

42 C.F.R. § 37.44

Approval of radiographic facilities that use digital radiography systems.

(a) 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.

(1) 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.

(2) 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.

(3) 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.

(4) 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).

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