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Specifications for Medical Examinations of Underground Coal Miners; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 37

[Docket No. CDC–2011–0013; NIOSH–225]

RIN 0920–AA21

Specifications for Medical Examinations of Underground Coal Miners

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule modifies the Department of Health and Human Services (HHS) regulations for medical examinations of underground coal miners. Existing regulations established specifications for providing, interpreting, classifying, and submitting film-based roentgenograms (now commonly called chest radiographs or X-rays) of underground coal miners. The revised standards modify the requirements to permit the use of film-based radiography systems and add a parallel set of standards permitting the use of digital radiography systems. An additional amendment requires coal mine operators to provide the National Institute for Occupational Safety and Health (NIOSH) with employee rosters to assist the Coal Workers' Health Surveillance Program in improving participation by miners.

DATES: This final rule is effective October 15, 2012. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of October 15, 2012.

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SUPPLEMENTARY INFORMATION: The preamble to this notice of final rulemaking is organized as follows:

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I. Public Participation

HHS received comments from 11 individuals and organizations. Four of the commenters are B Readers; two are West Virginia physicians; one is a private citizen; and one is a U.S. Senator. Comments were also submitted on behalf of the National Council on Radiation Protection and Measurements (NCRP), the American Society of Radiologic Technologists, and a law firm representing two coal companies and the West Virginia Coal Workers' Pneumoconiosis Fund.

II. Background

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 chronic bronchitis, emphysema, chronic obstructive pulmonary disease, silicosis, and coal workers' pneumoconiosis (CWP).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 statutes included an enforceable 2 milligrams per cubic meter limit on respirable dust exposure during underground coal mine work (30 U.S.C. 842(b)(2)). The science available at that time indicated that enforcement of this limit would greatly reduce the development of CWP, but could not ensure that all miners would be protected from developing disabling or lethal disease.

The NIOSH Coal Workers' Health Surveillance Program (CWHSP), also mandated by the Mine Act, was developed to detect CWP and prevent progression in individual miners, while at the same time providing information

¹ Petsonk EL, Parker JE [2008]. Coal workers' lung diseases and silicosis. In: Fishman AP, Elias J, Fishman J, Grippi M, Senior R, Pack A eds. Fishman's Pulmonary Diseases and Disorders. 4th ed. New York: McGraw-Hill, pp. 967–980.

for evaluation of temporal and geographic trends in pneumoconiosis. The Mine Act grants NIOSH general authority to issue regulations as the Institute deems appropriate in carrying out provisions of the Act and specifically directs that medical examinations for underground coal miners shall be given in accordance with specifications prescribed by NIOSH (30 U.S.C. 843(a), 957).

To inform each miner of his or her health status, the Act requires that underground coal mine operators offer new workers 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 an underground coal mine must be offered a chest radiograph approximately every 5 years. All chest radiographs are to be given in accordance with specifications prescribed by the Secretary of Health and Human Services (30 U.S.C. 843(a)).

Chest radiographs taken for the CWHSP are assessed by qualified and licensed physicians who are A or B Readers. A Readers are physicians who interpret chest radiographs for clinical purposes. They will have demonstrated knowledge of the International Labour Office (ILO) Classification of Radiographs of Pneumoconioses by completing a NIOSH-approved course or submitting six radiographs with satisfactory classifications, as specified in 42 CFR 37.51. B Readers are physicians who have demonstrated proficiency in the use of the ILO classification system by taking and passing a specially-designed proficiency examination offered by NIOSH, as specified in 42 CFR 37.51.

HHS proposed amendments to the existing part 37 regulations in a document published in January, 2012 (77 FR 1360, January 9, 2012).

A. Scope of Rulemaking

Existing regulations under 42 CFR part 37 provide rules and specifications for giving, interpreting, classifying, and submitting chest radiographs as required under section 203 of the Federal Mine Safety and Health Act of 1977, as amended (30 U.S.C. 843). Those rules will remain in effect. This rulemaking does not substantially alter the current standards.

Significantly, the new rule expands the availability of chest radiographic examinations by establishing additional

options for giving, interpreting, classifying, and submitting digitally-acquired radiographs under the same scope as the existing rule does for film radiographs. The final rule establishes the minimum specifications for methods, procedures, quality assurance, documentation, and equipment including computer software for facilities seeking approval to perform and submit digital radiographic examinations as well as the physician readers who interpret, classify, and submit reports using those radiographs. The final rule also makes limited changes to general requirements to reflect current terminology (such as the use of “radiograph” instead of “roentgenogram” which is no longer commonly used), practice or needs, such as requiring mine operators to provide a roster of current miners to NIOSH, which uses this information to promote miner participation in the Coal Workers’ Health Surveillance Program. The final rule does not modify existing requirements for miner radiographic examinations, eligibility, or other rights, including transfer of affected miners in accordance with 30 CFR part 90.

B. Impact of Rulemaking

The U.S. Department of Labor (DOL) will likely amend its Black Lung Benefits Act (BLBA) program regulations to correspond with this final rule. The BLBA provides disability compensation and medical benefits to

miners disabled by pneumoconiosis and monthly compensation to their eligible survivors (30 U.S.C. 901–944). Because DOL is required to consult with NIOSH on the development of criteria for medical tests for coal miners (30 U.S.C. 902(f)(1)(D)), DOL has modeled its technical requirements for chest radiographs on those adopted by NIOSH for the Coal Workers’ Health Surveillance Program (see 20 CFR 718.102 and 20 CFR part 718 Appendix A). DOL’s Occupational Safety and Health Administration (OSHA) might enable the use of digital chest images for medical surveillance under its asbestos regulations for general industry, shipyard employment, and construction (29 CFR 1910.1001 Appendix E, 29 CFR 1915.1001 Appendix E, and 29 CFR 1926.1101 Appendix E, respectively). OSHA’s asbestos regulations include requirements for screening asbestos-exposed individuals using chest radiography. Enabling the use of modern digital chest imaging in that setting will involve similar technical considerations as are addressed in this final rule. However, OSHA’s asbestos regulations are not linked by statute or regulation to this final rule.

The DOL standards refer to chest “roentgenograms,” an outdated term which NIOSH is replacing with the more contemporary “radiograph.” The DOL standards also rely upon the same ILO standards for the classification of radiographs, and might need to be

amended to comport with the 2011 version of the ILO Classification, as referenced in this final rule. Finally, the DOL standards refer to film-based images and might need to be expanded to refer to digitally-acquired images in order to allow for such images to be used for purposes of determining eligibility for compensation.

III. Summary of Final Rule and Response to Public Comments

This final rule establishes new requirements for digital radiography under existing part 37 of 42 CFR—Specifications for Medical Examinations of Underground Coal Miners. The new provisions supplement and update the existing requirements for film-screen radiographs by establishing standards for digital radiographs. The following is a section-by-section introduction to each rule section, including a summary of the public comments and NIOSH responses to them. In general, the commenters are supportive of this rulemaking and welcome its implementation. Commenters offered thoughtful and practical suggestions for improvement of the final rule text, and HHS has adopted many of those suggestions.

Table 1 matches the current regulatory provisions with the corresponding final provisions. The final regulatory text is provided in the last section of this notice.

TABLE 1—CURRENT AND FINAL PROVISIONS

Current regulation	Final regulation
37.2 Definitions	37.2 Definitions.
37.3 Chest roentgenograms required for miners	37.3 Chest radiographs required for miners.
37.4 Plans for chest roentgenographic examinations	37.4 Plans for chest radiographic examinations.
37.5 Approval of plans	37.5 Approval of plans.
37.6 Chest roentgenographic examinations conducted by the Secretary.	37.6 Chest radiographic examinations conducted by the Secretary.
37.7 Transfer of affected miner to less dusty area	37.7 Transfer of affected miner to less dusty area.
37.8 Roentgenographic examination at miner’s expense	37.8 Radiographic examination at miner’s expense.
	37.10 Standards incorporated by reference.
37.20 Miner identification document	37.20 Miner identification document.
37.40 General provisions	37.40 General provisions.
37.41 Chest roentgenogram specifications	37.41 Chest radiograph specifications—film.
37.42 Approval of roentgenographic facilities	37.42 Chest radiograph specifications—digital radiography systems.
37.43 Protection against radiation emitted by Roentgenographic equipment.	37.43 Approval of radiographic facilities that use film.
	37.44 Approval of radiographic facilities that use digital radiography systems.
	37.45 Protection against radiation emitted by radiographic equipment.
37.50 Interpreting and classifying chest roentgenogram	37.50 Interpreting and classifying chest radiographs—film.
37.51 Proficiency in the use of systems for classifying the pneumoconioses.	37.51 Interpreting and classifying chest radiographs—digital radiography systems.
37.52 Method of obtaining definitive interpretations	37.52 Proficiency in the use of systems for classifying the pneumoconioses.
	37.53 Method of obtaining definitive interpretations.
37.53 Notification of abnormal roentgenographic findings	37.54 Notification of abnormal radiographic findings.
	37.60 Submitting required chest radiographs and miner identification documents.
37.60 Submitting required chest roentgenograms and miner identification documents.	37.70 Review of interpretations.
37.70 Review of interpretations	37.80 Availability of records.
37.80 Availability of records	37.200 Scope.
37.200 Scope	

TABLE 1—CURRENT AND FINAL PROVISIONS—Continued

Current regulation		Final regulation	
37.201	Definitions	37.201	Definitions.
37.202	Payment for autopsy	37.202	Payment for autopsy.
37.203	Autopsy specifications	37.203	Autopsy specifications.
37.204	Procedure for obtaining payment	37.204	Procedure for obtaining payment.

Section 37.1 Scope

This existing section provides the scope of these provisions, and remains unchanged from the current regulation. HHS received no comments on this section.

Section 37.2 Definitions

HHS amends a number of terms in the existing § 37.2 to reflect updated terminology and references.

Comment: One commenter supports and agrees with the definition of “radiologic technologist” included in Section 37.2 but suggests that the definition contained in this section be amended to *require* the individual to 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 in radiography offered by the American Registry of Radiologic Technologists.” The definition proposed by HHS would make those credentials “optimal,” but not required.

HHS response: HHS considers the described training, certification, and ongoing renewals as optimum for radiologic technologists. However, because State and Territorial governments have regulatory authority for oversight of radiologic technologists, the Federal government cannot require such credentials. Accordingly, the commenter’s suggestion cannot be implemented.

Section 37.3 Chest Radiographs Required for Miners

This existing section requires mine operators to provide miners an opportunity to receive a chest radiograph. HHS amends this provision to delete and replace outdated text. HHS received no comments on § 37.3.

Section 37.4 Plans for Chest Radiographic Examinations

This existing section requires that mine operators submit to NIOSH a Coal Mine Operator’s Plan (Form CDC/NIOSH (M)2.10, OMB 0920–0020, exp. June 30, 2014) for chest radiographic examinations, including the beginning and ending dates of the 6-month period

for voluntary examinations, and the name and location of the approved X-ray facility or facilities. HHS received no comments on § 37.4.

Section 37.5 Approval of Plans

This existing section outlines the process undertaken by the Secretary of HHS to approve or deny approval of a Coal Mine Operator’s Plan (Form CDC/NIOSH (M)2.10, OMB 0920–0020, exp. June 30, 2014). HHS amends this section to redact outdated text and to correct gender-exclusive language. HHS received no comments on § 37.5.

Section 37.6 Chest Radiographic Examinations Conducted by the Secretary

This existing section details the conditions under which the HHS Secretary will determine whether to conduct a chest radiographic examination. HHS amends this section to replace outdated text with current terminology. HHS received no comments on § 37.6.

Section 37.7 Transfer of Affected Miner to Less Dusty Area

Under 30 CFR part 90, miners whose radiographs show specific categories of pneumoconiosis are offered the right to frequent workplace dust monitoring, and transfer to another position in an area of the mine where the concentration of respirable dust in the mine atmosphere is in compliance with MSHA requirements in 30 CFR 90.3. HHS received no comments on § 37.7.

Section 37.8 Radiographic Examination at Miner’s Expense

This existing section provides for any miner who wishes to obtain a radiographic examination at his or her own expense. HHS received no comments on § 37.8.

Section 37.10 Standards Incorporated by Reference

HHS has added § 37.10 to consolidate all of the standards incorporated by reference in Part 37. There are no substantive changes to the referenced standards.

Section 37.20 Miner Identification Document

This existing section requires the completion of a Miner Identification Document (Form CDC/NIOSH (M)2.9, OMB 0920–0020, exp. June 30, 2014) for each miner when the chest radiograph is made. HHS received no comments on § 37.20.

Section 37.40 General Provisions

This existing section outlines general provisions for chest radiographic examinations. HHS received no comments on § 37.40. However, paragraph (c) is edited to indicate that a radiograph may also be performed by a radiologic technologist to comport with the requirements in §§ 37.41 and 37.42.

Section 37.41 Chest Radiograph Specifications—Film

This existing section establishes performance standards for the acquisition of chest radiographs using film-screen technology. HHS amends this section to update terminology and standards. In response to comments, discussed below, subsection (c) is amended to require that chest radiographs be performed by either a physician or a person working under the supervision of a physician, or by a radiologic technologist. Subsection (d) is amended in response to a comment to § 31.42, below, to specify that the size of the focal spot should be described as the measured size and not the nominal size. Subsection (n) is also amended in response to comments (see below) to require that each radiograph be marked with the miner’s date of birth, in addition to the identification of the facility where it was made, the miner’s Social Security number, and the date on which the X-ray was made.

Comment: One commenter supports the change to subsection (c), requiring that a radiologic technologist perform chest radiography using film. According to the commenter, a registered radiologic technologist in radiography is educationally prepared and clinically competent to perform chest radiography. Several commenters do not approve of the proposed requirement, asserting that when radiographs of miners under this regulation are taken

by State approved and licensed radiology facilities in a physician's office or clinic and that X-ray is performed under the direct supervision of a facility medical or osteopathic physician, it is not necessary to employ a radiology technician. Commenters state that allowing other trained professionals to make radiographs will improve the availability of surveillance health examination in mining regions.

HHS response: The intent of the wording in this section is to assure that coal miners are provided high quality radiographic examinations using professionally-accepted methods that minimize radiation exposure. In order to optimize quality, safety, and accessibility goals, the wording of § 37.41(c) has been edited to indicate that the X-ray may be made either a physician or a person working under the supervision of a physician, or by a radiologic technologist.

Comment: One commenter states that use of Social Security number as an identifier is increasingly difficult. The individual suggests that for examinations under this regulation, the image file or DICOM header include the date of birth of the individual whose chest is imaged.

HHS response: HHS concurs and has accordingly modified the regulatory text in § 37.41(m) to require that the X-ray also be marked with the miner's date of birth.

Section 37.42 Chest Radiograph Specifications—Digital Radiography Systems

This new section establishes performance standards for the acquisition of chest radiographs using digital radiography systems, including digital radiography and computed radiography. Section 37.42(b), (c), (d), and (i)(4) is amended in response to comments, as discussed below. Section 37.42(i)(5)(i)(A) is amended to include DICOM Standard PS 3.3–2001, Annex A, Computed Radiography Image Information Object Definition. This section title was inadvertently omitted, and references an image information object which was already a required component of older CR equipment models.

Comment: One commenter notes that the regulations “do not require certification that the individual digital image taken both complied with the specifications of 42 CFR 37.42 and that the facility where the digital image was taken has been approved, and that its approval was current under 42 CFR 37.44, when the digital image was taken.” The comment suggests either the recording form be revised or

alternatively, a web-based listing of NIOSH-approved radiographic facilities be made available.

HHS response: CWHSP will continue to maintain a web-based listing of radiographic facilities that are NIOSH-approved under 42 CFR part 37, including directions and maps to locate approved facilities. (See, <http://www.cdc.gov/niosh>.)

Comment: One commenter indicates that the size of the detector specified in § 37.42(b) would exclude one prominent equipment provider, and also would unnecessarily prohibit use of larger detectors. The commenter further suggests that the specification of a 5 megapixel matrix size be eliminated since the requirements for pixel pitch and detector size are sufficient, and these are not entirely consistent with the specified matrix size. The commenter further expresses concern that the requirement that “Spatial resolution shall be at least 2.4 line pair per millimeter” is not adequately defined. The commenter offers several methods to clarify the requirement, including the suggestion that the modulation transfer function be included in the system performance requirements in § 37.42(i)(4).

HHS response: In response to this comment, the text of the final rule is modified to specify only pixel pitch and detector size, without a specific matrix size. Specifically, HHS has omitted the proposed maximum size for image detectors. The final rule text now specifies a minimum area and width for detectors which will accommodate the equipment mentioned in the comment (§ 37.42(b)). Per the commenter's suggestion, § 37.42(i)(4) is also amended to address the modulation transfer function (MTF). However, HHS reminds stakeholders that under § 37.42(i)(6), NIOSH retains the discretion to evaluate image quality by requiring the facility to include a test object on each X-ray.

Comment: One commenter states that when radiographs of miners under this regulation are taken by State-approved and licensed radiology facilities in a physician's office or clinic and that X-ray is performed under the direct supervision of a facility medical or osteopathic physician, it is not necessary to employ a radiologic technologist (§ 37.42(c)).

HHS Response: In order to optimize quality, safety, and accessibility goals, the wording of § 37.42(c) has been edited to indicate that the X-ray may be made by either a physician or a person working under the supervision of a physician, or by a radiologic technologist.

Comment: A commenter suggests that, in relation to the specifications for X-ray generators in 37.42(d), the size of the focal spot should be described as the measured size and not the nominal size.

HHS response: HHS has amended the final rule text to specify the measured, rather than nominal width of the focal point. A similar change is made to § 37.41(d), specifications for film radiographs.

Comment: One commenter suggests that the application of edge enhancement techniques in image processing may result in inaccurate appearances and emphasizes the importance of using full uncompressed DICOM image files, and requiring medical grade monitors (§ 37.42(i)).

HHS response: HHS concurs with the commenter and believes that the provisions in § 37.42(i) appropriately restrict use of edge enhancement techniques, require compression of DICOM image files to be fully reversible (lossless), and stipulate that the image display devices must meet the Grayscale Standard Display Function for diagnostic monitors specified in DICOM Part 14.

Comment: One commenter recommends that § 37.42(i)(5)(ii)(A) be amended to require that the image file or DICOM header include the date of birth of the individual whose chest is imaged. Another commenter indicates that determining whether imaging parameters have been met will be difficult because only basic information is contained in the DICOM header, thus placing a burden on small hospitals attempting to comply with quality assurance standards.

HHS response: HHS concurs that the miner's date of birth should be required for film radiographs. For digital radiographs, unique identification of each miner, chest image, facility, and date and time of the examination are encoded within the image information object according to Part 3 (PS 3.3–2009) of the DICOM standard, as specified in § 37.42. Accordingly, HHS has not amended the text of § 37.42(i)(5)(ii)(A).

With regard to the quality assurance standards, since the inception of the Program, there has been a continuing concern for both safety and image properties, and quality assurance has always been a component of the 42 CFR Part 37 specifications. In this final rule, this professionally recommended and prudent element is being extended to cover the newly permitted digital imaging systems.

Comment: A commenter expresses concern that images will be rejected and deleted even if, due to emergency situations, patients may be elderly, too

ill for a high quality standard PA image, etc. The commenter further states that all images have useful information, and that no images should be discarded (§ 37.42(i)(11)).

HHS response: The rule allows each physician reader to maintain his or her individual professional judgment in determining the quality of an image that is to be classified. The rule does not specifically require deletion of image files, but requires that when an image is deemed suboptimal and imaging is immediately repeated to obtain a better quality image, the original suboptimal file be fully deleted or rendered permanently inaccessible. The requirement to delete image files after they are transferred to NIOSH or if found substandard and thus immediately repeated is entirely analogous to the current rules regarding destruction of copies of film radiographs, and is only intended to assure maintenance of worker confidentiality for participants in the mandated Program. Approved facilities are permitted to forward to NIOSH all files of chest radiographic examinations that they have performed for any eligible coal miner, independent of image quality.

Section 37.43 Approval of Radiographic Facilities That Use Film

Section 37.43 comprises the current requirements in existing § 37.42—Approval of roentgenographic facilities. HHS received no comments on § 37.43.

Section 37.44 Approval of Radiographic Facilities That Use Digital Radiography Systems

Section 37.44 establishes standards for the approval of radiographic facilities that use digital radiography systems. These standards mirror those for film-screen technology.

Comment: A commenter states that it is the position of the American Society of Radiologic Technologists that radiographic technique charts be used by persons performing radiography and that all health care facilities make radiographic technique charts available to persons performing radiography. The commenter is pleased to see this position reflected by the inclusion of the provision in § 37.44(g)(2) along with the requirement that facilities have in place a documented quality assurance program.

HHS response: HHS appreciates this comment.

Section 37.45 Protection Against Radiation Emitted by Radiographic Equipment

This provision requires that radiographic equipment conform to applicable State, territorial, and Federal regulations. Where no State, Territorial or Federal regulations apply, the section incorporates by reference the recommendations of the National Council on Radiation Protection and Measurements (NCRP).

Comment: A commenter representing the NCRP provided updated references to the publications of his organization for the text of the regulation.

HHS response: HHS appreciates the comment and has amended the final rule text accordingly.

Section 37.50 Interpreting and Classifying Chest Radiographs—Film

Procedures for classifying radiographs are unchanged from the existing § 37.50, but for updating the requirement that images be interpreted and classified in accordance with the Guidelines for the Use of the ILO International Classification of Radiographs for Pneumoconioses, 2011 edition.² HHS received no comments on § 37.50. HHS is changing the rule text in § 37.50(a) and (c) to clarify that the Guidelines are being incorporated by reference.

Section 37.51 Interpreting and Classifying Chest Radiographs—Digital Radiography Systems

Section 37.51 establishes requirements for the classification of radiographs. Of note, the ILO has recently authorized the use of the ILO Classification for digital images and authorized a set of standard digital image files for use during classification. HHS is changing the rule text in § 37.51(b) and (c) to clarify that the Guidelines are being incorporated by reference.

Comment: A commenter observes that it can be difficult for a reader to load the subject images on his or her picture archiving and communication (PACS) system, due to software issues from the system manufacturers. The commenter further states that that software in most PACS systems does not permit viewing of the miner radiograph side-by-side with another image folder, such as the ILO standard images.

HHS response: NIOSH is aware of this concern, and has applied considerable resources and effort to make available a

specific software package (NIOSH BViewer®) which is designed to address this issue (the BViewer software is available for free download at <http://www.cdc.gov/niosh/topics/chestradiography/digital-images.html>). Although initially it is anticipated that some readers may have difficulty in displaying the standard ILO images along with the miner radiograph, over time, NIOSH believes that PACS manufacturers will incorporate software with functionality similar to B Viewer to further ameliorate this concern.

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

This section establishes the A and B Reader approval programs, and is modified from existing § 37.51 to make clarifications in the current requirements and update older terminology. HHS received no comments on § 37.52.

Section 37.53 Method of Obtaining Definitive Interpretations

Section 37.53 maintains the standards in existing § 37.52, which establishes that radiographs will be independently interpreted by an A Reader and B Reader, or two B Readers, whose classifications must be in agreement as defined in § 37.53(b); if sufficient agreement is lacking, NIOSH will obtain a third interpretation.

Comment: One commenter indicates that if the B Reader feels the image is satisfactory for identifying the abnormality, then it should not be disqualified if quality assurance standards have not been met. The commenter feels technical issues should not be used to disqualify evidence and therefore deny benefits if the individual is not able to return for repeat testing, and suggests that consensus among 2 or more B Readers be required where the quality of an image is in dispute.

HHS response: A digital or screen film radiograph will not be disqualified for technical reasons if two or more B Readers do not find it unreadable and are able to classify it. The B Reader rates the quality of the image and classifies it for the presence and severity of findings associated with pneumoconiosis, but does not assess whether the facility making the image complied with the quality assurance specifications in Part 37. The rule does not constrain the reader in determining whether the image is either satisfactory or unreadable due to quality issues. Thus, responding to this comment does not necessitate a change to the rule text.

² International Labour Office [2011]. Guidelines for the use of ILO International Classification of Pneumoconiosis, revised edition 2011). Geneva, Switzerland: International Labour Organization. Occupational Safety and Health Series No. 22 (Rev. 2011).

Section 37.54 Notification of Abnormal Radiographic Findings

Section 37.54, redesignated from § 37.53, would be revised to update outdated terminology. The provision would also allow the first reader to communicate certain information directly to the miner, including abnormal findings other than pneumoconiosis. As discussed below, § 37.54(b) is amended in response to public comment.

Comment: One commenter believes that the side-by-side review referenced in § 37.54(b) can be confusing to the miner, and that all information regarding X-ray results should be communicated at one time. The commenter suggests that because the evaluation of findings other than pneumoconiosis does not require a B Reader, this section should permit the comparisons to be done by any licensed physician, and/or that the miner be provided with copies of the relevant images so that their personal physician can perform the comparison. Finally, the commenter suggests that communication about health issues be to the miner, and not the designated physician to reduce the chance of failure of important communications. Another commenter recommends that NIOSH utilize available in-house medical expertise to complete the “side-by-side” readings. Outside consultation could still be obtained, where deemed useful or necessary.

HHS response: HHS agrees with commenters that the use of a B Reader to interpret findings other than pneumoconiosis is unnecessary. In response to these comments, HHS has amended § 37.54(b) to indicate that, instead of a B Reader, NIOSH will arrange for a licensed physician to compare the most recent image and interpretation to older ones and inform the miner of any significant changes or progression of disease or other comments. The rule text is also changed to clarify that the Department means to refer to abnormal findings other than pneumoconiosis and substitutes the phrase “abnormality of cardiac shape or size” for “enlarged heart.”

Section 37.60 Submitting Required Chest Radiographs and Miner Identification Documents

Section 37.60 is essentially unchanged from existing § 37.60, which establishes the protocol for submitting radiographs. HHS received no comments on § 37.60.

Section 37.70 Review of Interpretations

This section is amended only to update terminology. HHS received no comments on § 37.70.

Section 37.80 Availability of Records for Radiographs

Section 37.80 remains unchanged from the existing requirement, although terminology in this section is updated. HHS received no comments on § 37.80.

Section 37.200 Scope

Section 37.200 remains unchanged from the existing explanation that provisions in this subpart establish conditions under which pathologists will be paid to conduct autopsies on deceased miners. HHS received no comments on § 37.200.

Section 37.201 Definitions

Section 37.201 retains the existing definitions for Secretary, miner, and pathologist, but updates “ALFORD,” in the existing provision to “NIOSH.” HHS received no comments on § 37.201.

Section 37.202 Payment for Autopsy

Section 37.202 retains the existing provision setting forth circumstances under which a pathologist may be paid by the Secretary for performing an autopsy. HHS received no comments on § 37.202.

Section 37.203 Autopsy Specifications

Section 37.203 retains the existing standards establishing the manner in which autopsies are conducted. HHS received no comments on § 37.203.

Section 37.204 Procedure for Obtaining Payment

Section 37.204 retains the existing procedure for submitting a claim for payment to NIOSH (“NIOSH” replaces “ALFORD” in the rule text). HHS has received no comments on § 37.204.

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 being treated as a “significant” action under E.O. 12866. It provides for the use of digital radiography systems in the Coal Workers’ Health Surveillance Program (CWHSP) administered by NIOSH under 42 CFR part 37, in cooperation with coal mine operators, to monitor and protect the health of U.S. coal miners, particularly for the prevention of coal workers’ pneumoconiosis. The current regulations at 42 CFR part 37 only allow for the use of film-screen radiography systems in this program. The addition of digital X-ray standards in part 37 does not require mine operators to change their plans to accommodate digital radiographs, but it is expected to substantially increase the amount of access miners will have to radiograph facilities because the use of film-screen radiography is declining markedly throughout the United States and specifically in areas where coal mining is located and where coal miners live. In fact, many clinics participating in the Program have indicated that they are maintaining their outdated X-ray film capabilities only because of Program requirements, and that they intend to switch to digital radiography when NIOSH allows its use by promulgating this final rule. In general, most health care facilities have abandoned the use of film-based X-rays. Mammography was the last mainstream radiology procedure that required use of film; many facilities made the final switch to digital several years ago when digital mammography systems became available.

Increased access to radiograph facilities that offer digital X-rays is expected to result in cost savings to coal miners because they will not have to drive as far to visit an approved clinic.

Digital radiographs are more cost-effective than their film-based counterparts because they do not require costly chemical processing, they eliminate the need for a separate device to develop the image, and they avoid costs associated with managing and archiving hard-copy images. Over the past 5 years approximately 100 clinics have submitted film-screen radiographs to CWHSP. NIOSH queried several clinics on the costs associated with film-screen radiography, including equipment maintenance, chemicals, film, and processing. Based on the responses, it is estimated that the cost to facilities of maintaining film X-ray technology to provide radiographs for approximately 2,500 coal miners is between \$7,000 and \$15,000 per clinic per year. Because NIOSH expects that most facilities participating in the Program will switch entirely to digital radiography when this rule is

promulgated, we estimate a first year cost savings to facilities that currently provide both film and digital radiographs of between \$700,000 and \$1,500,000 after they have discontinued the use of film radiographs.

Although this rule does not require any facility to upgrade to digital technology, facilities that choose to do so will necessarily incur costs associated with its acquisition. HHS invited public comment on these estimates and received one comment asserting that meeting the rule's quality assurance standards will be prohibitively expensive for small facilities. As discussed here, HHS expects that facilities voluntarily upgrading to digital technology will necessarily incur costs associated with acquiring the technology and meeting regulatory standards. However, the quality assurance standards in this rule reflect standard industry practice and should not create burdens for small facilities already using, or planning to use, digital chest imaging and wishing to join the CWHSP.

Furthermore, the final rule does not require any radiography facility to perform digital radiographs for this NIOSH program. Facilities may continue to perform film-screen radiography under the current requirements of Part 37 applicable to film-screen radiography, which would not be substantially changed by this final rule.

The provisions for using the DICOM standard and incorporating by reference standard best practices for digital radiography used in lung imaging ensure that the final requirements reflect standard practice and technology. For these reasons, the rule provisions allowing for the use of digital radiography and specifying equipment and practice parameters would not impose any additional costs on coal mine operators who provide for their miners' participation in this program nor on the radiography facilities that serve the participating coal miners.

The final rule establishes a new requirement for coal mine operators to provide to NIOSH a roster of current miners under § 37.4(a)(3). The provision of this roster to NIOSH is current practice by almost all of the approximately 500 U.S. underground coal mine operators; therefore codifying this practice in regulation will not result in any additional cost to mine operators. For these reasons, the final rule is not considered economically significant, as defined in sec. 3(f)(1) of E.O. 12866.

The rule is consistent with the requirements of 42 U.S.C. 7384n(c). 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 standards for the delivery of digitally-acquired chest radiographs for underground coal miners. It does not impose any new requirements on small radiographic facilities that participate in the Coal Workers' Health Surveillance Program (CWHSP) administered by NIOSH under 42 CFR part 37. These facilities may continue to exclusively use film-screen technology for radiography under provisions that would be essentially unchanged by this rulemaking. The rule will benefit these facilities by allowing and facilitating their transition to digital radiography for the purposes of this program. In this respect, the reliance in the rule on the DICOM standards, standard technology, and current best practices for lung imaging radiography ensure that the rule is consistent with current medical practices in digital radiography. It should also be noted that if this standard permits some facilities to switch entirely to digital imaging, rather than maintaining two duplicate technologies, the facilities may be able to achieve savings in radiography operating costs, as discussed in the Executive Orders 12866 and 13563 analysis above. The final rule also introduces a substantial benefit in allowing the participation in CWHSP of radiography facilities that solely use digital radiography; such facilities currently are prohibited from participation due to the current lack of digital radiography standards for CWHSP under part 37.

This final rule is expected to increase access to medical facilities for small and larger coal mine operators, since many medical facilities exclusively use digital radiography or are transitioning to this technology. The rule may also decrease the cost to coal mine operators of providing X-ray screenings to miners. Lower cost is likely to be one of the factors in the trend among radiography facilities to adopt or switch entirely to digital radiography. In any event, allowing and facilitating the provision of digital radiography under part 37 will impose no new costs on small coal mine operators.

The final rule establishes a new requirement for coal mine operators to provide to NIOSH a roster of current

miners under § 37.4(a)(3). The provision of this roster to NIOSH is current practice by almost all coal mine operators. HHS estimates that, of 488 underground coal mines that can be considered small as of the first quarter of 2011,³ 130 coal mine plans are submitted to the Agency annually. HHS further estimates that a clerical worker spends 0.5 hours per year preparing the roster. According to the Bureau of Labor Statistics, the average salary of a coal mine clerical worker is \$17.38/hour; HHS estimates the annual cost for an individual coal mine operator to supply a roster to NIOSH is approximately \$9 and the total cost to all coal mines combined amounts to approximately \$1170 annually. In HHS's judgment, this \$9 cost would not be significant for any coal mine operator. Therefore, a regulatory flexibility analysis as provided for under the RFA is not required. 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 rule continues to impose the same information collection requirements as under the current rule, including the submission of the following forms:

- Roentgenographic Interpretation Form [CDC/NIOSH (M)2.8]
- Miner Identification Document [CDC/NIOSH (M)2.9]
- Coal Mine Operator's Plan [CDC/NIOSH (M)2.10]
- Facility Certification Document [CDC/NIOSH (M)2.11]
- Interpreting Physician Certification Document [CDC/NIOSH (M)2.12]
- Consent, Release, and History Form [CDC/NIOSH (M)2.6]

These forms are approved by OMB for data collected under the CWHSP (OMB Control No. 0920-0020, exp. June 30, 2014).

The additional reporting burden associated with the Coal Mine Operator's Plan which requires underground coal mine operators to submit a roster of current employees (§ 37.4(a)(3)), and the Facility

³ U.S. Department of Labor, Mine Safety and Health Administration. Mining Industry Accident, Injuries, Employment, and Production Data—Address & Employment Self-Extracting Files. <http://www.msha.gov/stats/part50/p50y2k/aetable.htm>. Accessed June 26, 2012.

Certification Document which is required of participating digital radiography facilities (§ 37.44(a)(2)), are both accounted for in the OMB

information collection approval referenced above. There is no additional recordkeeping burden associated with the quality assurance program

referenced in § 37.44(g) because this provision reflects standard industry practice and does not impose any new recordkeeping requirements.

Type of respondent	Form name and No.	Number of respondents	Number of responses per respondent	Hours/response	Response burden (in hrs)
Physicians (B Readers)	Roentgenographic Interpretation Form—CDC/NIOSH (M) 2.8.	10,000	1	3/60	500
Miners	Miner Identification Document—CDC/NIOSH (M) 2.9	5,000	1	20/60	1,667
Coal Mine Operators	Coal Mine Operator's Plan—CDC/NIOSH (M) 2.10	200	1	30/60	100
Supervisors at X-ray Facilities.	Facility Certification Document—CDC/NIOSH (M) 2.11.	100	1	30/60	50
Physicians (B Readers)	Interpreting Physician Certification Document—CDC/NIOSH (M) 2.12.	300	1	10/60	50
Spirometry Test—Coal Miners.	No form involved	2,500	1	20/60	833
X-ray—Coal Miners	No form involved	5,000	1	15/60	1250
Pathologist	(Invoice)	50	1	5/60	4
Pathologist	(Final diagnosis)	50	1	5/60	4
Next-of-Kin	Consent, Release, and History Form—CDC.NIOSH (M) 2.6.	50	1	15/60	13
Totals	23,250	4,471

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. For 2012, the inflation adjusted threshold is \$139 million.

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 interpretations 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 rule would affect 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 promulgating the final rule consistent with the Federal Plain Writing Act guidelines.

V. Final Rule

List of Subjects in 42 CFR Part 37

Black lung benefits, Incorporation by reference, Lung diseases, Mine safety and health, Occupational safety and health, Pneumoconiosis, Respiratory and pulmonary diseases, Underground coal mining, Workers' compensation, 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 UNDERGROUND 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.

Subpart—Chest Radiographic Examinations

■ 2. Revise § 37.1 to read as follows:

§ 37.1 Scope.

The provisions of this subpart set forth the specifications for giving, interpreting, classifying, and submitting chest radiographs required by section 203 of the Act to be given to

underground coal miners and new miners.

■ 3. Revise § 37.2 to read as follows:

§ 37.2 Definitions.

Any term defined in the Federal Mine Safety and Health Act of 1977 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.*).

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

Convenient time and place with respect to the conduct of any examination under this subpart means that the examination 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 paragraph.

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

(1) *Computed radiography (CR)* is the term for digital X-ray image acquisition systems that detect X-ray signals using a cassette-based photostimulable storage phosphor. Subsequently, the cassette is processed using a stimulating laser beam to convert the latent radiographic image to electronic signals which are then processed and stored so they can be displayed.

(2) *Digital radiography (DR)* is the term used for digital X-ray image acquisition systems in which the X-ray signals received by the image detector are converted nearly instantaneously to electronic signals without movable cassettes.

ILO Classification means the below-referenced classification of radiographs of the pneumoconioses 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 accepted by NIOSH as equivalent.

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

Miner means any individual including any coal mine construction worker who is working in or at any underground coal mine, but does not include any surface worker who does not have direct contact with underground coal mining or with coal processing operations.

NIOSH means the National Institute for Occupational Safety and Health (NIOSH), located within the Centers for Disease Control and Prevention (CDC). Within NIOSH, the Division of Respiratory Disease Studies (DRDS), Box 4258, Morgantown, WV 26504, formerly called the Appalachian Laboratory for Occupational Safety and Health, is the organizational unit that has programmatic responsibility for the chest radiographic examination program.

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

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

Panel of B Readers means the group of physicians that are currently approved by NIOSH as B Readers.

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

Qualified medical physicist means an individual who is trained in evaluating the performance of radiographic equipment including radiation controls and facility quality assurance programs, and has the relevant current certification by a competent U.S. national board, or unrestricted license or approval from a U.S. State or territory.

Radiographic technique chart means a table that specifies the types of cassette, intensifying screen, film or digital detector, grid, filter, and lists X-ray machine settings (timing, kVp, mA) that enables the radiographer to select the correct settings based on the body habitus or the thickness of the chest tissue.

Radiologic technologist means an individual who has met the requirements for privileges to perform general radiographic procedures and for

competence in using the equipment and software employed by the examining facility to obtain chest images as specified by the State or Territory and examining facility in which such services are provided. Optimally, such an individual will have completed a formal training program in radiography leading to a certificate, an associate degree, or a bachelor's degree and participated in the voluntary initial certification and annual renewal of registration for radiologic technologists offered by the American Registry of Radiologic Technologists.

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

Soft copy means the image of a coal miner's chest radiograph acquired using a digital radiography system, viewed at the full resolution of the image acquisition system using an electronic medical image display device.

■ 4. 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 underground coal mines and who was employed in underground coal mining prior to December 30, 1969, or who has completed the required examinations under § 37.3(b) an opportunity for a chest radiograph in accordance with this subpart:

(1) Following August 1, 1978 NIOSH will notify the operator of each underground 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 October 15, 2012 and end no later than a date specified by NIOSH separately for each coal mine. The termination date of the period will be approximately 5 years from the date of the first examination that was made on a miner employed by the operator in its coal mine under the former regulations of this subpart adopted July 27, 1973. Within the period specified by NIOSH for each mine, the operator may select a 6-month period within which to provide examinations in accordance with a plan approved under § 37.5.

Example: NIOSH finds that between July 27, 1973, and March 31, 1975, the first radiograph for a miner who was employed at mine Y and who was employed in underground coal mining prior to December 30, 1969, was made on January 1, 1974. NIOSH will notify the operator of mine Y that the operator may select and designate on

its plan a 6-month period within which to offer its examinations to its miners employed at mine Y. The 6-month period must be scheduled between August 1, 1978 and January 1, 1979 (5 years after January 1, 1974).

(2) For all future voluntary examinations, NIOSH will notify the operator of each underground coal mine when sufficient time has elapsed since the end of the previous 6-month period of examinations. NIOSH will specify to the operator of each mine a period within which the operator may provide examinations to its miners employed at its coal mine. The period must begin no sooner than 3½ years and end no later than 4½ 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 by NIOSH for each mine, the operator may select a 6-month period within which to provide examinations in accordance with a plan approved under § 37.5.

Example: NIOSH finds that examinations were previously provided to miners employed at mine Y in a 6-month period from July 1, 1979, to December 31, 1979. NIOSH notifies the operator at least 3 months before July 1, 1983 (3½ years after December 31, 1979) that the operator may select and designate on its plan the next 6-month period within which to offer examinations to its miners employed at mine Y. The 6-month period must be scheduled between July 1, 1983, and July 1, 1984 (between 3½ and 4½ years after December 31, 1979).

(3) Within either the next or future period(s) specified by NIOSH 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 a coal mine for the first time after December 30, 1969:

(1) An initial chest radiograph, as soon as possible, but in no event later than 6 months after commencement of employment. An initial chest radiograph given to a miner according to former regulations for this subpart prior to August 1, 1978 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 underground coal mining. A second radiograph given to a miner according to former regulations under this subpart prior to August 1, 1978 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 underground coal mining and if the second radiograph shows evidence of category 1 (¼, ½, ¾), category 2 (⅓, ⅔, ⅞), category 3 (⅔, ¾, ⅞+) simple pneumoconioses, or complicated pneumoconioses (ILO Classification).

(c) NIOSH will notify the miner when he or she is due to receive the second or third mandatory examination under (b) of this section. Similarly, NIOSH will notify the coal mine operator when the miner is to be given a second examination. The operator will be notified concerning a miner's third examination only with the miner's written consent, and the notice to the operator must not state the medical reason for the examination nor that it is the third examination in the series. 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 Coal Mine Operator's Plan (Form CDC/NIOSH (M)2.10) 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) The opportunity for chest radiographs to be 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 subpart.

■ 5. Amend § 37.4 by revising paragraphs (a) introductory text, (a)(3), (a)(4), (a)(6), (a)(7), and (d) through (f) to read as follows:

§ 37.4 Plans for chest radiographic examinations.

(a) Every plan for chest radiographic examinations of miners must be submitted on the Coal Mine Operator's Plan form (Form CDC/NIOSH (M)2.10) to NIOSH within 120 calendar days after August 1, 1978. In the case of a person who after August 1, 1978, becomes an operator of a mine for which no plan has been approved, that person must submit a plan within 60 days after such event occurs. A separate plan must be submitted by the operator and by each construction contractor for each underground coal mine that has a

MSHA identification number. The plan must include:

* * * * *

(3) The proposed beginning and ending date of the 6-month period for voluntary examinations (see § 37.3(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 X-ray facility or facilities, and the approximate date(s) and time(s) of day during which the radiographs will be given to miners to enable a determination of whether the examinations will be conducted at a convenient time and place;

* * * * *

(6) The name and address of the A or B Reader who will interpret and classify the chest radiographs. In the event a plan lists an approved facility with a digital radiography system, the name and address of the physician(s) who will perform the initial clinical interpretation.

(7) Assurances that:

(i) The operator will not solicit a physician's 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 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 for the imaging system used, digital radiographs and all related digital 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 subpart) the physician's radiographic and other findings, as well as the occupational history information obtained from a miner will not be disclosed in a manner that would permit identification of the individual with their information, and

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

* * * * *

(d) 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.

(e) The operator must promptly display in a visible location on the bulletin board at the mine its proposed plan or proposed change in plan when it is submitted to NIOSH. The proposed

plan or change in plan must remain posted in a visible location on the bulletin board until NIOSH either grants or denies approval of it at which time the approved plan or denial of approval must be permanently posted. In the case of an operator who is a construction contractor and who does not have a bulletin board, the construction contractor must otherwise notify its employees of the examination arrangements. Upon request, the contractor must show NIOSH written evidence that its employees have been notified.

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

■ 6. Revise § 37.5 to read as follows:

§ 37.5 Approval of plans.

(a) If, after review of any plan submitted pursuant to this subpart, the Secretary 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, the Secretary will approve the plan and notify the operator(s) submitting the plan of the approval. Approval may be conditioned upon such terms as the Secretary deems necessary to carry out the purpose of § 203 of the Act.

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

(c) If a plan is denied approval, the Secretary must advise the operator(s) in writing of the reasons for the denial.

■ 7. Amend § 37.6 by revising paragraphs (a) and (d) to read as follows:

§ 37.6 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:

* * * * *

(d) Operators of mines selected by NIOSH to participate in the National Study of Coal Workers' Pneumoconiosis (an epidemiological study of respiratory diseases in coal miners) and who agree to cooperate will have all their miners afforded the opportunity to have a chest radiograph required hereunder at no cost to the operator. For future examinations and for mandatory examinations each participating operator must submit an approvable plan.

■ 8. Amend § 37.7 by revising paragraph (a) to read as follows:

§ 37.7 Transfer of affected miner to less dusty area.

(a) Any miner who, in the judgment of the Secretary based upon the interpretation of one or more of the miner's chest radiographs, shows category 1 ($\frac{1}{6}$, $\frac{1}{4}$, $\frac{1}{2}$), category 2 ($\frac{2}{1}$, $\frac{2}{2}$, $\frac{2}{3}$), or category 3 ($\frac{3}{2}$, $\frac{3}{3}$, $\frac{3}{4}$) simple pneumoconioses, or complicated pneumoconioses (ILO Classification) 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 90.3.

* * * * *

■ 9. Revise § 37.8 to read as follows:

§ 37.8 Radiographic examination at miner's expense.

Any miner who wishes to obtain an examination at the miner's own expense at an approved 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 an interpretation and report of the examinations made at the miner's expense in the same manner as if it 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 § 37.7.

■ 10. Add § 37.10 to read as follows:

§ 37.10 Standards incorporated by reference.

(a) Certain material is incorporated by reference into this part 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, Division of Respiratory Disease Studies, 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 the American Institute of Physics 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/~media/ACR/Documents/PGTS/guidelines/Reference_Levels.pdf:

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

■ 11. Revise § 37.20 to read as follows:

§ 37.20 Miner identification document.

As part of the radiographic examination, a Miner Identification Document (Form CDC/NIOSH (M)2.9) which includes an occupational history questionnaire must be completed for each miner at the facility where the radiograph is made at the same time the chest radiograph required by this subpart is given.

■ 12. Revise the undesignated center heading and § 37.40 to read as follows:

Specifications for Performing Chest Radiographic Examinations

§ 37.40 General provisions.

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

(b) The chest radiographic examination consists of the chest radiograph, and a complete Roentgenographic Interpretation Form (Form CDC/NIOSH (M)2.8), and Miner Identification Document (Form CDC/NIOSH (M)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.

■ 13. Amend § 37.41 as follows:

■ a. Revise the section heading.

■ b. Redesignate paragraphs (a) and (b) as paragraphs (b) and (a) respectively.

■ c. Redesignate paragraphs (c) through (m) as (d) through (n).

■ d. Add new paragraph (c).

■ e. Revise newly designated paragraphs (a), (b), (d) through (h), (i) introductory text, (i)(1) through (i)(3), (i)(7), (j)(2), (k), (m), and (n) to read as follows:

§ 37.41 Chest radiograph specifications—film.

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

a clean gown. Facilities must be heated to a comfortable temperature.

(b) Every chest radiograph must be a single posteroanterior projection at full inspiration on a film being no less than 14 by 17 inches and no greater than 16 by 17 inches. The film and cassette must be capable of being positioned both vertically and horizontally so that the chest radiograph will include both apices and costophrenic angles. If a miner is too large to permit the above requirements, then the projection must include both apices with minimum loss of the costophrenic angle.

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

(1) By or under the supervision of a physician who makes chest radiographs in the normal course of practice and who has demonstrated ability to make chest radiographs of a quality to best ascertain the presence of pneumoconiosis; or

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

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

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

(1) The generators of existing radiographic units acquired by the examining facility prior to July 27, 1973, must have a minimum rating of 200 mA at 100 kVp;

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

(f) Radiographs made with battery-powered mobile or portable equipment must be made with units having a minimum rating of 100 mA at 110 kVp at 500 Hz, or of 200 mA at 110 kVp at 60 Hz.

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

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

(i) To ensure high quality chest radiographs:

(1) The maximum exposure time must not exceed 50 milliseconds except that with single phase units with a rating less than 300 mA at 125 kVp and subjects with chests over 28 cm posteroanterior, the exposure may be increased to not more than 100 milliseconds;

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

(3) Medium speed film and medium speed intensifying screens are recommended. However, any film-screen combination, the rated "speed" of which is at least 100 and does not exceed 300, that produces radiographs with spatial resolution, contrast, latitude and quantum mottle similar to those of systems designated as "medium speed" may be employed;

* * * * *

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

* * * * *

(j) * * *

(2) If mineral or other impurities in the processing water introduce difficulty in obtaining a high-quality radiograph, a suitable filter or purification system must be used.

(k) Before the miner is advised that the examination is concluded, the radiograph must be processed and inspected and accepted for quality by the physician, or if the physician is not available, acceptance may be made by the radiologic technologist. In a case of a substandard radiograph, another must be immediately made. All substandard radiographs must be clearly marked as rejected and promptly sent to NIOSH for disposal.

* * * * *

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

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

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

(ii) The miner's Social Security number;

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

(iv) The date of the radiograph.

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

§§ 37.42 and 37.43 [Redesignated as §§ 37.43 and 37.45]

■ 14a. Redesignate § 37.42 and § 37.43 as § 37.43 and § 37.45 respectively.

■ 14b. Add new § 37.42 to read as follows:

§ 37.42 Chest radiograph specifications—digital radiography systems.

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

(b) Every digital chest radiograph taken as required under this section must be a single posteroanterior projection at full inspiration on a digital detector with sensor area being no less than 1505 cm square centimeters with a minimum width of 35cm. The imaging plate must have a maximum pixel pitch of 200µm, with a minimum bit depth of 10. Spatial resolution must be at least 2.5 line pairs per millimeter. The storage phosphor cassette or digital image detector must be positioned either vertically or horizontally so that the image includes the apices and costophrenic angles of both right and left lungs. If the detector cannot include the apices and costophrenic angles of both lungs as described, then two side-by-side images can be obtained that together include the apices and the costophrenic angles of both right and left lungs.

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

(1) By or under the supervision of a physician who makes chest radiographs in the normal course of practice and who has demonstrated ability to make chest radiographs of a quality to best ascertain the presence of pneumoconiosis; or

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

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

(e) Radiographs must be made with units having generators which have a minimum rating of 300 mA at 125 kVp. Exposure kilovoltage must be at least the minimum as recommended by the manufacturer for chest radiography.

(f) An electric power supply must be used that complies with the voltage, current, and regulation specified by the manufacturer of the machine. If the manufacturer or installer of the radiographic equipment recommends equipment for control of electrical power fluctuations, such equipment must be used as recommended.

(g) Radiographs must be obtained only with equipment having a beam-limiting device that does not cause large unexposed boundaries. The beam limiting device must provide

rectangular collimation. Electronic post-image acquisition "shutters" available on some CR and DR systems that limit the size of the final image and that simulate collimator limits must not be used. The use and effect of the beam limiting device must be discernible on the resulting image.

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

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

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

(i) To ensure high quality digital chest radiographs:

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

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

(3) The exposure setting for chest images must be within the range of 100–300 equivalent exposure speeds and must comply with ACR Practice Guideline for Diagnostic Reference Levels in Medical X-Ray Imaging, Section V—Diagnostic Reference Levels For Imaging With Ionizing Radiation and Section VII—Radiation Safety in Imaging (incorporated by reference, see § 37.10). Radiation exposures should be periodically measured and patient radiation doses estimated by the medical physicist to assure doses are as low as reasonably achievable.

(4) Digital radiography system performance, including resolution, modulation transfer function (MTF), image signal-to-noise and detective quantum efficiency must be evaluated and judged acceptable by a qualified medical physicist using the specifications in AAPM Report No. 93, pages 1–68 (incorporated by reference, see § 37.10). Image management software and settings for routine chest

imaging must be used, including routine amplification of digital detector signal as well as standard image post-processing functions. Image or edge enhancement software functions must not be employed unless they are integral to the digital radiography system (not elective); in such cases, only the minimum image enhancement permitted by the system may be employed.

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

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

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

(C) DICOM Standard PS 3.10–2011.

(D) DICOM Standard PS 3.11–2011

(E) DICOM Standard PS 3.12–2011.

(F) DICOM Standard PS 3.14–2011.

(G) DICOM Standard PS 3.16–2011.

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

(iii) Exposure parameters as defined in the DICOM Standard PS 3.16–2011 must additionally be provided, when such parameters are available from the facility digital image acquisition system or recorded in a written report or electronic file and either transmitted to NIOSH or stored at the facility and available for inspection by NIOSH for 5 years after the examination.

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

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

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

(9) The geometry of the radiographic system must ensure that the central axis (ray) of the primary beam is perpendicular to the plane of the CR imaging plate, or DR detector and is correctly aligned to the grid;

(10) Radiographs must not be made when the environmental temperatures and humidity in the facility are outside the manufacturer’s recommended range of the CR and DR equipment to be used.

(11) Before the miner is advised that the examination is concluded, the radiograph must be processed and inspected and accepted for quality by the physician, or if the physician is not available, acceptance may be made by the radiologic technologist. In a case of a substandard radiograph, another must be made immediately. Unacceptable digital image files must be fully deleted immediately or rendered permanently inaccessible in the event that permanent deletion is not technologically feasible.

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

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

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

■ 15. Revise newly designated § 37.43 to read as follows:

§ 37.43 Approval of radiographic facilities that use film.

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

¹ The plastic step-wedge object is described in Trout ED, Kelley JP [1973]. A phantom for the evaluation of techniques and equipment used for roentgenography of the chest. *Amer J Roentgenol* 117(4):771–776.

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. The chest radiographs will be returned and may be the same radiographs submitted pursuant to § 37.50.

(b) Each radiographic facility submitting chest radiographs for approval under this section must complete and include an X-ray Facility Certification Document (Form CDC/NIOSH (M) 2.11) describing each X-ray 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 X-ray 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 Facility Certification Document for quality control purposes. 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. 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, interpretations, and images) consistent with applicable statutes and regulations governing the treatment of individually identifiable health information, including, as applicable, the HIPAA Privacy and Security Rules (45 CFR part 160 and subparts A, C, and E of part 164).

■ 16. Add § 37.44 to read as follows:

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

(a) *Applications for facility approval.*

(1) 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. 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. 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. 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. 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).

(2) Each radiographic facility submitting chest radiographic image files for approval under this section must complete and include an X-ray Facility Certification Document (Form CDC/NIOSH (M)2.11) describing each X-ray 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:

(i) 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;

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

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

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

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

(b) 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.

(c) 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.

(d) 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 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.

(e) 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.

(f) 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 (b), (e), and (g) of this section.

(g) 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 X-ray 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. 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). In addition, the medical physicist must submit 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.

(h) 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 treatment of individually identifiable health information, including, as applicable, the HIPAA Privacy and Security Rules (45 CFR Part 160 and Subparts A, C, and E of Part 164).

■ 17. Revise newly designated § 37.45 to read as follows:

§ 37.45 Protection against radiation emitted by radiographic equipment.

Except as otherwise specified in § 37.41 and § 37.42, radiographic equipment, its use and the facilities

(including mobile facilities) in which such equipment is used, must conform to applicable State or Territorial and Federal regulations. Where no applicable regulations exist, radiographic equipment, its use and the facilities (including mobile facilities) in which such equipment is used must conform to the recommendations in NCRP Report No. 102, NCRP Report No. 105, and NCRP Report No. 147 (incorporated by reference, see § 37.10).

■ 18. Revise the undesignated center heading and § 37.50 to read as follows:

Specifications for Interpretation, Classification, and Submission of Chest Radiographs

§ 37.50 Interpreting and classifying chest radiographs—film.

(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 Roentgenographic Interpretation Form (Form CDC/NIOSH (M)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 § 37.50(a) must be provided by a qualified physician who has all required licensure and privileges, and interprets 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) In all view boxes used for making interpretations:

(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.

§§ 37.51 through 37.53 [Redesignated as §§ 37.52 through 37.54]

■ 19a. Redesignate § 37.51 through § 37.53 as § 37.52 through § 37.54 respectively.

■ 19b. Add new § 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 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 interpretations and classifications must be recorded on a paper or electronic Roentgenographic Interpretation Form (Form CDC/NIOSH (M)2.8).

(c) All interpreters, 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 provided for use with the Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses (incorporated by reference, see § 37.10). Only NIOSH-approved standard digital images may be used for classifying digital chest images for pneumoconiosis. 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.

■ 20. Revise newly designated § 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 as an A Reader must continue if established prior to October 15, 2012.

(2) Physicians who desire to be 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 interpretations must be on the Roentgenographic Interpretation Form (Form CDC/NIOSH (M)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. 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. 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 an Interpreting Physician Certification Document (Form CDC/NIOSH (M)2.12).

■ 21. Revise newly designated § 37.53 to read as follows:

§ 37.53 Method of obtaining definitive interpretations.

(a) All chest radiographs which are first interpreted by an A or B Reader will be submitted by NIOSH to a B Reader qualified as described in § 37.52. If there is agreement between the two interpretations, as described in paragraph (b) of this section, the result will be considered final and reported to MSHA for transmittal to the miner. When agreement is lacking, NIOSH must obtain a third interpretation from the panel of B Readers. If any two of the three interpretations demonstrate agreement, the result must be considered the final determination. If agreement is lacking among the three interpretations, 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 interpretations must be considered to be in agreement when they are derived from complete classifications recorded using approved paper or electronic versions of the Roentgenographic Interpretation Form (Form CDC/NIOSH (M)2.8) and received by NIOSH, and both find either stage A, B, or C complicated pneumoconiosis, or, for simple pneumoconiosis, are both in the same major category or (with one exception noted below) are within one minor category (ILO Classification 12-point scale) of each other. In the last situation, the higher of the two interpretations must be reported. The only exception to the one minor category principle is a reading sequence of 1/1, 1/0, or 1/0, 1/1, which is not considered agreement.

■ 22. Revise newly designated § 37.54 to read as follows:

§ 37.54 Notification of abnormal radiographic findings.

(a) Findings of, or findings suggesting, abnormality of cardiac shape or size, tuberculosis, lung cancer, or any other significant abnormal findings other than pneumoconiosis must be communicated by the first physician to interpret the radiograph to the miner indicated on the Miner Identification Document or to the miner's designated physician. A notice

² NIOSH Safety and Health Topic. Chest Radiography: Radiographic Classification [<http://www.cdc.gov/niosh/topics/chestradiography/radiographic-classification.html>]. Date accessed: June 27, 2012.

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) In addition, 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 and interpretation to older images and NIOSH will inform the miner of any significant changes or progression of disease or other findings.

(c) All final findings regarding pneumoconiosis will be sent to the miner by MSHA in accordance with section 203 of the Act (see 30 CFR part 90). Positive findings with regard to pneumoconiosis will be reported to the miner or to the miner's designated physician by NIOSH.

(d) 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. The information forwarded to MSHA will be in a form intended to facilitate prompt dispatch of the findings to the miner. The results of an examination made of a miner may not be processed by NIOSH if the examination was made within 6 months of the date of a previous acceptable examination.

■ 23. Amend § 37.60 by revising paragraphs (a) through (d) to read as follows:

§ 37.60 Submitting required chest radiographs and miner identification documents.

(a) Each chest radiograph required to be made under this subpart, together with the completed Roentgenographic Interpretation 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 and 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 Roentgenographic Interpretation 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 within 14 calendar days after the radiographic examination. 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.

(2) [Reserved]

(b) If NIOSH deems any submission under paragraph (a) of this section inadequate, it will notify the operator of the deficiency. The operator must promptly make appropriate arrangements for the necessary reexamination.

(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.

* * * * *

■ 24. Revise § 37.70 to read as follows:

§ 37.70 Review of interpretations.

(a) Any miner who believes the interpretation 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. If the interpretation was based on agreement between an A Reader and a B Reader, NIOSH will obtain one or more additional interpretations by B Readers as necessary to obtain agreement in accord 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 § 37.7. If the reported interpretation 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 made subsequent to August 1, 1978, 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.

■ 25. 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, radiographs will be made available for examination only at NIOSH.

■ 26. Amend § 37.201 by revising paragraph (d) to read as follows:

§ 37.201 Definitions.

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

■ 27. Amend § 37.202 by revising paragraphs (a)(2) and (b) to read as follows:

§ 37.202 Payment for autopsy.

(a) * * *

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

* * * * *

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

■ 28. Amend § 37.204 by revising the introductory text and paragraph (b), and removing Figure 1, to read as follows:

§ 37.204 Procedure for obtaining payment.

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

* * * * *

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

* * * * *

Dated: August 28, 2012.

Kathleen Sebelius,
Secretary, Department of Health and Human Services.

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