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