

Integrating the Healthcare Enterprise



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**IHE Radiology
Technical Framework Supplement**

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**Extensions to the
Portable Data for Imaging (PDI)
Integration Profile**

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Trial Implementation Draft

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This is a supplement to the IHE Radiology Technical Framework Rev. 9.0.

25 It is submitted for Trial Implementation as of June 21, 2009. Comments are invited and may be submitted on the IHE forums at <http://forums.rsna.org/forumdisplay.php?f=12> or by email to radiology@ihe.net.

General Information about IHE® may be found at: www.ihe.net.

Information about the IHE Radiology domain may be found at: <http://www.ihe.net/domains/index.cfm>.

30 Information about the structure of IHE Technical Frameworks and Supplements may be found at: <http://www.ihe.net/about/process.cfm> and <http://www.ihe.net/profiles/index.cfm>.

The current version of the IHE Radiology Technical Framework may be found at: http://www.ihe.net/technical_framework/index.cfm.

35 Editor's Note

This supplement describes the changes to the existing technical framework documents and where indicated amends text by addition (**bold underline**) or removal (~~**bold strikethrough**~~), as well as addition of large new sections introduced by editor's instructions to "add new text" or similar, which is not bolded or underlined for readability.

40 "Boxed" instructions like the sample below indicate to the volume editor how to integrate the relevant section(s) into the relevant Technical Framework volume:

<i>Replace Section X.X by the following:</i>
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CONTENTS

45

Editor’s Note 1

Introduction 3

 Profile Abstract 3

 Open Issues and Questions 3

50

 Closed Issues 3

Volume 1 – Integration Profiles 8

Glossary 8

 1.7 Scope Additions for 2008-2009 8

 2.1.13 Portable Data for Imaging (PDI)..... 8

55

 2.4 Transaction Descriptions..... 9

15

 Portable Data for Imaging Integration Profile 10

 15.1 Actors/ Transactions 11

 15.2 Portable Data for Imaging Integration Profile Options 12

 15.3 Portable Data for Imaging Process Flow 14

60

 15.3.1 Use Cases 15

 15.3.2 Process Flow Description 16

 15.4 Media Content 20

 15.4.1 DICOM Content..... 20

 15.4.2 Web Content Option 20

65

 15.4.3 Other Content..... 20

 15.4.4 Media Type (CD, DVD and USB)..... 21

 15.5 Security and Privacy Aspects 21

 15.5.1 Privacy Protection Options 22

Volume 3 - Transactions 25

70

 4.47 Distribute Imaging Information on Media 25

 4.47.1 Scope 25

 4.47.2 Use Case Roles 25

 4.47.3 Referenced Standard 26

 4.67 Media Information Stored 44

75

 4.67.1 Scope 44

 4.67.2 Use Case Roles 44

 4.67.3 Referenced Standards 45

 4.67.4 Interaction Diagram..... 45

Appendix E: DICOM Media Interchange – Critical DICOM Compatibility Tips 50

80

Introduction

85 This supplement adds options to Vol 1 Section 15 Portable Data for Imaging Integration Profile, to broaden from CD media only to include DVD and USB, adds support for lossless and lossy
 compression and encryption, and an application included on the media to decompress and
 90 decrypt the contents to send over the network. It amends Vol 3 Section 4.47 Distribute Imaging Information on Media transaction to define the behavior of these options, and adds a new transaction, Media Information Stored, to support the Portable Media Sender. Vol 3 Appendix E, DICOM Media Interchange – Critical DICOM Compatibility Tips, is updated to be consistent with the new options.

Profile Abstract

<200 words or less describing this profile – goes in Executive Summary document>

Open Issues and Questions

#	Issue/ (Question)
	•

95 Closed Issues

#	Issue/ (Answer)
1	Media profiles using MPEG Transfer Syntaxes are out of scope, since introducing them in a general purpose profile would lead to widespread interoperability problems, and they do not address the primary use case of exchange of images for radiology (as opposed to other use cases, such as for endoscopy).
2	Need to be able to “grandfather” exiting JPEG lossless (XA) and lossy (US) compressed CDs and creators – this precludes requiring JPEG 2000 compression and encryption on the creator side, but the readers still need to support everything and can’t be grandfathered. This is addressed in the description of the Portable Media Creator, which can choose the Transfer Syntax used under the DVD Media Option; this means that an existing XA or US creator or created media will be readable by a receiver supporting the DVD Media Option. The RLE Transfer Syntax used by some US devices is not supported.
3	Multi-component (Part2) and 3D (Part 10) JPEG 2000, theoretically potentially useful for 3D datasets, are not supported, since there are no DICOM media application profiles for either, no DICOM transfer syntaxes for the latter, and no freely available reference implementations.

#	Issue/ (Answer)
4	Compression on CD is supported through the use of the DVD Media Option, since CDs created with that option are readable in DVD drives.
5	There are no known practical issues related to licensing or patents restricting the use of JPEG or JPEG 2000.
6	There are no quality or compatibility issues with existing free or commercial JPEG or JPEG 2000 codecs that are not well described and promulgated, and it is the implementers responsibility to select an appropriate quality codec accordingly.
7	There is no issue with providing web content compressed in a different form than the DICOM content (e.g., JPEG 2000 or lossless JPEG DICOM content versus ordinary 8-bit JPEG web content), since web content has to be pre-windowed from 16 bit content, annotations burned in, etc. anyway.
8	The physical robustness of DVD is sufficient for interchange media, and IHE does not address media suitability for archival.
9	The inherent rewritable nature of most USB memory devices is both a strength and a weakness depending on the application; they are sufficiently useful to include in an IHE profile and it is outside the scope of IHE to describe appropriate procedures for their safe use.
10	Physical labeling of small form (e.g., USB memory) media is problematic, and is specifically addressed in the appropriate option description.
11	There is no need to specify the type of USB Mass Storage Device used, since they are interoperable. The physical interface is confined to the Type A interface supported by most all computers, and the version of USB supported is already defined in DICOM to be 1.1 and 2.0, and no further constraint is required.
12	File system size limits are addressed on a per media basis by use of the appropriate DICOM media and a CP 905 to DICOM to add FAT32 support for USB media (which would otherwise be limited to FAT16, which is impractical).
13	Though high capacity media may pose challenges for viewers and importers related to memory limitations, this is beyond the scope of IHE to specify or solve, even for software with specified requirements such as the Sending Software and Basic Image Reviewer Options.
14	The presence of a viewer on the media (whether conforming to the Basic Image Reviewer Profile or not) cannot likely be mandated (as opposed to being optional) due to potential intellectual property restrictions.
15	The additional DICOMDIR keys required by the DICOM DVD and USB Media Application profiles have been reviewed and are not thought to be problematic for the Portable Media Creator to extract from the images; regardless, IHE cannot weaken the

#	Issue/ (Answer)
	DICOM Media Application Profile Requirements.
16	The need to support encryption in some jurisdictions (e.g., UK NHS), especially for provider-to-provider and organization-to-organization transport, is unavoidable, even though for provider-to-patient interchange it is usually deemed unnecessary. Accordingly a DICOM and Internet standard mechanism that does not require the receiver to have pre-installed software or administrative privileges has been chosen to support this, rather than endorsing or depending on any proprietary mechanism. If desired, National Extensions can be added to mandate what is presently defined as a Named Option.
17	Password-Based Encryption (PBE) is chosen, since it seems more practical and popular than depending on a (non-existent) Public Key Infrastructure (PKI); that said, the mechanism used (Cryptographic Message Syntax and AES for the content encryption) is compatible with the use of public keys and could easily be used that way and the PDI profile extended in the future. Any weakness in the choice of passwords and their exchange can be addressed by local policies and procedures, which are outside the scope of IHE to define.
18	One encryption scheme (AES rather than 3DES) has been chosen, though there is no need to chose a minimum or maximum key length, since this is addressed in DICOM.
19	After discussion with the users (esp. AMA), the presence of reports on the media is thought to be problematic and potentially unsafe; therefore they remain optional. Nor is it practical to once again try to standardize their encoding, though more language about the possibilities has been added. See the Basic Image Review Profile for discussion of the requirement for a viewer to be able to display any report that is present on the media.
20	It is understood that a limitation of the use of Sending Software on media is the need for the user to specify details of the SCP to be sent to, and that SCP has to give permission to receive. Language is introduced to describe this need.
21	A specific Actor (to be included on the media) is added to allow for the definition of a transaction from that Actor to the receiving sites' own Actors.
22	Good practices are described with respect to not including patient's address, telephone number and other sensitive information embedded in images and other instances that are unnecessary for the use case.
23	Web content images have been clarified to indicate that they must be readable (i.e., not tiny icons) and that all relevant frames must be rendered. The "faithful representation" requirement has been emphasized that no content other than a list is insufficient.
24	Avoidance of viewer-related clutter of the root directory has been emphasized.
25	Clarify what happens when JavaScript and CSS fail in the browser.
26	Clarify that a Portable Media Creator shall not perform lossy compression for the

#	Issue/ (Answer)
	purpose of creating the media (i.e., if it did not receive the instances that way).
27	Reorganization of the Actors associated with the PDI profile and transaction required (Image Display, Report Reader and Print Composer Actors) is not addressed in this profile.
28	Lossy compression is prohibited unless that is the form in which the images are received by the Media Creator, to avoid quality loss merely to record stuff on media.
29	Image Display is specifically NOT added as an actor for the Sending Software Option and as the recipient of the Media Instances Stored transaction.
30	We need to determine the correct mapping for ATNA events to the new Media Information Stored transactions to Rad TF Vol 3 “Table 5.1-2 IHE Radiology transactions and resulting ATNA trigger events”
31	<p>Both DVD and USB options specify the mandatory support by recipients of all forms of compression defined in DICOM for these media types (specifically, lossy and lossless JPEG and reversible and irreversible JPEG 2000); this means that Media Importers supporting either of these options shall be capable of decoding all of these compressed transfer syntaxes, whereas Media Creators may chose to use whichever compression mechanism they choose (or none at all). This burden of responsibility on the Media Importer is thought to be appropriate since:</p> <ul style="list-style-type: none"> • codecs for all of these forms are readily available (including free and open source versions), • increasing the number of options in the profile (e.g., to decompressed versus compressed or specific types of compression) would hamper interoperability, • selection of a smaller subset of compression schemes would exclude many existing or proposed applications (e.g., JPEG lossy is in widespread use for echocardiography, JPEG 2000 is widely assumed to be more appropriate for large matrix projection radiography images, etc.) <p>non-application (or modality) specific profiles are thought to be more likely to achieve widespread interoperability</p>
32	Limited restrictions and recommendations for auto-run are provided (currently deprecated for security reasons, yet some users find it useful), and there is some interaction with the BIR Profile, which requires auto-run for the viewer if permitted by site and OS configuration.
33	The supplement is constructed as a set of named options to the exist PDI profile that creators and receivers may or may not support, since each is appropriate to a specific application; requiring support for all of them in a new comprehensive “PDI2” profile would both be excessively burdensome for those implementers and users that did not need them and would also potentially weaken support for the existing PDI “brand”. That

#	Issue/ (Answer)
	said, all users of new media (DVD and USB) are required to support decompression of all schemes on the receiving side, though the creator may elect not to send it. The Sending Software and Privacy Protection Options also are defined as Options, since it is thought to be excessively burdensome to mandate their presence even for new media.
34	The Web Content remains optional for new media, since there are many use-cases in which Web Content is not useful (based on discussion with AMA representatives) or is difficult to generate in an automated manner by an unattended device with quality (e.g., windowing of MR images) or for which definition of a “clinically equivalent” subset is difficult, particularly for very large datasets. This is also thought to be less of an issue with the introduction of the Basic Image Reviewer Option and Profile. Web Content is also mutually exclusive with the Privacy Protection Option.
35	The Sending Software Option describes the presence of executable software with the ability to coerce identifiers, decompress, decrypt and fallback SOP Classes as necessary to send to a network SCP device. All these capabilities are thought to be necessary to maximize the probability that media contents can be accessed “no matter what” on even the most primitive DICOM recipients. The SOP Class fallback strategy is required, as this already been demonstrated to fundamental to the success of CR -> DX and CT/MR -> Enhanced object modality transitions.
36	The use of Icon Image Sequences (pre-computed thumbnails) in the DICOMDIR at Series level or at Image level for multi-frame is recommended (but not required) as a means to potentially improve speed of initial navigation. These are not required, even though it may be hard for a creator to chose an appropriate frame or window center and width for an icon, since the growth in size of the DICOMDIR might be counterproductive with respect to performance in some circumstances.
37	PDI and this supplement are essentially silent on the format of any reports included on the media; this conflicts with DRG expectations – specifically “the DRG specification contains a recommendation that all information on the CD that is clinically relevant for the current clinical condition of the patient should be stored in DICOM format”. The BIR Profile described separately, does require the ability to display any report on the media, regardless of format.
38	There is no defined escrow system for recovering a lost password in an emergency. If one were to be defined, what scheme would be used and what would the scope of the escrow domain (e.g., one enterprise, one region, one country, etc.)? Does this need to be standardized by IHE, or can it be left to the discretion of the implementers and or local deployment?

Volume 1 – Integration Profiles

Glossary

Add the following terms to the Glossary:

100 Terms Specific to this Document

...

DVD: A trademark of the DVD Forum that is not an abbreviation

...

Acronyms and Abbreviations

105 ...

CD: Compact Disk

...

JPEG: Joint Photographic Experts Group

...

110 **PBE: Password-Based Encryption**

PKI: Public Key Infrastructure

USB: Universal Serial Bus

...

1.7 Scope Additions for 2008-2009

115 *Add the following bullet to the end of the bullet list in section 1.7*

- **Added options to the PDI profile to support DVD and USB media, JPEG and JPEG 2000 lossless and lossy compression on CD, DVD and USB, privacy protection using PBE or PKI encryption, and on-media image sending software**

120

Amend the following section:.

2.1.13 Portable Data for Imaging (PDI)

125 The Portable Data for Imaging Integration Profile specifies actors and transactions that allow users to distribute imaging related information on interchange media. The intent of this profile is to provide reliable interchange of evidence objects and diagnostic reports for import, display or print by a receiving actor. ~~A single physical transport means is specified that supports the~~

130 ~~multiple usage scenarios described in this profile.~~ The CD format **with uncompressed content** was chosen ~~as the baseline for supporting the described use cases.~~ **Options for the support of DVD media and USB media, JPEG and JPEG 2000 lossless and lossy compression on CD, DVD and USB, privacy protection using PBE or PKI encryption, and on-media image sending software are also defined.**

Amend the following section:

2.3 Actor Descriptions

135 ...

Portable Media Creator – This actor assembles the content of the media and writes it to the physical medium.

140 **Portable Media Importer** – This actor reads the DICOM information contained on the media, and allows the user to select DICOM instances, reconcile key patient and study attributes, and store these instances. The actor grouped with the Media Importer can then process the instances.

Portable Media Sender – This actor encoded on the Portable Media itself by a Portable Media Creator actor reads the DICOM information contained on the media, allows the user to select DICOM instances, reconcile key patient and study attributes, decompress, decrypt and convert and then store these instances.

145 ...

Amend the following section:

2.4 Transaction Descriptions

150 Transactions are interactions between actors that transfer the required information through standards-based messages. The following are the transactions defined by IHE and referenced throughout the rest of this document.

...

155 **67. Media Information Stored – Portable Media Sender reads, reconciles, decompresses, decrypts, converts and sends imported DICOM Composite Objects to the Image Archive or Report Manager.**

Amend Volume 1 section 15 PDI Profile to add options

15 Portable Data for Imaging Integration Profile

160 The Portable Data for Imaging Integration Profile specifies actors and transactions that provide for the interchange of imaging-related information on interchange media. The intent of this profile is to provide reliable interchange of image data and diagnostic reports for import, display or print by a receiving actor.

This profile addresses identification of the media content's source and the patient (where appropriate), reconciliation of data during import, and the structure of the media contents.

165 The central elements of the profile are:

- Reliable interchange of imaging-related information based on the DICOM standard
- A Web Content Option, ~~that~~ which provides guidelines for including web-viewable content on media.
- 170 • **A Sending Software Option, for including executable code on the media that can decompress, decrypt and transfer over the network any DICOM instances present on the media**
- **Privacy Protection Options using PBE and PKI, for encrypting the content to protect individually identifiable information from viewing by anyone other than the intended recipients**
- 175 • **DVD and USB Media Options**

The Web Content Option addresses the case of media containing both DICOM-encoded objects and objects in XHTML or JPEG derived from these DICOM-encoded objects.

The Privacy Protection Options provide for encryption of all files on the media (DICOM or non-DICOM) that contain individually identifiable information.

180 **15.1 Actors/ Transactions**

Figure 15.1-1 diagrams the actors directly involved in this profile and the transactions between actors.

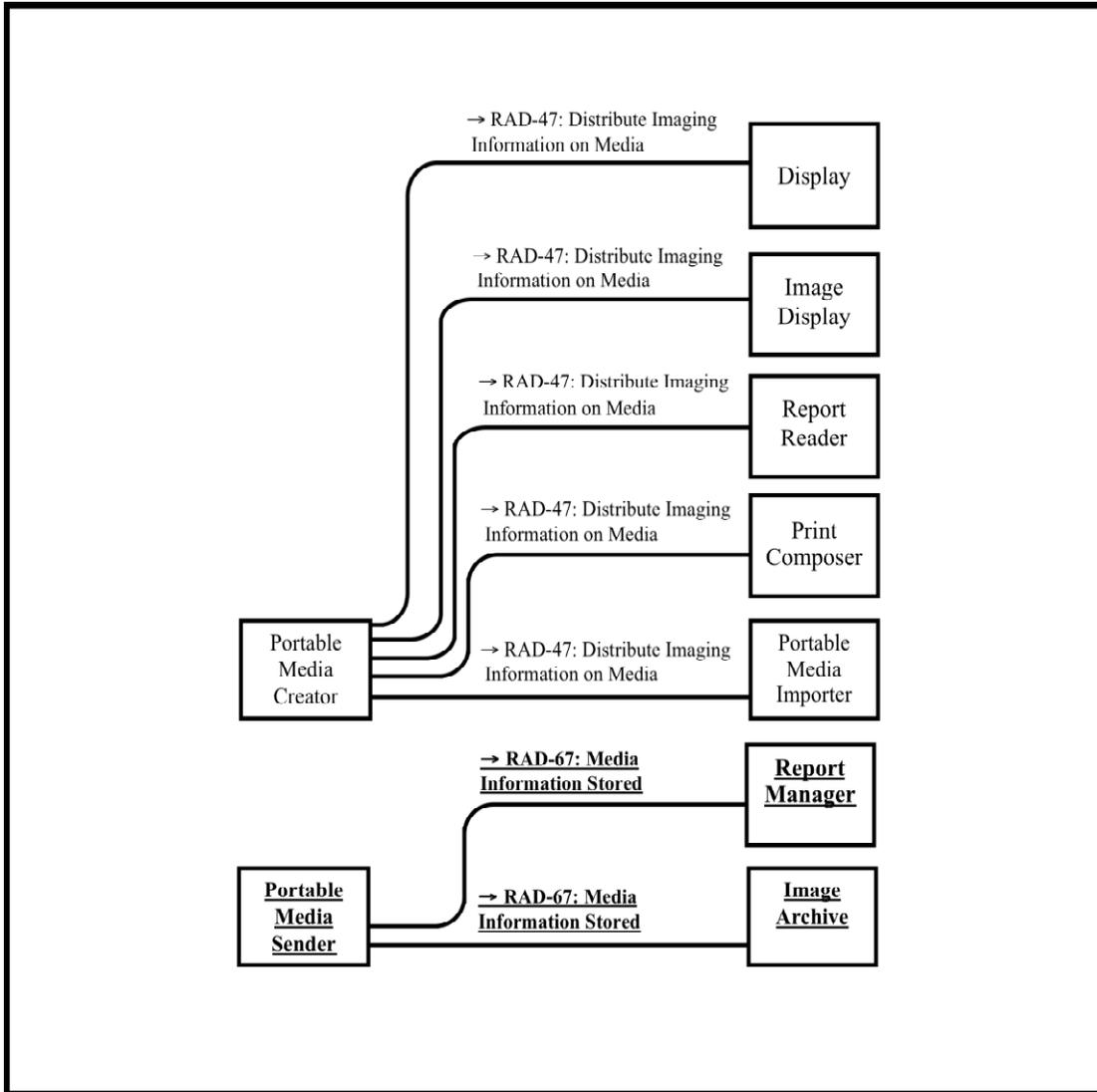


Figure 15.1-1. Portable Data for Imaging Diagram

185

Table 15.1-1 lists the transactions for each actor directly involved in the Portable Data for Imaging Profile. In order to claim support of this Integration Profile, an implementation shall perform the required transactions (labeled “R”). Transactions labeled “O” are optional. A complete list of options defined by this Integration Profile is listed in RAD TF-1: 15.2. Note that

190 one of a number of actors must be grouped with Portable Media Importer as described in RAD TF-1: 2.5.

Table 15.1-1. Portable Data for Imaging Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	Vol. II/III Section
Portable Media Creator	Distribute Imaging Information on Media [RAD-47]	R	4.47
Portable Media Importer	Distribute Imaging Information on Media [RAD-47]	R	4.47
Image Display	Distribute Imaging Information on Media [RAD-47]	R	4.47
Report Reader	Distribute Imaging Information on Media [RAD-47]	R	4.47
Print Composer	Distribute Imaging Information on Media [RAD-47]	R	4.47
Display- (ITI TF)	Distribute Imaging Information on Media [RAD-47]	R	4.47
<u>Portable Media Sender (see Note 1)</u>	<u>Media Information Stored [RAD-67]</u>	<u>R</u>	<u>4.67</u>
<u>Report Manager</u>	<u>Media Information Stored [RAD-67]</u>	<u>R</u>	<u>4.67</u>
<u>Image Archive</u>	<u>Media Information Stored [RAD-67]</u>	<u>R</u>	<u>4.67</u>

195 Notes: 1. The Portable Media Sender actor will never appear in an Integration Statement, since it only exists in the context of the Sending Software Option of the Portable Media Creator.

15.2 Portable Data for Imaging Integration Profile Options

Options that may be selected for this Integration Profile are listed in table 15.2-1 along with the Actors to which they apply. Dependencies between options when applicable are specified in notes.

200

Table 15.2-1: Portable Data for Imaging - Actors and Options

Actor	Options	Vol & Section
Portable Media Creator	<i>Web Content (see note 2)</i>	RAD TF-1: 15.4.2 RAD TF- 23 : 4.47.4.1.2
	<i>DVD Media</i>	<u>RAD TF-1: 15.4.4</u> <u>RAD TF-3: 4.47.4.1.4.1</u>
	<i>USB Media</i>	<u>RAD TF-1: 15.4.4</u> <u>RAD TF-3: 4.47.4.1.4.2</u>
	<i>Privacy Protection</i>	<u>RAD TF-1: 15.5.1</u>

Actor	Options	Vol & Section
	<u>Using PBE</u> <i>(see notes 1 and 2)</i> <u>Privacy Protection</u> <u>Using PKI</u> <i>(see notes 1 and 2)</i> <u>Sending Software</u> <i>(see note 1)</i>	<u>RAD TF-3: 4.47.4.1.2.3.3</u> <u>RAD TF-1: 15.5.1</u> <u>RAD TF-3: 4.47.4.1.2.3.3</u> <u>RAD TF-3: 4.47.4.1.5</u>
Portable Media Importer	<i>No options defined</i> <u>DVD Media</u> <u>USB Media</u> <u>Privacy Protection</u> <u>Using PBE</u> <u>Privacy Protection</u> <u>Using PKI</u>	- <u>RAD TF-1: 15.4.4</u> <u>RAD TF-3: 4.47.4.1.4.1</u> <u>RAD TF-1: 15.4.4</u> <u>RAD TF-3: 4.47.4.1.4.2</u> <u>RAD TF-1: 15.5.1</u> <u>RAD TF-3: 4.47.4.1.3.1</u> <u>RAD TF-1: 15.5.1</u> <u>RAD TF-3: 4.47.4.1.3.1</u>
Image Display	<i>No options defined</i> <u>DVD Media</u> <u>USB Media</u> <u>Privacy Protection</u> <u>Using PBE</u> <u>Privacy Protection</u> <u>Using PKI</u>	- <u>RAD TF-1: 15.4.4</u> <u>RAD TF-3: 4.47.4.1.4.1</u> <u>RAD TF-1: 15.4.4</u> <u>RAD TF-3: 4.47.4.1.4.2</u> <u>RAD TF-1: 15.5.1</u> <u>RAD TF-3: 4.47.4.1.3.1</u> <u>RAD TF-1: 15.5.1</u> <u>RAD TF-3: 4.47.4.1.3.1</u>
Report Reader	<i>No options defined</i> <u>DVD Media</u> <u>USB Media</u> <u>Privacy Protection</u> <u>Using PBE</u> <u>Privacy Protection</u> <u>Using PKI</u>	- <u>RAD TF-1: 15.4.4</u> <u>RAD TF-3: 4.47.4.1.4.1</u> <u>RAD TF-1: 15.4.4</u> <u>RAD TF-3: 4.47.4.1.4.2</u> <u>RAD TF-1: 15.5.1</u> <u>RAD TF-3: 4.47.4.1.3.1</u> <u>RAD TF-1: 15.5.1</u> <u>RAD TF-3: 4.47.4.1.3.1</u>
Print Composer	<i>No options defined</i> <u>DVD Media</u>	- <u>RAD TF-1: 15.4.4</u>

Actor	Options	Vol & Section
	<u>USB Media</u>	<u>RAD TF-3: 4.47.4.1.4.1</u> <u>RAD TF-1: 15.4.4</u> <u>RAD TF-3: 4.47.4.1.4.2</u>
	<u>Privacy Protection Using PBE</u>	<u>RAD TF-1: 15.5.1</u> <u>RAD TF-3: 4.47.4.1.3.1</u>
	<u>Privacy Protection Using PKI</u>	<u>RAD TF-1: 15.5.1</u> <u>RAD TF-3: 4.47.4.1.3.1</u>
Display (ITI TF)	<i>No options defined</i>	-
<u>Portable Media Sender</u>	<i>No options defined (see note 1)</i>	-
<u>Image Archive</u>	<u>No options defined</u>	=
<u>Report Manager</u>	<u>No options defined</u>	=

Note 1: If the Portable Media Creator makes use of one of the Privacy Protection Options then the Portable Media Creator shall also support and make use of the decryption capability of the Sending Software Option, in order to allow a recipient to view and import the media content even if the receiving systems do not support the corresponding Privacy Protection Option.

Note 2: The Privacy Protection Options and the Web Content Option are effectively mutually exclusive, since the Privacy Protection Options require all individually identifiable information on the media, whether DICOM files or not, to be protected (encrypted), which prevents an ordinary Web Browser from reading (decrypting) protected Web Content files. Though Web Content without individually identifiable information could be present, it would likely be unsafe to use clinically if it did not contain embedded information confirming, for example, the identity of the patient.

Note 3: There is no requirement that a viewer be present for the Sending Software Option, nor a requirement that the Portable Media Sender be “grouped with” or implemented in such a viewer.

15.3 Portable Data for Imaging Process Flow

This section describes the typical process flow related to the use of Interchange Media. The transactions covered **is are RAD-47- Distribute Imaging Information on Media and RAD-67 – Media Information Stored.**

The following steps can be identified in this process flow:

- The source actor (Portable Media Creator) writes a group of image dataset(s) and/or the associated diagnostic report(s) onto a piece of interchange media. It is presumed that the Portable Media Creator has access to the data from a grouped actor, or another source outside the scope of IHE.
- The media is physically transported to a destination where the imaging-related information contained on the media will be used.
- The Portable Media Importer reads DICOM objects (images, presentation states, key image notes, evidence documents and reports) on the media and imports them into the local information space. The Portable Media Importer reconciles the data as needed (e.g., to

- 230 change the recorded Patient ID to the local Patient ID). If some classes of DICOM objects are present on the media and cannot be imported, the Portable Media Importer actor notifies the operator of the studies and series affected and makes clear that they are not supported by the importing application.
- The Image Display, Report Reader, Display or Print Composer reads the objects it supports and renders them depending on the receiver's needs. If some objects are not supported by the reading application it notifies the operator that those objects are not supported.
 - 235 • **Optionally, the Portable Media Sender encoded on the media by the Portable Media Creator transfers the objects on the media to an Image Archive and/or Report Manager, reconciling key patient and study attributes, decompressing, decrypting and converting the instances as necessary.**

The potential usage scenarios of the data are described in the use cases below.

240 15.3.1 Use Cases

This profile is not intended to provide an archival solution. **The matter of whether or not CD, DVD or USB media are suitably robust for long-term archive is not addressed by IHE.**

- 245 **Use Case 1 - Patient/Referring Physician Viewing:** Diagnostic and therapeutic imaging data, such as images and reports, is received on media potentially serving multiple use cases. The patient or the referring physician can view the data, either with a viewer application residing on the same media or using a web browser. ~~This data is not necessarily intended as a basis for diagnostic or therapeutic processes, and may just be informative data.~~ For security and privacy reasons, media given to a patient would not contain data of other patients. **The use of privacy protection (encryption) may increase the risk that the data may not be readable by the recipient, unless Sending Software is also provided.** Refer to section 15.5 for additional security considerations.
- 250

Use Case 2 - Healthcare Enterprise Interchange: One or more patients' data, such as images, reports or complete studies, is received on media to enable a diagnostic or therapeutic care process. Media data are imported at a different site, generally for the purpose of a "second read import" or "reference import".

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- Second Read Import: Media data is imported to the Image Manager/Archive to be read/over read. In order to avoid data conflicts, key patient/study attributes may need to be reconciled with existing local data. Images and related presentation states can be sent to a Print Composer to be printed.
- 260 • Reference Import: Media data is imported to the Image Manager/Archive and/or Report Repository to become part of the patient history. It may be used as "relevant prior" data for future reads. In order to avoid data conflicts, key patient/study attributes may need to be reconciled with existing local data.

265 **Interchange of patient data between enterprises may be subject to local, regional or national requirements for privacy protection (encryption).**

270 **Use Case 3 - Operating Room Viewing:** Media data is used to enable diagnostic or therapeutic processes in environments without a reliable network connection. The volume of data can be very large and may contain image data, post-processing results and reports. In the operating room, the surgical staff receives the media and reads its contents using advanced viewing capabilities, which may include manipulating or processing images.

15.3.2 Process Flow Description

The use cases can be specified in terms of three media-related activities:

- Media Export
- Media Viewing
- 275 • Media Import

A) Media Export (All Use Cases):

The Portable Media Creator assembles the media content (DICOM and web-viewable content) and writes it to the physical medium.

The following sequence of activities will be performed during media creation:

- 280 • Export of DICOM data (FSC activity)
- Optionally, export of web-viewable data, which involves deriving easily accessible informative data from the DICOM data (Web Content Option).
- **Optionally, inclusion of a software component to transfer the DICOM data over the network (Portable Media Sender actor of the Sending Software Option)**
- 285 • **Optionally, encryption of the DICOM content (Privacy Protection Options)**
- Optionally, inclusion of additional content (e.g.: a DICOM Viewer or viewing software components on the media to access DICOM data)

B) Media Viewing:

290 **B1) Web (Use Case 1)** (care providers, other users and patients without DICOM viewing equipment or software):

Any web-viewable media content is received and displayed by a Display actor, which exists as a generally available resource (i.e. web browser). Note that the Portable Media Creator cannot rely on the presence of web-viewable content on all media since it will be included only on media created using the Web Content Option}.

295 **B2) DICOM (Use Case 1 and 3)** (users with DICOM viewing equipment or software):

300 The DICOM portion of the media content is displayed using specialized applications pre-existing in the reading environment or included on the media itself. The variety of DICOM objects that an Image Display and/or Report Reader actor can process is indicated by its support of the corresponding content profiles. The Print Composer actor sends images from the media to a Print Server for printing.

C) Media Import (Use Case 2):

305 The “Media Import” activity **is may be** accomplished by a Portable Media Importer and deals exclusively with the DICOM portion of the media content. The Portable Media Importer actor is grouped with one or more content actors (Evidence Creator, Report Creator, etc.), depending on the type of media content to be imported. The grouped actor provides storage capability for the media data accessed by the Portable Media Importer.

310 **The “Media Import” activity may be accomplished by a Portable Media Sender actor encoded on the media by the Portable Media Creator. The Portable Media Sender is not required to be grouped with any other actor, since it is a separate executable on the media. A transaction (RAD-67 Media Information Stored) is defined for sending the media content using the DICOM network protocol to an Image Archive Actor.**

The Portable Media Importer **or Portable Media Sender** actor accesses all DICOM instances referenced by the DICOMDIR file and enables the user to select a media patient dataset to be imported.

315 The Portable Media Importer **or Portable Media Sender** obtains local data that is known to be accurate within the importing institution/enterprise and reconciles “key attributes” of patient and study information (when required). A method for performing these steps is documented in the Import Reconciliation Workflow Profile (see Section 3.21). Refer to RAD TF-3: 4.47.4.1.3. for the list of “key attributes” and the related reconciliation actions to be performed.

320 Note: The Portable Media Importer may for example be grouped with an Evidence Creator to allow the storage of its diagnostic and therapeutic imaging content to an Image Manager/Image Archive, or grouped with a Report Creator to store reports in a Report Repository. This enables use of the content for subsequent “relevant prior” data for future reads. A grouping with an Acquisition Modality actor could also be used to allow subsequent “reads/over reads”. In the case of a Portable Media Importer grouped with the Print Composer actor, the imported content (images and presentation states) can be sent to the Print Server to be printed. **If a Portable Media Sender is present on the media, the diagnostic and therapeutic imaging content can be transferred to an Image Manager/Image Archive without the need for an additional actor at the receiving site, with the appropriate reconciliation of patient and study information performed through the user interface of the Portable Media Sender.**

325

330 Figure 15.3.2-1 shows an example flow of events covering the use cases described in the previous sections. **Figure 15.3.2-2 shows the additional process flow involved in using the Portable Media Sender.**

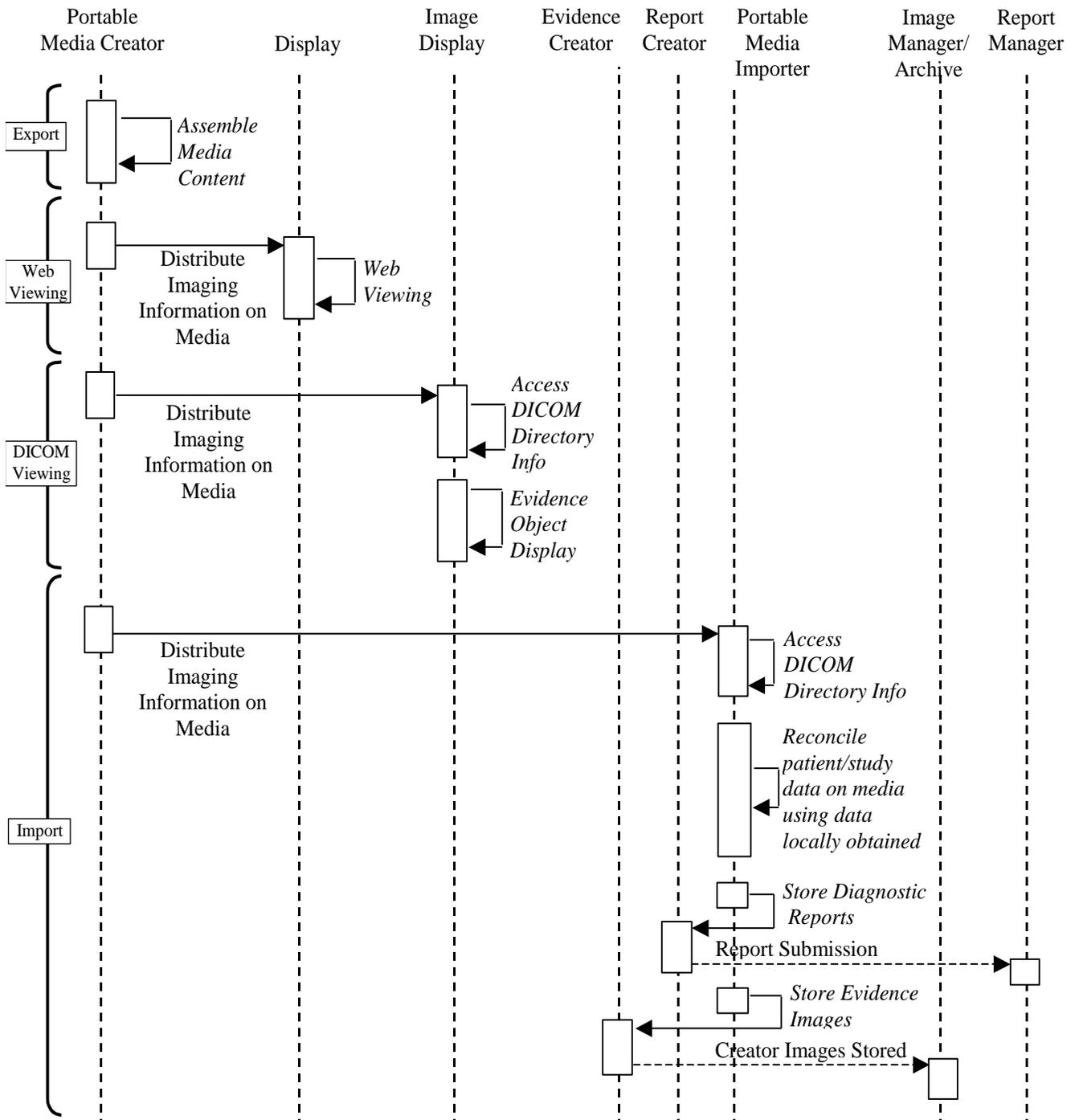


Figure 15.3.2-1. Portable Data for Imaging Process Flow

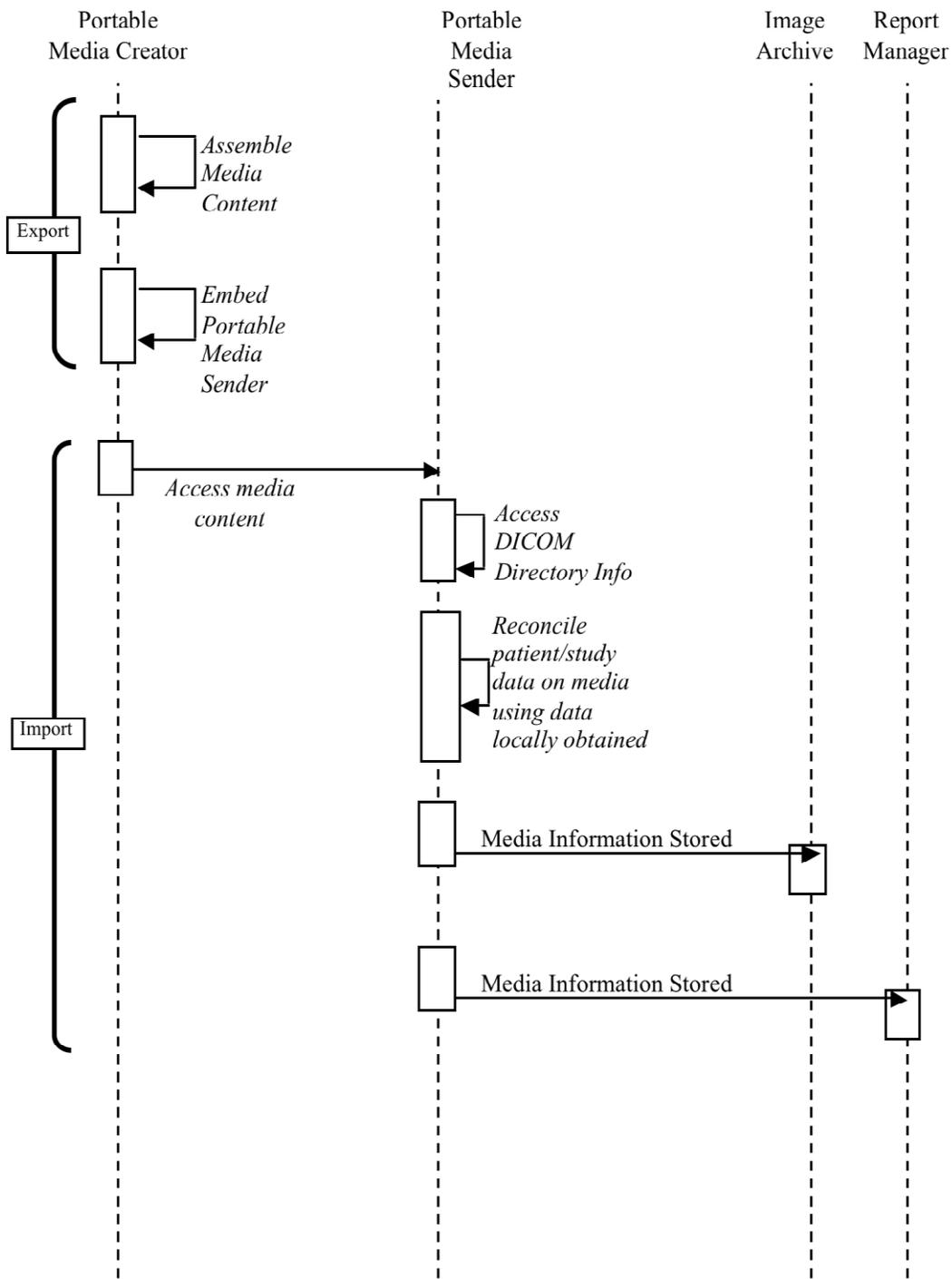


Figure 15.3.2-2. Portable Media Sender Process Flow

15.4 Media Content

340 The requirements on media content are intended to promote the reliable transfer of imaging data, including diagnostic reports, and to allow for the viewing of images and reports on general purpose computers.

The intent is that the media content be a “complete set of images of diagnostic quality” (a quote from a statement on the matter by the American Medical Association Expert Panel on Medical Imaging).

345 The media content can be accessed via two "entry points" on the media: the DICOMDIR file for DICOM imaging information and optionally the INDEX.HTM file for web-viewable content. Created media are required to contain DICOM data and may optionally include web-viewable data derived from it. This web-viewable data, if present, shall faithfully preserve the clinical intent of the original DICOM information.

350 15.4.1 DICOM Content

The DICOM data shall be created by using the DICOM ~~General Purpose~~ Media Storage Application Profile **appropriate for the content as defined in the Distribute Imaging Information on Media transaction and depending on the options supported by the Portable Media Creator.** The DICOMDIR file shall reference all DICOM files stored on the media.

355 DICOM files shall not be placed in the root directory, but no constraints are placed on the name of directory that contains them.

15.4.2 Web Content Option

Portable Media Creators implementing the Web Content Option may also include web-viewable data on the media.

360 The web-viewable data shall be derived from the DICOM information as XHTML files and referenced JPEG images. The XHTML entry page (INDEX.HTM) shall allow access to all of this data. This enables end-users to access relevant media content using a generally available web browser. The INDEX.HTM file shall be placed in the root directory.

365 Note that the web-viewable data specified in this integration profile reflects the full set of the exported DICOM data or a subset considered at the time of creation to faithfully represent the patient's clinical condition. For example, if a DICOM Structured Report references only Key Images and a larger DICOM dataset, the web-viewable data derived from it may selectively include the report in XHTML format and only JPEG images derived from the DICOM Key Images.

370 15.4.3 Other Content

Viewing applications (for example a DICOM Media Viewer) may optionally be included on the media. Such viewers may have launch links included in the HTML. Including such viewers on

the media is discouraged due to security issues discussed in the ~~next s~~Section **15.5**, as well as potential interoperability problems.

375 Additional data (e.g., a diagnostic report in non-DICOM format) may be also included on the media. Since the format of any such data is not specified by this profile, such data shall be placed in a separate directory on the media. If such data is referenced in the INDEX.HTM file, it shall be clearly indicated that this content was not generated in conformance with the IHE Radiology Technical Framework, and its reliable import has not been addressed.

380 **15.4.4 Media Type (CD, DVD and USB)**

The baseline media type is CD using the DICOM STD-GEN-CD Media Storage Application Profile.

385 **Named options for support of DVD and USB media are defined. Claiming either of these options requires support for compressed images (using JPEG lossy and lossless and JPEG 2000 reversible and irreversible).**

Compressed images on CD, such as are commonly used for cardiac angiography and for cine ultrasound, are supported through the use of the DVD Media option, which allows for CD as a media type that can be read by DVD drives.

15.5 Security and Privacy Aspects

390 Portable Media Creator actors shall **make a reasonable effort to** ensure that no malicious software (viruses, etc.) is present on created media.

The automatic launch of applications from media poses a risk that malicious software could be started and it is recommended that media reading actors not allow automatic launching. Portable Media Creators should therefore also avoid using automatic launching. This includes not
395 automatically launching a DICOM media viewer that may be present on the media.

Furthermore, if a DICOM media viewer is present, security issues **at the receiving actor** are minimized by:

- working under normal (restricted) user privileges and not requiring the user to work with administrator or root privileges and
- not needing software installed on the computer where the media is used.

Audit trails to track export/import/viewing activities are addressed in ITI TF-2: 3.20 and RAD TF-3: 5.1. Portable Media Creator and media reading actors that claim support of the Audit Trail and Node Authentication Integration Profile shall generate such audit trail entries. **Viewers and sending software executed from on board the media are not required to generate such audit trail entries, since they are not integrated into the local systems and may have no reliable means of authenticating the user or device; they are not precluded from participating in the ATNA profile, however.**

405

410 Encryption of data and other access controls to media content are not addressed in this profile **unless one of the Privacy Protection Options is used**. Media created using this profile **without a Privacy Protection Option** should be considered to be unlocked information (e.g., like paper records). Such media should be handled according to appropriate site policies (e.g., do not give a patient a disk containing data from other patients, do not leave disks where they can be taken by unauthorized persons, etc.).

415 For many Use Cases it is not appropriate to place data from **multiple multiple** patients on a single **volume of** media for **sSecurity and pPrivacy rReasons**. **The creation of multiple patients on single media for bulk transfer is not precluded, however, though in such cases encryption is likely to be required by local, regional or national authorities.**

420 **It is not good practice to include on media, either in the physical label, in the DICOMDIR or DICOM instances, the Web Content or any other content, such sensitive information as the patient's address or telephone number, which might be used for unauthorized purposes such as identity theft or fraud. Though it is not a requirement of this profile for the Portable Media Creator to remove any such information from any DICOM instances received prior to encoding on media, it is strongly recommended.**

15.5.1 Privacy Protection Options

425 **Portable Media Creators implementing one of the Privacy Protection Options shall be capable of encrypting the media content. When one of these options is used, the Portable Media Creator shall encrypt all of the DICOM files on the media, including the DICOMDIR, in addition to any other non-DICOM files that may contain individually identifiable information.**

430 **Notes: 1. The use of the Privacy Protection Options, like any method to protect the content of information in transit using encryption, creates the risk that a recipient will be unable to read the media despite a legitimate right of and need for access. There is no provision for an emergency ("break-glass") means of access. Accordingly, the use of encryption should be weighed against patient safety concerns, as well as alternatives, such as physical protection of the media in transit. The use of the Sending Software Option can be used to mitigate this risk.**

435 **2. Despite the risk to patient safety of the use of encryption, if encryption is required, a standard mechanism, such as a Privacy Protection Option, is always superior to a proprietary non-standard alternative, since it increases the probability that the recipient will be able to decrypt the media.**

Two Privacy Protection Options are defined:

- 440
- **Privacy Protection Using PBE, in which the encryption uses standard password-based encryption (PBE), which allows for the media to be sent to and viewed or imported by any receiving Actor that supports the Privacy Protection Using PBE Option and which is supplied with the password used by the Portable Media Creator to encrypt the media for the intended recipient**
- 445
- **Privacy Protection Using PKI, in which the encryption uses standard RSA Public Key Infrastructure (PKI), which allows for the media to be sent to and viewed or imported by any receiving Actor that supports the Privacy Protection Using PKI**

Option and which has access to the private key corresponding to the public key used to encrypt the media for the intended recipient

450 **A Portable Media Creator that supports one of the Privacy Protection Options shall also support the decryption capability (only) of the Sending Software Option (see RAD TF-3: 4.47.4.1.5 and RAD TF-3: 4.67.4.1.2.4). This allows a recipient to import the media content even if the receiving system does not support the corresponding Privacy Protection Option. It does not require that support for the Sending Software Option be claimed explicitly.**

455 **Though the content encryption scheme specified for use (AES) is regarded as robust, and the encryption key length chosen can be of high grade, the privacy protection provided is compromised if weak passwords are chosen or if the password is not sent separately from the encrypted media. The security policies and procedures for password choice and password communication are outside the scope of IHE to define.**

460 **The Privacy Protection Options do not provide a standardized mechanism for the recovery of a lost or missing password necessary to access the information in, for example, an emergency situation. That said, the provision of (unencrypted) contact information for a site from which the password could be recovered is recommended (for example, in the README.TXT file, even if the Web Content Option is not supported). The use of some**
465 **non-standard mechanism for recovering the password is not precluded by this Option.**

The mechanisms for generating and certifying RSA private/public key pairs for decryption, distributing certified public keys for encryption, and verifying that a public key is adequately certified and has not been revoked before use, is beyond the scope of IHE to define.

470 **The Privacy Protection Options may be used with both write-once and rewritable media. The IHE PDI profile does not distinguish a separate Media Updater actor, and does not require the Media Creator to be able to update media with existing content. However, if media is updated, the Media Creator shall ensure that all added files can be decrypted using the same key(s) as the pre-existing files, and that files that index the content of the**
475 **media, such as the DICOMDIR file, are replaced with encrypted files documenting the pre-existing and additional content.**

In addition to protecting the required image-related content on the media, the same per-file encryption mechanism and keys may be used to protect other content, such as other files that constitute a patient's longitudinal record stored or interchanged on the media.

480 **The Media Creator supporting the Privacy Protection Using PBE Option shall permit the user to generate passwords that are not restricted in length and that are different for different media volumes.**

The use of the Privacy Protection Using PKI Option presupposes that

- **the intended recipients are known at the time of media creation,**
 - **the Media Creator has a source of encryption keys for specific recipients, and**
- 485

- **that the receiving Actor of a particular recipient has access to the necessary decryption keys, either via local access (e.g., on physical token) or via some enterprise provided network solution.**

490

Volume 3 - Transactions

Amend Section 4.47:

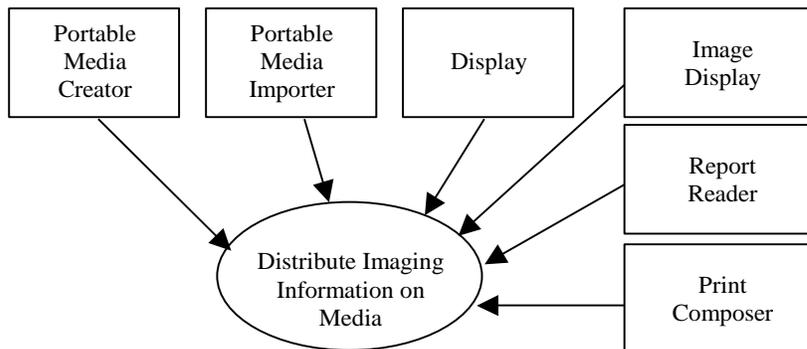
4.47 Distribute Imaging Information on Media

This section corresponds to Transaction RAD-47 of the IHE Technical Framework. Transaction RAD-47 is used by the Portable Media Creator and by media reading actors (Portable Media Importer, Image Display, Report Reader, Display and Print Composer).

4.47.1 Scope

In the Distribute Imaging Information on Media transaction the Portable Media Creator sends information to media reading actors by means of Interchange Media where it stores the information.

500 4.47.2 Use Case Roles



Actor: Portable Media Creator

Role: Assemble the media content and store it on the media to be distributed.

505 **Actor:** Portable Media Importer

Role: Read the DICOM content of distributed media in order to access information stored in the DICOMDIR file and its referenced instances (DICOM FSR) and perform import of media data.

Actor: Image Display

510 **Role:** Read the DICOM content of distributed media in order to access information stored in the DICOMDIR file (DICOM FSR) and display its referenced evidence objects.

Actor: Report Reader

Role: Read the DICOM content of distributed media in order to access information stored in the *DICOMDIR* file (DICOM FSR) and read its referenced diagnostic reports.

Actor: Print Composer

515 **Role:** Read the DICOM content of distributed media in order to access information stored in the *DICOMDIR* file (DICOM FSR) and send print data (images) to the Print Server.

Actor: Display-~~(from ITI TF)~~

Role: Read the web-viewable content of distributed media in order to access information stored in the *INDEX.HTM* file and display its referenced data (XHTML files and JPEG images).

520 **4.47.3 Referenced Standard**

DICOM 2008 PS 3.10: Media Storage and File Format for Data Interchange

DICOM 2008 PS 3.11: Media Storage Application Profiles

DICOM 2008 PS 3.12: Media Formats and Physical Media for Data Interchange

DICOM 2008 PS 3.15: Security and System Management Profiles + DICOM CP 895

525 **~~DICOM Supplement 80 (final text): DVD Media Application Profiles~~**

RFC 3211 Password-based Encryption for CMS, December 2001

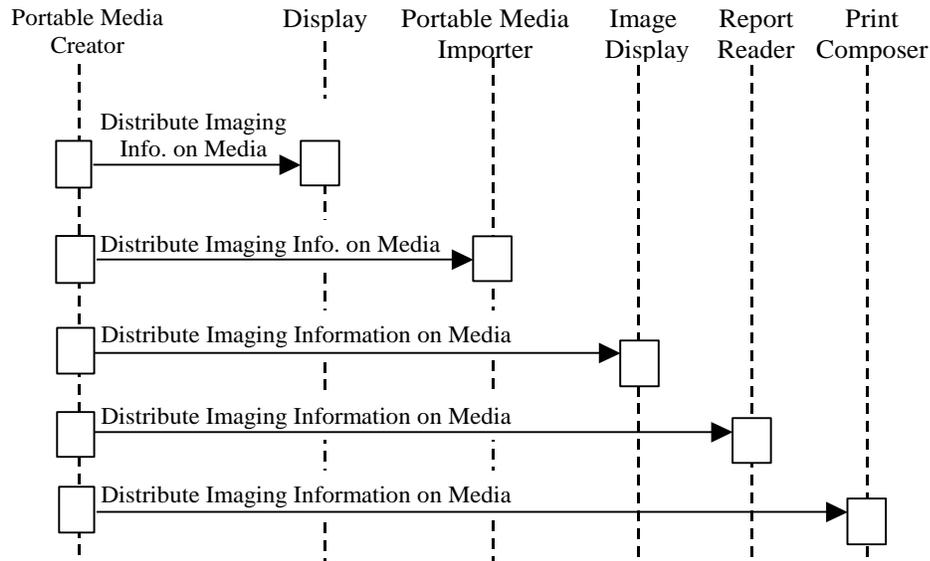
RFC 3852 Cryptographic Message Syntax, July 2004

XHTML™ 1.0 The Extensible HyperText Markup Language (Second Edition). A Reformulation of HTML 4 in XML 1.0. W3C Recommendation 26 January 2000, revised 1 August 2002.

530 <http://www.w3.org/TR/xhtml1>.

XHTML™ Basic. W3C Recommendation 19 December 2000. <http://www.w3.org/TR/xhtml-basic>.

4.47.4 Interaction Diagram



535

4.47.4.1 Distribute Imaging Information on Media

This transaction consists of the interchange of information on media by way of the physical transport of the created media from the Portable Media Creator to a media-reading actor.

4.47.4.1.1 Trigger Events

540 The user at the Portable Media Creator wishes to transport information by the creation and transport of interchange media. The Portable Media Creator assembles the Interchange Media content and stores it on the media.

4.47.4.1.2 Message Semantics

545 The message semantics of this transaction are described in terms of content specifications for the media.

The Portable Media Creator shall be able to include all DICOM objects supported by the IHE actors with which it is grouped. If not grouped with any IHE actors, it shall be able to include all DICOM Storage objects listed in its DICOM Conformance Statement.

4.47.4.1.2.1 Media Filesystem and File Naming Restrictions

550 Since the DICOM content on the media is required to conform to the DICOM standard, some of the requirements specified in PS 3.10, 3.11 and 3.12 are reiterated here for emphasis:

- Strict ISO 9660 Level 1 compliance **with respect to file naming**

- No packet writing
- File and folder names referenced by the *DICOMDIR* file restricted to 8 characters, uppercase letters, digits and underscore only, with no extension

555

Specifically, it is not permitted to name DICOM files based on their SOP Instance UID, since that would exceed the 8 character limit and use the illegal period character, and it is not permitted to add a “.dcm” extension or similar. Filenames should not be in lower case, nor have lower case equivalent file names encoded as Joliet or Rockridge extensions to the ISO 9660 filesystem.

560

Refer to Appendix E ~~of this supplement~~ for a reference to common implementation misinterpretations and/or errors that are detrimental to interoperability.

Non-DICOM data is restricted to ISO 9660 Level 1 compliance **for media encoded with ISO 9660 rather than UDF or FAT file systems**, but without the restrictions on file extensions and characters imposed by DICOM; i.e. a 3 character extension is permitted.

565

When the Portable Media Creator supports one of the Privacy Protection Options, file names for the encrypted files shall be the same as they would have been without encryption. E.g., the secure (encrypted) DICOMDIR file is still named DICOMDIR, with no file name extension to indicate that it is encrypted. This is a requirement of DICOM PS 3.10. Also, the file and folder names for the encrypted files shall be named in such a way as to not expose protected information (e.g., the patient’s name shall not be used as a folder name).

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4.47.4.1.2.2 Content Organization Overview

The following diagram illustrates the content organization principles (see Appendix F for examples):

575

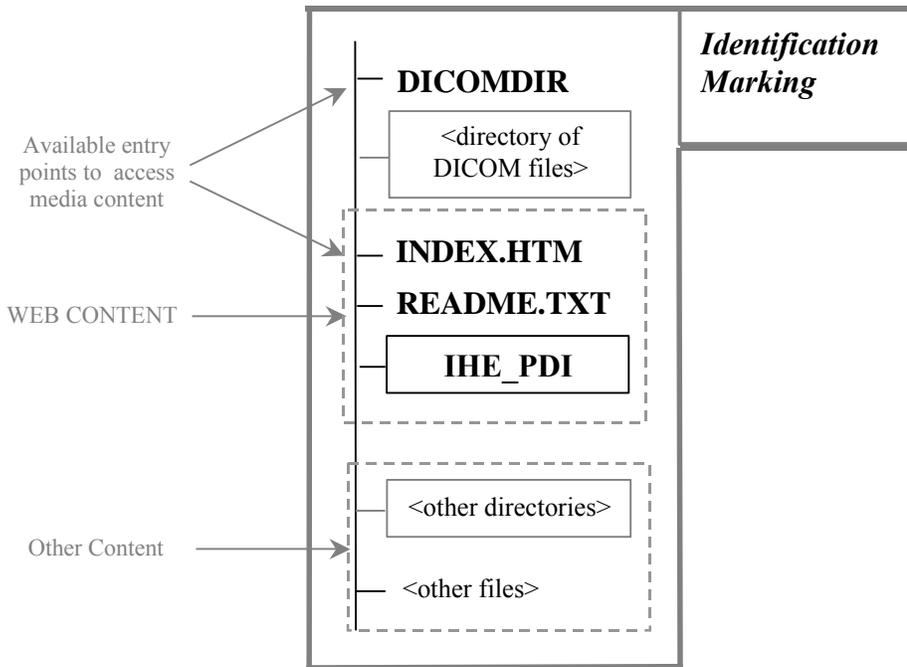


Figure 4.47.4.1.2.2-1. Media Content Organization

Description of the content to be contained in the media file system:

580 **4.47.4.1.2.2.1 DICOM Content**

The *DICOMDIR* file shall be located in the root directory and shall reference all DICOM instances contained in the media.

585 The DICOM instance files shall not be in the root directory or in the IHE_PDI sub-directory, instead they shall reside in a sub-directory whose name is not otherwise constrained. No other DICOM instance files shall be placed on the media.

It is recommended, though not required, to include the README.TXT file described below, even if the Web Content Option is not supported.

4.47.4.1.2.2.2 Web Content Option

590 Portable Media Creators implementing the Web Content option shall meet the following requirements:

- *INDEX.HTM* file located in the root directory, which shall portray the exact content of the interchange media. The file shall present:
 - An informative header containing:
 - Identification of the institution that created the interchange media
 - ~~Optionally, a disclaimer statement about privacy/security from the institution that created the interchange media~~
- 595

- **optionally, a link to an Internet-accessible site where, with the appropriate authentication and access control, a user may view the most recent version(s) of the report(s) about the media content, since any report content on the media may have been amended**

600

a link to an entry point for accessing the web content of the *IHE_PDI* directory

- a link to the *README.TXT* file
- a link to additional non-constrained data (if it exists) - See 4.47.4.1.2.2.3
- a manifest which lists the data that can be imported by a Portable Media Importer Actor. (i.e., all DICOM content on the media)
- a manifest which lists any patient-related data contained on the CD that cannot be imported (i.e., additional non-constrained content that doesn't have an importable DICOM equivalent on the media).
- a link to a launch point for a DICOM viewer, if present on the interchange media
- **a link to a launch point for a Portable Media Sender, if present on the interchange media**

605

610

Note: The file INDEX.HTM is required to present the content defined above to the user. This does not imply that the information must necessarily be contained in INDEX.HTM. Instead, INDEX.HTM might also open a frame set consisting of additional XHTML files that in total contains the information specified above.

615

- *README.TXT* file located in the root directory, that shall contain:
 - Contact information regarding the Institution that created the media.
 - Information regarding the Application that created the media.
 - Name of the product application and software version
 - Contact information of the vendor of the application that created the media
 - General information about the overall organization of the interchange media. This is not intended to be specific to the content stored on this instance of interchange media, which if necessary should be placed in the *INDEX.HTM* file.
 - Information regarding the Media Viewer **and/or Portable Media Sender** application (if **such applications are a Media Viewer** is contained)
 - Operating system(s) supported
 - Name of the product application and software version
 - Contact information of vendor that provided the **Media Viewer** application
 - ~~Disclaimer statement about the intended usage of the application~~
 - List of minimum requirements
 - Additional information regarding the usage of the application

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625

630

635 Note that generally the README.TXT file is independent of the clinical content of the media, i.e. the same README.TXT may be included on all media created by that application at that institution.

It is recommended that information is included in the README.TXT file about web browsers (including version number) that are known to be capable of displaying the web content as intended.

- 640
- ***IHE_PDI*** directory located in the root directory of the interchange media which shall contain:
 - Web-viewable objects in XHTML, JPEG, PNG and/or GIF derived from the DICOM encoded objects or used for web page navigation (**see 4.47.4.1.2.3.2**).
 - The web content shall faithfully represent the patient's clinical condition.
 - It is not allowed to place any other data in the *IHE_PDI* directory.
 - It is allowed to have sub-directories within the *IHE_PDI* directory
- 645

Note that these are IHE requirements (not DICOM requirements) that are intended to facilitate the overall organization of the media and make easier the access to the *INDEX.HTM* file, especially for non-expert users like patients and referring physicians.

650 Note: There is a recognized need for cine/video data, however a standardized method (format) has not yet been identified for endorsement by IHE and inclusion in this transaction.

4.47.4.1.2.2.3 Optional Content

It is permitted to place other data on the media outside the *IHE_PDI* directory. Any additional content shall take into account all constraints listed above especially:

- 655
- No DICOM instance files are allowed.
 - This data shall be described or referenced as defined in 4.47.4.1.2.2.2.

Furthermore any additional directory in the root directory **not specified by other IHE profiles (such as XDM)** cannot begin with “IHE”, **and those folders shall not be used by PDI.**

660 Additional files (files other than mandatory files) in the root directory are not expressly prohibited however their inclusion is discouraged. **Any viewing application or Portable Media Sender software on the media shall have the minimum number of files and launch file in the root directory and any supporting files shall be contained in a minimum number of sub-directories in the root directory.**

665 Note that it cannot be assumed that any automatically launching application will run on the receiving device.

4.47.4.1.2.2.3.1 DICOM Media Viewer

If a DICOM media viewer is present on the media, it is recommended that:

- 670 • the media viewer be capable of correctly rendering all DICOM objects stored on the medium.
- is recommended that a user manual in PDF format be included on the medium, in the root directory.
- a short manual in hardcopy be provided within the CD jewel case.
- 675 • if the viewing software is not capable of executing properly (e.g., wrong OS version, insufficient memory, insufficient display resolution), the software should terminate with an error message explaining the problem in human understandable form (e.g., not “exception 0xf800” or “sys12345.dll is missing”) and without negatively affecting other programs or the operating system (i.e. the software should not crash the machine)

4.47.4.1.2.2.4 Media Identification

680 The Portable Media Creator actor shall support a user in adding human-readable identification information on the outside of the physical medium. The method of media marking is outside the scope of this integration profile.

It is recommended that the **following be marked on the medium:**

- Patient Name
- Patient ID
- 685 • birthdate
- media creation date
- the study dates for the studies on the medium and
- the name of the originating institution ~~be marked on the medium. It is also recommended that the type of content (“DICOM ONLY” or “DICOM IHEPLUS WEB”) be marked on the medium.~~

690

If the Media Creator prints a label on, or to be applied to, the physical media, then the label shall include information about the type of content and which options are used by the Portable Media Creator:

- **The type of content (“DICOM ONLY” or “DICOM PLUS WEB”)**
- 695 • **When the Portable Media Creator supports one of the Privacy Protection Options and it is used, it shall be configurable to support local policy that dictates whether or not it is appropriate to label the media with the Patient’s identity. Note that the goal of the Privacy Protection Options is to protect the content, not the fact that content belongs to a particular patient, and if the media is not labeled appropriately, it may be unusable or unsafe. The password shall NOT be included on the label.**
- 700 • **If the DVD Option is used by the Portable Media Creator**
 - **if the physical media is not a CD, then the label shall include an indication that a DVD drive is required to read the media.**

- **if compression is used, then the label shall include an indication of which compressed Transfer Syntax (e.g., JPEG or JPEG 2000) was used.**

705

For example, a typical label might include:

- **St. Elsewhere's Radiology**
- **John Smith #54672354 1973/04/02**
- **CT Brain 2009/05/13**
- **Recorded 2009/05/14**
- **IHE PDI DICOM WEB DVD J2K BIR**

710

For media that is physically small (e.g., a USB memory stick that is not packaged in a larger form, such as credit card size), it may be difficult to fit the required and recommended information, in which case only the required information should be used.

715

The labeling requirements and recommendations apply to the physical media itself and any directly applied label; it is not sufficient merely to label the package in which the media is transported, since the media may become separated from the package.

4.47.4.1.2.3 Content Organization Detail

4.47.4.1.2.3.1 DICOM Content

720

The DICOM portion of the media content is defined by the current DICOM standard. It is required that created file-sets be correctly formatted in order to grant maximum interoperability.

All DICOM data shall be referenced by the *DICOMDIR* file.

~~**In order to assure interoperable use of the created media, a “widely-used” general purpose DICOM Media Application Profile is required.**~~ The Portable Media Creator, Portable Media

725

Importer, Image Display, Report Reader and Print Composer shall use the STD-GEN-CD Media Storage Application Profile to interchange DICOM information on interchange media, **unless the DVD or USB Options are specified (see 4.47.4.1.4).**

730

The Portable Media Creator is not required to be able to create media containing data from multiple patients. However, all media reading actors shall be able to import media containing multiple patients' data.

While the Portable Media Creator is not required to correct DICOM SOP instances from a source that incorrectly encodes the DICOM data, it is expected that the DICOM Media Creator will store the DICOM files in Explicit VR Little Endian, **unless the DVD or USB Options are specified (see 4.47.4.1.4).** The DICOMDIR, whose content is entirely the responsibility of the

735

Portable Media Creator, shall be correctly encoded regardless of the correctness of any referenced SOP Instances.

The Portable Media Creator may be requested to include DICOM SOP Instances that do not contain sufficient information to encode mandatory DICOMDIR information. For example, Patient ID and Study ID are Type 2 and may be zero length in image SOP Instances, but are

740 Type 1 in the Patient and Study Directory Records. The complete list of attributes which fall into this category **for the STD-GEN-CD Media Storage Application Profile** are listed in Table 4.47.4-1.

Table 4.47.4-1: Optional or Empty DICOM SOP Instance Attributes required in DICOMDIR

Directory Record Type	Attribute Name	Tag
PATIENT	Patient ID	(0010,0020)
STUDY	Study ID	(0020,0010)
	Study Date	(0008,0020)
	Study Time	(0008,0030)
SERIES	Modality	(0008,0060)
	Series Number	(0020,0011)
IMAGE	Instance Number	(0020,0013)

745

The DVD and USB Options contain additional such Attributes that are optional in the SOP Instance but are required in the DICOMDIR (see 4.47.4.1.4).

750 The Portable Media Creator is required to synthesize appropriate values for all such mandatory attributes. No specific guidance is given as to from whence appropriate values should be obtained or what default values are appropriate, except that different patients, studies, and series must remain distinct (e.g., two different Studies with differing Study Instance UIDs shall not be assigned the same synthesized Study ID). There is no firm requirement that a synthesized Patient ID must be globally unique as it is not a UID. However, it is the only Type 1 attribute for Patient Directory Records and is a key index value for searching. Any synthesized Patient ID values shall be unique, at least in the context of the DICOMDIR on the media being created, so that each corresponding Patient Directory Record will be guaranteed to be unique. Implementors must also be careful to ensure that multiple Patient Directory Records do not link to Study Directory Records with the same Study Instance UID. The requirements for synthesizing new Study ID values are less rigid as Study Directory Records are still guaranteed to have unique Study UID values. The Portable Media Creator is not required to add these synthesized values to the instances to be stored on media.

755

760

4.47.4.1.2.3.1.1 DICOM Instances Content

There are no additional requirements specified here on the Attributes contained within DICOM Instances on the media.

765 If the Portable Media Creator Actor is grouped with an Acquisition Modality (or other) Actor within the Scheduled Workflow Integration Profile, then the attributes may effectively be constrained beyond the normative requirements of the DICOM standard. For example certain attribute values in the Modality Worklist query shall be included.

770 However, since such grouping is not required under this profile, actors receiving created media such as the Portable Media Importer, Image Display, Report Reader and Print Composer may not assume that the DICOM Instance Attributes are constrained beyond the definitions of the IODs in the DICOM Standard.

775 The instances on the Interchange Media generated by a Portable Media Creator shall all be DICOM Composite IODs. Therefore the Interchange Media shall not contain instances from the following SOP Classes:

- Detached Patient Management SOP Class
- Detached Study Management SOP Class
- Detached Visit Management SOP Class
- Study Component Management SOP Class
- 780 • Modality Performed Procedure Step SOP Class
- Detached Result Management SOP Class
- Detached Interpretation Management SOP Class
- Stored Print Storage SOP Class

785 **The Media Creator shall not change the values of the stored pixels, though it may change the encoding. It is required that images on the PDI media be of diagnostic quality (IHE RAD TF-1:15.4), hence for Options that support the use of lossy (irreversible) image compression the Portable Media Creator shall not:**

- 790 • **apply lossy compression to images just for the purpose of exchange (e.g., to fit on the media or to accelerate load time); images can be encoded in lossy compressed form if and only if this is the form in which they had been made available to the Portable Media Creator (see also Media Exchange Certification Project of the German Radiological Society rule 3.1.3.8 <http://www.dicom-cd.de/docs/DRG-RequirementsSpecification-2006.pdf>)**
- 795 • **alter the bit depth or rescaling or color space of an image in such a manner that information is lost in order to allow compression (lossless or lossy) to be applied (e.g., to change an image containing 16 bits of data to 12 bits to allow JPEG compression to be applied).**

4.47.4.1.2.3.1.2 DICOMDIR Directory Content

800 There are no additional DICOMDIR keys required beyond those required by the DICOM STD-GEN-CD specification, **or the appropriate profile used with the DVD or USB Options (see 4.47.4.1.4).**

No private elements shall be included in the standard directory records and no private directory records shall be present.

805 The following types of Directory shall not be used in the Basic Directory object (DICOMDIR File):

- VISIT,
- RESULTS,
- INTERPRETATION,
- STUDY COMPONENT,
- 810 • STORED PRINT
- TOPIC
- PRIVATE

The PATIENT, STUDY, SERIES Directory Records shall follow the following rules:

- 815 • Only one Directory Record per Patient ID shall be present in the DICOMDIR.
- Only one STUDY Directory Record per Study Instance UID shall be present in the DICOMDIR; this implies that a study belongs to a single patient.
- Only one SERIES Directory Record per Series Instance UID shall be present in the DICOMDIR; this implies that a series belongs to a single study.
- 820 • Only one composite instance level Directory Record shall be present per SOP Instance UID; this implies that an instance belongs to only a single series.
- Only one HL7 STRUC DOC Directory Record shall be present per SOP Instance UID; this implies that an instance belongs to only a single Patient.
- Only one HANGING PROTOCOL Directory Record shall be present per SOP Instance UID

825 Users should review the supported Media Storage SOP Classes in the Conformance Statements of media creators and readers to ensure interoperability in the interchange of media objects. **The use of the Sending Software Option can be used to mitigate potential incompatibility between creators and readers.**

830 **There is no requirement to include Icon Image Sequences in DICOMDIR Directory Records. However, their presence at the SERIES level, or the IMAGE level for multi-frame images, may be helpful to improve performance in a viewer that provides visual information for the user to navigate. Accordingly, it is strongly recommended that such Icon Image Sequences be present, without causing excessive increase in size of the DICOMDIR file.**

835 **Note: The Transfer Syntax for the DICOMDIR is always Explicit VR Little Endian, and this precludes the use of any form of compression for Icon Image Sequences in the DICOMDIR, since the Transfer Syntax that defines the encoding of the nested Pixel Data is the same for the top level data.**

4.47.4.1.2.3.1.3 DICOM Report Content

It is **highly recommended possible** to place diagnostic reports on the media.

840 **Note: The report on or accompanying the media may be obsolete if a report is amended or corrected subsequently. Other means that recording on media are widely used to distribute up to date reports (e.g., fax and email), and it is potentially unsafe to rely on the report on media for clinical decision making.**

The Portable Media Creator actor, if grouped with a Report Creator actor, shall support the ability to create a diagnostic imaging report. A Basic Text DICOM SR, according to a proper
845 subset of the Simple Image Report Pattern as defined by the SINR Integration profile, can be created and this kind of diagnostic report can be imported by a Portable Media Importer.

Additional optional diagnostic reports in non-DICOM formats (such as HL7 CDA) are not defined by this transaction and may be placed on the media without the need to create DICOM SRs **or DICOM Encapsulated PDF or DICOM Encapsulated CDA**, but they **will may** be
850 non-importable data. **See also the XDM Integration Profile in the IHE ITI Technical Framework.**

Note: This requirement may be met with other DICOM SR SOP Classes that are used for diagnostic or therapeutic reports. For the most basic radiology report, a simple pattern with one or more sections including a paragraph of text meets this requirement. Image references do not have to be included, but may be if so desired.

855 **4.47.4.1.2.3.2 Web Content Option**

Portable Media Creators claiming the Web Content option shall meet the following requirements:

End-users should be able to access information at a minimum using a web browser to view content on media. In order to grant maximum interoperability using the stored XHTML files,
860 they shall be formatted according to the XHTML Basic and W3C HTML Compatibility Guidelines provided in Appendix C of the W3C XHTML 1.0 Recommendation.

The web-viewable data that is generated by Portable Media Creators claiming the Web Content option shall:

- 865 • contain the web representation of a subset **that faithfully preserves the clinical intent** of the media's DICOM information, using only XHTML files, JPEG referenced images, and PNG and/or GIF files used for navigation,
- contain hyperlinks within XHTML files which contain only lowercase letters to promote interoperability across O/S Platforms,
- 870 • reside in the *IHE_PDI*, while the corresponding DICOM data from which it is derived is located in a different sub-directory (see 4.47.4.1.2.2.1), and
- be completely referenced in the *INDEX.HTM* file

The web-viewable data included shall be a set or subset that was considered at the time of creation to faithfully represent the patient's clinical condition. **While it may be a subset, merely listing the contents is insufficient to satisfy this requirement, and if DICOM images are present on the media, for example, there shall be images in the Web Content. Though not required to be of diagnostic quality, Web Content images shall be a faithful representation and not excessively compressed nor excessively small (e.g., a 32x32 image of a 512x512**
875

original would not be a faithful representation). For multi-frame original images, a sufficient number of frames shall be rendered to be a faithful representation.

880 If the Portable Media Creator supports Presentation States, it shall have the capability to apply them to the relevant images when including web-viewable content. The user of the application may choose not to make use of this capability.

The constraints placed by DICOM on the ISO 9660 file system are not required for web-viewable content, i.e. a 3-character extension is permitted.

885 To ensure interoperability, JPEG means a file with a JFIF header and encoded using the sequential Huffman DCT 8bit per component process (baseline), and the progressive variant thereof.

To ensure interoperability the use of XHTML shall be limited to static and restricted forms of dynamic web content. At this time Dynamic Web Content such as DHTML and most Scripting Languages are explicitly prohibited as no single established Standard exists to ensure interoperability between web browsers. The use of JavaScript is explicitly permitted, recognizing that there may be issues with different browsers. Portable Media Creators should make every effort to use portable constructs or use JavaScript that works with or adapts to all known portable browsers; further, the failure of JavaScripts should not make the resulting web pages unusable,
890 **by which it is meant that the static content shall be understandable as a faithful representation of the clinical condition without JavaScript.**

Because XHTML rather than legacy HTML is required, it is necessary to provide information about appearance using either embedded styles or an external stylesheet, since legacy attributes controlling appearance are not permitted in XHTML Strict. The use of Cascading Stylesheets (CSS) is explicitly permitted, recognizing that there may be issues with different browsers. Portable Media Creators should make every effort to use portable constructs or use CSS that works with or adapts to all known portable browsers; further, the failure of CSS should not make the resulting web pages unusable, **by which it is meant that the static content shall be understandable as a faithful representation of the clinical condition without CSS.**

905 Additional optional web-viewable content not derived from DICOM objects may be stored on the media, but not in the *IHE_PDI* directory.

4.47.4.1.2.3.3 Privacy Protection Options

Portable Media Creators claiming the Privacy Protection Options shall be capable of protecting the content by meeting the following requirements:

- 910
- **the secure version of the DICOM Media Application Profile defined in PS 3.11 shall be used, specifically:**
 - **for Portable Media Creators without the DVD or USB Media Options, the STD-GEN-SEC-CD shall be used in place of the STD-GEN-CD profile**

- 915
- for Portable Media Creators with the DVD Media Option, the STD-GEN-SEC-DVD-JPEG or STD-GEN-SEC-DVD-J2K shall be used in place of the STD-GEN-DVD-JPEG or STD-GEN-DVD-J2K profile, respectively
 - for Portable Media Creators with the USB Media Option, the DICOM STD-GEN-SEC-USB-JPEG or STD-GEN-SEC-USB-J2K shall be used in place of the STD-GEN-USB-JPEG or STD-GEN-USB-J2K profile, respectively
- 920
- all of the DICOM instance files and the DICOMDIR shall be encrypted
 - all of the non-DICOM files on the media that potentially contain individually identifiable information (such as reports) shall be encrypted (including the IHE PDI directory and its sub-directories for the Web Content Option as well as any other optional content); note that any Web Content may be unusable if encrypted
- 925
- the INDEX.HTM and README.TXT files shall not be encrypted and shall not contain individually identifiable information
 - all encrypted files shall be CMS encapsulated; the CMS encryption shall be performed using a subset of the choices provided for DICOM secure media in PS 3.15:
 - AES shall be used for the key transport of the content-encryption keys
 - AES shall be used for content-encryption
- 930
- all of the encrypted files on a single volume shall be encrypted with the same password and/or one or more RSA keys (potentially for multiple recipients) (though the content-encryption key for each file may be different)
- 935
- any viewer present on the media shall be capable of requesting the password from the user if the media uses PBE, and using the RSA private key of the recipient if the media uses PKI, and with the supplied key decrypting all the encrypted DICOM content for display
- 940
- Portable Media Creators claiming the Privacy Protection Option Using PBE shall:
- use PBKDF2 PBE for transport of the content-encryption keys
- Portable Media Creators claiming the Privacy Protection Option Using PKI shall:
- use RSA encryption for transport of the content-encryption keys
- 945
- Portable Media Creators claiming the Privacy Protection Options shall encode a Portable Media Sender on the media that shall provide the decryption capabilities of the Portable Media Sender specified in RAD TF-3:4.67.4.1.2.4.
- The mechanism for transferring the password required to decrypt the content is not defined by IHE, other than to forbid its printing on the label of the media (see 4.47.4.1.2.2.4 Media Identification), inclusion in the package or encoded in an unencrypted file on the
- 950
- media.
-

4.47.4.1.3 Expected Actions

955 The receiving/reading actors (**Portable Media Importer, Image Display, Report Reader, Print composer and Display**) read the patient's data from the media and act upon it as specified below. The receiving actor shall document which DICOM objects it supports in its Conformance Statement. If a SOP Class on the media is not supported, the actor shall present the user with a summary of the data that could not be acted upon, containing the Patient Name(s) and ID(s), Study ID(s), Study Date(s), Study and Series Description(s) and Modality as obtained (if present) from the *DICOMDIR* file.

960 The automatic launching of applications is not expressly prohibited on media interchanged within this profile, however its use is discouraged.

To facilitate avoidance of malicious software, receiving actors (~~**Portable Media Importer, Image Display, Report Reader, Print composer and Display**~~) are not required to launch automatically running applications present on media.

4.47.4.1.3.1 Expected Actions Common to All Actors

965 **All receiving actors that support one of the Privacy Protection Options shall be able to request the password from the user and/or supply the recipient's RSA private key and decrypt the contents of the media.**

970 **All receiving actors that support the DVD Media Option or the USB Media Option shall be able to read all types of media and Transfer Syntaxes specified in the corresponding DICOM Media Application Profiles defined for the Option, which includes the ability to decompress all specified compression schemes.**

4.47.4.1.3.2 Image Display

975 The Image Display reads the DICOM image data from the media and provides the user with the ability to view all studies (that it supports) contained on the media. GSPS objects and Key Image Notes are read from the media and applied if the Consistent Presentation of Images and the Key Image Notes IHE Integration Profiles are supported. The Image Display actor may optionally be grouped with other actors ~~which~~ **that** view other evidence objects.

4.47.4.1.3.3 Report Reader

980 The Report Reader reads the DICOM SR Reports from the media and may process them (based on the SR object classes it supports). At a minimum, it provides the user with the ability to view all reports per the DICOM SR SCP requirements.

4.47.4.1.3.4 Portable Media Importer

985 The Portable Media Importer reads DICOM data from the media. Together with the actor with which it is grouped (see ~~vol-1~~ **RAD TF-1: 2.5**), it shall be able to perform key attribute reconciliation. Reconciliation may not be required in all cases (e.g., within the same importing

institution/enterprise). Refer to Table 4.47.4-2 for key attributes to be reconciled. Import Reconciliation Workflow provides a workflow to reconcile key attributes (See **Section RAD-TF-1:3.59**). Note that the Referenced Study Sequence and Requested Attributes Sequence are removed for consistency with behavior of the unscheduled cases in SWF and PIR.

990 The grouped actors provide the capability of storing the supported DICOM objects to an Image Manager/ Image Archive (for image objects like Images, Presentation States, Key Image Notes, Evidence Documents), or to a Report Repository (for Diagnostic Reports).

Table 4.47.4-2 Media instances - Key attributes to be reconciled

Attribute from Media	Updating action
Patient Name	Replace with value from ADT (See note 1)
Patient ID	Replace with value from ADT (See note 1)
Patient's Birth Date	Replace with value from ADT (See note 1)
Patient's Sex	Replace with value from ADT (See note 1)
Study Instance UID	Remains unchanged
Series Instance UID	Remains unchanged
SOP Instance UID	Remains unchanged
Workflow-related Identifying Attributes (e.g. Order, Requested Procedure, Scheduled and Performed IDs and UIDs).	<p>Values from such identifying attributes of media information</p> <ul style="list-style-type: none"> • remain unchanged, • are replaced with a value from the local environment, or • are removed (zero length value). <p>The exact method of reconciliation depends on the importing institution's procedures, and goes beyond the IHE scope.</p>
Descriptive performed procedure information (this is information that pertains to the manner in which the information was created (e.g. acquisition context) or it may be payload of the instance (e.g. image structure, document content))	Remains unchanged (see Note 2)

Note 1: The manner in which the Portable Media Importer receives the ADT value is beyond the scope of this profile.

995 Note 2: Handling of Coded information is beyond the scope of this ~~Integration Profile~~ **Transaction**.

4.47.4.1.3.5 Print Composer

The Print Composer reads the DICOM image data from the media and provides a means to print it.

4.47.4.1.3.6 Display

1000 The Display actor (~~defined in the IT Infrastructure TF~~) reads the web-viewable information from the media and displays it. Note that the web-viewable content will only be present if the Portable Media Creator involved supports the Web Content Option. **The web-viewable content**

will be unusable if it contains identifiable information and one of the Privacy Protection Options has also been used (i.e., it has been encrypted).

1005 **4.47.4.1.4 Media Options**

The baseline media type is CD using the DICOM STD-GEN-CD Media Storage Application Profile.

Options are provided for DVD Media and USB Media.

4.47.4.1.4.1 DVD Media Option

1010 **A Portable Media Creator that supports the DVD Media Option shall create media that complies with either the DICOM STD-GEN-DVD-JPEG or STD-GEN-DVD-J2K Media Application Profiles, as defined in DICOM PS 3.11 Annex H.**

1015 **A Portable Media Importer that supports the DVD Media Option shall be capable of reading any media written with the DICOM STD-GEN-DVD-JPEG and any media written with the STD-GEN-DVD-J2K Media Application Profiles.**

In summary, these DICOM Media Application Profiles specify:

- 1020 • **the use of any of the conventional (non-HD) 120 mm DVD-compatible media except DVD-RAM, specifically CD, DVD-R authoring and general, DVD-RW, DVD+R and DVD+RW (see DICOM PS 3.12 Annex P), which means that the Portable Media Creator can create any of these choices, but the receiving Actors shall be capable of reading all of them**
- **the use of UDF or ISO 9660 (or both) as a filesystem, which means the Portable Media Creator can create either (or both), but the receiving Actors shall be capable of reading either**
- 1025 • **the use of uncompressed images, or compressed images using JPEG lossy (8 or 12 bits) or lossless (up to 16 bit), or JPEG 2000 reversible or irreversible (up to 16 bit) schemes, which means the Portable Media Creator can make a choice, but receiving Actors shall be capable of decompressing all of them**
- 1030 • **additional DICOMDIR keys that shall be included by the Portable Media Creator (which are listed in DICOM PS 3.11 Annex H Section H.3.3.1)**

1035 **Several other DICOM Media Application Profiles are effectively subsumed by the DICOM STD-GEN-DVD-JPEG profile. In particular, a Portable Media Creator that creates media using such a DICOM Media Application Profile will create media that is readable by a receiving actor that supports the DVD Media Option and hence the DICOM STD-GEN-DVD-JPEG profile. This is true as long as the receiver supports the encoded SOP Classes, which is true of any PDI media, and any additional required DICOMDIR keys are present. This includes profiles that create CD media that is readable in a DVD drive. Those DICOM Media Application Profiles, with any exceptions related to specific Transfer Syntaxes noted, are:**

- 1040
- **STD-CTMR-CD**
 - **STD-US-ID-SF-CDR, STD-US-ID-MF-CDR, STD-US-SC-SF-CDR, STD-US-SC-MF-CDR, STD-US-CC-SF-CDR, and STD-US-CC-MF-CDR, except that RLE Lossless Image Compression is unsupported**
 - **STD-XABC-CD**
- 1045
- **STD-XA1K-CD**

4.47.4.1.4.2 USB Media Option

A Portable Media Creator that supports the USB Media Option shall create media that complies with either the DICOM STD-GEN-USB-JPEG or STD-GEN-USB-J2K Media Application Profiles, as defined in DICOM PS 3.11 Annex J.

- 1050
- A Portable Media Importer that supports the USB Media Option shall be capable of reading any media written with the DICOM STD-GEN-USB-JPEG and any media written with the STD-GEN-USB-J2K Media Application Profiles.**

The USB media shall have a Type A physical connector (DICOM has no such restriction).

In summary, these DICOM Media Application Profiles specify:

- 1055
- **the use of any USB-Connected Removable Storage Devices (see DICOM PS 3.12 Annex R), which includes the typical “memory stick” or “thumb drive”**
 - **the use of a FAT16 or FAT32 filesystem (see also DICOM CP 905)**
 - **the use of uncompressed images, or compressed images using JPEG lossy (8 or 12 bits) or lossless (up to 16 bit), or JPEG 2000 reversible or irreversible (up to 16 bit) schemes, which means the Portable Media Creator can make a choice, but the receiving Actors shall be capable of decompressing all of them**
- 1060
- **additional DICOMDIR keys that shall be included by the Portable Media Creator (which are specified in DICOM PS 3.11 Annex J Section J.3.3.1, and are the same as those for DVD specified in DICOM PS 3.11 Annex H Section H.3.3.1)**

1065

4.47.4.1.5 Sending Software Option

The intent of the Sending Software Option is to provide a fallback for when the media cannot be imported through other more formally established means, such as a pre-installed Importer Actor (see the Import Reconciliation Workflow). The need may arise when there are SOP Classes, compressed Transfer Syntaxes or encryption that an installed IRWF Importer Actor does not support.

1070

A Portable Media Creator that supports the Sending Software Option shall include on the Media executable software that implements the RAD-67 Media Information Stored Transaction.

1075 **The sending software shall be capable of executing:**

- **from the media without installation**
- **on desktop Windows operating systems (XP or later), though it is recommended that other operating systems also be supported**
- **without requiring the presence of or installation of supporting frameworks (e.g., .NET or JRE), other than to be able to execute them from the media if required**
- **without requiring administrative privileges**

1080

If the sending software is not capable of executing properly (e.g., wrong OS version, insufficient memory), the software shall either do nothing at all or terminate with an error message explaining the problem in human understandable form (e.g., not “exception 0xf800” or “sys12345.dll is missing”) and without negatively affecting other programs or the operating system (i.e. the software shall not crash the machine).

1085

Add new Section 4.67:

4.67 Media Information Stored

1090

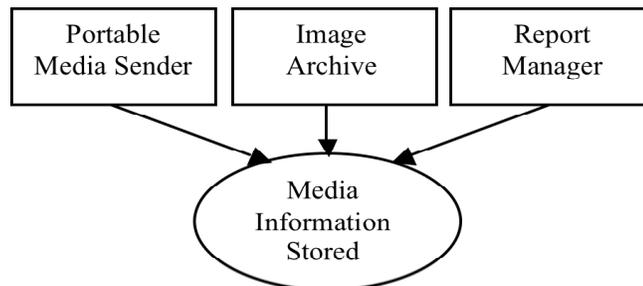
This section corresponds to Transaction RAD-67 of the IHE Technical Framework. Transaction RAD-67 is used by the Portable Media Sender and Image Archive and Report Manager actors.

4.67.1 Scope

1095

In the Media Information Stored transaction, the Portable Media Sender Actor executed from the code embedded on the Portable Media sends the DICOM information on the Portable Media to the Image Archive or Report Manager, decrypting, decompressing and converting it as necessary.

4.67.2 Use Case Roles



Actor: Portable Media Sender

1100

Role: Transmit imported image data to Image Archive or reports to Report Manager.

Actor: Image Archive

Role: Accept and store images from Portable Media Senders.

Actor: Report Manager

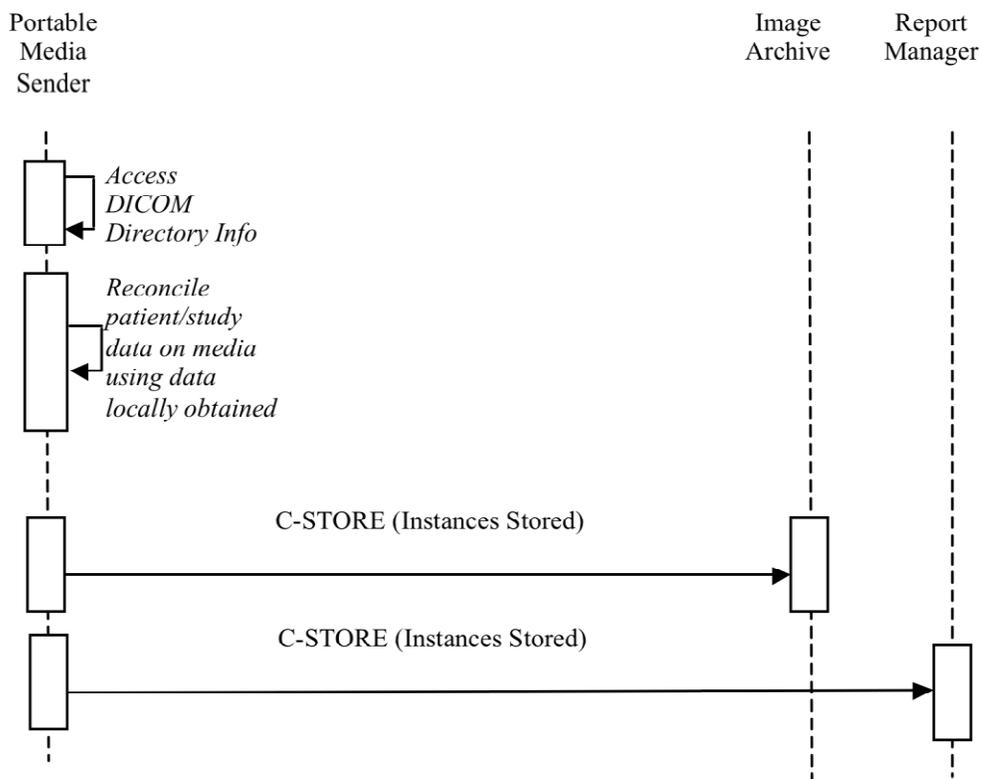
Role: Accept and store reports from Portable Media Senders.

1105

4.67.3 Referenced Standards

DICOM 2008 PS 3.4: Storage Service Class.

4.67.4 Interaction Diagram



1110 **4.67.4.1 Instances Stored**

4.67.4.1.1 Trigger Events

The Portable Media Sender transfers instances (images and related instances such as Presentation States, Evidence Document SR objects, Key Object Selection Documents, Structured Reports and Encapsulated PDF objects) to the Image Archive and/or Report Manager within one or more DICOM associations.

1115

4.67.4.1.2 Message Semantics

The Portable Media Sender uses the DICOM C-STORE message to transfer the instances. The Portable Media Sender is the DICOM Storage SCU and the Image Archive or Report Manager is the DICOM Storage SCP.

1120 4.67.4.1.2.1 Reconciliation

The Portable Media Sender shall have the capability to allow the user to reconcile patient/study information contain within the DICOM instances on the media before sending, as described for the Portable Media Importer Actor in the RAD-47 Distribute Imaging Information on Media Transaction. See RAD TF-3:4.47.4.1.3.4. Note that there is no expectation that the Portable Media Sender be able to receive information from any other Actor, such as an ADT system, but it is not precluded.

4.67.4.1.2.2 DICOM Storage SOP Classes

1130 The Portable Media Sender shall have the capability to send all of the instances that are present on the media, though the user may select a subset to be transferred through the user interface of the Portable Media Sender.

The ability of the SCP to receive the SOP Classes to be stored shall be established dynamically during Association Negotiation.

No support is required for SOP Classes that are not present on the media.

4.67.4.1.2.2.1 Image Storage SOP Classes

1135 The Portable Media Sender shall transform and send any Image Storage SOP Class that the SCP does not support into an Image Storage SOP Class of the same modality that the SCP does support, otherwise into a secondary capture SOP Class that the SCP does support, otherwise it shall not send the image.

1140 For example, an instance of an unsupported multi-frame Storage SOP Class might be converted to multiple instances of a supported single-frame SOP Class, or an unsupported modality-specific SOP Class instance might be converted to a secondary capture SOP Class.

This transaction specifies no requirements for the conversion of IODs or Attributes, other than that

- 1145 • the converted instance shall conform to the DICOM IOD for the resulting SOP Class and may be a Standard Extended SOP Class instance, and
 - new UIDs shall be created for resulting SOP Instances as necessary, such that:
 - referential integrity in the entire set of media contents of the same volume is preserved
 - references shall be inserted to the UIDs of the instances from which the new instances were derived, if any.
- 1150

There is no requirement that the Portable Media Creator create the same UIDs on subsequent imports (though it is not prohibited).

This “fall back” capability is required in order to maximize the amount of information transferred.

1155 **4.67.4.1.2.2.2 Non-Image Storage SOP Classes**

The Portable Media Sender is not required to transform non-image Storage SOP Classes (such as SRs or Presentation States) into other SOP Classes, though it shall have the capability to send them if the recipient accepts them.

1160 If Image Storage SOP Class instances referenced from within Non-Image Storage SOP Class instances have been assigned new SOP Instance UIDs as a result of transformation, then the Portable Media Sender shall make a reasonable effort to update the Non-Image Storage SOP Class instances to preserve referential integrity in the entire set of media contents of the same volume.

4.67.4.1.2.3 DICOM Transfer Syntaxes

1165 The Portable Media Sender shall have the capability to:

- send all of the instances that are present on the media in the Transfer Syntax encoded on the media, if supported by the SCP, as determined during Association Negotiation,
- send in Little Endian Explicit VR Transfer Syntax (i.e., decompressed) if the SCP does not support the Transfer Syntax encoded on the media and the SCP supports Little Endian Explicit VR Transfer Syntax, or
- send in Little Endian Implicit VR Transfer Syntax (i.e., the default DICOM Transfer Syntax that all SCPs are required to support) if the SCP supports neither the Transfer Syntax encoded on the media nor the Little Endian Explicit VR Transfer Syntax

1170
1175 The preference is for the Explicit rather than Default Implicit Transfer Syntax, in order to preserve the maximum information possible.

No support is required for Transfer Syntaxes other than Little Endian Explicit VR Transfer Syntax and Default Little Endian Implicit VR Transfer Syntax if there are no such encoded instances on the media.

1180 The Portable Media Sender shall be capable of decompressing the encoded instances, regardless of whether they are lossy or lossless compressed. This is a more burdensome requirement than that in the DICOM Standard, which requires such capability only for lossless compressed images. A consequence of this requirement is that decompressed instances for some lossy applications may become extremely large (e.g., a JPEG lossy compressed multi-frame ultrasound video stream). If lossy images have been decompressed, and new SOP Instance UIDs are assigned, references to predecessors shall be inserted and referential integrity maintained as described in Section 4.67.4.1.2.2.

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4.67.4.1.2.4 Decryption

1190 The Portable Media Creator that supports one of the Privacy Protection options shall encode a Portable Media Sender on the media that shall provide the ability for the user to supply the password or decryption keys and then decrypt all of the instances on the media before they are sent to the SCP.

4.67.4.1.2.5 Configuration

The Portable Media Sender shall provide the ability for the user to configure or enter the location (IP address, port, DICOM AET) of the SCP.

1195 The default configuration shall be port 11112 on the local host and an AET that is the local host name.

4.67.4.1.2.6 Failure Reporting

1200 In the event of a failure to store the instances, the Portable Media Sender shall display the reason for the failure to the user (e.g., whether or not the connection was refused, or the DICOM Association was rejected for a specified reason, or individual SOP Instances were rejected). The Portable Media Sender shall report the number of successful and failed operations.

There is no requirement to retry persistent or transient failed transactions.

4.67.4.1.3 Expected Actions

The Image Archive and the Report Manager shall store the received DICOM objects.

1205 The DICOM objects shall be stored such that they can be later retrieved (See IHE RAD TF-2: 4.16 Retrieve Images) in a fashion meeting the requirements defined for a DICOM Level 2 Storage SCP (Refer to DICOM PS 3.4 B.4.1).

4.67.4.1.3.1 DICOM Storage SOP Classes

1210 There are no restrictions or requirements placed on which Storage SOP Classes the Image Manager or Report Manager is expected to be able to receive.

4.67.4.1.3.2 DICOM Transfer Syntaxes

1215 There are no restrictions or requirements placed on which Transfer Syntaxes the Image Manager or Report Manager are expected to be able to receive, beyond the Default Little Endian Implicit VR Transfer Syntax required by DICOM. However, it is strongly recommended that the SCP support the Little Endian Explicit VR Transfer Syntax.

4.67.4.1.3.3 Configuration

The SCP may need to be configured to allow receipt and acceptance of instances from the Portable Media Sender acting as an SCU, since the SCU is not pre-installed. Alternatively, the

1220 SCP may limit the locations from which the SCU may be executed (e.g., by IP address), or may “quarantine” such imported instances for attention by an administrator before accepting them into the clinical workflow.

1225 **Amend existing Vol 3 Appendix E:**

Appendix E: DICOM Media Interchange – Critical DICOM Compatibility Tips

1230 This appendix presents a number of compatibility issues that result from not following the DICOM Media Interchange standard (PS 3.10, PS 3.11 and PS 3.12). This appendix is simply intended to be a reminder for the most common DICOM issues that have resulted in the past in incompatibilities between file set creators and readers.

1235 This list shall not be interpreted, as being the only DICOM requirements that implementers should pay attention to. DICOM has proven to be a very effective and thorough specification that implementers of ~~this~~ **the** IHE **PDI** profile shall be familiar with.

1. **If CD Media is used,** ~~t~~The CD Media shall be formatted according to ISO 9660 Level 1. (Extensions such as Joliet or Rock Ridge are not forbidden by DICOM and hence are permitted by the PDI profile. A UDF file system is not allowed **for CD Media**, unless an ISO 9660 Level 1 Filesystem is also present). Such extensions may be necessary to encode non-DICOM content on the media, such as long filenames for viewing software. Such extensions may result in ISO 9660 Level 1 uppercase filenames being presented to application software as lowercase or mixed case depending on the operating system's mount behavior; accordingly, all Portable Media Displays and Portable Media Importers shall be case insensitive in this respect, **whether the media is CD, DVD or USB.**
2. The *DICOMDIR* file shall be at the root directory of the Interchange Media
3. All DICOM file names (DICOM files as well as non-DICOM Files) shall contain only uppercase letters, numeric digits and the underscore character. The file name size without extensions shall not exceed 8 characters.
4. All Directory names in DICOM paths shall contain only uppercase characters, numeric digits and the underscore character. Directory names shall not contain extensions.
5. Non-DICOM files shall not have extensions with more than 3 characters (ISO 9660 Level 1).
6. DICOM files shall have no extension.
7. DICOM files shall have an ISO 9660 version of 1, which may be displayed by some operating systems as a ".;1" at the end. However, the ".;1" should not be included in the name of the file itself. **Some authoring software fails to include the required "." prior to the ";1", or omits the required ".;1" entirely, violating the ISO 9660 Level 1 standard; this common error has no interoperability impact, and may safely be ignored by a reader.**
8. The version number of the file name shall not be included in the reference data element in the *DICOMDIR*.

9. Only 8 levels of Directories are allowed, including the root directory (i.e. there may be up to 7 levels of sub-directories below the root).
- 1265 10. Objects in DICOM files shall be stored in Explicit VR Little Endian (not Implicit), **or the appropriate compressed Transfer Syntax for the DVD and USB Options.**
11. DICOM File Meta-Information shall be in Explicit VR Little Endian (not Implicit)
12. File Meta Information Version (0002,0001) shall contain a two byte OB value consisting of a 0x00 byte, followed by 0x01 byte, and not the value 0x0001 encoded as a little endian 16 bit short value, which would be the other way around.
- 1270 13. The file meta information shall include the Media Storage SOP Class UID (0002,0002) data element, and its value shall be equal to the SOP Class UID data element in the data set.
14. The file meta information shall include the Media Storage SOP Instance UID (0002,0003) data element, and its value shall be equal to the SOP Instance UID data element in the data set.
- 1275 15. No private elements shall be included in the file meta information.
16. The file meta information header shall contain an attribute (0002,0000) Group Length with a correct value as specified in DICOM PS 3.10.
- 1280 17. **The physical format of the DICOM DVD discs or USB media is specified in DICOM PS3.12.** The physical format of the DICOM CD-R discs shall comply with the application definitions within ISO/IEC 10149 Part II as specified in PS3.12. This allows discs to be written with
- Mode 1 sectors or
 - Mode 2, Form 1 sectors with CD-ROM-XA File Number = 0, Channel Number = 0 and Coding Information Byte = 0.
- 1285
18. **Secure DICOM files may be recognized (in the absence of a file extension, which is forbidden) by the absence of the “DICM” magic number from bytes 128 through 131 after the 128 byte preamble, and by the presence of the CMS ASN.1 initial bytes (which begin at byte 0 with an ASN.1 Sequence and the Object Identifier for envelopedData (1 2 840 113549 1 7 3), i.e. hexadecimal 30 80 06 09 2a 86 48 86 f7 0d 01 07 03).**
- 1290