

## SUBCHAPTER B—FEDERAL COAL MINE HEALTH AND SAFETY ACT OF 1969, AS AMENDED

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

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APPENDIX A TO PART 718—STANDARDS FOR ADMINISTRATION AND INTERPRETATION OF CHEST RADIOGRAPHS (X-RAYS)

APPENDIX B TO PART 718—STANDARDS FOR ADMINISTRATION AND INTERPRETATION OF PULMONARY FUNCTION TESTS. TABLES B1, B2, B3, B4, B5, B6

### APPENDIX C TO PART 718—BLOOD-GAS TABLES

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.

SOURCE: 45 FR 13678, Feb. 29, 1980, unless otherwise noted.

#### Subpart A—General

SOURCE: 65 FR 80045, Dec. 20, 2000, unless otherwise noted.

#### § 718.1 Statutory provisions.

Section 402(f) of the Act authorizes the Secretary of Labor to establish criteria for determining total disability or death due to pneumoconiosis to be applied in the processing and adjudication of claims filed under Part C of the Act. Section 402(f) further authorizes the Secretary of Labor, in consultation with the National Institute for Occupational Safety and Health, to establish criteria for all appropriate medical tests administered in connection with a claim for benefits. Section 413(b) of the Act authorizes the Secretary of Labor to establish criteria for the techniques used to take chest roentgenograms (x-rays) in connection with a claim for benefits under the Act.

[78 FR 59114, Sept. 25, 2013]

#### § 718.2 Applicability of this part.

(a) With the exception of the second sentence of § 718.204(a), this part is applicable to the adjudication of all claims filed on or after June 30, 1982 under Part C of the Act. It provides standards for establishing entitlement to benefits under the Act and describes the criteria for the development of medical evidence used in establishing such entitlement. The second sentence of § 718.204(a) is applicable to the adjudication of all claims filed after January 19, 2001.

(b) Publication of certain provisions or parts of certain provisions that apply only to claims filed prior to June 30, 1982, or to claims subject to Section

435 of the Act, has been discontinued because those provisions affect an increasingly smaller number of claims. The version of Part 718 set forth in 20 CFR, parts 500 to end, edition revised as of April 1, 2010, applies to the adjudication of all claims filed prior to June 30, 1982, as appropriate.

(c) The provisions of this part must, to the extent appropriate, be construed together in the adjudication of claims.

[78 FR 59114, Sept. 25, 2013]

### § 718.3 Scope and intent of this part.

(a) This part sets forth the standards to be applied in determining whether a coal miner is or was totally disabled due to pneumoconiosis or died due to pneumoconiosis. It also specifies the procedures and requirements to be followed in conducting medical examinations and in administering various tests relevant to such determinations.

(b) This part is designed to interpret the presumptions contained in section 411(c) of the Act, evidentiary standards and criteria contained in section 413(b) of the Act and definitional requirements and standards contained in section 402(f) of the Act within a coherent framework for the adjudication of claims. It is intended that these enumerated provisions of the Act be construed as provided in this part.

[65 FR 80045, Dec. 20, 2000, as amended at 78 FR 59114, Sept. 25, 2013]

### § 718.4 Definitions and use of terms.

Except as is otherwise provided by this part, the definitions and usages of terms contained in § 725.101 of subpart A of part 725 of this title shall be applicable to this part.

### § 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/codeofederalregulations/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](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

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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).

[79 FR 21611, Apr. 17, 2014]

### Subpart B—Criteria for the Development of Medical Evidence

SOURCE: 65 FR 80045, Dec. 20, 2000, unless otherwise noted.

#### § 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.

(b) The standards for the administration of clinical tests and examinations contained in this subpart shall apply to all evidence developed by any party after January 19, 2001 in connection with a claim governed by this part (see §§ 725.406(b), 725.414(a), 725.456(d)). These standards shall also apply to claims governed by part 727 (see 20 CFR 725.4(d)), but only for clinical tests or examinations conducted after January 19, 2001. Any clinical test or examination subject to these standards shall be in substantial compliance with the applicable standard in order to constitute evidence of the fact for which it is proffered. Unless otherwise provided, any evidence which is not in substantial

compliance with the applicable standard is insufficient to establish the fact for which it is proffered.

[65 FR 80045, Dec. 20, 2000, as amended at 78 FR 35555, June 13, 2013; 79 FR 21611, Apr. 17, 2014]

**§ 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.

[79 FR 21612, Apr. 17, 2014]

**§ 718.103 Pulmonary function tests.**

(a) Any report of pulmonary function tests submitted in connection with a claim for benefits shall record the results of flow versus volume (flow-volume loop). The instrument shall simultaneously provide records of volume versus time (spirometric tracing). The report shall provide the results of the forced expiratory volume in one second (FEV1) and the forced vital capacity (FVC). The report shall also provide the FEV1/FVC ratio, expressed as a percentage. If the maximum voluntary ventilation (MVV) is reported, the results of such test shall be obtained independently rather than calculated from the results of the FEV1.

(b) All pulmonary function test results submitted in connection with a claim for benefits shall be accompanied by three tracings of the flow versus volume and the electronically derived volume versus time tracings. If the MVV is reported, two tracings of the MVV whose values are within 10% of each other shall be sufficient. Pulmonary function test results developed in connection with a claim for benefits shall also include a statement signed by the physician or technician conducting the test setting forth the following:

- (1) Date and time of test;
- (2) Name, DOL claim number, age, height, and weight of claimant at the time of the test;
- (3) Name of technician;
- (4) Name and signature of physician supervising the test;
- (5) Claimant's ability to understand the instructions, ability to follow directions and degree of cooperation in performing the tests. If the claimant is unable to complete the test, the person executing the report shall set forth the reasons for such failure;
- (6) Paper speed of the instrument used;
- (7) Name of the instrument used;
- (8) Whether a bronchodilator was administered. If a bronchodilator is administered, the physician's report must detail values obtained both before and after administration of the bronchodilator and explain the significance of the results obtained; and
- (9) That the requirements of paragraphs (b) and (c) of this section have been complied with.

(c) Except as provided in this paragraph, no results of a pulmonary function study shall constitute evidence of the presence or absence of a respiratory or pulmonary impairment unless it is conducted and reported in accordance with the requirements of this section and Appendix B to this part. In the absence of evidence to the contrary, compliance with the requirements of Appendix B shall be presumed. In the case of a deceased miner, where no pulmonary function tests are in substantial compliance with paragraphs (a) and (b) and Appendix B, non-complying tests may form the basis for

a finding if, in the opinion of the adjudication officer, the tests demonstrate technically valid results obtained with good cooperation of the miner.

**§ 718.104 Report of physical examinations.**

(a) A report of any physical examination conducted in connection with a claim shall be prepared on a medical report form supplied by the Office or in a manner containing substantially the same information. Any such report shall include the following information and test results:

(1) The miner's medical and employment history;

(2) All manifestations of chronic respiratory disease;

(3) Any pertinent findings not specifically listed on the form;

(4) If heart disease secondary to lung disease is found, all symptoms and significant findings;

(5) The results of a chest X-ray conducted and interpreted as required by § 718.102; and

(6) The results of a pulmonary function test conducted and reported as required by § 718.103. If the miner is physically unable to perform a pulmonary function test or if the test is medically contraindicated, in the absence of evidence establishing total disability pursuant to § 718.304, the report must be based on other medically acceptable clinical and laboratory diagnostic techniques, such as a blood gas study.

(b) In addition to the requirements of paragraph (a), a report of physical examination may be based on any other procedures such as electrocardiogram, blood-gas studies conducted and reported as required by § 718.105, and other blood analyses which, in the physician's opinion, aid in his or her evaluation of the miner.

(c) In the case of a deceased miner, where no report is in substantial compliance with paragraphs (a) and (b), a report prepared by a physician who is unavailable may nevertheless form the basis for a finding if, in the opinion of the adjudication officer, it is accompanied by sufficient indicia of reliability in light of all relevant evidence.

(d) *Treating physician.* In weighing the medical evidence of record relevant to whether the miner suffers, or suf-

ferred, from pneumoconiosis, whether the pneumoconiosis arose out of coal mine employment, and whether the miner is, or was, totally disabled by pneumoconiosis or died due to pneumoconiosis, the adjudication officer must give consideration to the relationship between the miner and any treating physician whose report is admitted into the record. Specifically, the adjudication officer shall take into consideration the following factors in weighing the opinion of the miner's treating physician:

(1) *Nature of relationship.* The opinion of a physician who has treated the miner for respiratory or pulmonary conditions is entitled to more weight than a physician who has treated the miner for non-respiratory conditions;

(2) *Duration of relationship.* The length of the treatment relationship demonstrates whether the physician has observed the miner long enough to obtain a superior understanding of his or her condition;

(3) *Frequency of treatment.* The frequency of physician-patient visits demonstrates whether the physician has observed the miner often enough to obtain a superior understanding of his or her condition; and

(4) *Extent of treatment.* The types of testing and examinations conducted during the treatment relationship demonstrate whether the physician has obtained superior and relevant information concerning the miner's condition.

(5) In the absence of contrary probative evidence, the adjudication officer shall accept the statement of a physician with regard to the factors listed in paragraphs (d)(1) through (4) of this section. In appropriate cases, the relationship between the miner and his treating physician may constitute substantial evidence in support of the adjudication officer's decision to give that physician's opinion controlling weight, provided that the weight given to the opinion of a miner's treating physician shall also be based on the credibility of the physician's opinion in light of its reasoning and documentation, other relevant evidence and the record as a whole.

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### § 718.105 Arterial blood-gas studies.

(a) Blood-gas studies are performed to detect an impairment in the process of alveolar gas exchange. This defect will manifest itself primarily as a fall in arterial oxygen tension either at rest or during exercise. No blood-gas study shall be performed if medically contraindicated.

(b) A blood-gas study shall initially be administered at rest and in a sitting position. If the results of the blood-gas test at rest do not satisfy the requirements of Appendix C to this part, an exercise blood-gas test shall be offered to the miner unless medically contraindicated. If an exercise blood-gas test is administered, blood shall be drawn during exercise.

(c) Any report of a blood-gas study submitted in connection with a claim shall specify:

- (1) Date and time of test;
- (2) Altitude and barometric pressure at which the test was conducted;
- (3) Name and DOL claim number of the claimant;
- (4) Name of technician;
- (5) Name and signature of physician supervising the study;
- (6) The recorded values for PCO<sub>2</sub>, PO<sub>2</sub>, and PH, which have been collected simultaneously (specify values at rest and, if performed, during exercise);
- (7) Duration and type of exercise;
- (8) Pulse rate at the time the blood sample was drawn;
- (9) Time between drawing of sample and analysis of sample; and
- (10) Whether equipment was calibrated before and after each test.

(d) If one or more blood-gas studies producing results which meet the appropriate table in Appendix C is administered during a hospitalization which ends in the miner's death, then any such study must be accompanied by a physician's report establishing that the test results were produced by a chronic respiratory or pulmonary condition. Failure to produce such a report will prevent reliance on the blood-gas study as evidence that the miner was totally disabled at death. (e) In the case of a deceased miner, where no blood gas tests are in substantial compliance with paragraphs (a), (b), and (c), non-complying tests may form the basis for a finding if, in the opinion of the adju-

dication officer, the only available tests demonstrate technically valid results. This provision shall not excuse compliance with the requirements in paragraph (d) for any blood gas study administered during a hospitalization which ends in the miner's death.

### § 718.106 Autopsy; biopsy.

(a) A report of an autopsy or biopsy submitted in connection with a claim shall include a detailed gross macroscopic and microscopic description of the lungs or visualized portion of a lung. If a surgical procedure has been performed to obtain a portion of a lung, the evidence shall include a copy of the surgical note and the pathology report of the gross and microscopic examination of the surgical specimen. If an autopsy has been performed, a complete copy of the autopsy report shall be submitted to the Office.

(b) In the case of a miner who died prior to March 31, 1980, an autopsy or biopsy report shall be considered even when the report does not substantially comply with the requirements of this section. A noncomplying report concerning a miner who died prior to March 31, 1980, shall be accorded the appropriate weight in light of all relevant evidence.

(c) A negative biopsy is not conclusive evidence that the miner does not have pneumoconiosis. However, where positive findings are obtained on biopsy, the results will constitute evidence of the presence of pneumoconiosis.

### § 718.107 Other medical evidence.

(a) The results of any medically acceptable test or procedure reported by a physician and not addressed in this subpart, which tends to demonstrate the presence or absence of pneumoconiosis, the sequelae of pneumoconiosis or a respiratory or pulmonary impairment, may be submitted in connection with a claim and shall be given appropriate consideration.

(b) The party submitting the test or procedure pursuant to this section bears the burden to demonstrate that the test or procedure is medically acceptable and relevant to establishing or refuting a claimant's entitlement to benefits.

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SOURCE: 65 FR 80045, Dec. 20, 2000, unless otherwise noted.

#### § 718.201 Definition of pneumoconiosis.

(a) For the purpose of the Act, “pneumoconiosis” means a chronic dust disease of the lung and its sequelae, including respiratory and pulmonary impairments, arising out of coal mine employment. This definition includes both medical, or “clinical”, pneumoconiosis and statutory, or “legal”, pneumoconiosis.

(1) *Clinical Pneumoconiosis.* “Clinical pneumoconiosis” consists of those diseases recognized by the medical community as pneumoconioses, *i.e.*, the conditions characterized by permanent deposition of substantial amounts of particulate matter in the lungs and the fibrotic reaction of the lung tissue to that deposition caused by dust exposure in coal mine employment. This definition includes, but is not limited to, coal workers’ pneumoconiosis, anthracosis, anthracosilicosis, anthrosilicosis, massive pulmonary fibrosis, silicosis or silicotuberculosis, arising out of coal mine employment.

(2) *Legal Pneumoconiosis.* “Legal pneumoconiosis” includes any chronic lung disease or impairment and its sequelae arising out of coal mine employment. This definition includes, but is not limited to, any chronic restrictive or obstructive pulmonary disease arising out of coal mine employment.

(b) For purposes of this section, a disease “arising out of coal mine employment” includes any chronic pulmonary disease or respiratory or pulmonary impairment significantly related to, or substantially aggravated by, dust exposure in coal mine employment.

(c) For purposes of this definition, “pneumoconiosis” is recognized as a latent and progressive disease which may first become detectable only after the cessation of coal mine dust exposure.

#### § 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



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the claimant and/or his or her dependents who would be eligible for augmentation of the claimant's benefits if the claim were approved.

[79 FR 21612, Apr. 17, 2014]

### **§ 718.203 Establishing relationship of pneumoconiosis to coal mine employment.**

(a) In order for a claimant to be found eligible for benefits under the Act, it must be determined that the miner's pneumoconiosis arose at least in part out of coal mine employment. The provisions in this section set forth the criteria to be applied in making such a determination.

(b) If a miner who is suffering or suffered from pneumoconiosis was employed for ten years or more in one or more coal mines, there shall be a rebuttable presumption that the pneumoconiosis arose out of such employment.

(c) If a miner who is suffering or suffered from pneumoconiosis was employed less than ten years in the nation's coal mines, it shall be determined that such pneumoconiosis arose out of that employment only if competent evidence establishes such a relationship.

### **§ 718.204 Total disability and disability causation defined; criteria for determining total disability and total disability due to pneumoconiosis.**

(a) *General.* Benefits are provided under the Act for or on behalf of miners who are totally disabled due to pneumoconiosis, or who were totally disabled due to pneumoconiosis at the time of death. For purposes of this section, any nonpulmonary or nonrespiratory condition or disease, which causes an independent disability unrelated to the miner's pulmonary or respiratory disability, shall not be considered in determining whether a miner is totally disabled due to pneumoconiosis. If, however, a nonpulmonary or nonrespiratory condition or disease causes a chronic respiratory or pulmonary impairment, that condition or disease shall be considered in determining whether the miner is or was totally disabled due to pneumoconiosis.

(b)(1) *Total disability defined.* A miner shall be considered totally disabled if the irrebuttable presumption described

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in § 718.304 applies. If that presumption does not apply, a miner shall be considered totally disabled if the miner has a pulmonary or respiratory impairment which, standing alone, prevents or prevented the miner:

(i) From performing his or her usual coal mine work; and

(ii) From engaging in gainful employment in the immediate area of his or her residence requiring the skills or abilities comparable to those of any employment in a mine or mines in which he or she previously engaged with some regularity over a substantial period of time.

(2) *Medical criteria.* In the absence of contrary probative evidence, evidence which meets the standards of either paragraphs (b)(2)(i), (ii), (iii), or (iv) of this section shall establish a miner's total disability:

(i) Pulmonary function tests showing values equal to or less than those listed in Table B1 (Males) or Table B2 (Females) in Appendix B to this part for an individual of the miner's age, sex, and height for the FEV1 test; if, in addition, such tests also reveal the values specified in either paragraph (b)(2)(i)(A) or (B) or (C) of this section:

(A) Values equal to or less than those listed in Table B3 (Males) or Table B4 (Females) in Appendix B to this part, for an individual of the miner's age, sex, and height for the FVC test, or

(B) Values equal to or less than those listed in Table B5 (Males) or Table B6 (Females) in Appendix B to this part, for an individual of the miner's age, sex, and height for the MVV test, or

(C) A percentage of 55 or less when the results of the FEV1 test are divided by the results of the FVC test (FEV1/FVC equal to or less than 55%), or

(ii) Arterial blood-gas tests show the values listed in Appendix C to this part, or

(iii) The miner has pneumoconiosis and has been shown by the medical evidence to be suffering from cor pulmonale with right-sided congestive heart failure, or

(iv) Where total disability cannot be shown under paragraphs (b)(2)(i), (ii), or (iii) of this section, or where pulmonary function tests and/or blood gas studies are medically contraindicated, total disability may nevertheless be

found if a physician exercising reasoned medical judgment, based on medically acceptable clinical and laboratory diagnostic techniques, concludes that a miner's respiratory or pulmonary condition prevents or prevented the miner from engaging in employment as described in paragraph (b)(1) of this section.

(c)(1) *Total disability due to pneumoconiosis defined.* A miner shall be considered totally disabled due to pneumoconiosis if pneumoconiosis, as defined in § 718.201, is a substantially contributing cause of the miner's totally disabling respiratory or pulmonary impairment. Pneumoconiosis is a "substantially contributing cause" of the miner's disability if it:

(i) Has a material adverse effect on the miner's respiratory or pulmonary condition; or

(ii) Materially worsens a totally disabling respiratory or pulmonary impairment which is caused by a disease or exposure unrelated to coal mine employment.

(2) Except as provided in § 718.305 and paragraph (b)(2)(iii) of this section, proof that the miner suffers or suffered from a totally disabling respiratory or pulmonary impairment as defined in paragraphs (b)(2)(i), (b)(2)(ii), (b)(2)(iv) and (d) of this section shall not, by itself, be sufficient to establish that the miner's impairment is or was due to pneumoconiosis. Except as provided in paragraph (d), the cause or causes of a miner's total disability shall be established by means of a physician's documented and reasoned medical report.

(d) *Lay evidence.* In establishing total disability, lay evidence may be used in the following cases:

(1) In a case involving a deceased miner in which the claim was filed prior to January 1, 1982, affidavits (or equivalent sworn testimony) from persons knowledgeable of the miner's physical condition shall be sufficient to establish total (or under § 718.306 partial) disability due to pneumoconiosis if no medical or other relevant evidence exists which addresses the miner's pulmonary or respiratory condition.

(2) In a case involving a survivor's claim filed on or after January 1, 1982,

but prior to June 30, 1982, which is subject to § 718.306, affidavits (or equivalent sworn testimony) from persons knowledgeable of the miner's physical condition shall be sufficient to establish total or partial disability due to pneumoconiosis if no medical or other relevant evidence exists which addresses the miner's pulmonary or respiratory condition; however, such a determination shall not be based solely upon the affidavits or 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.

(3) In a case involving a deceased miner whose claim was filed on or after January 1, 1982, affidavits (or equivalent sworn testimony) from persons knowledgeable of the miner's physical condition shall be sufficient to establish total disability due to pneumoconiosis if no medical or other relevant evidence exists which addresses the miner's pulmonary or respiratory condition; however, such a determination shall not be based solely upon the affidavits or testimony of any person who would be eligible for benefits (including augmented benefits) if the claim were approved.

(4) Statements made before death by a deceased miner about his or her physical condition are relevant and shall be considered in making a determination as to whether the miner was totally disabled at the time of death.

(5) In the case of a living miner's claim, a finding of total disability due to pneumoconiosis shall not be made solely on the miner's statements or testimony.

(e) In determining total disability to perform usual coal mine work, the following shall apply in evaluating the miner's employment activities:

(1) In the case of a deceased miner, employment in a mine at the time of death shall not be conclusive evidence that the miner was not totally disabled. To disprove total disability, it must be shown that at the time the miner died, there were no changed circumstances of employment indicative of his or her reduced ability to perform his or her usual coal mine work.

(2) In the case of a living miner, proof of current employment in a coal mine

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shall not be conclusive evidence that the miner is not totally disabled unless it can be shown that there are no changed circumstances of employment indicative of his or her reduced ability to perform his or her usual coal mine work.

(3) Changed circumstances of employment indicative of a miner's reduced ability to perform his or her usual coal mine work may include but are not limited to:

(i) The miner's reduced ability to perform his or her customary duties without help; or

(ii) The miner's reduced ability to perform his or her customary duties at his or her usual levels of rapidity, continuity or efficiency; or

(iii) The miner's transfer by request or assignment to less vigorous duties or to duties in a less dusty part of the mine.

### § 718.205 Death due to pneumoconiosis.

(a) Benefits are provided to eligible survivors of a miner whose death was due to pneumoconiosis. In order to receive benefits based on a showing of death due to pneumoconiosis, a claimant must prove that:

(1) The miner had pneumoconiosis (*see* § 718.202);

(2) The miner's pneumoconiosis arose out of coal mine employment (*see* § 718.203); and

(3) The miner's death was due to pneumoconiosis as provided by this section.

(b) Death will be considered to be due to pneumoconiosis if any of the following criteria is met:

(1) Where competent medical evidence establishes that pneumoconiosis was the cause of the miner's death, or

(2) Where pneumoconiosis was a substantially contributing cause or factor leading to the miner's death or where the death was caused by complications of pneumoconiosis, or

(3) Where the presumption set forth at § 718.304 is applicable, or

(4) For survivors' claims filed after January 1, 2005, and pending on or after March 23, 2010, where the presumption at § 718.305 is invoked and not rebutted.

(5) However, except where the § 718.304 presumption is invoked, sur-

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vivors are not eligible for benefits where the miner's death was caused by a traumatic injury (including suicide) or the principal cause of death was a medical condition not related to pneumoconiosis, unless the claimant establishes (by proof or presumption) that pneumoconiosis was a substantially contributing cause of death.

(6) Pneumoconiosis is a "substantially contributing cause" of a miner's death if it hastens the miner's death.

[78 FR 59114, Sept. 25, 2013]

### § 718.206 Effect of findings by persons or agencies.

Decisions, statements, reports, opinions, or the like, of agencies, organizations, physicians or other individuals, about the existence, cause, and extent of a miner's disability, or the cause of a miner's death, are admissible. If properly submitted, such evidence shall be considered and given the weight to which it is entitled as evidence under all the facts before the adjudication officer in the claim.

## Subpart D—Presumptions Applicable to Eligibility Determinations

SOURCE: 65 FR 80045, Dec. 20, 2000, unless otherwise noted.

### § 718.301 Establishing length of employment as a miner.

The presumptions set forth in §§ 718.302 and 718.305 apply only if a miner worked in one or more coal mines for the number of years required to invoke the presumption. The length of the miner's coal mine work history must be computed as provided by 20 CFR 725.101(a)(32).

[78 FR 59114, Sept. 25, 2013]

### § 718.302 Relationship of pneumoconiosis to coal mine employment.

If a miner who is suffering or suffered from pneumoconiosis was employed for ten years or more in one or more coal mines, there shall be a rebuttable presumption that the pneumoconiosis arose out of such employment. (See § 718.203.)

## § 718.303 [Reserved]

## § 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.

[79 FR 21613, Apr. 17, 2014]

## § 718.305 Presumption of pneumoconiosis.

(a) *Applicability*. This section applies to all claims filed after January 1, 2005, and pending on or after March 23, 2010.

(b) *Invocation*. (1) The claimant may invoke the presumption by establishing that—

(i) The miner engaged in coal-mine employment for fifteen years, either in one or more underground coal mines, or in coal mines other than underground mines in conditions substantially similar to those in underground mines, or in any combination thereof; and

(ii) The miner or survivor cannot establish entitlement under § 718.304 by means of chest x-ray evidence; and

(iii) The miner has, or had at the time of his death, a totally disabling respiratory or pulmonary impairment established pursuant to § 718.204, except that § 718.204(d) does not apply.

(2) The conditions in a mine other than an underground mine will be considered “substantially similar” to those in an underground mine if the claimant demonstrates that the miner was regularly exposed to coal-mine dust while working there.

(3) In a claim involving a living miner, a miner's affidavit or testimony, or a spouse's affidavit or testimony, may not be used by itself to establish the existence of a totally disabling respiratory or pulmonary impairment.

(4) In the case of a deceased miner, affidavits (or equivalent sworn testimony) from persons knowledgeable of the miner's physical condition must be considered sufficient to establish total disability due to a respiratory or pulmonary impairment if no medical or other relevant evidence exists which addresses the miner's pulmonary or respiratory condition; however, such a determination must not be based solely upon the affidavits or testimony of any person who would be eligible for benefits (including augmented benefits) if the claim were approved.

(c) *Facts presumed*. Once invoked, there will be rebuttable presumption—

(1) In a miner's claim, that the miner is totally disabled due to pneumoconiosis, or was totally disabled due to pneumoconiosis at the time of death; or

(2) In a survivor's claim, that the miner's death was due to pneumoconiosis.

(d) *Rebuttal*—(1) *Miner's claim*. In a claim filed by a miner, the party opposing entitlement may rebut the presumption by—

(i) Establishing both that the miner does not, or did not, have:

(A) Legal pneumoconiosis as defined in § 718.201(a)(2); and

(B) Clinical pneumoconiosis as defined in § 718.201(a)(1), arising out of coal mine employment (see § 718.203); or

## § 718.306

(ii) Establishing that no part of the miner's respiratory or pulmonary total disability was caused by pneumoconiosis as defined in § 718.201.

(2) *Survivor's claim.* In a claim filed by a survivor, the party opposing entitlement may rebut the presumption by—

(i) Establishing both that the miner did not have:

(A) Legal pneumoconiosis as defined in § 718.201(a)(2); and

(B) Clinical pneumoconiosis as defined in § 718.201(a)(1), arising out of coal mine employment (*see* § 718.203); or

(ii) Establishing that no part of the miner's death was caused by pneumoconiosis as defined in § 718.201.

(3) The presumption must not be considered rebutted on the basis of evidence demonstrating the existence of a totally disabling obstructive respiratory or pulmonary disease of unknown origin.

[78 FR 59114, Sept. 25, 2013]

## § 718.306 [Reserved]

### 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

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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 sin-

gle 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  $\mu$ m, 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<sup>2</sup>, 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.

[79 FR 21613, Apr. 17, 2014]

#### APPENDIX B TO PART 718—STANDARDS FOR ADMINISTRATION AND INTERPRETATION OF PULMONARY FUNCTION TESTS. TABLES B1, B2, B3, B4, B5, B6.

The following standards are established in accordance with section 402(f)(1)(D) of the Act. They were developed in consultation with the National Institute for Occupational Safety and Health (NIOSH). These standards are promulgated for the guidance of physicians and medical technicians to insure that uniform procedures are used in administering and interpreting ventilatory function tests and that the best available medical evidence will be submitted in support of 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 given to the results of the ventilatory function tests.

(1) Instruments to be used for the administration of pulmonary function tests shall be approved by NIOSH and shall conform to the following criteria:



(i) The instrument shall be accurate within  $\pm 50$  ml or within  $\pm 3$  percent of reading, whichever is greater.

(ii) The instrument shall be capable of measuring vital capacity from 0 to 7 liters BTPS.

(iii) The instrument shall have a low inertia and offer low resistance to airflow such that the resistance to airflow at 12 liters per second must be less than 1.5 cm H<sub>2</sub>O/liter/sec.

(iv) The instrument or user of the instrument must have a means of correcting volumes to body temperature saturated with water vapor (BTPS) under conditions of varying ambient spirometer temperatures and barometric pressures.

(v) The instrument used shall provide a tracing of flow versus volume (flow-volume loop) which displays the entire maximum inspiration and the entire maximum forced expiration. The instrument shall, in addition, provide tracings of the volume versus time tracing (spirogram) derived electronically from the flow-volume loop. Tracings are necessary to determine whether maximum inspiratory and expiratory efforts have been obtained during the FVC maneuver. If maximum voluntary ventilation is measured, the tracing shall record the individual breaths volumes versus time.

(vi) The instrument shall be capable of accumulating volume for a minimum of 10 seconds after the onset of exhalation.

(vii) The instrument must be capable of being calibrated in the field with respect to the FEV<sub>1</sub>. The volume calibration shall be accomplished with a 3 L calibrating syringe and should agree to within 1 percent of a 3 L calibrating volume. The linearity of the instrument must be documented by a record of volume calibrations at three different flow rates of approximately 3 L/6 sec, 3 L/3 sec, and 3 L/sec.

(viii) For measuring maximum voluntary ventilation (MVV) the instrument shall have a response which is flat within  $\pm 10$  percent up to 4 Hz at flow rates up to 12 liters per second over the volume range.

(ix) The spirogram shall be recorded at a speed of at least 20 mm/sec and a volume excursion of at least 10mm/L. Calculation of the FEV<sub>1</sub> from the flow-volume loop is not acceptable. Original tracings shall be submitted.

(2) The administration of pulmonary function tests shall conform to the following criteria:

(i) Tests shall not be performed during or soon after an acute respiratory illness.

(ii) For the FEV<sub>1</sub> and FVC, use of a nose clip is required. The procedures shall be explained in simple terms to the patient who shall be instructed to loosen any tight clothing and stand in front of the apparatus. The subject may sit, or stand, but care should be taken on repeat testing that the same position be used. Particular attention shall be

given to insure that the chin is slightly elevated with the neck slightly extended. The subject shall be instructed to expire completely, momentarily hold his breath, place the mouthpiece in his mouth and close the mouth firmly about the mouthpiece to ensure no air leak. The subject will then make a maximum inspiration from the instrument and when maximum inspiration has been attained, without interruption, blow as hard, fast and completely as possible for at least 7 seconds or until a plateau has been attained in the volume-time curve with no detectable change in the expired volume during the last 2 seconds of maximal expiratory effort. A minimum of three flow-volume loops and derived spirometric tracings shall be carried out. The patient shall be observed throughout the study for compliance with instructions. Inspiration and expiration shall be checked visually for reproducibility. The effort shall be judged unacceptable when the patient:

(A) Has not reached full inspiration preceding the forced expiration; or

(B) Has not used maximal effort during the entire forced expiration; or

(C) Has not continued the expiration for least 7 sec. or until an obvious plateau for at least 2 sec. in the volume-time curve has occurred; or

(D) Has coughed or closed his glottis; or

(E) Has an obstructed mouthpiece or a leak around the mouthpiece (obstruction due to tongue being placed in front of mouthpiece, false teeth falling in front of mouthpiece, etc.); or

(F) Has an unsatisfactory start of expiration, one characterized by excessive hesitation (or false starts). Peak flow should be attained at the start of expiration and the volume-time tracing (spirogram) should have a smooth contour revealing gradually decreasing flow throughout expiration; or

(G) Has an excessive variability between the three acceptable curves. The variation between the two largest FEV<sub>1</sub>'s of the three acceptable tracings should not exceed 5 percent of the largest FEV<sub>1</sub> or 100 ml, whichever is greater. As individuals with obstructive disease or rapid decline in lung function will be less likely to achieve this degree of reproducibility, tests not meeting this criterion may still be submitted for consideration in support of a claim for black lung benefits. Failure to meet this standard should be clearly noted in the test report by the physician conducting or reviewing the test.

(iii) For the MVV, the subject shall be instructed before beginning the test that he or she will be asked to breathe as deeply and as rapidly as possible for approximately 15 seconds. The test shall be performed with the subject in the standing position, if possible. Care shall be taken on repeat testing that the same position be used. The subject shall breathe normally into the mouthpiece of the

apparatus for 10 to 15 seconds to become accustomed to the system. The subject shall then be instructed to breathe as deeply and as rapidly as possible, and shall be continually encouraged during the remainder of the maneuver. Subject shall continue the maneuver for 15 seconds. At least 5 minutes of rest shall be allowed between maneuvers. At least three MVV's shall be carried out. (*But see* §718.103(b).) During the maneuvers the patient shall be observed for compliance with instructions. The effort shall be judged unacceptable when the patient:

(A) Has not maintained consistent effort for at least 12 to 15 seconds; or

(B) Has coughed or closed his glottis; or

(C) Has an obstructed mouthpiece or a leak around the mouthpiece (obstruction due to tongue being placed in front of mouthpiece, false teeth falling in front of mouthpiece, etc.); or

(D) Has an excessive variability between the three acceptable curves. The variation between the two largest MVV's of the three satisfactory tracings shall not exceed 10 percent.

(iv) A calibration check shall be performed on the instrument each day before use, using

a volume source of at least three liters, accurate to within  $\pm 1$  percent of full scale. The volume calibration shall be performed in accordance with the method described in paragraph (1)(vii) of this Appendix. Accuracy of the time measurement used in determining the FEV1 shall be checked using the manufacturer's stated procedure and shall be within  $\pm 3$  percent of actual. The procedure described in the Appendix shall be performed as well as any other procedures suggested by the manufacturer of the spirometer being used.

(v)(A) The first step in evaluating a spirogram for the FVC and FEV1 shall be to determine whether or not the patient has performed the test properly or as described in (2)(ii) of this Appendix. The largest recorded FVC and FEV1, corrected to BTPS, shall be used in the analysis.

(B) Only MVV maneuvers which demonstrate consistent effort for at least 12 seconds shall be considered acceptable. The largest accumulated volume for a 12 second period corrected to BTPS and multiplied by five or the largest accumulated volume for a 15 second period corrected to BTPS and multiplied by four is to be reported as the MVV.





















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PREDICTION EQUATIONS FOR AMV

HEIGHT (10)	* PERCENT OF PREDICTED **											
	47	48	49	50	51	52	53	54	55	56	57	58
59.1	56	55	54	53	52	51	50	49	48	47	46	45
59.4	57	56	55	54	53	52	51	50	49	48	47	46
59.7	58	57	56	55	54	53	52	51	50	49	48	47
60.0	59	58	57	56	55	54	53	52	51	50	49	48
60.2	60	59	58	57	56	55	54	53	52	51	50	49
60.4	61	60	59	58	57	56	55	54	53	52	51	50
60.6	62	61	60	59	58	57	56	55	54	53	52	51
61.0	63	62	61	60	59	58	57	56	55	54	53	52
61.8	65	64	63	62	61	60	59	58	57	56	55	54
62.2	66	65	64	63	62	61	60	59	58	57	56	55
62.6	67	66	65	64	63	62	61	60	59	58	57	56
63.0	68	67	66	65	64	63	62	61	60	59	58	57
63.4	69	68	67	66	65	64	63	62	61	60	59	58
63.8	71	70	69	68	67	66	65	64	63	62	61	60
64.2	72	71	70	69	68	67	66	65	64	63	62	61
64.6	73	72	71	70	69	68	67	66	65	64	63	62
65.0	75	74	73	72	71	70	69	68	67	66	65	64
65.4	76	75	74	73	72	71	70	69	68	67	66	65
65.8	77	76	75	74	73	72	71	70	69	68	67	66
66.2	78	77	76	75	74	73	72	71	70	69	68	67
66.6	80	79	78	77	76	75	74	73	72	71	70	69
66.9	81	80	79	78	77	76	75	74	73	72	71	70
67.3	82	81	80	79	78	77	76	75	74	73	72	71
67.7	83	82	81	80	79	78	77	76	75	74	73	72
68.1	84	83	82	81	80	79	78	77	76	75	74	73
68.5	85	84	83	82	81	80	79	78	77	76	75	74
68.9	86	85	84	83	82	81	80	79	78	77	76	75
69.3	87	86	85	84	83	82	81	80	79	78	77	76
69.7	88	87	86	85	84	83	82	81	80	79	78	77
70.1	91	90	89	88	87	86	85	84	83	82	81	80
70.5	92	91	90	89	88	87	86	85	84	83	82	81
70.9	93	92	91	90	89	88	87	86	85	84	83	82
71.3	94	93	92	91	90	89	88	87	86	85	84	83
71.7	95	94	93	92	91	90	89	88	87	86	85	84
72.1	96	95	94	93	92	91	90	89	88	87	86	85
72.4	97	96	95	94	93	92	91	90	89	88	87	86
72.8	98	97	96	95	94	93	92	91	90	89	88	87
73.2	100	99	98	97	96	95	94	93	92	91	90	89
73.6	102	101	100	99	98	97	96	95	94	93	92	91
74.0	103	102	101	100	99	98	97	96	95	94	93	92
74.4	105	104	103	102	101	100	99	98	97	96	95	94
74.8	107	106	105	104	103	102	101	100	99	98	97	96
75.2	109	108	107	106	105	104	103	102	101	100	99	98
75.6	108	108	107	106	105	104	103	102	101	100	99	98
76.0	110	109	108	107	106	105	104	103	102	101	100	99
76.4	111	110	109	108	107	106	105	104	103	102	101	100
76.8	112	111	110	109	108	107	106	105	104	103	102	101
77.2	113	112	111	110	109	108	107	106	105	104	103	102
77.6	115	114	113	112	111	110	109	108	107	106	105	104
78.0	116	115	114	113	112	111	110	109	108	107	106	105
78.4	117	116	115	114	113	112	111	110	109	108	107	106
78.8	118	117	116	115	114	113	112	111	110	109	108	107
79.1	120	119	118	117	116	115	114	113	112	111	110	109
79.5	121	120	119	118	117	116	115	114	113	112	111	110
79.9	122	121	120	119	118	117	116	115	114	113	112	111
80.3	123	122	121	120	119	118	117	116	115	114	113	112
80.7	124	123	122	121	120	119	118	117	116	115	114	113
81.1	125	124	123	122	121	120	119	118	117	116	115	114
81.5	127	126	125	124	123	122	121	120	119	118	117	116
81.9	128	128	127	126	125	124	123	122	121	120	119	118
82.3	130	129	128	127	126	125	124	123	122	121	120	119
82.7	131	130	129	128	127	126	125	124	123	122	121	120





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**20 CFR Ch. VI (4-1-24 Edition)**

(1) For arterial blood-gas studies performed at test sites up to 2,999 feet above sea level:

Arterial PCO2 (mm Hg)	Arterial PO2 equal to or less than (mm Hg)
25 or below .....	75
26 .....	74
27 .....	73
28 .....	72
29 .....	71
30 .....	70
31 .....	69
32 .....	68
33 .....	67
34 .....	66
35 .....	65
36 .....	64
37 .....	63
38 .....	62
39 .....	61
40-49 .....	60
Above 50 .....	( <sup>1</sup> )

<sup>1</sup> Any value.

(2) For arterial blood-gas studies performed at test sites 3,000 to 5,999 feet above sea level:

Arterial PCO2 (mm Hg)	Arterial PO2 equal to or less than (mm Hg)
25 or below .....	70
26 .....	69
27 .....	68
28 .....	67
29 .....	66
30 .....	65
31 .....	64
32 .....	63
33 .....	62
34 .....	61
35 .....	60
36 .....	59
37 .....	58
38 .....	57
39 .....	56
40-49 .....	55
Above 50 .....	( <sup>2</sup> )

<sup>2</sup> Any value.

(3) For arterial blood-gas studies performed at test sites 6,000 feet or more above sea level:

Arterial PCO2 (mm Hg)	Arterial PO2 equal to or less than (mm Hg)
25 or below .....	65
26 .....	64
27 .....	63
28 .....	62
29 .....	61
30 .....	60
31 .....	59
32 .....	58
33 .....	57
34 .....	56
35 .....	55

Arterial PCO2 (mm Hg)	Arterial PO2 equal to or less than (mm Hg)
36 .....	54
37 .....	53
38 .....	52
39 .....	51
40-49 .....	50
Above 50 .....	( <sup>3</sup> )

<sup>3</sup> Any value.

[65 FR 80045, Dec. 20, 2000, as amended at 78 FR 59115, Sept. 25, 2013]

**PART 722—CRITERIA FOR DETERMINING WHETHER STATE WORKERS' COMPENSATION LAWS PROVIDE ADEQUATE COVERAGE FOR PNEUMOCONIOSIS AND LISTING OF APPROVED STATE LAWS**

Sec.

722.1 Purpose.

722.2 Definitions.

722.3 General criteria; inclusion in and removal from the Secretary's list.

722.4 The Secretary's list.

**AUTHORITY:** 5 U.S.C. 301, Reorganization Plan No. 6 of 1950, 15 FR 3174, 30 U.S.C. 901 *et seq.*, 921, 932, 936; 33 U.S.C. 901 *et seq.*, Secretary's Order 7-87, 52 FR 48466, Employment Standards Order No. 90-02.

**SOURCE:** 65 FR 80053, Dec. 20, 2000, unless otherwise noted.

**§ 722.1 Purpose.**

Section 421 of the Black Lung Benefits Act provides that a claim for benefits based on the total disability or death of a coal miner due to pneumoconiosis must be filed under a State workers' compensation law where such law provides adequate coverage for pneumoconiosis. A State workers' compensation law may be deemed to provide adequate coverage only when it is included on a list of such laws maintained by the Secretary. The purpose of this part is to set forth the procedures and criteria for inclusion on that list, and to provide that list.

**§ 722.2 Definitions.**

(a) The definitions and use of terms contained in subpart A of part 725 of this title shall be applicable to this part.

(b) For purposes of this part, the following definitions apply: