



Guidelines for Exchanging DICOM Media in Clinical Research

Second Edition
2012-08-30

OFFIS e.V.
Escherweg 2
26121 Oldenburg
Germany
<http://www.offis.de/>

Table of Contents

1	INTRODUCTION	4
1.1	Scope	4
1.2	Normative References.....	4
1.3	Abbreviations	5
1.4	Definitions.....	5
1.5	Document History.....	6
2	RECOMMENDATIONS FOR THE SCENARIO “Media Export”.....	6
2.1	Creating Media	7
2.1.1	Selecting Images.....	7
2.1.2	De-identifying Images.....	7
2.1.3	Adding Clinical Trial Data	7
2.1.4	Writing DICOM CD/DVD.....	8
2.1.5	Validating DICOM CD/DVD.....	8
3	RECOMMENDATIONS FOR THE SCENARIO “Media Import”	9
3.1	General Preparations.....	9
3.1.1	Checking the Hardware Prerequisites	9
3.1.2	Adaptation of Ambient Light	9
3.1.3	Monitor Setup	9
3.1.4	Display Calibration.....	10
3.1.5	Disabling the Autostart Functionality.....	10
3.1.6	Installation of Anti Virus Software.....	11
3.1.7	Installation of Firewall Software.....	11
3.1.8	Installation of Operating System Updates.....	11
3.1.9	Installation of a DICOM Viewer.....	11
3.1.10	Installation of Web Browsers	11
3.1.11	Installation of a PDF Viewer.....	12
3.2	Performing Media Import.....	12
3.2.1	Performing Manual Quality Check.....	12
3.2.1.1	Visualization of DICOM Content	12
3.2.1.2	Visualization of Web Content	12
3.2.1.3	Visualization of Other Content	13

3.2.1.4	Performing a Visual Inspection	13
3.2.2	Performing Automatic Quality Check.....	13
3.2.3	Import of DICOM Content.....	14
3.2.3.1	Manual Import.....	14
3.2.3.2	Image Reconciliation	14
3.2.3.3	Bad Media Scenario.....	14
3.2.4	Visualization of Images	14

1 INTRODUCTION

Medical imaging technologies play an increasingly important role in performing quantitative measurements and assessments in clinical trials. DICOM (Digital Imaging and Communication in Medicine) is used for the exchange of medical images in clinical routine for patient treatment and in clinical research for conducting clinical trial analysis on medical images for subjects involved in clinical trials. DICOM storage media so called patient CD/DVD are usually used for the exchange of medical images in clinical trials. Images acquired for subjects involved in clinical trials are often submitted to a clinical trial coordination center where images are collected, processed and analyzed. The assessments are reported then to the clinical trial sponsor.

In clinical trials, original patient identification information has to be removed to protect the patient's privacy. However, some information needs to be retained to perform a meaningful clinical trial analysis (e.g. patient's age, patient's weight, etc.). DICOM standard provides a mechanism for identifying images for subjects involved in clinical trials using the clinical trial data modules. The patient is uniquely identified as a subject by the combination of the clinical trial subject ID, the clinical trial site ID and the clinical trial protocol ID. Furthermore, the clinical trial study is identified by a Time Point to identify the clinical time point for the submission of a study in a clinical trial (e.g. clinical trial phase).

OFFIS initiated the SWABIK project (Software Tools for DICOM Media in Clinical Research) for supporting the exchange of DICOM media in clinical trials. The use of such media is the conventional method for the interchange of medical images in clinical research. This means of exchange is encouraged because it allows lossless image transmission in terms of image quality. Furthermore, the recipient is able to import the clinical trial medical images into a standard image archive system.

Within the scope of this project, OFFIS develops open source software tools for creating DICOM media and safely importing them at the recipient side. The exchanged media undergo quality assurance checks before export and import to ensure that they conform to the patient's privacy protection rules, that they meet the requirements of the clinical trial protocol to conduct a successful clinical trial analysis and they generally conform to the encoding rules of the DICOM standard.

This work is funded by the German federal ministry of research and education (BMBF) (grant 01 EZ 1023). Further information and background about the project can be found in the project website at the following Internet address www.dicom-cd.org

Contact:

OFFIS e.V.
Escherweg 2
26121 Oldenburg
Germany
<http://www.offis.de/>

1.1 Scope

This document serves as guidelines for the export and import of DICOM media in clinical research and particularly in clinical trials. The document provides recommendations on the workflow of exporting and importing such media in clinical trials. The document intends to boost the efficiency and effectiveness of exchanging media in clinical research.

1.2 Normative References

[DICOM 2009] NEMA Standards Publication PS 3.1-18: *Digital Imaging and Communications in Medicine (DICOM)*, National Electrical Manufacturers Association, Rosslyn VA, 1992-2009

<http://medical.nema.org/>

[DICOM Supp 70]	DICOM Supplement 70: Clinical Trial Identification
[DICOM Supp 142]	DICOM Supplement 142: Clinical Trial De-identification Profiles
[IHE TCE 2008]	HIMSS and RSNA: IHE Radiology Technical Framework 1998-2008: Teaching File and Clinical Trial Export (TCE) Profile, http://www.ihe.net/Technical_Framework/
[IHE PDI 2009]	HIMSS and RSNA: IHE Radiology Technical Framework Extensions for the Portable Data for Imaging (PDI) Profile: Draft for Trial implementation 2009 http://www.ihe.net/Technical_Framework/
[DRG 2006]	The Media Exchange Certification Project of the German Radiological Society (DRG) www.dicom-cd.de
[DIN V 6868-57]	DIN V 6868-57: Sicherung der Bildqualität in röntgendiagnostischen Betrieben – Teil 57: Abnahmeprüfung an Bildwiedergabegeräten, 2001
[AAPM TG18]	AAPM Task Group 18: Assessment of Display Performance for Medical Imaging Systems. AAPM Online Report No. 03. American Association of Physicists in Medicine, College Park, MD (2005). http://deckard.mc.duke.edu/~samei/tg18_files/tg18.pdf
[AAPM TG18 Patterns]	AAPM Task Group 18 Test Patterns in DICOM and TIFF format. http://deckard.duhs.duke.edu/~samei/tg18.htm

1.3 Abbreviations

The following abbreviations are used in this document:

CRT	Cathode Ray Tube
DICOM	Digital Imaging and Communications in Medicine
HIS	Hospital Information System
LCD	Liquid Crystal Display
PACS	Picture Archiving and Communication System
PC	Personal Computer
PDF	Portable Document Format
XHTML	Extensible Hypertext Markup Language

1.4 Definitions

Clinical Trial Subject: The clinical trial subject identifies the patient as a subject who is enrolled in the investigational protocol.

Clinical Trial Sponsor: The clinical trial sponsor identifies the agency or the institution responsible for conducting the clinical trial and assigning the clinical trial protocol identifier.

Clinical Trial Protocol: The clinical trial protocol identifies the investigational protocol in which the subject has been enrolled. The protocol is identified by a protocol ID and protocol name.

Clinical Trial Site: The clinical trial site identifies the institution where subjects' images are obtained and submitted.

Clinical Trial Coordination Center: The clinical trial coordinating center (CTCC) identifies the institution responsible for coordinating the collection, management, processing, and/or analysis of images of subjects in a clinical trial.

Clinical Trial Time Point ID: The Clinical Trial Time Point identifies an imaging Study within the context of an investigational protocol. A Time Point defines a set of studies that are grouped together as a submission in a clinical trial.

De-identification: The de-identification is defined as the removal of patient identifiers.

Pseudonymization: The pseudonymization is defined as the de-identification and replacement of patient identifiers with an artificial pseudonym that is unique to the individual and known within a specified context but not linked to the individual in the external world.

Anonymization: The anonymization is defined as full de-identification and removal of patient identifiers to reduce the probability of re-identification even with access to other information sources.

DICOM Media: Media is a plural word and its singular is “medium”. DICOM media is the term usually used for patient CD/DVD or USB mass storage.

Quality Assurance: The term quality assurance (QA) is used to identify the systematic procedure used to maximize the probability that minimum standards of quality are being attained by the production process. In a clinical research context, it ensures that the collected medical image data fits the intended purpose for performing clinical trial analysis and if any mistakes are found, they are eliminated.

1.5 Document History

Version	Changes	Date
0.9	Preliminary version	2010-11-30
1.0	Second version	2012-08-30

2 RECOMMENDATIONS FOR THE SCENARIO “Media Export”

This section provides recommendations for the scenario “Media Export”. In this scenario, a user is viewing images on a workstation and can select images which are relevant to a clinical trial for export. The user’s selection results in a manifest referencing the selected instances. The selected images are sent to a workstation where images are pseudonymized. The pseudonymization workstation is responsible for de-identifying images using pre-configuration rules and adding clinical trial attributes to the DICOM header to identify the images for the subject enrolled in the clinical trial. Furthermore, the paper transmittal form required by the clinical trial protocol is filled. The pseudonymized images and an updated manifest are received by the media creator who can burn a DICOM CD or DVD. The media DICOM content is validated before being handled to other institutions.

The Export of DICOM media involves the following procedures:

- Selecting Images
- De-identifying Images
- Adding Clinical Trial Data
- Writing DICOM CD/DVD
- Validating DICOM CD/DVD

In the following, the “media creator” is the term used to describe the distribution system or a publication authoring system with portable media creation capability to burn a DICOM CD or DVD. The following sections explain how each procedure works.

2.1 Creating Media

2.1.1 Selecting Images

While a user is viewing images, a study or series of interest for a clinical trial is selected. A key object selection document is generated for this selection. It is used as a manifest to identify the user's selection. The title of the manifest is chosen as “*For Clinical Trial Export*”. The description text value should be the clinical trial protocol identifier used for acquiring the subject's images. The observer context should be entered as the person who selected this assembly of images in order to be able later to track the collection to that individual. The observation date time is used to tell when these images have been selected. The selected images are sent through the network to a pseudonymization workstation where images are de-identified and clinical trial data is added [IHE TCE 2008].

Note 1: A user can select instances of multiple studies but only for the same subject (e.g. current and prior images) and these instances are referenced in one manifest.

Note 2: If the pseudonymization workstation has access to the image archive and the user knows that the images reside there, only the manifest can be sent to the pseudonymization workstation to identify the user's collection.

2.1.2 De-identifying Images

The pseudonymization workstation receives the selected images with a manifest and queues them for processing. When the user decides to export the received images, the images are automatically de-identified using pre-configuration rules and privacy protection policies specified by the user. In the process of pseudonymization patient identification attributes are removed or replaced. The user configures which attributes are removed and which are replaced with dummy values and how dummy values are generated. Finally, an updated manifest is automatically generated referencing the new generated UIDs.

Note 1: If pixel data de-identification option is required and supported, the user has to manually remove identification information burned in the image pixels by blacking out regions of these pixels in the image [DICOM Supp 142].

Note 2: if the clean DICOM structured report (SR) option is required, the rendered text of the SR report should be edited to remove any patient identification information [DICOM Supp 142].

2.1.3 Adding Clinical Trial Data

A subject in a clinical trial is uniquely identified using the combination of clinical trial site ID, clinical trial protocol ID and clinical trial subject ID. Each clinical trial protocol has its own submittal form that should be filled and attached with the exported medium. A transmittal form is used to identify the clinical trial protocol requirements, the clinical trial time point ID for the submission, the clinical trial site which acquired the images and the subject ID. Furthermore, the DICOM modules of clinical trial

subject, clinical trial study and clinical trial series are inserted into the header of the DICOM files to identify the subject's images [DICOM Supp 70].

After images are de-identified and clinical trial attributes are added, the pseudonymized images along with the updated manifest are transferred to the media creator.

Note 1: The subject ID is a unique identifier for the patient in a clinical trial. In some cases, the subject ID is issued by the coordination center as a globally unique identifier for the subject throughout all clinical trial sites for a particular clinical trial. In this case, the imaging site is responsible for assigning this subject ID to the patient and the clinical trial site ID is not required to identify the subject.

Note 2: Since some PACS systems don't use the DICOM clinical trial attributes, it is common practice not only to insert these attributes but also to replace the patient ID with the clinical trial subject ID, the patient name with a concatenation of clinical trial protocol ID, clinical trial site ID, clinical trial subject ID and to replace the institution name with the clinical trial site ID.

Note 3: Some clinical trial imaging sites could have an enrollment list for the subjects involved in clinical trials. A secure mapping could be maintained between the original patient ID and the subject ID so that it becomes possible to re-identify the subject if required.

2.1.4 Writing DICOM CD/DVD

The media creator is able to receive a list of de-identified DICOM instances and burn a DICOM CD or DVD. It is highly recommended that the media creator conforms to the specifications of the DRG media exchange project [DRG 2006] and the IHE PDI profile [IHE PDI 2008]. The DICOM media must contain a valid DICOM content and readable on other systems.

After writing the DICOM content to a medium, information about the subject, the study date, the clinical trial site, the clinical trial protocol and the clinical trial coordination center should be labeled externally on the medium in a human readable format. The kind of content should be also labeled on the medium as "DICOM ONLY" or "DICOM PLUS WEB" and whether "DICOM Viewer" is included. It is also recommended for the media creator to check the media for malicious software (viruses, spyware, trojans .etc) before handling it to other institutions. If such test was performed, the label should include a note about the absence of malware and the date of the malware scan. After labeling the medium concerning the absence of malware, no more data should be written on the medium.

Note 1: Although it is recommended to include images from only one subject per CD/DVD, studies from multiple subjects are allowed to be written on the same medium. In this case, the medium must be labeled accordingly.

Note 2: The user can choose a lossless DICOM compression to allow enough space for more than one study on the same medium. Lossy image compression types are only allowed when the images are originally available to the user only in that format.

Note 3: Some production media facilities available in the market are able to automatically generate CD/DVD and labeling it without user intervention with the possibility of configuring which information is used for labeling the media.

2.1.5 Validating DICOM CD/DVD

It is recommended to check-out images to validate the DICOM content before handling the media to other institutions to ensure interoperability of images when processed or visualized on the receiver side. Each type of modality is identified by the information object definitions (IOD) in the DICOM standard. A DICOM validation tool can be used to check for the conformance of the DICOM object to the IOD specification model and to check for the validity of the encoding of the DICOM attributes required by the clinical trial protocol.

3 RECOMMENDATIONS FOR THE SCENARIO “Media Import”

In the “Media Import” scenario, an organization or a central facility is receiving media with pseudonymized DICOM content in clinical trials context. When a DICOM medium is received, the medium content is visually inspected and an automatic quality check is performed to ensure that the medical image data meets the clinical trial protocol requirements. The media that pass the quality tests are forwarded to the image archive for import. The imported clinical studies are reviewed in a blind manner by radiologists.

In this section, general recommendations are given, which discuss the preparations of reading exchange media containing medical images. Furthermore, information about the scenario “Media Import” is provided.

3.1 General Preparations

3.1.1 Checking the Hardware Prerequisites

The recipient of an exchange medium is advised to check whether the existing hardware is adequate for reading and visualizing the medium’s content. In particular the suitability of the monitor visualizing radiological image data must be checked. Information concerning technical requirements for monitors can be found in the German X-ray Regulation Quality Assurance Rule [QS-RL 2003] (“Qualitätssicherungsrichtlinie zur Röntgenverordnung”), where section 8 defines requirements for display systems used for the diagnostic reporting or general display of medical images for all anatomic regions of the body.

In addition, it should be verified that at least 256 shades of gray can be displayed. This is the case if the graphics adapter addresses 24 bits or 32 bits per pixel, but not if only 16 bits per pixel (often referred to as “high color” or “medium color quality”) are available. Furthermore, the visualization of digital medical images is a processor and memory intensive task. Because of the fast evolution of computers a concrete recommendation for minimum requirements is difficult. However, a processor with a clock rate of 1 GHz could be seen as the absolute minimum regarding computational power. Normally, the computer’s main memory should not fall short of 512 MB, 1 GB or more is recommended.

3.1.2 Adaptation of Ambient Light

The recipient of an exchange medium is advised to adapt the ambient light in the room that is used for visualizing the data so that the visualization of the medium’s content is not negatively affected. Normally, low ambient light is used for the visualization of radiological images because this improves the perception of low contrast details in the dark parts of the image. Furthermore, ambient lighting is always kept constant, in order to prevent the human eye from having to frequently adapt to changing lighting conditions, and in order to retain a valid calibration, if the display system has been calibrated. In particular, when setting up the monitor, the place should be chosen such that there are as little reflections from ambient light on the screen as possible, especially from ceiling lighting, windows or light boxes for images on conventional film.

Note: [AAPM TG 18] recommends a room lightness range from 15 to 60 Lux for the reporting of CT, MRT and nuclear images, and from 2 to 10 Lux for reporting of X-ray images.

3.1.3 Monitor Setup

It is recommended that the brightness, contrast and other settings of the monitor used for the visualization of media content are adjusted (and optimized if necessary) on a regular basis. The following text suggests a procedure for adjusting a standard monitor:

At first, the monitor should be adjusted so that the image is displayed horizontally and vertically centered. If supported by the monitor, a color temperature of 9300 Kelvin should be set. Now, the user

should use the computer to display a completely black screen, e. g. by setting the “Desktop” background color to black. The contrast controller of the monitor should be set to its lowest level. Then the monitor’s black point should be adjusted: Using the brightness control, the user should look for the point where the screen is completely black but a light increase of brightness would turn the monitor into a very dark shade of grey. Now the brightness setting is complete and the corresponding controller is not be used during the rest of the setup. In the last step, the monitor’s white point is adjusted. First, the contrast controller should be turned up a bit so that the image is well recognizable. Now, the computer should be used to display a white background with some details in great contrast on top (e. g. a typical text window showing black text on white background). Now the contrast should be turned up as much as possible without an oversteering of the image (i.e. the image becoming blurred). This completes the monitor setup.

A better result can be achieved when using a test image. One such image called “TG18-QC Pattern” is available for download free for charge from [AAPM TG18 Patterns]. The workflow is identical to the one described above, the only difference being that the TG18-QC test image should be shown on the screen in its original size (i.e. not scaled to full screen). For adjusting the black point using the brightness control as described above, it is crucial that the raster lines and edges of the test images are just noticeable. For adjusting the monitor’s white point using the contrast controller, the user again must take care that the screen does not oversteer – this can be checked with the Cx pattern in the test image. [AAPM TG18] also notes that the controllers for brightness and contrast are not working fully independently, so that some fine tuning may be necessary to find the best settings for minimum and maximum luminance.

After the monitor setup, the settings for brightness and contrast should not be changed. Some monitors allow for the corresponding controls to be locked or deactivated, thus preventing an accidental change of these settings.

3.1.4 Display Calibration

A further improvement of the image display quality compared to a simple monitor setup as described in the previous section can be achieved with a calibration of the display system (consisting of the monitor, the graphics board of the PC and the operating system drivers) according to a standard display function such as the DICOM Grayscale Standard Display Function [DICOM 2009, part 14] or CIELAB. However, a calibration requires specific measurement devices (photometer), specific software and possibly also specific hardware. If possible, it is recommended that a display calibration of the system used for visualizing the content of exchange media be performed on a regular basis to ensure a consistent and authentic display of radiological images. Comprehensive information about calibration procedures can be found in [DIN V 6868-57] as well as [AAPM TG18].

Note: A calibration optimizes the image display of the monitor under consideration of the current settings for brightness and contrast and of the ambient lighting conditions. Therefore, the calibration remains valid only as long as the monitor settings and ambient lighting conditions remain unchanged.

3.1.5 Disabling the Autostart Functionality

The recipient of an exchange medium is advised to explicitly disable any autostart functionality of the operating system that automatically executes specific programs from the medium. The rationale behind this recommendation is the possible immediate and automatic execution of malware (viruses, trojans, spyware etc.) contained on the medium when the medium is inserted.

Note: For Microsoft Windows operating systems, there are different ways to disable autostart functionality, e. g. by means of the Windows Explorer or the Windows Registry. Further information is available in the Windows help system under the keyword “Autoplay”.

3.1.6 Installation of Anti Virus Software

It is recommended that an up-to-date antivirus software with up-to-date virus descriptions should be installed on the system. Furthermore, both should be updated on a regular, short-term basis.

3.1.7 Installation of Firewall Software

In case that the system used for reading exchange media is part of a computer network, it is recommended that an up-to-date firewall software should be installed on the system and configured appropriately. The regular update of the software as well as checking the configuration is recommended for the user or administrators of the system.

Note 1: A (software) firewall is an application that controls and restricts network communication to eliminate unwanted data flows. A firewall is typically used to control network communication within the local area network (LAN), or between the LAN and the Internet.

Note 2: Some software firewalls ("Personal Firewalls") are configured by default to block communication requests from outside, but to permit connections from "inside" to "outside". It is recommended to configure firewalls so that connections from "inside" to "outside" are also checked in order to avoid any accidental transmission of patient related data.

3.1.8 Installation of Operating System Updates

The recipient of an exchange medium is advised to install system updates for the installed operating system on a regular basis. Without these updates, some security vulnerabilities may remain unclosed, which causes the risk of malware execution on the system.

Note: For Microsoft Windows operating systems, the operating system update is started using the "Windows Update" menu item. For this activity an Internet connection is required in general.

3.1.9 Installation of a DICOM Viewer

In many cases, a DICOM viewer is available on the exchange media received that can be used for visualizing the DICOM Content of the medium. For the case that the medium does not contain a DICOM viewer, it is recommended to have such software installed on the system in advance. Regarding an installed DICOM viewer, it is also recommended to update the software on a regular basis in order to eliminate any security vulnerabilities.

Note 1: For visualization of DICOM Content many viewers are available free of charge on the Internet, for different operating systems. Furthermore, there are many commercial products available.

Note 2: Not every DICOM viewer is adequate for all kinds of DICOM images. Whether a viewer is suitable for a specific kind of image (X-ray images, CT, cine images such as Ultrasound or Angiography etc.) should be checked in advance.

Note 3: If the recipient of the medium is to perform diagnostic reporting of the images, and the images are within the scope of the German X-ray Regulation ("Röntgenverordnung"), then the system used for image display must pass an acceptance test according to the German X-ray Regulation Quality Assurance Rule [QS-RL 2003] ("Qualitätssicherungsrichtlinie zur Röntgenverordnung"). Since this acceptance test covers the overall system including hardware and software, a diagnostic reading of X-ray images is not permitted using a DICOM viewer contained on the CD.

3.1.10 Installation of Web Browsers

In case that the received media contains "Web Content" (web pages) to be visualized, a web browser should be installed on the system if the operating system does not provide a web browser or if the user prefers not to use the web browser provided by the operating system. It is recommended that updates for any web browser on the system should be installed on a regular, short-term basis. Without those updates, possible security vulnerabilities remain open. Also, some XHTML features used by the

Web Content may not be supported by outdated browser versions, leading to Web Content on the medium not being visualized appropriately.

3.1.11 Installation of a PDF Viewer

In case that the received media contain “Other Content” in the Portable Document Format (PDF) to be visualized, the installation of a PDF viewer is necessary. It is recommended to install updates for any installed PDF viewer on a regular, short-term basis to close any potential security vulnerabilities.

Note: The Portable Document Format is a cross platform file format developed by Adobe Systems, Inc. Many viewers for the visualization of PDF files are available freely on the Internet for different operating systems.

3.2 Performing Media Import

The following procedures are recommended for importing the received media:

- Performing Manual Quality Check
- Performing Automatic Quality Check
- Import of DICOM Content
- Visualization of Images

The importing system could be a dedicated workstation with a corresponding functionality for performing visual inspection and quality assurance.

3.2.1 Performing Manual Quality Check

The recipient of a media has to log the receipt of data. It is recommended to perform a basic visual inspection to identify the type of media content and its relevance to the clinical trial protocol requirements.

First of all, the media must contain real de-identified data. If any patient’s privacy rules are violated, the media is either returned to the imaging site which created them or they are possibly de-identified in the coordination center (see section 2.1.2).

Furthermore, the media could contain DICOM files, optional web content and possibly other content such as PDF files. The recipient is advised to review all the content and to query the imaging site for any missing information.

3.2.1.1 Visualization of DICOM Content

The DICOM Content consists of a central DICOMDIR file in the medium’s root directory plus additional DICOM files referenced from this file.

For the purpose of visualization, either a DICOM viewer possibly contained on the medium, or a previously installed DICOM viewer suitable for the objects on the medium (see section 2.1.9) can be used. The DICOMDIR file in the medium’s root directory serves as the entry point to the DICOM Content.

3.2.1.2 Visualization of Web Content

In case a medium contains additional Web Content, the recipient is advised to also review it. It should be noted that on a medium following the DRG requirements specification the Web Content has been derived from the DICOM Content on the same medium, and either reflects all DICOM Content on the medium or only the relevant part of the DICOM Content that truthfully reflects the clinical condition of the patient.

The file INDEX.HTM in the medium’s root directory serves as the entry point for the Web Content. The file INDEX.HTM and all Web Content referenced from this file should be viewable with a standard web

browser, at least with the browser that is mentioned in the file README.TXT, located in the medium's root directory.

3.2.1.3 Visualization of Other Content

If the medium contains so-called Other Content (e. g. reports in PDF format), the recipient is advised to also review this Other Content. It should be noted that for media following the DRG requirements specification there is no requirement for so-called Other Content to have a DICOM counterpart on the same medium. There is only a (non-binding) recommendation that a DICOM counterpart should be included on the medium for clinically relevant information. Normally, Other Content should be located in a separate directory on the medium. Other Content can be stored in any file format.

Note 1: For visualizing Other Content in the Portable Document Format (PDF) format, the previously installed PDF viewer can be used.

Note 2: Not all clinically relevant documents on the storage media are necessarily available in DICOM format. In particular, so-called Other Content may contain important documents such as discharge letters or diagnostic reports. An import of such documents into a DICOM archive is usually not possible. An import of such documents into a different IT system, such as an electronic patient record, may be possible but is not further discussed in this guideline.

3.2.1.4 Performing a Visual Inspection

The visual inspection quality procedures include but are not limited to the following:

- Check for the coverage of the anatomy of interest
- Check for the patient positioning during the scan.
- Check for specific attribute values required by the clinical trial protocol. For example, a clinical trial protocol may request a certain radiation dose values for the peak kilo volrage (kVP) of the x-ray generator and for the x-ray tube current and the exposure time to calculate the mAs. The corresponding DICOM attributes such as kVP (0018,0060) and Exposure (0018,1152) should be checked.
- Check for the absence of image artifacts. For example, patient motion during the scan could lead to undesired motion artifacts in the image.
- Check for the overall quality of images. For example, the image quality might be degraded due to inappropriate lossy image compression.

3.2.2 Performing Automatic Quality Check

In this type of quality check, a DICOM validation software tool can be used to check for the validity of encoding certain DICOM attributes.

The following procedures are recommended for automatically performing the quality test:

- Check the manifest against the received instances.
- Check for the validity of the values of the DICOM attributes required for advanced visualization applications (e.g. MPR, CAD, 3D etc.). For example, DICOM attributes specifying relative image orientation and slice thickness in addition to the mandatory image plane attributes are important to reconstruct MPR or 3D volume.
- Check for the conformance of the DICOM attributes required by the clinical trial protocol depending on each type of modality. For example, MR attributes such as Repetition Time (008,0080) and Echo Time (008,0081) are important to determine whether the MR image is T1-weighted or T2-weighted. Another example, if dynamic contrast enhanced (DCE) MR or PET imaging techniques are used to monitor a tumor change by injecting a contrast material, the Contrast Agent DICOM attribute (0018,0010) should be filled accordingly with the contrast.

DICOM images that don't pass the checks are either corrected if possible or quarantined. If the medium has successfully passed the quality and conformance check, it is manually imported to the image archive system.

3.2.3 Import of DICOM Content

3.2.3.1 Manual Import

When a user performs a manual import, information from the submittal form is entered manually to the import workstation software and a new patient is inserted into the database. The user has to check that the received medium is attached to the correct submittal form of the subject. The information entered includes the patient information (e.g. patient name, patient ID, date of birth etc.), study information (e.g. study date etc.) and clinical trial information (e.g. clinical trial protocol ID, site ID, time point ID, etc.). The DICOM images in the medium are then uploaded to associate the subject's images to this patient in the database.

Note: The patient ID should be entered as the subject ID. The patient name is entered as the concatenation of the clinical trial protocol ID, subject ID and site ID (if provided). For example, the first name is the subject ID, the middle name is site ID and the last name is the protocol ID.

3.2.3.2 Image Reconciliation

In the normal case, the information in the DICOM images should match the information in the transmittal form. In this case, no reconciliation is needed as long as the DICOM instances are de-identified and the clinical trial subject information is attached to the DICOM header. The importer matches the information from the DICOM files with the information attached in the submittal form to see if there is any reconciliation needed. If reconciliation is required, the import workstation software could be configured to automatically reconcile the DICOM images to match subject's information. The modified DICOM images are then forwarded to the image archive system.

3.2.3.3 Bad Media Scenario

If the importer experiences any import problems due to bad quality of the medium, the medium is checked against conformance and if it turns out that the medium is not usable, it is returned back to the clinical trial site which created it in the hope that images could be corrected and resent.

3.2.4 Visualization of Images

After safely importing the media images into the image archive database, the images are queried and retrieved from the image archive database. The images are then processed and reviewed by specialists in a blind manner using a dedicated visualization workstation to conduct the clinical trial analysis. Finally, the clinical trial assessments are submitted to the clinical trial sponsor.