Specifications for Completion of the Chest X-ray Screening Examination Quality Assurance Form (XRQ2)

This form is to be completed by a SC staff member and the QA Examiner for the chest X-ray examination. The QA Examiner is defined as the radiologist who re-interprets the chest X-ray film 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 top administrative section and the QA Radiologist will complete Parts B and C of the form. Part A of the form (Chest X-ray Examination Results) will be left blank.

Although this form is designed to be scanned by an Optical Mark Reader, it will be sent to the CC to be keyed. Therefore, bubbles for items which are also written do not need to be completed (e.g., dates).

Administrative Section:

PID: Affix a PID label to the space provided in the upper right corner of the form. The barcode should be aligned directly over the shaded box, with the eye-readable number toward the inside of the form. The barcode should be toward the outer edge of the form.

1. **Date of Examination:** Enter the date of the review of the chest X-ray film for quality assurance. Month and day should be zero filled (e.g., 02/07). For the year, all four (4) digits need to be filled.

2. **Satellite Center:** This field will not be used in the Lung Screening Study.

3. **Study Year:** This field will not be used in the Lung Screening Study

4. **Visit Number:** Darken the circle corresponding to the number of times the participant visited the SC to complete the original chest X-ray examination. Copy this information from the XRY2 form which contains the original results.

5. **Reason for Repeat Visit:** If the chest X-ray was completed at a repeat visit (visit number 2 or 3), copy the reason for the repeat visit from the original XRY2 form.

Form Processing: These are the steps that should be completed in order to process the examination form. The items that will be used in the Lung Screening Study SC will be Manual Review Completed, Data Retrieval, and Final Disposition. All others should be left blank.

Manual Review Completed: Darken this circle after the form has been reviewed by SC staff to make sure that the information is complete, legible and consistent. (Refer to Chapter 9 for instructions on performing a manual review of forms.)

Data Retrieval: Complete this item to indicate the status of data retrieval. If data retrieval was attempted, regardless of whether or not additional information was collected, darken the circle next to "Attempted." If no data retrieval was required, darken the circle next to "None Required."

Final Disposition: The SC is required to assign a final disposition to each form. There are two final dispositions:

- Final Complete (FCM): This disposition is assigned when all sections of the XRQ2 have been completed and edited by the SC.

- Final Incomplete (FIC): This disposition is assigned when information is missing from the XRQ2, which cannot be corrected. This includes errors that cannot be corrected because data retrieval is not required for the item, or because the information could not be obtained, even with data retrieval.

Part A: Chest X-Ray Examination Findings (Completed by Technologist):

This part of the form should be left blank.

Part B: Chest X-Ray Examination Findings (Completed by Radiologist):

Part B is to be completed by the QA radiologist. At some SCs, the SC staff will complete this section using the QA radiologist's written report. If the result of the examination (Item C.1) is "Inadequate," Part B should be left blank.

1. **Abnormality Noted:**

   No: No abnormality was seen. (Go to Part C.)

   Yes: An abnormality (either suspicious for lung cancer or abnormal for any other reason) was seen.

2. **Record Information for Each Abnormality:** Complete this item for up to five radiographic abnormalities. Complete the chart by darkening the circle corresponding to the correct response in each column and row. Enter information about the first abnormality in the row labeled "1", the second abnormality in the row labeled "2", etc.

   Location: If an abnormality is seen in both the right and left hemithorax or in more than one section of a hemithorax (e.g., a nodule or mass seen in more than one hemithorax) darken the circles for all locations that apply. In the case of abnormalities which may be widespread (e.g., fibrosis or chronic obstructive pulmonary disease (COPD)) the location "diffuse" may be applicable. If an abnormality is seen in only one hemithorax, darken the circle for NA for the other hemithorax.

   Right Hemithorax:

   Upper 1/3: The abnormality was found in the upper 1/3 of the right hemithorax.

Middle 1/3: The abnormality was found in the middle 1/3 of the right hemithorax.

Lower 1/3: The abnormality was found in the lower 1/3 of the right hemithorax.

Diffuse: The abnormality was spread throughout the right hemithorax. If diffuse is marked, no other location in the right hemithorax should be marked.

NA: The abnormality was not in the right hemithorax.

Left Hemithorax:

Upper 1/3: The abnormality was found in the upper 1/3 of the left hemithorax.

Middle 1/3: The abnormality was found in the middle 1/3 of the left hemithorax.

Lower 1/3: The abnormality was found in the lower 1/3 of the left hemithorax.

Diffuse: The abnormality was spread throughout the left hemithorax. If diffuse is marked, no other location in the left hemithorax should be marked.

NA: The abnormality was not in the left hemithorax.

The only instances where it is appropriate for the examiner to code NA for both the left and the right hemithorax is for the following abnormalities:

#20: Bone/soft tissue lesion;
#21: Cardiac abnormalitiy/cardiomegaly/congestive heart failure; and
#88: Other

Description of Abnormality: Darken one circle corresponding to the description of the abnormality. Please note that codes 01, 02, 07, and codes 13 through 16 (in bold) are considered to be a positive screen for lung cancer (i.e., for these abnormalities, the examination result in Part C.1. must be coded "Positive Screen - Referral Required"). The abnormalities are listed below:

01 = Nodule (1 - 30 mm)
02 = Mass (> 30 mm)
07 = Pleural mass
08 = Granuloma
13 = Right hilar/mediastinal lymph nodes (exclude calcified nodes)
14 = Left hilar mediastinal lymph nodes (exclude calcified nodes)
15 = Major atelectasis/collapse
16 = Infiltrate (consolidation/alveolar opacity)

17 = Scarring/pulmonary fibrosis/honeycombing
18 = Pleural fibrosis/pleural plaque
19 = Pleural fluid
20 = Bone/soft tissue lesion
21 = Cardiac abnormality/cardiomegaly/congestive heart failure
22 = COPD/emphysema/bullae
88 = Other (SPECIFY): The abnormality is other than those listed above. Specify the abnormality on the line provided in the "Description of Abnormality" column.

Part C: Chest X-Ray Interpretation Results

Part C is to be completed by the QA radiologist. At some SCs, the SC staff will complete this section using the QA radiologist's written report.

1. **Examination Results:** Darken the circle corresponding to the result of the examination. Definitions of examination results are given below:

   Positive Screen - Referral Required: Evaluation reveals any of the following pulmonary abnormalities:

   - nodule (a circular opacity less than or equal to 3.0 cm in diameter)
   - mass (any discrete opacity greater than 3.0 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

   A referral to the participant's physician of choice for evaluation of these results is necessary, unless s/he was already referred for follow-up of the results of the original interpretation of the chest X-ray film.

   Negative Screen - No Abnormalities :

   Evaluation reveals no abnormalities.

   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

Inadequate: The X-Ray films were inadequate and sufficient information could not be obtained. Record the reason(s) for an inadequate examination in Item C.2 below.

If there is an abnormality which is indicative of a positive screen and one which is indicative of a negative screen - other abnormalities, only "Positive Screen - Referral Required" should be marked.

2. Reason for Inadequate Exam: Darken one or more circles to indicate the reason for an inadequate exam. If the exam was inadequate for reasons other than or in addition to poor film quality and/or films lost, darken the circle for "Other" and specify the reason(s) on the lines provided.

3. Level of Referral: Darken the circle corresponding to the level of referral.

1 - Significant Abnormality, Referral: The examination result was "Positive Screen - Referral Required," or the result was "Negative Screen - Other Abnormalities" or "Inadequate" and an abnormality considered to be significant and requiring referral was found.

2 - Moderate Abnormality, Referral: The examination result was "Negative Screen - Other Abnormalities" or "Inadequate," and an abnormality considered to be moderate and requiring referral was found.

3 - Slight Variation from Normal, No Referral: The examination result was "Negative Screen - Other Abnormalities" or "Inadequate," and an abnormality considered to be a slight variation from normal, not requiring referral, was found.

4 - Normal/Result Not Available, No Referral: The examination result was "Negative Screen - No Abnormalities" or "Inadequate," and no abnormalities were seen or the result of the examination is not available.

4. Comments: The comments box should be used to record information that may help clarify a situation, provide further information for an item in another part of the form, and to record additional "Other (Specify)" information, if needed.

If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes." Enter the item number indicating the item to which the comments are related. The item number should include a letter indicating the section of the form, and a number indicating the item within that section (e.g., B.2.1). If the comment is not related to a specific item on the form, use the item number for the comments section itself (C.4). Then enter the comments in the space provided to the right of the item number. If more space is needed, darken the circle next to "Continued," and record additional comments on a Comments Continuation Form (CCF) (Appendix 9-11).

Note that if a dictated report is not provided, the Comments section should be used to describe significant and minor abnormalities occurring with a negative screen.

5. Radiologist Identification: *(This item should be completed by the QA Radiologist.)*

Sign the form in the space provided, enter your 4-digit ID number. If this section was completed by a member of the SC staff using the QA radiologist's written report, the SC staff member should enter the QA radiologist's name and staff ID, then sign his/her own name below the name of the QA radiologist.