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The American College of Radiology will periodically define new practice parameters and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice parameters and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice parameter and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review and approval. The practice parameters and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice parameter and technical standard by those entities not providing these services is not authorized.

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ACR–AAPM TECHNICAL STANDARD FOR DIAGNOSTIC MEDICAL PHYSICS PERFORMANCE MONITORING OF DUAL-ENERGY X-RAY ABSORPTIOMETRY (DXA) EQUIPMENT

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care¹. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents 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 practitioner in light of all the circumstances presented. Thus, an approach that differs from the guidance in this document, 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 this document 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 this document. However, a practitioner who employs an approach substantially different from the guidance in this document 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 the guidance in this document 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 this document is to assist practitioners in achieving this objective.

¹ [Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing](#) 831 N.W.2d 826 (Iowa 2013) Iowa Supreme Court refuses to find that the *ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures* (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, [Stanley v. McCarver](#), 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

This technical standard was developed collaboratively by the American College of Radiology (ACR) and the American Association of Physicists in Medicine (AAPM).

Dual-energy X-ray absorptiometry (DXA) is a material-decomposition imaging technique that utilizes the dependence of the material-specific attenuation coefficient on photon energy. Although primarily used to measure the material-specific density of hydroxyapatite (bone mineral), it is being increasingly applied to whole-body composition analysis and imaging. Medical ethics mandates the adoption of the most favorable and reasonably achievable risk-benefit ratio. Therefore, the risks associated with DXA, such as the risks associated with exposure to ionizing radiation and inaccurate diagnosis, should be quantified and mitigated by proper performance monitoring.

The aim of this technical standard is to provide guidance for the diagnostic medical physics performance monitoring of DXA systems. The performance of all DXA units should be evaluated upon installation and at least annually to ensure proper function. Additional or more frequent performance monitoring may be necessary in certain situations (eg, after major equipment repairs or upgrades). Although it is not possible to consider all possible variations of equipment to be monitored, the goal is to establish performance-monitoring standards to promote the production of high-quality density measurements and images that are consistent with the clinical use of DXA equipment and with the clinical objectives of procedures.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A Qualified Medical Physicist or Qualified MR Scientist is an individual who is competent to practice independently one or more of the subfields in medical physics. The American College of Radiology (ACR) considers certification, continuing education, and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice one or more of the subfields in medical physics and to be a Qualified Medical Physicist or Qualified MR Scientist. The ACR strongly recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physicists in Medicine, or by the American Board of Medical Physics (ABMP).

A Qualified Medical Physicist or Qualified MR Scientist should meet the [ACR Practice Parameter for Continuing Medical Education \(CME\)](#) [1] (ACR Resolution 17, adopted in 1996 – revised in 2012, Resolution 42)

The appropriate subfield of medical physics for this standard is Diagnostic Medical Physics (including medical physics certification categories of Radiological Physics, Diagnostic Radiological Physics, or Diagnostic Imaging Physics).

A Qualified Medical Physicist must be responsible for acceptance testing, routine performance and evaluation, and the technical aspects of radiographic procedures. Those responsibilities should be clearly defined (see section III).

Regardless of certification status, to be considered a Qualified Medical Physicist, a physicist should be trained to perform DXA system evaluations and be familiar with regulations pertaining to the performance of the DXA equipment being monitored; the function, clinical uses, and performance specifications of the DXA equipment; and calibration processes and limitations of the performance testing hardware, procedures, and algorithms.

The Qualified Medical Physicist is responsible for the test protocols, the test methods, and the acceptance criteria. The Qualified Medical Physicist may be assisted by properly trained individuals in obtaining performance data in accordance with applicable regulations. These individuals must be properly trained and approved by the Qualified Medical Physicist in the techniques of performing the tests, the function and limitations of the imaging equipment and test instruments, the reason for the tests, and the importance of the test results. The assisting individual must be under the general supervision² of the Qualified Medical Physicist during periodic performance evaluations. The

² General Supervision means the procedure is furnished under the Qualified Medical Physicist's overall direction and control, but the Qualified Medical Physicist's presence is not required during the performance of the procedure. Under general supervision, the training of the medical physics personnel who

Qualified Medical Physicist is responsible for all surveys and must review, interpret, and approve all data as well as provide a signed report with conclusions [2,3].

III. PERFORMANCE CHARACTERISTICS TO BE MONITORED

The Qualified Medical Physicist's monitoring of performance characteristics must comply with appropriate federal, state, and local regulations.

DXA equipment performance monitoring of systems used for body composition analysis must include additional cross-calibrations, precision assessments, and continuous quality control procedures for the additional materials being analyzed (eg, fat). Bone mineral density measurements are not adequate for quality control (QC) of these additional materials [4].

A. Acceptance Testing

A Qualified Medical Physicist must conduct an initial DXA equipment performance evaluation upon installation of the equipment and after major upgrades. This evaluation should be more comprehensive than periodic evaluation and should be completed before clinical use.

Prior to the initial equipment performance evaluation, electrical safety and digital image communication must be verified by appropriate personnel.

Acceptance tests must include tests performed during the annual performance evaluation and, additionally:

1. Compliance with all terms and line items of the purchase agreement or contract (if the documentation is available to the Qualified Medical Physicist)
2. Compliance with manufacturer's relevant imaging and safety performance specifications
3. Evaluation of radiation shielding [5]
4. Manufacturer-recommended calibration (if applicable)
5. Verification of alerts and interlocks operation
6. Measurement of leakage radiation³ [6]
7. Measurement of high-contrast spatial resolution. This needs to be done only if the unit is to be used for imaging applications and not if the unit is used only for bone densitometry.
8. Maximum scatter dose rate to operator
9. Verification of density measurement linearity over a clinically relevant range
10. Cross-calibration and calculation of the generalized least significant change between the system hardware being tested and the previous system/hardware as well as any other DXA systems in use at the facility (if applicable, detailed in Appendix). These should be performed immediately after clinical use begins.
11. Calculation of the system's least significant change (detailed in Appendix)

B. Performance Evaluation

1. The performance of each DXA system must be evaluated at least annually. At a minimum, this evaluation must include the following items:
 - a. Unit assembly integrity assessment
 - b. Tube-image receptor assembly motion assessment
 - c. Review Shewhart charts of routine QC (eg, daily, weekly) to verify that the density results remain in control [7,8]
 - d. Radiographic uniformity assessment, if provided by the vendor
 - e. Measurement of entrance air kerma for the most common clinical procedures
 - f. Verification of displayed dose and radiation output metrics (if applicable)

actually performs the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the Qualified Medical Physicist.

³ At the discretion of the Qualified Medical Physicist, these measurements do not need to be repeated if previously performed by a field engineer during installation.

Additionally, the performance evaluation should include the following items:

- a. Assessment of individual technologist measurement precision (see the Appendix)
 - b. Calculation of the system's least significant change (see the Appendix)
 - c. Acquisition display monitor(s) performance assessment. This needs to be done only if the unit is to be used for imaging applications and not if the unit is used only for bone densitometry.
2. Monitoring required after replacement or repair of a major component

If a major component is replaced or repaired, a Qualified Medical Physicist should evaluate, in a timely manner, the need for performance testing of the DXA system. The scope of the evaluation should be determined by the Qualified Medical Physicist based on the type of component that was replaced or repaired.

C. QC Program

A continuous QC program must be implemented for all DXA systems with the assistance of a Qualified Medical Physicist. The Qualified Medical Physicist should identify the person responsible for performing the tests and determine the test frequency and tolerances (in conjunction with manufacturer specifications). At a minimum, the QC program should include the following:

1. Measurement of phantom density
2. Comparison of current phantom density measurement with previously acquired measurements and control limits [7,8]
3. Additional manufacturer-required tests and calibration (if applicable)
4. Analysis of rejects and repeats (optional)
5. Receiving radiologist, physician, and technologist feedback regarding density measurement and, if used for imaging purposes, image quality (optional)

The results of the QC program must be monitored at least annually by the Qualified Medical Physicist. If any monitored QC parameter falls outside of the control limits, corrective action should be taken. A Qualified Medical Physicist should be consulted regarding corrective actions for unresolved problems.

D. Written Survey Reports and Follow-up Procedures

The Qualified Medical Physicist must provide a written report of the findings of acceptance testing and performance evaluation to the professional(s) in charge of obtaining or providing necessary service to the equipment and, if appropriate, to the responsible physician(s). Written reports must be provided in a timely manner consistent with the importance of any adverse findings.

If appropriate, the Qualified Medical Physicist should notify the facility to initiate the required service. The facility must complete corrective actions in a timely manner consistent with the importance of any adverse findings. The facility should retain service reports from competent service personnel as verification that the issue(s) were appropriately resolved. The reports may be reviewed by a Qualified Medical Physicist to confirm that the equipment is performing in a safe and acceptable fashion after the required service is performed or as required by federal, state, or local regulations.

If use of the equipment would pose a danger to life or health or potentially result in erroneous clinical findings, the Qualified Medical Physicist, in collaboration with the facility's Radiation or Safety Officer and interpreting physician, must take immediate action to either prevent equipment use or to indicate in writing what limited studies can be performed safely using the equipment until the hazard is addressed.

IV. 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/Pub1578_web-57265295.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).

V. 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 *ACR Position Statement on Quality Control and Improvement, Safety, Infection Control and Patient Education* on the ACR website (<https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement>).

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PRECISION AND CROSS-CALIBRATION ASSESSMENT

Because bone mineral density often changes slowly and gradually, it is essential to determine if measured changes are due to true physiological change or the unavoidable variability in measurement equipment. This can be accomplished by understanding and measuring both inter- and intra-system measurement deviations of DXA scanners. Precision assessment and cross-calibration should be performed in accordance with the recommendations of the International Society for Clinical Densitometry (ISCD) [9].

For the continuous quality control program, Shewhart charting should be used by DXA facilities to monitor system stability and drift using a phantom. Once appropriate baseline values are determined during acceptance testing, the five Shewhart rules (sometimes referred to as Westgard rules [8]) may be used to determine the stability of the system. The DXA system should be considered “out of control” if any of the following are measured:

1. A phantom bone mineral density (BMD) value differing from the established average value by more than three standard deviations (SD).
2. Two consecutive phantom BMD values differing from the established average value by more than two SD and on the same side of the average.
3. Two consecutive phantom BMD values differing by more than four SD.
4. Four consecutive phantom BMD values differing from the established average value by more than one SD and all are on the same side of the average.
5. Ten consecutive phantom BMD values falling on the same side of the average regardless of their distances from the average.

To aid in determining the statistical significance of clinical measurement differences, the precision error and coefficient of repeatability (commonly referred to as the least significant change [LSC]) should be calculated for each DXA system. This LSC represents the smallest difference between two clinical BMD measurements on a single scanner that can be considered clinically significant with 95% confidence. If the two measurements are taken on two different scanners, the change must be compared to the generalized LSC (GLSC) described below. If more than one technologist operates a DXA system, the precision error should be calculated for each technologist. Precision assessment is performed in vivo using patients representative of the facility’s typical population. Each technologist scans either 15 patients thrice or 30 patients twice, preferable at all clinically applicable anatomic sites. Patients must be repositioned between each scan. These results are used to calculate the group root-mean-square of standard deviations resulting from intra-patient measurements (RMS-SD). Minimum acceptable precisions (such as those suggested by the ISCD [9]) should be defined and enforced for individual technologists. The DXA system LSC is calculated from the combined technologist results at the 95% confidence interval ($LSC=2.77*\text{average RMS-SD}$ [10]). The above text describes the assessment of short-term precision, but long-term precision should also be assessed to account for DXA system drift over time [11]. The measurements obtained from cross-calibration (described below) may be additionally used for precision assessment.

BMD measurements can vary systematically from one scanner to another, even two scanners of the same model. To minimize these systematic errors, cross-calibration of DXA scanners may be necessary if the facility has more than one scanner or a scanner is replaced. If two systems consist of identical technology, cross-calibration may not be necessary, but the BMD of a phantom should be measured 10 times on both systems to verify the consistency of measurements. If the measurements are inconsistent or the two systems are from different manufacturers and/or use different technology, cross-calibration is required and should consist of scanning 30 patients once on the first system and twice on the second system. Individual patient scans should be completed within 60 days of each other. This cross-calibration should be performed for all clinically applicable anatomic sites. A tool, such as the ISCD DXA Machine Cross-Calibration Tool, should be used to generate a calibration equation to convert the density measurements from one scanner to the other. If the ISCD calculator cannot be used, the calibration line should be generated using a Deming regression [12] weighted by the precision measurements of the individual systems. Cross-calibration must be performed in vivo and cannot be substituted with phantom measurements [13-15]. Additionally,

the GLSC should be calculated to determine the least significant change (at 95% confidence) for densities measured on one system and then on the other system. The GLSC should be calculated using the standard deviation of the residual error of regression, S_{yx} , and the revised formula from Shepherd, Lu, and Li [16].

In agreement with the ISCD, both precision assessment and cross-calibration are considered standard clinical practice that is expected to provide benefit to patients. Therefore, these should not require institutional review board (IRB) approval, but patient consent is required. Adherence to the best practices in radiation safety and all applicable radiation safety regulations is required.

*Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

Development Chronology for this Technical Standard

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