

CASE STUDY: DICOM

Draft 2009-05-05 (Mattias Ganslandt, Jonas Andreasson and Martin Sutinen)

Work in progress, comments most welcome!

Brief facts about DICOM

Webpage

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

Organization tagline

DICOM is the leading standardization effort for digital medical imaging

Main standardization areas

Digital medical imaging

Best known standards

DICOM

Organization classification

ANSI-accredited, US-based with a specific focus area.

Does the SSO have any explicit or implicit policy relating to interoperability?

The vendors are responsible to uphold conformance to interoperability through testing. The vendors issues conformance statements to the DICOM standard.

Is there an explicit strategy to facilitate or contribute to interoperability?

DICOM organizes interoperability workshops occasionally, for example together with [ADA](#).

Procedures for testing of a proposed/developed standard with respect to interoperability and backward compatibility?

The vendors do the testing for interoperability and issue conformance statements. Third parties offer testing and validation services.

What are the procedures (internal or external) for implementation?

Implementation rests with the vendors which issue conformance statements.

How is compliance enforced and what are the consequences of defections and deviations from the standard?

Compliance is not enforced by DICOM. There are no particular consequences from being non-compliant but the customers will supposedly react negatively.

Did the SSO develop competing standards for the same or similar type of technical problem?

No.

What is the value of interoperability in the specific area in which the SSO is active?
DICOM is the leading standard in the area of medical imaging and a recognized international standard. Interoperability is valuable but not crucial due to the rather narrow scope and the existence of proprietary solutions.

What is the value of selection and conformity in the specific area in which the SSO is active?
The presence of proprietary standards indicates that selection might not be crucial. Compliance to the chosen technical specification is however very important.

Standardization Process

- Digital Imaging and Communications in Medicine (DICOM) begun standardization activities in 1983 and currently have 50 members.
- DICOM focuses on digital medical imaging standards and currently has produced 20 standards.
- Membership is open to any organization with a material interest in the standard and willingness to contribute but is conditional on approval from present members.
- There are two member classes, Full and Observation. Observation membership is free. Full membership costs 1000 or 5000 USD for companies depending on if it is also a member of any of the organizations [NEMA](#), [COCIR](#) or [JIRA](#). Organizations other than companies can become full members for free.
- All members may participate in working groups but only full members may vote on standards. Non-members can participate by submitting comments prior to approval decisions. Approval requires two thirds majority and formal approval is taken by the DICOM Standards Committee in which all members are represented. There are possibilities to appeal decisions and processes.
- All documentation and standards are publicly available for free. Specified voting information is however not made public.
- The DICOM Standards Committee can decide to initiate new work groups following a proposal of a new work item.

Improvement activities

- DICOM is prepared to revise the technology underlying the standard but currently is focused on improving the functionality. There are currently discussions to give third parties rights to supply copyrighted material by NEMA and this will likely be approved.
- The public can comment on standards during the Public Comment Draft period.
- The working groups and the organization list relationships to other standards.
- The DICOM standard is intended to achieve compatibility between imaging systems and other information systems and increase the efficiency of the workflow within the healthcare environment.
- The future goal of DICOM is to meet the needs of end-users by improving the functionality. Areas considered to be of strategic importance to reach this goal are: security, performance, workflow management, creating documents that are specifically coded and structured for the various clinical domains and finally resolving new modalities of technology.

- DICOM is active within the same standards domain as [ANSI](#), [CEN](#), [HL7](#), [IEC](#), [ISO](#) and JIRA. Cooperation agreements exist with ANSI, CEN, HL7, [IHE](#), ISO and [ITU](#) and liaison with ANSI, HL7, ISO and ITU.

Interoperability

- The IPR strategy of DICOM is RAND or RF as chosen by the patent owner. Copyright of submissions is transferred to NEMA.
- All Committee members are required to disclose any IPR, conditioned that such disclosure does not violate the IPR rights of the applicant, owned by the Member (or employer, affiliate or otherwise connected entity) and known to the Member (as an individual), that is required to implement the DICOM standard.
- DICOM hosts various events displaying connectivity of devices implementing the standard.
- Indirectly DICOM supports internal testing through events. External consultants have specialized in offering services connected to the DICOM standard. Interoperability is confirmed by vendors themselves through testing.

Case study

Digital Imaging and Communications in Medicine (DICOM) is a standard which enables a system for exchange and storage of medical images, by standardization of how technological medical equipment generates images. In the DICOM system only one single data file is generated which contains information about the patient, the scan that has been done and all the images in a three-dimensional format.

The system includes a number of other areas as well, such as for example a specified network protocol for exchange of files. DICOM is a widely accepted standard which is now used to handle images from different scanners in almost all hospitals worldwide.

The development of the DICOM standard, which actually is a family of close to 20 standards which are regularly revised and updated, was originally initiated in 1983 by a committee in cooperation between the [American College of Radiology \(ACR\)](#) and the National Electrical Manufacturers Association (NEMA). The first version was published in 1985, but it was not until the thoroughly reworked third version was published in 1993 that the standard gained wide acceptance. It was also at that time the standard was given the name DICOM.

The DICOM standard is managed by the [Medical Imaging & Technology Alliance \(MITA\)](#), a division of NEMA. NEMA is an American trade association and a standards development organization. However, development of the DICOM standard is not conducted by NEMA, but in the DICOM Standards Committee, which is an independent international committee.

Membership in the DICOM Standards Committee is open for any organization but with the requirements that the organization has to have a direct and material interest in the work of the committee and has to be willing to contribute to the development. Whether a potential member fulfills these requirements is

decided by the current members of the committee. The membership fee for companies is either 1 000 or 5 000 USD annually, depending on whether the company also is a member of one of the organizations NEMA, COCIR or JIRA or not. The fee for biomedical professional organizations is 2 500 USD, while membership is free for other types of organizations. However, organizations which do not meet the membership requirement, as well as individuals, may still be granted observer status. Observation status largely grants the same rights as membership except for the right to vote in ballots. The committee shall always have two co-chairs, one representing a company and one representing a biomedical professional organization, each serving on a two-year term.

Development of specifications is conducted within working groups, of which there currently are 27. These groups are appointed by the committee for specified tasks. Once a working group comes up with a suggested specification, a ballot is held in the committee on whether to approve it or not. Approval requires two thirds of the votes. As such, the development of a new specification is both initiated and approved by the committee while the work is conducted by a small group of experts. The committee does not provide any certification of products which are claimed to be implementations of the DICOM standard. DICOM is a cooperative standard, expected to be upheld by the vendors confirming that any new product is fully compatible with all existing products on the market. However, a number of independent consultants have specialized in offering services related to products supporting the DICOM standard.

The IPR related to any contribution in the standard documentation is transferred to NEMA, and these documents are made publicly available online. Meeting minutes are also made publicly available on the DICOM Webpage. As for IPR related to technologies included in the standard, members are expected to act in good faith and disclose such patents to the committee. The inclusion of such technologies in an approved standard requires that licenses are offered globally under Reasonable and Non-Discriminatory terms. A list of such technologies is also made publicly available on the DICOM Webpage. It should be noted though that for many parts of the DICOM system, such as server-client software for exchange and storage as well as viewers to read DICOM files, there is numerous open source software available.

As an already widespread standard, the work of the DICOM Standards Committee is extremely important, although in a narrowly defined market. DICOM is essential in all attempts to create systems for Electronic Health Records. Hence the committee is regularly working to harmonize the DICOM standard with other standards. A joint group between DICOM and HL7 has existed for a long time to continually enhance the integration of the DICOM system in HL7's much broader system for data exchange within medical care. The DICOM standard has since several years been adopted by CEN as a European reference standard, and since 2006 it is adopted by ISO as well as an international standard. DICOM is also involved in several other collaborations with other organizations focusing on eHealth, such as ANSI, IHE and ITU. The DICOM standard is related to a number of Internet and Web service standards, as the DICOM system is utilizing these standards.

In total, 26 companies and 23 other organizations are members of the DICOM Standards Committee. Among them are a number of large international companies such as [GE Health Care](#), [Siemens Health](#)

[Care](#), [Philips Health Care](#), [Boston Scientific](#), [Carl Zeiss](#), [Carestream Health](#), [Sony](#) and [FujiFilm Medical Systems](#). One of the members is the Swedish company [Sectra Imtec AB](#).

Key success factors

- The small organization gives large influence to voting members
- DICOM originated in the US which is the key developer of medical equipment and gave the organization an influential scope
- Narrow focus means full dedication to the target area, although at the cost of a lower membership rate and thus a smaller financial base
- The requirement of co-chairing from both the industry and the biomedical professional bodies guarantees a balancing of interest and the set terms for chairs ensures that no single organization will have a prolonged and undue influence.
- Intense competition between software packages implementing the standard.