STUDY OF OSTEOPOROTIC FRACTURES
Densitometry Procedures and Quality Assurance Manual

for use with the Hologic QDR-1000

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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 to the Hologic QDR 1000 and is intended as a supplement to the Hologic Users' Manual.

Prior to reading this document, it is essential that you read and understand the entire Hologic manual. The study operators are all experienced Hologic users and are expected to be intimately familiar with all the instrument features and procedures discussed in the Hologic Users' Manual. Some of the information from the Hologic manual 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.

Please be sure that you have upgraded your system software to Version 6.10. You can find your version number at the top of the blue Hologic menu. It will say "Hologic QDR 1000 6.10."

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

II. DUAL ENERGY X-RAY ABSORPTIOMETRY (DXA)

High quality bone mineral 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 and spot checking the data and will notify the clinical centers if we detect any inconsistencies. We will indicate possible error sources, suggest possible solutions, but will not be responsible for the solution of a hardware or software problem; 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 that you reanalyze a scan by applying an exception to the protocol. Any changes in the analysis will be then be returned to the coordinating center.

Data for the study will be sent at regular intervals to the coordinating center using the mailing labels provided. Any questions or correspondence regarding the manual or the technical aspects of the DXA measurements should be directed to:

Kenneth G. Faulkner, Ph.D.
University of California
Department of Radiology
Box 0628
San Francisco, CA 94143
phone: (415) 476-9805
FAX: (415) 502-BONE

III. PATIENT BIOGRAPHY

The patient biography should already be entered from the previous visit. Check the biography for accuracy, and correct any errors by 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.

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 4) values. Note that no further biography entry action is needed for a follow-up scan or for an additional site for the same individual. Do not create duplicate biographies.

IV. A/P SPINE MEASUREMENTS

A. SCANNING PROCEDURES

Before scanning the participant, load the baseline scan into the hard disk and have a printout of the baseline available. Remember to use the LOCATE feature of the Hologic software to load the most current version of the baseline scan on your workstation. Check the baseline to determine if it was analyzed properly; if the baseline was done improperly, it will be necessary to reanalyze it. 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.

When performing A/P scans, the following guidelines must be adhered to:

1. Change the scan length from 6.0 inches to 8.0 inches for all A/P participant scans. Note that the phantom scans should still be done at the default length of 6.0 inches.

2. The scan width should be 5.2 inches.

3. No metal or plastic object should remain in the scanning area. Check for jewelry, zippers, buttons, rivets, belts or any other clothing fasteners, as well as hip and back braces.

4. Lower any heavy clothing so that nothing obscures the scanning area.

5. Follow the instructions for patient positioning outlined in the Hologic Manual. Make sure that you can move the scanner arm from approximately 2 inches above the xiphoid process to 2 inches below the ASIS (anterior superior iliac spine). This guarantees that your scan does not abort prematurely. Reposition the participant if necessary.

6. Use a knee elevating pad to reduce lordosis. Always use the same pad for all participants.

7. Keep the participant's hands out of the scanning area by placing them at her sides for A/P scans.

8. The participant should be made as comfortable as possible to reduce the chance of unwanted movements. Use a pillow for the head, and maintain a comfortable body temperature for the participant throughout the scan.

9. Instruct the participant to remain still until the end of the measurement. Flag any scans in which the participant has moved and has not been rescanned. Movement during a spine scan appears as either a horizontal discontinuity or as a horizontal smear. An isolated discontinuous line is acceptable since it will not significantly alter values in its vicinity. Several discontinuities together will produce inaccurate data, and the participant will need to be rescanned. Try to resolve coughing or other causes you can control.

10. Use the midpoint of the ASIS and the iliac crest to determine the start line of the scan. This should place the lower end of the A/P scan at the midpoint of L5. Perform a preliminary scan to verify patient position, and then restart the scan.

11. Scan from the middle of L5 (include a portion of the iliac crest for reference) up to the middle of T12. Scans for the older women in our SOF study population can be difficult to interpret, so we want to be sure to collect sufficient data for accurate identification of vertebral levels L1-L4.

12. Use the rescan feature (F3 key) freely. It is imperative that the spine be well centered and that part of the pelvis be visible.

B. ANALYSIS PROCEDURES

Load the baseline scan into the hard disk. Display this baseline evaluation using the COMPARE feature along with the current scan to be analyzed.

Brightness and Contrast Be sure that the window and level are optimally adjusted.

Global Region of Interest The global region of interest (large, yellow box surrounding all vertebrae to be analyzed) should be the same as used for the baseline scan. Use the COMPARE feature to copy the baseline ROI over to the follow-up scan. The global ROI should meet the following guidelines:

1. The ROI should be no narrower than 119 pixels and match the ROI width of the baseline scan.

2. The ROI should be aligned symmetrically around the spine.

3. The ROI must be large enough to include at least 5mm of soft tissue outside the most extreme aspects of both the right and left bone edges of the spine. Special care must be taken with extremely scoliotic individuals to achieve this goal.

4. The above constraints must produce an ROI with all edges at least two steps away from the border of the scan field.

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 its global ROI sufficiently reduced to accommodate the follow-up scan. After the baseline scan has been reanalyzed, analyze the follow-up scan using the new baseline for the comparison. If the upper and lower edges of the global ROI do not match the corresponding intervertebral spaces on the follow-up scan (i.e., the follow-up spine is shorter), the global ROI of the follow-up may need to be shortened. Be certain that the vertebral levels correspond between baseline and follow-up; mismatched levels can give the appearance of shortening or lengthening of the spine on follow-up. **Never change the width of the global ROI on the follow-up scan from that used at baseline.**

Scoliotic Spines In the SOF study, the special scoliosis feature of the Hologic software is **never** used on A/P scans. This is because the feature was not available when the study started. Incorporation of the scoliosis feature at this point would require reanalysis of all baseline spine scans! Participants should be analyzed using the standard rectangular ROI from COMPARE. The upper and lower borders of the global ROI are adjusted using the same procedure as is used to adjust scoliotic intervertebral spaces (see below). Severely scoliotic spines (greater than about 5 degrees of curvature) should be flagged for later review by the coordinating center.

Intervertebral Spaces It is most important that the intervertebral space markers of the follow-up scan correspond as closely as possible to those of the baseline. The COMPARE

feature will generate the baseline vertebral spacing automatically. A slight manual adjustment may be necessary to place the line markers at the same level between the vertebrae. Large discrepancies in spacing may indicate that either the baseline or follow-up scan has had its vertebral levels mislabeled or that a crush fracture has occurred. If the baseline has been misinterpreted, reanalyze it; then repeat the analysis of the follow-up scan using the reanalyzed baseline for the comparison.

Labeling Vertebral Levels Matching corresponding vertebral levels from baseline to follow-up can be difficult. Look carefully at the darker low density features at the intervertebral spaces and count up from the pelvic girdle to determine levels. If levels were mislabeled on the baseline (e.g., T12 was called L1), reanalyze the baseline scan and correct the level numbers. Flag any scans with uncorrected levels for review by the coordinating center.

Crushed Vertebrae If a vertebra appears to have crushed since the baseline scan, both the crushed follow-up vertebra and the normal baseline vertebra must be excluded from these analyses. This will require reanalysis of the baseline scan. Perform the reanalyses and flag these for review by the coordinating center. If the crush is questionable, also flag it for review by the coordinating center.

Filling and Deleting Bone Use the "Autopaint" feature of the Hologic software to fill in any gaps within the bone mask. Manual filling of bone gaps will no longer be necessary if this feature is turned on. Delete all isolated bone mask structures. If boundary gaps were not filled in on the baseline and the baseline must be reanalyzed for another reason, make sure these are filled in when reanalyzing.

Bone Edges Do not alter the bone edges. Unusual bone edges or large differences in the bone edges between baseline and follow-up should be flagged for review by the coordinating center.

V. HIP MEASUREMENTS

A. SCANNING PROCEDURES

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.

If no baseline examination exists for the participant, or a different hip is to be scanned from that scanned at baseline, treat the examination as a baseline scan. Follow the scanning protocol below and analyze the scan without the COMPARE feature.

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

1. 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.

2. Lower any thick clothing that might obscure the scanning area.

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

4. Whenever possible, scan the same hip which was scanned at baseline. If the participant has suffered a hip fracture in that hip since baseline, scan the other hip. If she fractured both hips, scan the one with the least hardware. In the presence of bilateral hip replacement, do not scan the hip.

5. Ensure rotation of the hip by holding the knee and the ankle when positioning the leg. Optimum positioning of the legs is most important.

6. Attach the measured leg to the angled foot block supplied by the manufacturer.

7. 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 knees. Maintain the participant at a comfortable body temperature for the duration of the scan.

8. 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 vertical discontinuity or as a vertical smear.

9. Use the default settings for the hip scan.

10. Verify that the proximal femur is projected identically in every follow-up measurement. This requires that the corresponding foot is rotated inward by the same angle. Check the projection of the lesser trochanter -- it should be projected the same as at the baseline measurement.

11. 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.

12. 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.

13. 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 PROCEDURES

Load the baseline scan into the hard disk using the LOCATE feature in order to restore the most current scan. 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.

If no baseline examination exists for the participant, or a different hip was scanned from that scanned at baseline, treat the examination as a baseline scan. In this case, analyze the scan without the COMPARE feature as described in the Hologic manual, and follow the guidlines below as closely as possible.

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. In these cases, 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.

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. Flag any reanalyzed baseline scans.

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, flag these for review by the coordinating center. Do not attempt to adjust the midline yourself because it throws off the femoral box, Ward's Triangle, and the trochanteric line. Proper analysis would require too much operator interaction.

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 with an adjusted neck box size, and then analyze the follow-up scan.

3. In some patients, 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, try the following bone deletion method to reanalyze the scan:

   Reanalyze the scan and accept the same global ROI using <Control-End>. This will put all the region sizes back to default settings.

   When the yellow bone mask appears, reduce the green bone fill/delete box to a point; use it on delete mode to carefully trace the true course of the

lower neck up to just below the acetabulum. The soft tissue will show through the bone mask as a darker yellow.

Continue erasing with a horizontal line out into the ischium. The software will automatically erase the island of unwanted bone mask outside the neck.

If you are dissatisfied with your deletion, the original bone mask can be restored by pressing <Control-Home>.

Press <End> when you are satisfied with the deletion and proceed with the analysis.

4. 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 these scans 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. Large changes in the trochanteric line from baseline to follow-up should be flagged for review.

VI. 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

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 the same scan mode as used for the AP patient scans.

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 floppy disk.

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 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 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 floppies.

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. 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 in 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 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.

10. The quality control 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 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 two weeks 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 any reanalysis instructions using the grading sheets in the appendix. It will the be up to the site operator to reanalyze the scan according to the coordinating center comments and return a printout of the reanalyzed scan to the coordinating center for verification.

D. Other Quality Control Measures

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

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.

VII. DATA MANAGEMENT

The study site is responsible for maintaining both electronic and hard copies of all scans performed during the study. **Use prepunched paper when printing scan reports and store them in a study binder.**

For scan archival, each study site will be making archives of all patient scans to floppy disk. Phantom scans themselves are not archived: only the phantom database need be archived for subsequent analysis of machine performance. These floppy disks are retained at the study site.

In addition to the standard archive, a second set of all patient scans are to be generated using the COPY feature and sent to the coordinating center. This will serve as an alternative backup in the event that your local archive becomes corrupted. It will also allow the coordinating center to view any flagged scans on the workstation if the printout review is inconclusive.

Every two weeks, the written patient scan log sheets, patient database, scan disks of all patients scans acquired or reanalyzed since the previous data transfer (generated with the COPY feature) are sent to UCSF. The patient database and logsheets will provide a record of work performed.

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 using a grading sheet to verify correct analysis. Improper analysis procedures are noted directly on the scan for reanalysis.

Periodically, random scans selected by UCSF from the patient database will be requested from each site. Original printouts of these scans will be sent to UCSF and reviewed using the same grading sheets as for flagged scans. In the initial phases of the study, a relatively large number of scans will be checked to verify site performance. As the proportion of correct analyses increases, the number of spot checked scans will be decreased.

For all flagged, spot checked and followed scans received at UCSF which require reanalysis, the grading sheet and 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 saved 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.

IN SUMMARY

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

a) Copy of written patient scan log sheets.
b) Patient database (on floppy disk).
c) Floppy disks containing all patient scans acquired or reanalyzed since the last data shipment.
d) Original printouts of flagged scans and requested spot check scans since the last data transfer.
f) Original printouts of all scans which have been reanalyzed according to UCSF instructions since last data transfer.
g) Printout of the graph of your daily spine phantom BMD results.

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

a) Grading sheets and annotated printouts of flagged scans, and requested spot check 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.

Note that if a scan needs to be restored and reanalyzed for any reason, it will need to be rearchived.

Ship printouts of flagged scans for review with the patient and quality control databases every two weeks to the following address:

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

ACKNOWLEDGEMENT

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 COORDINATING CENTER

General

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.

Global region of interest for followup is different size from baseline.

Hip Scans

Positioning of hip on follow-up does not duplicate baseline positioning.

Bone edge is altered in any way, including deletion of ischial bone, exclusion of calcifications in ligments surrounding hip, or filling in neck notches.

Femoral neck has notch that throws off the alignment of the midline and is not corrected.

Midline looks off on either baseline or follow-up and the cause cannot be attributed to a neck notch (no apparent irregularities in neck).

Femoral neck box on followup is different width or position than on baseline.

Femoral neck box has been reduced in size to a width of 8 or less.

Ward's Triangle box touches either edge of the neck, is located on the greater trochanter, or differs in its placement between baseline and followup.

Analysis program repeatedly fails to place regions appropriately (i.e. neck box is located on femur rather than neck).

Spine Scans

Patient says she has had spinal fusion surgery.

Intervertebral space marker placement is different from baseline to followup.

Corresponding vertebral levels cannot be determined between baseline and follow-up, ie the vertebrae are very similar in appearance and landmarks such as ribs and iliac crest are missing.

Unusual edge or size variations between baseline and followup.

Any alterations to the bone edges made on either baseline or followup.

Crushed vertebrae: A vertebra that is shorter than the one above it or has a higher density than the one below it. Cases where L2 is much shorter than L3. Cases where L4 is much denser than L3.

A vertebra has been excluded or is missing from analysis for any reason.