Application of the ILO International Classification of Radiographs of Pneumoconioses to Digital Chest Radiographic Images

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Standardizing file formats, security, and integration of digital chest image files for pneumoconiosis classification

Author: David A. Clunie, CTO, RadPharm, Inc.

Background, scope, and assumptions

This paper considers the classification of PA projection chest radiographs for the purpose of identification and scoring of pneumoconiosis, by trained and certified human readers (NIOSH B readers), using radiographic images acquired, distributed, and displayed in digital form. Images digitized from traditional film-screen radiographs will not be considered, except with respect to the provision of reference images.

It is expected that the B readers are not necessarily affiliated with or credentialed by the acquisition site, and hence may not be providing direct patient care but rather independent review. This means that they may need to use their own local reading equipment, manufactured by a different vendor than the equipment used for acquisition. Further, the readers may or may not have duty of care to patient, which means that they may or may not have legitimate access to patient's identity (such as SSN).

Types of digital data

As discussed by others in these proceedings, there are essentially two families of imaging technology used for the acquisition of chest radiographs, Computed Radiography (CR), which uses a cassette-based workflow that involves a cassette "reader", and more recently Digital Radiography (DR), which uses a sensor that is in the x-ray path and directly connected to the processing and storage equipment. The DR sensor may be of the direct or indirect type, the latter using a phosphor in addition to the detector. The type of acquisition device makes little difference in the context of file format standardization, except to note that there are both historical factors as well as processing differences that result in difficulties in handling and displaying images with a comparable appearance.

File format

There is, for medical imaging, only one file “format” in widespread use. That is the Digital Imaging and Communications in Medicine, or DICOM, standard. Over the last 15 years, DICOM has become ubiquitous, and is supported by all modern devices sold in all countries. DICOM is a global standard. The committee that manages the standard is an international one, and recently the International Standards Organization has adopted DICOM, as ISO 12052. DICOM is the only non-proprietary inter-vendor standard in use between acquisition devices (modalities) and Picture Archiving and Communications Systems (PACS) and display workstations.

A format like DICOM is required for medical imaging, rather than consumer formats like TIFF and JPEG. There is a need to encode images with greater than an 8 bit depth, to preserve the full dynamic range of the types of sensors current utilized in acquisition devices. There is also a need to standardize and encode additional information in the image header, including patient identification and demographics, management information such as the date and time, as well as descriptors of radiograph acquisition techniques, such as kVP and exposure.

However, the DICOM standard defines many different capabilities for different applications, and also is evolving, adding new features to support new technologies. It is therefore important to define which “flavor” of DICOM format is used for the storage of digital chest radiographs for classification. In DICOM, each service is linked to a storage object and referred to as a service-object pair (SOP) class.

For projection radiographs there are two choices, the “old” CR SOP class, and the “new” DX SOP class. The CR SOP class was present in the first published DICOM standard in 1993. It was designed specifically for Computed Radiography and predated the development of direct digital acquisition technology. It is very loosely constrained in terms of which attributes are required or optional and does not define a consistent grayscale space. This makes it difficult to assure that images are displayed with a similar appearance on devices provided by different vendors. The more recent DX SOP class was added to DICOM in 1998 in order to support all forms of projection radiography, whether acquired using CR technology or DX technology. DICOM took the opportunity to incorporate the lessons learned

from half a decade of experience with the CR SOP class and defined a more robust and consistent object. To reiterate, the DX SOP class supports encoding of images regardless of the acquisition technology, and specifically was intended to replace the “old” CR SOP class for both CR and DX applications.

Unlike the CR SOP class, the DX SOP class clearly distinguishes two types of images, depending on the phase of processing:

- For Processing
- For Presentation

For Processing images are those that require further processing before they are suitable for viewing by a human, whereas *For Presentation* are those that are ready to view. The reason to make the distinction is to ensure that in a multi-vendor environment that there will be no confusion about which images a workstation should make available for display, and no ambiguity about which device is responsible for performing the processing. Furthermore, DICOM specifies that all devices are required to support *For Presentation* images, and that *For Processing* images are optional. This requirement is to prevent the possibility that one device produces only *For Processing* images and the other displays only *For Presentation* images, and hence are incompatible.

The DX SOP class, like all “modern” DICOM image objects, also defines a standard grayscale output space for *For Presentation* images, in order to achieve consistency of appearance regardless of the display device. This is achieved by specifying an output space in “P-Values”, which have a defined meaning for a display device that is calibrated according to the DICOM PS 3.15 Grayscale Standard Display Function (GSDF). Note that the goal is only to assure that a single image will have consistent perceived contrast on different display devices. It is not to make different images appear consistent with each other. Nor does GSDF compliance necessarily result in a “better” displayed image than another choice of display function.

The DX SOP class also makes mandatory many attributes that were optional in the CR SOP class, provides standard codes for attributes that were

previously text strings, to ensure that there will be sufficient information about such things as orientation and laterality to allow the images to be displayed correctly. The overall design objective of the new object was to enable all DX *For Presentation* images to be reliably and consistently displayed on any vendor's equipment. By contrast, the CR SOP class images' consistency depends on the type of image configured at acquisition. In particular images may need further "processing" at time of display, but there is no standard way to convey whether or not this is the case.

Having the ability to further process an image whilst it is displayed is a desirable feature. At a single site, it is a nice feature to have in the PACS if one has the same PACS vendor as the CR or DX vendor. However, one cannot be sure of the presence of processing capability when the images are sent elsewhere to be read. This is why DICOM established the concept of *For Presentation* images as a mandatory baseline, with *For Processing* images as a desirable option. Theoretically, a "standard" could describe a "raw" space in which *For Processing* images could be encoded, after vendor and detector specific corrections had been performed. Subsequently, "standard" processing methods could be applied to the raw image, regardless of acquisition vendor. However, for the time being this remains an area for further research.

Accordingly, in order to achieve interoperability with the current state of the art, it is essential to insist that as a minimum "processed" images are sent, whether they be DX SOP class *For Presentation* images, or CR SOP class images that have been processed appropriately. This requires an *a priori* choice of processing algorithm and parameters, and it may be desirable for NIOSH to specify these in advance for each manufacturer and system, to achieve consistency of appearance. In reality, one must consider that it may be difficult to influence the acquisition sites to configure their systems to use a particular processing choice, particularly if they are using the system for other work.

DICOM – more than a file format

The DICOM standard also defines many services, including protocols for transferring images and objects across both local networks and the Internet,

services for performing queries and retrieving lists of patients and studies, for supplying work lists, and for printing to film. Further, DICOM standardizes the use of interchange media, including the transfer of images using CD, DVD and USB. This allows for the establishment of a so-called “sneaker net”, which allows the transport or mailing of images. The purpose of these services is to allow automation of interoperability, and to avoid, for example, manual loading or dragging and dropping of image “files”. The relevant DICOM services for workflow and image transfer need to be considered in the context of classification of chest images for pneumoconiosis.

First, the radiology facility acquires digital images. From that point, if the site has a PACS, a DICOM transfer to PACS will occur; if there is no PACS, then the modality will burn the image files to a DICOM-compatible CD. If the images are to be read locally, then they will either be displayed on a workstation built-in to the PACS, or on a 3rd party DICOM workstation attached to the PACS or the modality.

However, if the images are to be sent to an off-site B reader and classified elsewhere, they need to be exported from the modality or PACS, which can be done by:

- burning them to a DICOM-compatible CD,
- sending them via a network to the remote reading site, or
- making then available over a network for remote viewing

Any of these possibilities are feasible, but as a matter of expedience, in the absence of a secure network infrastructure, the use of DICOM-compatible CDs may be most practical.

Software compatibility issues

Standards such as DICOM are required to achieved interoperability, but are not entirely sufficient. There remains the potential for incompatibility between acquisition, transfer and display software, arising from areas not addressed by the standard, ambiguities in the standard, optional features of

the standard that a vendor has chosen to not implement, and issues arising from software quality issues (bugs).

For an acquisition device, incompatibilities can arise because there is a choice of different SOP classes (CR, DX) as well as the difference between *For Processing* and *For Presentation* image types, as already discussed. Because the DICOM CR SOP class does not require use of GSDF P-values, there is also the problem of inconsistent grayscale contrast. For both CR and DX SOP classes, there may be problems caused by incorrect encoding of look-up tables applied to stored image pixels to derive display values; adherence to the standard in this respect is not universal among vendors, and display software may need to account for this. Other configuration issues may arise as a consequence of image acquisition vendors' need to make their equipment highly configurable to work with the vagaries and limitations of a range of PACS, old and new, commercial and homegrown. Though the configuration may satisfy the local users, the configuration choices may have unintended and undesirable consequences when images are sent off site. Insistence upon compliance with the DX *For Presentation* SOP class mitigates this class of issues.

The mechanics of transferring images using the DICOM protocol on a local network is rarely an issue, is widely tested, and is essentially a pre-requisite for PACS to work at all. However, DICOM CD compatibility is not universally reliable; some vendors default to proprietary CD formats, some vendors write incompatible DICOM CDs, while the use of data compression may raise issues. There is renewed emphasis by the industry on CD compatibility testing, but problems can arise with equipment that remains in the field. As a practical matter, given the limited number of sites acquiring and sending digital radiographic images for pneumoconiosis screening and research, each site can be prequalified and an appropriate transfer mechanism and procedure established and tested.

CDs are often burned with Windows-compatible digital image viewing software, nominally capable of displaying the images on the CD. Problems may arise with these viewers for a number of reasons. The issues relate to PC hardware and operating system versions, software installation, display speed (if the viewer is run from CD), and display compatibility, especially if a

calibrated display is required. Security policy in place at the facility may impose restrictions, since executing code from outside local systems and networks creates a risk of propagating viruses, as well as a risk of interference with locally installed applications. There are also training and usability issues; readers may need to learn to use multiple different viewing software products, depending on the number of sites sending images. Furthermore, image viewing software is typically designed for review and not for primary interpretation and may prominently display disclaimers to that effect. Such software may have limited functionality and in particular lack full grayscale pipeline support, so the displayed images may not demonstrate the intended grayscale contrast.

Accordingly, it is strongly recommended that a single dedicated viewing software product is used, and that the execution of the CD-based viewer be suppressed, either with an appropriate registry setting or holding the shift key down whilst inserting the CD.

Display software requirements

The display software product that is selected needs a number of specific features to minimize compatibility problems. The product must support the different DICOM SOP classes, specifically both CR and DX. It must utilize images that are *For Presentation* and “ready to view”, not *For Processing* or raw. The product must implement a full grayscale pixel processing pipeline, in order to produce a consistent grayscale contrast appearance, which includes the correct application of “lookup tables” in the image header, as well as support a pair of GSDF calibrated displays to enable side-by-side display of the selected ILO standard image and the subject image. The software should provide methods for managing the various LUT problems that have been recognized when using acquisition devices provided by some vendors.

A base set of features is essential, providing the user with the ability to zoom, pan, and window the image. Additional features can be considered, such as enhancement and image processing, and the ability to handle unprocessed images.

Image contrast adjustment is a particularly important feature. Despite the broad exposure latitude of digital acquisition, a single default presentation of image contrast is usually not sufficient. The user will often need to adjust the image to better evaluate light and dark areas. Traditionally, linear window center and width controls are available, but these work poorly for projection radiographic images beyond a very small range of adjustment. Non-linear contrast adjustment using a sigmoid shaped curve (analogous to the H and D curve of film response) may achieve more satisfactory results. This can be achieved using lookup tables (LUT) or continuous functions. Though the details are beyond the scope of this presentation, DICOM supports all three mechanisms. It is important that the display software product that is selected support them all and allow user adjustments. Note also that the image (or saved presentation states that can be reapplied to the image) may contain multiple choices of presentation, and the display software product should provide these choices to the user.

Compression

Compression was mentioned as a potential software compatibility issue. DICOM does support a range of ISO standard compression schemes, should they be necessary. Both lossless (reversible) compression (using JPEG, JPEG-LS or JPEG 2000) and lossy (irreversible) compression (using JPEG or JPEG 2000) are supported. The typical size of digital radiographic images is such that compression is rarely necessary on CD, though compression may increase the speed of network image transfer. However, given the uncertain impact on detection and characterization of subtle lung disease, it is recommended that lossy compression be avoided for pneumoconiosis classification functions.

Reference images

During the performance of pneumoconiosis classifications, the ILO requires that the subject radiograph be compared side-by-side to the appropriate comparison images from the ILO standard reference set of chest images. With digital image acquisition and soft copy display, there is an obvious need for the ILO standard reference chest images to also be digitally displayable alongside the patient images. Use of a separate light box on which to display

reference hard copy films is impractical, since it degrades workflow and alters perception (by being too bright). There is therefore a need for a digital version of the reference sets, with comparable contrast and processing to digital acquisitions. The process of digitizing (previously copied) reference films may result in significant quality degradation and dramatically different contrast characteristics when compared with digitally-acquired images. Ideally, a new set of digitally-acquired (rather than digitized) reference films will become available. Even then, there remains the issue that different acquisition technology, vendor, and processing may alter the chest image appearance.

The ILO digital reference image set should be encoded as DICOM DX *For Presentation* SOP class, to maximize consistency of display on different workstations and to allow images to be stored within the PACS for comparison. Digital encoding also provides the opportunity to distribute the standard images at negligible cost on the Internet, and hence increase their availability to the public, for training and research.

Displaying the reference images requires them to be made available as either a reference set “built in” to the display software, or as a “pseudo-patient” with dummy identifiers, allowing them to be used with ordinary software. In general, however, neither existing PACS workstations nor off-the-shelf (OTS) 3rd party DICOM generic workstations have explicit mechanisms to display “reference” images. For safety reasons, many systems prevent the showing of multiple “patients” simultaneously.

A customized workstation may need to be developed, dedicated to the classification task performed by B readers. Such a workstation could perform a DICOM query to the PACS to retrieve a patient’s images, and/or read them from CD, and have the ILO standard reference images installed and available locally. There are sufficient customizable open source and commercial toolkits for DICOM support and image display available to make this a feasible option.

Display equipment

As discussed elsewhere in these proceedings, achieving digital display quality comparable to film typically requires dedicated high intensity grayscale display devices, currently provided by flat panel digital displays rather than CRTs. These can be expensive, so the number of displays should be carefully considered. Traditional PACS workstations use a pair of portrait three-megapixel (3MP) displays, side-by-side, with the intent of displaying a current and prior or PA and lateral chest image pair with one image filling the area of each display.

The current film-based ILO viewing guidelines require simultaneous display of two films, the subject plus a single reference, though three are recommended to allow the subject film to be hung between references. One can simulate such a comparison with two digital displays, particularly if the software allows the user to rapidly toggle between one reference and another on a single comparison display; this presupposes that the software can order the reference images by increasing profusion and size. Accordingly, two displays are recommended.

Given the cost, some B readers may opt to re-use their existing infrastructure, particularly if classifications are for patients “outside” their hospital or office. This is analogous to importing patients’ images for “consultation”, a common practice. Some PACS already have explicit support for importation and reconciliation of foreign identifiers (see, for example, the IHE Import Reconciliation Workflow (IRWF) profile). Alternatively, readers may be able to view images from a CD inserted locally. When not possible, whether by policy or technology limitations, one can install a separate computer but share the expensive high resolution grayscale PACS displays by using KVM (keyboard-video-monitor) switches; devices that can support 3MP displays are available.

Remote reading

Rather than sending the images to the reader, it is possible to read “remotely”. Images can be provided on a central server and accessed via a secure Internet connection. Typically, the display software is remotely accessed, managed and maintained, and the reader’s local machine provides Internet access and high quality monitors.

The mechanism of implementation varies and may involve the use of a browser applet or plug-in, or an installable local client (ActiveX or Java Web Start). Acceptable performance and a satisfactory user experience is largely a function of the speed of the connection. Additionally, the patient and reference images can be pre-loaded locally in anticipation of their being needed (e.g., by looking ahead at work list tasks). Lossy compression is sometimes used to accelerate responsiveness, but this is unlikely to be acceptable for pneumoconiosis classification applications.

In the future, remote reading could be enabled by NIOSH providing a central archive server and a remote access mechanism and supplying the same client software for all readers.

Cross-enterprise sharing

The problem of sharing patient related images and documents between loosely coupled organizations is not new. The Integrating the Healthcare Enterprise (IHE) effort initially focused on using existing standards (DICOM and HL7) to support workflow within an enterprise but is now expanding to cross-enterprise document sharing (XDS), including images (XDS-I), and is starting to address cross-enterprise user authentication (XUA) and patient identifier cross-referencing (PIX).

The National Cancer Institute (NCI) Cancer Biomedical Informatics Grid (caBIG) also provides a mechanism for secure access to shared resources & services, including support for DICOM images.

In the future, it may be feasible and routine for authorized B readers to obtain remote access to images stored at the acquisition site, using an extension of infrastructure in place for routine patient care.

Security and privacy

Films, digital images, reports and forms may contain individually identifiable health information (IIHI), which is “protected” (PHI) under the HIPAA Privacy Rule. Unauthorized access to IIHI or PHI is a bad thing. It is necessary to either protect or remove such information.

Digital data is at risk when in physical form, for example when exchanged on CD, in the same manner as such information on film and paper. On-line digital information is also at risk, both locally, to access by unauthorized staff, and remotely, to access by unauthorized individuals when in transit.

Protection of PHI in transit requires encryption on the network, for example by using SSL, as is used in electronic commerce on the Internet. Also required are authentication, such as by login with username and password, access control such as by configuring access rights that are constrained based on identity, and maintenance of an audit trail, a record of who saw and did what, when and where.

DICOM provides network security services built on top of existing security mechanisms, using virtual private networks (VPN) or SSL connections for privacy. The user identity can be conveyed in a DICOM connection. The PACS can constrain access and maintain an audit trail. There are also standard mechanisms defined for web-based access to DICOM images (WADO), which use normal browser security mechanisms, and can also use VPN and SSL support. In such cases, the web server handles authentication, access, and audit trails.

An alternative approach is to remove PHI in digital images before transfer; if the information isn't there, then it does not need to be protected. Whenever readers do not need the patient's true identity, one can replace the patient's name, SSN and other identifiers with pseudonymous numbers. The association of the pseudonym and true identity can be securely maintained centrally. This process is used in clinical trials, in which independent readers are "blinded" to a subject's identity, both to reduce bias and protect privacy.

In DICOM images, the identity is normally stored in the digital image file headers, not burned into the image pixels, which makes it relatively easy to automate such de-identification.

Integrating results with images

The DICOM standard addresses not only the encoding of images, but also image-related structured information, through the Structured Reporting (SR)

mechanism. DICOM SR allows for the storage of codes, text, measurements, coordinates, references to images, locations and outlines, in a hierarchical organization. The structure can be pre-defined by “templates” for specific applications. Examples of such templates in the standard include the basic radiology report, computer-aided detection (CAD) results for mammography and chest images, radiation dose reports, and measurements for echocardiography, obstetrics, and cardiovascular CT.

The DICOM SR approach shares the same header structure as images, and in particular uses the same patient, study and series model. DICOM SR is widely used by modalities to encode measurements. They are easy to store in, and retrieve from, the PACS. They convert easily into other forms, and can, for example, be transformed into HL7 CDA XML, or extracted and rendered as plain text or PDF. The contents can be searched and specific structures and codes extracted. SR can also be considered as a DICOM “form” and can reference images and locations within images by coordinates.

Potentially, DICOM SR templates could be defined for ILO classification data, and could encode both the NIOSH Roentgenographic Interpretation and Miner Identification forms. Such templates would include standard codes for each concept, a reference to the unique identifier (UID) of the image being read, and possibly references to prior images used for comparison. Additionally, one could save image “annotations”, including pointers to locations of representative abnormalities in the image. An SR can also be digitally signed, as can any images referenced, using a standard cryptographic public key-based mechanism.

Conclusion and recommendations

An entire infrastructure already exists to support the clinical use of digital projection radiographs, based on the use of the DICOM standard between modalities, PACS, and workstations, with networks and CDs. Many sites now have considerable experience with exporting and providing outside access to digital images, including *For Presentation* digital radiographs. Correct choice, or construction, of an appropriate image viewer should allow consistent display and reliable review of images, side-by-side with ILO standards or

equivalent reference images. Expensive displays already installed can easily be utilized.

If advantageous, the results of pneumoconiosis classifications can be stored as a DICOM Structured Report, and the DICOM organization can help with adding templates and codes as requested. Matters of security and privacy can and should be addressed through conventional means.

In terms of specific recommendations for the NIOSH B reader program, both CR and DX DICOM images should be permitted, due to the large installed base of devices and the continuing availability of equipment that does not support the DX object. Processed (*For Presentation*) images should be required, to avoid the B reader being dependent on proprietary processing in display workstations. However, it is desirable to also obtain unprocessed (*For Processing*) images if possible, to allow for future research into CAD, as well as to permit development of standardized mechanisms for image processing.

Display workstations that support B readers should be qualified and certified; they must be fully compatible with test images from different vendors and software, must support all variations of encoding and grayscale pipeline, and must be able to display reference images side-by-side with the patient's image.

Images should be de-identified before sending for reading if possible, to minimize the risk of leakage of IIHI/PHI.

Ideally a digital, rather than digitized film, reference set should be created and released, which is comparable in contrast and resolution to CR and DX images.

Initially, it may be expedient to distribute images to B readers on DICOM CDs, but NIOSH should explore the creation of a managed distributed or centralized infra-structure, to allow for remote reading from a central PACS, or an XDS or caBIG network.

Workshop Overview

On March 12–13, 2008, the National Institute of Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) hosted a workshop to address issues for classifying digital chest radiographs for patients with pneumoconioses. The international group of scientists in attendance heard from representatives of the International Labour Organization (ILO), NIOSH, and academia. Expert presenters described current and future issues in digital radiography, especially as they relate to classification. The workshop participants broke into smaller groups to discuss (1) image acquisition, (2) image presentation, and (3) file interchange, and to develop recommendations for advancing digital classification for pneumoconioses.

Introductory Presentations

Perspectives for Revision of the ILO 2000 Classification of Radiographs

Igor A. Fedotov M.D., Ph.D.
Co-ordinator, Occupational & Environmental Health
International Labour Office (ILO)
Geneva, Switzerland

Presentation topics

1. Conventional chest radiography
2. Digital radiography
3. Revision of the ILO 2000 Classification

Presentation topic I

Conventional chest radiography

Chest Radiography

- Impressive technical advances in diagnosis of lung diseases during the last 20 years
- CXR has been useful in screening and health surveillance, clinical care, diagnosis and evaluation of response to treatment
- Widely used in epidemiologic studies of occupational and environmental lung disorders
- CXR remains universally available tool
- Minor radiation exposure and inexpensive

Conventional chest radiograph

Advantages

- Simple to perform
- Cost effective
- Relatively specific in certain conditions

    - advanced silicosis, advanced coal worker's pneumoconiosis or advanced asbestosis
    - extensive and/or calcified pleural thickening
- Low radiation exposure: effective dose 0.03 mSv
- Standardized classification method – ILO Scheme

Chest radiograph vs pathologic findings

- Relatively good correlation between lung pathological findings and radiographic interpretation for dust-exposed workers with high profusion of small opacities
- Good correlation between the dust content in the lung and the profusion of small opacities in coal miners

Chest Radiography in Dust Exposed Workers

- Chest radiography remains the most common and widely used tool in screening and surveillance of dust exposed workers
- Dust-related pulmonary disorders may amount up to 30% of all work-related illnesses
- Chest radiograph may be an important sentinel for failure of dust control
- Chest radiograph is helpful in exposure response relationships

Limitations of Radiographic Imaging

- Imperfect tool, not diagnostic gold standard
- Airway disorders are not always seen
- Functional impairment does not always correlate with imaging
- Can not provide certainty about the etiology of observed findings due to limited lung response patterns

Medical screening and health surveillance

- Chest radiography remains most widely used radiological tool for screening of large populations

- Radiographs of good quality, classified with the ILO scheme, reported with consistency and accuracy, are the most important tool for medical screening and health surveillance of workers exposed to mineral dust

Presentation topic II

Digital radiography

Digital techniques for chest radiograph

- Conventional radiograph: film-screen system
- Digital techniques
    - Computed radiography: using imaging plate to store x-ray image, then a scanning device convert x-ray image to digital data
    - Digital radiography: flat-panel detector for converting x-ray to digital data

Advantages of digital radiography

Film-less imaging system

- produces better quality of images for diagnosis
- eliminates over- and under-exposure
- digital images can be manipulated to help with interpretation
- easy access to images, cheaper storage, less subject to loss
- use of PACS for telemedicine
- teleradiology for image transmission through network connections

Digital radiography – challenges

- High equipment cost, lower film/image cost
- Hardware & software should be standardized
- Trials needed to decide on comparability of films
- Digital standard images are necessary
- Use of CR/DR will soon become standard practice in many countries
- Replacement of CXR in diagnosis, medical screening and health surveillance

Medical Monitor QA Standard

	IEC 61223-2-5	DIN V 6868-57	EUREF	AAPM-TG18	JESRA
Testing	Constancy testing	Acceptance testing + Constancy testing (QS guideline)	Acceptance testing+ Constancy testing	Acceptance testing+ Constancy testing	Acceptance testing+ Constancy testing
Established	1994	February 2001	November 2003	April 2005	August 2005
Performer		Vendors	Medical physicists	Medical physicists	Manufacturer Or Hospital
Performer of Constancy testing/ Interval	None specified 3 months	Hospitals 1/3, 6 months	Medical physicists 6 months	Medical physicists 1/3, 12 months	Hospitals 1/3/, 12 months
Other Information	Will be new IEC by 2009	Enshrined into law Acceptance testing: in July 2002 Constancy testing: in December 2003	Digital mammography QA guideline	OR3	Based on AAPM and IEC

Difficulties when introducing digital x-ray for diagnosis and screening of pneumoconiosis

- Does the law provides for use of CXR or digital images (CR/DR?)
- Compensation for lung injury
- Availability of equipment for digital radiography
- Cost as compared with CXR
- ILO digital standard images are not yet available for comparisons with CR/DR subject films

Future scheme for medical screening of Pneumoconioses

- Using digital subject films with standard digital images of ILO Classification
    - CRT/LCD reading
    - PACS: telemedicine
- Using CT Classification of pneumoconioses as supplementary method
- Classification of radiographs will remain a major screening tool

Presentation topic III

- Revision of ILO 2000 Classification

ILO 2000 Classification

Uses of the Classification

- Epidemiological research
- Screening and surveillance of workers in dusty occupations
- Clinical purposes
- Promotes improved international comparison of data concerning the pneumoconioses

ILO 2000 Classification

Object

- To codify the radiological abnormalities of pn in a simple, reproducible manner

The Classification:

- does not define pathological entities
- does not take into account working capacity
- does not imply legal definitions of pn for compensation purposes
- does not set or imply a level at which compensation is payable

In: Journal of Thoracic Imaging, 17:179-188, 2002

“The ILO system has worked, is working and has substantially achieved the intended task. It continues to play a key role in research and epidemiology of occupational lung disease and in the compensation of exposed individuals. Improvements in or modifications to the system, especially the integration of new imaging technologies, could provide both young and established investigators many opportunities.”

ILO Classification

- Evidence from many different disciplines has demonstrated that the ILO profusion score correlates with occupational exposure, dust burden in

the lung, histologic fibtosis and, more recently, with physiologic impairment and mortality.
- The ILO classification has therefore been validated as a scientific tool
- In: Am. J. Ind. Med. 50:63-67, 2007

ILO Classification

- Intensively used and validated over the last 25 years
- The Classification continues to provide the unviversally recognized method to systematically record abnomalities on chest radiographs of individuals exposed to dusts
- Voluntarily used for compesation of individuals exposed to dusts although it was not designed for this purpose
- New technologies such as digital radiography will be driving its modification

ILO 2000 CLASSIFICATION

ILO 2000 Classification of Radiographs of Pneumoconioses

Universal tool to improve health surveillance, conduct epidemiological research and compare statistical data

Legal requirements – voluntary use for compensation claims

ILO Panel at 10th ICORD

“Proceed with the selection of new standard films taken with the use of digital techniques”

Revision of ILO Classification – I

- Using “hard” copies of current 22 CXR standards
- Producing CD with the same 22 standard images as digital “soft” copies to respond to users of modern digital techniques
- Producing a chapter with recommendations for use of digital standard images
- Creating new edition of 2008 Classification

Revision of ILO Classification – II

- Selecting new 22 “soft” standards from digitally acquired images
- Producing new “hard” copies from 22 standard digital images
- Revising a chapter with recommendations for use of digital standard images
- Creating next edition of 200X Classification

Future of ILO Classification

- Use of hard copies will be decreasing
- Use of soft (digital) copies will be increasing
- New 200X edition may create a «filmless» environment

ILO 2008 Classification

Draft text with Recommendations

- Meeting in South Africa, 2007
- NIOSH/ILO consultations, 2007
- Meeting of experts in Japan, 2007
- To be finalized by ILO Panel – USA, 2008

Digital standard images

- Tests by Canon experts in Japan, 2007
- CD is prepared in Germany, 2008

Revision of ILO Classification

Technical issues

- standardization of digital file formats for pneumoconiosis classification
- implications for image processing and display with different brands of equipment
- assuring image quality for classification of digital chest radiographs
- compensation level determined with different sets? (1/1 analogue may look like 1/0 digital)

Revision of ILO Classification

Technical issues

- Protocol for selection – countries
- Compatibility of candidate digital radiographs
- Digital format of CRs/DRs – DICOM 3?
- New 22 digital standards to be used with different equipment – consistency
- Prescription of different parameters for diagnosis and for viewing/teaching
- Issues that can transpire from NIOSH Workshop

Aknowledgement

With thanks to:

Dr Jack Parker (United States)
Dr Jacques Ameille (France)
Dr Kurt Hering (Germany)
Dr Narufumi Suganuma (Japan)

The NIOSH Perspective

Edward L. Petsonk, MD
Senior Medical Officer
Division of Respiratory Disease Studies
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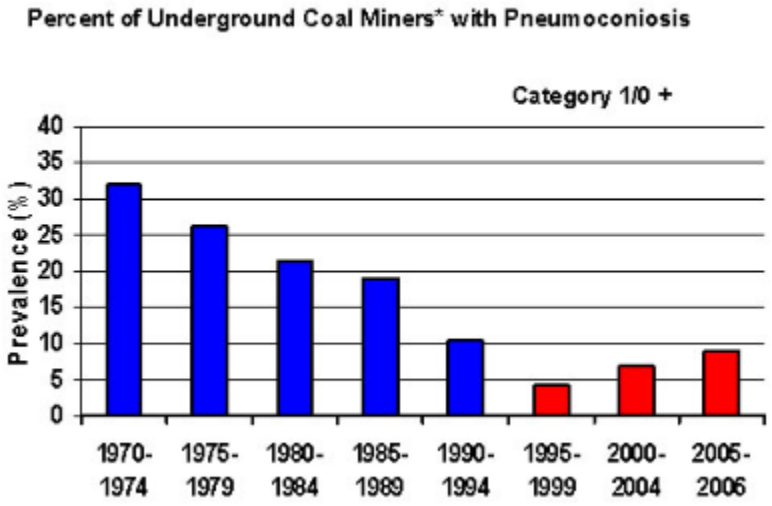
THIS IS AN IMPORTANT ISSUE.WE SINCERELY APPRECIATE YOUR TAKING THE TIME TO HELP.

The ILO Classification – Background

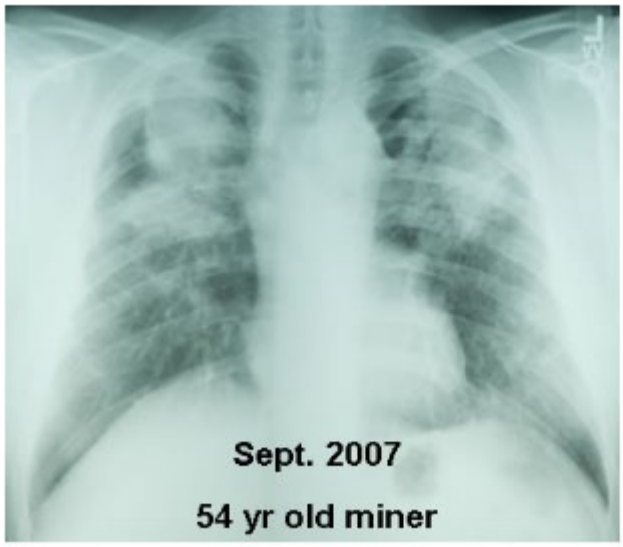
- "A means for describing and recording systematically the radiographic abnormalities in the chest provoked by the inhalation of dusts."
- International Conference on Silicosis, Johannesburg, 1930
  - Modifications/revisions 1950, 1959, 1970, 1980, 2002
- "Used internationally for epidemiological research, for screening and surveillance of those in dusty occupations, and for clinical purposes. May lead to better international comparability of data concerning the pneumoconioses."
- Object: "to codify radiographic abnormalities of the pneumoconioses in a simple, reproducible manner. Does not define pathological entities nor take into account working capacity. Does not imply legal definitions of pneumoconioses for compensation purposes."

The Challenge: ILO Classification of Digital Chest Radiographs

Why is there a need?



* Miners who worked at least 25 years and had a NIOSH x-ray



The Challenge: ILO Classification of Digital Chest Radiographs

- Why is there a need?
  - Digital imaging market penetration
  - Soon majority of facilities exclusively digital

The Challenge: ILO Classification Of Digital Chest Radiographs

- How to assure detailed and uniform images for classification?
  - Multiple hardware systems (DR, CR)
  - Software versions, compression algorithms
  - File formats, compatibilities
  - Display terminal: resolution, perception, image manipulation
  - Display of ILO Standard Radiograph images
- How best to merge science and practicality?
  - Adequate specification of procedures, software, and file formats
  - Objective evidence for equivalence with traditional approach
  - Commercially available systems (evolving technology)

The NIOSH Perspective

- Health Surveillance Programs
- Epidemiological and Clinical Research

- Compensation and Clinical Evaluations
- Coal Workers
- OSHA Regulations
- Private Industry
- Federal Benefits
- State Workers Compensation
- Tort Liability
- International Labor Organization
- National Institutes of Health

The outcome must be defensible – There will be someone who will not like it!

The NIOSH Perspective

- A science-based but practical specification for the acquisition and formation of digital chest radiographic images
    - Assure uniformity and integrity of digital images used for classification
    - Methods, equipment, procedures, and conditions that lead to images equivalent to traditional chest radiographs for reliably demonstrating the absence, presence, and extent of dust-related pulmonary abnormalities
    - Procedures and criteria to approve facilities
    - Practical and reliable performance criteria to assure continuing image quality

The NIOSH Perspective

- A science-based but practical specification for the classification of digital radiographs using the ILO system
    - Procedures, image processing, display hardware, file formats and storage, including software options
    - Comparison images (i.e., ILO standard radiograph images) for classification of digital images
    - Image manipulations permissible during classification

The NIOSH Perspective

- Local and disseminated systems for managing digital chest images
    - Interoperability
        - Data formats, file management
        - Software and hardware compatibility
    - Secure image transfers from x-ray facilities and to readers
    - Assure confidentiality, reliable file identification
    - Durable data archives

The NIOSH Perspective

- Capacity to examine and approve B Readers using digital chest radiographic images
    - Remote examination
    - Preservation of the integrity of the process
    - Equivalence of digital B reader examination with previous hard copy examination
        - Selection of digital examination images
        - Quality assurance and/or calibration functions

The NIOSH Perspective

- The integration of digital images into occupational practice must be done now.
- It requires the best information available and support from numerous partners.
- Thank you for agreeing to contributing your time, knowledge, and experience!

American College of Radiology Perspective

Daniel A. Henry, M.D., F.A.C.R
Chair
ACR Pneumoconiosis Committee

Objectives, organizational perspective

- To implement digital acquisition and display for local x-ray facilities
- To implement digital classification for readers who classify images

Stakeholder actions / challenges

- Facilitate the development of technical guidelines for the acquisition and display of digital chest images suitable for ILO classification
- Based on the above, transition established teaching methods of classification from an analog to digital format and environment

The Beginning

- Collaboration with National Institute of Occupational Safety and Health & ILO
- An Integrated Mission
    - Education
    - Technical development and support

ACR The Beginning

- 1969 – Federal Coal Mine Health & Safety Act
    - Active miners: CXR within 18 mos, 3yr, 5yr
    - Retired miners
    - Disability / compensation benefits
    - Length of exposure / radiographic findings
    - International Union Against Cancer/Cincinnati system (based on 1958 ILO system)
- NIOSH / US Public Health Service requests assistance
- 1970 – ACR Pneumoconiosis Task Force

ACR Education

- Meeting the Instructional Challenge
- A crash program was developed
- Weekend Symposia for attendee convenience
- 6 courses in the first year
- > 30 meetings since 1970
- 4,000-5,000 physician attendees

- Viewbox teaching method
- Test-Teach-Test sequence of instruction*
- Compels active participation in the learning process
- Incorporated into other ACR subspecialty teaching seminars
- Remains the backbone of the current ACR Symposia on the Pneumoconioses

*Felson B, Jacobson G, Pendergrass E, Bristol L, Linton O, Harrington R. Viewbox seminar: A new method for teaching roentgenology. Radiology 1975; 116:75-78.

- Symposia restricted to physicians
- 6 Technical Symposia for radiographers on chest radiographic technique
- Special seminars for administrative judges & lawyers interpreting the law for state and federal programs

- Development of Home Study Syllabi
    - Classification for Physicians / B-reader candidates
    - Chest technique for radiographers
- Exhibits detailing proper radiographic technique and the ILO classification system
- Cinematic production explaining the law and the obligation of physicians

- Support for and validation of the “B reader” examination
- Implementation of the step wedge for improving radiographic technique*
- Development of a teaching module on asbestos related diseases

*E. DALE TROUT and JOHN P. KELLEY A PHANTOM FOR THE EVALUATION OF TECHNIQUES AND EQUIPMENT USED FOR ROENTGENOGRAPHY OF THE CHEST Am. J. Roentgenol., Apr 1973; 117: 771 – 776.

- ACR Pneumoconiosis Task Force consulted with various federal agencies conducting related programs:
    - Food and Drug Administration
    - Department of Labor
    - Social Security Administration
    - National Cancer Institute

- Development of Technical Guidelines prepared for NIOSH
- Home Study Syllabus on Technique for Chest Radiography
- Technique for Chest Radiography for Pneumoconiosis

ACR

- Members of the Task Force have been or are members of ILO committees
- Participated in the development/revisions of ILO Guidelines 1971, 1980, & 2000
- ACR sponsored conferences in Washington, D.C. which subsequently led to the 1980 & 2000 Guidelines
- ACR instrumental in the production of the 1980 ILO Standard Radiographs & the subsequent quadrant standards
- Participated as consultants to NIOSH for the review of teaching materials including the transition to digital

- 1982-84: ACR-NEMA collaboration
- ACR members requested non-proprietary format for image production from digital sources (CT, NM, US)
- National Electrical Manufacturers Association
- ACR-NEMA Digital Communication Standard
- Digital Imaging and Communication in Medicine standard – DICOM

Technique for Chest Radiography for Pneumoconiosis

- Overview

- Equipment
- Technique guides
- Scatter control
- Quantum mottle
- Screen/film combinations
- Sensitometric monitoring
- Radiation protection

- ACR practice guidelines
    - Performance of Adult Chest Radiography (10/06)
    - Digital Radiography* (10/07)
- ACR Technical Standard for Electronic Practice of Medical Imaging (10/07)

*Developed collaboratively by American College of Radiology
American Association of Physicists in Medicine
Society for Imaging Informatics in Medicine

DICOM

- To promote communication of digital image information, regardless of manufacturer
- To facilitate the development and expansion of PACS that can interface with other systems of hospital information
- To allow the creation of information databases that can be accessed by a wide variety of devices distributed geographically

- Used by other specialties utilizing digital imaging such as cardiology, GI endoscopy, pathology, dentistry, & dermatology
- Consists of 13 layers or sections
- Ongoing evolution
- Critical to digital imaging and this transition

American College of Radiology "Dust to Digital"

- Collaboration with National Institute of Occupational Safety and Health
- An Integrated Mission
    - Education
    - Technical development and support

ACR: Dust to Digital

- Transition to digital “viewbox” seminars
- Maintain the individual or registrant oriented approach for instruction
- Test – Teach – Test, interactive model
- What type of digital display devices will be necessary?
- Emulate the test and practice environment

- The challenge for teaching
- Transition away from the viewbox
- Classroom of the future
- New logistical paradigm using digital media but maintaining the benefits of the viewbox seminar
- Converting analogue material

- New facility
- Site of future teaching seminars?
- Site of future b-reader testing?

- Image processing driving display market
- Industry has moved to color LCD monitors
- More versatile for cross sectional imaging and CR/DR
- Color monitors generally load images faster
- Cheaper
- Can we use color monitors for B-reading?
- Will we require a B/W monitor?

- Established models for image acquisition
- Reestablish the primacy of high quality standard procedures in acquiring images regardless of modality
- Integrate digital acquisition and display guidelines with basic elements of chest radiography
- Reinvent the 1984 monograph as “Technique for Digital Chest Radiography for Pneumoconiosis”

- Use past experience as template

- Transition the current ACR Pneumoconiosis Committee to a Task Force, once again
- Draw from ACR Digital Guidelines authors & collaborators and members of this workshop
- Expand the Task Force's role and composition from primarily education to a more integrated and supportive posture with NIOSH & ILO to assist in the "dust to digital" technical and educational transition
- Explore accreditation/ QA function

Main Topics

Manuscript Title	Manuscript PDF	Presentation PDF	Author
Standardizing file formats, security, and integration of digital chest image files for pneumoconiosis classification	Standardizing file formats, security, and integration of digital chest image files for pneumoconiosis classification [PDF – 56 KB]	Standardizing file formats, security, and integration of digital chest image files for pneumoconiosis classification [PDF – 3.3 MB]	David Clunie, MD
Image presentation: Implications of Processing and Display	Image presentation: Implications of Processing and Display [PDF – 2.1 MB]	Image presentation: Implications of Processing and Display [PDF – 6.4 MB]	Michael Flynn, PhD
Comparison of Digital Radiographs with Film-Screen Radiographs for Classification of Pneumoconiosis	Comparison of Digital Radiographs with Film-Screen Radiographs for Classification of Pneumoconiosis [PDF – 73 KB]	Comparison of Digital Radiographs with Film-Screen Radiographs for Classification of Pneumoconiosis [PDF – 97 KB]	Alfred Franzblau, MD
Acquisition of digital chest images for pneumoconiosis classification: Methods, procedures, and hardware	Acquisition of digital chest images for pneumoconiosis classification: Methods, procedures, and hardware [PDF – 345 KB]	Acquisition of digital chest images for pneumoconiosis classification: Methods, procedures, and hardware [PDF – 1.8 MB]	Ehsan Samei, PhD
Assuring image quality for classification of digital chest radiographs	Assuring image quality for classification of digital chest radiographs [PDF – 285 KB]	Assuring image quality for classification of digital chest radiographs [PDF – 3.2 MB]	Ehsan Samei, PhD
CR and FPD DR chest radiographic image parameters for the pneumoconioses: the Japanese approach and experience	CR and FPD DR chest radiographic image parameters for the pneumoconioses: the Japanese approach and experience [PDF – 192 KB]	CR and FPD DR chest radiographic image parameters for the pneumoconioses: the Japanese approach and experience [PDF – 2.1 MB]	Narufumi Suganuma, MD, PhD

Standardizing file formats, security, and integration of digital chest image files for pneumoconiosis classification

Author: David A. Clunie, CTO, RadPharm, Inc.

Background, scope, and assumptions

This paper considers the classification of PA projection chest radiographs for the purpose of identification and scoring of pneumoconiosis, by trained and certified human readers (NIOSH B readers), using radiographic images acquired, distributed, and displayed in digital form. Images digitized from traditional film-screen radiographs will not be considered, except with respect to the provision of reference images.

It is expected that the B readers are not necessarily affiliated with or credentialed by the acquisition site, and hence may not be providing direct patient care but rather independent review. This means that they may need to use their own local reading equipment, manufactured by a different vendor than the equipment used for acquisition. Further, the readers may or may not have duty of care to patient, which means that they may or may not have legitimate access to patient's identity (such as SSN).

Types of digital data

As discussed by others in these proceedings, there are essentially two families of imaging technology used for the acquisition of chest radiographs, Computed Radiography (CR), which uses a cassette-based workflow that involves a cassette "reader", and more recently Digital Radiography (DR), which uses a sensor that is in the x-ray path and directly connected to the processing and storage equipment. The DR sensor may be of the direct or indirect type, the latter using a phosphor in addition to the detector. The type of acquisition device makes little difference in the context of file format

standardization, except to note that there are both historical factors as well as processing differences that result in difficulties in handling and displaying images with a comparable appearance.

File format

There is, for medical imaging, only one file “format” in widespread use. That is the Digital Imaging and Communications in Medicine, or DICOM, standard. Over the last 15 years, DICOM has become ubiquitous, and is supported by all modern devices sold in all countries. DICOM is a global standard. The committee that manages the standard is an international one, and recently the International Standards Organization has adopted DICOM, as ISO 12052. DICOM is the only non-proprietary inter-vendor standard in use between acquisition devices (modalities) and Picture Archiving and Communications Systems (PACS) and display workstations.

A format like DICOM is required for medical imaging, rather than consumer formats like TIFF and JPEG. There is a need to encode images with greater than an 8 bit depth, to preserve the full dynamic range of the types of sensors current utilized in acquisition devices. There is also a need to standardize and encode additional information in the image header, including patient identification and demographics, management information such as the date and time, as well as descriptors of radiograph acquisition techniques, such as kVP and exposure.

However, the DICOM standard defines many different capabilities for different applications, and also is evolving, adding new features to support new technologies. It is therefore important to define which “flavor” of DICOM format is used for the storage of digital chest radiographs for classification. In DICOM, each service is linked to a storage object and referred to as a service-object pair (SOP) class.

For projection radiographs there are two choices, the “old” CR SOP class, and the “new” DX SOP class. The CR SOP class was present in the first published DICOM standard in 1993. It was designed specifically for Computed Radiography, and predated the development of direct digital acquisition technology. It is very loosely constrained in terms of which attributes are

required or optional, and does not define a consistent grayscale space. This makes it difficult to assure that images are displayed with a similar appearance on devices provided by different vendors. The more recent DX SOP class was added to DICOM in 1998 in order to support all forms of projection radiography, whether acquired using CR technology or DX technology. DICOM took the opportunity to incorporate the lessons learned from half a decade of experience with the CR SOP class, and defined a more robust and consistent object. To reiterate, the DX SOP class supports encoding of images regardless of the acquisition technology, and specifically was intended to replace the "old" CR SOP class for both CR and DX applications.

Unlike the CR SOP class, the DX SOP class clearly distinguishes two types of images, depending on the phase of processing:

- For Processing
- For Presentation

For Processing images are those that require further processing before they are suitable for viewing by a human, whereas *For Presentation* are those that are ready to view. The reason to make the distinction is to ensure that in a multi-vendor environment that there will be no confusion about which images a workstation should make available for display, and no ambiguity about which device is responsible for performing the processing. Furthermore, DICOM specifies that all devices are required to support *For Presentation* images, and that *For Processing* images are optional. This requirement is to prevent the possibility that one device produces only *For Processing* images and the other displays only *For Presentation* images, and hence are incompatible.

The DX SOP class, like all "modern" DICOM image objects, also defines a standard grayscale output space for *For Presentation* images, in order to achieve consistency of appearance regardless of the display device. This is achieved by specifying an output space in "P-Values", which have a defined meaning for a display device that is calibrated according to the DICOM PS 3.15 Grayscale Standard Display Function (GSDF). Note that the goal is only to assure that a single image will have consistent perceived contrast on different display devices. It is not to make different images appear consistent

with each other. Nor does GSDF compliance necessarily result in a “better” displayed image than another choice of display function.

The DX SOP class also makes mandatory many attributes that were optional in the CR SOP class, provides standard codes for attributes that were previously text strings, to ensure that there will be sufficient information about such things as orientation and laterality to allow the images to be displayed correctly. The overall design objective of the new object was to enable all DX *For Presentation* images to be reliably and consistently displayed on any vendor’s equipment. By contrast, the CR SOP class images’ consistency depends on the type of image configured at acquisition. In particular images may need further “processing” at time of display, but there is no standard way to convey whether or not this is the case.

Having the ability to further process an image whilst it is displayed is a desirable feature. At a single site, it is a nice feature to have in the PACS if one has the same PACS vendor as the CR or DX vendor. However, one cannot be sure of the presence of processing capability when the images are sent elsewhere to be read. This is why DICOM established the concept of *For Presentation* images as a mandatory baseline, with *For Processing* images as a desirable option. Theoretically, a “standard” could describe a “raw” space in which *For Processing* images could be encoded, after vendor and detector specific corrections had been performed. Subsequently, “standard” processing methods could be applied to the raw image, regardless of acquisition vendor. However, for the time being this remains an area for further research.

Accordingly, in order to achieve interoperability with the current state of the art, it is essential to insist that as a minimum “processed” images are sent, whether they be DX SOP class *For Presentation* images, or CR SOP class images that have been processed appropriately. This requires an *a priori* choice of processing algorithm and parameters, and it may be desirable for NIOSH to specify these in advance for each manufacturer and system, to achieve consistency of appearance. In reality, one must consider that it may be difficult to influence the acquisition sites to configure their systems to use a particular processing choice, particularly if they are using the system for other work.

DICOM – more than a file format

The DICOM standard also defines many services, including protocols for transferring images and objects across both local networks and the Internet, services for performing queries and retrieving lists of patients and studies, for supplying work lists, and for printing to film. Further, DICOM standardizes the use of interchange media, including the transfer of images using CD, DVD and USB. This allows for the establishment of a so-called “sneaker net”, which allows the transport or mailing of images. The purpose of these services is to allow automation of interoperability, and to avoid, for example, manual loading or dragging and dropping of image “files”. The relevant DICOM services for workflow and image transfer need to be considered in the context of classification of chest images for pneumoconiosis.

First, the radiology facility acquires digital images. From that point, if the site has a PACS, a DICOM transfer to PACS will occur; if there is no PACS, then the modality will burn the image files to a DICOM-compatible CD. If the images are to be read locally, then they will either be displayed on a workstation built-in to the PACS, or on a 3rd party DICOM workstation attached to the PACS or the modality.

However, if the images are to be sent to an off-site B reader and classified elsewhere, they need to be exported from the modality or PACS, which can be done by:

- burning them to a DICOM-compatible CD,
- sending them via a network to the remote reading site, or
- making then available over a network for remote viewing

Any of these possibilities are feasible, but as a matter of expedience, in the absence of a secure network infrastructure, the use of DICOM-compatible CDs may be most practical.

Software compatibility issues

Standards such as DICOM are required to achieved interoperability, but are not entirely sufficient. There remains the potential for incompatibility between acquisition, transfer and display software, arising from areas not addressed by the standard, ambiguities in the standard, optional features of

the standard that a vendor has chosen to not implement, and issues arising from software quality issues (bugs).

For an acquisition device, incompatibilities can arise because there is a choice of different SOP classes (CR, DX) as well as the difference between *For Processing* and *For Presentation* image types, as already discussed. Because the DICOM CR SOP class does not require use of GSDF P-values, there is also the problem of inconsistent grayscale contrast. For both CR and DX SOP classes, there may be problems caused by incorrect encoding of look-up tables applied to stored image pixels to derive display values; adherence to the standard in this respect is not universal among vendors, and display software may need to account for this. Other configuration issues may arise as a consequence of image acquisition vendors' need to make their equipment highly configurable to work with the vagaries and limitations of a range of PACS, old and new, commercial and homegrown. Though the configuration may satisfy the local users, the configuration choices may have unintended and undesirable consequences when images are sent off site. Insistence upon compliance with the DX *For Presentation* SOP class mitigates this class of issues.

The mechanics of transferring images using the DICOM protocol on a local network is rarely an issue, is widely tested, and is essentially a pre-requisite for PACS to work at all. However, DICOM CD compatibility is not universally reliable; some vendors default to proprietary CD formats, some vendors write incompatible DICOM CDs, while the use of data compression may raise issues. There is renewed emphasis by the industry on CD compatibility testing, but problems can arise with equipment that remains in the field. As a practical matter, given the limited number of sites acquiring and sending digital radiographic images for pneumoconiosis screening and research, each site can be prequalified and an appropriate transfer mechanism and procedure established and tested.

CDs are often burned with Windows-compatible digital image viewing software, nominally capable of displaying the images on the CD. Problems may arise with these viewers for a number of reasons. The issues relate to PC hardware and operating system versions, software installation, display speed (if the viewer is run from CD), and display compatibility, especially if a

calibrated display is required. Security policy in place at the facility may impose restrictions, since executing code from outside local systems and networks creates a risk of propagating viruses, as well as a risk of interference with locally installed applications. There are also training and usability issues; readers may need to learn to use multiple different viewing software products, depending on the number of sites sending images. Furthermore, image viewing software is typically designed for review and not for primary interpretation, and may prominently display disclaimers to that effect. Such software may have limited functionality and in particular lack full grayscale pipeline support, so the displayed images may not demonstrate the intended grayscale contrast.

Accordingly, it is strongly recommended that a single dedicated viewing software product is used, and that the execution of the CD-based viewer be suppressed, either with an appropriate registry setting or holding the shift key down whilst inserting the CD.

Display software requirements

The display software product that is selected needs a number of specific features to minimize compatibility problems. The product must support the different DICOM SOP classes, specifically both CR and DX. It must utilize images that are *For Presentation* and “ready to view”, not *For Processing* or raw. The product must implement a full grayscale pixel processing pipeline, in order to produce a consistent grayscale contrast appearance, which includes the correct application of “lookup tables” in the image header, as well as support a pair of GSDF calibrated displays to enable side-by-side display of the selected ILO standard image and the subject image. The software should provide methods for managing the various LUT problems that have been recognized when using acquisition devices provided by some vendors.

A base set of features is essential, providing the user with the ability to zoom, pan, and window the image. Additional features can be considered, such as enhancement and image processing, and the ability to handle unprocessed images.

Image contrast adjustment is a particularly important feature. Despite the broad exposure latitude of digital acquisition, a single default presentation of image contrast is usually not sufficient. The user will often need to adjust the image to better evaluate light and dark areas. Traditionally, linear window center and width controls are available, but these work poorly for projection radiographic images beyond a very small range of adjustment. Non-linear contrast adjustment using a sigmoid shaped curve (analogous to the H and D curve of film response) may achieve more satisfactory results. This can be achieved using lookup tables (LUT) or continuous functions. Though the details are beyond the scope of this presentation, DICOM supports all three mechanisms. It is important that the display software product that is selected support them all, and allow user adjustments. Note also that the image (or saved presentation states that can be reapplied to the image) may contain multiple choices of presentation, and the display software product should provide these choices to the user.

Compression

Compression was mentioned as a potential software compatibility issue. DICOM does support a range of ISO standard compression schemes, should they be necessary. Both lossless (reversible) compression (using JPEG, JPEG-LS or JPEG 2000) and lossy (irreversible) compression (using JPEG or JPEG 2000) are supported. The typical size of digital radiographic images is such that compression is rarely necessary on CD, though compression may increase the speed of network image transfer. However, given the uncertain impact on detection and characterization of subtle lung disease, it is recommended that lossy compression be avoided for pneumoconiosis classification functions.

Reference images

During the performance of pneumoconiosis classifications, the ILO requires that the subject radiograph be compared side-by-side to the appropriate comparison images from the ILO standard reference set of chest images. With digital image acquisition and soft copy display, there is an obvious need for the ILO standard reference chest images to also be digitally displayable alongside the patient images. Use of a separate light box on which to display

reference hard copy films is impractical, since it degrades workflow and alters perception (by being too bright). There is therefore a need for a digital version of the reference sets, with comparable contrast and processing to digital acquisitions. The process of digitizing (previously copied) reference films may result in significant quality degradation and dramatically different contrast characteristics when compared with digitally-acquired images. Ideally, a new set of digitally-acquired (rather than digitized) reference films will become available. Even then, there remains the issue that different acquisition technology, vendor, and processing may alter the chest image appearance.

The ILO digital reference image set should be encoded as DICOM DX *For Presentation* SOP class, to maximize consistency of display on different workstations and to allow images to be stored within the PACS for comparison. Digital encoding also provides the opportunity to distribute the standard images at negligible cost on the Internet, and hence increase their availability to the public, for training and research.

Displaying the reference images requires them to be made available as either a reference set “built in” to the display software, or as a “pseudo-patient” with dummy identifiers, allowing them to be used with ordinary software. In general, however, neither existing PACS workstations nor off-the-shelf (OTS) 3rd party DICOM generic workstations have explicit mechanisms to display “reference” images. For safety reasons, many systems prevent the showing of multiple “patients” simultaneously.

A customized workstation may need to be developed, dedicated to the classification task performed by B readers. Such a workstation could perform a DICOM query to the PACS to retrieve a patient’s images, and/or read them from CD, and have the ILO standard reference images installed and available locally. There are sufficient customizable open source and commercial toolkits for DICOM support and image display available to make this a feasible option.

Display equipment

As discussed elsewhere in these proceedings, achieving digital display quality comparable to film typically requires dedicated high intensity grayscale display devices, currently provided by flat panel digital displays rather than CRTs. These can be expensive, so the number of displays should be carefully considered. Traditional PACS workstations use a pair of portrait three-megapixel (3MP) displays, side-by-side, with the intent of displaying a current and prior or PA and lateral chest image pair with one image filling the area of each display.

The current film-based ILO viewing guidelines require simultaneous display of two films, the subject plus a single reference, though three are recommended to allow the subject film to be hung between references. One can simulate such a comparison with two digital displays, particularly if the software allows the user to rapidly toggle between one reference and another on a single comparison display; this presupposes that the software can order the reference images by increasing profusion and size. Accordingly, two displays are recommended.

Given the cost, some B readers may opt to re-use their existing infrastructure, particularly if classifications are for patients “outside” their hospital or office. This is analogous to importing patients’ images for “consultation”, a common practice. Some PACS already have explicit support for importation and reconciliation of foreign identifiers (see, for example, the IHE Import Reconciliation Workflow (IRWF) profile). Alternatively, readers may be able to view images from a CD inserted locally. When not possible, whether by policy or technology limitations, one can install a separate computer but share the expensive high resolution grayscale PACS displays by using KVM (keyboard-video-monitor) switches; devices that can support 3MP displays are available.

Remote reading

Rather than sending the images to the reader, it is possible to read “remotely”. Images can be provided on a central server, and accessed via a secure Internet connection. Typically, the display software is remotely accessed, managed and maintained, and the reader’s local machine provides Internet access and high quality monitors.

The mechanism of implementation varies, and may involve the use of a browser applet or plug-in, or an installable local client (ActiveX or Java Web Start). Acceptable performance and a satisfactory user experience is largely a function of the speed of the connection. Additionally, the patient and reference images can be pre-loaded locally in anticipation of their being needed (e.g., by looking ahead at work list tasks). Lossy compression is sometimes used to accelerate responsiveness, but this is unlikely to be acceptable for pneumoconiosis classification applications.

In the future, remote reading could be enabled by NIOSH providing a central archive server and a remote access mechanism, and supplying the same client software for all readers.

Cross-enterprise sharing

The problem of sharing patient related images and documents between loosely coupled organizations is not new. The Integrating the Healthcare Enterprise (IHE) effort initially focused on using existing standards (DICOM and HL7) to support workflow within an enterprise, but is now expanding to cross-enterprise document sharing (XDS), including images (XDS-I), and is starting to address cross-enterprise user authentication (XUA) and patient identifier cross-referencing (PIX).

The National Cancer Institute (NCI) Cancer Biomedical Informatics Grid (caBIG) also provides a mechanism for secure access to shared resources & services, including support for DICOM images.

In the future, it may be feasible and routine for authorized B readers to obtain remote access to images stored at the acquisition site, using an extension of infrastructure in place for routine patient care.

Security and privacy

Films, digital images, reports and forms may contain individually identifiable health information (IIHI), which is “protected” (PHI) under the HIPAA Privacy Rule. Unauthorized access to IIHI or PHI is a bad thing. It is necessary to either protect or remove such information.

Digital data is at risk when in physical form, for example when exchanged on CD, in the same manner as such information on film and paper. On-line digital information is also at risk, both locally, to access by unauthorized staff, and remotely, to access by unauthorized individuals when in transit.

Protection of PHI in transit requires encryption on the network, for example by using SSL, as is used in electronic commerce on the Internet. Also required are authentication, such as by login with username and password, access control such as by configuring access rights that are constrained based on identity, and maintenance of an audit trail, a record of who saw and did what, when and where.

DICOM provides network security services built on top of existing security mechanisms, using virtual private networks (VPN) or SSL connections for privacy. The user identity can be conveyed in a DICOM connection. The PACS can constrain access and maintain an audit trail. There are also standard mechanisms defined for web-based access to DICOM images (WADO), which use normal browser security mechanisms, and can also use VPN and SSL support. In such cases, the web server handles authentication, access, and audit trails.

An alternative approach is to remove PHI in digital images before transfer; if the information isn't there, then it does not need to be protected. Whenever readers do not need the patient's true identity, one can replace the patient's name, SSN and other identifiers with pseudonymous numbers. The association of the pseudonym and true identity can be securely maintained centrally. This process is used in clinical trials, in which independent readers are "blinded" to a subject's identity, both to reduce bias and protect privacy.

In DICOM images, the identity is normally stored in the digital image file headers, not burned in to the image pixels, which makes it relatively easy to automate such de-identification.

Integrating results with images

The DICOM standard addresses not only the encoding of images, but also image-related structured information, through the Structured Reporting (SR)

mechanism. DICOM SR allows for the storage of codes, text, measurements, coordinates, references to images, locations and outlines, in a hierarchical organization. The structure can be pre-defined by “templates” for specific applications. Examples of such templates in the standard include the basic radiology report, computer-aided detection (CAD) results for mammography and chest images, radiation dose reports, and measurements for echocardiography, obstetrics, and cardiovascular CT.

The DICOM SR approach shares the same header structure as images, and in particular uses the same patient, study and series model. DICOM SR is widely used by modalities to encode measurements. They are easy to store in, and retrieve from, the PACS. They convert easily into other forms, and can, for example, be transformed into HL7 CDA XML, or extracted and rendered as plain text or PDF. The contents can be searched and specific structures and codes extracted. SR can also be considered as a DICOM “form”, and can reference images and locations within images by coordinates.

Potentially, DICOM SR templates could be defined for ILO classification data, and could encode both the NIOSH Roentgenographic Interpretation and Miner Identification forms. Such templates would include standard codes for each concept, a reference to the unique identifier (UID) of the image being read, and possibly references to prior images used for comparison. Additionally, one could save image “annotations”, including pointers to locations of representative abnormalities in the image. An SR can also be digitally signed, as can any images referenced, using a standard cryptographic public key-based mechanism.

Conclusion and recommendations

An entire infrastructure already exists to support the clinical use of digital projection radiographs, based on the use of the DICOM standard between modalities, PACS, and workstations, with networks and CDs. Many sites now have considerable experience with exporting and providing outside access to digital images, including *For Presentation* digital radiographs. Correct choice, or construction, of an appropriate image viewer should allow consistent display and reliable review of images, side-by-side with ILO standards or

equivalent reference images. Expensive displays already installed can easily be utilized.

If advantageous, the results of pneumoconiosis classifications can be stored as a DICOM Structured Report, and the DICOM organization can help with adding templates and codes as requested. Matters of security and privacy can and should be addressed through conventional means.

In terms of specific recommendations for the NIOSH B reader program, both CR and DX DICOM images should be permitted, due to the large installed base of devices and the continuing availability of equipment that does not support the DX object. Processed (*For Presentation*) images should be required, to avoid the B reader being dependent on proprietary processing in display workstations. However, it is desirable to also obtain unprocessed (*For Processing*) images if possible, to allow for future research into CAD, as well as to permit development of standardized mechanisms for image processing.

Display workstations that support B readers should be qualified and certified; they must be fully compatible with test images from different vendors and software, must support all variations of encoding and grayscale pipeline, and must be able to display reference images side-by-side with the patient's image.

Images should be de-identified before sending for reading if possible, to minimize the risk of leakage of IIHI/PHI.

Ideally a digital, rather then digitized film, reference set should be created and released, which is comparable in contrast and resolution to CR and DX images.

Initially, it may be expedient to distribute images to B readers on DICOM CDs, but NIOSH should explore the creation of a managed distributed or centralized infra-structure, to allow for remote reading from a central PACS, or an XDS or caBIG network.

Image presentation: Implications of Processing and Display

Michael J. Flynn, PhD

Radiology Research
Henry Ford Health System
One Ford Place, Suite 2F
Detroit MI, 48202
Voice: 313-874-4483
FAX: 313-874-4494
Email: mikef@rad.hfh.edu

I. Introduction

For traditional film-screen (FS) radiography systems, the intensity of the radiation beam transmitted through the subject is directly transformed to film optical density and displayed with an illuminator. The display characteristics of a FS image cannot be altered after the radiograph has been acquired. For digital radiography (DR) systems, the recorded image is first stored temporarily as an array of raw image values and then transformed into presentation values that are used to display the image on an electronic device (see Figure 1). The visual characteristics of a DR image can be significantly improved by adjusting the brightness in light and dark regions, by enhancing detail contrast, by restoring blurred edges, and by reducing noise. Furthermore, the characteristics of the displayed image are also influenced by the transfer characteristics of the display system used for presentation. The influence of processing and display variables on the classification of pneumoconiosis in chest radiographs is considered in this paper.

II. Display Processing

Display processing methods perform the same function for all types of digital radiography detectors. The detector first produces raw image values that have a simple, usually linear or logarithmic, relationship to the input radiation intensity. Subsequently, display enhancement processes modify

these data to restore sharpness, reduce the appearance of quantum noise, and increase detail contrast. The modified data can be mapped to standardized presentation values that are used by a calibrated display device to generate the image. The specific processing methods used in current systems are described in this paper.

IIa. Display Processing: Raw Image Data Values

For most computed radiography (CR) and flat panel DR systems, at each image position, the detector produces an electronic charge that is monotonically related to the radiation energy absorbed. At this stage, the signal (charge) can be considered as a function of the incident radiation exposure*, S = k1 Kin*. The system's preamplifier and digital converter transform the charge to an integer representing the raw data image value, *Iraw*. A variety of instrument corrections are then applied to the raw image values to obtain values suitable for image processing, *IQ*. These include corrections to interpolate bad pixels and to adjust for non-uniformity.

Most systems transform the charge signal to a value proportional to the logarithm of the input exposure. Logarithmic signals have the property that a fractional change in *S,* due to the contrast of adjacent structures, produces a fixed change in the raw image value, D*IQ*, independent of subject penetration and input exposure. However, no medical or industry standards currently exist to define the scale of numbers used for raw image signal in digital radiographs. Systems may use logarithmic or square root transformations, and different vendors vary with respect to the constants used for the transformation. The final draft of the American Association of Physicists in Medicine Task Group 116, for publication in 2008, includes a recommendation for normalized *For Processing* values that are logarithmically related to exposure under standardized conditions, QK = 1,000*log10(KSTD/Ko) when KSTD is in microgray units, Ko = 0.001 μGy, and KSTD > Ko.

The wide variation in input signal transformations used by different vendors has hindered the introduction of consistent processing methods that can be applied at a workstation to images from various image acquisition products.

Industry adoption of the new standardized values in conjunction with storage using the DICOM *For Processing* digital radiographic object should permit consistent results from secondary processing of radiographs submitted by different systems. In this chapter, display processing is illustrated using *For Processing* image data in a logarithmic value representation of the type described in the example above.

IIb. Display Processing: Grayscale Rendition

For Processing digital radiographic image data can have a range of values, depending on exposure factors (kVp, mA-S, and filtration) and subject content (body part, body position, size, anatomy, pathology, and view). The highest signal intensities are found in regions outside of the subject where the direct beam is recorded. For chest radiographs, the lowest values are in regions below the diaphragm. Other anatomic regions are distributed with signal intensities ranging between these limits (see Figure 2).

In general, the grayscale rendition process maps the image values for anatomic regions that absorb the most radiation to the largest presentation values, for display at maximum brightness. Anatomic regions that absorb the least radiation are mapped to the smallest presentation values for display at minimum brightness. Intermediate image values are then mapped to presentation values in a monotonically decreasing fashion. This produces a presentation with a black background and white bones similar to that of conventional FS radiographs.

To emphasize the contrast of intermediate image values, the values of *IQ* are mapped to presentation values, *Ip* , using a non-linear relationship that emulates the Huerter-Driffeld curve (H-D curve) familiar from FS radiography. The maximum and minimum raw image values are extended and the intermediate values produce higher contrast than the extreme values. As with FS systems, the grayscale rendition may have an extended toe or shoulder to extend contrast into anatomic regions with low or high penetration. The values of *Ip* are defined with the expectation that the luminance response of the display, *L(Ip)*, is calibrated to follow a standardized gray scale display function (GSDF). For film printers, *Ip* is related to film density such that when the film is placed on a viewer, the brightness will

follow the standard GSDF. The commonly used DICOM GSDF produces similar contrast perception over the full range of brightness (2).

For electronic presentation using a PACS workstation, the raw *For Processing* image values may be sent along with DICOM header elements that indicate the minimum and maximum values of interest for presentation, i.e., the VOI LUT window width and window level elements (2). However, if *For Presentation* image data are sent to the workstation with a non-linear grayscale already applied, the ability of the observer to make further adjustments of image contrast and brightness is limited. Instead, images can be sent to a PACS station as raw image values along with a grayscale value of interest lookup table, i.e. the VOI LUT sequence (3).

Problems can arise if the same grayscale rendition is used to print films as is used to display images on an electronic display. This results from the extended density range of printed film, typically 0.12 OD to 3.2 OD, in relation to the more limited range of luminance for display monitors, typically 350-1. With film, dense regions are viewed using bright spot illuminators, whereas with review on a workstation the highly penetrated regions are viewed using adjustments to the grayscale rendition. This must be considered in protocols for standardized classification of radiographs.

IIc. Display Processing: Exposure Recognition

Exposure recognition processes are used to identify the minimum and maximum *IQ* values to be used for the grayscale rendition. In cases where the overall exposure to the image acquisition device is unusually high or unusually low, the histogram of *IQ* values will be shifted accordingly. When *IQ* is determined using a logarithmic transformation, a fractional change in the exposure level shifts the histogram a fixed amount. For example, if the exposure is doubled, the histogram may shift to the right by +301, whereas if the exposure is reduced by a factor of 2, the histogram may shift to the left by -301. If the desired range of *IQ* values can be identified for an individual image acquisition, the grayscale characteristics of displayed images can be similar, even if exposure variations shift the histogram.

Exposure recognition processes typically segment the signals due to anatomic regions from those recorded directly with no tissue attenuation or from areas that are outside the collimated radiation beam. Within the identified anatomic regions, intelligent algorithms then identify zones which should be displayed with maximum and minimum brightness. Segmentation may be aided by examining the noise characteristics of the image values and by identifying structures that have straight edge characteristics (4-6). Complex rules may be used to refine the segmentation and reduce errors to less that 1% of the cases (7). Once segmented, the correct range of *IQ* values is determined from the image values in the anatomic region. For views such as the PA chest, assumptions regarding the positions of the lung fields and mediastinum can be used; however, more complex approaches are required in general (8). These exposure recognition processes are analogous to the automatic exposure control systems used with modern photographic cameras. Like photographic camera products, many different approaches are employed on different DR products.

Another function of the exposure recognition process is to estimate the average radiation exposure to the receptor in the anatomic regions of interest. This is commonly reported to the operator as an index number that can be used to indicate whether the proper radiographic technique was used. CR systems made by Fuji Medical Systems report a number, S, which is inversely proportional to exposure1. CR systems made by Agfa Medical Systems report a number, lgM, which is proportional to the log of the exposure2. The lgM value varies with the user-selected speed, Sn. CR systems made by Eastman Kodak Company report an exposure index, EI, proportional to the log of the exposure3. Similar values are reported for the DR systems made by Eastman Kodak Company.

Unfortunately, the exposure index values used by different manufacturers vary in both scale and direction in relation to exposure. A primary objective of the American Association of Physicists in Medicine Task Group 116 reported referred to above was to make recommendations on a standardized exposure indicator for digital radiography. An international standard with similar definitions has recently been drafted and will be considered this year, IEC 62B/680/CDV. The adoption of common exposure

indicators will make it easier to define protocols for standardization of radiographic studies.

IId. Display Processing: Edge Restoration

The x-ray projection through patient tissues that is recorded by a digital radiography detector depicts fine detail with some blur. Blur can be related to the x-ray tube focal spot, patient motion, or the detector (described by the modulation transfer function, *MTF(f)* of the device). Edge restoration processes are used to transform the blurred radiograph such that the fine detail better reflects the actual attenuation characteristics of the tissue structures. Since the detector *MTF(f)* is generally the dominant source of blur, increasing the spatial frequencies in the recorded image in proportion to *1/MTF(f)* provides a better indication of the actual spatial frequency content of the tissue structures. In practice, unfortunately this can also produce a large increase in the high spatial frequency content and result in excessive amplification of quantum noise.

To limit noise amplification, edge restoration filters may principally amplify image components with low and intermediate spatial frequencies. As frequencies increase beyond the intermediate range, the *1/MTF(f)* filter function slowly returns to values of 1 or less. The Metz filter was developed for this purpose and has been shown to be effective in improving radiographic observer performance (10). The filter can be varied to control the amount of high frequency gain permitted (11). Similar shapes can be obtained by modifying the inverse *MTF(f)* filter with a Butterworth filter that gradually diminishes coefficients above a specified frequency.

Edge restoration of this type can only be performed with knowledge of the *MTF(f)* for the detector system. Of particular importance is the reduction in modulation transfer that can occur at low and intermediate frequencies (i.e. from about .1 to .5 of the limiting frequency associated with the spacing of the image values). For CR systems using powdered phosphor screens, *MTF(f)* is diminished at intermediated frequencies with *f1/2* equal to about 1.2 cycles/mm for *MTF(f)* = 0.5 (13). For Cesium Iodide flat panel detectors, the value of *f1/2* is slightly higher but a significant reduction in *MTF(f)* still occurs at mid frequencies. For detectors using photoconductors

such as Selenium, the *MTF(f)* is more appropriately described by the ideal response of a square detector element, *MTF(f) = sinc(pDx f)* (14).

When the edge restoration filter is appropriately specified, fine detail has a realistic appearance and the image will not have excessive noise. This is illustrated in figure 3 for a lateral knee view recorded using a CR system with a high-resolution phosphor screen. Inappropriate specification of the restoration filter can lead to artifacts. In some systems of earlier design, filters were implemented using spatial convolutions based on a small kernel that were not able to amplify image components with low and intermediate spatial frequencies. These were often applied with excessively high gain. This over-amplification of high spatial frequencies causes edge artifacts appearing as an oscillating signal that is sometimes referred to as 'edge ringing'.

If similar appearances are sought for images acquired from multiple medical centers as a part of a standardized classification protocol, it is important to recognize that edge restoration processes may need to be different, depending on whether the type of device that acquired the radiograph was a CR systems, indirect DR systems, and direct DR systems. However, important differences in appearance are not likely to results from using the same processing on devices of the same system type from different manufacturers.

IIe. Display Processing: Noise Reduction

All digital radiographic devices are designed such that the only visible noise is due to the limited number of x-rays detected per unit area. For photoconductive flat panel devices, the quantum noise appears with a very fine texture. The spatial frequency components of this noise are distributed with equal strength at all spatial frequencies, i.e. the noise power spectrum, *NPS(f)*, is constant in relation to frequency (14). For detectors using scintillation phosphors, either CR or flat panel, the noise appears as a more nodular texture with the higher frequency components somewhat diminished in strength (13). In both cases, the relative noise amplitude of *Idet* is largest when the input exposure is small. For systems using logarithmic transformation, this causes the absolute noise amplitude in *IQ* to vary as the tissue attenuation varies in different regions of the image.

A variety of processing methods can be used to reduce the visual appearance of the noise texture. In general these methods all reduce the high frequency components associated with the noise signal resulting in a more nodular texture with reduced amplitude. As a consequence, these processes will also reduce the high frequency components of the tissue signal, resulting in some increased blur. A general aim of noise reduction processes is to reduce the noise only in regions where the tissue contrast does not have noticeable fine detail.

If the frequency content of the tissue contrast is known along with the frequency content of the noise, the frequency dependant contrast to noise ratio can be used to develop a noise reduction filter. The classical Wiener filter (15,16) provides an optimal solution based on the power spectrum of the tissue contrast signal, however it is not applicable when the signal and noise vary in the image. Adaptive noise reduction processes attempt to locally filter the image in regions where the tissue contrast has little fine detail. In regions containing sharp edges, fine detail, or other structures producing high frequency components, the noise reduction is constrained and the detail preserved. Methods that have been used in commercial systems include the Lee filter (17), adaptive Wiener filtering (18), and noise coring (26). Noise reduction processes are difficult to successfully implement since the goals of reducing noise and preserving resolution can conflict.

The ability of noise reduction techniques to improve visual performance has been the subject of much debate. Because the human visual system can effectively recognize target patterns in the presence of noise, it is not necessarily true that a reduction in noise amplitude will improve detection performance. Moreover, if the noise texture is made coarser and the filtered noise has a power spectrum similar to the target objects, the noise reduction process may be deleterious. This can be of particular concern when considering the fine texture of lung tissue and pneumoconiosis pathology in the chest radiograph.

IIf. Display Processing: Contrast Enhancement

Traditional FS radiographs with large latitude have poor contrast. This problem is of particular significance for chest radiography. If it is considered

to be diagnostically important to visualize the contrast of lung tissue behind the mediastinum, behind the heart, or around the curved dome of the diaphragm, a wide latitude film-screen system is required and tissues in the primary lung region are recorded with flat contrast.

For digital radiography, contrast enhancement processes are able to greatly improve the contrast of local tissue structures without altering the global grayscale characteristics of the image. Image processing methods are used that maintain the low spatial frequency components of the image that are responsible for the average brightness in large regions while increasing the components with intermediate and high frequency that are responsible for detail contrast. Contrast enhancement processes result in both high contrast and wide latitude in a manner that is not possible with FS radiography.

The classical approach for contrast enhancement is the un-sharp mask method. A blurred representation of the image is first prepared. This is then subtracted from the image to reveal the detail contrast. The two are then combined with appropriate weighting to obtain an enhanced image (see Figure 4). The method originated as a photographic process where a blurred negative is placed in contact with a positive film to diffusely increase the light transmission in dark regions. A high contrast copy of the film is then made. This method has been commonly used to prepare prints for publication4 and was described in 1981 as a method to improve chest radiographs (19).

Fuji Medical Systems introduced unsharp mask processing of digital radiographs on their early CR systems (20, 21). Using appropriate weighting to diffusely increase low *Iraw* values and decrease high values, the range of values is compressed allowing the use of a narrow latitude grayscale rendition. The method is referred to as dynamic range control (DRC); however, the purpose is to permit increased contrast. Numerous enhancements to this method have subsequently been reported and are used in commercial systems (22-25). These approaches use varying numeric methods to obtain good control of the enhancement response in relation to spatial frequency.

The appearance of contrast enhanced images is dependent on the specific approach applied, in relation to spatial frequency affects, particularly at

boundaries which have a large change in the attenuation. At such boundaries, all methods produce an artifact with a gradual short-range shift in image values. This response can be considered in terms of the shape of a convolution kernel used to blur the original image to obtain an unsharp mask (see Figure 5a). Early methods used large size kernels (1 to 4 cm) having constant values that caused a linearly varying transition at edges (see Figure 5b). The frequency response for such a kernel has an undesirable oscillating response that can cause excessive amplification of certain tissue patterns. In comparison, if the kernel values are derived from a Gaussian function, the frequency response monotonically increases in a well-behaved manner (see Figure 5c). Modern methods use multi-scale and multi-frequency processing methods that can be rapidly applied to achieve a well behaved enhancement (27, 28).

III. Display Presentation

Images that have been processed and are ready to be displayed will have values that are intended for presentation, *Ip*. These values are appropriately communicated in the DICOM digital radiography *For Presentation* object. Within a medical center with central storage facilities for medical imaging, these images would be retrieved by a computer workstation and displayed on a monitor that has been calibrated for the display of medical *For Presentation* image values. With proper calibration, the appearance of the image will be the same for any workstation. The calibration must consider the luminance response (grayscale) as well as the luminance ratio as described below.

IIIa. Display Presentation – graphic controller and monitor

Modern computer work stations utilize graphic controllers to convert image values to brightness, more formally luminance, for which the SI unit is candelas/m2. For modern liquid crystal display (LCD) devices, digital values are sent to the monitor where they are stored to control the brightness signal for each discrete pixel in the panel. For cathode ray tube (CRT) devices, an analog voltage signal was sent that controlled the electron beam current in real time as the beam was swept in a raster pattern. The CRT devices produced a blurred image and were subject to analogue signal drift which

affected image contrast. As a consequence, current standardized protocols for digital radiography for which images are to be interpreted on workstations should avoid CRT devices.

The graphic controller converts the image values to the digital driving levels (DDL) of the computer monitor. Commonly this is done as a red, green, and blue (RGB) signal with 8 bits (256 levels) per channel. New standards are anticipated that will communicate more color levels to the monitor (10 to 16 bits). For the gray levels important in digital radiography, a variety of methods exist to communicate 256 or 1024 gray levels, each of which can be precisely defined from a palette with several thousand values. These more sophisticated methods are used in the graphic controllers and specialized calibration software designed for medical imaging. The transformation of *For Presentation* image values to the set of desired gray levels is done through a look up table (LUT). Determining and installing the LUT is the process that calibrates the display device.

IIIb. Display Presentation – Luminance Ratio

For a specific calibration LUT, the ratio of the luminance associated with the maximum gray level, *Lmax*, to the luminance of the minimum gray level, *Lmin*, is known as the calibrated luminance ratio, *LR* = *Lmax/ Lmin*. When a person is viewing a particular image, the eye and neuronal vision systems adapt to the overall scene brightness. The perception of contrast, as measured by the relative luminance change of a just visible target structure, is best when the target is located in a region of the image having a luminance equal to the adapted luminance (see figure 6). In brighter and darker portions of the image, the perception of contrast is diminished. If *LR* is too large, contrast in the very bright and very dark regions can become imperceptible. On the other hand, if *LR* is too small, the overall scene contrast is poor. An appropriate compromise is about 350, although values from 250 to 500 are used.

It is important to realize that if an image is viewed on a device with a specific *LR*, say 250, and later the image is viewed at a different LR, say 450, the appearance of the image will be significantly different. For chest radiographs at high *LR*, contrast is poorly demonstrated in the dark lung

regions. This is conceptually illustrated in figure 7. For standardization of viewing conditions in multi-center reading, it is important that all display devices be calibrated to the same *LR*.

IIIc. Display Presentation – Luminance Response (grayscale).

The luminance in relation to the digital driving level is referred to as the luminance response, which is often called the grayscale response. The grayscale establishes the display contrast transfer characteristics in the various regions of an image that will be in dark, mid-gray, and bright areas of the scene. The native luminance response of a typical LCD monitor is poorly suited for displaying digital radiographs (see figure 8). A dark region with no contrast is followed by a rapid increase in brightness. For the mid driving levels and higher, the luminance is high with low contrast. This characteristic is well suited for general purpose computer graphic applications but not for medical or photographic images.

The DICOM committee defined a Grayscale Standardized Display Function (GSDF) that has been widely adopted by medical imaging manufacturers (2). This functions provides a modest boost in contrast at dark levels where human visual contrast response is not as good. Devices used for the presentation of digital radiographs should be calibrated to follow the GSDF between *Lmin* and *Lmax*. This is done through generation of the appropriate LUT which usually requires a luminance meter, although some equipment is sold with a predetermined LUT stored within the monitor.

IIId. Display Presentation – Device requirements

To assure standardization for consistent and accurate image classification, methods must be in place to ensure calibration of electronic display devices. Additionally, devices must have sufficient brightness, small pixel pitch, and good reflective properties. Room lighting should be low enough that the ambient luminance *Lamb* (in Lux), measured from the monitor surface with the monitor power off, is much less than *Lmin*. The human visual basis for the desired requirements are not detailed here (29, 30), but appropriate requirements can be summarized as;

- GSDF luminance response with *LR* = 350.

- Maximum brightness of 450 candelas/m2 or more
- Pixel pitch of 0.210 mm or less.
- Diagonal size of 20-24 inches with 4:3 or 5:4 aspect
- *Lamb* less than 1/4th of *Lmin*.

IIIe. Display Presentation – Film Prints

Digital radiographs may be printed on transparent sheet film to be viewed on traditional view-box illuminators, although this process may not be readily available, since many facilities prefer to send images using standardized digital formats on computer disks (CD). If prints are made, it is difficult to print a digital image with an appearance similar to an electronic display. For a device calibrated for LR = 350, the corresponding optical density range is about 2.5. Typically OD ranges for film printers are about 3.1. Thus the grayscale rendition needs to be adjusted to cover a wider range of image values to achieve similar appearance. This can be a particular problem in printing digitally-acquired chest images, in that the lungs can appear unusually dark.

IV. Discussion

When done properly, digital radiography processing can produce significant improvements in image quality compared to FS techniques. However, modern processing methods can also produce image characteristics that are different than the traditional FS appearance. As a consequence, most manufacturers can adjust the manner in which processing is applied. For a reader with little experience viewing processed digital images, an approach may be taken that mimics traditional film-screen appearance. For readers with more experience viewing digital images, a more aggressive approach to processing may be selected. This creates problems when trying to standardize the classification of pneumoconiosis patterns using images from many centers.

The following should be considered for future programs involving digital radiography with electronic viewing for the classification of the pneumoconioses:

- Consider a program requiring that radiographs be acquired and communicated using normalized *For Processing* values in DICOM standard format. If achieved, the following can be considered;
    - Adoption of a NIOSH image processing engine that can be applied on a workstation to achieve a standardized appearance.
    - Implementation of a processing service whereby *For Processing* data is sent to NIOSH for conversion to *For Presentation* images that are then sent to qualified readers for interpretation.
- In the absence of standards for normalized processing values,
    - Utilize a chest phantom to qualify centers doing chest radiography
    - Specify the general characteristics of the processing to be applied with illustrations.
    - Require examples of processed images to be submitted as a part of the approval process.
    - Where possible, indicate the nominal processing parameters that are to be applied for different manufacturers and software versions.
- For B readers, communicate images electronically using DICOM standards and require a reader display device certification, including
    - Documentation of the device and its characteristics (see section IIId.)
    - Review of quality control image(s) on the monitor and demonstration of the visibility of specified findings.
    - Periodically verify the luminance calibration, potentially requiring the sending of a device and software to perform the verification.

Acknowledgement

Portions of the material contained in this report appeared in an RSNA course booklet on “Advances in Digital Imaging” that was published in 2003.

Figures

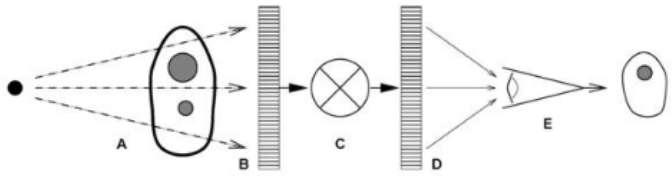


Figure 1. The examination of patients with digital radiography is illustrated as a six component model; A) generation of a beam of x-rays incident on the patient, B) modulation of the x-ray beam intensity by tissue structures, C) detection of the transmitted x-ray beam and creation of an array of raw image values (*Iraw*), D) transformation of *Iraw* values to presentation values (*Ip*) by display processing, E) display of the image with a standardized grayscale, and F) psycho-visual interpretation of the displayed image by the observer.

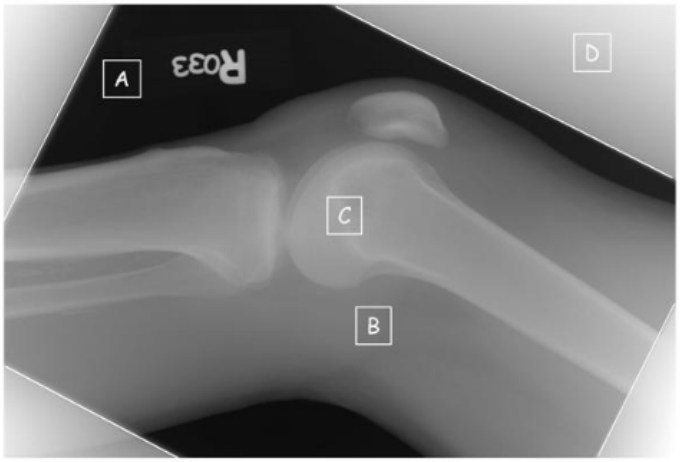


Figure 2a. Commonly observed regions are identified on an image of raw values, *Iraw*, from a knee radiograph; A) regions where the x-ray beam directly exposes the detector with no tissue attenuation, B) regions of modest tissue attenuation, C) regions of high attenuation from bone, and D) regions outside of the collimator edges exposed by scattered radiation.

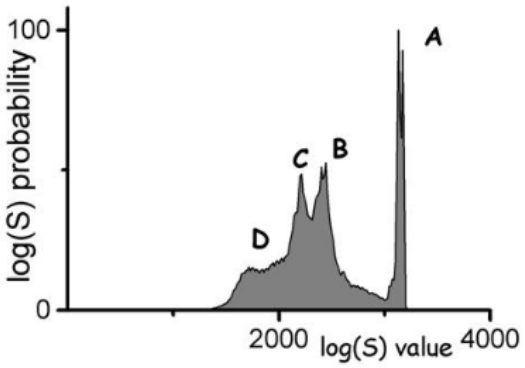


Figure 2b. A histogram of raw image values from a knee radiograph with commonly observed regions identified; A) direct exposure produces a narrow peak of high values, B) soft tissue regions produce a broad peak of values less than A, C) bone regions produce a broad peak of values less than B, and D) a diffuse peak of low values outside of the collimated region.

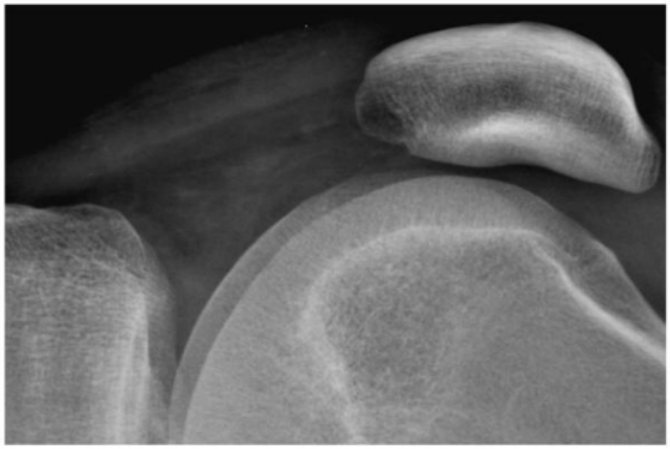


Figure 3a. A digital radiograph of the knee taken with a high resolution CR screen (HR screen, Eastman Kodak Company) is illustrated using display processing with no edge restoration.

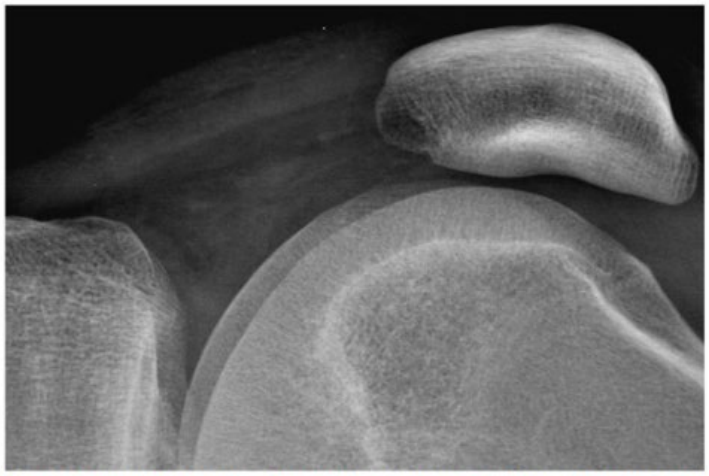


Figure 3b. The knee radiograph shown in figure 3a is illustrated using display processing with edge restoration.

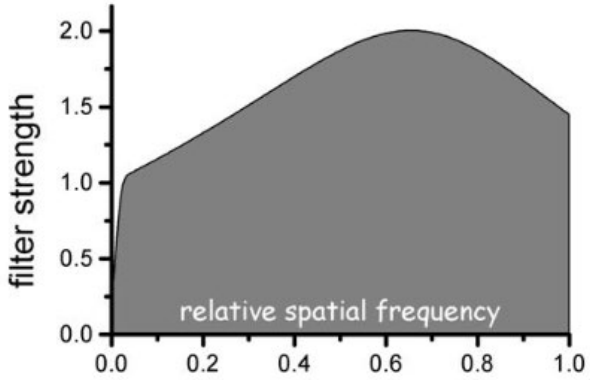


Figure 3c. The filter strength in relation to spatial frequency is shown for the edge processing used in figure 3b. Intermediate spatial frequencies are enhanced proportional to the inverse of the modulation transfer function (MTF). The inverse MTF filter is reduced at high spatial frequencies using a low pass Butterworth filter.

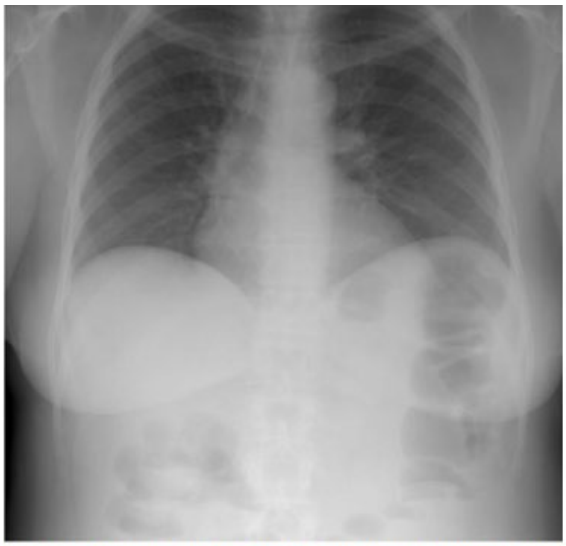


Figure 4a. A digital radiograph of the chest taken with a general purpose CR screen (GP screen, Eastman Kodak Company) is illustrated using no display processing. To display the wide range of raw image values, a wide latitude grayscale rendition has been used that results in poor tissue contrast.

Figure 4b. An unsharp mask image derived from the chest image in figure 4a is illustrated with the grayscale reversed.

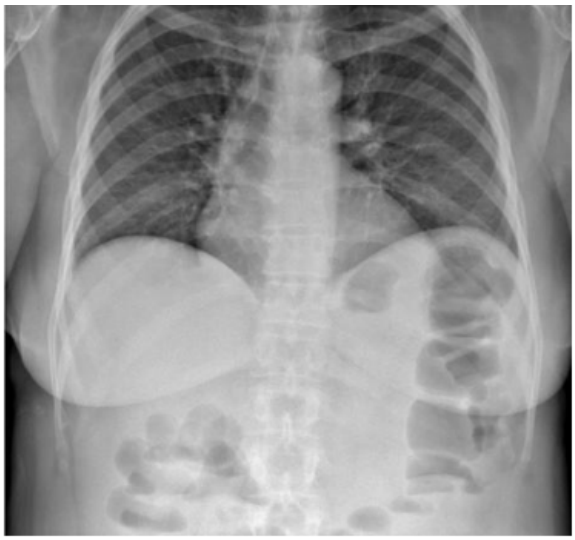


Figure 4c. The chest image in figure 4a is illustrated with contrast enhancement based on the unsharp mask of figure 4b. The unsharp mask values are used to adjust the raw image values so that the image may be displayed with a narrow latitude grayscale rendition resulting in improved tissue contrast. An equivalent photographic process would use the unsharp mask as illustrated to illuminate the orginal radiograph and make a high contrast copy.

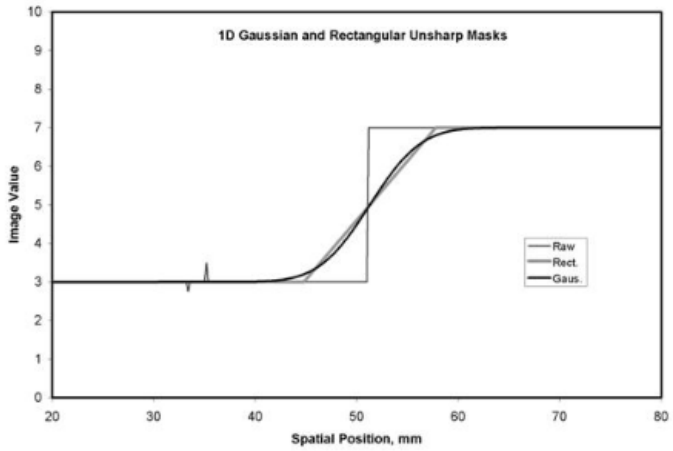


Figure 5a. Blurring of raw image values to obtain an unsharp mask is illustrated with a one dimensions (1D) line of data crossing a sharp edge. A rectangular smoothing kernel (Rect, 16 mm width) with constant kernel weights produces a linear transition at the edge. A Gaussian smoothing kernel (Gaus, 16 mm width at .27 of the maximum) produces a smoothly varying transition. The fine detail structures seen in the raw data on the left do not appear in the unsharp mask data.

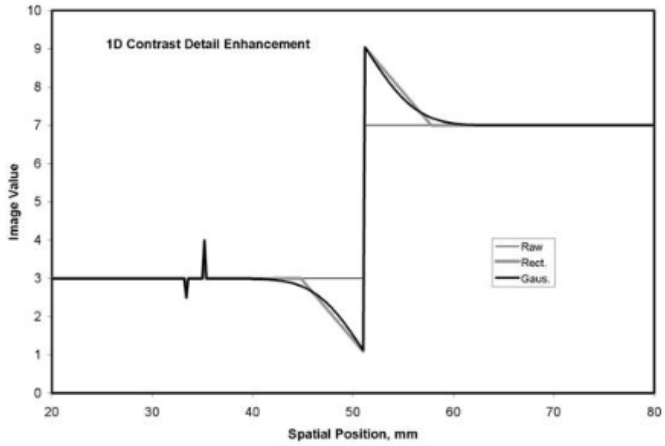


Figure 5b. Detail contrast enhancement based on an unsharp mask can be scaled so that the resulting image has the same values for low frequency components (i.e. the same latitude) but the contrast of edges and fine detail are amplified. This is illustrated using the 1D unsharp mask example from figure 5a. Note the smoothly varying overshoot at the edge that results from a Gaussian kernel (Gaus.). The detail contrast enhancement of the fine detail at the left is about 2 times that seen in the original data (see figure 5a).

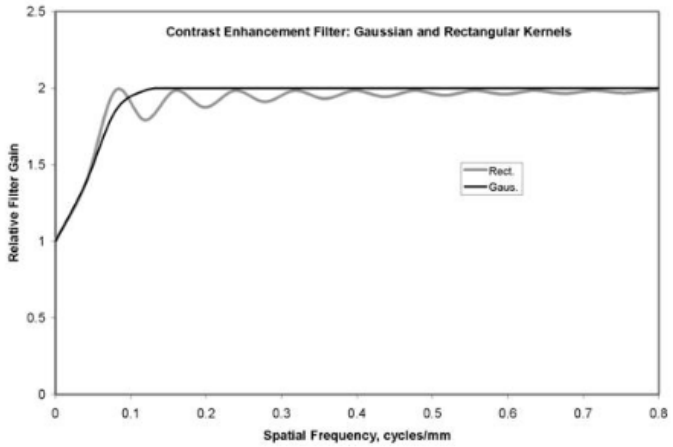


Figure 5c. The enhancement of image components as a function of spatial frequency is illustrated for the two examples of figure 5b. Using scaling to preserve latitude, the very low frequencies are amplified with a gain near 1.0. Amplication increases with frequency to a gain of 2.0 in order to enhance detail contrast. For the process with the rectangular kernel (Rect.), ringing of the amplification is seen. In comparison, the process with the Gaussian kernel (Gaus.) produces amplification that varies smoothly with spatial frequency.

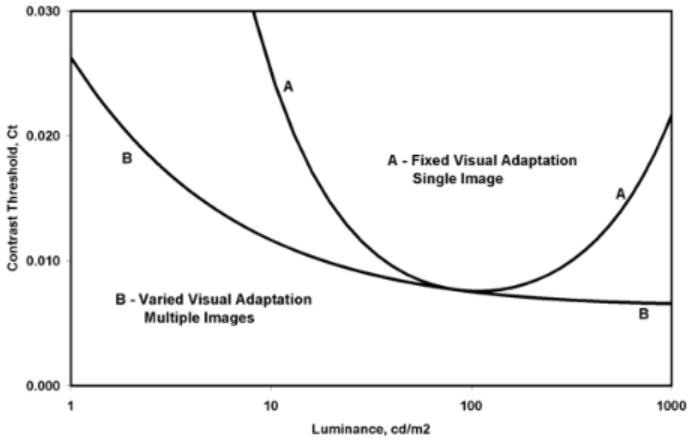


Figure 6. The contrast threshold is a psycho-visual measure of human vision based on the just noticeable contrast, measured as luminance change divided by mean luminance. It is typically made using grating patterns with sinusoidal luminance variation at a particular spatial frequency. If the target and background are of the same average luminance and the average luminance is changed for each measure, the result is for varied adaptation. If the background is kept at constant luminance, and the average luminance of the target is varied, the result is for fixed visual adaptation.

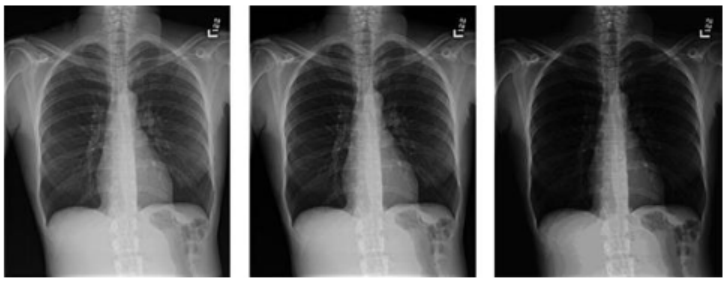


Figure 7. The appearance of the same image display with different display luminance ratios is simulated. At the left is the image presented with the desired luminance ratio. As the ratio is increased from left to right, the tissue structures in the lung become dark and contrast is not visible.

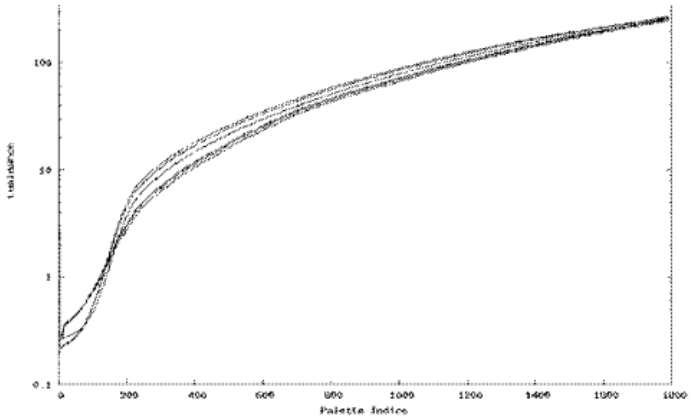


Figure 8. The native luminance response of a modern liquid crystal display, LCD, monitor is illustrated by the response of 6 devices of the same manufacturer and model. The luminance for a set of 1786 progressively increasing gray levels show abrupt increases in the low palette index range and poor contrast in the high index values. This type of response provides bright images for general purpose computer graphic images such as word processors, but provides poor rendering of medical or photographic images.

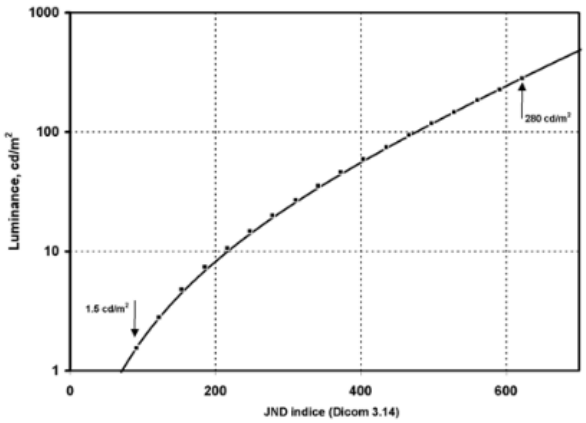


Figure 9. The DICOM Gray Scale Display Function, GSDF, provides a relationship between the Digital Driving Levels, DDL, of a display, and luminance. The values are tabulated in relation to an index, the Just Noticeable Difference index, whose spacing is proportional to the DDL levels.

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Footnotes

1. Fuji: S = 200/Ein for an 80 kVp unfiltered beam
2. Agfa: lgM = 2.22 + log(Ein) + log(Sn/200) for a 75 kVp beam with 1.5 mm Cu filtration
3. Kodak: EI = 1000 log(Ein) + 2000 for an 80 kVp beam with 0.5 mm Cu and 1.0 mm Al filtration
4. In 1972, logEtronics (Springfield, VA) patented a method to make photographic negatives of medical radiographs with un-sharp masking (US patent #3,700,329). A CRT was used to illuminate the radiograph with a blurred mask. The multi-dodge system is now sold by Egoltronics (Baker, WV).

Comparison of Digital Radiographs with Film-Screen Radiographs for Classification of Pneumoconiosis

Alfred Franzblau, MD*
Ella A. Kazerooni, MD
Ananda Sen, PhD
Mitchell M. Goodsitt, PhD
Shih-Yuan Lee, MS
Kenneth D. Rosenman, MD, MPH
James E. Lockey, MD, MS
Cristopher A. Meyer, MD
Brenda W. Gillespie, PhD
E. Lee Petsonk, MD
Mei Lin Wang, MD

*University of Michigan School of Public Health
109 South Observatory Street
Ann Arbor, Michigan 48109-2029, USA.
Email: afranz@umich.edu
Phone: (734) 936-0758
Fax: (734) 763-8095

Abstract

The International Labor Organization (ILO) system for classifying chest radiographic changes related to inhalation of pathogenic dusts is predicated on film-screen radiography (FSR). Digital radiography (DR) has replaced FSR in many centers, but there are few data to indicate whether DR is equivalent to FSR in identifying and quantifying interstitial and pleural abnormalities. Furthermore, DR images can be printed and viewed on film, so-called 'hard copy' (HC) DR, or can be viewed on a monitor at a computer workstation, so-called 'soft copy' (SC) DR. The goal of this investigation is to assess the equivalency of DR in comparison to FSR for diagnosis and quantification of parenchymal and pleural abnormalities due to pneumoconiosis and other forms of fibrotic lung disease, using the ILO classification system. This report is based on analyses of readings of FSR, HC and SC images from 107 subjects

by 6 NIOSH certified B-readers. Overall, there were few differences in the reliability of image classifications across image formats (i.e., most inter-rater kappa values of classifications for FSR, HC and SC images did not differ significantly from each other). Readings of HC images demonstrated a significantly greater prevalence of classifications of small parenchymal opacities compared to FSR and SC (e.g., in adjusted logistic models of the prevalence of small parenchymal abnormalities: the odds ratio of FSR versus HC = 0.72, 95% CI = 0.60-0.86; and, the odds ratio of HC versus SC = 1.26, 95% CI = 1.09-1.46); FSR and SC did not differ significantly. The prevalence of classifications for large opacities differed significantly among all three image formats, with HC>FSR>SC, however, the difference between FSR and SC disappeared when images with 'ax' were included as large opacities. The prevalence of pleural abnormalities differed significantly among all three image formats, with FSR>HC>SC (e.g., in adjusted logistic models of the prevalence of pleural abnormalities: the odds ratio of FSR versus HC = 1.28, 95% CI = 1.08-1.53; the odds ratio of FSR versus SC = 1.59, 95% CI = 1.35-1.88; and, the odds ratio of HC versus SC = 1.24, 95% CI = 1.08-1.42). These results suggest that while the inter-rater reliability of classifications using HC and SC appears to be largely equivalent to FSR, there are some significant differences among FSR, HC and SC with respect to the prevalence of specific outcomes. Based on our results, interpretation of soft copy digital images for small parenchymal opacities and large opacities (with 'ax') appears to result in the same prevalence of ILO classifications as traditional film images, and therefore can be recommended for this purpose.

Introduction

Since the early decades of the 20th century, standard posterior-anterior (PA) film-screen chest radiography (FSR) has been the primary method for screening, diagnosis, medical monitoring and epidemiological study of the pneumoconioses. In the 1930's the International Labour Office (ILO) based in Geneva, Switzerland, became involved in the development and evolution of a scoring system for standardizing the classification of radiographs for pneumoconioses. The system has undergone multiple revisions, most recently in 2000.2 The ILO system is predicated on use of films screen radiology (FSR) remains the most widely used method for classifying chest

radiographs for pleural and parenchymal abnormalities related to inhalation of pathogenic dusts.

The goal of the present investigation was to assess the impact of chest radiograph image format, including FSR, soft copy (SC), and hard copy digital imaging (HC), on the results of ILO classifications performed by experienced readers on images of individuals with abnormalities of the lung parenchyma and/or pleura that may result from dust inhalation. In particular, we sought to examine the impact of image format on both the reliability of classification results and the prevalence of findings.

Materials and Methods

This study was approved by the Medical Institutional Review Board of the University of Michigan. One hundred seven subjects were recruited from the University medical clinics and the Michigan and Ohio silicosis registries. A questionnaire recorded demographics, smoking history; occupational history; and past medical history. Height and weight were measured. A standard PA FSR image and a PA DR image were obtained on the same day. No other tests were performed as part of this investigation.

DR chest images were captured on a flat-panel amorphous Selenium digital detector of the Hologic DR 1000C system (Hologic, Inc., Bedford, MA). Each digital image was also printed on a Fuji FM-DPL high quality laser printer (FUJIFILM Medical Systems USA, Inc., Stamford, CT) using Fuji film.

In collection of the PA chest films, standard techniques were employed: 125 kVp, 150 mA, wall unit, 72” (183 cm) SID, all 3 phototimer sensors, using an Agfa film and cassette (Agfa-Gevaert Group, Wilmington, Delaware). The speed of the screen-film system was 200. A scatter rejection grid was uniformly employed.

Each B-reader classified each image in each format (FSR, HC-DR, SC-DR) on two separate occasions. The formats were presented in random order. Within each image format, the images were also presented in random order. There was at least 30 days between each reading cycle for each reader. All readers employed high-resolution physician-quality diagnostic display

monitors when reading SC images. With permission from the ILO, the entire set of ILO 1980 standard films was digitized and archived for display side-by-side in classification of soft copy subject images. B-readers recorded classifications using forms consistent with the 2000 revision of the ILO classification system.

Statistical Analyses

Statistical analyses were performed using SAS® for Windows version 9.1 and STATA®.
Kappa statistics were used to compare the reliability of classifications for image quality, parenchymal abnormalities and pleural abnormalities for each image format. Standard errors were calculated using a bootstrap method based on 2,000 replications. Further analyses investigated classification differences across image formats controlling for potential confounders such as age, smoking, and body mass index. A generalized estimating equations (GEE) approach was employed to incorporate the clustering effect in the analysis.

Results

Among the 107 subjects, 80% were male, mean age was 64.6 years, 64% had smoked at some time in their lives, and 56% reported occupational dust exposure. One FSR and one digital image were lost. A total of 3,816 image readings were analyzed (106 images x 3 formats x 6 readers x 2 rounds). The bulk of small opacity profusion scores for FSR images were “0” (43%) and “1” (30%. There was a substantial representation of both small rounded (34%) and small irregular opacities (66%). Fifteen percent of FSR readings indicated the presence of large opacities, and 41% indicated the presence of pleural abnormalities. Summaries of the classification results for the study images overall and for the three image formats are shown in Table 1 for parenchymal abnormalities, and Table 2 for pleural changes. Table 3 displays the results of the GEE model of agreement by image format, both adjusted and unadjusted for potential confounding and competing variables.

Conclusions

Overall, there were few differences in the reliability of image classifications across image formats. Readings of HC images demonstrated significant greater prevalence of small parenchymal opacities compared to FSR and SC; readings of FSR and SC for small parenchymal opacities did not differ significantly. The prevalence of large opacities differed significantly among all three image formats, with HC>FSR>SC, but the difference between FSR and SC disappeared when images with ‘ax’ were grouped with large opacities. The prevalence of pleural abnormalities differed significantly among all three formats, with FSR>HC>SC. The study results suggest that while the reliability of classifications using HC and SC appears to be equivalent to FSR, there are some significant differences among FSR, HC and SC with respect to the prevalence of some key dust-related abnormalities. It is difficult to formulate a consistent recommendation for use of digital chest images with regard to pleural outcomes, based on these results. In contrast, interpretation of soft copy digital images for small parenchymal opacities and large opacities (with ‘ax’) appears to result in equivalent ILO classifications as traditional film images, and therefore can be recommended for this purpose.

Table 1: Results of ILO Classifications Overall and by Chest Radiographic Image Format – Parenchymal changes

	Outcome variable	Overall n	Overall %	Film n	Film %	Hard Copy n	Hard Copy %	Soft Copy n	Soft Copy %
1. Image quality (n=3816*)	1	1130	29%	398	31%	301	24%	431	34%
	2	2282	60%	774	61%	778	61%	730	57%
	3	382	10%	98	8%	175	14%	109	9%
	4 (unreadable)	22	1%	2	0%	18	1%	2	0%
2A. Any Parenchymal Abnormalities (n=3794*)	No	1216	32%	443	35%	358	29%	415	33%
	Yes	2578	68%	827	65%	896	71%	855	67%
2Ba. Shape/Size of Primary Small Opacities (n=2578)	Round(p,q,r)	829	32%	281	34%	280	31%	268	31%
	Irregular(s,t,u)	1749	68%	546	66%	616	69%	587	69%
2Bc. Small Opacity Profusion	0	1529	40%	543	43%	455	36%	531	42%
	1	1158	31%	385	30%	392	31%	381	30%
	2	852	22%	265	21%	306	25%	281	22%
	3	255	7%	77	6%	101	8%	77	6%
2C. Large Opacities	O	3216	85%	1076	85%	1036	83%	1104	87%
	A	228	6%	78	6%	79	6%	71	6%
	B	271	7%	93	7%	101	8%	77	6%
	C	79	2%	23	2%	38	3%	18	1%
2C. Large Opacities	No (0)	3216	85%	1076	85%	1036	83%	1104	87%
	Yes(A/B/C)	578	15%	194	15%	218	17%	166	13%
2C. Large Opacities with 'ax'	No(0)	3026	80%	1020	80%	969	77%	1037	82%
	Yes(A/B/C/ax)	768	20%	250	20%	285	23%	233	18%

*Images were obtained for each of the three modalities in 107 subjects and were classified on two separate occasions by 6 B Readers. The number of images assessed for film quality is greater than for subsequent outcomes. For a small number readings image quality was rated 'unreadable' (n=22). These readings provide no data for subsequent outcomes. df = degrees of freedom

Table 2: Results of ILO Classifications Overall and by Chest Radiographic Image Format – Pleural changes

	Outcome variable	Overall n	Overall %	Film n	Film %	Hard Copy n	Hard Copy %	Soft Copy n	Soft Copy %
2C. Large Opacities with 'ax'	No(0)	3026	80%	1020	80%	969	77%	1037	82%
	Yes(A/B/C/ax)	768	20%	250	20%	285	23%	233	18%
3A. Pleural Abnormalities	No	2585	68%	795	59%	868	69%	922	73%
	Yes	1209	32%	475	41%	386	31%	348	27%
3C. Costophrenic angle Obliteration	No	3546	93%	1169	92%	1183	94%	1194	94%
	Yes(right/left)	248	7%	101	8%	71	6%	76	6%
3D. Diffuse Pleural Thickening	No	3620	95%	1199	94%	1201	96%	1220	96%
	Yes(right/left)	174	5%	71	6%	53	4%	50	4%

*Images were obtained for each of the three modalities in 107 subjects and were classified on two separate occasions by 6 B Readers. The number of images assessed for film quality is greater than for subsequent outcomes. For a small number readings image quality was rated 'unreadable' (n=22). These readings provide no data for subsequent outcomes. df = degrees of freedom

Table 3: Adjusted and Unadjusted Comparisons of Prevalence of Outcomes by Image Format (GEE – discrete models)

	Classification comparison	Film versus Hard Copy*	Film versus Soft Copy	Hard versus Soft Copy
1.A: Film Quality (Category 1 v 2,3,&4)	adjusted	0.65 (0.46-0.91)	1.12 (0.84-1.49)	1.72 (1.43-2.08)
	Unadjusted	0.67 (0.49 -0.92)	1.11 (0.85-1.45)	1.66 (1.39-1.96)
1.A: Film Quality (Cat 1&2 v 3&4)	adjusted	0.42 (0.24-0.71)	0.87 (0.50-1.54)	2.10 (1.63-2.70)
	Unadjusted	0.47 (0.31 -0.73)	0.89 (0.56-1.41)	1.87 (1.53-2.30)
2.A: Parenchymal Abnormalities (yes/no)	adjusted	0.72 (0.60-0.86)	0.90 (0.78-1.04)	1.26 (1.09-1.46)
	Unadjusted	0.75 (0.65-0.86)	0.91 (0.80-1.04)	1.22 (1.09-1.35)
2.C: Large Opacities (yes/no)	adjusted	0.83 (0.70-0.99)	1.23 (1.04-1.46)	1.48 (1.24-1.76)
	Unadjusted	0.86 (0.75-0.98)	1.18 (1.03-1.36)	1.38 (1.20-1.58)
2.C: Large Opacities with 'ax' (yes/no)	adjusted	0.79 (0.66-0.94)	1.12 (0.99-1.27)	1.43 (1.22-1.67)
	Unadjusted	0.83 (0.74-0.93)	1.07 (0.98-1.17)	1.29 (1.16-1.44)
3.A: Pleural Abnormalities (yes/no)	adjusted	1.28 (1.08-1.53)	1.59 (1.35-1.88)	1.24 (1.08-1.42)
	Unadjusted	1.30 (1.10-1.53)	1.53 (1.31-1.78)	1.18 (1.04-1.33)
3.C: Costophrenic Angle Obliteration (yes/no)	adjusted	1.41 (0.99-2.00)	1.39 (0.98-1.97)	0.98 (0.80-1.22)
	Unadjusted	1.45 (0.99-2.11)	1.36 (0.93-1.99)	0.94 (0.79-1.12)
3.D: Diffuse Pleural Thickening (yes/no)	adjusted	1.32 (0.97-1.80)	1.43 (1.04-1.98)	1.08 (0.84-1.40)
	Unadjusted	1.35 (0.94-1.95)	1.45 (0.99-2.12)	1.07 (0.84-1.37)

*Estimate of odds ratio (95% confidence interval).

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Acquisition of digital chest images for pneumoconiosis classification: Methods, procedures, and hardware

Ehsan Samei, PhD

Duke Advanced Imaging Laboratories (DAI Labs)
Department of Radiology
Duke University Medical Center, Durham, NC 27705
Phone: 919-684-1440
Fax: 919-684-1491
Email: samei@duke.edu

Introduction

Digital radiography is rapidly replacing analog screen-film radiography in most applications including chest radiography (1). This conversion is fueled by the general trend within the medical community to “go digital,” and the many operational advantages that digital systems can provide when compared to conventional screen-film systems. Those include the ability to manipulate the image post-acquisition, thus giving the physician full flexibility to visualize the features of interest within the image. Furthermore, most digital radiographic sensors offer a markedly wider dynamic range than that of screen-film systems. As such, digital systems can better “tolerate” some level of under- or over-exposure and still provide a clinically-acceptable image; such instances in analog operation leads to overly bright or dark film images of suboptimal quality. Furthermore, digital radiography conveniently provides the image information in digital format, enabling quantification and computer analysis of image features. Finally, a digital image enables electronic archival and distribution, which in turn provide certain economic advantages and enable concurrent access to images across the clinical enterprise. These attributes of digital radiography provide notable advantages of the technology for classification of pneumoconiosis as they enable accessible, standardized image data for visual interpretation or automated classification.

While the advantages noted above are valid and true, they are more reflective of the inherent *potentials* of digital radiography as opposed to its practical reality. Those advantages may only be realized with careful planning, proper implementation, and attention to operational issues unique to the technology. As an example, the flexibility of being able to manipulate the appearance of a digital image post-acquisition is rarely exploited. The actual software tools for post-processing an image are generallyprovided, not at the display workstation used by the physician, but rather at the imaging system console operated by the radiologic technologists. Most images are processed automatically with no intervention even by the technologist. The physician is only provided with the most rudimentary form of image manipulation, window/leveling and zooming. And even with those, the workload and time constraints of clinical practice prevent most physicians from taking full advantage of those functionalities.

The theoretical advantages of digital radiography can in fact become inconsequential or even disadvantages. First of all, if the flexibility of image appearance is not effectively used to provide superior visualization, that advantage is not realized. But more importantly, that flexibility creates a potential for images to be processed in a sub-optimal fashion: In most clinical settings, raw digital images undergo an automated post-processing governed by the post-processing techniques and parameters set by the vendor. There have been only rare studies on the impact of those parameters on diagnostic performance. An image can be presented in multiple different ways by different systems, even by those from the same manufacturer. In this non-standardized and variable form, the images, as presented, are interpreted by physicians. Therefore, unless image quality parameters are optimized and standardized, the flexibility of digital radiography systems can lead to inconsistent image appearance, inconsistent clinical decision-making, and possible misdiagnosis.

Similar examples may also be given for the other two noted advantages of digital radiography. The “tolerance” of digital systems enables technologists to capture higher quality images at increased dose to the patient. That tendency has led to a documented “exposure creep” in digital operations in multiple clinical operations, thus leading to patient over-exposure (2). Similarly, an improper set-up of the Picture Archiving and Communication

Systems (PACS) that enable electronic distribution and archiving of digital images has led to lost studies, inefficient workflows, and increased cost of operation due to uncontrolled printing and rapid turnover of computational equipment.

These examples highlight the fact that the potential advantages of digital radiography should not be considered automatic, or taken for granted. Implementers and users need to pay careful attention to the nuances associated with the features and practical use of digital radiographic systems, and to the way they are incorporated into the workflow of a clinical operation.

Common Aspects of Digital Radiography Systems

Digital radiography is accomplished using a host of differing technologies (Table 1, Figure 1), which are summarized in the subsequent sections. But while digital radiography systems differ from each other substantially, in terms of instrumentation and implementation, they all share certain common characteristics. Some of those characteristics are listed below:

1. Digital radiography systems are implemented similarly to screen-film systems in the way the image sensor is geometrically positioned with respect to the x-ray source and the patient. The only difference is that the sensor is now digital as opposed to analog.
2. X-ray scatter continues to be a prominent and undesirable component of x-ray imaging affecting the quality of digital images, as in analog images. Thus, the techniques traditionally used to reduce scatter in screen-film images, e.g., use of anti-scatter grid and air gap, will be similarly applicable to digital systems.
3. In nearly all digital radiography systems, initially the x-ray energy is captured by an analog (ie, continuous) medium. The capture medium converts the x-ray energy promptly or in a delayed fashion into either charge or visible light, which is then collected and digitized to form the digital image.
4. In all digital systems, the raw image data must be processed to make them suitable for viewing by a physician. Initially, images are corrected for *a priori* non-uniformity of response from the image detector. The

useful, anatomically-relevant range of signals from the sensor is then identified. Common techniques include collimation identification and histogram analysis. The data are then appropriately post-processed (ie, gray-scaled and contrast-enhanced) to provide an acceptable image appearance.

Table 1. Current technologies for digital chest radiography

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Technology	Capture element	Coupling	Sensor
CR	Barium halide	PSL light-guide	PSL signal digitization
CCD or CMOS-based	Gd2O2S or CsI	Lens or fiber-optic taper	CCD or CMOS
Indirect flat-panel	Gd2O2S or CsI	Contact layer	TFT array
Direct flat-panel	a-Se	None	TFT array
Fan-beam	CsI	Fiber-optic taper	CCD
Film digitization	Gd2O2S/film	digitizer	Variable

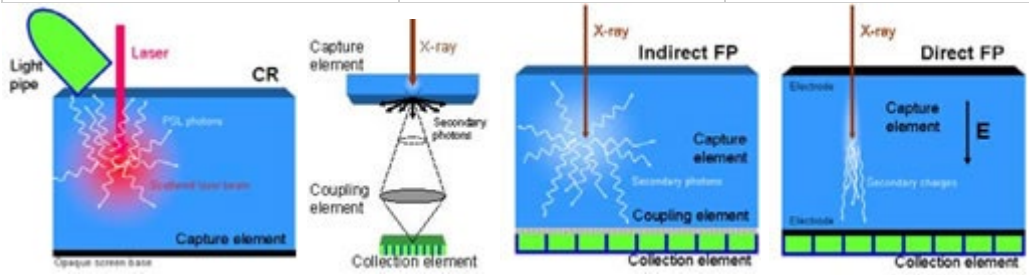

Figure 1. Conceptual schematic of detector components in CR (a), CCD-based (b), indirect flat-panel (c) and direct flat-panel (d) systems (Used by permission from 4. Samei E. Performance of Digital Radiography Detectors: Factors Affecting Sharpness and Noise. In: Advances in Digital Radiography, E Samei (ed). Radiological Society of North America (RSNA) Publication, Categorical Course Syllabus, Oak Brook, IL, 2003, pp. 49-61).

Computed Radiography (CR)

First commercially introduced in 1983, Computed radiography (CR) is the most commonly used digital radiography modality today. There are currently more than 10,000 systems in clinical use worldwide. CR technology is based on certain halide-based phosphor materials having an energy storage and excitation property, known as photostimulable luminance (PSL), which enables them to store x-ray energy temporarily and release that energy upon

excitation by a laser beam at a later time (3). Some common phosphor materials include BaFBr: Eu, and BaF(BrI):Eu. The phosphor particulates are bonded with a cohesive material forming a turbid structure, and deposited on a base for mechanical support.

The phosphor screen is positioned within a cassette not unlike screen-film cassettes. Once exposed to x-ray, a fraction of the x-ray energy is stored by the phosphor screen. After exposure, the cassette is processed by a scanning system which extracts the screen from the cassette, moves it across a scanning laser beam, collects the resulting light signal released by the screen, and digitizes and processes the signals to form the image (Figure 2). The screen is then exposed to a flood of uniform light to erase any residual signals that might have remained on the screen. The erased screen is reinserted back into the cassette for its next use.

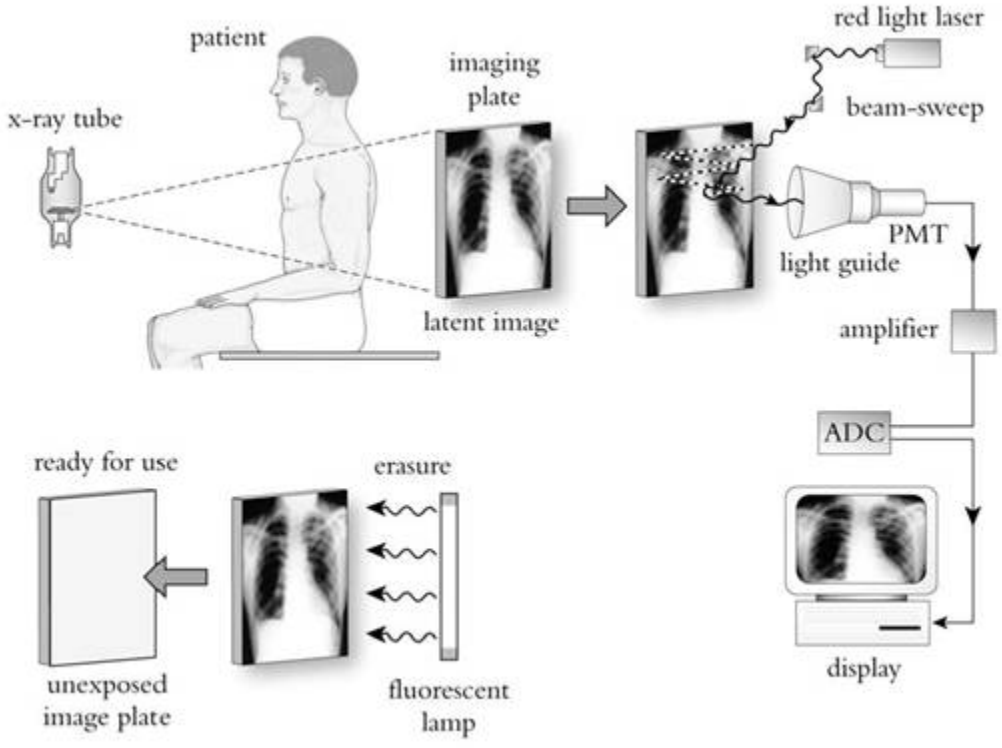

Figure 2. Image formation in CR (used by permission from Zhao W, Andriole K, Samei E. Digital Radiography and Fluoroscopy. In: Advances in Medical Physics 2006, AB Wolbarst, RG Zamenhof, and WR Hendee (eds). Medical Physics Publishing, Madison, WI, 2006, pp. 1-23).

One of clinical advantages of CR is its cassette-based operation. It enables easy retrofitting of existing film-based x-ray equipment and convenient positioning of patients, especially in portable settings. Furthermore, a single scanning system can serve multiple examination rooms, thus providing an added economic advantage. However, CR has historically offered lower image quality than flat-panel-based digital radiography systems. This is primarily due to spreading of the laser beam within the bulk of the turbid phosphor material during the scanning process. The dispersion of the laser energy causes a fundamental loss of image resolution. To keep that loss at clinically acceptable levels, the screen thickness cannot exceed certain limits, thus imposing a cap on the maximum detection efficiency that CR systems can provide.

The common metric by which the image quality of digital radiographic systems is measured is the detective quantum efficiency (DQE). The DQE is a measure of maximum SNR that an image system can provide in response to unit incident exposure. An ideal radiographic system will have a DQE of 100%, implying fully efficient use of incident exposure and the patient dose involved in the image formation. The DQE of CR systems at x-ray energies used for chest radiography is within the 15-25% range.

In recent years, there have been multiple developments in improving the DQE of CR systems. Those include better control of the distribution of the sizes of phosphor particulates in the screen, the use of structured CsBr phosphor to enable thicker phosphor screens without concern about the loss of resolution as in turbid phosphor screens, and the collection of the PSL light from both sides of the phosphor screen (4). These developments have generally led to a more favorable standing of CR among digital radiographic systems in terms of image quality and dose efficiency.

CCD/CMOS-based Systems

The advent of low-cost Charged Couple Device (CCD) and Complementary metal–oxide–semiconductor (CMOS) electronics has enabled their wide-spread use in the digital photography market. Naturally, the earliest developments in digital radiography have tried to take advantage of this technology. The digital radiography systems based on CCD or CMOS

generally employ a phosphor screen (either turbid, made of rare-earth scintillators, or needle-structured, such as cesium iodide – CsI). The screen is optically coupled to the CCD/CMOS sensor via a camera lens system or a fiber-optic coupler (Figure 1b) (1). Upon x-ray exposure, the light generated at the screen is thus captured by the CCD/CMOS sensor and recorded as a digital image, which is then further processed for display.

CCD/CMOS-based systems tend to be less costly than competitive technologies, considering the high volume (and thus lower cost) of CCD/CMOS sensors for the consumer market. However, they have generally lower performance when compared to flat-panel systems. This is primarily due to a poor light collection efficiency; the majority of light photons generated by x-rays at the screen are not collected by the CCD/CMOS sensor due to the fact that the sensor is generally smaller than the screen and the camera system is unable to capture an adequate fraction of light photons released from the phosphor screen. This loss of information is coined "secondary quantum sink" in the scientific literature (5). Newer systems have tried to remedy this issue to some extent, but the performance of these systems still falls short of that of flat-panel systems. The DQE of current CCD/CMOS systems at x-ray energies used for chest radiography is within 15-20% range.

Indirect Flat-Panel Systems

The inefficiency of light collection in CCD-based systems was a motivation to replace the light sensor with a sensor large enough to be directly coupled with the phosphor screen. In doing so, the light collection efficiency can be dramatically enhanced leading to improved image quality. The advent of digital flat-panel displays provided the technological foundation to enable that goal.

Indirect flat-panel detectors use a phosphor screen similar to that used in CCD/CMOS-based systems. Structured thallium-doped CsI is commonly used. The screen is directly coupled to a flat-panel sensor. The sensor is made of a thin-film transistor (TFT)/photodiode amorphous silicone array deposited on a sheet of glass (Figure 3) (6). Each transistor serves as a separate light sensor collecting the light photons and converting them to charge. The

charge deposited in pixel circuits is read line by line through the gate and data lines. The data are then corrected for panel non-uniformities and bad pixels and processed for display.

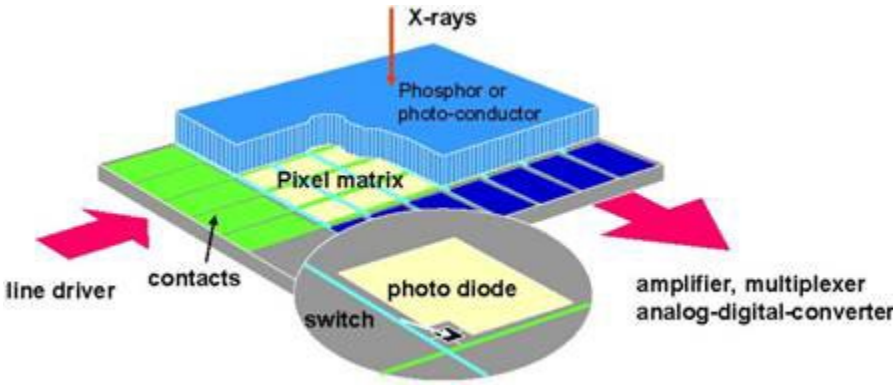

Figure 3. Schematic of a flat-panel detector.

As a phosphor-based imaging system, indirect flat-panel detectors have resolution properties similar to other phosphor-based systems (eg, CR, CCD/CMOS-based systems). Thicker phosphor layers enable better x-ray detection efficiency at the expense of lower resolution. The use of structured phosphor, such as CsI, however, provides a more favorable balance between resolution and detection efficiency, enabling improved DQE at comparable resolution to turbid-phosphor-based systems (Figure 4). The DQE of current systems at x-ray energies used for chest radiography is within 45-55% range for indirect detectors with CsI and about half of that for those with turbid phosphor.

Advancement in the development of indirect flat panel systems of improved quality have focused on the use of phosphors of higher efficiency and light yield, reducing the inherent fill factors of the pixels defining the useful real estate of the pixel area, an improved noise performance of the TFT array.

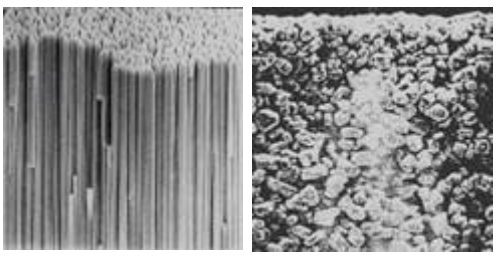

Figure 4. Structured (a) and turbid (b) phosphor.

Direct Flat-panel Systems

Direct flat-panel systems deploy a technology very similar to that of their indirect counterparts (Figure 1d, Figure 3). A direct flat-panel detector uses a TFT matrix array very similar to that used for the other detector type, thus the common “flat-panel” designation. However, the capture medium, instead of a phosphor, is a photo-conductor. Current detectors typically employ amorphous selenium for that purpose. The x-ray photons can be captured by the photo conductor layer and their energy is directly converted to charge with no intermediary light conversion stage. With a high voltage electric field applied across the capture layer, the generated charge is directed towards electrodes and eventually deposited in the capacitors associated with the pixels. The pixel charge is then read line by line through the gate and data lines. The data are then corrected for panel non-uniformities and bad pixels and processed for display.

An advantage of direct flat-panel detectors is that the collected charges do not disperse laterally in the bulk of the capture medium. This is in stark contrast to phosphor-based detectors for which the lateral dispersion of light limits their resolution and thus in turn their detection efficiency. Consequently, direct detectors offer near perfect sharpness. However, the “cost” of this sharpness is the artifactual enhancement of radiographic noise that is no longer blurred by the limited resolution of the detector. This enhancement, known as noise aliasing, limits the DQE of direct systems (6). Current direct flat-panel systems offer high resolution and DQE in the 20-30% range for x-ray energies applicable to chest radiography.

Fan-beam Radiography Systems

As noted earlier, scattered radiation is an ever-present source of image quality degradation in x-ray imaging. The common solutions to reducing that influence involve the use of anti-scatter grid and air gap. However, the former leads to increased patient dose due to attenuation of the primary beam, and the latter necessitates the use of smaller focal spots and larger detectors to provide adequate coverage of the anatomy of interest. An alternative approach involves the use of a fan beam (as opposed to a cone

beam) to acquire the image. This approach does not have the disadvantages associated with alternative techniques.

Fan-beam imaging can be undertaken with any type of imaging sensor listed above with certain hardware and software modifications. The current commercial offering uses a CsI-capture element optically coupled to a CCD sensor to capture the image from a moving fan beam (Figure 5) (7). The modulation transfer function and resolution are comparable to other phosphor-based systems, and system DQE ranges from 15-20% range for chest x-ray beams. However, the imaging geometry cuts the scatter fraction by 2-3 times compared to alternative cone-beam geometry, leading to a significant enhancement of eDQE and the image quality per unit incident exposure (7).

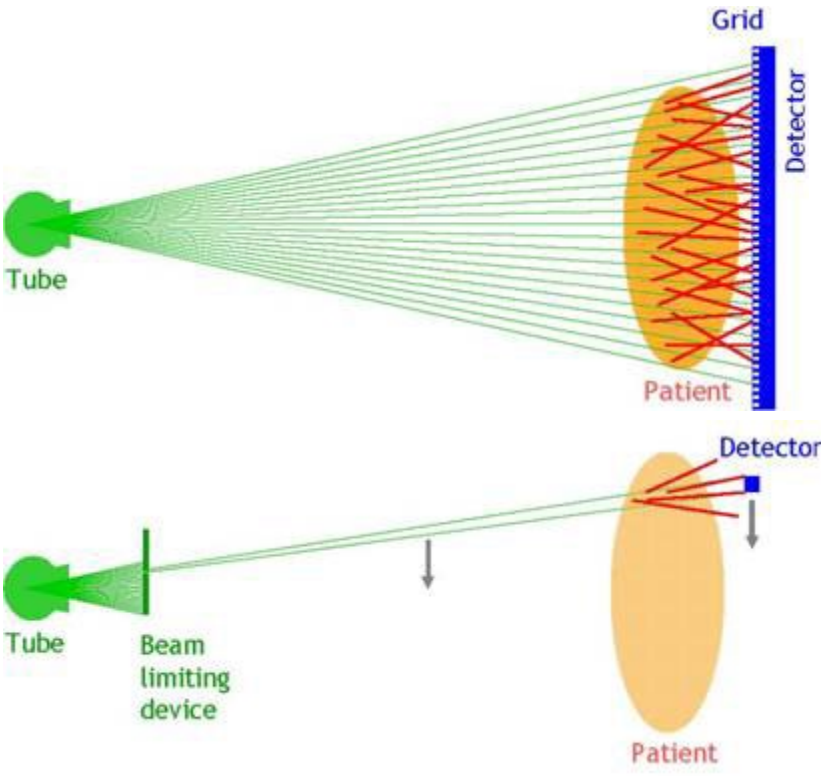

Figure 5. Cone-beam radiography (a) versus fan-beam radiography (b).

Digital Radiography via Digitization

The imaging systems noted above all utilize an electronic sensor to capture the image. However, it is also possible to obtain a digital image by digitizing

the analog screen film. That can provide a digital representation of the analog image, which can be used for electronic archival, transmission, and display.

While this approach for digital radiography has merits in enabling integration of prior analog images or those from other facilities with an existing digital operation, it has certain important shortcomings. These include loss of image quality in the digitization process, inconsistent image appearance from film to film due to variations in exposure levels or film/screen type, and sub-optimal display of the images which are optimally gray-scaled for viewing on a view-box as opposed to an electronic display. Because of these reasons, this mode of digital radiography is considered sub-optimal and supplemental at best.

Conclusions and Recommendations

Digital radiography offers distinct advantages in comparison to analog screen-film radiography. Current commercial offerings represent a host of differing technologies with different image quality attributes. As such, the current initiative needs address the similarities and differences among the diverse available systems. These similarities and differences must be taken into consideration when comparing images that might be generated by different technologies. Furthermore, considering the diversity of technologies and implementations as well as the added complexity of operational variability, it is equally important to ensure that the systems are utilized under controlled unifying conditions. Those should include the use of standardized image acquisition and processing protocols, and robust quality control and preventative maintenance programs. Proper operation should be further ensured through an accreditation program.

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Assuring image quality for classification of digital chest radiographs

Ehsan Samei, PhD
Carl E Ravin, MD

Duke Advanced Imaging Laboratories (DAI Labs)
Department of Radiology
Duke University Medical Center, Durham, NC 27705
Phone: 919-684-1440
Fax: 919-684-1491
Email: samei@duke.edu

Introduction

Digital radiography (DR) offers notable advantages when compared to its film-screen counterpart. As noted in an earlier paper in these proceedings, attributes of DR include a wide dynamic range during image acquisition, the ability to post-process the images, electronic archival and distribution, and the potential for automated analysis and quantification of data. These characteristics provide unique benefits for the identification and classification of pneumoconiosis. However, they may only be realized with proper implementation and utilization of the technology. As such, quality assurance is an integral part of a digital radiography operation.

Quality assurance (QA) and quality control (QC) are not new concepts in medical imaging. However, when utilizing digital radiography, and particularly when there is interest in the extraction of quantitative information from images, QA and QC become essential. Two key attributes of digital radiography are the “fluidity” of image quality, and the ability to quantify image information. The potential to maximize the advantages of these two apparently contradictory attributes makes approaches to the quality of digital radiography unique. For example, a digital image can take on any number of appearances depending on the post-processing technique applied. However, the classification of disease in quantitative terms using digital images makes it essential that the images are processed in a

predictable standardized fashion. Furthermore, if the classification of disease relies, at least in part, on automated analysis, the format, exposure dependency, and attributes of the image must be consistent, so that quantification can be performed with accuracy and precision. A rigorous quality control program is needed to enable optimum implementation of digital radiography.

In this paper, we outline the quantitative metrics of image quality, the elements of quality control for DR, and finally suggest requirements for classification of pneumoconiosis using either visual or automated approaches.

Quantitative Metrics of Image Quality

Imaging performance using digital radiography systems is based on attention to three fundamental aspects of image quality: resolution, noise, and signal-to-noise ratio. Quality control methods generally correspond to these three aspects.

Resolution: The resolution of a medical imaging system refers to the ability of the system to represent distinct anatomical features within the object being imaged. The resolution of an imaging system is best characterized in terms of its modulation transfer function (MTF), a measure of the ability of the system to reproduce image contrast from subject contrast at various spatial frequencies, or levels of detail (Figure 1) (1). Most radiographic systems are able to render lower frequencies (i.e., coarser detail) better than the higher frequencies (i.e., finer detail), leading to a loss of image sharpness. The MTF is a plot of the ratio of the output-to-input modulations as a function of their spatial frequency. The higher the MTF, the better the sharpness and resolution of an image, as illustrated in Figure 2.

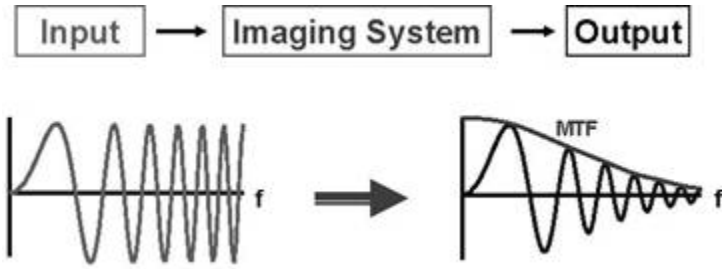

Figure 1, Schematic of the MTF representing the resolution attributes of a digital radiographic system.

The resolution properties of digital radiographic systems can be ascertained by measuring the blurriness of images obtained from sharp objects. Extensive experimental methods have been developed for the assessment of the MTF of digital radiographic systems from such test objects (2-4).

Noise: Noise, in the context of quality control, refers to superfluous variations within an image that do not originate within the imaged subject, and that interfere with the visualization of an anatomic abnormality of interest, and thus with the interpretation of the image. While often quantified in terms of variance or standard deviation, radiographic noise is best characterized by the noise power spectrum (NPS) (Figures 3-4). The NPS defines the magnitude of noise within an image associated with specific spatial frequencies (i.e., levels of coarseness) of the noise (5, 6). The integral of the NPS is equal to the noise variance.

Inherent fluctuations associated with acquisition of a digital radiograph are best revealed when viewing a uniform image with no object in the field of view. Broad, large-scale variation in such an image is conventionally characterized as non-uniformity, while finer-scale fluctuations are characterized as noise. Similar to MTF, extensive experimental methods have been developed to measure the NPS of digital radiographic systems from such uniform images (7-9).

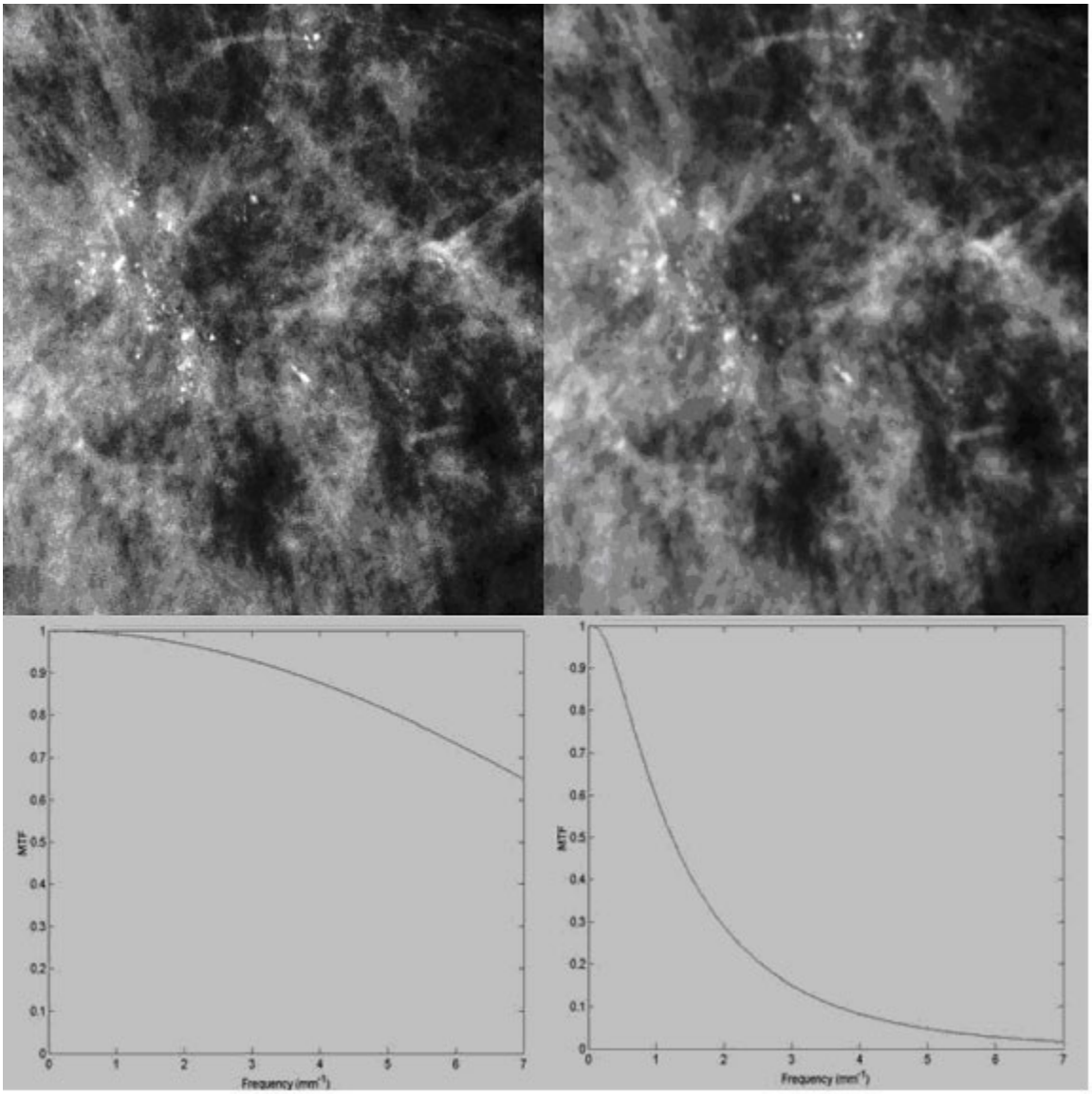

Figure 2, High MTF (left) and low MTF (right) reflecting the resolution properties of a magnified image.

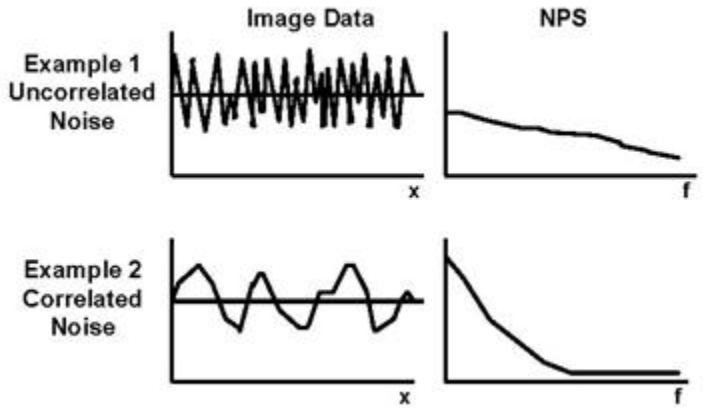

Figure 3, Schematic of the NPS (one-dimensionally) representing the noise attributes of a digital radiographic system.

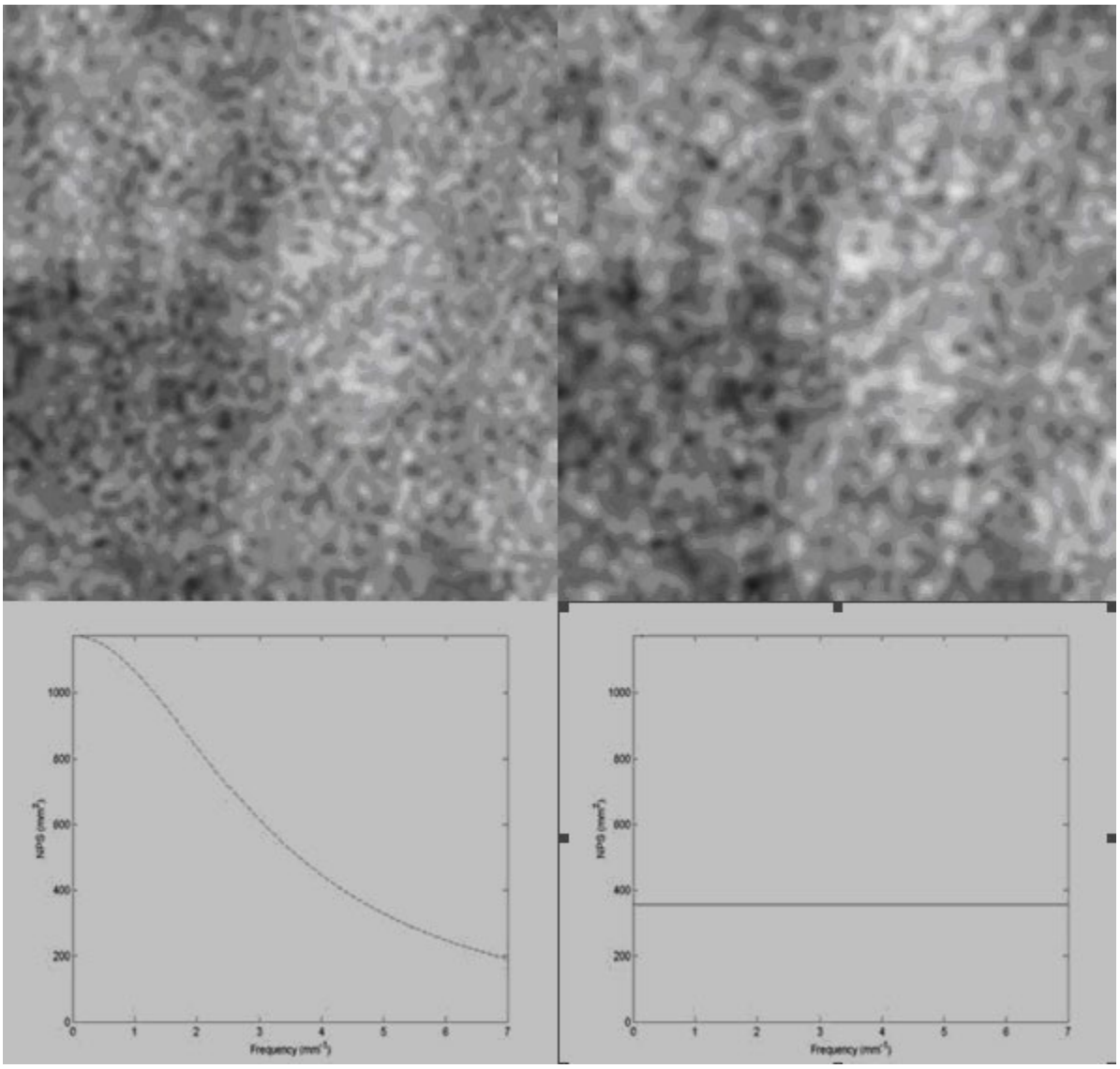

Figure 4, Correlated NPS (a) and uncorrelated NPS (b) reflecting the noise texture properties of a magnified image.

Signal-to-Noise Ratio: Resolution, described in terms of the MTF, reflects the ability of the imaging system to represent signal (i.e., contrast) within the image. Noise or the NPS, on the other hand, reflects the noise aspect of system performance. Image quality, in terms of the ability to see pathology of interest within an image, depends on a combination of these attributes in the form of the signal-to-noise ratio (SNR). Pioneering work by Albert Rose has demonstrated that (SNR)2 is inversely proportional to the image

contrast, determines and the diameter of objects that can be reliably detected in radiographic images (10). Images with higher SNR can render objects of lower contrast and smaller diameter.

Due to detector inefficiencies, non-x-ray-quanta sources of noise, and added blur in image formation, the magnitude of the SNR within a radiographic image is always less than that dictated by the incident exposure, even if all the x-ray quanta were to be most efficiently used to form the image. The ratio of actual SNR2 to ideal SNR2, known as the detective quantum efficiency (DQE), is a metric commonly used to characterize the intrinsic SNR performance of a digital radiographic detector (3, 11). Its value is always less than ideal unity, i.e., 100%.

The formulation and measurement of the DQE does not take into account the influence of the focal spot blur, magnification, scattered radiation, and anti-scatter grid on the SNR obtainable from a digital radiographic system. A recent extension of the concept of the *detector* DQE to *system* DQE, known as effective DQE (eDQE), has further included those factors so as to quantify the actual SNR obtainable from a digital radiographic system (12-14). The higher the DQE or eDQE values, the better the SNR characteristics of the detector or the system, respectively.

Quality Control of Digital Radiography Systems

To assure reliable performance and reproducible results from a digital radiographic system, the system needs to be properly installed, maintained, and monitored through a quality control program. A proper QC program consists of a number of key components.

Acceptance testing: Upon installation and prior to clinical use, a digital radiographic system needs to undergo an acceptance testing procedure. Such an undertaking insures that the device is capable of delivering the basic expected safety and performance requirements, which ideally are outlined in the purchase contract. It provides the basic performance attributes of the system in terms of resolution, noise, and SNR, necessary to enable the extraction of quantitative image features from images. Acceptance testing

also establishes the baseline performance characteristics as a starting point for subsequent periodic quality control tests.

Key aspects of the system performance to be included in acceptance testing are the MTF, the NPS, the DQE, scatter fraction, and, ideally, the eDQE at exposure levels representing those the system is designed to utilize. The knowledge of these inherent quantitative metrics is required to assure optimum appearance and accurate classification of the image. Other aspects of acceptance testing include the assessment of image artifacts, image non-uniformities, system linearity, noise in the absence of image signal (i.e., dark noise), visual high- and low-contrast imaging performance, accuracy of exposure indicator, and throughput (15) (Table 1).

System calibration: Digital radiographic systems are susceptible to systematic image non-uniformities due to inherent non-linearities of sensors. Such artifacts are generally corrected by a calibration procedure. Depending on the system specification, for some systems, this calibration needs to be performed on a daily basis at the outset of the clinical use for the day, while for others it needs to be done every few months.

Preventative maintenance: Any imaging device used clinically needs to undergo routine preventative maintenance to reduce the likelihood of down-time and performance degradation over time. This function is usually performance by service engineers contracted by the manufacturer's service providers.

Periodic assessments: The performance of a digital radiographic system is prone to degradation over time. As such, it is important to track the system performance over time to ensure patient dose is within acceptable limits, and image quality is maintained. This objective is best achieved by initiating a periodic assessment program through which the basic performance aspects of the system are regularly tested and benchmarked against the results of acceptance testing and prior system QC tests. Testing should include resolution, noise, and artifact aspects of the system performance as listed above. The QC program needs to include established quantitative acceptance criteria to determine whether a given result meets expectations. Failures should prompt corrective actions before the device is put back into service.

Table 1. Performance attributes of a digital radiographic system

Metric	Performance attribute
MTF	Resolution properties of the image/detector/system
NPS	Noise properties of the image/detector/system
DQE	SNR transfer properties of the detector
eDQE	SNR transfer properties of the system
Dark noise	Noise in the absence of signal
Uniformity	Signal uniformity in the absence of an object
Exposure Indicator	Accuracy of exposure indication by the system
Linearity	Exposure response behavior of the system
High-contrast resolution	Ability of the system to represent high-contrast patterns
Low-contrast resolution	Ability of the system to represent low-contrast patterns
Distortion	Geometrical accuracy of images
Artifact	Non-uniform features in the images not reflecting features of the object being imaged
Ghosting	Appearance of shadows of prior images on subsequent images
Throughput	Speed by which a system can sequentially capture images.
Normal exposure	The target exposure values for clinical use of a system reflecting the system speed

While periodic assessment is an important aspect of a quality digital imaging operation, it is equally important that it is executed in an efficient manner. In that regard, it is important for the program to focus less on aspects of the performance that are proven to be stable over time. Furthermore, the results should be placed in a database that can be readily queried and conveniently interrogated by the responsible parties for assessing performance trends over time.

Requirements for Classification of Pneumoconiosis

Digital radiography provides an unprecedented opportunity to provide a standardized classification of pneumoconiosis. It can do so through its quantitative nature and its tractable performance characteristics. However, this is only possible if those attributes are properly utilized. As such, a robust classification of pneumoconiosis would have the following prerequisites:

1. The performance of the digital imaging system should be maintained and monitored through robust preventative maintenance and quality control programs.
2. A standardized image acquisition protocol is necessary. The protocol should specify the kVp and filtration settings, and exposure levels to achieve certain target SNR levels within the image. The latter can be prescribed based on the measured eDQE performance of the system.
3. An index of the exposure level used to form the image (i.e., an exposure indicator) should be provided with values reported in a consistent fashion across systems from different manufacturers.
4. The image data from the system needs to be available in a raw, "**For Processing**" format. In this manner, the data can be processed to permit consistent visualization, or analyzed for automated quantification of pneumoconiosis.
5. The image data needs to be processed in a consistent, pre-defined manner, so that image appearance can be consistent across cases, hardware, software, and systems.
6. The image data needs to be displayed in a consistent fashion using the expected performance requirements for electronic medical displays (16)

7. Both raw and processed image data should be archived electronically for further assessment or analysis.

Provided that the minimum requirements outlined above are met, digital chest radiographs can be used for visual classification of pneumoconiosis, as images will provide a consistent appearance of the disease.

The digital image data can further be used in a computer-assisted classification algorithm to automatically or semi-automatically classify the extent of the disease. The analysis can be based on image features of segmented lesions such as contrast, size, and texture. Such an algorithm will need to operate on raw image data and will use the inherent image quality characteristics of the imaging system (MTF and noise) in order to “normalize” for those attributes.

Conclusions and Recommendations

Quality control is an essential component of a digital radiography operation, especially when the images are to be used for classification and quantification purposes. Key components of a quality control program include acceptance testing, system calibration, preventative maintenance, and periodic assessments. A robust QC program along with standardized acquisition and processing protocols would enable visual as well as automated classification of pneumoconiosis from digital chest radiographs.

To ensure robustness and integrity of digital image data and to enable a reliable classification scheme, the following are strongly recommended:

1. QC program: All NIOSH affiliated facilities should enact and maintain rigorous PM and QC programs as outlined above.
2. Protocols: All NIOSH affiliated facilities should follow predefined acquisition and processing protocols.
3. Web server: NIOSH should consider a central web server for affiliated facilities.
4. Communication: Using NIOSH’s server, all NIOSH affiliated facilities should register their imaging devices including uploading their inherent performance metrics. All raw, “for-processing” image data will also be

uploaded. The data will be consistently processed and analyzed for visual or automated classification.

5. Accreditation: NIOSH should consider a process by which it could accredit affiliated facilities to ensure adherence to its minimum performance and operational requirements.

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CR and FPD DR chest radiographic image parameters for the pneumoconioses: the Japanese approach and experience

Narufumi Suganuma MD PhD (Department of Environmental Medicine, Kochi Medical School, 783-8505 JAPAN)
Kiyoshi Murata MD PhD (Department of Radiology, Shiga Medical School)
Yukinori Kusaka MD PhD (Department of Environmental Health, University of Fukui School of Medicine)

Email: nsuganuma@kochi-u.ac.jp

Summary

Recently the Ministry of Health, Welfare and Labour, Japan (MHWL-J) has approved the flat-panel detector (FPD) Digital Radiography (DR) for its use in the legal medical judgment of pneumoconiosis. Computed radiography, requiring an imaging plate, has been already approved for the purpose since 2001. The pre-storage parameters for gray scale processing and spatial frequency processing are critical to the visualization of the image, more than the post-storage parameters, like window level and width. In this paper, we describe the approach that the Pneumoconiosis Taskforce for the MHWL-J has taken to decide the appropriate imaging parameters of FPD DR for the medical judgment of the presence of pneumoconiotic opacities as demanded by the Pneumoconiosis Law in Japan. In order to obtain comparable images, pre-storage processing considerably affects image, and storage using P-values as stated in DICOM part 14 is strongly recommended.

Introduction

Digital alternatives in radiography, both computed radiography (CR) and digital radiography (DR), have been well accepted in clinical use. Their benefits include easy handling, less chemical waste, less space for storage, and better latitude compared to the conventional film-screen (FS) radiography and they have almost replaced the FS radiography in the most of the big hospitals in Japan. The increasing use of Picture Archiving and

Communication Systems (PACS) in such hospitals prompted the trend toward digitization of radiography.

This trend has influenced the medical screening of pneumoconioses and corresponding legal judgments, which directly affect compensation of the patient. The Pneumoconiosis Law (1) in Japan demands that workers exposed to dust take medical examinations including chest radiographs. Each radiograph is reviewed by a physician according to the Japan Classification of Radiographs of Pneumoconiosis (2), which is almost parallel to the ILO International Classification of Radiographs of the Pneumoconioses (ILO/ICRP) (3, 4).

Recently the Ministry of Health, Welfare and Labour, Japan (MHWL-J) has approved the flat-panel detector (FPD) DR for its use in the legal medical judgment of pneumoconiosis (5). The other type of digital radiographic techniques, the CR that needs the storage phosphor, *i.e.* the imaging plate (IP), has been approved since 2001 (6). Because images from CR are somewhat dissimilar from FS radiographs, the MHWL-J had selected a number of typical case sets to supplement the Japan Pneumoconiosis Standard Radiographs. However, it is a complex task to introduce new technology that can be substituted for conventional FS radiographs. The Pneumoconiosis Law uses the scale from the radiographic judgment to categorize dust-exposed workers, and these categories determine whether or not compensation is applicable. Thus, revision of this law has been a socially sensitive issue. The taskforce was required to assure that the new modality provides similar results to the previous approach in categorizing pneumoconiotic opacities.

This article aims to describe the approach taken by the FPD DR Taskforce to determine the appropriate imaging parameters for FPD DR for the medical judgment of the presence and amount of pneumoconiotic opacities, as demanded by the Pneumoconiosis Law in Japan. Our approach has been, firstly, to decide the appropriate FPD DR parameters for the judgment of pneumoconiosis, and secondly to assess the appropriateness of the parameter through a reading trial using the proposed parameters. For the former purpose we took Canon CXDI as an example and made a thorough investigation on its imaging parameters. After we had decided the

appropriate imaging parameters, we performed a reading trial comparing FS radiographs and hard copies of FPD DR images. The approach was similar to that taken in deciding required parameters for CR, leading to approval of CR for pneumoconiosis judgments in 2001. As there are multiple venders producing the FPD DR systems, the taskforce demanded that venders submit typical pneumoconiosis images taken by their systems. Specific parameters that correspond to the taskforce recommendations were sought. The taskforce also decided upon a process to approve the new apparatus for the legal medical judgment of pneumoconioses.

I. Evaluation of appropriate FPD DR parameters for judging the grade of pneumoconiosis using Canon FPD DR system

As full technical support from engineers was available from Canon, Inc. as well as Canon has the leading share of the FPD DR market in Japan, the CXDI (Canon, Inc., Tokyo) was chosen as the product to fully assess its imaging parameters. All the FPD DR images and FS radiographs were obtained after receiving written informed consent from the subjects in the hospitals that had collaborated in this study. As new cases of pneumoconioses are not abundant in Japan, most of the cases were from the two major institutes that had operated an FPD DR system for a number of years.

In order to decide the appropriate parameters, four typical cases of silicosis were selected from the FPD DR case archives, each representing the mid-category of profusion 0, 1, 2, and 3. Imaging parameters concerning the gray scale processing and the spatial frequency processing were changed one by one to assess the difference caused by the parameter modification. The taskforce for CR approval had taken a similar approach to assess the comparability of FS chest radiographs and CR hard copies. The middle column of the Table 1 shows appropriate ranges for the gray-scale and spatial frequency processing that was recommended by the MHWL-J taskforce for CR approval in the legal medical judgment of pneumoconiosis in 2001 (6). The comparable imaging parameters for each vender of the CR and CXDI (Canon, Inc., Tokyo) are listed in Table 2. The FPD DR Taskforce performed the group-review using five experienced physicians, changing the parameters one by one for all the four cases. Table 3 compares the two parameter sets: one was recommended by the vender that keeps the image

within the CR Taskforce guideline and the other was approved by the FPD DR Taskforce after group-reviews of the images printed using various parameters.

Five experienced physicians, who were either radiologists or pulmonologists and served as regional or central Pneumoconiosis Examination Physicians appointed by the MHWL-J, reviewed hard copies of FPD DR images processed with various parameters, and provided a consensus decision regarding whether the image was appropriate for pneumoconiosis judgment or not. After the group readings, the taskforce decided to recommend the use of Enhancement, a parameter for the spatial frequency processing, only at a level less than 2 for the CXDI system.

Table 1 Appropriate imaging parameters for gray-scale and spatial frequency processing recommended by the CR Taskforce in 2001 and the FPD DR Taskforce in 2007

	CR-TF Recommendation	DR-TF Recommendation
Gray- scale (gradation) processing Lung field	1.6 – 2.0	1.6 – 2.0
Gray- scale (gradation) processing Mediastinum, heart	0.15 – 0.25	not defined
Spatial frequency processing High frequency (> 0.2 cycle/mm) Low frequency (0 cycle/mm)	1.0 – 1.2	OFF*

Note: CR-TF is the CR Taskforce, while **DR-TF is the FPD DR Taskforce. *Spatial frequency processing** was recommended to be basically OFF for the any FPD, except CXDI (Canon, Inc.). The range recommended by the CR Taskforce is equivalent to Enhancement 0-4 for CXDI as in the Vender's recommendation in Table 3. The FPD DR Taskforce accepted the Enhancement 0 and 1 for CXDI after the group review (See Table 3).

Table 2 Corresponding parameters of image processing: CR and CXDI

Table 2 Corresponding parameters of image processing: CR and CXDI

	CR – Fuji	CR – Konica	CR – Kodak	DR Canon (CXDI)
Gray-scale Processing	GA	G value	Contrast Factor	Contrast
	GC		Upper Contrast	
			Lower Contrast	
	GS	Lung density	Density Shift	Brightness
			Shoulder Shift	
			Toe Shift	
	GT	LUT		Curve shape
Spatial frequency processing	RN	Mask size	Matrix size	Frequency
	RE	Emphasized degree	High Density Boost	Enhancement
			Low Density Boost	

Note: The parameters for the multi-frequency processing are not included in this table.

Table 3 Appropriate imaging parameter for legal medical judgment of pneumoconiosis for CXDI (Canon, Inc., Tokyo)

	Vender's Recommendation	DR-TF Recommendation
Contrast	14 – 17	14 – 17
Brightness	17 – 20	17 – 20
Curve shape	Chest	Chest
Frequency	7	7
Enhancement	0 – 4	0 – 1

Note: See also the Note for **Table 1.**

II. Comparison of judgment of the grade of pneumoconiosis between film-screen system and Canon FPD DR system in the same patient

Using the parameters recommended by the FPD DR Taskforce, we have performed reading trials by the same five physicians who participated in the previous parameter study. In this study, we aimed to assess the consistency of classifications of profusion for hard copy radiographs from FPD DR compared to FS.

Methods

The FPD DR Taskforce compared the hard copy of the FPD DR against the film-screen radiograph of the same patient and chose FPD DR processing parameters that appeared to produce an image most similar to the FS radiograph. We have identified 35 cases with a pair of hard copy FPD DR and FS radiographs from the Occupational Safety and Health Compensation Hospitals (Rosai Hospitals) and other academic groups with an interest in the pneumoconioses (Fukui University Hospital and NHO-Kinki Chuo Chest Medical Center). Five readers who serve as the regional or central Pneumoconiosis Examination Physicians independently classified these 35 pairs of FPD DR hard copy and FS radiographs, applying a 4 point profusion scale (0, 1, 2, and 3) according to the Japan Classification, which is almost parallel to the ILO/ICRP.

Crude agreement and Cohen's κ statistics were used to assess the consistency between the classification results within the reader (intra-reader agreement), or between the readers (inter-reader agreement). Altman's criteria for the κ statistics interpretation was used to decide the agreement: poor <0.2, fair 0.21-0.40, moderate 0.41-0.60, good 0.61-0.80, and very good >0.81 (7).

Results

The median reading results of five readers' trial on the 35 pairs of the FPD DR hard copy and the FS radiograph were summarized in Table 4 and 5. Accumulation of 5 readers' individual reading results of 35 pairs showed crude agreement of 78.9% (138/175 readings) as well as 15.4% (27/175) DR's over-reading and 5.7% (10/175) DR's under-reading compared to FS radiograph (Table 4). Crude agreement between median profusion of FPD DR and FS radiograph as shown in Table 5 was 82.86% and its κ statistics was 0.74 (Std. Error 0.1078). The intra-reader agreement was good (κ = 0.6975; range: 0.4909-0.7886). The inter-reader agreement was also good as the average κ value between FS radiograph and FPD DR was 0.6072 and 0.6968, respectively. From the results of this study, the capability of FPD DR in judging the profusion category of pneumoconiosis is similar to FS chest radiography.

Table 4 Comparison of the profusion between FS and FPD DR chest radiography in 175 accumulated cases (5 readers, 35 patients)

FS – DR	Number of cases	FS>DR (Difference of the Profusion)	FS<DR (Difference of the Profusion)	FS=DR (Difference of the Profusion)
0 – 0	45			45
0 – 1	11		11	
1 – 0	3	3		
1 – 1	63			63
1 – 2	8		8	
2 – 1	3	3		
2 – 2	22			22
2 – 3	8		8	
3 – 2	4	4		
3 – 3	8			8
Total (%)	175 (100)	10 (5.7)	27 (15.4)	138 (78.9)

Table 5 Summary of the median profusion of five readers: FS vs DR

FS	0	1	2 DR	3	Total
0	9	3	0	0	12
1	0	14	1	0	15
2	0	0	4	1	5
3	0	0	1	2	3
Total	9	17	6	3	35

III. Evaluation of appropriate FPD DR parameters in other FPD DR systems

The taskforce is aware that FPD DR systems produced by Philips, Siemens, GE, Toshiba, Hitachi, and Shimazu are available in Japan. Each of these venders was asked to submit a few typical pneumoconiosis cases for the evaluation by the FPD DR Taskforce. Various sets of parameter modifications were assessed by the same manner described above for the CXDI. After the evaluation in section II, the taskforce concluded that spatial frequency processing should be off for pneumoconioses screening radiographs. The multi-frequency processing that enable differential processing at the areas with high and low frequencies was also not allowed for the judgment of

presence of pneumoconiotic opacities. The FPD DR Taskforce's recommendation was revised and is shown in the right in Table 1 . Also the gray-scale processing of the mediastinum was omitted, in contrast to the previous CR recommendations.

Table 6 Applicable imaging parameters for each vender to match the recommendation by the FPD DR Taskforce for MHWL-J in 2007

Canon	E	* or 1
	D	*****
	Brightness	17 – 20
	Contrast	14 – 17
Philips	Density (D)	15 – 17
	Gamma (G)	10 – 45
	NC (N)	00 – 03
	DCE	0.0
Siemens	SF	0/***
	H	0/***
	LUT	8
	W	2300 – 3300
	C	1900 – 2300
GE	Contrast (C)	119 – 130
	Brightness (B)	152 – 157
	Edge (E)	1
Toshiba	WL	1800 – 2400
	WW	1200 – 2800
	G	7
	E	0
	D	0
	I	0

Hitachi	Filter	0 – 3
	Mask Size	5
	DRC	0
	Gamma (γ)	3
	WL	2100
	WW	3850
Shimazu	W	11500 – 12500
	L	6000 -06500
	E	0

Note *, *****, *** are off.

As stated in the note of the table, the taskforce reviewed CXDI hardcopies and accepted the use of Enhancement, a parameter for the spatial frequency processing, up to 1, while the CR Taskforce recommendation was equivalent to the CXDI's Enhancement up to 4, as shown in the vender's recommendation in Table 3. For the other FPD DR venders, the taskforce only reviewed hardcopies produced with Spatial Frequency Processing OFF, and the images were considered acceptable. The sharpness of the opacity edges may to a great extent be affected by Enhancement, but other factors like the distance between the subject and the film-screen or the flat-panel detector may also affect the sharpness of the images.

In order to perform a group review, the taskforce requested the venders to submit hardcopies produced according to the recommendation shown in Table 1 . Table 6 summarizes the parameter set for the each vender which is compatible with the FPD DR Taskforce's recommendation for the processing of FPD DR. The contrast, the density, and the edge enhancement seem to be comparable parameters for the majority of the venders, although there is no detailed explanation. Some of the venders include window width and level, while the others do not.

Discussion

For most physicians who use images from CR or FPD DR systems in clinical practice, there is little importance attached to ensuring strict comparability to FS radiographs, and the present study may have little impact on their practice. The laser-printed hard copies or digital images viewed on medical

display monitors are produced routinely according to pre-selected processing parameters recommended by the system vender or by the hospital's chief radiologist; image processing is a 'black box' to most physicians. Because of limited storage media, PACS often only retain the processed and compressed **For Presentation** data needed for displaying the images. After compression, any pre-storage modified parameters for the gray scale processing and the spatial frequency processing cannot be restored. It is not the window level or width of the stored image but the pre-storage parameter settings that are critical to the visualization of the appropriate image.

Therefore, the images stored on PACS are usually different from the raw **For Processing** data and modification based upon the original image data may not be possible. DICOM Part 14 is the latest standard adopted to ensure compatibility of the image data for medical display monitors or medical laser printers. The DICOM Part 14 provides a standardized format for gray scale display, and requires P-values, *i.e.* the pixel value after all DICOM defined gray scale transformations have been applied (8). Such a standardized format for gray scale will be a minimum requirement for future data collections for pneumoconiosis applications. Certain DICOM formatted CR images cannot be properly visualized on high-resolution medical monitors, due to the inability to apply DICOM Part 14. For research purposes, image data should be obtained as raw, modifiable, **For Processing** data, and stored uncompressed or using lossless compression. Such data formats may not be available without the venders' assistance. It may not be practical at this time to require that all CR or FPD DR data be stored as raw **For Processing** data, but it is essential to demand that all the digital radiograph data be stored using P-values as defined in DICOM Part 14.

DICOM Part 14 guarantees the standardization of gray scale, but it does not guarantee the standardization of other parameters such as spatial frequency processing, multi-frequency processing, and dynamic range control. The multi-frequency processing enables differential processing in areas with higher and lower frequencies. The dynamic range control is a pre-storage processing that permits viewing detail behind the heart and diaphragm shadows, while retaining the gray-scale and detail of the lung fields; it may be useful for other clinical purposes but is not permitted for the legal medical

judgment of pneumoconiosis in Japan. These parameters were designed for better visualization of FPD DR images, and may enable demonstration of certain pathologic lesions more clearly, but standardization of those parameters has not been achieved yet.

Film-based hard copies of FPD DR were evaluated concerning the appropriate image processing parameters and the consistency of pneumoconiosis classification results, in comparison to conventional FS radiographs. When the recommended parameters were applied, hard copies of FPD DR were judged similar to FS in brightness and gray-scale contrast. The authors have recently reported a similar study, which included comparisons with both FPD DR and CR, using 10 definite, 10 borderline and 10 negative cases, with HRCT as the 'gold standard' (9). After technical optimization, the FPD DR images were very similar to the FS radiographs, while the CR hard copies were not as similar, when compared to the FPD DR, however, that study did not detect a difference among the three modalities' area under the curve (AUC) of the ROC analyses, when the HRCT-validated FS radiograph reading results were considered as the gold standard.

The present study, performed by the DR Taskforce, used the previous recommendations of the CR Taskforce for MHWL-J as a starting point. The new FPD DR Taskforce recommendations are more rigorous than the earlier one, in not allowing the use of the spatial frequency processing for FDP DR. This new report may urge reconsideration of the previous CR Taskforce recommendation in this regard.

Conclusion

The MHWL-J FPD DR Taskforce has concluded that the FPD DR chest radiography, with appropriate settings as presented in this article, can be used in the legal management of patients with pneumoconiosis. Accordingly, in Japan FPD DR was officially approved for the purpose of pneumoconiosis judgments in December 2007. The pre-storage parameters, both gray scale processing and spatial frequency processing, as well as the post-storage parameters like window level and width, are important in determining the image output. Those influences on the display of a chest image are universal when viewing either hard copy or soft copy images. DICOM Part 14 should be

included as the required grayscale format. Evaluation of soft copy images on a CRT or LCD monitor was not included in the scope of the evaluation performed by the MHWL-J FPD DR Taskforce. Implementation of the use of digital soft copy images for pneumoconiosis judgments will entail a rigorous evaluation of monitor specifications, maintenance, and calibration, as well as data storage, data compression, and pre-storage data processing.

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Group Discussions

Acquisition and QC for classification of digital chest radiographs Group discussion and outcome

3 phase approach

- Immediate terms (<1 yr)
- Medium term (1-3 yrs)
- Long term (3-6 yrs)

Immediate term (<1 yr) Approval elements

- Acceptance criteria for equipment/facility
- IQ consistency as the key goal
- ACR guidelines as a starting point
- Equipment attributes (eg, pixel size, bit- depth, baseline performance, resolution, MTF/NPS/DQE/eDQE, speed, QC utilities, DICOM compliance, …)

Immediate term (<1 yr) Approval elements

- QA process in the facility incorporating specific attributes
- QA process oversight (physicist oversight?)
- Documentation of IQ in an standardized fashion (via phantoms) – recommended but required within a longer period of time
- TG10 type testing performance

Immediate term (<1 yr) Approval elements

- Acquisition protocol requirements
    - Scatter reduction: Grid (moving/stat), air gap, slot-scan, photon-counting
    - Beam quality (kVp, filter)
    - kW rating of generators
    - Providing an exposure index (TG116)

    - Exposure monitoring over time
    - AEC and/or exposure chart
    - AEC testing

Immediate term (<1 yr) Approval elements

- Specific file format (processed and “for processing” as available, required for new equipment)
- QC guidelines
- Ongoing demonstration of quality
- Beta testing of the approach

Medium term (1-3 yrs)

- A more representative phantom with automated analysis and objective measures (MTF, NPS, eDQE, processing artifacts, imaging chain issues)
- Exposure requirements (based on eDQE)
- Integrated QC utility per image

Long term (3-6 yrs)

- Automated disease classification
- Automated IQ assessment based on image data

File Interchange Subgroup – Recommendations

Assumptions

- Focus on NIOSH-specific requirements
- Reusable approach for other similar settings
- Modest number of acquisition sites (≈ 100-200)
- Small number of B Readers (≈ 10)
- Small volume (≈ 2,000 patients per year)
- Limited technical support staff at NIOSH
- All equipment for readers supplied by NIOSH
- Digitized reference set available from ILO 2008
- No printed film but existing film-screen OK at sites’ discretion

- Two proposals
  - short term (≈ 3 month) – CD based workflow & paper forms
  - long term – get a (commercial) off-the-shelf (OTS) PACS

Caveats

- 42CFR 37
  - can't change a regulation in 3 months
  - is digital permitted under current regulation ?
  - does not seem to be explicitly prohibited
  - lack of authority to insist on CDs if digital ?
- Training
  - can all NIOSH B Readers be trained in 3 months ?
  - in use of digitized reference set
  - in use of equipment

Key requirements

- Acquisition site
  - Pre-qualification of system and transfer process
  - Transfer to NIOSH
- Central site
  - Pre-qualification process and tools
  - Quality control process and tools (including queries to sites)
  - Long term archival and disaster recovery
  - Management of readers
- Readers
  - Receipt of images
  - Performance of read
  - Return of results
  - Disposal of images

CD-based short term solution

- Acquisition sites
  - burn CR/DX to CD from modality or PACS
    - CD will be DICOM GPCDR & IHE PDI profile

        - one patient per CD
        - identity in header as per 42CFR 37.41(m)
        - uncompressed “for presentation” image
        - optional “for processing” image if possible
        - no lossy compression permitted
    - submission of initial pre-qualification CD
- Central site
    - receive CDs and check them
        - correct header identification
        - preliminary check of displayed quality
    - tools required
        - standalone PC + pair of displays + viewer (OTS)
        - automated CD format checker (OTS)
            - IHE PDI tool checks format/compliance of CD
        - automated DICOM file checker (customized)
            - DICOM is CR/DX uncompressed + identity + technique
        - CD duplicator +/- DICOM header editor (OTS)
    - duplicate CDs for archival & disaster recovery
        - make two additional copies
        - local archive/off-site archive/send to reader
        - option: pseudonymize copy sent to reader
        - option: remove site supplied viewer on reader CD
    - send CD + ID paper document to B Reader
    - receive completed paper form from B Reader
    - duplicate CDs for archival & disaster recovery
        - make two additional copies
        - local archive/off-site archive/send to reader
        - option: pseudonymize copy sent to reader
        - option: remove site supplied viewer on reader CD
    - send CD + ID paper document to B Reader
    - receive completed paper form from B Reader
- B Readers
    - equipment installed and calibrated by NIOSH
    - standalone PC + pair of displays + viewer
    - system supplied already configured

            - secure: user/local staff/family no permission to install software, modify system, connect to network
            - single approved viewer already installed
            - digitized reference set already installed
        - complete & return paper evaluation form
        - destroy CD with CD shredder
- Viewer requirements
    - custom or OTS – commercial or open source
    - support pair of calibrated (OTS) 3MP grayscale displays
    - read from DICOM CD (? auto detection of insertion)
    - display single PA CXR left monitor
    - display single reference image right monitor
    - scroll through reference set
    - support all known CR/DX grayscale variants
    - support window level/sigmoid LUT
    - support pan/zoom
    - identification & technique annotation (patient & reference)
    - linear distance measurements (no need to capture/save)

Long term solution

- Central site get OTS PACS/RIS (commercial or open source)
- Acquisition sites
    - continue to submit CDs or
    - submit via Internet (IHE Teaching File & Clinical Trial Export TCE)
        - using centrally supplied software on own PC
        - to read locally created CD or connect to local network
- Central site
    - PACS match identifiers (IHE Import Reconciliation IRWF)
    - long term archival of all images in PACS
    - PACS has off-site archive for disaster recovery
- B Readers
    - view images on PACS remotely & securely via high speed internet
    - completes form (IHE Retrieve Form for Data Capture Profile RFD)
    - re-use same local hardware and displays as for CD solution

Reference Set Requirements

- Assume ILO 2008 for short-term solution
  - highest fidelity digitized data available
  - data used to print digital copies, if “original” film not available ?
  - not re-digitized digital copies
- Choice of DICOM encoding
  - DX “for presentation”, not Secondary Capture
  - contrast adjusted for P-Value grayscale output space
  - window values sigmoid or linear ?
  - replace white borders with black to reduce glare
  - identifying attributes helpful to user, e.g.“3/3 r/r” not “0014”
  - identifying attributes that sort into useful order for comparison
  - spacing attributes added to allow nodule size measurement
  - orientation attributes that allow correct hanging
  - validated to be correct per DICOM standard

Identification in DICOM header

- 42CFR 37.41(m) “Each roentgenogram made hereunder shall be permanently and legibly marked with the name and address or ALOSH approval number of the facility at which it is made, the social security number of the miner, and the date of the roentgenogram. No other identifying markings shall be recorded on the roentgenogram.”
- DICOM attributes that modality operator can enter/change:
  - SSN -> DICOM Patient ID (0010,0020) & Patient Name (0010,0010)
  - Date -> DICOM Study Date (0008,0020)
  - ALOSH approval number -> prefix to Patient ID ??? Study Description ???
- Fixed by field engineer at installation/configuration:
  - Facility name -> DICOM Institution Name (0008,0080)
  - Facility address ->DICOM Institution Address (0008,0081)
- May be constrained by RIS and Modality Worklist
- Central site (NIOSH) may need to clean up during CD copy process