

§ 37.42

42 CFR Ch. I (10–1–13 Edition)

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

(i) To ensure high quality chest radiographs:

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

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

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

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

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

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

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

(8) The geometry of the radiographic system shall insure that the central axis (ray) of the primary beam is perpendicular to the plane of the film surface and impinges on the center of the film;

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

(j) Radiographic processing:

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

meticulously employed for manual processing.

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

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

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

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

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

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

(ii) The miner’s Social Security number;

(iii) The miner’s date of birth; and

(iv) The date of the radiograph.

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

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

§ 37.42 Chest radiograph specifications—digital radiography systems.

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

(b) Every digital chest radiograph taken as required under this section must be a single posteroanterior projection at full inspiration on a digital detector with sensor area being no less than 1505 cm square centimeters with a

minimum width of 35cm. The imaging plate must have a maximum pixel pitch of 200µm, with a minimum bit depth of 10. Spatial resolution must be at least 2.5 line pairs per millimeter. The storage phosphor cassette or digital image detector must be positioned either vertically or horizontally so that the image includes the apices and costophrenic angles of both right and left lungs. If the detector cannot include the apices and costophrenic angles of both lungs as described, then two side-by-side images can be obtained that together include the apices and the costophrenic angles of both right and left lungs.

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

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

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

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

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

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

(g) Radiographs must be obtained only with equipment having a beam-limiting device that does not cause large unexposed boundaries. The beam-limiting device must provide rectangular collimation. Electronic post-image acquisition “shutters” available on some CR and DR systems that limit the size of the final image and that simulate collimator limits must not be used. The use and effect of the beam

limiting device must be discernible on the resulting image.

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

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

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

(i) To ensure high quality digital chest radiographs:

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

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

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

(4) Digital radiography system performance, including resolution, modulation transfer function (MTF), image signal-to-noise and detective quantum efficiency must be evaluated and

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

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

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

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

(C) DICOM Standard PS 3.10–2011.

(D) DICOM Standard PS 3.11–2011

(E) DICOM Standard PS 3.12–2011.

(F) DICOM Standard PS 3.14–2011.

(G) DICOM Standard PS 3.16–2011.

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

(iii) Exposure parameters as defined in the DICOM Standard PS 3.16–2011 must additionally be provided, when

such parameters are available from the facility digital image acquisition system or recorded in a written report or electronic file and either transmitted to NIOSH or stored at the facility and available for inspection by NIOSH for 5 years after the examination.

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

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

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

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

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

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

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

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

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

[77 FR 56730, Sept. 13, 2012]