products of the same type design. This proposed AD would require a one-time inspection of the HP air bleed valve operating mechanism and, depending on findings, corrective action.

Costs of Compliance

We estimate that this proposed AD affects 52 Tay turbofan engines installed on airplanes of U.S. registry. We also estimate that it would take about 10 hours per engine to comply with this proposed AD. The average labor rate is $85 per hour. Required parts cost about $153 per product. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $52,156.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect 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.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866;

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Rolls-Royce Deutschland Ltd & Co KG Turbofan Engines (formerly Rolls-Royce plc): Docket No. FAA–2013–0397; Directorate Identifier 2013–NE–15–AD.

(a) Comments Due Date

We must receive comments by August 12, 2013.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Rolls-Royce Deutschland Ltd & Co KG (RRD) model Tay 650–15 turbofan engines.

(d) Reason

This AD was prompted by excessive deterioration of the high-pressure (HP) air bleed valve operating mechanism which affects the aerodynamic flutter margin, causing subsequent multiple fan blade failure. We are issuing this AD to prevent multiple fan blade failure, which could result in uncontained engine failure and damage to the airplane.

(e) Actions and Compliance

Unless already done, do the following actions.

(1) Within 1,500 flight cycles after the effective date of this AD, perform a one-time inspection of the HP air bleed valve operating mechanism. Use paragraphs 3.D. and 3.E. of RRD Alert Non-Modification Service Bulletin (NMSB) No. TAY–75–A1784, dated February 14, 2013, to do your inspection.

(2) If the measured torque necessary to open and close the HP air bleed valve is higher than the torque values referenced in paragraph 3.D.(1)(a) of RRD Alert NMSB No. TAY–75–A1784, dated February 14, 2013, then before next flight, accomplish paragraph 3.E. of RRD Alert NMSB No. TAY–75–A1784, dated February 14, 2013.

(f) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request.

(g) Related Information

(1) For more information about this AD, contact Frederick Zink, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7779; fax: 781–238–7199; email: *frederick.zink@faa.gov*.

(2) Refer to European Aviation Safety Agency Airworthiness Directive 2013–0086, dated April 9, 2013, and RRD Alert NMSB No. TAY–75–A1784, dated February 14, 2013, for related information.

(3) For service information identified in this AD, contact Rolls-Royce Deutschland Ltd & Co KG, Eschenweg 11, Dahlewitz, 15827 Blankenfelde-Mahlow, Germany; phone: 49 0 33–7086–1944; fax: 49 0 33–7086–3276. You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Issued in Burlington, Massachusetts, on June 6, 2013.

Colleen M. D'Alessandro,

Assistant Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2013–14034 Filed 6–12–13; 8:45 am]

BILLING CODE 4910–13–P

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: Notice of proposed rulemaking; request for comments.

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 their performance. These standards are currently limited to film radiographs. In recent years, many medical facilities have phased out film radiography in

favor of digital radiography. This proposed rule would update the existing film-radiograph standards and provide parallel standards for digital radiographs. The proposed rule would also update outdated terminology and remove certain obsolete provisions.

DATES: Comments on this proposed rule must be received by midnight Eastern Standard Time on August 12, 2013.

ADDRESSES: You may submit written comments, identified by RIN number 1240–AA07, by any of the following methods.

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions on the Web site for submitting comments. To facilitate receipt and processing of comments, OWCP encourages interested parties to submit their comments electronically.
- *Fax:* (202) 693–1395 (this is not a toll-free number). Only comments of ten or fewer pages, including a Fax cover sheet and attachments, if any, will be accepted by Fax.
- *Regular Mail:* Division of Coal Mine Workers' Compensation Programs, Office of Workers' Compensation Programs, U.S. Department of Labor, Room C–3520, 200 Constitution Avenue NW., Washington, DC 20210. The Department's receipt of U.S. mail may be significantly delayed due to security procedures. You must take this into consideration when preparing to meet the deadline for submitting comments.
- *Hand Delivery/Courier:* Division of Coal Mine Workers' Compensation Programs, Office of Workers' Compensation Programs, U.S. Department of Labor, Room C–3520, 200 Constitution Avenue NW., Washington, DC 20210.

Instructions: All submissions received must include the agency name and the Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Steven Breeskin, Director, Division of Coal Mine Workers' Compensation, Office of Workers' Compensation Programs, U.S. Department of Labor, 200 Constitution Avenue NW., Suite N–3464, Washington, DC 20210. Telephone: (202) 693–0824 (this is not a toll-free number). TTY/TDD callers may dial toll-free 1–800–877–8339 for further information.

SUPPLEMENTARY INFORMATION:

I. Proposed Rule Published Concurrently With Companion Direct Final Rule

In the Final Rules section of this **Federal Register** edition, OWCP is simultaneously publishing an identical rule as a ''direct final'' rule. In direct final rulemaking, an agency publishes a direct final rule in the **Federal Register** with a statement that the rule will go into effect unless the agency receives significant adverse comment within a specified period. The agency concurrently publishes an identical proposed rule. If the agency receives no significant adverse comment in response to the direct final rule, the rule goes into effect. If the agency receives significant adverse comment, the agency withdraws the direct final rule and treats such comment as submissions on the proposed rule. An agency typically uses direct final rulemaking when it anticipates the rule will be non-controversial.

OWCP has determined that this rule, which primarily adopts quality standards for administering and interpreting digital radiographs, is suitable for direct final rulemaking. The standards adopted by this rule are largely based on those the Department of Health and Human Services recently promulgated for use in the National Institute for Occupational Safety and Health (NIOSH) Coal Workers' Health Surveillance Program (CWHSP) (the NIOSH rules). Those standards were subject to full notice-and-comment rulemaking. The NIOSH proposal informed the public that the standards might also be used by the Department of Labor in the Black Lung Benefits Act (BLBA) context, and OWCP alerted the BLBA employer and claimant communities to the NIOSH proposed rule. NIOSH addressed all significant comments when it promulgated its final rule. OWCP's rule also 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. Thus, OWCP does not expect to receive significant adverse comment on this rule. Simultaneously publishing a companion direct final rule will expedite the rulemaking process to give parties the option of using digital radiographs as soon as possible.

By simultaneously publishing this proposed rule, notice-and-comment rulemaking will be expedited if OWCP receives significant adverse comment and withdraws the direct final rule. The proposed and direct final rules are substantively identical, and their respective comment periods run concurrently. OWCP will treat comments received on the proposed rule as comments regarding the companion direct final rule and vice versa. Thus, if OWCP receives a significant adverse comment on either this proposed rule or the companion direct final rule, OWCP will publish a **Federal Register** notice withdrawing the direct final rule and proceed with this proposed rule.

For purposes of the direct final rule, a significant adverse comment is one that explains: (1) why the rule is inappropriate, including challenges to the rule's underlying premise or approach; or (2) why the direct final rule will be ineffective or unacceptable without a change. In determining whether a significant adverse comment necessitates withdrawal of the direct final rule, OWCP will consider whether the comment raises an issue serious enough to warrant a substantive response if it had been submitted in a standard notice-and-comment process. A comment recommending an addition to the rule will not be considered significant and adverse unless the comment explains how the direct final rule would be ineffective without the addition.

OWCP requests comments on all issues related to this rule, including economic or other regulatory impacts of this rule on the regulated community. All interested parties should comment at this time because OWCP will not initiate an additional comment period on this proposed rule even if it withdraws the direct final rule.

II. Background of This Rulemaking

The BLBA, 30 U.S.C. 901–944, provides for the payment of benefits to coal miners and certain of their dependent survivors on account of total disability or death due to coal workers' pneumoconiosis. 30 U.S.C. 901(a); *Usery* v. *Turner Elkhorn Mining Co.,* 428 U.S. 1, 5 (1976). Benefits are paid by either an individual coal mine operator that employed the coal miner (or its insurance carrier), or the Black Lung Disability Trust Fund. *Director, OWCP* v. *Bivens,* 757 F.2d 781, 783 (6th Cir. 1985). The primary purpose of this proposed rulemaking is to update the quality standards applicable to chest radiographs (X-rays) used in diagnosing the existence of pneumoconiosis by implementing new standards for digital radiographs. The Department also proposes updating certain terminology and removing an obsolete provision as explained in the section-by-section analysis below.

From the black lung program's inception, physicians and adjudicators

have used chest X-rays as one tool in evaluating a miner's health. Recognizing their importance to claim adjudications, Congress has granted the Secretary of Labor explicit authority to, ''by regulation, establish specific requirements for the techniques used to take [chest X-rays]'' to ensure adequate and uniform X-ray quality. 30 U.S.C. 923(b). The BLBA also generally authorizes the Secretary of Labor, in consultation with NIOSH, to ''establish criteria for all appropriate medical tests'' administered in connection with benefit claims. 30 U.S.C. 902(f)(1)(D).

Based on these directives, the Department promulgated quality standards for administering and interpreting chest X-rays in 1980. *See* 45 FR 13678, 13680–81 (February 29, 1980). Codified at 20 CFR 718.102, 718.202, and Appendix A to Part 718, these standards were drawn largely from those adopted by NIOSH for what is now known as the Coal Workers' Health Surveillance Program (CWHSP). The CWHSP, mandated by the Coal Mine Health and Safety Act, was developed to detect coal workers' pneumoconiosis and prevent disease progression in individual miners, while at the same time providing information for evaluation of temporal and geographic trends in pneumoconiosis. 30 U.S.C. 843. To inform each miner of his or her health status, the CWHSP requires that underground coal mine operators offer new workers a chest X-ray through an approved facility as soon as possible after employment starts, another one three years later, and additional X-rays at periodic intervals thereafter. CWHSP chest X-rays must be administered and read in accordance with NIOSH's specifications. 30 U.S.C. 843(a). NIOSH set out these specifications—which included standards for administering, interpreting, classifying and submitting chest radiographs—for film-based radiography systems in regulations at 42 CFR part 37.

The Department modeled its 1980 BLBA chest X-ray quality standards on NIOSH's then-current regulations, which HHS had published on August 1, 1978. 43 FR 33713 (August 1, 1978). In consultation with NIOSH, the Department adopted (with minor revisions) those NIOSH rules that were relevant to ensuring that quality X-ray films would be submitted in BLBA claims. *See generally* 45 FR 13680–81 (February 29, 1980). Although NIOSH later revised two of the 42 CFR part 37 regulations the Department had adopted, 52 FR 7866–01 (March 13, 1987), the Department did not make similar changes to the BLBA quality standards. Nor did the Department revise the technical requirements (including those in Appendix A) when it amended other facets of §§ 718.102 and 718.202 in 1983 and 2000. *See* 48 FR 24273–74 (May 31, 1983); 65 FR 79929, 79945–46 (December 20, 2000). Thus, the Department's current technical quality standards for chest X-rays have not been changed since 1980.

In the past decade, digital radiography systems have been rapidly replacing traditional analog film-based systems. Claimants, coal mine operators, and the Department have been experiencing increasing difficulty in obtaining film chest X-rays—the only type the BLBA quality standards address—for miners. Interpretations of digital X-rays are admissible as ''other medical evidence'' under the catch-all provision at 20 CFR 718.107, but only if the interpretation's proponent establishes 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*); *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 has 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.

Recognizing the overarching technological shift from film to digital radiography systems, NIOSH recently promulgated new standards for administering, interpreting, classifying and submitting digital chest radiographs for the CWHSP. 77 FR 56718–56735 (September 13, 2012) (final rule). *See also* 77 FR 1360–1385 (January 9, 2012) (proposed rule). NIOSH adopted these rules only after fully investigating the validity of using digital chest X-rays for diagnosing pneumoconiosis and full notice-and-comment proceedings that allowed the public to participate. The NIOSH rules also retained the standards for film-based radiography systems with minor terminology modifications.

This proposed rule retains the current regulatory quality standards for film-based chest X-rays (with the minor modifications explained in the section-by-section analysis below) and adds parallel quality standards for digitally acquired chest radiographs. As it did when it first promulgated quality standards for film-based chest X-rays, the Department has derived its digital-radiography standards from those adopted by NIOSH for the CWHSP. The Department believes this is appropriate because Congress designated NIOSH as its statutory advisor for establishing standards for BLBA medical testing. These standards 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 Department believes that claimants, coal mine operators, and the BLBA program itself will benefit in a variety of ways from these new rules. The additional benefits are outlined in more detail below.

III. 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).

IV. Section-by-Section Explanation

Updated Terminology

The Department proposes two changes throughout the regulatory sections and Appendix that this rule revises. First, the Department has replaced the outdated term ''roentgenogram'' with the term ''radiograph,'' which is currently used in the medical community. *See, e.g.,* § 725.406(a).

Second, the Department has replaced the term ''shall.'' Executive Order 13563 states that regulations must be ''accessible, consistent, written in plain language, and easy to understand.'' 76 FR 3821 (January 21, 2011). *See also* E.O. 12866, 58 FR 51735 (October 4, 1993) (''Each agency shall draft its regulations to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty.''). To that end, the Department has replaced the imprecise term ''shall'' in those sections and the Appendix it is amending with ''must'' for obligations imposed and ''must not'' for prohibitions. *See generally* Federal Plain Language Guidelines, *http://www.plainlanguage.gov/howto/guidelines;* Black's Law Dictionary 1499 (9th ed. 2009) (''shall'' can be read

either as permissive or mandatory). These revisions required minor additional language changes in § 718.202(a)(2), (b), and (c). No change in meaning is intended.

20 CFR 718.5 Incorporations by Reference

This proposed section is new. It is added to comply with the Office of the Federal Register's rules on incorporation by reference. If any material is incorporated by reference in the final rule, OWCP will ask the Director of the Federal Register to approve the Department's incorporation of the materials. This section also explains how the public may obtain copies of the incorporated materials.

20 CFR 718.102 Chest Radiographs (X-Rays)

The Department proposes substantially revising § 718.102 to allow parties the option of submitting X-rays that are produced either by film or digital radiography systems, and to otherwise update the rule. Because these changes would require reorganization of the regulation, the Department would publish the new regulation in its entirety. The proposed revisions to each subsection of the regulation are described below.

Subsection (a) is retained and remains substantively unchanged.

Subsection (b) is new. It specifically allows for the submission of X-rays produced by either film or digital radiography systems as those systems are defined in Appendix A. Current subsection (b) has been amended and re-designated subsection (d).

Subsection (c) is new. In accordance with the NIOSH standards, subsection (c) bans the use of X-rays that have been converted from film to digital, or vice-versa. NIOSH found that these approaches do not assure similar performance to that obtained from film under the existing standards. *See* 77 FR 1366 (January 9, 2012). Current subsection (c) has been amended and re-designated subsection (e).

Subsection (d) establishes the standards for classifying both film and digital radiographs. The regulation continues to direct that classifications be made in accordance with the International Labour Organization's (ILO) classification system. For film X-rays, subsection (d)(1) lists the 1980, 2000, and 2011 editions of the ILO Guidelines. The Department has included these three editions to clarify that film X-rays acquired prior to the issuance of this regulation and interpreted under the earlier editions continue to meet the quality standards. Radiographs acquired and interpreted after implementation of this rule should be classified in accordance with the 2011 Guidelines. For digitally acquired X-rays, subsection (d)(2) requires classification using the ILO's 2011 Guidelines. The 2011 edition is the first one in which the ILO authorized the use of its classification system for digital images and developed a set of standard digital image files for use during classification. A party who wishes to introduce digital X-ray interpretations that pre-date issuance of the ILO 2011 Guidelines may still do so under the 20 CFR 718.107 ''other medical evidence'' standard. Subsection (d)(3) retains the provision that any X-ray classified as category 0 does not constitute evidence of clinical pneumoconiosis, whether acquired by film or digital systems. Finally, the Department has removed references to various classification systems published in 1958, 1968, and 1971 because they are obsolete.

Subsection (e) retains the current requirement that X-ray reports must include the name and qualifications of the medical provider who took the X-ray; the name and qualifications of the physician who interpreted it, including whether the physician is a Board-certified or Board-eligible radiologist or a Certified B Reader; the ILO classification; and a compliance statement. Definitions for Board-certified radiologist, Board-eligible radiologist, and Certified B Reader have been moved to subsection (e)(2) from their current location in 20 CFR 718.202(a)(1)(ii). The Department also updated the Certified B Reader definition by eliminating a reference to the Appalachian Laboratory for Occupational Safety and Health and adding a provision that the physician's certification must be maintained through the date he or she interprets the radiograph.

Subsection (f) is largely new. It describes the protocol for submitting film and digital X-rays to OWCP. The film protocol currently set forth under subsection (d) remains unchanged. The Department has added a protocol for submitting digital X-rays that requires parties to submit the data on DVD or other media OWCP specifies in a format that meets the standards set forth in Appendix A, paragraph (d). These standards preclude compression of the data unless the compression is lossless. *See* Appendix A, paragraph (d)(7)(v).

Subsection (g) allows an interpretation of a chest X-ray to be submitted even in the absence of the underlying X-ray film or digital data file where the miner is deceased and the film or data upon which the report is based has been lost or destroyed. This provision, currently set forth in subsection (d), remains unchanged.

Subsection (h) provides a rebuttable presumption that the technical requirements found in Appendix A have been met. This provision, currently set forth in subsection (e), remains unchanged except that the cross-reference to 20 CFR 718.202 for the definitions of Board-certified radiologist, Board-eligible radiologist, and Certified B Reader has been removed.

20 CFR 718.202 Determining the Existence of Pneumoconiosis

In addition to moving the definitions for radiology qualifications to § 718.102 (*see* explanation at § 718.102), the Department proposes revising this regulation to eliminate outdated material. The Department has deleted subsections (a)(1)(i) and (ii), which implement the BLBA's X-ray rereading prohibition that applies only to claims filed before January 1, 1982. *See* 30 U.S.C. 923(b). Similarly, the Department has eliminated the phrase ''filed on or after January 1, 1982'' in the second sentence of subsection (c), which implements the BLBA's limitations on using lay evidence to prove pneumoconiosis, and reordered that provision for clarity. Few, if any, claims filed prior to January 1, 1982 remain in litigation. Thus, it is no longer necessary to publish the criteria governing these claims or to draw distinctions based on that date. If any claim filed before January 1, 1982 results in litigation after the effective date of these regulations, and the X-ray rereading prohibition or the lay testimony provision is at issue, the version of § 718.202(a)(1)(i), (a)(ii), and (c) as reflected in the 2011 edition of the Code of Federal Regulations will continue to apply.

20 CFR 718.304 Irrebuttable Presumption of Total Disability or Death Due to Pneumoconiosis

The Department proposes revising this rule to update the references to the ILO classification system. Current subsections (a)(1), (a)(2), and (a)(3) set forth several outdated classification systems that could be used to diagnose complicated pneumoconiosis. The Department has eliminated these provisions and added a phrase to the end of subsection (a) that cross-references § 718.102(d): ''in accordance with the classification system established in Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses provided in § 718.102(d).'' As explained above, proposed § 718.102(d) sets out

the ILO classification systems that must be used when interpreting film and digital chest X-rays. This revision streamlines § 718.304 and makes it consistent with § 718.102(d).

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

Proposed Appendix A retains the current standards for acquiring chest X-rays using film-screen technology (with minor modifications) and establishes standards for acquiring and interpreting chest X-rays using digital radiography systems.

The Department's proposal divides Appendix A into four primary sections: paragraph (a) provides definitions applicable to either the film or digital chest X-ray standards, or both; paragraph (b) sets out general standards applicable to both film and digital X-rays; paragraph (c) retains the standards for film-based X-rays; and paragraph (d) establishes the new standards for acquiring and interpreting digital X-rays. The initial paragraph of the Appendix, which describes the background and purpose of the standards, remains unchanged.

Paragraph (a)'s definitions are adopted from the NIOSH rules and inform the remaining Appendix provisions.

Paragraph (b) includes general provisions that are applicable when obtaining both film and digital chest radiographs. Subparagraph (b)(1) is new and requires that facilities performing chest X-rays must continue to meet applicable local, State, and Federal licensing and certification requirements. In order to minimize the miner's risk from radiation exposure, (b)(1) also recommends that facilities conform to recognized industry standards regarding such exposure in the absence of other governing regulations. Subparagraph (b)(2) mirrors the NIOSH rules and requires that radiographs be performed by a qualified physician or radiologic technologist. *See* 42 CFR 37.40(c). This provision applies to both film and digital radiographs. Although the Department does not currently impose this requirement on film-based X-rays, doing so should not pose any problems for the regulated community because it comports with standard industry practice and the term ''radiologic technologist'' is broadly defined at Appendix A, subparagraph (a)(4). Finally, subparagraphs (b)(3) and (b)(4) retain general rules for performing X-rays that currently appear in paragraphs (2) and (10).

Paragraph (c) retains the existing standards for chest X-rays obtained by film with a few minor changes. For the sake of consistency with paragraph (d) of the Appendix, the Department has replaced the phrase ''1/20 of a second'' with 50 milliseconds, and the phrase ''1/10 of a second'' with ''100 milliseconds'' in current subparagraph (8)(i) (now located at subparagraph (c)(7)(i)). No change in meaning is intended. The Department has also amended the film speed requirements in current subparagraph (8)(iii) (now located at subparagraph (c)(7)(iii)) by adopting the NIOSH rule. *See* 42 CFR 37.41(i)(3). This change clarifies that the use of medium-speed film and intensifying screens is recommended but not required. Finally, the Department has deleted the term ''densitometric'' in current paragraph (12) (now located at subparagraph (c)(10)) because it is unnecessary.

Paragraph (d) is new and constitutes the bulk of the revisions to the Appendix. It sets out quality standards for acquiring chest radiographs using digital radiography systems as well as interpreting and transmitting them. As explained above, the Department adopted these provisions from the NIOSH rules. NIOSH fully explained these standards when it first proposed them and when it promulgated the final version. *See* 77 FR 56718–56735 (September 13, 2012) (final rule); 77 FR 1360–1385 (January 9, 2012) (proposed rule). In adopting the rule, NIOSH emphasized that the burden imposed by the standards would be low because they reflected standard industry practice and technology (*e.g.,* the DICOM standards). 77 FR 56724 (September 13, 2012); 77 FR 1372 (January 9, 2012). Moreover, many of the facilities that participate in the CWHSP will also be used to provide X-rays for BLBA claims because they are located in coal mining regions. These facilities already adhere to the NIOSH criteria and will not have to change their practices for the BLBA program. Thus, for the reasons stated by NIOSH, the Department believes that adopting these standards will ensure the quality of digital X-rays.

V. Administrative Law Considerations

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

This rulemaking would impose no new collections of information.

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 proposed rule with these principles in mind and has concluded that the regulated community will greatly benefit from this regulation.

This rule's greatest benefit is that it will increase the amount of access the Department and the parties to BLBA claims have to radiographic technology. From the Department's view, this rule will likely reduce delays in processing miners' benefits claims. The Department must offer each miner who files a claim an opportunity for a complete pulmonary evaluation. 30 U.S.C. 923(b); 20 CFR 718.101(a), 725.406. One component of that complete evaluation is a chest X-ray. 20 CFR 725.406(a). In recent years, many medical providers otherwise qualified to perform these evaluations have declined because they do not have film-based radiography systems available to them. This has led to a shortage of examining physicians. Because this rule will allow for routine acceptance of digital radiographs, the Department anticipates that it will be able to increase the number of providers available to conduct the initial complete pulmonary evaluation and reduce some delays in claim processing.

Claimants and coal mine operators (and their insurers) will similarly benefit. As the medical industry has transitioned from film to digital radiography systems over the past several years, the private parties have faced challenges in obtaining film-based X-rays. Miners have often had to travel long distances to obtain a film-based X-ray because the digital radiography services offered at a local clinic would not suffice. Not surprisingly, black lung claimants, coal-mine operators, and their representatives have repeatedly made informal requests for the Department to promulgate quality standards for digital X-rays.

This rule also will relieve parties of a demanding evidentiary burden they face when submitting interpretations based on digital X-rays. Digital X-ray interpretations are admissible in BLBA claim proceedings, but only if the interpretation's proponent establishes to the adjudicator's satisfaction that digital X-rays are medically acceptable and relevant to the claimant's entitlement to benefits. *See generally* 20 CFR 718.107;

Webber v. *Peabody Coal Co.,* 23 BLR 1–123 (2006) (*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*). If the proponent fails to meet this burden, the adjudicator does not have to consider the evidence. This rule will relieve all parties of this additional proof burden, putting digital X-rays on a similar footing to film X-rays. So long as the regulatory quality standards are met, a party need not prove medical acceptability to have interpretations of digital X-rays admitted and considered.

The Department has considered whether the parties will realize any monetary benefits or incur any additional costs in light of this proposed rule, and has concluded that it is a cost-neutral rule for several reasons. The rule expands opportunities for claimants and coal mine employers to obtain X-ray evidence. But it does not require any party to use digital X-ray systems. Thus, even if obtaining digital X-rays proved more costly, absorbing that cost is optional. In addition, the Department believes that medical facilities generally do not have different fee structures for film and digital radiographs. Instead, standard medical coding systems (*e.g.,* CPT codes) used to reimburse these facilities and process payments for chest X-rays use codes that do not reference the type of technology used to perform the X-rays. *See, e.g., http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.* Finally, to the extent miners will be able to use digital X-ray facilities closer to their homes, their lower travel costs—which in some instances are paid by the Department or passed on to the coal mine operator if the miner prevails on his benefits claim, 20 CFR 725.406(e)—will result in some minor savings.

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 section-by-section analysis above, this proposed rule revises obsolete terms (*e.g.,* replacing ''roentgenogram'' with ''radiograph'' or ''X-ray'') and removes outmoded provisions (*e.g.,* eliminating X-ray rereading prohibition provisions).

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 proposed 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.

The Department has determined that a regulatory flexibility analysis under the RFA is not required for this rulemaking. While many coal mine operators are small entities within the meaning of the RFA, *see* 77 FR 19471–72 (March 30, 2012), this rule, if adopted, will not have a significant economic impact on them for several reasons. First, this rule does not require operators to obtain digital radiographs. By promulgating quality standards specific to digital X-rays, the Department is simply providing another option to coal mine operators (and their insurers) for developing medical evidence in the BLBA claims process. Operators will be free to continue to use film-based technology. Second, even if an operator chooses to obtain digital radiographs, the Department believes that the cost for obtaining a digital X-ray will be comparable if not identical to a film-X-ray's cost. In considering this issue, the Department reviewed the medical reimbursement schedule published by the U.S. Department of Health and Human Services Centers for Medicare and Medicaid Services (CMS). The CMS schedule, which forms the basis for many public and private reimbursement schemes, does not differentiate between film-based and digitally acquired chest X-rays; instead, the schedule lists reimbursement computation formulas for different types of chest X-rays without reference to the technology used to obtain them. *See http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*). Moreover, NIOSH anticipates that lower costs for chest X-rays in general may result from medical facilities switching to digital radiography systems. *See* 77 FR 1372 (January 9, 2012). Third, this rule is expected to benefit all coal mine operators by increasing access to medical facilities that exclusively use digital radiography or are transitioning to this technology.

Based on these facts, the Department certifies that this rule will not have a significant economic impact on a substantial number of small entities. Thus, a regulatory flexibility analysis is not required. The Department invites comments from members of the public who believe the regulations will have a significant economic impact on a substantial number of small coal mine operators. The Department has provided the Chief Counsel for Advocacy of the Small Business Administration with a copy of this certification. *See* 5 U.S.C. 605.

E. Executive Order 13132 (Federalism)

The Department has reviewed this proposed 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 proposed 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 proposed 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.

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 proposes to amend 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 PS3.4–2011, 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.

(c) The images described in paragraphs (c)(1) and (2) 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, 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):

(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, § 718.305, or § 718.306 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), 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 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.

(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/m^2, 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.

* * * * *

(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 of this part.

Signed at Washington, DC, this 3rd day of June, 2013.

Gary A. Steinberg,

Acting Director, Office of Workers' Compensation Programs.

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910 and 1926

[Docket No. OSHA–2013–0005]

RIN 1218–AC77

Updating OSHA Standards Based on National Consensus Standards; Signage

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Notice of proposed rulemaking; request for comments.

SUMMARY: The Occupational Safety and Health Administration (''OSHA'' or ''the Agency'') proposes to update its general industry and construction signage standards by adding references to the latest versions of the American National Standards Institute (''ANSI'') standards on specifications for accident prevention signs and tags, ANSI Z535.1–2006(R2011), Z535.2–2011, and Z535.5–2011. OSHA also is proposing to retain the existing references to the earlier ANSI standards, ANSI Z53.1–1967, Z35.1–1968, and Z35.2–1968, in its signage standards, thereby providing employers an option to comply with the updated or earlier standards. In addition, OSHA is proposing to incorporate by reference Part VI of the Manual of Uniform Traffic Control Devices (''MUTCD''), 1988 Edition, Revision 3, into the incorporation-by-reference section of the construction standards, having inadvertently omitted this edition of the MUTCD from this