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]

§ 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 object[1] 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 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

[1] The 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.

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 56731, Sept. 13, 2012]

§ 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