Revised 2013 (Resolution 32)*

ACR–SPR–SSR PRACTICE GUIDELINE FOR THE PERFORMANCE OF QUANTITATIVE COMPUTED TOMOGRAPHY (QCT) BONE DENSITOMETRY

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I.   INTRODUCTION

This guideline was revised collaboratively by the American College of Radiology (ACR), the Society for Pediatric Radiology (SPR), and the Society of Skeletal Radiology (SSR).

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Quantitative computed tomography (QCT) bone densitometry is a clinically proven method of measuring bone mineral density (BMD) in the spine, proximal femur, and distal forearm [1-9]. QCT is used primarily in the diagnosis and management of osteoporosis and other disease states that may be characterized by abnormal BMD, as well as to monitor response to therapy for these conditions. This guideline outlines the principles of performing high quality QCT.

The primary goal of QCT is to measure BMD accurately and reproducibly and compare that measurement to reference population standards and/or to an individual's previous bone densitometry examination(s). This comparison contributes to the diagnosis of osteoporosis, helps in determining future fracture risk, and the need for pharmacologic therapy and fracture prevention programs. It is also useful in evaluating the effectiveness of prior or current therapy.

QCT has some advantages over dual-energy X-ray absorptiometry (DXA). DXA BMD estimates may be significantly biased by severe degenerative changes of the hip or spine, vascular calcifications, oral contrast agents, and foods or dietary supplements containing significant quantities of calcium or other heavier minerals or elements [10-12]. QCT is often more accurate in patients with extreme obesity or low body mass index [13-16].

There are well-documented differences in the response of cortical and trabecular bone to aging and therapeutic interventions. QCT spine BMD measurements are used to characterize only trabecular bone, while hip area-density measurements obtained using QCT predominantly characterize cortical bone. QCT spine BMD measurements provide a sensitive indication of spine fracture risk and a somewhat less sensitive indication of hip fracture risk [17,18].

For pediatric applications, see section II.B. It should be noted that peripheral QCT (pQCT) is commonly performed in children. It has the advantage of lower radiation dose [19].

II. INDICATIONS AND CONTRAINDICATIONS

BMD measurement is indicated whenever a clinical decision is likely to be directly influenced by the result of the test. QCT may be considered in place of or in addition to DXA in the following circumstances: [20-27].

A. Adults with established or clinically suspected low BMD, including:

1. All women age 65 years and older and men age 70 years and older (asymptomatic screening).

2. Women younger than age 65 years who have additional risk for osteoporosis, based on medical history and other findings. Additional risk factors for osteoporosis include:
    a. Estrogen deficiency.
    b. A history of maternal hip fracture that occurred after the age of 50 years.
    c. Low body mass (less than 127 pounds [57.6 kg]).
    d. History of amenorrhea (more than 1 year before age 42 years).

3. Women younger than age 65 years or men younger than age 70 years who have additional risk factors, including:
    a. Current use of cigarettes
    b. Loss of height, thoracic kyphosis.

4. Individuals of any age with osteopenia [28] or fragility fractures on imaging studies, computed tomography (CT) or magnetic resonance imaging (MRI) examinations.

5. Individuals age 50 years and older who develop a wrist, hip, spine, or proximal humerus fracture with minimal or no trauma, but excluding pathologic fractures.

6. Individuals of any age who develop 1 or more insufficiency fractures.

7. Individuals receiving (or expected to receive) glucocorticoid therapy for more than 3 months.

8. Individuals beginning or receiving long-term therapy with medications known to adversely affect BMD (e.g., anticonvulsant drugs, androgen deprivation therapy, aromatase inhibitor therapy, or chronic heparin).

9. Individuals with an endocrine disorder known to adversely affect BMD (e.g., hyperparathyroidism, hyperthyroidism, or Cushing's syndrome).

10. Hypogonadal men older than 18 years and men with surgically or chemotherapeutically induced castration [29,30].

11. Individuals with medical conditions that could alter BMD, such as:
    a. Chronic renal failure.
    b. Rheumatoid arthritis and other inflammatory arthritides.
    c. Eating disorders, including anorexia nervosa and bulimia.
    d. Organ transplantation.
    e. Prolonged immobilization.
    f. Conditions associated with secondary osteoporosis, such as gastrointestinal malabsorption, sprue, malnutrition, osteomalacia, vitamin D deficiency, endometriosis, acromegaly, chronic alcoholism or established cirrhosis, and multiple myeloma.
    g. Individuals who have had gastric bypass for obesity.

12. Individuals being considered for pharmacologic therapy for osteoporosis.

13. Individuals being monitored to assess the effectiveness of osteoporosis drug therapy [31-33] or to follow-up medical conditions associated with abnormal BMD.

14. Individuals with extremes of obesity or low body mass index.

B. Pediatric Indications and Considerations

Indications for performing BMD examinations and its subsequent assessment in children differ significantly from those in adults. Interpreting BMD measurements in children is complicated by the growing skeleton [34,35]. DXA is unable to take into account changes in body and skeletal size during growth, limiting its usefulness in longitudinal studies. For example, an increase in DXA measured areal BMD in the spine is more likely a reflection of change of vertebral size than a change in density [36]. Because QCT can assess both volume and density of bone in the axial and appendicular skeleton, it may be more useful than DXA in children [37]. Due to its lower radiation dose, peripheral QCT, which assesses the extremities, may be preferable to central QCT in pediatric patients.

In children, BMD measurement is indicated whenever a clinical decision is likely to be directly influenced by the result of the test. Indications for QCT/pQCT include, but are not limited to: [38]

1. Individuals receiving (or expected to receive) glucocorticoid therapy for more than 3 months.

2. Individuals receiving radiation or chemotherapy for malignancies.

3. Individuals with an endocrine disorder known to adversely affect BMD (e.g., hyperparathyroidism, hyperthyroidism, growth hormone deficiency or Cushing's syndrome).

4. Individuals with bone dysplasias known to have excessive fracture risk (osteogenesis imperfecta, osteopetrosis) or high bone density.

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5. Individuals with medical conditions that could alter BMD, such as:
   a. Chronic renal failure.
   b. Rheumatoid arthritis and other inflammatory arthritides.
   c. Eating disorders, including anorexia nervosa and bulimia.
   d. Organ transplantation.
   e. Prolonged immobilization.
   f. Conditions associated with secondary osteoporosis, such as gastrointestinal malabsorption, sprue, inflammatory bowel disease, malnutrition, osteomalacia, vitamin D deficiency, acromegaly, cirrhosis, HIV infection, prolonged exposure to fluorides.

C. Relative Indications

Central and peripheral BMD may be discordant. Individuals at high risk for osteoporosis who have a normal peripheral examination should be further evaluated by central QCT.

D. Contraindications

1. There are no absolute contraindications to performing QCT. However, a QCT examination may be of limited value or require modification of the technique or rescheduling of the examination in some situations, including:
   a. Administration of intravascular iodinated contrast. If a QCT of the spine and contrast enhanced examination of the abdomen are performed simultaneously, the BMD calculation may be altered by the contrast enhancement [39]. If both QCT and a contrast enhanced scan of the abdomen are planned for the same imaging session, this pitfall may be avoided by performing sequential scanning with the QCT portion as the first of the two examinations or by using a published conversion factor.
   b. Pregnancy.
   c. Severe degenerative changes or fracture deformity in the measurement area.
   d. Implants, hardware, devices, or other foreign material in the measurement area.
   e. Inability to position the patient completely within the scanning field of view.

2. For the pregnant or potentially pregnant patient, see the ACR–SPR Practice Guideline for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation [40].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

For the physician, medical physicist, and radiologic technologist qualifications see the ACR Practice Guideline for Performing and Interpreting Diagnostic Computed Tomography (CT). Additional specific qualifications and responsibilities include:

A. Physician [41]

1. The examination must be performed under the supervision of and interpreted by a licensed physician with the following qualifications:
   a. Knowledge and understanding of bone structure, metabolism, and osteoporosis.
   b. Documented training in and understanding of the physics of X-ray absorption and radiation protection, including the potential hazards of radiation exposure to both patients and personnel and the monitoring requirements.
   c. Knowledge and understanding of the process of QCT data and image acquisition, including proper patient positioning and placement of regions of interest, and artifacts and anatomic abnormalities that may falsely increase or decrease BMD values.
   d. Knowledge and understanding of the analysis and reporting of QCT, including, but not limited to: BMD values, T-score, Z-score, and fracture risk. Knowledge of the World Health Organization (WHO) classification system is important, although this classification system has not been validated for use with QCT.

    e. Knowledge and understanding of the criteria for comparison of serial measurements, including limitations of comparing measurements made by different techniques and different devices**.**

    f. Knowledge and understanding of the utility of the entire spectrum of bone densitometry techniques, including DXA, QCT, peripheral DXA, peripheral QCT, and quantitative ultrasound (QUS), to fulfill a consultative role in recommending further bone densitometry studies, future serial measurements, or diagnostic procedures to confirm suspected abnormalities seen on QCT images.

   2. The supervising physician is responsible for overseeing the QCT facility and its equipment quality control program. The physician accepts final responsibility for the quality of all QCT examinations.

B. Radiologic Technologist

   1. The examination must be performed by a technologist with the following responsibilities and qualifications:
    a. Ensuring patient comfort and safety, preparing and properly positioning the patient, placing regions of interest for BMD measurements, monitoring the patient during the procedure, and obtaining the measurements prescribed by the supervising physician.
    b. Determining the precision error of the equipment. (See section VII).
    c. Documented formal training in the use of the QCT equipment, including performance of all manufacturer-specified quality assurance (QA) procedures.
    d. Knowledge of and familiarity with the manufacturer's operator manual for the specific scanner model being used.
    e. State licensure and/or certification, if required.
    f. Certification by the American Registry of Radiologic Technologists (ARRT) is also   desirable.

   2. Continuing Medical Education

   The technologist's continuing medical education should be in accordance with the national registry or state licensure requirements, where applicable.

IV.   SPECIFICATIONS AND ANALYSIS OF THE EXAMINATION

A. The written or electronic request for a QCT examination should provide sufficient information to demonstrate the medical necessity of the examination and allow for the proper performance and interpretation of the examination.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). The provision of additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient's clinical problem or question and consistent with the state scope of practice requirements. (ACR Resolution 35, adopted in 2006)

B. A history should be obtained from the patient regarding risk factors as listed in section II, including family history, prior fragility fractures, and prior surgery that could potentially affect the accuracy of measurements. Questionnaires can be found on www.iscd.org or www.nof.org.

C. The QCT Data and Analysis

Most commonly, adults may have QCT of the spine and/or hip. Children usually have only a spine QCT.

A complete QCT examination should consist of the following:

1. Localizer images of the lumbar spine
   The spine localizer is a lateral CT scout image of the lumbar spine. The localizer should be reviewed by the radiologic technologist to determine if specific sites within the lumbar spine should be excluded from analysis. The lateral localizer should also document the spine region scanned and should span the entire lumbar spine with sufficient resolution for vertebral fracture assessment.

2. Localizer images of the hip
   The hip localizer is an AP CT scout image of the hip and should include the region from 2.0 cm cephalad to the acetabular roof through the lesser trochanter.

3. QCT acquisition
   a. There are three ways of acquiring spine QCT data:
      i. Acquisition of volumetric CT data of the spine (3D) with simultaneous scanning of the patient and a calibration device. Two consecutive vertebral bodies are scanned in a helical manner (usually 26 images).
      ii. Acquisition of single (2D) axial images through four consecutive vertebral bodies (10 mm slice through the midportion), with simultaneous scanning of a calibration device.
      iii. Acquisition of single axial images through a vertebral body (10 mm slice through the mid-portion) with separate scanning of a calibration device.
   b. CT data for the hip are acquired as axial images with slice spacing closest to 3 mm achievable with a pitch of 1.0. Scans are performed from mid-thigh upwards with a simultaneously placed phantom. Images are taken from 5 mm above the highest level of the femoral head to 10 to 15 mm below the lower aspect of the lesser trochanter. This will generate 35 to 40 contiguous scans.

4. Data analysis
   a. Labeled images of the anatomic site measured and relevant measurements must be archived in the patient's permanent record.
   b. For most systems, scanning with a phantom or other calibration standard is necessary to evaluate the accuracy and precision of BMD measurement. Quality control protocols are maintained according to the specifications of the specific QCT program used.
   c. In 3D acquisition mode, the images are electronically sent to the post-processing computer.
   d. In either 2D or 3D mode, software is used to compare the patient's CT data with normal young adult and age-matched and sex-matched control population standards specific to the equipment. Some population standards are matched for ethnicity, weight, and body mass index.

D. Positioning and soft-tissue-equivalent devices issued by the manufacturer should be used consistently and properly. Comfort devices, such as pillows under the head or knees, should not interfere with proper positioning and should never appear in the scan field.

E. Anatomic areas of prior surgery or known prior fracture and all fractured vertebrae should be excluded from measurement. If a vertebra is anatomically intact and review of the source images confirms the absence of a lytic or blastic process, it may be included in the densitometry.

F. If there is significant unexplained discordance between 2 measured areas, additional QCT acquisitions (e.g., opposite proximal femur) or other BMD measurement techniques (e.g., DXA) should be performed.

G. Currently there are no consensus standards for assigning diagnostic categories based on QCT spine BMD measurements. Depending on the software manufacturer and version, comparisons of QCT spine measurements may or may not be reported as T-scores. Nonetheless, QCT spine T-scores generally should not be used to assign a diagnostic category using World Health Organization (WHO) (DXA) guidelines. However, if only a QCT spine BMD measurement is available, then the following definitions are suggested for assigning a diagnostic category approximately equivalent to WHO diagnostic categories used with hip BMD measurements:

QCT Trabecular Spine BMD Range	Equivalent WHO Diagnostic Category
BMD >120 mg/cm^3	Normal
80 mg/cm^3 ≥ BMD ≥120 mg/cm^3	Osteopenia
BMD <80 mg/cm^3	Osteoporosis

The above categories are derived by selecting thresholds that result in approximately the same fraction of the population being assigned to a specific category based on QCT spine T-score as would be assigned based on QCT hip T-score. The use of T-scores has been avoided in this categorization to reinforce the fact that QCT spine T-scores and hip T-scores are frequently different. Assigning a WHO diagnostic category based on a QCT spine T-score may result in overstating a patient's risk of hip fracture.

H. For postmenopausal women and men age 50 and older, hip BMD measurements should be compared with those of a young adult reference population. Two-dimensional areal bone mineral density (aBMD) of the proximal femur measured by three-dimensional quantitative CT can be compared to DXA derived measurements that use the NHANES reference data [42]. This aBMD is calculated by the computer software using the acquired QCT data.

Comparisons should be reported as T-scores for QCT hip measurements. Current consensus standards emphasize hip fracture risk and hip fracture risk mitigation. Consequently, a WHO diagnostic category should be assigned based on consideration of only the QCT hip T-score in a standard QCT study. QCT data from scans of the hip can also be used to derive geometrical properties of the proximal femur, which are used in research protocols [32,43,44].

I. For children, premenopausal women, and men younger than age 50, QCT BMD measurements should be compared with population-specific age-matched values (Z-scores).

J. For follow-up examinations, comparison should be made to any prior comparable QCT examinations of the same site. The precision error of the specific scanner(s) should be determined to identify whether any changes are statistically significant [45]. Comparable scans include, in order of decreasing validity:

1. Previous examinations on the same well-maintained unit.
2. Previous examinations on another unit from the same manufacturer.
3. Previous examinations on a unit from another manufacturer, with results reported in standardized units.

It should be noted that a complete QCT "unit" includes a CT scanner, as well as calibration phantoms and software used in determining BMD estimates and population comparisons. Alterations in any of these components can affect BMD determinations. After such changes QA procedures, including precision testing, should be performed with determination of appropriate statistical parameters.

K. Due to radiation dose considerations, least significant change parameters are not used for clinical evaluations, although they may be obtained for research purposes. Appropriate quality assurance procedures should be performed according to hardware and software manufacturers' guidelines.

V.   DOCUMENTATION

Reporting should be in accordance with the ACR Practice Guideline for Communication of Diagnostic Imaging Findings.

A. A permanent record must be maintained and should include:

1. Patient identification, facility identification, examination date, image orientation, and unit manufacturer and model.
2. Clinical notes or patient questionnaire containing any pertinent history.
3. Positioning, anatomical information, and/or technique settings needed for performing serial measurements.
4. Printouts or their electronic equivalent of the images and regions of interest, if provided by the unit and the BMD values obtained.

B. For postmenopausal women and men age 50 and older, reports should include the BMD (in g/cm²) for area density, T-score, and WHO diagnostic classification at the hip; and BMD (in mg/cm³) for trabecular volume density at the spine. A statement about relative fracture risk should also be reported. Methodologies for determining absolute fracture risk have not been standardized for QCT, and a statement can only be made for relative fracture risk.

C. QCT derived hip T-scores may be used at this time to obtain a FRAX based 10 year fracture risk.

D. For premenopausal women, men younger than age 50, and children, the BMD and Z-score should be reported for each site examined. Z-scores above -2.0 are within the expected range. Z-scores of -2.0 or lower are considered to be below the expected range for age. T-scores should not be reported for children.

E. The report should indicate whether artifacts or other technical issues may have influenced the reported BMD measurement(s). A statement comparing the current study to prior available comparable studies should include an assessment of whether any changes in measured BMD are statistically significant. Recommendations for and the timing of follow-up QCT studies may be included. When appropriate, recommendations for alternative modality densitometry examinations, ancillary imaging tests, or other diagnostic measures should be provided. Reports may also reference the standard database(s) used for calculating the T-score and Z-score and estimating fracture risk.

VI. EQUIPMENT QUALITY CONTROL

QCT quality control is extremely important for accuracy in sequential monitoring of the effectiveness of therapy or progression of disease. All three of the methods for acquiring QCT provide accurate BMD determinations suitable for assessing bone status. There are, however, differences in their precision resulting in different sensitivities in detecting significant change in BMD through serial measurement comparisons. Precision is typically best when the patient and the calibration standard are imaged simultaneously, and volumetric QCT units often have better precision because of their reduced dependence on operator skills such as patient positioning and data processing.

Quality control is generally implemented at 2 levels. The first is maintenance of the CT system used to acquire image data. The second is maintenance of the QCT software, phantoms, and associated accessories.

A. CT System – For the CT system, basic quality control procedures, as specified by the manufacturer, should be performed and recorded by a trained technologist. The results should be interpreted immediately upon completion according to the guidelines provided by the manufacturer to ensure proper system performance. If a problem is detected according to manufacturer guidelines, the service representative should be notified, and patients should not be examined until the equipment has been cleared for use.

B. QCT Phantoms – Precision error measurements of the phantom or standard should be performed on a schedule according to manufacturer's specifications and the results recorded. The results of the phantom measurements should not exceed the specifications or recommendations of the manufacturer and generally should be within 1%.

C. For the QCT software, basic quality control procedures, as specified by the manufacturer, should be performed and recorded by a trained technologist. The results should be interpreted immediately upon completion according to the guidelines provided by the manufacturer to ensure proper system performance. If a problem is detected according to manufacturer guidelines, the service representative should be notified, and patients should not be examined until the software has been cleared for use.

D. Equipment performance monitoring should be in accordance with the ACR-AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment.

VII.   RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, registered radiologist assistants, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, "as low as reasonably achievable" (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel that work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection and application of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and the use of dose reference levels) http://www-pub.iaea.org/MTCD/Publications/PDF/p1531interim_web.pdf

Nationally developed guidelines, such as the ACR's Appropriateness Criteria®, should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

Facilities should have and adhere to policies and procedures that require varying ionizing radiation examination protocols (plain radiography, fluoroscopy, interventional radiology, CT) to take into account patient body habitus (such as patient dimensions, weight, or body mass index) to optimize the relationship between minimal radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used whenever appropriate. If such technology is not available, appropriate manual techniques should be used.

Additional information regarding patient radiation safety in imaging is available at the Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org) websites. These advocacy and awareness campaigns provide free educational materials for all stakeholders involved in imaging (patients, technologists, referring providers, medical physicists, and radiologists).

Radiation exposures or other dose indices should be measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR Technical Standards. Regular auditing of patient dose indices should be performed by comparing the facility's dose information with national benchmarks, such as the ACR Dose Index Registry, the NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director's National Evaluation of X-ray Trends. (ACR Resolution 17 adopted in 2006 – revised in 2009, 2013, Resolution 52).

VIII.   QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control*, *and Patient Education* on the ACR web site (http://www.acr.org/guidelines).

ACKNOWLEDGEMENTS

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