ISCD Facility Accreditation Glossary of Terms

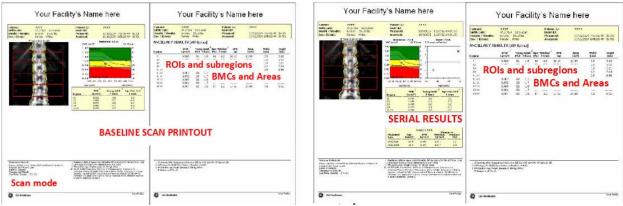
Baseline DXA – the earliest scan results for an individual patient used as a reference with which comparison to future scans are made

Essential Elements – Components of a quality DXA facility necessary for accreditation. The ISCD Facility Accreditation Program assesses compliance with these essential elements.

- 1. Proficiency of DXA Personnel
- 2. DXA Quality Assurance Control
- 3. DXA Scan Acquisition and Analysis
- 4. DXA Interpretation and Reporting

Follow-up (serial) DXA – scan results for an individual patient for which comparison is made back to an initial scan

GE Lunar DXA scan submissions – Remove Protected Health Information (PHI). Include BMD, BMC, Area, Scan mode, Regions-of-interest and sub-regions as shown below



Hologic DXA scan submissions - Remove Protected Health Information (PHI). Include BMD, BMC, Area, Scan mode, Regions-of-interest and sub-regions as shown below

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In-vivo Precision Assessment – A procedure in which either a group of 15 individuals is scanned 3 times each OR a group of 30 individuals is scanned 2 times each within a short period of time (may be the same day if repositioning occurs between each scan). The purpose of precision assessment is (1) to test a technologist's ability to reproduce precise positioning and analysis and (2) to obtain the LSC values used by your DXA interpreter when reporting a comparison between a patient's baseline and follow-up scans. Also see ISCD Official Positions for Precision Assessment. FAQs answered at http://www.iscd.org/resources/faqs/precision-assessment/

Interpretive Report submissions –MUST be in agreement with the ISCD Official Positions <u>http://www.iscd.org/official-positions/2013-iscd-official-positions-adult/</u> Check your reports for content compliance with the Positions before submitting your application. There should be a single overall diagnosis based on the lowest site (lumbar spine, femur neck, total femur, one-third radius). Make sure all skeletal sites and ROIs are identified. Give rationale for excluding ROI. Use T-scores and Z-scores on where appropriate. Fragility fracture history indicates osteoporosis regardless of BMD. Indicate the significance of any change in bone density and include the LSC values in g/cm2. Include a general fracture risk statement. If FRAX® is used, use only as appropriate, apply properly http://www.iscd.org/official-positions/2010-official-positions/2010-official-positions-adult/

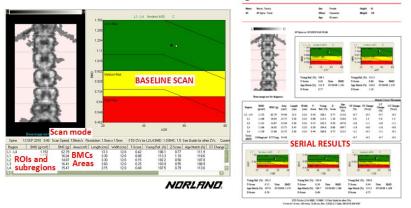
ISCD Precision Calculator – A tool that allows the user to manually type in values measured during in-vivo precision assessment. The "recommended calculator" will give LSC values in g/cm₂ at the 95% confidence level for serial BMD testing and precision error (PE) values in g/cm₂ (also called RMS SD). The advanced calculator will additionally give %CV (coefficient of variation) values. To calculate a %LSC, take the mean BMD of the scanned population and use this formula: [CV% = 100 x (SD/mean)] Calculators can be found at http://www.iscd.org/visitors/resources/calc.cfm

ISCD Facility Accreditation – A five-year accreditation awarded to DXA facilities (not individuals) demonstrating quality in their DXA services, based on the Essential Elements of Accreditation. The accreditation process is a practice-based assessment of facilities that perform and report bone densitometry measurements in clinical settings. Accreditation is not to be confused with certification of individuals as ISCD CCD, CBDT, or CDT(International).

ISCD Certification – Not to be confused with accreditation of an entire facility, certification is the attestation to successful completion of ISCD CCD, CDT, or CBDT certification requirements by an individual

Least Significant Change (LSC) – The least amount of BMD change that can be considered statistically significant (ISCD recommends calculating at the 95% confidence level which is done by multiplying the precision error by 2.77). For a change in a patient's BMD at follow-up to be considered significant, it must equal or exceed the LSC value

Norland DXA scan submissions - Remove Protected Health Information (PHI). Include BMD, BMC, Area, Scan mode, Regions-of-interest and sub-regions



Precision – (also known as reproducibility) With reference to a measurement technology, precision is the degree to which the same value is obtained when a measurement is repeated. Precision is usually presented as a percentage or standard deviation. In vivo precision is the degree to which the device gives the same bone mineral value when a measurement is repeated at the same site on the same subject.

Primary DXA Interpreter – For the purpose of ISCD Facility Accreditation, a DXA interpreter who is a Certified Clinical Densitometrist (CCD) at your DXA facility.

Primary DXA Technologist – For the purpose of ISCD Facility Accreditation, a DXA technologist who is a Certified Densitometry Technologist (CDT), Certified Bone Density Technologist (CBDT), or ARRT(BD)

Region-of-Interest (ROI) – A portion of the skeletal site selected for bone density measurement, such as the femoral neck or total femur

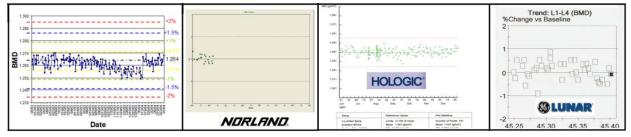
Satellite Office – Satellite offices are subordinate operations at secondary locations with a different business address. They contain separate DXA machines and may employ separate personnel. In some facilities personnel are rotated between satellite offices. A disclosure of your satellite office(s) is required in the Facility Accreditation application.

Spine Phantom Quality Control – QC test for the purpose of monitoring stability of the DXA machine using the same acquisition parameters as when scanning a patient

Spine Phantom Scan –



Spine Phantom Plot Graph – A trend graph plotting Spine Phantom BMD over time for the purpose of monitoring shifts, drifts, and fluctuations in DXA equipment over time



Spine Phantom – A test object of known densitometric properties that can be scanned on a bone densitometer using patient PA spine acquisition and analysis software. It is used as an independent check of machine calibration, cross-calibration of machines and to monitor long-term stability. Most manufacturers supply a unique spine phantom identified by a serial number with each bone densitometer. Several manufacturers also sell spine phantoms that are device independent and can be used on any brand bone densitometer.

Some of the most common spine phantoms are given in the table below.

Abbreviation	Description	Image
	Description	Image
ESP	European Spine Phantom Aluminum simulated bone	
HOLX- ASP(v1)	Hologic Anthropomorphic Spine Phantom (Pre-2007) Hydroxyapatite plastic simulated bone	. Nariate.
HolxASP(v2)	Hologic Anthropomorphic Spine Phantom 2007-current, aluminum simulated bone	and a second sec
GE-H ₂ 0	GE-Lunar aluminum "gold bar" phantom for use in a water bath	
GE-ACR	GE-Lunar aluminum "gold bar phantom encased in acrylic resin	
Bio-Imaging BSP	Bio-Imaging "Bone-Fide" spine phantom. Hydroxyapatite plastic simulated bone	
Norland ASP	Norland Anthropomorphic Spine Phantom – Hydroxyapatite plastic simulated bone.	

Facility Accreditation Frequently Asked Questions

What is ISCD Facility Accreditation?

- A five-year accreditation awarded to DXA facilities (not individuals) demonstrating quality in their DXA services, based on the Essential Elements of Accreditation.
- The accreditation process is a practice-based assessment of facilities that perform and report bone densitometry measurements in clinical settings.
- Accreditation is not to be confused with certification of individuals as ISCD CCD, CBDT, or CDT(International).

Why should my facility apply for ISCD Accreditation?

- Protect and reassure the public that your clinicians and technologists meet standards for quality patient assessment based on current scientific knowledge.
- Improve accuracy and precision by adhering to a uniform approach to nomenclature, data collection, acquisition, analysis and reporting.
- Verify to payers that quality standards are in place in your facility.
- Promote your DXA services: Your facility's name, contact information and website will be listed on the ISCD website. Patients and professionals can search for an ISCD Accredited Facility in their area.

How does my facility apply for ISCD Facility Accreditation?

All required forms can be found in the on the Accreditation <u>Application</u> page of the ISCD website or you can contact the Facility Accreditation Manager, Phone: 860.259.1000 ext 105; Fax: 860.259.1030; E-mail: <u>facility@iscd.org</u>

Who is eligible to apply for ISCD Facility Accreditation?

- Currently, all active DXA facilities in the United States, located in hospitals, medical clinics, private medical offices, research facilities (capable of generating DXA reports), mobile DXA centers, and free-standing imaging centers.
- Facilities perform DXA of the spine, hip, and forearm in human subjects for diagnosis, fracture risk assessment and monitoring.

Do all of our DXA facility's technologist's and interpreter's need to be ISCD certified?

• It is recommended but not required. DXA facilities must have at least one primary interpreter and at least one primary technologist certified by ISCD or an acceptable equivalent. If the Facility has more than one certified technologist or Clinician/Interpreter, the facility will designate one primary technologist and one primary clinician/interpreter for the application.

What is the purpose of a Designated Primary Technologist and Designated Primary Interpreter?

• The Designated Primary Technologist's submissions and Designated Primary Interpreter's submissions carry the most weight with assessors when the application is graded as a whole. Each facility shall designate a Designated Primary Interpreter (DPI) that is responsible for upholding and following established uniform approaches to DXA nomenclature, data collection, acquisition, analysis, and reporting within the facility and all satellites associated with the application. The DPI oversees the training of the other Interpreters (whether certified or not) and the quality of scans and reports from all locations associated with the application.

Why does our facility need to submit DXA scans and reports if all of the technologists and interpreters are ISCD certified?

• Certification is proof of knowledge, but DXA scan and report submissions demonstrate that a facility is using that knowledge in practice.

Why should ISCD Accredited facilities have the ability to scan the forearm?

• It is not uncommon to have situations calling for the use of forearm DXA. According to the ISCD Official Positions, Forearm BMD should be measured under the following circumstances:

- Hip and/or spine cannot be measured or interpreted.
- Hyperparathyroidism
- Very obese patients (over the weight limit for DXA table)

What is a Spine Phantom scan?

• A DXA quality control test in which an artificial spine of known density is scanned using the same acquisition parameters as when scanning a patient for the purpose of monitoring stability of the DXA machine over time.

Why should our facility perform Spine Phantom Scans if not recommended by the DXA manufacturer?

- Excerpt from the ISCD Official Positions on **Phantom Scanning and Calibration**:
 - The Quality Control (QC) program at a DXA facility should include adherence to manufacturer's guidelines for system maintenance. In addition, if not recommended in the manufacturer protocol, the following QC procedures are advised: Perform periodic (at least once per week) phantom scans for any DXA system as an independent assessment of system calibration.

What is a "short-term in-vivo precision assessment"?

- A procedure in which a group of individuals is scanned more than once within a short period of time (usually the same day as long as complete repositioning occurs between each scan).
 - o 15 individuals are scanned 3 times each OR
 - o 30 individuals are scanned 2 times each
- For the purpose of testing a technologist's ability to reproduce precise positioning and analysis. <u>When properly performed</u>, bone density measurements are one of the most precise quantitative measurements in use in clinical medicine today.
- To obtain the Least Significant Change (LSC) values used by your DXA interpreters when reporting a comparison between a patient's baseline and follow-up scans.
- Also see <u>Precision Assessment FAQs</u>

What is an LSC?

• Least Significant Change - The minimum amount of change in bone density needed to be statistically confident that a real change has occurred.

Why do all of our facility's technologist's need to perform a short-term in-vivo precision assessment?

- Excerpt from the ISCD Official Positions on **Precision Assessment**:
 - Each DXA facility should determine its precision error and calculate the LSC
 - Every technologist should perform and in-vivo precision assessment

When should precision assessment be performed?

- Excerpt from the ISCD Official Positions on Precision Assessment:
 - Each technologist should do one complete precision assessment after basic scanning skills have been learned
 - A repeat precision assessment should be done if a new DXA system is installed
 - A repeat precision assessment should be done if a technologist's skill level has changed

What is the ISCD Precision Calculator?

• A tool located on the ISCD website that allows the user to manually type in BMD values measured during in-vivo precision assessment. Automatic calculations are made for Precision Error (PE) and LSC values. ISCD offers the precision <u>Calculator</u> as both a web-based and downloadable tool available to registered users.

How do the Facility Accreditation assessors determine my DXA interpretive reports are acceptable to ISCD?

• Assessors use worksheets for grading DXA reports. All evaluation criteria may be found in the <u>2013 ISCD Official Positions</u>.

Here are some additional tips for submitting DXA interpretive reports for ISCD Facility Accreditation:

- 1. Reports must be in agreement with the <u>2013 ISCD Official Positions</u>. Be sure to check your reports for compliance with the Positions before submitting your application.
- Identify all skeletal sites and ROIs; HOWEVER, a <u>single diagnosis</u> should be made based on the lowest site (lumbar spine, femur neck, total femur, one-third radius).
- 3. Give a statement of technical quality of the scan including potential limitations and rationale for any excluded ROIs.
- 4. Appropriate use of T-scores vs. Z-scores according to the ISCD Official Positions (based on patient age and menopausal status).
- 5. When using T-scores, use proper category based on criteria in the World Health Organization Technical Report Series. Geneva: WHO, 1994
- 6. The presence of a fragility fracture can indicate a diagnosis of Osteoporosis regardless of T-score
- When reporting on serial scans, indicate the significance of any change in g/cm² and percentage. LSC values and dates of comparison scans should be included in all follow-up reports.
- 8. See report content sections of the ISCD Official Positions: **Baseline DXA Report Minimum Requirements**, **Follow-Up DXA Report**, and **DXA Report: Items That Should** <u>Not</u> be Included.
- 9. See DXA Interpretive Report Template
- 10. If FRAX ® is used, it must be in compliance with the <u>2010 Positions of the</u> <u>ISCD/IOF on the Interpretation and Use of FRAX in Clinical Practice</u> and the <u>NOF/ISCD FRAX Implementation Guide</u>