

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

(a) *Applications for facility approval.*

(1) Facilities seeking approval must demonstrate the ability to make high quality digital chest radiographs by submitting to NIOSH digital radiographic image files of a test object (*e.g.*, a plastic step-wedge or chest phantom which will be provided on loan from NIOSH) as well as digital radiographic image files from six or more sample chest radiographs that are of acceptable quality to one or more individuals selected by NIOSH from the panel of B Readers and a qualified medical physicist or consultant, both designated by NIOSH. Image files must be submitted on standard portable media (compact or digital video disc) and formatted to meet specifications of the Digital Imaging and Communications in Medicine (DICOM) standard PS 3.12–2011 (incorporated by reference, see § 37.10). Applicants will be advised of any reasons for denial of approval. All submitted images must be made within 60 days prior to the date of application using the same technique, equipment, and software as will be used by the facility under the requested approval. At least six chest radiographs and one test object radiograph must have been made with each digital radiographic unit to be used by the facility under the requested approval. The corresponding radiographic image files must be submitted on standard portable media (compact or digital video disc) and formatted to meet specifications of the current DICOM Standard PS 3.12–2011. Documentation must include the following: the identity of the facility where each radiograph was made; the X-ray machine used; and the model, version, and production date of each image acquisition software program and hardware component. The submitted sample digital chest image files must include at least two taken with the detector in the vertical position and two in the horizontal position where the imaging system permits these positions, and at least two chest images must be from persons within the highest quartile of chest diameters (28 cm or greater).

(2) Each radiographic facility submitting chest radiographic image files for approval under this section must complete and include an X-ray Facility Certification Document (Form CDC/NIOSH (M)2.11) describing each X-ray system component, and the models and versions of image acquisition hardware and software to be used to make digital chest radiographs under the Act. The form must include:

(i) A copy of a dated report signed by a qualified medical physicist, documenting the evaluation of radiation safety and performance characteristics specified in this section for each digital radiography system;

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

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

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

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

(b) Facilities must maintain ongoing licensure and certification under relevant local, State, and Federal laws and regulations for all digital equipment and related processes covered under this part.

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

(d) NIOSH may periodically require a facility to resubmit radiographic image files of the NIOSH-supplied test object (*e.g.*, step-wedge or chest phantom), sample radiographs, or a Facility Certification Document. Approvals granted to facilities under this section may be suspended or withdrawn by notice in writing when, in the opinion of NIOSH, deficiencies in the quality of radiographs or information submitted under this section warrant such action. A copy of a notice suspending or withdrawing approval will be sent to each

operator that has listed the facility for its use under this Part and must be displayed on the mine bulletin board adjacent to the operator's approved plan. The operator's approved plan may be reevaluated by NIOSH in response to such suspension or withdrawal.

(e) A qualified medical physicist who is familiar with the facility hardware and software systems for image acquisition, manipulation, display, and storage, must be on site or available as a consultant. The physicist must be trained in evaluating the performance of radiographic equipment and facility quality assurance programs, and must be licensed/approved by a State or Territory of the United States or certified by a competent U.S. national board.

(f) Facilities must document that testing performed by a qualified medical physicist has verified that performance of each image acquisition system for which approval is sought met initial specifications and standards of the equipment manufacturer and performance testing as required under paragraphs (b), (e), and (g) of this section.

(g) A formal written quality assurance program must be established at each facility addressing radiation exposures, equipment maintenance, and image quality, and must conform to the standards in AAPM Report No. 74, pages 1-19, 47-53, and 56, and AAPM Report No. 116, sections VIII, IX, and X (incorporated by reference, see §37.10).

(1) Applications for facility approval must include a comprehensive assessment by a qualified medical physicist within 12 months prior to application addressing the performance of X-ray generators, automatic exposure controls, and image capture systems. The assessment must comply with the following guidelines: AAPM Report No. 93, pages 1-68; AAPM Report No. 74, pages 6-11; and AAPM Report No. 14, pages 1-96 (incorporated by reference, see §37.10).

(2) Radiographic technique charts must be used that are developed specifically for the X-ray system and detector combinations used, indicating exposure parameters by anatomic measurements. If automated exposure control devices are used, calibration for chest imaging must be documented

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

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

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

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

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(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]

§ 37.45 Protection against radiation emitted by radiographic equipment.

Except as otherwise specified in § 37.41 and § 37.42, radiographic equipment, its use and the facilities (including mobile facilities) in which such equipment is used, must conform to applicable State or Territorial and Federal regulations. Where no applicable regulations exist, radiographic equipment, its use and the facilities (including mobile facilities) in which such equipment is used must conform to the recommendations in NCRP Report No. 102, NCRP Report No. 105, and NCRP Report No. 147 (incorporated by reference, see § 37.10).

[77 FR 56733, Sept. 13, 2012]

SPECIFICATIONS FOR INTERPRETATION, CLASSIFICATION, AND SUBMISSION OF CHEST RADIOGRAPHS

§ 37.50 Interpreting and classifying chest radiographs—film.

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

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

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(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.

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§ 37.51 Interpreting and classifying chest radiographs—digital radiography systems.

(a) For each chest radiograph obtained at an approved facility using a digital radiography system, a qualified and licensed physician who reads chest radiographs in the normal course of practice must provide an initial clinical interpretation and notification, as specified in § 37.54, of any significant abnormal findings other than pneumoconiosis.

(b) Chest radiographs must be classified for pneumoconiosis by physician readers who have demonstrated ongoing proficiency, as specified in § 37.52(b), in classifying the pneumoconioses in a manner consistent with the Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses (incorporated by reference, see § 37.10). Chest radiograph interpretations and classifications must be recorded on a paper or electronic Roentgenographic