

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 37

[Docket No. CDC–2014–0011; NIOSH–276]

RIN 0920–AA57

Specifications for Medical Examinations of Coal Miners

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Final rule.

SUMMARY: With this action, the Department of Health and Human Services (HHS), in accordance with recent rulemaking by the Department of Labor's Mine Safety and Health Administration (MSHA), finalizes amendments to Coal Workers' Health Surveillance Program regulations to establish standards for the approval of facilities to conduct spirometry and requires that all coal mine operators submit a plan for the provision of spirometry testing and X-ray examinations to all surface and underground coal miners.

DATES: This rule is effective on November 23, 2016.

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I. Public Participation

Interested persons or organizations were invited to participate in this rulemaking by submitting written views, arguments, recommendations, and data. Comments were invited on any topic related to this rulemaking.

HHS received submissions to the docket from two commenters, including a trade association representing coal mine operators and a spirometry expert.

II. Background

A. History of Coal Workers' Health Surveillance Program and Statutory Authority

All mining work generates fine particles of dust in the air. Coal miners who inhale excessive dust are known to develop a group of diseases of the lungs and airways, including coal workers' pneumoconiosis (pneumoconiosis), silicosis, and chronic obstructive pulmonary disease, including chronic bronchitis and emphysema.¹ To address such threats to the U.S. coal mining workforce, the Coal Mine Health and Safety Act was enacted in 1969 (Pub. L. 91–173) and amended by the Federal Mine Safety and Health Act of 1977 (Pub. L. 95–164, 30 U.S.C. 801 *et seq.*) (Mine Act).

The National Institute for Occupational Safety and Health (NIOSH) Coal Workers' Health Surveillance Program (CWHSP), also authorized by the Mine Act, was established to detect pneumoconiosis and prevent its progression in individual miners, while at the same time providing information for evaluation of temporal and geographic trends in pneumoconiosis. To inform each miner of his or her health status, the Act requires that coal mine operators provide each miner who begins work at a coal mine for the first time a chest roentgenogram (hereafter chest radiograph or X-ray) through an approved facility as soon as possible after employment starts. Three years later a miner must be offered a second chest radiograph. If this second examination reveals evidence of pneumoconiosis, the miner is entitled to a third chest radiograph 2 years after the second. Further, all miners working in a coal mine must be offered a chest radiograph approximately every 5 years.

All chest radiographs and other supplemental tests deemed necessary to protect the health and safety of U.S. coal

miners are to be given in accordance with specifications prescribed by the Secretary of Health and Human Services (30 U.S.C. 843(a)). The Mine Act also grants the Secretary, HHS general authority to issue regulations as is deemed appropriate to carry out provisions of the Act (30 U.S.C. 957), and grants NIOSH the authority to conduct activities in the field of coal mine health on behalf of the Secretary, HHS (30 U.S.C. 951(b)).

B. Need for Rulemaking

On May 1, 2014, the Mine Safety and Health Administration (MSHA) in the Department of Labor published a final rule amending existing health and safety standards in 30 CFR part 72 to improve health protections for coal miners, including the expansion of requirements for medical surveillance.² The amendments added a new section, § 72.100, to require that both underground and surface coal mine operators provide to each miner chest X-rays and spirometry tests using facilities approved by NIOSH, as well as the documentation of occupational history and symptom assessment.

The expansion of MSHA's medical surveillance requirements caused HHS to amend regulations in 42 CFR part 37 pertaining to the CWHSP, thereby expanding the scope of the Program to include coal miners who work in surface coal mines and adding spirometry testing and symptom assessment for all miners. In response to MSHA's rulemaking, NIOSH published an interim final rule on August 4, 2014 (August 2014 IFR) to expand the existing CWHSP to provide chest radiographic examinations to miners who work in surface coal mines and establish requirements for spirometry testing for all coal miners under part 37.³ This action finalizes those provisions promulgated by the August 2014 IFR.

III. Summary of Final Rule and Response to Public Comment

This document finalizes the August 2014 IFR. The following section-by-section summary describes and explains the amendments to certain provisions of part 37. Public comments are also summarized and answered. The final regulatory text is provided in the last section of this document.

¹Edward L. Petsonk and John E. Parker, Coal Workers' Lung Diseases and Silicosis, in *Fishman's Pulmonary Diseases and Disorders*, 967 (Alfred P. Fishman ed., McGraw-Hill, 4th ed., 2008).

²79 FR 24814.

³79 FR 45110.

A. Subpart—Chest Radiographic Examinations

Section 37.1 Scope

Section 37.1 provides the scope of the provisions in Subpart—Chest Radiographic Examinations, and is amended to clarify the purpose of this subpart. 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 according to the standards established in this subpart. Because no comments were submitted on this section and no changes are made to the regulatory text, this section is not included in the regulatory text below.

Section 37.2 Definitions

Section 37.2 contains definitions for terms that appear throughout this subpart and the new subparts (Subpart—Spirometry Testing and Subpart—General Requirements). The existing definitions of several terms are revised and a new definition of “B Reader” is added, as discussed below.

The definition “Act,” which refers to the Federal Mine Safety and Health Act of 1977, is revised to include reference to the Public Law number and amendments.

The definition “convenient time and place” is revised to strike the phrase “with respect to the conduct of any examination under this subpart,” because that phrase is not used in part 37. Additional language is added to clarify how this term is to be interpreted. Although this definition was not included in the August 2014 IFR, revising it to be consistent with the language in §§ 37.40 and 37.100 is thus a logical outgrowth of this rulemaking.

The definition “digital radiography systems” is changed to replace the word “X-ray” with “radiographic.” Although this definition was not included in the August 2014 IFR, revising it is consistent with changes made to § 37.51 in this final action and is thus a logical outgrowth of this rulemaking.

The definition “ILO Classification” is revised to clarify that using the term “digital chest image file” includes all electronic standard chest images included in the set of film radiographs provided by the International Labour Office (ILO) in the International Classification of Radiographs of Pneumoconioses. The definition is also revised to recognize that NIOSH must approve other sets of chest images files as equivalent to the ILO Classification. The ILO Classification is incorporated by reference into certain sections in part 37. Although this definition was not

included in the August 2014 IFR, revising it to recognize digitized image files is consistent with changes made to § 37.51 in this final action, and is thus a logical outgrowth of this rulemaking.

The definition “NIOSH” is revised to replace the former name of the NIOSH division responsible for the CWHSP with its new name, Respiratory Health Division (RHD). RHD is the organizational unit within NIOSH responsible for administration of the CWHSP.

The definition “Panel of B Readers” is revised to clarify that B Readers are certified by NIOSH and classify or otherwise evaluate radiographs for the CWHSP.

The definition “radiologic technologist” is revised to clarify terminology by replacing “chest images” with “chest radiographs.”

A new definition of “B Reader” is added to direct readers to § 37.52, which requires physicians who wish to evaluate and classify chest radiographs for pneumoconiosis to take and pass a specially designed proficiency examination given by NIOSH. This definition is predicated on existing language in § 37.52, and is thus a logical outgrowth of the August 2014 IFR.

Finally, the definition “facility” is moved from § 37.91 and is unchanged. No comments were submitted on this section.

Section 37.3 Chest Radiographs Required for Miners

Section 37.3 requires mine operators to provide miners an opportunity to receive a chest radiograph. Paragraphs (a)(1) and (2), concerning the provision of each employed miner an opportunity for a chest radiograph at least 3.5 to 4.5 years after the previous period for the conduct of such examinations, are revised to eliminate redundancy and provide greater clarity regarding the deadlines for voluntary examinations. The sentence specifying that the period during which examinations must begin is removed because it does not provide any additional information and may be confusing. The example provided in paragraph (a)(2) is also removed for similar reasons.

No changes are made to paragraph (b), which establishes the periodicity of three required initial chest radiographs. Paragraph (c), which establishes that NIOSH will notify the miner when it is time for a second or third radiography examination and will notify the operator under certain circumstances, is revised for clarity.

Paragraph (d), concerning the availability of chest radiographs, is revised to replace “subpart” with “part”

to clarify that radiographs must be made available by an operator in accordance with a plan submitted and approved by NIOSH in accordance with this part. As discussed in the August 2014 IFR, the section requiring operator plans for medical examinations has been removed from this subpart and replaced in Subpart—General Requirements.

One commenter asked that HHS require miners to submit to mandatory respiratory examinations. NIOSH does not have legal authority to require coal miners to submit to medical examinations. Although section 203(a) of the Mine Act (30 U.S.C. 843(a)) states that medical examinations shall be given to miners at certain intervals, it states elsewhere in that section that miners are to have “the opportunity” to have such examinations. Moreover, NIOSH concurs with MSHA’s position, as addressed in the agency’s May 1, 2014 final rule in response to public comment, that requiring miners to submit to medical examinations against their will would not be appropriate.⁴ No changes are made to the regulatory text in response to public comment.

Section 37.4 Chest Radiographic Examinations Conducted by the Secretary

Section 37.4 details the conditions under which the HHS Secretary will determine whether to conduct a chest radiographic examination. Paragraph (a), which details the circumstances under which the Secretary, HHS, will arrange for chest radiographs at a particular mine, is unchanged.

“Shall” is replaced with “must,” in accordance with Federal plain language guidelines, in paragraph (b), which requires the operator to reimburse the Secretary or person, agency, or institution directed by the Secretary to conduct radiography examinations, and paragraph (c), which requires the examinations arranged by the Secretary to be given according to the periodicity requirements in § 37.3.

Paragraph (d), which stipulates that operators participating in the National Study of Coal Workers’ Pneumoconiosis would not be responsible for assuming the cost of providing chest radiographs, is removed in its entirety because that study no longer exists. No comments were submitted on this section and no changes are made to the regulatory text.

Section 37.10 Standards Incorporated by Reference

Section 37.10 provides references to the standards incorporated by reference

⁴ See MSHA final rule, 79 FR 24814, at 24928 (May 1, 2014).

into part 37. This section is amended slightly to update the name of the NIOSH Division of Respiratory Disease Studies, now known as the Respiratory Health Division. The link to the American College of Radiology publication has been updated. No public comment was received and no further edits are made to this section.

Section 37.20 Miner Identification Document

Section 37.20 requires the use of a Miner Identification Document as a component of the examination. Although this section was not amended by the August 2014 IFR, revising it here is consistent with the addition of spirometry to part 37, and is thus a logical outgrowth of this rulemaking. The text is revised slightly to reference both radiographic and spirometry examinations. The section is also changed to clarify that the form (CDC/NIOSH 2.9) is required for both types of examination.

Section 37.40 General Provisions

Section 37.40 outlines general provisions for chest radiographs. Paragraphs (a) and (c), which require that the radiographic examination must be given at a convenient time and place and performed in an approved facility, respectively, are unchanged. Paragraph (b) is revised to update the name of the completed form that must accompany the chest radiographic examination, the Chest Radiograph Classification Form (CDC/NIOSH 2.8). No comments were submitted on this section.

Section 37.43 Approval of Radiographic Facilities That Use Film Radiography Systems

Section 37.43 establishes standards for the approval of radiography facilities that use film. Although this section was not included in the August 2014 IFR, revisions are a logical outgrowth of other changes throughout the part. The section heading is revised to clarify that it applies to film radiography systems. Paragraph (a), concerning application to NIOSH for facility participation in the CWHSP, is unchanged except to divide it into smaller paragraphs for clarity. Paragraph (a)(1) concerns the submission of sample radiographs made on the equipment intended to be used to perform radiographs under this part; (a)(2) concerns the submission of sample radiographs within 15 days of being made; (a)(3) concerns the return of such radiographs submitted as a component of the A Reader approval process. The reference provided for those chest radiographs is corrected to read § 37.52(a)(2)(i).

The name of the form referenced in paragraph (b), the Radiographic Facility Certification Document, is updated to be consistent with updates in other sections of Part 37.

Paragraphs (c), (d), and (f), concerning the evaluation of radiographs submitted with applications for NIOSH approval, the inspection of the applicant facility by NIOSH, and the establishment of a quality assurance program at the applicant facility, respectively, are unchanged.

The name of the form referenced in paragraph (e), the Radiographic Facility Certification Document, is updated to be consistent with updates in other sections of part 37. The paragraph is also divided into smaller paragraphs for clarity. Paragraph (e)(1) now concerns the suspension or withdrawal of NIOSH approval of a radiograph facility; paragraph (e)(2) requires a copy of a withdrawal notice be displayed on the mine bulletin board.

In paragraph (g), concerning the maintenance of records in accordance with Federal privacy laws, the word “interpretations” is replaced with “classifications,” to clarify that B Readers are responsible for recording classifications on the Chest Radiograph Classification Form (CDC/NIOSH 2.8). The term “classifications” describes surveillance activities, such as providing standardized descriptions of chest radiographs, while “interpretations” is a broader term meant to describe clinical activities, such as assessing radiographic findings and generating radiological differential diagnoses. This revision is consistent with similar changes in other sections of part 37.

Section 37.44 Approval of Radiographic Facilities That Use Digital Radiography Systems

Section 37.44 establishes standards for the approval of radiography facilities that use digital radiography. Although this section was not included in the August 2014 IFR, the new organization and content revisions are a logical outgrowth of other changes throughout the part. Paragraph (a), concerning application to NIOSH for facility participation in the CWHSP, is unchanged. Paragraph (a)(1), regarding the submission of digital radiographic image files with an application for facility approval, is redesignated as paragraph (a) and divided into smaller paragraphs for clarity. Paragraph (a)(1) now concerns the submission of image files; (a)(2) concerns the submission of images within 60 days of the application date; (a)(3) concerns the documentation that must accompany the image files;

and (a)(4) concerns the orientation of submitted images.

Paragraph (a)(2) is redesignated as paragraph (b). The name of the form referenced in paragraphs (b) and (e), the Radiographic Facility Certification Document, is updated to be consistent with updates in other section of part 37; similarly, the word “X-ray” is replaced with “radiograph” in paragraph (g)(2).

Paragraphs (b), (c), (e), (f), and (h), concerning facility licensure, physical inspections by NIOSH, the medical physicist requirement, documentation of compliance, and maintenance of records in accordance with Federal privacy laws are redesignated as paragraphs (c), (d), (e), (f), and (i), respectively.

Paragraph (g)(2), regarding radiation exposure parameters, is redesignated as paragraph (h)(2) and is divided into smaller paragraphs for clarity. Paragraph (h)(2)(i) now concerns the monitoring of radiological exposures; paragraph (h)(2)(ii) now concerns annual assessments of radiation exposures conducted by a medical physicist. The substance of paragraph (h) is otherwise unchanged.

Section 37.50 Interpreting and Classifying Chest Radiographs—Film Radiography Systems

Section 37.50 establishes procedures for the classification of film radiographs. The section heading is revised to clarify that the procedures herein apply specifically to film radiography systems. Paragraphs (a), which requires radiographs to be interpreted in accordance with the ILO Classification, and (c), which requires those interpreting chest radiographs to have a complete set of standard radiographs for use with the ILO Classification immediately available for reference, are unchanged.

Paragraph (b) requires radiographs to be interpreted and classified by physicians who read chest radiographs in the normal course of practice and who have demonstrated proficiency in classifying pneumoconiosis in accordance with the standards in § 37.52. Non-substantive revisions to the regulatory text in paragraph (b)(1), which requires that interpretations of findings other than pneumoconiosis must be provided by a qualified physician who provides these services for the examining facility, clarify that the physician must have all required licensure and privileges and must interpret chest radiographs in the normal course of his or her practice.

Paragraph (c), which requires all interpreters to have immediately available a set of standard radiographs

for use with the ILO Classification, is unchanged.

Paragraph (d), which establishes standards for view boxes, is revised to clarify that view boxes must comply with the requirements in paragraphs (d)(1)–(4). No comments were submitted on this section.

Section 37.51 Interpreting and Classifying Chest Radiographs—Digital Radiography Systems

Section 37.51 establishes procedures for the classification of digital chest radiographs. Paragraph (a), which requires that significant abnormal findings other than pneumoconiosis must be initially interpreted and notification provided by a qualified physician, is not changed in this action.

Paragraph (b), requiring that classifications be made by B Readers and recorded on a Chest Radiograph Classification form, is revised to clarify that physician readers who have demonstrated proficiency in the classification of pneumoconiosis in accordance with § 37.52(b) are B Readers. The paragraph is also changed to remove the term “interpretations,” for the reasons discussed above.

Paragraph (c), which requires B Readers to have a complete set of NIOSH-approved standard digital radiographs for use with the ILO Classification immediately available for reference, is changed to clarify that NIOSH-approved digital standard images used for making classifications include all approved electronic standard chest images, thus encompassing the current digitized standard chest radiographs provided by ILO. This paragraph is also divided into smaller paragraphs to aid the reader; no substantive changes are made. Paragraph (c)(1) now concerns the use of only NIOSH-approved standard digital images for classification; (c)(2) prohibits the modification of the appearance of the standard images.

Paragraphs (d) through (g), which concern viewing systems, quality control for display devices, use of soft copy images, and the impermissibility of classifications based on digitized copies of chest radiographs are also unchanged. No comments were submitted on this section.

Section 37.52 Proficiency in the Use of Systems for Classifying the Pneumoconioses

Section 37.52 establishes the A and B Reader approval programs. Paragraph (a) establishes standards for the approval of A Readers; paragraph (a)(1), which allows A Reader approvals to continue if established prior to October 15, 2012,

is changed to clarify that the approval continues indefinitely. Paragraph (a)(2) details the requirements for becoming a NIOSH-approved A Reader; paragraph (i), which requires the submission of six properly-classified sample radiographs, is revised to remove the word “interpretations” and replace it with “classifications,” and to update the name of the form to Chest Radiograph Classification Form (CDC/NIOSH 2.8), for the reasons discussed above. Paragraph (a)(2)(ii), requiring the completion of a NIOSH-approved ILO Classification course in lieu of the six sample radiographs referenced in paragraph (a)(2)(i), is unchanged.

Paragraph (b), which establishes standards for the approval of B Readers, and paragraph (b)(1), which establishes that B Reader approvals received prior to October 1, 1976 are terminated, are unchanged. Paragraph (b)(2) requires that physicians pass a proficiency examination in order to be approved as a NIOSH B Reader and is revised to clarify that B Reader proficiency examinations are only given on behalf of or by NIOSH. This paragraph is also revised to divide the large paragraph into smaller paragraphs; no substantive revisions are made. Paragraph (b)(2)(i) now concerns the provision of a complete set of NIOSH-approved standard reference digital radiographs to physicians taking the B Reader exam; (b)(2)(ii) states that physicians who qualify as B Readers need not be qualified as A Readers.

Paragraph (c) requires physicians who wish to participate in the CWHSP to apply to NIOSH. The name of the form is changed to Physician Application for Certification; the paragraph is otherwise unchanged. No comments were submitted on this section.

Section 37.53 Method of Obtaining Definitive Chest Radiograph Classifications

Section 37.53 establishes the method used by NIOSH to obtain definitive classifications of chest radiographs. For the reasons discussed above, the name of this section is revised to replace “interpretations” with “chest radiograph classifications,” to clarify that B Readers provide classifications according to the ILO system for classifying radiographs. Paragraph (a) establishes that radiographs will be independently classified by an A Reader and B Reader or two B Readers, or if agreement is lacking, NIOSH will obtain a third classification. This paragraph is revised to clarify that B Readers are qualified by NIOSH pursuant to § 37.52, and is also divided into smaller paragraphs to aid the reader. Paragraph

(a)(1) now concerns agreement among the two classifications; (a)(2) concerns the procedure NIOSH follows when agreement is lacking, and is further divided into smaller paragraphs. Paragraph (a)(2)(i) concerns agreement between two of three classifications resulting in a final determination; (a)(2)(ii) concerns lack of agreement among three classifications. No other changes are made to this paragraph.

Paragraph (b), which establishes what NIOSH considers to be agreement between chest radiographs, is revised to clarify that two classifications are considered to be in agreement when they meet the standards now in paragraphs (b)(1), (2), and (3). Paragraph (b)(3), which contains the current standard for a determination of simple pneumoconiosis, is further divided into smaller paragraphs (i) and (ii) and is revised slightly to comport with the new structure. No comments were submitted on this section.

Section 37.54 Notification of Abnormal Radiographic Findings

Section 37.54 requires that findings of abnormalities identified by chest radiograph be communicated to the miner. Although this section was not included in the August 2014 IFR, the revisions discussed below are consistent with other changes in this final action.

A new heading is added to clarify the intent of paragraph (a), which provides that findings suggesting heart abnormalities, tuberculosis, lung cancer, or any other significant health condition other than pneumoconiosis must be communicated to the miner or the miner's designated physician. The paragraph is also rearranged to clarify that the first physician to interpret a miner's radiograph must communicate the findings.

A new heading is added to clarify the intent of paragraph (b), which provides that NIOSH will arrange for a physician to compare a recent radiograph found to show significant abnormal findings, including pneumoconiosis, with older images that NIOSH may have in its possession. The word “interpretation” is removed from this paragraph to clarify that NIOSH will arrange for a physician to compare the most recent image showing an abnormality to older images. This change is consistent with other similar changes throughout part 37, for the reasons discussed above.

A new heading is added to paragraph (c), to clarify the intent of the paragraph regarding notice to the miner of eligibility for Part 90 transfer rights. The term “final findings” is replaced with “final determinations,” which are reported to the miner or the miner's

designated physician by NIOSH, when such determinations provide evidence for the development of pneumoconiosis. Revisions also clarify that NIOSH will coordinate with MSHA regarding notification of part 90 eligibility.

Finally, a heading is added to clarify the intent of paragraph (d), which states that NIOSH makes every effort to process pneumoconiosis determinations within 60 days of receipt of chest radiograph images and other documents. The paragraph is also divided into smaller paragraphs to aid the reader. Paragraph (d)(1) now concerns timely notice by MSHA; this paragraph is revised to clarify that NIOSH will work with MSHA to provide notice within the 60-day timeframe established in paragraph (d). Paragraph (d)(2) now states that examination results may not be processed by NIOSH if the examination was made within 6 months of the date of a prior acceptable examination.

One public commenter recommended that this section be changed to allow the results of the radiography examinations and spirometry to be made available to a health professional designated by the mine operator. According to the commenter, because operators are required to establish a plan for the examinations and pay for them, they are entitled to have access to the results. The commenter argued that section 203 of the Mine Act (30 U.S.C. 843) does not support excluding mine operators from the notification requirements in this section or in the spirometry results notification requirements in the new § 37.97. According to the commenter, the decision to not provide examination results to mine operators is inconsistent with a 2006 NIOSH guidance document concerning refractory ceramic fibers and with the DOL Occupational Safety and Health Administration (OSHA) asbestos standards, both of which allow notification of employers. Further, according to the commenter, section 103(h) of the Mine Act provides for the sharing of reports and findings to any interested person. Finally, the commenter argued that sharing the examination findings with operators would allow the operators to provide health counseling and medical management to miners showing evidence of early disease.

NIOSH declines to make results of radiography or spirometry available to either mine operators or health professionals designated by operators. Section 203 of the Mine Act specifically identifies the parties that must be notified of examination results (*i.e.*, Secretary, DOL; Secretary, HHS; miner; and miner's designated physician).

NIOSH is not authorized to expand notification to mine operators. Section 103 of the Mine Act, referenced by the commenter and described above, is not relevant to the matter of medical examinations of individual miners because it only addresses the conduct of mine inspections. Finally, NIOSH concurs with MSHA in its response to the question of providing examination results to operators, published in MSHA's 2014 final rule on respirable coal mine dust, which explained that the individuals notified of the miner's test results are limited in order to protect miners' confidentiality and uphold Federal privacy laws.⁵

Section 37.60 Submitting Required Chest Radiographs and Miner Identification Documents

Section 37.60 establishes the protocol for submitting radiographs to NIOSH. Paragraph (a) is revised to clarify that all submitted items, including each required chest radiograph, the Chest Radiograph Classification form, and the Miner Identification Document, become the property of NIOSH. Paragraph (a)(1) is further revised to remove the redundant sentence concerning the 14-day deadline for submission of documents after the date of the radiographic examination. The sentence concerning NIOSH's notification to the submitting facility of receipt of image files and forms is moved into paragraph (a)(2).

Paragraph (b) is revised to clarify that the operator must arrange for reexamination at no expense to the miner, in the event that NIOSH finds any submission to be inadequate.

Paragraph (c), which establishes that failure to comply with paragraph (a) or (b) may result in revocation of approval of a plan, is unchanged, as is paragraph (d), which states that chest radiographs and required forms must only be submitted for miners.

Paragraph (e) is revised to replace "shall" with "must" or "will" throughout the paragraph in accordance with Federal plain language guidelines. References in this paragraph concerning the collection of Social Security numbers are revised slightly to clarify that only the last four digits are required by NIOSH; this change is not substantive and reflects current Program practice. No comments were submitted on this section.

Section 37.70 Review of Classifications

Section 37.70(a) establishes that a miner may request that NIOSH

reevaluate a pneumoconiosis classification that the miner believes is in error. The section heading is changed to replace "interpretations" with "classifications," consistent with previous edits discussed above. The paragraph is also divided into smaller paragraphs to aid the reader. Paragraph (a)(1) establishes that after a written request from a miner, NIOSH will obtain one or more additional classifications by B Readers if the contested classification was based on agreement between an A Reader and a B Reader, pursuant to § 37.53. A reference in this paragraph to the section in part 37 that addresses the transfer of miners to a less dusty area is corrected to read § 37.102. Paragraph (a)(2) establishes that a classification based on agreement between two or more B Readers will be considered final and will be not be reevaluated. No comments were submitted on this section and no other changes are made to the regulatory text.

§ 37.80 Availability of Records for Radiographs

Section 37.80 requires that written consent be provided to NIOSH for the release of medical information and radiographs. This section was not included in the August 2014 IFR, but is revised in this final action to clarify that original film radiographs are available for examination at the NIOSH facility in Morgantown, WV. No comments were submitted on this section.

B. Subpart—Spirometry Testing

This subpart establishes standards for spirometry testing for all coal miners, working in both underground and surface mines. As discussed in the August 2014 IFR, the provisions in this subpart are consistent with MSHA regulations in 30 CFR 72.100, which requires that operators offer periodic spirometry and respiratory assessments to document miner respiratory symptoms and lung function. This is in addition to chest radiographic examinations and occupational history questionnaires. The subpart heading is revised to replace the word "examinations" with the word "testing," and similar changes are made throughout the subpart to reflect the correct terminology for describing spirometry.

Section 37.90 Scope

Section 37.90 provides the scope of the provisions in Subpart—Spirometry Testing. The text of this section is changed slightly to clarify that operators are required to provide spirometry testing to both current and newly

⁵ See 79 FR 24814, at 24928 (May 1, 2014).

employed coal miners. No comments were submitted on this section.

Section 37.91 Definitions

Section 37.91 defines terms used in this subpart. Several revisions are made to this section. The definition “facility” is removed, unchanged, from this section and moved to the definitions section in § 37.2.

The definition “FET” is revised to clarify that forced expiratory time is the time from the beginning of a forced exhalation maneuver to the end of the expiration.

The definition “FEV1” is revised to clarify that forced expiratory volume in one second is the greatest volume of air that can be forcibly blown out within the first second after full inspiration.

A new definition of the FEV1/FVC is added to mean the ratio between the largest acceptable FEV1 and the largest acceptable FVC following the forced vital capacity maneuver.⁶ Although this definition was not included in the August 2014 IFR, it is considered to be a logical outgrowth of this rulemaking. (See § 37.96(b)(1).)

The existing definition of “FEV6” is revised to clarify that forced expiratory volume in six seconds is the greatest volume of air that can be forcibly blown out in six seconds after full inspiration.

The existing definition of “FVC” is revised to clarify that forced vital capacity is the greatest volume of air that can be forcibly blown out after full inspiration.

The existing definition of “PEF” is revised to clarify that peak expiratory flow is the maximal airflow generated during a forced vital capacity maneuver.

No comments were submitted on this section.

Section 37.92 Spirometry Testing Required for Miners

Section 37.92 requires coal mine operators to provide all miners an opportunity to receive spirometry testing. Paragraph (a), which requires that each operator must provide an opportunity for miners to perform spirometry testing at least once every 5 years, is unchanged except for the heading, in which “Voluntary examinations” is replaced with “Voluntary tests.”

Paragraphs (b)(1), (2), and (3) establish the periodicity of initial, second, and third spirometry tests. The headings for the lower subparagraphs, “Initial spirometry examination,” “Second examination,” and “Third examination”

are removed to mirror the structure of § 37.3, “Chest radiographs required for miners.” The word “examination(s)” is replaced with “test(s)” throughout all three. Paragraph (b)(3) is revised to clarify that a third spirometry test and respiratory assessment will be provided if the second spirometry test results demonstrate more than a 15 percent age adjusted decline in the percent predicted FEV1 value since the initial baseline test. This paragraph is also divided into smaller paragraphs to aid the reader; the two new sub-paragraphs clarify how the percent predicted FEV1 value will be calculated (paragraph (b)(3)(i)) and the appropriate correction factor for calculating the percent predicted FEV1 for an individual of Asian descent (paragraph (b)(3)(ii)). One comment was received on paragraph (b)(3), supporting the decision to establish the 15 percent decline in the percent predicted FEV1 value.

Paragraph (c) establishes notification requirements for second and third spirometry testing sessions. This paragraph is also divided into smaller paragraphs to aid the reader. Paragraph (c)(1) stipulates that the operator would be notified of a miner’s eligibility for a third spirometry test only with the consent of the miner. If the operator is notified, NIOSH will not specify the medical reason for the third test nor reveal that it is the miner’s third. Paragraph (c)(2) establishes that if the miner is notified of the time for a third test and the operator is not notified, provision for the test in the NIOSH-approved operator’s plan will constitute the operator’s compliance with this requirement; no changes are made to the text of this paragraph.

No revisions are made to paragraph (d) and no other public comment was received on this section.

Section 37.93 Approval of Spirometry Facilities

Section 37.93 establishes standards by which NIOSH approves facilities that conduct spirometry tests, including ensuring that spirometry results are of adequate quality, and specifying programmatic approaches to quality assurance and addressing deficiencies. Paragraph (a) requires that NIOSH-approved facilities be able to provide spirometry of high technical quality by meeting the standards in this subpart. The paragraph is revised to replace the term “spirometry examinations” with the more common “spirometry testing,” and to remove the link to the Spirometry Facility Certification Document to avoid incorrect information if the NIOSH Web site is updated.

Paragraph (b) establishes that a spirometry quality assurance program must be in place at the facility to minimize the rate of invalid test results. Paragraph (b)(1) requires instrument calibration checks, performed in accordance with the 2005 ATS/ERS Standardisation of Spirometry guidelines. The regulatory text is revised to clarify that instrument calibration check records must be maintained by the facility and available for inspection by NIOSH, as deemed necessary. One public commenter stated that the calibration check procedures as described in the proposed rule were most relevant to volume spirometers, which are no longer being produced and are increasingly unavailable for purchase. In response to the public comment, the regulatory text in paragraph (b)(1) is revised and divided into smaller paragraphs to clarify which calibration check procedures are expected for volume spirometers (paragraph (b)(1)(i)) and flow-type spirometers (paragraph (b)(2)(ii)). These procedures are consistent with guidance cited by the commenter and published by the Occupational Safety and Health Administration.⁷ A new paragraph (b)(1)(iii) contains the existing sentence regarding the retention and maintenance of instrument calibration check records, and is changed to clarify that records will be available for inspection by NIOSH, as deemed necessary.

Paragraph (b)(2) requires automated maneuver and test session quality-checks. The paragraph is revised to clarify that the screen displayed error messages must alert the technician to maneuver acceptability and test session non-repeatability. The paragraph is also revised to clarify that each spirometry test session must have the goal of obtaining 3 acceptable with 2 repeatable forced vital capacity maneuvers. A public commenter also expressed concern that technicians understand that although the error messages referenced in paragraph (b)(2) are helpful, they are unreliable and cannot be relied on alone to evaluate and determine test validity. NIOSH agrees that technicians should not rely on the equipment alone to alert them of testing errors. Accordingly, § 37.95(a) requires all providers who collect spirometry data to successfully complete a NIOSH-approved spirometry training course. The spirometry course curriculum includes the identification and

⁶ See Gregg L. Ruppel, *Manual of Pulmonary Function Testing*, 51 (St. Louis: Mosby Inc., 9th ed., 2009).

⁷ Occupational Safety and Health Administration, U.S. Department of Labor, Spirometry Testing in Occupational Health Programs: Best Practices for Healthcare Professionals, OSHA 3637-03 2013, <https://www.osha.gov/Publications/OSHA3637.pdf>.

correction of technical and subject performance errors.⁸ Course participants are given additional curriculum materials to use as guides for correcting these testing errors, which they can retain for future reference in their clinics.⁹ Paragraph (b)(2) is not changed in response to the public comment.

Paragraph (b)(3) requires ongoing monitoring of spirometry test quality. The paragraph is revised to clarify that NIOSH may provide quality performance feedback to the spirometry technician(s). The word “examination,” used to characterize spirometry data, is removed from paragraph (b)(4), which concerns quality assurance audits.

The word “as” is inserted into paragraph (c), which concerns noncompliance, to improve the first sentence; the word “examination” is removed, for the reasons discussed above. Paragraph (d), revocation of approval, is unchanged.

Finally, in paragraph (e), references to chest radiographs are removed and/or changed to reference spirometry tests, in keeping with the theme of this subpart. These changes include replacing the term “medical examinations” with “spirometry tests” and removing the reference to radiograph examinations, classifications, and images.

Section 37.94 Respiratory assessment form

Section 37.94 requires that a respiratory assessment form must be completed for each miner upon testing. The link to the form on the NIOSH Web site is removed and the word “examination” is replaced with “testing.” No comments were submitted on this section.

Section 37.95 Specifications for Performing Spirometry Tests

Section 37.95 establishes standards for the performance of spirometry tests; the term “examinations” is replaced with “tests” in the section heading. Paragraph (a) of this section requires that persons administering spirometry tests for the CWHSP demonstrate completion of NIOSH-approved spirometry training, and maintain their knowledge by periodically completing an approved refresher course. The paragraph is revised to remove the link

to the Spirometry Results Notification Form.

Paragraph (b) establishes specifications for the spirometry testing equipment used to conduct tests pursuant to this Part. A public commenter recommended that the real-time displays should be large in order to allow the technician to quickly identify issues with the tests. NIOSH agrees with the commenter’s concern and has required that spirometry testing equipment conform with the 2005 ATS/ERS Standardisation of Spirometry specifications for graphics (real-time displays and test reports), which should be a minimum size for the proper recognition of errors and acceptability of test maneuvers. As part of the approval process, clinics are required to provide information pertaining to spirometer manufacturer, model, and serial number for each spirometer used during miner testing. This spirometer information allows NIOSH to confirm that the system display meets minimum requirements. No changes are made to paragraph (b).

Paragraph (c) specifies certain required documents and procedures during performance of spirometry testing, including the pre-test checklist, Respiratory Assessment form, collection of anthropometric and demographic information, and the spirometry procedure itself, which must be conducted in accordance with testing procedures described in the 2005 ATS/ERS Standardisation of Spirometry and the 2010 Standardisation of Lung Function Testing, authors’ replies to readers’ comments, which are incorporated by reference. The paragraph is revised to include a new paragraph (c)(1), which clarifies that the Miner Identification Document described in § 37.20 must be completed for each miner at the facility where spirometry is performed; the remaining numbered paragraphs are re-numbered accordingly. In the paragraphs now designated (c)(2) and (3), which require completion of the pre-test checklist and the Respiratory Assessment form, respectively, the links to those documents are removed, for the reason discussed above. Paragraph (c)(4), which requires the collection of anthropometric and demographic information, is revised to clarify that the data must either be entered into the facility’s computer and transmitted electronically with the spirometry data file or submitted, if required under the facility’s approval, on the Spirometry Results Notification form. Language concerning spirometry equipment that does not permit electronic transfer of data files is removed because all

facilities that are approved to participate in the CWHSP will submit spirometry data electronically, whether in the form of spirometry data files or in the form of a completed Spirometry Results Notification Form (CDC/NIOSH 2.15) accompanied by a spirometry report PDF that contains graphics for NIOSH inspection of FVC maneuver quality. The paragraph (c)(5) heading is revised to clarify that the topic of the paragraph is test procedures.

Paragraph (d), concerning the submission of test results by the approved facility to NIOSH, is removed because it is redundant. Requirements for the submission of spirometry results to NIOSH are consolidated in § 37.96(c). No changes are made to former paragraph (e), now designated paragraph (d), concerning records retention, other than to substitute “test” and “sessions” for “examination” and “examinations,” and no other public comments were received on this section.

Section 37.96 Spirometry Interpretations, Reports, and Submission

Section 37.96 establishes requirements for the interpretation of spirometry test results, as well as specifications for the content, deletion, and transmission of test reports. The heading of this section is revised to replace the word “notifications” with “submission” to reflect a reorganization of this section, discussed below.

Paragraph (a) of this section requires qualified health care professionals at the facilities to interpret results using a standardized approach, described in the 2005 ATS/ERS Interpretative Strategies for Lung Function Tests, and the 2014 Official ATS Standards: Spirometry in the Occupational Setting, which are incorporated by reference. No changes are made to paragraph (a).

Paragraph (b) specifies the content of spirometry test reports and the deletion of files and forms associated with the testing. The title of paragraph (b) is edited for clarity, “Spirometry reports at NIOSH-approved spirometry facilities.” The phrase “at a minimum” is removed from paragraph (b)(1) to clarify that spirometry reports must contain the elements listed in this paragraph. Paragraph (b)(1) is also divided into smaller paragraphs to clarify the required elements, and revised by adding the word “threshold” to describe the lower limit of normal values required. Paragraph (b)(2) is unchanged.

The language in paragraph (c), which requires that findings are communicated to the miner or the miner’s designated physician, is moved from § 37.96 to a new § 37.97; the existing section

⁸ See Spirometry: What is the Design and Content of an Approved Course? <http://www.cdc.gov/niosh/topics/spirometry/content-approved-course.html>.

⁹ See NIOSH, *Get Valid Spirometry Results EVERY Time*, DHHS (NIOSH) Publication No. 2011–135, March 2011, <http://www.cdc.gov/niosh/docs/2011-135/>, and NIOSH, *Spirometry Quality Assurance: Common Errors and Their Impact on Test Results*, DHHS (NIOSH) Publication Number 2012–116, January 2012, <http://www.cdc.gov/niosh/docs/2012-116/default.html>.

containing references to documents incorporated by reference into this subpart is renumbered § 37.98. The notifications to miners section, public comment, and NIOSH response to comment are discussed below.

With the removal of the language in paragraph (c), paragraph (d), concerning the submission of spirometry results to NIOSH, is redesignated paragraph (c). The text in this paragraph is revised to clarify that each facility must submit spirometry results and completed forms to NIOSH within 14 days of a spirometry test. The link to the Spirometry Notification Form is removed, as discussed above, and the name of the form is corrected. This paragraph is divided into smaller paragraphs to aid clarity. Paragraph (c)(1) concerns the submission of spirometry test results in the form of an electronic data file. CWHP prefers the submission of all test results and data points using CSV or XML files. The submission must be carried out as specified in the facility's approval. Paragraph (c)(2) allows the submission of test results electronically using the Spirometry Results Notification form, when specified under a facility's approval. Electronic submission of test results via ePDF is acceptable when facilities are otherwise unable to submit electronic files in CSV or XML format. These changes are not substantive.

The final paragraph, concerning the confidentiality of test results, is redesignated paragraph (d). The word "examinations" is removed from the paragraph heading. The text in this paragraph is revised to clarify that medical records containing protected health information must be maintained pursuant to the requirements in § 37.93(e). Finally, paragraph (d) is divided into two smaller paragraphs for clarity. No public comment was received on this section.

Section 37.97 Notification of Spirometry Results

New § 37.97, concerning the notification to miners or the miner's designated physician of spirometry results, comprises text that was located in § 37.96(c). It is moved to a new section to make information about notification procedures more accessible and to mirror the structure of the subpart concerning chest radiographs. The original text is revised slightly to clarify that a comparison between current and previously submitted spirometry tests will be provided by NIOSH to the miner if the results from more than one set of spirometry results are available. One public commenter recommended that the results of both

radiography and spirometry be made available to a health professional designated by the mine operator. NIOSH declines to adopt this recommendation; a summary of the public comment and NIOSH's response is located above, in the discussion concerning § 37.54.

Section 37.98 Standards Incorporated by Reference

Existing § 37.97, concerning standards incorporated by reference into this subpart, is redesignated § 37.98. Paragraph (a) is revised to update the name of the NIOSH Respiratory Health Division, as discussed above. The link to the ATS Standardization of Spirometry; 1994 Update, is updated, as is the link to the 2005 ATS/ERS Standardisation of Spirometry. No comments were submitted on this section.

C. Subpart—General Requirements

This subpart establishes general requirements for all surface and underground coal mine operators.

Section 37.100 Coal Mine Operator Plan for Medical Examinations

Section 37.100 requires that all coal mine operators submit a plan for providing miners with radiography and spirometry examinations. Paragraph (a) requires operators to submit and receive NIOSH approval for a plan to provide the examinations, as well as occupational histories and respiratory assessments; it is unchanged. Paragraph (a)(1) specifies that on or after August 1, 2014, a person becoming a coal mine operator, for example by purchasing an existing mine or developing a new mine, or a mine operator without an approved plan must submit a plan within 60 days that provides for chest radiographs and occupational histories. The paragraph is revised, inserting the word "only," to clarify that the provision of spirometry tests need not be included for a plan approved pursuant to this paragraph.

Paragraph (a)(2) states that all operators with approved examination plans providing only for chest radiographs and occupational histories will be notified by MSHA when they are required to submit an amended plan that includes spirometry and respiratory assessments.

In paragraph (b), which lists the required components of the operator's plan, the term "X-ray" is replaced with "radiograph" and "tests" are replaced with "examinations" in paragraph (b)(4); "shall" is replaced with "must" or "will" in paragraph (b)(5) in

accordance with the Federal Plain Language Guidelines.¹⁰

Paragraph (c), which allows operators to provide for alternate examination facilities, is revised to clarify that the alternate facilities should be identified in the operator's plans submitted to NIOSH for approval.

"Shall" is also replaced with "must" and "shall be" is replaced with "is" in paragraph (d), which states that an approved plan remains in effect even when the mine operator has transferred responsibility for the mine to a new operator.

Paragraph (e), concerning changes in mine plans, is unchanged. Paragraph (f), which requires the display of a proposed plan or a proposed change in plan, is revised slightly to clarify that only changes to a NIOSH-approved plan need be displayed.

In paragraph (g), which requires that mine operators resubmit a plan for each mine upon notification from NIOSH, the word "will" is replaced with "must" in accordance with Federal Plain Language Guidelines.

No public comment was received and no other changes are made to this section.

Section 37.101 Approval of Plans

Section 37.101 establishes that the operator's plan will be approved by NIOSH if it is found to meet the requirements in this subpart. Paragraphs (a) and (b), concerning approval and denial of mine operator plans, are unchanged. Paragraph (c) is revised to clarify that NIOSH will inform MSHA if an operator's plan is denied, in addition to the existing requirement for NIOSH to inform the operator. No comments were submitted on this section.

Section 37.102 Transfer of Affected Miner to Less Dusty Area

Section 37.102 requires that any miner who has evidence of the development of pneumoconiosis, as determined by NIOSH, must be given the option of transferring to a less dusty area of the mine. A public commenter recommended that transfer to a less dusty area should be mandatory for all miners with ILO classifications greater than or equal to category 2. According to the commenter, only 19 percent of over 3,000 miners who were offered an opportunity to transfer to a less dusty area since 1980 have exercised that option. Thus, the commenter thinks that the intervention program is ineffective "in preventing pulmonary function

¹⁰ See Federal Plain Language Guidelines, <http://www.plainlanguage.gov/howto/guidelines/FederalPLGuidelines/index.cfm>.

loss,” and that “stronger measures must be put in place to increase the participation in the transfer option.” NIOSH cannot require transfer of a miner who demonstrates evidence of development of pneumoconiosis to a less dusty area. NIOSH concurs with MSHA’s position, as addressed in the agency’s May 1, 2014 final rule, that a mandatory transfer program would compromise the confidentiality of the CWHSP. In addition, section 203 of the Mine Act (30 U.S.C. 843) only speaks of optional transfers, and does not authorize mandatory transfers. No additional public comment was received, and no changes are made to the regulatory text.

Section 37.103 Medical Examinations at Miner’s Expense

Section 37.103 states that any miner who wishes to obtain a radiography examination or spirometry test at his or her own expense may do so. For clarity, the word “interpretation” is replaced with “evaluation of spirometry test results.” No public comment was received on this section.

General

One commenter asserted that NIOSH must take into account the effects of cigarette smoking on the health outcomes of coal miners, particularly chronic obstructive pulmonary disease (COPD). The commenter referred to a 1995 NIOSH Criteria Document concerning occupational exposure to respirable coal mine dust, which recommended that underground and surface coal mine operators prohibit smoking in all mines and other work areas associated with mining, provide counseling to smokers about their increased risk of lung cancer and COPD, and encourage them to participate in a smoking cessation program.¹¹

NIOSH acknowledges the effects of smoking and dust exposure on the development of occupational respiratory disease. Accordingly, NIOSH uses the Respiratory Assessment Form (CDC/NIOSH 2.13) in the course of conducting a spirometry test; the form includes detailed questions designed to establish the miner’s smoking history.¹² At the population level, this data collection will allow NIOSH to take smoking into account in evaluations of coal miners’ respiratory health and will assist NIOSH in developing interventions to benefit underground and surface coal miners. At the level of the individual miner, the

goal of the radiography and spirometry conducted pursuant to part 37 is to identify radiographic evidence of pneumoconiosis and spirometric evidence of respiratory impairment, not to establish disease causation.

NIOSH lacks authority to prohibit smoking in underground and surface coal mines, but includes information about health effects of smoking in notifications to individual miners. Fortunately, many mines prohibit smoking onsite.

IV. Regulatory Assessment Requirements

A. Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This final rule is not being treated as a “significant” action under E.O. 12866. It finalizes and makes non-substantive revisions to those sections in 42 CFR part 37 which added requirements for mine operators to provide symptom assessment and spirometry testing for the surveillance of decreased lung function to all coal miners, and extended existing requirements to provide chest X-rays and occupational histories for underground coal miners to surface coal mine operators. The non-substantive revisions made in this final action to those sections of 42 CFR part 37 that were promulgated by interim final rule in August 2014 (79 FR 45110) will not result in costs to either the agency or its stakeholders.

The rule does not interfere with State, local, or Tribal governments in the exercise of their governmental functions.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, requires each agency to consider the potential impact of its regulations on small entities including small businesses, small governmental units, and small not-for-profit organizations. This rule

establishes requirements for the provision of chest X-rays and spirometry tests to all coal miners, and sets standards for the approval of testing facilities and transmission of test data.

The potential impact on small businesses has been analyzed by MSHA, in the Regulatory Economic Analysis published in support of that agency’s May 1, 2014 final rule (*see http://www.msha.gov/REGS/REA/CoalMineDust2010.pdf*). This final rule does not impose any new requirements on small radiographic or spirometry facilities that participate in the Coal Workers’ Health Surveillance Program administered by NIOSH under 42 CFR part 37. This final rule will not impose a significant economic burden on small coal mines. Accordingly, HHS certifies that this rule will not have a significant economic impact on a substantial number of small entities within the meaning of the RFA.

C. Paperwork Reduction Act

The Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, requires an agency to invite public comment on, and to obtain OMB approval of, any regulation that requires 10 or more people to report information to the agency or to keep certain records. This final action continues to impose the same information collection requirements as under the August 2014 IFR, including the submission of the following forms:

- Consent, Release, and History Form for Autopsy [CDC/NIOSH (M)2.6]
- Chest Radiograph Classification Form [CDC/NIOSH 2.8]
- Miner Identification Document [CDC/NIOSH 2.9]
- Coal Mine Operator’s Plan [CDC/NIOSH (M)2.10]
- Radiographic Facility Certification Document [CDC/NIOSH (M)2.11(E)]
- Physician Application for Certification [CDC 2.12 (E)]
- Respiratory Assessment Form [CDC/NIOSH 2.13]
- Spirometry Facility Certification [CDC/NIOSH 2.14]
- Spirometry Results Notification Form [CDC/NIOSH 2.15]
- Coal Contractor Plan [CDC/NIOSH (M) 2.18 (E)]

These forms are approved by OMB for data collected under the National Coal Workers’ Health Surveillance Program (CWHSP) (OMB Control No. 0920–0020, expires June 30, 2018). HHS estimates that the paperwork burden associated with this rulemaking is 20,282 hours.

¹¹ National Institute for Occupational Safety and Health, HHS, *Criteria for a Recommended Standard: Occupational Exposure to Respirable Coal Mine Dust*, DHHS (NIOSH) Publication No.

95–106, September 1995, <http://www.cdc.gov/niosh/docs/95-106/pdfs/95-106.pdf>.

¹² See Respiratory Assessment Form (CDC/NIOSH 2.13), questions 9, 9a, 9b, 9c, 9d, 10, 11, <http://www.cdc.gov/niosh/topics/surveillance/pdfs/cwhsp-respiratoryassessment-2-13.pdf>.

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Coal Mine Operator	2.10	388	1	30/60	194
Coal Mine Contractor	2.18	575	1	30/60	288
Radiograph Facility Supervisor	2.11	40	1	30/60	20
Coal Miner	2.9	14,560	1	20/60	4,854
Coal Miner—Radiograph	No form required	14,560	1	15/60	3,640
B Reader Physician	2.8	10	3014	3/60	1,507
Physicians taking the B Reader Examination	2.12	100	1	10/60	17
Spirometry Facility Supervisor	2.14	100	1	30/60	50
Spirometry Facility Employee	2.13	14,560	1	5/60	1,214
Spirometry Technician	2.15	14,560	1	20/60	4,854
Coal Mine—Spirometry	No form required	14,560	1	15/60	3,640
Pathologist	Invoice—No standard form	5	1	5/60	1
Pathologist	Pathology Report—No standard form.	5	1	5/60	1
Next-of-kin for deceased miner	2.6	5	1	15/60	2
Total	20,282

D. Small Business Regulatory Enforcement Fairness Act

As required by Congress under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), the Department will report the promulgation of this rule to Congress prior to its effective date. The report will state that the Department has concluded that this rule is not a “major rule” because it is not likely to result in an annual effect on the economy of \$100 million or more.

E. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531 *et seq.*) directs agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector “other than to the extent that such regulations incorporate requirements specifically set forth in law.” For purposes of the Unfunded Mandates Reform Act, this rule does not include any Federal mandate that may result in increased annual expenditures in excess of \$100 million by State, local or Tribal governments in the aggregate, or by the private sector.

F. Executive Order 12988 (Civil Justice)

This rule has been drafted and reviewed in accordance with Executive Order 12988, “Civil Justice Reform,” and will not unduly burden the Federal court system. Chest radiograph classifications that result in a finding of pneumoconiosis may be an element in claim processing and adjudication conducted by DOL’s Black Lung Compensation Program. This final action affects radiographs submitted to DOL for the purpose of reviewing and administering those claims. This rule

has been reviewed carefully to eliminate drafting errors and ambiguities.

G. Executive Order 13132 (Federalism)

The Department has reviewed this rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have “federalism implications.” The rule does not “have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.”

H. Executive Order 13045 (Protection of Children From Environmental Health Risks and Safety Risks)

In accordance with Executive Order 13045, HHS has evaluated the environmental health and safety effects of this rule on children. HHS has determined that the rule would have no effect on children.

I. Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use)

In accordance with Executive Order 13211, HHS has evaluated the effects of this rule on energy supply, distribution or use, and has determined that the rule will not have a significant adverse effect.

J. Plain Writing Act of 2010

Under Public Law 111–274 (October 13, 2010), executive Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal government administers or enforces. HHS has attempted to use plain language in drafting this final action consistent with

the Federal Plain Writing Act guidelines.

List of Subjects in 42 CFR Part 37

Chronic obstructive pulmonary disease, Coal workers’ pneumoconiosis, Incorporation by reference, Lung diseases, Mine safety and health, Occupational safety and health, Pneumoconiosis, Respiratory and pulmonary diseases, Silicosis, Spirometry, Surface coal mining, Transfer rights, Underground coal mining, X-rays.

Text of the Rule

For the reasons discussed in the preamble, the Department of Health and Human Services amends 42 CFR part 37 as follows:

PART 37—SPECIFICATIONS FOR MEDICAL EXAMINATIONS OF COAL MINERS

■ 1. The authority citation for part 37 continues to read as follows:

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

■ 2. Amend § 37.2 by revising the introductory text and the definitions of “Act”, “Convenient time and place”, “Digital radiography systems”, “ILO Classification”, “NIOSH”, “Panel of B Readers”, and “Radiologic technologist” and by adding definitions of “B Reader” and “Facility” to read as follows:

§ 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).

* * * * *

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).

* * * * *

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.

* * * * *

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.

* * * * *

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.

* * * * *

■ 3. Revise § 37.3 to read as follows:

§ 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.

■ 4. Revise § 37.4 to read as follows:

§ 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.

■ 5. Revise § 37.10 to read as follows:

§ 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).

■ 6. Revise § 37.20 to read as follows:

§ 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).

■ 7. Revise § 37.40 to read as follows:

§ 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.

■ 8. Revise § 37.43 to read as follows:

§ 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 object¹ 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).

■ 9. Revise § 37.44 to read as follows:

§ 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).

■ 10. Revise § 37.50 to read as follows:

§ 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.

■ 11. Revise § 37.51 to read as follows:

§ 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.

■ 12. Revise § 37.52 to read as follows:

§ 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 pneumoconioses² and apply using a Physician Application for Certification Form (CDC 2.12(E)).

■ 13. Revise § 37.53 to read as follows:

§ 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.

■ 14. Revise § 37.54 to read as follows:

§ 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.

■ 15. Revise § 37.60 to read as follows:

§ 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

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

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.

■ 16. Revise § 37.70 to read as follows:

§ 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.

■ 17. Revise § 37.80 to read as follows:

§ 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.

■ 18. Revise the subpart heading above § 37.90 to read as follows:

Subpart—Spirometry Testing

■ 19. Revise § 37.90 to read as follows:

§ 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.

■ 20. Revise § 37.91 to read as follows:

§ 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.

■ 21. Revise § 37.92 to read as follows:

§ 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.

■ 22. Revise § 37.93 to read as follows:

§ 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).

■ 23. Revise § 37.94 to read as follows:

§ 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).

■ 24. Revise § 37.95 to read as follows:

§ 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.

■ 25. Revise § 37.96 to read as follows:

§ 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 spirometry 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.

■ 26. Revise § 37.97 to read as follows:

§ 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.

■ 27. Add § 37.98 to read as follows:

§ 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>.

■ 28. Revise § 37.100 to read as follows:

§ 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.

■ 29. Revise § 37.101 to read as follows:

§ 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.

■ 30. Revise § 37.102 to read as follows:

§ 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.

■ 31. Revise § 37.103 to read as follows:

§ 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.

Dated: October 4, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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