SUMMARY:

This final rule updates the Department’s existing film-radiograph standards and provides parallel standards for digital radiographs. This rule also updates outdated terminology and removes certain obsolete provisions.

DATES: This rule is effective May 19, 2014. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of May 19, 2014.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:

I. Background of This Rulemaking

On June 13, 2013, the Office of Workers’ Compensation Programs (OWCP) published a direct final rule (78 FR 35549) and a companion notice of proposed rulemaking (NPRM) (78 FR 35575) to update the existing quality standards for administering and interpreting film-based chest radiographs and to add parallel standards for digital radiographs for claims under the Black Lung Benefits Act (BLBA), 30 U.S.C. 901–944. Both documents stated that if OWCP received significant adverse comment, the direct final rule would be withdrawn. OWCP asked for comments on all issues related to the rule, including economic or other regulatory impacts on the regulated community. Because OWCP received significant adverse comment, OWCP withdrew the direct final rule on August 30, 2013, 78 FR 59645. This final rule completes the process begun by the notice of proposed rulemaking.

As explained in the NPRM, OWCP proposed adding digital radiography standards to the existing standards.
because digital radiography systems are rapidly replacing traditional analog film-based systems in medical facilities. 78 FR 35576–35577. Because of this technology shift, claimants, coal mine operators, and the Department had been experiencing increasing difficulty in obtaining film 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 to benefits. See generally Webber v. Peabody Coal Co., 23 BLR 1–123 (2006) [en banc] aff’d on recon., 24 BLR 1–1 (2007) [en banc]; Harris v. Old Ben Coal Co., 23 BLR 1–98 (2006) [en banc], aff’d on recon., 24 BLR 1–13 (2007) [en banc]. This led to mixed results from adjudicators, with some admitting digitally based interpretations and others refusing to consider them or affording them less weight based on the technology employed. This final rule fills the technological gap with regulatory quality standards for digital radiographs. As it did when it first promulgated quality standards for film-based chest X-rays, see 78 FR 35576–35577 (summarizing history of X-ray quality standards and Department’s authority to adopt them), the Department has based the standards adopted in this final rule largely on those promulgated in 2012 by the Department of Health and Human Services for use in the National Institute for Occupational Safety and Health (NIOSH) Coal Workers’ Health Surveillance Program (CWHSP) (the NIOSH rules). See 42 CFR 37.1 et seq.; see also 77 FR 56718–56735 (September 13, 2012) (NIOSH final rule); 77 FR 1360–1385 (January 9, 2012) (NIOSH proposed rule). Under the CWHSP, NIOSH approves medical facilities for participating in monitoring the health of the nation’s coal miners through periodic chest X-ray screening. See 42 CFR 37.44–37.45; see also 78 FR 35577 (discussing the CWHSP). Congress designated NIOSH as the Department’s statutory advisor for establishing standards for BLBA medical testing. 30 U.S.C. 902(f)(1)(D).

The standards adopted here will ensure that claim adjudications continue to be based on high-quality, uniform radiographs. By adopting quality standards for digitally acquired chest X-rays, the Department intends that interpretations of film and digital X-rays—so long as they are made and interpreted in accordance with the applicable quality standards—will be put on equal footing both for admission into evidence and for the weight accorded them. The final rule also retains the current regulatory quality standards for film-based chest X-rays with the minor terminology modifications explained in the NPRM. See 78 FR 35579. The final rule does not impose any new requirements on the parties in BLBA claims; instead, it merely provides the parties another option for developing medical evidence in claim proceedings.

II. Statutory Authority

Section 426(a) of the BLBA, 30 U.S.C. 936(a), authorizes the Secretary of Labor to prescribe all rules and regulations necessary for the administration and enforcement of the Act. The BLBA also authorizes the Secretary of Labor, in consultation with NIOSH, to “establish criteria for all appropriate medical tests” administered in connection with a benefits claim, 30 U.S.C. 902(f)(1)(D), and to “establish specific requirements for the techniques used to take [X-rays] of the chest” to ensure their quality. 30 U.S.C. 923(b).

III. Discussion of Comments

The Department received comments from only three sources: The American College of Radiology (ACR), a coal mine operator, and an insurance company that insures coal mine operators for BLBA liabilities. The latter two submissions (industry comments) were identical in all substantive respects. While the commenters commend the Department for moving forward with digital radiograph standards, they also criticize the proposed rules. Their comments pertain primarily to very limited portions of §718.102 and Part 718, Appendix A. The Department had proposed substantially revising these regulations to allow parties the option of using converted images is a common practice and that disallowing their use is inconsistent with the Guidelines for the Use of ILO International Classification of Radiographs of Pneumoconiosis, 2011 edition. Both the ACR and the industry argue that determining whether any particular converted image is of sufficient quality and suitable for classification under the ILO Guidelines should be left to a qualified B-reader’s discretion.

All parties recognize the importance of valid, accurate medical evidence in claims adjudications. In promulgating these rules, the Department is expanding accessibility to medical providers by permitting the use of digitally acquired images. But it must still assure that decisions regarding a miner’s physical condition do not vary depending on the radiographic technology used for evaluations. A primary difficulty with using converted images is that, at the current time, the Department is unaware of specifications for equipment, procedures, and methods that can assure the accuracy and precision of converted images when used for ILO classification purposes. In fact, the available scientific evidence casts doubt on the accuracy of some converted images. Studies of digital images converted to film showed that the apparent profusion of small opacities was greater on printed hard copies of digital images than on either digitally acquired radiographs displayed on a monitor or analog film-based radiographs obtained at the same time. Franzblau A, Kazerooni EA, Sen A, Goodis MM, Lee SY, Rosenman KD, Lockey JE, Meyer CA, Gillespie BW, Petsonk EL, Wang ML [2009]. Comparison of digital radiographs with
film radiographs for the classification of pneumoconiosis. Acad Radiol
16(6):669–677. See also 78 FR 35578 citing 77 FR 1366 (NIOSH discussion of scientific studies). Moreover, there is no
standardized approach to the process of creating the hard copy or for the
equipment used to do so.

The Department also lacks data about the accuracy of scanned, digitized
images obtained from analog chest radiographs when used for ILO
classification purposes. Theoretically, available image receptors for digital
radiography systems can detect a depth of gray scale that is considerably greater
than for analog photographic film, and the additional gray scale is not available
when analog images are scanned to digital. Signal processing after digital
image acquisition also generally improves the visualization of structures
that might not be visible on an analog film image, for example those overlying
the mediastinum and heart. This post-processing cannot generally be done
when analog images are digitized. Another barrier to using scanned,
digitized versions of analog images is the absence of an industry-wide
standard for the digitizing process that is documented to provide image
characteristics that are relatively uniform and acceptable for
pneumoconiosis classification. Specifications, operation, and
maintenance of the scanning equipment used to digitize images can all affect
the quality of the resulting image.

The industry comments state that disallowing converted radiographs is contrary to the ILO Guidelines and that the
ILO itself converted its standard film radiographs to create standardized
digital images for use with the ILO classification system. While the ILO
Guidelines do not prohibit application of the classification system to converted
radiographs, the Guidelines are necessarily broad because they are used
worldwide, including countries where the industry has strict standards for
conversion processes and the associated hardware (e.g., printers and scanners). In fact, the ILO’s experience in
digitizing its standard analog films highlights the problems with the digital conversion process and the difficulty of
preserving the integrity of pneumoconiotic findings during that process. It is a highly subjective process that is not easily routinized; multiple
iterations and software manipulations were required to provide images with
characteristics that the ILO experts felt adequately reflected their original
standard films. These labor-intensive efforts are simply not a normal part of
current clinical practice in the United

States, and it is unlikely a clinician
would go to such extraordinary lengths to ensure accurate conversion of an
individual miner’s radiographs. Although the ACR comment asserts that existing technology can display excellent analog images converted from
digitally-acquired images, it does not include any details or other information on that technology for the Department to consider.

The Department also does not agree that detection of quality problems in the conversion process should be left to
certified B readers for several reasons. First, even assuming a B-reader could detect quality problems, parties are not required to submit interpretations made
by B-readers or physicians who specialize in radiology. Readings made by
the miner’s treating physician or pulmonologist are often offered as
evidence, even when these physicians are not certified B-readers. Thus, it is important that the radiographs
themselves are consistently high-quality for all interpreting physicians. Second, the Department is not confident that a
B-reader could reliably detect quality deficiencies such as data loss from the
converted image alone, and the Department is unaware of any scientific studies suggesting otherwise. Finally,
leaving the validity of converted radiographs to resolution on a claim-by-
claim, radiograph-by-radiograph basis would generate additional litigation in
BLBA claims. The quality standards are designed to avoid such a result.

In sum, the Department is unaware of any scientific evidence supporting the use of converted radiographs for
pneumoconiosis classification, and the comments point to none. The
Department intends to monitor the scientific literature, and will consider
further modification of the rule if additional evidence becomes available regarding specific methods of
converting images between analog and digital formats, and the equivalence of
ILO classifications of such converted images.

The commenters suggest two alternatives to banning converted radiographs. First, they ask the
Department to allow interpretations of converted images to be submitted under
§ 718.107, which permits submission of “any medically acceptable test or
procedure reported by a physician and not addressed in this subpart[,]” 20 CFR
718.107(a) (emphasis added). The submitting party must demonstrate the
medical acceptability of the test or procedure and its relevance to the
claim’s adjudication. 20 CFR 718.107(b). Section 718.107 is a flexible catch-all
provision for admitting existing or

future types of testing not specifically addressed by the regulatory quality
standards at 20 CFR 718.101–718.106 (standards for chest X-rays, pulmonary
function tests, reports of physical examinations, arterial blood gas studies,
and autopsy and biopsy evidence). For instance, parties may submit chest
computed tomography (CT) scan results under § 718.107 if the submitter satisfies the
adjudicator as to its reliability and

relevance because the Department has not established quality standards for
that particular test. Likewise, prior to this final rule’s promulgation, parties
could submit interpretations based on
digital chest radiographs under
§ 718.107 because the Department had not addressed that particular
technology. See, e.g., Harris v. Old Ben
Coal Co., 23 BLR 1–98 (2006) (en banc),
aff’d on recon., 24 BLR 1–13 (2007) (en
banc). Because the final rule now provides standards for digital
radiographs, § 718.107’s catch-all
provision, by its plain language, no
longer applies. Instead, the new rule
embodies the Department’s
determination of what digital
radiographs (and their interpretations) are medically acceptable for purposes of
adjudicating BLBA claims. This relieves
parties of the burden of proving medical acceptability in each case and sets

a quality threshold for digital
radiographic evidence used for
entitlement determinations. To accept
the commenter’s suggestion and allow
submission of digital radiographs under
§ 718.107 that do not meet the new
criteria would effectively create a
loophole that negates the very purpose
of those criteria.

Second, the commenters ask the
Department to delay the effective date of
§ 718.102(c) and Appendix A, paragraph
(d)(16) for 2 to 3 years so that medical
facilities and state regulatory bodies
have time to comply with the rule. In
support, the ACR states that some
facilities may not have a system that
allows for digital image transmission and that they should be allowed time to
modernize their equipment to comply
with the new standards. The ACR also
notes at least one state requires film
radiographs for workers’ compensation
claims have the ability to display digital images on
medical-grade monitors.

The Department does not agree that
delaying the effective date of
§ 718.102(c) is necessary. While some
facilities may not yet have acquired the
equipment necessary to meet the final
rule’s requirements, many have. In
2011, prior to NIOSH’s promulgation of
its digital radiography regulations, approximately sixty-one analog film facilities were approved to participate in the CWHSP. After NIOSH adopted digital radiography standards in 2012, the total number of NIOSH-approved facilities rose to ninety in 2013, with forty-two of these facilities approved to perform digital radiographs. This dramatic growth in the number of NIOSH-approved facilities would not have occurred so quickly if facilities either did not already have the capacity or could not easily acquire it to perform digital radiographs in compliance with the standards adopted in this final rule. More importantly, the regulations do not force any party to use digital radiography systems; the traditional analog film option remains available. Thus, if a state requires film radiographs, interpretations of those films will also be admissible in BLBA claims, provided the X-rays were administered and interpreted in compliance with the analog-film standards set forth in §718.102 and Appendix A.


The industry comments state that no commercial picture archiving and communications system (PACS) vendors provide software that allows side-by-side display of the miner’s radiograph with the ILO standard digital images. This method of interpreting digital radiographs is set forth in proposed Part 718 Appendix A, paragraph (d)(14). Although software availability is limited, facilities seeking to provide this service are not without options. Facilities can use the NIOSH BViewer software, which is offered free to the public and available on NIOSH’s Web site. Facilities can also work with their PACS vendor to adapt existing software, utilize the BViewer software, or develop other innovative solutions. Indeed, at least one PACS vendor has given NIOSH a software supplement that permits chest image classifications to be performed side-by-side with the ILO standard digital images on its commercially available system. The Department believes the availability of chest image classification software will increase as more of the industry utilizes digital systems. Moreover, limited software availability should not forestall the Department from adopting a rule for classifying digital radiographs for use by those facilities that currently have the capacity to meet the quality standards. Accordingly, no change has been made in response to this comment.

Remaining Provisions

No comments were received on several proposed provisions—§718.5 (incorporations by reference), §718.202 (determining the existence of pneumoconiosis), and §718.304 (irrebuttable presumption of total disability or death due to pneumoconiosis). These regulations are therefore promulgated in this final rule as proposed with one technical revision to §718.202(a)(3). As proposed, section 718.202(a)(3) included a cross-reference to §718.306. 78 FR 35582. After the proposal was published, however, the Department promulgated a final rule revising §718.202(a)(3) to remove the cross-reference because the Department had ceased publication of §718.306. 78 FR 39114 (September 25, 2013). This final rule conforms §718.202(a)(3) to the intervening September 25, 2013 final rule.

IV. Administrative Law Considerations

A. Information Collection Requirements (Subject to the Paperwork Reduction Act)

In the NPRM, the Department stated that the proposed rules did not impose any new information collections under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. 78 FR 35579. The final rule at §718.102(f) requires physicians obtaining radiographs of miners on digital radiography systems to submit the radiograph in electronic format, rather than analog film format. The Department is incorporating this format change into an existing approved information collection titled “Claim Adjudication Process for Alleged Presence of Pneumoconiosis,” OMB Control Number 1240–0023. Although the Department does not believe this is a new information collection, changes the actual data collected, or alters the estimated information collection (paperwork) burdens imposed on the public, the additional electronic format option could be considered a change to an existing information collection currently approved under the PRA.

Accordingly, the Department published a notice in the Federal Register on November 19, 2013, 78 FR 69449, requesting comments from the public on revising the collection to include information in electronic format. The notice directed the public to submit comments to the Office of Management and Budget (OMB) on or before December 19, 2013. No comments were received. The Department also submitted a revised information collection to OMB. OMB preapproved the revisions to the information collection on December 27, 2013. See http://www.reginfo.gov/public/do/PRAOBHistory?ombControlNumber=1240-0023 (last visited Feb. 24, 2014).

B. Executive Orders 12866 and 13563 (Regulatory Planning and Review)

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The Department has considered this rule with these principles in mind and has concluded that the regulated community will greatly benefit from this regulation. The Department fully explained this conclusion in the NPRM (78 FR 35579–80). The rule will increase access to radiographic technology, which in turn will increase the number of medical providers available to OWCP and reduce delays in processing miners' benefits claims; increase access for claimants and coal mine operators (and their insurers) to additional radiographic facilities; and relieve parties of the demanding evidentiary burden of proving medical acceptability of digital X-rays under §718.107. The Department also considered whether the parties will realize any monetary benefits or incur any additional costs in light of this rule, and concluded that it is a cost-neutral rule. The rule expands opportunities for claimants and coal mine employers to obtain X-ray evidence, but does not require any party to use digital X-ray systems; medical facilities generally charge the same fee for film and digital radiographs; and miners' reimbursable travel costs may decrease if miners have access to a digital facility in their locality.

The industry comments state that the Department has underestimated the cost impact of the rule. They note that to comply with the requirements set forth in Part 718, Appendix A, medical facilities will need to obtain physics support, conduct annual testing of monitors, and purchase additional medical-grade monitors so that the X-ray interpreter can display the miner’s digital radiograph side-by-side with the standard ILO-approved digital images when reviewing the radiograph. They believe these requirements will impose additional costs on medical facilities.
In the context of this rulemaking, the Department’s primary concern is the direct financial impact on parties to BLBA claims. Cf. Mid-Tex Elec. Coop., Inc. v. Fed. Energy Regulatory Comm’n, 773 F.2d 327, 343 (D.C. Cir. 1985) (recognizing that “Congress did not intend to require that every agency consider every indirect effect that any regulation might have on small businesses in any stratum of the national economy”). The comments neither suggest that the parties will incur higher costs to obtain digital radiographs than analog film radiographs nor disagree with the Department’s analysis of that cost as set out in the NPRM. Thus, the Department continues to believe that the rule is cost-neutral for the parties in claim proceedings.

Looking further downstream at potential costs imposed on medical facilities, the Department notes that any costs incurred for purchasing and maintaining digital radiography systems is at the facilities’ option and is not required by these rules. The final rule continues to allow submission of traditional analog film radiographs. Thus, facilities may proceed as they have in the past with no change in cost burden.

Facilities that choose to transition to a digital environment are already investing in the core hardware, software, and maintenance needed to perform digital radiography and evaluate digital images. As both the Department and NIOSH have noted, the burden imposed by these standards is low because they reflect standard industry practice and technology that digital-radiography facilities already follow. See 78 FR 35579; 77 FR 56724 (September 13, 2012); 77 FR 1372 (January 9, 2012). Although a particular facility might incur an added cost for purchasing an additional medical-grade monitor or computer processing unit so that images may be displayed side-by-side with the ILO standard images when interpreting them for pneumoconiosis—a requirement imposed by both NIOSH regulations and this final rule—the Department believes that many, if not most, radiography facilities already have this capacity. Notably, no member of the medical community commented on this requirement or raised cost-related concerns in response to either the NPRM or NIOSH’s proposed rule.

Executive Order 13563 also instructs agencies to review “rules that may be outdated, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them.” As explained in the NPRM, this rule revises obsolete terms (e.g., replacing “roentgenogram” with “radiograph” or “X-ray”), discontinues publication of obsolete provisions (e.g., the X-ray rereading prohibition provisions), and replaces the imprecise term “shall.” 78 FR 35577–35578. Because the Department received no comment on these revisions, the affected regulations have been promulgated as proposed. Finally, because this is not a “significant” rule within the meaning of Executive Order 12866, the Office of Management and Budget has not reviewed it prior to publication.

C. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531 et seq., directs agencies to assess the effects of Federal Regulatory Actions on State, local, and tribal governments, and the private sector, “other than to the extent that such regulations incorporate requirements specifically set forth in law.” 2 U.S.C. 1531. For purposes of the Unfunded Mandates Reform Act, this rule does not include any Federal mandate that may result in increased expenditures by State, local, tribal governments, or increased expenditures by the private sector of more than $100,000,000.

D. Regulatory Flexibility Act and Executive Order 13272 (Proper Consideration of Small Entities in Agency Rulemaking)

The Regulatory Flexibility Act of 1980, as amended, 5 U.S.C. 601 et seq. (RFA), requires agencies to evaluate the potential impacts of their proposed and final rules on small businesses, small organizations, and small governmental jurisdictions and to prepare an analysis (called a “regulatory flexibility analysis”) describing those impacts. See 5 U.S.C. 601, 603–604. But if the rule is not expected to “have a significant economic impact on a substantial number of small entities[,]” the RFA allows an agency to so certify in lieu of preparing the analysis. See 5 U.S.C. 605. For the reasons set forth in the NPRM, the Department determined that a complete regulatory flexibility analysis was not necessary, and certified that the proposed rules would not have a significant economic impact on a substantial number of small entities. 78 FR 35580. The Department invited public comment on the certification and delivered a copy of the certification to the Chief Counsel for Advocacy of the Small Business Administration. See generally 5 U.S.C. 605.

The Chief Counsel for Advocacy has not filed comments on the certification. Although the industry comments state generally that medical facilities could incur additional costs under the new rule, these comments do not challenge the Department’s stated factual basis for the certification: (1) Using digital radiography (and incurring associated additional costs, if any) is optional; (2) the costs for a party to obtain a film or digital radiograph are equivalent; and (3) the rule will benefit all parties by providing access to additional medical facilities. These comments also were not couched in terms of small businesses and made no allegation that the parties in claim proceedings would incur additional costs. See, e.g., United Distrib. Companies v. Fed. Energy Regulatory Comm’n, 88 F.3d 1105, 1170 (D.C. Cir. 1996) (holding that agency has “no obligation to conduct a small entity impact analysis of effects on entities which it does not regulate”); Mid-Tex Elec. Coop., Inc., 773 F.2d at 343; see also White Eagle Cooper. Ass’n v. Conner, 553 F.3d 467, 480 (7th Cir. 2009) (holding that milk producers did not have standing to bring challenge to regulation of milk market under the RFA where the regulation reached the producers only indirectly).

Because the comments provide no basis for departing from its prior conclusion, the Department again certifies that this rule will not have a significant economic impact on a substantial number of small entities. As a result, no regulatory impact analysis is required.

E. Executive Order 13132 (Federalism)

The Department has reviewed this rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have “federalism implications.” E.O. 13132, 64 FR 43255 (Aug. 4, 1999). The final rule will not “have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” Id.

F. Executive Order 12988 (Civil Justice Reform)

This rule meets the applicable standards in Sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden. 61 FR 4729 (Feb. 5, 1996).

G. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must
submit a report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. OWCP will report this rule’s promulgation to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States simultaneously with publication of the rule in the Federal Register. The report will state that the rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 20 CFR Parts 718 and 725

Black lung benefits, Claims, Coal miners’ entitlement to benefits, Incorporation by reference, Survivors’ entitlement to benefits, Total disability due to pneumoconiosis, Workers’ compensation, X-rays.

For the reasons set forth in the preamble, the Department of Labor amends 20 CFR parts 718 and 725 as follows:

PART 718—STANDARDS FOR DETERMINING COAL MINERS’ TOTAL DISABILITY OR DEATH DUE TO PNEUMOCONIOSIS

1. The authority citation for part 718 is revised to read as follows:


2. Add § 718.5 to Subpart A to read as follows:

§718.5 Incorporations by reference.

(a) The materials listed in paragraphs (b) through (f) of this section are incorporated by reference in this part. The Director of the Federal Register has approved these incorporations by reference under 5 U.S.C. 522(a) and 1 CFR part 51. To enforce any edition other than that specified in these regulations, OWCP must publish notice of change in the Federal Register. All approved material is available from the sources listed below. You may inspect a copy of the approved material at the Division of Coal Mine Workers’ Compensation, OWCP, U.S. Department of Labor, Washington, DC. To arrange for an inspection at OWCP, call 202–693–0046. These materials are also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to http://www.archives.gov/federalregister/codofederalregulations/ibrlocations.html.

(b) American Association of Physicists in Medicine, Order Department, Medical Physics Publishing, 4513 Vernon Blvd., Madison, WI 53705, http://www.aapm.org/pubs/reports:

(1) AAPM On-Line Report No. 03, Assessment of Display Performance for Medical Imaging Systems, April 2005, IBR approved for Appendix A to part 718, paragraph (d).

(2) AAPM Report No. 93, Acceptance Testing and Quality Control of Photostimulable Storage Phosphor Imaging Systems, October 2006, IBR approved for Appendix A to part 718, paragraph (d).

(c) American College of Radiology, 1891 Preston White Dr., Reston, VA 20191, http://www.acr.org/~/media/ACR/Documents/PGTS/guidelines/Reference_Levels.pdf:

(1) ACR Practice Guideline for Diagnostic Reference Levels in Medical X-Ray Imaging, Revised 2008 (Resolution 3), IBR approved for Appendix A to part 718, paragraph (d).

(2) [Reserved]

(d) International Labour Office, CH–1211 Geneva 22, Switzerland, http://www.ilo.org/public: (1) Occupational Safety and Health Series No. 22, Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses, Revised edition 2011, IBR approved for §718.102(d) and Appendix A to part 718, paragraph (d).

(2) Occupational Safety and Health Series No. 22 (Rev. 2000), Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses, Revised edition 2000, IBR approved for §718.102(d).


(2) NCRP Report No. 105, Radiation Protection for Medical and Allied Health Personnel, issued October 30, 1989, IBR approved for Appendix A to part 718, paragraph (b).

(f) National Electrical Manufacturers Association, 1300 N. 17th Street, Rosslyn, VA 22209, http://medical.nema.org:


(2) DICOM Standard PS 3.4–2011, Digital Imaging and Communications in Medicine (DICOM) standard, Part 4: Service Class Specifications, copyright 2011, IBR approved for Appendix A to part 718, paragraph (d).


3. Revise §718.101(a) to read as follows:

§718.101 General.

(a) The Office of Workers’ Compensation Programs (hereinafter OWCP or the Office) must develop the medical evidence necessary to determine each claimant’s entitlement to benefits. Each miner who files a claim for benefits under the Act must be provided an opportunity to substantiate his miner claim by means of a complete pulmonary evaluation including, but not limited to, a chest radiograph (X-
§ 718.102 Chest radiographs (X-rays).

(a) A chest radiograph (X-ray) must be of suitable quality for proper classification of pneumoconiosis and must conform to the standards for administration and interpretation of chest X-rays as described in Appendix A.

(b) Chest X-rays may be produced by either film or digital radiography systems as defined in Appendix A to this part.

(c) The images described in paragraphs (c)(1) and (2) of this section will not be considered of suitable quality for proper classification of pneumoconiosis under this section:

(1) Digital images derived from film screen chest X-rays (e.g., by scanning or digital photography); and

(2) Images that were acquired using digital systems and then printed on transparencies for back-lighted display (e.g., using traditional view boxes).

(d) Standards for classifying radiographs:

(1) To establish the existence of pneumoconiosis, a film chest X-ray must be classified as Category 1, 2, 3, A, B, or C, in accordance with the International Labour Organization (ILO) classification system established in one of the following:

(i) Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses, revised edition 2011 (incorporated by reference, see § 718.5).

(ii) Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses, revised edition 2000 (incorporated by reference, see § 718.5).

(iii) Guidelines for the Use of ILO International Classification of Radiographs of Pneumoconioses, revised edition 1980 (incorporated by reference, see § 718.5).

(2) To establish the existence of pneumoconiosis, a digital chest radiograph must be classified as Category 1, 2, 3, A, B, or C, in accordance with the ILO classification system established in Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses, revised edition 2011.

(3) A chest radiograph classified under any of the foregoing ILO classification systems as Category 0, including subcategories 0-, 0/0, or 0/1, does not constitute evidence of pneumoconiosis.

(e) An X-ray report must include the following:

(1) The name and qualifications of the person who took the X-ray.

(2) The name and qualifications of the physician who interpreted the X-ray. The interpreting physician must indicate whether he or she was a Board-certified radiologist, a Board-eligible radiologist, or a Certified B Reader as defined below on the date the interpretation was made.

(i) Board-certified radiologist means that the physician is certified in radiology or diagnostic radiology by the American Board of Radiology, Inc., or the American Osteopathic Association.

(ii) Board-eligible radiologist means that the physician has successfully completed a formal accredited residency program in radiology or diagnostic radiology.

(iii) Certified B Reader means that the physician has demonstrated ongoing proficiency in evaluating chest radiographs for radiographic quality and in the use of the ILO classification for interpreting chest radiographs for pneumoconiosis and other diseases by taking and passing a specially designed proficiency examination given on behalf of or by the National Institute for Occupational Safety and Health (NIOSH), and maintained that certification through the date the interpretation is made. See 42 CFR 37.52(b).

(f) A description and interpretation of the findings in terms of the ILO classification described in paragraph (d) of this section.

(g) A statement that the X-ray was interpreted in compliance with this section.

(h) Radiograph Submission: For film X-rays, the original film on which the X-ray report is based must be supplied to OWCP. For digital X-rays, a copy of the original digital object upon which the X-ray report is based, formatted to meet the standards for transmission of diagnostic chest images set forth in Appendix A, paragraph (d), must be provided to OWCP on a DVD or other media specified by OWCP. In cases where the law prohibits the parties or a physician from supplying the original film or a copy of the digital image, the report will be considered as evidence only if the original film or digital image is otherwise available to OWCP and the other parties.

(3) If the presumptions described in § 718.304 or § 718.305 are applicable, it must be presumed that the miner is or was suffering from pneumoconiosis.

(4) A determination of the existence of pneumoconiosis may also be made if a physician, exercising sound medical judgment, notwithstanding a negative X-ray, finds that the miner suffers or suffered from pneumoconiosis as defined in § 718.201. Any such finding must be based on objective medical evidence such as blood-gas studies, electrocardiograms, pulmonary function studies, physical performance tests, physical examination, and medical and
work histories. Such a finding must be supported by a reasoned medical opinion. (b) A claim for benefits must not be denied solely on the basis of a negative chest X-ray.

(c) A determination of the existence of pneumoconiosis must not be made—

(1) Solely on the basis of a living miner’s statements or testimony; or

(2) In a claim involving a deceased miner, solely on the basis of the affidavit(s) (or equivalent testimony) of the claimant and/or his or her dependents who would be eligible for augmentation of the claimant’s benefits if the claim were approved.

§ 718.304 Irrebuttable presumption of total disability or death due to pneumoconiosis.

There is an irrebuttable presumption that a miner is totally disabled due to pneumoconiosis, that a miner’s death was due to pneumoconiosis or that a miner was totally disabled due to pneumoconiosis at the time of death, if such miner is suffering or suffered from a chronic dust disease of the lung which:

(a) When diagnosed by chest X-ray (see § 718.202 concerning the standards for X-rays and the effect of interpretations of X-rays by physicians) yields one or more large opacities (greater than one centimeter in diameter) and would be classified in Category A, B, or C in accordance with the classification system established in Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses as provided in § 718.102(d); or

(b) When diagnosed by biopsy or autopsy, yields massive lesions in the lung; or

(c) When diagnosed by means other than those specified in paragraphs (a) and (b) of this section, would be a condition which could reasonably be expected to yield the results described in paragraph (a) or (b) of this section had diagnosis been made as therein described: Provided, however, that any diagnosis made under this paragraph must accord with acceptable medical procedures.

§ 718.305 Definitions.

(a) Definitions.

(1) Digital radiography systems, as used in this context, include both digital radiography (DR) and computed radiography (CR). Digital radiography is the term used for digital X-ray image acquisition systems in which the X-ray signals received by the image detector are converted nearly instantaneously to electronic signals without moveable cassettes. Computed radiography is the term for digital X-ray image acquisition systems that detect the X-ray signals using a cassette-based photostimulable storage phosphor. Subsequently, the cassette is processed using a stimulating laser beam to convert the latent radiographic image to electronic signals which are then processed and stored so they can be displayed.

(2) Qualified medical physicist means an individual who is trained in evaluating the performance of radiographic equipment including radiation controls and facility quality assurance programs, and has the relevant current certification by a competent U.S. national board, or unrestricted license or approval from a U.S. State or Territory.

(3) Radiographic technique chart means a table that specifies the types of cassette, intensifying screen, film or digital detector, grid, filter, and lists X-ray machine settings (tuning, kVp, mAs) that enables the radiographer to select the correct settings based on the body habitus or the thickness of the chest tissue.

(4) Radiologic technologist means an individual who has met the requirements for privileges to perform general radiographic procedures and for competence in using the equipment and software employed by the examining facility to obtain chest images as specified by the State or Territory and examining facility in which such services are provided. Optimally, such an individual will have completed a formal training program in radiography leading to a certificate, an associate’s degree, or a bachelor’s degree and participated in the voluntary initial certification and annual renewal of registration for radiologic technologists offered by the American Registry of Radiologic Technologists.

(5) Soft copy means the image of a coal miner’s chest radiograph acquired using a digital radiography system, viewed at the full resolution of the image acquisition system using an electronic medical image display device.

(b) General provisions.

(1) Facilities must maintain ongoing licensure and certification under relevant local, State, and Federal laws and regulations for all digital equipment and related processes covered by this Appendix. Radiographic equipment, its use and the facilities (including mobile facilities) in which such equipment is used must conform to applicable State or Territorial and Federal regulations. Where no applicable regulations exist regarding reducing the risk from ionizing radiation exposure in the clinical setting, radiographic equipment, its use and the facilities (including mobile facilities) in which such equipment is used should conform to the recommendations in NCRP Report No. 102, NCRP Report No. 105, and NCRP Report No. 147 (incorporated by reference, see § 718.5).

(2) Chest radiographs of miners must be performed:

(i) By or under the supervision of a physician who makes chest radiographs in the normal course of practice and who has demonstrated ability to make chest radiographs of a quality to best ascertain the presence of pneumoconiosis; or

(ii) By a radiologic technologist.

(3) Miners must be disrobed from the waist up at the time the radiograph is given. The facility must provide a dressing area and for those miners who wish to use one, the facility will provide a clean gown. Facilities must be heated to a comfortable temperature.

(4) Before the miner is advised that the examination is concluded, the radiograph must be processed and inspected and accepted for quality standards by the physician, or if the physician is not available, acceptance may be made by the radiologic technologist. In a case of a substandard radiograph, another must be made immediately.

(c) Chest radiograph specifications—film

(1) Every chest radiograph must be a single posteroanterior projection at full inspiration on a film being no less than 14 by 17 inch film. Additional chest films or views must be obtained if they are necessary for clarification and classification. The film and cassette must be capable of being positioned both vertically and horizontally so that the chest radiograph will include both apices and costophrenic angles. If a miner is too large to permit the above requirements, then a projection with minimum loss of costophrenic angle must be made.

(2) Radiographs must be made with a diagnostic X-ray machine having a rotating anode tube with a maximum of a 2 mm source (total spot).

(3) Except as provided in paragraph (c)(4) of this appendix, radiographs must be made with units having generators that comply with the following:

(i) Generators of existing radiographic units acquired by the examining facility prior to July 27, 1973, must have a minimum rating of 200 mA at 100 kVp;

(ii) Generators of units acquired subsequent to that date must have a minimum rating of 300 mA at 125 kVp. A generator with a rating of 150 kVp is recommended.

(4) Radiographs made with battery-powered mobile or portable equipment must be made with units having a minimum rating of 100 mA at 110 kVp at 500 Hz, or 200 mA at 110 kVp at 60 Hz.

(5) Capacitor discharge and field emission equipment is not acceptable.
(6) Radiographs must be given only with equipment having a beam-limiting device that does not cause large unexposed boundaries. The use of such a device must be discernible from an examination of the radiograph.

(7) To ensure high quality chest radiographs:
(i) The maximum exposure time must not exceed 50 milliseconds except that with single phase units with a rating less than 300 mAs at 125 kVp and subjects with chest parameters over 28 cm, if postero-anterior, the exposure may be increased to not more than 100 milliseconds;
(ii) The source or focal spot to film distance must be at least 6 feet.
(iii) Medium-speed film and medium-speed intensifying screens are recommended. However, any film-screen combination, the rated “speed” of which is at least 100 and does not exceed 300, which produces radiographs with spatial resolution, contrast, latitude, and quantum mottle similar to those of systems designated as “medium speed” may be used.
(iv) Film-screen contact must be maintained and verified at 6-month or shorter intervals.
(v) Intensifying screens must be inspected at least once a month and cleaned when necessary by the method recommended by the manufacturer.
(vi) All intensifying screens in a cassette must be of the same type and made by the same manufacturer;
(vii) When using over 90 kV, a suitable grid or other means of reducing scattered radiation must be used;
(viii) The geometry of the radiographic system must ensure that the central axis (ray) of the primary beam is perpendicular to the plane of the film surface and impinges on the center of the film.

(8) Radiographic processing:
(i) Either automatic or manual film processing is acceptable. A constant time-temperature technique must be meticulously employed for manual processing.
(ii) If mineral or other impurities in the processing water introduce difficulty in obtaining a high-quality radiograph, a suitable filter or purification system must be used.

(9) An electric power supply must be used that complies with the voltage, current, and regulation specified by the manufacturer of the machine. If the manufacturer or installer of the radiographic equipment recommends equipment for control of electrical power fluctuations, such equipment must be used as recommended.

(5) Radiographs must be obtained with units having generators which have a minimum rating of 300 mAs at 125 kVp. Exposure kilovoltage must be at least the minimum as recommended by the manufacturer for chest radiography.

(4) An electric power supply must be used that complies with the voltage, current, and regulation specified by the manufacturer of the machine. If the manufacturer or installer of the radiographic equipment recommends equipment for control of electrical power fluctuations, such equipment must be used as recommended.

(10) A test object may be required on each radiograph for an objective evaluation of film quality. The storage phosphor cassette or digital image detector must be positioned either vertically or horizontally so that the image includes the apices and costophrenic angles of both right and left lungs. If the detector cannot include the apices and costophrenic angles of both lungs as described, then the two side-by-side images can be obtained that together include the apices and costophrenic angles of both right and left lungs.

(11) The geometry of the radiographic system must ensure that the central axis (ray) of the primary beam is perpendicular to the plane of the CR imaging plate or DR detector and is correctly aligned to the grid.

(8) A specific test object may be required under the conditions (a) and (b) as defined in the DICOM Standard PS 3.3–2011, Information Object Definitions, sections: (a) Digital Imaging and Communications in Medicine (DICOM) standard (incorporated by reference, see Section 718.5).

(C) Exposure parameters as defined in the DICOM Standard PS 3.16–2011 must additionally be provided when such parameters are available from the facility digital image acquisition system or recorded in a written report or electronic file and transmitted to OWCP.
(12) Radiographs must not be made when the environmental temperatures and humidity in the facility are outside the manufacturer’s recommended range of the CR and DR equipment to be used.

(13) All interpreters, whenever classifying digitally acquired chest radiographs, must have immediately available for reference a complete set of ILO standard digital chest radiographic images provided for use with the Guidelines for the Use of the ILO International Classification of Radiographs of Pneumocystis (2007 Revision) (incorporated by reference, see §718.5). Modification of the appearance of the standard images using software tools is not permitted.

(14) Viewing systems should enable readers to display the coal miner’s chest image at the full resolution of the image acquisition system, side-by-side with the selected ILO standard images for comparison.

(i) (A) Image display devices must be flat panel monitors displaying at least 3 MP at 10 bit depth. Image displays and associated graphics cards must meet the calibration and other specifications in the Digital Imaging and Communications in Medicine (DICOM) standard PS 3.14–2011 (incorporated by reference, see §718.5).

(B) Image displays and associated graphics cards must not deviate by more than 10 percent from the grayscale standard display function (GSDF) when assessed according to the AAPM On-Line Report No. 03, pages 1–146 (incorporated by reference, see §718.5).

(ii) Display system luminance (maximum and ratio), relative noise, linearity, modulation transfer function (MTF), frequency, and glare should meet or exceed the recommendations listed in AAPM On-Line Report No. 03, pages 1–146 (incorporated by reference, see §718.5). Viewing displays must have a maximum luminance of at least 171 cd/m², 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, after light sources have been minimized, must be included in luminance measurements.

(iii) Displays must be situated so as to minimize front surface glare. Readers must minimize reflected light from ambient sources during the performance of classification.

(iv) Measurements of the width and length of pleural shadows and the diameter of opacities must be taken using calibrated software measuring tools. If permitted by the viewing software, a record must be made of the presentation state(s), including any noise reduction and edge enhancement or restoration functions that were used in performing the classification, including any annotations and measurements.

(15) Quality control procedures for devices used to display chest images for classification must comply with the recommendations of the American Association of Physicists in Medicine AAPM On-Line Report No. 03, pages 1–146 (incorporated by reference, see §718.5). If automatic quality assurance systems are used, visual inspection must be performed using one or more test patterns recommended by the medical physicist every 6 months, or more frequently, to check for defects that automatic systems may not detect.

(16) Classification of CR and DR digitally-acquired chest radiographs under this Part must be performed based on the viewing images displayed as soft copies using the viewing workstations specified in this section. Classification of radiographs must not be based on the viewing of hard copy printed transparencies of images that were digitally-acquired.

(17) The classification of chest radiographs based on digitized copies of chest radiographs that were originally acquired using film-screen techniques is not permissible.

PART 725—CLAIMS FOR BENEFITS UNDER PART C OF TITLE IV OF THE FEDERAL MINE SAFETY AND HEALTH ACT, AS AMENDED

§ 725.406 Medical examinations and tests.

(a) The Act requires the Department to provide each miner who applies for benefits with the opportunity to undergo a complete pulmonary examination at no expense to the miner. A complete pulmonary examination includes a report of physical examination, a pulmonary function study, a chest radiograph, and, unless medically contraindicated, a blood gas study.

(b) As soon as possible after a miner files an application for benefits, the district director will provide the miner with a list of medical facilities and physicians in the state of the miner’s residence and states contiguous to the state of the miner’s residence that the Office has authorized to perform complete pulmonary examinations. The miner must select one of the facilities or physicians on the list, provided that the miner may not select any physician to whom the miner or the miner’s spouse is related to the fourth degree of consanguinity, and the miner may not select any physician who has examined or provided medical treatment to the miner within the twelve months preceding the date of the miner’s application. The district director will make arrangements for the miner to be given a complete pulmonary examination by that facility or physician. The results of the complete pulmonary examination must not be counted as evidence submitted by the miner under §725.414.

(c) If any medical examination or test conducted under paragraph (a) of this section is not administered or reported in substantial compliance with the provisions of part 718 of this subchapter, or does not provide sufficient information to allow the district director to decide whether the miner is eligible for benefits, the district director must schedule the miner for further examination and testing. Where the deficiencies in the report are the result of a lack of effort on the part of the miner, the miner will be afforded one additional opportunity to produce a satisfactory result. In order to determine whether any medical examination or test was administered and reported in substantial compliance with the provisions of part 718 of this subchapter, the district director may have any component of such examination or test reviewed by a physician selected by the district director.