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No. 28

Worldwide Implementation of Digital Imaging in Radiology

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WORLDWIDE IMPLEMENTATION OF DIGITAL IMAGING IN RADIOLOGY

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WORLDWIDE IMPLEMENTATION OF DIGITAL IMAGING IN RADIOLOGY

A RESOURCE GUIDE

IN COOPERATION WITH THE WORLD HEALTH ORGANIZATION

INTERNATIONAL ATOMIC ENERGY AGENCY
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FOREWORD

The application of radiation in the field of human health, for both diagnosis and treatment of disease, is an important component of the work of the IAEA. While much of this work has typically centred on components of radiation medicine such as quality assurance, dosimetry and calibration, more recently it has become apparent that patients can benefit significantly from developments in information technology. This publication is intended to cover issues associated with the introduction of information technology in radiology, which has the potential to make diagnostic radiology more dependable by removing the necessity for film processing, which has an inherently unreliable nature. Digital detector technology can also reduce cost compared with chemicals, film, film handling and film storage. Finally, it has the ability to make expert diagnostic opinion available irrespective of the distance between the place where the image is acquired and the location of the expert. Such technologies have been widely implemented in developed countries; however, the potential for implementation in developing countries is currently still very limited.

In response to the need to advise Member States, and as a result of a request from the World Health Organization (WHO) made through the Scientific Committee of the IAEA/WHO Network of Secondary Standards Dosimetry Laboratories in 2006, work was begun to investigate this topic. Preliminary discussions identified the possible advantages for developing countries arising from (a) the removal of obsolete technologies, (b) greater access to expertise in centralized locations, both within and external to a Member State, and (c) increased effectiveness of training of health professionals through digital archives and rapid external review. WHO has had a long-standing interest in the use of technology in medicine, which includes diagnostic radiology. WHO also identified that a significant number of clinical radiologists had experienced great difficulty with the implementation of digital radiology and that radiology departments could benefit from an unbiased and independent resource guide to assist them. In 2009, a meeting of international experts concluded that a publication on this topic would be useful and viable. In 2010, a second meeting of experts was held, which resulted in a draft of this publication; the publication was then sent for external review by experts with experience in the implementation and use of digital radiology.

This publication is aimed at administrative, clinical and technical staff who are faced with the introduction of digital technology to diagnostic radiology in their clinics. This includes hospital administrators and managers, radiologists and radiographers, technologists, medical physicists and clinical engineers as well as information technology staff. It will ideally also be of interest to government and other funding agencies, including philanthropic and non-governmental

organizations. The publication provides a basic introduction to digital technology and digital networks as well as an overview of the issues to consider when implementing such technology in diagnostic radiology.

The IAEA acknowledges the special contribution of the drafting committee chaired by Shih-Chang (Ming) Wang (Australia), I.D. McLean (Austria and Australia), R. Rankin and D. Veeneman (Canada), S. Kristinsson (Iceland) and D. Clunie (USA). The contributors from the WHO were F. Shannoun, A. Geissbuhler and A. Velazquez Berumen. The IAEA officers responsible for this publication were (in chronological order) I.D. McLean, W.J. van der Putten and H. Delis of the Division of Human Health.

EDITORIAL NOTE

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1. CONTEXT AND AIMS

1.1. INTRODUCTION

Until the end of the last century, the vast majority of medical imaging examinations used film as a medium for image capture, display and storage. The digital image revolution in medical diagnostic imaging, however, began as early as the 1970s with the invention of the computed tomography (CT) scanner. This was followed by magnetic resonance imaging (MRI) in the 1980s and digital X ray acquisition systems (such as computed radiography (CR) and digital radiography (DX)) in the 1990s. The momentum of digital medical imaging has grown to the extent that digital image management is currently the preferred method for medical imaging. The reasons for this include the efficiencies inherent in digital capture, storage and display and the competitive cost structures of such systems when compared to alternatives involving film. Despite this, implementing fully digital medical imaging systems from request to report, including image distribution, remains a non-trivial exercise and is not a turnkey, one size fits all technological solution.

1.2. FILM BASED IMAGING

Before considering digital imaging, it is appropriate to briefly discuss film based radiology. In this type of radiology, a film is used for image acquisition, display and storage. Traditional film based operations require the use of chemicals to develop the film. These chemicals require careful handling, specific storage and usage conditions, special drainage or waste facilities, and have a limited lifespan. In a setting with limited resources, the use of chemicals is a major factor in reliability, quality and cost. Consistent film processing requires:

- A tightly controlled range of processing temperatures;
- Adequate and consistent chemical replenishment;
- The regular replacement of processing chemicals;
- Regular washing of the processing system with clean water;
- Environmental sensitivity demonstrated by appropriate waste disposal.

The chemicals used for film development are sensitive to climate variations, such as high temperature, and oxidize rapidly on contact with air. Failure to maintain film processing systems to a very high standard leads to poor and inconsistent image quality and rapid deterioration of the processed film due

to incomplete washing and chemical contamination, even under good storage and display conditions. Processing chemicals must be:

- Available in a steady and consistent supply;
- Stored under the recommended temperature and humidity conditions;
- Regularly replenished and replaced;
- Used before their expiry date.

The inherent low cost of one sheet of film is deceptive and misleading. General radiology was based on silver-halide film. Such film:

- Is fragile;
- Has a short shelf life, which is further shortened by suboptimal storage conditions;
- Can be affected by poor processing;
- Is the only original of the captured images;
- Can be easily lost or damaged;
- Incurs major costs in handling, storage and retrieval over time;
- Has a limited lifespan;
- Requires specific storage conditions;
- Requires considerable administrative resources to manage.

In a resource limited setting, the use of traditionally processed film is a major barrier to reliability and quality (Fig. 1).

Other drawbacks are that in many countries, film:

- Must be purchased by patients;
- May have expired by the time it is used;
- May have been partly exposed to light before use.

Once film is used for recording of an image, archiving and retrieval are major factors in the reliability of a film based system. In settings where there has been extensive implementation of medical digital imaging, the use and availability of film has dropped drastically. Currently, the widespread adoption of ‘filmless’ digital radiology in developed nations has led to a rapid and marked decline in the use of standard film as a medium for radiological examinations. This has resulted in a substantial reduction in the demand for most medical film, and indeed, some manufacturers have ceased producing conventional film altogether.

FIG. 1. One drawback of using film is the need for a darkroom. This image shows an old darkroom used for manual processing of X ray film (photograph courtesy of David Marsh, Ireland).

Non-silver based laser film is an alternative to traditional silver-halide film with the same advantages, such as portability and the lack of special display requirements. It is increasing in utilization and availability, and offers some advantages over traditional film screen processing:

- Laser printed film is more consistent and reproducible;
- Quality assurance processes are more robust;
- No chemicals are required to print the image;
- Multiple copies can be produced easily.

However, there are also some disadvantages:

- Laser film is more expensive per sheet;
- Laser printers are currently expensive;
- Supplies of laser film in resource constrained environments may be even more limited than for traditional film.

Laser film offers some advantages for a digital imaging system for longer term archive and distribution, particularly when filmless image distribution is not practical. Laser printed film can, if judiciously used, be a useful additional means of image distribution to complement a digital imaging storage system. However, laser film is considerably more expensive than comparable silver-halide film.

1.3. REASONS FOR USING DIGITAL IMAGING

Film based imaging (also called analogue imaging), requires chemical processing of the film to create a medical image. This processing was initially performed manually with all the variability and inconsistency that that entails. The introduction of automatic processors, however, revolutionized the consistency of image quality and efficiency of radiological departments. While the overwhelming majority of radiological examinations take place in the developed world, most X ray departments in developing countries are still restricted to film based imaging, with its limitations, combined with automatic or even inefficient manual film processing.

There are many other reasons to use digital technology:

(1) Efficient information dissemination and increased access to images.
(2) Significantly better dynamic range of digital image acquisition systems.
(3) Improved reliability, error free retrieval of images without loss.
(4) Ease of use.
(5) Potential for multimodality, composite imaging.
(6) Retention of dynamic diagnostic information.
(7) Simultaneous transmission and display of images to multiple geographical areas.
(8) Image manipulation and processing, feature extraction and enhancement.
(9) Ease of interaction between specialists, e.g. between radiologists and referring physicians.
(10) Expertise in subspecialties of diagnostic imaging can be widely disseminated.
(11) Studies are available to authorized viewers immediately after image acquisition.
(12) Examination sequencing and tailoring and the integration of diagnostic data are possible.
(13) Elimination of environmental problems caused by film based imaging.

The challenge for developing countries is to find a methodology that is appropriate to their cultural and financial situation to move effectively from conventional film processing and storage to digital acquisition and display. Although the cost of digital radiology has fallen dramatically in the first decades of the 21st century, it still remains expensive and is technically challenging to implement. It also brings its own challenges for cost effective support, technical sustainability and training.

1.4. BASIC OBJECTIVES AND PURPOSE OF THIS PUBLICATION

For the reasons outlined above — technological, medical, financial, managerial and political — there is an ever increasing move away from film based radiological examinations in favour of digital acquisition, processing and display. This shift is most predominant in the developed world, which has the overwhelming share of resources, such as access to technology and to radiologists for image interpretation. In contrast, however, it has been proposed by the World Health Organization (WHO) that developing countries could also benefit significantly by embracing digital technology for radiological examinations. Digital imaging is a more forgiving technology which has a wider tolerance of radiographic technique. Digital medical imaging also enables teleradiology (the remote review, consultation and interpretation of medical images) to become a practical and effective method to address the uneven geographical distribution of and local shortages of imaging specialists. The increasing role of technology may help to alleviate staff shortages, though other and new roles in technical infrastructure support will be necessary.

The rapid adoption of digital technology and PACS (picture archiving and communications system) in many countries, including some of the main teaching hospitals in Member States, has made it necessary to develop a set of guidelines for the proper introduction and application of this technology and to assist in its implementation. The recently developed clinical audit document for diagnostic radiology [1] does not address this topic, so there is a specific need for a dedicated publication on this.

The purpose of this publication is to identify resources based on standards to enable radiological facilities to function in a digital communication environment. This should increase the quality of radiological imaging using digital equipment, particularly in a low resource setting. It is acknowledged that this covers a wide spectrum of possibilities, and two particular scenarios are given attention; the first

is a developing country that wishes to make a transition from hand processing of film to a digital solution, and the second, a more developed facility that requires more sophisticated digital image communication systems.

This publication recognizes the importance of the goals of both WHO and IAEA of sustainability and system maintenance. It also acknowledges that the large diversity and level of development of clinical radiology services in Member States make it likely that a graded approach to standards and implementation of digital technology will be adopted.

1.5. SCOPE AND TARGET AUDIENCE

This publication examines many of the issues surrounding digital image acquisition, storage, display and distribution, and acts as a practical guide for anyone who is considering the implementation of digital imaging, including teleradiology. It should also be helpful to those users who are considering an upgrade of their existing imaging facility.

Although radiology encompasses a wide range of different modalities, the prime focus of this publication is on X ray equipment. This equipment still accounts for the vast bulk of examinations carried out worldwide and also requires the extensive storage of images. This is not the case with ultrasound, for instance. Nevertheless, the general principles and recommendations in this publication will be valid for every imaging modality.

The target audience for this publication includes all those involved in the provision of radiology services. This includes radiologists, radiographers/technologists, other attending and consulting medical staff, hospital administrators including finance directors, civil servants within a country's Ministry of Health, medical physicists, biomedical engineers, IT specialists and their staff, and philanthropists.

The sections of this publication are self-contained and can be read in isolation. To enable each Section to be used independently, there is some duplication of content. Table 1 gives a summary overview of the content and target audience of each section.

TABLE 1. SECTION INFORMATION AND TARGET AUDIENCE OF EACH SECTION OF THIS PUBLICATION

Section	Summary of section content	Section target audience
1	Introduction	All staff involved with, or interested in, the introduction of digital technology in radiology.
2	Section 2 provides a basic introduction to all aspects of digital radiology. It should provide a basic understanding of the principles and practices of digital imaging.	Non-technical readers faced with the requirement to implement a digital radiology system.
3	Section 3 discusses in some detail the technical issues and the IT standards associated with the use of digital imaging systems and IT networks.	Technical staff involved with the implementation and support of digital radiology installations such as equipment vendors, medical physicists, clinical engineers and IT staff.
4	Section 4 concentrates on more practical issues related to the implementation of a digital radiology system, be it a small, single room unit with one workstation, to a more complex, hospital-wide PACS.	It is aimed at individuals involved in the implementation of digital radiology, from radiologists and technologists, to hospital management, building and maintenance staff, IT staff, medical physicists and bioengineers.
5	Section 5 addresses issues such as the maintenance of equipment and the training of staff. It also discusses the sustainability of the digital radiology system.	It is aimed at individuals who are responsible for the management of digital radiology and the management and training of staff who have to work with it. This includes radiologists, technologist managers, to hospital management, medical physicists and bioengineers.
6	Section 6 describes the practical implementation of digital radiology and presents a number of implementation scenarios, which illustrate the different benefits digital technology can bring.	This section is aimed at all individuals involved in the implementation and subsequent operation of digital radiology, from radiologists, technologists, to hospital management, building and maintenance staff, IT staff, medical physicists and bioengineers. It is also aimed at funding agencies, such as governments and non-governmental organizations, which are funding such equipment.

2. DIGITAL RADIOLOGY: A BASIC OVERVIEW

This section provides a basic introduction to all aspects of digital radiology, is written with a non-technical reader in mind and should provide a basic understanding of the principles and practices of digital imaging. It is aimed at those who find themselves faced with the requirement to implement a digital radiology system, be it a small single X ray unit, or a complex hospital-wide system involving multiple units and modalities and distributed X ray reporting.

2.1. DIFFERENCES IN LOCAL AND NATIONAL HEALTH CARE SYSTEMS

2.1.1. Technical capabilities

Medical imaging requires the combination of an adequate infrastructure that includes well-maintained equipment, suitably trained personnel and a quality assurance programme which ensures that diagnostically and clinically valuable information about the patient under examination is obtained using the minimal amount of radiation. The provision of a sustainable, high quality, safe and effective medical imaging service requires that all these factors be in place. The purchase and installation of the appropriate imaging equipment is a necessary pre-condition, but this alone is insufficient to ensure that such a service can be provided or sustained.

The availability of imaging services is highly variable between countries, but also within countries, irrespective of their development status. Even in low income countries, major medical centres based in capital cities tend to offer most modern imaging modalities, almost regardless of the per capita gross national income. It is in smaller regional centres and rural areas that the discrepancy between developed and developing nations becomes very apparent in relation to medical imaging capabilities.

These discrepancies exist in all but the wealthiest nations, particularly with regard to availability of the skilled workforce required to deliver such services to acceptable standards, with the ability to ensure a reliable and consistent service. By and large, the purchase and installation of equipment tends to be the simplest step in obtaining imaging services, and it can be argued that this is less important than ensuring such services can be delivered, utilized, interpreted and maintained in an effective manner in clinical practice. In this, a well-trained and skilled workforce is essential. Vendors can be very effective in installing digital

radiology technology, but achieving the change in people and processes necessary for the digital world is considerably more difficult.

Digital medical imaging solves some technical issues inherent in film based imaging, but creates many others, which can also be very complicated. The ability of digital imaging to be more consistent in image production than traditional methods, to allow teleradiology and thereby to solicit expert opinions from remote sites is counterbalanced by increased technical challenges. These include ensuring the availability of reasonable quality power supplies, telecommunications infrastructure, and the transport and installation of such equipment, together with the hiring of the expert personnel required to utilize it effectively. Therefore, the technical capabilities necessary for providing effective imaging services are clearly beyond simple physical infrastructure.

2.1.2. Health care infrastructure

In general, the nature of the health care infrastructure tends to dictate the level of technology required to deliver effective imaging services. In low income countries, in particular, the quality of electricity, water and telecommunications can have a major impact on the effectiveness of these services. The availability of suitably trained service personnel and the appropriate parts for any repair of the equipment in use is crucial to enable a reliable and consistent imaging service. As the availability of resources varies in different settings, it is salient to consider them separately, differentiating between urban and rural, hospital and clinic, and to consider remote and crisis settings.

In low income countries, particularly in the urban environment, there is generally a higher level of expertise, utilities and amenities available than in rural settings. This usually means that high end imaging facilities offering technologies such as computed tomography (CT) or magnetic resonance imaging (MRI) are limited to urban centres, with rural clinics restricted to simpler technology (X ray and ultrasound). However, greater diagnostic efficiency may be attained by the use of equipment that is less operator dependent (such as CT). Special situations that are relevant to many countries are when crises occur, such as natural disasters, warfare or large scale refugee situations. Recently, these have been seen during tsunamis and earthquakes in Asia and South America, and in civil wars all across the globe. During such crises, the provision of emergency medical services through foreign aid and internal mobilization of medical personnel is commonplace. When infection and trauma are significant considerations (as often occurrs during armed conflict and in refugee camps), imaging has a vital role to play in patient management.

Digital equipment is especially sensitive to adverse climatic and environmental conditions such as humidity, moisture and extreme temperatures. Such conditions are likely to be prevalent in low income countries. To minimize the impact of such conditions, there are a wide range of technical solutions available, notably:

— Transportable equipment using mobile vans or trailers;
— Reliable power supply using portable power generation systems;
— Appropriate weatherproof protected installation;
— The capability of operating under a wide range of temperatures.

These elements are discussed in more detail in this section and in Section 4.

2.1.3. Workflow and productivity

In general, digital imaging workflow has many similarities to traditional film based systems. However, it is critical that each patient is uniquely identified in a consistent manner. This will ensure that the images for each patient are correctly and permanently linked within the database. There are well-documented and established DICOM (Digital Imaging and Communication in Medicine) standards that define these processes, and most modern digital imaging equipment is compliant with one or more of the standards which make up the DICOM framework. A major benefit of DICOM is its independence both from vendors and from the underlying network technology. According to the DICOM strategic document [2]:

> "Independence from the underlying network technology allows DICOM to be deployed in many functional areas of application, including but not limited to communication within a single site (often using various forms of Ethernet), between sites over leased lines or virtual private networks (VPNs) within a metropolitan area (often using asynchronous transfer mode), across dial-up or other remote access connections (such as by modem, ISDN or DSL), and via satellite (with optimized protocol stacks to account for increased latency)".

Another aspect of digital imaging is its positive impact on productivity and throughput. In general, the improved consistency, reliability and reproducibility of digital imaging compared with conventional film based approaches to image capture and storage result in improved productivity. This means that the same staff can examine more patients in a given time, and the images can be displayed and reviewed rapidly and more consistently by more people. Other

major advantages of digital image management are: freedom from geographic constraints; elimination of chemical processing; increased information content (due to increased dynamic range); and elimination of physical film handling and storage.

2.1.4. Financing a radiology service

The delivery of medical imaging services will depend on a combination of financial resources available for the service, the education and training of the workforce delivering them and the political will behind them, factors which may not be linked to the resources and technical capabilities available in a country in general. For digital imaging, these factors determine the type and level of equipment and the facilities and staff available, since the capital acquisition cost of digital imaging equipment is generally more expensive than that of film based systems. However, low end ultrasound equipment, CT, MRI and nuclear medicine may enjoy a cost advantage due to the lack of film usage in most practices with these capabilities.

In countries where labour costs are low, the capital cost of equipment is often perceived to be the main limiting factor in implementing an imaging service. Funding efforts are often skewed towards the procurement of equipment, rather than ensuring that sufficient staff are employed and trained to provide a high quality, reliable and consistent service. Furthermore, the cost of maintenance, spare parts and software upgrades is often underestimated at the time of purchase and therefore not adequately budgeted for. It is crucial, then, that the appropriate total cost of ownership (TCO) is considered in the purchase, maintenance, staffing and running of any medical imaging device over the projected lifetime of the equipment.

2.2. DIGITAL IMAGING AND INFORMATICS REQUIREMENTS

Digital imaging offers many advantages over conventional film based imaging, the most compelling of which is the ability to store, retrieve, distribute and review images at any time and in any location which is appropriately networked. This means that the referring physician, the patient and the radiologist can all be in different locations, both to one another and to the stored image, but still communicate effectively. They do not even need to communicate at the same time. Imaging informatics involve the computerized management of imaging data and related information, extending from patient demographic information and referral data to reports, statistics and image diagnosis, review and distribution through teleradiology platforms [3]. Digital medical images

are typically managed in a dedicated image network and database known as a picture archiving and communications system (PACS), whereas all other patient information is typically recorded in a Radiology Information System (RIS).

2.2.1. PACS/RIS

A PACS is a system used for the storage, distribution and review of medical images. A RIS is an information system where patients are registered, examinations are scheduled and radiologists' reports are recorded, stored and distributed. The RIS can also provide management information and may hold information that is important for revenue generation. Needless to say, a PACS and a RIS need to work seamlessly together. Proper integration of the RIS and PACS can provide productivity improvements in radiology departments resulting in, for instance, faster study turnaround times for patients and clinicians.

PACSs, although still not universal, are now common in developed nations for the archiving and distribution of medical images. However, there are significant barriers to the seamless sharing of images between relevant medical practice settings. These are partly technical (e.g. lack of appropriate interconnected network infrastructure), partly logistical (e.g. lack of a universal and unique patient identification system), partly political (e.g. unwillingness of institutions to share medical data) and partly legislative (e.g. patient privacy, information security).

The recent widespread deployment of PACS has revolutionized medical care through medical image communication. Within a hospital, immediate availability of images and reports is possible for physicians who have requested X ray examinations. Large countries with a relatively scattered radiology workforce can be serviced from major centres by PACSs in large networks. Centres with limited expertise in specific imaging modalities, or in less common diseases, are able to obtain expert opinions from subspecialists located in major centres. Such opinions are often obtained during a live conversation, either via voice over IP or telephone, and can dramatically and rapidly alter the management of any patient.

There are, however, still many technical problems inherent in PACS installations that require intense preparation and troubleshooting, particularly in the planning and initial implementation phases (Appendix I). The implementation of digital image capture does not require PACS. Digital radiology equipment can work without PACS or its requirements. However, the archiving, storage and transmission of such images in a seamless and efficient manner requires at least a minimal PACS to function.

While it is entirely feasible to organize and manage a digital imaging service using a PACS alone, the absence of a RIS will mean significant limitations. These will be in terms of lack of integration with hospital information systems, and

of difficulties with the consistency of patient identification and the management of multimodality and multiservice imaging data over time. Patient and room scheduling, radiology workload balancing and the automatic scheduling of patient lists on imaging equipment are more difficult without a RIS. The RIS is also a more effective means of managing report transcription, storage and distribution than a PACS. Furthermore, it is very difficult to manage image data for the same patient across more than one imaging centre without a RIS to match patient and image data and without the ability to merge the patient image data in a logical fashion.

Ultimately, a RIS allows for much more effective design of workflow, improves efficiency and reduces the chance of redundant data entry, duplicates and incorrect patient data entry. However, for many smaller clinics with a low to moderate case load, it may not be necessary to purchase and install a full RIS, as this adds significantly to the cost and complexity of installation, and also increases the need for training and service support.

2.2.2. Teleradiology

Teleradiology can be defined in many ways, but for the purposes of this publication, it is considered to be the transmission of a full set of full resolution, full integrity images to a centre distant from where the images were acquired, for one or all of these purposes:

— Primary diagnostic interpretation;
— Expert secondary consultation;
— Preoperative surgical planning.

Thus, teleradiology is to be clearly distinguished from the situation in which a small number of limited quality images are sent primarily for the purposes of discussion or demonstration. An example of the latter is, for instance, when non-medical communication technologies such as mobile telephony or email are used. Most mobile phones and other forms of portable computing currently in use have limitations in memory size, networking and processor speed, and are therefore unlikely to be used for primary diagnostic interpretation and reporting. However, this situation is changing rapidly and it can be expected that in the near future, such devices will become increasingly important in the sending and reviewing of medical images.

Teleradiology can be performed locally (and even within the same facility), between buildings in the same grounds, or in collaboration with other health facilities anywhere in the world. It offers alternatives to traditional imaging

interpretation approaches, which require on-site staff capable of radiological interpretation. Teleradiology can:

— Improve access to expert medical opinion, either for primary or secondary interpretation;
— Provide access to medical image reporting for underserviced centres;
— Support patient consultations and inform patient treatment decisions (for instance, on the need to transfer patients to a higher level of care facility);
— Provide access to image interpretation for remote regions;
— Provide reporting in shifts to provide timely interpretation after normal working hours;
— Balance reporting workloads between centres with differing levels of staff to ensure timely turnaround of reports.

The effective provision of a medical imaging report depends on the availability of an appropriate clinical request form including relevant clinical detail, and may also need access to relevant prior studies. This means that effective teleradiology services are possible even when the requirements for a full fidelity image set cannot be met. Despite these advantages, several important factors must be considered to provide sustainable and effective teleradiology services:

— Image transmission technologies;
— Archive and distribution systems;
— Quality of medical image displays at the site of interpretation;
— Medical registration, credential checking and establishing indemnity for reporting radiologists;
— Funding to support payment for remote interpretation;
— Compatibility of information systems so that reports can be transmitted back to the originating site;
— Accuracy and relevance of reports from remotely reported studies;
— Access to relevant prior studies;
— There may be less consultation between clinicians and radiologists to establish the most appropriate imaging test (or no test) for the given clinical situation.

A number of professional and national organizations have addressed these issues, and have developed standards mandating or recommending that specific technologies and approaches are used in teleradiology implementations. Some of these documents are referenced in the appendices.

2.2.3. DICOM and compliance with the Integrating the Healthcare Enterprise initiative

In general, all modern imaging equipment will capture images in a format compatible with the DICOM standard published and updated by the Medical Imaging Technology Alliance, a division of the Association of Electrical and Medical Imaging Equipment Manufacturers (NEMA), on whose web site the standard is openly available.

DICOM is a standard for medical device intercommunication and for the storage and transmission of medical images. The standard preserves fidelity and metadata on each image and examination, and in particular, specific patient identification and the details of image acquisition. The DICOM standard can properly preserve cross-sectional imaging data from modern multislice tomographic imaging systems such as CT, MRI, positron emission tomography (PET) and single photon emission computed tomography (SPECT). It then allows manipulation and reconstruction of the images using various software tools, which can enhance depiction and visualization well beyond that possible with the originally captured image data. DICOM formats retain the full fidelity of the acquired image and also contain metadata that:

— Identify the patient;
— Identify the equipment used for the examination;
— Describe the examination type and date;
— Retain the order and collation of images into series within an examination;
— Describe the manner of acquisition (e.g. pulse sequence parameters, X ray factors);
— Describe the image characteristics (e.g. slice thickness, location, acquisition matrix);
— Store the desired image display parameters specific to that examination;
— Store the presentation modes specific to that type of examination.

Under the DICOM standard for storage and transmission, if images have been acquired with more than 8 bits of display data, this full dataset is preserved to permit interactive window width and level changes to be made, to optimize detection of pathology and to display normal anatomy.

DICOM images may be compressed for the purposes of storage and transmission, typically being compressed to half or one third of the original image data size. Sets of images may be large and thus impose a significant storage and transmission burden. Lossy compression is where some of the original image data are irretrievably discarded. Because of the concern over medico-legal and future diagnostic capabilities, most sites routinely store only uncompressed images, but

often use web based distribution methods that automatically scale and transmit the images to a compressed lower resolution and faster transmission format to match the receiving computer display resolution, only sending a full data image on demand (progressive to lossless transmission). In general, the maximal fidelity of the captured image should ideally be preserved whenever possible for diagnostic reasons. For some referral, consultation and review purposes, images can be transmitted in various lossy compression schemes to optimize the speed of transfer. JPEG or JPEG 2000 is often used, both within DICOM and on web servers. Additional details on image compression can be found in Appendix II.

The amount of lossy compression permitted to achieve diagnostically acceptable irreversible compression depends on the diagnostic task. Various efforts have been made to define acceptable levels of compression for different tasks, but these are not universally accepted (Table 2) [4]. It is difficult to make general statements about the type or amount of compression that is appropriate to any particular modality, disease or clinical application to achieve a diagnostically acceptable goal. Scientific literature and national guidelines may assist the user in choosing appropriate types and amounts of compression, weighing the risk of degraded performance against the benefits of reduced storage space or transmission time [5].

TABLE 2. MEDICALLY ACCEPTABLE COMPRESSION RATIOS IN DIFFERENT COUNTRIES

Modality	UK	Canada (JPEG)	Canada JPEG 2000	Germany
Radiography — chest	10	30	30	10
Radiography — skeletal	10	30	20	10
Radiography — body	10	30	30	10
Radiography — paediatric	—	30	30	—
Radiography — mammography	20	25	25	15
CT — head	5	12	8	5
CT — skeleton/chest/lung	5	15	15	8
CT — body	—	15	10	10

TABLE 2. MEDICALLY ACCEPTABLE COMPRESSION RATIOS IN DIFFERENT COUNTRIES (cont.)

Modality	UK	Canada (JPEG)	Canada JPEG 2000	Germany
CT — angiography	—	15	15	—
CT — paediatric	—	15	15	—
MRI	5	24	24	7
Nuclear medicine	—	11	11	—
Ultrasound	10	12	12	—
Digital angiography	10	—	—	6
Fluoroscopy	—	—	—	6
Images for radiotherapy planning	None	—	—	—

In most countries (by no means only in low income countries), network transmission speed limitations can be problematic owing to the following reasons:

— Public network infrastructure is often limited outside metropolitan regions.
— Private network infrastructure is often limited to wireless or telephone line connections such as ADSL (asymmetric digital subscriber line).
— Government or public organization network infrastructure may be of limited capacity.
— Even if connectivity between hospitals and clinics is well-established, connectivity for other referring physician sites may be very limited.
— There is often a dominant telecommunications company (or monopoly) that limits competition. This tends to be particularly the case for high speed networks (such as symmetrical cable or optical fibre connectivity). This often makes effective image transmission a costly affair and thus places a high barrier on the introduction of digital medical imaging.
— As mentioned above, efficient workflow requires a close integration between the PACS, the RIS and also the main hospital information system (HIS). Protocols to achieve such integration are described in documents issued by the initiative Integrating the Healthcare Enterprise (IHE) (www.ihe.net) [6]. This initiative is not a standard in itself but rather represents a process

whereby common workflow processes in radiology which use information systems (HIS, RIS and PACS) are automated. For further details regarding DICOM and IHE standards, please refer to Section 3.

In order to ensure compatibility between IT and image acquisition systems, and display and storage equipment from different vendors, it is important that equipment comply with the appropriate subsets of the DICOM standard and relevant IHE protocols (this will be further clarified in Section 3.1).

2.3. RESOURCES

2.3.1. Reliable power supply

Film based and digital imaging equipment, and particularly computers and network equipment, require a reliable and stable supply of power. Provision of uninterruptable power supplies (UPS) should be considered a necessary part of this installation. These systems are particularly useful for computers and are relatively inexpensive. Backup power sources such as generators may be critical for consistent use of the imaging systems.

2.3.2. Climate control

Extreme temperatures and very high humidity levels can permanently damage electrical and electronic equipment. Most computer and imaging equipment requires certain temperature and humidity ranges for safe and reliable operation. This may require specific building requirements to provide for air cooling/heating and humidity control, with appropriate housing and maintenance. Weatherproof and climate controlled housing of imaging equipment is thus not a luxury, but should be considered essential for safe and reliable operation of such equipment over any significant length of time.

2.3.3. Storage media

2.3.3.1. Optical media

As almost all current imaging systems capture and store their image data in digital format, at least locally, distribution through CD or DVD media has become commonplace. Such media are widely available, cheap and relatively reliable. In a digital imaging environment, they are readily used for storage and transport. Typically, equipment vendors will ensure that patient data are packaged

with an image viewer that is automatically included when the disc is burned. Images are usually written to disk in a DICOM compliant format, also referred to as the IHE portable data for imaging (PDI) format, although care should be taken that the format is consistently applied; some software burns non-DICOM images, but these should be avoided since the images cannot be imported.

However, although optical discs are a useful method of storage and distribution and are used worldwide, there are several caveats to their use:

— The quality of optical media is variable.
— Optical media deteriorate over time, especially under conditions of high humidity and temperature.
— Optical media are subject to disintegration of the reflective aluminium coating (so-called ‘disk rot’).
— Discs can be lost, misplaced or damaged, and can create a long term filing and storage problem if used as the primary archival method.
— Unlike film, discs always require a compatible computer and software system for display.
— Disk robots can be subject to electromechanical failures.
— Display software is often platform dependent.

Nevertheless, CDs and DVDs are a very useful and valuable method of image distribution and can be kept for personal archival purposes by the patient, especially in the short term. Long term storage and distribution using such optical media alone, however, is not optimal, and is not much better than for film. Ideally, high volume, high quality disk burning requires a dedicated disk burning system to:

— Manage and retrieve image files;
— Collate files from one or more examinations;
— Queue files in the correct order for the appropriate patient;
— Burn images to disk in the correct selected format;
— Burn appropriate runtime image display software onto disk;
— Print a permanent descriptive label on the disk.

There are many types of DICOM display software that are usually included on the CDs or DVDs at the time of burning. Such software usually conforms to defined standards in terms of the user interface, but its performance when reading images directly from optical media is poor. It may very well be that developments in network and storage technology will rapidly make the use of CDs obsolete. Many institutions are considering outsourcing storage and archiving to cloud based infrastructures (see Ref. [7] and Section 3.1.4).

Freeware viewers and workstation software are widely available on various computer platforms and permit much faster review of images once they are copied to the local hard drive. Some of these are open source or free (Appendix III), and for many users are sufficient for limited volume storage and display of digital images. However, such systems are generally not sufficient for high volume storage, archiving and distribution. IHE profiles define the capabilities and performance of such viewers (see the IHE Basic Image Review Profile on www.ihe.net) [8].

2.3.3.2. Paper

Paper can be used as a viewing medium, and has been used extensively in ultrasound. However, its use is limited and it has poor archival qualities. For best results, special papers are necessary, and printing supplies may become a problem. Compared to film, laser printing on paper is vastly inferior, inkjet printing is impermanent, and dye sublimation printing requires special paper and printing inks that are very expensive. Wax printers are a special case, as the quality of output is largely independent of the type of paper, but replacement costs are high and limited to very few suppliers.

2.4. COMPUTER SYSTEMS

In the past, the demands of digital image acquisition, storage, networking and processing required highly customized and expensive computer hardware. A powerful dedicated computer (often called a graphics workstation) was usually the only available solution and thus the norm. Rapid advances in hardware development combined with falling costs of memory and storage mean that standard off the shelf computers are often adequate for all but the most demanding of digital medical imaging tasks. A good quality PC with adequate memory (typically >2 GB RAM), good graphics performance, display and hard drive space can be purchased for a very competitive price and can function as an effective image review station. However, it is important when purchasing such computers to specify minimum specifications. Not only will older machines or very low end machines not have the performance which is required for an efficient review of medical images, but the likelihood of the need to upgrade soon after purchase is also maximized.

2.5. MOBILE AND PORTABLE IMAGING SYSTEMS

2.5.1. Mobile imaging systems

Digital imaging particularly shows its worth when used in mobile imaging systems. Such systems are often used when a local hospital cannot or will not invest the capital for a permanent system. Examples of this are mobile MRI and mobile CT and PET in some developed countries. Mammography imaging systems for breast screening are often installed in mobile vehicles to bring the imaging system to the population in order to ensure high uptake of the screening. In other settings, particularly during a crisis situation, it may be necessary to provide transportable medical imaging systems in remote locations such as refugee camps and field hospitals.

Ultrasound systems are increasingly compact and portable and offer a simple method of obtaining at least some cross-sectional imaging on a particular site. X ray systems can be considered mobile if they can be transported by vehicle, as they are heavy and bulky and may be fragile, and specially designed vehicles or trailers need to be used to prevent damage to the vacuum tube or detector systems. Such devices have limited power output and capabilities compared to standard fixed installations.

2.5.2. Mobile and portable image review

Mobile telephony has driven the rapid development of hand-held devices with good quality colour displays, reasonably large internal storage capacities and relatively powerful processing power of the on-board computer chip. These phones are typically called smartphones. Development of dedicated graphics applications now permits entire radiology studies, such as a CT or MRI study, to be loaded on such a device and reviewed in a clinically practical manner. These devices can be smartphones, tablet computers or laptops. For some limited applications, tablet computers and some smartphones can provide sufficient image quality, but may not be sufficient for primary interpretation. In fact, several of these devices have recently obtained approval (2011) as a medical image review system from the Food and Drug Administration (FDA) of the United States of America. There are, however, significant caveats with the use of such systems such as restricted image matrix size, limited spatial resolution, limited contrast resolution and limited ability to access stored medical images without proprietary software. Nevertheless, for certain applications, these devices are now clinically useable (Fig. 2).

FIG. 2. Display of a CT image on a tablet PC (photograph courtesy of www.carestream.com).

In general, at the time of writing, high end laptops have sufficient internal hard disk storage, processor and graphics performance and even screen resolution to permit both PACS based image review and primary interpretation using a RIS client for many imaging studies, especially for ultrasound, nuclear imaging, angiography, fluoroscopy, CT and MRI, where the native resolution of the acquired images is relatively low.

Some users already take advantage of the capabilities of modern smartphones with in-built cameras and multimedia messaging. These devices can take photographs of medical images from film or monitors and send these to senior medical practitioners for rapid notification. This purpose facilitates medical communication and potentially speeds and improves medical care. However, the users of such devices should be very aware of their limitations and should not rely on them for primary diagnosis. It is not to be recommended for regular use and any such use should be circumspect and followed by full image transmission for final interpretation.

2.6. STAFF

The staff of a radiology facility is part of a multidisciplinary team that typically includes radiological medical practitioners (referred to as radiologists

in this text), radiographers, technical assistants, sonographers, nurses, medical physicists, service engineers, IT specialists and administrative staff. The staffing levels of the organization and the professional competence of the staff should be sufficient to provide safe imaging examinations of good quality, and to meet the specified objectives of the institution for radiological services. Facilities should implement processes to ensure that staff work in a collaborative relationship as part of a team.

It is assumed that the minimum qualifications and continuing education of all staff involved in delivery, supervision, support and management of diagnostic imaging services are consistent with clinical requirements, and meet appropriate national and local regulatory requirements. Resources for training and education are often difficult to access and this may be an area where distance education (tele-expertise) may be the first option for isolated professionals.

2.6.1. Radiologists

Every imaging installation should have clinical imaging specialists, usually radiologists, available to:

— Provide medical oversight and leadership in imaging;
— Give advice regarding selection of imaging examinations;
— Interpret imaging findings;
— Develop protocols (including referral criteria) for imaging examinations;
— Ensure appropriate safety protocols are in place for radiation exposure and contrast injections;
— Consult with other clinicians.

For the provision of an optimal service, it would be preferable to have radiologists available on-site. However, when this is not feasible, off-site teleradiology presence can be considered a real alternative in many cases. Such a service can also support services delivered by on-site radiologists. In such teleradiology applications, there should be appropriate involvement of the off-site radiologists with the local department regarding operational matters, imaging protocols and consultations in addition to the reporting of studies.

2.6.2. Radiographers and imaging technologists

Medical radiographers should be appropriately qualified, according to the requirements of their country of work, or possess some other diploma or certification that is locally recognized. Relevant focused imaging training may be needed if the position is multifunctional, i.e. covers more than one imaging

modality. Within the context of digital radiology, radiographers can take on the role of PACS administrators and as such would require additional training to allow them to appropriately manage those aspects of the radiology service.

2.6.3. Medical physicists

Large facilities may have full time medical physicists available. All practices should have access to a medical physicist; the level and extent of involvement of the physicist should be dependent on the complexity and number of the procedures undertaken. A medical physicist with competence in diagnostic radiology should have primary responsibility for assuring the quality and consistency of most of the technical aspects of radiology, including equipment acquisition, quality assurance, dosimetry and calibration. This includes supervision of quality assurance programs, whether provided by hospital or clinic staff or provided as part of a service contract. Because of their technical backgrounds, medical physicists are often good resources to use in the conversion to digital imaging and implementation of PACS. Furthermore, the medical physicist would also act as a radiation protection officer, providing specialist expertise with respect to radiation protection of the patients and staff. Alternatively, the facility may have procured the services of a separate radiation protection officer.

2.6.4. IT staff

IT is a key element of any digital radiology facility that intends to store, review and distribute images electronically. Even in facilities with digital acquisition systems that choose to store and distribute using hard copy, IT is still very important. Although much IT hardware is now commercialized, and imaging vendors provide specialised software and even some imaging system connectivity, any other electronic connectivity and networking requires some IT expertise for planning, deployment, testing and maintenance. Such support can range from solving simple printer problems to the design of complex networks and backup strategies.

The complexity of the installation may determine the extent of IT expertise needed on-site. In general, large complex facilities usually require resident IT staff to ensure consistent and reliable operation of all facets of the imaging facility's computing technologies. Smaller facilities usually need IT personnel to help plan and implement the technical aspects of the initial installation, undertake modality connections and assist in troubleshooting DICOM association setups, and assist where necessary with DICOM device mappings and configurations. IT expertise can also be accessed through off-site and remote support technologies for many tasks that do not involve hardware

repairs. Such IT support should be seen separately from the management support of the digital radiology system, which really requires a different skill set.

2.6.5. PACS management

Digital imaging facilities usually have a database to manage images, requests and reports. This is usually in the form of a PACS, often combined with a RIS, which can be used in a localized fashion within radiology, or be scaled to distribute images within the facility to clinical areas outside the radiology department, or off-site, for remote interpretation and consultation. These systems, despite best attempts and technologies, will accumulate problems requiring local administration to correct errors in data entry, incomplete studies and so on. The management of these problems is the role of the PACS administrator. This is an individual who (a) has a detailed understanding of the PACS and any RIS, (b) understands the radiology workflow and (c) understands the clinical processes.

The PACS administrator often relies on superusers to carry out his or her duties. These are trained people (often radiographers) who have some administrative privileges needed to ensure that the data integrity of the system is maintained regularly and frequently. PACS managers and superusers may be radiographers, imaging technologists or administrative officers who have been trained and who regularly perform these tasks. External IT personnel as discussed above are still needed for overall technical system maintenance.

2.6.6. Non-imaging clinical experts

Imaging does not operate in a vacuum; all referrals come from a clinician, and all results go back to a clinician. Appropriate selection of imaging tests requires clinical judgement and understanding of the limitations and strengths of the available imaging tests. The relationship between the imaging service and the clinical staff of the health centre is important to ensure appropriate consultation, collaboration and cooperation in obtaining satisfactory imaging outcomes for referred patients. Any digital system should facilitate these processes.

2.7. COMMUNICATIONS INFRASTRUCTURE

2.7.1. Local area network

In the simplest set-up, the minimum requirement for digital imaging is a machine specific local area network (LAN), for example, from a CT scanner to an

imaging workstation. The extent of the network will be dependent on the number of imaging machines served (including imaging modalities, control workstations, image reporting stations, PACS and RIS servers, image review stations and other network devices, such as storage drive arrays). The level of complexity in a facility has a direct impact on the technical IT support needed at all stages of development, implementation and maintenance.

2.7.2. Internet and external connectivity

One of the major advantages of digital imaging is electronic image distribution. Within a facility, this is achieved through the local networking infrastructure. Outside a facility, a connection of some type is needed to ensure images and text can be transmitted for off-site storage, reading, consultation and review, as well as for Internet based medical resources such as standards and teaching web sites, and medical journals that can be used to support local image interpretation.

Dedicated data networking (e.g. ISDN (integrated services digital network) cable, satellite) is often preferable as performance is usually fast and more consistent than public Internet access. However, such approaches are expensive and may not necessarily permit Internet access. On the other hand, public Internet performance is usually more variable and also asymmetrical (faster for download than upload). It is often less reliable. Usually, ISDN and satellite links are also up-links to public networks. However, satellite connections have extremely high latency times related to the great distances at which geostationary satellites are situated.

There are several options for external connectivity:

— Public Internet connections:
  - Landline copper or fibre optic cable using a cable modem;
  - Distributed subscriber line (DSL) through a wired telephone network;
  - Wireless telecommunications network (3G/4G, WiMAX, Wi-Fi (IEEE802.11a–n, etc.));
— Dedicated connections:
  - ISDN through dedicated cables;
  - Microwave transmission (requires dedicated hardware and a line of sight relay, and performance may be influenced by weather conditions);
  - Satellite connection (requires dedicated hardware; can be used anywhere).

Each of these technologies has advantages and disadvantages that will be discussed in subsequent sections. For instance, satellite connectivity (geostationary satellite) has significant, intrinsic latency, and is thus less efficient

on highly conversational protocols (which include DICOM). Selection of the most appropriate networking technology will depend on the rationale for image transmission (e.g. urgent immediate review versus delayed batch reading or backup), location of the imaging centre, the relationship of the imaging facility to other health care facilities, and health care organization in the Member State. Furthermore, many of these technologies continue to improve in performance and fall in cost over time, so the choice of networking technology for any centre should be reviewed periodically.

2.8. REPORTING

In principle, the written opinion of a radiologist has a greater medico-legal status than the images that are reported upon. The provision of a formal expert opinion in the form of a radiological report is therefore a crucial component of the delivery of any imaging service, digital or otherwise.

Digital imaging infrastructures where PACS and RIS are involved make the provision and accessibility of the report easier and more reliable, and ensure that the images are always accompanied by any associated reports. Reporting can occur remotely once images are transferred for reporting at another site. In addition, reports can be amended and added to by one or more radiologists to provide a more complete or accurate report if additional opinions are sought, or new clinical information comes to light.

Reporting is a specialized skill that requires formal training and experience to produce a clear, coherent and consistent report that provides useful information for clinical decision making. However, the traditional free text report is highly variable in length, structure and quality, and varies considerably from radiologist to radiologist. To improve this situation, structured templates have been proposed. In many sites, individual radiologists develop a set of their own templates to facilitate and speed up their reporting tasks.

In many instances, templates are not necessary, but they do offer a method of improving not only the consistency of report writing, but also help to reduce clinical confusion over the meaning of a report. This is particularly true of examinations that are repeated in the same patient over time for the purposes of disease or treatment monitoring. Examples of such applications are serial monitoring of oncology patients, or orthopaedic measurements of chronic disorders such as scoliosis.

Clearly structured reports are even more important in the context of teleradiology, where the reporting radiologist will often have little clinical interaction with the primary clinical team members, and will not always have full access to all clinical information about the patient.

2.9. QUALITY ASSURANCE PROGRAMME

Quality assurance is a system designed to ensure that a consistent quality of service is delivered, regardless of when an examination is performed or by whom. It is a holistic approach to imaging that should:

— Identify sources of variation in service quality;
— Take active steps to reduce variation to within predefined standards;
— Regularly maintain and repair equipment to operate within the manufacturer's specifications;
— Monitor the process and system to correct for deviations;
— Repeat the cycle to continuously improve quality over time.

Such steps are an essential component of any clinical imaging service. One can have the best equipment, staff and facilities but still deliver poor and inconsistent quality if key steps in the imaging cycle are not properly designed, adjusted and improved. Typically, such quality assurance programmes will be focused on an individual system such as an X ray machine, film processor or CT scanner. However, this same approach can be used to ensure that a PACS, an information system or even a patient transport process is optimized and performs consistently and reliably. Digital imaging, while more robust than traditional film based imaging, is no less in need of a good, robust quality assurance process to ensure that the imaging service is safe, effective, reliable and available at all times. This area is dealt with at some length in Section 5.

2.10. CLINICAL AUDIT

Clinical audit is the process of evaluating clinical performance, outcomes and complications, for the purposes of improving quality, reducing variation and minimizing adverse events and poor clinical outcomes. It tries to identify the many potential areas of weakness in the clinical imaging cycle, from patient referral to the communication of results to the referrer. In an analogous fashion to quality assurance, clinical audit is a crucial element of improving clinical quality that is intended to:

— Improve the quality of patient care;
— Promote the effective use of resources;
— Enhance the provision and organization of clinical services;
— Further professional education and training.

Many imaging centres do not conduct regular audits, and this can perpetuate systemic flaws that can lead to adverse patient outcomes. The methodology for clinical audit is now well-established, but is beyond the scope of this publication. It is addressed in Ref. [1].

While different terms are currently in use to describe quality systems, both generally and specifically within radiology, there is general agreement that the effective management of imaging services demands a quality culture which includes a systematic approach to the elements that govern the delivery of that service.

Therefore, the concept of quality assurance within the radiological facility covers, in its widest sense, all those factors that affect the intended outcome, which is a clinical diagnosis. More detail on quality assurance for equipment and procedures is given in Section 5.

2.11. SAFETY ISSUES

Safety in digital imaging systems encompasses at least two aspects: (1) ionizing radiation safety and (2) information safety. Ionizing radiation safety (such as occupational radiation exposure and safety, management of radioisotopes), but also other safety issues such as contrast reactions, resuscitation and life support, are generic to all aspects of medical imaging, and are not specific to digital imaging and teleradiology. In all digital imaging systems that deliver ionizing radiation (i.e. CR, DR, fluoroscopy, angiography and CT), there are methods of automatically recording the exposures and doses delivered, and these systems can store and report these doses for the purposes of calculation of effective dose and monitoring dose delivery over time. More detail on radiation protection can be found in the literature [9, 10].

Information safety might include:

— Study data quality — i.e. correct patient identification;
— Data reconciliation — ensuring that reports are associated with the correct images;
— Data integrity — e.g. separation of images and demographics;
— Network safety (antivirus and anti-hacking prevention and protection).

2.12. SECURITY

In a non-digital medical imaging environment, security of imaging data is innately associated with the one-to-one relationship between the image and the

storage medium, i.e. the film. Physical security is relatively simple and involves controlled access to sites where imaging systems and films are stored.

In a digital medical imaging system, security considerations involve both physical and operational security. Physical security requires physical protection of the computer equipment used to control the imaging systems and to manage, transmit, store, review and interpret medical images. This may require secure locks or cables to prevent theft, and often some sort of controlled access to prevent unauthorized entry, especially when imaging personnel are not present.

Operational security involves ensuring the computer systems are only available to authorized and recognized users, and are safe from external unauthorized access and hacking. Usually, a superuser is tasked with administering the list of authorized users, their passwords and login identity codes. This must be maintained regularly for every individual user, and shared common passwords and login identity codes are not advisable. In addition, systems must be protected from viruses, spyware and other malicious software. Such software can:

— Reduce workstation performance;
— Reduce network performance;
— Cause a workstation to crash;
— Cause the RIS or PACS servers to crash;
— In the worst case, corrupt the entire RIS or PACS database;
— Covertly acquire and distribute private patient and staff information externally;
— Incubate and spread to other computers and modalities on the network.

This security must be taken very seriously. Malicious software can be introduced through external CDs and flash drives, or through surfing to web sites that have associated spyware or viruses. A useful approach is to coordinate with the workstation vendors and the local IT department to ensure that appropriate antivirus software is installed, functional and regularly updated during the life of the system.

2.13. PRIVACY

A patient's clinical image data are considered part of their medical record and access to such images and their related reports should be restricted for privacy reasons. Again, in a non-digital environment this is largely confined to ensuring that paper records and films are kept in a secure filing system. However, in a digital environment, the widespread distribution and ease of access outside the imaging facility are challenges to patient privacy.

It is important when preserving patient privacy not to make systems so protective as to impede appropriate clinical care delivery. For example, confining access to a patient's images to only the referring medical team may mean that other medical staff who are being consulted or acting in an emergency situation may not be able to see the images when medically necessary.

Image access in some web based image distribution systems may be 'all or nothing', i.e. any user once logged in can browse the system for any patient or study at will. Login access should be restricted to different types of users. Image access can be restricted to the images of an individual patient if portal software is used to filter the request first, and then linked to the individual imaging examination or patient through the PACS web access system. This issue is closely linked to operational security to ensure that people accessing medical images are authorized to do so.

The importance of privacy and security of information is an area that needs extra attention in the people and process components of any installation. Depending on the local legal environment, image data encryption should be considered if images and data are sent outside the LAN. User account management is needed to address: security issues; practical implementation — timely access to accounts; user name and password regimens; user authentication and external access issues.

3. CORE TECHNICAL ISSUES

This section discusses in some detail the technical issues associated with the use of digital imaging systems and IT networks. It is aimed at technical staff involved with the implementation and support of digital radiology installations such as equipment vendors, medical physicists, clinical engineers and IT staff. This section goes into some detail on the IT standards behind digital radiology. It is, however, not a treatise on the topic but will give the interested reader sufficient pointers to further their own knowledge (also see section 16 of Ref. [11]).

3.1. KEY TECHNOLOGIES

3.1.1. Standards

Before discussing the technical issues associated with the digital radiology network, it is appropriate to outline in some detail the role which standards play in

making digital radiology work. This includes a comprehensive discussion of the DICOM (Digital Imaging and Communication in Medicine) standard, followed by the Health Level Seven (HL7) standard which allows a picture archiving and communications system (PACS) to communicate with a Radiology Information Systems (RIS). This is followed by a new series of protocols (based on the above standards) which are part of the initiative Integrating the Healthcare Enterprise (IHE). IHE is expected to become more important in the future.

3.1.1.1. Digital Imaging and Communications in Medicine (DICOM)

(a) Background

The earliest digital medical imaging devices were both proprietary in nature and provided output in the form of printed film. Users had no expectation that digital images would be extracted from such devices, or that they could be exchanged between devices or software from different manufacturers. Manufacturers developed practical solutions for transferring, storing and remotely displaying images electronically. These were initially in a proprietary form, and different systems would not communicate (or were not interoperable). One could, for example, equip an entire hospital with X ray, computed tomography (CT) and magnetic resonance imaging (MRI) acquisition devices as well as a PACS and review workstations, but only if everything was purchased from one vendor, or if custom interfaces were developed for each acquisition device. This approach was neither scalable nor affordable, and the need to develop open standards to promote interoperability between equipment from different manufacturers quickly became acute.

The first open standard effort for medical imaging, jointly sponsored by the American College of Radiology (ACR), representing the users, and the National Electrical Manufacturers Association (NEMA), representing the producers, was the ACR-NEMA standard, which was published in 1985. This standard defined a mechanism for encoding the pixel data of the images themselves, together with information about the images in the form of a list of data elements and a set of commands, and a means of exchanging this data over a point-to-point connection between two devices using a 50-pin parallel interface. There was little adoption of this standard at the time, and it was not until 1993, when an extensively revised version of the standard was produced and renamed Digital Imaging and Communications in Medicine (DICOM), that significant progress was made. A key feature of DICOM that distinguished it from its predecessor was the use of evolving computer networks and Internet technology and protocols. Today, the use of DICOM is ubiquitous, and no manufacturer would be able to market a device that did not conform to the standard. The standard is not static,

but rather evolves through extension with additional features, as new imaging and communication technology is developed. Although DICOM is ubiquitous in medical imaging, two DICOM-conformant devices may or may not be able to interoperate, depending on the specific details of how the standard has been implemented in each device.

Although initially targeted towards radiology applications, at the time of writing, the DICOM standard is not so restricted in scope and includes support for many other medical specialties, such as radiotherapy, cardiology, dentistry, endoscopy, dermatology and pathology. DICOM has also been extended beyond the scope of medicine to include the non-destructive testing of aircraft parts as well as baggage screening and other security applications.

(b) Composite information model and information objects

A primary purpose of DICOM is the interchange of images and their accompanying information. To this end, the standard describes Information Object Definitions (IOD), each of which is specific to a type of image produced by a particular modality, but shares a common structure. For example, there is an IOD for CT and another IOD for ultrasound. What these have in common is the same set of information about the patient and the management of the study, but different information about the acquisition technique, spatial and temporal relationships, and encoding of the pixel data. Accordingly, DICOM describes this information in modules that are either general or modality specific. The Patient Module, for example, includes the patient's name, their birth date and their identifier, i.e. characteristics of the patient that are fixed. The Patient Study Module contains information about the patient that may vary over time but is important to the interpretation of the study, such as their weight and height. In addition to information about the patient, additional information is required to manage the study, such as the date and time that the study was started, the identifiers of the request and the study itself, and descriptors of the type of procedure; these can be found in the General Study Module. All DICOM images of patients, regardless of the type of acquisition device, will contain such modules (Fig. 3).

CT images will contain additional modules that are applicable to all forms of cross-sectional imaging, or which may be specific to CT (Fig. 4). For example, CT, MR and PET images all share the concept of an image as a slice in a well-defined three dimensional space. The Frame of Reference Module defines the patient-relative coordinate system shared by a set of slices acquired in the same procedure, and the Image Plane Module defines the position and orientation of an individual slice. Ultrasound images, on the other hand, which are traditionally acquired with a free-hand transducer and do not have a Cartesian geometry, do not contain these modules.

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0002,0002  Media Storage SOP Class UID: 1.2.840.10008.5.1.4.1.1.2
0002,0003  Media Storage SOP Inst UID: 1.3.12.2.1107.5.1.4.54557.30000007022009213898400000546
0002,0010  Transfer Syntax UID: 1.2.840.10008.1.2
0002,0012  Implementation Class UID: 1.2.124.113532.1.1
0002,0013  Implementation Version Name: MITRA22JAN97
0002,0016  Source Application Entity Title: UCHGD801
0008,0005  Specific Character Set: ISO_IR 100
0008,0008  Image Type: ORIGINAL\PRIMARY\AXIAL\CT_SOMS SPI
0008,0016  SOP Class UID: 1.2.840.10008.5.1.4.1.1.2
0008,0018  SOP Instance UID: 1.3.12.2.1107.5.1.4.54557.30000007022009213898400000546
0008,0020  Study Date: 20070220
0008,0021  Series Date: 20070220
0008,0022  Acquisition Date: 20070220
0008,0023  Image Date: 20070220
0008,0030  Study Time: 103112.671000
0008,0031  Series Time: 103246.562000
0008,0032  Acquisition Time: 103229.687782
0008,0033  Image Time: 103229.687782
0008,0050  Accession Number: 00233107
0008,0060  Modality: CT
0008,0070  Manufacturer: SIEMENS
0008,0080  Institution Name: UCH GALWAY
0008,0081  Institution Address: Newcastle Road
Galway
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FIG. 3. Example of a DICOM header with data element tag in left hand column, followed by description and value.

Since CT images are acquired using an X ray beam, the CT images contain specific attributes that describe the characteristics of that beam and its production, including the kVp (peak tube voltage), tube current, exposure time, filtration, etc. Ultrasound images include such information about the type of transducer used and the transducer frequency. Accordingly, there are CT and Ultrasound Image Modules defined to record this modality specific information.

Modules describe information that is not only either general or modality specific, but that is also shared between multiple images during the same procedure. This commonality is defined in a DICOM information model, which describes entities, such as Patients, Studies, Equipment, Series and Images, and the relationships between them. By this means, all images that are acquired as part of the same procedure will contain exactly the same information about the patient and study. If the procedure is performed on the same device, then the information about the equipment will be identical in all such images. Multiple images may be grouped into the same series if they have something in common, such as being acquired in a single run of the CT gantry. When images are encoded, however, all this common information is replicated into each instance; that is, every image will contain a full set of information, and for this reason they are referred to as Composite instances (as opposed to Normalized instances in which the information about each entity would be managed and transmitted

FIG. 4. DICOM Header of a CT scan. Acquisition details specific to the CT scan are indicated.

separately). The intent is that a single image may be separated from other images in the system on which it is produced or stored, yet will still contain a full set of information necessary to identify and interpret it.

The standard describes modules as consisting of attributes, and defines the meaning of each attribute in the context of its use in that module, as well as the sets of values that may be used for each attribute, whether an attribute has one single or multiple values, and any requirements or conditions for the presence of the attribute. Attributes are defined as Type 1 (shall be present with a value), Type 2 (shall be present but may be empty if the value is unknown), and Type 3 (optional). Additionally, Type 1 and Type 2 attributes may be conditional, that

is, they are required only if the condition is satisfied, and may not be present otherwise unless the latter is specified.

(c) Attributes, data elements, encoding and Transfer Syntaxes

Modules are defined as a list of attributes, each of which describes a specific piece of information, such as a name or a numeric value. For transmission and storage, these attributes are encoded as data elements in a single binary dataset. Each data element in the DICOM standard is assigned a unique 32-bit numeric tag, usually described as a pair of 16-bit hexadecimal group and element numbers. For example, the Patient's Name attribute is assigned a data element tag of (0010 0010). A textual description of the name of each data element is not included in the encoding; hence, the format is not self-describing and the recipient needs to have prior knowledge of what each element means.

The IOD and module organization is not explicitly preserved during the encoding; rather, each numbered data element is encoded sequentially by ascending tag number. This encoding is an artefact of the evolution from the ACR-NEMA standard, which defined a dictionary of data elements, but which did not describe an information model, nor the concept of IODs or modules. This means that the recipient needs to have prior knowledge of the DICOM information model, for example, if they wish to factor out common attributes into entity specific relational database tables.

Each data element is of a predefined type, or Value Representation (VR), and the standard defines a variety of such types. There are binary types for signed and unsigned integers of 16- and 32-bit lengths, IEEE floating point binary types of 32- and 64-bit length, as well as specific and general string types, such as those for names, integers and decimal values, dates and times, and codes, as opposed to free text descriptions. A specific VR, a sequence known as SQ VR, allows for the nesting of one or more subordinate datasets within a sequence of items in a single data element. This extends the original ACR-NEMA encoding to allow for much more complex data structures, including recursive tree structures.

The VR is fixed for each data element defined by the standard, and may be either encoded explicitly or omitted, in which case the recipient needs a data dictionary to know how to interpret the value of each data element. The value length of each data element is always explicitly encoded. Value lengths are always even, and, where necessary strings are required to be padded to even length, another historical consequence of the ACR-NEMA standard that defined a 16-bit parallel data stream, rather than the 8-bit byte that is typical on modern networks. In summary, each data element is encoded as a data element tag, with optional VR and value length, followed by an even number of bytes encoding the value.

The pixel data are included as another attribute (7FE0,0010) in the binary dataset, albeit a very large one with some specific encoding rules. The pixel data element is not restricted to being the last data element; indeed, there are specific data elements with higher tag values that may follow the pixel data (such as those related to digital signatures and trailing padding). Furthermore, a dataset may contain multiple pixel data elements nested in sequence items in some cases, such as to encode thumbnails (icon image sequences). An important consideration is therefore that a DICOM dataset does not consist of a fixed length header that may be skipped to reach the pixel data, nor are the pixel data necessarily at the end of the dataset. Full parsing of the successive data elements, including recursion into any variable length sequences, is necessary to reliably recover the pixel data.

The actual encoding is defined by a Transfer Syntax, which is, in essence, a set of encoding rules between communicating systems. DICOM permits alternative uncompressed Transfer Syntaxes, to permit sending 16-bit words as either little endian (low byte first) or big endian, to better match the characteristics of the sending and receiving computer hardware. As mentioned, the VR may be explicitly encoded or omitted. The DICOM standard defines the Implicit VR Little Endian Transfer Syntax as the default for network transfer that all implementations must support. It should be noted that this is now largely of historical interest, but these factors were once thought to have a significant impact on data transmission speed.

As the standard is extended, new data elements are defined and an existing implementation of a receiver may not have been updated with a new data dictionary. To preserve the VR known by the sender but otherwise lost in transmission if the VR is not encoded, the Explicit VR Little Endian Transfer Syntax should be used. Similarly, the standard allows manufacturers to define private data elements for their own use (all those with an odd rather than even value for the group number), and again, the use of Explicit VR during transfer preserves that information. In the event that a recipient does not recognize a data element and the VR is not explicit, an Unknown VR is specified, which allows the opaque contents of that data element to be preserved.

The Transfer Syntax is also used to distinguish images whose entire dataset or pixel data may be compressed in some manner, as is discussed later. In addition to the standard Transfer Syntaxes defined by DICOM, a manufacturer may define their own private Transfer Syntaxes, which can be used if both the sender and recipient agree to support them.

(d) Service Classes, Service–Object Pair Classes, Associations and conformance statements

Once an instance of an image information object has been assembled and encoded in a particular Transfer Syntax, how is it transmitted on the network? This is achieved using one of the many network services that DICOM defines, which includes the Storage Service Class (other services will be discussed later, such as those for query and retrieval, worklist management and printing).

Not all devices support all types of images from different modalities. Accordingly, DICOM defines the combination of a Service Class and an IOD as a Service–Object pair (SOP) class. For example, the combination of the Service Class 'Storage' and the CT Image IOD is the CT Image Storage SOP Class. The purpose of defining SOP classes is to allow the sender and receiver to negotiate their mutual capabilities when establishing a connection, what DICOM refers to as an Association, on the network. When establishing an Association, the sender (or the Service Class User (SCU)) proposes a series of presentation contexts, each with one SOP Class and one or more Transfer Syntaxes, and the receiver (or Service Class Provider (SCP)) accepts or rejects each presentation context and, if accepted, one of the Transfer Syntaxes. This negotiation mechanism allows the sender to offer, for example, CT and MR images each in uncompressed and compressed form, and the receiver to accept the one that it supports or prefers, and for the sender to then select which to use among the accepted choices.

In some cases, a sender may have images to send with different SOP Classes, for example, CT and ultrasound, yet the receiver, which could be a 3-D workstation, may not support ultrasound images, and will reject the corresponding SOP Class (and consequently not display the ultrasound images). In general, such limitations can be inferred from a comparison of the DICOM Conformance Statements of the products. This should ideally be performed prior to purchase and installation. Each manufacturer is required by the DICOM standard to document their product's capabilities in a conformance statement. These statements contain, among other information, a tabulation of which SOP classes and Transfer Syntaxes are supported. A simple statement by a vendor that a device is DICOM compliant is inadequate and not sufficient to describe interoperability; rather, a specific and detailed review of every pair of devices' conformance statements is required to assure compatibility.

The devices at either end of the Association are referred to as Application Entities (AEs); this term is used as there is no requirement that there be one-to-one correspondence between physical devices or software applications and AEs.

(e) Interchange media and archival storage

In addition to providing for transfer of DICOM instances on a network, the standard also includes rules for the use of removable storage media (sometimes called interchange media), such as recordable CDs, DVDs, magneto-optical disks (MODs) and USB devices. These are thought to be sufficiently robust to allow the information to be preserved for transfer from one physical location to another, such as by mail or courier. They are typically cheap and are often used to provide patients with their clinical image set.

Standardizing interchange media requires the choice of a physical medium, recording format, file system type, a means of encapsulating a DICOM dataset in a file, and a directory of patient and procedure specific information to index the files. The DICOM standard has chosen conventional consumer format media and file systems whenever possible to maximize reuse of affordable technology. For CDs, the standard ISO 9660 file system is used, for DVDs the UDF file system, and for MODs and USB, the FAT (file allocation table) file system is used; these are all readable with the typical operating systems found on ordinary standard computers without the need for special hardware or software.

For the file format, a short meta-information header is required, since there is no network connection which would require a negotiated Transfer Syntax. The meta-information header provides a recognition string (magic number) by which DICOM files can be distinguished from other files, as well as the meta-information header, encoded in a fixed Transfer Syntax, describing the Transfer Syntax actually used to encode the dataset that follows.

Since no interactive negotiation is possible, various application specific or general purpose combinations of SOP Class, Transfer Syntax and media type are grouped into predefined Media Application Profiles to provide a conformance description mechanism as well as a constrained set of possibilities to maximize the likelihood that a recipient will be able to use the media.

All DICOM media also need to contain a DICOMDIR file in the root directory, which encodes a summary of the contents of the media, listing each patient, study, series and instance present, together with a summary of the characteristics of each of those entities. An application can read this file and quickly summarize the contents in a browser for the user, without having to read every file on the media.

In contrast, DICOM does not define standards for long term archival media as opposed to interchange. This is both because the questions of longevity and reliability of the various media types have not been addressed, and because performance and accessibility within a proprietary archive system may be negatively affected by the use of DICOM files. DICOM also does not address any standardization of a database structure to index the content of an archive,

neither for tape formats, nor for hard disk storage. That said, many manufacturers do choose to use the standard DICOM PS 3.10 file formats, and standard DICOM Transfer Syntaxes for compression within their archives. This greatly simplifies the extraction and recovery of images during data migration from one vendor's archive to another. This is something that is an unfortunate but not infrequent necessity and needs to be planned.

(f) Composite instances other than images

The initial focus of DICOM was only the interchange of images. However, there are other types of bulk data that can be handled in a similar manner to images, such as time based waveforms (e.g. electrocardiograms), spectroscopic data (e.g. MR spectroscopy), documents of various types (for instance PDF) and even the raw data acquired prior to image reconstruction. These different types of data need description in a similar manner to the information model for images, and hence can share the composite information model that is used for images. Each can be described as a composite IOD with the addition of the appropriate modules, attributes, data elements and encoding mechanisms. The same Storage Service Class can be used for transfer of these objects on the network, and they can be encoded on interchange media in the same manner as images.

Additionally, information that can be described adequately as a set of individual attributes (but do not consist of bulk data that need to be described) can be also acquired. For example, a radiotherapy plan can be described in such a manner, as distinct from a radiotherapy image (portal image) or a radiotherapy dose map which are encoded as images. There is an entire family of radiotherapy related objects to support both external beam radiotherapy and brachytherapy.

The need to encode data in a flexible structured form is common to many applications. Examples include the recording of quantitative and categorical data from acquisition devices (such as obstetric or cardiac ultrasound measurement), computer assisted detection (CAD) of abnormalities on images such as mammograms, as well as the encoding of non-machine-generated reports. This is the province of the DICOM structured report family of objects that use nested recursive sequence (SQ) attributes to encode a flexible tree of categorical, coded, numeric and free text information using templates defined for specific applications. A distinguishing feature of the DICOM structured report, as compared to other structured document formats, is a mechanism for making reference not only to DICOM images (and waveforms) in their entirety, but also to specific coordinates referencing locations in space or time. These are used, for example, to illustrate findings or to define the locations at which measurements were made.

When displayed, medical images are often manipulated by the user to zoom or pan to a specific location, or adjusted in contrast and brightness (window width and centre) and may be annotated with text or graphics. These manipulations can be captured as a presentation state, and such states can be stored as composite instances for retrieval and application to the same images at a later time. References to images in structured report instances also may contain an accompanying reference to a presentation state, for example, to capture the appearance of the display of a particular region when a measurement was made.

The structured report and presentation state instances are exchanged in the same way as the non-image bulk data composite instances using the normal Storage Service Class and interchange media profiles.

(g) Service classes other than storage

The major use of DICOM network services is to transfer (and store) images and other composite instances from one Application Entity (AE) to another, but there are many other Service Classes defined. Some of these exist primarily to support storage activity. For instance, the Storage Commitment service allows the sender of a set of instances to ask the receiver if it will take responsibility for the persistence of the stored objects. This service is used by an acquisition modality prior to deleting its local copies of images.

The Query/Retrieve Service Class provides a family of SOP classes to allow one to query an AE to determine what events it has stored, and to retrieve those. In their simplest form, queries are performed hierarchically against a query information model that is closely related to the composite information model used for storage. These hierarchical models allow for queries about patient and study level attributes, series level attributes, and image (instance) level attributes. The models define a minimum subset of attributes that must be supported for matching and return, but allow for any other attributes to be optionally supported. Typically, the AE performing the query will do so at the patient or study level, from which the user will select a particular study, then for that study perform a query for all of the contained series, then for that series perform a query for all of the contained images or other composite instances; this is the hierarchical, as opposed to relational, query.

Having determined what is available and required, retrieval can then be performed using the unique identifiers of the different levels of entity returned in the query. That is, an AE can retrieve an entire study or list of studies, an entire series or list of series within a defined study, or an instance or list of instances within a defined series. Two forms of retrieval are available: move and get. ‘Move’ allows an AE to request that the retrieval take place over one or more separate associations (connections), and they may be to the same AE

that issued the retrieval request, or to a different AE. 'Get' allows the retrieval to be performed on the same Association as that on which the request is made, although it behaves in the opposite direction to the retrieval request for the storage suboperations, i.e. the initiator of the Association becomes the recipient (storage SCP). 'Move' is more flexible, but has the disadvantage that separate incoming connections must be supported, which may be problematic across firewalls. 'Get' has the limitation that whatever storage SOP Classes are needed for the storage suboperations must have been anticipated when the Association was initially established and negotiated.

Other Service Classes are defined for applications that are not directly related to storage. When the acquisition process for an image producing device was described earlier, mention was made of the use of demographic and request and scheduling information being available via a worklist. The Worklist Management Service Class includes a Modality Worklist SOP Class. This allows a modality to perform a simple single level query on a management system acting as a source of ordering and scheduling, and demographic information. The responses obtained, referred to as scheduled procedure steps, provide the modality with the necessary information to choose the correct patient, perform the work of image acquisition and to populate the attributes in the resulting images. Once the image acquisition is complete, it is useful not only to store the images, but also to provide feedback to the management system about the work performed. This is performed using the Modality Performed Procedure Step SOP Class.

As electronic distribution and soft copy review become routine, printing to film or paper is less commonly used with digital modalities, so standard services for communicating between modalities or workstations and printers are defined. The DICOM Print Management Service Class includes a family of SOP classes that support printing to both greyscale and colour printers.

(h) Application hosting

A recent extension to the DICOM standard defines a boundary between hosts and hosted applications that is independent of computing platform and programming language. This allows the separation of applications (plug-ins) that perform visualization or analysis from the infrastructure that is needed to find, retrieve and store images and associated information. The goal is to allow a PACS to provide the host implementation and one or more separate third party plug-in Hosted Applications to perform specific tasks. Hosted Applications can be as simple as basic imaging viewing, or they can perform more sophisticated analyses. Traditionally, general purpose PACS have been deficient in their support of advanced or modality specific display requirements, and integration of third party applications has required expensive custom development for each vendor.

The implementation of the standard between the host and the application uses standard http based web services with access to binary DICOM files as well as XML versions of DICOM headers and abstract models of the multidimensional image information. This permits memory mapped file based exchange of bulk data, which in turn allows for high performance.

3.1.1.2. RIS/HIS interfacing, Health Level 7 (HL7)

(a) Background

Just as DICOM is ubiquitous and unchallenged as the single standard for interchange of medical images, other information systems in a health care enterprise depend upon the HL7 standard for communication. The first version dates back to 1987, but varieties of Version 2.x are the most common in use today, particularly since Version 2.3 (1997). An almost completely different and much more complex standard, HL7 Version 3, has been defined, but has yet to supplant the dominance of Version 2.x in the field. The HL7 organization has also grown to absorb, embrace or define several other standards. This includes the Clinical Context Object Workgroup, which defines a means of loosely coupling different desktop applications to share the same context (for example, to enable recognition that the patient being viewed has changed).

(b) HL7 Version 2.x

Unlike DICOM, HL7 Version 2.x messages are encoded as text messages, rather than as binary strings. The format and meaning of messages are defined in detail, as are the circumstances under which they will be sent (trigger events). However, very few fields are mandatory, there are no conformance requirements, and there is no formal exchange protocol defined.

Two implementations that wish to communicate must reach an a priori agreement on how messages will be exchanged, what real world activities will correspond to the trigger events and what fields the messages will contain. For example, two devices might agree to communicate over a serial port at a certain bit rate, with certain special characters indicating the beginning and end of a message. Two other devices might communicate over a network using the ubiquitous TCP/IP (transmission control protocol/Internet protocol) standard, with the so-called minimal lower level protocol (MLLP), which is defined not in the standard but in an informative implementation guide. That said, the use of MLLP is extremely common, and where necessary third party ‘interface engines’ can be used to centralize the messages produced by individual sources, transform them and propagate them to other devices that need the information.

This mitigates the need for expensive customization when a new device is added into the mix. Nevertheless, some customization is always inevitable.

HL7 messages are composed of 'segments' separated by carriage returns. The first segment is always the message segment header (MSH), which, among other things, assigns an ID to the message, specifies the separator (delimiter) characters used, and specifies the trigger event that stimulated the message to be sent. Subsequent segments carry the payload of a message. Many segments are common to multiple different types of message. HL7 segments are composed of fields that have a data type associated with them. There are no explicitly conveyed tags to identify a field in a segment, and no explicit data type conveyed. The meaning of a field is conveyed by its position in a segment alone.

A simple example of a typical message is that of an Admission Discharge Transfer (ADT) admit/visit notification (A01) message. This serves to illustrate some of these characteristics:

```
MSH|^~\&|ADT|ST.ELSE|XRAY|ST.ELSE|200008091837|
|ADT^A01|MSG0001|P|2.3.1|\r
EVN|A01|200008091820||\r
PID||MRN1234|||SMITH^JOHN||19501009|M||C
|220 WHITE PLAINS RD^^TARRYTOWN^NY^10591
||(914)332-4800|\r
NK1||SMITH^MARY|WI^WIFE||||NK^NEXT OF KIN\r
PV1||I|CATHLAB||||919191^JONES^P.|||RAD||||ADM|A0|\r
OBX||ST|1010.1^BODY WEIGHT||62|kg|||||F\r
DG1||19||BIOPSY||00|\r
```

In this example, it can be noted that:

— The message type and trigger event (ADT^A01) are conveyed in the MSH segment, and the trigger event is repeated in the EVN segment.
— Segments are identified by three character letters, such as PID for patient identifier, NK1 for next-of-kin, PV1 for patient visit, OBX for observation and DG1 for diagnosis.
— Various data types are in use, including those to describe names, for instance "SMITH^JOHN", coded entries such as "1010.1^BODY WEIGHT", and dates and times like "200008091820".
— The scope of HL7 Version 2.x message types and trigger events is broad, and only a few are relevant to imaging applications. Of specific interest are those related to the management of patient identification, which includes the ADT messages, and those related to order entry (OE) such as

the general order message (ORM). Both are commonly used to construct the set of information required to respond as a DICOM Modality Worklist query provider. More complex examples, such as managing changes to patient identity, are also supported by HL7 messages. These are, however, also addressed under the subject of IHE (see below).

An important side project related to Version 3, but not dependent on it, is the definition of a clinical document architecture (CDA), a means of encoding and managing structured documents with consistent metadata. CDA documents may be exchanged using Version 2.x mechanisms, persist independently of the communication mechanism, and even be exchanged and stored using DICOM services.

3.1.1.3. Integrating the health care enterprise

(a) Background

The DICOM and HL7 standards define rules for very specific services or messages, but neither defines an overall architecture for building a complete system to support an entire enterprise such as a hospital. Significant gains in interoperability were achieved using both standards, and large and complex systems were built without dependence on proprietary interfaces. However, further progress towards producing turnkey devices that could be 'plug and play' required the definition of specific applications and specific architectures to support them. The Radiological Society of North America (RSNA), an organization that had been instrumental in the promotion and adoption of DICOM, began in 1997 to convene key stakeholders to establish momentum and direction, and in 1998 allied with the Healthcare Information and Management Systems Society to initiate the IHE project.

The premise was that an annual cycle of release of technical specifications, testing of implementations in 'connectathons', followed by public demonstrations, would quickly demonstrate value to product vendors and customers. The first year focused on one particular problem, that of scheduling radiology workflow from patient registration through ordering and scheduling, to image acquisition, transfer, archival storage and distribution. This problem involved two standards (DICOM and HL7), multiple types of device manufacturers (HIS, RIS and PACS), and resulted in 24 vendors demonstrating 47 systems at the first connectathon, followed by a public demonstration at the RSNA annual meeting in 1999. Initially conceived as a three to five year project, as of 2009 the project is in its eleventh year and is ongoing, and IHE is now a global organization spanning multiple domains well beyond radiology.

(b) Profiles, actors and transactions

The IHE approach is to identify a set of applications that require a common infrastructure and then to define an Integration Profile composed of Actors and Transactions sufficient to support those applications. The resulting profile may not be the only way to solve the problem, but it is designed to be sufficient as well as consistent with other integration profiles and, where possible, the installed base of equipment in the field.

For each profile, a family of Actors are defined. Actors are defined as (often) virtual devices that in the real world serve different purposes and are often, but not necessarily, provided by different manufacturers. For example, the part of a hospital information system (HIS) or RIS that performs the scheduling function is referred to as a Department System Scheduler/Order Filler (DSS/OF) Actor, and is distinct from the Actor that performs the ordering function, the Order Placer Actor. Yet in reality, these may be grouped together in a single implementation. Similarly, the management and archival functions of a PACS are grouped as the Image Manager/Image Archive (IM/IA) Actor, distinct from the image display functions of a PACS workstation, the Image Display (ID) Actor. The various actors are common between various profiles where appropriate.

The behaviour of an actor is not defined generically, but is rather specified in the context of transactions between actors in the context of a profile. IHE profiles do not define new standards to implement transactions if possible, but rather use existing messaging standards such as DICOM or HL7, if necessary specializing or constraining particular HL7 messages or DICOM SOP classes to achieve objectives.

For example, in a Scheduled Workflow (SWF) profile (Fig. 5 [12]), HL7 messages are specified for patient registration and order entry and the protocol to be used, the version of HL7 and the content of certain segments and fields are explicitly defined. Furthermore, since other transactions in the same profile use DICOM SOP classes, such as the provision of a Modality Worklist, the mapping from the HL7 messages, segments and fields to the DICOM query return attributes is defined, providing a deterministic bridge between two similar, but not identical, standards. The degree of specificity in the definition of the profiles serves to eliminate uncertainty on the part of the implementers and purchasers.

The profiles are in general an all or nothing proposition; for instance, rather than having to match the specific capabilities in the DICOM conformance statements of two different devices, the purchaser can compare the IHE integration statements of two devices. For example, a CT scanner claiming to be an Acquisition Modality (AM) Actor supporting the IHE SWF profile and a RIS claiming to be a DSS/OF Actor for the same profile should interoperate, without the need to evaluate the specifics of the DICOM Modality Worklist implementation.

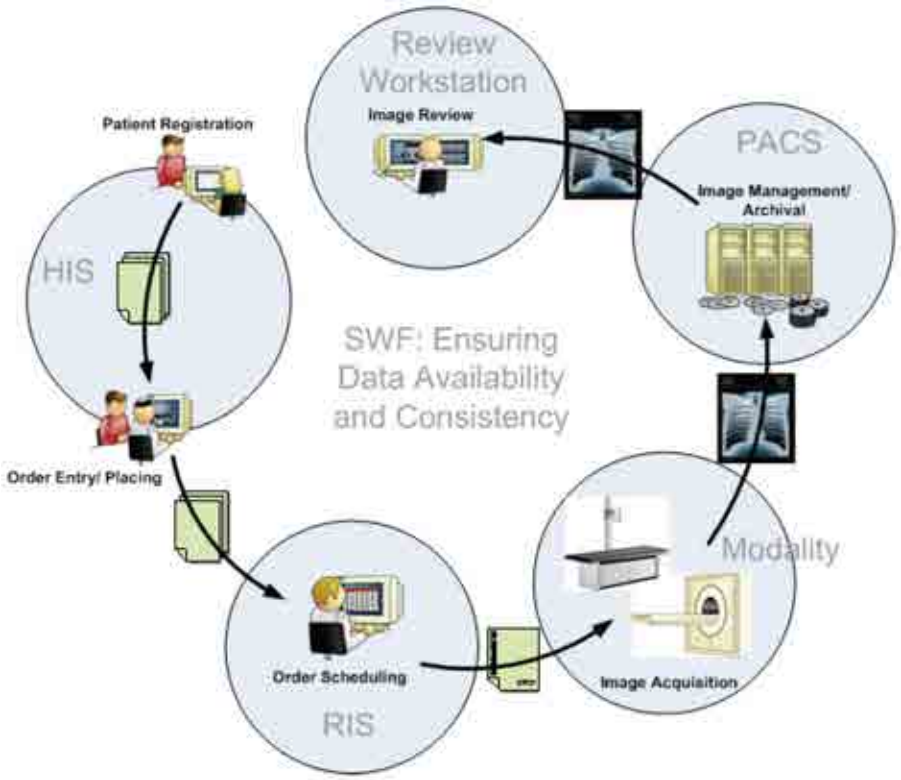

FIG. 5. Example of an IHE Profile, in this case Scheduled Workflow [12].

However, IHE profiles can contain options and their impact should be considered when matching integration statements. For example, the Import Reconciliation Workflow (IRWF) profile addresses concerns encountered when importing images performed outside the enterprise and provided on interchange media e.g. CDs, such as reconciling external patient identifiers with internal identifiers. It has two options, Scheduled and Unscheduled. The Scheduled option pre-supposes that an order for the external study has been entered, and uses a Modality Worklist to provide the order to the Importer Actor from the DSS/OF, whereas the Unscheduled option obtains demographics via an HL7 query to a Patient Demographics Supplier Actor. One or both of these options is required, but a purchaser must carefully compare support for the options to avoid incompatibility.

IHE integration profiles are not exclusively concerned with workflow. Another type of profile addresses matters concerned with interchange media. The IHE portable data for imaging (PDI) profile requires the use of the DICOM

standards for media, but selects and limits the choices provided to those in common use, specifically to the use of uncompressed images on CD. Subsequent extensions to the PDI profile adopt more DICOM features, and allow for the use of DVD and USB media, as well as the selective use of compression, and encryption for privacy protection. Encrypted media are required in IHE PDI to provide accompanying on-media decryption software.

Another type of integration profile addresses the behaviour of single actors in terms of the features available to the user. The Image Display (ID) Actor, which describes the functions expected in a workstation or viewer, is included in several profiles that specify detailed application specific behaviour. The Mammography Image (MAMMO) profile describes a list of detailed requirements that a display must implement, such as achieving the proper orientation, comparable size of current and prior images, justification to the chest wall, consistency of greyscale contrast (window) settings, completeness of annotations and the display of computer aided diagnosis (CAD) marks. This profile requires that particular DICOM attributes be used to implement specific behaviour, rather than leaving this discretion to the implementer, and also burdens the Acquisition Modality with requirements to populate these attributes. The MAMMO profile and the more general Consistent Presentation of Images (CPI) profile, also require the display to implement and conform to the DICOM Greyscale Standard Display Function (GSDF) to facilitate the consistency of the perceived contrast of displayed images.

Another profile related to the image display is the Basic Image Review (BIR) profile, which enumerates the minimal features that a clinical review user requires, down to the level of detail that provides a similar user experience regardless of manufacturer, to the point of defining standardized icons and minimum performance requirements. The goal of this profile is to improve the consistency of viewers included on PDI media, although it is not limited to that application.

(c) Cross-enterprise document sharing

IHE was originally conceived to address issues within a single organization/institution, but the spread of electronic records and the need for interoperability between enterprises has driven the development of a new family of profiles categorized as XDS (cross-enterprise document sharing). The first of these IHE profiles was XDS for imaging (XDS-I), which provides for a central Document Registry Actor that keeps track of document metadata (including images). These documents actually reside in multiple document repositories, originally intended to be collocated with the sites that originated them, perhaps implemented as a gateway to the local PACS. The sequence of operations is to query the registry,

identify the documents required and then retrieve them from the appropriate repository. For imaging, the document retrieved is a manifest encoded as a DICOM SR, and an additional level of retrieval is then used to return the images themselves.

Since neither DICOM nor HL7 had defined support for several of the transactions required, and the necessary actors did not exist in the real world (particularly the registries), there was an opportunity to reuse conventional Internet and web technology for this application. The first attempt at XDS made use of the ebXML (electronic business using extensible markup language) standard (developed by the OASIS consortium), web services using the XML Simple Open Access Protocol (SOAP), and generic queries using the SQL language standard. Document retrieval was defined via the http 'Get' protocol, although for the second level imaging application, DICOM transactions are permitted instead. As experience with trial implementations was gained, and as the web service standards evolved rapidly in the general community, it was found necessary to discard the original approach (now referred to as XDS.a), and replace it with revised transactions (called XDS.b) which include the use of revised Web Services, updated ebXML registry services, a web service based retrieval transaction protocol and replacement of SOAP with its optimized version (called MTOM/XOP).

Mechanisms are continuously evolving to address additional complexities encountered with loosely coupled, externally accessible systems, including security and privacy and access control, incorporation of centralized (regional or national) rather than local data repositories, and support for distributed consistency after local corrections and updates.

3.1.2. Digital image acquisition

A digital acquisition modality is responsible not only for the acquisition of the raw data for the construction of an image suitable for display to a human observer, but also for associating that image with the clinical request and demographic metadata. The human operator of the device may provide this information by direct data entry at the modality console (notoriously error prone), by scanning previously printed bar-code information, or by selection from a predefined schedule on a work list or other source of demographic information provided electronically to the modality. The modality includes this metadata in a tag associated with the overall patient image file.

The modality then transmits the acquired images and related information to another device on the local network, such as a quality control or interpretation workstation, an analysis system, an image manager or archive, or a digital film printer. Typically, a modality will send the images once to a single preconfigured

location, which will take responsibility for interpretation, archiving and distribution, and will then purge any local copies after a predetermined interval. Alternatively, some modalities provide local archival storage, e.g. on removable media such as CD or MOD of the reconstructed image data, the raw data, or both.

Other information, including images from previous examinations, is often vital for correct interpretation of the current examination. Digitizers may be used to capture physical material, such as radiographic film, printed images and other paper documents, such as request forms and operators' notes and worksheets. Digital images and reports previously recorded on interchange media, such as CDs, can be imported. These devices are integrated in a similar manner to any other acquisition device, although the workflow may be specialized, for example, to reconcile the identifiers on externally provided material with local record numbers.

Film digitizers designed for scanning radiographic film or laser printed medical film differ significantly from their consumer counterparts. The mechanism of scanning is transmissive rather than reflective, the range of optical density of the film is dense, and the requirements for spatial and contrast resolution are demanding. Specialized physical handling of the film transport is also required. Both laser and charged couple devices (CCDs) are available that provide for at least a spatial resolution of 2.5 lp/mm (line pairs per mm), a contrast resolution of 10 bits and a maximum optical density of 4.0. Mechanisms of calibration are available that allow for predictable values of optical density such as values that provide for an optical density which increases linearly, as far as human perception is concerned, with light transmission (also called standard perceptually linear space).

3.1.2.1. Computed radiography

Computed radiography (CR) replaces a conventional screen film cassette with what is essentially a 'digital cassette' that is placed under the body part being examined prior to X ray exposure. As such, it can be used with the existing gantry, tube, bucky cassette holder and generator, without requiring replacement of most of the parts of the entire system. However, grids often need to be replaced as the digital sampling of the image, arising from the CR reader, can interfere with the fine lines produced by the grid. If this is not performed, aliasing can occur, resulting in highly visible dark lines across the image. CR can also be used in portable situations. The cassettes are relatively durable and tolerate considerable physical mishandling, such as being dropped. The cassette contains a photostimulable storage phosphor plate from which the image can only be extracted using a cassette reader. This device uses an electro-optical mechanical scanning system to obtain a digital signal from the latent image on the plate.

Although historically these readers have been large and expensive, at the time of writing, low cost desktop sized readers were becoming increasingly available. The CR plate and reader, combined with vendor supplied image processing software, result in a relatively wide dynamic range, tolerant of operator error in terms of X ray technique.

Since the exposure of the cassette and the reading of the data are separated, some means of identifying the patient and the examination is required. Generally, some kind of bar-code system is used, coupled with a database of patient identity information and codes for procedures and views, which allows for a fully automated cassette reading process, i.e. an unattended box with no user interface. However, if such an infrastructure is not supported, then the cassette reader can be coupled to a workstation into which the identifying information can be entered manually.

Throughput is limited by the number of operator workflow steps and the location of the plate readers relative to where the patient is exposed. A cassette reader and workstation in every room allow for immediate quality control and higher throughput compared to the use of a central cassette reader shared between multiple rooms.

The result of the CR process is a set of DICOM images containing the image data and the identifying information in the DICOM header. These are generally sent to a separate workstation or PACS for quality control, followed by interpretation and then distribution to referring doctors. Alternatively, in a limited resource environment, the plate reader can be combined with an interpretation workstation. CR images also can be printed to laser film in a partially digital environment.

3.1.2.2. Digital X ray

Digital radiography or digital X ray, as it is referred to in the DICOM standard, is a different technology to CR and is referred to by the abbreviation DX or DR. X ray photons are converted to digital data using a sensor. The sensor is not a phosphor storage plate, but produces a digital readout without an intermediate storage and reading step. In typical use, large flat panels contain an array of sensor elements, which either directly sense X ray photons, or indirectly sense the light emissions of a scintillator that converts X ray photons to a digital output signal. Although portable forms are becoming available, the primary advantage of DX over CR is its high throughput (with fewer workflow steps for the operator) in a fixed environment, and its typically higher image quality, or, more specifically, higher detective quantum efficiency (DQE). A higher DQE will allow for a lower patient dose.

Like CR, DICOM images are created with the processed image data and headers containing identifying information. In a fixed installation, data from the gantry and generator may automatically be incorporated into the DICOM headers without manual entry being required. Quality control is usually performed using dedicated workstations combined with the processing software. DX images can also be printed to film in a non-digital environment.

3.1.2.3. Ultrasound

Ultrasound devices use reflected sound waves from a hand-held transducer to generate cross-sectional images of the body, often including superimposed colour cardiac and vascular velocity information obtained through the Doppler effect. There is no ionizing radiation dose to the patient. These systems are typically small, often portable and inexpensive relative to the clinical value of the images obtained. Their use is extremely operator dependent, requiring skilled operators with good anatomical knowledge. The images obtained are displayed in real time on an integrated display, but single snapshot images as well as cine loops of moving structures can be either captured for storage and playback on the same machine or transferred to storage devices and workstations. A major benefit of digital workstations is the ability to capture dynamic image streams.

Quantitative measurements are often made directly on the machine; either of the size of structures, e.g. biparietal diameter or femur length for the estimation of gestational age, or velocity information for quantification of vascular stenosis or cardiac function, such as gradient across a valve. These measurements are displayed on the screen and can be hand transcribed onto worksheets, printed on an attached paper printer, recorded as screen shots stored as DICOM images, or the information can be transferred in a DICOM structured report (see 3.1.1.1). In a non-digital environment, ultrasound images and measurements can both be printed to film or on paper.

3.1.2.4. CT

CT uses a rotating gantry containing an X ray tube on one side of the patient, and a row of detectors on the other side to measure the X ray absorption along lines passing through the patient's body. From these raw 'views', a cross-sectional image is reconstructed. Older scanners acquired one slice at a time, then stepped the table a small distance for each subsequent slice. Modern scanners allow for continuous rotation and continuous table motion during rotation, enabling helical or spiral acquisition. Multiple rows of detectors acquiring images simultaneously now result in very short acquisition times, sufficient for cardiac imaging and breath-holding acquisitions of large areas. The

acquired images are reconstructed and presented to the operator on the built-in display of the acquisition workstation, either in real time or very shortly after acquisition, at which point quality control is performed. The operator can also perform multiplanar reconstruction, providing images that are sagittal and/or coronal in cross-section (as well as the required axial images). Generally, the images are then transferred in DICOM format to a separate workstation or PACS for interpretation or review, or printed to film in a non-digital environment.

CT images are reconstructed with a wide range of pixel intensities corresponding to the absorption characteristics of different tissues. These are quantified in Hounsfield units (HU). The range of HU that can be found in a CT image greatly exceeds the capacity of current display monitors. If uncorrected, this would result in loss of contrast and lack of visibility of subtle lesions. Therefore, the CT images need to be 'windowed' at a particular greyscale level (by changing the contrast between a narrow range of greyscale values, centred around a particular value) for display. On an interactive digital display, this is typically performed with both multiple preset window values (for example, bone, soft tissue and lung windows) and tools that allow adjustment by the user. This is an enormous advantage of digital imaging and display over conventional film based imaging. Modern CT scanners can produce several hundred images in a few seconds and only through the tools available on a modern display workstation can the clinician perform an effective diagnosis.

3.1.2.5. MRI

MRI takes advantage of the phenomenon of nuclear magnetic resonance, in which hydrogen nuclei (protons), which have an inherent magnetic moment, are aligned in a very strong external magnetic field. This induces macroscopic magnetization of the body. When this induced magnetization is subjected to a sequence of radiofrequency (RF) pulses of appropriate energy, a phenomenon of resonance takes place. This causes some of the energy of each RF pulse to be absorbed through a change in magnetization. Upon termination of the RF pulse, some of this absorbed energy is radiated back out with characteristics indicative of the local environment of the protons. Based on the ability to spatially localize the returning RF signal using sets of radio receivers (gradient coils), cross-sectional images can be produced in any arbitrary plane. These images have inherent contrast influenced by the proton density of the tissue along with factors that depend strongly on the tissue and its environment, such as the longitudinal and transverse relaxation times of the protons. MRI is unique in that image contrast can be changed, depending on the timing of the pulse sequences selected by the operator. MRI involves no ionizing radiation dose to the patient.

There are however, some hazards associated with the strong magnetic field and the RF pulses.

As in CT, the acquired images are reconstructed in the required planes and presented to the operator on the built-in display of the acquisition workstation, at which point quality control is performed. The images are then generally transferred in DICOM format to a separate workstation or PACS for interpretation or review, or printed to film in a non-digital environment. Even more than CT, a typical MR study of a patient can involve up to 1000 individual images. Reviewing such a large number of images is really only possible using digital display workstations.

3.1.2.6. Non-DICOM equipment

Digital equipment that does not meet the DICOM standards (such as older modalities) may require an acquisition gateway or convertor 'box' of some type to perform these functions. Similarly, non-medical devices used to capture images from other sources, such as a digital camera or digital video recorder attached to an endoscope or microscope, may require such a gateway to convert the consumer format images (such as JPEG or TIFF) to a standard medical format containing the additional metadata for transmission. Such devices are typically provided by niche companies rather than the major medical imaging suppliers.

3.1.3. Image reporting

The ultimate end product of any radiological examination is not a set of images, but the report which is issued by the radiologist. Medical images are often different from consumer format images (such as those used in a web browser or digital camera) in that:

— They are usually greyscale (monochromatic) with no true colour.
— They are often greater than 8 bits in depth, given the wide dynamic range of the modality.
— They need to be accompanied by header information (metadata) on the image that specifies the identity of the patient, the date and type of the study, the identity of the acquisition device and operator, the technique factors used, and the spatial and temporal relationships of successive slices.

Digital images need to be displayed to the radiologist and interpreted by them, usually on a digital display (called soft copy reading) rather than after printing onto film (called hard copy reading). An image display should not only provide the appropriate clinical images, but also provide the user with a worklist

of unreported studies to interpret or a list of all available studies from which to choose, preferably with their reported state; the former is more efficient but requires greater integration with the information systems. Images need to be made available in a timely manner, including those from relevant prior examinations. These may be obtained on demand or prefetched, depending on integration with the RIS, the network architecture and the performance of the system.

When a study is selected, the full available screen area should be populated automatically with images in the most efficient manner for interpretation according to the user's preferences. This is achieved by the application of default display protocols that recognize the type and content of current and prior images, and which layout the images for comparison accordingly, flipping and rotating into the correct orientation as necessary. Such protocols are often called hanging protocols after the old practice of films being hung on stacks of viewing boxes.

The workstation software should support adequate display of the range of image types from the different modalities being supported, including support for:

— Projection (e.g. X ray) and cross-sectional (e.g. CT and MR) images;
— True colour (e.g. endoscopy, slide microscopy) and pseudo-colour (e.g. colour Doppler ultrasound, nuclear medicine) images;
— Multiframe and cine images (e.g. cardiac ultrasound and angiography).

Support for 3-D multiplanar reconstruction and maximum intensity projection and volume rendering are expected for CT and MR, especially for musculoskeletal and angiographic interpretation and tumour size measurement. A recent development has been that of hybrid imaging modalities. In these, more than one imaging modality acquires images from a patient during the same study. Examples are a combination of a PET scanner with a CT scanner, which is also called PET/CT. The interpretation of hybrid PET/CT examinations requires not only multiplanar reconstruction support, but also display of fused images (for instance through the display of pseudo-coloured PET images superimposed on CT images).

Basic image review features required include:

— Visual navigation of the available series of images using thumbnails or a hierarchical browser;
— Side by side comparison of at least two sets of images, whether they be a series from the same study or from different studies, with synchronized scrolling, panning and zooming in the case of cross-sectional modalities;
— Annotation of laterality, orientation, and spatial localization of cross-sectional images for anatomical reference;

— Annotation of demographics, management and basic technique information to provide for safe identification and usage;
— Simple measurements of linear distance and angle as used for change detection and treatment planning.

If the PACS is integrated with a RIS, then the diagnostic workstation will often also have facilities for administrative tasks, such as review of clinical requests and reporting. This can be in combination with voice recognition. This combination allows for a faster and more efficient clinical reporting system than systems that require a separate transcription and approval process.

There are different classes of monitors, and for optimal results monitors should be subject to quality assurance testing and calibration (see Appendix IV).

3.1.3.1. Workstation computer

The DICOM standard defines the header data elements in which this information is encoded, with a separate class of object for each different modality. Each defines common data elements (such as patient identification), and modality specific data elements, such as those specific to a modality technique (e.g. mAs (current time products) for X ray modalities such as CR, DX and CT, and pulse sequence times for MR). The computer used to display medical images therefore must be able to:

— Receive and load DICOM images for various modalities;
— Display a list of available patients, studies, series and images and allow the user to select those to be displayed;
— Display the selected images side by side for comparison with other images;
— Annotate the displayed images with identifying and other information from the image header;
— Allow the user to navigate, manipulate, analyse and annotate the images as desired.

Common image manipulation functions should include:

— Windowing the greyscale contrast of the image to allow optimal display of the medical image utilizing the full display range of the monitor;
— Zooming and panning;
— Inverting the greyscale (such that white appears black);
— Flipping and rotating the image (usually in 90 degree increments only).

Common navigation functions include:

— Stepping to the next and previous frame, image, series, study or patient;
— Scrolling continuously through successive cross-sectional slices;
— Synchronized scrolling (and zooming and panning) of different sets of slices through the same body part displayed side by side (e.g. different MR pulse sequences with different contrast weighting);
— Display of slice or point location on synchronized or orthogonal slices;
— Playing a cine (video) view of successive frames.

Common analysis and annotation functions include:

— Measurement of size (e.g. distance, area, volume);
— Measurement of angle;
— Measurement of intensity (e.g. CT HU) of a voxel or region of interest;
— Localization of a point of interest annotated with text;
— Flagging selected images or frames as being of key interest.

Computer workstations that allow for analysis and annotation should have a means of saving the appearance of the user's work, and the DICOM standard includes support for saving and sending presentation states and structured reports containing such information for later review on another workstation, which can be within or external to the original PACS.

3.1.3.2. Medical grade displays

Assessment of the quality of a medical image can only be defined within the context of particular imaging tasks. This also applies to the quality of an image displayed on a computer monitor. A monitor which is adequate for one particular imaging task (for example, display of an 8-bit greyscale ultrasound image) may be completely unsuitable for another imaging task (e.g. display of mammography images). Issues related to the quality of a display are (among others) [13]:

— Luminance (brightness) and uniformity of brightness;
— Ability to display contrast and contrast differences;
— Bit depth output;
— Digital image matrix size and display size;
— Display or spatial resolution;
— Presence of noise;
— Reflectivity of screen.

In the early days of PACS, large, heavy and expensive cathode ray tube monochromatic medical grade displays with high brightness, high contrast ratios and high spatial resolution were used in an attempt to replicate the appearance of film as closely as possible. These displays had a limited lifespan and required frequent recalibration. Today, medical grade LCDs (liquid crystal displays) have largely replaced cathode ray tube displays, as they are more reliable and higher performing devices at lower initial and total cost of ownership (TCO). These medical grade LCDs are suitable for the display of both large and small format images. They may be accompanied by dedicated calibration tools, hardware and software, and may have a built-in look-up table greater than 8 bit to reduce quantization during calibration. They also may be self-calibrating and adaptive to ambient light, and may feature remote monitoring of quality and calibration.

As there is considerable difference in cost and performance for different types of displays and workstations, several professional bodies have issued guidelines on the type of display to be used [14]. It is common practice to make a distinction between a monitor display used for primary diagnosis and one used for clinical review by a referring physician. Specific requirements have been issued for monitors intended for primary diagnosis in mammography [15].

One significant disadvantage of dedicated monochromatic displays is that colour cannot be used for annotation, and images with colour information (such as Doppler ultrasound, pseudo-coloured nuclear medicine or PET images) cannot be displayed. Typically, such displays are paired with equal or lower resolution colour monitors on the same computer workstation to alleviate this drawback. Such additional monitors are often used for administrative functions, such as to display a browser page of patients, the contents of requests and reports, or the medical record.

A new class of display that is becoming available is the medical grade colour monitor, which combines the brightness, contrast ratio, spatial resolution and calibration capabilities of the medical greyscale display with the ability to display true colour. A disadvantage of medical grade colour monitors is the reduced backlight life (compared with monochrome monitors) owing to the additional colour filters between the backlight and the observer.

Monitors that are used for primary diagnosis require frequent quality control to ensure that the performance of the device has not degraded. Some monitor vendors have equipped their monitors with small sensors and software which allows for the central monitoring of a large number of workstations equipped with such displays. To take advantage of the quality of a medical grade monitor, the deployment environment should be carefully considered, including control of the ambient light, sources of specular reflections (such as from view boxes and

doctors' white coats), and the physical distance between the eye and screen and the angle of viewing.

3.1.3.3. Consumer displays

Ordinary consumer displays do not come close to approaching the spatial resolution (number of pixels, line pairs per mm) or the contrast resolution (bit depth, number of shades of grey) of traditional X ray film, which is a very high quality medium. Furthermore, a traditional film view box has a higher light intensity by several orders of magnitude compared to an ordinary display.

However, modern consumer flat panel LCD displays used for ordinary office work are physically larger in size (18 in. or greater), have a larger number of pixels (1.5 or 2 megapixels), and have a higher brightness (several hundred cd/m^2) and contrast ratio (several hundred to one) than in the past. Arguably, such displays, when used in conjunction with software tools such as windowing, panning and zooming, are sufficient for a diligent user to review large format images such as X ray CR and DX images. Certainly, for small format images that are initially computer reconstructed such as ultrasound, CT and MR, such consumer displays are often adequate for the task.

Arguably, consumer colour LCDs are adequate for performing large format image interpretation without degradation of observer performance (sensitivity and specificity), although this is hotly debated in the scientific literature. There is no question that the appearance of the same image on a dedicated medical grade monochromatic image is more pleasing to the eye than on a consumer colour display, and the literature suggests that radiologists read faster on such displays and with greater confidence, if not with more accuracy. This is true not only for large format images, but also for small format images.

Consumer displays are generally driven by 8-bit data paths, limiting the number of driving levels available both for image display and for calibration. That said, consumer displays can and should be calibrated to the DICOM GSDF (greyscale standard display function) if the perceived contrast of the displayed images is to be consistent for side by side display with other monitors throughout the organization, and with the original acquisition modality. Third party tools (photometers and PC software) are available to perform such calibration of consumer monitors. The perception of colour can also vary depending on monitor calibration and ambient lighting conditions. It should be noted, however, that most radiology applications that utilize colour do this by assigning a particular colour to pixel values. This is termed false colour. Radiology applications rarely utilize true colour.

3.1.3.4. Mobile display devices

Although laptops, smartphones, tablets, and other devices with wireless connectivity will undoubtedly play a major role in both diagnosis and review and communication of images and related information, the pace of advancement in this area is so rapid that no definitive statement on the utility or suitability of mobile devices for medical image display will be relevant for long. It may be noted that, at the time of writing, a few software apps that use portable tablet computers or smartphones to display DICOM images have been approved for medical use (see also Section 2.5.2). Within a hospital, this can be highly effective and reduce the need to access images on a traditional PACS workstation or PC, thus facilitating bedside and 'on the run' discussions on patient diagnosis and management; more remotely, this can be used for urgent off-site consultation. At present, these apps typically require either direct access to the DICOM archive, or an intermediary server that streams the images to the tablet computer or smartphone; therefore, wireless access and security for such portable computers are additional issues that must be addressed by DICOM administrators.

3.1.4. Image storage

Images must be stored, both in the short term for immediate use, for use as relevant priors for subsequent examinations, for referral for subsequent treatment and for statutory retention purposes. Many types of storage technology have been used for PACS archives, including hierarchical storage management systems that attempt to provide fast access to current images and slower access to older images, but prefetching from slower storage in anticipation of demand. In the early days, when reliable high capacity high speed hard drives were prohibitively expensive, hierarchical systems used various forms of tape or optical disk in juke boxes as the second or third tiers to support relatively small on-line hard drives. With the advent of redundant arrays of independent disks (RAID), network attached storage (NAS), storage array networks (SAN), fixed content storage, and the plummeting cost of high capacity hard drives, the trend in PACS archive technology has reversed. The use of so-called all spinning media, where all images are always available on-line on hard drives with the same level of service, is now routine. A variant on the hierarchical storage management concept is to use hard drives of differing performance to minimize cost for less frequently accessed content. A recent trend is to separate the archiving function from the PACS, with a vendor neutral archive, which can allow for easier exchange of images between sites, and also simplifies migration to a new PACS if and when this is necessary.

Today, the cost of archiving is usually not dominated by the price of the storage media but rather the TCO, i.e. the infrastructure required to support it, including the cost of power, cooling and network bandwidth for off-site replication. One aspect that has become apparent in digital storage is the rapid and never-ending evolution of the technology — better, faster, cheaper. Any significant archive or repository should be designed with the understanding that continued migration of the stored data to newer storage devices is inevitable over the lifetime of the PACS. Data migration policies should be created at the outset to deal with this inevitability.

Access to images has become mission critical, so any inaccessibility of the PACS is unacceptable, whether it is for scheduled (maintenance) or unscheduled (failure) reasons. This requirement drives the need for high availability in the entire system design, but particularly with respect to recent examinations for current inpatients. Satisfying high availability requirements may require the use of an off-site replica of the archive maintained to a state that is near real time consistent with the local primary archive, and a means of redirecting requests for images if the local archive fails.

A separate requirement from high availability is the need for backup in the event of significant local data loss. Since images are now stored exclusively as electronic data, the loss of the only copy results in total loss, and this is unacceptable either for clinical care or to meet statutory retention requirements. Backups must be performed and stored off-site in a sufficiently distant and robust facility to protect them. High availability and backup requirements can be satisfied with a single solution, but the needs are distinct. The design and procedures associated with high availability and backup solutions are defined in an organization's disaster recovery or business continuity plan, which analyses failure scenarios and provides predefined procedures to follow for likely contingencies. These plans must be regularly tested and include estimates of the time that will be taken to recover.

The possibility of using national or regional storage, either in addition to, or in place of local archives, is being considered. These afford an opportunity to provide access across enterprises and to community physicians, and could potentially be reused for backup purposes or as the primary archive. Commercial services also offer off-site storage, not only for high availability and backup, but also as the primary archive. Sometimes referred to as application service providers, or more recently as 'software as a service', this approach may make sense for smaller organizations, for whom the cost of maintaining the IT infrastructure to support a local archive compares unfavourably against the cost of the bandwidth required to communicate with an off-site provider.

Local regulations, site policies, standard of care, risk management and cost dictate what type of information needs to be archived for patient care and medico-legal purposes, and for how long. Not only the radiological report, but also the digital images themselves may form a critical component of the medical record. When images are acquired in multiple forms, for example, thin CT slices intended for post-processing, and thicker reconstructions intended for distribution and viewing, policy will dictate whether the former are retained or not. Retention of raw (unreconstructed) data for CT and MR is not typical, but retention of images for processing for screening mammography CAD may be of benefit to the patient, as may the retention of CAD results to improve accuracy at the next round of screening. In some jurisdictions, it is conventional and sufficient to provide a copy of the images in digital form to the patient (e.g. on standard DICOM CDs) and not to maintain a long term archive.

3.1.4.1. Film and paper

Although digital images can be printed to films for interpretation and distribution, they are less satisfactory for long term storage owing to their physical bulk, vulnerability to unsatisfactory storage environments (humidity, mould, etc.), and susceptibility to loss (e.g. not returned to film library by users). Indeed, in the foreseeable future, film may no longer be manufactured. Paper is simply not a suitable long term storage medium.

3.1.4.2. Optical disk and tape

Digital optical media includes those familiar to consumers, such as CD and DVD, and more specialized media intended for professional applications, such as magneto-optical disks in cartridges. The former are ubiquitous and relatively cheap and long lasting if handled and stored correctly. The latter are expensive, since they are not subject to the economies of scale of consumer media, and may be proprietary and difficult to obtain in some geographic regions. DICOM defines standards for the encoding of all of these forms of optical media.

Individual disks may be created manually and labelled either manually or by using a printer. They can be managed by storage on a shelf, but this is not a solution that scales well. It is generally used for producing disks to give to patients or referring physicians. These CDs or DVDs are typically encoded in DICOM format and there is an IHE profile, PDI, which further specifies how to create media. They may contain on-board viewing software for use on any PC, and there is also an IHE profile for the viewer, the Basic Image Review (BIR) profile, which is specified as the basic image viewing option to PDI.

For backup or for on-line archiving, optical media may be used in a jukebox with accompanying software, which automates the indexing and fetching of images stored on media. Such jukeboxes are available for both consumer media (CD and DVD) and professional media (MOD).

Various forms of high capacity tape are also available for backup, and these too are typically used in jukeboxes. Tape technology evolves rapidly and older capacities soon become obsolete, although most tape drives are capable of reading several generations of previous capacity media. Tapes are generally proprietary, with only a single or limited number of drive vendors supporting a particular type, although there may be multiple third parties who manufacture the media. Tape is even more vulnerable to physical storage conditions than optical media. Tape also can be 'shelf managed' rather than used in a jukebox. The unit cost of the media relative to the capacity is generally much lower than for optical media. All forms of backup or archival media should regularly be tested for the ability to retrieve information, and multiple copies may be required to lower the probability of loss or damage. Older media may need to have its content migrated to newer media periodically.

Although the use of a standard (DICOM) format on storage (as opposed to distribution) media is arguably less important, since the images are retrieved by the software controlling the jukebox, a standard format is recommended to allow for migration to new software or systems in the future. Migration of images stored in a proprietary form to a new archive or PACS may be expensive, difficult or impossible, depending on the vendor support.

The longevity of optical media and tapes is heavily dependent on the physical conditions in which they are stored. CDs are more tolerant of humidity and temperature extremes than tapes, but are not immune. It should be noted that both large storage utilizing optical disks and tape technology is now rapidly being replaced by RAID hard disks. It can be expected that tape and tape readers may soon no longer be manufactured.

3.1.4.3. Servers

The servers required to support storage of digital images are typically no different from conventional servers for any other high performance, high volume data driven application. Commercial and open source PACS software typically runs on ordinary servers, with the choice of operating system being a matter of vendor and customer preference. Some PACS software is hardware- and operating system neutral. Such servers should make use of, and integrate with existing infrastructure as much as possible, using the security and authentication mechanisms already in place, e.g. LDAP (lightweight directory access protocol), so as not to require separate usernames and passwords. As access to images at

all times is essential, these servers are typically designed as high availability systems.

3.1.4.4. Disk arrays

Usually, the most recently acquired images are stored on some form of hard disk or disk array so they are immediately accessible to the users. Older images that are unlikely to be needed quickly may be offloaded (manually or automatically) to slower forms of media, such as optical disk or tape, or lower performance hard disks. Given the rapid increase in disk capacity relative to price each year, many sites elect to maintain all their historical images on-line in the same disk array, without different tiers of accessibility. Depending on the modality, a single hard drive (e.g. 1 TB capacity) can store a substantial number of studies and patients. This may be sufficient for a small facility.

Larger facilities will need arrays of disks combined into a single storage solution from the perspective of the PACS software. These arrays may be separate disks in a single box, such as JBOD (just a bunch of disks), or a RAID. Different levels of RAID allow for different trade-offs with respect to performance and redundancy. For example, RAID level 0 maximizes speed but has no redundancy, and all data will be lost if one disk fails. RAID level 5 has some redundancy, allowing for a single disk failure with no data loss, with moderate performance. RAID is usually implemented in hardware controllers, although it is feasible in software with some operating systems. The individual disks within an array may be of different types and performance levels and may use different interfaces with different characteristics. Increasingly, consumer disks using the Serial ATA (advanced technology attachment) interface are being used to provide satisfactory performance and reliability at a lower price than more advanced disks using Small Computer System Interface (SCSI) or Fibre Channel (FC) disks. Disks also have different rotational speeds, cache sizes and firmware, and need to be qualified specifically for server, rather than desktop use.

The disk array may be connected to the server by various means. DAS (direct attached storage) may provide high performance, but may be more difficult to manage than NAS (network attached storage) and SAN (storage array networks), which provide increasing levels of separation between the server and the storage, and allow for virtualization of the storage arrays for both expansion and for sharing with other applications as well as image storage.

3.1.4.5. Cloud computing and data centres

Where high speed reliable access to the Internet exists, it is not absolutely essential to have storage co-located with the site at which the images are acquired

or interpreted. Cloud computing offers the ability to outsource hardware and software requirements to service providers which are accessible over the Internet, so that acquisition modalities can send images to a remote site for storage, distribution or interpretation. Likewise, radiologists and referring physicians may interpret and review images remotely from such an off-site storage solution. Alternatively, there may be a local storage mechanism, but off-site backup is provided over the network by a third party service. Only recent images may be stored locally, and relevant prior images are retrieved on demand or prefetched when examinations are scheduled.

Early in the history of remotely hosted storage and distribution solutions, the term application service provider was used. At the time of writing, distributed third party storage hosting is becoming popular for many non-medical applications, including consumer applications, and the term cloud storage has been popularized in this context. Several consumer service providers have expressed interest in medical applications.

3.1.5. Image distribution

Although some referring clinicians are satisfied with the radiological report alone, many require the images, whether to make their own clinical and diagnostic decisions, for surgical or other treatment planning, for patient education or for teaching. Digital images have an advantage over film in that, subject to the appropriate authorization and access controls, they can be made available at multiple internal and external locations simultaneously via a secure network or via interchange media. If necessary for teaching or research purposes, the digital images may be anonymized to protect the patient's confidentiality.

Many PACSs provide for local and remote network access by authorized users other than the primary interpreting radiologists, often utilizing a web browser component or a software application that has significantly constrained functionality, or with images of limited quality, and on displays that may not be calibrated or be of medical grade. This may be unsatisfactory for many sophisticated users, and a complete set of diagnostic quality images must be made available, preferably routinely, but certainly on request. If necessary, the providers of clinical care must be able to import the images into their own systems if necessary.

Different users require different functions to be available in their image display software. It is often assumed that referring physicians only require rudimentary image manipulation tools. In fact, examples such as dedicated software needed for orthopaedic prosthesis template application, neurosurgical robotic surgery planning and radiotherapy planning indicate otherwise.

The issue of allowing patients to access their own medical images is often neglected. The authorization and access control issues of providing external network access to patients are non-trivial, but institutions deploying electronic medical record (EMR) systems are increasingly providing patient portals. More commonly, a set of images on interchange media (typically a CD) is routinely provided to all patients, either immediately after examination or after the final report is issued. This is often complicated by the often non-DICOM compliant storage mechanisms and viewing software which may be operating system dependent.

3.1.5.1. Hard copy

Film is a familiar medium for most physicians. Films may be printed from digital images, with multiple copies distributed to different people if necessary. However, once printed, one cannot take advantage of the properties of the digital images (e.g. windowing). Another disadvantage is that in resource constrained environments, film may be expensive and difficult to obtain. Indeed, the transition to digital is often driven by the cost of film. Digital images also can be printed to paper, although the quality of the result may not be diagnostic, particularly if the quality of the printer, paper or ink is deficient in some respect.

3.1.5.2. Optical disk

Recordable CDs are the single most popular means of distribution of digital images. This is particularly true in the absence of high speed network connections, or the absence of a relationship and security mechanism between the sender and recipient sufficient to protect the patient's privacy. CDs are sufficiently low cost that they may be regarded as disposable in most environments. DVDs may be used when CDs are insufficient in size, although not all recipients have computers that can read DVDs. Also, the increasing prevalence of multislice CT scanners is leading to situations where sometimes even a CT study may need more than one DVD for storage. CDs are currently also useful for sending images that require additional post-processing or quantitative analysis (such as organ or tissue volumetry, voxel based analysis of enhancement, etc.), as standard viewing software usually does not have such capabilities.

All commercial PACS vendors provide CD burning options and the DICOM standard and IHE PDI profile define the required content. A viewer may be present on the media. Some vendors write proprietary format CDs that may be unusable by the recipient if they cannot run the proprietary viewer, and since these cannot be imported into the recipient's own PACS, they should be avoided. If necessary, a third party DICOM and IHE compliant CD burning solution

should be used to replace any proprietary PACS format. Free and open source applications for multiple platforms are also available for reading and displaying the content of DICOM CDs.

3.1.5.3. Network

Within a single site, the purpose of a PACS is to distribute images across the local area network (LAN). Early large scale PACS used dedicated workstations to access the central server, sometimes over proprietary networks to achieve satisfactory performance, but at the time of writing, conventional switched Ethernet offers sufficient local performance. Conventional PC workstations are used, albeit with specialized software and, if appropriate, specialized graphic controllers and displays. The software may be in the form of a 'thick client', which has software installed on the workstation, or a 'thin client', which uses software that is distributed over the network and is updated automatically. The thin client solution may be web based, in that it uses Internet and web browser technology as the basis for its implementation, even if deployed locally.

For access from outside the institution, or for access to a centralized solution not hosted by one site, the same thin client and web based solutions scale naturally, given sufficient network speed. Although it remains common to have different solutions for network access for radiologists performing primary interpretation, as opposed to referring physicians reviewing the images and reports, increasingly, the methods for network access are distinguished by the need of the user, rather than whether that user is situated locally or remotely.

3.1.5.4. Telemedicine

Traditionally, telemedicine, and particularly teleradiology, referred to point-to-point communication and collaboration between two physically separated sites or individuals. A basic solution involved the use of a film scanner, computer, software and modem transmission of the digitized image over a phone line or satellite to a remote user with the receiving and display software which can exchange data and display the images and other relevant clinical information. In addition to the transfer of the film, audio communication over the phone, with or without videoconferencing, provided the collaborative component. These implementations were typically proprietary and not standards based. The scenarios in which teleradiology was originally useful included: consultation with a radiologist at home after hours to avoid delay or travel, and consultation with a specialist or expert (perhaps in another state or country with different time zones).

Teleradiology has evolved to adopt modern technology and different use cases. In the presence of a PACS that is remotely accessible, or a centralized archive, teleradiology is no longer distinct from any other form of remote access and the Internet and web based thin client technology is typically used. It should be clear that, from a technical point of view, it is not a problem to transfer any image across the world, but effective telemedicine solutions also require a proper workflow to handle large numbers of telemedicine cases in an efficient way.

Additional use cases that are now possible include part or full time interpretation work from home, load balancing of interpretation work between different sites, including across time zones, outsourcing of emergency and/or final interpretation work to third parties who can provide more expert or lower cost services.

Currently, where point-to-point communication remains necessary, in the absence of generic Internet connectivity the same Internet and standards based (DICOM) technology is typically used, e.g. PC based web browser deployed thin clients exchanging DICOM images via TCP/IP over dedicated satellite links (with the TCP layer appropriately modified for latency issues). However, extension of local systems to provide remote access may be limited by network performance issues as well as security issues, particularly the need to provision external users with authenticated credentials and control their access.

3.1.5.5. Image compression

When stored or transmitted in uncompressed form, digital images occupy a finite amount of space linearly proportional to the matrix size of the image, i.e. each pixel occupies a fixed number of bytes. However, images typically contain a significant amount of redundant information that can be represented more compactly. For example, there is often a large amount of black space around the 'useful' parts of the image. Reducing the amount of space occupied by an image is a priority, since the cost of storage and bandwidth are significant, and sometimes there is insufficient time to transmit a large set of images over a slow connection to meet the clinical need.

(a) Lossless compression

Some forms of compression allow complete and exact recovery of the original data from the compressed data, and these are referred to as lossless or reversible compression schemes. Schemes typically used in consumer applications to compress text documents, for example, would be unacceptable if characters changed when decompressed, regardless of how infrequently

this occurred. Likewise, medical imaging applications may require perfect reproduction of the input, and hence lossless compression is widely used.

In practice, lossless compression of medical images produces compression ratios (relative to the original number of bytes occupied by an unpacked image) ranging from approximately 2.5–5 to 1, depending on the modality and type of image. Typically, medical images contain a significant amount of noise, texture and other high frequency content, and this interferes with the ability to achieve higher lossless compression ratios. Even background air or collimated regions contain noise. Despite this, cost and transmission time savings of this order are often sufficient to satisfy the use case. For example, lossless compression of 512 × 512 by 8-bit cardiac angiograms using a relatively simple scheme is commonly used to fit an entire such examination on a single CD.

(b) Lossy compression

Lossy, or irreversible compression, occurs when the decompressed result is not identical to the original, yet the amount and type of loss is acceptable for some purpose. For example, lossy compression is routinely applied to colour photographic images obtained from consumer digital cameras and is widely used in consumer Internet web browser pages.

Lossy compression results in artefacts becoming visible in the reconstructed image. For images that are compressed as an entire frame, these artefacts may involve subtle smoothing of the entire image, alterations in perceived texture of complex regions or the introduction of distinct small structures that were not present in the original (for example, in the case of wavelet transformation, reflections of the wavelet basis functions may appear, and in the case of truncated high frequency coefficients, ringing may appear around sharp edges, such as text). For schemes that involve splitting the image into small tiles before compression, block artefacts may appear where the boundaries of such tiles become distinctly visible.

Despite these artefacts, lossy compressed images may be sufficient for many clinical purposes. Establishing the appropriate levels of compression for each such modality, body part and diagnostic task is likely to require observer-performance studies with sufficient statistical power to detect that any lack of difference found is owing to a genuine absence of a clinically significant difference caused by compression, as opposed to a study that is too small to detect any difference. Such studies are expensive and few in number. Despite this, in a few countries there are emerging guidelines from various professional societies on the appropriate use of lossy compression (see Section 2, Table 2).

A confounding factor is whether or not to perform lossy compression before or after primary interpretation if one is going to compress for archiving or subsequent distribution. As long as there is the potential for a misdiagnosis, some advocate that optimum patient care requires interpretation of uncompressed images; indeed, the Food and Drug Authority of the USA requires this by regulation for digital mammography. Lawyers argue, however, that exactly what was interpreted should be archived. The most conservative strategy is to avoid lossy compression, regardless of the attractiveness of the potential infrastructure cost savings. In any case, as network speed increase and storage cost reduce, the use of lossless compression may not be a problem anymore.

3.1.5.6. Reports

Reporting styles vary, and some radiologists use conventional dictation (often using recorded digital audio), some use speech recognition and others fill in predefined structured report templates on the screen. Integration of reporting technology with image display and other information systems for optimal user efficiency and workflow remains challenging but is becoming more prevalent. Advanced reporting systems may integrate links to DICOM images and viewers, or use embedded multimedia.

3.2. INTEGRATION OF PACS IN DEPARTMENTAL WORKFLOW

3.2.1. Ordering and scheduling

Digital images may be acquired in response to a request or order (scheduled), or in the course of investigation or treatment of the patient by a clinician (unscheduled). In either case, there is a source of demographic information about the patient, including their identity and characteristics, as well as other information about their condition, and the identity of those placing the orders. This information may come from admission, discharge and transfer systems. Orders may be placed in a computerized physician order entry system or other form of order placer, such as an HIS. Scheduling may occur in a separate DSS/OF system, such as a RIS.

The use of an electronic source of identity, ordering and scheduling information, and the integration of disparate sources of information, reduces the opportunity for operator error caused by re-entry of data, and allows for images to be associated with information in other systems. This is particularly so if a single ‘point of truth’ can be established within an enterprise, i.e. a single source for patient ID can be accessed, thereby eliminating duplicate entries for an individual

across multiple clinical systems, which can lead to confusion and the incorrect assignment of clinical data. Otherwise, the error rate may be as high as 30%, potentially resulting in mismatches between patient records, requests, images and reports.

3.2.2. Quality control

After acquisition, quality control by a human operator is usually required to confirm positioning, technique, absence of motion or other artefact, and correct labelling and identification. A display device may be present at the modality console itself, or a separate quality control workstation may be provided to which the images have been automatically routed, or the images may be available from a central location via an ordinary PACS workstation but sequestered from general availability until quality control has been completed. The choice of mechanism is dictated by both the type of modality and local optimization of workflow. A direct digital X ray system may have an integrated display, whereas a CR cassette reader may require a separate workstation. Separation of acquisition and quality control responsibility to different operators may improve efficiency. Whatever workstation is used for quality control, it should have a display adequate for the purpose, in terms of size, functionality, calibration and viewing environment.

3.2.3. Analysis and post-processing

Some types of digital images are amenable to automated image processing and analysis to provide for CAD and CADx (computer assisted diagnosis). Cancer detection on X ray mammography is the primary application for CAD, but it is also applied for cancer detection to dynamic contrast enhanced MRI, chest X rays and chest CT, as well as CT virtual colonoscopy.

Aside from CAD, other types of post-processing may be appropriate for some applications and modalities. A human operator may create additional reconstructions of the acquired image data, for example, 3-D reconstruction, or perform quantitative measurements on the images prior to transmission to the physician for interpretation. A typical example would be quantitative analysis of coronary arteries on CT angiograms, which requires segmentation of the vessels, presentation in specialized 3-D software and semi-automated quantification of stenosis. Depending on the preferred workflow, specialization and expertise of staff, reimbursement pattern and the capabilities of the PACS, this may be performed as a separate workflow step or by the physician themselves during reporting.

CAD and other post-processing devices receive digital images from the modality, either directly or via the PACS, and produce additional information to be used during human interpretation of the examination. The images required for processing may be different from those required for presentation to a human observer, and a modality may be required to send raw data rather than processed images to the CAD system.

The output of any post-processing step may be in the form of derived and annotated images, or structured information that can be rendered and analysed by a user's workstation. The CAD or analysis workstation transmits this information to the PACS for the subsequent workflow steps.

3.2.4. Information management

No system is perfect and human error is possible at each stage of the process. Images may be inadvertently assigned to the wrong patient or order. The wrong study may be performed or images may be of poor quality and need repeating, which may require rescheduling and recall of the patient. The wrong side may be inadvertently recorded in the image header or pixel data.

These problems require that systems provide a management function that allows corrections to be made by authorized personnel, and a record of these corrections (audit trail) to be reliably maintained. These corrections may involve changes to various databases but need to be promulgated to everywhere the images may be used. It is not sufficient to correct a name or identifier only in the database viewer. The correction must also be performed in the header of any images that are archived or exported (such as on interchange media), or which are later migrated to a new system.

Over time, the PACS archive will fill with images that no longer need to be immediately available, for example, when statutory retention periods expire. Prior examinations for reporting rapidly decrease in usefulness over time. The ability to purge selected studies may be desirable, both manually and in a rule based automated manner.

Patients frequently need to be referred elsewhere for further treatment, and their records must be available to accompany them, so export capabilities, both over the network to remote facilities and via standard interchange media, are required.

A PACS may be linked to EMR systems that provide access to a broader range of information about a patient in one facility, or to a longitudinal patient health record system that provides for information to span facilities. The link may be bidirectional, in that it is useful for the radiology facility to have access to the patient's record (for prior images, reports, laboratory results and clinical

information), as well as to provide access to current images and reports to the clinical team.

3.3. LANGUAGE AND LOCALIZATION

The majority of medical imaging equipment sold worldwide has good support for English and Western European languages and character sets, both in terms of software (user interface), hardware (keyboards) and printed or soft copy documentation. Other language markets may be less well supported, or depend on local manufacturers or distributors to develop localized material. Given the widespread support for Unicode in modern software and operating systems and standards such as DICOM, HL7 and XML, the ability to support character input methods and display, as well as communication of names and other text, is considerably easier than in the past. Notwithstanding, even if fonts are available to display Asian, Arabic or Cyrillic characters, there is still work required to localize the user interface, both in terms of how text is rendered, as well as on other issues specific to the location, such as date and time and other numeric formatting conventions.

Not uncommonly, although the user interface may not be localized, the patients' names and the names of procedures may be localized in other systems, supplied through a worklist, and displayed on a device or encoded in an image in the correctly localized form. This may have a significant beneficial impact on the reliability of such demographic information in the system, especially when operators have limited skills in the language of the interface.

In many cases, especially in acquisition modality hardware, standard symbols rather than text (e.g. IEC standards for X ray equipment, IHE BIR symbols for image viewers) mitigate the absence of a localized user interface based on text.

3.4. DIGITAL IMAGING AND RADIATION DOSE

It is well documented that the migration to digital imaging from film based imaging has unintended effects on the dose to a population of patients examined under this technology, owing to the disconnection of image receptor dose to the image brightness. Typically, this results in increases in patient dose or 'dose creep', as the reward for increased image receptor dose is lower image noise, which is more generally pleasing to the viewer, but does not provide any additional diagnostic information.

To counteract this trend, it is important to optimize the radiographic technique [10, 14, 16] to reduce the dose to the patient while maintaining acceptable image quality. One effective implementation is to set the automatic exposure control (AEC) device to terminate the radiological examination for the optimal dose to the image receptor (see also Section 4.7.2). The simplest optimization process is to reduce the mAs for the procedure under controlled conditions, ensuring that the image quality is acceptable. More advanced optimization would involve investigating the use of image processing, as well as other radiographic parameters such as kVp and mAs for a specific examination (see also section 23 of the IAEA diagnostic radiology handbook [11]).

Another increasingly important feature of digital imaging and the use of PACS networks involves the use of DICOM structures to record dose related parameters. Such information is found in the image DICOM header and increasingly also in radiation dose structured reports. These indicators have the potential to allow the collection of large amounts of dosimetric data suitable for analysis and comparison to benchmarks. However, care must be exercised as the relationships between particular DICOM dose indicators, and accepted dosimetric parameters, should be carefully considered. A system for the verification and standardization of the DICOM recorded dose indicators used at a facility and their established tolerance values is required to give this data the reliability needed for dosimetric comparisons. An IHE Radiation Exposure Monitoring profile has been published (Fig. 6). This is based on the DICOM Standard PS3.16 (2009). The IHE profile is currently undergoing trial implementation.

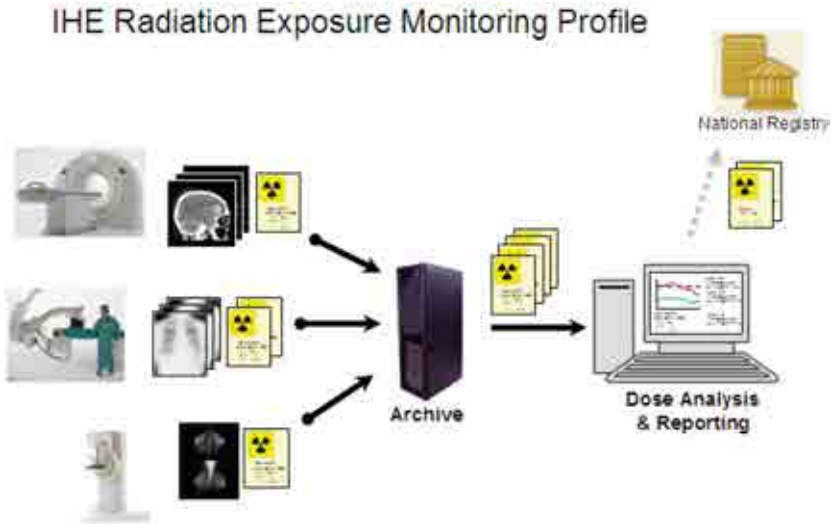

FIG. 6. Diagram of the IHE Radiation Exposure Monitoring profile [12].

4. CORE IMPLEMENTATION ISSUES

The previous sections deal in some detail with the technical issues associated with digital radiology. This section will concentrate on more practical issues related to the implementation of a digital radiology system, be it a small, single room unit with one workstation, to a more complex, hospital-wide picture archiving and communications system (PACS). It addresses issues such as project management, planning and procurement. It is aimed at individuals who will become involved with the implementation of digital radiology, from radiologists and technologists to hospital management, building and maintenance staff, IT staff, medical physicists and bioengineers. Additional information and checklists that can be utilized during the implementation process can be found in Appendix V.

4.1. INTRODUCTION

The implementation of a digital imaging project is a complex undertaking that requires a management strategy with significant input from all stakeholders to create a useable end product. The importance of this strategy cannot be overemphasized. The process should deliver a project fulfilling the stated requirements in a timely and financially responsible way. Success is dependent on careful management, coordination and execution of many highly specialized tasks. Even though the overall impact of digital imaging projects is mostly very positive, all major changes carry some disruptive aspects that need to be resolved. Successful implementation of digital imaging depends as much on the management of the social, cultural and organizational aspects of the changes it brings as it does on the management of the technological change itself.

A project management approach is often helpful. This can involve a structured project management methodology, such as PRINCE2 (projects in controlled environments) or PMBOK (project management body of knowledge), or it may involve a less formal approach. In any case, the management and governance of the implementation requires careful attention.

The establishment of a formal governance process is a critical success factor. This may be a formal project board (as in the PRINCE2 approach) or may involve a local steering committee empowered to make decisions to guide the implementation project.

Depending upon the complexity and formality of the project management process it may be necessary to undertake a formal business requirements analysis. This process should identify and document the requirements of the users and

the expected outcomes of the project in a business requirements specification document. Following this, an implementation planning study can be commenced — guided by the business requirements specification. Creating an implementation plan begins with a list of all the main activities with their expected start and end dates. A list of those involved in or affected by the resulting change (stakeholders) is also helpful in managing expectations and training. If possible, the cost of each listed activity should be itemized to verify whether the project is within the allocated budget.

Correct task scheduling is essential throughout implementation. Some specialists whose skills are required may have to travel to the site; their visits will have to be planned around other time commitments. In these circumstances, their tasks can only be commenced if preceding dependency tasks are already completed.

If there is little or no local experience in planning and executing projects of this kind, engaging the services of external consultants should be considered. Valuable information may also be gained by contacting colleagues who have completed similar projects. A thorough implementation plan will lay the foundation for successful implementation, which in turn will lay the bedrock for a reliable and sustainable medical service, based on the constraints and conditions set out at the time of the project definition.

4.2. LOCAL CHAMPION

Depending on their scale and complexity, digital imaging projects may require consistent and stable management for a relatively long time. As noted above, the potential success of projects is dependent upon effective governance, and is greatly enhanced if there is clear local project ownership. It is therefore recommended to identify and engage a ‘local champion’ for each digital radiology project. A local champion would typically be recognized for his or her skills in the domain of medical imaging (either technical or clinical) and might be described as a person who:

— Has good communication skills;
— Is a respected member of the medical community;
— Has experience in working with medical technology;
— Is well connected to and belongs to the local community;
— Has a background in project leadership.

4.3. INVOLVEMENT OF STAKEHOLDERS

One way to involve stakeholders is to form a project group with representatives from all groups with an interest in the project. Leadership roles should be clearly defined from the beginning. The goal is to harvest all the available knowledge to improve the project outcome, but not necessarily to reach unanimous consensus on each subject. Rather, the leaders should make decisions based on the available knowledge and within the economic constraints.

Transformation from film based radiology to digital imaging is a major change for all involved and must be well managed. The expectation is for methods that have been used for a century to be abandoned almost overnight, and this will present challenges for some users. To ease the transition, it is important to inform all interested parties in a timely manner with a clear explanation of the issues, to allow people to prepare for the change. Communication strategies and a clear understanding of the principles of change management are essential in this. The absence of film may compromise the work of some physicians and it should be made very clear in each situation which media will be used to replace film. It is important to realize and to communicate the fact that a digital imaging service benefits the users of radiology services more than the radiology staff themselves. There will be a teething period where the transition may be confusing, disruptive or dysfunctional at worst. This period can be minimized by careful planning and involvement of the stakeholders. The good news is that almost universally, after a 1–3 month period of use of digital imaging, users do not want to 'go back' to film based imaging. The advantages are that significant and dramatic.

4.3.1. Administration

Most formal project methodologies define a role of project sponsor. The sponsor is responsible for securing and managing resources, and overseeing the procurement and implementation processes (i.e. requesting offers and writing contracts with vendors). In this sense, the sponsor is the administrator of the project. The role of administration during implementation is in support and project management, with financial controls and documentation of progress being key responsibilities. Those responsible for project management, with the support of those responsible for administration, must follow the project plans, but also be sufficiently flexible to constantly encourage and support new solutions to resolve upcoming issues in a timely manner. A well-documented administration of the project budget in harmony with verifiable project milestones is the most powerful management tool of every project.

4.3.2. IT

If a facility has an in-house or local IT department or section, that group should be engaged early in preparing the transition to digital imaging. It is, however, crucial that the IT group understands that solutions must follow standards and practices within the digital imaging community. This may require the development of a memorandum of understanding between the project and the IT group to define the required inputs. If freeware and off the shelf hardware become part of the solution, the local IT group should prepare those components well in advance of the planned installation of the image acquisition equipment.

It should be understood that digital radiology, radiology information systems (RISs) and PACSs are not simple IT projects which can use standard, low end equipment and freeware or open source software to build up complex infrastructures. A PACS and a RIS are medical devices, and in a medical environment, the loss or mix-up of data can lead to incorrect treatments being given to patients, or worse, and can have a legal impact to the health care organization. On the other hand, the digital imaging project team should understand that imaging is just one piece of the overall hospital information system (HIS) and that good integration with transversal services (e.g. scheduling, reporting, billing) is essential to obtain optimal benefits at the institutional level. The involvement of IT and their relationship and communication with diagnostic imaging personnel is critical. A good relationship will very significantly promote the speedy implementation and reliable maintenance of the digital department. The opposite will almost certainly guarantee frustration and failure.

4.3.3. Clinician partners

The ultimate users of any radiology service are the physicians who refer patients. The introduction of digital imaging may affect their clinical service delivery. Clinicians require training to use computer systems for image distribution, and they will act as a valuable source of feedback, both positive and negative, for the effectiveness of digital imaging distribution outside radiology. At the project planning stage, it should be clear how existing clinical partners will be served during and after the transition to digital imaging. The planning should also identify those clinicians and departments who will have particular requirements for the medical imaging service (for example cardiology or orthopaedics, to name but two). New service opportunities based on digital image distribution may allow extension of the existing services to a much larger clientele. Close interaction between these individuals and the PACS implementation team is essential. It cannot be overemphasized that it should be made clear that the service is developed to benefit most them as users of the radiology services.

4.3.4. Radiology staff

Radiology staff should be at the heart of any implementation programme, and must be adequately represented on the project steering committee. Ideally, they will also be part of a wider staff consulting group that provides subject matter expertise to the project. This will allow all radiological staff members (radiologists, radiographers and assistance personnel) the opportunity to comment on and contribute to plans and drawings in process. Planning and providing the necessary new training, including basic computer literacy, should be a part of the implementation plan. The maximum speed of any transition is set by the ability of the staff to adopt changes [17], therefore an effective staff development and training programme is one of the most important components of a digital imaging project. It will be necessary to plan to train, retrain and retrain again.

4.4. CONSULTATION AND ADVICE

In larger health centres in major urban areas, there is often significant internal expertise in medical imaging planning, digital imaging modalities and IT infrastructure development, allowing for effective planning and implementation of digital imaging, PACS and RIS. This is probably not the case in smaller centres, where it may be more appropriate to bring in external advisors. These could be lead consultants with comprehensive knowledge of digital imaging and its implementation, or specialists of a particular kind. Often, local biomedical engineers will be the most appropriate to analyse the needs and propose technical solutions. If at all possible, every project should have at least one leading person who has first-hand knowledge in implementing digital imaging projects.

4.5. NEEDS ANALYSIS

Needs analysis can vary from being a simple task to a very complex undertaking depending on the size and nature of the project. It is essential that the project has a well-defined and communicated scope with goals, objectives and procedures that are clearly understood by all concerned. If film based systems are to be replaced by digital devices, the needs analyses should be based on existing demand plus a realistic future forecast. If there is no local experience, then models from a similar facility in the same country, or in a neighbouring country which has similar social and economic structures, should be used. Needs analysis should include visiting equipment vendors' web sites and studying

brochures, as well as direct communication with salespeople and current users of the technology. For medical imaging, just as for any other service, the supply and demand interaction is complex and careful advance planning is required to maximize the chances of a successful implementation.

The real workflow efficiency of digital radiographic equipment depends on the design and characteristics of the equipment as well as the physical workflow layout at the site. A computed radiography (CR) system that directly replaces a film based system will have similar throughput efficiency, while many digital radiography (DX) solutions have the potential to further increase acquisition throughput. As human resources are scarce, more expensive digital solutions may have shorter repayment time compared to film based alternatives. Depending on the local requirements, redundancy may be more important than throughput, and this would be true for sites demanding a reliable 24/7 emergency service. In such cases, buying two CR readers and two X ray units would be a more reliable solution than buying one DX unit. These are examples of issues that can be considered as part of the business requirements analysis process. Awareness of any special requirements where general versions of digital imaging devices may fail to provide adequate solutions is important. The most common special requirement examinations that may not be fulfilled by general equipment are within paediatric and neonatal chest imaging.

All the clinical requirements should be clearly spelled out as the technical deliverables are linked to the clinical properties of the technology. A list of every type of examination to be performed with the equipment should be included in a clinical requirement section of the equipment specifications.

Technical requirements should focus on core technical issues. Items that should be specified include power standards to be followed, power quality (how many outages per month or year), available backup power, air conditioning requirements and the reliability requirements for the medical imaging service.

4.5.1. Current status

It is important to establish the current status of the medical imaging services before defining a new project. The status of buildings and support systems (power, temperature control, humidity and dust levels etc.) and available human resources (radiologists, radiographers, medical physicists, IT staff and biomedical engineers, as well as other personnel), together with operational budgets, should be reviewed and summarized in a written report to support the necessary decision making and, later, the project management.

4.5.2. Site considerations

The nature of the elements that building and utility systems must withstand varies greatly throughout the world. Geological and meteorological phenomena constantly threaten the stability of any service in large parts of the world, but in some areas, human-made disasters are the predominant threats. An important general rule is that maintaining long term sustainability is more complex than the original purchase and installation. As digital imaging is based on more complex technology than film based X ray systems, the reliability of digital imaging services depends even more on the sustainable quality of the building and the necessary utility systems. In addition to the utility services necessary to run film based medical imaging, digital imaging may require one or more computer servers and a computer network. If the medical imaging department is a part of a medical facility, a facility-wide network with a single central server room should be considered. Existing networks may well have the capacity of 100 Mbit/s or better, which is necessary to transfer medical images in a timely manner.

4.5.2.1. Internet connections

If teleradiology and/or remote image access is a part of the project, an external network connection is required. The type of network will depend on local availability, and the required bandwidth will depend on the image volume to be transferred, as shown in Table 3. Data overhead and congestion are the reason that the transfer time is not simply image size divided by data speed. The required bandwidth will also depend upon the modalities and the workload. For example, a multislice computed tomography (CT) scanner may well require 100 Mbit/s, but a facility with only CR and ultrasound will probably be able to manage with as little as 4 Mbit/s.

4.5.2.2. Physical safety of digital imaging equipment

Measures must be taken to prevent loss of or damage to patient information. Many centres have already being using computers for some time and have developed solutions pertinent to this issue. It is important to protect the integrity of the system as a whole, and to ensure that computers or other vital components are not allowed to be removed without permission.

TABLE 3. TYPICAL BANDWIDTHS AND TRANSFER TIMES FOR DIFFERENT CONNECTION TYPES

Type of connection	Typical bandwidth up/download	Transfer time of one 5 MB image
ISDN	64–128 kbit·s^{-1}	About 6–12 min
ADSL	from 64 kbit·s^{-1}/256 kbit·s^{-1} to 1 Mbit·s^{-1}/10 Mbit·s^{-1}	6 min to 50 s
DSL	from 256/256 to 10 Mbit·s^{-1}/10 Mbit·s^{-1}	3 min to 5 s
Fibre optics	up to 1 Gbit·s^{-1}	As low as 50 ms
Microwave	50 Mbit·s^{-1} to 1 Gbit·s^{-1}	1 s to 50 ms
Mobile data networks	up to 7 Mbit·s^{-1}	As low as 10 s
Satellite	64 kbit·s^{-1} to 1 Mbit·s^{-1}	12 min to 50 s

4.5.2.3. Site planning

All vendors should offer site planning and installation guidelines. It is strongly suggested that site planning is included in the request for proposal (RFP) made to potential vendors. If a request for a site planning proposal was not a part of the RFP, it should then be requested from the vendor as a part of the site preparation project. It is absolutely necessary to have a signed site planning agreement with the vendor. This should include a final floor plan, with the equipment correctly placed and to scale, before site preparation work starts. This will facilitate correct installation and document the responsibility of the vendor to deliver a correct installation. In this way, the successful vendor will be responsible for meeting planning requirements and that the proposed equipment actually fits and works in the facility.

It is important to respect all local building, electrical and safety codes. Site planning depends on the size and the nature of the project, local traditions, climate and available budget. All medical imaging equipment that produces X rays requires a radiation shielding plan [9, 10, 18, 19].

4.5.2.4. Physical room layouts

CR readers should be placed close to, or even inside the X ray rooms for maximum efficiency. When replacing a film based system or a CR system with DX, bottlenecks that prevent doubling of the daily patient volume should be checked. Typically, the reception area has to be enlarged as new tasks are moved there, and as the interaction time of the reception staff with each patient remains the same. A central space in the X ray department should be chosen for image interpretation using computer workstations. If a reading room with light boxes exists, this may be the best place. If the practice of retrieving prior images to assist with image interpretation is not usual, the transition to digital could be instantaneous and any light boxes removed. Otherwise, light boxes may still be required for up to two years, until the demand for the use of old films diminishes. For reading room requirements, see Section 4.5.6. Consideration must also be given to the need for space to hold prior films during the transition to a fully digital workflow.

A secure space for servers is required when going digital, and this may be shared with other IT services. The server room must be physically safe to prevent theft of the equipment and the data. For electricity and climate control of the server room, see Section 4.5.7. Figure 7 shows an example of remodelling a small X ray suite to transition from film based to digital X ray.

FIG. 7. An example of remodelling of a small X ray suite to go from film based to digital X ray. On the left is the facility before conversion to digital imaging. The introduction of digital technology has also improved workflow functionality through a limited removal of existing walls.

4.5.3. Electrical power supply

The power supply is the lifeline of all imaging equipment. Without reliable power of the correct quality, modern medical imaging equipment becomes unuseable. In large parts of the world, the power supplies are unreliable and destructive to delicate equipment. This can be somewhat compensated for by using battery driven backup power supplies with power cleanup circuits that supply short term power and correct any malfunctions on the power lines. Depending on the nature of the unreliability of the main electrical supply and the total power (kW) needed, there may be a choice between using battery driven uninterruptable power supplies (UPS) only, or supplementing a UPS solution with backup generators [20]. To bridge short term outages measured in minutes or even hours, a powerful UPS solution might be the best and only option needed. For long outages measured in hours and days, backup generators powered by internal combustion engines are necessary. Alternative solutions could be backup systems based on solar panels and/or windmills. It is, generally speaking, a good idea to have UPS backup as well as power conditioners for computer systems, as these would be the most vulnerable to power spikes and fluctuations. The choice of design solutions and technology should depend on the perceived and documented needs for the X ray unit, the reliability of the local power supply and the local availability of technology, expertise and tradition. Any existing business continuity, disaster, and recovery plan should be updated to include the digital imaging equipment.

Ideally, all medical imaging installations that are expected to serve the public 24/7 require fault tolerant and redundant power systems. This means that only multiple failures can terminate the service after single points of failure have been eliminated. This requirement adds considerable complexity to the installation design, capital costs and maintenance. Only with the correct design, proper implementation and professional proactive maintenance, will the power supply fulfil and sustain the stated requirements. Regular emergency exercises are necessary to verify the actual status of a critical power system and to maintain the necessary level of training. The information gained from the emergency exercises should be used to refine the maintenance work and also to improve the system design.

The most power demanding imaging device at each site is usually the X ray unit. X ray systems with an energy storage option may also maintain full functionality for a short period of time without external electrical power (see Section 4.7.1).

For large installations, the equipment should be classified as mission critical or non-critical at the time of design. All mission critical equipment should be powered by the most reliable power supply design available at that site. All

computer and network equipment should be protected by a UPS with a power conditioning system. This includes the viewing workstations.

UPS batteries have a limited lifespan and need to be checked regularly with a plan to replace batteries every few years as they fail (in most cases, batteries can be expected to last for at least 3 years and up to 5 years). Without such a plan, the power supply to the imaging equipment is not guaranteed beyond a fairly short period of one battery lifetime cycle. At the time of purchase, prospective UPS bidders should state the battery lifetime expectancy for the conditions specified to allow for fair comparison of the offers and proper planning of battery replacement intervals. The cost of batteries should be included in the total cost of ownership (TCO) calculations. To maximize battery lifetime, the environmental requirements and the instructions in the UPS user manual must be observed.

4.5.4. Climate control

All digital radiology devices are based on electronics and are computer controlled. Most computer equipment is specified for ambient operating temperatures between 18 and 30°C, and between 20% and 80% condensing humidity for long term reliable operation. It is important to favour low humidity conditions rather than low temperature, as humidity may severely degrade or destroy the equipment. It is also important to implement energy efficient solutions as cooling can be very energy demanding. It is important to block all direct sunlight from entering all examination rooms (X ray, CT, ultrasound, etc.) and server rooms.

Prior to installation, all rooms should be monitored for a couple of weeks to verify conformance to environmental requirements, and then for at least four weeks after the installation. From then on, automatic SMS temperature and humidity alarms, or at least thermo- and humidity meters with audible alarms, should be used to indicate climate control malfunction. Note that failure to follow the vendor's requirements may render the equipment useless and/or cause serious failures not covered by service contracts or vendor warranties.

For small scale projects, it is recommended to use standard air conditioning equipment, preferably available locally to secure timely service and correct maintenance. Air conditioning systems intended for office temperature control are recommended for cost effective solutions. To create redundancy, at least two or three units of the same type should be installed to serve a small imaging department. To calculate the air conditioning requirements, add the dissipation figures for each piece of equipment. The equipment specification normally shows the dissipation figure in kW. Also add contributions from other heat sources (incoming energy, electrical lights, humans, etc.), and then consult the vendor's specifications to size the A/C units.

4.5.5. Structural changes

Digital imaging in itself normally does not require structural modifications of the buildings unless a new imaging modality is planned that requires floor reinforcement or special shielding (e.g. CT and MRI). However, the introduction of digital technology may allow for structural changes that improve workflow (see Fig. 7). Any planned structural alterations must be approved by the pertinent authorities to ensure that the structural integrity of the buildings is maintained.

4.5.6. Reading room

Control of incoming light (especially daylight, stray reflections from light boxes, monitors, and light from other rooms) in the reading room is an important factor. Given the relatively low maximum luminance of displays, it is necessary to ensure optimization of human contrast detection. This is essential for efficient reading, to reduce radiologist eyestrain, and to ensure the best perception of displayed contrast and detail. Control of the light level in the reading room is also important, and soft, indirect, adjustable lighting is recommended. If paper document reading is necessary, spotlights (i.e. adjustable neck reading lamps) that are not reflected in computer displays are the best option [14].

4.5.7. Server room

A server room is a room dedicated to the location of computers. They are characterized by having air conditioning, as well as an appropriately protected and reliable power supply. No dedicated server room is needed for entry level digital imaging systems as the computer requirements tend to be low and no long term storage is necessary. For facilities that plan on establishing long term in-house storage, existing server rooms can be shared with other IT functions. The servers are the core units of server based systems and therefore the quality of the server rooms will have a big impact upon system reliability. Server room quality depends on power quality, cooling system quality, and the efficiency of the physical protection. One key aspect, which should also not be overlooked, is adequate fire protection. It is recommended that, in the case of a dedicated server room, an appropriate fire extinguishing solution suitable for electronic equipment is deployed.

4.5.7.1. Power

All servers should be connected to an appropriate UPS supply with enough battery capacity to keep systems up for at least 15 minutes without power from

the grid. Within that time, the backup power should engage, and failing that, the servers should shut down gracefully and in a programmed fashion. Vendors of UPS systems have calculators available on-line which allow for the specification of the required UPS to be determined. A backup generator, if available, must be able to run both the computer equipment and the cooling systems.

4.5.7.2. Air conditioning

The permitted temperature range for computer and digital imaging equipment is typically from about 10°C (50°F) to 28°C (82°F), and common recommended server room temperature settings are close to 20°C (68°F) [21]. Cooling requirements vary greatly depending on the local latitude, distance from the sea and elevation. If at all possible, the server room should be located adjacent to the wall with the lowest heat load to minimize heat transfer from the environment and to allow installation of an air conditioning unit through the wall. It is recommended to use commonly available units.

If water for cooling is available, water cooling solutions may be economical and reliable. Water cooling systems can use the same components as water heating systems, but work in reverse. Cold water (8°C colder than the set temperature) runs through radiators that lower the room temperature. Thermal valves adjust the flow depending on the difference between the set temperature and the room temperature. The cooling system wastewater can be utilized for irrigation, sanitation and other purposes. In climates with high humidity, it is necessary to collect the runoff dew water from the radiators and channel it to a drain.

Standard office grade air conditioning equipment is suitable for smaller server rooms. Redundancy should be built into the system, and therefore at least two units should be installed, each sized to cope with the full heat load. It is important to adjust the units to different set temperatures, e.g. with a 3–5°C difference between then. The settings on each machine should be alternated every six months to maintain equal utilization of both units.

Air conditioning units consume large amounts of energy and can therefore be costly to operate. When selecting an air conditioning solution, energy efficiency should be one of the most important selection criteria. It is therefore important to isolate the server room with rockwool or other standard building insulation materials. If the outside temperature is 10°C higher than the set temperature, the difference in energy inflow between a non-insulated wall and a wall insulated with 10 cm of rockwool is approximately 10:1.

4.5.7.3. Humidity

In very humid climates, water saturation may become a problem. If there are signs of dew on the equipment or the walls, the set temperature should be raised within the allowed limits to prevent saturation. In humid climates, it is very important to collect and drain all condensation water from the air conditioning equipment.

In very dry climates, static electricity may become a problem when humidity in the server room is below 20%. In this case, a humidifier should be installed; ultrasonic type humidifiers are recommended. The manufacturer's recommendations should be followed to establish the correct sizing.

4.5.7.4. Monitoring and preventive maintenance

Several critical parameters must be continuously monitored. Temperature, power off, intrusion detection, and humidity out-of-spec signals should generate alerts which are automatically sent to the responsible persons via SMS and email. Free open source monitoring software is available (Appendix III). At an absolute minimum, two good quality audible thermometers should be installed.

The importance of regular preventive maintenance of both power supplies and air conditioning cannot be overemphasized. This will allow the critical and expensive radiology service to continue to function according to specification.

4.6. FUNCTIONAL SPECIFICATION OF THE DIGITAL RADIOLOGY SYSTEM

4.6.1. Organizational goals

The functional or performance specifications of the proposed system should be aligned with the organizational goals of both the radiology department and of the organization, and the main objectives should be clear. This includes goals such as productivity, quality of service and cost savings and will impact on diverse parameters such as:

— The expected throughput of patients for each modality;
— The required image quality;
— Type of reading monitors;
— The number of referring physicians to be served by web servers;
— The time to retrieve an image or examination of a defined type from a network server or web server.

4.6.2. Uptime

The uptime for the medical imaging system within the expected service life will be a combination of many factors (Fig. 8). The main factors are reliability of power and quality of service, followed by the quality of control of environmental factors such as temperature and humidity.

During the run-in phase (6–12 months), reliability may be compromised for a number of reasons. It is important to analyse and correct all problems as quickly as possible to bring all systems into full utilization and normal operation. Digital equipment is more prone to early failure and has a shorter lifetime than most analogue acquisition X ray equipment. Some components or subsystems should be replaced rather than repaired. Important factors to check and analyse during implementation include:

— User training;
— Environmental control (temperature and humidity);
— Installation failures (systems not correctly installed or configured);
— Initial equipment problems.

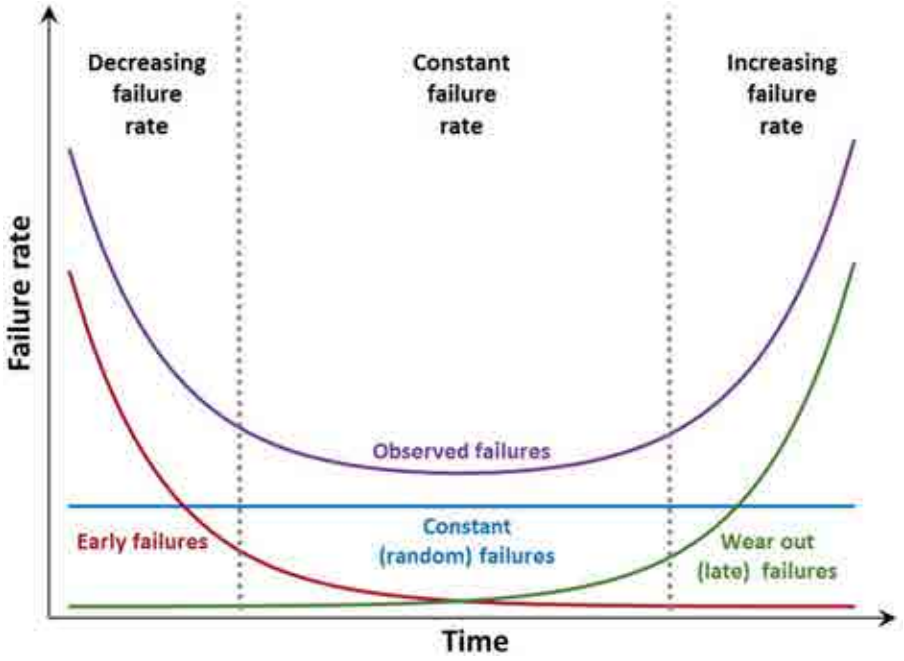

FIG. 8. Equipment failure rate as a function of time. The purple curve shows the failure rate which one can expect in practice.

Close cooperation with vendors is extremely important in rectifying post installation problems of technical and human origin. It is important that a senior person is identified who will manage relations with the vendor. One of the ways of ensuring correct delivery and installation is to require that final acceptance payment is held back until all issues are satisfactory resolved, and also that penalties are imposed when agreed specifications are not met. These would have to be written into the original RFP. The expected long term uptime for medical imaging devices (not taking extreme environmental factors into account) should be defined and agreed on with the vendor. It should be clear to both vendor and client whether this, for example, refers to normal working hours or whether it refers to 24/7 availability. For instance, an agreed uptime of better than 99% (calculated over 3 months), not including scheduled downtime, would allow for a single 20 hour breakdown without penalty. It is up to the facility to decide whether this is acceptable.

4.6.3. Networking and standards

Existing networks may well have the capacity to transfer medical images. The most common local area networks (LAN) at the time of writing were made up of CAT5e Ethernet cables and 10/100/1000Mbits/sec switches and therefore have maximum transfer rates of 1 Gbits/s. Ethernet cable runs cannot exceed 90 m between switches. The switches should therefore be placed close to the centre of the building with at least one on each floor to minimize the need for repeaters. In large buildings, the switches should be interconnected with fibre optic cables. Appropriate consideration should be given to having such switches protected with adequate UPS systems.

Wireless network solutions might be considered for small installations as it will remove the need to install cables. Wireless network solutions [22] may also be necessary to allow physicians to use their laptops or hand-held devices to access the imaging network within certain areas. Access to the wireless network should be limited to a list of identified computers, and a secure configuration should always be used. Network design proposals (shown conceptually in Fig. 9) should be requested from local network infrastructure companies. Medical grade wireless networks (which provide both reliability and security) are now becoming available and should be used wherever possible.

4.6.4. Network safety and security

Safety threats arise mostly from the Internet and from data exchange through shared storage devices such as CDs and USB memory sticks. The main rule is to use virus protection that is automatically updated through an Internet

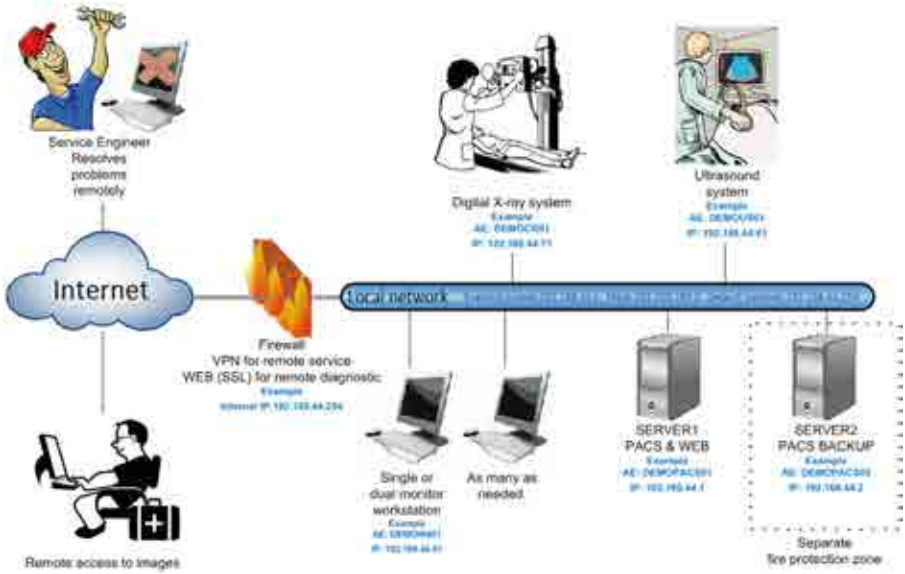

FIG. 9. Conceptual diagram showing medical imaging network infrastructure.

connection. Most virus protection software licenses have to be maintained by regular payments, but free alternatives are available [23, 24]. A physical proprietary imaging network is recommended to protect patient information and IT systems from malware and viruses. All connections to the network should be through routers to internal networks and through firewalls to external networks. However, before installing a particular virus protection software solution, it should be verified that is does not interfere with the operation and performance of the medical imaging solution.

The ability of Digital Imaging Systems to support virus protection software needs to be considered as part of the procurement process. If it is not possible to install such software, the equipment (and the overall network) must be protected by other means. The most secure set-up is to have no connection to outside web sites from computers on the X ray or medical network, and no use of incoming storage media, for example, by physically blocking the USB ports on all computers on the medical network. A high level of security is appropriate in medical applications. General Internet surfing should be prevented on all medical computers. However, Internet access is an important tool to support diagnostic reading, such as access to medical journals, radiological reference web sites and other on-line resources. For larger sites, Internet access may be obtained on the diagnostic workstations, or alternatively, by utilizing a desktop virtualization server or other high security solution. For low volume sites, the best solution may

be to install a separate computer with general Internet access but no connection to the medical network. Finally, when constructing the network, consideration has to be given to the reliability of the components which make up the network (servers, routers, switches, etc.) and a disaster recovery plan needs to be developed which can be implemented if, for whatever reason, the network (or parts thereof) fail. Appropriate drills using such a plan will need to be conducted at regular intervals.

4.6.5. Teleradiology

If teleradiology and/or remote image access is a part of the project, an external network connection is required. The type of network will depend on local availability. The required bandwidth will depend on the image size and volume to be transferred (see Section 4.5.2.1). As previously discussed, options are:

- Internet connections (e.g. cable modem or DSL);
- Mobile Internet technologies (e.g. 3G, 4G or WiMAX);
- Dedicated digital lines (e.g. ISDN);
- Microwave transmission;
- Satellite transmission.

Teleradiology equipment, (including all acquisition equipment) should be DICOM (Digital Imaging and Communication in Medicine) compliant for communication with workstations, telecommunication devices and image storage (see Section 3) [25, 26]. Some locations have no means (or plans to find a means) of connecting to referring physicians or teleradiology reading services, while other locations can utilize internal and external networks as a part of the medical imaging chain. If a direct network-to-network link is possible, an issue which needs to be considered is that of patient identification. Correct patient identification is, of course, necessary for clinical reasons but also to avoid misfiling patient images under the wrong name or in the wrong location. In the worst case, it could result in the wrong image being attached to a patient, with obvious clinical consequences. Most countries do not have any central registry with unique ID numbers, thus the names on the DICOM work list cannot be verified against a validated reference. This lack of consistency in entering patient identifiers may lead to errors in image storage as the same person may have multiple electronic image folders. There are some Integrating the Healthcare Enterprise (IHE) profiles that may assist in the reconciliation of patient identification in the absence of unique identifiers (for example, the IHE PIX/PDQ profile provides for patient identification cross referencing).

Finally, as there is now a considerable distance between the location where the clinical images are generated and where these are reviewed and reported, it is important that both sites have a clear understanding and agreement on the access privilege policies which are to be followed in order to ensure that patient data remains confidential.

4.7. TECHNICAL SPECIFICATIONS

4.7.1. X ray equipment

The specifications recommended for an X ray generator used in digital imaging are the same as for film screen systems. The power specification depends on the power available at the site (see Section 4.5.3). It is of paramount importance to verify that the power requirements stated in an RFP are in full agreement with the actual capabilities at the installation site.

The output power of the X ray generator has a major impact on the image quality as higher power means shorter exposure time and fewer motion artefacts (better temporal resolution). For most imaging tasks, an X ray generator between 20 and 30 kW is sufficient. Generators are available as three phase, single phase, and with or without an energy storage option. Sites with low capacity power networks and unreliable power need X ray generators with energy storage options.

The power requirements for generators with an output power of 30–50 kW typically go down to 2–3 kW with the energy storage unit installed. This output can be delivered from most standard single phase outlets. The WHO WHIS-RAD (World Health Imaging System for Radiography) would meet these requirements (Fig. 10).

To ensure the optimal use of radiation received by the patient, X ray equipment used for digital imaging should have the use of an automatic exposure control (AEC) device that must be correctly installed and set up. Most modern generators offer this option, as well as the ability to store exposure protocols called anatomical programming. Correct anatomical programming with calibrated AEC can greatly enhance consistency and productivity.

Connectivity requirements are different for CR and DX use. In the case of CR, an existing X ray room may be utilized and thus the CR unit (and possibly the X ray generators for CR imaging) may need a remote service connection. (It should be noted, however, that at the time of writing, DX detectors which fit into existing X ray units had recently come onto the market; such detectors may have wired or even wireless connectivity built into the detector. This blurs one of the distinctions between CR and DX). In contrast, most, if not all DX systems

FIG. 10. The WHO WHIS-RAD (photograph courtesy of T. Kalolo, United Republic of Tanzania).

have an integrated detector and X ray generator system and normally use conventional network connections. Such systems are also DICOM compliant (DICOM Modality Worklist and DICOM Storage should be supported) and support remote service.

The following should be specified:

— Types of examinations planned;
— Number of examinations per year as well as expected 8 hour peak loads and annual growth;
— Examination room size;
— Connectivity requirements;
— Power standards;
— Energy storage requirements;
— Type of tube stands;
— Floor stands (specify if lateral decubitus view is to be supported);
— Ceiling suspended tubes (observe the minimum ceiling height and structural requirements);
— Location of vertical bucky stand.

4.7.2. CR equipment

A CR device replaces film processing and is the most common entry level into digital imaging, as the CR cassettes can directly replace conventional film screen cassettes without any mechanical modification of the X ray equipment (also see Section 3.1.2.1).

Different software and hardware options tailoring a system to certain types of examinations may be available. Some of the most challenging requirements come from neonatal and paediatric imaging. The following should be specified:

— Types of examinations planned;
— Number of examinations per year as well as expected 8 hour peak loads and annual growth;
— The size and number of cassettes needed;
— Whether a CD/DVD writer is required (for image distribution);
— Whether a DICOM worklist is required (required if patient demographics are available from a HIS or RIS);
— Shall be delivered with a UPS (specify the required capacity and runtime).

There are a number of imaging plate/cassette solutions. For example the imaging plate can be embedded inside a proprietary cassette or placed in a protective sleeve in an ordinary X ray cassette without the intensifying screens. The embedded systems protect the plate from mechanical wear and tear, resulting in a longer lifetime of the plates. If an old X ray unit is upgraded with CR (or DX cassette) to provide digital imaging, care should be taken that the correct anti-scatter grids are provided as the original grids may not be adequate for CR.

Figure 11 shows a picture of a compact modern CR unit with quality assurance computer and an imaging plate.

Sites with limited access to IT expertise require preconfigured image acquisition equipment to facilitate the installation. For acceptance testing and commissioning of CR systems, see Appendix IV.

4.7.3. DX equipment

The main advantage of DX over cassette based systems claimed is the potential for higher patient throughput. DX solutions come with either fixed and integrated or portable detectors. Also, in-between solutions with fixed and portable detectors exist. Portable DX detectors are available in the 43 cm × 35 cm cassette format and thus enable integration with existing cassette based X ray systems. The fixed DX detector size is usually 43 cm × 43 cm. Generally, DX systems have marginally better image quality (based on a higher Detective Quantum Efficiency compared to CR systems) (see Section 3.1.2.2). However both CR and DX systems are suitable for all clinical applications. The price of DX systems is mostly driven by the type of detector used. The charged couple

FIG. 11. Modern compact CR reader with quality assurance review station (also acts as patient ID station) and imaging plate (photograph courtesy of W. van der Putten, Ireland).

device based systems carry the lowest price tags and the flat panel detectors with the highest resolution are the most expensive. DX systems specially designed for thorax examinations are available. These solutions can be very cost effective for high volume sites and lung screening projects. The following should be specified:

— Types of examinations planned;
— Number of examinations per year with expected 8 hour peak loads and annual growth;
— Whether a CD/DVD writer is required (for image distribution);
— Whether a DICOM worklist is required (required if patient demographics are available from a HIS or RIS);
— DX workstation shall be delivered with a UPS (specify the required capacity and runtime).

Systems based on portable DX detectors allow for the direct upgrade of new or existing analogue X ray equipment to digital imaging, as detector cassettes with wireless transmitters are placed directly in cassette trays in the bucky. This, of course, pre-supposes the installation of a wireless network. The portable detectors can also replace the film cassettes in bedside imaging. Other DX solutions have detectors that are fixed inside the equipment.

Sites with limited access to IT expertise should require preconfigured image acquisition equipment to facilitate the installation. For information on acceptance testing and commissioning of DX systems, see Appendix IV.

4.7.4. Diagnostic workstation

A diagnostic workstation replaces films and film viewers (for features and requirements see Section 3.1.2). In a limited resource environment, the quality assurance station, which is a part of the CR or DX system, may also serve as an interpreting workstation (see Section 3.1.2) [25]. A common PACS/RIS workstation configuration consists of three displays (one RIS monitor and two reading monitors) as well as workstation software connected to both RIS and PACSs [26]. See also Fig. 12.

The reading is controlled from the RIS that contains the request and the patient demographics. Selecting the examination on the RIS display retrieves the correct images from the PACS server using the patient ID, the Association Number that was created when the examination was booked and the rules in the hanging protocol.

FIG. 12. Typical layout for a workstation for primary diagnosis (incl. RIS terminal) in radiology (note that, in normal use, the curtain would be closed). Photograph courtesy of J. Schillebeeckx, Belgium.

With a PACS without RIS connection, the radiologist has to retrieve images by entering some of the patient demographic data and select the correct examination (CT, CR, ultrasound, etc.), or by selecting the correct examination from the day's list.

Hanging protocols are important tools to make diagnostic work more consistent and more effective. Hanging protocols should be defined and created by the installation team or an application specialist in cooperation with the radiologists during the installation and the run-in period.

The reading displays should fulfil the DICOM Greyscale Display Function Standard PS 3.14 if used for the primary interpretation of plain radiographic or mammographic examinations. In a resource limited setting, medical grade displays may be substituted by good quality PC monitors (however, this does not apply to mammography). Studies have shown that the accuracy of observer performance of, for example, wrist fractures, is equal for medical grade displays and good quality PC displays if both are correctly calibrated, although non-medical displays may take more time to read or require more diligence in the use of image processing controls such as windowing, zooming and panning. Entry level workstations would typically have a standard PC computer with one high quality PC monitor of at least 19 in. and a freeware viewer [27].

The light intensity should be measured for acceptance and regular testing. Visual test patterns should be used on a regular basis (e.g. the test patterns SMPTE or TG18) to check basic display quality for gross defects (see Appendix IV).

The role of quality control of monitors as well as control of ambient light cannot be overemphasized. A poorly performing monitor, or ambient light levels which are too high, will lead to missed or wrong diagnosis, directly affecting patient care. A large amount of literature is available in the bibliography. Test equipment for monitor quality control is also needed for quality assurance equipment in radiology and if not already available, should be included in the RFP for the digital system.

4.7.5. PACS storage

Image storage requirements will vary greatly depending on examination volume, the workflow to be supported, local regulation and local traditions. An entry level installation using a CR reader, ultrasound, or DX unit may not need any long term storage. Images will be available on the acquisition console for a limited time; as older images fill the disk, they will be deleted (automatically or manually). If a diagnostic workstation is installed, that also will store images for a limited time. Alternatively, some limited storage can be provided using tape and/or CD systems according to the descriptions in Section 3.1.4.2.

If a long term archive is required, a pair of 2 TB mirrored (to ensure high availability) hard drives running free or open source DICOM storage software with a capacity to store approximately 200 000 images (1 CR image is typically 10 MB) is a logical first step. Such a drive system can be controlled using a standard off the shelf computer (with appropriate UPS protection). However, if at all possible, a server-grade computer is recommended for higher reliability. An intermediate step would be a separate dedicated RAID based storage server with faster and more reliable drives, but with correspondingly higher physical equipment, power and air conditioning costs. At the high end is a national or regional storage grid with central fail-safe PACS storage that functions as a utility service to the diagnostic imaging providers and the referring physicians.

PACS storage always needs secure utility resources and physical protection (see Section 4.5.7), and is a 24/7 operation, so steps must be taken to minimize downtime. As identical hardware may not be available when downtime of the PACS storage occurs, and/or to establish a well planned and executed hardware refresh cycle, it is necessary to store critical parts locally at the time of installation. These parts and configuration information must be stored in a safe

location and clearly marked to identify to which system they belong. An example list of critical spare parts might be:

— Spare computers;
— Extra HDs;
— Extra CD/DVD writers;
— Ghosts (disk images) for each installed computer;
— Extra network switches.

Of course, these spare parts should also be factored in when considering an equipment hardware refresh programme.

4.7.6. Web based image distribution

An effective method of image distribution between a diagnostic imaging service and its users is a web browser based DICOM viewer. Through the web service, referring physicians can order examinations, read the reports and visualize the images using standard PC hardware and software. This service can, of course, be used on closed internal hospital or health institution networks and/or over the public Internet. This real time, two-way communication between a diagnostic imaging centre and its customers greatly lowers the cost of image distribution and improves efficiency and productivity.

Web software in general offers a limited toolset and reduced functionality compared to a dedicated workstation, although this situation is changing rapidly with improvements in technology. Web based software often sends a compressed image dataset which is sufficient for the receiving computer's display. The user is usually able to optionally request the full resolution dataset to be sent if required.

Entry level web servers can utilize free software and may share hardware with the PACS storage server. Physically separate server hardware is preferred for more robust service. Some web server software permits on demand image compression and distribution directly from the PACS server, and some requires physically separate caching of the web distribution images on a separate drive array for faster performance. However, the latter approach leads to discrepancies between the contents of the PACS array and the web cache.

As another alternative to web viewers, consideration can be given to the use of remote desktop sharing software such as Windows Remote Desktop, which is a part of the Windows operating system. However, this and similar software solutions might be useful for remote service diagnosis but are rarely suitable for even simple image review.

An alternative approach is to use a client server architecture where the dedicated computing power resides in a central computer dedicated for this purpose and where the workstation only interacts with the main processor through a small amount of client software. Superficially, it resembles the Windows Remote Desktop, but it is in fact quite different. Such dedicated serverside rendering solutions are typically used for advanced 3-D visualization and analysis. These types of 'thin client' solutions, in which client software is downloaded via a web brower and used within it, is increasingly forming the basis of many commercial PACS viewer solutions because of the ubiquity of web enabled computers, and the relative ease of installation and maintenance of such a solution for a large number of users who may require arbitrary access from many different locations. They are distinct from and usually less powerful than 'thick client' applications, where the dedicated image processing software is preinstalled on each specific workstation.

All the server based visualization solutions offer the potential to lower the maintenance burden of deploying updates to each local machine. The option of virtualization and centralization also allows for provision of more advanced tools with limited licenses to a larger number of users.

4.7.7. HIS/RIS reconciliation issues and migration issues

If available, interoperable HIS and RISs can respond to worklist requests from the imaging modalities [25]. This supports a workflow with a single point of positive patient identification, e.g. at reception or at a referring physician's office using ID certificates, in compliance with local rules and regulations, and then verification at points of interactions, such as in the examination room, where the patient has to respond to a name and ID number. Patient demographics and ID data are transferred into DICOM tags that then become an integral part of each image.

4.7.8. Worklists

RIS and HIS systems link the patient's radiological history with patient demographics. If it is DICOM compliant, the acquisition modality can request the names and ID numbers for patients scheduled that day. The patient to be examined is then selected from a drop down list on the acquisition console. This should ensure that the same name and ID number used in the RIS or HIS is transferred to the images, as long as the operator chooses the correct entry.

Unique identification becomes critical if long term storage is to be implemented. In countries without national ID databases and unique identifiers, medical service providers should consider using local solutions to link the digital

images uniquely to the patient. This should be performed by using identifiers (preferably two or more, e.g. name and date of birth) that are part of the rest of the patient's medical record. If several providers are planning to use a common archive, then they must all use the same system of unique identifiers. Ideally, the same identifier(s) will be used among all connected institutions to prevent major potential errors when patient data are transferred between systems. As mentioned in Section 4.6.5, there are some IHE profiles that may assist in the reconciliation of patient identification in the absence of unique identifiers.

4.8. RFP PROCESS

The procurement of a complex system such as a digital radiology system typically proceeds with the issuing of a RFP by the buyer. This is a document that an organization sends to vendors inviting submission of a bid for equipment and/or services. An organization typically issues the RFP to assess competing bids and to clearly define what its needs are. A successful RFP process should result in a contract meetinging the described requirements at a market price, as well as establishing a framework for reliable installation and quality operation throughout the life cycle of the equipment or services purchased (see Sections 5.3 to 5.3.3 for details on life cycle management).

The RFP should describe the overall goals of the project, the main purpose, who the project will serve, and list the main known challenges. The RFP should be specific because the specialists on the vendor's site need this information to tailor their bids to the requirements.

The RFP documents should describe the clinical requirements (types of examinations and expected volume of each type, the patients' age groups and the volume of each group), technical requirements (number of diagnostic workstations, network speed, etc.), the expected annual total examination volume, and a description of the existing or planned building with at least the floor plans of the spaces intended for installation of the equipment. It is recommended that a complete floor plan of the medical imaging facilities and adjacent areas be submitted as part of the RFP.

4.8.1. Documentation

Depending on the nature and scale of a project, an RFP can range from a simple document (issued on-line or via email) to a complex document running to several hundred pages and involving legal advice. In essence, an RFP outlines the purchasing process with a detailed description of the requirements. In many countries, RFPs must be publicly posted if the anticipated cost is above a defined

limit. Fortunately, competition in the medical imaging market is strong in most parts of the world. This means that an organization needs to be prepared to be challenged on the decision by vendors who fail to win bids through available complaints channels. Therefore, it is important to:

— Have a well-organized process for processing the RFP, from initial concept to final document;
— Have a single point of contact with the vendor to ensure that questions and queries are fairly and expeditiously dealt with prior to the submission date;
— Have as part of the RFP process established criteria against which the bid is to be judged.

The selection criteria are not only the lowest cost but may include level of technology, capability of vendor to support equipment, training provided, etc. It is essential that every step taken in the RFP process is documented. The optimal method is to use an electronic system in which all changes are tracked and texts cannot be permanently deleted. Expect each and every purchasing process step to be retrospectively scrutinized by the vendors and regulatory bodies such as government accounting offices. The development of an RFP can be a daunting task. However, examples are available, for instance on-line (see the Canadian InfoHealth Highway web site [28]). Also, often RFPs can be developed with the help of colleagues who are experts in the field.

4.8.2. Purchasing contracts

Contracts are very important tools to execute projects and to maintain sustainable services. In establishing the terms of the final contract, negotiations with the vendor take place, based on its submission to the RFP. As digital imaging projects are, in general, much more complex than film based radiological systems, it is highly recommended to write a contract with the vendor(s) instead of accepting the vendor's standard template contract. The final contract can state explicitly that, for instance, the vendor's terms and conditions of sale are not recognized. In writing contracts, local business practices and laws should be followed. Each contracting entity should create and maintain medical imaging contract templates to ensure consistency and continuity in all the purchase agreements in this field (see Appendices II and IV for more information on sample contract templates). Depending on local law, there may be a difference in the issuing of contracts between privately owned institutions and government facilities, with the latter typically having less flexibility to negotiate. Use of legal expertise is recommended in establishing the templates and in writing any major contracts.

Recommended acceptance milestones (which should all be described in the purchasing contract) are:

— Verification of delivery of all parts;
— Functional testing of all equipment (an operator should go through a few operational cycles);
— Radiation safety testing (for X ray and nuclear equipment only);
— Acceptance testing (see Section 5.5.2);
— Clinical audit/evaluation [1] (see Section 2.10);
— Generally meeting the terms of the contract.

Ultimately, a contract is a legal document between the buyer and the successful bidder. In it, the obligations on both the buyer and vendor are described. The contract gives legal expression to the promises made by the vendor as a response to the RFP. It should include penalties (including cancellation of the order) if the vendor does not meet all or most of the RFP.

4.8.3. Warranties

A standard warranty is 12 months from the date of acceptance. However, some system parts may carry different warranty schemes and different conditions apply to software. Extended warranties may be available at the time of purchase. The detectors in direct radiology may have a prorated warranty of up to five years. Similarly, X ray tubes normally carry a prorated warranty based on the number of exposures. In the RFP, it is important to request a full disclosure of the rules of the warranties offered. It should be noted that the extent of warranties is also one of the items which can be negotiated with the vendor. It should be clear to both buyer and vendor, at the start of the contract, what is included in the warranty and for what time period.

4.8.4. Service agreements

Service agreements are the cornerstones of reliable medical imaging operations. Sites with little or no expertise should negotiate comprehensive life cycle (see Section 5.3) service contracts, including all service work and all spare parts. All service contracts should have an embedded service level agreement. Service level agreements detail specific measurable standards for the services that are being purchased, as well as specifically outlining what services are expected of the service provider. Uptime guarantees, response times, mean time to repair and maximum hardware replacement times should all be clearly defined and agreed between buyer and vendor. Service contracts should also

state explicitly the requirements for on-site preventative maintenance visits. The contract should specify the escalation steps that will be taken during problem reporting and resolution, as well as detail what remediation steps are taken when service levels are breached. Financial penalties and/or service contract rebates should be considered in case of poor or non-performance.

Expected maximum response times should be stated in the service contract for at least the following levels of urgency:

— Complete system failure;
— Partial system failure, but acceptable images still being produced;
— Request for regular or PM service, as well as correction of failures with little or no effect on the production of images.

In the cost of service contracts, it is important to make a distinction between consumables and spare parts. Consumables (components whose use are part of normal day to day operation) are almost always excluded in service agreements. Spare parts that need to be replaced on a regular basis or based on the usage of the equipment are often defined as consumables. Typically, items such as MRI cryogen and cooling parts, imaging plates and cassettes are defined as consumables. Often, even parts such as X ray tubes and image intensifiers are considered by the vendor to be consumables. However, such parts can be included in a service contract. Therefore, service agreements should have a section on costs not covered to clarify what costs are included and which are excluded in the contract.

A clear distinction needs to be made between updates and upgrades. Updates are system improvements that are necessary for safety or performance improvements. They do not add significant additional capability to the system. Such updates should be part of the normal service contract. On the other hand, upgrades are system enhancements that add new capabilities or an additional function (for details, see Section 5.3.3). Upgrade costs can be included in a service contract; however, both buyer and vendor need to be quite clear what is understood, as this area is frequently one of dispute. Irrespective of the type and nature of the service contract, the vendor should be obliged to implement safety related updates. The vendor should clarify which mechanism they employ to communicate safety issues.

Sites with internal service organizations should define in the RFP their expectations for training requirements, access to spare parts (expected delivery time, shipping methods, site contact(s), delivery address and specific labelling as needed), test tools (such as software) as well as consumables and backup support for their own service engineers. The price of every service and part should be

listed in the purchasing contract or special service agreement. If special tools are required to service equipment, then this should also be stated.

Remote service is becoming more and more important as it can dramatically reduce service costs. Available remote service options should be analysed and evaluated as a means to improve reliability, quality and to reduce costs (for details, see Section 5.4.2).

On a final note, conflicts do occur regarding what customers feel they should receive from a vendor and what the vendor actually delivers. A formal dispute resolution procedure should be detailed in the service contract. Additionally, the terms and conditions under which the customer or the service provider can exit the service agreement should be clearly defined.

4.8.5. Penalties

All service contracts should include penalty clauses. Penalties are important factors in managing equipment uptime and service delivery by providing clear discipline to both the service provider and the medical imaging provider. The uptime requirements and penalties should be balanced to reflect the needs and means of each site.

4.8.6. Quality assurance

The responsibilities for quality assurance may be shared among different groups. A common practice is that frequent (daily, weekly, monthly) routine checks are made by the radiographers, and semi-annual or annual tests are made by medical physicists or engineers (see Section 5.5). The quality assurance requirements should be detailed in the RFP, including the required test equipment and planned test procedures. The RFP should specify whether the equipment vendors are expected to provide test equipment and procedures.

4.9. BUSINESS CONSIDERATIONS

4.9.1. New or pre-owned equipment

There is a lively worldwide market for pre-owned digital medical imaging equipment, and some pre-owned equipment is passed on as a donation; however, in all cases, such transactions should comply with WHO requirements [29]. Vendors of pre-owned equipment range from some of the major imaging companies, which refurbish and re-sell slightly older technology with a full factory warranty, to primitive dealers who sell used equipment in an unknown

condition. Purchasing pre-owned equipment is more complex than purchasing new, but substantial cost savings can be achieved. Older equipment cannot be expected to last as long as equipment which is new from the factory, and spare parts may become difficult to source over time. Some vendors who specialize in refurbishing, selling and maintaining pre-owned equipment, as well as providing application training, may provide good value for money. Due diligence by the buyer is crucial to ensure that satisfactory performance, maintenance and repair of the equipment can be delivered over the expected remaining lifespan of the equipment.

Purchase and use of refurbished PACS computer equipment is generally not recommended. Hardware and software refresh and upgrade cycles are much faster and obsolescence occurs earlier than with imaging acquisition equipment (see Sections 5.3.1 and 5.3.2). The buyer should be wary of:

— Older storage/archive systems — storage technology may become rapidly obsolete, capacity may be limited or not upgradeable, and performance may not be adequate for modern PACSs;
— Older displays — CRTs become unstable and drift out of alignment, and LCD back lights degrade and deteriorate over time;
— Older PCs — these typically have limited RAM, video graphics performance, slow in-built networking, older PACS software that may not be upgradable, older operating systems and lack standards compliance (DICOM).

4.9.2. Different purchasing models

Depending on the financial status of the buyer and funding options available, the purchase of new equipment may be by either direct lump sum purchase or leasing. In a long term stable financial environment with an ongoing stream of operating revenue and little upfront capital, leasing may be the most favourable option. However, although the avoidance of a large initial equipment purchase sum is initially attractive, leasing can be more expensive than direct purchase in the longer term, owing to loan interest and administrative overheads. This may depend, however, on the terms of the agreement and on the agreed residual value of equipment at the end of the term of the lease. Also, in an area where there is rapid evolution in technology, leasing can be a favourable model, especially if software and equipment refresh can be built in. However, it is realized that in most publicly funded institutions, finance to purchase equipment typically comes in a discrete grant that cannot be extended or used over a long period of time.

4.9.3. Payment schemes

Payment is normally scheduled according to contract milestones. These are typically:

— Signing of the purchasing contract (5–10%);
— Delivery of the equipment (20–40%);
— Complete installation of operational equipment (20–40%);
— The installation passing clinical and technical acceptance (10–20%).

However, local custom and practice may dictate this. The acceptance report should be ready after at least three months of clinical use and no more than six months from the date of completed installation. The acceptance report is written on behalf of the buyer, either using internal resources or by external consultants. It is of paramount importance to resolve every single technical discrepancy issue before the final payment is made. To hold back the final payment until all issues are resolved can be a challenge but might be an essential tool to urge the vendor to fulfil its liabilities.

4.9.4. Capital costs

The estimated costs of the equipment can be approximated by requesting budgetary offers from at least two vendors (if possible, avoid using a price from a particular vendor for budgeting unless there already is a decision to make business with this vendor). There would be little point in using list prices as these tend to be greatly inflated on a per item basis.

4.9.5. Planning costs

The preparation and planning of a project may involve a number of people from different professions from different companies and institutions. Common examples of external planning resources (over and above the internal resources) that would be contracted for a project are: an architect, a civil engineer, an electrical engineer, a health planner and an IT engineer. Some or all of the planning costs may be absorbed as an overhead by the buyer's institution, or by certain governmental agencies that have planning and support for projects of this kind as their core functions. At the onset of the project, the costs of planning and managing the project should be estimated and should be part of the overall budget.

4.9.6. Installation costs

Installation costs of the purchased equipment are almost always included in the purchase price. Other installation costs may include any site modification or pre-installation costs, such as building modifications and upgrades of electrical and digital networks.

4.9.7. Operating costs

In the case of digital imaging, the operation cost can be lower than in conventional screen-film imaging due to the absence of chemical consumables and films. Operating costs for digital imaging will include:

— Service cost (including labour and parts);
— Salaries (the upgrade to digital imaging may require additional staff or different use of staff time);
— Consumables;
— Utility costs (higher cooling demands, Internet connections).

4.9.8. Contingencies

All complex projects can experience problems in implementation, unexpected delays and unforeseen problems that raise the cost of installation. Funding projections should always factor in approximately 15% of the total cost to support such contingencies.

4.9.9. Total cost of ownership (life cycle cost)

Life cycle expectations (see Section 5.3) are different for different devices within an imaging unit. X ray systems may have a lifetime of 10 to 15 years without reduced reliability or image quality, but digital imaging devices, especially computer parts, normally have to be replaced within 3 to 4 years, depending on the operating environment and workload. Overall life cycle planning should be based on the expected life cycle of the constituent parts of an installation as well as any accounting practice guidelines for depreciation (if applicable).

Life cycle cost estimations are affected by the environment. Hot and humid environments with low quality power supplies may have substantially higher life cycle costs. Examples of life cycle estimation are as follows:

— X ray system: 10 years (with normal maintenance and spare parts available, most plain X ray systems can be used for another 5–10 years thereafter);
— CR system: 5 years (with good maintenance and some updates, 8–10 years);
— DR detectors: 6–10 years;
— Computers: 5–6 years.

Life cycle costs components:

— Purchasing costs;
— Equipment maintenance costs (price of service contract or internal service);
— Revenue costs associated with equipment (e.g. DX detectors, X ray tubes, etc.);
— Building and utility maintenance costs;
— Upgrade or change costs;
— End of life service costs;
— It should be noted that the environment in which the system operates has a large effect on the life cycle costs.

Table 4 shows a hypothetical example of a calculation of TCO. For more complex systems, such spreadsheets can become quite complicated. TCO calculations also depend on the accounting practices one needs to follow.

4.10. PROJECT MANAGEMENT

Project management plays a key role in delivering a successful outcome and should normally be the assigned to someone with experience in running technical health care projects. Digital imaging projects are significantly more complex than analogue imaging projects, owing to the higher number of tasks to be controlled, and the more complex cross-disciplinary communication with experts. It would be good practice to request the vendor to appoint a project manager as well. Overall implementation of the project can then proceed through those two project managers. Having single points of contact also facilitates communication.

TABLE 4. HYPOTHETICAL EXAMPLE OF A CALCULATION OF TCO FOR SIMPLE SYSTEMS[a]

	Original price (US $)	Upgrade costs (US $)	Maintenance costs (over 9 years)[b] (US $)	Total (US $)
X ray system	65 000	10 000	45 000	120 000
CR system	30 000	10 000	27 000	67 000
PACS (entry level)	50 000	30 000	45 000	125 000
Quality assurance instruments	15 000	3 000	9 000	27 000
Cassettes	3 000	1 500	1 500	6 000
Training	10 000	10 000	5 000	25 000
Planning installation and building related costs	50 000	25 000	25 000	100 000
		TCO over a period of 10 years		470 000

[a] Consisting of one X ray room, a local PACS with one diagnostic workstation. Note that many of the factors are highly variable.
[b] It is assumed that any repair costs in year 1 are covered by a warranty (no maintenance costs).

4.10.1. Project manager

A project manager needs to have the authority to organize the project, including managing the project resources. A person with excellent management experience and a working knowledge of medical imaging workflows should be the first choice.

4.10.2. Site considerations

Site considerations can be rather complex and depend on local needs and traditions. Typical key items that need attention are: power standards, power quality, temperature and humidity control, dust, room sizes and layouts, and transport routes from the freight drop off point to the point of installation (see Sections 4.5.2.3 and 4.5.2.4).

4.10.3. Timeline

Timelines are useful tools to help team members know which milestones need to be achieved and when. The timeline should include the purchasing process, building construction, and installation and acceptance testing. A project timeline should be included in purchasing contracts. Timelines need to be maintained during the project as plans are realized and deviations occur. For more complex projects, tools such as Gantt charts can be used.

4.10.4. Configuration and customizations of RIS and PACS

Integrated RIS and PACSs used to support a complex workflow need to be customized to support the planned workflow. Simpler systems with basic workflow support have limited configuration options and thus will only support some major steps in the workflow.

Customization can be very costly both to implement and maintain, and is normally only feasible in large scale projects. Customer specific customizations that involve code (software) changes are expensive, unreliable and difficult to maintain (e.g. may be negated by updates and upgrades). Required feature enhancements should be integrated into the vendor software development cycles.

Configuration should be distinguished from customization. Configurable choices may be available to adapt the software to an institution's workflow. Configurable code sets (procedure ordering and billing codes) are routinely provided. The choice of vendor and/or product may be influenced by whether it is sufficiently configurable to adapt to the local site. The use of standards for

communication between components (DICOM, HL7 and IHE) greatly reduces the need for customization.

4.10.5. Digital imaging workflow

The new workflow can be a challenge in both planning and implementation (see Fig. 13). If the project is an upgrade from a film based system, the goal is to provide at least the same service as before the upgrade. However, the introduction of digital technology affords the opportunity to critically evaluate existing workflow patterns and staff responsibilities, especially if the project involves the conversion of an entire hospital from film to digital technology. Everything depends on the extent of the digital implementation. When using cassette based systems without a RIS, the acquisition workflow is almost identical, especially if film is still printed. However, if digital images are now stored on computers, all aspects associated with film handling, storage and management are drastically changed, if not completely eliminated.

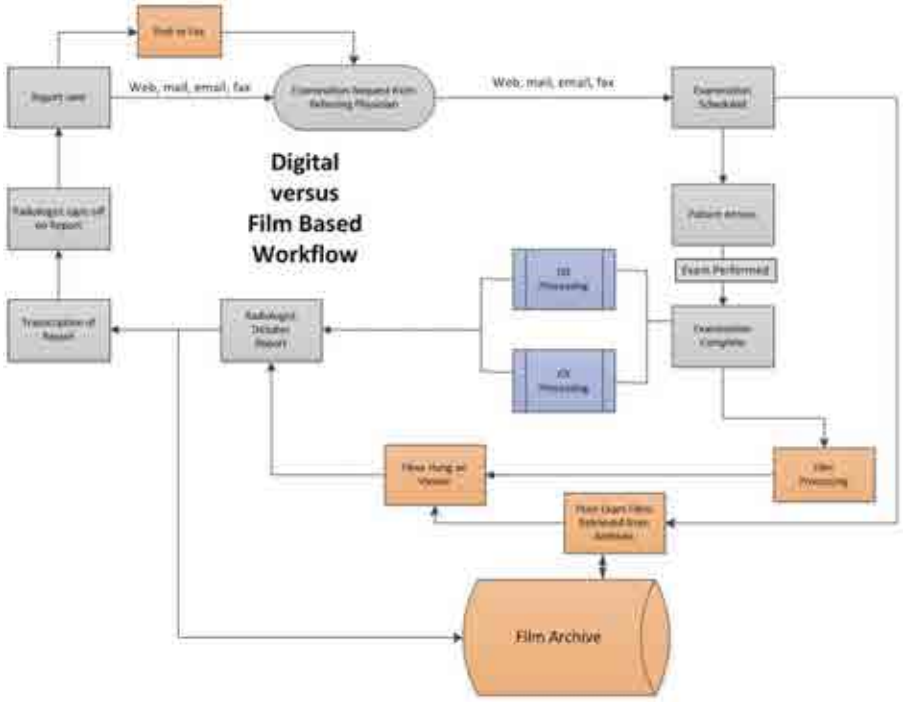

FIG. 13. Simple workflow model. The steps in grey are common to both digital and film based imaging, however, the steps in orange are extra tasks related to a non-digital i.e. film based environment. The blue tasks are specific to either CR or DX.

In the planning stage of such an upgrade project, requirements can be determined by studying the existing workflow as part of a business requirements analysis process. The underlying cues that drive the workflow from step to step need to be understood, and it should be anticipated which cues will be lost in the transition and so will have to be replaced with new methods of initiating the next process step. It should be known who needs a film, where they need it and which viewers should be replaced by a viewing station or diagnostic workstation. After a run-in time of 3–6 months, a workflow review is recommended. The outcome of the review then can be used for further workflow optimization.

In a resource limited environment, the digital system (most likely a CR system) will not be connected to a DICOM worklist, and thus the patient demographics must be entered into the workstation, often directly from a handwritten or printed request. It is important to formalize the rules on which fields must be completed. Checklists detailing the rules should be close to the workstations. The use of at least two reliable patient identifiers is recommended.

CR systems normally comprise two physical components, the plate reader and the computer workstation, plus the cassettes (Fig. 11). Usually the computer workstation is placed close to the X ray generator console and the reader is either placed in or just outside the X ray examination room. The cassette shelves should be conveniently located at an appropriate height adjacent to the generator and CR reader consoles. It should be noted that the CR cassettes are highly sensitive to ionizing radiation and therefore need to be protected from X rays.

5. SUSTAINABILITY AND AUDIT

Previous sections discuss the technical requirements for both X ray technology and IT. No matter how well-designed and installed the digital system has been, without considerable effort to maintain the equipment and to keep the training of staff involved with the digital system up to date, it will fail. Such failures reflect poorly on the organization, lower morale, and also involve a considerable loss of scarce financial resources. In contrast to Section 4 (which was aimed at individuals implementing the technology), this section is aimed at individuals who are responsible for the management of digital radiology and the management and training of staff who have to work with it. This includes radiologists, technologist managers, hospital management, medical physicists and bioengineers.

5.1. INTRODUCTION

Digital imaging, coupled with a picture archiving and communications system (PACS) and/or teleradiology, is a powerful tool for both a host radiological facility and for an extended set of clinical users. For a well-designed, constructed and commissioned radiology facility to operate effectively, the management should follow recognized standards. In the case of a digital imaging facility with connectivity, the principles and criteria of good practice need to be applied, especially to the areas of training and support, and also to the equipment life cycle including maintenance and various aspects of equipment and image quality assurance. These principles can then serve as standards from which key performance indicators for audits designed to assure the sustainability of the service can be obtained.

5.2. TRAINING

In a radiology facility, staff acceptance of new working conditions is critical to the feasibility and sustainability of digital imaging and a PACS and radiology information system (RIS) based workflow. In many cases, this represents a change from an old work practice and a successful transition is dependent on careful planning and open communication from the management of the organization. The role of staff training for both radiology staff and all end users cannot be overemphasized.

There are two broad groups of personnel who will require training, firstly the users, and secondly the providers and supporters of the technology.

Users of digital technology: Since the implementation of digital imaging communications will potentially change the entire workflow of a facility, every staff member will be impacted by the technology. General seminars giving information on the introduction of, and changes associated with digital imaging systems are therefore essential for all staff. However, there are certain user groups that will require specialized training, specifically all clinicians viewing and using digital images outside the imaging centre, radiographers acquiring the images, radiologists interpreting the images and dictating or typing reports, and administrative staff who support the departmental workflow. Specific user training might be performed on-site by either in-house or external experts. In all of this, it may be appropriate to involve change management and communication specialists.

Providers and supporters of technology: These personnel include the PACS administrator, medical physicist, IT expert and superusers who need to understand technical details of the systems including:

— The theory and operations of acquisition, processing and display of digital images;
— Computer hardware and communications;
— Computer software and communications;
— Facility work flow and communication models.

Typically, the required training for these personnel is not on-site but external, using varying modes including attendance at specialized courses, on-line training, private study and peer support.

5.2.1. Guidelines for effective training

During design or implementation of the training program, the following key points should be taken into account to assure its effectiveness:

— Avoid overestimating a staff member's computer knowledge. Some basic computer training (e.g. how to use a mouse) may need to be provided. As part of the project definition, the business requirement analysis will identify the need for this level of training.
— Plan sufficient time and financial resources as part of a dedicated implementation plan. This rapidly improves both workflow efficiency and image quality.
— Create a comprehensive training plan incorporating training components for all staff.
— Negotiate with the equipment vendor to include training components as part of the equipment purchase.
— Employ a superuser model, where a limited number of key individuals receive additional on-site and/or factory training to become site specialists for future training requirements. It is these individuals who will provide the day to day training which is required owing to staff turn-over, new trainee doctors starting, etc.
— Focus on reusability of training plans and materials. Computer based training programs are sometimes inexpensive and can be reused.

5.2.2. User training

Non-imaging clinical experts: These individuals are among the most important users of the system. Training for these clinicians should be around their functional workflow that is primarily aimed at accessing and using images for clinical purposes directly related to patient management. Training should include understanding workstation access (user accounts and passwords), how to find an image, how to pull up a report and how to use worklists (if applicable). This training can be provided by numerous methods, including in-service training and self-study using self-guided tutorials and user guides. Selected clinical users require additional training for specialized applications, such as use of orthopaedic templates. Importantly, clinicians need to understand how images can be accessed anywhere where previously hard copy image review was possible, in an effort to move to a completely filmless clinical workflow over time. It is well worth spending time devising strategies for training these individuals, bearing in mind that they tend to be very busy. (Note that other applications for training, such as using an ultrasound scanner for midwives, may need to be considered, but are not discussed further in this publication.)

Radiologists: Training to interpret digital images is complex, and is typically delivered through one-on-one instruction sessions over an extended time period, ideally a number of days. In addition, computer based training can also be a valuable option to reach these users. Instruction on features and tool sets, such as window, level, mag, zoom, cine, region of interest, hanging protocols, measurement and data reconstruction for CT and MR images should be provided to enhance clinical interpretation and to take full advantage of the digital image and workstation potential.

Radiographers: Moving from conventional film screen radiography to digital radiography will require additional knowledge and training in radiographic technology and technique, and in IT communication knowledge. Radiographers should have a basic understanding of the underlying image capture technology, and of the image quality and patient dose implications of radiographic technique. This training should come from senior radiographers, a medical physicist and the equipment vendor application specialists. A training plan for a radiographer new to digital imaging should include:

— Patient registration and interfacing with a RIS;
— Equipment acquisition and processing modes;
— Uniform instruction on suitable radiographic techniques;
— Post-processing;
— Basic image manipulation tools;
— Quality considerations including identification of artefacts;

— Application of radiation dose indicators;
— Methods for retake analysis in a digital image management environment.

Administrative staff training: Staff responsible for the tracking and transfer of radiological requests, images and radiological reports must be fully trained in new digital and communication technology. Often, senior clerical staff will be critical for the planning of the digital department transition owing to their detailed knowledge of department workflow, electronic scheduling, RIS and administrative processes.

5.2.3. Provider and support training

Internal radiology personnel who will be responsible for providing or supporting the digital and communication equipment will require specialized training, probably requiring off-site instruction. These people will include superusers such as clinicians and radiographers, IT engineers and other staff and physics personnel with responsibilities for optimization [1].

5.2.4. Staying current — knowledge management and continuing education

One of the most important elements of maintaining a system is staying current with the latest information on vendor capabilities and changes in technology. The field of digital diagnostic imaging is still evolving quickly, with regular changes to IHE Integration Profiles and standards such as DICOM, HL7, RadLex and SNOMED Clinical Terms. A selection of resources for staying up to date are listed below:

Colleagues: Colleagues can often be valuable sources of information for new developments in their field. Clinicians with IT knowledge, local technology support, medical physicists, technologists and biomedical engineers can all be sources of information.

User groups: User groups can provide a wealth of information and support. They can be an excellent resource to solicit for advice for hard to solve problems, and can provide insights into industry best practices. In regions lacking an existing user group focused on digital imaging, an existing technology user group could be asked to perform this function. If not, the organization can consider starting such a group themselves.

Participation: In addition to user groups, existing committees, either locally, regionally or globally, also provide a great opportunity to keep learning. Standards working groups, governing bodies and colleges and professional memberships can all provide potential opportunities.

Internet: Perhaps the greatest single source of information, the Internet can be an invaluable resource. A few reliable sites are listed below:

— Society for Imaging Informatics in Medicine. SIIM is devoted to advancing the field of medical imaging informatics through education and research. www.siimweb.org
— Radiological Society of North America. A non-profit medical society with an international membership. Includes database of funding opportunities and the journals Radiology and RadioGraphics. www.rsna.org
— PACS Administrators Registry and Certification Association (PARCA). PARCA's mission is to develop and provide certification for professionals who are engaged with the support, maintenance and day-to-day management of health care imaging and IT systems such as PACS and electronic medical records. http://www.pacsadmin.org/index.cfm
— Integrating the Healthcare Enterprise (IHE). Home site of the IHE initiative that includes useful resources and news. http://www.ihe.net
— Digital Imaging and Communication in Medicine. The web site of DICOM includes a wide range of information, ranging from e-books to very technical DICOM standards. http://dicom.nema.org

5.3. EQUIPMENT LIFE CYCLE MANAGEMENT

All equipment in a radiographic department has a limited lifespan and management is crucial to enable efficient operation with minimum disruptions in service. Good management should ensure a lower total cost of ownership (TCO), sustained and improving technology infrastructure, and formalized planning and associated budgeting.

Typical life cycle components for an imaging system are seen in Fig. 14. Previously, in Section 4, the important areas of needs analysis, equipment specification, tender process and purchase contract, installation, and acceptance and commissioning were addressed. The areas discussed here relate to clinical use, maintenance and support, and routine performance testing, as a part of a more general quality assurance programme.

The management of equipment components in a digital environment is made more complex by:

— The introduction of software as well as traditional hardware equipment;
— The uncertainty in the expected performance of newly introduced cutting edge technology;

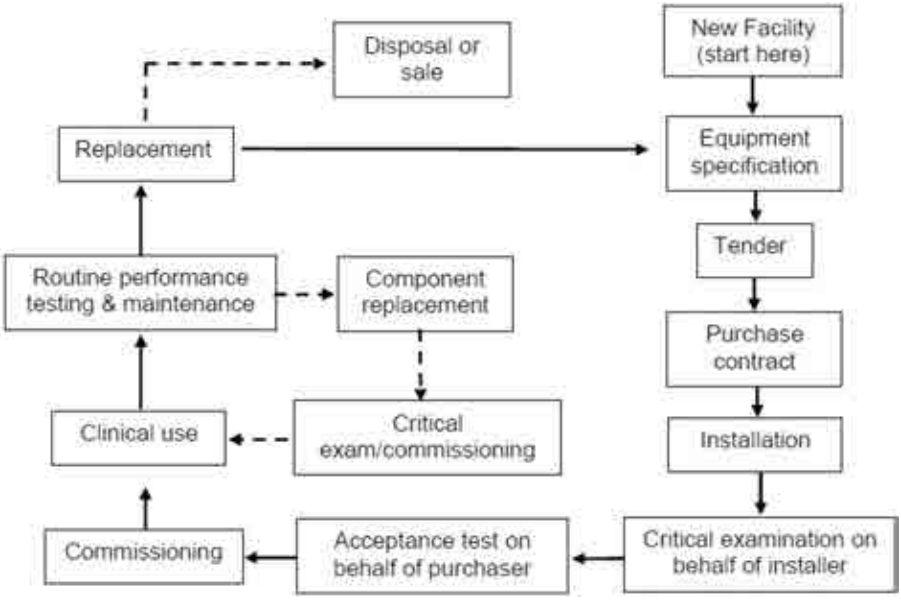

FIG. 14. Example of the life cycle of an imaging system.

— Short life cycle periods for both hardware and software products owing to technological obsolescence;
— Uncertain maintenance support;
— Lack of adequately trained persons to oversee equipment performance.

The problems mentioned above, which are associated with cutting edge technology, can be avoided by procuring more mature technology. On the other hand this, in turn, will be obsolescent sooner. It is also essential that the performance testing criteria are specified as part of the contract and agreed with the vendor.

5.3.1. Hardware cycles

When integrating to a digital imaging environment, hardware considerations increase owing to:

— Increased complexity in the imaging equipment itself because of its digital nature;

— Increased auxiliary hardware needed to support digital equipment, such as air conditioning units, uninterruptible power supplies (UPS) and computer hardware.

All this equipment needs to be considered as part of the equipment life cycle management. The complexity of equipment used for particular image acquisition modalities, such as CT, digital radiology and digital mammography is well documented; however, it must also be noted that the ancillary hardware is complex and needs to be managed.

5.3.2. Software cycles

Software life cycles require the same diligence and planning as do hardware life cycles, despite the fact that they may vary more significantly. This planning will:

— Reduce the risk that software will fall out of support;
— Align clinical requirements with software functionality;
— Improve service levels and uptime.

A feature that distinguishes software from hardware is that updates and upgrades are an inherent part of the software life cycle management. Software is typically updated periodically (perhaps every 18–24 months) to enhance performance or to improve security and safety. Updates are usually provided at no cost to the user but any associated engineering services are likely to be charged (e.g. for installing the updated software). Upgrades, on the other hand, often provide additional features or capabilities, typically require additional payment, and may be linked to a need for additional or upgraded hardware. In both cases, the time of update or upgrade should be planned to give the maximal clinical benefit for the least operational impact. It is also important to plan the upgrade and the consequent system downtime at a time that will cause minimal disruption to workflows.

5.3.3. Upgrades

Upgrades are inevitable. Both hardware and software platforms will eventually reach the end of their life owing to either an increasing rate of component failure, or, more commonly, obsolescence. Careful planning is required to prepare for this eventuality and so to minimize service disruption and reduce overall costs.

Software and hardware platforms have varying amounts of interdependency that must be recognized in any life cycle management plan. This, however, may not necessarily mean that both platforms should be upgraded at the same time. The key planning considerations for updates and upgrades are:

— Potential interdependencies between hardware and software;
— Manageablity of upgrades, as clinical service will need to be continued while the upgrade is in progress;
— The possibility for a staggered upgrade to avoid each piece of equipment being upgraded simultaneously;
— Advance planning to align upgrades with operational requirements;
— The need for application testing and assurance. This may require the establishment of a dedicated test environment for a complex installation.

Figure 14 shows that an upgrade may be considered as a special case of a component replacement. In this case, the next step is to commission the equipment for the new situation. While this need is clear when a hardware component, such as a new X ray tube, is replaced, it may not be as obvious for software upgrades. Commissioning testing is essential on new software upgrades, with the extent of the testing depending on the nature of the upgrade. However, as the effects of software change are not always known, it is best practice to carefully check key functions of new software before they go into clinical use. The section on quality assurance (Section 5.5) explores this area more fully.

5.4. SERVICE SUPPORT AND MAINTENANCE

As mentioned in Section 4, the essential requirement for the necessary environmental conditions for digital equipment to operate properly needs careful study. Often, this requirement may be conducted centrally by a hospital based bioengineering service. However, it is essential that this in-house service is fully aware of the demands of the digital environment, and that budget for maintenance is adequately in place. These aspects of equipment purchase, cost of ownership and budgeting are often underestimated and often subject to budgetary cuts in the mistaken belief that this will save money.

Service contracts are commonly offered by equipment vendors for major equipment purchases and should be incorporated into the original purchase agreement (Section 4.8.4). While Section 4 discusses the cost–benefit equation for various service and support models, a number of critical factors to maintenance are discussed below.

— *Replacement parts:* The location of spare parts can be critical to turnaround time during a maintenance repair. Wherever possible, the use of parts located in other countries should be avoided, because of the possibility of delays owing to customs clearance. Local knowledge here is essential.
— *Service personnel:* The location and effective training of service personnel is also critical. While the use of local service personnel, either in-house, from the supply company or from a third party provider, is advantageous, the training of these individuals also must be considered. The limitations of the local service personnel, and the use of factory trained experts in some situations, must be recognized and carefully discussed by the equipment provider and the user.
— *Preventative maintenance:* This component of equipment management is often underestimated. In many instances, equipment is not maintained consistently and eventually requires major repairs that result in periods where the equipment is unavailable for an extended period of time. The use of local bioengineering staff and/or medical physics staff should be considered for at least first line regular scheduled preventative maintenance. There are many areas in which this can be effective, even with limited training of a competent engineer or IT specialist. Given the complexity of modern equipment, such an approach usually cannot replace the need for a maintenance agreement with the equipment vendor, but such first level in-house support should be recognized when negotiating the service agreement (see Sections 5.4.1 and 5.4.2 below regarding on-site and remote servicing). Examples for this kind of support include:
  • Responding to regular quality control tests to keep equipment within factory specifications;
  • Improving performance, particularly through display set-up;
  • Troubleshooting improperly configured system settings.
— *Business requirements:* The business requirements of an imaging facility should be reviewed periodically to assess the current impact of maintenance issues on the business model. The impact of downtime for a PACS component or an image acquisition unit needs to be weighed against the cost of increased maintenance. The effectiveness of downtime and disaster recovery procedures needs to be reviewed periodically. Ultimately, the maintenance management/support plan, including the hardware and software life cycles and service level agreements (see Section 4.9.9) should all be aligned with the defined business requirements of the facility.

5.4.1. On-site

On-site service requirements are mainly for hardware failures or faults. Some types of equipment, notably mobile X ray and ultrasound machines, can usually only be repaired by on-site service support.

5.4.2. Remote service

Remote service capabilities (see below) are commonplace for digital equipment. Ideally, it should be possible to diagnose common failures remotely, so as to improve the effectiveness and efficiency of on-site repairs. Modern radiology image acquisition systems, such as CR and DX units, can commonly be networked to permit remote service and repair. More complex equipment such as computed tomography (CT), magnetic resonance imaging (MRI), RIS and PACS routinely have networked remote service diagnostic and service capabilities. Such systems allow service engineers to interrogate the local system to diagnose faults, thus avoiding a service call. It is important that the vendor has a proactive remote monitoring service, where the technology identifies issues and sends warnings and alerts before a breakdown has occurred. This is something where other users of the same equipment can be very informative. The issues of security and patient confidentiality must be considered to prevent the transfer of patient images unless they have been de-identified. For this to function effectively, the IT infrastructure must be at a necessary standard [1, 14]. To properly secure a network environment, the machines (e.g. imaging device, PACS archive, laptop, a system implementing an IHE profile, or Internet kiosk) that will receive or transmit sensitive data must be identified. Identity management is required to authenticate both machine and personal identities.

5.5. QUALITY ASSURANCE

Quality assurance is the mechanism used to ensure the quality of a provided service. In the case of PACSs, the quality of a diagnostic service is ultimately assured through a comprehensive audit process [1]. In terms of equipment, quality assurance is provided by procedures (Appendix IV) that include:

— Administrative procedures to manage the quality process, the scheduling and review of quality control testing, the provision of adequate training, observance of appropriate equipment selection processes and the maintenance of records;

— Acceptance testing of equipment and commissioning or configuring to the required clinical requirements;
— Routine quality control testing of equipment;
— Control of quality control test instrumentation through calibration;
— Follow-up of the correction of defects found through quality control testing;
— Education of all staff (see Section 5.2).

For digital radiological facilities, equipment testing is simplified by the removal of film processing quality control processes. This is, however, replaced by the need to conduct extensive testing of the display systems of the workstations. There remains a major requirement for quality control of the X ray and digital acquisition systems.

5.5.1. Administrative procedures

The processes required to effect a quality assurance programme should be recorded in a quality assurance manual which includes the required procedures and records. It should ideally specify (a) the tests to be performed, their frequency and the identification of the person responsible for performing them; (b) a description of the procedure, including test parameters and their acceptable tolerances; (c) the equipment to be used for testing; and (d) sample results. Records of test results must be accessible. They should be maintained for each operational unit and include (a) initial test results (acceptance testing and radiation safety survey as appropriate); and (b) successive testing results. Resources must be made available for these processes. Quality assurance processes require ongoing monitoring, and this is often overseen by a quality assurance committee. While the facility manager has the overall responsibility for the quality assurance programme in the facility, a medical physicist with competence in diagnostic radiology should have primary responsibility for assuring the quality and consistency of most of the technical aspects within radiology, including equipment quality assurance, dosimetry and calibration.

5.5.2. Acceptance of equipment and commissioning testing

All major items of equipment need to undergo acceptance and commissioning testing. This testing assures the facility that the equipment installed is safe and is performing to the specifications of the tender process. The commissioning process establishes the baseline conditions required for routine quality control testing, and also investigates the image quality and patient dose properties of the equipment. Initial optimization should also be performed at this time. Optimization should be reviewed regularly by a multidisciplinary

team that includes, at a minimum, the radiologist, radiographer and medical physicist [1, 10].

The details of acceptance testing for various equipment are included within the references given below for quality control testing.

5.5.3. Routine quality control testing

The range of equipment that needs to be under a quality assurance programme is determined by the size and complexity of the radiological facility. A minimum set of equipment in a digital department might include a digital X ray acquisition unit, probably a CR unit, and a number of display monitors. More complex facilities will include a wider variety of equipment, such as direct digital acquisition equipment, mammography equipment, CT scanner, ultrasound unit and MRI unit.

Each facility should determine the quality control tests to be performed for each type of equipment. It is strongly recommended that recognized testing programmes are selected, and, if appropriate national guidelines exist, these should be followed. In the absence of appropriate national guidelines, international guidelines, such as those from the IAEA, may be followed. In other cases, guidelines from well-established national professional bodies, such as those from the United Kingdom or the USA, also are recommended. Many newer digital units have equipment specific performance tests in the equipment documentation, along with the required test phantoms or objects. This is particularly the case with display monitors, so the equipment recommended tests should be followed, although additional tests from national protocols may still be required. Often, it may be necessary to provide test instructions in the language of the country, at least in the case of tests undertaken by radiographic staff.

A key to successful performance testing is the consistency of the test procedures and the details of test setups used for measurements over an extended period of time, which is assisted by using detailed data collection sheets.

Facilities with equipment under warranty or service contract with an original equipment manufacturer or an independent service organization are advised to follow the testing and preventive maintenance schedule required to keep the warranty or contract valid. Such testing and maintenance schedules are usually included in the manual. Facilities should perform all the quality control tests that the manufacturer-supplied phantom will allow, and they should ensure that the correct phantoms are used to support the scheduled testing protocols.

References to quality assurance protocols for specific equipment types are given in Appendix IV.

5.5.4. Calibrated test instrumentation

The quality assurance radiographer(s) and the medical physicist should have access to appropriate, calibrated instrumentation, phantoms and other test equipment to perform measurements and testing. To assure accuracy of dosimetry and quality control measurements, instruments used for testing must be calibrated at regular intervals against accepted standards. The use of an accepted field cross check methodology is encouraged as a cost effective way of maintaining acceptable dosimetry standards. The facility should have a calibration policy and a record of equipment calibration and equipment cross checks [30].

5.5.5. Metrics and audits

Even with a well-designed and implemented workflow and integration of information systems, there are still errors that arise in RIS and PACS data. Regular maintenance and audit is required to report, correct and identify the root causes of such errors, so that preventive steps are implemented to ensure these errors are kept to a minimum.

A non-exhaustive list of examples that are suitable for measurement, audit and quality improvement include:

— Patients with incorrect identifiers;
— Patients with duplicate examinations;
— Mismatched entries in the RIS and PACS;
— Mismatched report and request;
— Unreported examinations;
— Incomplete examinations (studies not ready for reporting);
— Incompletely reported examinations (reports not validated);
— Incompletely sent studies (from modalities to PACS);
— Number of studies with deleted images (corresponds to analogue measure of discarded films/repeated X rays).

For the process of performing clinical audits, the reader is referred to Ref. [1].

6. IMPLEMENTATION SCENARIOS

This section deals with the practical implementation of digital radiology and does this through a number of implementation scenarios, which illustrate the different benefits digital technology can bring. This section is aimed at all individuals who will become involved with the implementation and subsequent operation of digital radiology, from radiologists, technologists, to hospital management, building and maintenance staff, IT staff, medical physicists and bioengineers. It is also aimed at funding agencies such as governments and non-governmental organizations that will fund such equipment.

6.1. COMMON FRAMEWORK

In general, the principles for design, purchase, installation and maintenance of digital imaging installations should have a common framework, and this topic is covered extensively in Section 4. This section focuses on considerations that are specific to three types of imaging installations presented in the form of typical implementation scenarios. Implementation scenarios have been developed for a short term, very limited field service facility that is deployed acutely in an emergency or crisis situation, a small limited modality facility and a small multimodality imaging centre.

For the purposes of this section, we have excluded larger health centres with multimodality imaging and networked technologies, such as major hospitals. Such centres would generally have easier access to local or internal expertise, and as such might require less guidance from a publication such as this to prepare, plan, purchase and install imaging equipment. This is probably not the case for a lot of smaller sites with low resources that require some medical imaging. These would typically be established health centres providing services in an outer metropolitan region or small clinics in regional towns or in a rural environment.

In all three scenarios presented below, there are certain key elements in common with regard to digital imaging.

6.1.1. Imaging technologies

All equipment requires DICOM (Digital Imaging and Communication in Medicine) compatibility for interoperability; this may be an extra cost option on the image acquisition equipment (especially ultrasound), which should be purchased as connectivity should be anticipated (even for basic teleradiology). DICOM compliance for interoperability will be a requirement for the image

acquisition equipment. Some DICOM interoperability functionality may require the purchase of optional extras (e.g. modality worklist). This may particularly be the case for ultrasound scanners. As interoperability will be necessary for teleradiology, the DICOM conformance statements for all equipment should be thoroughly checked and any required options should be included in the procurement.

In general, all digital X ray systems using computed radiography (CR) plate readers or digital radiography (DX) direct capture detectors are DICOM compatible and computer controlled. Desktop sized CR plate readers are widely available, relatively low cost, provide an effective balance between image quality (contrast and spatial resolution) and patient throughput, and have the ability to use multiple imaging plates of various sizes that can be replaced easily if damaged (Fig. 11).

Alternatively, portable tethered DX detector plates are available and can be a high performance alternative to CR, as there is no need to move the detector between patients, and images are usually processed and displayed much more rapidly than with CR systems. A high volume, high throughput setting using such DX detectors will be much more effective than a CR system, which offers little improvement in patient throughput compared to conventional film screen capture. Such DX detectors are quite robust, but are considerably more expensive to replace than CR plates.

In addition, some lower cost digital X ray systems have fixed, relatively low resolution digital detectors, but are still capable of high quality radiography for a reduced range of examinations. This is owing to the very low noise characteristics and high contrast to noise ratio of such systems, even though the absolute pixel resolution is lower than that for film screen or CR capture.

Typically, a suitable ultrasound system would be compact and portable and be able to perform standard 2-D greyscale ultrasound with at least two probes (linear high frequency for small parts and convex low frequency for the abdomen and pelvis). The ability to perform Doppler imaging, duplex Doppler flow measurements and other more advanced capabilities are highly desirable but not mandatory. All ultrasound systems can be powered from standard single phase mains sources, and some can use internal rechargeable batteries for a short period of time. For a digital imaging facility, ultrasound systems must be DICOM compatible.

CT scanners vary greatly in cost and capability; there are systems of good performance and relatively low cost, which can readily be installed in a small footprint and offer near turnkey capability with in-built DICOM connectivity. These are best considered for larger and more complex installations, but smaller facilities may have a CT scanner with some networked capabilities, without necessitating a full-blown PACS or RIS implementation.

6.1.2. Identity management

Digital systems require the reliable entry of a patient's name and identifier, especially the latter as names are often similar — this requires firstly the registration of the patient and the assignment of an identifier (e.g. hospital medical record number), or the use of a reliable identifier, then either manual data entry by the X ray (CR plate reader) equipment operator, or the use of an automated systems, such as a radiology information system (RIS) providing a modality worklist to the acquisition device and the operator chooses the correct option from the list (the use of a RIS is unlikely in resource constrained environment), or the use of printed bar-codes and a bar-code reader at the modality (this is unlikely in an environment with limited consumable supplies). Any failure to adequately identify images may impact short term usage (report on wrong patient) and long term usage (comparison with previous visits or saving for later visits).

6.1.3. Storage

This simple scenario requires acquisition, display, interpretation and printing of film (which is then used as the storage medium) while discarding the digital patient images. In fact, in the absence of a medico-legal requirement, there may be no long term storage. Image storage for longer periods (a few days) may be achieved by storage within the local hard drive in the modality. Local sharing and teleradiology may be achievable by point-to-point transmission to the intended recipient without the need for local storage. If there is a need for storage from visit to visit, a separate storage device attached directly to the modality or via a local area network will generally be required, unless there is sufficient Internet connectivity to provide long term storage to and retrieval from cloud storage. Though images can be burned to CD for long term storage, shelf storage and management creates access and reliability problems.

Low cost backup software and redundant robust hard drive array systems are available for small installations at a reasonable cost to enable end users to obtain reliable data backup without significant IT expertise. Such systems are often easily scalable as storage needs grow, and allow for individual hard drive failure with minimal risk of lost data.

6.1.4. Display quality

Typically, the monitor provided with the acquisition system may not be ideal either for image quality control, or primary interpretation. Alternatives include replacing the display with a more capable one, or sending the images

point-to-point or over the network to a second PC with a more capable display (and the appropriate receiving and viewing software).

Monitors that are produced specifically for medical image viewing can be more expensive than consumer or business grade displays. A significant advantage of the specialized medical monitors is that they usually include automatic internal measurement of luminance output and automatic calibration in accordance with DICOM Part 14 (Greyscale Standard Display Function, or GSDF). They may have a higher light output than more commonly available lower cost monitors. High resolution applications such as X rays may require greyscale monitors of at least 2 megapixel (MP) resolution to ensure adequate diagnostic performance. However, for small matrix applications (ultrasound, fluoroscopy and CT), good quality standard PC monitors of less than 2MP can be effective. The absence of features such as DICOM Part 14 calibration and backlight saving (for extended monitor life) on the standard monitors represent a significant disadvantage [13].

In general, displays should be flat screen LCD monitors with either bright CCFL (cold cathode fluorescent light) or LED (light emitting diode) backlighting. The ACR's Practice Guideline for Digital Radiology [14] specifies a maximum monitor luminance of at least 250 cd/m^2 and a contrast ratio of at least 500. These metrics are readily achievable with current commercial and medical grade monitors and exceeded in most cases. The somewhat older ACR standard for teleradiology (2003) specification requires a minimum value of maximum luminance of 170 cd/m^2 (50 ftL). Note that the ACR standard does not specify the maximum acceptable luminance for black. At this level — assuming standard conditions for monitor black and ambient light levels — the display is capable of delivering rendering of around 512 jnd (just noticeable differences) for monochrome images (thus meeting the 500:1 CR requirement). That represents 2 × jnds per presentation value (for an 8-bit data bus (i.e. 256 numerical value) available to an image pixel).

Regardless of the technology used, the light output of all monitors will degrade over time, and will fall progressively over a period of a few years.

6.1.5. Connectivity

The most basic deployment is with a self-contained image acquisition and a display unit for quality control and interpretation usage (Fig. 15). If any additional connection to other devices is required for distribution (image review on separate workstations), teleradiology (image review remotely), or storage, machines may be directly connected (point-to-point network with cross-over Ethernet cable) to one or more PCs with displays and optionally an archive (Fig. 16). In practice, at least a small local area network (LAN) can deliver an inexpensive and practical solution for this application. If running cable is not feasible, then a

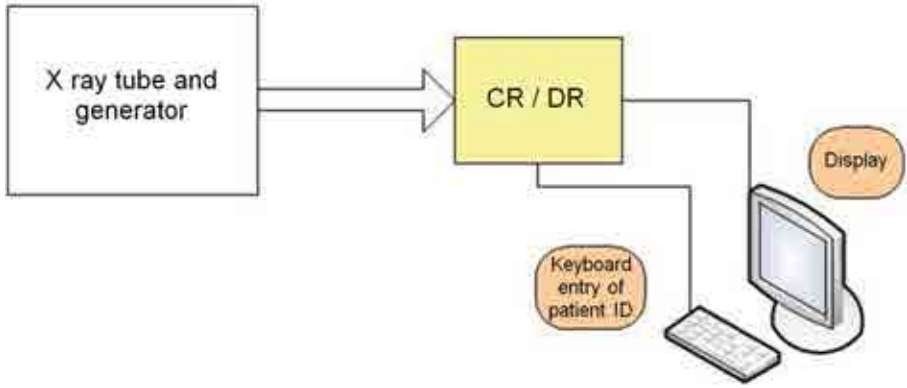

FIG. 15. An example of a self-contained image acquisition and a display unit for quality control and interpretation usage.

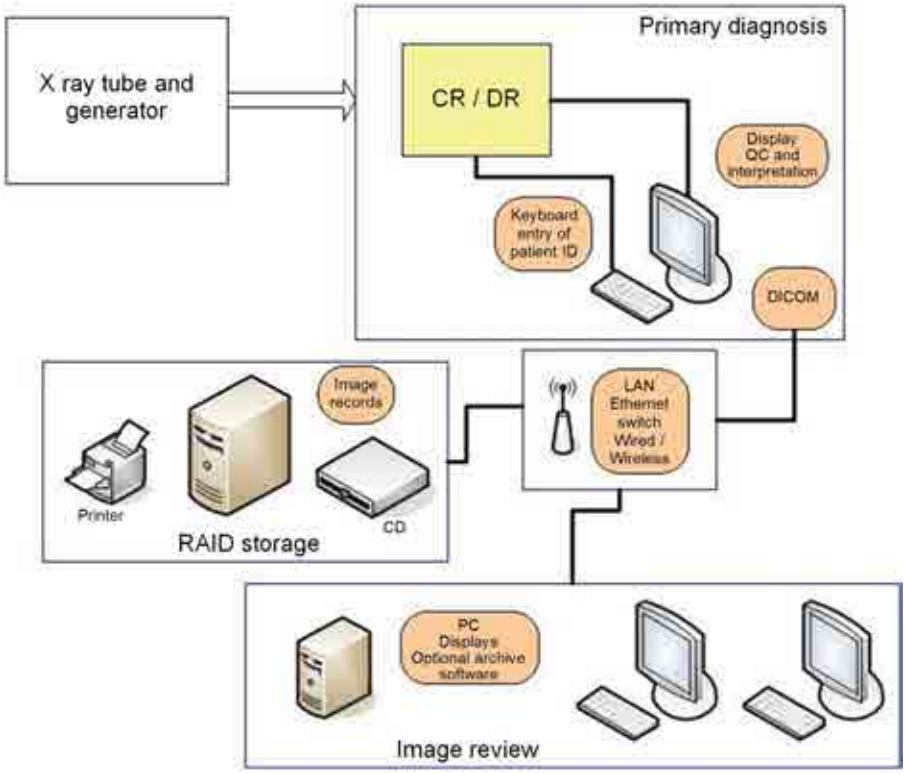

FIG. 16. An example of a self-contained image acquisition and a display unit for quality control and interpretation usage with added connectivity.

short range wireless network may be low cost, sufficient and reliable. Depending on configuration, wired 1 GB (1000BaseT) switched Ethernet provides sufficient bandwidth for near real time transmission. For mobile deployment, effective transmission for plain images is unlikely to require GB networking. Using an existing low bandwidth (e.g. 10BaseT) network may have a negative impact on other network traffic. If radiology applications are expected to dominate networking requirements, this is not recommended. Vendor software may be available for the management and display of received images, usually at a cost.

6.1.6. Distribution

The staff performing the acquisition may interpret the images and manage the patient, but in general both the report and the images may need to be distributed. Networked workstations may be an option. Images can be burned on a CD (with viewing software) for the receiving physician. From the outset, the proposed solution should be compliant with the Integrating the Healthcare Enterprise (IHE) portable data for imaging (PDI) profile. This avoids problems with the CD being platform dependent. Hard copy paper may be sufficient but is likely to be of very limited quality. Printing film is generally not favoured owing to the cost.

6.1.7. Imaging site requirements

All medical imaging equipment requires a fairly narrow range of operating temperatures and humidity. Adequate housing and climate control are necessary to ensure consistent operation and that equipment has a reliable lifespan. (See Section 4.5.)

6.1.8. Teleradiology

Teleradiology raises several non-technical issues related to:

— Funding for remote interpretation;
— Medical registration of remote readers;
— Indemnity and liability insurance;
— Credentialing of remote readers.

These are outside the scope of this publication but will nevertheless need to be considered.

6.1.9. Project management

Digital imaging projects are usually complex to implement in a robust and technically sound manner. It is entirely possible to spend a large amount of money with a poor functional outcome because of poor project management. With careful planning and involvement of key stakeholders from beginning to end, such systems can be planned, delivered, installed and implemented smoothly and seamlessly with few technical problems. The use of competent consultants should be carefully considered, including the use of an external project manager. For a more detailed discussion on this, see Sections 4.9 and 4.10.

6.2. SCENARIO 1: DISASTER RELIEF

Disaster relief takes place in an emergency setting with limited short term resources, deployment and lifespan.

6.2.1. Typical installations

There is a sporadic but important need to deploy limited imaging capabilities in situations where no existing health care facility is in place, to provide support to emergency medical teams working to provide aid to populations displaced by war, famine and natural disasters.

In such situations, digital imaging is crucial as there is neither the option nor the need to produce conventional film. Orthopaedic surgeons will require access to imaging and this is can be provided using small hard copy printers or through digital transmission. Often, in this case, remote reporting or teleradiology consultation may be the only way to obtain formal radiological opinions. In general, X ray is the main imaging technology that needs to be deployed, but portable ultrasound is also often used as an adjunct to physical examination for soft tissue pathology and obstetric applications.

The main challenges in such installations are:

— Obtaining an adequate power supply;
— Providing climate controlled housing for the imaging equipment;
— Transporting equipment to such sites safely;
— Installing such equipment with limited IT expertise;
— Implementing external data transmission for teleradiology.

6.2.2. Typical use cases

In such extreme medical settings, imaging is primarily used in cases of:

— Acute trauma (especially musculoskeletal);
— Infectious diseases (especially chest);
— Obstetric — e.g. in the case of displaced person camps.

Depending on the acuteness of the situation, many patients may have to be imaged in a short period of time. A highly robust, readily transportable, turnkey X ray system that can be used with very little training is a priority.

6.2.3. Proposed technologies

X ray is the primary imaging modality in such situations. Portable X ray systems that use standard single phase mains power are probably most suitable as they are transportable by design, are easily moved on-site and have adequate power to perform most common X ray tasks. Of all the other imaging modalities in this setting, portable ultrasound is probably the only practical technology to use. However, portable ultrasound machines may not have the DICOM functionality required for full interoperability and thus cannot be easily integrated into a remote teleradiology setting. In these situations, ultrasound is best considered in this setting as an extension of physical examination.

6.2.4. Staffing and expertise

Usually, a radiologist will only be available remotely. The presence of medical staff and a trained technologist would be desirable, but there may only be nursing or other staff with limited imaging training.

6.2.5. Networking and teleradiology issues

— Local networking and archiving are not usually required;
— There is little need for hard copy products or CDs, although many orthopaedic surgeons probably will wish to review images;
— Remote teleradiology may be necessary to provide formal interpretation of some images;
— Some image interpretation expertise may be present among medical staff on the ground;
— Use of cabled Internet or wireless telephony is usually not feasible;

— Satellite communication may be the only practical means of obtaining adequate connectivity;
— A formal link with a reporting centre is necessary, which may be in a nearby city or even another country.

6.2.6. Project management issues

Imaging facilities in this specialized setting may be quite self-contained and have the potential to be almost completely configured and packaged to offer a rapidly deployed turnkey solution at the health care site once the site has been properly prepared.

Stakeholders:

— Medical staff on-site;
— Logistics experts;
— On-site technical staff;
— Equipment vendor service engineers;
— Remote radiology technical staff;
— Remote consultant radiologists;
— Administrating and funding agency (e.g. government, military, NGO).

6.3. SCENARIO 2: SMALL FACILITY

Scenario 2 describes a small facility, which may be urban or regional, and which has few resources and limited imaging (CR/DR and ultrasound).

6.3.1. Typical installations

These centres usually are in pre-existing low volume health centres such as a clinic in a small town. They would have significant siting and resource limitations:

— Building structures are often suboptimal and/or poorly maintained;
— Power supply may be available only for part of the day;
— IT expertise is typically minimal;
— Networking infrastructure is usually absent or of low technical quality and low bandwidth;
— Telecommunications infrastructure is often limited to mobile telephony;
— Sustained funding source.

For digital imaging, such sites therefore offer challenges in planning, implementation and maintenance. However, if such sites require upgrading or modernization, then digital implementations are most appropriate. Such facilities are often single-room installations with a single fixed X ray machine (or a mobile device with a fixed room including a table and chest receptor), and a portable ultrasound system that can be used in the wards, clinics or even transported off-site for imaging services. The ultrasound machine would also serve for gynaecological and obstetric conditions, especially in low resource settings where mother and infant mortality is a significant issue.

6.3.2. Typical use cases

6.3.2.1. General radiology

Medical imaging in such centres is usually limited to common conditions, including:

— Acute trauma;
— Orthopaedic injuries and fractures;
— Infectious diseases of the chest, abdomen or musculoskeletal system;
— Gynaecology/obstetric imaging (ultrasound only).

For such conditions, X ray and ultrasound offer the most cost effective and reliable imaging technologies. Ideally, the X ray system would be a fixed installation supplemented by a mobile device for non-ambulatory work, and be robustly engineered, simple to operate and require quite limited training to operate competently. The ability to run off standard mains power is highly desirable, as is the ability to take images when mains power is interrupted. The WHO Basic Radiology System (WHIS-RAD) was specifically designed with such considerations in mind.

Fluoroscopy using a portable C-arm system can be useful, especially for intraoperative orthopaedic work or for limited forms of intervention. Some portable fluoroscopy systems are capable of limited vascular imaging, and can also be used for a limited form of digital radiography. Such systems are often located outside the imaging facility, such as in the operating theatre or emergency department, but are operated by imaging staff. Usually, only a few images are captured and stored using such systems.

Such centres typically have a low imaging volume per day, as most patients presenting for care require medical attention and often do not require any imaging. Conditions where imaging is considered routine in the West, such as early pregnancy, would be rarely studied as a matter of course in such centres.

In many cases, there is no plan for any imaging network and dedicated reading workstations may not be initially required. Image review and interpretation may occur on the ultrasound or CR/DR console screen or control computer, which usually have a small amount of internal local storage. In this setting, it would be useful to install a large high quality computer monitor to allow for dedicated image viewing at appropriate quality (spatial and contrast resolution).

A secondary reading or review workstation may not be required in the smallest installations, but would be the next logical stage in implementation. Such workstations would be stand-alone, may be sited at the point of care, such as in the emergency department and may have a moderate amount of local storage, a large good quality PC monitor and be able to print or burn CDs using in-built software drivers and hardware. In this situation, a low cost consumer wireless or wired Ethernet router or switch would be suitable for networking.

Images will not usually be stored digitally for the long term, but may be distributed by CD or paper printing. Printing technologies are plagued by consumable supply cost and availability problems, but would include:

— Inkjet (large ink volume printers preferred);
— Laser (toner supplies can be problematic);
— Wax printers (limited selection and availability).

6.3.2.2. Screening for infectious diseases

Screening for diseases requires a more streamlined approach and more focused implementation. Typically, imaging is high throughput and stereotyped, and reading is delayed and performed elsewhere in a batch fashion. The most common application for this in developing countries would be chest radiographs for tuberculosis/HIV/coal workers' pneumoconiosis screening. Such screening almost always involves only one imaging modality (usually X ray), and the emphasis is on robust identification, highly consistent image quality and rapid turnaround in the imaging suite. This usually requires an integrated registration and identification process, staff to help manage patient flow and radiographic staff who spend almost all their time performing imaging. Turnkey self-contained systems have been developed expressly for this purpose [31].

When digitized, such images can be steadily transmitted to a reading workstation in another part of the imaging centre, or elsewhere in the same health centre, or even another centre for batch delayed reading and interpretation. A limitation of such a system is that other forms of medical imaging and provision of general imaging services are not feasible with such dedicated equipment and workflow.

6.3.3. Staffing and expertise

Such centres typically have staff trained to perform X ray acquisition, and may have a medical practitioner who is trained in ultrasound. A radiologist may or may not be available locally, but there may be the ability to send images for review externally either by hard copy or disk, or a radiologist may travel to the centre to read locally on a periodic basis once a day or every few days.

6.3.4. Networking and teleradiology issues

In such a small imaging facility, a full network infrastructure is unnecessary if imaging volume per day is low. The use of good quality consumer grade computer hardware, software (e.g. open source or low cost) and networking technologies are recommended. As discussed above, a wireless router or cabled switch for local internal networking would be adequate for such a limited use case, and no PACS or RIS server would be necessary. This architecture would still permit small volume remote consultation and secondary reporting to occur if the small local imaging network was connected to the Internet.

6.3.5. Project management issues

This site could be implemented using a turnkey solution that minimizes the technical skills necessary for the design, purchase and maintenance of the site. Alternatively, local personnel could configure the site, particularly with the assistance of an external consultant.

Such sites often do not have a full time radiologist on-site, and are usually staffed primarily by radiographers. Such sites may have teleradiology capabilities for selected cases, or sometimes, for all primary interpretation.

Stakeholders:

— Project management team;
— Designated radiologist;
— Medical and technical staff on-site;
— Facility health administrators;
— Facility finance department;
— Vendor’s technical support engineers;
— Vendor’s application specialists;
— Remote radiology technical staff;
— Remote consultant radiologists;
— Health governance agency (e.g. government health department);
— Funding body (government, NGO, philanthropic organization).

6.4. SCENARIO 3: SMALL URBAN MULTIMODALITY IMAGING CENTRE

6.4.1. Typical installations

A centre of this type would represent the next step up from the very small limited modality centre in Scenario 2, with 3–4 digital imaging modalities, but may not be sufficiently complex to require a fully networked PACS and RIS architecture. Typically, such installations will be in a pre-existing health centre that is usually a small hospital. More robust power supply and external connectivity will usually be available, permitting consideration of a CT scanner that requires three phase power.

6.4.2. Typical use cases

In such small multimodality imaging centres, the range of conditions treated will usually be wider and more chronic diseases will become important considerations. Typical conditions that may be encountered include:

— Acute trauma to head, spine, skeletal system, chest, abdomen or pelvis;
— Acute or chronic infectious diseases;
— Neurological conditions, such as stroke;
— Cardiovascular diseases;
— Arthritis;
— Cancer;
— Abdominal pathology (e.g. bowel obstruction, appendicitis);
— Obstetric conditions;
— Genitourinary pathology including gynaecologic conditions;
— Paediatric conditions.

6.4.3. Proposed technologies

In general, the combination of reasonably good quality X ray, fluoroscopy, ultrasound and CT scan will enable adequate primary diagnostic work across the range of conditions listed above.

— X ray systems will typically be robust fixed installations with either DX or CR capabilities.

— Ultrasound systems should be mobile but ideally not portable, as such systems often have significantly more flexibility and image quality than portable systems, and DICOM compatibility is usually standard.
— Portable C-arm fluoroscopic units can be useful for simple contrast studies of the bowel or to support orthopaedic procedures. As noted above, some are capable of limited vascular studies, including digital subtraction angiography.
— CT scanners for such an installation would be multislice in a compact installation that does not normally require a separate computer room.

6.4.4. Staffing and expertise

The key features of the staffing and expertise of such a centre are:

— On-site radiologist present for at least part of each working day;
— Several imaging technologists;
— May have dedicated staff for CT and ultrasound;
— May have some internal IT expertise.

6.4.5. Networking and teleradiology issues

Typically, such installations would benefit from installation of some form of limited network for short term image storage, interpretation and review. Storage and distribution can be based on a mini-PACS environment, which does require at least a small server, or on stand-alone workstations. However, once the facility needs extend beyond this level, professional PACS and RIS installation may be required with involvement of dedicated vendor solutions.

6.4.6. Project management issues

The increasing size and complexity of this case may require a more formal project management process to that of a smaller site — but the same project management principles will apply. As the complexity increases, it becomes more important to consider a PACS solution from a major manufacturer of radiological equipment. This decision should shield the site from the instability of smaller companies and allow the system to be upgraded with improvements in technology in line with local demands. It is, however, strongly advised that an external expert is consulted before and during negotiation with large PACS companies.

Such centres usually will have one or more resident full time radiologists on-site, who are typically closely involved in planning, organizing and managing the project.

Stakeholders:

— Project management team;
— Designated radiologist;
— Medical and technical staff on-site;
— Facility health administrators;
— Facility finance department;
— Vendor’s technical support engineers;
— Vendor’s application specialists;
— Remote radiology technical staff;
— Remote consultant radiologists;
— Health governance agency (e.g. government health department);
— Funding body (government, NGO, philanthropic organization).

Appendix I

IMPLEMENTING A LOW COST PACS

I.1. OVERVIEW

I.1.1. Minimum system

An absolute minimum system consists of the imaging device(s) with a display workstation and the capability to burn CDs to distribute the images. This may be an X ray system plus a CR reader or a DR system. No network connection is necessary, except for remote service.

I.1.2. Entry level system

The entry level system has no long term storage, but uses the diagnostic workstation as a temporary storage. This solution may be acceptable for medical imaging services that have no tradition of storing films.

I.1.3. Full service system

The next step would be a system as shown in Fig. 9 in Section 4.6.3. Such a system would include imaging equipment, workstations and storage servers, and options for remote reading or teleradiology.

I.1.4. Full scale system

A full scale system would include all the above with the addition of radiology information system (RIS) terminals with RIS-PACS (picture archiving and communications system) synchronization.

I.2. WORKFLOW DIAGRAMS

A generic work flow diagram is seen in Fig. 9 in Section 4.6.3.

I.2.1. Network

The network is the spinal cord of the system. If the network is not working or not correctly configured, the system becomes paralysed. Incorrect

configuration or defective networking equipment or cabling can cause errors that can be difficult to track down. If possible, professional services should be engaged to establish and maintain the network.

I.2.2. Cables

The use of prefabricated cables that have moulded connectors is highly recommended, since homemade solutions are less reliable. For very small internal networks, where all equipment is within one or two rooms, the network costs can be kept low by running the cables in small plastic channels and placing the switch in a safe, cool spot. Larger sites should have professional installation of network cabling into the building to a central switch cabinet. It is important that the cables are certified for the correct network speed and that only Cat5e cables are used.

I.2.3. Switches

Almost any switch can be used for smaller networks. Sites with only one workstation, one server, ultrasound system and X ray system could even use a router with a built-in switch. Larger sites should use higher quality switches with 1-Gbit ports, which preferably are VLAN capable.

I.2.4. Firewall/router

If the network is connected to the Internet or other external networks, firewalls are essential to protect the network from outside attacks, and to provide the network with the necessary connectivity. It is highly recommended to use brand name firewalls with virtual private network (VPN) capabilities. Building a Linux firewall or using ‘no name’ firewalls may cost more in the long term (owing to the high TCO of ‘free’ software). Configuring and maintaining the firewalls is best left to experts. Firewalls can be configured and maintained remotely.

Note that X ray systems and workstation software are relatively sensitive to changes in the operating system and software ‘environment’ (.Net, Java, video driver versions, etc.).

I.2.5. Software updating

When automatic updates via the Internet are enabled, or even during web browsing, the computer software is constantly being changed by various updates and the addition of new plug-ins. Imaging network computers therefore should

either not have general access to the Internet, or the update and browser security settings should be constrained. Only a limited set of work related web sites should be allowed. This will reduce the risk of different types of problems related to incompatible software versions.

Automatic update of the Windows OS should, for example, be turned off, and updates should be manually installed in a controlled way that maintains the capability to revert to the previous state if the update causes problems. This manual updating should be performed on a regular basis, since many such updates are security related and failure to update may place the system at risk.

Imaging system manufacturers release updates of software of their systems, including OS patches, on a regular basis. Open source software providers will advise on OS upgrades.

I.2.6. Power

Production networks should always have firewalls and switches powered through a UPS system to reduce the risk of problems related to unstable power. Ideally, all the computers, and especially storage servers, should have a UPS as well, to assure clean shutdown and restarting and in particular to ensure that all pending data has been written to disk.

I.2.7. Redundancy

Correctly installed and configured networking devices are generally stable and require little attention if the physical environment is within specifications regarding heat, humidity, dust, etc. If they do fail then the whole system is paralysed, so immediate action is necessary. For smaller networks, the recommended approach is to have arranged local access to replacement parts in advance, so that faulty systems can be replaced within a reasonable time. Large network designs should have redundant switches and firewalls, but the configuration and deployment of network redundancy is relatively complex and not within the scope of this publication.

I.2.8. IP addresses

Most DICOM applications require that the applications with which they are communicating have a stable configuration, and in particular that the application entity (AE) titles, host names and port numbers do not change. Although dynamic configuration mechanisms exist, they are not widely used. Accordingly, it is conventional to use static IP addresses for most DICOM devices, rather than to rely on DHCP (dynamic allocation). This can be achieved with either static

IP addresses or long term leases issued by a DHCP server, which achieves the same effect as static IP addresses.

I.3. INSTALLATION AND CONFIGURATION

I.3.1. PACS image storage

The smallest sites may decide to forgo any image storage and to give all images to patients on CDs. At that point, the preservation of the image is no longer the responsibility of the imaging site. However, once a site decides to maintain long term image storage, backup storage becomes necessary. It is recommended that off-site backup be used, preferably in a different hazard zone. For small, low volume sites, it may be adequate to have the primary and backup storage servers in two different rooms in the same building, but then they should be as far apart as possible. The consequences of total data loss should always be weighed against the cost of providing a more secure backup.

I.3.2. Software considerations

There are several options for software. There are numbers of commercial PACS software solutions offering different features over a large price range. The licence and maintainance costs are often linked to the numbers of new studies stored per year.

Free and open source applications are mostly without official validations; however, there are a few free software DICOM storage solutions that have a good reputation and are supported by excellent support forums.

Mostly, the OS of the server should be selected to fulfil the requirements of the chosen applications, which are rarely OS neutral.

These are points to look for in the software, not necessarily in order of importance:

— Is there a tool to correct patient info? (There will be human errors to correct.)
— Is there a tool to ensure that the 1st and 2nd archives contain the same images?
— Is there a web viewer for the images, and is it actually usable?
— Are there routeing options fitting the site requirements?
— Can data be anonymized?
— Does the software store the images uncompressed or compressed?

— Can the software change compression methods (e.g. receive in one format and store in another)?
— Does the software support the DICOM SOP classes to be used?

When using the free software solutions, more than one software package may be needed to meet all the requirements. For example, a PACS solution may not have the capability to correct patient information or to route images, so other tools must be found to fulfil these requirements.

I.3.3. Hardware considerations

When selecting hardware, one must be prepared for when it will fail. It should be bourne in mind that, as with many things, regarding the durability of the hardware, the required maintenance and available support, one gets what one pays for. It is highly recommended to choose a big brand name vendor. Buying generic brands from a local computer shop may seem cheaper initially, but it is likely that the hardware component combination is substandard and has not been tested or verified as extensively as the brand name systems. This may cause severe problems. The brand name server may include many important features, such as built-in hardware monitoring utilities, the ability to turn power on and off remotely, and, most of all, that the hardware combination has been tested and validated to work properly over time.

Regarding storage, the use of redundant disks is recommended. Both the OS of the servers and the data storage should be installed on redundant arrays of independent disks (RAID). In a case of failure, the disks may need to be moved to the same type of hardware to be able to access the information on the RAID. Another good reason to use brand name hardware is that the same hardware will be available for at least two or three years, first from the vendor and then from Internet sources, such as on-line second hand marketplaces.

When the storage need exceeds the original capacity built into the server, there are several options. The first is a larger server with more slots for disks. This is not necessarily the best idea, but it is a workable solution. A second option is NAS (network attached storage). The business types should be selected, as those designed for home users mostly have limited throughput. NAS can be a good solution for backup storage as well, and the software on the NAS boxes is often designed for that capability. An advantage of NAS boxes is that they generally need little power to run, so they do not generate a lot of heat, and can, in some of the cooler parts of the world, be kept in rooms without special air conditioning. A final and ultimate option is a SAN (storage area network). SANs are enterprise level devices that carry considerably higher price tags than NAS,

but they have more sophisticated capabilities. The SAN can be in a server room on location, or in a remote data centre.

Occasionally, the software vendors recommend certain hardware for their software, which they have tested it on and can assure that it works, so these recommendations should be taken seriously. Storage hardware for medical images should always be protected by an UPS (uninterruptible power system). A reputable brand name UPS should be selected and it should be ensured that it can handle the expected load (see Section 4.5.3. for information on the selection of a UPS).

Servers and disk storage systems generate heat. If possible, air conditioning with a closed loop (with no or little outside air) should be used to cool the servers in a server room. If correctly installed and configured, good quality servers in clean and controlled environments can run for years without problems. If they are operated in a dusty environment, the fans and cooling soon get clogged with dust and the temperature of the components rises, causing premature failure. If there is no dedicated server room a spot should be selected where there is little risk of someone tampering with the system, and which has good ventilation.

I.4. DIAGNOSTIC WORKSTATIONS

I.4.1. Software considerations

As with the server software, the first step is to decide what software is to be used. The number of DICOM viewers available is enormous, and this software is the one the users see and will refer to as the PACS (whether this is the correct terminology or not). When selecting the software, there are some points to keep in mind (not in order of importance):

— Is the software FDA or CE certified? (Other similar certifications may be legally required.)
— What types of tools are there?
— Can the user perform 3-D reconstruction?
— Can the user query and retrieve from PACS storage?
— Can the user burn CDs or DVDs with the software?
— Can the user save annotations back to the PACS?
— Can the user create display or hanging protocols (auto arrange images)?

The above items should be kept in mind when selecting commercial software or when looking for free solutions. When the workstation software has been selected, the hardware can then be chosen.

I.4.2. Hardware considerations

The same rules apply here as with the server hardware regarding the use of brand names and recommendations from the software vendor. If the workstation is also to be used for temporary image storage, it is important to use redundant disk systems.

I.4.3. Display requirements

Low cost PACSs use standard computer displays.

I.5. INSTALLATION AND CONFIGURATION

During the installation, planning should precede action. Advance planning should be performed and network diagrams made using images of the equipment (instead of using boxes to represent the equipment), so that everyone who is familiar with the site will see how things are connected. Once installation begins, it is of utmost importance to log all actions, including making screenshots of configuration settings and/or saved log files. A good installation log and good documentation can save a great deal of time when things go wrong.

During installation it is important to plan where the installation log and other material related to the computer system will be kept. Most of the time, all such material is kept close to the servers. It is recommended that time be spent on organizing the manuals, installation CDs and other related material needed or acquired during installation, since ready access to that information can also save a considerable amount of time when things go wrong.

Plastic boxes should be used for extra cables and other hardware material, and CD storage folders for the CDs. In times of equipment failures, it will be helpful if notes on the contents are written on the boxes using marker pens. For example, all extra material from one server can be collected in a box with notes written on it on what server this material belongs to, who installed it, the date, and a list of the contents. All this material should be locked away so that unauthorized people do not have access.

Regarding the software installation, there will be some passwords, usernames, port numbers, etc., needed for the various utilities. There should preferably be a structure to how usernames and passwords are selected and they should be recorded. This is even more important if there are local administrators who should not have a defined access. It should be remembered that at the time of installation, the usernames and passwords will make perfect sense and seem easy to remember. After a few months of not using them, they may not be easy to

retrieve from internal human memory, so they should be noted down and stored in a safe place.

The modalities, workstations and PACS all communicate with one another using DICOM. During installation, hostnames, AE titles and port numbers must be selected. As a rule of thumb, hostnames and AE titles should be the same, the only difference being that it is traditional to keep hostnames in lowercase and AE titles in uppercase. AE titles can be up to 16 characters long. The standard DICOM port numbers are 11112 and 104, and these should be used if the vendor does not require another port number. All AE titles, hostnames and port numbers should be documented, preferably on the network diagram.

When selecting the AE titles and hostnames, it is helpful to make them descriptive and to consider what may happen in the future. AE titles should be unique within the network (no two devices should have the same AE title). Anticipate that equipment will be replaced, possibly with equipment from other vendors, so although ACMEXRAY might sound logical initially, if that Acme Company X ray system is replaced with another manufacturer's system, the AE title will no longer make sense. Of course, some will decide to replace the AE title whenever new equipment replaces old equipment, but when sites grow and services that the modalities connect to are added, or the site is connected to another remote site with automatic routeing of images, accession control, etc., this adds several complications and changing all configuration related to this X ray room becomes a bigger task than it should.

A recommended AE Title should be similar to XRAY1, but this can also create a big problem if the site is connected to another site, and both have a XRAY1 AE title. One recommendation is to use 'abbreviation of the site name' + 'modality type' + 'running number' to reduce the likelihood of problems when connecting sites. For example, for an X ray system and workstation in Anytown General Hospital, one could use AGHXRAY1 and AGHWS01.

It should not be assumed that the network outlets in the wall of the server room are fully functional, even if they were recently installed. Bad wiring of the network is a common problem, and the error rate is rather high. A long network cable should be kept at hand to bypass wall plugs for troubleshooting.

Finally, after installing workstations and servers, backups or images of the disks should be made using dedicated software, and the backups and images should be stored in a safe place (e.g. the same location as the installation media).

Appendix II

IMAGE COMPRESSION

II.1. TRANSFORMATION AND CODING

Compression schemes typically consist of a series of steps that first transform the original data into an alternate representation that exposes redundancy and then encodes the information in a more compact form.

If one is compressing a series of symbols, such as plain text represented as successive characters, one byte per character, it may be directly encoded using a mechanism that substitutes a short encoding for more frequently occurring characters, and a long encoding for less frequently occurring characters. For example, the letter ‘e’ might be encoded with a single bit, whereas the letter ‘z’ might be encoded with a large number of bits. This is referred to as variable length coding, as opposed to the one byte per character fixed length coding. One very common approach to encoding data in this way is Huffman encoding. More complex analysis of the plain text entails storing sequences of characters in a dictionary, computing their frequency and representing entire sequences with single variable length symbols, an approach referred to as dictionary coding. Another approach is to encode the entire message as a very long binary fraction, which can produce near optimal output for a given set of symbols and probabilities, given an accurate model of the frequencies of each symbol. A special case that is often considered separately is that of the same symbol occurring multiple times, in which case it may be encoded as the symbol and the number of occurrences, rather than repeating the symbol, referred to as run length encoding.

These approaches are equally applicable to encoding images, except they do not account for the additional redundancy that is present in two (or more) dimensions in an image. Transformation steps may be used prior to coding to expose such redundancy in an image. For example, where successive pixels differ little from their predecessors most of the time, encoding the difference between the current and previous pixel may result in a more compact value to code, or a more compact frequency distribution. For some types of image, more regional context can be considered. For example, the difference between the pixel above as well as the pixel to the left may be included in the difference signal, and even more complex models that consider the rate of change in the local region can be constructed.

Other types of transformation that are specific to images may expose redundancy in multiple colour channels. For example, colour images are typically

encoded uncompressed as red, green and blue channels, yet all three channels carry the same luminance information. Transformation of the colour space into a luminance and pair of chrominance channels may expose this redundancy. Similarly, transformation from the spatial to the frequency or wavelet domain may also allow for a more compact representation.

II.2. LOSSY AND LOSSLESS COMPRESSION

Lossless compression schemes for images may utilize such transformation steps as described previously, with the proviso that the transformation be implemented in a mathematically reversible manner. Difference transformations must have sufficient depth to preserve the maximum possible difference value and its direction (sign) with full fidelity; this requires one more bit to encode than the original values. Similarly, frequency domain or colour space transformations require the use of equations and implementations that use fixed, not floating, point arithmetic, and of sufficient precision.

In lossy compression, the process involved is similar to that used for lossless compression, with transformation and encoding steps, except that since a finite amount and type of loss is permitted, neither of these steps is required to be entirely reversible. For example, the colour space and frequency or wavelet domain transformations can involve a certain amount of loss, and the use of continuous functions with finite precision can expose more redundancy. Additionally, deliberate steps may be applied to discard specific types of information. For example, higher frequency coefficients may be represented with fewer bits of precision than more important lower frequency coefficients, and this can be controlled in a quantization step applied after transformation and before coding. In some compression schemes, this is the step at which the quality of the result is explicitly controlled.

Two levels of compression may be defined for medical imaging, visually lossless and diagnostically lossless. Visually lossless compression is a type and level of compression at which a human observer is unable to visually distinguish the original from the reconstructed image, even though mathematical loss has occurred. This can be determined by relatively simple experiments and is known to vary considerably depending on the modality and body part of the image. However, whether such images, or images compressed more or perhaps less, are sufficient for primary interpretation, i.e. are diagnostically lossless, depends on the diagnostic task. As an extreme example, for the purpose of locating the tip of a catheter, a chest X ray could undergo extreme degradation and still be sufficient, yet detection of the pneumothorax caused by the insertion of that catheter might require an image with much less compression.

II.3. STANDARD AND COMMON COMPRESSION SCHEMES

Up to this point, compression has been described in general terms. In practice, although the literature abounds with creative schemes, several formal and de facto standard methods of image compression have achieved widespread use.

The International Standards Organization and the International Electrotechnical Commission joint technical committee has established subcommittees responsible for both still image and video compression standards, resulting in the Joint Photographic Experts Group (JPEG) and the Moving Picture Experts Group (MPEG) families of standards, respectively.

In consumer digital camera and web applications, the widely used JPEG format is actually only a subset of a large number of schemes defined in several standards. This scheme subset entails the use of 8 × 8 pixel blocks, a lossy colour space transformation to luminance and chrominance channels, spatial downsampling of the chrominance channels, use of the discrete cosine transform to perform a frequency domain transformation, and Huffman coding. It is this scheme that is used for medical imaging, involving lossy compression in 8-bit greyscale or colour, but additional JPEG schemes are used for other types of medical images, including:

— 12-bit discrete cosine transform, applicable to greyscale images of greater bit depth;
— 16-bit lossless compression with Huffman and Difference coding;
— JPEG 2000 with wavelet transformation and arithmetic coding, in both lossless and lossy variants.

For medical images involving multiple frames that contain redundancy between frames, e.g. cine images acquired over time or successive 3-D cross-sections, although each frame may be encoded separately using JPEG or JPEG 2000, other schemes, such as multicomponent or 3-D JPEG 2000 or MPEG, may be applied.

There are several other common proprietary or de facto standard file formats, such as GIF, PNG and TIFF, with inherent compression schemes widely used on the web and for other professional applications, but these are rarely used for medical imaging owing to bit depth constraints or lack of sufficient compression support. Although file formats with compression schemes that are commonly used for text and data files, such as ZIP, may also be applied to images, they are generally not as effective as methods that take advantage of the image structure.

II.4. COMPRESSION IN DIGITAL IMAGING AND COMMUNICATION IN MEDICINE (DICOM) STANDARDS

The Digital Imaging and Communication in Medicine (DICOM) standards make use almost exclusively of the standard compression schemes of the joint technical committee of the International Organization for Standardization and the International Electrotechnical Commission, and defines Transfer Syntaxes for each of the appropriate JPEG and MPEG lossless and lossy schemes. This approach allows devices communicating on the network to negotiate the most appropriate compression scheme to use depending on the circumstance. Association negotiation allows the sender to propose combinations of the type of image (SOP Class) and the type of compression (Transfer Syntax) and the receiver to accept or reject each combination depending on its capabilities. For lossless compressed images, there is a fall back mechanism to allow the default, uncompressed, Transfer Syntax to be used, in case the recipient does not support any proposed compression scheme. This is not required for lossy compressed images, the principle being that the sender may not have access to the original uncompressed image.

As technology evolves and new compression schemes are standardized, DICOM adds them as new Transfer Syntaxes, potentially making them available for any type of image, since the Transfer Syntax is independent of the Service–Object Pair (SOP) Class. DICOM is a technology standard and does not address the appropriate use of any particular compression scheme for any particular purpose. The inclusion of a scheme in DICOM is not an endorsement of such a scheme.

Appendix III

FREE AND OPEN SOURCE SOFTWARE

III.1. THE MEANING OF THE TERM ‘OPEN SOURCE’

To understand the concept of open source software, one must understand how software is created. When a software developer creates software, so-called source code is written for the software that is compiled into an executable program that is understandable to a computer. In other words, the software developer writes functionality text in a language that he understands and then translates the functionality text to a language that the computer understands. In the past, most developers and development companies kept their own source code secret to keep other developers and companies from using or stealing their ideas and programs. This software is commonly called proprietary, or closed source software.

Today, many developers and companies release their product’s source code to benefit all, but protect their code with licences. The companies that develop this type of software must be ready to give access to the source code upon request, but this can take a lot of their employees’ time, so most just point to the source code on their web site instead. This type of software is called open source software.

III.2. LICENSING FOR OPEN SOURCE SOFTWARE

Purists still debate the distinction between ‘free’ software and ‘open source’ software. For example, see the definitions of the Open Source Initiative [32] and the Free Software Foundation [33, 34]. In practice, the majority of open source software can be used without paying licence fees depending on the manner in which it is used.

Today, there are a lot of open source licencing models available [32], and choosing an application with the right licence can be a demanding task. A significant issue is licence compatibility. Open source licences are not all compatible with one another. This means that users may not be able to integrate or use one open source application with another. An example is the incompatibility of the licences for the Linux kernel and the ZFS file system native Linux kernel port, which are incompatible. It is therefore impossible to merge and ship the ZFS native kernel driver alongside the Linux kernel [32]. Developers must choose the

licence for their source code wisely beforehand to prevent licence incompatibility with other software.

System designers, however, cannot choose the licences for the software they are bundling together; they can only choose the software with compatible licences. The system designer is thus forced to either choose software with compatible licences and bundle those together, or bundle only a partial software suite and manually install the software with incompatible licences in each suite installation.

The issue is less significant for end users who are assembling their own solution, i.e. using the software as opposed to distributing it to others.

III.3. COSTS ASSOCIATED WITH OPEN SOURCE SOFTWARE

Even though open source software often is free to use, there are costs involved with using it just as with proprietary software, and sometimes there are even costs for initial purchasing or support and maintenance costs. There are three ways that open source software (or any software) can generate costs in support and maintenance; support and maintenance services from the software manufacturer, support and maintenance services from a third party and support and maintenance services from internal staff.

III.3.1. Price models

There are a number of price models that are used by software providers to fund the continued development of their software. Below are the some of the common models.

III.3.1.1. Free of charge software, support fee charged

Some software manufacturers allow the opportunity to download and use their software for free, but they will offer support for a fee. Generally, the support fee pays for a period of time and the most common period is a year at a time.

III.3.1.2. Free of charge software, donations accepted

Some software developers give their software for free, but they encourage donations to them to support the continued development of the software. This provides an incentive to continue their development of the software.

III.3.1.3. Software for purchase, support fee optional

Some software developers will offer their software for a fee and provide the option to purchase additional support for the product. Often, this software is of different types:

— A community edition, which is free to download and use but has often limited ability compared to the purchasable editions.
— A small edition that is often for small businesses or some home users. This often includes some additional functionality that is not available in the community edition.
— An enterprise edition that is for large businesses. This often includes all functionality, no limitations and the highest quality support.

III.3.2. The cost of free

The health care software total costs of ownership (TCO) calculations are difficult at best. Often, there are no original purchasing costs and no licence fee costs that will, in most cases, reduce the capital needs for new projects or the extension of existing ones. Maintenance costs can be similar or higher compared to using proprietary software.

The buyers of solutions that use open source software mixed with proprietary solutions adapted to their unique needs should be aware of the lock-in risks involved. That said, purchase of any health care information system carries a considerable lock-in factor as the effort and complexity in moving to another system can be considerable.

III.3.3. Sustainability

A key question that must be answered before using open source software is, who will maintain it and who will improve it? All software has defects, and when defects are discovered they may need to be fixed. No organization's requirements are static and, as they evolve, deployed open source solutions may need to be enhanced. Underlying hardware and operating systems become obsolete and must be replaced, and this may break or degrade the performance of old software, including open source software. A key theoretical benefit of open software is that as the source code is available, anyone can maintain it if they have the expertise. Many open source projects end, often prematurely, before the software is completed with respect to the original goals or before thorough testing, as the developers lose interest. Projects that have proved popular may be taken up by others who enhance or maintain the code. Often, however, the burden for further

development falls on the end users, or someone with the appropriate expertise with whom they contract.

Another critical factor that is a source of cost is the need for testing and validation. Commercially marketed medical devices that include software are subject to strict regulatory scrutiny of quality, safety and efficacy. Free and open source software that is deployed by the end user is not generally subject to such scrutiny, and the amount of testing and validation against requirements that has been performed is often modest or non-existent. The burden therefore falls on the end user to assure that the software is sufficient for their intended use. Further, free and open source software is often not accompanied by material for regression testing, which assures that when changes are made, the code remains unbroken. This complicates and adds to the cost of local maintenance and enhancement.

III.4. OPEN SOURCE POLICES TO CREATE KNOWLEDGE CLUSTERS

The use of open source software creates opportunities for local development tailored to meet the existing needs and requirements on a continuous basis. This local development may be in the form of health care providers, educational and private health care service entities and others working together in resolving tasks that would be beyond their single capabilities without having cross-disciplinary cooperation of some kind. There is on-line access to a wealth of information in addition to collaborators (who usually respond to support questions without charge) on a wide variety of subjects.

The open source world opens opportunities for health care technology companies to start small by offering service and support to existing solutions and later moving into customized solutions based on existing open source codes and standards.

III.5. OPEN SOURCE IN MEDICAL IMAGING

Open source software is widely used in medical imaging, and currently, free and/or open source software can support all necessary functionality within a digital imaging department. At present, there is a lot of medical imaging software to choose from, but software maturity varies dramatically. There are relatively advanced open source image viewers available that can be used as stand-alone workstations or PACS client software. There are also many open source PACS servers available. Some suppliers bundle a complete solution that includes the RIS, PACS, and workstation software, etc., either written by a single source or

assembled from different sources, but the maturity and reliability of the individual components may vary.

A good resource for medical imaging software (both open source and proprietary) is the I Do Imaging web site [23], and a simple web search will uncover a multitude of sources and discussions about such software.

III.5.1. Medical IT knowledge requirements

The extra flexibility that comes with full access to the source code allows for everything from bug fixing to a major undertaking in adapting the software to the specified requirements by writing new components. It requires a high level of medical IT knowledge to be able to choose, install and maintain medical imaging systems that are fully based on open source software or use open source software components.

III.5.2. Legalities

Open source medical imaging solutions (such as RIS/PACS software) may not fulfil local medico-legal certification requirements such as US FDA approval and CE marking. Disclaimers on the software web page may further exacerbate non-compliance to international or local legal requirements. In most jurisdictions, the regulators exercise control over what is marketed to a greater extent than how it is actually used. For example, in the USA, the FDA regulates the marketing of medical devices, but not the practice of medicine (except for mammography). In other countries, the use of unapproved devices may be illegal.

It is possible for an open source software solution to gain regulatory approval, but the business incentive for doing so may be absent, and the regulatory requirements for tracking the use of the software (for recalls and safety notifications), is difficult, if not impossible, to satisfy using an open source distribution model that does not involve registration of the users.

Approval by authorities and third parties may be required for use. For example, accreditation may be a requirement for payment, and accreditation bodies or payers themselves may not be willing to sanction the use of devices or software that has not been approved by the regulatory authorities.

Many free and open source software applications have licences that disclaim any liability for harm arising out of their use, or indeed disclaim fitness for any particular purpose. Whether these disclaimers have legal validity in the jurisdiction in which the software is used may be questioned, but the burden on the user of the software for any harm caused may be significantly greater than by the use of a commercial source of software, in which case product liability

for harm may apply. Even in the absence of an adverse event, this factor may influence the insurance that is available to the end user.

Appendix IV

RADIOGRAPHIC QUALITY ASSURANCE PROTOCOLS

A general review of performance testing of diagnostic radiology equipment can be found at the IAEA Human Health Campus web site:

http://nucleus.iaea.org/HHW/MedicalPhysics/DiagnosticRadiology/PerformanceTesting/index.html

A brief discussion of some quality assurance protocols along with key references and given below for the areas of visual display monitors, CR and DR units, CT units and digital mammography units.

IV.1. VISUAL DISPLAY MONITORS

The most comprehensive treatment of this subject is found in the AAPM report below:

AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE, Task Group 18, Imaging Informatics Subcommittee, Assessment of display performance for medical imaging systems, AAPM On-line Report 03, AAPM, College Park (2005),
http://www.aapm.org/pubs/reports/OR_03.pdf
Supplemental files available at
http://www.aapm.org/pubs/reports/OR_03_Supplemental/

Other good sources of information include:

ROYAL COLLEGE OF RADIOLOGISTS, Picture archiving and communication systems (PACS) and quality assurance Rep. BFCR(08)8 (2008)
http://www.rcr.ac.uk/docs/radiology/pdf/IT_guidance_QAApr08.pdf
Also: http://www.pacsgroup.org.uk

LEUVENS UNIVERSITAIR CENTRUM VOOR MEDISCHE FYSICA IN DE RADIOLOGIE, MoniQA, Monitor Quality Assurance,
http://www.kuleuven.be/radiology/lucmfr/moniqa/

AMERICAN COLLEGE OF RADIOLOGY (ACR) — AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE (AAPM) — SOCIETY

OF IMAGING INFORMATICS IN MEDICINE (SIIM), Technical Standard for Electronic Practice of Medical Imaging. Reston, VA, USA (2012), http://www.acr.org/~/media/ACR/Documents/PGTS/standards/ElectronicPracticeMedImg.pdf

DICOM STANDARD, Digital Imaging and Communications in Medicine (DICOM), http://medical.nema.org

INTERNATIONAL ELECTROTECHNICAL COMMISSION, Evaluation and Routine Testing in Medical Imaging Departments — Part 2–5: Constancy Tests — Image Display Devices, IEC-61223-2-5, IEC, Geneva (1994).

IV.2. DR AND CR EQUIPMENT

Protocols for this area from the UK group KCARE include performance tests for both CR and DR units. These tests are further categorized as acceptance and commissioning tests and also as routine quality control tests. These test protocols include the use of specific phantoms that require purchase. Other appropriate test phantoms could be used if needed.

KCARE, Protocols, (2005), http://www.kcare.co.uk/content.php?page=protocols.htm&folder=Education

Other protocols available and freely downloadable include:

AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE, Acceptance Testing and Quality Control of Photostimulable Storage Phosphor Imaging Systems, AAPM Rep. 93, New York (2006), http://www.aapm.org/pubs/reports/RPT_93.pdf

AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE, An Exposure Indicator for Digital Radiography, AAPM Rep. 116, New York (2009), http://www.aapm.org/pubs/reports/rpt_116.pdf

There are other tests from national or international bodies that are not freely available and include DIN 6868-58 (2001) and 6868-13 (2002) and also IEC 62220-01 (2003), Method for determining DQE of digital systems.

IV.3. COMPUTED TOMOGRAPHY

INTERNATIONAL ATOMIC ENERGY AGENCY, Quality Assurance Programme for Computed Tomography: Diagnostic and Therapy Applications, IAEA Human Health Series No. 19, IAEA, Vienna (2012).

IV.4. DIGITAL MAMMOGRAPHY

INTERNATIONAL ATOMIC ENERGY AGENCY, Quality Assurance Programme for Digital Mammography, IAEA Human Health Series No. 17, IAEA, Vienna (2011).

EUROPEAN COMMISSION, European Guideline for Quality Assurance in Mammography Screening, Office for Official Publications of the European Communities, Luxembourg (2006),
http://www.euref.org

Appendix V

CHECKLISTS AND TEMPLATES

V.1. SITE READINESS

— Has the radiation and safety planning been accepted by the radiation protection authorities?
— Does the site fulfil the requirements in the manufacturer's installation or site planning manuals?
— Is the equipment transport route from the transport vehicle to the examination room acceptable?
— Is an adequate power supply with necessary backup units available?
— Is adequate temperature control available?

V.2. REQUEST FOR PROPOSAL (RFP) PROCESS

— Has the necessary funding for the purchase been secured?
— Do the prepared documents and the planned process fulfil the local legal requirements?
— Have all the stakeholders accepted the documents and the planned purchasing process?
— Does the RFP have a payment plan where the last part of the purchase price is paid when the equipment has passed clinical and technical acceptance?

V.3. TRAINING

— Have the necessary resources for training been identified and secured?
— Is there a training schedule for all employees and referring physicians?

V.4. SUPPORT

— Has professional support for doctors, radiographers, physicists and local engineers been secured?

V.5. MAINTENANCE

— Is there a maintenance contract with secure funding, or an adequate in-house service arrangement that has support from the seller?
— Are equipment and procedures for regular quality assurance testing available?
— Has service been secured for all critical components (this includes support systems such as power and cooling)?

V.6. LIFE CYCLE MANAGEMENT

— Has a life cycle cost calculation been made?
— Has funding that matches the life cycle cost calculations been secured?

V.7. TECHNOLOGY SELECTION

— Does the selected technology match the clinical requirements?
— Do all items fulfil the local regulatory requirements?
— Have all the stakeholders accepted the chosen technology?

V.8. ELEMENTS IN A CONTRACT AND CHECKLIST

(a) Project mission

What expectations should be fulfilled? The management of the buyer should write the contract. If the mission fails, this text should facilitate direct communication between the management of both the buyer and the seller to resolve the failures. No technical jargon should be permitted under this heading.

(b) Subject of the contract

The deliverables of the contract: typically, the types and volume of examinations to be carried out are a part of this section.

(c) Items to be delivered

This is a detailed numbered list of items to be delivered. It should be remembered to list all items, including non-tangible items such as training, software or warranties. The list should be as specific as possible.

(d) Applicable norms and standards

Reference should be made to important local and international norms and standards. The most important ones are electricity and radiation standards.

(e) Acceptance testing

An explanation of what will be tested and what results are expected. Mostly, the results should be within the published specifications of the equipment.

(f) Clinical evaluation

If a clinical evaluation is needed, the design of the evaluation should be specified.

(g) Acceptance conditions

This is a complete list of conditions that are to be fulfilled before the payment is finalized.

(h) Application training

A description of the number of people and from what professional groups are to be trained, their current level of training and the expected outcome of the training.

(i) Service training

If a third party engineers are to serve the equipment, the training requirements should be a part of the contract.

(j) Service and service support

A description of the kind of service that is expected, including what kind of support (phone, remote, on-site) will be provided. A reference should be made to a service contract as applicable.

(k) Spare parts delivery

How should spare parts be ordered? A parts order template should be attached to the agreement. Spare Parts Delivery method and delivery time should be specified.

Example: 'Critical parts ordered before noon local time will be shipped the same working day using the XYZ or other dependable courier service'.

(l) Updates of hardware and software

Continuous field modifications of hardware and software are necessary to maintain the safety and quality of the equipment. Bugs and safety issues are normally corrected free of charge for the lifetime of the equipment. The contract should state where to send the updates and how to follow up on the update implementation.

(m) Upgrades and renewal of hardware and software

During the lifetime of the equipment, the manufacturer may offer important functional upgrades. Installing the upgrades may have a significant impact on anything from improving image quality to extending the useful life of the equipment. The seller should be notified on a regular (annual) basis of all available upgrades for the purchased equipment.

(n) User documentation

This is the specification of the user documents and manuals to be delivered with the system.

(o) Service documentation

If in-house or third party service providers are to be responsible for all or part of the service, all service manual and regular document updates should be a part of the contract. The contract should also state how service requests and

service actions are to be documented and who is responsible for approving the outcome of service actions.

(p) Quality assurance

There should be a list of all quality assurance manuals, procedures, training and tools to be included in the contract.

(q) Warranty

The warranty terms should be clearly spelled out. Note that some non-repairable parts such as X ray tubes, DR detectors and image intensifiers often carry a pro rata warranty. Under this warranty, if an item fails before the end of the warranty period, it is replaced at a cost that depends on the age or the usage of the item at the time of failure. The replacement item is then covered by an identical new warranty. DR detectors may be covered by a 5 year pro rata warranty. The contract should state that the warranty be measured from the date the purchased system passes the acceptance testing.

(r) Equipment delivery and installation

The following should be stated: the delivery dates, the installation-site details with complete address, contacts with phone numbers, the escalation path on both seller and buyer sides. List the site preparation items that have to be completed before the installation can begin and the name of the person responsible for accepting the site pre-installation.

State the name of the person responsible for accepting the delivery by checking the delivered items against the 'items to be delivered' in the contract.

(s) Price

A breakdown of the prices, at least into the main assembly and the price for each option, is recommended. State if the price reference is FOB, CIF or at the installation site, and if taxes are included in the price.

(t) Transport insurance

The contract should specify that the equipment be fully covered by the seller's transport insurance until each part of the system has been brought to its final position and fixed according to the site planning schedule.

(u) Payment

Payment schedules and payment terms and conditions should be stated.

(v) Confidentiality

In some contracts there are items that should not be disclosed to any third party. Is the contract or parts of it confidential? If so, the confidentiality agreement should be specified in the contract. Confidentially can be complex to maintain. The agreement should be limited to items that are of importance to one or both parties.

(w) Force majeure

The contract should also include a description of the common understanding of the term 'force majeure' and the conditions that could evoke the force majeure clauses.

(x) Applicable law and arbitration

Owing to the added complexity of digital imaging, contract disputes become much more likely. Most contracting entities have a standard text for this purpose. Example:

> 'For the interpretation of the contract, the laws of [country name] shall apply. Any dispute out of and in connection with the contract shall be settled, if possible, by mutual agreement between the contracting parties. If no agreement is reached, disputes shall be finally settled by arbitration, with three arbitrators, one each appointed by the contracting parties, and the third by the chamber of arbitration in the country of arbitration. The country of arbitration shall be [country name] and the language of arbitration shall be [name of language].'

If at all possible, the jurisdiction should be in the buyer's country, as out of country jurisdiction may not leave the buyer any real chances to resolve disputes on equal terms with the seller. The buyer's second option should be a third country jurisdiction acceptable to both parties.

(y) Contract amendments

It should be stated that amendments may be added to the contract, such as to close or clarify the agreement. It is important to describe what will constitute a valid amendment. For example: 'All amendments and additions to the contract shall be valid only if made in writing and accepted by both contracting parties'.

(z) Contract effectiveness

What does it take for the contract to become effective? Usually a contract becomes effective when both parties sign the contract in a legal manner and a confirmation payment has been made.

(aa) Contract exhibits

Mostly, all communication between the seller and the buyer or their representatives should be attached as exhibits to the contract. This may not seem relevant but can prove extremely helpful in resolving disputes.

RFP and the chosen vendor's response/offer shall be an addendum and a part of the contract. The contract should also state the main project milestones as: revised installation and acceptance dates, together with the responsibilities for each component of the project including, but not limited to, items as: payments, site preparation, installation, training, acceptance testing and clinical acceptance. All relevant names and roles of the organizations/persons responsible for the execution of the contract shall be listed. Payment terms and payment milestones have to be clearly defined and listed in the contract.

V.9. CR SELECTION AND INSTALLATION

(a) CR selection and installation considerations

What is the maximum number of patients that could arrive at the same time?

What length of waiting times is acceptable?

How long can patients reasonably be kept waiting?

A CR reader may be used for 5 or more years. A steady increase in the number of examinations on the order of 5 to 10% might be expected. Local medical personnel may be able to predict the underlying future demand for medical imaging.

Rule of thumb: the CR reader should be capable of reading the expected 8 hour workload in 2 hours or fewer.

CR reader capacity varies from around 20 plates/h to around 80 plates/h.

(b) What are the allowed max and min temperatures in the CR room?
The operational limits for most equipment are in the range of 20–30°C. The temperature should be maintained towards the lower end of this range, but above dew point temperature at all times to prevent humidity saturation.
High temperatures can reduce the lifetime of the equipment and reduce the reliability.

(c) What are the max and min humidity values in the room?
Typical operational limits are between 20% and 80% relative humidity.
Too low humidity causes static electrical charge buildup. Static discharge can seriously damage or destroy electronic equipment.
Overly high humidity and consequent condensing can permanently damage the equipment.

(d) Is the room free from dust?
The CR room must be kept free of dust as possible at all times.
Abrasive dust particles have a very damaging effect on the plates and the CR mechanics. If dust levels are generally high (in dry areas), select CR models that have been designed for use in dusty environment.

(e) Is there a grounded electrical outlet in the CR room?
Proper grounding is an essential personal safety issue. If at all possible, there should be one unbroken cable from the CR unit to a wall outlet to ensure the integrity of the ground connection.
If the circuit to be used for the CR and its computer is also loaded by other equipment, an overload causing malfunction may occur. It is strongly recommended to run the CR and associated computers on a dedicated electrical circuit.

(f) What is the mains voltage?
Some CR systems need to be adjusted to the available mains voltage. Others adjust automatically to any voltage between 100V and 240V.

(g) What type is the electrical outlet (what standard)?
Many different types of incompatible electrical outlets are commonly encountered. To maintain acceptable security level a correct plug that matches the outlet must be used at all times.

(h) Is there enough space for the CR and the workstation?

The working conditions are important. To save time and money, the site planning and pre-installation preparation should be made in advance, not when the CR system has already arrived.

(i) In case of teleradiology, what is the bandwidth of the available connection? The file sizes are typically large (of the order of 10 MB). If images are to be transmitted to other sites then Internet connections are important. It should be recognized that most connections are asymmetrical, allowing much higher download than upload.

(j) What consumables are needed?
Typical consumables are: writable CDs for image distribution, paper for image printout and anti-static fluids for image plate cleaning.

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GLOSSARY

ACR-NEMA. Joint Committee of the American College of Radiology and the National Electrical Manufacturer's Association, which developed the DICOM standard for medical image communication.

American College of Radiology (ACR). Professional body in the USA which regulates practice and sets standards in radiology (www.acr.org).

angiography. Radiography of blood vessels. The blood vessels are made visible using either a radio-opaque contrast agent or alternatively a radiolucent agent (such as CO_2 gas). Imaging is often through the use of fluoroscopy.

application entity (AE). The name used in DICOM to represent a system that is the end point of DICOM communication. For instance, each X ray unit and workstation in a hospital would have a separate AE title. This needs to be locally unique and cannot exceed 16 characters.

application hosting. Software is owned and hosted on a computer separate from the user, and the latter pays a fee for use. (See also application service provider.)

application service provider. A business which provides a computer based service to customers over a network (also sometimes called software as a service). The application is based on the supplier's computer system and is typically accessed through a web browser using HTML or dedicated client server architecture.

anatomical programming (APR). Exposure factors which are preprogrammed in an X ray system. Factors are based on the anatomical region to be X rayed. APR is often used in conjunction with automatic exposure control (AEC).

asymmetric digital subscriber line (ADSL). Data communications technology which utilizes copper telephone lines. ADSL can generally only be distributed over a short distance (<4 km). One characteristic is that download speeds are typically higher than upload speeds. This is rarely a problem for a home user; it may, however, be a problem in a PACS environment.

asynchronous transfer mode (ATM). Data communications technology dating from the 1990s. Designed to carry voice, data and video signals. Now superseded to a considerable degree by IP based protocols.

automatic exposure control (AEC). Radiation detector in an X ray system which is positioned post patient. AEC will terminate exposure after a threshold signal has been reached, thus ensuring consistency in exposure (e.g. thick patient = low transmission = low dose rate, and hence long exposure; the converse is true for a thin patient).

bit. A binary digit (0 or 1).

brachytherapy. Radiotherapy using source of radiation within the patient's body, in or near the target organ.

byte (B). Eight bits. One character is typically equivalent to one byte. One typewritten page is approximately 2000 B (or 2 KB) of data. A CT image is about 0.5 MB in size, whereas a diagnostic quality chest X ray is about 10 MB. A small hospital would generate about 2000 GB (or 2 TB) of image data in a year.

charge coupled device (CCD). Imaging device based on the conversion of light to electric charge, in which the latter is moved from within the device to an area where it can be detected. CCD image sensors are widely used in professional, medical and scientific applications.

client server architecture. A network in which each computer within it is either a client or a server. Typically, the application process takes place on both client and server, with the presentation/display of data taking place on the client and the data storage and processing being performed on the server.

clinical context object workgroup (CCOW). A protocol which is part of the HL7 standard. It allows separate applications to synchronize in real time at the user interface. For the user, it means a single log in allowing access to multiple applications.

cloud computing. This is in essence the delivery of applications and data storage as a service over a network. The name is derived from the traditional abstract diagrams which depict the applications, storage, etc., as being enclosed in a cloud. The user typically accesses such services through a web browser.

computed aided detection and diagnosis (CAD and CADx). Software which uses complex algorithms to either detect or diagnose abnormalities in clinical images. The most widespread application is the detection of breast abnormalities in mammography.

computed radiography (CR). X ray imaging system where X ray detection is based on a phosphor plate in a cassette. X rays cause the material inside the phosphor plate to be excited and this excitation can be read out by scanning the plate with a laser. An advantage of CR is that the cassettes are similar to those used for film screen radiography, allowing a conventional X ray unit to be used for digital radiography.

computed tomography (CT) scanner. X ray system which acquires images from computer reconstruction of individual projections acquired with the X ray tube and detector rotating around the patient. CT offers superior contrast and 3-D images compared to conventional radiography, albeit at a higher radiation dose.

configuration. The adaptation of a computer system to a customer's preferences and environment. This is performed using the flexibility which is built into the software. Configuration of software is normally a standard part of a software installation process.

customization. The adaptation of a computer system to a customer's preferences. This is performed using custom designed modifications. These can be both costly to procure and maintain. Customization is typically only performed when configuration does not provide the functionality that the customer requires.

data compression. Mathematical algorithms which reduce the size of a data file. Compression can be lossless, where no original information is lost when reconstructing the original dataset, or lossy, where some of the original information is discarded. Lossless compression can typically reduce file sizes by a factor of three. This factor can be significantly higher during lossy compression.

data encryption. Mathematical algorithms which convert information which is readable into something which is unreadable to anyone except to those who possess special knowledge (often referred to as a key or cypher). Encryption is used to ensure the protection of sensitive data such as patient records and images. There are a wide range of standards of encryption with varying levels of security.

desktop virtualization. A computing concept where the local computer desktop environment is separated from the physical hardware using the local PC as a client with the main software located on a central server (which can support many such local computers). It allows multiple users to have individual desktop computers, with the main application on a different, central computer. Advantages are lower costs, ease of maintenance and reduction in energy use.

detective quantum efficiency (DQE). A value which describes the performance of an imaging detector. It takes into account the noise produced in the imaging system. DQE is a function of the spatial frequency content of the image. A high DQE detector will operate at a lower radiation dose compared to a low DQE system for the same image quality.

Digital Imaging and Communications in Medicine (DICOM) standard. A standard for the management of information (including images) in medical imaging. The DICOM standard is based on industry standards such as the TCP/IP network protocol. The DICOM standard has been developed for a wide range of imaging systems (www.dicom.nema.org).

digital versatile disk (DVD). DVD is an optical disk storage format designed for the storage of data, including audio, static images and video. There are several versions of DVD on the market, with DVD-R allowing a recording to be made once, whereas DVD-RW allows multiple read and write cycles. Storage capacity ranges from 1.5 to 17 GB.

directory. Often called file directory. It is the structure of the file system in which computer files are stored. The file directory is often called a folder and is typically depicted on the computer screen as a physical (card) folder.

electronic medical record (EMR). Electronic version of the traditional medical chart. Its advantages are that patient information is available instantaneously at multiple locations. Also sometimes called an electronic patient record (EPR).

external beam radiotherapy. Radiotherapy which uses a radiation source outside the body. An example is radiotherapy using linear accelerators.

flash drive. Portable solid state memory device which utilizes a USB connector as an input/output device. These devices are small and often removable. These devices are now available in anything from several MB to up to 256 GB. Data transfer rates range from 12 Mbit/s (USB 1.1), to 5 Gbit/s (USB 3). The read speed tends to be twice the write speed. They are limited by having a finite number of write/erase cycles and storage life (typically up to 10 years).

fluoroscopy. X ray imaging using a detector (typically an image intensifier) which allows for dynamic image sequences to be acquired.

greyscale standard display function. Part of the DICOM standards, which aims to standardize the display of medical images, ensuring consistency and optimal performance. Diagnostic workstations need to be regularly checked for compliance with the GSDF standard.

high availability (HA). A type of system design which is optimized for reliability and maximum availability. Employed for systems which are critical to patient care or business continuity.

hospital information system (HIS). Hospital information systems are comprehensive, integrated software systems designed to manage the medical, administrative, financial and legal aspects of a hospital. HIS systems would normally be a repository of patient demographics and often provide the patient data input for the RIS and PACSs.

HL7 standard. The most widely used standard for the exchange, integration, sharing and retrieval of electronic health information. The standard is continuously being developed and is now available in Version 3.0 (www.hl7.org).

information object definition (IOD). Part of the DICOM Standard. It is an abstract data model used to specify information about objects in the real world. An IOD provides communicating application entities (AE) with a common view of the information to be exchanged.

Integrating the Healthcare Enterprise (IHE). IHE is not a standard as such, but an initiative to utilize standards (such as DICOM and HL7) to support the integration of different clinical information systems through the use of well-defined profiles based on clinical workflow, content and display. Profiles have been developed for a range of clinical services including radiology. IHE was established through collaboration between the Radiological Society of North America (RSNA) and the Health Information and Management Systems Society (HIMSS). See also www.ihe.net.

integration profile. IHE definition of the actual profiles which achieve the integration between different systems through the coordinated implementation of standards (such as DICOM, HL7, W3C, etc.).

integrated services digital network (ISDN). A set of standards for the simultaneous transmission of voice, video and data over a traditional fixed line telephone network. With respect to data transmission, its use has been superseded by (A)DSL. It still has a place in standard telephone lines.

Internet Protocol (IP). IP is the principal protocol used for relaying data (also known as network packets) across a network using a set of software (Internet protocol suite). The IP protocol is responsible for routeing packets across network boundaries. Together with the transmission control protocol (TCP), it is the primary protocol that establishes the Internet.

life cycle. The entire process of the life and management of equipment, from the time when equipment is procured and installed to the time when it is removed and scrapped. It includes all activities relating to preventative and corrective maintenance and user support.

lightweight directory access protocol (LDAP). An application protocol which manages access and maintenance of distributed directory information over the Internet (using Internet protocol IP).

local area network (LAN). A local area network is a computer network that interconnects computers in a relatively small area. A typical defining property of a LAN is that control of the network is typically the same as that of the computers which connect to it. It also can have high data transfer rates.

magnetic resonance imaging (MRI). Imaging system which utilizes the properties of nuclear magnetic resonance to visualize internal structures of

the body. An MRI scanner utilizes a very large magnet. When a patient is placed inside the magnet, protons align with the magnetic field. Subsequent to a disturbance of this alignment, a signal can be measured which can then be used to reconstruct an image of the scanned area of the body. MRI is especially good at distinguishing between different soft tissues in the body, such as those found within the brain and in tumours. It also does not use ionizing radiation so there is no radiation dose from MRI.

magneto-optical drive. An optical disk drive which can write and rewrite data on a magneto-optical medium in the form of a 90 mm or 130 mm disk. Typical storage capacity is up to several GB. First introduced in 1985, they are now increasingly being replaced and are increasingly being replaced by conventional (all magnetic) storage drives.

mammography. Radiography of the breast often performed using a dedicated X ray system (mammography unit).

microwave transmission. The technology of transmitting information by the use of radio waves with frequencies of 1.0 gigahertz (GHz) to 30 GHz (wavelengths from 30 cm down to 1.0 cm). Microwave radio transmission is commonly used in point-to-point communication on the surface of the Earth. The communication is limited to line of sight, a distance between stations of 30 or 40 miles.

modality. Generic term which describes an image acquisition system such as an ultrasound scanner, CT scanner or MR Imager.

order entry. The process of the entry of instructions by a medical practitioner for the treatment of patients; often a computerized order entry, where the instructions are entered in a computer system.

positron emission tomography (PET). Cross-sectional imaging method which utilizes positron emitting radiopharmaceuticals as an imaging source. Typically used for staging of cancer. The most widely used radiopharmaceutical is ^{18}Fluoro-Deoxy-Glucose (FDG).

picture archiving and communications systems (PACS). Computer system for the storage and display and transmission of medical images. Often combined with a radiology information system (RIS) so that the system can display images as well as clinical information and final diagnosis.

quality assurance. A structured set of planned processes and procedures implemented in a quality system to ensure that quality requirements for a product or service are fulfilled. It consists of systematic measurement, comparison with standards, monitoring of processes and an associated feedback loop that promotes error prevention.

radiation dose. Energy deposited in a patient. Unit of absorbed dose is gray (Gy). Radiation risk is calculated from radiation dose multiplied by organ and radiation specific risk factors.

radiology information system (RIS). A radiology information system (RIS) is software used to acquire, store, manipulate, and distribute patient radiological data and imagery. The system generally consists of patient tracking and scheduling, result reporting and image tracking capabilities. RIS often interfaces with a HIS (hospital information systems) for patient demographic, and with a PACS for image data, and is critical to efficient workflow in radiology.

redundant array of independent disks (RAID). Storage technology which combines multiple hard disks into a logical unit. Data are distributed across the disks in a way which allows failure of one or more drives to occur without catastrophic data loss. RAID drives exist in different levels (0–6), depending on the level of redundancy required.

region of interest (ROI). Region of interest. Area in an image of interest to viewer and often outlined with computer graphical tools.

remote service. Provision of troubleshooting and service support through the use of computer networks. The service provider can be in a different part of the hospital or on the other side of the world. This is used frequently for IT based imaging systems such as CT and MR, but also for PACS.

request for proposal (RFP). Legal document issued by a buyer which requests interested vendors to place a bid. It would include the requirements, specifications and terms and conditions of the tender.

satellite transmission. Data transmission which utilizes a satellite to relay information from a transmitting ground station to another which may be thousands of miles away. Data transmission is achieved through microwave transmission (from 4 to 15 GHz) and the satellites would be typically in a geostationary orbit, i.e. fixed with respect to a point on earth. Satellite

transmission plays an important role in providing communication in very remote and rural locations which are otherwise difficult to access.

server. A dedicated computer (or software) dedicated to running applications for other computers (clients) on a network.

service class provider (SCP) and service class user (SCU). Part of the DICOM standard. Can be seen as a client server architecture, with the SCU (client) requesting a service from the SCP (server). In DICOM, an entity can act in several service classes as an SCU and an SCP, and often as both. In any interaction between two DICOM entities, one has to act as an SCP and the other as an SCU.

Service–object pair (SOP) class. Part of the DICOM standard. The standard defines any given capability (such as storage of an X ray image) as consisting of both an object (the image) and a service (storage). SOP Classes are identified by unique identifiers (defined in the standard) and a name. For instance, Computed Radiography Image Storage has the SOP Class Name: CR Image Storage and the unique identifier: 1.2.840.10008.5.1.4.1.1.1. SOP Classes range from Storage Service, Query/Retrieve Service, and many more.

service level agreement. A legal document that specifies the nature of the service and measurable parameters which determine the quality of this service. Signed between the service purchaser (clinical user or hospital) and service provider.

simple object access protocol (SOAP). A protocol designed to allow for the exchange of structured information in the implementation of web services in computer networks. It relies on XML, as well as protocols such as HTTP and others.

single photon emission computed tomography (SPECT). Cross-sectional Imaging method which utilizes gamma ray emission for a radiopharmaceutical which has been injected into the patient. SPECT has wide applications and is typically used as a functional imaging method to complement anatomical imaging methods such as computed tomography (CT) and magnetic resonance imaging (MRI).

smartphone. A mobile telephone which has at its core a small computer. A smartphone has significantly more computing ability and connectivity compared to a normal mobile telephone. Smartphones typically have features such as Wi-Fi access, touch screens and the ability to run multiple software applications, over and above the ability to make telephone calls over the mobile phone network.

software as a service (SaaS). See Application Service Provider.

structured report. Part of the DICOM Standard. A standard and structured method to exchange data produced in the course of image acquisition, post-processing and reporting. Structured reports use DICOM data elements and DICOM network services such as storage, query/retrieve etc.

telemedicine. The use of telecommunication and IT to deliver medical care at a distance. Often classified by medical discipline, e.g. telepathology, teleradiology etc. It requires at a minimum three components: a transmitting station, a network and a receiving station.

transmission control protocol (TCP). TCP is one of the two core protocols that define the Internet (the other is Internet Protocol, IP). TCP is the application which breaks up a large data file into small pieces ('packets') which are then passed on to the IP application for transmission. TCP detects signal degradation such as packet loss or out of sequence delivery and corrects for this. Together with the IP, it is the primary protocol that establishes the Internet.

Transfer Syntax. Part of the DICOM Standard. It is the language used in DICOM which describes the DICOM File Format and network transfer methods. It allows Application Entities to negotiate common encoding techniques which they both support, thus allowing transfer of data.

turnkey solution. Within the context of the purchase of an imaging system, this is a solution where the equipment vendor is also responsible for building and associated installation costs.

value length. DICOM term which describes length of a data element (note: length is always an even number).

value representation. Method of coding data elements within DICOM. The DICOM Standard defines a wide variety of Value Representations.

virtual private network. A virtual private network is technology which uses the Internet or another intermediate network to connect isolated computers or computer networks to one another. A VPN provides security similar to that available on a local area network. For example, individual radiologists can connect from their homes to a PACS network in their hospital using a VPN.

web browser. Software application which allows for the retrieval, display and transfer of information on the World Wide Web. Examples of the most widely used web browsers are Internet Explorer, Mozilla Firefox, Google Chrome and Apple Safari. Web browsers typically rely on HTTP for data communication.

web services. Software designed to support machine to machine communication and interaction over the Internet or another network.

wireless network (Wi-Fi). Computer network (typically LAN) where the individual computers are linked to each other and to the Internet through the use of small radiofrequency transmitter/receivers operating between 2–5 GHz. The main standard for Wi-Fi are various versions of IEEE802.11 Versions a–n; with increasing transmission speeds (bandwidth), now up to over 100 Mbit/sec, with Gbit/s probably available in the near future.

worklist. Part of the DICOM Standard. It relates to the management of tasks on an imaging system (modality) where a list is created of the patients to be examined or diagnosed. Typically, worklists are created by the RIS for the individual modality and by the RIS/PACS for the radiologist's workstation. Effective worklist management is essential for the efficient operation of a radiology department.

workstation. A computer designed for the diagnosis and display of medical imaging data. It is characterized by high performance graphics display, large internal memory and high computing performance. Such computers are considerably more expensive than conventional PCs. An example of a standard for diagnostic workstations can be found in the ACR Technical Standard for Digital Imaging Data Management[1].

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[1] SOCIETY FOR IMAGING INFORMATICS IN MEDICINE, ACR Technical Standard for Digital Imaging Data Management (2012), http://www.siim.org/practice-guidelines-technical-standards

World Wide Web. The system of interlinked documents (typically based on Hypertext Markup Language), which can be accessed through the Internet and viewed with a web browser.

XDS. Cross-Enterprise Document Sharing; XDS-I (XDS-Imaging) is the IHE profile which provides for a central document registry that keeps track of file metadata (including metadata for image files).

ebXML. Electronic Business using Extensible Markup Language. A variant of the XML based standard that enables the global use of business information in an interoperable, secure and consistent manner by all communicating entities.

LIST OF ABBREVIATIONS

3-D	three dimensional
3G/4G	3rd respectively 4th Generation of mobile telecommunications technologies
ACR	American College of Radiology (www.acr.org)
ADSL	asymmetric digital subscriber line
AE	application entities
ASP	application service providers
ATM	asynchronous transfer mode
BIR	basic image review
CAD	computer assisted detection
CADx	computer aided diagnosis
CAT5e	twisted pair cable designed for carrying signals such as Ethernet
CCD	charge coupled device
CCFL	cold cathode fluorescent light
CCOW	clinical context object workgroup
CD	compact disk
CDA	clinical document architecture
CPI	consistent presentation of images
CPOE	computerized physician order entry
CR	computed radiography
CRT	cathode ray tube
CT	computed tomography
DAS	direct attached storage
DICOM	Digital Imaging and Communication in Medicine (www.medical.nema.org)
DICOMDIR	DICOM directory
DICONDE	Digital Imaging and Communication for Non-destructive Evaluation
DICOS	Digital Imaging and Communication in Security
DQE	detective quantum efficiency
DR	digital radiography
DSL	distributed subscriber line
DSS/OF	department system scheduler/order filler
DVD	digital versatile (or video) disk
DX	digital X ray
EMR	electronic medical record
FAT	file allocation table
FC	fibre channel

FDA	Food and Drug Administration (USA) (www.fda.gov)
GSDF	greyscale standard display function
HA	High availability
HIMSS	Health care Information and Management Systems Society (www.himss.org)
HIS	hospital information system
HL7	Health Level Seven (www.hl7.org; organization dedicated to the health care informatics interoperability)
HSM	hierarchical storage management
HTTP	hypertext transfer protocol
HU	Hounsfield units
ID	image display
IEC	International Electrotechnical Commission (www.iec.org)
IEEE	Institute of Electrical and Electronics Engineers (www.ieee.org)
IHE	Integrating the Healthcare Enterprise (www.ihe.net)
IM/IA	image manager/image archive
IOD	information object definitions
IRWF	import reconciliation workflow
ISDN	integrated services digital network
IT	information technology
JBOD	just a bunch of disks
JND	just noticeable differences
JPEG	joint photographic experts group (www.jpeg.org)
kVp	peak tube voltage
LAN	local area network
LASER	light amplification by stimulated emission of radiation
LCD	liquid crystal display
LDAP	lightweight directory access protocol
LED	light emitting diode
MAMMO	mammography
mAs	current time product
Mbit/s	megabit per second (Data transmission speed of 1 million bits per second)
MITA	Medical Imaging Technology Alliance
MLLP	minimal lower level protocol
MOD	magneto-optical disk
MP	megapixels (million pixels)
MPEG	Motion Picture Expert Group (www.mpeg.org)
MPR	multiplanar reconstruction
MR	magnetic resonance

MRI	magnetic resonance imaging
MSH	message segment header
MTOM/XOP	message transmission optimization mechanism / XML-binary Optimized Packaging
NAS	network attached storage
NEMA	National Electrical Manufacturers Association (www.nema.org)
NGO	non-governmental organization
NM	nuclear medicine
NMR	nuclear magnetic resonance
OASIS	Organization for the Advancement of Structured Information Standards (www.oasis-open.org)
OE	order entry
ORM	order message
OS	operating system
PACS	picture archive and communications system
PC	personal computer
PDF	portable document format (www.adobe.com)
PDI	portable data for imaging
PET	positron emission tomography
PID	patient identification
PIX/PDQ	patient identity cross-reference / patient demographics query
PMBOK	Project Management Body of Knowledge (Project Management Standard) (http://www.pmi.org/PMBOK-Guide-and-Standards.aspx)
PRINCE2	Project Management In Controlled Environments 2, Project Management Standard (www.prince2.com)
QC	quality control
RAID	redundant arrays of independent (or inexpensive) disks
RAM	random access memory
RF	radiofrequency
RFP	request for proposal
RIS	radiology information system
RSNA	Radiological Society of North America (www.rsna.org)
RT	radiotherapy
SAN	storage area networks
SATA	serial advanced technology attachment
SCP	service class provider
SCSI	small computer system interface
SCU	service class user
SMS	short message service

SMPTE	Society of Motion Picture and Television Engineers (often refers to test image used to assess visual display units)
SOAP	simple open access protocol
SOP	service–object pair
SPECT	single photon emission computed tomography
SQL	structured query language
SQ VR	sequence value representation
SR	structured report
SSDL	secondary standards dosimetry laboratories
SWF	scheduled workflow
TCO	total cost of ownership
TCP/IP	transmission control program/Internet protocol
TG18	Report of American Association of Physicists in Medicine Task Group 18: Assessment of Display Performance for Medical Imaging Systems
TIFF	tagged image file format
UDF	universal disk format
UPS	uninterruptable power supplies
USB	universal serial bus
VL	value length
VPN	virtual private network
VR	value representation
WHO	World Health Organization (www.who.org)
WHO WHIS-RAD	WHO World Health Imaging System for Radiography
Wi-Fi	data transfer (including high speed Internet connection)
WiMAX	worldwide interoperability for microwave access
WS	web services
XDS	cross-enterprise document sharing
XML	extensible markup language

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