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

The American College of Radiology, with more than 40,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

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.

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 care[1]. 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 considering 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 variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and 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 purpose of this document is to assist practitioners in achieving this objective.

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

The aim of this technical standard is to provide guidance for diagnostic medical physics performance monitoring of DXA systems. The performance of all DXA units must 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 BMD 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 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. 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 (CCPM), the American Board of Science in Nuclear Medicine (ABSNM), or the American Board of Medical Physics (ABMP).

A Qualified Medical Physicist should meet the ACR Practice Parameter for Continuing Medical Education (CME) [1]

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). (ACR Resolution 17, adopted in 1996 – revised in 2008, 2012, 2022, Resolution 41f)

A Qualified Medical Physicist must be responsible for acceptance testing and routine performance evaluations, and should support the technical aspects of DXA procedures. Those responsibilities should be clearly defined.

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 as permitted by applicable regulations. These individuals must be properly trained 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 supervision[1] of the Qualified Medical Physicist during periodic performance evaluations. The Qualified Medical Physicist is responsible for all surveys and must review, interpret, and approve all data as well as sign reports [3-5].

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

III. PERFORMANCE CHARACTERISTICS TO BE MONITORED

The Qualified Medical Physicist's monitoring of performance characteristics must comply with all pertinent regulations.

DXA equipment performance monitoring of systems used for body composition analysis and/or trabecular bone score must include applicable additional cross-calibrations, precision assessments, and continuous quality control procedures. Quality Control (QC) applicable to BMD measurements is insufficient for QC related to these additional modes of operation[6].

III. PERFORMANCE CHARACTERISTICS TO BE MONITORED

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 comprehensive and completed before clinical use.

A table that lists the recommended parameters to be evaluated during acceptance testing for DXA equipment is presented in Appendix A. The Qualified Medical Physicist responsible for acceptance testing may diverge from these recommendations and the extent of the measurements depending on the designated use(s) of the DXA equipment.

III. PERFORMANCE CHARACTERISTICS TO BE MONITORED

B. Performance Evaluation

1. The performance of each DXA system must be evaluated at least annually. Equipment performance and usage may necessitate increased periodic testing. The table in Appendix A lists the recommended parameters to be evaluated during annual performance evaluation for DXA equipment.

   If a major component is replaced or repaired (eg, x-ray tube replacement, detector replacement, software changes, etc.), 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 component that was replaced or repaired.

III. PERFORMANCE CHARACTERISTICS TO BE MONITORED

C. QC Program

A continuous QC program must be implemented for all DXA systems with the assistance of a Qualified Medical Physicist. The responsible physician or Qualified Medical Physicist should identify the person responsible for performing the tests and determine testing frequencies and tolerances in conjunction with manufacturer specifications. The QC program should include, but not necessarily be limited to, the QC tests listed in Appendix A.

The results of the QC program must be monitored routinely by the person responsible for performing the tests and at least annually by a Qualified Medical Physicist. If any monitored QC parameter falls outside of the control limits, corrective action must be taken. A Qualified Medical Physicist should be consulted regarding corrective actions for issues that cannot be resolved or are difficult to resolve.

III. PERFORMANCE CHARACTERISTICS TO BE MONITORED

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 facility, professional(s) in charge of obtaining or providing necessary service, 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.

The facility must complete corrective actions in a timely manner consistent with the importance of any adverse findings. The facility should retain service reports 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 pertinent 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 Safety Officer and interpreting physician, must take immediate action to either prohibit equipment use or to indicate in writing what limited studies can be performed safely until the hazard is addressed.

IV. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, non-physician radiology providers, 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 who work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection, application of dose constraints and limits) and the principles of proper management of radiation dose to patients (justification, optimization including the use of dose reference levels). https://www-pub.iaea.org/MTCD/Publications/PDF/PUB1775_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 unnecessary radiation exposure.

Facilities should have and adhere to policies and procedures that require ionizing radiation examination protocols (radiography, fluoroscopy, interventional radiology, CT) to vary according to diagnostic requirements and patient body habitus to optimize the relationship between appropriate radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used, except when inappropriate for a specific exam. If such technology is not available, appropriate manual techniques should be used.

Additional information regarding patient radiation safety in imaging is available from the following websites – Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org). 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 periodically measured by a Qualified Medical Physicist in accordance with the applicable ACR Technical Standards. Monitoring or regular review of dose indices from patient imaging should be performed by comparing the facility's dose information with national benchmarks, such as the ACR Dose Index Registry and relevant publications relying on its data, applicable ACR Practice Parameters, 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; 2006, 2009, amended 2013, revised 2023 (Res. 2d).

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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*As of May 2015, all practice parameters and technical standards that are collaborative with only the American Association of Physics in Medicine are approved by the ACR Council Steering Committee and the ACR Board of Chancellors and will not go through the ACR Council (ACR Resolution 54, 2015). The effective date is the first day of the month following a 60-day period that begins on the date the document was approved.

<u>Development Chronology for this Technical Standard</u>

2020 (CSC/BOC)

Amended 2022 (Resolution 41f)

Appendix A

DXA Equipment Evaluation Parameters

The recommended parameters to be evaluated are listed below, with designations for acceptance testing, performance evaluation, and quality control.

Parameter	Acceptance Testing	Performance Evaluation	Quality Control	Comments, Details, and Other Considerations
Evaluation of radiation shielding [7]	Y	N	N	Ie, structural and operator shielding (if applicable).
Manufacturer-recommended calibration and quality control procedures not otherwise described	Y	Y	Y	If applicable.
Measurement of maximum scatter dose rate to operator	Y	N	N	
Measurement of high contrast spatial resolution	Y*	N	N	
Verification of BMD measurement linearity over a clinically relevant range	Y*	N	N	
Cross-calibration between the system hardware being tested and the previous system/hardware as well as any other DXA systems in use at	Y	Y	N	If applicable (detailed in Appendix B). Established at acceptance and verified during performance evaluation.

the facility				
Verification of the calculation of the system's least significant change and generalized least significant change	Y	Y*	N	If applicable (detailed in Appendix B). These calculations should be performed immediately after clinical use begins (and when operators or procedures are changed) by a person identified by the responsible physician or Qualified Medical Physicist.
Mechanical and system safety evaluation	Y	Y	N	Eg, all mechanical parts move smoothly, without obstructions. Unit is mechanically stable. All electrical wiring is secured as designed and undamaged. All system protective coverings are intact. Emergency power switches are operational.
Verification of Visual and Audible	Y	Y	N	

Indicators				
Review of routine QC, (eg, daily/weekly) to verify that BMD remains in control [9,10]	Y	Y	Y	Detailed in Appendix B. Established at acceptance and verified thereafter.
Radiographic uniformity assessment	Y	Y	N	If provided by vendor.
Diagnostic and modality display monitor(s) performance assessment [11]	Y*	Y*	N	
Measurement of entrance air kerma for the most common clinical procedures	Y	Y*	N	
Verification of displayed dose and radiation output metrics	Y*	Y*	N	If applicable.
Measurement of phantom BMD and comparison of current measurement with previously acquired measurements and control limits [9,10]	N	N	Y	
Repeat Analysis	N	N	Y*	Eg, determine the number and cause of repeated DXA scans to improve

				clinical practice.
Facility Quality Management Review	N	N	Y*	Eg, Documented review of radiologist, physician, and technologist feedback regarding DXA study quality.

*These tests are optional.

Appendix B

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) [12].

For the continuous quality control program, manufacturer-recommended phantom testing must be followed. If manufacturer recommendations are unavailable or as a supplement to manufacturer-recommended phantom testing, Shewhart charting should be used by DXA facilities to monitor system stability and drift using a phantom, which may be ~~is~~ different from the phantom used for system calibration. Once appropriate baseline values are determined during acceptance testing, the five Shewhart rules (sometimes referred to as Westgard rules [10]) 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 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 facility. 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 from two different facilities, 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 that are representative of the facility's typical population. Each technologist scans either 15 patients thrice or 30 patients twice, preferably 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 [12]) should be defined and enforced for individual technologists. The DXA facility LSC is calculated from the averaged technologist results at the 95% confidence interval (LSC=2.77*average RMS-SD [13]). 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 [14]. 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. Therefore, cross-calibration of DXA scanners may be necessary if the facility has more than one scanner or a scanner is replaced, and it is necessary to compare BMD measurements acquired from two or more scanners. 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 BMD measurements from one scanner to the other. If the ISCD calculator cannot be used, the calibration line should be generated using a Deming regression [15] weighted by the precision measurements of the individual systems. Cross-calibration must be performed in vivo and cannot be substituted with phantom measurements [16-18]. 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 and Lu,[19].

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.