STUDY OF OSTEOPOROTIC FRACTURES
Densitometry Procedures and Quality Assurance Manual

for use with the Hologic QDR-2000

VISIT 6

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TABLE OF CONTENTS

I. INTRODUCTION

The purpose of this manual is to standardize the scanning and evaluation procedures among the clinical centers participating in the Study of Osteoporotic Fractures. It provides information specific the Hologic QDR 2000 to insure consistent data collection and analysis. It is intended as a supplement to the Hologic Users' Manual.

Prior to reading this document, it is essential that the Hologic Users' Manual for the QDR 2000 be understood. The study operators are all experienced Hologic users and are expected to be familiar with all the instrument features and procedures discussed in the Hologic Users' Manual. Some of the information from each of the Hologic manuals is repeated in this document for emphasis; note, however, that some of the scanning evaluation protocols for this study differ from those detailed by Hologic. In these cases, the protocol changes are clearly explained below.

The Hologic software for the QDR 2000 should be version 7.10.

> **Unauthorized software changes must be avoided. Contact the coordinating center regarding any recommendation concerning a change in software.**

II. DUAL ENERGY X-RAY ABSORPTIOMETRY (DXA)

High quality bone mineral and body composition densitometry requires competent and consistent quality assurance. This manual contains information that will help to obtain accurate and reproducible results. Procedures for three major areas are covered:

Scanning the participant
Analysis of participant data
Quality control measures

Each of these procedures is of equal importance. To obtain consistent results, the technologist in charge of the densitometry has to be aware of possible sources of error that may affect data collection and analysis.

Bone density measurements for this particular study will be obtained at four clinical centers. Quality control measures will be carried out to cross-calibrate the individual scanners. Care should be taken to ensure that every participating clinical center obtains results of comparable precision. The SOF study coordinating center will be reviewing the data and will notify the clinical centers if inconsistencies are detected. Possible error sources and

solutions will be suggested. The coordinating center will not be responsible for the solution of a hardware or software problems; that will rest with the clinical center and the scanner manufacturer.

During the study, any questions regarding procedures that arise should be directed to the coordinating center. Instances in which the operator is unsure of the analysis should be identified by each clinical center on the patient data log sheet (see Appendix A: "When to Flag Scans For Review"). These cases should be compiled and forwarded to the coordinating center for review. Often these problem cases have been analyzed correctly and will require no further action; however, in some instances the coordinating center may request re-analysis of a scan. Such instances of re-analysis must be re-archived at the clinic as well as returned to the coordinating center.

Data for the study will be sent monthly to the coordinating center using the a Batch Record Form (see Appendix B: "Batch Record Form"). In addition any questions or correspondence regarding the DXA manual, technical aspects of the DXA measurements or other DXA quality control issues should be directed to:

Maurice Dockrell/Elizabeth Edwards
UCSF Prevention Sciences Group
New Montgomery, Suite 600
San Francisco, CA 94105
(415) 597-9318 (Elizabeth) 597-9287 (Maurice)
FAX (415) 597-9213

III. PATIENT BIOGRAPHY

Throughout Visit 6, baseline and follow-up scans will be acquired. If the participant has been scanned at an earlier SOF visit, check the patient biography for accuracy, and correct any errors following the instructions in the Hologic Users' Manual. The following fields should have been entered at baseline:

NAME
PAT ID
SCAN CODE
DOB
SEX
WEIGHT
HEIGHT

All other fields may be left blank. If the participant has not been scanned previously create a new patient biography per the directions in the Hologic Users' Manual.

Important: Enter the SOF staff ID number for the person performing the scan in the SCAN CODE field. Also update the patient height and weight in the biography with the current (visit 6) values. Note that no further biography entry action is needed for a follow-up scan. Do not create duplicate biographies.

Whole Body and Hip DXA scans will be acquired on the QDR 2000.

IV. HIP MEASUREMENTS on the QDR 2000

A. SCANNING PROCEDURES

Baseline (year 10)

When performing hip scans, the following guidelines must be adhered to:

Have the patient remove all clothing, including shoes, and have her dress 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.

Keep the participant's hands out of the scanning area by placing them well away from the hips.

Whenever possible, scan the **right** hip. Scan the left hip if the right is fractured. In the presence of a bilateral hip replacement, do not scan the hip.

Ensure rotation of the hip by holding the knee and the ankle when positioning the leg. Optimum positioning of the leg is most important to achieve a consistent projection of the femur.

After proper rotation, attach the leg to be scanned to the angled foot block supplied by the manufacturer.

The participant should be made as comfortable as possible to reduce the chance of unwanted movements. Use a pillow for the head and a small pillow under the knee of the leg not being scanned. Maintain the participant at a comfortable body temperature for the duration of the scan.

Instruct the participant to remain still until the end of the measurement. Make sure that the leg is not moved during the scan. Flag any scans in which the participant has moved and has not been rescanned.

Use the array left hip or array right hip mode as appropriate. Also use the default settings for the hip scan.

Length: 6.0040 inches
Width: 4.2445 inches
Spacing: 0.03950 inches
Resolution: 0.03735 inches

If the scan shows a "short" neck with little space between itself and the ischium, this could be due to poor rotation of the leg. Reposition the participant if possible and rescan.

In order to obtain the best position for the measurement, the rescan option (F3 key) should be used freely. When restarting a femur scan, place the repositioning marks so that the intersection of the two lines touches the most lateral aspect of the greater trochanter.

Interrupt scanning about 1.5cm (15 lines) beyond the medial extent of the acetabulum if scan width limit has not yet been reached.

Follow-Up (year 12)

Before scanning the participant, load the baseline scan into the hard disk and have a printout of the baseline available. Refer to the baseline printout as you go through the positioning of the participant for the follow-up; this is to ensure consistent scanning of the same area. Careful positioning and visual comparison of the current scan with baseline are essential for producing precise measurements. Consistent projection of the femur is more important than the actual angle of the foot rotation. Use the rescan feature as soon as any positioning errors are detected during the current scan.

B. ANALYSIS PROCEDURES

High quality data analysis is strongly dependent on the ability to duplicate the placement of each of the four subregions of the hip. The Hologic analysis software calculates and displays all four regions using default values without any required operator interaction. The default size and location of these regions is usually not altered by the operator. However, to adapt them more closely to the optimal anatomic location for an individual participant, changes can be made as detailed in the sections which follow.

In a given population, large variations in weight, hip condition, and hip anatomy can result in scans which are difficult to analyze. Adjustment of the brightness and contrast will frequently be necessary to improve the appearance of the image so that regions of interest can most easily be placed.

Baseline (year 10)

Global Region of Interest The procedures outlined in the Hologic Manual are to be followed. The points listed below are for emphasis.

1. The left side of the global ROI should be at least 5mm (5 lines) beyond the outer edge of the greater trochanter to provide sufficient soft tissue for analysis, although it should not extend outside the participant's body.

2. The bottom edge of the global ROI should be at least 1cm (10 lines) below the lesser trochanter to provide sufficient soft tissue for analysis.

3. In the event that the global ROI must be expanded to allow complete filling of the bone edges (see below) in low BMD participants, all edges must be at least two steps away from the border of the scan field. This will be important when the baseline scan is used with the COMPARE feature on the follow-up scan analysis.

Bone Edges If the bone edges are not properly determined by the analysis program, increase the size of the global ROI by first moving the top border up 10 lines further from the femoral head, then by moving the medial border 10 lines further out, if possible, to include more soft tissue in the analysis. Repeat as needed. Do not move the bottom or lateral border. Do not fill in bone edges manually unless absolutely necessary. The software will automatically fill any "holes" within the bone. Occasionally, the bursa or tendons surrounding the greater trochanter can be calcified. This will produce "knobs" that can merge with the trochanter and throw off the automatic placement of the four regions. Expanding the global ROI will not always separate these from the trochanter and they will have to be manually excluded. Flag for review by the coordinating center any cases in which you manually alter the bone edge.

Femoral Midline Unevenness (notches) in the upper or lower edge of the femoral neck can throw off the femoral midline so that it does not run down the center of the neck. This will in turn cause the femoral neck box to twist. If the midline looks like it might be off or the box is twisted on either the baseline or follow-up scan, it may be necessary to adjust the bone mask (e.g. filling in neck notches, deleting the ischium) in order to obtain appropriate positioning of the midline. **The position of the midline itself should not be altered.** Alterations of the bone edges need not be flagged for review unless the operator is new to the SOF study. However, if the midline is off in spite of the bone edge changes, flag the scan for review at the CC.

Femoral Neck Box If the default neck box provided by the Hologic program looks reasonably placed, leave it unchanged.

1. The femoral neck region (the area of the neck covered by the neck box as listed on the scan analysis) should be at least 2.5 cm^2 (about 8-10 lines wide), and the neck box should be perpendicular to the neck axis. If the maximum area of the neck that can be covered by the femoral neck box is less than 1 cm^2, the participant should be rescanned with special care taken to improve the rotation and degree of adduction of the leg. Since such a narrow neck box would be only 2-3 lines wide, you will only rarely have a problem with this constraint.

2. If the area of the neck region is less than 2.5 cm^2, attempt to increase the width of the neck box to the maximum possible while still avoiding inclusion of the trochanter, ischium, or femoral head and acetabulum.

3. If the default neck box partially extends into the trochanter, ischium, or femoral head and acetabulum, adjust its location or size while maintaining the maximum possible area.

4. The Hologic software is sometimes unable to provide an appropriate placement of the neck box and other regions. This can occur if the projected neck axis is too short or the neck is too close to the ischium. Soft tissue between the neck and ischium will be read as bone, and the automatic placement of the femoral midline will fail. If this happens, use the procedure in chapter 4 of the Hologic manual for deleting the bone of the ischium. Deleting this will not adversely affect the analysis, as this bone is not included in the reported regions of interest.

Ward's Triangle The Hologic software should place the square marking Ward's triangle adjacent to the femoral neck box. In participants with low BMDs or short femoral neck projections, the Ward's Triangle box may be misplaced considerably. If this happens, follow the instructions in the Hologic manual to modify the search region. Flag extreme cases for review by the coordinating center.

Trochanteric Line The trochanteric line should intercept the bone edge just below the lateral aspect of the greater trochanter. There is no need to correct minor deviations (up to about 3 pixels).

Follow-Up (Year 12)

Load the baseline scan into the hard disk. Display this baseline evaluation using the COMPARE feature along with the current scan to be analyzed. It is important to realize that proper comparison of a follow-up hip scan to its baseline depends upon maintaining the identical size and relative position of the region markers. Vertical or

horizontal shifts of these regions by one or more pixels can greatly alter the final values of the analysis.

Global Region of Interest

1. The width and height of the global ROI must be the same as that used on the baseline.

2. The dotted lines from the baseline defining the bone region should overlay the follow-up as closely as possible. Occasionally there are small changes in adduction and rotation of the leg which were not eliminated by rescanning. The region surrounding the neck should have the best fit.

3. If the global ROI cannot be moved to the appropriate position because it is too large, the baseline scan will have to be reanalyzed with a properly reduced global ROI. Then the follow-up should be analyzed comparing it to the reanalyzed version of the baseline. Flag cases in which the baseline had to be reanalyzed.

4. **Use <Control> <End> to accept the global ROI and bone mask.**

Bone Edges If the bone edges do not fill in properly on the follow-up analysis, first the baseline will have to be reanalyzed with a larger ROI, and then the comparison analysis may proceed.

Femoral Midline Unevenness (notches) in the upper or lower edge of the femoral neck can throw off the femoral midline so that it does not run down the center of the neck. This will in turn cause the femoral neck box to twist. If the midline looks like it might be off or the box is twisted on either the baseline or follow-up scan, it may be necessary to adjust the bone mask (e.g. filling in neck notches, deleting the ischium) in order to obtain appropriate positioning of the midline. **The position of the midline itself should not be altered.** Such changes to the bone edge need not be flagged except in cases when performed by operators new to the SOF study. Flag scans were the midline does not correct with bone edge alterations.

Femoral Neck Box If the current location is optimally matched to the location of the neck box of the baseline analysis, use it unchanged.

1. If the current location is not optimally matched to the location of the neck box on the baseline, adjust the current region to achieve maximum correspondence. The size of the neck box must be the same on both baseline and follow-up.

2. If the current location cannot be satisfactorily adjusted while maintaining the same sized neck box, reanalyze the baseline within the constraints outlined above.

3. It is most important to have the neck box location and size correspond as closely as possible. If you cannot get the neck boxes to match, flag the scan for review by the coordinating center.

Ward's Triangle If the Ward's triangle box appears on the follow-up scan in a significantly different position than on the baseline, or if after reanalysis of the baseline its location is different than that of the original baseline placement, flag the scan for review by the coordinating center.

Trochanteric Lines The trochanteric line should intercept the bone edge at the same point on all scans. Matching is easily done during the compare analysis, especially since you will have the baseline to consult during the compare.

V. WHOLE BODY MEASUREMENTS on the QDR 2000

A. SCANNING PROCEDURES

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

Use the array whole body scan mode.

Position the patient in the center of the scanning table with her head just below the head of 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.

Loosely tape the ankles together to avoid motion during the scan. Inversion of the feet will bring the femoral neck into better position.

Verify that the patient 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.

*** Participants who are too large for the scan field, i.e. the arms feather at the edge of the scan, should be positioned so that the **left** arm is completely out of the scan field and the right arm is clearly and completely visible in the scan field. **Flag such scans for review.** These scans will be entered in the review data base at the CC so that the values for the right arm can be substituted for the values of the missing left arm.***

The patient should be positioned as comfortably as possible since this reduces the chances of unwanted movements. In general, try to avoid the use of 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.

When extra support cushions are used, record their placement for use in follow-up studies.

Instruct the patient not to move until the end of the measurement.

Place the Step Phantom (Tissue Bar) provided by Hologic alongside the participant. The Step Phantom must be placed on the participants right, parallel with the back edge of the table mattress, with the tall end of the Step Phantom level with the participant's feet. If the participant is very short, the Step Phantom can extend below the feet. **The entire Step Phantom must be scanned.**

B. ANALYSIS PROCEDURES

High quality data analysis critically depends on the reproducible placement of the regions to be analyzed:

- head
- left arm
- right arm
- left ribs
- right ribs
- thoracic spine
- lumbar spine
- pelvis
- left leg
- right leg
- total body

Use the Enhanced Whole Body Analysis protocol which is the default algorithm for Array Whole Body. The Hologic whole body analysis software requires that the operator align the default regions to the patient's anatomy. The following general rules should be acknowledged:

Baseline

Locate the horizontal shoulder line just below patient's chin.

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.

Align the spine ROI with the curvature of the spine, if possible. Divide the spine at the T12-L1 disc space.

The horizontal line above the pelvis should be just above the iliac crest. The angled lines defining the pelvic triangle should bisect the femoral neck.

The vertical line between the legs should run between the patient's feet.

Since body composition will be an emphasis in visit 6, care should be taken so that sub-region lines do not cut through soft tissue. It is important that all the soft tissue is included within each sub-region. Adjust the leg/thigh sub-regions so that thigh tissue is located within the appropriate leg region, not the arm region. It may be necessary to have the hands partially in the thigh region. The yellow sub-region lines may over lap the tissue bar. Flag any scans where sub-region placement is difficult and/or where sub-region lines cut soft tissue.

Follow-up

Some of the SOF participants receiving Whole Body scans may have had a Whole Body scan at visit 4 as part of the SOF Body Composition Cohort. If this is the case, the visit 4 scan will be the baseline and the visit 6 scan will be analyzed with the compare feature.
For evaluations of follow-up measurements, display the baseline evaluation using the <COMPARE> feature and compare it to the current image on the screen. The exception would be if the positioning of the current scan is extremely different i.e. the left arm is out of the scan field, then it will not be possible to do the analysis in compare.

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. Again, it is most important that the region markers of all measurements correspond as closely as possible. If it is necessary to reanalyze the baseline measurement, all subsequent follow-up measurements should also be reanalyzed using COMPARE.

VI. ARCHIVING PROCEDURES for Hip and Whole Body

There are two archiving procedures for scan storage and scan transfer to the CC on the QDR 2000. Whole Body and Hip scans should be archived to an optical disk cartridge (ODC1) for storage at the clinic. The transfer of scans to the CC should be done on floppy disk. Use the <COPY> feature under the <ARCHIVE> function at the Hologic main menu. Disks should be labeled with SOF ID's and sent to the CC with the regular monthly batches. Send both the baseline and visit 6 scans to the CC. Baseline scans need not be archived a second time to the clinic optical unless the baseline has been reanalyzed. The Whole Body and Hip scans on disk will be downloaded to the CC data base; the disks will be erased and returned to the clinic.

VII. SOF VISIT 6 DXA SCAN LOGS

The Scan Log is a paper record of SOF participants, their baseline and visit 6 scans (Appendix B). It has evolved into a useful cross-check and reference for the bone density data. It is important that the scan logs be filled out carefully and accurately. Note that there are two columns to check the archiving status of each scan, to the clinic optical (ODC1)) and for the coordinating center (CC), <COPY> to floppy disk. The scan logs should always accompany the monthly batches.

VIII. QUALITY CONTROL MEASURES

Quality control measures are the responsibility of the individual clinical centers and must be performed to monitor scanner performance throughout the period of the study.

A. PHANTOM SCANS

QDR 2000

If the QDR 2000 at the SOF clinical site is monitored on the concurrent study, Fracture Intervention Trial (FIT), with daily quality control procedures in place, additional daily QC scan acquisition will not be necessary.

For the QDR 2000 which is not monitored on the FIT protocol perform the daily quality control measures outlined by the Hologic manual. Points of procedure to note:

1. Scan and analyze the Hologic spine phantom daily. **Use BOTH the array spine mode (as used for the AP patient scans) and the pencil beam mode when scanning the spine phantom.**

2. Create only one patient biography per phantom. *** IMPORTANT: enter the phantom serial number, e.g. Q-135, as PATIENT ID.**

Avoid duplication of patient biographies by using the patient menu to select the appropriate biography prior to scanning the phantom.

3. Scan the phantom on top of the pad. Ensure alignment with the scanner axis by running the laser light up and down the edge of the phantom or by using the phantom case as a spacer between the ledge on the back of the scanner table and the phantom block.

4. Evaluate the QC scans using the COMPARE feature. Update the QC data base daily; back up to floppy (diskette) once a week. **Keep the original that you use as "baseline" for the compare permanently stored on the hard disk.** Additional backup copies of this baseline phantom scan should be stored on your optical disks.

5. Add the scan to the QC database immediately after scanning and analysis, following the procedure outlined in the Hologic manual.

6. Use the plot feature daily to verify that the BMD and the BMC of your scanner is within normal limits. To do this, select the PLOT option from the QC menu and then press F10 to generate a graph with the default settings. If the most recent scan falls outside the limits, repeat the scan. **IF THE SECOND SCAN ALSO FALLS OUTSIDE THE LIMITS, CONTACT BOTH HOLOGIC AND THE SOF COORDINATING CENTER.** If the phantom scan results fall within the normal limits, the scan file (not the database) may be deleted from the hard disk; it should not be archived to the optical disk.

7. Be sure to eliminate any unanalyzed scans from the QC database (these will appear as white dots at the bottom of the QC plot). Unanalyzed scans in the QC database will adversely affect the coefficient of variation (CV). The CV should be less than 0.5%; if it is greater than 0.5%, contact both Hologic and the coordinating center.

8. Check the system drift weekly by pressing <R> while viewing the QC plot. The slope of the calculated regression line should be within the range of the standard deviation shown. If this is not the case, check for unanalyzed QC data (white dots at the bottom of the plot). If the drift is greater than the standard deviation, contact both Hologic and the coordinating center.

9. Generate a printout of the QC plots (BMC and BMD) once a week on your designated "QC day." This will facilitate detection of long term drifts as well as short term inconsistencies. The quality control database should be archived on floppy disk on your "QC day" using the archive option from the QC menu. Follow the instructions in

the Hologic manual. Please archive the QC database on two separate floppy disks; one copy will be sent to the coordinating center.

10. An update of the QC database on floppy disk and actual printouts of the QC plots (BMC and BMD) are to be sent to the coordinating center for review on the first of each month.

B. CROSS-CALIBRATION OF SCANNERS

In order to accurately assess absolute variations in scanner performance between clinical centers, periodically throughout the study phantoms will be either mailed or brought to each of the clinical centers and scanned. Hologic spine, femur, and linearity (block) phantoms will be used. A detailed protocol will accompany the phantoms.

C. FLAGGED SCANS

Original printouts of any scans flagged for review should be sent to the coordinating center every month with the updated patient database. Note any reasons for flagging on the original printout. The printouts will be reviewed and returned to the centers with the appropriate reanalysis instructions. It will be up to the site operator to reanalyze the scan according to the coordinating center comments. Reanalyzed scans must be reachived to the ODC1 and copied to floppy disk on the QDR 2000. Return a printout of the reanalyzed scan to the coordinating center for verification with the monthly batch.

D. OTHER QUALITY CONTROL MEASURES (on any QDR 2000 not on the FIT study)

If the QDR needs to be repaired or if any adjustment has to be made that possibly might affect the data: Perform 5 scans of the Hologic spine phantom before and after the change. In addition, contact the coordinating center before the repairs or adjustments are made to find out whether additional measures have to be taken. A SOF HOLOGIC REPAIR/SERVICE LOG SHEET (Appendix B) should be filled out and returned to the coordinating center along with a copy of the Hologic Customer Service Report.

Unauthorized software changes must be avoided. If for any reason you think you have to change the software, contact the coordinating center before any changes are made.

IX. DATA MANAGEMENT

If a <dB archive> is done on the QDR 2000 for the Fracture Intervention Trial, it will not be necessary for an additional dB archive for SOF visit 6. Should this situation change in the future, clinics will be notified. A <dB

archive> should be done each month on any QDR 2000 which is not used for the FIT study.

Whole Body and hip scans will be archived and copied from the QDR 2000. Whole Body and hip scans will be archived to an Optical Disk Cartridge (ODC1) using the <1st Optical> function under the <ARCHIVE> selection at the Hologic main menu and stored at the clinic. Whole Body and HIP scans will then be copied to floppy disk using the <COPY ONLY> function under the <ARCHIVE> selection at the Hologic main menu and sent to the coordinating center with each monthly batch.

Data transfer to the CC occurs monthly. Each monthly batch should include: the written patient scan log sheets, and disks with all scans acquired or reanalyzed since the previous data transfer. In addition, scans which the study site wishes to have reviewed (flagged scans) are printed before archival and sent directly to UCSF. The printouts of these scans are visually checked to verify correct analysis. Improper analysis procedures are noted directly on the scan for reanalysis.

For all flagged scans received at UCSF which require reanalysis, the annotated printouts are returned to the study site with specific instructions for reanalysis when indicated. The study site then reanalyzes the problem scans according to the UCSF recommendations. The reanalyzed scan is then rearchived and the database at the study site is automatically updated. A printout of the reanalyzed scan is sent to UCSF to verify compliance with the next data transfer.

SUMMARY

Every month the following items are sent to UCSF from each site:

a) Batch Record Form (Appendix B)
b) Copy of written patient scan log sheets (Appendix B).
c) Disks with all Whole Body and Hip scans acquired during the month
d) Original printouts of flagged scans.
e) Original printouts of all scans which have been reanalyzed according to UCSF instructions since last data transfer.
f) dB Archive disk for any QDR 2000 which is not on the FIT study.
g) A **SOF HOLOGIC REPAIR/SERVICE LOT SHEET** on any QDR 2000 which is not on the FIT study

Ship the preceding via **Fed Ex, UPS or Regular Mail** monthly to the following address:

Elizabeth Edwards
SOF DXA Quality Control
Prevention Sciences Group - UCSF
New Montgomery Street Suite 600
San Francisco, CA 94105

UCSF will return the following items to the study site after review:

a) Annotated printouts of flagged scans which require reanalysis with explicit instructions for reanalysis, as necessary.
b) Any recommendations for service, additional phantom scans, etc., as necessary based on the quality control database.
c) Erased floppy disks.

ACKNOWLEDGMENT

Several of the procedures that are specific to the Hologic QDR-1000 and QDR 2000 Series Bone Densitometer have been designed with the technical assistance of Hologic, Inc.

APPENDIX A - Flagging Instructions
WHEN TO FLAG SCANS FOR REVIEW
BY THE COORDINATING CENTER FOR VISIT 6

General
Scan has unusual appearance or is difficult to analyze.

Patient has moved and scan cannot be repeated without movement.

Unusual anatomical variations; surgical hardware; superimposed buttons, pins, zippers, vitamin pills, pacemakers; or anything else which might affect scan results.

Whole Body
Patient motion without rescanning (these scans are extremely susceptible to motion artifacts)

Significant changes in positioning between baseline and follow - up scan.

Anatomical replacements/implants including knee and hip replacements and breast implants.

Scans in which the sub-region lines cut through soft tissue.

Scans in which the left arm is positioned out of the scan field.

Hip Scans
Ischium deletions and neck notch fills need not be flagged but any other bone edge alteration should be flagged. (New operators should flag all bone edge adjustments.

Midline looks off-center.

Femoral neck box on follow-up cannot be matched to baseline size or placement.

Neck box width reduced from default.

Ward's triangle located outside of normal region.

Trochanteric lines cannot be matched between baseline and follow up.

APPENDIX B - Forms

Batch Record Form

Whole Body and Hip Scan Log

SOF REPAIR/SERVICE LOG SHEET

BMD BATCH RECORD

STUDY OF OSTEOPOROTIC FRACTURES

Batch Number: _____ **Date Batch Mailed:** ____/____/____

Clinic Name: _____ **Staff ID#:** _____

Contents: (check Yes or No below)

DB Archive Disk ☐ Yes ☐ No Date Archived: ____/____/____

QC DB Printout ☐ Yes ☐ No Date Printed: ____/____/____

Scan Log Sheet ☐ Yes ☐ No

Flagged Scans ☐ Yes ☐ No Number: _____

Reanalyzed Scans ☐ Yes ☐ No Number: _____

Random Sample Scans ☐ Yes ☐ No Number: _____

Other (specify) _____

Certification Scans:

Staff ID	Number of Scans	Scan Type

DXA Hip and Whole Body Scan Log for the QDR 2000

Clinic

Date	Tech ID	Pat ID	ACRO	Scan Type	Scan Number	Flagging Comments	Archive Clinic Opt	Copy to CC floppy
				Hip				
				V6 Whole Body				
				Baseline W/Body				
				Hip				
				V6 Whole Body				
				Baseline W/Body				
				Hip				
				V6 Whole Body				
				Baseline W/Body				
				Hip				
				V6 Whole Body				
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				Baseline W/Body				
				Hip				
				V6 Whole Body				
				Baseline W/Body				
				Hip				
				V6 Whole Body				
				Baseline W/Body				
				Hip				
				V6 Whole Body				
				Baseline W/Body				

SOF HOLOGIC REPAIR / SERVICE LOG SHEET

Clinic : ..... Date: .....

1. Describe problem (incl. dates): .....
.....
.....
.....

2. Did problem affect scans or BMD data?

o Yes o No

If yes, describe: .....
.....
Machine downtime .....
.....

3. Describe the action taken by you (including repair by Hologic)? .....
.....
.....
.....

4. Was the problem resolved?

o Yes o No

If not, please specify: .....
.....

5. Was a recalibration of the device necessary?

o Yes o No

6. Were phantom scans performed after the repair or the recalibration?

o Yes o No

If yes, did you notice a change in the phantom BMD values?

o Yes o No

Please fill in the form thoroughly and attach a copy of the Hologic service report. Send one copy to the SOF coordinating center. Keep one copy with your scanner in your own repair log.