5. CHEST X-RAY SCREENING EXAMINATION

5.1 Overview

A chest X-ray (one postero-anterior view) will be obtained for each participant in the chest X-ray group at each Screening Center (SC). SCs are responsible for scheduling the participant for the X-ray, taking the X-ray, having the X-ray read and interpreted by a radiologist and documenting the performance and results of the X-ray. This chapter describes these procedures. It also provides the Lung Screening Study requirements for examiner training and certification and quality assurance procedures for this examination.

The chest X-ray should be scheduled as soon as possible after randomization. In cases where the participant does not complete the chest X-ray as scheduled, SCs may attempt to reschedule through January 31, 2001. Procedures for scheduling screening visits are discussed in Chapter 3. The Lung Screening Study protocol requires that every attempt be made to reschedule the examination if it is inadequate or cannot be done for some reason. It is anticipated that such problems should be minimal for the chest X-ray examination. If the radiology technologist determines that the quality of the film is inadequate, it is expected that every attempt will be made to repeat the chest X-ray during the same visit. However, if the interpreting radiologist finds the chest X-ray to be inadequate, the participant should be asked to return for a repeat examination. All screening examinations must be completed by January 31, 2001.

5.2 Participant Preparation

Several steps in the process of participant preparation will be standardized across all SCs. The participant will be told that the examination is a screening examination for lung cancer, not a routine examination, and that s/he should consult his/her own physician for evaluation of any symptoms and for routine medical care. In addition, the participant will be told that s/he will receive written documentation of the results of all screening examinations within three weeks, and will be contacted by telephone or certified mail for all positive screens. The participant will be given a brief description of the examination.

5.3 Examination Procedures

A postero-anterior X-ray will be taken at a tube-to-receiver distance of 6 to 10 feet. The participant will disrobe above the waist. Hospital gowns will be provided in accordance with standard procedures at the SC. The technologist will explain the procedure and position the participant. The participant will be instructed to inhale deeply and to hold his/her breath while the X-ray is taken.

If a participant has a condition such as severe kyphosis and cannot assume the correct position for a PA view of the lung, it is acceptable to do an AP view of the lung. The fact that an AP film was taken and the reason for it must be recorded in the Comments section of the Chest X-ray Screening Examination Form (XRY2).

The technologist performing the X-ray will make the initial judgement about quality of the X-ray before the participant leaves the SC. The quality will be such that the lung vessels are clearly visible and the mediastinal structures are sufficiently penetrated to allow for adequate visualization. If the X-ray is determined to be inadequate it will be repeated. Reasons for inadequacy are described in section 5.7.1. The SCs will do their best to ensure that when a repeat X-ray is necessary, it is taken during the same visit. No more than two X-ray attempts will be made in one visit. No more than three visits are allowed to obtain a chest X-ray. If an X-ray is initially determined to be adequate but upon quality assurance review it is found to be inadequate, a second X-ray should not be performed.

X-rays determined by the technologist to be adequate will be sent to the study radiologist for interpretation. The radiologist may, at this point, determine the X-ray examination to be inadequate due to poor film quality, because the X-ray film has been lost, or for some other reason. In such cases, the participant will be asked to return for a repeat examination. If the X-ray is judged to be adequate, it should be read by the study radiologist in a timely manner such that the results can be reported to the participant in accordance with the protocol.

5.4 Equipment Specifications

The chest X-ray will be taken using high-kVp equipment (110-150 kVp) at a tube-to-receiver distance of 6-10 feet. Film will be wide latitude type with a 12 to 1 standard grid or higher. Thoravision and CR chest X-ray systems may be used in addition to conventional.

The SC is required to send documentation of equipment specifications, including information on film type (e.g., symmetric or asymmetric film screen combination, etc.) to the CC. The CC will forward all equipment specifications to the NCI for approval. The NCI will be responsible for reviewing equipment specifications sent from each SC and will make the final approval decision. This should be done before screening begins and whenever equipment is replaced during the course of the study.

The quality of the X-ray will be such that lung vessels are clearly visible and the mediastinal structures are sufficiently penetrated to allow for adequate visualization. The quality of the X-ray also shall be judged as adequate by the reviewing radiologist.

5.5 Examiner Qualifications, Training, and Certification

The chest X-ray examination requires two examiners: the radiology technologist and the radiologist. The minimum qualifications for these individuals and the Lung Screening Study training protocol are discussed in this section.

5.5.1 Minimum Qualifications for Examiners

Technologists will be American Registry of Radiologic Technologists (ARRT) certified radiologic technologists. The radiologists (interpreters and QA examiners) will be American Board of Radiology (ABR) board certified or board eligible (chest). The SC must report the qualifications and licensure of each examiner by submitting a completed Record of Experience, Credentials, and Training (ECT) (Appendix 9-1) to the CC. In lieu of submitting copies of diplomas and certificates, the SC should attach a letter from the department chairman stating that the technologist is an ARRT certified radiologic technologist and that the radiologist is ABR board certified. For any technologist who is not ARRT certified or any radiologist/interpreter/QA examiner who is not ABR board certified or board eligible, the SC Principal Investigator must document and certify adequate training and experience in a letter to be submitted with a completed ECT to the CC. The CC will review all ECTs and if the qualifications meet the CC criteria, the CC will recommend approval to the NCI. If the qualifications do not match the requirements, the CC will request an exception approval from the NCI on a case-by-case basis. The ECT must be approved by the NCI prior to the initiation of screening activities.

5.5.2 Training Protocol

The SC Coordinator will be responsible for training the technologist and the interpreting radiologist on the use of the study forms and SC administrative procedures.

5.5.3 Examiner Certification

No additional certification of the technologist or radiologist is required for this examination. The qualifications of these individuals will serve as certification of their technical expertise.

5.6 Documentation of the Examination

Information documenting that the X-ray was taken and the interpretation by the radiologist will be recorded on the Chest X-ray Screening Examination Form (XRY2). In addition to the examination result, the Lung Screening Study films will be stored, and the radiologist will assign a level of referral for the exam indicating the severity of the abnormality, if any, and whether or not the SC recommends follow-up for this examination.

5.6.1 XRY2

The Chest X-ray Screening Examination Form (XRY2) (Appendix 5-1) will be used to document the results and findings of the examination. The form provides documentation of the fact that the examination was carried out, whether the results were negative or abnormal, and a description of abnormal findings. The SC Coordinator will complete the top administrative section, and the Technologist will complete Part A. If adequate films are obtained, Parts B and C of the form will be completed by the interpreting radiologist. If the technologist does not obtain adequate films, Part B will be left blank and the technologist will complete Part C. Thoravision and CR chest X-ray systems may be used in addition to conventional. If more than one chest X-ray system (e.g., Thoravision, CR, or conventional) is used at an SC, record the type of system used for specific X-rays in the XRY2 Comments section. Specifications for the XRY2 are provided in Appendix 5-2. It is the responsibility of the SC Coordinator to train the technologists and radiologists in the use of the form.

After completion, the SC Coordinator will manually edit the examination form. Any data retrieval involving the examiner will be performed as expeditiously as possible. The form will be transmitted to the CC for data entry, as described in Chapter 9.

5.6.2 The Chest X-ray Screening Examination Quality Assurance Form

The Chest X-ray Screening Examination Quality Assurance Form (XRQ2) (Appendix 5-3) will be used to document the results and findings of the quality assurance review of an X-ray examination. The form provides documentation of the QA review, and a description of the findings. This form will be used as part of the QA review of selected X-rays described in section 5.9.3. This form is to be completed by a staff member and the QA Examiner for the chest X-ray exam. The QA Examiner is defined as the radiologist who re-interprets the chest X-ray for QA purposes. The QA Examiner must be blinded to the results of the original chest X-ray examination.

The SC staff member will complete the administrative section and Part A, and the QA Radiologist will complete Parts B and C. Specifications for the XRQ2 are provided in Appendix 5-4. It is the responsibility of the SC Coordinator to train the technologists and radiologists in the use of the form.

After completion, the SC Coordinator will manually edit the examination form. Any data retrieval involving the examiner will be performed as expeditiously as possible. The form will be transmitted to the CC for data entry, as described in Chapter 9.

5.6.3 Storage of Lung Screening Study Chest X-ray Films

The X-ray films will be labeled with the participant's name and PID. The SC is responsible for storing the films for each of the participant's chest X-ray screening examination. Inadequate films should be retained at the SC until adequate films are obtained. Upon collection of an adequate film, inadequate films may be discarded. Chest X-ray films for the Lung Screening Study should be stored in a way that is consistent with the confidentiality agreement for the study. It is recommended that a participant's films not be stored with the participant's medical record or with other films that are not related to the Lung Screening Study, but if an SC wishes to store Lung Screening Study data in the regular medical record, it must submit to NCI (via the CC) documentation of the methods that will be used to maintain confidentiality of the data.

The chest X-ray films will be the photo documentation. It is acceptable for SCs to utilize digital storage of films (as in CR systems), but the capability to retrieve the films at any time must be maintained. If digital storage is used, a backup digital copy of the films should also be maintained.

5.7 Interpretation of Findings

Each examination will be reviewed by a board certified or board eligible (chest) radiologist and abnormalities will be recorded. The examination result should be an interpretation of the examination findings only. The participant's prior medical history or prior radiologic examinations should not be considered when assigning an examination result. The following definitions of negative and abnormal findings are provided. These definitions will be used by the radiologist in recording his/her findings on the Chest X-ray Screening Examination Form.

5.7.1 Criteria for Determination of a Negative or an Inadequate X-ray

- Negative Screen, No Abnormalities (NG):
  - Chest X-ray evaluation reveals no abnormalities.

- Inadequate (IN):
  - An X-ray will be judged to be inadequate if the entire lung and mediastinal structures are not included on the film. Reasons for inadequacy may include, but are not limited to:
    - Participant refusal;
    - Motion or processing artifact;
    - Inadequate inspiration;
    - Excessive rotation;
    - Over or under penetration.

5.7.2 Classification and Definition of Abnormal Examination Results

- Positive Screen – Abnormalities suggestive of malignancy (Referral Required):

  Evaluation reveals any of the following pulmonary abnormalities:

  - nodule (circular opacity $\leq$ 3.0 cm in diameter);
  - mass (any discrete opacity > 3.0 cm in diameter without regard to contour, homogeneity, or border characteristics);
  - hilar or mediastinal lymph node enlargement (exclude calcified nodes);
  - major atelectasis/lobar collapse;
  - infiltrate/consolidation/alveolar opacity;
  - pleural mass.

- Negative Screen, Other Abnormalities (Referral Required):

  Evaluation reveals, but is not limited to, any of the following pulmonary abnormalities:

  - scarring, pulmonary fibrosis, honeycombing;
  - pleural fluid;
  - bone or soft tissue lesion;
  - cardiac abnormality, cardiomegaly, congestive heart failure.

- Negative Screen, Other Abnormalities (Referral Optional):

  Evaluation reveals, but is not limited to, any of the following pulmonary abnormalities:

  - granuloma(s);
  - pleural fibrosis, pleural plaque;
  - COPD/emphysema/bullae.

5.8 Reporting Results to Participants and Physicians

The SC will report results and all findings of the X-ray screening examination in writing to the participant and to the participant's primary care physician within three weeks of the screening visit. Results and findings will be sent with a cover letter from the SC. The SC may choose to incorporate results and findings into the cover letter, may attach a copy of the XRY2 form, may attach a copy of the radiologist's dictated report, or may produce a customized report of results and findings. The combination of documents sent must reflect the result and all findings of the examination. In addition to written notification, positive screens will also be reported to participants by telephone. If the participant is unavailable by telephone, results will be sent via certified mail. Positive screens will be reported to physicians either by telephone, FAX, or certified mail. Negative screens with abnormalities will be reported to the participant and his/her physician according to standard radiologic practice at the SC.

Participants with a result of "Positive Screen" will be referred to their primary care physician or their physician of choice for diagnostic evaluation and possible treatment. If a participant does not have a primary care physician, the SC will offer a list from which the participant may choose a physician to receive the results. In all cases where there is a positive chest X-ray screen, referral will be recommended as outlined in Section 5.8.1 below. The SC will continue to monitor and follow-up all participants who have a positive screening result.

The examiner will assign the results of the examination exclusively according to the findings of the examination, without taking into consideration the results of findings of any previous examination. If, after the result has been assigned, the SC wishes to compare the result or findings of the examination to those of prior examinations (radiographs taken prior to the participant's enrollment in the trial), it may do so as an "internal referral." The participant will be notified of the results of the internal referral. If the SC deems it necessary, or if the participant requests it, the SC may then refer the participant "externally" for further evaluation to the participant's physician of choice. All internal and external referrals for a positive screen will be considered part of the diagnostic evaluation of the positive screen.

5.8.1 Diagnostic Follow-up Recommendations

Participants with positive chest X-ray screens will be referred to their primary care physicians or their physicians of choice. They and their personal physicians will also be advised that it is recommended that they be referred to a recognized specialist for follow-up until nodule status is determined. The Follow-Up Log (Appendix 6-15) will be used to document the status of this referral (e.g., saw physician, has not seen physician but appointment scheduled, plans to schedule appointment, no plans for follow-up). If requested by the participant, the SC Coordinator will offer the participant a list from which s/he may choose a specialist to receive the findings of the examination.

No formal recommendations for diagnostic follow-up of positive screens will be given. The SC should refer inquiries to providers they deem to be expert in the field, and provide the 1-800-4-CANCER hotline number as an additional source of information. It is expected that diagnostic follow-up will be state of the art when handled by SC referral providers.

5.8.2 Lung Cancer Confirmation

The final diagnosis of lung cancer will be based on histopathologic or cytopathologic criteria. The cancer will be coded according to ICD-O codes by a trained medical coder at the SC. Pathology reports that support the cancer diagnosis will be obtained for all participants.

5.8.3 Treatment Recommendations for Individuals Diagnosed with Lung Cancer

No treatment recommendations will be given for individuals diagnosed with cancer. Participation in the Lung Screening Study does not preclude a participant from involvement in any treatment protocol.

5.9 Examination Standardization and Quality Control

For the chest X-ray, there are several aspects of the procedure that will be part of the quality assurance plan. These include quality control of the equipment, quality control of the image produced by the technologist, and quality control of the interpretation of the findings by the radiologist.

5.9.1 Quality Control of Equipment

Quality control of the equipment will be assured by each individual institution, all of which will be state licensed. The SCs should maintain and update quality assurance records for processor testing, including sensitometric testing. Quality control will also include yearly documentation of kVp calibration within 5 percent, radiation output assessed by use of an anatomic phantom, documentation of film-screen contact, and demonstration that the X-ray spectrum is free of low energy contaminants through use of half-value layer, collimation, dose exposure and function of automatic exposure control.

The SC will maintain quality assurance records for maintenance and quality assurance checks of the equipment such that the records are readily available for auditing during site visits. These records should not be sent to the CC or NCI.

5.9.2 Quality Assurance of Technologists

For each radiology technologist, the CC will monitor the number of and reasons for inadequate examinations. Based on the data from the examination forms, the CC will summarize the number of inadequate examinations and the reasons for the inadequate examinations. These reports will be provided to NCI and the SCs on a weekly basis during the screening period of the study (through January 31, 2001). Additionally, the CC will develop reports to monitor the number of chest X-rays that are inadequate by technologists and by SC, and the number of chest X-rays reported due to poor film quality.

5.9.3 Quality Control of X-ray Interpretations

Quality control of X-ray interpretations will be performed at each SC. A sample of 20 screening X-rays will be reinterpreted by a second designated qualified radiologist (QA examiner). Films for QA review should be chosen using either the scheme employed to select chest X-rays for PLCO quality assurance or a similar scheme. To the extent possible, participants with abnormal findings should be included in the sample of examinations that are reinterpreted. Second radiologists are blinded to the results of the initial interpretation. If circumstances are such that examiners review their own film, a letter should be submitted to NCI explaining and justifying why this situation is occurring. If, in the process of selecting exams for QA review/repeat an exam with a result of Inadequate (IN) is chosen, the

QA exam should not be performed and another exam should be chosen. Such exams should not be selected for QA because the original reason for inadequacy may be out of the examiner's control and lead to further inadequate exams. If upon QA review of an "adequate" exam, the QA examiner determines that it was actually inadequate, the X-ray procedure should not be repeated, that is, a new X-ray should not be obtained.

To assist the QA process, a form is provided on which the second radiologist will record his/her findings. This form is the same as the XRY2, except that it is titled XRQ2 (Appendix 5-3).

It should be noted that referral of the participant will be based on the "worst case" result when two radiologists have reviewed the X-ray film. Because reporting to the participant is required within three weeks of the visit, it is important that review by a second radiologist be completed in a timely manner so that reporting can take place within the designated time period.

It is the responsibility of the SC to develop a SC-specific plan for the duplicate reading for chest X-rays for quality assurance purposes. In addition, each SC will report the results of quality assurance of the technologists and radiologists to NCI at the end of the screening phase. Information to be reported includes the number of positive (Abnormal Suspicious) examinations, the number of X-rays repeated due to poor film quality, the number of X-rays (negative and abnormal) read by a QA radiologist and the level of agreement between the two radiologists.

Appendices for Chapter 5

5-1 Chest X-ray Screening Examination Form

5-2 Specifications for Completion of the Chest X-ray Screening Examination Form

5-3 Chest X-ray Screening Examination Quality Assurance Form

5-4 Specifications for Completion of the Chest X-ray Screening Examination Quality Assurance Form