



Media Exchange Certification Project of the
German Radiological Society
(Deutsche Röntgengesellschaft e. V.)

REQUIREMENTS SPECIFICATION
FOR EXCHANGE MEDIA
CONTAINING PATIENT
INFORMATION
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1 INTRODUCTION

Radiological images are increasingly exchanged in digital form using storage media, so-called "patient CDs/DVDs". This approach is desirable in principle since it allows for a lossless exchange of medical images in diagnostic original quality and, if need be, for an import into the digital infrastructure (PACS, diagnostic workstations) of the receiving institution. This enables the attending physician to perform a direct comparison between the current and any former examinations of the patient.

However, in practice it has shown that the exchange of radiological images and accompanying information on storage media still has many problems that are increasingly reported to the German Medical Association ("Bundesärztekammer") and the German Radiological Society ("Deutsche Röntgengesellschaft", DRG). In addition to ambiguity in the work processes at the receiving institution (e. g. registration of the patient in the RIS, import into a temporary archive, reconciliation of patient and order IDs before image import into a local PACS), erroneous and non standard conformant storage media are a significant hurdle for a seamless exchange of storage media.

Because of the multitude of vendors and medical institutions, it is hardly possible to address these issues in each single case. Against this background the German Radiological Society has decided to initiate a central Media Exchange Certification Project.

Within the scope of this project, a requirements specification precisely defines the internal structure of storage media with radiological images. The German Radiological Society also organizes the awarding of certificates for systems that create storage media that are suitable for use in the context of radiology, based on a technical validation of storage media for patient information. Furthermore, a suitable work process for recipients of storage media is described in a recommendation.

The background and goals of the project are described in the whitepaper "General Information and Background of the Certification Project for Storage Media of the German Radiological Society", available for download from the Internet at the following address: <http://www.dicom-cd.de/>

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1.1 Scope

This document contains the requirements specification of the internal structure of exchange media containing radiological images. The underlying intention of the rules described in this document is to promote the reliable exchange of image data between medical institutions. Media complying with the requirements of this document are considered "correct" in the context of the Media Exchange Certification Project of the German Radiological Society.

1.2 Normative References

- [CompuServe GIF] CompuServe Incorporated: *Graphics Interchange Format*, 1987-1990
[DICOM 2006] NEMA Standards Publication PS 3.1-18: *Digital Imaging and Communications in Medicine (DICOM)*, National Electrical Manufacturers Association, Rosslyn VA, 1992-2006
- [DICOM Supplement 104] DICOM Standards Committee, Working Group 6: *Digital Imaging and Communications in Medicine (DICOM), Supplement 104: DICOM Encapsulation of PDF Documents*, National Electrical Manufacturers Association, Rosslyn VA, 2005
- [DRG-DE] Deutsche Röntgengesellschaft e. V.: Anforderungskatalog für Datenträger mit Patientenfür Informationen, Ausgabe 2006, <http://www.dicom-cd.de/docs/DRG-Anforderungskatalog-2006.pdf> (in German language)
- [ECMA-262] ECMA-262: *ECMAScript Language Specification*, 1999, <http://www.ecma-international.org/publications/files/ECMA-ST/Ecma-262.pdf>
- [IEEE P1282] IEEE P1282: *Rock Ridge Interchange Protocol*, 1994
- [IHE RTF 6.0] HIMSS and RSNA: *IHE Radiology Technical Framework*, Revision 6.0, 2005, http://www.ihe.net/Technical_Framework/
- [IHE RTF 6.0 vol. III] HIMSS and RSNA: *IHE Radiology Technical Framework vol. III: Transactions, Continued*, Revision 6.0, 2005, http://www.ihe.net/Technical_Framework/
- [ISO 9660:1988(E)] ISO 9660:1988(E): *Information processing – Volume and file structure of CD ROM for information interchange*, 1988
- [ISO 10918-1] ISO 10918-1: *Information Technology – Digital Compression and Coding of Continuous-Tone Still image*, 1994
- [ISO/IEC 10149] ISO/IEC 10149: *Information technology – Data interchange on read-only optical discs (CD-ROM)*, 1989
- [ISO/IEC 11172] ISO/IEC 11172: *Information technology – Coding of moving pictures and associated audio for digital storage media at up to about 1,5 Mbit/s*, 1993
- [ISO/IEC 13818] ISO/IEC 13818: *Information Technology – Generic coding of moving pictures and associated audio (MPEG-2)*, 1994
- [ISO/IEC 15948:2003] ISO/IEC 15948:2003: *Information technology – Computer graphics – PNG (Portable Network Graphics)*, 2003
- [Microsoft Joliet] Microsoft Corporation: *Joliet Specification*, 1995
- [Orange book, Part III] Philips/Sony: *Orange book, Part III – Technical Specification for rewritable compact discs*, 1996
- [OSTA UDF] OSTA: *Universal Disk Format Specification (UDF)*, <http://www.osta.org/specs/>
- [XHTML 1.0] W3C: *XHTML 1.0: The Extensible HyperText Markup Language*, W3C Recommendation, 2000, <http://www.w3.org/TR/2000/REC-xhtml1-20000126/>

1.3 Abbreviations

The following abbreviations are used in this document:

CD	Compact Disc
CD-R	Compact Disc Recordable
CD-RW	Compact Disc Rewritable
DICOM	Digital Imaging and Communications in Medicine
DVD	Digital Versatile Disc
DVD-R	DVD Recordable
DVD-RW	DVD Rewritable
DVD+R	DVD Plus Recordable
DVD+RW	DVD Plus Rewritable
GIF	Graphics Interchange Format
HTML	Hypertext Markup Language
ID	Identification
IHE	Integrating the Healthcare Enterprise
IOD	Information Object Definition
JPEG	Joint Photographic Experts Group
MPEG	Moving Picture Experts Group
PACS	Picture Archiving and Communication System
PDI	Portable Data for Imaging
PNG	Portable Network Graphics
RIS	Radiology Information System
SOP	Service Object Pair
UDF	Universal Disk Format
XHTML	Extensible Hypertext Markup Language

1.4 Document History

Version	Changes	Date
1.0	English translation of the final 2006 edition (2006-10-27) of the German document. Translation by Michael Onken, Marco Eichelberg, Jörg Riesmeier (OFFIS)	2007-12-04

1.5 Status of this Document

This document is a translation of the original document written in German language [DRG-DE]. Although the translation has been done with the best of one's knowledge, there might still be inaccuracies. In the case of differences between this document and the German original, the German text shall be normative. Comments and suggestions regarding this document or the certification project in general should be sent to info@dicom-cd.de.

2 GENERAL REQUIREMENTS

This section describes the general requirements placed on exchange media in the context of the Media Exchange Certification Project. General requirements are those rules not dealing with the medical content of the exchange media but with the media itself and its general contents.

2.1 Exchange Media and File Systems

2.1.1 Exchange Media

In the context of the Media Exchange Certification Project only optical media with a size of 120 mm are allowed. The following list describes all supported variants of these media:

- CD-R [ISO/IEC 10149]
- CD-RW [Orange book, Part III]

Note: It is planned to add support for DVD media in a future version of this specification. However, due to the limited exchangeability of media between different DVD readers, DVD media are not supported in this version of the requirements specification.

2.1.2 File Systems for CD Media

For CD media a file system according to ISO 9660 Level 1 [ISO 9660:1988(E)] is required. Use of the UDF file system [OSTA UDF] with version numbers 1.02, 1.5, 2.0 or 2.01 on CD media is not permitted unless there is also an ISO 9660 Level 1 file system on the corresponding CD.

2.1.3 File System Extensions on CD Media

The use of ISO 9660 extensions, like Joliet [Microsoft Joliet] or Rock Ridge [IEEE P1282], is permitted for CD media.

Note: Extensions like Joliet or Rock Ridge may be necessary for the storage of non-DICOM content on the media, e. g. DICOM viewer software. The use of these technologies may lead to filenames specified in uppercase letters in ISO 9660 Level 1 to be presented to other applications in lowercase or a mixture of uppercase and lowercase, depending on how the underlying operating system mounts the media. Because of that, it is recommended to keep applications reading such storage media insensitive to uppercase/lowercase spelling of filenames.

2.1.4 File Systems for DVD Media (inactive)

This rule is inactive because DVD media are not supported in this version of the requirements specification (see section 2.1.1).

2.1.5 File System Extensions for DVD Media (inactive)

This rule is inactive because DVD media are not supported in this version of the specification (see section 2.1.1).

2.1.6 Packet Writing

The use of packet writing technologies, where information is written incrementally to the medium, is not permitted.

2.1.7 Multisession Media

The creation of multisession media, where directories of all present sessions are linked, is permitted.

Note 1: The unintentional storage of information belonging to different patients on a multisession medium is a potential source of error. Therefore, it is recommended to finalize completed storage media after writing, in order to prevent the unintentional appending of additional sessions.

Note 2: A correct labeling of a medium (see section 2.4 and section 2.2.2) is not trivial for multisession media written in more than one session, because only after finishing the last session it is known which data for which patient was burnt onto the medium. This document does not specify how correct labeling in such a case can be guaranteed, but the rules for media labeling mentioned above also apply for multisession media.

2.2 Malicious Software

2.2.1 Absence of Malicious Software

The creator of a medium must ensure that there is no malicious software (viruses, trojans, spyware etc.) on the medium.

Note: It is up to the vendor of the media creation system to select appropriate technical means to ensure the absence of malware on the medium. However, the selected solution must be documented and traceable. It is recommended to use an anti-virus software with up-to-date virus information at the time of creation of the storage medium.

2.2.2 Labeling regarding Malicious Software (Recommendation)

It is recommended to mark media concerning a successful test for the absence of malware, so that this property is clearly visible to the recipient of the storage medium.

Note 1: In the context of requirement 2.2.3, multisession media must be finalized before the test for the absence of malicious software and the related labeling takes place.

Note 2: A labeling of the media concerning the absence of malware suggests itself especially if an automatic CD production facility is used that can print on the storage media without user interaction.

2.2.3 Writing to Media after Labeling

No data shall be written to a medium that has already been labeled concerning the absence of malware.

2.3 Autostart Functionality

2.3.1 Usage of Autostart Functionality (Recommendation)

It is recommended that the creator of a medium should *not* make use of any autostart feature that launches a specific application when the medium is inserted into a computer. In particular, due to the possibility of an automatic execution of malicious software on the recipient's computer it is recommended that the media creator refrain from the use of the autostart function. Furthermore, the creator cannot assume that an automatically starting application will work with every computer into which the medium is inserted.

Note: For Microsoft Windows operating systems, the file "autorun.inf" in the medium's root directory is responsible for providing autostart functionality. For Unix-like operating systems, it depends on the shell or the window manager which scripts are executed for providing autostart capabilities.

2.4 Media Labeling

2.4.1 External Labeling

For the purpose of a clear identification of the storage medium, the medium must be labeled with human readable information.

Note: For media production systems that can print on the medium without user interaction, such a labeling is a requirement. Systems that cannot automatically label the medium must support the user with the correct labeling, e. g. by displaying the suggested labeling on screen when the medium is ejected after creation.

2.4.2 Contents of External Labeling (Recommendation)

It is recommended to label the medium with name and birth date of the patient, the patient ID, date of media creation, date information about the studies on the medium and name of the institution where the medium was created. In case of multiple patients on a single medium, it is recommended to label the medium accordingly. Additionally, it is recommended to provide information about the kind of content (DICOM, Web, DICOM Viewer) on the medium's label.

3 MEDIA CONTENT REQUIREMENTS

Regarding the medical content on the medium, DICOM Content, Web Content, DICOM Viewers and Other Content are distinguished. This section describes which requirements are placed on these types of content.

3.1 DICOM Content

Media must contain DICOM Content. In detail, the DICOM Content is comprised of a central *DICOMDIR* file in the media's root directory and further DICOM files referenced from the *DICOMDIR* containing DICOM objects. In the following sections, all requirements placed onto the DICOM Content are described.

3.1.1 General Requirements for DICOM Content

3.1.1.1 DICOM Standard

The precise format of DICOM Content is unambiguously defined by the DICOM standard [DICOM 2006]. All corresponding rules defined in the DICOM standard have to be applied directly and without restriction to guarantee maximum interoperability of the storage media.

3.1.1.2 Clinically Relevant Information (Recommendation)

It is recommended to store all information that is relevant for the current clinical condition of the patient(s) (including reports, discharge letters etc.) in DICOM format on the medium.

Note: DICOM Supplement 104 ("DICOM Encapsulation of PDF Documents") [DICOM Supplement 104] defines how PDF documents can be encapsulated into DICOM objects. This feature – together with DICOM Structured Reporting – can be utilized for this purpose.

3.1.1.3 The File README.TXT (Recommendation)

It is recommended to include a file *README.TXT* corresponding to the requirements laid out in section 3.2.3 in the root directory of the storage medium also on media that only contain DICOM data, and no Web Content.

3.1.2 Requirements for the DICOMDIR File

3.1.2.1 Location of DICOMDIR File

The *DICOMDIR* file must be present in the medium's root directory.

3.1.2.2 Format of DICOMDIR File

The format of the *DICOMDIR* file has to follow the rules of the DICOM standard directly and without restriction, even if other DICOM files on the medium violate any requirements of the standard. The software creating the medium is fully responsible for the correctness of the *DICOMDIR* concerning syntax, content and encoding.

3.1.2.3 References to DICOM Content in the DICOMDIR File

The DICOM Content on the storage medium must be referenced from the *DICOMDIR* file. All DICOM objects on the medium must be referenced; this implies that no DICOM objects besides the ones referenced from the *DICOMDIR* file shall be placed on the medium.

3.1.2.4 Directory Records Requirements

The Directory Records of the *DICOMDIR* shall not contain private data elements; the *DICOMDIR* shall not contain private Directory Records. Furthermore, the following Directory Record types are not permitted in the *DICOMDIR*:

- VISIT

- RESULTS
- INTERPRETATION
- STUDY COMPONENT
- STORED PRINT
- TOPIC
- MRDR
- PRIVATE

For the remaining types of Directory Records, the following rules apply:

- For each *Patient ID*, there is exactly one PATIENT Directory Record in the DICOMDIR.
- For each *Study Instance UID*, there is exactly one STUDY Directory Record in the DICOMDIR; this implies that each study belongs to exactly one patient.
- For each *Series Instance UID*, there is exactly one SERIES Directory Record in the DICOMDIR; this implies that each study belongs to exactly one patient.
- For each *SOP Instance UID*, there is exactly one IMAGE, OVERLAY, MODALITY LUT, VOI LUT, CURVE, KEY OBJECT DOC, ENCAP DOC, RAW DATA, FIDUCIAL, SPECTROSCOPY, REGISTRATION, RT DOSE, RT STRUCTURE SET, RT PLAN, RT TREAT RECORD, PRESENTATION, WAVEFORM, VALUE MAP, SR DOCUMENT or STEREOMETRIC Directory Record in the DICOMDIR; this implies that every DICOM instance belongs to exactly one series.

Additionally, the following directory record types are permitted: HANGING PROTOCOL (for Hanging Protocols that are not assigned to a patient) and HL7 STRUC DOC (for HL7 CDA documents that are assigned to a patient but not to a study).

Note: Directory Records of type OVERLAY, MODALITY LUT, VOI LUT and CURVE are retired as a result of Supplement 98 (approved in January 2006). Therefore, they should not be used anymore in new implementations.

3.1.2.5 File and Directory Naming

File and directory names that are referenced from the DICOMDIR are restricted to a length of eight characters, only allowing capital letters, digits and the underscore character. File and directory name extensions shall not be used. This is also required for the equivalent Joliet or Rockridge coded file and directory names that are specified on a medium with corresponding ISO 9660 file system extension.

Note: These requirements particularly imply that DICOM objects cannot be named based on their *SOP Instance UID*, because this would exceed the required maximum length of eight characters and also would use the dot in the file name. For the same reason, it is not allowed to append a file extension (like ".dcm") to the file.

3.1.2.6 Missing Information in Mandatory DICOMDIR Attributes

If DICOM objects are referenced from the DICOMDIR that do not contain sufficient information for filling mandatory attributes in the DICOMDIR, the media creation software must be able to create suitable values for all mandatory attributes. In this context, no specific recommendations are given concerning the creation of suitable values, or which values are to be considered suitable. However, all inserted values have to be consistent with the existing attribute values and all patients, studies and series shall be encoded so that they remain different from each other.

Note: For example, the attributes *Patient ID* and *Study ID* are of type 2 in DICOM objects (mandatory, null-value allowed) and, therefore, can contain an empty value. In contrast, the corresponding attributes for the PATIENT and STUDY Directory Records in the DICOMDIR are type 1 (mandatory, null-values not allowed) and must contain a value. For these cases, the software must be able to create suitable values for all mandatory attributes.

3.1.3 DICOM Object Requirements

3.1.3.1 Location of DICOM Objects (Recommendation)

All DICOM objects on the medium – except the DICOMDIR file – should be placed outside the root directory of the medium, in a single directory located in the root directory. The naming of this directory is only limited by requirements defined in section 3.1.2.5. The directory can contain further subdirectories, e. g. to group relating DICOM objects. As a maximum, a hierarchy of eight directory levels is allowed on the medium (including the root directory).

Note: In the IHE PDI Integration Profile, this recommendation is a requirement.

3.1.3.2 DICOM Object Format

The format of the DICOM objects on a medium is fully defined in the DICOM standard; all corresponding rules must be applied without any restrictions.

Note: The media creator is responsible for generating correct meta-header information. If the content of DICOM objects has been taken over from different systems (modality or image archive), the media creating system is not required to correct erroneous DICOM attributes (i. e. violations against the underlying Information Object Definitions of the DICOM standard) in the DICOM objects. These faulty images may cause problems for the receiver of the medium, but the corresponding errors must be corrected at the system creating the objects, not at the media creator.

3.1.3.3 Referenced Patients

The DICOM objects on a medium can be related to one or more patients.

Note: Media containing information about more than one patient are not suitable for media exchange in the common treatment context, because the data of a single patient cannot be handed over to a different person if the treatment context changes. In particular, media handed over to patients must not contain information about other patients. Multi-patient media are permitted for clinical trials or the State Medical Chambers (“Ärztliche Stellen”) in Germany which explicitly requested this capability during the development of this specification.

3.1.3.4 Supported Application Profiles

DICOM application profiles define which kinds of DICOM objects can be placed on which media using which encoding. The following DICOM application profiles are permitted in the context of the Media Exchange Certification Project:

- STD-GEN-CD
- 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
- STD-US-CC-MF-CDR
- STD-XABC-CD
- STD-XA1K-CD

As a special exception, it is permitted to use the STD-GEN-DVD-JPEG application profile on CD media (CD-R and CD-RW).

Note: According to this exception, it is permitted to place DICOM objects containing JPEG compressed (*lossy* or *lossless*) image data on a medium that in other respects conforms to the STD-GEN-CD application profile.

3.1.3.5 Mixing of Application Profiles

Mixed forms of application profiles, where some DICOM objects and related DICOMDIR entries conform to one application profile, and other DICOM objects and related DICOMDIR entries conform to another application profile, are not permitted and are not considered correct.

3.1.3.6 Coding of DICOM Objects

All DICOM objects on the medium must be encoded using permitted transfer syntaxes as defined in the application profile used.

3.1.3.7 Unsupported Object Types

All DICOM objects on the medium shall be based on *Composite IODs*. In particular, it is not allowed to include objects of the following SOP classes on the medium:

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

3.1.3.8 Utilization of Lossy Compression

DICOM image data may be written to a medium using lossy image compression only if the original image data as available to the media creator is lossy compressed.

Note 1: In particular, this rule applies in the context of digital photography or video.

Note 2: Lossy compression can only be used if permitted by the application profile used (see section 3.1.3.4).

3.2 Web Content

Created media may optionally contain Web Content which has to comply with the rules defined in the following sections. In general, these rules ensure a clear organization of the storage medium and simplified access to Web Content, especially for users not experienced with the use of such media.

3.2.1 General Web Content Requirements

3.2.1.1 Derivation of Web Content

If Web Content is included on the medium, it must be derived from the DICOM Content found on the same medium. The derived Web Content must either reflect the complete DICOM Content on the medium or only that part of the DICOM Content that truthfully reflects the clinical condition of the patient at the time of medium creation.

Note: If for example a DICOM Structured Report references some key images out of a larger set of DICOM objects as relevant for the report, then the Web Content may only show the Structured Report in an adequate format along with the clinically relevant key images that are derived from the DICOM Content.

3.2.1.2 Entry Point for Web Content

As an entry point a file named *INDEX.HTM* is used that must be placed in the root directory of the medium (see section 3.2.2).

3.2.1.3 Location of Web Content

All Web Content (except *INDEX.HTM*) must be placed in a single, separate directory located in the root directory of the medium. This directory has to be different from the directory containing the

DICOM Content. There are no restrictions on the directory name. Furthermore, it is explicitly permitted to have subdirectories (including further subdirectories etc.) within the Web Content directory.

Note: The IHE PDI specification requires the Web Content directory to be called "IHE_PDI".

3.2.1.4 Format of Web Content

Web Content has to consist of files coded in XHTML format [XHTML 1.0] with referenced JPEG images [ISO 10918-1], PNG images [ISO/IEC 15948:2003], GIF images [CompuServe GIF], MPEG-1 movies [ISO/IEC 11172] and/or MPEG-2 movies [ISO/IEC 13818] (either generated from the DICOM Content or for navigation inside the Web Content). GIF and PNG files shall only be used for navigation, not for representing medical images.

3.2.1.5 Files not Referenced from Web Content

Inside the Web Content directory there shall not be any file that does not belong to the Web Content itself; in particular, this applies to files/content that can be displayed by web browsers but is not referenced from the Web Content.

3.2.1.6 Conformance to File System used

Depending on the type of storage medium used, file names of the Web Content must comply with the rules of the underlying file system (ISO 9660, UDF). For storage media containing an ISO 9660 file system, a complete access to all Web Content must be possible also on operating systems that only support ISO 9660 (and neither Joliet, nor Rock Ridge or UDF).

3.2.1.7 Display of Web Content

Web Content on a storage medium must be accessible to a user utilizing a usual web browser.

3.2.1.8 W3C HTML Compatibility Guidelines

In order to achieve a maximum amount of interoperability, Web Content must be formatted according to the *W3C HTML Compatibility Guidelines* (see Appendix C in [XHTML 1.0]).

3.2.1.9 Hyperlinks

To enhance operability between operating systems, hyperlinks in XHTML files must consist of lower case characters only (plus the period character as file extension separator).

3.2.1.10 Dynamic Web Content

The use of XHTML is restricted to specific kinds of dynamic content: Dynamic Web Content such as DHTML, Cascading Style Sheets and all scripting languages except JavaScript [ECMA-262] are explicitly prohibited, because no standard exists to assure interoperability between web browsers. The usage of JavaScript is explicitly allowed, even against the background that this might cause problems when using specific browsers. Web Content creators are requested to use portable web code (especially for JavaScript), so that Web Content can be rendered by the usual web browsers. In particular, the failure of JavaScript code shall not result in unusable web pages.

3.2.2 Requirements for the INDEX.HTM File

3.2.2.1 Location of INDEX.HTM File

The file *INDEX.HTM* must be located in the medium's root directory.

3.2.2.2 Content of INDEX.HTM File

The file *INDEX.HTM* must present the following information to the user:

- An informative header containing an identification of the institution that created the medium
- A link to an entry point for the Web Content (derived from the DICOM Content)
- A link to the *README.TXT* file (see section 3.2.3)
- One or more links for starting DICOM viewers (see section 3.2.3.4), if present on the medium

- A link to Other Content (see section 3.4) if present on the medium
- An overview that lists all DICOM Content on the medium in detail
- An overview of all patient data on the medium that does not have a corresponding DICOM counterpart (see section 3.4)

Optionally, a disclaimer statement about privacy/security from the institution that created the interchange media may be present as part of the header in *INDEX.HTM*.

Note: The use of frames is permitted. Therefore, the content as described above can be placed outside of *INDEX.HTM* in another HTML file that is referenced from *INDEX.HTM* as part of a frame set. The requirement is that opening *INDEX.HTM* results in a presentation of the content as described above to the user.

3.2.3 Requirements for the *README.TXT* File

3.2.3.1 Existence of *README.TXT* File

If a medium contains Web Content, the file *README.TXT* must also be present.

Note: It is recommended to write *README.TXT* to the medium even if it does not contain any Web Content.

3.2.3.2 Location of *README.TXT* File

In the case *README.TXT* is written to the medium, it must be placed into its root directory.

3.2.3.3 Content of *README.TXT* File

The file *README.TXT* shall contain the following information:

- Contact information regarding the institution that created the medium
- Information about the software used to create the medium:
 - Name and version of the software
 - Contact information of the software vendor
- General information describing the directory structure of the medium
- Information about any optional DICOM viewer contained on the medium:
 - Supported operating system(s)
 - Name and version number of the software
 - Contact information of the software vendor
 - Disclaimer statement about privacy/security and the intended use of the software
 - List of minimum requirements for executing the software
 - Additional information regarding the use of the software

In particular, *README.TXT* is independent of the clinical information on the medium. Therefore, it is explicitly permitted to write the same *README.TXT* file to all media created by the same software.

3.2.3.4 Additional Content of *README.TXT* File (Recommendation)

Besides the mandatory content described above, the file *README.TXT* should optionally provide the following information:

- Information about the web browsers (including version number) that can be used for viewing the Web Content.

3.3 DICOM Viewer

A DICOM viewer is an executable application used to visualize the DICOM objects on the medium. A medium can optionally contain one or more DICOM viewer applications.

3.3.1 Starting the Software

It must be clear for the end user which file must be executed for launching the DICOM viewer.

Note: It is recommended to provide such information in the file *README.TXT* (see section 3.2.3), if present on the medium.

3.3.2 Reference to the DICOM Viewer from INDEX.HTM

If the medium contains Web Content, the file *INDEX.HTM* must contain links that allow for a start of all DICOM viewers present on the medium.

3.3.3 Execution without Installation and without Administrator Privileges

A DICOM viewer on the medium shall be able to run with normal user privileges, i. e. without administrator privileges. The execution of the DICOM viewer must be possible without the installation of any additional software, i. e. it must be executable directly from CD.

Note: For Windows operating systems, a DICOM viewer on the medium must run without administrator or main user privileges.

3.3.4 Execution on Inappropriate Systems

If the DICOM viewer is launched on a system where the software cannot work, e. g. because of a wrong operating system version or insufficient memory, the viewer must terminate with a corresponding error message and without negatively affecting the functionality of other active programs or the operating system.

3.3.5 Display of all DICOM Objects

A DICOM viewer on the medium must be able to correctly display all DICOM objects present on the same medium based on the requirements described in the DICOM standard.

Note: In certain areas, e. g. primary diagnosis, diagnosis of images under the scope of the German X-Ray Regulation ("Röntgenverordnung"), the German Quality Assurance Guideline ("Qualitätssicherungsrichtlinie") etc., there may be further legal requirements on the properties of a DICOM viewer and the hardware used, beyond the requirements of the DICOM standard. Such additional requirements are not explicitly addressed in this specification, but have to be followed in the corresponding fields of application.

3.3.6 Short Manual in Jewel Case Inlet (Recommendation)

For every DICOM viewer on the medium, it is recommended to add a short manual to the inlet of the jewel case of the storage medium.

3.3.7 Manual in PDF Format (Recommendation)

For every DICOM viewer on the medium it is recommended to include a corresponding manual in PDF format on the medium.

Note: A manual in PDF format belongs to the "Other Content" as described in section 3.4. As an exception from recommendation 3.4.1, the manual can be written to the medium's root directory.

3.3.8 Export of Anonymized Images (Recommendation)

It is recommended that DICOM viewers on the medium should allow for an export of images in anonymized form in a general purpose image format such as JPEG.

3.4 Other Content

In addition to DICOM Content, Web Content and content related to the DICOM viewer, other kinds of content may be included on the medium. These are called "Other Content" in this specification.

3.4.1 Location of Other Content (Recommendation)

It is recommended that Other Content be stored in one or more subdirectories, i. e. Other Content should not be placed in the medium's root directory.

Note: The IHE Technical Framework explicitly forbids writing Other Content to directories having names beginning with "IHE".

3.4.2 Format of Other Content

Other Content can be of any format.

3.4.3 Existence of Corresponding DICOM Counterparts (Recommendation)

There is no requirement that Other Content must have a corresponding counterpart in DICOM format. However, for content being relevant for the current clinical condition of the patient it is recommended to put a DICOM counterpart for this information on the medium.

Note: Supplement 104 of the DICOM standard ("DICOM Encapsulation of PDF Documents") [DICOM Supplement 104] defines the encapsulation of PDF documents into DICOM objects. Based on this mechanism, it is possible to create corresponding DICOM objects and to include them on the medium.

ANNEX A RELATION TO THE IHE PDI INTEGRATION PROFILE

IHE (Integrating the Healthcare Enterprise) is an initiative aiming at an improvement of the exchange of information between IT systems in the health care sector. In the so-called IHE Technical Framework [IHE RTF 6.0], relevant healthcare IT systems are identified and the most important interactions between those IT systems are specified through so-called transactions.

In detail, the IHE Technical Framework is comprised of so-called Integration Profiles, each of them describing a specific application scenario for which an interaction of IT systems is required. In analogy to the goals of the Media Exchange Certification Project, there is an IHE Integration Profile called "Portable Data for Imaging" (PDI). This integration profile is driven by the intention to define actors and transactions to allow for an exchange of media containing diagnostic and therapeutic information with the goal to make this information available at the receiver's side for import, visualization and/or printing.

The following sections describe the differences between the requirements specified in this document and the guidelines provided by the IHE PDI Integration Profile. To simplify the comparison of both specifications for the reader, the corresponding parts of this document and Volume III of the IHE Radiology Technical Framework [IHE RTF 6.0 vol. III] are referenced in the following sections.

In collaboration with IHE, a harmonization of the PDI Integration Profile and the requirement specification defined in this document is in progress. It is expected that this will cause changes to both specifications. Changes to the IHE PDI Integration Profile for the harmonization with this specification that have already been resolved are mentioned below.

A.1 Differences in General Requirements

Regarding the general requirements, the following differences between the DRG specification and the PDI Integration Profile exist:

- **External Labeling of the medium:** While IHE PDI recommends to put the patient's name, the date of media creation and the name of the institution that created the medium, onto the medium (see section 4.47.4.1.2.2.4), the DRG additionally recommends to print birth date, patient ID and date information concerning the studies onto the medium (see section 2.4.1). Both, IHE and DRG, recommend that the kind of content on the medium be labeled: In IHE PDI, the labels "DICOM ONLY" and "DICOM PLUS WEB" are defined. For the DRG specification, no specific requirements are defined in this regard (see section 2.4.1).
[Note: This modification will be integrated into the next edition of the IHE Technical Frameworks and is handled in IHE as Change Proposal TF-6.0-CP-068].
- **Malicious Software:** Regarding malicious software (viruses, trojans etc.), the DRG recommends marking a medium that was successfully tested for the absence of malicious software (see 2.2.2). Furthermore, it is not allowed to write to a (multisession) medium already labeled that way (see section 2.2.3). In IHE, both rules do not exist.

A.2 Differences in DICOM Content Requirements

Differences between IHE PDI and the DRG specifications regarding DICOM content are as follows:

- **Supported Application Profiles:** While IHE PDI just permits the STD-GEN-CD application profile (see section 4.47.4.1.2.3.1), the DRG specification supports 11 different application profiles (see section 3.1.3.4).
- **STD-GEN-DVD-JPEG Application Profile for CD media:** The DRG specification also allows for applying the STD-GEN-DVD-JPEG application profile to CD media (see section 3.1.3.4).
- **Use of lossy compression:** Lossy compression (in accordance with the application profile used) is permitted if the original image data is only available in a lossy coded format (see section 3.1.3.8). Because IHE PDI does not permit compression at all, there is no corresponding rule in IHE PDI.
- **Location of DICOM objects:** The requirement defined by IHE PDI to put all DICOM objects except the DICOMDIR into a separate directory (see section 4.47.4.1.2.2.1) but not into the

medium's root directory is only a recommendation in the DRG specification (see section 3.1.3.1).

- **Directory Records inside the DICOMDIR file:** Regarding the Directory Records inside the DICOMDIR, IHE PDI defines that for each SOP Instance UID exactly one IMAGE, OVERLAY, MODALITY LUT, VOI LUT, CURVE, RT DOSE, RT STRUCTURE SET, RT PLAN, RT TREAT RECORD, PRESENTATION, WAVEFORM or SR DOCUMENT Directory Record has to exist (see section 4.47.4.1.2.3.1.2). Additionally to these twelve explicitly listed records, the DRG specification permits the following Directory Records: KEY OBJECT DOC, ENCAP DOC, RAW DATA, FIDUCIAL, SPECTROSCOPY, VALUE MAP and REGISTRATION (see section 3.1.2.4), furthermore HANGING PROTOCOL (not assigned to a patient) and HL7 STRUC DOC (assigned to patient but not to a study) (see section 3.1.2.4).

[Note: This modification will be integrated into the next edition of the IHE Technical Frameworks and is handled in IHE as Change Proposal TF-6.0-CP-069].

A.3 Differences in Web Content Requirements

Differences between IHE PDI and the DRG specifications regarding Web Content are as follows:

- **Web Content directory name:** While IHE PDI requires the web directory name to be "IHE_PDI" (see section 4.47.4.1.2.3.2), the DRG specification does not restrict the name of this directory (see section 3.2.1.3).
- **Image formats for Web Content:** IHE PDI permits JPEG and GIF as image formats for Web Content (see section 4.47.4.1.2.3.2). Besides these formats, the DRG additionally permits the PNG format (see section 3.2.1.4).
[Note: This modification will be integrated into the next edition of the IHE Technical Frameworks and is handled in IHE as Change Proposal TF-6.0-CP-070]
- **Movie formats in Web Content:** IHE PDI does not support including any movies in the Web Content (see section 4.47.4.1.2.3.2); the DRG permits the movie formats MPEG-1 and -2 in the Web Content (see section 3.2.1.4).
- **Visualization of Web Content:** The DRG recommends listing a web browser with version number inside the *README.TXT* file that can be used for visualizing the Web Content (see section 3.2.3.4). This recommendation is not part of IHE PDI.
[Note: This modification will be integrated into the next edition of the IHE Technical Frameworks and is handled in IHE as Change Proposal TF-6.0-CP-071]
- **Frames in the file INDEX.HTM:** In contrast to IHE PDI the DRG explicitly points out that the usage of frames is permitted in this file.
[Note: This modification will be integrated into the next edition of the IHE Technical Frameworks and is handled in IHE as Change Proposal TF-6.0-CP-072]

A.4 Differences in DICOM Viewer Requirements

In comparison with IHE PDI the DRG specification contains some additional guidelines that are not part of IHE PDI:

- **Running a DICOM viewer:** It must be possible to start the DICOM viewer as a standard user, i. e. without administrator privileges (see section 3.3.3).
[Note: This modification is discussed for the integration into the IHE Technical Frameworks and is handled by IHE as Change Proposal TF-6.0-CP-073]
- **Running a DICOM viewer on inadequate systems:** A DICOM viewer not capable running on a specific system (wrong OS version, insufficient memory), has to terminate (see section 3.3.4) with a corresponding error message and without affecting other running programs or operating system functionality.
- **Visualization of DICOM content:** A DICOM viewer on a medium must be able to display all DICOM objects on the medium (see section 3.3.5).
[Note: This modification is discussed for the integration into the IHE Technical Frameworks and is handled by IHE as Change Proposal TF-6.0-CP-073]
- **Short manual:** It is recommended that for every DICOM viewer on a medium there should be a short manual of the software in the jewel case inlet (see 3.3.6).
[Note: This modification is discussed for the integration into the IHE Technical Frameworks and is handled by IHE as Change Proposal TF-6.0-CP-073]

- **Manual in PDF format:** It is recommended that for every DICOM viewer on a medium there should be a corresponding manual in PDF format on the medium (see section 3.3.7).
[Note: This modification is discussed for the integration into the IHE Technical Frameworks and is handled by IHE as Change Proposal TF-6.0-CP-073]
- **Export of anonymized images:** It is recommended that a DICOM viewer on a medium should permit users to export DICOM images on the medium into a general purpose image format such as JPEG in an anonymized form (see section 3.3.8).
[Note: This modification is discussed for the integration into the IHE Technical Frameworks and is handled by IHE as Change Proposal TF-6.0-CP-073]

A.5 Differences in Other Content Requirements

Regarding the requirements placed on Other Content, the DRG specification and the PDI Integration Profile of IHE differ in the following point:

- **DICOM counterpart for clinically relevant Other Content:** If part of the Other Content is clinically relevant for the current clinical condition of the patient, the DRG recommends writing a DICOM counterpart for this content to the medium (see section 3.4.3). This recommendation is not part of IHE PDI.

A.6 Conclusions

The IHE Integration Profile “Portable Data for Imaging” (PDI) and the DRG specification are not in conflict with each other. An IHE PDI conformant medium is valid in the context of the DRG specification (i. e. follows all mandatory requirements), if the following, additional rules apply:

- It is not permitted to append data to media that has already been labeled regarding the absence of malicious software (i. e. finalization of multisession media).
- If a DICOM viewer is available on the medium, it has to meet some additional requirements: Executable with standard user privileges, adequate behavior when executed on insufficient systems and visualization of all DICOM content on the medium.

The converse implication is not valid: Not every medium conforming to the DRG specification also is conformant to IHE PDI, because the DRG specification is not as strict as IHE PDI Integration Profile on some points.