

§ 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 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

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.

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).

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