

TABLE OF CONTENTS

I. INTRODUCTION	1
II. DUAL ENERGY X-RAY ABSORPTIOMETRY (DXA).....	1
III. PATIENT BIOGRAPHY	2
IV. HIP MEASUREMENTS on the QDR 1000	3
A. SCANNING PROCEDURES	3
B. ANALYSIS PROCEDURES	4
C. ARCHIVING DATA.....	7
V. REPEAT DXA MEASUREMENTS	7
VI. SOF VISIT 8 DXA PARTICIPANT SCAN LOGS.....	7
VII. EXCESSIVE BONE LOSS (EBL)	7
VIII CERTIFICATION	9
IX. QC MEASURES	9
A. PHANTOM SCANS	9
B. CROSS-CALIBRATION OF SCANNERS	10
C. FLAGGED SCANS	10
D. OTHER QC MEASURES	10
X. DATA MANAGEMENT	11
APPENDIX A - Flagging Instructions.....	13
APPENDIX B - Forms.....	14

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 (SOF). It provides information specific to the Hologic QDR 1000 to ensure consistent data collection and analysis. It is intended as a supplement to the Hologic User's Manual.

Prior to reading this document, it is essential that the Hologic User's Manual for the QDR 1000 be understood. The study operators are all experienced Hologic users and are expected to be familiar with all of the instrument features and procedures discussed in the Hologic User's 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 1000 should be version 6.20

Unauthorized software changes must be avoided. Contact the Coordinating Center (CC) regarding any recommendation concerning a change in software.

II. DUAL ENERGY X-RAY ABSORPTIOMETRY (DXA)

High quality bone mineral densitometry requires competent and consistent quality assurance (QA). 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 (QC) 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. QC 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 CC will be reviewing the data and will notify the clinical centers if inconsistencies are detected. Possible sources of error and solutions will be suggested. The CC will not be responsible for the solution of 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 CC. Instances in which the operator is unsure of the analysis should be identified on the Participant Scan Log (Appendix B; see Appendix A for flagging criteria). These cases should be compiled and forwarded to the CC for review. Often these problem cases have been analyzed correctly and will require no further action; however, in some instances, the CC 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 CC.

Data for the study will be sent monthly to the CC using the Batch Record Form (see Appendix B: “Batch Record Form”). Additionally, any questions or correspondence regarding the DXA manual, technical aspects of the DXA measurements or other DXA QC issues should be directed to:

Michaela Rahorst
UCSF Prevention Sciences Group
74 New Montgomery, Suite 600
San Francisco, CA 94105
Tel (415) 597-9318
Fax (415) 597-9213
Email: mrahorst@psg.ucsf.edu

III. PATIENT BIOGRAPHY

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 User’s 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 User’s Manual.

Important: Enter the SOF staff ID number of the person performing the scan in the SCAN CODE field. Also update the patient height and weight in the biography with the Visit 8 values. Note that no further biography entry action is needed for the Visit 8 scan. Do not create duplicate biographies.

IV. HIP MEASUREMENTS on the QDR 1000

Hip DXA scans will be acquired on the QDR 1000 for the main cohort. Participants in the African American cohort who had their baseline scan on the QDR 2000 will be scanned on the QDR 2000. (This does not apply to African Americans scanned in Minneapolis because they no longer have their QDR 2000 scanner. They should be scanned on the QDR 1000 scanner.) Lumbar spines **will not** be scanned at Visit 8.

A. SCANNING PROCEDURES

Before scanning the participant use the <LOCATE> function at the Hologic main menu to find the most recent analysis of the **hip baseline scan**. *For most SOF participants, baseline refers to Visit 2.* To choose the appropriate baseline scan to use for the compare analysis and the correct side to scan, please refer to the lists provided by the CC. Load the baseline scan onto the hard drive and have a printout of the scan available. In general, scan on the same side as the baseline scan. Refer to the baseline printout for the positioning of the participant at Visit 8; 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 while acquiring the Visit 8 scan.

If no baseline examination exists for the participant, or if a different hip is to be scanned from that scanned at baseline, treat Visit 8 as a baseline scan. Follow the scanning protocol below and analyze the scan without the <COMPARE> feature. (See **Baseline Analysis Procedure** section in the *Analysis Procedure* section.)

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

- No metal or plastic object should remain in the scanning area. Check for jewelry, coins or other objects in the hip pockets, zippers, buttons, rivets, belts or any other clothing fasteners, as well as hip and back braces.
- Lower any thick clothing that might obscure the scanning area.
- Keep the participant's hands out of the scanning area by placing them well away from the hips.
- Whenever possible, scan the same hip that was scanned at baseline. If the participant has suffered a hip fracture in that hip since baseline, scan the other hip. In the presence of bilateral hip replacements or bilateral hip fractures, do not scan the hip. Log such participants on the Participant Scan Log and write the reason that no scan was acquired.
- Ensure rotation of the hip by holding the knee and the ankle when positioning the leg. Optimum positioning of the legs is most important.
- Attach the measured leg 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 opposite to the scanned hip. 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. Movement during a hip scan appears as either a discontinuity or as a smear.
- Use the default settings for the hip scan.
- Verify that the proximal femur is projected identically in every follow-up measurement. This requires that the corresponding foot is rotated inward at the same angle. Check the projection of the lesser trochanter—it should be projected the same as at the baseline measurement.
- 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. If the positioning is not consistent with the baseline, then reposition the participant and rescan.
- In order to improve the positioning for the measurement, the rescan option (F3 key) should be used freely. Start the hip scan and keep scanning until the lateral contour of the greater trochanter becomes clearly visible. Initiate rescan (F3) and position the blue arrow that appears in a way that it points to the most lateral aspect of the greater trochanter. Allow for approximately 5 scan lines between the arrow and the trochanter. Restart the scan.
- Interrupt scanning about 1.5cm (15 lines) beyond the medial extent of the acetabulum if scan width limit has not yet been reached.

B. ANALYSIS PROCEDURE

To analyze the Visit 8 scan, use the <COMPARE> feature to compare it to the baseline scan. If the participant had a new baseline scan (due to hip replacement, fracture, hardware, etc.) use that scan do the compare analysis for the Visit 8 scan. If the baseline scan is irretrievable, use the oldest scan you can locate on the workstation. For more detailed instructions, please see **Follow-up Analysis Procedures** in the section that follows.

High quality data analysis is strongly dependent on the ability to duplicate the placement of each of the four subregions of the hip. In a given population, large variations in weight, hip condition, and hip anatomy can result in scans that 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 Analysis Procedures

Global Region of Interest (ROI): The procedures outlined in the Hologic User’s Manual are to be followed. The points listed below are for emphasis.

The outer (lateral) side of the global ROI should be at least 5mm (5 lines) beyond the outer edge of the greater trochanter; the inner (medial) side and the top of the global ROI should be 5mm (5 lines) beyond the femoral head, to provide sufficient soft tissue for analysis; 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.

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 CC any cases in which the bone edge is manually altered.

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.** If changes have been made to the scan such as filling in bone in order to alter the midline, or if the midline is still off, flag these cases for review by the CC.

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

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 cm² (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 cm², 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.

If the area of the neck region is less than 2.5 cm², 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.

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.

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 procedures given in the Hologic User's 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 in or adjacent to the femoral neck box. In participants with low BMD 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 CC.

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 Analysis Procedures

Display the baseline evaluation using the <COMPARE> feature along with the Visit 8 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 ROI

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

The dotted lines from the baseline defining the bone region should overlay the follow-up scan 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.

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 each follow-up scan should be reanalyzed comparing it to the reanalyzed baseline scan. Flag cases in which the baseline scan has been reanalyzed.

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.

C. ARCHIVING DATA

There are two archiving functions to be carried out at Visit 8: 1) All Visit 8 scans should be archived to the clinic disk, along with any reanalyzed baseline and intermediate scans; 2) **All Visit 8 and baseline scans should be copied to the traveling optical disk, along with any reanalyzed intermediate scans, and scans (Visit 6, or other) used to assess EBL.**

The traveling optical disk should be sent with the monthly batches. The scans on the traveling optical disk will be downloaded to the CC database and the disk will be returned to the clinic. Each clinic should plan to archive analyzed hip scans to the clinic optical disk on a daily basis for the safety of the data. Optimal use of the both the clinic and traveling optical disks can be achieved by archiving/copying larger batches of scans at a time (instead of one scan at a time).

V. REPEAT DXA MEASUREMENTS

In rare circumstances, DXA scans may need to be repeated. If this occurs, the CC will contact the clinic about the repeat scan. The clinic should then follow the steps below:

1. Contact participant to come back into the clinic. Schedule repeat scan as soon as possible.
2. Repeat scan, paying particular attention to problem described by the CC.
3. On the original TELEform form for the scan, change necessary information on the form (the date of the scan, for example). DO NOT REFAX the form. Make changes to the data system (by posting a query to the website), as needed.
4. Send the repeat scan and a hard copy of the TELEform form to the DXA QA Center at the CC.

VI. SOF VISIT 8 DXA PARTICIPANT SCAN LOGS

The Participant Scan Log is a paper record of SOF baseline and Visit 8 scans (Appendix B). It has evolved into a useful crosscheck and reference for the BMD data, and should always accompany the monthly batches. It is important that the Participant Scan Logs be filled out carefully and accurately. The baseline scan should be identified by its visit number and scan ID.

VII. EXCESSIVE BONE LOSS

For information on assessing EBL in the African American cohort, please refer to the end of Section VII on the following page.

Participants who lose an excessive amount of bone mass during the study must be identified and appropriately counseled.

To determine the annual loss of bone mass, it is necessary to compare the results of the previous and the recent bone scans. The Hologic software provides a very convenient option to calculate the annual bone loss from two or more scans. Total hip BMD will be used to calculate excessive bone loss (EBL).

The following thresholds will be in effect for Visit 8:

Approximate Time between V8 and comparison scans		Annualized Loss Greater Than
V7	3 yr.	5.0%
V6	5 yr.	4.5%
V5	7 yr.	4.0%
V4	10 yr.	3.5%
V3	11 yr.	3.5%
V2	13 yr.	3.0%

Determine the rate-of-change at the total hip directly after doing the Compare analysis of the Visit 8 scan:

Select the Visit 8 hip scan under the *Select* menu.

Go to the *Normals* menu (use arrow keys or type 'N' or type key 'F7'). The program will show a list of patient scans available for analysis.

Mark the appropriate comparison visit scan by using the '+' key. After you have chosen the scan, press the <Enter>.

****Note:** To choose the scan to which you will compare the Visit 8 scan for EBL assessment, follow this guide:

1. Use Visit 6
2. If Visit 6 scan was done on the QDR 2000 or is unavailable, use Visit 4.
3. If Visit 4 is unavailable, use Visit 2.
4. If Visit 2 is unavailable, use Visit 5 or 7.

Select the menu option *Rate-of-change* using the arrow keys and press <Enter>. The **TOTAL** under the **% change/yr.** column is the value to use.

If the *Rate-of-Change* shows EBL according to the criteria listed above, the Visit 8 scan should be reanalyzed by the lead DXA operator (or a second operator), if possible, and the above procedures should be repeated. If EBL is still evident, print out the Visit 6 scan (or scan used for comparison), the Visit 8 scan and *Rate-of-Change* plot, fill out the Excessive Bone Loss Form (Appendix B), and send to the CC with your monthly shipment.

The CC will review and confirm the technical accuracy or request reanalysis of the scan.

****Exceptions for the African American cohort:**

1. For African Americans in Minneapolis whose Visit 6 scan was done on the QDR 2000, EBL will not be assessed at Visit 8.
2. African Americans in Baltimore, Pittsburgh and Portland whose Visit 6 scan was done on the QDR 2000 will also have their Visit 8 scan on the

QDR 2000. The Visit 8 scan will be compared to the Visit 6 scan for analysis and for EBL assessment.

VIII. CERTIFICATION

Only those operators who have been certified through Hologic training and the CC are allowed to perform the scanning and analysis for SOF. It is the clinical center's responsibility to ensure that as new operators are brought into the study, all of the certification criteria are met.

If an operator has previously been certified by the CC to scan on a QDR 1000 or QDR 2000 pencil beam, there is no need to repeat the certification procedures. The names, SOF Staff ID numbers, and certification information of such operators should be sent to the CC.

Operators who have not been certified by the CC to scan on a QDR 1000 or QDR 2000 pencil beam should send their first ten SOF hip scans for review along with printouts of the baseline scans. Write "Certification" on the top of the page and include the operator's SOF Staff number and name. If it will take more than two months to scan 10 SOF participants, non-SOF hips on a QDR 1000 or QDR 2000 pencil beam can be sent for review. Please cross out any identifying patient information. Write "Certification" on the top of the page and include the operator's SOF Staff number and name.

After successful review of ten hip scans, an operator will be considered certified and the appropriate documentation will be sent to the clinical center.

IX. QC MEASURES

QC 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 1000

Perform the daily QC measures outlined by the Hologic manual. Points of procedure to note:

Scan and analyze the Hologic spine phantom daily.

Create only one patient biography per phantom. * **IMPORTANT: Enter the phantom serial number (i.e. 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.

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.

Evaluate the QC scans using the <COMPARE> feature. Update the QC database 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 floppy disk. Phantom scans themselves are not

archived: only the phantom database need be archived for subsequent analysis of machine performance.

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

Use the plot feature daily to verify that the BMD 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 CC. 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.

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 CC.

Periodically check the system drift 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 CC.

Generate a printout of the QC spine phantom BMD plot once a week on your designated "QC day." This will facilitate detection of long term drifts as well as short-term inconsistencies.

The QC database is archived using the archive option from the QC menu. Follow the instructions in the Hologic manual.

B. CROSS-CALIBRATION OF SCANNERS

In order to access accurately the absolute variations in scanner performance between clinical centers, phantoms will be sent 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 CC every month on the traveling optical disk. **Note any reasons for flagging on the original printout.** The printouts will be reviewed and returned to the centers if reanalysis is necessary. It will be up to the site operator to reanalyze the scan according to the CC comments. Reanalyzed scans must be re-copied to the traveling optical and re-archived to the clinic optical. Return a printout of the reanalyzed scan to the CC for verification with the monthly batch. Please refer to Appendix A for specific guidelines regarding when to flag a scan.

D. OTHER QC MEASURES

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 CC before the repairs or adjustments are made to find out whether additional measures have to be taken. A SOF DXA Hologic Repair/Service/Upgrade Log (Appendix B) should be filled out and returned to the CC 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 CC before any changes are made.

X. DATA MANAGEMENT

An archive of the patient database, using the <DBARCHIVE> function, will be sent to the CC at the end of Visit 8.

Each study site should have optical disks to use for storing scans at the clinic and another optical disk for transferring scans to the CC. In each monthly transfer, all baseline and Visit 8 hip scans, along with reanalyzed follow-up scans, should be copied to a traveling optical using the <COPY> function under <ARCHIVE> selection at the Hologic main menu. (Be sure to include the Visit 6 hip scan if the participant appears to have EBL.) The traveling optical should be sent to the CC with each monthly batch. It will be returned to the clinic before it is needed for the next monthly batch. Study sites will archive newly acquired and reanalyzed participant scans to the clinic optical using the <ARCHIVE> selection at the Hologic main menu. Baseline scans that have not been reanalyzed do not need to be re-archived.

Data transfer to the CC occurs monthly. Each monthly batch should include:

1. Completed Batch Record Form – Appendix B
2. QC printouts (spine phantom – BMD, BMC & Area)
3. Participant Scan Log – Appendix B
4. Printouts of flagged hip scans for review (See Appendix A for flagging criteria)
5. Printouts of reanalyzed hip scans from previous transfer
6. Electronic copies of all SOF scans since last transfer on the traveling optical disk
7. DXA Hologic Repair/Service/Upgrade Logs (as necessary) – Appendix B
8. Excessive Bone Loss forms (as necessary) – Appendix B
9. dbArchive of patient database (on floppy disk) at the end of Visit 8.

Ship the batch contents via **FedEx or UPS** monthly to the following address:

Michaela Rahorst
Prevention Sciences Group - UCSF
74 New Montgomery Street, Suite 600
San Francisco, CA 94105
Tel 415-597-9318

The CC will return the following items to the study site after review:

1. Annotated printouts of flagged scans that require reanalysis with explicit instructions, as necessary.
2. Any recommendations for service, additional phantom scans, etc., as necessary based on the QC database.
3. The traveling optical disk
4. Confirmation of EBL, if necessary

ACKNOWLEDGMENT

Several of the procedures that are specific to the Hologic QDR-1000 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 CC FOR VISIT 8

General

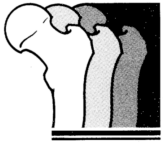
- Scan has unusual appearance or is difficult to analyze.
- ROI on follow-up is different size than that of baseline
- Patient has moved and scan cannot be repeated without movement.
- Unusual anatomical variations, surgical hardware, superimposed buttons, pins, zippers, vitamin pills, or anything else that might affect scan results.

Hip Scans

- Midline looks misplaced on either baseline or follow-up.
- Femoral neck box on follow-up cannot be matched to baseline size or placement.
- Neck box width reduced or extended from default.
- Ward's triangle located outside of normal region.
- Trochanteric lines cannot be matched between baseline and follow-up.
- Positioning changes are so great that compare does not work.

APPENDIX B - Forms

1. Batch Record Form – Photocopy as needed
2. Participant Scan Log – Photocopy as needed
3. DXA Hologic Repair/Service/Upgrade Logs – Photocopy as needed
4. Excessive Bone Loss (EBL) Form – Photocopy as needed
5. DXA Bone Density Form (TELEform) – Do NOT photocopy



DXA Batch Record Form

Batch Number: _____

Date Batch Mailed: _____ / _____ / _____
Month Day Year

Circle City: Baltimore, Minneapolis, Pittsburgh, Portland

SOF
Staff ID #: _____

Contents

QC Plots (BMD, BMC, Area) No Yes →

Date Printed: _____ / _____ / _____
Month Day Year

Participant Scan Log No Yes

Flagged Hip Printouts No Yes →

Number: _____

Reanalyzed Hip Printouts No Yes →

Number: _____

Other Scans (Specify: _____) No Yes →

Number: _____

Traveling Optical No Yes

Repair/Service/Upgrade Log & Hologic Service Report (If service performed) No Yes

db Archive Disk [Send once at end of Visit 8.] No Yes →

Date Archived: _____ / _____ / _____
Month Day Year

Certification Scans: No Yes

Please printout & mark 'Certification'. We need 10 hip scans from each staff. Can be split between batches.

SOF Staff ID

Number of Scans

Scan Type

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____



<u>Date</u>	<u>SOF ID</u>	<u>Acroscopic</u>	<u>Staff ID #</u>

Excessive Bone Loss (EBL) Form

Be sure to follow all procedures for participants with suspected EBL.

Suspected Excessive Bone Loss checklist

Please make sure that this form is accompanied by all the items listed below for hip with suspected EBL.

- Printouts of the Visit 6 (or EBL comparison scan) and Visit 8 scans
- Printouts of the “rate of change” report(s)
- Copies of the Visit 6 (or EBL comparison scan) and Visit 8 scans on the traveling optical disk

Your Comments: _____

To be filled out by the QA Center

- Yes, we can confirm an excessive bone loss. The scans are technically correct and the analyses are performed appropriately.
- Yes, we can confirm an excessive bone loss. However, the scans were not analyzed properly. Please reanalyze the scan(s) following our instructions and inform the participant of the correct bone loss %.

For those with confirmed excessive bone loss:

TOTAL HIP BMD: Follow-up scan: _____ Visit ___: _____

 Annual % Change: _____

- After scan review we cannot confirm an excessive bone loss.

Comments: _____

Signature of QA Center Reviewer _____ Date _____



DXA
Bone Density Form

Office Use Only
SOF ID#

Acrostic

Staff ID#

SAMPLE							
--------	--	--	--	--	--	--	--



1 Which hip was most recently scanned as indicated on list provided?

- Right
- Left
- Missing

2 Which hip was scanned at this visit?

- Right
- Left
- Neither



Record reason:

- Refused radiation
- Unable to lie on table
- Home visit
- Bilateral hip replacement
- Other

Describe: _____

a. Is the side scanned at this visit different than the side most recently scanned?

- Yes
- No



Record reason:

- Fracture
- Hip replacement
- Other

Describe: _____

b. Date of scan:

		/			/				
Month			Day			Year			

c. Last 2 characters of scan ID #:

--	--

d. Temperature of room during scan:

--	--

degrees Celsius

26368

