

NIOSH Guideline

Application of Digital Radiography for the Detection and Classification of Pneumoconiosis

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health



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I. OBJECTIVE

Monitoring the health of individuals involved in dusty work is intended to provide assurance to the worker that ongoing exposure controls are adequate. Recognition of minor health abnormalities serves as an early warning to both workers and managers when there is need for more effective control measures to prevent work-related impairment and disability. Since 1970, NIOSH and other organizations have successfully applied traditional film screen chest radiography, interpreted using the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses, toward these objectives¹. Imaging of interstitial lung diseases such as the pneumoconioses represents one of the most difficult challenges in diagnostic radiology, and comprehensive attention to technological, methodological, and human factors is required to assure that the image quality and interpretation are satisfactory for achieving early disease detection. This NIOSH Guideline is based upon accepted contemporary professional recommendations, and provides technical and operational guidance for radiographic facilities and physician readers who obtain digital chest radiographs for the evaluation of pneumoconiosis. The intent is to assure that the recognition of pneumoconiosis using digitally-acquired chest radiographs is at least as safe and effective as traditional film screen radiography. The Guideline should not be considered a mandate for medical practice; however participating practitioners and facilities who deviate from the specifications should have a sound medical rationale for using alternative approaches.

II. RADIOLOGY FACILITIES

Each facility that acquires, stores, transfers, or interprets digital chest images for occupational disease (hospital, outpatient department, clinic, radiology practice,

¹ International Labour Office (ILO). Guidelines for the use of ILO international classification of radiographs of pneumoconioses. Revised edition 2000. International Labour Office, Geneva. 2002. (Note: The ILO has indicated its intention to issue an Appendix to this publication devoted to providing standard digital images and guidance on classification of digital chest images in a way that maintains continuity and consistency with the ILO 2000 Classification. When the ILO Appendix becomes available, readers are encouraged to obtain that publication along with the associated standard images, in order to provide classifications that adhere to the ILO recommendations.)

mobile radiography unit, or physician office that performs radiographic examinations of the chest) should review its personnel, procedures, equipment, software, security, and documentation in comparison with current technical standards and guidelines of relevant professional organizations.² Scanned, photographed, or other forms of digital copies of analog film screen radiographs are often used for teaching pneumoconiosis classification but are not recommended for pneumoconiosis classification of worker chest radiographs until the scientific basis for their use is more fully documented.

A. Qualifications and Responsibilities of Personnel

1. MEDICAL PHYSICISTS

Hardware and software systems for digital radiographic image acquisition, manipulation, display, and storage are technically complex. To assure imaging is both safe for the worker and adequate for pneumoconiosis classification, facilities should employ a qualified medical physicist on site or as a consultant. The physicist should be: 1) trained in evaluating the performance of radiographic equipment and facility quality assurance programs, 2) familiar with or trained on the specific systems at the facility, 3) licensed, approved, or certified by the competent jurisdiction or body, and 4) have a masters degree in physical science from an accredited institution/program and on-going experience and continuing training since obtaining his or her degree.

2. RADIOLOGIC TECHNOLOGISTS

Radiologic technologists who obtain chest images should: (1) be certified and experienced with or trained on the equipment and software utilized at the facility, and (2) have an appropriate unrestricted license and relevant privileges and certification to perform general radiographic procedures from the competent jurisdiction or body.

3. PHYSICIANS

Physicians who provide ILO classifications should have appropriate training and experience, including regularly interpreting digital chest radiographs, and demonstrated competence in reading radiographs of the pneumoconioses such as current approval by NIOSH as a B Reader, and/or board certification in pulmonary or occupational medicine, or radiology.

² The reader is referred to the following documents that serve as source materials for this NIOSH Guideline: Petsonk EL, ed. Application of the ILO International Classification of Radiographs of Pneumoconioses to Digital Chest Radiographic Images. Proceedings of a NIOSH Scientific Workshop. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. DHHS (NIOSH) Publication No. 2008-139.

American College of Radiology (ACR) Practice Guideline for Digital Radiography 2007 or current revision, ACR Technical Standard for Electronic Practice of Medical Imaging 2007 or current revision, ACR Practice Guideline for the Performance of Pediatric and Adult Chest Radiography 2006 or current revision, Digital Imaging and Communications in Medicine (DICOM) standard 3.14 or current revision. National Electrical Manufacturers Association, <http://medical.nema.org/>.

B. Imaging Equipment and Software

1. IMAGING EQUIPMENT

Images for classification should only be acquired at facilities that maintain ongoing licensure and certification under relevant laws and regulations for all equipment and examination processes. When digital imaging equipment is installed, facilities should receive documentation from the equipment suppliers that, after delivery, the system meets performance specifications and standards of the manufacturer and applicable industry guidelines, including documentation of performance that meets or exceeds the current professional recommendations.³

2. X-RAY GENERATOR FACTORS

Diagnostic radiographic equipment should be used with a rotating anode tube with a 1.0 millimeter (mm) source (focal spot), if available and capable of sufficient output. The focal spot should be no larger than a 2.0 mm. The voltage, current, and regulation of the electric power supply for the X-ray generator should comply with the manufacturer's specification. Standard beam filters should be included to assure an appropriate energy profile. If the manufacturer or installer of the radiographic equipment recommends equipment for control of electrical power fluctuations, this should also be installed and utilized. The generators of units should have a minimum rating of 300 milliamperes (mA) at 125 kVp or 35 kW, ratings of 65 kW can increase image sharpness for larger workers.

3. IMAGE CAPTURE HARDWARE AND SOFTWARE

The imaging plate should be a minimum of 35×43 centimeter (cm) or 1505 cm², with maximum pixel pitch of 200 micrometers (μm), and a minimum matrix size of 3.75 megapixels (MP), with a minimum bit depth of 10. Spatial resolution should be at least 2.5 line pairs per mm in both vertical and horizontal directions. Detector signals should undergo routine amplification as well as standard image post-processing. Image signal-to-noise and detective quantum efficiency should meet or exceed current professional recommendations for chest radiography. For facilities with digital systems that do not allow horizontal positioning of the image detector, two side by side images can be used if they include all lung fields, as well as both apices and costophrenic angles.

4. IMAGE MANIPULATION

Image management software and settings for routine chest imaging should be used, but addition of image or edge enhancement functions is discouraged. Minimal edge

³ American Association of Physicists in Medicine AAPM REPORT NO. 93. Acceptance Testing and Quality Control of Photostimulable Storage Phosphor Imaging Systems, 2006.

enhancement is permissible, but chest and test object images should appear similar to traditional film screen radiographs when displayed.⁴

5. OTHER ISSUES

The image data file and associated transmission and storage should conform to the current DICOM® standard and relevant substandards. Data systems should have error-checking capability, reliability, and redundancy sufficient to assure integrity of information, and sufficient physical, technical, and administrative controls to prevent unauthorized access to protected health information and confidential medical findings during data transfers. If data compression is performed, it should be lossless.

C. Image Acquisition

1. BEAM LIMITING DEVICES

Radiographic equipment should have a beam-limiting device whose use should be discernible from an examination of the radiographic image and which does not cause unexposed boundaries. Electronic post-image acquisition “shutters” available on some digital systems that limit the size of the final image and that simulate collimator limits should not be used.

2. EQUIPMENT SPECIFICATIONS

To insure high quality chest radiographs, the distance from source or focal spot to digital detector should be at least 70 inches (180 cm), and the maximum exposure time should not exceed one-twentieth of a second except that in subjects with chests over a 28 cm postero-anterior (PA) dimension, the exposure may be increased to not more than one-tenth of a second (classifications are only performed on PA projections). Examinations should utilize at least the minimum voltage recommended by the digital imaging system manufacturer for chest radiography, preferably using high kV technique (up to 125 kVp), and at least 90 kVp, while minimizing radiation exposure. The exposure should be at a 200 speed equivalent exposure (range of speed 100–300), which requires specific settings depending on the manufacturer of the digital imaging system. A suitable grid (for example with a ratio of 12:1 or 14:1) or air gap for reducing scattered radiation should be used; however special caution is required in the selection of grids for use with digital systems so that Moiré interference patterns do not occur. The absence of Moiré pattern should be confirmed in both horizontal and vertical images.

⁴ Suganuma N, Murata K, Kusaka Y. CR and FPD DR chest radiographic image parameters for the pneumoconioses: the Japanese approach and experience. IN: Petsonk EL, ed. Application of the ILO International Classification of Radiographs of Pneumoconioses to Digital Chest Radiographic Images. Proceedings of a NIOSH Scientific Workshop. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. DHHS (NIOSH) Publication No. 2008-139.

3. RADIOGRAPHIC GEOMETRY

Computerized Radiography (CR) imaging plates should be inspected at least once a month and cleaned when necessary and at the frequency and by the method recommended by the manufacturer. The geometry of the radiographic system should be periodically assessed to verify that the central axis (ray) of the primary exposure beam is perpendicular to the plane of the CR imaging plate, or Direct Radiography (DR) detector.

4. TEMPERATURE AND HUMIDITY

Radiographs should not be made when the environmental temperatures and humidity in the facility are outside the digital equipment manufacturer's recommended range.

5. IMAGE QUALITY

Before the subject is advised that the examination is concluded, the radiographic image should be processed to an image file and inspected and accepted for quality by the physician, or if the physician is not available, acceptance may be made by the radiologic technologist.

D. Documentation

1. IMAGE IDENTIFICATION AND DOCUMENTATION

To facilitate uniformity of image files used for pneumoconiosis classification, images should be stored as Digital Imaging and Communications in Medicine (DICOM)⁵ "DX" objects, and include grayscale softcopy presentation states. Identification of the image, patient, facility, date and time of the examination should be included within the file header according to the DICOM⁵ standard format. Exposure parameters (kVp, mA, time, beam filtration, scatter reduction, radiation exposure) should also be saved for auditing purposes, either in the DICOM⁵ file when possible, or in another accessible file.

2. SECURITY AND CONFIDENTIALITY POLICIES/PROCEDURES

Facilities have a responsibility, under laws, regulations, and professional ethics, of assuring the safety of patients and employees, as well as the confidentiality of both hard copy and electronic media that include patient information, medical images, and associated data. Meeting these obligations requires implementation of effective administrative policies and procedures, and physical and technical systems.⁵

⁵ American College of Radiology (ACR) Practice Guideline for Electronic Medical Information Privacy and Security 2009 or current revision.

E. Quality Control Systems

1. RADIATION SAFETY AND DOSE MONITORING

Each facility should obtain a comprehensive assessment of radiation safety and quality performed by a qualified medical physicist. Based upon the assessment, comprehensive procedures should be implemented to assure radiation exposures are as low as reasonably achievable, following current professional recommendations.⁶ Radiographic technique charts should be used that are developed specifically for the X-ray system and detector combinations used, indicating exposure parameters by anatomic measurements. If automated exposure control devices are used, calibration for chest imaging should be documented using the actual exposure parameters and image capture systems. Radiation exposures during chest examinations should be monitored, documented, and evaluated on at least an annual basis, according to accepted professional standards, to detect and institute corrective action for potential dose creep.⁷ For each digital radiography device and system, performance monitoring should comply with the equipment manufacturer specifications, applicable industry guidelines, and governmental regulations. For CR systems, professional recommendations for performance testing methods and frequencies should be followed, as applicable.⁸ For DR systems, these same methods and frequencies should be used except it is not necessary to perform the following tests:

- A. Section 8.4.5: Laser beam function
- B. Section 8.4.11: Imaging Plate (IP) throughput.
- C. Section 8.4.9: Erasure thoroughness should be evaluated per manufacturers instructions.

2. IMAGING SYSTEM QUALITY ASSURANCE

Facilities need to maintain documentation of the ongoing implementation of policies and procedures for monitoring and evaluating the effective management, safety, and proper performance of chest image acquisition, digitization, processing, compression, transmission, display, archiving, and retrieval functions of digital radiographic devices and systems. Quality assurance testing should be performed periodically as recommended by the equipment manufacturers and suppliers, and the results documented for the important parameters, such as reproducibility of X-ray output, linearity and reproducibility of mA settings, accuracy, and reproducibility of timer and kVp settings, accuracy of source-to-detector distance, and X-ray field focal spot size, selection, beam quality, congruence and collimation. Periodically (e.g., annually) image quality assurance and equipment maintenance should be reviewed. Estimated or

⁶ American College of Radiology (ACR) Practice Guideline for the Performance of Pediatric and Adult Chest Radiography 2006 or current revision.

⁷ American College of Radiology (ACR) Practice Guideline for Diagnostic Reference Levels in Medical X-Ray Imaging, Revised 2008 (Res. 3) or the current version of these guidelines.

⁸ American Association of Physicists in Medicine (AAPM) REPORT NO. 74. Quality Control in Diagnostic Radiology, July 2002, or the most current revision of this report.

measured radiation doses from an exposure indicator should be determined during routine PA chest radiography for at least 10 (randomly selected) examinations using typical settings and configurations. Radiation exposures should be compared to a professionally-accepted reference level, and when indicated, measures implemented to reduce undue exposures to the satisfaction of the professionals involved.^{7,9} For each image acquisition unit (X-ray generator and digital detector, plate reader or processor, and associated software), image quality should be demonstrated to be satisfactory based upon physician review of the digital image files from routine PA chest radiographs for patients examined within the previous 6 months, as well as from exposure of a test object or digital chest phantom satisfactory to the equipment supplier. Similarly, the performance of diagnostic display devices used for classification purposes should periodically (e.g., annually) be confirmed in accordance with the most stringent recommendations from professional organizations and the equipment vendors, and to assure compliance with applicable laws and regulations (see below).^{10,11} Automated quality assurance systems are available for display devices, but users should also perform regular (e.g., monthly) visual inspections using professionally-recommended test patterns to check for defects that automatic quality assurance systems may not detect.⁶

III. IMAGE CLASSIFICATION

A. Image Display

Because of the inherent difficulty in recognizing small pneumoconiotic shadows, it is important that image display hardware and software used for interpretation of chest images meet or exceed professionally recommended specifications.⁶ Freely downloadable software is available (NIOSH-B-Viewer™) which facilitates meeting these criteria. Use of NIOSH-B-Viewer™ or equivalent software appropriately limits the reader's ability to modify the appearance of the ILO standard comparison images, and also permits documentation of the specific settings used for displaying the chest images during the classification. To further enhance consistency when performing ILO classifications of chest images, the reader should use two side-by-side flat panel color-matched diagnostic quality medical displays capable of monochrome display and compliant with the DICOM[®] Grayscale Standard Display Function (GSDF) standard. The viewing devices should be of the identical make and model, displaying at least 3 MP at 10 bit depth; 12 bit and 5 MP are preferred. Display system luminance (maximum and ratio), relative noise, linearity, modulation transfer function, frequency, and glare should meet or exceed applicable professional recommendations. In addi-

⁹ American Association of Physicists in Medicine AAPM Report No. 31, Standardized Methods for Measuring Diagnostic X-ray Exposures, 2005 or current revision.

¹⁰ American College of Radiology (ACR) Practice Guideline for Digital Radiography 2007 or latest revision. AAPM On-Line Report No. 03, Task Group Report No. 18: Assessment of Display Performance For Medical Imaging Systems April 2005

¹¹ American Association of Physicists in Medicine (AAPM) On-Line Report No. 03, Task Group Report No. 18: Assessment of Display Performance for Medical Imaging Systems April 2005

tion, if radiographs are classified using different display hardware and software, image uniformity can be maximized if image displays and associated graphics cards meet the calibration and other specifications of the current DICOM® standards and not deviate by more than 10% from the grayscale standard display function. Readers should minimize reflected light from ambient sources during the performance of classifications. Viewing displays should provide a maximum luminance of at least 171 candelas/meter², a ratio of maximum luminance to minimum luminance of at least 250, and a glare ratio greater than 400. (The contribution of ambient light reflected from the display surface should be included in luminance measurement considerations since some level of ambient light is always present.) Color displays may be used if the devices demonstrate adherence to the above specifications.

B. Reader Qualifications

Classification of chest radiographs for medical diagnosis, medical screening and worker monitoring, government programs, and contested proceedings should be performed by physicians who have experience with, and competence in use of, the ILO International Classification of Radiographs, and a commitment to serve the welfare and best interests of patients, workers, and society by striving to classify chest radiographs as accurately as possible. Readers should familiarize themselves with the four necessary components for attainment of reliable classification of chest radiographs for the pneumoconioses: 1) appropriate methods for image collection and viewing, 2) reader competency, 3) commitment to ethical classification¹², and 4) proper radiographic reading methods.¹³ Readers should have ongoing experience, training, and demonstrated competence, such as through participation in the NIOSH B Reader approval program.¹⁴ In the United States, readers who perform classifications of digital images for NIOSH research and health surveillance programs may be required to have current approval as NIOSH B Readers.

C. ILO Classification Process

Classification of ‘soft-copy’ digital chest radiographs for pneumoconiosis should adhere to the recommended practices of the International Labour Organization.¹ Classification of transparencies derived from images that have been acquired using digital systems and printed for display on tradition view boxes is a common practice in some countries, although some studies have challenged the equivalence of printed digital

¹²NIOSH Safety and Health Topic: Chest Radiography. Ethical Considerations for B Readers. <http://www.cdc.gov/niosh/topics/chestradiography/breader-ethics.html>

¹³NIOSH Safety and Health Topic: Chest Radiography. Recommended Practices for Reliable Classification of Chest Radiographs by B Readers. <http://www.cdc.gov/niosh/topics/chestradiography/radiographic-classification.html>

¹⁴NIOSH Safety and Health Topic: Chest Radiography. The NIOSH B Reader Program. <http://www.cdc.gov/niosh/topics/chestradiography/breader.html>

images and traditional film screen radiographs in detecting pneumoconiosis.¹⁵ Additional studies are needed to define the conditions which can ensure equivalence of this approach. Digitized copies of film screen images are often used for teaching pneumoconiosis classification, but are not considered optimal for classification of worker chest radiographs. For most purposes, classifications can be performed using digitally-acquired PA chest images collected with equipment and procedures discussed above. Images should be displayed using equipment, software, and procedures as specified in IIIA. Viewing systems should enable readers to display the chest image at the full resolution of the image acquisition system, side-by-side on an identical display device with the selected ILO standard images for comparison. Only authorized ILO standard digital images should be used for classifying digital chest images for pneumoconiosis. To ensure consistency in classifications of digital chest radiographs, the ILO standard images should not be modified using software tools. Although the *ILO standard images* should not be modified using software tools, readers are encouraged to attempt to visually match the general appearance of the *subject image* being classified to that of the comparison ILO standard image (i.e., by modifying the size, window, and level of the subject image). Calibrated software measuring tools should also be used to measure the width and length of pleural shadows and the diameter of opacities. In contrast, software tools whose purpose is to reduce noise, enhance edges, or restore image appearances *should not be applied* to the subject image. The presentation state(s) that were used in performing the actual classification should be saved, if possible. Any annotations and measurements performed during the classification should also be included as part of the classification record, as permitted by the viewing software.

¹⁵Franzblau A, Kazerooni EA, Sen A, Goodsitt MM, Lee SY, Rosenman KD, Lockey JE, Meyer CA, Gillespie BW, Petersonk EL, Wang ML. Comparison of Digital Radiographs with Film Radiographs for the Classification of Pneumoconiosis. *Acad Radiol* 2009;16:669–677.



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