If the chosen contrast transformation is a lookup table defined in a VOI LUT sequence, the review workstation is able to stretch and translate the input value of the lookup table so as to give the affect of adjusting contrast and brightness whilst applying the same general shape as the curve encoded in the lookup table. To provide feedback to the user, the "window width" can be reported as the adjusted range of input values to the LUT, and the "window center" can be reported as the center value of that range.
- If the VOI LUT function is absent, then the window width and window center parameters are assumed to follow a linear window operation.
- If the VOI LUT function is sigmoid, then the review workstation allows the window width and window center to be adjusted by the users and then the sigmoid function to be reapplied parameterized by the new window width and window center values. Contrast adjustment does not act as a linear window transformation when the VOI LUT function is defined as sigmoid.
- Contrast adjustments to digital mammography images only affect the areas of the images covered by breast tissue, while those areas exposed to air remain unchanged.
- Selecting a different image presentation from a list of available presentations encoded in the images only affect those images that encode such presentations. For example, if certain images are encoded with the sigmoid VOI LUT function and other images with the linear VOI LUT function, when the user selects a default window width and window center referencing the sigmoid VOI LUT function does not change the presentation of those images encoded with the linear VOI LUT function.

Display calibration is another factor that affects image presentation and contrast adjustments on the mammography diagnostic review workstation. It is advisable for a mammography practice to calibrate all similar type displays (CRT or LCD) to the same standard. The same minimum and maximum luminance is to be applied to all same type displays. In addition, effort should be made to standardize the ambient lighting conditions around all review workstations.

Since analog mammography films or printed digital films may be used during image review, a mammography practice should also standardize to a single maximum lightbox luminance as well as a single maximum optical density for printing digital mammography images.

## 2.2.2.1.5 Patient, Study, and Image Information in Images

The IHE Mammography Image Profile extends requirements in DICOM to more fully identify the patient and exam information. You need to test that the mammography diagnostic review workstation is able to display the following information to the user:

- Patient information: patient's name, patient ID, patient's age, birth date
- Study, series and image information: acquisition date, acquisition time, operator's name, compression force, body part thickness, positioner primary angle
- Equipment information: manufacturer, institution name, institution address, manufacturer's model name, device serial number, detector ID, software versions
- X-Ray acquisition dose information: kVp, exposure, exposure time, filter material, anode target material, relative x-ray exposure, entrance dose and organ dose in mGy.

If the review workstation is not able to display some of this information check to make sure that the acquisition modality encoded such information into the header of the digital mammography images. To ensure that all required information is encoded into the image header examining the DICOM conformance statements of your digital mammography modality or confirm whether or not the acquisition modality provides this information with the modality's vendor.

The review workstation may group some of this information into a *clinical* group and an *investigative* group. The clinical group may include all those attributes that are useful during interpretation and review of images for clinical purposes, and which under normal circumstances are displayed to the user. Such attributes may include patient information, view information, technique attributes as well as sizing information. The investigative group may include those attributes that are useful for investigative purposes, such as troubleshooting image quality issues, and which under normal circumstances should not be displayed unless requested by the user.

In general, all information displayed on the image is positioned opposite the chestwall and the review workstation may allow the user to turn such information on and off from displaying.

### 2.2.2.2 Access to Radiology Information (ARI)

It is important that the mammography diagnostic review workstation is able to inquire for available images and other evidence documents in PACS and retrieve them for use within the image review and reporting phases. The following are examples of the high-level list of tests that may need to be run on a new mammography diagnostic review workstation for assure access to radiology information:

- Query, retrieve and display digital mammography images from PACS. Verify that any mammography "For Presentation" images in PACS can be retrieved and correctly displayed on the review workstation. Check with your vendor to find out what the behavior of the review workstation should be regarding retrieving and displaying mammography "For Processing" images.
- If your workstation supports other IHE Profiles like Evidence Documents, Consistent Presentation of Images or Key Image Notes, then you may also test if evidence documents such as CAD objects or Presentation States and key image note objects are retrievable and appropriately displayed.

### 2.2.3 Considering Installation Issues

Even with IHE, installation is not "plug & play". Some thought must be given to the workflow and dataflow of mammography images and CAD results. In addition, systems are not self-configuring and they must be configured properly to communicate with other devices. This section provides tips on typical considerations and actions necessary for installation and system communications of a mammography diagnostic review workstation.

### 2.2.3.1 Define and Understand your Workflow and Dataflow

Due to variability in system features among modalities, PACS, and workstations, there is not one model of data and workflow that fits all situations. Typically, mammography diagnostic review workstations are specialty workstations that may or may not be tightly integrated with your modality or PACS. Careful consideration must be given as to how images and CAD results are routed through your system—this normally needs productspecific configuration. The following questions may help in planning your dataflow:

- 1. What type of data is needed in my system, and by what devices? The digital mammography modality can send both "For Processing" and "For Presentation" images. Typically, CAD operates on "For Processing" images and generates a *mammography CAD structured report*. Review workstations generally display "For Presentation" images and CAD results, although some may also support displaying "For Processing" images, too. Determine the source and destination of each type of data needed for your system devices.
- 2. Do I want to archive "For Processing" images in my PACS, as well as "For Presentation" images? For basic operation, archiving only the "For Presentation" images is adequate for most facilities. However, a site may have additional reasons to store the "For Processing" images in addition to storing the "For Presentation" images. Examples of some reasons include a specialty review workstation that offers additional processing features that operate only on "For

Processing" images. This usually only occurs when the acquisition modality vendor and review workstation vendor are of the same manufacturer. Additionally, by archiving "For Processing" images, CAD results can be regenerated from the archived data, although storing the CAD structured reports is more efficient and practical. When archiving "For Processing" images, it is important to note that both review workstation and CAD systems may change their processing algorithm over time. It may be viewed as a benefit or liability to reprocess archived images with a different algorithm.

- 3. Do I want to archive CAD results in my PACS? Some facilities prefer to not archive CAD results, while others feel strongly about preserving the results. If CAD results are to be archived, make sure that your Image Manager supports the DICOM mammography CAD structured report. Not all do.
- 4. How will images get to the mammography diagnostic review workstation(s)? There are a variety of ways that images can get to image displays. Images can be sent directly from the modality, retrieved from the image manager, or be sent from an image manager that has store and forward capabilities. If your image manager does not have store and forward capabilities, for workflow efficiency, the acquisition modality will likely need to send images to at least 3 destinations: the image manager, the review workstation(s), and CAD system.
- 5. How will images get to my CAD system(s)? Images are typically sent directly from the acquisition modality to the CAD system. For sites that want to archive "For Processing" images and have the ability to store and forward images from the image manager, the image manager may be the source of "For Processing" images for the CAD system.
- 6. How will CAD results get to the review workstation? Mammography CAD structured reports will most likely follow the same destination routing as images. Either the CAD results will be sent directly to review workstation(s), sent directly to the image manager (if archiving), and/or sent to an image manager that has the ability to forward the results to the review workstation(s).
- 7. Make sure that you consider the total number of acquisition modalities, review workstations, and mammography CAD systems in context of all desired data routing. Review study volume along with data routing requirements to ensure that you have adequate bandwidth and proper network design to handle the volume of traffic generated by your workflow design.

## 2.2.3.2 Getting Devices to Communicate

First, you should be aware of the capabilities, licensing and configuration requirements for the devices within your system. Experience has shown that even devices that PACS Administrators believe to be "promiscuous" (able to receive data from any device), may have to be configured specially to handle digital mammography images and related objects.

# 2.2.3.2.1 Integrating the Mammography Diagnostic Review Workstation with the Image Manager

If you have a PACS and want the mammography diagnostic review workstation to have access to all images and objects available on PACS, the following installation steps need to be considered.

- 1. The mammography diagnostic review workstation will need to know the AE title, internet protocol (IP) address, and port for the DICOM storage service class provider (SCP) of the image manager. The person installing the interface will need to be aware of the review workstation's behavior when retrieving "For Presentation" or "For Processing" images from PACS. Check with your PACS vendor on whether or not adding or replacing a review workstation requires an updated license.
- 2. The image manager will need to know the AE title, IP address and port of the review workstation's Store service class user (SCU). Some image managers that are "promiscuous" may not require this information, but it is good practice not to assume.

# 2.2.3.2.2 Integrating the Mammography Diagnostic Review Workstation with the Digital Mammography Modality

The following configuration steps may apply if your digital mammography modality needs to send acquired images to the mammography diagnostic review workstation(s) directly, mainly in case you do not have or cannot use a PACS.

- 1. The digital mammography modality will need to know the AE title, IP address, and port of each review workstation, and whether or not it is to send "For Processing" or "For Presentation" images. Note: it is typical to send "For Presentation" images to a review workstation, especially when the acquisition modality vendor and review workstation vendor are different manufacturers.
- 2. The review workstation system will need to know the AE title and IP address of the digital mammography modality's Store service class user (SCU). Some image displays that are "promiscuous" may not require this information, but it is good practice not to assume.

## 2.2.3.2.3 Integrating the Mammography Diagnostic Review Workstation with CAD Systems

If the mammography CAD system forwards the CAD structure reports directly to the review workstation(s) the following configuration steps become relevant.

- 1. The review workstation will need to know the AE title, IP address, and port of the CAD system.
- 2. The CAD system will need to know the AE title and IP address of the review workstation's Store service class user (SCU).

# 2.2.3.2.4 Integrating the Mammography Diagnostic Review Workstation with Printers

The review workstation that is acting as the IHE Actor "Print Composer" will need to know the AE title, IP address, and port for the DICOM Printer service class provider (SCP) of the printer (a.k.a. Print Server). This information needs to be shared with the printer vendor so the printer can be configured. At the review workstation (Print Composer), configure the printer properties supported for the specific printer, such as medium type, minimum and maximum density, film orientation, film size ID, magnification type, trim, configuration information and polarity. Note that the Presentation LUT Shape value of "LIN OD" allows the review workstation (Print Composer) to have greater control over the optical density of the printed film, and to take what action is necessary to result in consistency of appearance for the anticipated viewing conditions.

- 1. Print the "For Presentation" images from the review workstation application (Print Request with Presentation Look-Up Table). Verify that film images are identical to original post-processed images. See DICOM 2003 PS 3.4: Presentation LUT Class for a full list of print attributes.
- 2. You may also verify the following for the review workstation:
  - a. True size printing: the pixels of a single view are printed so that distance measurements made optically on the printed film are approximately equivalent to those made on a film-screen mammography exposure. The attributes *imager pixel spacing* (0018, 1164) and *requested image size* (2020,0030) are to be used, without correcting the *imager pixel spacing* by *estimated radiographic magnification factor* (0018,1114).
  - b. Justifying the images: the chest wall will be printed as close to the edge of the film as the Print Server is capable. Note that this function may be printer dependent.
  - c. The review workstation is able to send the Maximum Density attribute (2010,0130).
  - d. The review workstation is able to burn into the pixel a set of clinical, institution, technical and view annotations as defined in the Transaction Print Request with Presentation LUT in the IHE Radiology Technical Framework, vol.2, 4.23.4.8.
  - e. Burning in a ruler, caliper or other form of distance scale into the pixel data.
  - f. Transmitting a pixel data bit depth of 12 bits to the Print Server.
  - g. Burning a VOI LUT transformation (linear, sigmoid or tabular) into the pixel data.
- 3. For the printer, you may perform these tests to verify their Print Server capabilities:
  - a. True size printing (see above) with a precision of a maximum 2% error in linear distance.
  - b. Printing with a border between the chest wall edge of the digital mammography image and the physical edge of the film no greater than 5mm.
  - c. Applying the *maximum density* attribute (2010,0130) in the request, and printing with a maximum optical density no less than 3.5.

- d. Receiving a pixel data bit depth of 12 bits.
- e. Using a Presentation LUT Shape value of "IDENTITY" and "LIN OD" and the Presentation LUT Sequence (2050,0010).

## 2.2.3.2.5 Additional Integration beyond the IHE Mammography Profile

Although not necessarily part of the IHE Mammography Image Profile, consider what other IHE profiles and services the mammography diagnostic review workstation supports. Refer to the IHE Radiology User Handbook for assistance on installing other IHE profiles, especially chapters on modality and PACS integration.

## 2.2.4 Identifying and Addressing "Legacy" Problems

IHE integration profiles are built assuming that all relevant systems support these profiles. If some systems do not support the profiles you have selected but do support the standards the profile is built on, some benefit is still possible. If you have deficient systems, consider how to work around the deficiencies in the short term and when you plan to replace or upgrade those systems.

The following legacy issues need to be considered in the scope of implementation of a mammography diagnostic review workstation:

- 1. Prior images on film—how do you proceed with prior images that exist on film? One possibility is to digitize the film and store it in the PACS archive, so the transition time to 'softcopy' reading is going to be reduced. A good reason to proceed with this approach is that adapting one's vision from lightbox to display takes some time and reduces sensitivity on the displays. Problems that might arise in this area are: patient identification, images generated shall be DICOM MG objects, so that the proper definitions of 'hanging' the images on the displays can take place.
- 2. Old modalities that do not create digital mammography images according to IHE —many of the features on the mammography diagnostic review workstation depend on the availability of information encoded in the header of the digital mammography images. If the digital mammography modality does not comply with the IHE Mammography Image Profile, then the functions on the workstation may be performed incorrectly. For example, measurements performed on the review workstation may be inaccurate or images may appear upside-down if the appropriate information is missing from the image DICOM header.
- 3. Old "For Processing" images—prior digital mammography images may only exist in the "For Processing" mode, since originally the image processing took place at the proprietary review workstation. In this case, the review workstation is not able to display the prior digital images next to the new current images correctly if at all, since the review workstation is not required to perform the conversion of "For Processing" images to the corresponding "For Presentation" counterparts (and it might not be capable of doing, if the review workstation is from another vendor).

- 4. VOI LUT function interpretation—images created prior to DICOM CP 467 that expect sigmoid interpretation of window width and window center without encoding the VOI LUT function in the image header will be displayed with suboptimal image presentation and will not allow the user to perform adequate contrast adjustment.
- 5. Non-IHE PACS—this probably is the most difficult item to accommodate. Non-IHE PACS might cause difficulties, since information may be changed in the image objects, so that there may be no consistency between the image being sent from the acquisition modality to the review workstation and being retrieved from PACS as a prior to the review workstation. Problems being encountered so far:
  - a. Images have been converted to another DICOM SOP Class, e.g. Secondary Capture. In this case automatic hanging will most likely fail and CAD will not be available for these images.
  - b. New UIDs are generated, due to internal 'copy-processes' taking place within the PACS for internal mechanisms. In this case it will happen that CAD marks cannot be associated with the images anymore.
  - c. Information that is stored on image level is suddenly lifted to the series level, so that individual images suddenly appear to have the same information in all images.

It is difficult to find simple solutions that may address these legacy issues completely. Each vendor may try to address the most common and obvious legacy problem of their images or images generated by other vendors. Some of these issues may be addressed completely, some partially and some not at all until the vendor solves the problem at its root. You should talk to your vendors and work with them to understand legacy issues of the systems installed in your enterprise. Your vendors may already have solutions to resolve many legacy issues or they may be willing to work with you to "patch" the system.

# 3 Integration of a Digital Mammography Film Printer

Some national healthcare regulations mandate that their facilities provide original mammograms to patients upon request. These images are sometimes needed in places where a network is not available or not trusted, such as operating rooms or a physician's office or the images are to be transferred to a facility without digital capability. Whether or not the facility is using hardcopy for final interpretation, it needs to be able to produce final interpretation quality hardcopy images for those patients, their representatives, and healthcare providers who request hardcopy transfer of the mammogram. In addition, accreditation or certification programs may require submission of printed mammogram images. In order to conform to this requirement, facilities need access to a printer. In addition, if the facility is retaining the mammogram in hardcopy rather than electronic form, the hardcopy image must be of final interpretation quality. When considering the purchase of a printer, whether it is to serve for hardcopy interpretation and reporting of mammography images and/or transfer of the digital mammograms, it is important to ensure that the printer is capable of producing diagnostic quality films that are properly annotated and conform to regional requirements.

The IHE Mammography Image Profile specifies how digital mammography images and evidence objects are created, exchanged, and used. It specifies the basic capabilities a digital mammography modality or a mammography diagnostic review workstation (Print Composers) and the printer (Print Server) are expected to provide and which attributes should be used to implement those capabilities. In order to claim support of the IHE Mammography Image Profile an IHE integrated system must perform the required transactions. The IHE Mammography Image Profile leverages existing DICOM standards for print functionality yet goes a step further by specifying attributes and requirements that ensure vendor compatibility and performance. When specified, it ensures essential functionality required for printing mammography images.

The IHE Mammography Image Profile defines actors and the transactions between them. A required transaction for the Print Composer and Print Server is Print Request with Presentation LUT. This transaction supports the capability of the Print Composer to ensure display consistency for films produced by the Print Server. The IHE Mammography Image Profile specifies additional required attributes and requirements for printing mammography images.

When buying a printer for mammography interpretation and/ or transfer of images, it is essential that it provides not only basic DICOM interoperability but also fulfills the requirements specified by the IHE Mammography Image Profile.

## 3.1 The Planning and Purchasing Process of a Mammography Film Printer

Intended for administrators and radiologists who make purchasing decisions, this section walks you through the different IHE profiles that may apply to a mammography film printer and helps you select the IHE integration profiles that will address your organizational goals. This section will also show you how to clearly state IHE requirements in a request for proposals (RFP) and how to interpret vendor responses.

It is not always possible to address all goals by making a single IHE-related equipment purchase. Achieving the full benefit of an IHE integration profile requires that the

systems interacting with the mammography film printer, such as acquisition modalities and review workstations, also play their roles as defined in the corresponding profiles. Appendix A provides a general discussion of sequencing requirements and planning individual purchases as part of a long-term plan.

To track progress toward organizational goals and determine return on investment, a well-defined set of performance metrics is needed—see Appendix I.

Having clear organizational goals is important for defining the requirements for equipment acquisition. Each IHE integration profile is designed to meet a specific set of organizational goals. Below is a list of the IHE integration profiles that may apply to a digital mammography modality and the contributions that each relevant integration profile makes in supporting a range of institutional goals.

# **3.1.1** The IHE Mammography Image Profile as it Applies to a Mammography Film Printer

The IHE Mammography Image Profile defines certain features for the mammography film printer as a "print server" and corresponding features for the printing digital mammography modality and the mammography diagnostic review workstation as "print composers".

The following are profile requirements for the mammography film printer:

- Be capable of supporting a print request with the Presentation LUT, including support for a Presentation LUT shape of 'LIN OD' to ensure display consistency of printed films
- Be capable of printing on transmissive media
- Be capable of *true size* printing with a precision of no more than 2% error in linear distance to ensure accurate measurements
- Be capable of printing with a border between the chest wall edge of the image and the physical edge of the film that is no greater than 5 mm so that the printed films can be hung on a light box with the chest wall edges of corresponding views directly abutted
- Be capable of applying and printing with a maximum optical density no less than 3.5 to assure adequate density range
- Be capable of receiving a pixel depth of 12 bits from the print composer to provide adequate image quality.

The following are profile requirements for the system preparing and sending mammography images to be printed, e.g. an acquisition modality or review workstation:

- Be capable of creating a print request with the Presentation LUT, including support for a Presentation LUT shape of 'LIN OD' to ensure display consistency of printed films
- Be capable of *true size* printing using the DICOM attributes *imager pixel spacing* and *requested image size* so that distance measurements made optically on the

printed film are equivalent to those made on a film-screen mammography exposure

- Be capable of justifying the images so that the chest wall will be printed as close to the edge of the film as the mammography film printer is capable so that the printed films can be hung on a light box with the chest wall edges of corresponding views directly abutted
- Be capable of burning a defined set of patient demographics into the printed image, assuring proper film annotation
- Be capable of burning a ruler, caliper or other form of distance scale into the printed image for use as a size reference
- Be capable of transmitting a pixel data bit depth of 12 bits to the mammography film printer to provide adequate image quality
- Be capable of burning a window width and window center values (VOI LUT) into the printed image for the intended image visualization
- Be capable of requesting a maximum optical density no less than 3.5 to assure adequate density range.

## 3.1.2 Selecting IHE Integration Actors on the Digital Mammography Modality

Each IHE integration profile contains several *actors*. Frequently, partial benefits can be achieved when your systems implement integration profiles partly (a subset of a profile's actors, such as acquisition modality) and not all of the IHE functions are available (see Appendix A for planning individual purchases as part of a long-term plan).

The <u>*Print Server Actor*</u> is the key role played by a mammography film printer: it prints images on film at diagnostic quality.

Additional IHE actors a mammography film printer may implement include:

• <u>Secure Node or Secure Application Actors</u>: protect patient health information on the printer and for all printer transactions with other actors.

# 3.1.3 Putting Integration Requirements in Your RFP

Requiring IHE support in your RFP in order to meet your goals as shown above is achieved by stating which IHE work scenarios (integration profiles and options) and which system functions (IHE actor/roles) the mammography film printer should support. Sample statements to specify the IHE integration profiles and actors relevant to a mammography film printer are:

- Print Server actor: IHE Mammography Image Profile
- Print Server actor: IHE Consistent Presentation of Images Profile
- Secure Node or Secure Application actor: IHE Audit Trial and Node Authentication

## 3.1.4 Identifying Suitable Printers

While you may choose to proceed directly to sending your RFP to a broad group of potential vendors, find out which vendors have products with relevant IHE integration capabilities by referring to public sources. For a description of these sources, see Appendix D.

Another criteria for identifying suitable printers will be the requirement for the printer equipment conforming to the NEMA Standards Publication XR 23-2006 for "Quality Control Manual" Template for Manufacturers of Hardcopy Output Devices Labeled for Final Interpretation in Full-field Digital Mammography.

## 3.1.5 Reading Integration Statements from Vendors

Vendors may respond to your RFP by providing an IHE integration statement. These documents are also available for many products at *www.ihe.net/Resources/ihe\_integration\_statements.cfm*.

An integration statement is a direct statement of which IHE profiles, actors and options are supported by a particular product from a particular vendor (see Appendix E).

# **3.2** The Configuration and Implementation Process of a Mammography Film Printer

The acquisition modality or review workstation (Print Composer) prepares images for printing. It must be configured with the printer's Called AE Title, Internet Protocol (IP) address, and communication port number. The Print Composer interface must also allow the configuration of basic printer settings such as the image display format (1-up, 2-up, etc.), film orientation (portrait or landscape), film size (8x10, 10x12, etc.), magnification and smoothing type, minimum and maximum density, configuration information (printer dependent as defined in the manufacturer's DICOM conformance statement), medium type (blue or clear base film), image polarity (normal or reverse), and border density and trim.

The Print Composer additionally provides post-processing capabilities to prepare an image and annotations for printing using the specified settings. The mammography film printer (Print Server) does the actual printing. It must interpret the printer settings and annotations specified by the Print Composer and apply them to the image data in order to create a printed film. The Print Server and Print Composer configuration should be described in the manufacturer's DICOM conformance statements. See an example of DICOM Conformance Printer Configuration in DICOM PS3.2-2007, Annex E, section E.4.4.

### Appendix A Developing an Integration Strategy

Integration does not begin and end with the purchase of a single piece of equipment. Integration involves all the systems in the department or enterprise contributing efficiently and intelligently to the overall flow of work and information. It is important to develop an overall departmental or enterprise strategy for integration. Envision what the completed integration will look like and how it will work, and consider what steps will lead you from where you are now to that destination. This will help dictate what integration interfaces and capabilities your current purchase should support to play its part in the grand scheme.

Information technology is a crucial component of an efficient workflow process. The implementation of such a process usually requires purchasing new equipment or upgrading existing equipment. IHE provides a useful vocabulary for writing the integration portions of purchasing specifications.

On rare occasions, an opportunity arises to outfit a complete healthcare enterprise with all new equipment. In these situations, it is relatively easy to implement a fully integrated system. Usually however, a complete or nearly complete suite of partially integrated information systems already exists, and a pragmatic stepwise development and integration strategy is easier to manage and fund.

In either case, the planning method is the same: Focus on integrating operational workflow processes. Start by understanding the basic process flow, and then include "tributaries" and special cases. Next, identify the systems and transactions involved in those processes. Then, for each system involved in the process and already existing in the enterprise, determine whether the product can be upgraded to implement the required actors. For existing product upgrades or new products to be purchased, include the requirement to implement the necessary IHE Actors in the purchasing specification.

There are two ways to specify your integration needs: the hard way and the easy way.

- The hard way: understand each of the transactions defined in the IHE TF, decide which specific transactions are required to meet the objectives of the current phase of the project, and require in the purchasing specification that the purchased product or upgrade implement those IHE Actors / Transactions. You need to understand the technical basis as described in Volumes 2 and 3 of the Radiology Technical Framework.
- The easy way: systematically check use cases and solutions specified in IHE Integration Profiles, which offer a smooth evolution path toward higher interoperability. You will find this process-related and less technical information in Volume 1 of the Radiology Technical Framework.

Unless you purchase all your equipment at once, a single purchase will not achieve all the goals but will typically result in incremental benefits immediately, and the integration features will bear additional fruit as other components are added and integrated in the future.

For instance, consider a radiology department where there are some modalities connected to a printer, and there is no RIS to control the workflow in the department. What IHE

brings you in this situation is the vision, blueprint and strategy for the quest toward the IHE. The next steps for gradual integration can be:

- 1. In order to enhance quality assurance and interpretation of the acquired images, you may want to introduce a few postprocessing workstations. the IHE CPI Profile ensures that images have the same perception when looked at from the workstation and on film.
- 2. You may want to introduce automatic transport of patient and procedure data to the modalities by connecting a RIS to the modalities by means of DICOM MWL. The IHE SWF Profile specifies the behavior of the RIS and the modalities.
- 3. You are now prepared to store and make available acquired images throughout the radiology department (or beyond) by introducing a PACS. The full power of the IHE TF comes to play, by now using the following Integration Profiles: SWF, PIR, Presentation of Grouped Procedures, and Access to Radiology Information.
- 4. Some time after PACS introduction, you will be ready for enhancing workflow and productivity by measurement and Computer-Aided Diagnosis, and flagging of important images. These IHE Integration Profiles support this phase: Postprocessing Workflow, Key Image Note and Evidence Documents.
- 5. To close the loop for the patient's imaging procedures in the radiology department your workflow will be extended to include the reporting tasks and the preparation of the procedure billing. For this, IHE has the following Integration Profiles available: Reporting Workflow, Simple Image and Numeric Report and Charge Posting.

In summary, with the IHE approach to enterprise integration, one may expect a reduction of the hospital's integration costs, which represent 20%-25% of the total hospital's IT budget. The reduction is caused by using standard protocols in products according to IHE specifications.

IHE provides a proven and pragmatic roadmap for integrating existing IT systems within and among hospitals. The roadmap covers several clinical domains, such as Cardiology and Laboratory, and the infrastructure for the patient's Electronic Health Record in a Regional Health Information Network.

The user- and iteration-driven process ensures that IHE specifications address real-world integration problems. The IHE roadmap is divided into 1-year iterations, where each iteration provides self-contained integration solutions.

The availability of IHE-compliant products from multiple vendors is ensured, since IHE is endorsed by a growing number of healthcare IT vendors. As a result, a hospital can choose from a large variety of available products to build best-of-breed IHE-based systems and reduce its dependencies on single vendors. The interoperability among IHE products from different vendors is improved because of the detailed message description, the validation of IHE implementations at multi-vendor testing sessions (Connectathons) and the publication of "Integration Statements" describing specific IHE capabilities of a product.

That this strategy is successful in practice is shown by the many IHE success stories available at <u>www.ihe.net/Resources/user\_success\_stories.cfm</u>. You will not be the first to start this integration journey—many others paved the way for you. Along the way, you can set a baseline and measure progress toward your goals (see Appendix I).

### A.1 Integration Approaches in IT Environments with Legacy Systems

Interoperability between systems in the IHE means that the systems use precisely defined interfaces for data exchange. In addition, essential system behavior on how to compose data to be exchanged or how to process data received in such an exchange is often defined. This reduces installation or configuration efforts and realizes communication of essential data in a defined quality.

In legacy systems that do not follow such integration mechanisms, specific adaptation of existing interfaces may help to establish data exchange in a less comprehensive but potentially transitionally sufficient manner. Therefore, common legacy integration approaches are described here that may be a viable step to connect non-IHE-capable equipment to IHE-capable machines to match integration needs at your institution.

In the "non-IHE" integration scenarios described above, the communicating systems provide at least the most important standards-based interfaces, mainly DICOM, HL7 v2.x interfaces. This should ease integration efforts because defined messages with a limited variability need to be adapted.

The "non-DICOM," non-HL7 integration scenarios are based primarily on proprietary interfaces between communicating systems, which may complicate the integration effort. In these cases, interface adaptation may work.

Interface adaptation or conversion can be a tedious but valuable effort. Check relevant interfaces, including data structures, content meanings and configuration options or variability on each side of the systems to be prepared for communication. If the message types, structures or contents do not match between sending and receiving systems (e.g., different message versions, data differently structured, different codes used), the receiving system cannot accept or understand the sent message. A message conversion mechanism may solve this communication and integration problem. Depending on the purpose, scope of the involved systems, and your organization or equipment, there are different approaches to interface adaptation:

- 1. Individual mapping of interfaces ("manual interfacing"): The adaptation is done for this specific case, and for the two communicating systems only. Such a non-reusable solution can only be recommended for peripheral systems with specific usage in a limited organizational scope—e.g., to realize data collection for research.
- 2. Specific adaptation mechanisms for certain system types ("broker," "interface converter"): Such integration systems sit between specific system types (e.g., HIS-RIS, RIS-PACS) and translate a certain set of messages, often with considerable preconfigured message translations. They allow easier legacy integration for specific scenarios, mostly on a departmental level—e.g., a RIS-PACS converter may translate a RIS' HL7 data into DICOM MWL services that it can offer to modalities. Such a mechanism may be appropriate if you need to

implement a rather dedicated message conversion for specific imaging purposes or in your imaging department.

3. General, multipurpose, high-throughput message adaptation system ("interface engine"): Such a system has highly configurable message conversion mechanisms, often combined with different message distribution functions—e.g., routing, broadcasting. It can connect many system types and is normally offered as a central service in an enterprise. For instance, a RIS may get laboratory data via the interface engine from a legacy laboratory system. If your enterprise operates such a central interface engine, it may be possible to use it for your imaging integration scenario instead of installing separate interfacing software in your imaging department.

If the cost/benefit ratio of above described interface adaptation does not seem satisfying to you, a newer software version of one or both of the communicating systems may be an alternative in solving the integration problem at hand, and possibly additional integration problems with other systems.

### Appendix BUnderstanding IHE Integration Profiles

There are several sources of additional information for understanding the Integration Profiles, depending on the depth you are interested in.

### **B.1 Integration Profile Summaries and Tutorials**

Presentations and documents providing summaries and tutorials on IHE and its Profiles are available at <u>www.ihe.net</u>. You may want to start with

- a basic description and graphics for each of the Profiles (<u>www.ihe.net/pdf/iheyr3\_integration\_Profiles.pdf</u>).
- a brief graphic overview of the basic Profiles ( "What Does IHE Offer", SCAR 2003, www.ihe.net/presentations/ihe\_scar\_2003.html).
- a textual overview of the first 7 Radiology Profiles (radiographics.rsnajnls.org/cgi/content/full/21/5/1343)
- presentations from recent IHE Workshops to learn about newer profiles (e.g. www.ihe.net/participation/workshops/).

You get the most comprehensive overview in Vol. 1 of the IHE TF (see B.3 on reading the TF).

### **B.2 User Success Stories**

You may want to learn from users how their sites have deployed IHE Profiles. These success stories are available at <u>www.ihe.net/resources/success\_stories/index.html</u>. Each document is a concise one-page summary of the experience of the site, the Profiles they deployed and the specific products involved.

### **B.3 Reading the IHE Technical Framework**

IHE TF is available for download The complete at www.ihe.net/Technical\_Framework/index.cfm. Each IHE domain publishes a separate TF; however, they are completely compatible and interoperable. In fact, domains often make use of Transactions and Profiles from other domains, and products often implement Profiles from more than one domain. The TF published covers the domains of Radiology, IT Infrastructure, Laboratory and Cardiology. Others will likely be added soon.

The Technical Framework is the reviewed, tested and final integration specification. When new Profiles are published for trial implementation, they will appear on the site as Supplement documents. Once a Profile has been tested and judged stable and correct enough for final text, the Profile Supplement document is merged into the next release of the appropriate TF document.

A TF is broken down in roughly the same way in each of the domains:

• Vol. 1 has a chapter for each Integration Profile. It explains what problem the Profile is intended to solve and then outlines a solution in terms of Actors (the different roles to be played in the solution) and Transactions (how the Actors are required to communicate and behave). Chapter 2 provides an overview of all Profiles, including a summary table that maps Actors and Transactions to

Integration Profiles. Chapter 3 and onward document each Profile in detail, including required/ optional Actor behavior, process flow and specific aspects.

- Vol. 2 specifies in great detail how each Transaction is performed technically and how to use relevant standards. It is essentially an implementation guide for the vendor engineers. Technical staff at healthcare sites that wish to understand the operation of IHE in detail may also find it useful.
- Vol. 3 includes additional transactions for those domains, where the number of transactions is large.
- Vol. 4 of the TF, when required, includes any variations required to meet the particular needs of individual countries. These are referred to as National Extensions. Since the goal of IHE is to serve common global needs, Vol. 4 is generally brief.

## Appendix C Writing Integration Capabilities into an RFI/RFP

An RFI asks a vendor to describe their technology and how it would solve your problems. An RFP is a proposal of what you plan on doing and includes a project schedule, budget, and statement of need. This Appendix describes an RFI. To make this RFI into an RFP, your time table and budget will be added to the RFI.

Integration Profiles provide precise short-hand communication between purchasers and vendors of medical equipment. A purchaser can include a requirement for a particular Profile, and IHE provides several hundred pages documenting what the vendor needs to do to claim conformance to that requirement. Referencing an IHE Profile has the advantage of being both brief and precise. When using IHE Integration Profiles to express your requirements, you may want to reference the IHE Radiology TF and include a link to *www.ihe.net/Technical\_Framework/index.cfm* in your RFI/RFP. The simplification of using IHE leaves the details of the TF for the vendors to implement in their products. You may want to specifically request that vendors provide the IHE Integration Statement for applicable products either before or in response to the RFI/RFP.

### C.1 Methodology for Ranking Vendors on Integration

Integration is key for evaluating and ranking competing systems. For each area of integration, the buyer will need to determine their "LIMits": Like to haves, Intend to haves, and Must haves. For each IHE Integration Profile, identify the integration problem it solves for you and internally assign a rating of how important this integration is for you to accomplish successful implementation in your facility: Use 1 for Like to haves, 3 for Intend to haves, and 5 for Must haves.

Perform this task internally and then decide if you want to share this prioritization of integration features with your vendors. For each Integration Profile, provide a brief description of what you intend to accomplish through integration and ask how the vendor's solution can solve that problem. Rate the answers from the vendors on the following scale: 0 points if they cannot perform that integration, 1 point if they integrate through proprietary methodologies, 3 points if they integrate through DICOM/HL7 but not according to IHE specifications, 4 points if they use IHE but not with all the options you want, and 5 points if they integrate fully through IHE methodologies. An evaluation of integration features might look like the following example for a PACS:

Integration Profile	Problem	Internal	Vendor	Rank*
		Rating	Capability	
Scheduled	Integration of orders into scheduling and acquisition	5	4	20
Workflow (SWF)	process, providing a MWL on the modality and			
	procedure status information back on the RIS and or			
	PACS.			
Patient Information	Synchronizing the RIS, PACS and HIS databases	5	3	15
Reconciliation (PIR)	automatically to PID changes.			
Patient	Sharing patient context information to multiple "aware"	3	0	0
Synchronized	applications on the user's computer to synchronize to			
Applications (PSA)	the same patient.			
Total				35

Summing the total product of the all the ranks together with their respective vendor capability will provide an objective metric for the vendor's ability to integrate to your individual needs.

## C.2 The Language of the RFP

For your Must haves and perhaps your Intend to haves, use "shall" terminology in your RFP, as shown in the following examples. "The PACS system <u>shall</u> support the IHE SWF Integration Profile and the IHE PIR Profile as the Image Manager/Image Archive Actor." "The PACS system <u>shall</u> support the IHE SWF Integration Profile as the Evidence Creator Actor and the Image Display Actor."

For your Like to haves and especially for newer Integration Profiles, vendors may not yet be able to comply with shall language, as they may not currently offer that functionality in their product offering. Decide how you will include promissory components of a contract negotiation to include future roadmaps. You are putting unrealistic expectations on a vendor to deliver functionality if it is not incorporated in the contract.

## Appendix D Identifying Suitable Products

There are several ways to find vendors and products involved in IHE.

#### **D.1 IHE Connectation Results**

IHE Connectation results indicate which vendors are developing and successfully testing which Integration Profiles. IHE Connectations are annual testing events that vendors participate in on a voluntary basis. They allow vendors to test the IHE integration capabilities of their products with those of many other vendors in a structured and supervised environment. The results indicate which vendors have demonstrated proficiency in implementing a given Actor in a given Profile.

The results do not list specific products or versions. Vendors are not required to participate in the Connectathon to claim support for IHE in their products. The Connectathon should not be considered a certification of a vendor or product; rather, published results can be considered a useful litmus test. When a vendor that has successfully tested a given Profile at a Connectathon makes a direct claim that their product has implemented said Profile, you have some evidence they know what they are talking about. For direct claims of conformance to IHE for a specific version of a specific product, refer to the IHE Integration Statements published by the vendor, which is discussed in the next section.

IHE Connectathons are held each year in North America, Europe and Asia. Obtain Connectathon Results from <u>www.ihe.net/</u> and <u>www.ihe-europe.org/con\_result</u>. The results are generally laid out with a row for each vendor and a dot showing which Actors in which Profiles the vendor was judged to have tested successfully at the Connectathon. Success is judged by the Connectathon Project Management Staff, who are independent technical experts hired by the sponsoring professional society (e.g., HIMSS, RSNA, ACC). Success generally means a vendor successfully tests their product with products from at least three other vendors.

### **D.2 IHE Integration Statements**

IHE Integration Statements are declarations by vendors of support for specific IHE Integration Profiles in specific products. Many vendors post product ISs on their Web sites. These are linked to a single index page at *www.ihe.net/Resources/ihe\_integration\_statements.cfm*. Vendors who wish to have a link to their Integration Statements on this page can follow the instructions there for submitting a request.

An Integration Statement is a claim made by the vendor to the consumer. Vendors are not required to test the system in question at a Connectathon before publishing an Integration Statement. See Appendix E for details on interpreting the contents of an Integration Statement.

## Appendix E Reading Integration Statements

IHE Integration Statements are simple statements (frequently a single page) of which IHE Integration Profiles are supported by a product and which IHE Actor roles the system plays in those Profiles. Vendors may publish Integration Statements on their Web sites or provide them in response to an RFP. Here's an example:

Appendix F IHE Integration Statement				
Vendor	Product Name	Version	Date	
Integrated Medical Systems	Mega CT	V3.2	17 Oct. 2002	
This product implements all trar Actors and Options listed below:	nsactions required in the IHE TF to s	upport the IHE In	tegration Profiles,	
Integration Profiles Implemented	Actors Implemented	Options Implemented		
SWF	Acquisition Modality Patient-ba Assisted Setting		Worklist Query, uisition Protocol	
Portable Data for Imaging	Media Creator	No options defined		
Web address for vendor's IHE information: www.integratedmedicalsystems.com/ihe				
Links to Standards Conformance Statements for Implementation				
HL7	N/A			
DICOM	DICOM www.integratedmedicalsystems.com/dicom/MegaCT-DCS.pdf			
Links to general IHE information				
In North America: www.ihe.net	In Europe: www.ihe-europe.org	In Japan: www.	.ihe-j.org	

Integration Statements are discussed in detail in the IHE Radiology TF, Vol. 1, Appendix D.

## Appendix G Obtaining and Reading DICOM Conformance Statements

Vendors will generally provide a DICOM Conformance Statement (DCS) for each product at the customer's request. A DCS provides a detailed description of a product's DICOM capabilities. You can find these documents on the vendor's Web site for download or obtain it from your vendor representative.

Because DICOM leaves many details up to the vendor and many things are optional, the vendor must document what their product does in a detailed DCS (for further details, see Part 2 of the DICOM Standard, available at *dicom.nema.org*).

The DCS will describe which services the vendor has implemented (such as DICOM Storage or DICOM MWL Management), whether they have implemented support for the service as a client (SCU) of the service, a server (SCP) or possibly both; and what objects are supported for certain key services (e.g., storage of the enhanced MR object or cath lab procedure reports).

Often, key details such as finding out if the product supports a particular service as an SCU or an SCP can be found by looking on the title page or in the table of contents. Often, a search for the phrase "SOP Class Unique Identifier" will answer questions about the specific objects supported by a product.

Although an IHE Integration Statement provides a much simpler approach to some of the issues addressed by DCSes, the Integration Statement does not replace the DCS. Further, the DCS will be particularly useful when handling legacy integrations with non-IHE systems. Detailed analysis of the contents of DCS documents is beyond the scope of this Appendix.

#### Appendix H Obtaining and Reading HL7 Interface Specifications

Although vendor claims of conformance to HL7 are not as widely distributed or as strictly formatted as DCSes, it is often possible to ask the vendor to provide an HL7 "interface specification" that details the types of messages their system produces and accepts, the fields in those messages, when the messages are sent or expected and how the fields are filled. Often, HL7-based systems can be quite flexible, and their HL7 interface behavior can be adapted to your needs. Depending on the complexity of your needs, you may want to hire someone experienced with these sorts of interfaces to help you in the process of evaluating and customizing your HL7 interfaces.

If your vendor asks you to provide some details on what you want their interface to do, you may find it useful to provide the vendor with a pointer to the IHE TF and tell them which Profile and Actor roles you expect their system to fulfill. While this does not address the full use to which you will put their system, it will at least provide detailed specifications for part of the functionality.

## Appendix I Conducting Acceptance Testing

Sites are strongly encouraged to include Acceptance Testing as part of the implementation phase. This requires developing an Acceptance Plan, which includes the Acceptance Tests to be performed, specification of what constitutes a pass or failure and some kind of a schedule. Typically, Acceptance Tests to be included in the plan are agreed on by the vendor and the customer. Acceptance Tests can be developed once the systems to be integrated have been identified. It is preferable to run the Acceptance Tests only after all of the physical systems are installed and properly connected to the network. It may be possible to do Acceptance Tests on a subset of the systems, but that may require additional analysis and test setup.

The development of the Acceptance Plan requires technical staff (consultants or internal development resources). Note that this Handbook deals only with Acceptance Testing of interoperability features and not all the other features provided by the individual systems. Also, the testing here focuses on functionality, not on performance issues such as speed.

Once all of the IHE Profiles, Actors and transactions involved in the installation have been identified, a list of Acceptance Tests can be written for each of the systems involved. Using Vol. 1 of the IHE TF, a high-level list of transaction tests can be developed by reviewing the Table of Actors/Transactions for each of the relevant Profiles. Using Vols. 2 and 3 (and 4 for country-specific changes) of the IHE TF (along with your project specifications, HL7 specifications and DCSes), details of Acceptance Test data sets and expected results of running the tests can be developed.

Once all of the test specifications are brought together, the test plan is developed. The test plan should include the following components: What systems are required to perform the testing? What is the list of tests that should be run? What data are required to perform the testing? How will the operation of the test be verified? (E.g., what test tools are required?) What are the expected results for each of the tests? Each of the components is critical, and time should be dedicated to developing them.

<u>Test System Suite</u>: The Test System Suite needs to include all of the systems that interconnect. In some cases, a separate test environment will need to be set up to ensure that the live environment is not impacted by testing. In other cases, the live environment may be used, but the timing and the data used to test the system will need to be carefully thought through.

<u>Development of Tests</u>: Test strategies will depend on which systems are being integrated. Likewise, confirmation of the results will depend on the capabilities of the systems being deployed and the workflow of the institution itself. Note that if non-IHE systems are involved in the enterprise, additional evaluation is needed to determine what the expected results should be, since they may deviate from what would happen in a full IHE environment.

Some test specifics are listed in the Acceptance Testing section of each chapter/scenario in this Handbook. Additionally, many of the Profiles documented in Vol. 1 of the TF include use cases, which detail variations addressed by IHE that you may want to include in your tests—e.g., unscheduled acquisitions, simple single-step scheduled acquisitions, appended acquisitions and "group case" acquisitions.

<u>Test Data</u>: Specific test data will depend on the use cases being tested and what data are relevant to the operations of the site. The data should be representative of real cases and include complete sets of PID and order and procedural information. In some cases, it may be necessary to have representative "canned results," such as DICOM images and reports. An array of modality systems from several manufacturers with specific data fields may be required to fully test interoperability features.

Not all IHE use cases may be relevant to implementation for a given site. For example, a site may always construct their procedures so that there is only a single procedure step per requested procedure. In this case, IHE functionality dealing with multiple scheduled procedure steps is not relevant.

Test Tools: Verification of results may require the use of tools and multiple systems. For example, HL7 tools, DICOM tools, the use of the modality to display result images, or alternatively the use of a PACS system to verify that the information within the DICOM images contains all of the retrieved MWL information. The following are classes of tools that may be used to validate results. (a) HL7 Parsers: Parse out the fields of HL7 messages and present the components in a more human-readable way. (b) DICOM Validators: Check the content of DICOM Image Headers for conformance to the DICOM standard. (See www.dclunie.com/ for freeware.) (c) DICOM Sniffers: Watch traffic on a TCP/IP network, identify DICOM-related traffic and provide a way to assemble and store the contents of DICOM communications for review. (See www.dclunie.com/ for freeware.) (d) MESA Tools: As a part of the IHE testing process, HIMSS and RSNA commissioned the development of a set of software tools by the Electronic Radiology Laboratory at the Mallinckrodt Institute of Radiology, Washington University of St. Louis. They provide communication partners, test data and test plans to allow vendors to perform baseline testing as they implement the IHE TF. These tests are limited in scope but may be useful in the development of test plans. (See www.erl.wustl.edu/mesa) In some cases, it may be advantageous to use multiple tool sets to verify different system behaviors. Your vendors may also provide tools to test their systems. It should be noted that IHE cannot promote specific vendor tools.

## Appendix J Performance Metrics

Use of relevant performance metrics is extremely important to any process you intend to effectively manage and improve. The workflow and other processes of radiology are no different. Selecting relevant metrics, collecting measurements and responding to resulting feedback can make the difference between informed management and ad-hoc intervention. Even considering what metrics to measure is a useful exercise in reflecting on your current priorities and goals and what they should be.

Diligently selecting, measuring and tracking relevant metrics has proven to be easier said than done. Automated data collection for metrics from electronic workflow may alleviate that situation.

When considering an integration project, the time to start collecting metrics is now. Metrics are particularly useful when planning changes. Good metrics help with establishing a baseline measurement of your current practice, making the case that there is room for improvement, estimating the impact from the proposed process and technology changes, tracking the potential initial disruption caused by the changes and the return to equilibrium, and confirming/revising the impact on the process and ultimately the success of the project.

Additionally, metrics are useful for the healthcare industry at large, as they deal with pressures to improve care, reduce costs and effectively apply new technologies for those goals. Sites that collect metrics are strongly encouraged to share results. In particular, RSNA is interested in publishing comparative studies of before-and-after IHE implementations.

### J.1 What to Measure

Choosing what to measure and optimize can be a non-trivial task, e.g. because not all clinical benefits can be boiled down to a representative measurable value. Select metrics that reflect your priorities and your process. Some values to consider are given below as a starting point.

*Department Operational Metrics:* patients per year per specialty, patients per day per piece of equipment, procedures per year, steps per procedure, film media costs per year, film processing and disposal costs per year, film storage and handling costs per year, report turnaround time, repeated exams per year, "reconciliation events" per year, time spent per reconciliation event and manual demographic data entry error rate

Patient Experience Metrics: patient "turnaround time" from arrival to departure and patient waiting time in radiology

*Project Implementation Metrics:* time to specify systems and interfaces, time to test integration and time/money spent on custom interfaces

One approach to metrics is to record for each exam the time stamps at certain key milestones/progress points in your process.

*Inpatient exam:* order written, exam scheduled (optional), prior films available (optional), procedure protocol selected (optional), patient consent obtained (optional), transport dispatched, patient arrival in department, patient in procedure room, scan started, scan completed, patient out of procedure room and patient returned to room

*Outpatient exam:* exam scheduled (optional), patient arrival, order written, prior films available (optional), procedure protocol selected (optional), patient consent obtained (optional), patient in procedure room, scan started, scan completed, patient out of procedure room and patient dispatched

*Image handling:* exam transferred to PACS, current exam matched with prior exam, current exam interpreted, current exam placed in active file, exam moved to less active files and exam purged

*Reporting:* preliminary report called, report dictated, report transcribed, report edited, report signed, report distributed and report archived

*Reimbursement:* financial data per patient, as per Patient ID.

With raw time stamps, many time-related metrics can be calculated, and the order of the time stamps will depend on your institution's workflow.

Many other sources of information and ideas exist on the use of metrics in radiology. Some sources to consider are papers and publications from RSNA, including *Radiology* and *RadioGraphics*; SCAR (Society for Computer Applications in Radiology) and their publication, *Journal of Digital Imaging*; AHRA (American Healthcare Radiology Administrators) and their publication, *Radiology Management*; RBMA (Radiology Business Managers Association) and their publications on Radiology Productivity Measurement; ECR (European Congress of Radiology) and their publication, *European Radiology*; EuroPACS (European Association for PACS); and MIR (Management in Radiology).

Another source is your peers: Ask about their goals and what they measure. To find "best in class" hospitals, consider winners of the annual HIMSS Davies Award of Excellence in healthcare IT.

### J.2 Sample Measurement Results

This section discusses measurements considered useful by some sites and what values they recorded. This is a quick sample of some of the available information. More can be found by referring to the sources listed above. Many sites have focused on the time until availability of the report as the performance metric of most significance to the customers of a radiology operation. Different studies start the timer at different points: some from when the study is ordered, others from when the patient arrives for the exam, others from when the images are available for review. Having clear definitions of your selected metrics is a key point to making them comparable and useable as references to other sites.

A study at one 450+ bed hospital found their average report turnaround time (defined as the time from order to finalized report) to be 26 hours. They established a target goal to get the average below 18 hours.

A study by RDI Marketing Service comparing performance of sites with a RIS to sites without a RIS found:

Procedures per month	5,760 with RIS	1,690 without RIS
Report turnaround time	24 hours	30 hours
Transcription turnaround	11 hours	14 hours

From "Reinventing the Radiology Report, 2: Time to Adapt" by Bruce Reiner, MD, and Eliot Siegel, MD: "One recent study reported that the average report turnaround time for a CT examination was 3.7 days for the preliminary report alone and 5.5 days for final reports. These numbers speak clearly to the inefficiencies and delays of conventional reporting and resultant dissatisfaction among referring clinicians."<sup>2</sup>

One site found that by converting all imaging appointment slots to 30 minutes and expanding hours of operation, they were able to boost diagnostic imaging productivity, volume and revenue. With the ability to scan over lunch breaks and rest periods, potential appointment capacity increased by 140 CT scans per month. Overall, the CT project increased potential for outpatient appointment capacity by nearly 75% and projected over \$1.5 million in additional annual gross revenue (*www.ahraonline.org/AHRAArticles/AHRAArticles.dll/Show?ID=414*).

Many institutions have documented improvements in some of these turnaround types. In one institution, the time between study performance and interpretation averaged approximately 20 minutes (down from 8–24 hours), and between interpretation and transcription (and made immediately available for reading with the PACS or HIS) from 1-2 days down to 2 hours (available immediately after being read by phoning the digital dictation system).<sup>3</sup> Other reports of decreases in turnaround times are similarly impressive.

<sup>&</sup>lt;sup>2</sup> Mehta A, Dreyer K, Boland G, et al. Does PACS improve report turnaround time? Journal of Digital Imaging 2000;13:105–107.

<sup>&</sup>lt;sup>3</sup> Mattern CW, King BF Jr, Hangiandreou NJ, et al. Electronic imaging impact on image and report turnaround times. Mayo Medical Center, Rochester, MN 55905.