Appendix 7-4

Lung Screening Study

Medical Records Abstraction Quality Assurance Plan

It is the responsibility of the Coordinating Center (CC) to ensure the Quality Assurance of the Medical Record Abstraction at each SC. The CC MRA Coordinator will monitor the Quality Assurance of Medical Record Abstraction at each SC and provide input for resolution of Medical Record Abstraction issues. To achieve this, the CC MRA Coordinator will implement the following Medical Records Quality Assurance Plan. The primary goals of the plan include:

- Ensuring that the SC MRAs utilize standard abstracting procedures;
- Ensuring a high level of accuracy for data elements;
- Evaluating the quality of data abstracted from the diagnostic evaluation procedures; and
- Improving the quality of data abstracted by providing continuous feedback to the SC MRA in areas where problems are identified.

The CC will re-abstract 20% of all DE forms. This process will be concurrent with the SC Medical Record Abstraction to ensure timely feedback to SCs. Qualified MRAs at the CC will re-abstract this 20% sample of Medical Records. The CC and the SCs will follow these procedures for the Quality Assurance of Medical Record Abstraction:

- The SCs will submit DE forms to the CC on a weekly basis as they are finalized;
- The CC will receipt each DE form;
- The CC will identify every fifth DE form from each SC receipted for MRA Quality Assurance;
- The CC will record the PIDs from those DE forms identified;
- Each week, the CC MRA Coordinator will request that the SCs provide copies of all Medical Records documenting diagnostic evaluation and staging procedures for the identified PIDs;
- The SC MRA will copy the requested Medical Records, remove all personal identifiers from the Medical Records, and submit these on a weekly basis to the CC on a Forms Transmittal Log (Manual of Operations, Appendix 9-15);
- The CC MRAs will re-abstract these Medical Records on a separate DE form;
- The CC MRA Coordinator will compare the re-abstracted DE form to the DE form submitted by the SC for each identified PID;
- The CC MRA Coordinator will list the discrepant information by PID at each SC;
- The CC MRA will report the results to the NCI for review and discussion; and
- The CC MRA Coordinator will provide feedback to the SCs on a regular basis.

The CC MRA Coordinator will continue to monitor the number of positive screens reported at each SC to determine whether to modify the number of cases requested from each SC and re-abstracted at the CC.