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units for approval when listed by a facility seeking approval under §§ 37.43 or 37.44.

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

(i) To ensure high quality chest radiographs:

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

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

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

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

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(j) * * *

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

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

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

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

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

(ii) The miner's Social Security number;

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

(iv) The date of the radiograph.

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

§ 37.42 Approval of roentgenographic facilities.

(a) Approval of roentgenographic facilities given prior to January 1, 1976, shall terminate upon August 1, 1978 unless each of the following conditions have been met:

(1) The facility must verify that it still meets the requirements set forth in the regulations for the second round of roentgenographic examinations (38 FR 20076) and it has not changed equipment since it was approved by NIOSH.

(2) From July 27, 1973, to January 1, 1976, the facility submitted to ALOSH at least 50 roentgenograms which were interpreted by one or more "B" readers not employed by the facility who found no more than 5 percent of all the roentgenograms unreadable.

(b) Other facilities will be eligible to participate in this program when they demonstrate their ability to make high quality diagnostic chest roentgenograms by submitting to ALOSH six or more sample chest roentgenograms made and processed at the applicant facility and which are of acceptable quality to the Panel of "B" readers. Applicants shall also submit a roentgenogram of a plastic step-wedge object (available on loan from ALOSH) which was made and processed at the same time with the same technique as the roentgenograms submitted and processed at the facility for which approval is sought. At least one chest roentgenogram and one test object roentgenogram shall have been made with each unit to be used hereunder. All roentgenograms shall have been made within 15 calendar days prior to submission and shall be marked to identify the facility where each roentgenogram was made, the X-ray machine used, and the date each was made. The chest roentgenograms will be returned and may be the same roentgenograms submitted pursuant to § 37.51.

NOTE: The plastic step-wedge object is described in an article by E. Dale Trout and John P. Kelley appearing in "The American Journal of Roentgenology, Radium Therapy and Nuclear Medicine," Vol. 117, No. 4, April 1973.

(c) Each roentgenographic facility submitting chest roentgenograms for approval under this section shall complete and include an X-ray facility document describing each X-ray unit to be used to make chest roentgenograms 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. 33 (see § 37.43); (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.

(d) Roentgenograms submitted with applications for approval under this section will be evaluated by the panel of "B" Readers or by a qualified radiological physicist or consultant. Applicants will be advised of any reasons for denial of approval.

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

(f) ALOSH may require a facility periodically to resubmit roentgenograms of a plastic step-wedge object, sample roentgenograms, or a Roentgenographic Facility Document for quality control purposes. Approvals granted hereunder may be suspended or withdrawn by notice in writing when in the opinion of ALOSH the quality of roentgenograms 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 roentgenograms and shall be displayed on the mine bulletin board adjacent to the operator's approved plan. The approved plan will be reevaluated by ALOSH in light of this change.

[43 FR 33715, Aug. 1, 1978; 43 FR 38830, Aug. 31, 1978]

EFFECTIVE DATE NOTE: At 77 FR 56730, Sept. 13, 2012, § 37.42 was redesignated as § 37.43 and the newly designated section was revised, and a new § 37.42 was added, effective

Oct. 15, 2012. For the convenience of the user, the added and revised text is set forth as follows:

§ 37.42 Chest radiograph specifications—digital radiography systems.

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) To ensure high quality digital chest radiographs:

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

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

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

(4) Digital radiography system performance, including resolution, modulation transfer function (MTF), image signal-to-noise and detective quantum efficiency must be evaluated and judged acceptable by a qualified medical physicist using the specifications in AAPM Report No. 93, pages 1–68 (incorporated by reference, see § 37.10). Image management software and settings for routine chest imaging must be used, including routine amplification of digital detector signal as well as standard image post-processing functions. Image or edge enhancement software functions must not be employed unless they are integral to the digital radiography system (not elective); in such cases,

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only the minimum image enhancement permitted by the system may be employed.

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

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

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

(C) DICOM Standard PS 3.10-2011.

(D) DICOM Standard PS 3.11-2011

(E) DICOM Standard PS 3.12-2011.

(F) DICOM Standard PS 3.14-2011.

(G) DICOM Standard PS 3.16-2011.

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

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

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

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

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

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

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

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

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

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

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

§ 37.43 Approval of radiographic facilities that use film.

(a) Facilities become eligible to participate in this program by demonstrating their ability to make high quality diagnostic chest radiographs by submitting to NIOSH six or more sample chest radiographs made and processed at the applicant facility and which are of acceptable quality to one or more individuals selected by NIOSH from the panel of B Readers. Applicants must also submit a radiograph of a plastic step-wedge object¹ or other test object (available on loan from NIOSH) that was made and processed at the same time with the same technique as the radiographs submitted and processed at the facility for which approval is sought. At least one chest radiograph and one test object radiograph must have been made with each unit to be used hereunder. All radiographs must have been made within 15 calendar days prior to submission and must be marked to identify the facility where each radiograph was made, the X-ray machine used, and the date each was made. The chest radiographs will be returned and may be the same radiographs submitted pursuant to § 37.50.

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

¹The 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.

to be used to make chest radiographs under the Act. The form must include:

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

(2) The deficiencies found;

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

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

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

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

(e) NIOSH may require a facility periodically to resubmit radiographs of a test object, sample radiographs, or a Facility Certification Document for quality control purposes. Approvals granted hereunder may be suspended or withdrawn by notice in writing when in the opinion of NIOSH the quality of radiographs or information submitted under this section warrants such action. A copy of a notice withdrawing approval will be sent to each operator who has listed the facility as its facility for giving chest radiographs and must be displayed on the mine bulletin board adjacent to the operator's approved plan. The approved plan will be reevaluated by NIOSH in light of this change.

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

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