Attachment 2 –
42 CFR Part 37

PART 37—SPECIFICATIONS FOR MEDICAL EXAMINATIONS OF COAL MINERS

Contents

Authority: Sec. 203, 83 Stat. 763; 30 U.S.C. 843, unless otherwise noted.

Source: 43 FR 33715, Aug. 1, 1978, unless otherwise noted.

Subpart—Chest Radiographic Examinations

§37.1 Scope.

Under this subpart, coal mine operators are required to provide radiographic examinations to each current and new coal miner, using medical facilities approved by NIOSH in accordance with standards established in this subpart.

[79 FR 45118, Aug. 4, 2014]

§37.2 Definitions.

Any term defined in the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801 *et seq.*, Pub. L. 95-164, as amended) and not defined below will have the meaning given it in the Act. As used in this subpart:

Act means the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801, *et seq.*, Pub. L. 95-164, as amended).

B Reader means a physician certified by NIOSH as able to classify chest radiographs using the ILO Classification system, pursuant to §37.52(b).

Chest radiograph means a single posteroanterior radiographic projection or radiograph of the chest at full inspiration recorded on either film or digital radiography systems.

Convenient time and place means that an examination conducted pursuant to this part must be given at a reasonable hour in the locality in which the miner resides or a location that is equally accessible to the miner. For example, examinations at the mine during, immediately preceding, or immediately following work and a “no appointment” examination at a medical facility in a community easily accessible to the residences of a majority of the miners working at the mine will be considered of equivalent convenience for purposes of this definition.

Digital radiography systems, as used in this context, include both Digital Radiography (DR) and Computed Radiography (CR) systems.

(1) *Computed radiography (CR)* is the term for digital radiographic image acquisition systems that detect radiographic 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) *Digital radiography (DR)* is the term used for digital radiographic image acquisition systems in which the radiographic signals received by the image detector are converted nearly instantaneously to electronic signals without movable cassettes.

Facility means a facility or organization licensed to provide health care by the State or Territory in which services are provided, such as a hospital, a clinic, or other provider that performs medical examinations.

ILO Classification means the classification of radiographs using the International Classification of Radiographs of Pneumoconioses, a system devised by an international committee of the International Labour Office (ILO), including a complete set of standard film radiographs or digital chest image files available from the ILO or other set of chest image files approved by NIOSH as equivalent. The ILO Classification is incorporated by reference into §§37.50(a) and (c) and 37.51(b).

MSHA means the Mine Safety and Health Administration, Department of Labor.

Miner means any individual working in a coal or other mine.

NIOSH means the National Institute for Occupational Safety and Health (NIOSH), located within the Centers for Disease Control and Prevention (CDC). Within NIOSH, the Respiratory Health Division (RHD), 1095 Willowdale Road, Morgantown, WV 26505, is the organizational unit that has programmatic responsibility for the Coal Workers' Health Surveillance Program.

NIOSH representative means employees of CDC/NIOSH and employees of CDC contractors.

Operator means any owner, lessee, or other person who operates, controls, or supervises a coal or other mine or any independent contractor performing services or construction at such mine.

Panel of B Readers means the group of physicians that are currently certified by NIOSH as B Readers and who classify or otherwise evaluate radiographs for the Coal Workers' Health Surveillance Program.

Pre-placement physical examination means any medical examination that includes a chest radiographic examination given in accordance with the specifications of this Part to a person not previously employed by the same operator. Such examinations should be conducted consistent with applicable law, including the Americans with Disabilities Act of 1990, which provides that pre-placement examinations take place only after an offer of employment has been made and subject to certain restrictions (42 U.S.C. 12112(d)).

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.

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.

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 radiographs 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 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.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved may be delegated.

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.

[77 FR 56726, Sept. 13, 2012, as amended at 79 FR 45118, Aug. 4, 2014; 81 FR 73279, Oct. 24, 2016]

§37.3 Chest radiographs required for miners.

(a) *Voluntary examinations.* Every operator must provide to each miner who is employed in or at any of its coal mines and who was employed in coal mining prior to December 30, 1969, or who has completed the required examinations under paragraph (b) of this section an opportunity for a chest radiograph at no cost to the miner in accordance with this subpart:

(1) NIOSH will notify the operator of each coal mine of a period within which the operator may provide examinations to each miner employed at its coal mine. The period must begin no sooner than 3.5 years and end no later than 4.5 years subsequent to the ending date of the previous 6-month period specified for a coal mine either by the operator on an approved plan or by NIOSH if the operator did not submit an approved plan. Within the period specified for each mine, the operator may select a 6-month period within which to provide examinations in accordance with a plan approved under §37.101.

(2) Within either the next or future period(s) specified to the operator for each of its coal mines, the operator of the coal mine may select a different 6-month period for each of its mines within which to offer examinations. In the event the operator does not submit an approved plan, NIOSH will specify a 6-month period to the operator within which miners must have the opportunity for examinations.

(b) *Mandatory examinations.* Every operator must provide to each miner who begins working in or at an underground coal mine for the first time after December 30, 1969 or in or at a surface coal mine for the first time after August 1, 2014:

(1) An initial chest radiograph, as soon as possible, but in no event later than 30 days after commencement of employment or within 30 days of approval of a plan to provide chest radiographs. An initial chest radiograph

given to a miner according to former regulations for this subpart prior to August 1, 2014 will also be considered as fulfilling this requirement.

(2) A second chest radiograph, in accordance with this subpart, 3 years following the initial examination if the miner is still engaged in coal mining. A second radiograph given to a miner according to former regulations under this subpart prior to August 1, 2014 will be considered as fulfilling this requirement.

(3) A third chest radiograph 2 years following the second chest radiograph if the miner is still engaged in coal mining and if the second radiograph shows evidence of category 1 (1/0, 1/1, 1/2), category 2 (2/1, 2/2, 2/3), category 3 (3/2, 3/3, 3/+) simple pneumoconiosis, or complicated pneumoconiosis (ILO Classification) or if the second spirometry examination specified in §37.92(b)(2) shows evidence of decreased lung function to the extent specified in §37.92(b)(3).

(c) *Notification.* NIOSH will notify the miner when he or she is due to receive the second or third mandatory examination under paragraph (b) of this section. NIOSH will notify the coal mine operator when the miner is to be given a second examination.

(1) The operator will be notified of a miner's third examination only with the miner's written consent. The notice to the operator will not state the medical reason for the examination or that it is the third examination in the series.

(2) If the miner is notified by NIOSH that the third mandatory examination is due and the operator is not so notified, availability of the radiographic examination under the NIOSH-approved operator's plan will constitute the operator's compliance with the requirement to provide a third mandatory examination even if the miner refuses to take the examination.

(d) *Availability of chest radiographs.* The opportunity for chest radiographs to be made available by an operator for purposes of this subpart must be provided in accordance with a plan that has been submitted and approved in accordance with this part.

[81 FR 73280, Oct. 24, 2016]

§37.4 Chest radiographic examinations conducted by the Secretary.

(a) The Secretary will give chest radiographs or make arrangements with an appropriate person, agency, or institution to give the chest radiographs and with A or B Readers to interpret the radiographs required under this subpart in the locality where the miner resides, at the mine, or at a medical facility easily accessible to a mining community or mining communities, under the following circumstances:

(1) Where, in the judgment of the Secretary, due to the lack of adequate medical or other necessary facilities or personnel at the mine or in the locality where the miner resides, the required radiographic examination cannot be given.

(2) Where the operator has not submitted an approvable plan.

(3) Where, after commencement of an operator's program pursuant to an approved plan and after notice to the operator of his failure to follow the approved plan and, after allowing 15 calendar days to bring the program into compliance, the Secretary determines and notifies the operator in writing that the operator's program still fails to comply with the approved plan.

(b) The operator of the mine must reimburse the Secretary or other person, agency, or institution as the Secretary may direct, for the cost of conducting each examination made in accordance with this section.

(c) All examinations given or arranged by the Secretary will comply with the time requirements of §37.3. Whenever the Secretary gives or arranges for the examinations of miners at a time, a written notice of the arrangements will be sent to the operator who must post the notice on the mine bulletin board.

[81 FR 73281, Oct. 24, 2016]

§37.10 Standards incorporated by reference.

(a) Certain material is incorporated by reference into this subpart, Subpart—Chest Radiographic Examinations, with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, NIOSH must publish notice of change in the Federal Register and the material must be available to the public. All approved material is available for inspection at NIOSH, Respiratory Health Division, 1095 Willowdale Road, Morgantown, WV 26505. To arrange for an inspection at NIOSH, call 304-285-5749. Copies 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/federal_register/code_of_federal_regulations/ibr_locations.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, into §37.51(d) and (e).

(2) AAPM Report No. 14, Performance Specifications and Acceptance Testing for X-Ray Generators and Automatic Exposure Control Devices, Report of the Diagnostic X-Ray Imaging Committee Task Group on Performance Specifications and Acceptance Testing for X-Ray Generators and Automatic Exposure Control Devices, published by the American Institute of Physics for AAPM, January 1985, into §§37.42(h) and 37.44(g).

(3) AAPM Report No. 31, Standardized Methods for Measuring Diagnostic X-Ray Exposures, Report of Task Group 8, Diagnostic X-Ray Imaging Committee, published by the American Institute of Physics, July 1990, into §37.44(g).

(4) AAPM Report No. 74, Quality Control in Diagnostic Radiology, Report of Task Group 12, Diagnostic X-Ray Imaging Committee, published by Medical Physics Publishing for AAPM, July 2002, into §§37.42(h), 37.43(f), and 37.44(g).

(5) AAPM Report No. 93, Acceptance Testing and Quality Control of Photostimulable Storage Phosphor Imaging Systems, October 2006, into §§37.42(i) and 37.44(g).

(6) AAPM Report No. 116, An Exposure Indicator for Digital Radiography, Report of AAPM Task Group 116, published by AAPM, July 2009, into §37.44(g).

(c) American College of Radiology, 1891 Preston White Dr., Reston, VA 20191, *http://www.acr.org*:

(1) ACR Practice Guideline for Diagnostic Reference Levels in Medical X-Ray Imaging, Revised 2008 (Resolution 3), into §§37.42(i) and 37.44(g).

(2) [Reserved]

(d) International Labour Office, CH-1211 Geneva 22, Switzerland, *http://www.ilo.org/publns*:

(1) Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses, Revised Edition 2011, into §§37.50(a), 37.50(c), and 37.51(b).

(2) [Reserved]

(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, into §37.45.

(2) NCRP Report No. 105, Radiation Protection for Medical and Allied Health Personnel, issued October 30, 1989, into §37.45.

(3) NCRP Report No. 147, Structural Shielding Design for Medical X-Ray Imaging Facilities, revised March 18, 2005, into §37.45.

(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, into §37.42(i).

(2) DICOM Standard PS3.4-2011, Digital Imaging and Communications in Medicine (DICOM) standard, Part 4: Service Class Specifications, copyright 2011, into §37.42(i).

(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, into §37.42(i).

(4) DICOM Standard PS 3.11-2011, Digital Imaging and Communications in Medicine (DICOM) standard, Part 11: Media Storage Application Profiles, copyright 2011, into §37.42(i).

(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, into §§37.42(i) and 37.44(a).

(6) DICOM Standard PS 3.14-2011, Digital Imaging and Communications in Medicine (DICOM) standard, Part 14: Grayscale Standard Display Function, copyright 2011, into §§37.42(i)(5) and 37.51(d).

(7) DICOM Standard PS 3.16-2011, Digital Imaging and Communications in Medicine (DICOM) standard, Part 16: Content Mapping Resource, copyright 2011, into §37.42(i).

[81 FR 73281, Oct. 24, 2016]

§37.20 Miner identification document.

As part of the examination, a Miner Identification Document (CDC/NIOSH (M)2.9) which includes an occupational history questionnaire must be completed for each miner at the facility where the examination is made (this document is required for both radiographic and spirometry examinations conducted pursuant to this part).

[81 FR 73282, Oct. 24, 2016]

Specifications for Performing Chest Radiographic Examinations

§37.40 General provisions.

(a) The chest radiographic examination must be given at a convenient time and place.

(b) The chest radiographic examination consists of the chest radiograph, a completed Chest Radiograph Classification Form (CDC/NIOSH 2.8), and a completed Miner Identification Document (CDC/NIOSH 2.9).

(c) A radiographic examination must be made in a facility approved in accordance with §37.43 or §37.44. Chest radiographs of miners under this section must be performed:

(1) 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

(2) By a radiologic technologist as defined in §37.2.

[81 FR 73282, Oct. 24, 2016]

§37.41 Chest radiograph specifications—film.

(a) 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.

(b) Every chest radiograph must be a single posteroanterior projection at full inspiration on a film being no less than 14 by 17 inches and no greater than 16 by 17 inches. 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 the projection must include both apices with minimum loss of the costophrenic angle.

(c) Chest radiographs of miners under this section must be performed:

(1) 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

(2) By a radiologic technologist as defined in §37.2.

(d) 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.

(e) Except as provided in this paragraph (e), radiographs must be made with units having generators that comply with the following:

(1) The 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;

(2) Generators of units acquired subsequent to that date must have a minimum rating of 300 mA at 125 kVp.

(f) 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 of 200 mA at 110 kVp at 60 Hz.

(g) Capacitor discharge and field emission units may be used if the model of such units is approved by NIOSH for quality, performance, and safety. NIOSH will consider such units for approval when listed by a facility seeking approval under §§37.43 or 37.44.

(h) Radiographs must be given only with equipment having a beam-limiting device that does not cause large unexposed boundaries. The beam limiting device must provide rectangular collimation and must be of the type described in 21 CFR 1020.31(d), (e), (f), and (g). The use of such a device must be discernible from an examination of the radiograph.

(i) To ensure high quality chest radiographs:

(1) 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 posteroanterior, the exposure may be increased to not more than 100 milliseconds;

(2) The source or focal spot to film distance must be at least 6 feet;

(3) 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, that produces radiographs with spatial resolution, contrast, latitude and quantum mottle similar to those of systems designated as “medium speed” may be employed;

(4) Film-screen contact shall be maintained and verified at 6 month or shorter intervals;

(5) Intensifying screens shall be inspected at least once a month and cleaned when necessary by the method recommended by the manufacturer;

(6) All intensifying screens in a cassette shall be of the same type and made by the same manufacturer;

(7) A suitable grid or other means of reducing scattered radiation must be used;

(8) The geometry of the radiographic system shall insure 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;

(9) A formal quality assurance program shall be established at each facility.

(j) Radiographic processing:

(1) Either automatic or manual film processing is acceptable. A constant time-temperature technique shall be meticulously employed for manual processing.

(2) 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.

(k) Before the miner is advised that the examination is concluded, the radiograph must be processed and inspected and accepted for quality 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 immediately made. All substandard radiographs must be clearly marked as rejected and promptly sent to NIOSH for disposal.

(l) An electric power supply shall be used which complies with the voltage, current, and regulation specified by the manufacturer of the machine.

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

(n)(1) Each radiograph made hereunder must be permanently and legibly marked with:

(i) The name and address or NIOSH approval number of the facility at which it is made;

(ii) The miner's Social Security number;

(iii) The miner's date of birth; and

(iv) The date of the radiograph.

(2) No other identifying markings may be recorded on the radiograph.

[43 FR 33715, Aug. 1, 1978, as amended at 52 FR 7866, Mar. 13, 1987; 77 FR 56729, Sept. 13, 2012]

§37.42 Chest radiograph specifications—digital radiography systems.

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

(b) Every digital chest radiograph taken as required under this section must be a single posteroanterior projection at full inspiration on a digital detector with sensor area being no less than 1505 cm square centimeters with a minimum width of 35cm. The imaging plate must have a maximum pixel pitch of 200µm, 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 two side-by-side images can be obtained that together include the apices and the costophrenic angles of both right and left lungs.

(c) Chest radiographs of miners under this section must be performed:

(1) 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

(2) By a radiologic technologist as defined in §37.2.

(d) 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.

(e) 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.

(f) 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.

(g) 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 and 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.

(h) 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.

(1) If automated exposure control devices are used, performance must be documented by a medical physicist utilizing the image capture systems and exposure parameters used at the facility for chest imaging, using methods recommended in AAPM Report No. 74, pages 17-18, and in AAPM Report No. 14, pages 61-62 (incorporated by reference, see §37.10).

(2) Exposure parameters achieved during the evaluation of the automated exposure system must be recorded by the medical physicist in a written report or electronic file that is stored at the facility and available for inspection by NIOSH for a minimum of 5 years after the miner's examination.

(i) To ensure high quality digital chest radiographs:

(1) The maximum exposure time must not exceed 50 milliseconds except for subjects with chests over 28 centimeters posteroanterior, for whom the exposure time must not exceed 100 milliseconds;

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

(3) The exposure setting for chest images must be within the range of 100-300 equivalent exposure speeds and must comply with ACR Practice Guideline 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 §37.10). Radiation exposures should be periodically measured and patient radiation doses estimated by the medical physicist to assure doses are as low as reasonably achievable.

(4) 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 §37.10). 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.

(5)(i) The image object, transmission and associated data storage, file format, and transmission of associated information must conform to the following components of the Digital Imaging and Communications in Medicine (DICOM) standard (incorporated by reference, see §37.10):

(A) DICOM Standard PS 3.3-2011, Annex A—Composite Information Object Definitions, sections: Computed Radiography 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.

(B) DICOM Standard PS3.4-2011, Annex B—Storage Service Class; Annex N—Softcopy Presentation State Storage SOP Classes; Annex O—Structured Reporting Storage SOP Classes.

(C) DICOM Standard PS 3.10-2011.

(D) DICOM Standard PS 3.11-2011

(E) DICOM Standard PS 3.12-2011.

(F) DICOM Standard PS 3.14-2011.

(G) DICOM Standard PS 3.16-2011.

(ii) 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.

(iii) 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 either transmitted to NIOSH or stored at the facility and available for inspection by NIOSH for 5 years after the examination.

(6) A specific test object may be required on each radiograph for an objective evaluation of image quality at the discretion of NIOSH.

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

(8) 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.

(9) 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;

(10) 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.

(11) Before the miner is advised that the examination is concluded, the radiograph must be processed and inspected and accepted for quality 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. Unacceptable digital image files must be fully deleted immediately or rendered permanently inaccessible in the event that permanent deletion is not technologically feasible.

(j) The following are not authorized for use under this section:

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

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

[77 FR 56730, Sept. 13, 2012]

§37.43 Approval of radiographic facilities that use film radiography systems.

(a) Facilities become eligible to participate in this program by demonstrating their ability to make high quality diagnostic chest radiographs by submitting to NIOSH six or more sample chest radiographs made and processed at the applicant facility and which are of acceptable quality to one or more individuals selected by NIOSH from

the panel of B Readers. Applicants must also submit a radiograph of a plastic step-wedge object[1] or other test object (available on loan from NIOSH) that was made and processed at the same time with the same technique as the radiographs submitted and processed at the facility for which approval is sought.

[1]The plastic step-wedge object is described in E. Dale Trout, John P. Kelley, *A Phantom for the Evaluation of Techniques and Equipment Used for Roentgenography of the Chest*, Amer J Roentgenol 1973;117(4):771-776.

(1) At least one chest radiograph and one test object radiograph must have been made with each unit to be used hereunder.

(2) All radiographs must have been made within 15 calendar days prior to submission and must be marked to identify the facility where each radiograph was made, the X-ray machine used, and the date each was made.

(3) The chest radiographs will be returned and may be the same radiographs submitted pursuant to §37.52(a)(2)(i).

(b) Each radiographic facility submitting chest radiographs for approval under this section must complete and include a Radiographic Facility Certification Document (CDC 2.11) describing each unit to be used to make chest radiographs under the Act. The form must include:

(1) The date of the last radiation safety inspection by an appropriate licensing agency or, if no such agency exists, by a qualified expert as defined in NCRP Report No. 102 (incorporated by reference, *see* §37.10);

(2) The deficiencies found;

(3) A statement that all the deficiencies have been corrected; and

(4) The date of acquisition of the unit. To be acceptable, the radiation safety inspection must have been made within 1 year preceding the date of application.

(c) Radiographs submitted with applications for approval under this section will be evaluated by one or more individuals selected by NIOSH from the panel of B Readers or by a qualified medical physicist or consultant. Applicants will be advised of any reasons for denial of approval.

(d) NIOSH or its representatives may make a physical inspection of the applicant's facility and any approved radiographic facility at any reasonable time to determine if the requirements of this subpart are being met.

(e) NIOSH may require a facility periodically to resubmit radiographs of a test object, sample radiographs, or a Radiographic Facility Certification Document for quality control purposes.

(1) Approvals granted hereunder may be suspended or withdrawn by notice in writing when in the opinion of NIOSH the quality of radiographs or information submitted under this section warrants such action.

(2) A copy of a notice withdrawing approval will be sent to each operator who has listed the facility as its facility for giving chest radiographs and must be displayed on the mine bulletin board adjacent to the operator's approved plan. The approved plan will be reevaluated by NIOSH in light of this change.

(f) A formal written quality assurance program must be established at each facility addressing radiation exposures, equipment maintenance, and image quality, and must conform to the standards in AAPM Report No. 74, pages 1-19, 47-53, and 56 (incorporated by reference, *see* §37.10).

(g) In conducting medical examinations pursuant to this part, physicians and radiographic facilities must maintain the results and analysis of these examinations (including any hard copies or digital files containing individual data, classifications, and images) consistent with applicable statutes and regulations governing the

handling and protection of individually identifiable health information, including, as applicable, the HIPAA Privacy and Security Rules (45 CFR part 160 and 45 CFR part 164, subparts A, C, and E).

[81 FR 73282, Oct. 24, 2016]

§37.44 Approval of radiographic facilities that use digital radiography systems.

(a) Facilities seeking approval must demonstrate the ability to make high quality digital chest radiographs by submitting to NIOSH digital radiographic image files of a test object (*e.g.*, a plastic step-wedge or chest phantom which will be provided on loan from NIOSH) as well as digital radiographic image files from six or more sample chest radiographs that are of acceptable quality to one or more individuals selected by NIOSH from the panel of B Readers and a qualified medical physicist or consultant, both designated by NIOSH.

(1) Image files must be submitted on standard portable media (compact or digital video disc) and formatted to meet specifications of the Digital Imaging and Communications in Medicine (DICOM) standard PS 3.12-2011 (incorporated by reference, *see* §37.10). Applicants will be advised of any reasons for denial of approval.

(2) All submitted images must be made within 60 days prior to the date of application using the same technique, equipment, and software as will be used by the facility under the requested approval. At least six chest radiographs and one test object radiograph must have been made with each digital radiographic unit to be used by the facility under the requested approval. The corresponding radiographic image files must be submitted on standard portable media (compact or digital video disc) and formatted to meet specifications of the current DICOM Standard PS 3.12-2011.

(3) Documentation must include the following: the identity of the facility where each radiograph was made; the X-ray machine used; and the model, version, and production date of each image acquisition software program and hardware component.

(4) The submitted sample digital chest image files must include at least two taken with the detector in the vertical position and two in the horizontal position where the imaging system permits these positions, and at least two chest images must be from persons within the highest quartile of chest diameters (28 cm or greater).

(b) Each radiographic facility submitting chest radiographic image files for approval under this section must complete and include an Radiographic Facility Certification Document (CDC 2.11) describing each system component, and the models and versions of image acquisition hardware and software to be used to make digital chest radiographs under the Act. The form must include:

(1) A copy of a dated report signed by a qualified medical physicist, documenting the evaluation of radiation safety and performance characteristics specified in this section for each digital radiography system;

(2) A copy of the report of the most recent radiation safety inspection by a licensing agency, if such agency exists;

(3) A listing of all deficiencies noted in either of the reports;

(4) A statement that all the listed deficiencies have been corrected; and

(5) The names and relevant training and experience of facility personnel described in paragraphs (c), (e), and (f) of this section. To be acceptable, the report by the medical physicist and radiation safety inspection specified in this paragraph (b) must have been made within 1 year prior to the date of submission of the application.

(c) Facilities must maintain ongoing licensure and certification under relevant local, State, and Federal laws and regulations for all digital equipment and related processes covered under this part.

(d) NIOSH or its representatives may make a physical inspection of the applicant's facility and any approved radiographic facility at any reasonable time to determine if the requirements of this subpart are being met.

(e) NIOSH may periodically require a facility to resubmit radiographic image files of the NIOSH-supplied test object (*e.g.*, step-wedge or chest phantom), sample radiographs, or a Radiographic Facility Certification Document. Approvals granted to facilities under this section may be suspended or withdrawn by notice in writing when, in the opinion of NIOSH, deficiencies in the quality of radiographs or information submitted under this section warrant such action. A copy of a notice suspending or withdrawing approval will be sent to each operator that has listed the facility for its use under this part and must be displayed on the mine bulletin board adjacent to the operator's approved plan. The operator's approved plan may be reevaluated by NIOSH in response to such suspension or withdrawal.

(f) A qualified medical physicist who is familiar with the facility hardware and software systems for image acquisition, manipulation, display, and storage, must be on site or available as a consultant. The physicist must be trained in evaluating the performance of radiographic equipment and facility quality assurance programs, and must be licensed/approved by a State or Territory of the United States or certified by a competent U.S. national board.

(g) Facilities must document that testing performed by a qualified medical physicist has verified that performance of each image acquisition system for which approval is sought met initial specifications and standards of the equipment manufacturer and performance testing as required under paragraphs (c), (f), and (h) of this section.

(h) A formal written quality assurance program must be established at each facility addressing radiation exposures, equipment maintenance, and image quality, and must conform to the standards in AAPM Report No. 74, pages 1-19, 47-53, and 56, and AAPM Report No. 116, sections VIII, IX, and X (incorporated by reference, *see* §37.10).

(1) Applications for facility approval must include a comprehensive assessment by a qualified medical physicist within 12 months prior to application addressing the performance of X-ray generators, automatic exposure controls, and image capture systems. The assessment must comply with the following guidelines: AAPM Report No. 93, pages 1-68; AAPM Report No. 74, pages 6-11; and AAPM Report No. 14, pages 1-96 (incorporated by reference, *see* §37.10).

(2) Radiographic technique charts must be used that are developed specifically for the radiography system and detector combinations used, indicating exposure parameters by anatomic measurements. If automated exposure control devices are used, calibration for chest imaging must be documented using the actual voltages and image capture systems.

(i) Radiological exposures resulting from at least ten (randomly selected) digital chest images obtained at the facility must be monitored at least quarterly to detect and correct potential dose creep, using methods specified in AAPM Report No. 31 (incorporated by reference, *see* §37.10). Radiation exposures must be compared to a professionally accepted reference level published in the American College of Radiology (ACR) Practice Guideline for Diagnostic Reference Levels in Medical X-Ray Imaging, pages 1-6 (incorporated by reference, *see* §37.10).

(ii) The medical physicist must conduct an annual assessment of measured or estimated radiation exposures, with specific recommended actions to minimize exposures during examinations performed under this part.

(3) For each digital radiography device and system, performance must be monitored annually in accordance with the recommendations of AAPM Report No. 93 (incorporated by reference, *see* §37.10), except for the testing specifically excluded below. Documentation must be maintained on the completion of quality assurance testing, including the reproducibility of X-ray output, linearity and reproducibility of mA settings, accuracy and reproducibility of timer and kVp settings, accuracy of source-to-detector distance, and X-ray field focal spot size, selection, beam quality, congruence and collimation. For DR systems, the following tests listed in AAPM Report No. 93 are not required under this part:

(i) Section 8.4.5: Laser beam function.

(ii) Section 8.4.9: Erasure Thoroughness.

(iii) Section 8.4.11: Imaging Plate (IP) Throughput.

(4) Facilities must maintain documentation, available for inspection by NIOSH for 5 years, of the ongoing implementation of policies and procedures for monitoring and evaluating the effective management, safety, and proper performance of chest image acquisition, digitization, processing, compression, transmission, display, archiving, and retrieval functions of digital radiography devices and systems.

(i) In conducting medical examinations pursuant to this part, physicians and radiographic facilities must maintain the results and analysis of these examinations (including any hard copies or digital files containing individual data, interpretations, and images) consistent with applicable statutes and regulations governing the handling and protection of individually identifiable health information, including, as applicable, the HIPAA Privacy and Security Rules (45 CFR part 160 and 45 CFR part 164, subparts A, C, and E).

[81 FR 73282, Oct. 24, 2016]

§37.45 Protection against radiation emitted by radiographic equipment.

Except as otherwise specified in §37.41 and §37.42, 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, radiographic equipment, its use and the facilities (including mobile facilities) in which such equipment is used must conform to the recommendations in NCRP Report No. 102, NCRP Report No. 105, and NCRP Report No. 147 (incorporated by reference, see §37.10).

[77 FR 56733, Sept. 13, 2012]

Specifications for Interpretation, Classification, and Submission of Chest Radiographs

§37.50 Interpreting and classifying chest radiographs—film radiography systems.

(a) Chest radiographs must be interpreted and classified in accordance with the Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses (incorporated by reference, *see* §37.10). Chest radiograph interpretations and classifications must be recorded on a paper or electronic Chest Radiograph Classification Form (CDC/NIOSH 2.8).

(b) Radiographs must be interpreted and classified only by a physician who reads chest radiographs in the normal course of practice and who has demonstrated proficiency in classifying the pneumoconioses in accordance with §37.52.

(1) Initial clinical interpretations and notification of findings other than pneumoconiosis under paragraph (a) of this section must be provided by a qualified physician who provides these services for the examining facility. This physician must have all required licensure and privileges, and must interpret chest radiographs in the normal course of practice.

(2) [Reserved]

(c) All interpreters, whenever interpreting chest radiographs made under the Act, must have immediately available for reference a complete set of the standard radiographs for use with the Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses (incorporated by reference, *see* §37.10).

(d) View boxes used for making interpretations must comply with the following:

(1) Fluorescent lamps must be simultaneously replaced with new lamps at 6-month intervals;

(2) All the fluorescent lamps in a panel of boxes must have identical manufacturer's ratings as to intensity and color;

(3) The glass, internal reflective surfaces, and the lamps must be kept clean;

(4) The unit must be so situated as to minimize front surface glare.

[81 FR 73284, Oct. 24, 2016]

§37.51 Interpreting and classifying chest radiographs—digital radiography systems.

(a) For each chest radiograph obtained at an approved facility using a digital radiography system, a qualified and licensed physician who reads chest radiographs in the normal course of practice must provide an initial clinical interpretation and notification, as specified in §37.54, of any significant abnormal findings other than pneumoconiosis.

(b) Chest radiographs must be classified for pneumoconiosis by physician readers (B Readers) who have demonstrated ongoing proficiency, as specified in §37.52(b), in classifying the pneumoconioses in a manner consistent with the Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses (incorporated by reference, *see* §37.10). Chest radiograph classifications must be recorded on a paper or electronic Chest Radiograph Classification Form (CDC/NIOSH 2.8).

(c) All B Readers, whenever classifying digitally-acquired chest radiographs made under the Act, must have immediately available for reference a complete set of NIOSH-approved standard digital chest radiographic images, including electronic images such as scanned images, provided for use with the Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses (incorporated by reference, *see* §37.10).

(1) Only NIOSH-approved standard digital (electronic) images may be used for classifying digital chest images for pneumoconiosis.

(2) Modification of the appearance of the standard images using software tools is not permitted.

(d) 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 NIOSH-approved standard images for comparison.

(1)(i) 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* §37.10).

(ii) 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* §37.10).

(2) 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* §37.10). Viewing displays must have a maximum luminance of at least 171 cd/m2, a ratio of maximum luminance to minimum luminance of at least 250, and a glare ratio greater than 400. The contribution of ambient light reflected from the display surface, after light sources have been minimized, must be included in luminance measurements.

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

(4) 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.

(e) 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* §37.10).

(1) 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.

(2) [Reserved]

(f) Classification of CR and DR digitally-acquired chest radiographs under this part must be performed based on the viewing of 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.

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

[81 FR 73284, Oct. 24, 2016]

§37.52 Proficiency in the use of systems for classifying the pneumoconioses.

(a) First or A Readers:

(1) Approval of a physician as an A Reader continues indefinitely if established prior to October 15, 2012.

(2) Physicians who desire to become A Readers must demonstrate their proficiency in classifying the pneumoconioses by either:

(i) Submitting to NIOSH from the physician's files six sample chest radiographs which are considered properly classified by one or more individuals selected by NIOSH from the panel of B Readers. The six radiographs must consist of two without pneumoconiosis, two with simple pneumoconiosis, and two with complicated pneumoconiosis (these may be the same radiographs submitted for facility approval pursuant to §§37.43 and 37.44). The films will be returned to the physician. The classifications must be on the Chest Radiograph Classification Form (CDC/NIOSH 2.8); or

(ii) Satisfactory completion, since June 11, 1970, of a course approved by NIOSH on the ILO International Classification of Radiographs of Pneumoconioses.

(b) Final or B Readers:

(1) Approval as a B Reader established prior to October 1, 1976, is hereby terminated.

(2) 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 must be demonstrated by those physicians who desire to be B Readers by taking and passing a specially-designed proficiency examination given on behalf of or by NIOSH at a time and place specified by NIOSH.

(i) Each physician who desires to take the digital version of the examination will be provided a complete set of the current NIOSH-approved standard reference digital radiographs.

(ii) Physicians who qualify under this provision need not be qualified under paragraph (a) of this section.

(c) Physicians who wish to participate in the program must familiarize themselves with the necessary components for attainment of reliable classification of chest radiographs for the pneumoconioses[2] and apply using a Physician Applicati

on for Certification Form (CDC 2.12(E)).

[2]NIOSH Safety and Health Topic, *Chest Radiography: Radiographic Classification*, *http://www.cdc.gov/niosh/topics/chestradiography/radiographic-classification.html*.

[81 FR 73284, Oct. 24, 2016]

§37.53 Method of obtaining definitive chest radiograph classifications.

(a) All chest radiographs which are first classified by an A or B Reader will be submitted by NIOSH to a B Reader qualified pursuant to §37.52.

(1) If there is agreement between the two classifications, as described in paragraph (b) of this section, the result will be considered final and reported to MSHA for transmittal to the miner.

(2) When agreement is lacking, NIOSH must obtain a third classification from the panel of B Readers.

(i) If any two of the three classifications demonstrate agreement, the result must be considered the final determination.

(ii) If agreement is lacking among the three classifications, NIOSH will obtain independent classifications from two additional B Readers selected from the panel, and the final determination will be the median category derived from the total of five classifications.

(b) Two classifications are considered to be in agreement when:

(1) They are derived from complete classifications recorded using approved paper or electronic versions of the Chest Radiograph Classification Form (CDC/NIOSH 2.8) and received by NIOSH; and

(2) Both find either stage A, B, or C complicated pneumoconiosis; or,

(3) For simple pneumoconiosis, are both in the same major category or are within one minor category (ILO Classification 12-point scale) of each other (subject to the exception in paragraph (b)(3)(ii) of this section).

(i) The higher of the two classifications must be reported.

(ii) The only exception to the one minor category principle is a reading sequence of 0/1, 1/0 or 1/0, 0/1, which are not considered agreement.

[81 FR 73285, Oct. 24, 2016]

§37.54 Notification of abnormal radiographic findings.

(a) *Significant abnormal findings other than pneumoconiosis.* The first physician to interpret the radiograph must communicate findings of, or findings suggesting, abnormality of cardiac shape or size, tuberculosis, lung cancer, or any other significant abnormal findings other than pneumoconiosis to the miner indicated on the Miner Identification Document or to the miner's designated physician. A notice of the communication must be submitted to NIOSH. When significant abnormal findings are reported, NIOSH will also notify the miner to contact his or her physician.

(b) *Significant changes or progression of disease.* When NIOSH has more than one radiograph of a miner in its files and the most recent examination was found by the first physician to interpret the radiograph or subsequently by NIOSH B Readers to show an abnormality of cardiac shape or size, tuberculosis, cancer, complicated pneumoconiosis, and any other significant abnormal findings, NIOSH will arrange for a licensed physician to compare the most recent image to older images and NIOSH will inform the miner of any significant changes or progression of disease or other findings.

(c) *Notice of eligibility for part 90 transfer option.* All final determinations of radiographic classifications providing evidence for development of pneumoconiosis will be reported to the miner or to the miner's designated physician by NIOSH. In addition, NIOSH will coordinate with MSHA to assure that such miners are notified of eligibility to transfer to a less dusty area, in accordance with section 203 of the Act (*see* 30 CFR part 90 and §37.102).

(d) *Prompt dispatch of findings.* NIOSH will make every reasonable effort to process the findings described in paragraph (c) of this section within 60 days of receipt of the information described in §37.60 in a complete and acceptable form.

(1) NIOSH will coordinate with MSHA to provide notice of eligibility for the part 90 transfer option within the same time frame.

(2) The results of an examination may not be processed by NIOSH if the examination was made within 6 months of the date of a previous acceptable examination.

[81 FR 73285, Oct. 24, 2016]

§37.60 Submitting required chest radiograph classification and miner identification documents.

(a) Each chest radiograph required to be made under this subpart, together with the completed Chest Radiograph Classification Form and the completed Miner Identification Document, must be submitted together for each miner to NIOSH within 14 calendar days after the radiographic examination is given. All submitted items become the property of NIOSH.

(1) When the radiograph is digital, the image file for each radiograph, together with either hard copy or electronic versions of the completed Chest Radiograph Classification Form and the completed Miner Identification Document, must be submitted to NIOSH using the software and format specified by NIOSH either using portable electronic media, or a secure electronic file transfer.

(2) NIOSH will notify the submitting facility when it has received the image files and forms from the examination. After this notification, the facility will permanently delete, or if this is not technologically feasible for the imaging system used, render permanently inaccessible all files and forms from its electronic and physical files.

(b) If NIOSH deems any submission under paragraph (a) of this section inadequate, the operator will be notified of the deficiency. The operator must promptly make appropriate arrangements for the necessary reexamination at no expense to the miner.

(c) Failure to comply with paragraph (a) or (b) of this section will be cause to revoke approval of a plan or any other approval as may be appropriate. An approval that has been revoked may be reinstated at the discretion of NIOSH after it receives satisfactory assurances and evidence that all deficiencies have been corrected and that effective controls have been instituted to prevent a recurrence.

(d) Chest radiographs and other required documents must be submitted only for miners.

(e) If a miner refuses to participate in all phases of the examination prescribed in this subpart, no report need be made. If a miner refuses to participate in any phase of the examination prescribed in this subpart, all forms must be submitted with his or her name and the last four digits of the Social Security number on each. If any form cannot be completed because of the miner's refusal, it must be marked “Miner Refuses,” and submitted to NIOSH. No submission will be made, however, without a completed Miner Identification Document (CDC/NIOSH 2.9) containing the miner's name, address, last four digits of the Social Security number and place of employment.

[81 FR 73285, Oct. 24, 2016]

Review and Availability of Records

§37.70 Review of classifications.

(a) Any miner who believes the classification for pneumoconiosis reported to him or her by MSHA is in error may file a written request with NIOSH that his or her radiograph be reevaluated.

(1) If the classification was based on agreement between an A Reader and a B Reader, NIOSH will obtain one or more additional classifications by B Readers as necessary to obtain agreement in accordance with §37.53, and MSHA must report the results to the miner together with notification from MSHA of any rights which may accrue to the miner in accordance with §37.102.

(2) If the reported classification was based on agreement between two (or more) B Readers, the reading will be accepted as conclusive and the miner must be so informed by MSHA.

(b) Any operator who is directed by MSHA to transfer a miner to a less dusty atmosphere based on the most recent examination may file a written request with NIOSH to review its findings. The standards set forth in paragraph (a) of this section apply and the operator and miner will be notified by MSHA whether the miner is entitled to the option to transfer.

[81 FR 73286, Oct. 24, 2016]

§37.80 Availability of records for radiographs.

(a) Medical information and radiographs on miners will be released by NIOSH only with the written consent from the miner, or if the miner is deceased, written consent from the miner's widow or widower, next of kin, or legal representative.

(b) To the extent authorized, original film radiographs will be made available for examination only at the NIOSH facility in Morgantown, WV.

[81 FR 73286, Oct. 24, 2016]

Subpart—Spirometry Testing

Source: 79 FR 45119, Aug. 4, 2014, unless otherwise noted.

§37.90 Scope.

Under this subpart, coal mine operators are required to provide spirometry testing to both current and newly employed coal miners, using medical facilities approved by NIOSH in accordance with standards established in this subpart.

[81 FR 73286, Oct. 24, 2016]

§37.91 Definitions.

Definitions provided in §37.2 will have the same meaning in this subpart. Any term defined in the Federal Mine Safety and Health Act of 1977 (Pub. L. 95-164, as amended) and not defined in §37.2 or this section will have the meaning given it in the Act. As used in this subpart:

ATS means American Thoracic Society.

ERS means European Respiratory Society.

FET means forced expiratory time, which is the time from the beginning of a forced exhalation (the back-extrapolated "time zero") maneuver to the end of expiration.

FEV1 means forced expiratory volume in one second, which is the greatest volume of air that can be forcibly blown out within the first second, after full inspiration.

FEV1/FVC means the ratio between the largest acceptable FEV1 and the largest acceptable FVC following the forced vital capacity maneuver. It is usually reported as a percentage.

FEV6 means forced expiratory volume in six seconds, which is the greatest volume of air that can forcibly be blown out in six seconds, after full inspiration.

FVC means forced vital capacity, which is the greatest volume of air that can forcibly be blown out after full inspiration.

PEF means peak expiratory flow, which is the maximal airflow generated during a forced vital capacity maneuver.

Spirometry test means a pulmonary function test that measures expiratory volume and airflow rates and may determine the presence and severity of lung function impairments, if such are present.

[81 FR 73286, Oct. 24, 2016]

§37.92 Spirometry testing required for miners.

(a) *Voluntary tests.* Each operator must provide to all miners who are employed in or at any of its coal mines the opportunity to have a spirometry test and a respiratory assessment at no cost to the miner at least once every 5 years in accordance with this subpart. The tests will be available during a 6-month period that begins no less than 3.5 years and not more than 4.5 years from the end of the last 6-month period.

(b) *Mandatory tests.* Every operator must provide to each miner who begins work in or at a coal mine for the first time on or after August 1, 2014, spirometry testing and respiratory assessment at no cost to the miner in accordance with this subpart.

(1) Initial spirometry testing and respiratory assessment will be provided to all miners who begin work in or at a coal mine for the first time on or after August 1, 2014 within the first 30 days of their employment or within 30 days of approval of a plan to provide spirometry testing.

(2) A follow-up second spirometry test and respiratory assessment will be provided to the miner no later than 3 years after the initial spirometry if the miner is still engaged in coal mining.

(3) A third spirometry test and respiratory assessment will be provided no later than 2 years after the tests in paragraphs §37.3(b)(2) and paragraph (b)(2) of this section if the chest radiograph shows evidence of pneumoconiosis as defined in §37.3(b)(3) or if the second spirometry test results demonstrate a 15 percent or greater decline in the percent predicted FEV1 value since the initial (*i.e.*, baseline) test.

(i) Percent predicted FEV1 will be calculated according to prediction equations published in Spirometric Reference Values from a Sample of the General U.S. Population, American Journal of Respiratory and Critical Care Medicine, 159(1):179-187, January 1999 (incorporated by reference, *see* §37.98).

(ii) A correction factor to Caucasian reference values will be applied when testing individuals of Asian descent as specified in the ATS Technical Standards: Spirometry in the Occupational Setting, p. 987 (incorporated by reference, *see* §37.98).

(c) *Notification.* NIOSH will notify the miner when he or she is due to receive the second or third mandatory test under paragraph (b) of this section. NIOSH will notify the coal mine operator when the miner is to perform a second spirometry test.

(1) The operator will be notified of a miner's eligibility for a third test only with the miner's written consent. The notice to the operator will not state the medical reason for the test or that it is the third test in the series.

(2) If the miner is notified by NIOSH that the third mandatory test is due and the operator is not so notified, availability of spirometry testing under the NIOSH-approved operator's plan will constitute the operator's compliance with the requirement to provide a third spirometry test even if the miner does not take the test.

(d) *Availability of spirometry testing*. The opportunity for spirometry to be available for purposes of this subpart must be indicated in an operator's plan that has been submitted and approved in accordance with this subpart.

[81 FR 73286, Oct. 24, 2016]

§37.93 Approval of spirometry facilities.

(a) *Application for facility approval.* Facilities seeking approval to provide the spirometry testing specified under this subpart must have the ability to provide spirometry of high technical quality. Thus, NIOSH-approved facilities must meet the requirements specified in this subpart for the following activities: Training of technicians who perform the tests; conducting spirometry tests using equipment and procedures that meet required specifications; collecting the respiratory assessment form; transmitting data to NIOSH; and communicating with miners as required for scheduling, testing, and notification of results. Facilities seeking approval may apply to NIOSH using the Spirometry Facility Certification document (CDC/NIOSH 2.14).

(b) *Spirometry quality assurance.* A spirometry quality assurance program must be in place to minimize the rate of invalid test results. This program must include all of the following components:

(1) *Instrument calibration checks.* Testing personnel must fully comply with the 2005 ATS/ERS Standardisation of Spirometry guidelines for instrument calibration check procedures, pp. 322-323, including Table 3 (incorporated by reference, *see* §37.98).

(i) For volume spirometers, calibration check procedures must include daily (day of testing) leak and volume accuracy checks. In addition, volume linearity checks must be performed according to the frequency established by the 2005 ATS/ERS guidelines.

(ii) For flow-type spirometers, calibration must be checked daily by injecting 3 liters of air from a calibration syringe at 3 different speeds (fast, medium, slow). Flow linearity must be checked weekly as established by the 2005 ATS/ERS guidelines.

(iii) Instrument calibration check records must be maintained by the facility and available for inspection by NIOSH, as deemed necessary.

(2) *Automated maneuver and test session quality checks.* The spirometer software must automatically perform quality assurance checks on expiratory maneuvers during each spirometry testing session. Screen displayed error messages must alert the technician to maneuver acceptability and test session non-repeatability. Each

spirometry test session must have the goal of obtaining 3 acceptable with 2 repeatable forced vital capacity maneuvers, as defined by the 2005 ATS/ERS Standardisation of Spirometry, p. 325 (incorporated by reference, *see* §37.98).

(3) *Ongoing monitoring of test quality.* Facilities must submit spirometry results to NIOSH within 14 calendar days of testing as specified in §37.96(c) to permit NIOSH to monitor test quality and provide a results report to each miner. NIOSH may provide quality performance feedback to the appropriate technician(s) along with suggestions for improvement.

(4) *Quality assurance audits.* NIOSH may periodically conduct audits to review tests submitted by approved facilities and assess the quality of spirometry provided. Such audits may include a review of all spirometry data obtained during a specified time period or review of spirometry test data collected over time on selected miners.

(c) *Noncompliance.* If NIOSH determines that a facility is not compliant with the policies and procedures specified in this subpart, or determines as the result of a quality assurance audit as specified in this section that a facility is not performing spirometry of adequate quality, the facility will be notified of the deficiency. The facility must promptly make appropriate arrangements for the deficiency to be rectified.

(d) *Revocation of approval.* If a facility fails to rectify deficiencies within 60 days of notification, NIOSH approval of the facility may be revoked. An approval which has been revoked may be reinstated at the discretion of NIOSH after it receives satisfactory assurances and evidence that all deficiencies have been corrected and that effective controls have been instituted by the facility to prevent a recurrence.

(e) *Maintenance of records.* When conducting spirometry tests pursuant to this subpart, physicians and facilities must maintain the results and analyses of these tests (including any hard copies or digital files containing individual data, such as interpretations) in a manner consistent with applicable statutes and regulations governing the handling and protection of individually identifiable health information, including, as applicable, the HIPAA Privacy and Security Rules (45 CFR part 160 and 45 CFR part 164, subparts A, C, and E).

[81 FR 73287, Oct. 24, 2016]

§37.94 Respiratory assessment form.

As part of the spirometry testing and concurrent with it, personnel at the facility must complete a Respiratory Assessment Form (CDC/NIOSH 2.13).

[81 FR 73287, Oct. 24, 2016]

§37.95 Specifications for performing spirometry tests.

(a) *Persons administering spirometry tests.* Each person administering spirometry tests for the Coal Workers' Health Surveillance Program must successfully complete a NIOSH-approved spirometry training course and maintain a valid certificate by periodically completing NIOSH-approved spirometry refresher training courses, identified on the NIOSH Web site at *http://www.cdc.gov/niosh/*. A copy of the certificate of completion from a NIOSH-approved spirometry training or refresher course, with validation dates printed on the document, must be available for inspection. NIOSH will assign each person administering spirometry tests a unique identification number, which must be entered into the spirometry system computer whenever instrument quality assurance or miner testing is done or on the Spirometry Results Notification Form (CDC/NIOSH 2.15).

(b) *Spirometer specifications.* Spirometry testing equipment must meet the 2005 ATS/ERS Standardisation of Spirometry specifications for spirometer accuracy and precision and real-time display size and content, pp. 331-333, including Table 2 on p. 322 and Table 6 on p. 332 (incorporated by reference, *see* §37.98). Facilities must make available for inspection written verification from a third-party testing laboratory (not the manufacturer or distributor) that the model of spirometer being used has successfully passed its validation checks as required by the Standardization of Spirometry; 1994 Update protocol, Appendix B pp. 1126-1134, including Table C1 (incorporated by reference, *see* §37.98). Facilities may request such documentation from spirometer manufacturers. For each forced expiratory maneuver submitted for a miner under this part, the spirometry data file must retain a record of the parameters defined in the 2005 ATS/ERS Standardisation of Spirometry, p. 335 including Table 8 (incorporated by reference, *see* §37.98). Spirometers that provide electronic transfer of spirometry data results files must use the format, content, and data structure specified by the 2005 ATS/ERS Standardisation of Spirometry, p. 335, or a procedure for data transfer that is approved by NIOSH.

(c) *Spirometry procedures.* Administration of spirometry must include the following:

(1) *Miner Identification Document.* The Miner Identification Document (CDC/NIOSH (M)2.9), described in §37.20, must be completed for each miner at the facility where spirometry is performed.

(2) *Pre-test checklist.* The Spirometry Pre-Test Checklist portion of the Spirometry Results Notification Form (CDC/NIOSH 2.15) must be completed prior to each spirometry session to identify possible contraindications to testing, or factors that might affect results.

(3) *Respiratory Assessment Form.* A standardized Respiratory Assessment Form (CDC/NIOSH 2.13) must be completed at the initial spirometry and repeated at each spirometry testing procedure.

(4) *Collection of anthropometric and demographic information.* The miner's standing height must be measured in stocking feet using a stadiometer (or equivalent device) each time the miner performs spirometry. The miner's weight must also be measured (in stocking feet). The miner's birth date, race, and ethnicity must also be recorded. These data will be entered into the spirometry system computer and transmitted with the spirometry data file or, if required under the facility's approval, on the Spirometry Results Notification Form (CDC/NIOSH 2.15).

(5) *Test procedures.* Spirometry will be conducted in accordance with test procedures defined in the 2005 ATS/ERS Standardisation of Spirometry, pp. 323-326, and the Standardisation of Lung Function Testing, Replies to Readers, pp. 1496-1498 (both incorporated by reference, *see* §37.98).

(i) The technician must be able to view real-time testing display screens as specified in the 2005 ATS/ERS Standardisation of Spirometry, p. 322 (incorporated by reference, *see* §37.98).

(ii) A miner will be tested in the standing position, but may be seated if he or she experiences lightheadedness or other signs or symptoms that raise a safety concern relating to the standing position during the spirometry test.

(d) *Records retention.* On-site records of the results will include spirometry test reports and retention of all spirometry sessions, pre-test checklists, and standardized respiratory assessment results in electronic or printed format until notification to delete or render the information inaccessible, as described in §37.100(b)(6)(ii), is received from NIOSH.

[81 FR 73287, Oct. 24, 2016]

§37.96 Spirometry interpretations, reports, and submission.

(a) *Interpretation of spirometry tests.* Interpretations will be carried out by physicians or other qualified health care professionals with expertise in spirometry who have all required licensure and privileges to provide this service in their State or Territory. Interpretations must be carried out using procedures and criteria consistent with recommendations in the ATS Technical Standards: Spirometry in the Occupational Setting, pp. 987-990, and the ATS/ERS Interpretative Strategies for Lung Function Tests, p. 950, p. 956 including Table 5, and p. 957 including Table 6 (both incorporated by reference, *see* §37.98).

(b) *Spirometry reports at NIOSH-approved spirometry facilities.* (1) Spirometry test reports must contain the following:

(i) The miner's age, height, gender, race, and weight;

(ii) Numerical values (FVC, FEV6, FEV1, FEV1/FVC, FEV1/FEV6, FET, and PEF) and volume-time and flow-volume spirograms for all recorded expiratory maneuvers; normal reference value set used; and the predicted, percent predicted, and lower limit of normal threshold values;

(iii) Miner position during testing (standing or sitting);

(iv) Dates of test and last calibration check;

(v) Ambient temperature and barometric pressure (volume spirometers); and

(vi) The technician's unique identification number.

(2) NIOSH will notify the submitting facility when to permanently delete or, if this is not technologically feasible for the spirometry system used, render permanently inaccessible all files and forms associated with a miner's spirometry test from its electronic and physical files.

(c) *Submission of spirometry results.* Facilities must submit results of spirometry tests electronically with content as specified in §37.96(b), completed pre-test screening checklists (found in Spirometry Results Notification Form CDC/NIOSH 2.15), and completed Respiratory Assessment Form (CDC/NIOSH 2.13) within 14 calendar days of testing a miner.

(1) *Electronic spirometry test results.* Submission of spirometry test results in the form of an electronic data file in a format approved by NIOSH is preferred. Facilities must utilize a secure internet data transfer site specified by NIOSH. Data submission must be performed as specified in the facility's approval. The transmitted spirometry data files must include a variable length record providing all parameters in the format, content, and data structure described by the 2005 ATS/ERS Standardisation of Spirometry, p. 335 including Table 8 (incorporated by reference, *see* §37.98), or an alternate data file that is approved by NIOSH.

(2) *Spirometry test results submitted using the Spirometry Results Notification form.* If specified under a facility's approval, spirometry results may be provided using the Spirometry Results Notification Form (CDC/NIOSH 2.15). The form must be completed and submitted electronically, accompanied by image files in a format approved by NIOSH that documents the flow-volume and volume-time curves for each trial reported on the form. The method of electronic submission must be approved by NIOSH and carried out securely as specified for electronic data files in §37.96(c)(1).

(d) *Confidentiality of spirometry results.* Individual medical information and spirometry results are considered protected health information under HIPAA and may only be released as specified by HIPAA or to NIOSH, as discussed in paragraph (d)(1) of this section, and maintained by the spirometry facility as specified in §37.93(e).

(1) Personally identifiable information in the possession of NIOSH will be released only with the written consent of the miner or, if the miner is deceased, the written consent of the miner's next of kin or legal representative.

(2) To provide on-site back-up and assure complete data transfer, facilities must retain the forms and results (in electronic or paper format) from a miner's test until instruction has been received from NIOSH to delete the associated files and forms or, if this is not technologically feasible, render the data permanently inaccessible.

[81 FR 73288, Oct. 24, 2016]

§37.97 Notification of spirometry results.

(a) Findings must be communicated to the miner or, if requested by the miner, to the miner's designated physician. The health care professional at the NIOSH-approved facility must inform the miner if the spirometry shows abnormal results or if the respiratory assessment suggests he or she may benefit from the medical follow-up or a smoking cessation intervention.

(b) NIOSH will notify the miner of his or her spirometry test results, a comparison between current and previously submitted spirometry tests (if available), and will advise the miner to contact a health care professional as appropriate based on the results.

[81 FR 73289, Oct. 24, 2016]

§37.98 Standards incorporated by reference.

(a) Certain material is incorporated by reference into this subpart, Subpart—Spirometry Testing, with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, NIOSH must publish notice of change in the Federal Register and the material must be available to the public. All approved material is available for inspection at NIOSH, Respiratory Health Division, 1095 Willowdale Road, Morgantown, WV 26505. To arrange for an inspection at NIOSH, call 304-285-5749. Copies 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/federal_register/code_of_federal_regulations/ibv_locations.html*.

(b) American Journal of Respiratory and Critical Care Medicine, American Thoracic Society (ATS), 25 Broadway, 18th Floor, New York, NY 10004. Phone: (800) 635-7181, extension 8065. Email: *Hope.Robinson@sheridan.com*. *http://www.atsjournals.org/action/showHome:*

(1) Standardization of Spirometry; 1994 Update. Official Statement of the ATS, adopted November 11, 1994. American Journal of Respiratory and Critical Care Medicine 152(3):1107-1136, September 1995, into §37.95(b). This ATS Official Statement is also available at *http://www.atsjournals.org/doi/pdf/10.1164/ajrccm.152.3.7663792*.

(2) Official American Thoracic Society Technical Standards: Spirometry in the Occupational Setting (“ATS Technical Standards: Spirometry in the Occupational Setting”). Redlich CA, Tarlo SM, Hankinson JL, Townsend MC, Eschenbacher WL, Von Essen SG, Sigsgaard T, and Weissman DN. American Journal of Respiratory and Critical Care Medicine 189(8):983-994, April 15, 2014, into §§37.92(b) and 37.96(a).

(3) Spirometric Reference Values from a Sample of the General U.S. Population. Hankinson JL, Odencrantz JR, Fedan KB. American Journal of Respiratory and Critical Care Medicine, 159(1):179-187, January 1999, into §37.92(b).

(c) European Respiratory Journal, 442 Glossop Road, Sheffield, S10 2PX, UK. Phone: 44 114 267 28 60; Fax: 44 114 266 50 64. Email: *info@ersj.org.uk*. *http://erj.ersjournals.com/*.

(1) Standardisation of Spirometry ("2005 ATS/ERS Standardisation of Spirometry"). ATS/ERS Task Force: Standardization of Lung Function Testing. Miller MR, Hankinson J, Brusasco V, Burgos F, Casaburi R, Coates A, Crapo R, Enright P, van der Grinten CPM, Gustafsson P, Jensen R, Johnson DC, MacIntyre N, McKay R, Navajas D, Pedersen OF, Pellegrino R, Viegi G, and Wanger J. European Respiratory Journal 26(2):319-338, August 2005, into §§37.93(b); 37.95(b) and (c); and 37.96(c). The ATS/ERS Standardisation of Spirometry is also available on the ATS Web site at *https://www.thoracic.org/statements/resources/pfet/PFT2.pdf*.

(2) Interpretative Strategies for Lung Function Tests ("ATS/ERS Interpretative Strategies for Lung Function Tests"). ATS/ERS Task Force: Standardisation of Lung Function Testing. Pellegrino R, Viegi G, Brusasco V, Crapo RO, Burgos F, Casaburi R, Coates A, van der Grinten CPM, Gustafsson P, Hankinson J, Jensen R, Johnson DC, MacIntyre N, McKay R, Miller MR, Navajas D, Pedersen OF, and Wanger J. European Respiratory Journal 26(5):948-968, November 2005, into §37.96(a). The ATS/ERS Standardisation of Lung Function Testing is also available on the ATS Web site at *http://www.thoracic.org/statements/resources/pft/pft5.pdf*.

(3) Standardisation of Lung Function Testing, the Authors' Replies to Readers' Comments ("Standardisation of Lung Function Testing, Replies to Readers"). Miller MR, Hankinson J, Brusasco V, Burgos F, Casaburi R, Coates A, Enright P, van der Grinten C, Gustafsson P, Jensen R, MacIntyre N, McKay RT, Pedersen OF, Pellegrino R, Viegi G, and Wanger J. European Respiratory Journal 36(6):1496-1498, December 2010, into §37.95(c). The Standardisation of Lung Function Testing, Replies to Readers is also available on the ATS Web site at *http://www.thoracic.org/statements/resources/pft/clarification-12-2010.pdf*.

[81 FR 73289, Oct. 24, 2016]

Subpart—General Requirements

Source: 79 FR 45123, Aug. 4, 2014, unless otherwise noted.

§37.100 Coal mine operator plan for medical examinations.

(a) Each coal mine operator must submit and receive NIOSH approval of a plan for the provision of chest radiographs, occupational histories, spirometry tests, and respiratory assessments of miners, using the appropriate forms provided by NIOSH.

(1) During the transition from August 1, 2014 until the time when spirometry facilities are approved by NIOSH, any person becoming a coal mine operator on or after August 1, 2014, or any coal mine operator without an approved plan as of that date must submit a plan within 60 days that provides for chest radiographs and occupational histories only.

(2) Coal mine operators with previously approved plans for only chest radiographs and occupational histories, or with plans developed pursuant to paragraph (a)(1) of this section, will be notified by MSHA when the plans must be amended to include spirometry testing and respiratory assessments. Amendments must be submitted to NIOSH within 60 days of MSHA's notification.

(b) The coal mine operator's plan must include:

(1) The name, address, and telephone number of the operator(s) submitting the plan;

(2) The name, MSHA identification number for respirable dust measurements, and address of the mine included in the plan;

(3) The proposed beginning and ending date of the 6-month period(s) for voluntary radiography exams and spirometry tests (*see* §§37.3(a) and 37.92(a)), the estimated number of miners to be given or offered examinations during the 6-month period under the plan, and a roster specifying the names and current home mailing addresses of each miner covered by the plan;

(4) The name and location of the approved radiograph and spirometry facility or facilities, and the approximate date(s) and time(s) of day during which the radiograph examination and spirometry will be given to miners to enable a determination of whether the examinations will be conducted at a convenient time and place;

(5) If a mobile medical examination facility is proposed to provide some or all of the surveillance tests specified in paragraph (a) of this section, the plan must provide that each miner be given adequate notice of the opportunity to have the examination and that no miner will have to wait for an examination more than 1 hour before or after his or her work shift. The plan must include:

(i) The number of change houses at the mine.

(ii) One or more alternate non-mobile approved medical examination facilities for the reexamination of miners and for the mandatory examination of miners when necessary (*see* §§37.3(b) and 37.92(b)), or an assurance that the mobile facility will return to the location(s) specified in the plan as frequently as necessary to provide for medical surveillance examinations in accordance with these regulations.

(iii) The name and location of each change house at which examinations will be given. For mines with more than one change house, the examinations must be given at each change house or at a change house located at a convenient place for each miner.

(6) Assurances that:

(i) The operator will not solicit a physician's spirometric, radiographic or other findings concerning any miner employed by the operator;

(ii) Instructions have been given to the person(s) giving the examinations that duplicate spirograms or copies of spirograms (including copies of electronic files) and radiographs or copies of radiographs (including, for digital radiographs, copies of electronic files) will not be made, and to the extent that it is technically feasible all related electronic files must be permanently deleted from the facility records or rendered permanently inaccessible following the confirmed transfer of such data to NIOSH, and that (except as may be necessary for the purpose of this part) the physician's spirometric, radiographic and other findings, as well as the occupational history and respiratory assessment information obtained from a miner will not be disclosed in a manner that would permit identification of the individual miner with his or her information; and

(iii) The spirometry and radiographic examinations will be made at no charge to the miner.

(c) Operators may provide for alternate spirometry or radiography facilities in plans submitted to NIOSH for approval.

(d) The change of operators of any mine operating under a plan approved pursuant to §37.101(a) must not affect the plan of the operator which has transferred responsibility for the mine. Every plan is subject to revision in accordance with paragraph (e) of this section.

(e) The operator must advise NIOSH of any change in its plan. Each change in an approved plan is subject to the same review and approval as the originally approved plan.

(f) The operator must promptly display in a visible location on the bulletin board at the mine its proposed plan or proposed change in a NIOSH-approved plan when it is submitted to NIOSH. The proposed plan or change in a NIOSH-approved plan must remain posted in a visible location on the bulletin board until NIOSH either grants or denies approval at which time the approved plan or denial of approval must be permanently posted. In the case of an operator who does not have a bulletin board, such as an operator that is a contractor, the operator must otherwise notify its employees of the examination arrangements. Upon request, the contractor must show NIOSH written evidence that its employees have been notified.

(g) Upon notification from NIOSH that sufficient time has elapsed since the previous period of examinations, the operator must resubmit a plan for each of its coal mines to NIOSH for approval for the next period of examinations (*see* §§37.3(a)(2) and 37.92(a)). The plan must include the proposed beginning and ending dates of the next period of examinations and all information required by paragraph (b) of this section.

[81 FR 73289, Oct. 24, 2016]

§37.101 Approval of plans.

(a) If, after review of any plan submitted pursuant to this subpart, NIOSH determines that the action to be taken under the plan by the operator meets the specifications of this subpart and will effectively achieve its purpose, NIOSH will approve the plan and notify the operator submitting the plan of the approval. Approval may be conditioned upon such terms as the Secretary deems necessary to carry out the purpose of section 203 of the Act.

(b) Where NIOSH has reason to believe that it will deny approval of a plan NIOSH will, prior to the denial, give notice in writing to the operator(s) of an opportunity to amend the plan. The notice must specify the ground(s) upon which approval is proposed to be denied.

(c) If a plan is denied approval, NIOSH will advise the operator(s) in writing of the reasons for the denial and inform MSHA that the plan was denied.

[81 FR 73290, Oct. 24, 2016]

§37.102 Transfer of affected miner to less dusty area.

(a) Any miner who, in the judgment of NIOSH, has evidence of the development of pneumoconiosis, must be afforded the option of transferring from his or her position to another position in an area of the mine where the concentration of respirable dust in the mine atmosphere is in compliance with the MSHA requirements in 30 CFR part 90. A classification of one or more of the miner's chest radiographs as showing category 1 (1/0 , 1/1 , 1/2), category 2 (2/1 , 2/2 , 2/3), or category 3 (3/2 , 3/3 , 3/+) simple pneumoconiosis, or complicated pneumoconiosis (ILO Classification) will be accepted as such evidence. NIOSH will, at its discretion, also accept other medical examinations provided to NIOSH for review, such as computed tomography scans of the chest or lung biopsies, as evidence of the development of pneumoconiosis.

(b) Any transfer under this section shall be in accordance with the procedures specified in 30 CFR part 90.

[81 FR 73290, Oct. 24, 2016]

§37.103 Medical examination at miner's expense.

Any miner who wishes to obtain a medical examination at the miner's own expense at an approved spirometry or radiography facility and to have the complete examination submitted to NIOSH may do so, provided that the examination is made no sooner than 6 months after the most recent examination of the miner submitted to NIOSH. NIOSH will provide radiographic classification, evaluation of spirometry test results, and reporting of the results of examinations made at the miner's expense in the same manner as if they were submitted under an operator's plan. Any change in the miner's transfer rights under the Act that may result from this examination will be subject to the terms of §37.102.

[81 FR 73290, Oct. 24, 2016]

Subpart—Autopsies

Authority: Sec. 508, 83 Stat. 803; 30 U.S.C. 957.

Source: 36 FR 8870, May 14, 1971, unless otherwise noted.

§37.200 Scope.

The provisions of this subpart set forth the conditions under which the Secretary will pay pathologists to obtain results of autopsies performed by them on miners.

§37.201 Definitions.

As used in this subpart:

(a) *Secretary* means the Secretary of Health and Human Services.

(b) *Miner* means any individual who during his life was employed in any underground coal mine.

(c) *Pathologist* means

(1) A physician certified in anatomic pathology or pathology by the American Board of Pathology or the American Osteopathic Board of Pathology,

(2) A physician who possesses qualifications which are considered “Board of eligible” by the American Board of Pathology or American Osteopathic Board of Pathology, or

(3) An intern, resident, or other physician in a training program in pathology who performs the autopsy under the supervision of a pathologist as defined in paragraph (c) (1) or (2) of this section.

(d) *NIOSH* means the National Institute for Occupational Safety and Health, United States Public Health Service, Department of Health and Human Services, Post Office Box 4258, Morgantown, WV 26504.

[43 FR 33715, Aug. 1, 1978, as amended at 77 FR 56735, Sept. 13, 2012]

§37.202 Payment for autopsy.

(a) The Secretary will pay up to $200 to any pathologist who, after the effective date of the regulations in this part and with legal consent:

(1) Performs an autopsy on a miner in accordance with this subpart; and

(2) Submits the findings and other materials to NIOSH in accordance with this subpart within 180 calendar days after having performed the autopsy; and

(3) Receives no other specific payment, fee, or reimbursement in connection with the autopsy from the miner's widow, his family, his estate, or any other Federal agency.

(b) The Secretary will pay to any pathologist entitled to payment under paragraph (a) of this section and additional $10 if the pathologist can obtain and submits a good quality copy or original of a chest radiograph (posteroanterior view) made of the subject of the autopsy within 5 years prior to his death together with a copy of any interpretation made.

[35 FR 13206, Aug. 19, 1970, as amended at 38 FR 16353, June 22, 1973; 77 FR 56735, Sept. 13, 2012]

§37.203 Autopsy specifications.

(a) Every autopsy for which a claim for payment is submitted pursuant to this part:

(1) Shall be performed consistent with standard autopsy procedures such as those, for example, set forth in the “Autopsy Manual” prepared by the Armed Forces Institute of Pathology, July 1, 1960. (Technical Manual No. 8-300. NAVMED P-5065, Air Force Manual No. 160-19.) Copies of this document may be borrowed from ALFORD.

(2) Shall include:

(i) Gross and microscopic examination of the lungs, pulmonary pleura, and tracheobronchial lymph nodes;

(ii) Weights of the heart and each lung (these and all other measurements required under this subparagraph shall be in the metric system);

(iii) Circumference of each cardiac valve when opened;

(iv) Thickness of right and left ventricles; these measurements shall be made perpendicular to the ventricular surface and shall not include trabeculations or pericardial fat. The right ventricle shall be measured at a point midway between the tricuspid valve and the apex, and the left ventricle shall be measured directly above the insertion of the anterior papillary muscle;

(v) Size, number, consistency, location, description and other relevant details of all lesions of the lungs;

(vi) Level of the diaphragm;

(vii) From each type of suspected pneumoconiotic lesion, representative microscopic slides stained with hematoxylin eosin or other appropriate stain, and one formalin fixed, paraffin-impregnated block of tissue; a minimum of three stained slides and three blocks of tissue shall be submitted. When no such lesion is recognized, similar material shall be submitted from three separate areas of the lungs selected at random; a minimum of three stained slides and three formalin fixed, paraffin-impregnated blocks of tissue shall be submitted.

(b) Needle biopsy techniques shall not be used.

§37.204 Procedure for obtaining payment.

Every claim for payment under this subpart must be submitted to NIOSH and must include:

(a) An invoice (in duplicate) on the pathologist's letterhead or billhead indicating the date of autopsy, the amount of the claim and a signed statement that the pathologist is not receiving any other specific compensation for the autopsy from the miner's widow, his surviving next-of-kin, the estate of the miner, or any other source.

(b) Completed PHS Consent, Release and History form (Form CDC/NIOSH (M)2.6). This form may be completed with the assistance of the pathologist, attending physician, family physician, or any other responsible person who can provide reliable information.

(c) Report of autopsy:

(1) The information, slides, and blocks of tissue required by this subpart.

(2) Clinical abstract of terminal illness and other data that the pathologist determines is relevant.

(3) Final summary, including final anatomical diagnoses, indicating presence or absence of simple and complicated pneumoconiosis, and correlation with clinical history if indicated.