

## HALT-C Trial Q x Q

### SPECT Scan – QLFT AS

Form # 192 Version A: 06/15/2000 (Rev. 04/04/2003)

**Purpose of Form #192:** This form is used to record the results of the SPECT liver-spleen scan as determined by the University of California – Irvine SPECT scan reading center.

**When to complete Form #192:** This form is completed for all patients participating in the QLFT Ancillary Study at the following clinical sites.

- Site 14 (University of Colorado Health Sciences Center).
- Site 15 (University of California - Irvine).
- Site 19 (Virginia Commonwealth University).

The SPECT scan reading center should complete and data enter form #192 for patients at the following study visits:

- Lead-In Phase patients: Baseline visit (W00)
- Express patients: Randomization visit (R00)
- Randomized patients: Month 24 (M24) and Month 48 (M48).

**How to access Form #192:** Data entry of this form will take place only at the University of California – Irvine SPECT scan reading center. In order to data enter Form #192, NERI must set up a special data entry account for your user name.

In order to access Form #192, log on to the HALT-C Production Data Management System (DMS). From the main menu, select "Central Lab D E". Then select "Enter Form 192". Enter the HALT-C patient ID number and the visit number in the appropriate boxes. Click the "Submit" button. A data entry screen for Form #192 will appear.

- The patient ID will begin with 14 (UCHSC), 15 (UCI), or 19 (VCU).
- Valid visit numbers are W00, R00, M24, and M48.

After you have data entered the entire form, it will be saved in the system. You may perform edits to the form by following the same directions above for the given patient.

**Note on form completion and data entry:**

- Forms must be completed in black ink. Pencil is not acceptable. Blue ink does not photocopy well.
- The DMS has been programmed to expect specific ranges for the values of its data. If the obtained value falls outside of this range, however, it should still be recorded on the paper form and data entered. Upon entering an out of range value in the DMS, a data entry validation error screen will appear. If the value originally entered by the user is the actual obtained value and matches the value recorded on the paper, then this problem value may be overridden. In order to override the value, explain your reasons for doing so in the space provided (e.g., "This is the correct value."), and enter your initials in the appropriate box. Then click on the button to "Set Override".
- Corrections are made by drawing a single line through the errant data and writing in the correct data. You must initial and write the date you make any change.

- When a result will not completely fill the blank spaces, use a "0" to fill the space.
  - If a result of 592 has space for 4 digits, write in: 0 5 9 2
  - If a result of 3.647 has space for 5 digits, write in: 3 . 6 4 7 0
- If data was not collected or not analyzed, the data collector should write a concise explanation including her/his initials and the date on the hard copy of the form. When data entering the form, enter the special value "-9" in the DMS. An error message will now appear on your screen.
- If the value will never be obtained in the future, type the explanation in the "Reason" box. Enter the data collector's initials in the space provided and click on the "Set Override" button.
- If the value may be obtained in the future, click on the "Ignore Value" button. An edit report will be generated after the rest of the form is entered. The form will have a "Pending Edits" status until the value is completed and data entered, or determines to be unobtainable and an override "Reason" provided.

### **SECTION A: GENERAL INFORMATION**

- A1. Affix the patient ID label in the space provided.
  - If the label is not available, record the ID number legibly.
- A2. Enter the patient's initials exactly as recorded on the Trial ID Assignment form.
- A3. Enter the three-digit code corresponding to this visit.
- A4. Record the date the form was completed using MM/DD/YYYY format.
- A5. Enter the initials of the person completing the form.

### **SECTION B: SPECT SCAN**

- B1. Enter the date the SPECT scan test was performed in MM/DD/YYYY format.
- B2. Record ROI's around the summarized transaxial SPECT LSS for Total Liver Counts.
  - The expected range is range is  $1.00 \times E^6 - 1.00 \times E^7$  CPM.
- B3. Record ROI's around the summarized transaxial SPECT LSS for Total Spleen Counts.
  - The expected range is range is  $1.00 \times E^5 - 4.00 \times E^7$  CPM.
- B4. Record ROI's around the summarized transaxial SPECT LSS for Total BM Counts.
  - The expected range is  $2.00 \times E^3 - 2.00 \times E^6$  CPM.
- B5. Record the number of frames.
  - The number of frames can be no fewer than 20 and no greater than 60.
- B6. Record the Pixel Counts on the posterior planar LSS for the hottest area over the liver.
  - The pixel count can be no fewer than 30 CPM and no greater than 700 CPM.
- B7. Record the Pixel Counts on the posterior planar LSS for the hottest area over the spleen.
  - The pixel count can be no fewer than 30 CPM and no greater than 700 CPM.

- B8. Record the Pixel Counts of Bone Marrow.
  - The pixel count can be no fewer than 2 CPM and no greater than 70 CPM.
- B9. Record the Liver Right Lobe Length.
  - The length can be no fewer than 10.0 CM and no greater than 40.0 CM.
- B10. Record the Liver Left Lobe Length.
  - The length can be no fewer than 6.0 CM and no greater than 30.0 CM.
- B11. Record the Spleen Length.
  - The length can be no less than 0.0 CM and no greater than 30.0 CM.

Note on Questions B12 – B17: The expected range for these questions is 1000 – 5000 CPM/Voxel.
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- B12. Record the Large ROI Maximum Concentration Liver.
- B13. Record the Large ROI Mean Concentration Liver.
- B14. Record the Standard Deviation (SD) for Large ROI Liver.
- B15. Record the Large ROI Maximum Concentration Spleen.
- B16. Record the Large ROI Mean Concentration Spleen.
- B17. Record the Standard Deviation (SD) for Large ROI Spleen.

Note on Questions B18 – B23: The expected range for these questions is 100 – 5000 CPM/Voxel.
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- B18. Record the Liver Small ROI Mean for probe 1.
- B19. Record the Liver Small ROI Max for probe 1.
- B20. Record the Liver Small ROI Mean for probe 2.
- B21. Record the Liver Small ROI Max for probe 2.
- B22. Record the Liver Small ROI Mean for probe 3.
- B23. Record the Liver Small ROI Max for probe 3.

Note on Questions B24 – B29:

The expected range for these questions is 50 – 1000 CPM/Voxel.

- B24. Record the Spleen Small ROI Mean for probe 1.
- B25. Record the Spleen Small ROI Max for probe 1.
- B26. Record the Spleen Small ROI Mean for probe 2.
- B27. Record the Spleen Small ROI Max for probe 2.
- B28. Record the Spleen Small ROI Mean for probe 3.
- B29. Record the Spleen Small ROI Max for probe 3.
- B30. Record the Voxel length/side (mm).
  - The Voxel length/side value can be no less than 0.01 mm and no greater than 9.99 mm.

**SECTION C:**

The calculations from the SPECT scan data can be accessed through the AS Reports menu item on the DMS by clicking on Main Menu\ AS Reports\QLFT Study\ SPECT Scan Calculations.