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The DICOM Conformance Black Paper

What Your Vendors Don't Want You To Know

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The problem with DICOM

Digital Imaging and Communications in Medicine or DICOM, is a global Information-Technology standard that is designed to ensure the interoperability of systems used to Produce, Store, Display, Process, Send, Retrieve, Query or Print medical images and derived structured documents as well as to manage related workflow – at least this is what the official DICOM Homepage (at http://medical.nema.org/) claims.

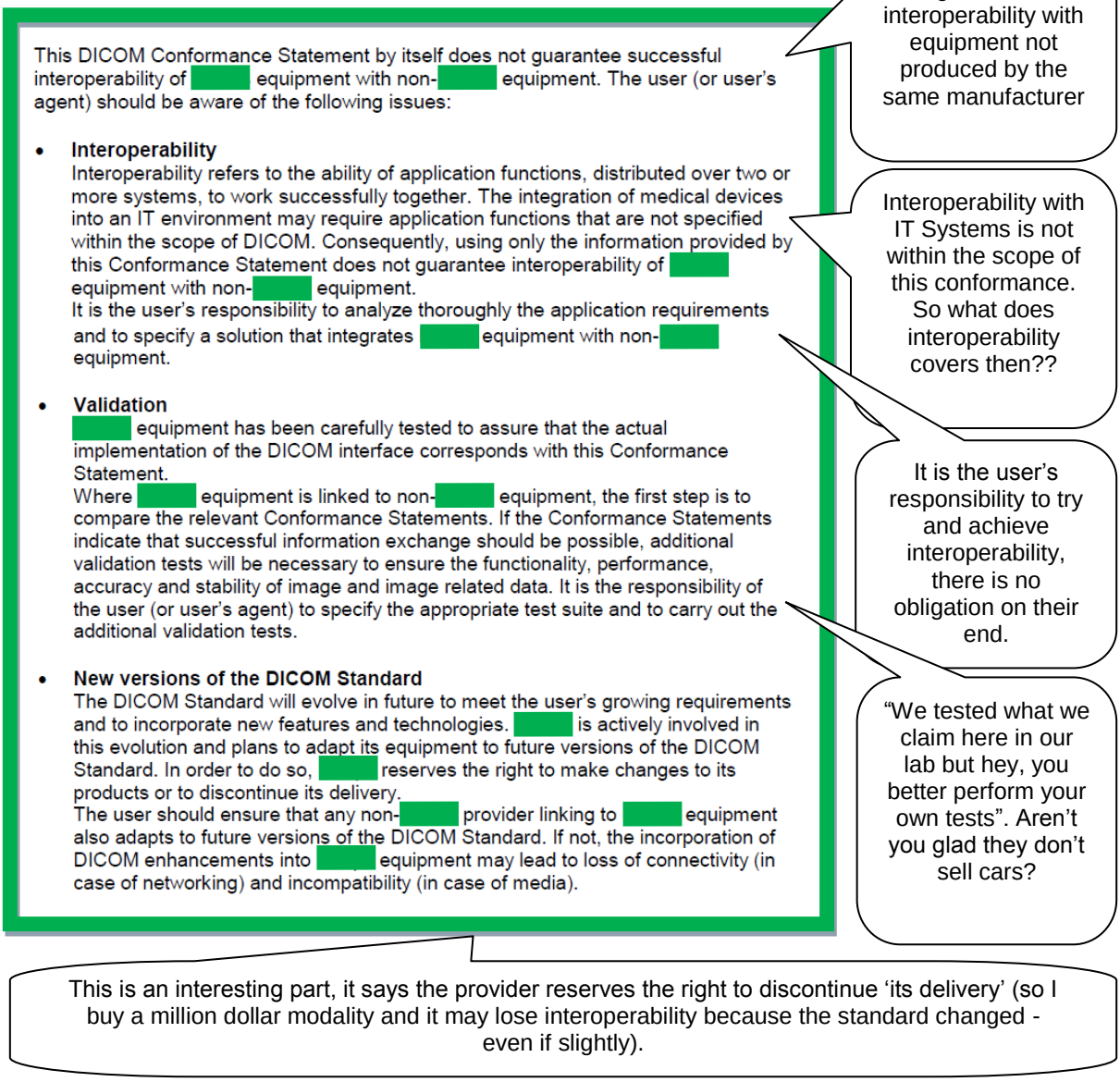
In all fairness, DICOM has played an instrumental role in the quest of achieving medical images interoperability by serving as a common standard but the problem with DICOM is that it is a cooperative standard - this means that DICOM it is not an enforced or governed standard.

To illustrate what a governed standard is, let's use the TCP/IP (for computer networking) standard as an example; regardless of what TCP/IP variant is used (e.g. the multiple versions of Windows, Sun systems, Open Source etc) reliable, guaranteed and spontaneous communication / data exchange will take place in a 'plug and play' manner. This is the level of interoperability a governed standard conveys.

DICOM on the other hand, requires one to first review the DICOM Conformance Statement of the device (e.g. a modality) or software (e.g. a PACS) involved in order to determine exactly how that device conforms to the DICOM standard.

DICOM Conformance Statements - No Guarantees

Now this sound reasonable, while DICOM is not 'plug and play', there is still an established process to verify and determine what parts of the standard a particular device or software supports. Unfortunately, even this process suffers the bane of non governance, to illustrate this, let us examine abstracts of DICOM Conformance Statements from two leading modality and PACS providers (at this point of writing), taken randomly off the Internet.



This DICOM Conformance Statement by itself does not guarantee successful interoperability of [redacted] equipment with non-[redacted] equipment. The user (or user's agent) should be aware of the following issues:

- **Interoperability**
  Interoperability refers to the ability of application functions, distributed over two or more systems, to work successfully together. The integration of medical devices into an IT environment may require application functions that are not specified within the scope of DICOM. Consequently, using only the information provided by this Conformance Statement does not guarantee interoperability of [redacted] equipment with non-[redacted] equipment.
  It is the user's responsibility to analyze thoroughly the application requirements and to specify a solution that integrates [redacted] equipment with non-[redacted] equipment.

- **Validation**
  [redacted] equipment has been carefully tested to assure that the actual implementation of the DICOM interface corresponds with this Conformance Statement.
  Where [redacted] equipment is linked to non-[redacted] equipment, the first step is to compare the relevant Conformance Statements. If the Conformance Statements indicate that successful information exchange should be possible, additional validation tests will be necessary to ensure the functionality, performance, accuracy and stability of image and image related data. It is the responsibility of the user (or user's agent) to specify the appropriate test suite and to carry out the additional validation tests.

- **New versions of the DICOM Standard**
  The DICOM Standard will evolve in future to meet the user's growing requirements and to incorporate new features and technologies. [redacted] is actively involved in this evolution and plans to adapt its equipment to future versions of the DICOM Standard. In order to do so, [redacted] reserves the right to make changes to its products or to discontinue its delivery.
  The user should ensure that any non-[redacted] provider linking to [redacted] equipment also adapts to future versions of the DICOM Standard. If not, the incorporation of DICOM enhancements into [redacted] equipment may lead to loss of connectivity (in case of networking) and incompatibility (in case of media).

No guarantee of interoperability with equipment not produced by the same manufacturer

Interoperability with IT Systems is not within the scope of this conformance. So what does interoperability covers then??

It is the user's responsibility to try and achieve interoperability, there is no obligation on their end.

"We tested what we claim here in our lab but hey, you better perform your own tests". Aren't you glad they don't sell cars?

This is an interesting part, it says the provider reserves the right to discontinue 'its delivery' (so I buy a million dollar modality and it may lose interoperability because the standard changed - even if slightly).

Let us take a look at another abstract of a DICOM Conformance statement taken randomly off the Internet.

No guarantee of interoperability between equipment produced by the **same** manufacturer

The DICOM standard doesn't cover integration (really!?!?)

The use of these DICOM Conformance Statements, in conjunction with the DICOM Standards, is intended to facilitate communication with [redacted] imaging equipment. However, **by itself, it is not sufficient to ensure that inter-operation will be successful**. The **user (or user's agent)** needs to proceed with caution and address at least four issues:

Integration - The integration of any device into an overall system of interconnected devices goes beyond the scope of standards (DICOM), and of this introduction and associated DICOM Conformance Statements when interoperability with non-[redacted] equipment is desired. The responsibility to analyze the applications requirements and to design a solution that integrates [redacted] imaging equipment with non-[redacted] systems is the **user's** responsibility and should not be underestimated. The **user** is strongly advised to ensure that such an integration analysis is correctly performed.

Validation - Testing the complete range of possible interactions between any [redacted] device and non-[redacted] devices, before the connection is declared operational, should not be overlooked. Therefore, the **user** should ensure that any non-[redacted] provider accepts full responsibility for all validation required for their connection with [redacted] devices. This includes the accuracy of the image data once it has crossed the interface between the [redacted] imaging equipment and the non-[redacted] device and the stability of the image data for the intended applications.

Such a validation is required before any clinical use (diagnosis and/or treatment) is performed. It applies when images acquired on [redacted] imaging equipment are processed/displayed on a non-[redacted] device, as well as when images acquired on non-[redacted] equipment is processed/displayed on a [redacted] console or workstation.

Future Evolution – [redacted] understands that the DICOM Standard will evolve to meet the user's growing requirements. [redacted] is actively involved in the development of the DICOM Standards. DICOM will incorporate new features and technologies and [redacted] may follow the evolution of the Standard. The [redacted] protocol is based on DICOM as specified in each DICOM Conformance Statement. Evolution of the Standard may require changes to devices which have implemented DICOM. **In addition, [redacted] reserves the right to discontinue or make changes to the support of communications features, on its products, as described by these DICOM Conformance Statements**. The **user** should ensure that any non-[redacted] provider, which connects with [redacted] devices, also plans for the future evolution of the DICOM Standards. Failure to ensure this could likely result in the loss of function and/or connectivity as the DICOM Standards change and [redacted] products are enhanced to support these changes.

Interaction - It is the sole responsibility of the **non-[redacted] provider** to ensure that communication with the interfaced equipment does not cause degradation of [redacted] imaging equipment performance and/or function.

It is the user's responsibility to try and achieve interoperability, there is no obligation on their end.

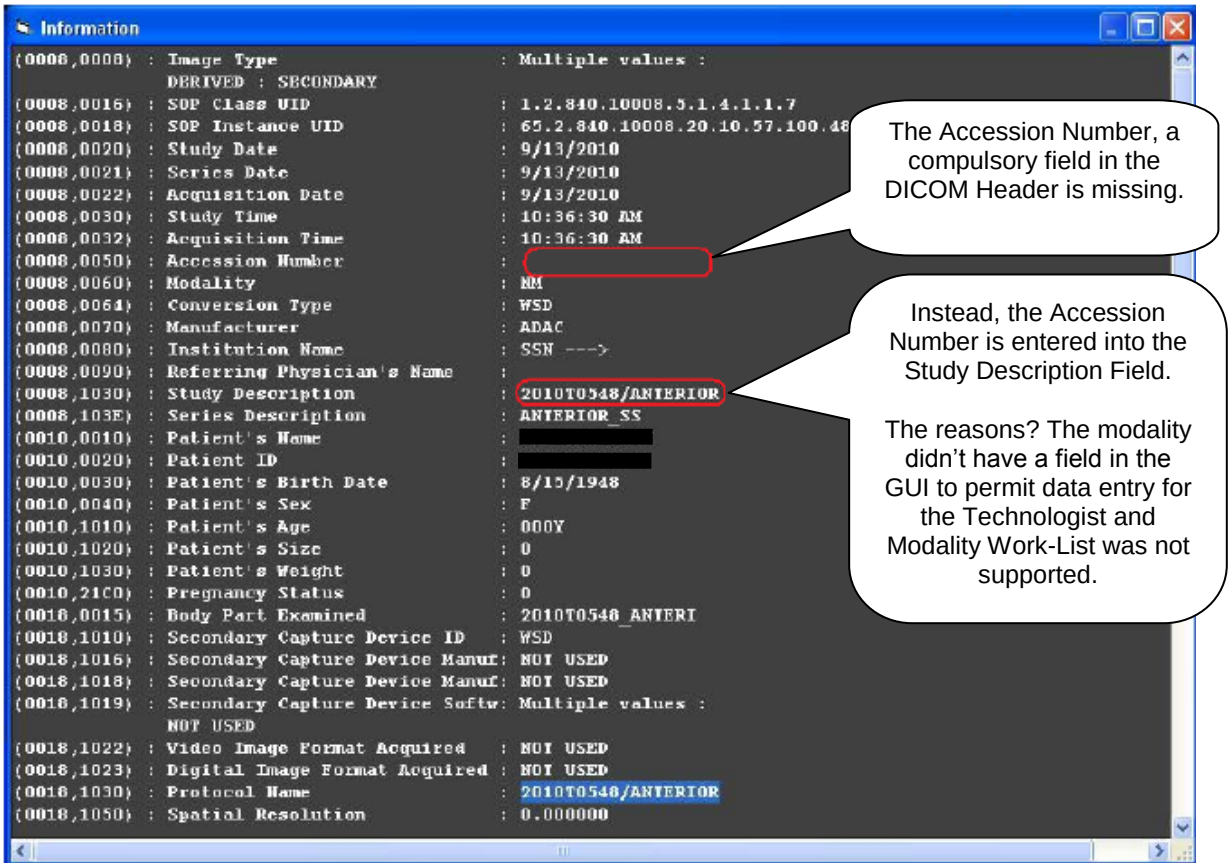
In events you uncover issues pertaining to interoperability, the fault lies with the other guy, go bug the other guy, not them!

Again, the 'reserves the right to discontinue its delivery.

In event you uncover issues other than interoperability (e.g. performance or function) after successful interface, the fault lies with the other guy, go bug the other guy, not them.

Now one might think that it is normal to have disclaimers to limit responsibility in the event of problems or lawsuits, after all, I have seen disclaimer on figurines of 'superheroes' that says "Notice: Actual figurine does not fly" but those of us working in the medical imaging informatics domain will know that it is not the case of 'disclaimer against stupidity' because the problem with DICOM interoperability is very real.

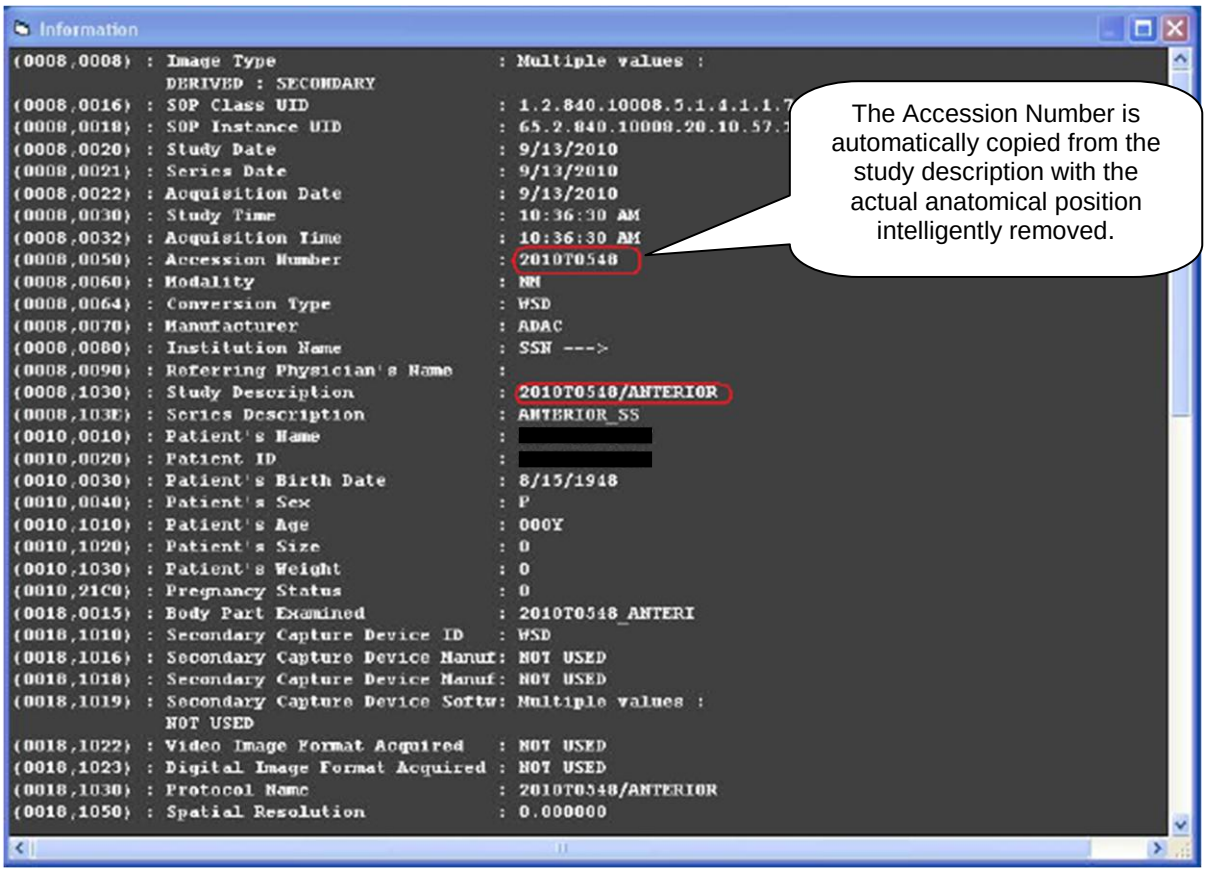
The following example would be a familiar sight for those working in medical imaging informatics;



The problems with such 'dirty data' (non conformance and private tags – vendor specific DICOM Tags understood only by the vendor) in the DICOM Header pose not only problems in workflow across the entire image management lifecycle but also future retrieval of these medical images for reference and diagnosis, all these translates directly to issues pertaining to patient safety and quality of care – the very two aspects that effective Health IT implementation is supposed to help achieve.

Dynamic DICOM Tag Morphing – Attribute Modification

In the quest to achieve true vendor neutrality in the world of DICOM, the concept of dynamic DICOM tag morphing was developed. Essentially, this refers to an application engine that performs rule-based attribute modification to the DICOM Header, normalizing the DICOM tags to ensure it adheres to DICOM Standard (eliminating non-conformance and usage of private tags), hence achieving true interoperability, even for future data migration.



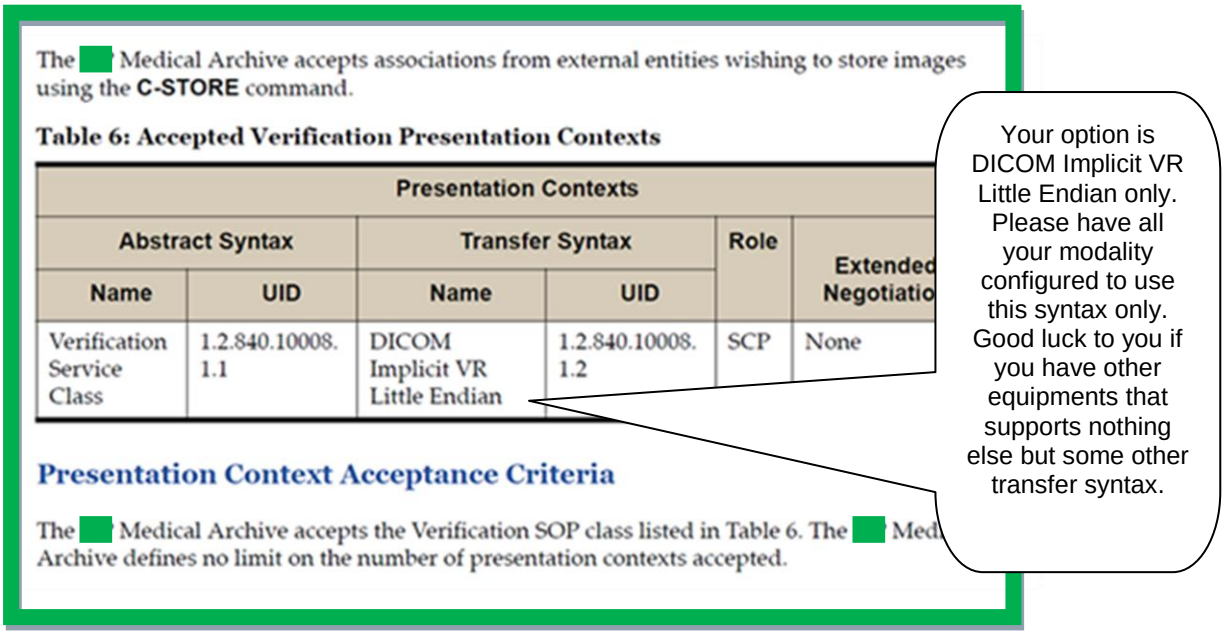
However, having Dynamic DICOM Tag Morphing by itself is not enough, in order to ensure 'backward interoperability' with the providers of these 'dirty data' and private tags, the application engine must also **Bi-Directional Dynamic Tag Morphing** – the ability to store and send the original DICOM file received independently in its pristine form.

Transfer Syntax

In addition to 'dirty data' and private tags, there is also non-conformance in the transfer syntax, the more common ones being;

- Implicit VR Little Endian
- Explicit VR Little Endian
- Explicit VR Big Endian
- RLE Lossless
- JPEG Baseline (Process 1)
- JPEG Extended (Process 2 & 4)
- JPEG Progressive (Process 10 & 12)
- JPEG Lossless (Process 14)
- JPEG Lossless (Process 15)
- JPEG Lossless (Process 14, Selection Value 1)
- JPEG-LS Lossless
- JPEG-LS Near-lossless
- JPEG 2000 Lossless
- JPEG 2000

As the DICOM standard grows, more transfer syntax being added as supplements, a good example would be MPEG2, which is a good addition for clinical discipline like cardiology and endoscopy. Given that there are so many options and ongoing additions, it is understandable if an equipment or software provider misses out an occasional one or two transfer syntax, but how about a total elimination of all options except one?



The [redacted] Medical Archive accepts associations from external entities wishing to store images using the **C-STORE** command.

Table 6: Accepted Verification Presentation Contexts

Presentation Contexts					
Abstract Syntax		Transfer Syntax		Role	Extended Negotiatio
Name	UID	Name	UID		
Verification Service Class	1.2.840.10008.1.1	DICOM Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None

Presentation Context Acceptance Criteria

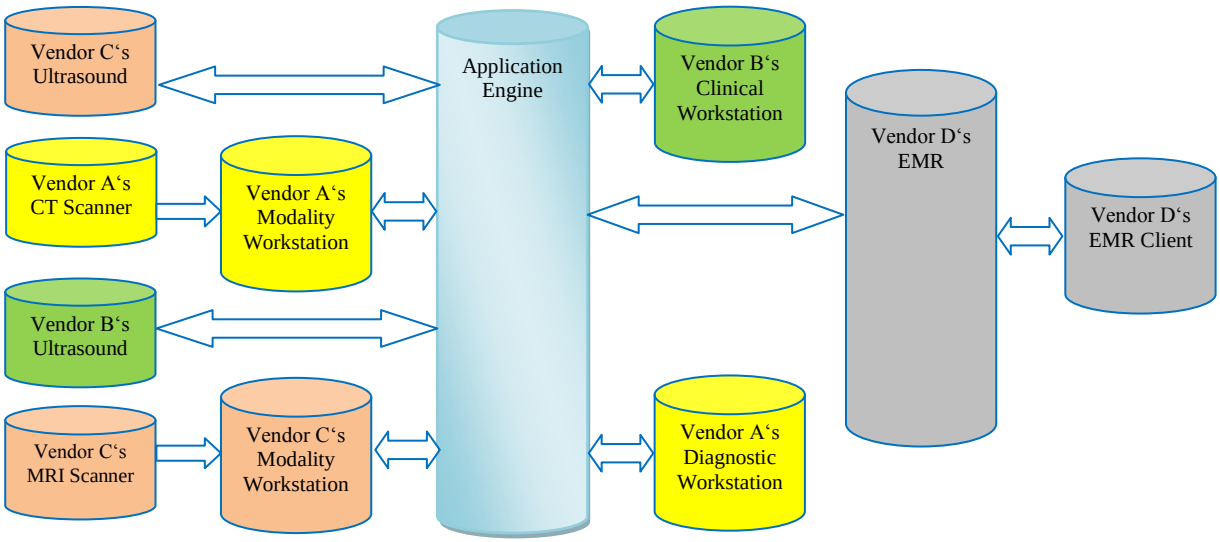
The [redacted] Medical Archive accepts the Verification SOP class listed in Table 6. The [redacted] Medical Archive defines no limit on the number of presentation contexts accepted.

Your option is DICOM Implicit VR Little Endian only. Please have all your modality configured to use this syntax only. Good luck to you if you have other equipments that supports nothing else but some other transfer syntax.

Again, the only way around this limitation is to adopt an application engine that is able to receive data using a vendor's preferred syntax and then transmit those same studies using the preferred syntax of the target system (or in this case, the only syntax allowed) in order to ensure true interoperability.

Other Considerations

In the world of medical imaging informatics, speed is of essence to the interpreting physician (be it a radiologist, cardiologist etc), the industry standard for image retrieval is 3 seconds upon clicking the retrieval button; hence it is of utmost importance that the application engine you choose is able to deliver "on the fly". Ideally, the application engine should sit in between the modalities and the facility' PACS solutions, performing DICOM Tag morphing and routing 'instantaneously'.



How Do We Resolve DICOM Non-Conformance?

In all honesty, there is no cookie cutter solution to how we can resolve this global 'catastrophe', the best method in my opinion is education of folks in a position of procurement and to increase the awareness on problems cause by DICOM non-conformance of devices and software vendors and apply consumer pressure for conformance.

In the meantime, the problem of DICOM non-conformance remains. The good news? An effective Vendor Neutral Archive (VNA) solution with an application engine that performs Dynamic DICOM Tag Morphing and DICOM Transfer Syntax with the speed to match will help bridge the gap and aid in the quest for true interoperability.

The topic of VNA is huge and will take more than a whitepaper to be effectively communicated. To find out more about Vendor Neutral Archive and how it will change the world of medical imaging informatics, please stay tuned for the upcoming release of the Ebook entitled the "**Vendor Neutral Archive & How It Will Change the World** *(of Medical Imaging Informatics)*" a community project by binaryHealthCare.

This Ebook will address related topics including;

- What PACS vendors are not telling you about VNA
- Areas of assessment in selecting a VNA solution
- Best practices associated with VNA in areas of PACS Administration, Change Management, Data Migration etc
- What new exciting possibilities exists for your facility if it achieved an effective implementation of VNA
- Emerging trends in imaging informatics after the impact of VNA

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