

## Chapter 17

### DXA Scanning and Reading Protocol

1.0	Introduction .....	17-3
2.0	Study Logistics .....	17-3
2.1	Screening, Eligibility and Enrollment.....	17-3
2.2	Division of Quality Assurance Responsibilities .....	17-4
2.2.1	Clinical Center Responsibilities.....	17-4
2.2.2	LIFE DXA Reading Center Responsibilities .....	17-4
2.3	Training and Certification of LIFE DXA Operators .....	17-5
2.4	LIFE DXA Reading Center Review of DXA Scans.....	17-6
2.4.1	Certification Scans.....	17-6
3.0	DXA Scan Acquisition and Analysis .....	17-6
3.1	Participant Data.....	17-6
3.1.1	Patient Biography.....	17-7
3.3	Whole Body Scans.....	17-7
3.3.1	Participant Set-up.....	17-8
3.3.2	Whole Body Analysis.....	17-8
3.4	Scan Flagging Criteria .....	17-9
4.0	Scanner Quality Control .....	17-9
4.1	Daily Phantom Scans.....	17-10
4.2	Cross-Calibration of Scanners.....	17-11
4.3	Machine, Software and Service Problems .....	17-11
4.4	Software Change Control .....	17-12

<b>5.0</b>	<b>Data Management .....</b>	<b>17-12</b>
<b>5.1</b>	<b>Hard Copies of Scans .....</b>	<b>17-12</b>
<b>5.2</b>	<b>Transfer of Data to LIFE Reading Center .....</b>	<b>17-12</b>
<b>5.3</b>	<b>Return Materials Sent by the Reading Center .....</b>	<b>17-12</b>
<b>APPENDIX A. CROSS CALIBRATION PHANTOM PROTOCOLS...</b>		<b>17-15</b>
<b>Whole Body Phantom Protocol .....</b>		<b>17-16</b>

#### **Study Documents**

- Batch Record Form
- Body Composition Form
- Hologic Maintenance/Repair Log Sheet
- DXA Scanning Log

## **Chapter 17**

### **DXA Scanning and Reading Protocol**

#### **1.0 INTRODUCTION**

The purpose of this manual is to describe the DXA whole body composition quality assurance program for the clinical centers participating in the LIFE study. It provides information specific to the LIFE Study and is intended as a supplement to the Hologic Users' Manual.

To use this manual effectively, it is essential that to have read and understood the entire Hologic User's Manual. The study densitometry operators are required to have participated in a Hologic training session and should be familiar with all instrument features and procedures discussed in the Hologic Users' Manual.

This manual was developed primarily for the QDR 4500 series of scanners, but later model scanners may also be used.

During the study, any questions regarding procedures that arise should be directed to:

LIFE DXA Reading Center  
Telephone:  
Fax:  
Email:

#### **2.0 STUDY LOGISTICS**

During the first year of the study, DXA scans will be acquired using the Hologic Scanners as described below. At the end of the first year, follow - up scans will only be acquired on the same machine.

##### **2.1 Screening, Eligibility and Enrollment**

DXA scans will be obtained on the QDR 4500 or later Hologic model scanner in the LIFE study. No other scanner should be used.

Scans will be acquired at the baseline visit and at the 12-month follow-up visit.

##### **2.2 Division of Quality Assurance Responsibilities**

### **2.2.1 Clinical center responsibilities**

The clinical centers must ensure the overall quality and completeness of the DXA data and that all protocols and procedures are strictly followed. Specific responsibilities include the following:

1. Require that technicians are properly trained and certified;
2. Identify a chief densitometry operator to train and supervise other operators;
3. Perform and review daily QC scans and scheduled calibration scans of phantoms;
4. Assure that proper archiving and back-up procedures for patient scans are performed and that archives are stored securely on optical disks until the end of the study;
5. At specified intervals, send the following materials to the LIFE DXA Reading Center :
  - a. printouts of plots of the daily QC data
  - b. updated copies of patient scan and machine repair logs
  - c. original printouts of other requested scans
6. Reanalyze centrally reviewed scans, as requested by the Reading center;
7. Assure proper functioning of hardware and service from Hologic
  - a. notify Hologic and the LIFE DXA Reading Center of any machine or software problems, or if the QDR machine is being relocated
  - b. record machine/software problems and service on the "service log"
  - c. perform 5 QC phantom scans before, (if possible) and after service
  - d. perform 5 QC phantom scans before and after a machine relocation
8. Contact the densitometry specialists at the Reading Center with any questions or problems which cannot be dealt with in the monthly batch mailings.

### **2.2.2 LIFE DXA Reading Center responsibilities**

The following are the responsibilities of the LIFE DXA Reading Center:

1. Promptly review the daily QC phantom scan data received from each clinical center in order to identify surges or drifts in machine performance;
2. Incorporate new participant data into the study wide database;
3. Review certification scans and return results to each clinical center;
4. Arrange for calibration of all DXA instruments using phantoms;
1. Prepare quality control summary reports for LIFE Steering Committee review;
2. Identify possible sources of error, and suggest possible solutions.

**(However, the LIFE DXA Reading Center will not be responsible for the solution of a hardware or software problem; that will rest with the clinical center and Hologic.)**

Any questions or correspondence regarding the manual or the technical aspects of the DXA measurements should be directed to:

LIFE DXA Reading Center  
Telephone:  
Fax:  
Email:

### **2.3 Training and Certification of LIFE DXA Operators**

To obtain consistent results, the densitometry operators must be aware of possible sources of error that may affect data collection and analysis. Only those operators who have been certified through Hologic training and the LIFE DXA Reading Center review are allowed to perform the scanning and analysis for this study.

Anyone performing scans for the LIFE study must meet the following requirements:

1. Read and understand both the Hologic Densitometer manual and this manual;
2. Satisfactory review of each operator's initial scans by coordinating center.  
In order for an individual technician to be certified to perform scans of a given skeletal site, the first 10 scans done on study participants for each operator must be sent to the coordinating center for review. Original printouts of scans should be sent to the reading center at the address listed above as soon as the first 10 scans have been completed.
3. Successfully pass the Reading center scan analysis tests;

It is the clinical center's responsibility to ensure that as new operators are brought into the study, all of the above certification criteria are met. Since the Hologic central training sessions are held infrequently, there may be several months delay between when a new operator is hired and when certification is complete.

### **2.4 LIFE DXA Reading Center Review of DXA Scans**

Scan analysis quality will be ensured by a central review of analyzed participant scans. Whenever scans are to be reviewed centrally:

1. An original printout of the scan should be sent to the Reading Center.
2. It is the responsibility of the LIFE clinic operator to reanalyze the scan according to the Reading Center comments and return a printout of the reanalyzed scan with an electronic copy to the Reading Center for verification.

#### **2.4.1 Certification Scans**

10 whole body scans done on study participants by each operator must be sent to the LIFE DXA Reading Center to certify the operator.

### **3.0 DXA Scan Acquisition and Analysis**

Standard scanning and analysis procedures for the whole body bone density measurements are described in detail in the Hologic Users' manual. Some of the information from the Hologic manual is repeated in this document for emphasis. Please note, however, that some of the scanning evaluation protocols for this study differ from those detailed by Hologic.

#### **3.1 Participant data**

This section describes in detail the specific procedures to be conducted for the LIFE study with respect to entering the patient biography, scanning the patient and analyzing the scans.

Prior to scanning each participant, a LIFE Body Composition Scan form should be completed for that participant.

Each participant visit will be assigned a visit code. This code should be entered on the Bone Density form and in the Comment field in the Patient Biography. Use 0 (zero) for baseline, 1 for the first annual visit.

##### **3.1.1 Patient Biography**

Operator scan code, DOB, Sex, Weight, Height and Ethnic fields should be entered as described in the Hologic manual.

Patient Name Field: Enter the participant's Study ACROSTIC. Use Capital letters.

**Comment: (Enter visit number, 0 or 1)**

**Scan Code: \*\*\* Zip:**

**DOB:** 10/20/30 **Sex:** F **Weight:** 120 **Height:** 5' 0"

**Ethnic:** W **Ref MD:**LIFE

### Figure 1. Patient Biography Screen

Patient ID Field: The enrollment ID consists of a 6 character combination of the clinic letter code and the patient number. **It is the single most important piece of information associated with each patient and must be entered precisely.**

Consider the sample patient discussed above. Suppose the clinic ID is P4 and the patient number is 1000, then Figure 1 demonstrates the correct method for entering the study ID within the Patient ID field.

Comment Field: Please enter the number (0, or 1.) corresponding to the particular visit in the "Comment" field.

Ref MD Field: Enter LIFE

Be sure to use zeroes (0) and not the letter "O" when entering data into the Patient Biography field.

## **3.3 Whole Body Scans**

The HOLOGIC Operator's Manual should be consulted for the proper whole body scanning and analysis procedures. Clarifications and exceptions for the LIFE Study are noted below.

### **3.3.1 Participant set - up**

When performing whole body scans, attention has to be paid to the following points:

1. Have the participant remove all clothing, including shoes, and dress them in a hospital gown. Check that no metal or plastic objects remain in the scanning area. This includes hair clips and pins, underwire bras, snaps, zippers and buttons. Have patient remove any jewelry, earrings, bracelets, watches, or rings.
2. For follow-up (repeat) scans in the same subject, retrieve prior (baseline) scan using patient ID code as the record locator. Note the subject position on the baseline scan and duplicate this position as closely as possible on the follow-up scan. If, for example, part of the subject's body was outside the scan field on the baseline scan, try to duplicate this as closely as possible in the repeat the scan. All other scanning position parameters should be followed per instructions below.
3. Position the participant in the center of the scanning table with their head

just below the head of the table. It is extremely important that the participant is correctly positioned dead center on the table. The arms should be separated from the sides of the body with the hands placed palm down, within a few centimeters of the table edge.

4. Place a loop of tape around the top of the feet so that the feet are straight (or slightly inverted) - this will help to prevent motion during the scan and bring the femoral necks into better position for scan analysis.
5. Verify that the participant is aligned with the scanner axis (solid line on the table). If during scanning it is apparent that part of the patient's body lies outside the scan field, restart the scan.
6. The participant should be positioned as comfortably as possible since this reduces the chances of unwanted movements. In general, try to avoid to use any pillows or blankets. If the participant feels uncomfortable in that position, you may use pillows for the head only after the upper half of the scan is done. You may then carefully place a pillow under the head of the participant without causing motion artifacts. This procedure should be practiced with the participant before scanning. If the participant cannot lie flat at all without the aid of a pillow (due to kyphosis), use a radio- lucent pillow.
7. If the participant is very tall, try to include their feet in the scan by placing their head near the very top of the table.
8. Instruct the participant not to move until the end of the measurement.

Scan acquisition

QDR 4500

Scan mode - single beam. Scan mode - Array

### **3.3.2. Whole Body Scan**

#### **Analysis Baseline**

1. Locate the horizontal shoulder line just below patient's chin.
2. The vertical shoulder lines should bisect the shoulder joints and separate the arms from the trunk. Avoid including any body soft tissue in the arm ROI.
3. Align the spine ROI with the curvature of the spine, if possible. Divide the spine at the T12-L1 disc space.
4. The horizontal line above the pelvis should be just above the iliac crest. The angled lines defining the pelvic triangle so that they bisect the femoral neck.
5. The vertical line between the legs should run between the patient's feet and evenly divide the legs. The lateral leg lines should be moved to include as much of the thigh soft tissue as possible without crossing the hands.
6. Cutline placement should be such that left/right symmetry is maintained i.e. placement of lines on the left side of the body should match those on the right.



## Follow-up

For evaluations of follow-up measurements, display the baseline evaluation using the COMPARE feature and compare it to your current image on the screen. Match the location of the region markers as closely as possible to the baseline measurement. Optimally matched in this context means that the markers should be at the same position between the body regions as on the baseline image. If adjustment cannot be done satisfactorily, it will be necessary to reanalyze the baseline scan. If it is necessary to reanalyze the baseline measurement, all subsequent follow-up measurements should be reanalyzed using COMPARE.

### 3.4 Scan Flagging criteria **General**

- Scan has unusual appearance or is difficult to analyze
- Any of the following in scan field (either in the bone or soft tissue)

Unusual anatomical variations

Surgical hardware

Patient motion during scan

Superimposed buttons, pins, zippers, pacemakers, vitamin pills, etc.

- ROI used on follow-up is different size than used at baseline
- Bone edges have been altered in any way
- Follow-up scans cannot be reasonably matched to baseline analysis

### **Whole Body**

- Patient motion without rescanning (these scans are extremely susceptible to motion artifacts)
- Significant changes in positioning between baseline and follow - up scan.
- Unable to fit both arms in scan field

## 4.0 Scanner Quality Control

Monitoring of machine performance throughout the study is the joint responsibility of the individual clinical centers and the LIFE DXA Reading Center.

### 4.1 Daily Phantom Scans

Perform the daily QC phantom scans as outlined in the Hologic manual. The results of these scans should be reviewed locally for abrupt changes in machine performance and the results sent to the coordinating center once a month. Points of procedure to note:

## QDR 4500

1. Create only one patient biography per phantom. Avoid duplication of phantom biographies by using the patient menu to select the appropriate biography prior to scanning the phantom.
2. Scan the phantom on top of the pad. Ensure alignment with the scanner axis by using the laser cross - hairs.
3. Add the scan data to the QC database immediately after scanning and analysis are complete.

Use the plot feature daily to verify that the BMD, BMC and AREA values of your scanner are within normal limits - for the Whole Body phantom, check BMD and %Fat values and plot manually on graph paper. If the most recent scan falls outside the limits, reposition the phantom and repeat the scan. **If the second scan also falls outside the limits, contact both Hologic and the LIFE DXA Reading Center.**

After the phantom scan has been analyzed and added to the QC database, delete that day's **scan** from the hard disk. **Note: the Whole Body phantom scans should be archived to an optical disk before being deleted from the hard drive.**

If the CV of the BMD exceeds 0.60% please contact both the Reading Center and Hologic to initiate appropriate action.

Check the system drift weekly by pressing <R> while viewing the plot. The slope of the calculated regression line should be within the range of the standard deviation shown. If the drift is greater than the standard deviation, contact both Hologic and the Reading center.

Generate a printout of the daily phantom plots (BMD, BMC and AREA for hip, spine and ESP phantoms; BMD and % Fat for the Whole Body phantom) once a week on your designated "QC day." This will facilitate detection of long-term drifts as well as short-term inconsistencies.

Original printouts including the scan results of the most recent daily phantom QC plots (BMD, BMC and AREA for hip, spine and ESP phantoms; BMD and %Fat for the Whole Body phantom) are to be sent to the Reading Center for review biweekly. The date range for the plots should cover the previous 6 months to the present. The plots for the Whole Body phantom will need to be charted manually.

Perform a dBArchive at least once a week.

In addition to the daily scanning of the Hologic spine phantom, a number of different phantoms will be used for LIFE to monitor machine performance and for calibration purposes. The schedule for scanning these various phantoms can be found in the table below.

Phantom	Scanning frequency
Local Hologic Whole Body phantom	3 times/week (4500)

## 4.2 Calibration of Scanners

In order to accurately assess absolute variations in scanner performance between clinical centers, the Hologic Whole Body phantom will be used at each site. A detailed protocol will accompany the phantoms.

Hard copies of analyzed Whole Body phantom scans should be sent to the Reading center with each batch of study scans.

## 4.3 Machine, Software and Service Problems

**If your machine needs to be repaired or if any adjustment has to be made that possibly might affect your data:**

1. Do a dBArchive before any work is done on your QDR.
2. Contact the Reading Center before the repairs or adjustments are made to find out whether additional measures are required.
3. Perform 5 scans of the Hologic daily QC spine phantom before (if possible) and after the repairs or adjustments are made.
4. After repairs or adjustments are completed, send the repair technician's notes and a copy of the completed study repair log to the LIFE DXA Reading center. The repair log should contain complete information on all repairs done on your machine. Please keep a repair log with your machine.

## 4.4 Software Change Control

**Unauthorized software changes must be avoided. If for any reason you think you have to change the software, or your Hologic service representative recommends a software change, contact the LIFE DXA Reading center before any changes are made.**

The system software installed on the LIFE QDR 4500 densitometers should be Version 9.03. You can find your version number at the top of the blue Hologic menu. It will say "Hologic QDR 4500 version 9.03". Future software upgrades will be checked by the LIFE DXA Reading Center in conjunction with Hologic technical support personnel to assure that the upgrade will not adversely affect the study. Authorized upgrades must be cleared by the LIFE DXA Reading Center before installation at the study sites.

## **5.0 Data Management**

### **5.1 Hard Copies of Scans**

The study site is responsible for maintaining original hard copies of all scans performed during the study. **Hard copies of all participant scans will be batch mailed monthly to the LIFE DXA Reading Center for QC review and data entry.** Another set of hard copies of all scans will be kept in order to send to the National Institute on Aging at specified intervals. Keep the original printouts in the participant's scan printout folder. The following printed reports are needed for each scan:

**Whole body:** print the BMD and body composition reports (2 pages).

### **5.2 Transfer of Data to the LIFE DXA Reading Center**

The following items are to be sent to Reading center at the end of each month (except QC plots):

1. QC PRINTOUT. Send a printout of the most recent plots of the QC database, (Whole Body phantoms -BMD, BMC and AREA). The plots are reviewed at Reading Center, and problems are reported back to the clinic. (**Send monthly**)
2. PARTICIPANT SCAN LOG. Send a copy of the written patient scan log sheet covering participants scanned since the last data transfer.
3. SCANS FOR REVIEW. Send original printouts of certification scans and any scans requested for review by the Reading Center. Please write the reason the scan was flagged, requested or being sent directly on the printout. These scans will be triaged visually based on the original printouts and analyzed on the Hologic workstation if necessary.
4. REANALYZED SCANS. Send original printouts of all scans which have been reanalyzed according to the coordinating center instructions since the last data transfer. Attach the annotated printouts sent by the coordinating center which indicated the problems requiring reanalysis. You MUST also send back the reanalyzed scan images on the traveling optical.
5. ANALYZED Whole Body Phantom Scans

7. Copy of the Maintenance/Repair Log (with a copy of the Hologic service report).

Assign a number to each batch of BMD data, beginning with the first batch of BMD materials sent. Start with batch number 001. The batch number should be the clinic identifier followed by this 3 digit number. Thus the batch number should be a 5 digit field: e.g. for the Cooper clinic, batch number 1, the number should be P1001.

Complete a BMD Batch Checklist, indicating the number and which materials are included in the batch, and send it along with the batch materials.

The materials in the batch should be bundled separately by type.

Ship these items monthly to the following address:

LIFE DXA Reading Center  
Telephone:  
Fax:  
Email:

### **5.3 Return Materials Sent by the Reading Center**

The LIFE DXA Reading Center will return the following items to the study site after review:

1. Annotated printouts of any other requested scans are returned to the study site with explicit instructions for reanalysis, as necessary. The clinic then reanalyzes the problem scans according to the Reading Center recommendations. The reanalyzed scan is then saved and rearchived and the database at the study site is automatically updated. An original printout of the reanalyzed scan is sent to the Reading Center with the next data transfer to verify compliance.
2. Any recommendations for service, additional phantom scans, etc., as necessary based on the quality control database.

## **APPENDIX B. CALIBRATION PHANTOM PROTOCOLS**

The following protocols are included in this Appendix:

### **Body Phantom Protocol**

#### **DXA Scanner Cross - Calibration using the Hologic Quality Control Phantoms**

#### **Scanning and Analysis Procedures for Hologic QDR Systems: QDR-4500**

## **Whole Body Phantom Protocol**

### **I PHANTOM ASSEMBLY**

Before lifting or transporting the phantom, break it down into its individual components. Use care, the impact force of a phantom component dropped from table height can cause severe injury, particularly if the impact is delivered through one of the phantom's beveled edges. Having another person help move the phantom components is strongly recommended.

A thin, gray PVC sheet is attached to the large white plastic piece that contains the two plastic locating pins. This HDPE/PVC combination is the bottom layer (base) of the phantom. Position it on the scanner table such that the PVC is on the bottom (i.e. the gray PVC is in contact with the table pad and the two plastic locating pins project out of the plane of the table towards the ceiling.

Place the second large white plastic piece on top of the phantom base, using the locating pins as a guide. The second piece should be placed such that the beveled edge forms a "V" with the base.

Next, place the medium size white plastic pieces on the phantom, again forming a "V" with the two beveled edges of the middle pieces. Then place the small white plastic pieces on top, forming another "V" with the small pieces. The final assembly will form a pyramid (see Figure 1, side view). This is the only valid configuration for the phantom measurement. All other configurations including adding materials to the phantom, removing pieces of the phantom, scanning the phantom upside down, etc. violate the intended use of the phantom and may produce invalid results.

### **II PHANTOM POSITIONING**

Carefully position the whole body phantom in the center of the scanner table with the head of the phantom at the head of the table. Allow 24" (61cm) of empty air space at the head of the table. Carefully position the phantom parallel with the long axis of the table, using the table pad markings as a guide. When properly centered, there will be a constant 3.5" (8.9 cm) gap between the side of the phantom and the front and back limits of the 4500A scanner table (see Figure 1).

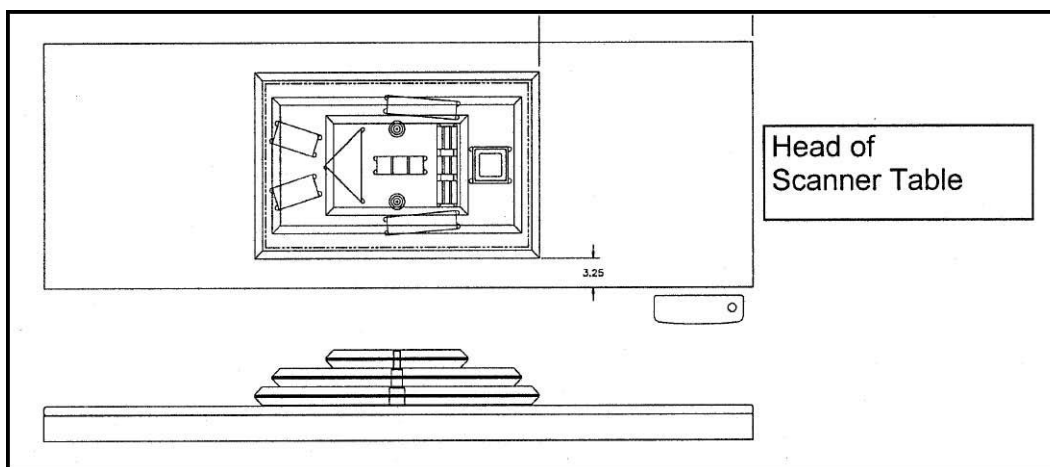


Figure 1. Layout of Whole Body Phantom positioned on the 4500A scanner table. Also shown, the fully assembled phantom viewed from the side. (Note that the amount of empty space between the side of the phantom and the sides of the table will vary depending upon scanner model).

### III DATA ACQUISITION - SCANNING THE WHOLE BODY PHANTOM

Make sure that the phantom is centered, is parallel to the long axis of the table and is correctly oriented with respect to the head of the table.

Enter **"WB PHANTOM #xxx"** in the Patient Name field of the Patient Biography (where **xxx** is the serial number of the Whole Body Phantom).

Remove all artifacts from the table surface. Extraneous objects in the scan field will interfere with the measured results in an unpredictable fashion.

Select the standard Adult Whole Body scan mode commonly employed at your facility. Accept the default scan length and scan width. Perform a complete scan of the entire table surface including the phantom. Do not interrupt the scanner during the measurement.

Carefully inspect the scan image to ensure that the phantom was (i) centered, (ii) parallel to the long axis of the scanner table and (iii) the phantom's head appears at the top of the image. If the scan image appears satisfactory, proceed to the analysis section. If not, carefully reposition the phantom according to the instructions in Section II and repeat the scan.

### IV ANALYSIS

A. General Comments The goal of the analysis is to carefully delineate the various body regions in a standard and reproducible fashion, so that measured results will reflect instrument performance, not variations in analysis techniques.



Of particular importance are the placement of the head ROI cutline and the cutlines that delineate the ribs, since these two regions affect global body composition and BMD. It is essential that the baseline measurement is technically adequate and that the analysis is performed by direct comparison to the sample analysis on the Hologic diskette labeled: "SAMPLE ANALYSES: WB PHANTOM".

#### B. Specific Instructions - Hologic QDR systems

Follow the instructions in Sections II and III to acquire a technically adequate scan of the Whole Body phantom. Restore the appropriate scan from the Hologic diskette labeled "SAMPLE ANALYSES: WB PHANTOM" to the analysis workstation. (See Table 1 for the correct scan to restore for your QDR model). Select the newly acquired WB Phantom scan. Then use the Compare feature to register the ROI cutlines of the Sample scan to the newly acquired scan of the WB Phantom. Once the ROI's have been matched as nearly as possible, complete the analysis and print the first and last pages of the report.

Archive the baseline measurement for safekeeping but do not delete it from the analysis workstation. All future whole body phantom measurements will be compared to the initial baseline measurement. After the initial measurement, the sample scan restored from the sample diskette should be deleted.

<b>QDR MODEL #</b>	<b>WB PHANTOM SCAN (RESTORE FROM SAMPLE DISK)</b>
4500W	4500W WB Phantom
4500A	4500A WB Phantom

Table 1. Scans to restore for a given QDR model #.

### **V. INTERPRETATION OF MEASURED VALUES**

The phantom measurements should be printed out and placed in a log book. Copies should be sent the DEXA Reading Center.