

**U.S. DEPARTMENT OF LABOR**

**JUN 02 2014**

Office of Workers' Compensation Programs  
Division of Coal Mine Workers' Compensation  
Washington, DC 20210



**BLBA BULLETIN NO. 14-08**

Issue Date: June 2014

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Expiration Date: Indefinite

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Subject: Digital X-rays

Background: In recent years, digital radiography systems have been rapidly replacing traditional analog film-based systems in medical facilities. Because of this technology shift, claimants, coal mine operators, and DCMWC had been experiencing increasing difficulty in obtaining analog chest X-rays of miners. Although interpretations of digital X-rays were admissible as “other medical evidence” under the catch-all provision at 20 CFR 718.107, the interpretation’s proponent had to establish to the adjudicator’s satisfaction that digital X-rays are medically acceptable and relevant to the claimant’s entitlement of benefits. With the implementation of the Final Rule establishing digital radiography standards for the Black Lung Benefits Act (BLBA) program, DCMWC will now allow chest X-rays produced by either film or digital radiography systems, as defined in Appendix A to Part 718 of the Regulations, to be used in determining the presence or absence of pneumoconiosis in coal miners.

Purpose: To provide guidance for DCMWC’s employees on the acceptable standards, format and storage for digital X-rays.

Applicability: Appropriate DCMWC Personnel

References: The Final Rule establishing digital radiography standards for the BLBA program was published on April 17, 2014 and became effective on May 19, 2014. Digital X-rays must conform to all standards found in the Final Rule. Section 20 CFR 718.102 and Appendix A to Part 718 have been substantially revised to adopt specific standards that digital chest X-rays and radiography equipment must meet to be in compliance. The Final Rule also makes minor technical changes to these sections as well as to 20 CFR 718.101, 718.202, 718.304 and 20 CFR 725.406. These changes update terminology, correct subsection references, and remove obsolete provisions contained in the prior regulations.

Below is a summary of several important provisions for digital chest X-rays and digital equipment in the Final Rule. Refer to 20 CFR 718.102 and the Appendix A to Part 718 in the Final Rule for complete details.

- **20 CFR 718.102** – Digital X-rays must be classified using the 2011 International Labour Organization (ILO) Classification of Radiographs of Pneumoconiosis Guidelines (Issuance

date: November 17, 2011). Film X-rays must not be converted into digital images and digital X-rays must not be converted and printed as transparencies. This section also specifies what information must be included in all X-ray reports (film and digital X-rays) as well as important definitions.

- **Appendix A to 20 CFR Part 718** – Facilities must maintain ongoing licensure and certification under relevant local, State and Federal Laws and Regulations for all digital equipment and related processes. Digital equipment must be evaluated by qualified medical physicists and judged acceptable per the American Association of Physicists in Medicine (AAPM) report No. 93, pages 1 – 68. The classifying of digitally acquired X-rays must be performed based on the viewing of images displayed as soft copies using the viewing workstations specified in subsection (d). Classification of radiographs must not be based on viewing hard copies printed on transparencies of images digitally acquired. All of the exact standards and specifications for digital radiography systems and equipment can be found beginning in Subsection (d) of Appendix A to 20 CFR Part 718.
- Instructions contained in the Black Lung Benefits Act Procedure Manual, Chapter 3-400: X-Ray, are still instructive; particularly relevant sections are referenced below. This chapter will be revised to incorporate digital radiography references.

Actions:

1. Digital X-rays must be submitted to DCMWC by physicians and/or medical facilities on computer discs (CD) or Digital Video Disc (DVD), that conform to the standards noted in Subsection (d)(7)(v)(A) of Appendix A to 20 CFR Part 718.
  - a. The CD/DVD must be in a tear resistant ‘paper’ sleeve and mailed to the District Office in a protective jacket to avoid damage.
  - b. Currently, digital X-rays cannot be stored and submitted to DCMWC on Blu-Ray disc (BD) or electronically transmitted to DCMWC.
2. Upon receipt of a CD/DVD in the District Office, handle and process the CD/DVD using the established policies outlined in the BLBA Procedure Manual, Chapter 3-400: X-Ray. That is: check to be sure the digital X-rays contain the patient’s name, SSN, DOB, date the X-ray was taken, etc.
  - a. If the CD/DVD is for the DCMWC provided pulmonary examination, the necessary identification is created and placed on the CD/DVD.
  - b. Two labels must be created and the label must contain the claimant’s name; date of X-ray; SSN and case number (if one exists).
  - c. One label is placed on the CD/DVD tear-resistant cover sleeve and the other along the 9 inch edge of a 6x9 manila envelope. The tear-resistant paper sleeve with CD/DVD shall then be placed in the manila envelope.

3. Although OWCP is transitioning to an electronically imaged case file system, storage of digital X-rays in the district offices will be handled in the same manner as analog films. The district office will determine the nature of their storage requirements on a local basis. Any CD/DVDs received from private parties in the claim will be stored in this same manner, except they will be placed in a non-manila colored 6X9 envelope to help differentiate them from the DOL's X-rays.
4. Claims personnel must review the "Other" section of the forms CM-933 and CM-933b to ensure that the physician has stated whether the report is for analog film or digital X-rays. The Consultant Determination Claim Form (CM-978) will no longer be used with digital X-rays. Instead, the HCFA 1500 will be used for all X-rays.
5. Consideration of digital X-ray interpretations.
  - a. Digital X-ray interpretations made prior to November 17, 2011 (the date the ILO made its Guidelines applicable to digital radiographs) will not be considered because they are not in substantial compliance with the new quality standards, *see generally* 20 CFR 718.101(b), 718.102, and they are also not admissible under 20 CFR 718.107's "Other medical evidence" provision because they are no longer "medically acceptable."
  - b. Digital X-ray interpretations made after November 17, 2011 and prior to May 19, 2014—regardless of when the radiograph was taken—should be considered unless there is evidence that the interpretation was based on a hard copy of the digital image printed on a transparency (*i.e.*, a "converted" X-ray), or that the administration or interpretation of the X-ray does not comply with the quality standards in some other significant way. In that instance, the interpretations should not be considered because they are neither in substantial compliance with the new quality standards, *see generally* 20 CFR 718.101(b), 718.102, nor "medically acceptable" under 20 CFR 718.107.
  - c. Special rule for deceased miners. The new rules retain special provisions for considering X-rays when the miner is deceased. If the radiograph in question has been destroyed or is otherwise unavailable, readings of that X-ray submitted by any party must be considered. 20 CFR 718.101(g). If the only available X-ray does not substantially comply with the quality standards, it may still be used to show the presence or absence of pneumoconiosis if its quality is adequate to allow a reading and it is read by a Board-certified or Board-eligible radiologist, or a Certified B-Reader. 20 CFR 718.101(h).
  - d. Please refer any questions you have about considering specific X-ray interpretations to DCMWC national office staff.

Disposition: Retain this Bulletin until further notice or its incorporation into the Coal Mine (BLBA) Procedural Manual.

A handwritten signature in blue ink, appearing to read "Michael A. Chance". The signature is stylized with a large initial "M" and "A".

Michael A. Chance  
Director, Division of Coal  
Mine Workers' Compensation

Distribution: All DCMWC staff

**U.S. DEPARTMENT OF LABOR**

Office of Workers' Compensation Programs  
Division of Coal Mine Workers' Compensation  
Washington, DC 20210



Dear <insert name of 413(b) provider>:

A Final Rule establishing digital radiography standards for the Federal Black Lung Benefits Program was published in the Federal Register on April 17, 2014, and became effective May 19, 2014. The rule sets standards for administering, interpreting, and transmitting digital radiographs when used to detect the presence or absence of pneumoconiosis in a Black Lung Benefits Act claim. As a result, the Division of Coal Mine Workers' Compensation (DCMWC) will now accept interpretations based on digital radiographs administered and interpreted in compliance with the new standards. You may also continue to use analog film radiography systems.

The new standards will appear in the regulations at 20 CFR 718.102 and Appendix A to Part 718. They are based on rules used by the National Institute of Occupational Safety and Health for the Coal Workers' Health Surveillance Program. Please refer to the Final Rule for complete details and to ensure compliance. You may access these regulations in their entirety on our website:

[http://dol.gov/owcp/dcmwc/Digital\\_X-ray\\_Final\\_Rule\\_Fed\\_Reg.pdf](http://dol.gov/owcp/dcmwc/Digital_X-ray_Final_Rule_Fed_Reg.pdf)

Some of the important standards for digital chest X-rays and digital equipment include:

- **20 CFR 718.102** – Digital X-rays must be classified using the 2011 International Labour Organization (ILO) Classification of Radiographs of Pneumoconiosis Guidelines (Issuance date: November 17, 2011). Film X-rays must not be converted into digital images and digital images must not be printed and read as transparencies. This section of the regulations also specifies the information that must be included in all X-ray reports (film and digital X-rays); contains important definitions; and addresses submission of X-rays to OWCP.
- **Appendix A to 20 CFR Part 718** – Facilities must maintain ongoing licensure and certification under relevant local, State and Federal laws and regulations for all digital equipment and related processes. Digital equipment must be evaluated by qualified medical physicists and judged acceptable under the American Association of Physicists in Medicine (AAPM) report No. 93, pages 1 – 68. Classification of digitally acquired X-rays must be performed by viewing images as soft copies using the workstations specified in paragraph (d). Classification of radiographs must not be based on viewing hard copy printed transparencies of digitally acquired images. All of the exact standards and specifications for digital radiography systems and equipment can be found beginning in paragraph (d) of Appendix A.

DCMWC does not presently have the capability to accept digital X-rays by electronic transmission, so all digital X-ray images must be stored on computer discs (CD) or Digital Video Disc (DVD) only. (Digital X-rays cannot be submitted to DCMWC on Blu-Ray disc (BD) at this time). The digital image must conform to the standards noted in paragraph (d)(7)(v)(A) of Appendix A. The CD/DVD must be placed in a tear resistant 'paper' sleeve for protection and must be mailed in a protective jacket, such as a bubble wrap type envelope, to the District Office that authorized the X-ray examination.

DOL providers must indicate whether the X-ray for which the report is written was produced by film or digital radiography system in the "Other Comments" section (4C & 2C respectively) on the CM-933 and CM-933b forms. Also, the Consultant Determination Claim Form (CM-978) will no longer be used by DOL for billings associated with X-ray re-reads. It has been replaced with the HFCA 1500, which will be completed by District Office staff and sent to consultants for completion and return to DOL.

Additionally:

- Readers will need to display the ILO Standard Digital Images side-by-side with the miner's digital X-ray. You may purchase a set of the ILO Standard Digital Images in DICOM format from the ILO. Additional information is available at:  
[http://www.ilo.org/safework/info/publications/WCMS\\_168337/lang--en/index.htm](http://www.ilo.org/safework/info/publications/WCMS_168337/lang--en/index.htm)
- You may also consider downloading and using the *NIOSH BViewer*© Software. The software is specifically designed for displaying chest images for classification under the ILO Guidelines. The software can be downloaded for free and is available at:  
<http://www.cdc.gov/niosh/topics/chestradiography/digital-images.html>
- If you are a B-Reader, recertification is not necessary at this point. Please review the NIOSH digitized study syllabus and DICOM teaching images. The download can be found at:  
<http://www.cdc.gov/niosh/topics/chestradiography/breader.html>

Sincerely,



Michael A. Chance  
Director, Division of Coal Mine Workers' Compensation