Governance of Picture Archiving and Communications Systems: Data Security and Quality Management of Filmless Radiology

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Preface

Picture archiving and communications system (PACS) is a filmless and computerized method of communicating and storing medical images. Quite a number of professionals including clinicians, medical physicists, radiographers, nurses, computer engineers, and manufacturers are involved in this emerging technology. Most of the professionals found PACS not only a new technology; it also leads the next digital imaging revolution. “Governance of Picture Archiving and Communications Systems: Data Security and Quality Management of Filmless Radiology” is a book intended for radiologists, networks technologists, information technologists and managers, hospital administrators, support and training consultants, quality managers, project managers, healthcare providers and suppliers. Anticipated growth in the take-up of picture archiving and communication systems (PACSs) by healthcare providers throughout North America, Europe, and Asia brings with it promise of a widening need for professionals to manage smooth transitions during, and uninterrupted services after, PACS implementations. Effective change management is vital in the installation of such systems; and the process needs to be planned before the new hardware and software are introduced. The purpose of this book is to explain the key techniques for effective governance of a PACS in filmless radiology operation.

This book is organized in four sections. Section I provides an introduction of PACS and Information Security Management. Chapter I describes the historical development of PACS and its infrastructure. Chapter II depicts the major components of ISO27000 Information Security Management System. Chapter III explains the High Availability Technologies used for the design of a PACS. Chapter IV provides a practical guide on the Implementation of ISO 27000 ISMS.

In Section II, the implementation of filmless hospital is described. Chapter V shows the planning for a filmless hospital. Chapter VI explains different designs of a filmless hospital. Chapter VII discusses the implementation procedure of a filmless hospital. Chapter VII presents the Quality Control, Quality Assurance, and Business Continuity Plan in PACS.
Section III describes the enhancement of key PACS quality dimensions through a Total Quality Management (TQM) approach. This approach comprises an application of Six Sigma, Reliability and Human Factor Engineering tools. This section subdivides into seven chapters that highlight the need to address key PACS quality dimensions individually and collectively. The quality dimensions addressed are: hardware, software, system, and human factors.

Over the last 20 years healthcare leaders seeking to improve quality and enhance patient services have an array of tools to help them in this task. These tools can be broadly grouped into two categories: (1) quality improvement tools—including Continuous Quality Improvement, Six Sigma, and Toyota Production System, and (2) hazard analysis tools—including Healthcare Failure Mode and Effect Analysis, Hazard Analysis and Critical Control Point, Hazard and Operability Studies, Proactive Risk Analysis. Each tool has common origin in the application of the scientific method to process analysis pioneered by Shewhart and Deming; each has unique attributes and advantages. However, a review of current PACS practices and previous research indicates the phenomenon of a fragmented approach in addressing PACS quality issues, thus offering limited discussion of more comprehensive views of PACS quality and practical guidance to its successful implementation and operation. Based on the experience of competing for a Quality Management Award in Hong Kong in 2005 and the subsequent PACS operations research, the authors have developed a cost-effective TQM approach for the enhancement of PACS quality. In this HSSH quality model, analytic and graphical tools are used to deal with each of the four PACS quality dimensions. In Chapter IX, practical PACS problems and feasible methods for the enhancement of the PACS quality dimensions are discussed.

Prior to a treatment of the key quality dimensions, it is essential to define the customer requirements of a PACS. The PACS customers include patients, hospital administrators, nursing staff, physicians, radiologists, quality and maintenance engineers, and so forth. Chapter X describes the process of capturing customers’ requirements through a widely used Six Sigma tool: Quality Function Deployment (QFD). Essentially, the Voice of the Customer (VOC) is a market research technique that produces a detailed set of customer wants and needs, organized into a hierarchical structure, and then prioritized in terms of relative importance and satisfaction with current alternatives. Voice of the Customer studies typically consist of both qualitative and quantitative research steps. They are generally conducted at the start of a new product, process, or service design initiative in order to better understand the customer’s wants and needs, as the key input for QFD, and the setting of detailed design specifications.

There are many ways to gather the relevant information, for example through focus groups, individual interviews, contextual inquiry, ethnographic techniques, and so forth. But all involve a series of structured in-depth interviews, which focus
on the customers’ experiences with current products or alternatives within the category under consideration. Needs statements are then extracted, organized into a more usable hierarchy, and then prioritized by the customers. It is emphasized that the PACS development team be highly involved in this process. They must take the lead in defining the topic, designing the sample (i.e. the types of customers to include), generating the questions for the discussion guide, either conducting or observing and analyzing the interviews, and extracting and processing the needs statements.

Although the concept of VOC may seem straightforward, it is actually quite complex. Surveys, focus groups, and interview processes are not easy to set up in a manner that gathers unbiased data. People often give the answer that they believe the interviewer desires to hear, as opposed to their actual opinion. This leads to biased results that often do not correlate well with the customer’s actual transactions.

Customers have real needs, and healthcare organizations offer real solutions. VOC research is driven by this common interest and a sincere desire to share and listen. Customer driven organizations are the result of technology used to forward the idea that “the common good” can be explored best through democratic systems. Tools such as “Critical to Quality” trees and “Kano” models can help the PACS development team to uncover the specific requirements, and determine their relative importance to the customer.

Besides customer satisfaction, today healthcare demands a high PACS reliability. At the same time, it places ever-increasing demands on medical imaging services that push the limits of their performance and their functional life, and it does so with the expectation of lower per-unit production costs. To meet these demands, PACS design now requires a streamlined and concurrent engineering process that will produce a modern system at the lowest possible cost in the least amount of time. Not long ago, PACS primarily focused on image storage, retrieval, and viewing within radiology departments. Today, it is evolving into a mission-critical component of a broad enterprise system, including billing, management, and an electronic patient record.

Design for PACS reliability provides a systematic approach to the design process that is sharply focused on reliability and firmly based on the mechanisms of hardware and software failures. It imparts an understanding of how, why, and when to use the wide variety of reliability engineering tools available and offers fundamental insight into the total life cycle. Applicable from the concept generation phase of the system development cycle through system obsolescence, design for PACS hardware and software reliability, when integrated with Failure Modes and Effects Analysis (FMEA), Internet flow control and Human Factor Engineering (HFE), would form a coherent design process that helps ensure that the end product will meet PACS administrators’ reliability objectives. Readers will learn to meet
that goal and move beyond solidifying a basic offering to the healthcare industry to creating a quality PACS service.

The selection of probability distributions suitable for modelling PACS hardware or software failure characteristics is typically challenging. Such data often exhibit substantially larger variances than expected under a standard count assumption, that of the Poisson distribution. The over-dispersion may derive from multiple sources, including heterogeneity of PACS components, differing life histories for components collected within a single collection in space and time, and autocorrelation.

Chapter XI shows a novel reliability modelling technique for PACS hardware and software using a widely used spreadsheet. The process of fitting probability distributions to PACS failure data is usually computationally intensive, and it is not feasible to perform this task using manual methods. The authors found that among the failure distributions commonly used in the aviation and manufacturing industries, the Weibull model is used mostly—owing to its ability to represent various failure behaviour. As shown, the mathematically demanding process of verifying the distributional assumption has been simplified to a large extent through the method of matching of moments. This distribution is therefore recommended for PACS reliability predictions. Based on the reliability models constructed for the key PACS components, one can then improve the system reliability through the provision of equipment and/or software redundancy and practical arrangements such as the parallel and cross-linked connections are shown. While most PACS hardware failures are attributed to physical deterioration, software faults are mainly due to design problems. This is mainly due to the fact that most software developers would not spend too much time on non-productive tests and they do not want to see competitors launching a similar product earlier. In this chapter a case study on the detection of critical software errors during the acceptance test is given. The purpose is to illustrate a practical way of evaluating software reliability during PACS development and improvement.

The challenge facing PACS administrators is to design in quality and reliability early in the planning and development cycle. In this regard, FMEA is recommended for analyzing potential PACS reliability problems early in the development cycle where it is easier to take actions to overcome these issues, thereby enhancing reliability through design. FMEA is used mainly to identify potential failure modes, determine their effect on the operation of the system concerned, and identify actions to mitigate the failures. A crucial step is anticipating what might go wrong with a system or its components. While anticipating every failure mode is not possible, the PACS development team should formulate as extensive a list of potential failure modes as possible. The early and consistent use of FMEAs in the PACS design process allows the PACS team to design out failures and produce reliable, safe, and customer-oriented services. FMEAs also capture reliability data for use in future
system improvement. The PACS-FMEA procedure is explained and illustrated through a case study in Chapter XII.

As shown in Section I, the implementation of DICOM into PACS requires the use of standard protocols such as Transmission Control Protocol/Internet protocol (TCP/IP). The IP architecture is based on a connectionless end-to-end packet service using the IP protocol. The advantages of its connectionless design, flexibility and robustness, have been amply demonstrated in the literature. However, these advantages are not without cost: careful design is required to provide good service under heavy load in an integrated system. Indeed, lack of attention to the dynamics of packet forwarding can result in severe service degradation or “Internet meltdown”. This phenomenon was first observed during the early growth phase of the Internet of the mid 1980s, and is technically called “congestion collapse”. In Chapter XIII, the simulation results of a proposed fluid flow model, realized by using inside tcl/tk script executed from Scilab (a free and open software), show that with a certain anticipated level of Internet traffic flow, one can find a practical TCP congestion control method by combining TCP with Active Queue Management (AQM) algorithms. It was found that the algorithms work reasonably well in complex environments involving multiple senders, multi-level routers, and multiple TCP flows.

Corporate culture can help drive healthcare results, but it takes a cultural analysis to differentiate which aspects of the culture can lead to superior performance. In Chapter XIV a cultural comparison adapted from Geert Hofstede’s cultural Dimensions was carried out and the implications for the local PACS community were given. With access to people working for the same organization in over 40 countries of the world, Hofstede collected cultural data and analyzed his findings. He scored each country using a scale of roughly 0 to 100 for each dimension. The higher the score, the more that dimension is exhibited in society. Based on this cultural comparison, suggestions on improving the organizational structure and the communication process have been made. For a PACS regional network to be competitive and successful in a dynamic environment characterized by constantly changing customer demands and technological innovations, it must be capable of rapid adjustment in order to reduce the time and cost needed to deliver to the patient quality healthcare service. The factors critical to the success of a PACS regional network are also noted.

While Statistical Process Control (SPC) is extensively used in the healthcare industry, especially in patient monitoring, it is rarely applied in the PACS environment. Some of the anticipated benefits characteristic to PACS through the use of SPC includes:

- Decreased image retake and diagnostic expenditure associated with better process control.
• Reduced operating costs by optimizing the maintenance and replacement of PACS equipment components.
• Increased productivity by identification and elimination of variation and out-of-control conditions in the imaging and retrieval processes.

Statistical process control (SPC) involves the use of mathematics, graphics, and statistical techniques such as control charts to analyze the PACS process and its output, so as to take appropriate actions to achieve and maintain a state of statistical control. The objective of SPC differs significantly from the traditional QC/QA process. In the traditional process, the QC/QA tests are used to generate a datum point and this datum point is compared to a standard. If the point is out of specification, then action is taken on the product and action may be taken on the process. To move from the traditional QC/QA process to SPC, a process control plan should be developed, implemented and followed. Implementing SPC in the PACS environment is not a complex process. However, if the maximum effect is to be achieved and sustained, PACS-SPC must be implemented in a systematic manner with the active involvement of all employees from the frontline staff to the executive management.

The present study demonstrates for the first time that use of this monitoring tool can be extended to the PACS. The way in which one could construct, choose and interpret control charts associated with PACS condition monitoring is provided in Chapter XV. To illustrate the benefits of implementing the proposed TQM approach in PACS, a successful case based on the HSSH model is given in Chapter XVI. Besides shows the winning details of a project aiming at the 2005 Hong Kong Quality Management Award, the real purpose is to show how the Quality Management Award criteria could be used as a guide to focus improvement methodology on the whole department. A brief description of the judging criteria is given, followed by an outline of the Grand Award holder’s submission and the Project Leader’s explanation of project-related issues during the Judging Panel interview.

A review of the application of the suggested approaches to deal with PACS security and quality management aspects would indicate potential issues for future research and these are given in Chapter XVII. For instance, the HSSH model is particularly useful in examining Human Factors issues in microsystems in healthcare, such as the emergency room or the operating theatre PACS—mismatches at the interface between the components in these PACS microsystems may lead to medical errors. The authors are of the view that the HSSH quality model may have some unexploited potential in PACS overall enhancement. A chart showing the sequence of each section and the corresponding chapters is shown below.
Flow chart showing the sequence of different Sections

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Introduction

INTRODUCTION OF PACS

Picture archiving and communications system (PACS) is a filmless and computerized method of communicating and storing medical image data such as computed radiographic, digital radiographic, computed tomographic, ultrasound, fluoroscopic, magnetic resonance and other special X-ray images. A PACS consists of image and data acquisition, storage, display stations integrated with various digital networks.

A PACS handling images from various medical imaging modalities is called a full PACS. Small-scale systems that handle images from a single modality (usually connected to a single acquisition device) are sometimes called mini-PACS. A hospital-wide PACS is a PACS which entirely replaces conventional X-ray film by displaying digital images on a network of workstations throughout the hospital. This kind of hospital is called a “Filmless Hospital” (Strickland, 2000). In healthcare environment, the practicing of radiology without X-ray film is called “Filmless Radiology”.

PACS replaces hard-copy based means of managing medical images, such as film archives. It expands on the possibilities of such conventional systems by providing capabilities of off-site viewing and reporting (tele-education, tele-diagnosis).
Typically a PACS network consists of a central server which stores a database containing the images. This server is connected to one or more clients via a local area network (LAN) or a wide area network (WAN) which provides and/or utilizes the images. Client workstations can use local peripherals for scanning image films into the system, printing image films from the system and interactive display of digital images. PACS workstations offer means of manipulating the images (crop, rotate, zoom, brightness, contrast and others).

Modern radiology equipment feeds images directly into PACS in digital form. For backwards compatibility, most hospital imaging departments and radiology practices employ a film digitizer.

The medical images are stored in an independent format. The most common format for image storage is DICOM (Digital Imaging and Communications in Medicine) (NEMA, 2008).

There are many benefits of introducing PACS technology into the conventional paper and film-based operation in hospital. Using PACS, it is possible to manipulate a digital image for value-added diagnosis, treatment or surgery. The efficiency of radiographers and radiologists is improved. Errors of radiographers are considerably reduced during data input. Film waiting time for clinicians is minimized and there are no film losses. A PACS can be as simple as a film digitizer connected to a display workstation with a small image database, or as complex as a total hospital image management system. No matter what the scale of a PACS is, like other information systems such as banking, security is always one of the major problems that have to be addressed.

Information security (Calder, 2006) is a large research topic. It consists not only of the disclosure of patient information but it also covers accuracy, accessibility, misuse, mishandling and management of data. In banking and finance industries, billions of dollars have been spent on daily security issues on their information systems which handle our properties and money. Comparing to the healthcare industry, less than one percentage of the annual hospital budget was spent on the security of clinical information systems on which saving of our lives depends.

Before 1999, there was no standard for information security. In 1999, British Standards Institution (BSI) published their BS 7799 standard for Information Security Management System (ISMS) was then adopted by International Organization for Standardization as ISO 17799 which is a code of practice for ISMS. In 2000, BSI published the requirements of BS 7799 ISMS as part II of BS 7799 standard. In 2005, both standards were re-arranged as ISO 27000 series of ISMS standards

The purpose of this book is to provide some information on security issues and handling of security in PACS. It emphasizes the design of a secure PACS and the implementation of ISO 27000 standard on PACS.
HISTORY OF PACS

The principles of PACS (Huang, 1999) were first discussed at meetings of radiologists in 1982. Various people are credited with the coinage of the term PACS. Cardiovascular radiologist Dr Andre Duerinckx reported in 1983 that he had first used the term in 1981. Dr Samuel Dwyer, though, credits Dr Judith M. Prewitt for introducing the term.

In UK, Dr Harold Glass, a medical physicist working in London in the early 1990s secured UK Government funding and managed the project over many years which transformed Hammersmith Hospital in London as the first filmless hospital in the United Kingdom. Dr Glass passed away a few months after the project went live but is credited with being one of the pioneers of PACS.

One of the earliest research projects related to PACS in the United States was a teleradiology project sponsored by the US. Army in 1983. A follow-up project was the Installation Site for Digital Imaging Network and Picture Archiving and Communication System (DIN/PACS) funded by the US. Army and administered by the MITRE Corporation in 1985. Two university sites were selected for the implementation, the University of Washington in Seattle, and Georgetown University/George Washington University Consortium in Washington, D.C., with participation of Philips Medical Systems and AT&T. The U.S. National Cancer Institute funded UCLA, one of its first PACS-related research projects in 1985 under the title of Multiple Viewing Stations for Diagnostic Radiology.

Baltimore Veterans Administration Medical Center

The Baltimore VA Medical Center (Siegel, Kolodner, 2001), operating with approximately 200 beds, has been totally digital except in mammography since its opening in 1994. All examinations are 100% archived in PACS with bidirectional HIS/RIS (Hospital Information System/Radiology Information System) interface. Currently the system serves three other institutions in the region: the VA Medical Center Fort Howard Hospital (259 beds), the Perry Point Hospital (677 beds), and the Baltimore Rehabilitation and Extended Care Facility. Surveys of clinicians have consistently indicated a preference for the filmless system over conventional films. An economic analysis also indicates that filmless operations costs are offset by reduced equipment depreciation and maintenance costs. The general statistics are as follows: radiology department volumes increased by 58%, lost examinations decreased from 8% to 1%, productivity increased by 71%, repeated examination decreased by 60%, and image reading time decreased by 15%. These results suggest that the medical centre and the networked hospitals as a whole have increased healthcare efficiency and reduced operational cost as a result of PACS implementation.
Hammersmith Hospital

When the Hammersmith Hospital (Strickland, 2000) in London, England decided to build a new radiology department, a committee was set up and chaired by the Hospital Director of Finance and Information. A top-down approach was adopted for the hospital-wide PACS project. The hypothesis of the project was that there would be cost savings arising from PACS and at the same time PACS would contribute to increased efficiency in the hospital. Hammersmith Hospital includes the Royal Postgraduate Medical School and the Institute of Obstetrics and Gynaecology. It has 500 beds and serves 100,000 people. The justification of the project was based on direct cost/saving and indirect cost/saving components. In direct cost/saving, the following components were considered: archive material and film use, labour, maintenance, operation and supplies, space and capital equipment, and buildings. Indirect cost/saving comprised of junior medical staff time, reductions in unnecessary investigations, saving of the time of radiologists, technologists, and clinicians, redesignation and change of the use of a number of acute beds, and reduction in the length of stay. Currently the system consists of a 10-terabyte long-term archive, and a 256-giga-byte short-term storage servicing 168 workstations. Since the start of system operation in 1993, the PACS has improved hospital-wide efficiency, the number of filing clerks has been reduced from 8 to 1, 3.3 radiologists have been eliminated, physicist/information technology personnel has increased to 1.5, and no films are stored on site. PACS has a number of advantages over conventional films. These include time savings, space savings, economies in consumables and personnel, reduced patient irradiation, efficiency of data management, accessibility of images, teaching benefits and system reliability.

Samsung Medical Center

Samsung Medical Center, an 1100-bed general teaching hospital, started a four phases PACS implementation plan since 1994. The medical centre had over 4000 outpatient clinic visits per day and performed about 340,000 examinations per year. The departments of orthopaedic surgery, neurosurgery, neurology, emergency room and surgical intensive care unit were selected for the first phase of PACS implementation. The PACS in Samsung serves the following functions: primary and clinical diagnosis, conference, slide making, generation of teaching materials, and printing hard copies for referring physicians. A total of 218 PACS terminals are currently installed throughout all departments, operating rooms and wards, boasting the largest scale worldwide. All examinations and diagnosis are performed digitally except mammography.
Hong Kong Hospital Authority (HA)

In Hong Kong, there are 44 government funded public hospitals under the administration of Hong Kong Hospital Authority. Since 1999, all the territory’s hospitals under the HA network have used a proprietary Clinical Management System (CMS) with Electronic Patient Records (ePR) that tracks a patient’s medical history by allowing all hospitals and clinics to access a patient’s entire medical history. In 2005, a PACS module was added to integrate radiological images with the existing ePR system backbone as part of any patient’s ePR. The radiological information and images have also been centrally available to doctors across all the HA’s hospitals. In the long term, private medical practitioners would be given access to the system as well. This is part of HA’s strategy to foster a closer co-operation between the public and private health sectors in Hong Kong. In the future, HA intends to implement filmless radiology in all of its hospitals.

National Health Service (NHS) in UK

PACS has been available in the UK since the early 90s, so some installations in trusts in England including Norfolk and Norwich University Hospital, Princess Royal Hospital, Telford, St George's Hospital, London, pre-date the work of NHS Connecting for Health's National Programme for IT. Since 2008, NHS PACS has lived in NHS Trusts across England including the following areas:

• Barnsley Hospital NHS Foundation Trust
• Essex Rivers Healthcare NHS Trust
• Hull and East Yorkshire Hospitals NHS Trust
• Mid-Yorkshire Hospitals NHS Trust
• Nottingham University Hospitals NHS Trust
• United Lincolnshire NHS Trust
• Ashford and St Peters NHS Trust
• Royal Free Hampstead NHS Trust

The initiative has the added benefit of saving money, with trusts where the programme is being used reporting an average saving of £250,000 in its first year.

INTRODUCTION OF ISO 27000

The international standard on information security management is ISO 27000 (British Standards Institution, 2005) and the origin of this standard goes back to the days of
the UK Department of Trade and Industry's (DTI) Commercial Computer Security Centre (CCSC). Founded in May 1987, the CCSC had two major tasks. The first was to help vendors of IT security products by establishing a set of internationally recognized security evaluation criteria and an associated evaluation and certification scheme. This ultimately gave rise to the ITSEC and the establishment of the UK ITSEC Scheme. The second task was to help users by producing a code of good security practice and resulted in a "Users’ Code of Practice" that was published in 1989. This was further developed by the National Computing Centre (NCC), and then later a consortium of users, primarily drawn from British Industry, ensured that the Code was both meaningful and practical from a user’s point of view. The final result was first published as a British Standard's guidance document PD 0003, then a code of practice for information security management, and then after having followed a period of further public consultation recast as British Standard BS 7799:1995. A second part BS 7799-2:1998 was added in February 1998. Following an extensive revision and public consultation period, which began in November 1997, the first revision of the standard, BS 7799:1999, was published in April 1999. Part 1 of the standard was proposed as an ISO standard via the "Fast Track" mechanism in October 1999, and published with minor amendments as ISO/IEC 17799:2000 on 1st December 2000. BS 7799-2:2002 was officially launched on 5th September 2002. In 2005, BS 7799-2 finally entered the ISO Fast Track mechanism and emerged on 14th October 2005 as ISO/IEC 27001:2005 after significant re-ordering of controls and general restructuring.

**Tseung Kwan O Hospital**

Tseung Kwan O Hospital is a newly built general acute hospital in 1999 with 458 in-patient beds and 140 day beds. The hospital has several clinical departments including medicine, surgery, paediatrics & adolescent medicine, eye, Ear, nose & throat, accident & emergency and radiology. A PACS was built in its radiology department in 1999. The PACS was connected with the CR, CT, US, Fluoroscopy, DSA, and MRI system in the hospital or clustered hospital. The hospital has become filmless since a major upgrade of the PACS in 2003.

A BS 7799 ISMS was introduced to TKOH PACS in 2003. When it was introduced, a PACS security forum was also established with members from radiologists, radiographers, medical physicist, technicians, clinicians and Information Technology Department (ITD). After a BS 7799 audit was conducted at the beginning of 2004 and it was upgraded to ISO 27000 in 2006, TKOH PACS was the world's first system with an ISO 27000 certified ISMS established.
EIEMENTS OF PACS

PACS is a electronic system which could manage the communication, display, and archiving of diagnostic image information

DICOM Standard

DICOM (Digital Imaging and Communications in Medicine) (NEMA, 2008) (Huang, 2004) is the industry standard for transferral of radiological images and other medical information between computers. Patterned after the Open System Interconnection of the International Standards Organization, DICOM enables digital communication between diagnostic and therapeutic equipment and systems from various manufacturers.

Such connectivity is important to cost-effectiveness in healthcare. DICOM users can provide radiology services within facilities and across geographic regions, gain maximum benefit from existing resources, and keep costs down through compatibility of new equipment and systems. For example, workstations, CT scanners, MR imagers, film digitizers, shared archives, laser printers, and host computers and mainframes made by multiple vendors and located at one site or many sites can “talk to one another” by means of DICOM across an “open-system” network. As a result, medical images can be captured and communicated more quickly, physicians can make diagnoses sooner, and treatment decisions can be made sooner.

The DICOM 3.0 standard evolved from versions 1.0 (1985) and 2.0 (1988) of a standard developed by the American College of Radiology (ACR) and National Electrical Manufacturers Association (NEMA).

ACR-NEMA, formally known as the American College of Radiology and the National Electrical Manufacturers Association, created a committee to draft a set of standards to serve as the common ground for various medical imaging equipment vendors in developing instruments that can communicate and participate in sharing medical image information, in particular in the PACS environment. The committee, which focused chiefly on issues concerning information exchange, interconnectivity, and communications between medical systems, began work in 1982. The first version, which emerged in 1985, specifies standards in point-to-point message transmission, data formatting, and presentation, and includes a preliminary set of communication commands and data format dictionary. The second version, ACR-NEMA2.0, published in 1988, was an enhancement to the first release. It included hardware definitions and software protocols, as well as a standard data dictionary. Networking issues were not addressed adequately in either version. For this reason, a new version aiming to include network protocols was released in 1992. Because
of the magnitude of the changes and additions, it was given a new name: Digital Imaging and Communications in Medicine (DICOM 3.0). The latest version was released in 1996, consisting of 13 published parts. Each DICOM document is identified by title and standard number in the form: PS 3.X-YYYY where "X" is the part number and "YYYY" is the year of publication. Thus, PS 3.1-1996 means DICOM 3.0 preliminary specification document part 1 (Introduction), released in 1996, and PS is an internal ACR-NEMA code. Although the complexity and involvement of the standards were increased by manifold, DICOM remains compatible with the earlier ACR-NEMA versions. The two most distinguishing new features in DICOM are adaptation of the object oriented data model for message exchange and utilization of existing standard network communication protocols.

Although the standard committee is influential in the medical imaging community, in the beginning, medical imaging equipment manufacturers were slow to respond and comply with the ACR-NEMA standards. As the specification of DICOM 3.0 becomes widely accepted, the manufacturers have taken a very cooperative manner and have begun to develop new versions of software and equipment totally based on this standard. Modalities that do not conform to the DICOM standard either follow the ACR-NEMA standard or have their own format. To accommodate the former, a conversion from ACR-NEMA to DICOM should be developed. And for the latter, a translator is needed to convert the manufacturer’s specifications to either the ACR-NEMA or DICOM standard. A set of software modules, collectively called the encoder library, is needed for these purposes. A well-developed encoder library should have the following characteristics:

1. Generic for multimodalities and various vendors’s imaging equipment.
2. Portability to various hardware platforms.
4. Standard programming language, such as C.

The ACR-NEMA standard consists of image format and point-to-point communication standard. Since point-to-point communication has been completely replaced by DICOM network protocols, we will not consider it further. Instead, we focus on its data format, as many existing PACS systems and components are still using ACR-NEMA format standard. Let us use an encoder to explain how images are converted from a manufacturer's modality to ACR-NEMA format standard. According to the ACR-NEMA 2.0 data dictionary, each image should contain two parts: a command group and a data set. The data set can be further divided into information groups: identifying, patient, acquisition, relationship, image presentation, overlay, and image pixel data. The data in these groups, when transmitted across
equipment, constitutes a message. When an image is generated from an imaging modality by a manufacturer, it consists of an image header that describes the nature of the image, and the image pixel values. Since the image header has no standard, its content is pretty much up to the manufacturer. For this reason, not every piece of header information from a modality will have a corresponding group-element category specified in the ACR-NEMA format. On the other hand, not every element defined in the ACR-NEMA dictionary will cover data types included in the image headers of various equipment vendors. Therefore, a minimum set of groups and a minimum set of elements within those groups as the core data structure should first be defined. In other words, all images, regardless of modality and manufacturer, should bear this minimum set once it has been formatted. Additional groups and elements are then defined based on the header information provided by the specific modality and the manufacturer. Additional information can be defined in two shadow groups: display shadow group and a raw header shadow group. The display shadow group stores the information that is vital to support workstation display and provide fast access. The raw header group retains the entire header information to permit the retrieval of data item not formatted, should it become necessary. Additional groups and elements, such as acquisition information (group 0018), relationship information (group 0020), image presentation (group 0028), and overlay (group 6000-60 IE; even numbers only) will be applied depending on the type of information provided by the manufacturers. Dependent on the modality, the numbers of groups and elements to be formatted differ considerably. To provide a systematic way for an encoder program to extract and map data from the image header to the ACR-NEMA format, a configuration file which describes the included groups and elements, is needed for each modality. The encoder of a modality reads in a specific configuration file and calls various module in its program to convert image data to the ACR-NEMA format. The last data group to be converted should be the pixel data group (7fe0), which is attached to the end of the message. In addition, for each modality, these encoders are grouped in a library with all the necessary modules for encoding. This library resides in the acquisition gateway computer to perform the data conversion once the image data has been received from the imaging modality. The general algorithm of converting raw image data into ACR-NEMA format is as follows. First, an image is acquired from a modality. If it is not in the ACR-NEMA format upon arrival at the acquisition gateway computer, it goes through the encoding process and is converted to the standard format. After that, the formatted image is sent to the PACS controller for archiving, and subsequently, is transmitted to display workstations.

The DICOM 3.0 standard provides several major enhancements of the earlier ACR-NEMA versions. Among these are:
1. DICOM 3.0 is applicable to a networked environment.
2. It specifies how devices claiming conformance to the standard react to commands and data being exchanged.
3. It provides guidelines on levels of conformance.
4. It structures as a multiple part document.
5. It uses information objects to describe entities (images, graphics, studies, reports, etc.).
6. It uses the entity-relationship model for uniquely identifying any information objects.

Two fundamental components of DICOM are the information object class and the service class. Information objects define the contents of a set of images and their relationship, and the service classes describe what to do with these objects. The service classes and information object classes are combined to form the fundamental units of DICOM, called service object pairs (SOPs). This section describes these fundamental concepts and provides some examples.

PACS DESIGN

PACS Design Concept

A picture archiving and communication system consists of image and data acquisition, storage, and display subsystems integrated by various digital networks. It can be as simple as a film digitizer connected to a display workstation with a small image data base, or as complex as a total hospital image management system. PACS developed in the late 1980s, were designed mainly on an ad hoc basis to serve small subsets of the total operations of many radiology departments. Each of these PACS modules functioned as an independent island, and was unable to communicate with other modules. Although this piecemeal approach demonstrated the PACS concept and worked adequately for each of the different radiology and clinical services, it did not address all the intricacies of connectivity and cooperation between modules. This weakness surfaced as more PACS modules were added to hospital networks. Maintenance, routing decisions, coordination of machines, fault tolerance, and the expandability of the system became sources of increasingly difficult problems. The inadequacy of the early design concept was due partially to a lack of understanding of the complexity of a large-scale PACS and to the unavailability at that time of certain PACS-related technologies.

PACS design should emphasize system connectivity. It should be a general multimedia data management system that is easily expandable, flexible, and versatile.
in its operation calls for both top-down management to integrate various hospital information systems and a bottom-up engineering approach to build a foundation (i.e., PACS infrastructure). From the management point of view, a hospital-wide PACS is attractive to administrators because it provides economic justification for implementing the system. Proponents of PACS are convinced that its ultimately favourable cost benefit ratio should not be evaluated as a resource of the radiology department alone but should extend to the entire hospital operation. This concept has gained momentum. Several hospitals around the world have implemented large-scale PACS and have provided solid evidence that PACS improves the efficiency of healthcare delivery and at the same time saves hospital operational costs. From the engineering point of view, the PACS infrastructure is the basic design concept to ensure that PACS includes features such as standardization, open architecture, expandability for future growth, connectivity, and reliability. This design philosophy can be constructed in a modular fashion with an infrastructure design described in the next section.

**PACS Infrastructure Design**

The PACS infrastructure design (Nesbitt, Schultz, Dasilva, 2005) provides the necessary framework for the integration of distributed and heterogeneous imaging devices and makes possible intelligent database management of all patient related information. Moreover, it offers an efficient means of viewing, analyzing, and documenting study results, and furnishes a method for effectively communicating study results to the referring physicians. The PACS infrastructure consists of a basic skeleton of hardware components (imaging device interfaces, storage devices, host computers, communication networks, and display systems) integrated by standardized, flexible software subsystems for communication, database management, storage management, job scheduling, interprocessor communication, error handling, and network monitoring. The infrastructure as a whole is versatile and can incorporate rules to reliably perform not only basic PACS management operations but also more complex research job and clinical service requests. The software modules of the infrastructure embody sufficient understanding and cooperation at a system level to permit the components to work together as a system rather than as individual networked computers.

The PACS infrastructure is physically composed of several classes of computer systems connected by various networks. These include radiological imaging devices, device interfaces, and the PACS controller with database and archive, and display workstations. Figure 1 shows the PACS basic components and data flow. This diagram will be expanded to present additional detail in later chapters.
**Introduction**

Interoperability of medical imaging modality, PACS and HIS is a crucial point for determining the effectiveness of the performance of a digital diagnostic radiology department. The common imaging modalities (Dreyer, and Kalra., 2005) used in radiology department include the following technologies.

**Computed Radiography (CR)**

Storage phosphor based luminescence imaging plates (IP) (Seibert, Filipow, and Andriole, 2000) (Huang, 2004), which consists of a photostimulable phosphorus layer made of BaFx:Eu²⁺ (X = Cl, Br, I), europium activated barium fluorohalide compounds, for computed radiography are a new medium for filmless radiography. This technology is based on the principle that after the X-ray exposure, the photostimulable phosphor crystal is able to store a part of the absorbed X-ray energy in a quasi-stable state. Stimulation of the plate by a helium-neon laser beam having a wavelength of 633 nm leads to emission of luminescence radiation, the amount