

## Lung Screening Study

### Specifications for Completion of the Spiral CT Examination Form (SCT)

This form is to be completed by an SC staff member and the Examiners (Technologist and Radiologist). The SC staff member will complete the Administrative Section (A-D), the Technologist will complete Section E, and the Radiologist will complete Section F and G of the form.

Specifications for completing each item of the form are given below:

#### Administrative Section:

**Participant ID:** Affix a PID label to the space provided.

**A. Screening Center:** Enter the 2-digit SC ID.

**B. Date of Examination:** Enter the date of the examination. Month, day and the last two digits of the year should be zero filled (e.g., 01/07/01).

**C. Visit Number:** Enter the number of times the participant visited the SC to complete this examination. For example, if this is the first time the participant has come to the SC, enter "1." If the examination was not completed for some reason in the first visit and the participant returned to the SC a second time to complete the spiral CT examination, enter "2." If this is the third visit, enter "3."

**Reason for Repeat Visit:** If this is a repeat visit, record the reason for the repeat visit. Refer to the examination form from the previous visit for this information. The purpose of this item is to provide important information to the Examiner regarding why the participant is returning for a repeat visit. Some example reasons:

*"Prior scan was of poor quality."*

This might be entered if the participant's prior scan was of poor quality during the previous visit, but s/he was willing to return to the SC for a repeat scan. This information will alert the Examiner to explore the reasons for this problem.

*"Participant out of time. Unable to complete Spiral CT exam."*

This might be entered if the participant's schedule did not allow him to remain at the SC to complete the spiral CT screening examination during a previous visit, and the examination was rescheduled.

**D. Form Processing:** These are the steps that should be completed in order to process the examination form.

**Manual Review Completed:** Check this box after the form has been reviewed by SC staff to make sure that the information is complete, legible and that the appropriate boxes are checked. (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, check the box next to "Attempted." If no data retrieval was required, check the box 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 SCT have been completed and edited by the SC.
- Final Incomplete (FIC): This disposition is assigned when information is missing from the SCT, 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.

### **SCT Examination Findings:**

#### **E. SCT Examination Findings (Completed by Technologist):**

1. **Number of Attempts:** Check the box corresponding to the number of attempts made to take the spiral CT. No more than two attempts are permitted at one visit. Responses are explained below:

**None:** There is no attempt to take the spiral CT. This might occur if the participant entered the dressing room to prepare for the exam, but for some reason there was no attempt to take the spiral CT (participant became ill, could not wait, etc.). (Go to Item 3.)

If the participant never prepared for the exam in any way, the exam is considered not done. The SCT would not be filled out in such cases.

**One:** The spiral CT is attempted once, regardless of whether or not it is successfully completed.

**Two:** The spiral CT is attempted twice, regardless of whether or not it is successfully completed.

2. **Adequate Scans Obtained:** Before the participant leaves the SC, the Technologist will evaluate the spiral CT for quality. Scans judged to be adequate by the Technologist are then sent to the study Radiologist who will also judge their adequacy. A scan cannot be judged to be adequate if both lungs are not completely scanned, from apex through the lung bases, including both costophrenic angles. Responses are explained below:

**No:** The scan is judged to be inadequate. (Go to Item 3 and complete Section E and G of the examination form.)

**Yes:** The scan is judged to be adequate. (Go to Item 4).

3. **Reason for Inadequate Scans:** This item is completed only if the answer to Item 2 is "No." Check one or more boxes to indicate the reason(s) for the inadequate scans. An explanation of each reason for inadequate scans is given below:

Participant Refusal: The participant is unwilling to cooperate, i.e., stand in the proper position, hold breath, etc.

Equipment Malfunction: This includes any problem with the radiographic equipment that prevents the successful completion of the spiral CT scan.

Poor Image Quality: An image was obtained, but it is not adequate for interpretation. Poor image quality may be due to motion artifact, incomplete evaluation of the thorax, inappropriate CT technique, excessive noise.

Other (SPECIFY): Describe any other situation in which adequate scans could not be obtained in the space provided.

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, check the box next to "No." If there are additional comments, check the box 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., E.3). If the comment is not related to a specific item in Section E of the form, use the item number for the comments section itself (E.4). Then enter the comments in the space provided to the right of the item number. If more space is needed, check the box next to "Continued" and record additional comments on a Comments Continuation Form (CCF) (Appendix 9-11).

5. **mA setting (1 second scan):** Enter a three digit mA setting used to perform the spiral CT scan. The setting will range from 60-120 mA. For two digit doses, zero-fill the first digit.
6. **Technologist Identification:** Sign the form in the space provided, and enter your 4 digit staff ID number.

## F. SCT Examination Findings (Completed by Radiologist)

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

1. **Abnormality Noted:**

**No:** No abnormality was seen. (Go to Part G.)

**Yes:** An abnormality (either suspicious for lung cancer or abnormal for any other reason) was seen. Record information for each abnormality in the chart.

2. **Record Information for Each Abnormality:** Complete this item for up to six abnormalities. Complete the chart by recording or circling the number(s) corresponding to the correct response(s) 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.

**Description of Abnormality:** Record one number corresponding to the description of the abnormality from the list below. Please note that codes 01, 03, 04, and 05 are considered to be a positive screen for lung cancer. For these abnormalities, the examination result in Part G.1. must be coded "Positive Screen – Abnormalities Suggestive of Malignancy." Please note that 88 Other (SPECIFY) should be used to designate all other abnormalities not listed below, including any other abnormalities suspicious for malignancy.

- 01 = **Spiculated nodules/masses  $\leq$  3 mm**
- 02 = Smooth, non-calcified nodules/masses  $\leq$  3 mm
- 03 = **Non-calcified nodules/masses  $>$  3 mm**
- 04 = **Focal parenchymal opacification (consolidation or ground glass attenuation)**
- 05 = **Endobronchial lesions**
- 08 = Granuloma
- 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): This category should be used to designate all other abnormal findings, including any suspicious for malignancy. Specify the abnormality on the line provided in the "Description of Abnormality" column.

**Size:** Record the length of the lesion's maximum dimension in millimeters in the first column; record the length of the maximum perpendicular dimension (that is, the longest length that is perpendicular to the maximum dimension) in millimeters in the second column. Record dimensions for codes 01, 02, 03, 04, 05, 08, and 20. Do not record dimensions for codes 17, 18, 19, 21, and 22. In the case of code 88, Other (SPECIFY), record the dimensions if applicable; if dimensions are not available or not applicable, record 99 or place a line through the coding boxes. Zero-fill all measurements (e.g., 005).

**Location:** Record the slice number for abnormality codes 01, 02, 03, 04, 05, 08, 20 and any applicable 88's. Abnormality codes 17, 18, 19, 21, and 22 do not require slice numbers. If an abnormality appears on more than one slice, record the slice number where it is first seen. Circle all appropriate lobe numbers that apply for each abnormality. If the location is not determined, circle 08. If codes 01-07 are not applicable (this will only be the case for #20, bone/soft tissue lesion, #21, cardiac abnormality/cardiomegaly/ congestive heart failure, and in certain situations, #88, other), circle 08.

## G. SCT Interpretation Results

Section G is to be completed by the interpreting radiologist. At some SCs, the SC staff will complete this section using the interpreting radiologist's written report. In cases where an adequate scan was not obtained (E.2 = No), Part G should be completed by the technologist to document the result of the examination as "Inadequate."

- 1. Examination Results:** Check the box corresponding to the result of the examination. Definitions of examination results are given below:

Negative Screen – No Abnormalities

Evaluation reveals no abnormalities.

Inadequate:

The Spiral CT scans were inadequate and sufficient information could not be obtained to determine the examination result. Record the reason(s) for an inadequate examination in Item G.2 below.

Positive Screen – Abnormalities Suggestive of Malignancy:

Evaluation reveals any of the following pulmonary abnormalities:

- Spiculated, non-calcified nodules/masses  $\leq 3$  mm
- non-calcified nodules/masses  $> 3$  mm
- focal parenchymal opacification (consolidation or ground glass attenuation)
- endobronchial lesion
- other abnormalities such as large hilar masses, large mediastinal masses, bony or pleural masses, major atelectasis, or other findings suspicious for malignancy

Negative Screen - Significant abnormalities requiring further evaluation, but not suggestive of malignancy:

Evaluation may include, but is not limited to:

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

Negative Screen – Smooth, non-calcified nodules/masses  $\leq 3$  mm:

- limited to smooth, non-calcified nodules/masses  $\leq 3$  mm

Negative Screen - Minor abnormalities:

These may include, but are not limited to:

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

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 – Abnormalities Suggestive of Malignancy" should be marked.

2. **Reason for Inadequate Exam:** Check one or more boxes to indicate the reason for an inadequate exam. If the exam was inadequate for reasons other than those listed, check the box for "Other" and specify the reason(s) on the lines provided.
3. **Comments:** The comments box should be used to record information from sections F and G 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, check the box next to "No." If there are additional comments, check the box 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., F.2). If the comment is not related to a specific item in parts F or G of the form, use the item number for the comments section itself (G.3). Then enter the comments in the space provided to the right of the item number. If more space is needed, check the box 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.

4. **Radiologist Identification:**  
This item should be completed by the radiologist. In the case where an adequate scan was not obtained, the technologist will complete this item.

Sign the form in the space provided, and enter your 4-digit ID number. If this section was completed by a member of the SC staff using the radiologist's written report, the SC staff member should enter the radiologist's name and staff ID, then sign his/her own name below the name of the radiologist. If adequate scans were not obtained and the technologist assigned the examination result of "Inadequate," the technologist should record his/her name and ID in the space provided.