

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
5/1/2014	OR	Aurora	Aurora State	4/5599	03/05/14	RNAV (GPS) RWY 17, Orig-C.
5/1/2014	CA	Porterville	Porterville Muni	4/6546	03/03/14	GPS RWY 30, Orig.
5/1/2014	CA	Petaluma	Petaluma Muni	4/6727	03/05/14	VOR RWY 29, Orig-A.
5/1/2014	CA	Oakland	Metropolitan Oakland Intl	4/6734	03/05/14	VOR RWY 10R, Amdt 9A.
5/1/2014	CA	Sacramento	Sacramento Executive	4/6869	03/03/14	VOR RWY 2, Amdt 10A.
5/1/2014	CA	Sacramento	Sacramento Executive	4/6871	03/03/14	RNAV (GPS) RWY 2, Orig-A.
5/1/2014	MT	Havre	Havre City-County	4/6966	03/05/14	VOR RWY 26, Amdt 9.
5/1/2014	MT	Havre	Havre City-County	4/6967	03/05/14	RNAV (GPS) RWY 8, Orig.
5/1/2014	MT	Havre	Havre City-County	4/6968	03/05/14	RNAV (GPS) RWY 26, Orig.
5/1/2014	OR	John Day	Grant Co Rgnl/Ogilvie Field.	4/7331	03/03/14	RNAV (GPS) Y RWY 9, Orig-C.
5/1/2014	OR	John Day	Grant Co Rgnl/Ogilvie Field.	4/7332	03/03/14	RNAV (GPS) Z RWY 9, Orig-C.
5/1/2014	WA	Shelton	Sanderson Field	4/7378	03/03/14	GPS RWY 5, Amdt 1A.
5/1/2014	TX	Crockett	Houston County	4/7394	03/05/14	RNAV (GPS) RWY 2, Orig.
5/1/2014	TX	Crockett	Houston County	4/7395	03/05/14	RNAV (GPS) RWY 20, Orig.
5/1/2014	IL	Marion	Williamson County Rgnl ..	4/7398	03/03/14	VOR RWY 2, Amdt 13B.
5/1/2014	IL	Marion	Williamson County Rgnl ..	4/7399	03/03/14	RNAV (GPS) RWY 20, Amdt 1.
5/1/2014	IL	Marion	Williamson County Rgnl ..	4/7400	03/03/14	RNAV (GPS) RWY 2, Amdt 1.
5/1/2014	IL	Marion	Williamson County Rgnl ..	4/7401	03/03/14	NDB RWY 20, Amdt 10B.
5/1/2014	IL	Marion	Williamson County Rgnl ..	4/7402	03/03/14	VOR RWY 20, Amdt 17B.
5/1/2014	IL	Marion	Williamson County Rgnl ..	4/7403	03/03/14	ILS OR LOC RWY 20, Amdt 12.
5/1/2014	FL	Pensacola	Pensacola Gulf Coast Rgnl.	4/8771	03/03/14	LOC RWY 26, Amdt 1.
5/1/2014	AL	Floral	Floral Muni	4/9175	03/03/14	RNAV (GPS) RWY 22, Amdt 1.
5/1/2014	MO	St Louis	Lambert-St Louis Intl	4/9239	03/05/14	ILS OR LOC RWY 30R, ILS RWY 30R (CAT II), ILS RWY 30R (CAT III), Amdt 10A.
5/1/2014	MO	St Louis	Lambert-St Louis Intl	4/9240	03/05/14	ILS OR LOC RWY 11, ILS RWY 11 (CAT II), ILS RWY 11 (CAT III), Orig-B.
5/1/2014	WA	Moses Lake	Grant Co Intl	4/9457	03/03/14	RNAV (RNP) Z RWY 14L, Orig.
5/1/2014	WA	Moses Lake	Grant Co Intl	4/9458	03/03/14	RNAV (GPS) Y RWY 14L, Amdt 1A.
5/1/2014	CA	Oroville	Oroville Muni	4/9765	03/05/14	VOR A, Amdt 7A.
5/1/2014	AZ	Fort Huachuca Sierra Vista.	Sierra Vista Muni-Libby AAF.	4/9914	03/03/14	VOR RWY 26, Amdt 5.
5/1/2014	AZ	Fort Huachuca Sierra Vista.	Sierra Vista Muni-Libby AAF.	4/9915	03/03/14	RNAV (GPS) RWY 8, Amdt 1A.

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DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

20 CFR Parts 718 and 725

RIN 1240-AA07

Black Lung Benefits Act: Standards for Chest Radiographs

AGENCY: Office of Workers' Compensation Programs, Labor.

ACTION: Final rule.

SUMMARY: Physicians and adjudicators use chest radiographs (X-rays) as a tool in evaluating whether a coal miner suffers from pneumoconiosis (black lung disease). Accordingly, the Department's regulations implementing the Black Lung Benefits Act allow the submission of radiographs in connection with benefit claims and set out quality standards for administering

and interpreting film-based chest radiographs. 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: Gerald Delo, Deputy Director, Division of Coal Mine Workers' Compensation, Office of Workers' Compensation Programs, U.S. Department of Labor, 200 Constitution Avenue NW., Suite C-3520, Washington, DC 20210. Telephone: (202) 343-5907 (this is not a toll-free number). TTY/TDD callers may dial toll-free 1-800-877-8339 for further information.

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 53645. 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 participation 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 submitting X-rays that are produced either by film or digital radiography systems. The Department explained in detail each of the proposed revisions, deletions, and additions in the NPRM. *See* 78 FR 35577–79.

The Department has considered the comments received but declines to revise the proposed rule for the reasons set forth in this section. In reaching this conclusion, the Department consulted extensively with NIOSH, and NIOSH has reviewed this final rule. The Department’s response to cost-related comments is set forth below in the section on Executive Orders 12866 and 13563.

20 CFR 718.102(c) and Part 718 Appendix A, Paragraph (d)(16): Converted Radiographs

Section 718.102(c) and paragraph (d)(16) of Appendix A, as proposed, prohibit the use of interpretations of X-rays that have been converted from digital to film, or vice-versa. The Department proposed the limitation because NIOSH had determined that these “converted” radiographs do not assure similar results to that obtained from film under the existing standards. *See* 78 FR 35578.

The ACR and the industry comments ask the Department to remove this provision from the regulation. Acknowledging that converted images are not ideal, the ACR states that they nevertheless can be adequate for interpretation. The industry comments claim that 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, Goodsitt 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 evaluations and that it is unclear whether legal entities involved in state 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.

Part 718 Appendix A, Paragraph (d)(14): Software Availability for Interpreting Digital Radiographs

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 provider 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 request to OMB. OMB preapproved the revisions to the information collection on December 27,

2013. See <http://www.reginfo.gov/public/do/PRAOMBHistory?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 reading 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 in both the 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 outmoded, 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 business 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 Coop. 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:

Authority: 5 U.S.C. 301; Reorganization Plan No. 6 of 1950, 15 FR 3174; 30 U.S.C. 901 *et seq.*, 902(f), 934, 936; 33 U.S.C. 901 *et seq.*; 42 U.S.C. 405; Secretary's Order 10–2009, 74 FR 58834.

■ 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/codeoffederalregulations/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/publns>: (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).

(3) Occupational Safety and Health Series No. 22 (Rev. 80), Guidelines for the Use of ILO International Classification of Radiographs of Pneumoconioses, Revised edition 1980, IBR approved for § 718.102(d).

(e) National Council on Radiation Protection and Measurements, NCRP Publications, 7910 Woodmont Avenue, Suite 400, Bethesda, MD 20814–3095, Telephone (800) 229–2652, <http://www.ncrppublications.org>:

(1) NCRP Report No. 102, Medical X-Ray, Electron Beam, and Gamma-Ray Protection for Energies Up to 50 MeV (Equipment Design, Performance, and Use), issued June 30, 1989, IBR approved for Appendix A to part 718, paragraph (b).

(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).

(3) NCRP Report No. 147, Structural Shielding Design for Medical X-Ray Imaging Facilities, revised March 18, 2005, 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>:

(1) DICOM Standard PS 3.3–2011, Digital Imaging and Communications in Medicine (DICOM) standard, Part 3: Information Object Definitions, copyright 2011, IBR approved for Appendix A to part 718, paragraph (d).

(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) DICOM Standard PS 3.10–2011, Digital Imaging and Communications in Medicine (DICOM) standard, Part 10: Media Storage and File Format for Media Interchange, copyright 2011, IBR approved for Appendix A to part 718, paragraph (d).

(4) DICOM Standard PS 3.11–2011, Digital Imaging and Communications in Medicine (DICOM) standard, Part 11: Media Storage Application Profiles, copyright 2011, IBR approved for Appendix A to part 718, paragraph (d).

(5) DICOM Standard PS 3.12–2011, Digital Imaging and Communications in Medicine (DICOM) standard, Part 12: Media Formats and Physical Media for Media Interchange, copyright 2011, IBR approved for Appendix A to part 718, paragraph (d).

(6) DICOM Standard PS 3.14–2011, Digital Imaging and Communications in Medicine (DICOM) standard, Part 14: Grayscale Standard Display Function, copyright 2011, IBR approved for Appendix A to part 718, paragraph (d).

(7) DICOM Standard PS 3.16–2011, Digital Imaging and Communications in Medicine (DICOM) standard, Part 16: Content Mapping Resource, 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 or her claim by means of a complete pulmonary evaluation including, but not limited to, a chest radiograph (X-

ray), physical examination, pulmonary function tests, and a blood-gas study.

* * * * *

■ 4. Revise § 718.102 to read as follows:

§ 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 has maintained that certification through the date the interpretation is made. *See* 42 CFR 37.52(b).

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

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

(f) *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.

(g) Where the chest X-ray of a deceased miner has been lost or destroyed, or is otherwise unavailable, a report of the chest X-ray submitted by any party may be considered in connection with the claim.

(h) Except as provided in this paragraph (h), no chest X-ray may constitute evidence of the presence or absence of pneumoconiosis unless it is conducted and reported in accordance with the requirements of this section and Appendix A. In the absence of evidence to the contrary, compliance with the requirements of Appendix A must be presumed. In the case of a deceased miner where the only available X-ray does not substantially comply with paragraphs (a) through (e) of this section, the X-ray may form the basis for a finding of the presence or absence of pneumoconiosis if it is of sufficient quality for determining whether pneumoconiosis is present and it was interpreted by a Board-certified radiologist, Board-eligible radiologist, or Certified B Reader.

■ 5. Revise § 718.202 to read as follows:

§ 718.202 Determining the existence of pneumoconiosis.

(a) A finding of the existence of pneumoconiosis may be made as follows in paragraphs (a)(1) through (4) of this section:

(1) A chest X-ray conducted and classified in accordance with § 718.102 may form the basis for a finding of the existence of pneumoconiosis. Except as otherwise provided in this section, where two or more X-ray reports are in conflict, in evaluating such X-ray reports consideration must be given to the radiological qualifications of the physicians interpreting such X-rays (*see* § 718.102(d)).

(2) A biopsy or autopsy conducted and reported in compliance with § 718.106 may be the basis for a finding of the existence of pneumoconiosis. A finding in an autopsy or biopsy of anthracotic pigmentation, however, must not be considered sufficient, by itself, to establish the existence of pneumoconiosis. A report of autopsy must be accepted unless there is evidence that the report is not accurate or that the claim has been fraudulently represented.

(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.

■ 6. Revise § 718.304 to read as follows:

§ 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.

■ 7. Revise Appendix A to Part 718 to read as follows:

Appendix A to Part 718—Standards for Administration and Interpretation of Chest Radiographs (X-rays)

The following standards are established in accordance with sections 402(f)(1)(D) and 413(b) of the Act. They were developed in consultation with the National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and

Prevention in the Department of Health and Human Services. These standards are promulgated for the guidance of physicians and medical technicians to ensure that uniform procedures are used in administering and interpreting X-rays and that the best available medical evidence will be submitted in connection with a claim for black lung benefits. If it is established that one or more standards have not been met, the claims adjudicator may consider such fact in determining the evidentiary weight to be assigned to the physician's report of an X-ray.

(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 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 (timing, kVp, mA) 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 (focal 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 units may be used.

(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 mA at 125 kVp and subjects with chests over 28 cm 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 employed;

(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 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.

(10) A test object may be required on each radiograph for an objective evaluation of film quality at the discretion of the Department of Labor.

(11) Each radiograph made under this Appendix must be permanently and legibly marked with the name and address of the facility at which it is made, the miner's DOL claim number, the date of the radiograph, and left and right side of the film. No other identifying markings may be recorded on the radiograph.

(d) *Chest radiograph specifications—digital radiography systems.*

(1) Every digital chest radiograph must be a single posteroanterior projection at full inspiration on a digital detector with sensor area being no less than 1505 square centimeters with a minimum width of 35 cm.

The imaging plate must have a maximum pixel pitch of 200 μm , with a minimum bit depth of 10. Spatial resolution must be at least 2.5 line pairs per millimeter. 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.

(2) Radiographs must be made with a diagnostic X-ray machine with a maximum actual (not nominal) source (focal spot) of 2 mm, as measured in two orthogonal directions.

(3) Radiographs must be made with units having generators which have a minimum rating of 300 mA 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.

(5) Radiographs must be obtained only with equipment having a beam-limiting device that does not cause large unexposed boundaries. The beam limiting device must provide rectangular collimation. Electronic post-image acquisition "shutters" available on some CR or DR systems that limit the size of the final image and that simulate collimator limits must not be used. The use and effect of the beam limiting device must be discernible on the resulting image.

(6) Radiographic technique charts must be used that are developed specifically for the X-ray system and detector combinations used, indicating exposure parameters by anatomic measurements.

(7) To ensure high quality chest radiographs:

(i) The maximum exposure time must not exceed 50 milliseconds except for subjects with chests over 28 cm posteroanterior, for whom the exposure time must not exceed 100 milliseconds.

(ii) The distance from source or focal spot to detector must be at least 70 inches (or 180 centimeters if measured in centimeters).

(iii) The exposure setting for chest images must be within the range of 100–300 equivalent exposure speeds and must comply with ACR Practice Guidelines for Diagnostic Reference Levels in Medical X-ray Imaging, Section V—Diagnostic Reference Levels for Imaging with Ionizing Radiation and Section VII—Radiation Safety in Imaging (incorporated by reference, *see* § 718.5). Radiation exposures should be periodically measured and patient radiation doses estimated by the medical physicist to assure doses are as low as reasonably achievable.

(iv) Digital radiography system performance, including resolution, modulation transfer function (MTF), image signal-to-noise and detective quantum

efficiency must be evaluated and judged acceptable by a qualified medical physicist using the specifications in AAPM Report No. 93, pages 1–68 (incorporated by reference, *see* § 718.5). Image management software and settings for routine chest imaging must be used, including routine amplification of digital detector signal as well as standard image post-processing functions. Image or edge enhancement software functions must not be employed unless they are integral to the digital radiography system (not elective); in such cases, only the minimum image enhancement permitted by the system may be employed.

(v)(A) The image object, transmission and associated data storage, film format, and transmissions of associated information must conform to the following components of the Digital Imaging and Communications in Medicine (DICOM) standard (incorporated by reference, *see* § 718.5):

(1) DICOM Standard PS 3.3–2011, Annex A—Composite Information Object Definitions, sections: Computed Radiographic Image Information Object Definition; Digital X-Ray Image Information Object Definition; X-Ray Radiation Dose SR Information Object Definition; and Grayscale Softcopy Presentation State Information Object Definition.

(2) DICOM Standard PS 3.4–2011: Annex B—Storage Service Class; Annex N—Softcopy Presentation State Storage SOP Classes; Annex O—Structured Reporting Storage SOP Classes.

(3) DICOM Standard PS 3.10–2011.

(4) DICOM Standard PS 3.11–2011.

(5) DICOM Standard PS 3.12–2011.

(6) DICOM Standard PS 13.14–2011.

(7) DICOM Standard PS 3.16–2011.

(B) Identification of each miner, chest image, facility, date and time of the examination must be encoded within the image information object, according to DICOM Standard PS 3.3–2011, Information Object Definitions, for the DICOM "DX" object. If data compression is performed, it must be lossless. Exposure parameters (kVp, mA, time, beam filtration, scatter reduction, radiation exposure) must be stored in the DX information object.

(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.

(8) A specific test object may be required on each radiograph for an objective evaluation of image quality at the Department of Labor's discretion.

(9) CR imaging plates must be inspected at least once a month and cleaned when necessary by the method recommended by the manufacturer.

(10) A grid or air gap for reducing scattered radiation must be used; grids must not be used that cause Moiré interference patterns in either horizontal or vertical images.

(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.

(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 Pneumoconioses (2011 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 of 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 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 classifications.

(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

■ 8. The authority citation for part 725 is revised to read as follows:

Authority: 5 U.S.C. 301; Reorganization Plan No. 6 of 1950, 15 FR 3174; 30 U.S.C. 901 *et seq.*, 902(f), 921, 932, 936; 33 U.S.C. 901 *et seq.*; 42 U.S.C. 405; Secretary's Order 10–2009, 74 FR 58834.

■ 9. In § 725.406, revise paragraphs (a), (b), (c) and (e) to read as follows:

§ 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 evaluation at no expense to the miner. A complete pulmonary evaluation 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 evaluations. 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 evaluation by that facility or physician. The results of the complete pulmonary evaluation 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.

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(e) The cost of any medical examination or test authorized under this section, including the cost of travel to and from the examination, must be paid by the fund. Reimbursement for overnight accommodations must not be authorized unless the district director determines that an adequate testing facility is unavailable within one day's round trip travel by automobile from the miner's residence. The fund must be reimbursed for such payments by an operator, if any, found liable for the payment of benefits to the claimant. If an operator fails to repay such expenses, with interest, upon request of the Office, the entire amount may be collected in an action brought under section 424 of the Act and § 725.603.

Gary A. Steinberg,

Acting Director, Office of Workers' Compensation Programs.

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