

§ 37.50

control devices are used, calibration for chest imaging must be documented using the actual voltages and image capture systems. Radiological exposures resulting from at least ten (randomly selected) digital chest images obtained at the facility must be monitored at least quarterly to detect and correct potential dose creep, using methods specified in AAPM Report No. 31 (incorporated by reference, see §37.10). Radiation exposures must be compared to a professionally accepted reference level published in the American College of Radiology (ACR) Practice Guideline for Diagnostic Reference Levels in Medical X-Ray Imaging, pages 1-6 (incorporated by reference, see §37.10). In addition, the medical physicist must submit an annual assessment of measured or estimated radiation exposures, with specific recommended actions to minimize exposures during examinations performed under this part.

(3) For each digital radiography device and system, performance must be monitored annually in accordance with the recommendations of AAPM Report No. 93 (incorporated by reference, see §37.10), except for the testing specifically excluded below. Documentation must be maintained on the completion of quality assurance testing, including the reproducibility of X-ray output, linearity and reproducibility of mA settings, accuracy and reproducibility of timer and kVp settings, accuracy of source-to-detector distance, and X-ray field focal spot size, selection, beam quality, congruence and collimation. For DR systems, the following tests listed in AAPM Report No. 93 are not required under this part:

- (i) Section 8.4.5: Laser beam function
- (ii) Section 8.4.9: Erasure Thoroughness
- (iii) Section 8.4.11: Imaging Plate (IP) Throughput

(4) Facilities must maintain documentation, available for inspection by NIOSH for 5 years, of the ongoing implementation of policies and procedures for monitoring and evaluating the effective management, safety, and proper performance of chest image acquisition, digitization, processing, compression, transmission, display, archiving, and retrieval functions of

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digital radiography devices and systems.

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

[77 FR 56732, Sept. 13, 2012]

EFFECTIVE DATE NOTE: At 77 FR 56732, Sept. 13, 2012, §37.44 was added, effective Oct. 15, 2012.

SPECIFICATIONS FOR INTERPRETATION, CLASSIFICATION, AND SUBMISSION OF CHEST ROENTGENOGRAMS

EFFECTIVE DATE NOTE: At 77 FR 56733, Sept. 13, 2012, the undesignated center heading above §37.50 was revised, effective Oct. 15, 2012. For the convenience of the user, the revised text is set forth as follows:

SPECIFICATIONS FOR INTERPRETATION, CLASSIFICATION, AND SUBMISSION OF CHEST RADIOGRAPHS

§37.50 Interpreting and classifying chest roentgenograms.

(a) Chest roentgenograms shall be interpreted and classified in accordance with the ILO Classification system and recorded on a Roentgenographic Interpretation Form (Form CDC/NIOSH (M)2.8).

(b) Roentgenograms shall be interpreted and classified only by a physician who regularly reads chest roentgenograms and who has demonstrated proficiency in classifying the pneumoconioses in accordance with §37.51.

(c) All interpreters, whenever interpreting chest roentgenograms made under the Act, shall have immediately available for reference a complete set of the ILO International Classification of Radiographs for Pneumoconioses, 1980.

NOTE: This set is available from the International Labor Office, 1750 New York Avenue, NW., Washington, DC 20006 (Phone: 202/376-2315).

(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.

[43 FR 33715, Aug. 1, 1978, as amended at 49 FR 7564, Mar. 1, 1984]

EFFECTIVE DATE NOTE: At 77 FR 56733, Sept. 13, 2012, § 37.50 was revised, effective Oct. 15, 2012. For the convenience of the user, the revised text is set forth as follows:

§ 37.50 Interpreting and classifying chest radiographs—film.

(a) Chest radiographs must be interpreted and classified in accordance with the Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses (incorporated by reference, see § 37.10). Chest radiograph interpretations and classifications must be recorded on a paper or electronic Roentgenographic Interpretation Form (Form CDC/NIOSH (M) 2.8).

(b) Radiographs must be interpreted and classified only by a physician who reads chest radiographs in the normal course of practice and who has demonstrated proficiency in classifying the pneumoconioses in accordance with § 37.52.

(1) Initial clinical interpretations and notification of findings other than pneumoconiosis under § 37.50(a) must be provided by a qualified physician who has all required licensure and privileges, and interprets chest radiographs in the normal course of practice.

(2) [Reserved]

(c) All interpreters, whenever interpreting chest radiographs made under the Act, must have immediately available for reference a complete set of the standard radiographs for use with the Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses (incorporated by reference, see § 37.10).

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

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

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

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

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

§ 37.51 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 (insert) 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 ALOSH from the physician's files six sample chest roentgenograms which are considered properly classified by the Panel of "B" readers. The six roentgenograms shall consist of two without pneumoconiosis, two with simple pneumoconiosis, and two with complicated pneumoconiosis. The films will be returned to the physician. The interpretations shall be on the Roentgenographic Interpretation Form (Form CDC/NIOSH (M) 2.8) (These may be the same roentgenograms submitted pursuant to § 37.42), or;

(ii) Satisfactory completion, since June 11, 1970, of a course approved by ALOSH on the ILO or ILO-U/C Classification systems or the UICC/Cincinnati classification system. As used in this subparagraph, "UICC/Cincinnati classification" means the classification of the pneumoconioses devised in 1968 by a Working Committee of the International Union Against Cancer.

(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 roentgenograms for roentgenographic quality and in the use of the ILO Classification for interpreting chest roentgenograms 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 ALOSH at a time and place specified by ALOSH. Each physician must bring a