Interoperability Assessment for the Commissioning of Medical Imaging Acquisition Systems

**The Report of AAPM
Task Group 248**

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The Report of AAPM Task Group 248

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1. Introduction

The relatively straight-forward imaging chain of a film-based environment has given way to a more complex digital environment that stretches beyond the acquisition unit for processing, storage, and display. Each interface between devices and information systems provides an opportunity for communication errors which could affect the quality of the image or the accuracy of the associated patient-encounter information. While the development of data and communication standards has allowed for greatly enhanced interoperability, there still remains complexity and variability that can create risk for patient image and information fidelity.

Maintaining medical image and information fidelity in an electronic practice is a key aspect of providing for patient safety. Poor system interoperability can create errors in patient information, compromising patient safety. This risk to patient safety is described by the Joint Commission in Sentinel Event Alert #54 (JC 2015): "Incorrect or miscommunicated information entered into health IT systems may result in adverse events. In some cases, interfaces built into the technology contribute to the events." The Joint Commission identified 120 sentinel events between January 1, 2010, and June 30, 2013, that were related to health information technology. Of the sentinel events analyzed, a significant percentage could be linked to issues with system interoperability. This task group report on interoperability assessment for medical imaging systems outlines recommendations to address the need for keeping medical images and image information free from error.

The basic principle behind interoperability assessment during equipment commissioning is to ensure system functionality with clinical dataflow and workflow prior to releasing an imaging system for clinical service. What is important to recognize is that the functionality of a diagnostic imaging system extends beyond the acquisition console and depends on interoperability with a host of other systems, such as the Radiology Information System (RIS), a Picture Archive and Communication System (PACS), post-processing software, treatment planning software, and clinical viewers. While interoperability might be assured by a vendor in an Integrating the Healthcare Enterprise (IHE) Integration Statement, describing conformance with particular IHE integration profiles (IHE-App. F 2018), this is no guarantee of interoperability once installed at any given facility with its own particular system interfaces. The medical physicist often has responsibility for imaging equipment commissioning, validating that a system is ready for clinical use. For this role, it is helpful for the clinical medical physicist to understand what might go wrong, what the risks are, and what aspects of interoperability are desirable to validate as part of equipment commissioning.

A decision on which system aspects should be evaluated as part of commissioning, and how, should be made on the basis of addressing real risks to interoperability. The interoperability assessment may aim to confirm purchasing contract specifications; protect the electronic environment to which the system connects; and promote efficient clinical integration, patient safety, and quality of care. It is expected that there may be significant variability in interoperability needs and issues at different sites, for different workflows, and for different equipment. These differences in workflow and site variability make it difficult to write a detailed list of tests that should apply to every system and installation. Instead this document is intended to provide guidance for the clinical physicist to gain understanding of the overall goal of interoperability assessment, to encourage learning the basics of a site-specific dataflow or workflow, and to appreciate what can go wrong and what should be validated. The list of interoperability tests in this document, if not warranted for inclusion in commissioning, may be used as a troubleshooting guide.

While clinical medical physicists may seek to ensure that interoperability testing is included in commissioning, they may find it difficult to perform this assessment alone. Interoperability testing may involve engagement with systems to which they do not have direct access, and if one is unfamiliar with a site's dataflow or workflow, help will be needed. In interoperability testing, a team effort is

expected, with likely team members including service engineers, the PACS system administrators, technologists, and other stakeholders. Each of these individuals will have special knowledge of the workflow, the dataflow, and the possible factors that could affect image quality and information integrity at different points in the imaging chain. The medical physicist should have an understanding of the variables that can affect an image between acquisition and display, and to know where to go for additional assistance in order to isolate the source of image quality or information integrity problems.

2. Expected Dataflow and Performance

Prior to interoperability testing or troubleshooting, there must be an understanding of how a system will be integrated into clinical practice. Physicists are encouraged to ask for, or to outline for themselves, a dataflow diagram of system integration for any particular installation. In addition to the dataflow, it is important to know who is responsible for each component of the system, as their help may be needed for testing or troubleshooting. Typically, such information on dataflow might be available from a vendor, gathered as part of site planning and installation, or from a PACS administrator. Creating a system connection diagram, as in Figure 1, is helpful for understanding the relationship between devices in the imaging network. This can be used for mapping the dataflow and workflow.

Good practices for dataflow and workflow in a diagnostic imaging practice are outlined in IHE Integration Profiles (IHE-Rad 2018). The IHE Profiles describe application of standards such as Digital Imaging and Communication in Medicine (DICOM 2018) and Health Level 7 (HL7 2018) to address different use scenarios. For example, the IHE Scheduled Workflow Integration Profile
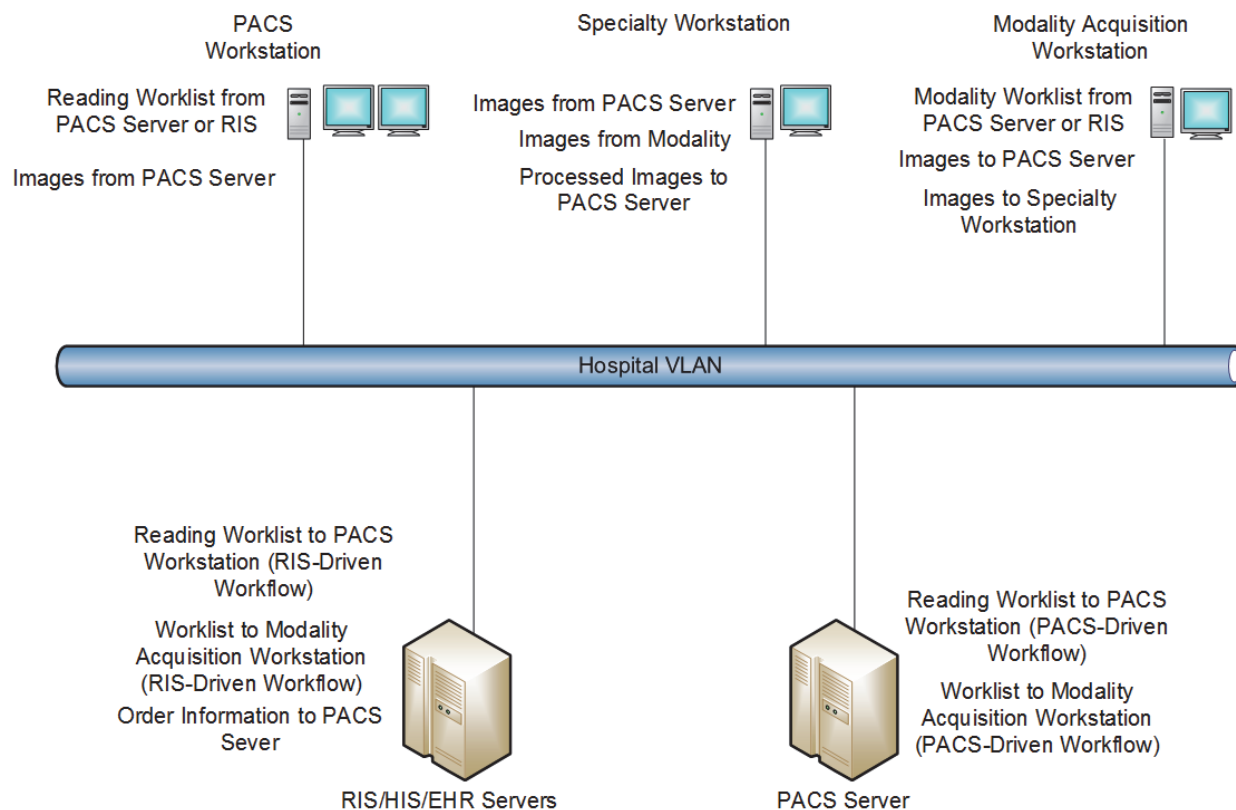

Figure 1: Typical, simplified imaging system diagram which can be used for describing dataflow and workflow.

describes a number of use cases which may be encountered (Moore 2003). The medical physicist should be familiar with the IHE profiles relevant to the equipment and workflows being implemented. Equipment vendors may also provide an IHE integration statement to describe the conformance of their product with the IHE Technical Framework. Vendors can test the conformance of their implementations at IHE Connectathons (IHE-Connectathon 2018) and may seek IHE certification of conformity assessment with IHE Profiles (IHE-Conformity 2018).

While successful testing at an IHE Connectathon is a good indicator of a system's interoperability capabilities, neither DICOM nor IHE conformance guarantees that a particular system will correctly interoperate with the various systems at an installation site[*]. For any particular new installation, not all connected systems or workflows may follow IHE Profiles, or have demonstrated interoperability with the exact same infrastructure and settings for this installation. It is the responsibility of the customer to check interoperability during commissioning of any new device or software, and crucial aspects of interoperability may be wise to negotiate into purchase contracts.

3. Testing Scope

The scope of this document focuses on image acquisition devices and the need for interoperability assessment with the systems to which they connect. While not within the scope of this report, it should be acknowledged that other changes to systems in the electronic dataflow may also affect the image acquisition unit's performance. Changes in a RIS or PACS affect everything connected to it, and for these systems, too, acceptance testing and commissioning criteria should be defined and assessed (Allison 2005).

Interoperability (or even the basic functionality of the equipment itself) may also be compromised by unanticipated and undesirable changes wrought by malware (e.g., computer viruses). Increasingly, medical physicists must be aware of electronic security risks to equipment and procure, configure, patch, and maintain equipment with these issues in mind. Physicists should also be aware that system changes intended to increase security can also affect interoperability, and these changes should be assessed and tested as needed, along with other intentional system upgrades. Guidelines for minimal standards, configuration, maintenance, monitoring, and usage related to protecting patient information and system integrity can be found in the American College of Radiology–Society for Imaging Informatics in Medicine (ACR-AAPM-SIIM) Practice Guideline for Electronic Medical Information Privacy and Security (Morin 2014).

End-to-end interoperability evaluation essentially consists of doing a "dress rehearsal" of the clinical workflow using test patient studies from upstream ordering systems to downstream systems that accept images. The description of a "downstream system" is meant to describe any clinical system or interaction point which lies after the acquisition system in the dataflow, i.e., a system that receives or displays the images for the next stage in the clinical workflow, e.g., quality control (QC) by a technologist, primary interpretation by a radiologist, or viewing by a referring clinician.

Downstream systems may include:

- PACS

- clinical viewer (mobile device or computer based)

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[*] This point is stated explicitly in the following excerpt from a DICOM Conformance Statement: "The use of these DICOM Conformance Statements, in conjunction with the DICOM Standards, is intended to facilitate communication with GE imaging equipment. However, by itself, it is not sufficient to ensure that inter-operation will be successful." (GE 2013)

- printers

- CD/DVD-burners for patient image distribution

- archive

- post-processing or image analytics services that may use the images (e.g., computer aided detection (CAD), volumetric image analysis or reformatting software, dose registry)

4. Risk Analysis and Testing Scenarios

Different degrees of evaluation effort may be warranted based on probability and potential impact of adverse occurrences when a new image acquisition system is integrated into a clinical electronic environment (Table 1).

The following are descriptions of testing scenarios and recommendations for different levels of interoperability-related risk with the introduction of a new or upgraded imaging acquisition unit.

4.1 High Risk for Clinical Impact: Start with a Test System

A high-risk scenario may include the commissioning of new or unknown image acquisition units that could pose a risk to wider network resources or other systems that an imaging practice may rely upon. For example, the acquisition unit may manage network associations in such a way as to tie up the resources of a practice, essentially "taking down" an electronic imaging practice. With concern for wider risk to other parts of the networked components of the imaging dataflow, the unit might first undergo interoperability testing within a test environment or test system. A test environment is a non-production network of RIS/PACS or other systems that duplicates production resources but is not relied upon for clinical patient care. Test systems are often employed as part of good information tech-

Table 1: Possible Testing Scenarios for Different Types of Interoperability-Related Risks to Clinical Operation

Example Situations	Probability of Problem Occurrence		Potential Impact	Overall Risk	Suggested Testing Scenario
	Scope: System-wide	Scope: Images and Information from New System Only			
4.1 A new, unsupported, image output type may compromise functioning of connected systems, significantly interfering with clinical workflow.	Low to High	Low to High	Very High	High	First evaluate in test system (non-production) environment. Follow with thorough evaluation in production environment (Test Scenario B).
4.2 Image output type has previously been tested, but fidelity of specific equipment and software version in the imaging chain has not been validated.	Negligible	Low to High	Low to High	Moderate	Evaluate test exams for test patients in production environment. See list of tests (Section V).
4.3 Repeat install of known image output type, system and configuration.	Negligible	Negligible	Low	Low	Send a test patient image through to ensure that it arrives at intended destinations.

nology (IT) management practices for validating software updates in a medical imaging IT infrastructure without impacting production resources. It may be possible to also use these test environments to validate the introduction of new acquisition equipment for higher-risk integrations that have the potential for significant negative clinical impact if issues arise.

Recommended end-to-end workflow assessment in a test environment may include acquiring images under a test-system patient order and checking that the study is received satisfactorily by all downstream systems without compromise to those systems. In this scenario, it may be most efficient to focus solely on confirmation of image transmission. More complete validation of study quality, integrity, and downstream functionality can follow using a test patient in the production environment, described in section 4.2. Medical physicists should consult with their on-site IT or engineering staff to see if such a test environment already exists or can be created at their institution when encountering high-risk scenarios. The IT or engineering staff may be willing to assist with the testing of new high-risk systems.

4.2 Moderate Risk for Clinical Impact: Perform Relevant Tests in Production Systems

A moderate-risk commissioning scenario may include a software upgrade that hasn't previously been tested or a new install of a relatively well-known vendor software platform. For moderate-risk installs, an end-to-end dataflow test of image and information integrity is warranted instead of just a configuration check that simply assures that images can be received. For moderate risk, the commissioning of the image acquisition unit does not pose any obvious danger to the functioning or availability of other networked systems and is deemed safe to test in a production environment. Interoperability tests will follow a clinical workflow to ensure proper functioning prior to patient imaging. For software upgrades, to the extent that details are known about the nature of system modifications, the tests outlined can be tailored to the scope affected by changes.

4.3 Low Risk for Clinical Impact: Check for Proper Configuration in Production Systems

A low-risk scenario may be one where the acquisition unit being tested is identical to one that is already operating satisfactorily in an identical electronic environment and with an identical dataflow. In this case, it is still beneficial to assure proper configuration for interfacing with adjacent systems prior to release for clinical use. The recommended configuration test involves checking whether the worklist shows up properly filtered at the image acquisition system and whether images were received at a PACS diagnostic workstation (or the nearest downstream platform for viewing images). This configuration check can be accomplished by creating a production-system test patient order, seeing that it shows up correctly on the modality worklist, and sending a test image for that order to PACS to validate configuration prior to patient imaging. It is still recommended that a representative image be visualized to see if any further testing may be warranted.

5. List of Tests

The following recommended tests are provided to help assure that a system is ready for clinical use. These tests provide examples of things that can go wrong, but do not necessarily provide the solution to fix the issues. The physicist may need to work with the vendor technical staff or the IT specialist (e.g., PACS administrator) responsible for connected systems in order to remediate issues identified in the course of testing. Tests are organized into those which are conducted at the image acquisition system (tests 1–4,14) and those that are evaluated at downstream systems (tests 5–13). "Downstream Systems" in this context are defined to be the clinical systems or interaction points which lie after the acquisition system in the dataflow, i.e., the system that receives or displays the images for the next

stage in the clinical workflow, e.g., quality control (QC) by a technologist, primary interpretation by a radiologist, or viewing by a referring clinician. Many tests may be efficiently combined. Tests may refer to a set of numbers of the form like (0008,0032): these refer to a specific DICOM tag in a DICOM header of an image, like Acquisition Time (DICOM 2018).

5.1 DICOM Modality Worklist Configuration

5.1.1 Rationale

The purpose of this test is to verify that the arrival of a radiology order results in the appearance of the patient and study information on the worklist at the image acquisition unit. In order to perform this test, you must know in which information system radiology orders are generated and what triggers availability of the order information at the image acquisition system. For many systems this is called "arriving" the patient. Further discussion of the modality worklist can be found in published articles (Gale 2000; Kuzmak 2001).

5.1.2 Testing Procedure

1. Place a test patient order for both a study and location that is appropriate for the equipment being tested.

2. "Arrive" the patient in the relevant information system specifying a location appropriate for the equipment being tested. This should trigger the patient study to appear on the acquisition worklist.

3. Refresh the modality worklist at the acquisition system and verify that the test patient is present.

5.1.3 Potential Pitfalls and Troubleshooting

1. Worklist configuration is set up incorrectly and the imaging system cannot communicate with the worklist broker.

2. Worklist query is not adequately filtered, and studies from another area of the practice show up on the worklist.

3. Worklist query is improperly filtered, and required studies do not show up on the worklist.

5.2 DICOM Modality Worklist Information Accuracy

5.2.1 Rationale

The purpose of this test is to ensure the required information about the patient and the ordered study is accurate.

5.2.2 Testing Procedure

1. Compare the information from the worklist with the information in the system from which the order was generated, either from a printout of the order or by pulling up the order on an information system terminal.

2. Ensure that the patient name, patient ID, study Accession Number, procedure code, procedure description, location, and other information is correct.

5.2.3 Potential Pitfalls and Troubleshooting

1. Data fields tied to the location or study have not been appropriately set in the relevant information system (e.g., EMR/RIS).

2. Information from the ordering system is rewritten at the modality or improperly mapped between the ordering system and modality.

5.3 DICOM Modality Worklist Information Display

5.3.1 Rationale

The purpose of this test is to verify that the data fields displayed on the worklist are sufficient to uniquely identify the ordered study, and that exams are removed from the worklist as they are completed. For some systems this is also called "ending the patient."

5.3.2 Testing Procedure

1. Ensure that desired information (e.g., patient name, study type, accession, etc.) is displayed (worklist data columns are often configurable). Ensure that data columns are wide enough to clearly distinguish one study from another.

2. Select the patient from the worklist as might be used clinically (e.g., barcode reader, mouse selection, typing the patient's name, etc.).

3. Acquire images for that study and "complete" the study (i.e., send the study to PACS).

4. Ensure that the study falls off the worklist.

5.3.3 Potential Pitfalls and Troubleshooting

1. A patient's exam doesn't fall off the acquisition worklist once the study is performed.

2. The data columns displayed or their widths are not sufficient to provide information that uniquely distinguishes a study.

3. String length limitations in the imaging acquisition system truncate information provided from the ordering system. Additional specificity can be obtained by including the exam code from the RIS as part of the modality worklist information display.

5.4 Procedure or RIS Code Mapping

5.4.1 Rationale

Image acquisition units may have the capability to establish default exam selection (including technique and image processing parameters) based on the procedure code or exam description of the ordered study. This functionality is described in the IHE Scheduled Workflow Profile *Assisted Acquisition Protocol Setting option* (IHE-Rad 2018). Validation of correct protocol mapping is recommended to ensure that settings provided by the radiology department are properly loaded into the imaging modality. Often this is done by the vendor's application specialist at the time of initial configuration. Evaluating that individual protocols (technique and processing parameters) are set up as expected for a given exam is a separate, recommended commissioning activity that extends beyond the scope of interoperability testing. The use of standard procedure codes in the RIS may reduce the burden in maintaining RIS code mapping with new installations or upgrades (Sippel 2014).

5.4.2 Testing Procedure

1. Each RIS Code or name is individually mapped to a specific protocol on the acquisition unit. The easiest way to review them all would be to obtain a summary document of the mapping table.

2. For interoperability testing, the focus is on making sure the table is properly loaded and that the mappings can be recognized by the acquisition unit. This can be accomplished by a spot check. Test patient orders should be placed for a variety of procedures to verify that the RIS codes or exam description mapping table has been loaded without error. The variety may include a range of exam descriptions or RIS codes to ensure a relevant range of information can be recognized by the acquisition system.

3. Verify that the study protocol and acquisition settings are in agreement with the department's standard technique chart or protocol reference.

5.4.3 Potential Pitfalls and Troubleshooting

1. RIS and modality vendors' implementations are not compatible. Compare respective (RIS and modality) vendors' DICOM Conformance Statements and IHE Integration Statements to ensure compatibility. For example, a modality may not accept RIS codes but instead may use exam descriptions. In some cases, the modality may not recognize all characters that are used in the RIS exam descriptions.

2. An older RIS Code Mapping database is loaded that has not been updated with more recent changes made on the RIS. This can be evaluated by spot checking the most recently modified exams.

3. There can be issues in loading a procedure code database from similar equipment running a different software revision. The databases may have to be separately created for different software revisions.

4. The Modality worklist is not being populated with the correct DICOM attributes, or the populated values (text string or codes) are incorrect.

5.5 Images Appear in a Timely Fashion and Are Associated with the Correct Downstream Worklist

5.5.1 Rationale

The purpose of this test is to ensure that images are accessible at the designated downstream system in a timely fashion, without excessive delay, and, if applicable, that they appear on the appropriate technologist, radiologist, or referring clinician worklist. Excessive delays in transmission relative to similar exams sent during similar times of the day (not compromised by excessive background network traffic) may indicate the presence of issues in system configuration. Issues in image transmission could create delays in QC or interpretation, poor user experience at the downstream workstation, or compromise performance at the acquisition unit by monopolizing system resources.

5.5.2 Testing Procedure

1. At the modality, create a series of test studies. These test studies should cover all of the types of DICOM Image Object Definitions (IOD) that will be utilized clinically from that modality (e.g., Secondary Capture, XA, DICOM Structured report). It is helpful if the image, series, or study created covers both representative and potential maximum ("worst-case scenario") clinical study size. If the new installation or configuration might impact the appropriate routing or filtering of images to intended worklists (technologist or radiologist), it is also helpful to create test images with appropriate clinical orders or scenarios that would populate the worklists in question.

2. Determine what action initiates the send of an image, series, or study from an acquisition unit or what image-sending scenario will be used clinically for the unit. Normal operational configuration is often designed to automatically send an image or series after processing or reconstruction, or on ending the exam, without explicit operator action to initiate transmission. For automated sends, symbols or messages on the user interface may indicate when to start timing rather than an operator-initiated manual send.

3. Making note of the time, initiate a send from the acquisition modality to the designated downstream system(s). Pay attention to intended clinical dataflow. In some cases different types of objects may be sent to different destinations or the same study may need to be sent to multiple

destinations. Ensure that the downstream systems relevant to the clinical workflow have been addressed.

4. For measurements to be repeatable or comparable over time, they need to be performed in the same manner, i.e., during times of similar network load and utilizing the same cues for starting the clock. One should also ensure that the number and size (resolution) of the images in the study are kept constant between tests. The exact procedure used for a pair of devices and their configuration should be documented in this respect. This allows comparison with established baselines.

5. Perform any operations required for the images to appear on the designated downstream system. The downstream workflow may be driven by triggering specific events that enable the study to appear on a downstream worklist. Depending on the department's workflow, the triggering event may require updating the status (e.g., "verification" or "completion") in the PACS, RIS, or Speech Reporting system, or even performing a status update directly from the modality using DICOM Modality Performed Procedure Step (MPPS). If needed, perform a "manual refresh" or other task that allows an image or study to appear on the downstream system.

6. Transfer performance should be monitored for appearance at the next downstream system(s). Make note of the time to first image and the time to when the last image can be visualized (ensure all images are received and can be displayed). It is helpful to understand relevant transmission time baselines provided by existing systems with similar workflows and output. Assess whether the transfer performance is as expected. Be aware that transmission time can be affected by network peak load.

7. Ensure that the images are associated with the appropriate downstream worklist.

5.5.3 Potential Pitfalls and Troubleshooting

In order to troubleshoot downstream transmission issues one must understand the relevant dataflow, routing, triggering operations, and any intermediary workflow operations that facilitate availability of the images at the desired destination. Studies may not be available on the appropriate downstream workstation in a timely fashion for the following reasons:

1. The sending destination(s) may not be properly configured at the modality. Even if the acquisition modality indicates that images were sent, it could be that the study was transmitted to an incorrect destination.

2. There are system-wide issues in image transmission related to an intermediary DICOM routing system being down or other network faults. Any of these would prevent an image from getting to a downstream system and onto the appropriate worklist.

3. For a network architecture that physically routes image files to specific workstations, an image routing issue may be isolated to just the new modality. This could be related to image routing system architecture not having filters appropriately set to transmit images from the new modality. To address issues related to image routing architecture one would need to contact the responsible parties for intermediary routing systems.

4. Studies may not appear on the correct worklist if there is a mismatch between the study metadata (e.g., imaging location, body part, or study description) and the filters established for the worklist. Metadata associated with the study may originate with the ordering system feed, RIS feed, or the image header itself. The metadata mismatch could also result from an improperly

set worklist filter. In order to address the latter, one would need to know where the worklist is generated and where those filters are set.

5. Necessary workflow steps have not been completed or system messaging required for data-flow is not occurring. Example: Often worklists will not place an unread study on the interpretation worklist until the PACS has sent a message to it that the study has been verified by the technologist. Check that the QC step has been done and that those messages are flowing to the worklist manager.

6. Exams may be partially accepted by the downstream entity immediately, but later sends are not immediately accepted or accepted at all. Latency in image acceptance may be related to PACS architecture inhibiting other images from being added to that exam or appearing on the worklist. Some PACS architectures also include a limited window in which images may be added to an exam "folder": if the time of later sends exceeds the window of acceptance, they may not merge with the initial intended exam. Neither of these situations pertains strictly to the modality, but are dataflow issues that pertain to PACS architecture that the end-user and practice needs to be aware of in their workflow.

7. If MPPS is used to allow the modality to update study status at the PACS or RIS, the MPPS may be improperly configured at the modality.

8. Images or studies may not appear in a timely fashion or at all because of improperly negotiated transfers between systems. Log files from the acquisition modality or the downstream receiver can be reviewed and scrutinized for messages indicating time-outs, broken connections, or simply reviewing the time-stamps on the system to determine when files were sent or received. If it is not possible to perceive the issues from failed transfer information on the acquisition unit, it may be helpful to have administrators of downstream systems interrogate those log files to understand how the transfer negotiation failed.

9. Insufficiency of network resources (e.g., low bandwidth switches) may create delays if a new system represents a significant increased burden during a peak network traffic time. Many new systems require significantly more networking resources due to image size and number compared to the systems they replaced.

10. Image sends occur only as foreground processes. As a result, image transmission from the modality may be delayed until a reconstruction or other operation is completed.

5.6 Appropriate Exam Appearance

5.6.1 Rationale

The purpose of this test is to ensure that the image appearance is as intended on downstream systems based on visual inspection. This test involves assessment of image fidelity and propagation of image adjustments between the acquisition workstation and downstream systems. These tests include determining if the adjustments made by a technologist at an acquisition modality are retained when viewed on downstream systems and verifying that the images can be readjusted as required on downstream systems.

5.6.2 Testing Procedure

1. Select a suitable modality-specific QC phantom. The phantom should contain test objects for the evaluation of dynamic range. Many CT and MRI manufacturers provide phantoms for routine QC which can be used for this test. ACR accreditation phantoms for CT and MRI also contain appropriate test objects. For digital x-ray systems, a step wedge, vendor-provided quality control phantoms, or test objects such as the DIGI-13 (Iba Dosimetry), NORMI 13

(PTW), or Pro-Digi (RaySafe) are suitable. For digital Rad/Fluoro systems, suitable test objects may include the Primus-L (Iba Dosimetry), NORMI RAD/FLU (PTW), and P Fluoro (RaySafe). The CT number accuracy module can be used for this test on a CT scanner. For MRI, the low-contrast test module could be used in lieu of a dynamic range object. These CT, MR, and x-ray phantoms represent only a subset of possibly suitable choices for the purposes of this test.

2. Acquire two test images of the phantom.

3. At the modality workstation, view the first "default" image in a "wide-window" setting that maximizes the visualization of the dynamic range test objects or step wedge steps, and note the number that are visible. For the second "adjusted" image, if possible, narrow the window so that only one of two of the dynamic range test objects is visible, and save the adjusted appearance. Send both images to the downstream device. It may also be useful to send a system-generated test pattern such as a SMPTE or a TG18 QC pattern to a downstream system like a film-printer for image quality evaluation.

4. At the downstream device, note the initial appearance of the first "default" image. For testing purposes, it would be wise to use a hanging protocol that does not include any additional image processing, including a window/level operation. Assess whether the downstream images match what was seen on the acquisition workstation, except for expected variation attributable to different display hardware and calibration. Assess whether the image can be fully manipulated (e.g., window/level) as expected on the downstream device. There may be reasons why images may look different between an acquisition system and a downstream device, including different display qualities, display calibration, or window/level settings in a PACS hanging protocol. The purpose of this test is to ensure there are no unanticipated differences.

5. For the second "adjusted" image, first assess if the appearance matches what was seen on the acquisition workstation. Assess whether the image can be fully manipulated (e.g., window/level) as expected on the downstream device. Assess whether the image can be readjusted to visualize all of the dynamic range test objects that were visible in the first "default" image.

6. If applicable, ensure appropriate optical densities and overall quality for any printed test patterns.

5.6.3 Potential Pitfalls and Troubleshooting

If the default (first) image appearance on the downstream device does not match what was seen on the acquisition workstation:

1. Information on the presentation of default image appearance may be saved into pixel information, Values-of-Interest (VOI) Look-Up Table (LUT), Presentation-LUT, DICOM GSPS (Grayscale Presentation State) object, or contained in a slope/intercept DICOM header field. If the intended image appearance information is not recognized by a downstream device or is encoded in multiple locations with conflicting information, the image appearance at a downstream system may not match the acquisition unit. You may need to investigate potential settings on the acquisition workstation with a field service engineer to find a solution where default image appearance does not present as intended.

2. Differences in display hardware, display calibration, or viewing conditions may result in differences in appearance between acquisition and downstream viewers. If consistent image presentation between acquisition display and a downstream device is desired, it may be necessary

to match both luminance response (e.g., calibrated to the DICOM GSDF) and luminance ratio (including ambient light) between the downstream and modality display. Other considerations—such as viewing angles, protective panels, and lighting—can also affect the appearance of image contrast, as discussed in AAPM Report TG 18 (Samei 2005).

3. Transfer properties—such as bit depth, image compression, and byte ordering—can also affect the appearance of the image.

4. In assessing the "adjusted" (second) image appearance on the downstream device:

   • If image modifications are not maintained between modality and downstream display, image modifications may be saved as a VOI LUT or DICOM GSPS object that is not accepted or properly interpreted by a downstream system.

   • If the image cannot be restored to the appearance of the first non-adjusted image, the adjustments by the technologist may actually be changing the image processing parameters of the image, or burning the changes into the pixel information, rather than changing default window and level settings.

5.7 Quantitative Measurement Consistency

5.7.1 Rationale

Most PACS display systems include functionality to measure physical dimensions (length) of anatomy in an image. In addition to pixel dimensions, pixel values may also relate to important quantitative measures, such as Hounsfield units on a CT scanner. Inconsistency in the interpretation of DICOM attributes, or unintended scaling, may lead to inconsistency in quantitative measurements between different image viewers. System calibration for quantitative measurement accuracy is assumed to be addressed with other aspects of the physics acceptance testing of a modality, with the primary focus in this case being fidelity of data between the acquisition system and downstream systems.

5.7.2 Testing Procedure

1. Acquire an image of an object of known dimension and that provides an array of image pixel values, if pixel value fidelity is also being assessed.

2. Make whatever quantitative measures are relevant for the specific image acquisition system at the acquisition unit. These measurements may already be made in the course of physics acceptance testing. Examples of relevant measurement may include physical size of a known object or pixel value. Repeat this measurement at each viewing platform to ensure consistency of measurement.

3. For cross-sectional imaging, in order to rigorously assess potential issues with physical dimension encoding, it is recommended to acquire multiple test images at different orientations, varying slice spacing, and to create reformats (e.g., a double oblique multi-planar reconstruction). Size measurements should include linear distance, area, and volume.

5.7.3 Potential Pitfalls and Troubleshooting

1. Physical dimensions of the image are encoded incorrectly or are missing in the DICOM header at the image acquisition unit. For example, an image acquisition unit may report a spacing parameter in the wrong units (e.g., centimeters instead of millimeters), or may leave out or leave blank attributes that downstream systems would need to make measurements.

   DICOM attributes that impact a physical dimension measurement may vary between different DICOM Information Object Definitions (IOD), and whether or not the images are cross-sec-

tional (for which spacing within the body is known) or projectional (for which the diverging x-ray beam means that the plane and offset from the central ray impact measurements). To ascertain which attributes are relevant, it may be helpful to consult DICOM Information Object Definitions (DICOM-PS3.3 2018). Alternatively, one can visually inspect a dump of the DICOM attributes of the image created for those that seem pertinent to physical dimensions.

- DICOM attributes that relate to image physical dimension for cross-sectional images include: Pixel Spacing (0028,0030), Image Position (Patient) (0020,0032), and Image Orientation (Patient) (0020,0037). Distance measurements in the plane of acquisition are affected only by Pixel Spacing (0028,0030); other measurements, such as of distance across slices, or volumetric measurements, are affected by the in-plane spacing and the spacing between the (centers of) parallel slices. Contrary to popular belief, Slice Thickness (0018, 0050) is not generally relevant to physical dimension measurements, since it describes the thickness, not the spacing between slices, and these may be different for overlapping slices and slices acquired with a gap (especially MR). Spacing Between Slices (0018,0088) is not often present (nor is it required) in acquired images, and may need to be computed from the interval between Image Position (Patient) (0020,0032) values for adjacent slices along the normal to Image Orientation (Patient) (0020,0037). Slice Location (0020,1041) should not be used since it is often absent, vendor-specific, and redundant with Image Position (Patient) (0020,0032).

- DICOM attributes that relate to image physical dimension for projection radiography images include: Imager Pixel Spacing (0018,1164), Estimated Radiographic Magnification (0018,1114), Distance Source to Detector (0018,1110), and Distance Source to Patient (0018,1111). If the image has been calibrated, Pixel Spacing (0028,0030) may be present and have different values than Imager Pixel Spacing (0018,1164). The use of these for mammography is specifically defined in the IHE Mammography Image Integration Profile (IHE-Rad 2018), and issues are discussed in a published report (Clunie 2003).

- DICOM attributes that relate to image physical dimension for Ultrasound are encoded within Sequence of Ultrasound Regions (0018,6011), though Pixel Spacing (0028,0030) may also sometimes be present.

2. Downstream viewers do not correctly utilize DICOM attributes related to physical dimensions that are created at the acquisition unit. For example, when doing measurements in a 3D volume, a downstream system might determine the slice spacing from the Slice Thickness attribute instead of using or the Spacing Between Slices attribute.

5.8 Patient Demographics

5.8.1 Rationale

While IHE Profiles do not include modification of study information at an acquisition modality, this task may be part of a site's practice, and subsequent modification can be advantageous for patient safety to allow for workflows that correct mistakes at the source. The capability of a modality to allow editing of patient demographic information on previously obtained images can vary widely among systems. Similarly, the ability of a PACS to accept revised information from the modality when the images have already been stored or interpreted varies, and depends on the PACS and its configuration. If patient information editing or movement of images between studies or patients at an acquisition modality is part of the expected QC practice for a site, this feature should be very carefully validated, as should the resulting impact on the downstream systems.

The standard IHE approach to correction of demographics and handling of images containing incorrect demographics are defined in the IHE Patient Information Reconciliation (PIR) and Imaging Object Change Management (IOCM) Integration Profiles (IHE-Rad 2018).

5.8.2 Testing Procedure

1. Determine what patient demographic editing is expected at the acquisition unit for your clinical workflow.

2. Generate two orders (with unique Accession Numbers) for two different test patients (or use an "emergency" patient for one exam). For testing of edits to workflows for both in-progress and already-acquired studies, one additional order for one of the test patients may be needed.

For editing a study <u>in progress</u>:

3. Select the source "incorrect" study off the modality worklist or hand enter an "emergency" patient. During the study acquisition, attempt to edit the study information to match the correct destination order. You may try variations on this for different combinations of incorrect fields if the options for editing are limited. Finish acquiring the study on the acquisition unit and send to downstream systems.

For editing a study <u>after</u> it has been acquired, completed, and sent from the acquisition unit:

4. Select the source study or series or image that is incorrect. You may be able to edit the information to match the correct destination, or you may need to move or copy a study, series, or image to the correct study. You may need to investigate at what level you are able to make modifications, whether at the study, series, or image level. If a "copy" or "move" is required (rather than editing the study information), the destination order may need to be arrived or previously entered on the acquisition unit. It may be necessary for a user with administrative privileges to first delete any incorrect images in the receiving system.

5. Verify that changes made at the modality are propagated as expected to all downstream systems.

5.8.3 Potential Pitfalls and Troubleshooting

1. Many imaging modalities will retain the Study UID (unique identifier) of the original study after edits are made, and work may be required at PACS or other downstream systems to ensure that images are associated with the correct study. If an image retains the original study UID after edits are made at the acquisition unit, the behavior of the downstream system may or may not be to overwrite any demographic edits with the information originally associated with that study UID (there is no standard behavior defined for receiving information with the same UID but different identifiers: it may be ignored, replaced, an error signaled, or all involved objects quarantined, depending on the implementation). In this case, the images may stay with the old study.

2. Many systems will not allow for manual corrections and instead require that images, series, or studies be copied into another order on the unit.

3. Some systems will only allow moves at the study level and after a study has been acquired, completed, and sent to a downstream system.

4. You may wish to investigate the implications of hand-entering an order on a unit for an order that already has images in PACS to see what is required to ensure images get associated with the desired study.

5.9 User Annotation Display

5.9.1 Rationale

User annotations may appear very differently on downstream viewing than on an acquisition unit: the font may be unreadable, they may be applied in a different location in the image covering anatomy, or they may even be outside of the viewing area. User annotations can also be stored in different forms: saved into pixel information, stored in the image object as part of an overlay, as part of a GSPS object, in Structured Reports (SRs), in non-standard private data elements in the image object, or only in the modality or PACS database and not exportable. Downstream systems may not be able to display user annotations at all, or may display them differently, depending on the form in which they are saved.

Safety-critical user annotations, such as correction of the laterality or orientation (side) of an image should not be made using electronic user annotations unless it will be validated that all current and future downstream receiving systems (including those outside the enterprise) will ALWAYS display them satisfactorily. In practice, user annotations saved into pixel information are a safe choice to satisfy this criterion, relieving the need for ongoing validation.

5.9.2 Testing Procedure

1. Determine how annotations are being sent, whether saved into pixel information or otherwise, and whether this can be configured differently for each send destination.

2. Add image annotations to a test image at the acquisition workstation. Text annotation could be entered manually or selected from a predefined menu. Other common annotations are graphical in nature, such as an arrow pointing to or a circle surrounding a region of interest.

3. The image with the test annotations should then be transmitted to and viewed on applicable downstream devices to verify that the annotations are displayed correctly.

4. Change the orientation of the image (rotate, flip) to verify that annotations change appropriately (annotations may theoretically be located relative to the pixel data or the displayed area, depending on what type of annotation was made by the user). Pixel data anchor points (such as arrow heads) should rotate and flip appropriately so as to designate the same location, but associated text may not rotate or flip in order to remain readable.

5.9.3 Potential Pitfalls and Troubleshooting

Annotations are absent, minimized, distorted, pushed outside of the field of view, made difficult to see (i.e., white writing on a white background), or made to obscure the image (i.e., the annotation moves or is of different size relative to what was shown on the acquisition system). Automatic masking may also hide annotations depending on the layer or image to which they are added.

5.10 Orientation and Laterality Markers

5.10.1 Rationale

There are various ways that orientation and laterality information may be captured. Orientation and laterality may already be present in the image because lead markers were used when obtaining an x-ray image. Orientation and laterality may be known to the device (through user entry or deduced from the position of the gantry and detector) and either recorded into the image pixel data electronically, encoded in specific DICOM attributes, or both.

If downstream viewing systems automatically display laterality orientation markers using DICOM attributes, it is important to assure that all downstream systems correctly detect and display them.

Orientation and laterality may also be added manually as a user annotation. User annotation is evaluated in section I, and it should be ensured that this type of laterality or orientation marker is persistent on downstream viewers.

5.10.2 Testing Procedure

1. Potential clinical variations for patient orientation should be investigated using persistent markers in the image (lead markers) to keep track of intended presentation.

2. Ensure that laterality markers are consistent and appear as desired.

5.10.3 Potential Pitfalls and Troubleshooting

1. Downstream systems incorrectly interpret information for laterality or orientation and mislabel the image. If there are issues, look to where the information is encoded in the image DICOM header and work with the support team for the downstream systems to correct how the images are handled.

2. Potentially misleading information may be added by the downstream system. For example, based upon the image orientation information in the DICOM header, a system may add "L" and "R" markers electronically to the image display intending to show the left and right sides of the image. This can present confusion on the part of an individual viewing the image if they are anticipating only an R or an L to indicate a right extremity or a left extremity (i.e., "laterality" is confused with "orientation").

3. Clinical workflow variation in image acquisition may discourage the utilization of the automated application of orientation labels in an image. For example, in digital radiographic chest imaging, the technique and processing may be set up for PA acquisition, but occasionally for certain patients AP will be acquired. If the technologist utilizes the same menu item for acquisition, this may automatically apply the wrong orientation information in the header. This orientation information may not be visible at the acquisition workstation or downstream if the software chooses not to display this information. This can make it more difficult to detect errors that could show up later on. Generally, for equipment where acquisition orientation may be variable, it may be wise to turn off automatic orientation labeling and require manual labels from the acquiring technologists. Additionally, if not acquired as part of the image with a lead marker, persistence of intended orientation or laterality marking may be better assured if those labels are incorporated into the pixel data.

5.11 Transfer Fidelity of Information Stored in the DICOM Header

5.11.1 Rationale

A user of a system should be able to robustly and unambiguously communicate to a user of a different system displaying the same study how to locate a particular image of interest in a particular series. This information exchange is often done by communicating an image number, time stamp, or slice position between the users. If the two systems do not correctly or consistently interpret the various DICOM attributes where this information is recorded, the two users may fail to communicate vital information, leading to user frustration and potential inconsistency in reporting.

5.11.2 Testing Procedure

Checking for the proper interpretation of numbering and time stamps generally can be done in conjunction with other tests.

1. Check displayed dates and times on upstream and downstream systems. They should be consistent with each other.

2. Check the image stacking (i.e., display order when scrolling through the images within a single series) between upstream and downstream systems. The order should be reasonable for the device's use and consistent with other systems.

3. Inspect how series and images are identified, comparing upstream and downstream systems. A particular slice or frame should be identified consistently by different systems.

5.11.3 Potential Pitfalls and Troubleshooting

1. Multiple time stamps are available in the DICOM header corresponding to Acquisition Time, Study Time, and Series Time. Inconsistencies in time may appear between an acquisition unit and downstream viewer depending on which time is selected for display.

2. Systems may not correctly handle seasonal time changes (e.g., daylight savings or summer time changes). Time calculations may be incorrect due to software obsolescence on the modality or the downstream systems. Studies that span midnight may present similar problems.

3. The acquisition system may not be synchronized to a common time server, leading to inconsistencies in time with other systems.

4. A system may limit the string length of fields like an exam description. This may end up truncating text that may have been entered in an ordering system. If there is concern for this, you may wish to use an exam order or other input data to test for this limitation.

5. Image numbering, seen with image stacks, may depend on how cross-sectional images are viewed. Depending on which end of the stack the system begins counting, the image numbering may change. It is important to understand the relationship between slice ordering and image numbering between an acquisition unit and various downstream viewers of those images to ensure that radiologists are able to communicate with technologists or clinicians about which image they are referring to.

6. It is important to understand that Instance Number (0020,0013) (sometimes referred to as Image Number) does not consistently define any particular position in space or time for a given series, and its use varies between modalities, vendors, and systems. Spatial location is often provided in a vendor-specific manner as a single value in Slice Location (0020,1031), which usually corresponds to what the modality console displays, and as 3D patient-relative coordinates in Image Position (Patient) (0020,0032) and orientation in Image Orientation (Patient) (0020,0037). In the case of a dynamic or multi-phasic acquisition (e.g., fMRI) the timing for each slice should be present in Acquisition Time (0008,0032), but modality and application specific Attributes that may be present include Temporal Position (0020,0100) and Number of Temporal Positions (0020,0105) and may serve to describe each slice into its correct time slot within the entire acquisition. Other Attributes describe timing relative to the cardiac cycle. Reliance on Image Number will eventually lead to difficulties with hanging protocols and communication between the technologist at the modality and the interpreting physician due to a reordering of the images as specified by the hanging protocol, e.g., sagittal acquisition scanned left-to-right but displayed right-to-left at the PACS workstation.

7. Similarly, Series Number (0020,0011), Acquisition Number (0020,0012), and, in general, any of the 'Number' Attributes in DICOM do not imply any particular order in space or time. These numbers are merely for referential convenience, do not generally have any semantic meaning, and are often misused by systems and misinterpreted by users.

5.12 DICOM Structured Report Validation

5.12.1 Rationale

Image acquisition systems may create non-image data to be used by other systems. In particular, DICOM Structured Reports (SRs) are intentionally created for use by other systems with standardized

data encoding. Furthermore, with the increase in use of Radiation Dose Structured Reports (RDSRs) in Radiation Dose Index Monitoring software, accuracy of this particular SR is critical to accurate data for reporting or tracking dose.

5.12.2 Testing Procedure

1. Create an exam on the system that will generate the desired Structured Report. Utilize a valid order that is consistent with the needs for clinical dataflow. A clinical exam copied to a test patient order at the imaging acquisition system may serve this purpose for meaningful validation.

2. Send the structured report to all intended downstream destinations or to a system with a viewer to enable the SR to be fully interrogated.

3. Assess that the information extracted from the SR or output that utilizes data from the SR is consistent with what is anticipated for that particular exam.

5.12.3 Potential Pitfalls and Troubleshooting

1. Information may be mis-mapped between systems. Utilizations of SR may involve manual mapping to a reporting system or may involve automatic selection of fields for entry into another database. In either case, mapping errors may occur.

2. Not all systems may be set to accept or display Structured Reports.

5.13 Post-Processing Functionality

5.13.1 Rationale

Post-processing systems may be used to extract parameters or information from data after the initial acquisition or to prepare data for subsequent review by clinicians. Examples include Computer Aided Detection (CAD) systems and systems that generate multidimensional views of data for subsequent review. Changes in upstream systems (e.g., acquisition units, other post-processing systems) can potentially impact a downstream post-processing system (Huo 2013). In addition, post-processing systems generally must be able to store their results to be useful clinically. Furthermore, post-processing systems often are integrated into automated workflow engines. Hence, changes to surrounding systems, such as the image archive or workflow manager, can also impact a post-processing system and should trigger retesting of interoperability with the post-processing system.

5.13.2 Testing Procedure

1. Generate the relevant variety of exams on an upstream system (e.g., acquisition unit) that could trigger the use of the post-processing system during normal workflow. Note that some post-processing systems, such as Computer Aided Detection systems, may only work with actual clinical images. Non-clinical phantom images used for acquisition system testing may not be sufficient for testing certain post-processing systems. For such cases, it may work best if a clinical patient exam is copied to a test patient order on the acquisition unit and sent to the post-processing system for testing. If automated dataflow management is used for post-processing, it should also be used during testing to fully validate realistic clinical interoperability.

2. Confirm that the post-processing system can locate and obtain the test image set and associated data.

3. Perform the desired post-processing functions.

4. Validate appearance, labeling, and quantitative measurement values as described in other tests.

5. Perform common functions, such as window-level, flip/rotate, cross-referencing, image fusion, subtraction, etc. as applicable.

6. Confirm that the post-processing system both generates and is able to store expected results. The results of a post-processing system often are derived DICOM images or DICOM Structured Reports (e.g., measurements) that must be further displayed or processed on downstream systems.

7. Confirm that downstream systems, such as additional post-processing or reporting systems, can access and utilize the generated data.

8. If an automated workflow is in play, confirm that the subsequent steps were triggered.

5.13.3 Potential Pitfalls and Troubleshooting

1. Post-processing systems often have specific requirements for data being fed into them in order to function properly. Examples of these requirements may include the presence of certain DICOM attributes that the post-processing systems utilize as processing parameters. If a post-processing step is failing, the tester might check that needed DICOM attributes were correctly included by upstream or acquisition systems. Examples of such Attributes include such things as exam description, dimensionality, units, spacing, and acquisition parameters.

2. Post-processing systems may also be dependent on receiving a certain type or quality level of data, and may fail if the upstream or acquisition data quality is not sufficient. For example, a non-clinical phantom image may not be recognized by a CAD system, with the result that the post-processing system does not generate the expected output data.

3. In some cases, post-processing systems are part of a network of interconnected systems, with each post-processing system performing a function necessary to obtain an overall result. When one system in the chain is not performing correctly, the cause often can be traced to some other system in the processing network that has failed to perform a needed function. Sometimes the cause could be that the processing network or chain is not configured correctly, and needed precursor steps have been skipped. A review of how data is being routed may help diagnose the problem.

4. For dataflows that utilize redundant, load-balanced resources, source images may be received from multiple senders. If not designed to anticipate this scenario, software may improperly handle an exam by writing over or ignoring data within the same exam if received from different senders.

5.14 Downtime Procedures

5.14.1 Rationale

For situations in which full device interoperability is reduced due to scheduled or unscheduled loss of connectivity to an essential component of the imaging workflow, the department may have established alternative procedures for continuing operations until full interoperability is restored. Emergency preparedness plans for situations, including IT outages, are not only wise, but also are required by the Joint Commission for accreditation (JC 2018). It is important to validate that equipment is capable of accommodating a site's emergency procedures.

5.14.2 Testing Procedure

Emergency operations with limited interoperability fall into two general categories: loss of PACS connection or loss of RIS connection. The ability of the imaging modality to operate under emergency procedures for each of these scenarios and to revert back to normal operation should be validated.

1. For loss of PACS connection, confirm that images can be sent to a designated alternative destination for viewing and interpretation and that the quality is acceptable. Relevant tests for downstream systems should be conducted on this alternative connection.

2. For loss of RIS/modality worklist connection, confirm that required patient study information can be manually entered at the modality. The hospital emergency procedures may include how certain data, such as an off-line accession number, should be formatted. Confirm that the study can be sent to the desired destination and is available for review and interpretation.

3. Assure that if the modality participates in any image archive or data cleanup after a downtime that expected workflow is achievable.

5.14.3 Potential Pitfalls and Troubleshooting

1. Only one send destination can be configured at a time, and changing the destination may require service-level system access.

2. The PACS may reject or quarantine a study if attributes such as name or medical record number are incorrectly entered at the modality.

6. Conclusion

The relatively straight-forward imaging chain of a film-based environment has given way to a more complex digital environment that stretches beyond the acquisition unit for processing, storage, and display. While the DICOM standard and IHE integration profiles have largely made interoperability possible, the complex and changing nature of electronic imaging still creates challenges for ensuring image fidelity and information accuracy. In order to provide clinical quality assurance for an image acquisition system, the clinical medical physicist must also validate its interoperability with relevant destinations required for its use. The physicist should be aware of the interactions between image acquisition devices and the systems to which they send, the types of issues that might arise, and how to test for many common problems.

This report is aimed at building awareness in the clinical physics community for:

• the need for interoperability testing;

• how to gather the information and help needed for interoperability assessment; and

• the types of interoperability issues that might occur, how to identify them, and, in many cases, how to address them.

The tests and potential pitfalls listed in this report provide a framework by which the most common types of interoperability errors and their possible sources can be identified.

Further depth and detail for interoperability assessment would depend on specific equipment, infrastructure, and utilization. With an understanding of both the technology and utilization, and with this report as a guide, physicists can play a key role as to help design a risk-appropriate test strategy and providing interoperability assurance for the commissioning of new imaging equipment and equipment software.

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