

**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, HHS.**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** With this notice of proposed rulemaking, the Department of Health and Human Services (HHS) proposes to modify its regulations on Specifications for Medical Examinations of Underground Coal Miners. Existing regulations establish specifications for providing, interpreting, classifying, and submitting film-based roentgenograms (now commonly called chest radiographs or X-rays) of underground coal miners for the surveillance of coal workers' pneumoconiosis (black lung) under the Coal Workers' Health Surveillance Program, administered by the National Institute for Occupational Safety and Health (NIOSH). The current standards specify requirements that permit the use of film-based radiography systems only; proposed amendments would retain those standards (with minor modifications that reflect more commonly-used terms) and add a parallel set of standards to specify requirements that would permit the use of digital radiography systems. An additional proposed amendment would require coal mine operators to provide NIOSH with employee rosters to assist the Program in improving participation by miners.

**DATES:** Comments must be received by March 9, 2012.

**ADDRESSES:** You may submit comments, identified by "RIN 0920-AA21," by any of the following methods:

- *Internet:* Access the Federal e-rulemaking portal at <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Email:* NIOSH Docket Officer, [nioshdocket@cdc.gov](mailto:nioshdocket@cdc.gov). Include "RIN 0920-AA21" and "42 CFR 37" in the subject line of the message.

- *Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, OH 45226.

**Instructions:** All submissions received must include the agency name and docket number or Regulation Identifier Number (RIN) for this rulemaking. All relevant comments will be posted

without change to <http://www.regulations.gov> including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Public Participation" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

**Docket:** For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> or <http://www.cdc.gov/niosh/docket/NIOSHdocket0225.html>.

**FOR FURTHER INFORMATION CONTACT:**

Anita Wolfe, Public Health Analyst, Division of Respiratory Disease Studies, National Institute for Occupational Safety and Health, 1095 Willowdale Road, MS B208, Morgantown, WV, 26505, Telephone (888) 480-4042 (this is a toll-free number). Information requests can also be submitted by email to [cwhsp@cdc.gov](mailto:cwhsp@cdc.gov).

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

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**I. Public Participation**

Interested persons or organizations are invited to participate in this rulemaking by submitting written views, arguments, recommendations, and data. Comments are invited on any topic related to this proposal. In addition, HHS invites comments specifically on the following questions related to this rulemaking:

(1) Does the current scientific evidence support the assertion that the application of digital chest imaging can

be equivalent to film-screen radiography, if appropriate equipment, procedures, and methods are applied, in meeting the objectives of the Coal Workers' Health Surveillance Program mandated by 30 U.S.C. 843?

(2) Is there evidence that the proposed specifications for equipment, personnel, procedures, and methods will not be adequate to assure that the application of digital chest imaging will be equivalent to film-screen radiography in meeting the objectives of the Coal Workers' Health Surveillance Program? What specific changes are needed to ensure equivalence and what is the evidence supporting those changes?

(3) Is there evidence that any element of the specifications will not be feasible (for technological or financial reasons) for a significant proportion of the digital radiology facilities in coal mining regions? If yes, what changes in the specifications for equipment, personnel, procedures, and/or methods can improve feasibility while continuing to ensure the equivalence of digital chest imaging to film-based chest imaging for accurately detecting occurrence and progression of coal workers' pneumoconiosis (CWP) among coal miners?

**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 CWP.<sup>1</sup> 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)).<sup>2</sup> 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

<sup>1</sup> 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.

<sup>2</sup> The Mine Safety and Health Administration (MSHA) has recently published a notice of proposed rulemaking that seeks to lower the existing exposure limit from 2.0 mg/m<sup>3</sup> to 1.0 mg/m<sup>3</sup> (75 FR 64412, October 19, 2010).

mandated by the Mine Act, was developed to detect CWP and prevent progression in individual miners, while at the same time providing information 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 physician 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. The NIOSH B Reader Program aims to ensure competency in the detection of pneumoconiosis by evaluating the ability of readers to classify a test set of radiographs, thereby creating and maintaining a pool of qualified readers having the skills and ability to provide accurate and precise classifications in accordance with ILO standards.<sup>3</sup> The B

Reader examination currently offered by NIOSH consists of the classification of 125 chest radiographs over the course of 6 hours; the test addresses proficiency in classification of small opacities, large opacities, pleural abnormalities, and certain other abnormalities that may appear in the lung radiographs.

B Readers participate in national pneumoconiosis programs directed at coal miners and others who suffer from dust-related illness, and are also involved with epidemiologic evaluations, surveillance, and worker monitoring programs involving many types of pneumoconioses. In applying the ILO Classification, B Readers compare sets of standard images, which represent different types of abnormalities and levels of disease severity, with images of the individual being evaluated to identify parenchymal abnormalities (small and large opacities), pleural changes, and other features associated, or sometimes confused, with occupational lung disease. In the current ILO Classification, the B Reader is first asked to grade film quality and is then asked to categorize small opacities according to their presence, shape and size, location, and profusion. Large opacities are classified according to their presence and size. The B Reader also assesses the presence, location, width, extent, and degree of calcification of pleural abnormalities.<sup>4</sup>

Under NIOSH supervision (see 42 CFR 37.53, as amended, below), a summary report based upon the readings of the periodic chest radiograph is sent to each participating coal miner, who then has the opportunity to take action to reduce further dust exposure if early dust-induced lung disease is detected.

Miners with evidence of pneumoconiosis have specific rights to transfer to jobs with lower dust levels under 30 CFR part 90 (see also 42 CFR 37.7). The combined results of these radiographic examinations of miners (radiographic surveillance) also enable NIOSH to track rates and patterns of CWP among the participating miners, so as to evaluate whether the implemented dust controls are effective in controlling CWP.

#### A. Need for Rulemaking

One goal of the Mine Act is to ensure that respirable dust concentrations in underground coal mines are sufficiently low to permit each miner the

opportunity to be employed underground for a working lifetime without incurring any disability from pneumoconiosis or any other occupational lung disease (30 U.S.C. 841(b)). Mine operators use primary prevention to accomplish this health outcome objective; that is, they implement procedures for recognizing, controlling, and monitoring exposures to hazardous conditions.

However, because primary prevention measures may not be fully effective, secondary measures are recommended as a means to further protect workers. Secondary prevention involves ongoing miner health monitoring to recognize abnormalities early so that the miner has the necessary information to take appropriate action to prevent disease progression. Monitoring data are also periodically reviewed and analyzed to evaluate whether the primary preventive measures have been effective. This review permits the identification of work processes, exposures, or hazardous situations that require better control. Secondary prevention is particularly important when a risk to health remains in spite of adherence to recommended or permissible exposure levels, as has been demonstrated for coal miners.<sup>5</sup>

Chest radiography has historically been a valuable tool for monitoring the health of coal miners and other individuals potentially exposed to fibrogenic dusts such as silica or asbestos. Early changes due to pneumoconiosis are frequently identifiable on a high quality chest radiograph before an individual would otherwise seek medical attention. Over the years, methods for acquiring and interpreting film-screen chest radiographs have been continuously refined, to enhance the accuracy and usefulness of this technique as part of comprehensive occupational health protection programs. However, over the past decade digital radiography systems have been progressively replacing traditional analog film-based radiography for chest imaging.<sup>6</sup>

<sup>3</sup> NIOSH [1995]. Criteria for a recommended standard: Occupational exposure to respirable coal mine dust. Cincinnati, Ohio: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 95-106.

See also NIOSH [2010]. A review of information published since 1995 on coal mine dust exposures and associated health outcomes. NIOSH Docket Number 210 [<http://www.cdc.gov/niosh/docket/review/docket210/>]. Date accessed: January 5, 2011.

<sup>4</sup> NIOSH [2007]. Roentgenographic Interpretation Form [<http://www.cdc.gov/niosh/topics/surveillance/ords/pdfs/CWHSP-ReadingForm-2.8.pdf>]. Date accessed: January 5, 2011.

Continued

<sup>5</sup> International Labour Office [2011]. Guidelines for the use of ILO International Classification of Pneumoconiosis, revised edition 2011. Geneva, Switzerland: International Labour Office. Occupational Safety and Health Series No. 22 (Rev. 2011).

<sup>6</sup> NIOSH [2008]. Application of the ILO International Classification of Radiographs of Pneumoconioses to Digital Chest Radiographic Images: A NIOSH Scientific Workshop. Cincinnati,

In order to retain the recognized benefits of radiographic health monitoring as a preventive health measure that is easily accessible by dust-exposed workers, it is necessary to require that underground coal mine operators furnish NIOSH with a current roster of miners' names and addresses. CWHSP has found that directly contacting coal miners who are due for a chest examination results in a higher number of miners who participate in the Program. In 1990, NIOSH responded to declining underground coal miner participation in the Program by obtaining work rosters for contact information and sending notifications of availability of chest X-ray surveillance directly to the miners. Over the next few years, this led to increased participation in the Program.<sup>7</sup> Coal miners themselves have indicated that they would prefer to receive a letter from CWHSP at their residence, rather than being notified by their employer, because they feel that direct contact with the Program provides them greater confidentiality. Also, in the experience of CWHSP, the increased family involvement that follows from receipt of a letter at home improves Program participation. Almost all underground coal mine operators (approximately 505 establishments<sup>8</sup>) provide CWHSP with a roster of employees. The rare instance of an operator refusing to comply with the request resulted in no coal miners employed by a non-compliant operator participating in the Program. NIOSH is concerned that further noncompliance with CWHSP's request will lead to lower rates of participation in the Program, and result in higher rates of pneumoconiosis. An alternative to the roster requirement—asking the mines to post Program information on a bulletin board in the mine—has been found to be ineffective and has not resulted in the same level of participation that has been demonstrated by direct mailings.

OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. DHHS (NIOSH) Publication No. 2008-139.

<sup>7</sup> See Work-Related Lung Disease (WoRLD) Surveillance System, Volume 1: Coal Workers' Pneumoconiosis: Morbidity, Table 2012. CWXSP: Number and percentage of examined underground miners with coal workers' pneumoconiosis (ILO category 1/0+) by tenure, 1970–2009, <http://www2a.cdc.gov/drds/WorldReportData/FigureTableDetails.asp?FigureTableID=2550&GroupRefNumber=T02-12>. Accessed November 17, 2011.

<sup>8</sup> 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/atable.htm>. Accessed July 7, 2011.

Finally, previously effective approaches to radiographic monitoring need to be modified to reflect the different characteristics of digital imaging compared to film-screen radiography. Additionally, due to the broad diversity of hardware and software utilized in digital imaging, specifications are required to assure that the operational characteristics of the image acquisition and display systems are sufficiently standardized to support uniformity among these health assessments. In addition, they must assure confidentiality to the extent permitted by law, data integrity, and interoperability.<sup>9</sup> Most importantly, they must permit accurate identification of the early changes seen in dust-related diseases.

#### B. 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 essentially remain in effect: This rulemaking will not substantially alter the current standards, but will update the terminology used in the current standards (e.g., “roentgenogram” to “radiograph”) and include edits to maintain the accuracy of external references.

Significantly, the new rule would expand 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 proposed rule would establish 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 proposed rule would also make limited changes to general requirements to reflect current terminology (such as the use of “radiograph” instead of

<sup>9</sup> Samei E, Ravin CE [2008]. Assuring image quality for classification of digital chest radiographs. In: NIOSH. Application of the ILO International Classification of Radiographs of Pneumoconioses to Digital Chest Radiographic Images: A NIOSH Scientific Workshop. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. DHHS (NIOSH) Publication No. 2008-139.

“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 proposed rule will not modify existing requirements for miner radiographic examinations, eligibility, or other rights, including transfer of affected miners in accordance with 30 CFR part 90.

#### C. Impact of Rulemaking

The U.S. Department of Labor (DOL) will likely amend its Black Lung Benefits Act (BLBA) program regulations to correspond with the changes proposed here. 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 also consider amending its current 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 are related to this proposed rulemaking, although they are not explicitly linked by statute or regulation.

The DOL standards refer to chest “roentgenograms,” an outdated term which NIOSH proposes to replace with the more contemporary “radiograph” as discussed below in the summary of the proposed digital standards. 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 proposed 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 Proposed Rule****A. Subpart—Chest Radiographic Examinations**

This proposed rule would establish new requirements for digital radiography under existing part 37 of 42 CFR—Specifications for Medical

Examinations of Underground Coal Miners. The new provisions would supplement and update the existing requirements for film-screen radiographs by establishing standards for digital radiographs. The following is a section-by-section summary which describes and explains the provisions of

the rule. Table 1 matches the current regulatory provisions with the corresponding proposed provisions. The public is invited to provide comment on any aspect of the proposed rule. The proposed regulatory text for the proposed rule is provided in the last section of this notice.

TABLE 1—NEW AND PROPOSED PROVISIONS

Current regulation	Proposed 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
37.20 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
37.50 Interpreting and classifying chest roentgenogram	37.44 Approval of radiographic facilities that use digital radiography systems
37.51 Proficiency in the use of systems for classifying the pneumoconioses	37.45 Protection against radiation emitted by radiographic equipment
37.52 Method of obtaining definitive interpretations	37.50 Interpreting and classifying chest radiographs—film
37.53 Notification of abnormal roentgenographic findings	37.51 Interpreting and classifying chest radiographs—digital radiography systems
37.60 Submitting required chest roentgenograms and miner identification documents	37.52 Proficiency in the use of systems for classifying the pneumoconioses
37.70 Review of interpretations	37.53 Method of obtaining definitive interpretations
37.80 Availability of records	37.54 Notification of abnormal radiographic findings
37.200 Scope	37.60 Submitting required chest radiographs and miner identification documents
37.201 Definitions	37.70 Review of interpretations
37.202 Payment for autopsy	37.80 Ability of records
37.203 Autopsy specifications	37.200 Scope
37.204 Procedure for obtaining payment	37.201 Definitions
	37.202 Payment for autopsy
	37.203 Autopsy specifications
	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.

**Section 37.2 Definitions**

This existing section contains definitions for terms that appear throughout part 37. A number of terms appearing in the current regulations remain unchanged, including “Act,” “convenient time and place,” “MSHA,” “miner,” “operator,” and “Secretary.”

This section proposes to amend the following terms to reflect updated terminology and references: “NIOSH,” and “chest radiograph.” We propose to change “pre-employment physical examination” to “pre-placement physical examination” to be consistent with the requirements of the Americans with Disabilities Act of 1990 (42 U.S.C. 12112(d)) (ADA). The ADA prohibits an

employer from asking or requiring a job applicant to take a medical examination or inquiring about whether an applicant has a disability before an offer of employment has been made. However, the ADA does allow an employer to require a medical examination after an offer of employment has been made, subject to certain restrictions. “Panel of B Readers” would be amended to indicate that the panel comprises all currently-approved B Readers.

Finally, this section includes definitions of the following proposed new terms: “digital radiography systems,” “computed radiography,” “digital radiography,” “NIOSH representatives,” “qualified medical physicist,” “radiographic technique chart,” “radiologic technologist,” and “soft copy.”

**Section 37.3 Chest Radiographs Required for Miners**

This existing section requires mine operators to provide miners an opportunity to receive a chest radiograph. We propose a change to this provision to delete and replace outdated text. For example, in § 37.3(a), “roentgenogram” would be replaced by “radiograph.” Similarly in § 37.3(a)(1), “ALOSH” would be replaced with “NIOSH.”

Paragraph (b)(1) would be amended to remove reference to a pre-employment physical examination, which is prohibited by the Americans with Disabilities Act of 1990 (42 U.S.C. 12112(d)). Paragraph (b)(3) would be amended to further clarify the classification of simple pneumoconioses.

### 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.

We propose to amend § 37.4(a), (d), (e), and (f) to update terminology to reflect "radiographic" for "roentgenographic" and "NIOSH" for "ALOSH."

We propose to amend § 37.4(a)(3) to specifically require the mine operator to submit a roster with the names and current addresses of covered miners with the operator's proposed plan. This is current practice and permits mailings directly from NIOSH to miners, which both emphasizes the extent of the confidentiality exercised by the program and explains the importance of the health surveillance program. As discussed above, such direct communication from NIOSH has proven important in encouraging miners' participation.

We propose to amend § 37.4(a)(6) to specify that when a coal mine operator examination plan lists a NIOSH-approved X-ray facility that uses a digital radiographic system, the listed physician who provides the first clinical reading of a coal miner's digital chest radiograph must have appropriate qualifications, but is not required to perform an ILO classification for pneumoconiosis. These initial clinical readings would therefore not be required to meet the specifications for pneumoconiosis classification listed in § 37.51 (b), (c), (d), and (e). This should increase the number of digital radiographic facilities available to miners that can be listed by coal mine operators on examination plans.

We propose to amend § 37.4(a)(7)(ii) to extend the existing confidentiality provisions for film radiographs to digital radiographs, including requiring, to the extent that is technically feasible for the imaging system used, the permanent deletion or rendering permanently inaccessible of all digital files at the facility. We further propose to amend this section to be consistent with the requirements of the Americans with Disabilities Act, which prohibits the use of pre-employment medical examinations. We propose to strike the reference in this paragraph to the pre-employment examination and

disclosure of information gained during that examination.

### 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). We propose to amend this section to redact outdated text and to correct gender-exclusive language.

### 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. We propose to amend this section to replace outdated text with current terminology.

### 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 a job environment with not more than 1 mg/m<sup>3</sup> respirable dust levels, if needed and such a job is available at the mine. If such a work location is not available, transfer is offered to the job with the lowest exposure below 2 mg/m<sup>3</sup>, which is the current permissible exposure limit for respirable dust enforced by MSHA in coal mines. We propose to amend this section to replace outdated text with current terminology. Also, we propose to replace "2 mg/m<sup>3</sup>" with "the maximum respirable dust concentration permitted by MSHA" and replace "1 mg/m<sup>3</sup>" with "50 percent of the maximum respirable dust concentration permitted by MSHA." The revised wording would not impact current requirements; however it would remain consistent with any MSHA rulemaking that alters the relevant permissible exposure limits.

### 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. We propose to amend this section only to replace the outdated "ALOSH" with "NIOSH."

### 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. We propose to amend this section only to replace "roentgenographic" and "roentgenogram" with "radiographic" and "radiograph."

### Section 37.40 General Provisions

This existing section outlines general provisions for chest radiographic examinations. We propose to amend this section to update the terminology.

### Section 37.41 Chest Radiograph Specifications—Film

This existing section establishes performance standards for the acquisition of chest radiographs using film-screen technology. We propose to amend this section to update terminology and standards. We propose to add § 37.41(c) to require that a radiologic technologist perform the radiograph. This requirement is new. The existing rule does not clearly specify the qualifications of the provider who performs the radiologic examination. In light of ongoing concerns related to radiation exposure, it is necessary to specify that this provider have documented qualifications.

We propose to amend § 37.41(i)(7) to remove the current language, "[w]hen using over 90kV," because proposed § 37.42(e), below, would require that radiographs be made by units having generators with a minimum rating of 300 mA at 125 kVp. We also propose to amend § 37.41(m) to remove the word "densitometric," as the test object may evaluate characteristics of the exposure in addition to density.

We also propose to amend § 37.41(h) to remove the reference to Part F of the Suggested State Regulations for the Control of Radiation, of the Conference of Radiation Control Program Directors (Rev 2009). The beam limiting device must be of the type described in 21 CFR 1020.31(d), (e), (f), and (g).

Finally, we propose to remove § 37.41(i)(9), which requires that each facility shall establish a formal quality assurance program. This requirement would be instead inserted into proposed § 37.43, which would set standards for the approval of radiographic facilities that use film (see below).

### Section 37.42 Chest Radiograph Specifications—Digital Radiography Systems

This proposed section establishes performance standards for the acquisition of chest radiographs using digital radiography systems, including digital radiography and computed radiography. We propose adding this

new section in its entirety; it is patterned after the existing § 37.41—Chest radiographic specifications for film.

Proposed § 37.42(a) would establish basic logistical requirements for conducting chest radiographic examination. For example, under this provision, the imaging facility would be required to provide a dressing area. This provision is identical to the existing regulation for film, § 37.41(b).

Proposed § 37.42(b) would specify minimum requirements for the position of the subject of the radiograph and for the resolution and positioning of the resulting image. The required size and positioning of the X-ray detectors for digital systems is identical to that in the existing regulation for film-screen systems (§ 37.41(a)). Exact specifications for the digital imaging detector are provided because detectors must provide sufficient image size and gray scale depth to demonstrate the required subtle contrasts, and sufficient density of pixels to offer adequate resolution for the fine linear fibrotic shadows.<sup>10</sup> The specification of a maximum pixel pitch of 200  $\mu\text{m}$ , a minimum gray-scale bit depth of 10, and spatial resolution of at least 2.5 line pairs per millimeter are based upon the existing peer-reviewed research comparing digital and traditional imaging and ensures that the use of digital radiography systems will not result in reduced ability to recognize and quantify the abnormalities.<sup>11</sup> Commercially-available imaging systems are able to meet these specifications.<sup>12</sup>

<sup>10</sup> Samei E [2008]. Acquisition of digital chest images for pneumoconioses classification: Methods, procedures, and hardware. In: NIOSH. Application of the ILO International Classification of Radiographs of Pneumoconioses to Digital Chest Radiographic Images: A NIOSH Scientific Workshop. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. DHHS (NIOSH) Publication No. 2008-139.

<sup>11</sup> Franzblau A, Kazerooni EA, Sen A, Goodsitt MM, Lee SY, Rosenman KD, Lockey JE, Meyer CA, Gillespie BW, Petsonk EL, Wang ML [2009]. Comparison of digital radiographs with film radiographs for the classification of pneumoconiosis. *Acad Radiol* 16(6):669-677.

<sup>12</sup> Sen A, Lee SY, Gillespie BW, Kazerooni EA, Goodsitt MM, Rosenman KD, Lockey JE, Meyer CA, Petsonk EL, Wang ML, Franzblau A [2010]. Comparison of reliability of classification for pneumoconiosis of film and digital radiographs: A modeling approach. *Acad Radiol* 17(4):511-519.

Laney AS, Petsonk EL, Wolfe AL, Attfield MD [2009]. Comparison of storage phosphor computed radiography with conventional film-screen radiography in the recognition of pneumoconiosis. *Eur Respir J*, published ahead of print November 19, 2009.

<sup>12</sup> Flynn MJ [2008]. Image presentation: Implications of processing and display. In: NIOSH. Application of the ILO International Classification of Radiographs of Pneumoconioses to Digital Chest

Proposed § 37.42(c) would require that chest radiographs obtained pursuant to these provisions must be made by a qualified radiologic technologist.

Proposed § 37.42(d) would specify the required size of the X-ray machine's focal spot. This proposed provision would follow the existing regulation for film (§ 37.41(c)).

Proposed § 37.42(e) would specify the minimum amperage and voltage required to produce chest radiographs. This section would be identical to the existing regulation for film, § 37.41(d), but with updated terminology.

Proposed § 37.42(f) would require radiographic equipment be used with a power supply that complies with the X-ray machine's manufacturer specifications. Adequately conditioned power is needed for consistent generation of the radiation exposure needed for imaging. The requirement to meet minimum power supply recommendations for the equipment assures that the imaging system can perform as intended and specified by the manufacturer.

Proposed § 37.42(g) would require that radiographic equipment has a beam-limiting device to reduce the amount of scatter and off-focus radiation. While this provision largely mirrors the provision for film-screen systems (§ 37.41(g)), it also specifies that electronic means for limiting the size of the final image shall not be used. Electronic "shutters" are available for some digital radiography systems and can constrain image size but do not limit radiation exposure, and thus their use is prohibited to reduce the adverse health impact on the miner of unnecessary exposure to ionizing radiation associated with the radiograph.

Proposed § 37.42(h) would require the use of radiographic technique charts that are developed specifically for the X-ray system and detector combination used at a facility. If automated exposure control devices are used, they should be documented using professionally recommended methods; such information should be stored for 5 years after the miner's examination. NIOSH believes that retaining such records for 5 years is already standard business practice. Maintaining records is necessary to permit individuals at the facility to audit their own adherence to the guidance. Failure to maintain

Radiographic Images: A NIOSH Scientific Workshop. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. DHHS (NIOSH) Publication No. 2008-139.

documentation is much easier to demonstrate and enforce than specific elevated radiation exposures for individual examinations. Five years was chosen as a compromise between minimizing records storage burden and maintaining the ability to perform meaningful audits both for NIOSH and for the facility staff.

The proposed specifications for digital radiography systems follow existing regulations for film (§ 37.41(h)(3)) requiring specified exposure settings. Because of the recognized potential for higher ionizing radiation exposures using digital radiography systems, we have included additional requirements to limit these exposures in accordance with recommendations established by the American Association of Physicists in Medicine.<sup>13</sup>

Proposed § 37.42(i)(1) would require that the maximum exposure time not exceed 50 milliseconds except for subjects of a certain size. This provision would mirror the existing regulation for film-screen technology (§ 37.41(h)(1)), although the text is modified to use contemporary timing units.

Proposed § 37.42(i)(2) would specify the required distance from the source or focal spot to the detector. This provision mirrors the existing regulation for film (§ 37.41(g)) but with additional text clarifying metric units.

Proposed § 37.42(i)(3) would specify the required exposure setting for digital radiographs and incorporate by reference current professional standards intended to limit exposures from digital radiographs. This proposed section mirrors existing regulations for film-screen technology (§ 37.41(h)(3)).

Proposed § 37.42(i)(4) would establish that digital radiography system performance, including image signal-to-noise and detective quantum efficiency, be evaluated and meet the standards of

<sup>13</sup> Shepard SJ, Wang J, Flynn M, Gingold E, Goldman L, Krugh K, Leong DL, Mah E, Ogden K, Peck D, Samei E, Willis C [2009]. An exposure indicator for digital radiography. Report of AAPM Task Group 116. College Park, MD: American Association of Physicists in Medicine. AAPM Report No. 116.

Rossi R, Lin PJ, Rauch P, Strauss K [1985]. 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. AAPM Report No. 14.

Seibert JA, Bogucki TM, Ciona T, Huda W, Karella A, Mercier J, Samei E, Shepard SJ, Steward B, Strauss K, Suleiman O, Tucker D, Uzenoff R, Weiser JC, Willis C [2006]. Acceptance testing and quality control of photostimulable storage phosphor imaging systems. Report of AAPM Task Group 10. College Park, MD: American Association of Physicists in Medicine. AAPM Report No. 93.

a qualified medical physicist in accordance with current professional standards, which are incorporated by reference in this section. This section would also govern the use of image management software. Digital systems use direct or indirect quantification of electronic signals from the detectors, and thus the character and quality of the resulting image is affected by both hardware and software signal management. To ensure that images collected for the purposes of this regulation using digital systems are adequate, it is important that approved imaging systems satisfy the relevant contemporary professionally recommended minimum performance criteria. Further, to improve comparability in the character of chest radiographic images submitted by different approved facilities for the purposes of this regulation, this section would require that image management software and settings for routine chest imaging be used.

In addition to management software, manufacturers of digital radiography systems provide unique proprietary versions of image modifying software, and the resulting images have distinctly different appearances. There is currently no scientific consensus that a specific approach to image enhancement software provides superior performance in imaging pneumoconiotic opacities. Therefore, this section would prohibit the use of image enhancement, except to the extent that some enhancement features might be integral to the digital radiography system and hence are not elective; for such cases, this section would specify that image enhancement be minimized to the extent permitted by the system.

Proposed § 37.42(i)(5) would establish the Digital Imaging and Communications in Medicine (DICOM) standard<sup>14</sup> as the relevant data storage and transmission standard. At a 2008 NIOSH workshop, entitled Application of the ILO International Classification of Radiographs of Pneumoconioses to Digital Chest Radiographic Images, participants evaluated digital chest radiographic image file formats, and found that aside from DICOM, there are currently no other adequately specified digital image formats that support the resolution, security, and interoperability required for this application.<sup>15</sup> Chest

<sup>14</sup> DICOM is a widely-accepted standard for handling, storing, printing, and transmitting medical imaging information. DICOM is managed by the National Electrical Manufacturers Association.

<sup>15</sup> NIOSH [2008]. Application of the ILO International Classification of Radiographs of Pneumoconioses to Digital Chest Radiographic

radiographic images obtained using digital systems are stored and transferred as electronic data files. To ensure the integrity of the information, patient/worker confidentiality, full access by appropriate parties to the complete data file, compatibility with hardware systems from various manufacturers, and uniformity of image viewing and data management, the proposed rule would require that images collected for the purposes of this regulation using digital systems be formatted using the industry standardized electronic format, and that any data compression employed be lossless. Physical, technical, and administrative controls are specified to prevent unauthorized access to protected health information and confidential medical findings, during data acquisition, storage, and transfer. To support the uniform grayscale standard display function of image display devices, images must be formatted as DICOM “DX” objects.<sup>16</sup> To enable auditing of radiation exposure data over time, the facility would be required to maintain either written or electronic records, formatted according to industry standards when possible.

Proposed § 37.42(i)(6) would allow NIOSH the discretion to require the use of a test object for an evaluation of image quality. This section is identical to existing film regulation § 37.41(l), although the term ‘densitometric’ has been omitted in describing the test object, as the object may evaluate characteristics of the exposure in addition to density.

Proposed § 37.42(i)(7) would require computed radiography (X-ray image acquisition systems that detect signals using a cassette-based photostimulable storage phosphor) imaging plates to be inspected regularly and cleaned when necessary. This specification preserves the existing required periodicity of cleaning because, for storage phosphor digital systems as with film-screen systems, periodic cleaning of equipment is necessary to reduce the possibility of image artifacts.

Images: A NIOSH Scientific Workshop. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. DHHS (NIOSH) Publication No. 2008-139.

<sup>16</sup> Clunie DA. Standardizing file formats, security, and integration of digital chest image files for pneumoconiosis classification. In: NIOSH. Application of the ILO International Classification of Radiographs of Pneumoconioses to Digital Chest Radiographic Images: A NIOSH Scientific Workshop. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. DHHS (NIOSH) Publication No. 2008-139.

Proposed § 37.42(i)(8) would require the use of a grid or air gap for reducing radiation scatter. This section mirrors the existing regulation for film (§ 37.41(h)(7)) with additional language addressing interference patterns. Such patterns can arise using digital techniques, and can interfere with image classification and the detection of abnormalities.

Proposed § 37.42(i)(9) would establish the geometry of the radiographic system. This section mirrors existing film regulation § 37.41(h)(8), with text amended to reflect the digital technology rather than film.

Proposed § 37.42(i)(10) would require that radiographic equipment meet recommended environmental temperature and humidity thresholds set by the manufacturer. This requirement would be exclusive to digital radiography systems, and would ensure that the imaging system can perform as intended and as specified by the manufacturer.

Proposed § 37.42(i)(11) would ensure that the miner receives a chest radiograph determined to be of acceptable quality before being advised that the examination is concluded. In the event of a substandard radiograph, under this section, a miner would immediately be given another. Finally, this section would also require that unacceptable digital image files immediately be permanently deleted or rendered inaccessible in the event that permanent deletion is not technologically feasible. These requirements are identical to that for film (§ 37.41(j)) except that the text refers to the deletion of digital files rather than the disposal of films.

Proposed § 37.42(j)(1) and (2) would prohibit the use of digital images derived from film-screen chest radiographs for the purposes of this rule. Similarly, images acquired using digital systems and then printed on transparencies would also be prohibited. Research has shown that these approaches do not assure similar performance to that obtained from film under the existing regulations (§ 37.41).<sup>17</sup>

<sup>17</sup> Samei E [2008]. Acquisition of digital chest images for pneumoconiosis classification: Methods, procedures, and hardware. In: NIOSH. Application of the ILO International Classification of Radiographs of Pneumoconioses to Digital Chest Radiographic Images: A NIOSH Scientific Workshop. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. DHHS (NIOSH) Publication No. 2008-139.

Franzblau A, Kazerooni EA, Sen A, Goodsitt MM, Lee SY, Rosenman KD, Lockey JE, Meyer CA, Gillespie BW, Petsonk EL, Wang ML [2009].

### Section 37.43 Approval of Radiographic Facilities That Use Film

Proposed § 37.43 would comprise the current requirements in existing § 37.42—Approval of roentgenographic facilities. Proposed § 37.43(a) would base facility eligibility to participate in the Coal Workers' Health Surveillance Program on a demonstrated ability to make high quality diagnostic chest radiographs. This section remains unchanged from the existing provision but for the addition of text indicating that an object other than the plastic step wedge objects may be used. Newer test objects have become available, and in the future, NIOSH may want to use a more compact and capable test object that is simpler to use than the step wedges.

Proposed § 37.43(b) would specify requirements for an X-ray Facility Certification Document (Form CDC/NIOSH (M)2.11, OMB 0920-0020, exp. June 30, 2014) describing each X-ray unit to be used to make chest radiographs. This section would be unchanged from the existing § 37.42(c) except for the replacement of outdated terminology, including incorporation by reference of National Council on Radiation Protection and Measurements (NCRP) Report No. 102.

Proposed § 37.43(c) would establish that radiographs submitted with a facility application be evaluated by a qualified consultant or one or more individuals selected by NIOSH from the panel of B Readers. This section would be substantively unchanged from the existing § 37.42(d), although we propose to amend this section to replace outdated text with current terminology, specifically by substituting the term 'medical physicist' for 'radiological physicist.'

Comparison of digital radiographs with film radiographs for the classification of pneumoconioses. *Acad Radiol* 16(6):669-677.

Suganuma N, Murata K, Kusaka Y [2008]. CR and FPD DR chest radiographic image parameters for the pneumoconioses: The Japanese approach and experience. In: NIOSH. Application of the ILO International Classification of Radiographs of Pneumoconioses to digital chest radiographic images: A NIOSH Scientific Workshop. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. DHHS (NIOSH) Publication No. 2008-139.

Franzblau A, Kazerooni EA, Goodlett M [2009]. Digital X-ray imaging in pneumoconiosis screening: Future challenges for the NIOSH B Reader Program. In: NIOSH. The NIOSH B Reader Certification Program: Looking to the future. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. DHHS (NIOSH) Publication No. 2009-140.

Proposed § 37.43(d) would describe NIOSH's authority to conduct a physical inspection of the applicant's facility to determine if the requirements of this subpart are being met. We propose to amend this section from the existing § 37.42(e) by updating outdated terminology.

Proposed § 37.43(e) would allow NIOSH the discretion to require a facility to resubmit radiographs of a test object, sample radiographs, or a Facility Certification Document for quality control purposes. It would also establish the conditions under which NIOSH may suspend or withdraw a facility's approval and how notice must be given. We propose to amend this section from the existing § 37.43(f) by updating outdated terminology.

Proposed § 37.43(f) would require that facilities establish a formal quality assurance program conforming to standards published by the American Association of Physicists in Medicine and incorporated by reference here. This provision would replace existing § 37.41(h)(9), which requires that facilities establish a formal quality assurance program, with more specific quality assurance program guidelines. We propose that the program must be written, address radiation exposures, equipment maintenance, and image quality, and conform to the referenced professional standards. Several years ago, NIOSH initiated an image quality feedback program to try to improve the film quality; NIOSH therefore wishes to ensure that the facilities have documented quality assurance programs. This provision will also permit NIOSH to easily request copies of the documentation, and thus more easily determine if a facility has adequately addressed their image quality issues.

Proposed § 37.43(g) would add the explicit requirement that facilities adhere to Federal, State, and local laws, as applicable, to protect the confidentiality and privacy of coal miners participating in the Program. Through this provision, NIOSH seeks to ensure that X-ray facilities maintain miners' sensitive health information securely and protect it from disclosure to the extent permitted by law.

### Section 37.44 Approval of Radiographic Facilities That Use Digital Radiography Systems

Proposed § 37.44 would establish standards for the approval of radiographic facilities that use digital radiography systems. These standards mirror those for film-screen technology.

Proposed § 37.44(a)(1) would specify the requirements for a facility approval

application, including an image of a test object, and six or more sample radiographs of quality acceptable to one or more individuals selected by NIOSH from the panel of B Readers and a qualified medical physicist. The existing requirements for facilities to demonstrate radiograph quality are continued (§ 37.42(b)) but to reduce the burden on facilities, radiographs made up to 60 days prior to the application may be submitted. The time extension (from the existing 15 days for film-based systems) eases the burden on applicants by giving them a longer window of time to select a representative image, while continuing to ensure that the images that are submitted reflect the facility's contemporary image quality; changes in digital image quality are unlikely to occur in the time frame indicated (*i.e.*, 60 days). In the past, wet systems such as film processors and chemicals could get diluted or dirty in shorter times when many films were processed, however, because there are no liquids and very few moving parts in digital systems, the time frame for quality deterioration is longer, and thus a longer time is more convenient but still should be representative of the digital image quality. This provision would also require the image files to be submitted using a secure electronic file transfer method approved by NIOSH, or on standard portable media and meet the current DICOM specifications for diagnostic media interchange.

Proposed § 37.44(a)(2) would specify the contents of the X-ray Facility Certification Document. This paragraph would continue the existing requirement for documentation and inspection of eligible facilities by a qualified expert within 1 year preceding the date of the application (§ 37.42(c)), and would clarify that the expert must be a medical physicist. NIOSH has always expected that a medical physicist perform these evaluations, and now intends to codify that expectation.

Proposed § 37.44(b) would require that facilities maintain relevant local, State, or Federal licensure and certification. The existing requirement that radiographic facilities conform to applicable State and Federal regulations (§ 37.43) is continued.

Proposed § 37.44(c) would allow NIOSH the discretion to conduct a site inspection of the facility. Existing regulations for film (§ 37.42(e)) specify periodic inspections, and this requirement is continued for digital systems.

Proposed § 37.44(d) would allow NIOSH the discretion to require a facility to resubmit image files of the test object, sample radiographs, or

Facility Certification Document. The provision would also authorize NIOSH to suspend or withdraw a facility's approval when warranted due to noncompliance with provisions of this rule.

Proposed § 37.44(e) would require that facilities have a qualified medical physicist on site or available as a consultant. To minimize risks and assure standardized and predictable image quality from sophisticated digital radiography systems, facilities must have available highly trained individuals who are skilled in evaluating the equipment, methods, and procedures.<sup>18</sup>

Proposed § 37.44(f) would require that facilities document the findings by the medical physicist that each image acquisition system has met initial specifications and standards of the equipment manufacturer and performance testing. Since the 1980s, major advances have occurred in the practice of clinical radiology, most notably in the widespread adoption of digital technologies and systems for image acquisition, storage, transfer, and display.<sup>19</sup> These digital technologies offer unique benefits for the identification and classification of pneumoconiosis, but due to the added complexities of digital radiography systems compared with film-screen radiology, these benefits may only be realized with proper implementation and utilization of the digital systems.<sup>20</sup> To assure that the systems perform at the level required to meet the purposes of this Part, performance must be assessed by qualified individuals.

<sup>18</sup> Samei E [2008]. Acquisition of Digital Chest Images for Pneumoconiosis Classification: Methods, Procedures, and Hardware. In: NIOSH. Application of the ILO International Classification of Radiographs of Pneumoconioses to Digital Chest Radiographic Images: A NIOSH Scientific Workshop. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. DHHS (NIOSH) Publication No. 2008-139.

<sup>19</sup> NIOSH [2008]. Application of the ILO International Classification of Radiographs of Pneumoconioses to Digital Chest Radiographic Images: A NIOSH Scientific Workshop. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. DHHS (NIOSH) Publication No. 2008-139.

<sup>20</sup> Samei E, Ravin CE [2008]. Assuring image quality for classification of digital chest radiographs. In: NIOSH. Application of the ILO International Classification of Radiographs of Pneumoconioses to Digital Chest Radiographic Images: A NIOSH Scientific Workshop. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. DHHS (NIOSH) Publication No. 2008-139.

Proposed § 37.44(g) would require facilities to implement a quality assurance program, and would incorporate by reference the standards set by the American Association of Physicists in Medicine. This provision continues the existing requirement for a quality control program, (§ 37.41(h)(9)) and further specifies professionally recommended procedures that must be an integral part of the operation of each digital radiography system. To ensure that radiologic examinations required under this Part are safe, reliable, and accurate, facilities that are approved to provide examinations using digital equipment must demonstrate that personnel, equipment, and procedures adhere to professionally accepted guidelines.<sup>21</sup>

Proposed § 37.44(g)(1) would require that facility approval applications include a comprehensive assessment by a qualified medical physicist within 12 months prior to application. This paragraph would incorporate by reference guidelines established by the American Association of Physicists in Medicine. This provision continues the existing requirement (§ 37.42(c)).

Proposed § 37.44(g)(2) would require the use of radiographic technique charts developed for the specific X-ray system and detector combination used at the facility. This section would incorporate by reference monitoring methods specified by the American Association of Physicists in Medicine, and radiation exposure reference levels specified by the American College of Radiology. Unlike film-screen radiology, digital radiography systems are susceptible to *dose creep*.<sup>22</sup> Dose creep in this setting involves increasing examinee radiation exposures over time for similar types of examinations (e.g., chest radiographs) performed at a facility. The tendency to increase radiation exposures over time,

<sup>21</sup> Franzblau A, Kazeroni EA, Goodsitt M [2009]. Digital X-ray imaging in pneumoconiosis screening: Future challenges for the NIOSH B Reader Program. In: NIOSH. The NIOSH B Reader Certification Program: Looking to the future. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. DHHS (NIOSH) Publication No. 2009-140.

NIOSH [2008]. Application of the ILO International Classification of Radiographs of Pneumoconioses to Digital Chest Radiographic Images: A NIOSH Scientific Workshop. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. DHHS (NIOSH) Publication No. 2008-139.

<sup>22</sup> Schaefer-Prokop C, Neitzel U, Venema HW, Uffmann M, Prokop M [2008]. Digital chest radiography: An update on modern technology, dose containment and control of image quality. *Eur Radiol* 18(9):1818-1830.

beyond the levels necessary, results from the characteristics of digital image detectors (which provide excellent image quality when images are overexposed, but suboptimal image quality when underexposed) combined with the desire on the part of facilities to avoid repeat examinations. For this reason, as recommended by professional bodies, facilities utilizing digital systems for examinations under this Part are required to take additional steps to ensure optimal exposures, and to maintain records of annual monitoring and evaluation of representative radiation exposures over time, using standardized methods, metrics, and documentation.<sup>23</sup>

Proposed § 37.44(g)(3) would require that the performance of a digital radiography device be monitored according the recommendations of the medical physicist. Facilities would be required to maintain documentation upon the completion of quality assurance testing, and make it available to NIOSH for 5 years. NIOSH believes that retaining such records for 5 years is already standard business practice. This provision would also specify that certain tests are not required as a part of the quality assurance program for digital radiography systems (digital image acquisition systems in which the X-ray signals received by the image detector are converted to electronic signals without movable cassettes). This section provides more detailed guidance specific to the contemporary types of digital systems.

Proposed § 37.44(g)(4) would require that facilities maintain documentation on the implementation and monitoring of policies and procedures required under this section. Documentation of key metrics is essential for facility management to assure adherence to internal policies, and provides a mechanism for NIOSH inspections to determine if the purposes of this Part are being met.

Proposed § 37.44(h) would add the explicit requirement that facilities adhere to Federal laws to protect the confidentiality and privacy of coal miners participating in the program.

<sup>23</sup> Shepard SJ, Wang J, Flynn M, Gingold E, Goldman L, Krugh K, Leong DL, Mah E, Ogden K, Peck D, Samei E, Willis C [2009]. An exposure indicator for digital radiography. Report of AAPM Task Group 116. College Park, MD: American Association of Physicists in Medicine. AAPM Report No. 116.

ACR Practice Guideline for diagnostic reference levels in medical X-ray imaging. Revised 2008 (Res. 3).

ACR Technical Standard for diagnostic medical physics performance monitoring of radiographic and fluoroscopic equipment. Revised 2006 (Res. 29,16g,17).

NIOSH seeks to ensure that miners' sensitive health information remains secure and is protected to the extent permitted by law.

#### Section 37.45 Protection Against Radiation Emitted by Radiographic Equipment

This proposed provision would require that radiographic equipment conform to applicable State, territorial, and Federal regulations. Where no State, territorial or Federal regulations apply, the section would incorporate by reference the recommendations of the NCRP. This provision is unchanged from the existing § 37.45, although references for the NCRP recommendations and contact information would be updated.

#### Section 37.50 Interpreting and Classifying Chest Radiographs—Film

Proposed procedures for classifying radiographs would be unchanged from the existing § 37.50, but for updating the requirement that images be interpreted and classified in accordance with the ILO International Classification of Radiographs for Pneumoconioses, 2011 edition.<sup>24</sup> The revised 2011 edition of the Guidelines for the use of the ILO International Classification of Radiographs of Pneumoconioses extends the applicability of the prior edition of the Classification to digital radiographic images of the chest. The proposed section would retain the existing provision that radiographs must be interpreted by an A or B Reader who has access to a complete set of the ILO Classification standard images, but would clarify that initial interpretations and notification of any findings other than that of pneumoconiosis shall be performed by a qualified physician. Provisions referring to view boxes would also be retained. Further, this section would be newly designated to apply only to film-screen radiographs.

#### Section 37.51 Interpreting and Classifying Chest Radiographs—Digital Radiography Systems

Proposed § 37.51(a) and (b) are similar to the first two provisions of § 37.50 for film radiographs, discussed above. Clinical readings of digital chest radiographs obtained under this Part must be performed by physicians who are qualified and licensed and who read chest radiographs in the normal course of practice. However, in NIOSH's

judgment, it would not be feasible to require that all physicians who provide the initial readings demonstrate proficiency with the ILO Classification of digital radiographs as specified in this Section. Such physicians are not sufficiently available to conduct these initial readings for coal miners in all locations in the United States. Thus the proposed rule specifies that a qualified and licensed physician who reads chest radiographs in the normal course of practice is qualified to provide interpretation and notification of any abnormal findings other than pneumoconiosis.

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. Paragraph § 37.51(b) would specify that the classification of digital images be done "in a manner consistent with the ILO International Classification of Radiographs of Pneumoconioses 2011."

Proposed § 37.51(c) would require radiograph interpreters to have available to them a complete set of NIOSH-approved standard digital chest radiographic images. The ILO classification system has provided a standardized approach to recognizing, describing, and quantifying abnormalities on the chest radiograph caused by dust.<sup>25</sup> A set of standard film images is provided by the ILO and required to be used in side-by-side comparisons when classifying radiographs. These ILO standard images were originally obtained using film-screen radiography, without application of edge enhancement or noise reduction software. Research using film-screen radiographs and classifications based upon the current ILO standard film radiographs has demonstrated that chest radiograph classification results correlate significantly with objective independent measures of dust exposure or lung dust content.<sup>26</sup> To maintain the documented validity of the ILO classification system, the rule specifies that each reader compare digital images submitted under this regulation with NIOSH-approved digital versions of the standard images, and that no software

modification of the standard images can be permitted.

Proposed § 37.51(d) would require that viewing systems enable readers to display the chest image at full resolution, side-by-side with the selected NIOSH-approved standard image for comparison. This section would establish specifications for image display devices, including megapixels (MP) and bit depth; displays and associated graphics cards should meet the specifications of the current DICOM standard. This section would also set standards for display system luminance, relative noise, linearity, modulation transfer function (MTF), frequency, and glare by incorporating AAPM recommendations by reference. Finally, this section would require that displays be situated to minimize front surface glare.

Visualization of the shadows on the chest radiograph caused by dust-related fibrosis is one of the most difficult challenges in medical diagnostic imaging. The viewing systems must provide sufficient luminance and gray scale depth to demonstrate the required subtle contrasts, and sufficient display size and density of pixels to reflect the resolution of the image file provided by the image detectors and required to visualize the fine linear fibrotic shadows.<sup>27</sup> Research studies have demonstrated that reader recognition of pneumoconiosis on digital radiology systems can be equivalent to that achieved using film-screen radiology systems when appropriate system specifications and devices are employed.<sup>28</sup> Additionally, adherence to the grayscale standard display function is required to assure that the appearance

<sup>24</sup> Flynn MJ [2008]. Image presentation: Implications of processing and display. In: NIOSH. Application of the ILO International Classification of Radiographs of Pneumoconioses to Digital Chest Radiographic Images: A NIOSH Scientific Workshop. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. DHHS (NIOSH) Publication No. 2008-139.

<sup>25</sup> Franzblau A, Kazerooni EA, Sen A, Goodis MM, Lee SY, Rosenman KD, Lockey JE, Meyer CA, Gillespie BW, Petsonk EL, Wang ML [2009]. Comparison of digital radiographs with film radiographs for the classification of pneumoconiosis. *Acad Radiol* 16(6):669–677.

<sup>26</sup> Sen A, Lee SY, Gillespie BW, Kazerooni EA, Goodis MM, Rosenman KD, Lockey JE, Meyer CA, Petsonk EL, Wang ML, Franzblau A [2010]. Comparison of reliability of classification for pneumoconiosis of film and digital radiographs: A modeling approach. *Acad Radiol* 17(4):511–519.

<sup>27</sup> Laney AS, Petsonk EL, Wolfe AL, Attfield MD [2009]. Comparison of storage phosphor computed radiography with conventional film-screen radiography in the recognition of pneumoconiosis. *Eur Respir J*, published ahead of print November 19, 2009.

<sup>24</sup> International Labour Office [2011]. Guidelines for the use of ILO International Classification of Pneumoconiosis, revised edition 2011). Geneva, Switzerland: International Labour Office. Occupational Safety and Health Series No. 22 (Rev. 2011).

<sup>25</sup> *Id.*

<sup>26</sup> Ruckley VA, Fernie JM, Chapman JS, Collings P, Davis JM, Douglas AN, Lamb D, and Seaton A [1984]. Comparison of radiographic appearances with associated pathology and lung dust content in a group of coalworkers. *Br J Ind Med* 41(4): 459–467.

<sup>27</sup> Cockcroft A, Lyons JP, Andersson N, and Saunders MJ [1983]. Prevalence and relation to underground exposure of radiological irregular opacities in South Wales coal workers with pneumoconiosis. *Br J Ind Med* 40(2): 169–172.

of the images is independent of the specific digital device used for display.

Proposed § 37.51(d)(4) would also require that the measurements of pleural shadows and parenchymal opacities shall be taken using calibrated software measuring tools. This section would also require that, if possible, a record be made of the presentation state. Each individual reader is generally offered the option to select a specific setting that he or she judges to optimize the display characteristics of the chest radiographic image during the classification process; however, recording of the presentation states and annotations would be required (with compatible software) and would permit subsequent evaluation, using a Grayscale Standard Display Function (GSDF) compliant monitor, of the specific image that was displayed and interpreted by the reader who performed the classification.<sup>29</sup>

Proposed § 37.51(e) would require that quality control procedures for devices used to display images for classification comply with the recommendations of the American Association of Physicists in Medicine, which are incorporated by reference. Further, this section would require that if automatic quality assurance systems are used, regular visual inspection also be performed using test patterns recommended by the medical physicist. Periodic maintenance and assessment of the display devices is essential to document that performance continues to meet current professional recommendations.<sup>30</sup> Because various automated systems may not detect all defects in digital display devices (such as distortion, dropout of pixels, or surface reflections), periodic visual inspections are also important to assure the display performance is adequate.

Proposed § 37.51(f) would establish that the classification of digitally-acquired radiographs be based on the viewing of images displayed as soft copies, and not as hard copy printed transparencies. Further, proposed § 37.51(g) would prohibit the use of digitized copies of film-screen acquired images. There is currently no sufficient scientific consensus regarding the equivalence of classifications performed

using either 1) hard copies of digitally-acquired images or 2) digitized versions of film-screen radiographs in comparison to classifications performed using traditional film screen radiographic methods. For this reason, classifications based upon these two alternative approaches will not be accepted at this time.<sup>31</sup>

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

Proposed § 37.52(a) and (b), establishing the A and B Reader approval programs, would be modified from existing § 37.51 to make clarifications in the current requirements and update older terminology. Section 37.52(a)(3) would clarify that initial clinical interpretations and notification of findings other than pneumoconiosis under § 37.51(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. Proposed § 37.52(b)(1) would retain the requirement under existing § 37.51(b)(1) that B Reader approval prior to October 1, 1976 be terminated.

Proposed § 37.52(b)(2) would retain the requirement under existing § 37.51(b)(2) that physicians who desire to be B Readers demonstrate their

<sup>29</sup> Samei E. Acquisition of digital chest images for pneumoconiosis classification: Methods, procedures, and hardware. In: NIOSH. Application of the ILO International Classification of Radiographs of Pneumoconioses to Digital Chest Radiographic Images: A NIOSH Scientific Workshop. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. DHHS (NIOSH) Publication No. 2008-139.

Franzblau A, Kazerooni EA, Sen A, Goodsitt MM, Lee SY, Rosenman KD, Lockey JE, Meyer CA, Gillespie BW, Petsonk EL, Wang ML [2009]. Comparison of digital radiographs with film radiographs for the classification of pneumoconiosis. *Acad Radiol* 16(6):669-677.

Suganuma N, Murata K, Kusaka Y [2008]. CR and FPD DR chest radiographic image parameters for the pneumoconioses: The Japanese approach and experience. In: NIOSH. Application of the ILO International Classification of Radiographs of Pneumoconioses to digital chest radiographic images: A NIOSH Scientific Workshop. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. DHHS (NIOSH) Publication No. 2008-139.

Franzblau A, Kazerooni EA, Goodsitt M [2009]. Digital X-ray imaging in pneumoconiosis screening: Future challenges for the NIOSH B Reader Program. In: NIOSH. The NIOSH B Reader Certification Program: Looking to the future. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. DHHS (NIOSH) Publication No. 2009-140.

proficiency in evaluating chest radiographs by taking an examination. The 6-hour initial certification examination was commissioned by NIOSH and developed under a contract through the American College of Radiology by the Department of Radiology and Radiological Science, Johns Hopkins School of Medicine. The test has been given about once a month by NIOSH since 1978. Beginning in 1984, physicians who wish to maintain B reader status have been required to pass a 3-hour recertification examination every 4 years. Examinees for recertification who do not obtain a passing grade are permitted to take the initial 6-hour certification examination at the next available opportunity. Examinees who do not obtain a passing grade on the 6-hour certification examination must wait 6 months before they are eligible to sit again for the examination. The performance of the examination has been described in two manuscripts published in the peer-reviewed literature.<sup>32</sup>

The examination will be based on either film or digital images. The existing provision would be modified to indicate that each physician desiring to take the digital version of the B Reader examination will be provided with a complete set of the NIOSH-approved digital standard reference radiographs. NIOSH intends to offer both the film and digital versions of the examination for a number of years. A satisfactory grade in either examination will qualify the physician to interpret both formats. NIOSH has not found that the format of the exam has any effect on performance, and finds no justification for requiring that a prospective B Reader take both versions of the exam. NIOSH welcomes public comment on the potential benefits as well as the disadvantages to requiring prospective readers to demonstrate competence in classifying both film and digital images.

Finally, § 37.52(c) would require that physicians who wish to participate in the A and B Reader program familiarize themselves with the necessary components for attainment of reliable classification of chest radiographs for the pneumoconioses. The proposed requirement that prospective A and B Readers review NIOSH guidance on radiographic classification is included to ensure that each reader has studied recommended classification methods

<sup>32</sup> Morgan RH. Proficiency examination of physicians for classifying pneumoconiosis chest films. *Am J Roentgenology* 1979;132:803-08.

Wagner GR, Attfield MD, Kennedy RD, Parker JE. The NIOSH B Reader Certification Program—An update report. *Journal of Occupational Medicine*. 1992; 34:879-884.

<sup>29</sup> Samei E, Ravin CE [2008]. Assuring image quality for classification of digital chest radiographs. In: NIOSH. Application of the ILO International Classification of Radiographs of Pneumoconioses to Digital Chest Radiographic Images: A NIOSH Scientific Workshop. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. DHHS (NIOSH) Publication No. 2008-139.

<sup>30</sup> *Id.*

and approaches. The referenced NIOSH guidance document is newly-developed and released;<sup>33</sup> approval as an A or B Reader requires this basic level of knowledge.

Records pertaining to the provisions in § 37.52 are maintained by NIOSH under CDC/ATSDR Privacy Act System of Records Notice 0920–0001, Certifying Interpreting Physician File.

#### Section 37.53 Method of Obtaining Definitive Interpretations

Proposed § 37.53 would maintain 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 shall obtain a third interpretation. Text added to § 37.53(a) amends the existing provision to clarify procedures in the event that independent classifications from three B Readers do not demonstrate sufficient agreement. In that case, the final determination would be based upon the median (middle) classification of five interpretations derived from the three initial readings plus two other classifications from B Readers selected from the panel. This provision is intended to codify the process used to resolve disagreements among three or more B Readers. Text added to § 37.53(b) would clarify that substantial agreement is assessed by NIOSH after complete classifications are received on either a paper or electronic version of the standard Roentgenographic Interpretation Form (Form CDC/NIOSH (M)2.8).

#### Section 37.54 Notification of Abnormal Radiographic Findings

Proposed § 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. The notification procedure is intended to facilitate and expedite the process by which a miner is informed of potentially important medical problems and could seek treatment.

Notification of important results to miners routinely occurs twice, providing a particularly robust notification process. The first

<sup>33</sup>NIOSH [2011]. NIOSH Guideline: Application of Digital Radiography for the Detection and Classification of Pneumoconiosis. DHHS (NIOSH) Publication Number 2011-198. August 2011. <http://www.cdc.gov/niosh/docs/2011-198/>. Accessed November 16, 2011.

notification is provided by the first physician to review a chest image in the community, who is required to provide documentation of miner notification to NIOSH. Subsequently, the image is sent to NIOSH and reviewed by NIOSH B readers. Within 60 days of completion of the physician readings, NIOSH will send a letter to each miner describing all findings in layman's terminology, and recommending a specific course of action appropriate to the findings. Current regulations specify 60 days for receipt of the letters describing pneumoconiosis and any other findings. From many years of experience, NIOSH has found this time interval to be both appropriate and reasonable. Text for this letter is standardized, and has been used by CWHSP for many years. A booklet describing local medical and other resources and contact information will be included with each letter.

#### Section 37.60 Submitting Required Chest Radiographs and Miner Identification Documents

Proposed § 37.60 would be essentially unchanged from existing § 37.60, which establishes the protocol for submitting radiographs. Paragraph (a)(1) would also allow for the submission of image files for digital radiographs, and permit the use of either hard copy or electronic versions of the forms. We propose to strike the reference to a pre-employment physical examination from paragraph (d) to be consistent with the requirements of the Americans with Disabilities Act.

Records pertaining to the provisions in § 37.60 are maintained by NIOSH under CDC/ATSDR Privacy Act System of Records Notice 0920–0149, Morbidity Studies in Coal Mining, Metal and Non-Metal Mining and General Industry.

#### Section 37.70 Review of Interpretations

This section would be amended only to update terminology. Proposed § 37.70(a) would retain the existing requirement that, in the situation in which a mine plan provides an A reader to perform the first reading of a miner's radiograph, a miner may request, and NIOSH will obtain, an additional classification of his or her radiograph, performed by a B reader. Proposed § 37.70(b) would retain the existing requirement that allows a mine operator who is directed by MSHA to transfer a miner to a less dusty atmosphere based on a recent examination to request that NIOSH review its findings. Terminology in both (a) and (b) would be updated.

#### Section 37.80 Availability of Records for Radiographs

Proposed § 37.80 would remain unchanged from the existing requirement. Terminology in this section would be updated.

#### B. Subpart—Autopsies

##### Section 37.200 Scope

Proposed § 37.200 would remain unchanged from the existing explanation that provisions in this subpart establish conditions under which pathologists will be paid to conduct autopsies on deceased miners.

##### Section 37.201 Definitions

Proposed § 37.201 would retain the existing definitions for Secretary, miner, and pathologist, but would update "ALFORD," in the existing provision to "NIOSH."

##### Section 37.202 Payment for Autopsy

Proposed § 37.202 would retain the existing provision setting forth circumstances under which a pathologist may be paid by the Secretary for performing an autopsy.

##### Section 37.203 Autopsy Specifications

Proposed § 37.203 would retain the existing standards establishing the manner in which autopsies are conducted.

##### Section 37.204 Procedure for Obtaining Payment

Proposed § 37.204 would retain the existing procedure for submitting a claim for payment to NIOSH ("NIOSH" would be updated, replacing "ALFORD").

#### 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 proposed 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 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 CWP. 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 would 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 the rule proposed here. 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 a suitable 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, NIOSH believes 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 one-time 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. NIOSH invites public comment on these estimates.

The proposed rule would 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 proposed rule.

The proposed provisions for using the DICOM standard and incorporating by reference standard best practices for digital radiography used in lung imaging ensure that the proposed 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 proposed rule would establish a new requirement for coal mine operators to provide to NIOSH a roster of current miners as proposed 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 proposed rule is not considered economically significant, as defined in § 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 would establish standards for the delivery of digitally-acquired chest radiographs for underground coal miners. It would not impose any new requirements on small radiographic facilities that participate in the Coal Workers' Health Surveillance Program 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 would 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 proposal 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 proposed standard would also introduce a substantial benefit in allowing the participation in the program 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 the program under part 37.

This proposed rule should 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 would impose no new costs on small coal mine operators.

The proposed rule would establish a new requirement for coal mine operators to provide to NIOSH a roster of current miners as proposed under § 37.4(a)(3). The provision of this roster to NIOSH is current practice by almost all coal mine operators. NIOSH estimates that, of 488 underground coal mines that can be considered small as of the first quarter of 2011,<sup>34</sup> 130 coal mine plans are submitted to the Agency annually. NIOSH 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; NIOSH estimates the annual cost for an individual coal

<sup>34</sup> 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/actable.htm>. Accessed July 7, 2011.

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 NIOSH'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. NIOSH 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 proposed 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 would require underground coal mine operators to submit a roster of current employees (§ 37.4(a)(3)), and the Facility Certification Document which would be 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
<b>Totals .....</b>	<b>.....</b>	<b>23,250</b>	<b>.....</b>	<b>.....</b>	<b>4,471</b>

#### D. Small Business Regulatory Enforcement Fairness Act

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

#### E. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531 *et seq.*) directs agencies to assess the effects of Federal regulatory actions on State, local, and tribal governments, and the private sector "other than to the extent that such regulations incorporate requirements specifically set forth in law." For purposes of the Unfunded

Mandates Reform Act, this rule does not include any Federal mandate that may result in increased annual expenditures in excess of \$100 million by State, local or tribal governments in the aggregate, or by the private sector.

#### F. Executive Order 12988 (Civil Justice)

This rule has been drafted and reviewed in accordance with Executive Order 12988, "Civil Justice Reform," and will not unduly burden the Federal court system. Chest radiograph 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 proposed 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 proposed rule consistent with the Federal Plain Writing Act guidelines.

**V. Proposed 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 proposes to amend 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 shall 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, shall 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 which 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 which 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 shall 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 shall begin no sooner than the effective date of these regulations 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 which 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 shall 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 shall 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 shall 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 shall have the opportunity for examinations.

(b) **Mandatory examinations.** Every operator shall 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 (1/0, 1/1, 1/2), category 2 (2/

1, 2/2, 2/3), category 3 (3/2, 3/3, 3/+), 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 shall 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) shall 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 shall be provided in accordance with a plan which 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 shall 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 shall submit a plan within 60 days after such event occurs. A separate plan shall be submitted by the operator and by each construction contractor for each underground coal mine which has a MSHA identification number. The plan shall 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 shall 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 shall 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 shall 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 shall 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 shall 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 shall 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 section 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 shall specify the ground upon which approval is proposed to be denied.

(c) If a plan is denied approval, the Secretary shall 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 shall 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 (1/0, 1/1, 1/2), category 2 (2/1, 2/2, 2/3), or category 3 (3/2, 3/3, 3/+) simple pneumoconioses, or complicated pneumoconioses (ILO Classification) shall 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 not more than 50 percent of the maximum respirable dust concentration permitted by MSHA, or if such level is not attainable in the mine, to a position in the mine where the concentration of respirable dust is the lowest attainable below the maximum respirable dust concentration permitted by MSHA.

\* \* \* \* \*

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 which may result from this examination will be subject to the terms of § 37.7.

10. 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 shall 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.

11. 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 shall 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 shall be made in a facility approved in accordance with § 37.43 or § 37.44 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.

12. Amend § 37.41 as follows:

- Revise the section heading.
- Redesignate paragraphs (a) and (b) as paragraphs (b) and (a) respectively.
- Redesignate paragraphs (c) through (m) as (d) through (n).
- Add new paragraph (c).
- 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 shall be disrobed from the waist up at the time the radiograph is given. The facility shall provide a dressing area and for those miners who wish to use one, the facility shall provide a clean gown. Facilities shall be heated to a comfortable temperature.

(b) Every chest radiograph shall 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 shall 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 shall include both apices with minimum loss of the costophrenic angle.

(c) Chest radiographs shall be performed by a radiologic technologist.

(d) Radiographs shall be made only with a diagnostic X-ray machine having a rotating anode tube with a maximum of a 2 mm source (focal spot).

(e) Except as provided in paragraph (e) of this section, radiographs shall be made with units having generators which comply with the following:

(1) The generators of existing radiographic units acquired by the

examining facility prior to July 27, 1973, shall have a minimum rating of 200 mA at 100 kVp;

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

(f) Radiographs made with battery-powered mobile or portable equipment shall 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 of this subpart.

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

(i) To ensure high quality chest radiographs:

(1) The maximum exposure time shall 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 shall 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, which 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 shall 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 shall be used.

(k) Before the miner is advised that the examination is concluded, the radiograph shall 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 shall be immediately made. All substandard radiographs shall 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) Each radiograph made hereunder shall be permanently and legibly marked with the name and address or NIOSH approval number of the facility at which it is made, the social security number of the miner, and the date of the radiograph. No other identifying markings shall be recorded on the radiograph.

### §§ 37.42 and 37.43 [Redesignated]

13a. Redesignate §§ 37.42 and 37.43 as §§ 37.43 and 37.45 respectively.

13b. Add new § 37.42 to read as follows:

### § 37.42 Chest radiograph specifications—digital radiography systems.

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

(b) Every digital chest radiograph taken as required under this regulation shall be a single posteroanterior projection at full inspiration on a digital detector being no less than 35 by 43 cm (14 by 17 if measured in inches) and no greater than 41 by 43 cm (16 by 17 inches). The imaging plate shall have a maximum pixel pitch of 200 $\mu$ m, and a minimum matrix size of 5 megapixels (for 35 by 43 cm), with a minimum bit depth of 10. Spatial resolution shall be at least 2.5 line pairs per millimeter.

The storage phosphor cassette or digital image detector shall 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 which together include the apices and the costophrenic angles of both right and left lungs.

(c) Chest radiographs shall be given by a radiologic technologist.

(d) Radiographs shall be made with a diagnostic X-ray machine with a maximum of a 2 mm source (focal spot).

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

(f) An electric power supply shall be used which 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 shall be used as recommended.

(g) Radiographs shall be obtained only with equipment having a beam-limiting device that does not cause large unexposed boundaries. The beam limiting device shall 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 shall not be used. The use and effect of the beam limiting device shall be discernible on the resulting image.

(h) Radiographic technique charts shall 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 shall be documented by a medical physicist utilizing the image capture systems and exposure parameters used at the facility for chest imaging, using methods recommended by the American Association of Physicists in Medicine in AAPM Report No. 74, Quality Control in Diagnostic Radiology, Report of Task Group #12, Diagnostic X-Ray Imaging Committee, published by Medical Physics Publishing for AAPM, July 2002, pages 17–18, and in 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, pages 61–62. These reports are incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of AAPM Report No. 74 from the AAPM Web site at [http://www.aapm.org/pubs/reports/rpt\\_74.pdf](http://www.aapm.org/pubs/reports/rpt_74.pdf) or from Medical Physics Publishing, 4513 Vernon Blvd., Madison, WI 53705.

You may obtain a copy of AAPM Report No. 14 from [http://www.aapm.org/pubs/reports/rpt\\_14.pdf](http://www.aapm.org/pubs/reports/rpt_14.pdf) or from AAPM, 335 E. 45 Street, New York, NY 10017. You may inspect a copy of AAPM Report No. 74 or AAPM Report No. 14 at the NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, OH 45226, or at the National Archives and Records Administration (NARA). For information on the availability of these materials at NARA, call (202) 741–6030 or go to [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(2) Exposure parameters achieved during the evaluation of the automated exposure system shall 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 shall not exceed 50 milliseconds except for subjects with chests over 28 centimeters posteroanterior, for whom the exposure time shall not exceed 100 milliseconds;

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

(3) The exposure setting for chest images shall be within the range of 100–300 equivalent exposure speeds and shall comply with the American College of Radiology (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, Revised 2008 (Res. 3). The ACR Practice Guideline is incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of the ACR Practice Guideline from the ACR Web site at [http://www.acr.org/SecondaryMainMenuCategories/quality\\_safety/guidelines/med\\_phys/reference\\_levels.aspx](http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/med_phys/reference_levels.aspx).

You may inspect a copy of the ACR Practice Guideline at the NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, OH 45226, or 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](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html). 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 image signal-to-noise and detective quantum efficiency shall be evaluated and judged acceptable by a qualified medical physicist using the specifications of the American Association of Physicists in Medicine, AAPM Report No. 93, Acceptance Testing and Quality Control of Photostimulable Storage Phosphor Imaging Systems, Report of AAPM Task Group 10, published by AAPM, October 2006, pages 1–68. This report is incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of AAPM Report No. 93 from the AAPM Web site at [http://www.aapm.org/pubs/reports/RPT\\_93.pdf](http://www.aapm.org/pubs/reports/RPT_93.pdf) or from AAPM, One Physics Ellipse, College Park, MD 20740. You may inspect a copy of AAPM Report No. 93 at the NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, OH 45226, or at the National Archives and Records Administration (NARA). For information on the availability of these materials at NARA, call (202) 741–6030 or go to [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html). Image management software and settings for routine chest imaging shall be used, including routine amplification of digital detector signal as well as standard image post-processing functions. No image or edge enhancement software functions shall 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 shall be employed.

(5) (i) The image object, transmission and associated data storage, file format, and transmission of associated information shall conform to the following components of the National Electrical Manufacturers Association's Digital Imaging and Communications in Medicine (DICOM) standard:

(A) Part 3 (PS 3.3–2011): Information Object Definitions, Annex A—Composite Information Object Definitions, sections: Digital X-Ray Image Information Object Definition; X-Ray Radiation Dose SR Information Object Definition; and Grayscale Softcopy Presentation State Information Object Definition.

(B) Part 4 (PS3.4–2011): Service Class Specifications, sections: Annex B—Storage Service Class; Annex N—Softcopy Presentation State Storage SOP Classes; Annex O—Structured Reporting Storage SOP Classes.

(C) Part 10 (PS 3.10–2011): Media Storage and File Format for Data Interchange.

(D) Part 11 (PS 3.11–2011): Media Storage Application Profiles.

(E) Part 12 (PS 3.12–2011): Media Formats and Physical Media for Media Interchange.

(F) Part 14 (PS 3.14–2011): Grayscale Standard Display Function.

(G) Part 16 (PS 3.16–2011): Content Mapping Resource, section: X-Ray Radiation Dose SR IOD Templates.

(ii) The sections of the DICOM standard indicated above are incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of the DICOM standard from the NEMA Web site at <ftp://medical.nema.org/medical/dicom/2011/> or from the National Electrical Manufacturers Association, 1300 N. 17th Street, Rosslyn, VA 22209. You may inspect a copy of the DICOM standard at the NIOSH Docket Office, Robert A. Taft Laboratories, MS–C34, 4676 Columbia Parkway, Cincinnati, OH 45226, or at the National Archives and Records Administration (NARA). For information on the availability of these materials at NARA, call (202) 741–6030 or go to [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(A) Identification of each miner, chest image, facility, date and time of the examination shall be encoded within the image information object, according to Part 3 (PS 3.3–2011) of the DICOM standard, Information Object Definitions, for the DICOM “DX” object. Part 3 is incorporated by reference and is available as indicated above. If data compression is performed, it shall be lossless. Exposure parameters (kVp, mA, time, beam filtration, scatter reduction, radiation exposure) shall be stored in the DX information object.

(B) Exposure parameters as defined in the DICOM Standard PS 3.16–2011: Content Mapping Resource, shall 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 shall 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 shall be used; grids shall not be used that cause Moiré interference patterns in either horizontal or vertical images.

(9) The geometry of the radiographic system shall 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 shall 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 shall 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 shall be made immediately. Unacceptable digital image files shall 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).

14. 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 shall also submit a radiograph of a plastic step-wedge object<sup>1</sup> or other test object (available on loan from NIOSH) which

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 shall have been made with each unit to be used hereunder. All radiographs shall have been made within 15 calendar days prior to submission and shall 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 shall 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 shall 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 (see § 37.45);

(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 shall 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 shall be displayed on the mine bulletin board adjacent to the operator's approved

<sup>1</sup> 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.

plan. The approved plan will be reevaluated by NIOSH in light of this change.

(f) A formal written quality assurance program shall be established at each facility addressing radiation exposures, equipment maintenance, and image quality, and shall conform to the standards set by the American Association of Physicists in Medicine in AAPM Report No. 74, Quality Control in Diagnostic Radiology, Report of Task Group #12, Diagnostic X-Ray Imaging Committee, published by Medical Physics Publishing for AAPM, July 2002, pages 1–19, 47–53, and 56. This report is incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of AAPM Report No. 74 from the AAPM Web site at [http://www.aapm.org/pubs/reports/rpt\\_74.pdf](http://www.aapm.org/pubs/reports/rpt_74.pdf) or from Medical Physics Publishing, 4513 Vernon Blvd., Madison, WI 53705. You may inspect a copy of AAPM Report No. 74 at the NIOSH Docket Office, Robert A. Taft Laboratories, MS–C34, 4676 Columbia Parkway, Cincinnati, OH 45226, or at the National Archives and Records Administration (NARA). For information on the availability of these materials at NARA, call (202) 741–6030 or go to [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(g) In conducting medical examinations pursuant to this Part, physicians and radiographic facilities shall 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).

15. 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 shall 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 which are of acceptable quality to (1) one or more individuals selected by NIOSH

from the panel of B Readers and (2) a qualified medical physicist or consultant, both designated by NIOSH. Image files shall 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 for diagnostic media interchange Part 12 (PS 3.12–2011): Media Formats and Physical Media for Media Interchange. Applicants will be advised of any reasons for denial of approval. All submitted images shall 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 shall have been made with each digital radiographic unit to be used by the facility under the requested approval. The corresponding radiographic image files shall be submitted on standard portable media (compact or digital video disc) and formatted to meet specifications of the current Digital Imaging and Communications in Medicine (DICOM) standard for diagnostic media interchange Part 12 (PS 3.12–2011): Media Formats and Physical Media for Media Interchange. DICOM Part 12 is incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of the DICOM standard from the NEMA Web site at <ftp://medical.nema.org/medical/dicom/2011/> or from the National Electrical Manufacturers Association, 1300 N. 17th Street, Rosslyn, VA 22209. You may inspect a copy of the DICOM standard at the NIOSH Docket Office, Robert A. Taft Laboratories, MS–C34, 4676 Columbia Parkway, Cincinnati, OH 45226, or at the National Archives and Records Administration (NARA). For information on the availability of this document at NARA, call (202) 741–6030 or go to [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html). Documentation shall 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 shall 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

shall 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 shall 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 shall 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 regulation 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 shall have been made within 1 year prior to the date of submission of the application.

(b) Facilities shall 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 shall 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, shall be on site or available as a consultant. The physicist shall be trained in evaluating the performance of radiographic equipment and facility quality assurance programs, and shall be licensed/approved by a State or territory of the United States or certified by a competent U.S. national board.

(f) Facilities shall 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 shall be established at each facility addressing radiation exposures, equipment maintenance, and image quality, and shall conform to the standards set by the American Association of Physicists in Medicine in AAPM Report No. 74, Quality Control in Diagnostic Radiology, Report of Task Group #12, Diagnostic X-Ray Imaging Committee, published by Medical Physics Publishing for AAPM, July 2002, pages 1–19, 47–53, and 56, and AAPM Report No. 116, An Exposure Indicator for Digital Radiography, Report of AAPM Task Group 116, published by AAPM, July 2009, sections VIII, IX, and X. These reports are incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of AAPM Report No. 74 from the AAPM Web site at [http://www.aapm.org/pubs/reports/rpt\\_74.pdf](http://www.aapm.org/pubs/reports/rpt_74.pdf) or from Medical Physics Publishing, 4513 Vernon Blvd., Madison, WI 53705. You may obtain a copy of AAPM Report No. 116 from the AAPM Web site at [http://www.aapm.org/pubs/reports/RPT\\_116.PDF](http://www.aapm.org/pubs/reports/RPT_116.PDF) or from American Association of Physicists in Medicine, One Physics Ellipse, College Park, MD 20740. You may inspect a copy of AAPM Report No. 74 and No. 116 at the NIOSH Docket Office, Robert A. Taft Laboratories, MS–C34, 4676 Columbia Parkway, Cincinnati, OH 45226, or at the National Archives and Records Administration (NARA). For information on the availability of these materials at NARA, call (202) 741–6030 or go to [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(1) Applications for facility approval shall 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 shall comply with the following guidelines: American Association of Physicists in Medicine, AAPM Report No. 93, Acceptance Testing and Quality Control of Photostimulable Storage Phosphor Imaging Systems, Report of AAPM Task Group 10, published by AAPM, October 2006, pages 1–68; AAPM Report No. 74, Quality Control in Diagnostic Radiology, Report of Task Group #12, Diagnostic X-Ray Imaging Committee, published by Medical Physics Publishing for AAPM, July 2002, page 6–11; and 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, January 1985, pages 1–96. These reports are incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of AAPM Report No. 93 from the AAPM Web site at [http://www.aapm.org/pubs/reports/RPT\\_93.pdf](http://www.aapm.org/pubs/reports/RPT_93.pdf) or from the American Association of Physicists in Medicine, One Physics Ellipse, College Park, MD 20740. You may obtain a copy of AAPM Report No. 74 from the AAPM Web site at [http://www.aapm.org/pubs/reports/rpt\\_74.pdf](http://www.aapm.org/pubs/reports/rpt_74.pdf) or from Medical Physics Publishing, 4513 Vernon Blvd., Madison, WI 53705. You may obtain a copy of AAPM Report No. 14 from the AAPM Web site at [http://www.aapm.org/pubs/reports/rpt\\_14.pdf](http://www.aapm.org/pubs/reports/rpt_14.pdf) or from the Executive Secretary, American Association of Physicists in Medicine, 335 E. 45 Street, New York, NY 10017. A copy of AAPM Reports No. 93, 74, and 14 may be inspected at the NIOSH Docket Office, Robert A. Taft Laboratories, MS–C34, 4676 Columbia Parkway, Cincinnati, OH 45226, or at the National Archives and Records Administration (NARA). For information on the availability of these materials at NARA, call (202) 741–6030 or go to [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(2) Radiographic technique charts shall 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 shall 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 shall be monitored at least quarterly to detect and correct potential dose creep, using methods specified in: American Association of Physicists in Medicine in 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, March 2005. This report is incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of AAPM Report No. 31 from the AAPM Web site at [http://www.aapm.org/pubs/reports/RPT\\_31.pdf](http://www.aapm.org/pubs/reports/RPT_31.pdf) or from the American Institute of Physics, c/o AIDC, 64 Depot Road, Colchester, VT 05446. A copy of AAPM Report No. 31 may be inspected at the NIOSH Docket Office, Robert A. Taft Laboratories, MS–C34, 4676 Columbia Parkway, Cincinnati, OH 45226, or at the National Archives and Records Administration (NARA). For information on the availability of these materials at NARA, call (202) 741–6030 or go to [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html). Radiation exposures shall 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, Revised 2008 (Res. 3), pages 1–6. The ACR Practice Guideline is incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of the ACR Practice Guideline from the ACR Web site at [http://www.acr.org/SecondaryMainMenuCategories/quality\\_safety/guidelines/med\\_phys/reference\\_levels.aspx](http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/med_phys/reference_levels.aspx). You may inspect a copy of the ACR Practice Guideline at the NIOSH Docket Office, Robert A. Taft Laboratories, MS–C34, 4676 Columbia Parkway, Cincinnati, OH 45226, or 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](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html). In addition, the medical physicist shall 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 shall be monitored annually in accordance with the recommendations of AAPM Report No. 93, except for the testing specifically excluded below.

Documentation shall 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, Acceptance Testing and Quality Control of Photostimulable Storage Phosphor Imaging Systems, 2006, 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 shall 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 shall 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. 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, shall 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 shall conform to the recommendations of the National Council on Radiation Protection and Measurements in NCRP Report No. 102, Medical X-ray, Electron Beam, and Gamma-Ray Protection for Energies Up to 50 MeV, Equipment Design, Performance, and Use, 1989; NCRP Report No. 105, Medical Radiation Protection for Medical and Allied Health Personnel, 1989; and in NCRP Report No. 49, Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies up to 10 MeV, 1976. These documents are incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of the NCRP reports from NCRP Publications, 7910 Woodmont Avenue, Suite 400, Bethesda, MD 20814–3095, Telephone (800) 229–2652 or from <http://www.ncrponline.org/Publications/Publications.html>. You may inspect a copy of the ACR Practice Guideline at the NIOSH Docket Office, Robert A. Taft Laboratories, MS–C34, 4676 Columbia Parkway, Cincinnati, OH 45226, or at the National Archives and Records Administration (NARA). For information on the availability of these materials at NARA, call (202) 741–6030 or go to [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

17. 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 shall be interpreted and classified in accordance with the International Labour Office (ILO) International Classification of Radiographs for Pneumoconioses, 2011. The ILO Classification is incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may purchase a copy of the ILO Classification from ILO Publications, International Labour Office, CH–1211 Geneva 22, Switzerland, or from the ILO

Web site at <http://www.ilo.org/publns>. You may inspect the ILO Classification at the NIOSH Docket Office, Robert A. Taft Laboratories, MS–C34, 4676 Columbia Parkway, Cincinnati, OH 45226, or at the National Archives and Records Administration (NARA). For information on the availability of these materials at NARA, call (202) 741–6030 or go to [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html). Chest radiograph interpretations and classifications shall be recorded on a paper or electronic Roentgenographic Interpretation Form (Form CDC/NIOSH (M)2.8).

(b) Radiographs shall 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) shall be provided by a qualified physician who has all required licensure and privileges, and interprets chest radiographs in the normal course of practice.

(c) All interpreters, whenever interpreting chest radiographs made under the Act, shall have immediately available for reference a complete set of the ILO International Classification of Radiographs for Pneumoconioses, 2011.

(d) In all view boxes used for making interpretations:

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

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

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

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

##### **§§ 37.51–37.53 [Redesignated]**

18a. Redesignate §§ 37.51 through 37.53 as §§ 37.52 through 37.54 respectively.

18b. 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 shall provide an initial clinical interpretation and notification, as

specified in § 37.54, of any significant abnormal findings other than pneumoconiosis.

(b) Chest radiographs shall 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 ILO International Classification of Radiographs of Pneumoconioses 2011. The ILO Classification is incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may purchase a copy of the ILO Classification from ILO Publications, International Labour Office, CH-1211 Geneva 22, Switzerland, or from the ILO Web site at <http://www.ilo.org/publns>. You may inspect the ILO Classification at the NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, OH 45226, or at the National Archives and Records Administration (NARA). For information on the availability of these materials at NARA, call (202) 741-6030 or go to [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html). Chest radiograph interpretations and classifications shall 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, shall have immediately available for reference a complete set of NIOSH-approved standard digital chest radiographic images provided for use with the ILO International Classification of Radiographs of Pneumoconioses, 2011. Only NIOSH-approved standard digital images shall 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) Image display devices shall be flat panel monitors displaying at least 3 MP at 10 bit depth. Image displays and associated graphics cards shall meet the calibration and other specifications of the National Electrical Manufacturers Association's Digital Imaging and Communications in Medicine (DICOM) standard Part 14 (PS 3.14-2011): Grayscale Standard Display Function.

DICOM Part 14 is incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of the DICOM standard from the NEMA Web site at <ftp://medical.nema.org/medical/dicom/2011/> or from the National Electrical Manufacturers Association, 1300 N. 17th Street, Rosslyn, VA 22209. You may inspect a copy of the DICOM standard at the NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, OH 45226, or at the National Archives and Records Administration (NARA). For information on the availability of this document at NARA, call (202) 741-6030 or go to [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

Image displays and associated graphics cards shall not deviate by more than 10 percent from the grayscale standard display function (GSDF) when assessed according the American Association of Physicists in Medicine (AAPM) On-Line Report No. 03, Assessment of Display Performance for Medical Imaging Systems, Task Group 18, Imaging Informatics Subcommittee, published by AAPM, April 2005, pages 1-146. This report is incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of On-Line Report No. 03 from American Association of Physicists in Medicine, One Physics Ellipse, College Park, MD 20740 or from [http://www.aapm.org/pubs/reports/OR\\_03.pdf](http://www.aapm.org/pubs/reports/OR_03.pdf). You may inspect a copy of AAPM On-Line Report No. 03 at the NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, OH 45226, or at the National Archives and Records Administration (NARA). For information on the availability of this document at NARA, call (202) 741-6030 or go to [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(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, Assessment of Display Performance for Medical Imaging Systems, Task Group 18, Imaging Informatics Subcommittee, published by AAPM, April 2005, pages 1-146. This report is incorporated by reference. The Director of the Federal

Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of On-Line Report No. 03 from American Association of Physicists in Medicine, One Physics Ellipse, College Park, MD 20740 or from [http://www.aapm.org/pubs/reports/OR\\_03.pdf](http://www.aapm.org/pubs/reports/OR_03.pdf). You may inspect a copy of AAPM On-Line Report No. 03 at the NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, OH 45226, or at the National Archives and Records Administration (NARA). For information on the availability of this document at NARA, call (202) 741-6030 or go to [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html). Viewing displays shall have a maximum luminance of at least 171 cd/m<sup>2</sup>, a ratio of maximum luminance to minimum luminance of at least 250, and a glare ratio greater than 400. The contribution of ambient light reflected from the display surface, after light sources have been minimized, shall be included in luminance measurements.

(3) Displays shall be situated so as to minimize front surface glare. Readers shall 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 shall be taken using calibrated software measuring tools. If permitted by the viewing software, a record shall 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 shall comply with the recommendations of the American Association of Physicists in Medicine AAPM On-Line Report No. 03, Assessment of Display Performance for Medical Imaging Systems, Task Group 18, Imaging Informatics Subcommittee, published by AAPM, April 2005, pages 1-146. This report is incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of On-Line Report No. 03 from American Association of Physicists in Medicine, One Physics Ellipse, College Park, MD 20740 or from [http://www.aapm.org/pubs/reports/OR\\_03.pdf](http://www.aapm.org/pubs/reports/OR_03.pdf). You may inspect a copy of AAPM On-Line Report No. 03 at the

NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, OH 45226, or at the National Archives and Records Administration (NARA). For information on the availability of this document at NARA, call (202) 741-6030 or go to [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(1) If automatic quality assurance systems are used, visual inspection shall 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 shall be performed based on the viewing of images displayed as soft copies using the viewing workstations specified in this section. Classification of radiographs shall not be based on the viewing of hard copy printed transparencies of images that were digitally-acquired.

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

19. 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 shall continue if established prior to the effective date of these regulations.

(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 shall 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 shall 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, shall hereby be 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 shall 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 shall familiarize themselves with the necessary components for attainment of reliable classification of chest radiographs for the pneumoconioses<sup>2</sup> and apply using an Interpreting Physician Certification Document (Form CDC/NIOSH (M)2.12).

20. 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 shall be considered final and reported to MSHA for transmittal to the miner. When agreement is lacking, NIOSH shall obtain a third interpretation from the panel of B Readers. If any two of the three interpretations demonstrate agreement, the result shall 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 shall 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 shall be reported. The only exception to the one minor category principle is a reading sequence of 0/1, 1/0, or 1/0, 0/1, which is not considered agreement.

21. Revise newly designated § 37.54 to read as follows:

**§ 37.54 Notification of abnormal radiographic findings.**

(a) Findings of, or findings suggesting, enlarged heart, tuberculosis, lung cancer, or any other significant abnormal findings other than pneumoconiosis shall be communicated by the first physician to interpret the radiograph to the miner or to the designated physician of the miner indicated on the Miner Identification Document. A notice of the communication shall be submitted to NIOSH. NIOSH will also notify the miner to contact his or her physician when any physician who interprets and classifies the miner's radiograph reports significant abnormal findings other than pneumoconiosis.

(b) In addition, when NIOSH has more than one radiograph of a miner in its files and the most recent examination was interpreted to show enlarged heart, tuberculosis, cancer, complicated pneumoconiosis, and any other significant abnormal findings, NIOSH will submit all of the miner's radiographs in its files with their respective interpretations to a B Reader. The B Reader will report any significant changes or progression of disease or other comments to NIOSH and NIOSH shall submit a copy of the report to the miner or to the miner's designated physician.

(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

<sup>2</sup>NIOSH Safety and Health Topic. Chest Radiography: Radiographic Classification [<http://www.cdc.gov/niosh/topics/chesteradiography/radiographic-classification.html>]. Date accessed: January 25, 2011.

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.

22. 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, shall 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, shall 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 shall promptly make appropriate arrangements for the necessary reexamination.

(c) Failure to comply with paragraph (a) or (b) of this section shall be cause to revoke approval of a plan or any other approval as may be appropriate. An approval which has been revoked may be reinstated at the discretion of NIOSH after it receives satisfactory assurances

and evidence that all deficiencies have been corrected and that effective controls have been instituted to prevent a recurrence.

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

\* \* \* \* \*

23. 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 shall 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 shall 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.

24. 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.

25. 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.

26. 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.

26. 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 shall be submitted to NIOSH and shall 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: October 11, 2011.

**Kathleen Sebelius,**

*Secretary.*

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