Standards for Clinical Bone Densitometry Practice

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Prepared for:
The Australian & New Zealand Bone and Mineral Society (ANZBMS)
The Australasian Association of Nuclear Medicine Specialists (AANMS)
The Royal Australian & New Zealand College of Radiologists (RANZCR)
The Endocrine Society of Australia (ESA)

These revised Standards prescribe staff qualifications, training and work practices, facility and regulatory requirements plus elements of a comprehensive quality assurance (QA) platform for the application of dual-energy X-ray absorptiometry (DXA) to the safe, precise and efficacious clinical measurement of areal bone mineral density (aBMD, usually written as BMD) and certain other body-tissue composition variables.

Other bone densitometry modalities such as pQCT and HRpQCT could be included in adapted versions of these Standards, with appropriate technical modifications. Together with the appendices and recommended references, some of the physical and mathematical principles that provide scaffolding for the Standards are also described.

The Standards are designed to serve for several years, while acknowledging that certain technical and operational details therein may evolve; along with innovations in the technologies and practices of bone densitometry, as well as its role in the clinical management of diseases and disorders that affect bone in particular, but also the physical compositions of other body tissues, amenable to DXA analysis.

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Abbreviations

AANMS	Australasian Association of Nuclear Medicine Specialists
aBMD	Areal bone mineral density = BMC/Area, usually in units of g/cm^2
AHPRA	Australian Health Practitioner Regulation Agency
ALARA	As low as reasonably achievable (relating to radiation exposures)
ANZBMS	Australian & New Zealand Bone & Mineral Society
AUC	Area under the curve (statistics)
ARPANSA	Australian Radiation Protection & Nuclear Safety Agency
BMC	Bone mineral content, usually in units of g of mineral-equivalent
BMD	Bone mineral density, which unless specifically stated otherwise is "shorthand" for areal bone mineral density, aBMD
CPD	Continuing professional development
CV	Coefficient of variation = SD/Mean, often expressed as a percentage
DAP	Dose-area product
DXA	Dual-energy X-ray absorptiometry
ESA	Endocrine Society of Australia
ESP	European Spine Phantom
EWMA	Exponentially weighted moving average
FSD	Focal-spot to skin distance (X-ray beam)
GLSC	Generalized least significant change
HRpQCT	High resolution peripheral quantitative computed tomography
IAEA	International Atomic Energy Agency
ICRP	International Commission for Radiation Protection
ISCD	International Society for Clinical Densitometry
KPI	Key performance indicator
LSC	Least significant change
LVA	Lateral vertebral assessment
MA	Moving average
MBS	Medical Benefits Schedule
MC	Monte Carlo
MTI	Monitoring time interval
PA	Postero-anterior
pQCT	Peripheral quantitative computed tomography
QA	Quality assurance

QC	Quality control
QCT	Quantitative computed tomography
RANZCR	Royal Australian & New Zealand College of Radiologists
RANZCGP	Royal Australian & New Zealand College of General Practitioners
RMSD	Root mean squared deviation
sBMD	Standardised areal bone mineral density, usually in units of mg/cm^2
SD	Standard deviation
SEM	Standard error of the mean
SND	Standard Normal probability distribution
SOP	Standard operating procedure
T	T-score (bone densitometry-specific)
TLD	Thermoluminescence dosimeter
Unit	Clinical bone densitometry facility, performing & reporting routine DXA assessments
VFA	Vertebral fracture assessment
z (lower case)	Standard (parametric ["Gaussian"]) *z*-statistic
Z	Z-score (bone densitometry-specific)

STANDARD 1: Staff

There shall be sufficient professional and support staff with adequate training and experience to supervise and conduct the work of the clinical bone densitometry unit ("Unit").

Commentary

Work assignment and scope of activities in clinical bone densitometry shall be consistent with the education, training, qualifications and experience of the staff. Only staff trained and certified in bone densitometry shall operate bone densitometers and such staff shall only perform scans for which they have been specifically trained as bone densitometry technologists. A technologist in dual-energy X-ray bone densitometry (DXA) shall be tertiary educated (degree or diploma) in the field of radiography, nuclear medicine, science or nursing, and shall have additional post-graduate training in DXA.

Technologists performing peripheral quantitative computed tomography (pQCT) or high resolution peripheral quantitative computed tomography (HRpQCT) shall be trained specifically in the appropriate field in a manner, and with a scope of competencies plus access to appropriate resources, analogous to that required for DXA. Staff performing axial skeletal quantitative computed tomography (QCT) shall be trained medical imaging technologists ("radiographers").

Appropriate documentation shall be available to demonstrate that the procedures used and measurements performed are within the scope of the education, training, qualifications and experience of the individual technologist (App. 1). Duties of the technologist shall include patient scanning, scans analysis, personal reviewing of results plus preparation of these results for review and reporting by a medical specialist. In addition, they shall execute or supervise a comprehensive and integrated quality assurance (QA) program (Standard 8) that includes all relevant quality control (QC) procedures (App. 3).

Basic training of the technologist shall include at least the following elements:

- Appropriate tertiary qualifications as noted above.
- Radiation safety training that complies with the requirements of the Radiation Regulator. This would normally include basic physics, hazard analysis, ALARA principles & practices, regulations, technologist monitoring plus licensing of individuals and the Unit.
- Patient management (reception, advising [including radiation safety], questionnaire completion, positioning, supervision of moving & lifting, etc).
- DXA scanning & scans analysis training. (May include specific procedures for pQCT and/or HRpQCT.)
- DXA QA/QC, including equipment performance. (May include specific procedures for pQCT and/or HRpQCT.)
- Relevant data manipulation including storage and archiving, some statistical analysis, plus report generation for specialist medical evaluation and interpretation.

Staff operating the equipment shall be competent as well as formally trained. They may be required to produce evidence of their qualifications and training, as well as demonstrating their competence in a practical sense.

STANDARD 2: Consultation

The unit shall have staff who, within the limits of their clinical responsibilities, can advise clinicians on evaluation and interpretation of results of bone densitometry examinations, plus the precision[1] and accuracy of methods employed.

Commentary

Prior to their release, the interpretation and reporting of all bone densitometry services must be provided by a specialist or consultant physician, who shall be cognisant of the current requirements (where relevant) of the Medical Benefits Schedule (MBS) of the Australian Govt Dept of Health & Aged Care, pertaining to bone densitometry (#17, App. 8).

An additional essential service of the Unit is to provide further advice to the referring clinician, on request. This consultancy shall be readily accessible, and clinicians shall be able to obtain authoritative advice from the medical specialist or (when a query is specifically within their scope of practice) the technologist on:

- precision[1] and accuracy of methods used in the Unit, including *in vivo* precision and related estimates for all reported scans, including the source of these estimates.
- The statistical significance of results (e.g., in relation to the measured least significant change [LSC] for that scan type) and their relation to reference intervals - if employed by the Unit (Apps 2 & 3). This includes data on the source of the reference interval used for each scan interpretation.
- Also, placing the current report in the context of any previous reports created by the Unit for that patient, and where feasible and helpful, known results from other centres.
- The scientific basis and the clinical significance of the results.
- The suitability of the requested procedure to solve the clinical problem in question.
- Any further suggested procedures, and their scientific basis, which may be helpful.

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[1] In these Standards and their Appendices, "precision" (or reproducibility) represents the minimum difference in repeated measurements (usually duplicate) on the same patient, over any specified time period, before a clinically significant change has occurred. It is a combination of the statistical within-Unit-derived " least significant change" (LSC) for that scan type on a specified DXA machine *plus the important qualitative contributions of the intuition and experience of the physician*. "Real" precision is thus always $\geq$ the LSC, which itself may be quoted at the discretion of the Unit. Practitioners should be aware of different usages of the term "precision" in the literature, particularly when a value of less than (say) 3% of mean BMD is quoted. Likely, this is a statistical construct such as "$RMSD_d$" in Eq. (4) of App. 2, used for assessing phantom QC scatterplots or for calculation of the LSC. If applied solo and thus incorrectly to serial patient scans, such a value will markedly underestimate measurement errors in bone densitometry and may lead to false conclusions about real changes. Note that for clarity there is no nomenclature distinction made between "repeatability" & "reproducibility" or between "precision" & "imprecision" in the discussion - acknowledging the slightly different meanings (#18, App. 8).

STANDARD 3: Bone Densitometry Unit Facilities

The Unit shall provide sufficient space and other facilities for the satisfactory and safe provision of the service.

Commentary

- The Unit environment shall be conducive to the Best Practice performance of personnel and equipment.
- Facilities shall be adequate for patient comfort and privacy, plus safety and efficacy of DXA operations.
- There shall be sufficient space around each DXA machine such that staff and (occasionally) necessary support person(s) accompanying the patient are out of the radiation hazard zone of the X-ray unit. If (rarely) necessary, appropriate radiation shielding shall be provided.
- If relevant, the long term safety of staff and patients occupying spaces adjacent to the Unit will also be considered, particularly in the initial design of the facility (App. 7).
- Communication facilities shall be adequate for proper consultation, confidential patient interviews (if necessary) and report writing.

STANDARD 4: Health and Safety

Compliant and effective levels of control with respect to all aspects of health and safety shall be maintained.

Commentary

4.1 *Radiation Safety*

Radiation safety is emphasised because of the hazards inherent in use of ionizing radiation in the form of X-rays of "diagnostic" energies. Unit personnel, employees, patients and the community at large must be protected. Attention is drawn to relevant guidance documents describing internationally recognised standards of radiation protection and how these may be achieved. The following references are particularly pertinent (see also App. 8):

- ARPANSA Safety Guide: Radiation Protection in Diagnostic and Interventional Radiology (RPS14.1, 2008).
- ARPANSA Code for Radiation Protection in Medical Exposure (Series C-5, 2019).
- ARPANSA Statement on the Use of Dual Energy X-ray Absorptiometry (2016).
- NZ Government Ministry of Health Code of Practice for Diagnostic and Interventional Radiology (ORS C1, 2018).
- ARPANSA Code of Practice: Exposure of Humans to Ionizing Radiation for Research Purposes (RPS8, 2005); (if within the scope of activities of the Unit).
- ICRP 2007 Recommendations of the ICRP (Vienna, Publication 103).

The Unit must comply with all relevant State or (where applicable) Federal radiation safety and occupational health & safety regulations, plus legal obligations, as required by the relevant authorities. In order to achieve these objectives most efficiently, it is highly recommended that the design and construction of the facility be carefully planned from the outset (see App. 7).

Key requirements of the Unit, relevant for radiation safety are:

- In accord with all diagnostic medical uses of ionizing radiation, the internationally-accepted key pillars of radiation protection should be followed; *justification*, *optimisation* and *dose limitatio*n (#19; App. 8). A major contributor to achieving the latter two is a comprehensive QA program described in Standard 8 and related appendices.
- A qualified *radiation safety officer* (as defined by the requirements of the Radiation Regulator, including the duties of the appointee) shall be appointed and shall be accessible for consultations related to all radiation safety issues.
- It is strongly recommended that an *accredited medical physicist* with experience in the design of radiation facilities be consulted to assist with the design, construction and validation of the facility, to facilitate minimising radiation doses to all stakeholders. Further comments on facility design are in Appendix 7.
- The maximum projected historical work capacity of the Unit should be estimated. These data can then be combined with a breakdown of the expected numbers per annum of each scan type (including regular QC) for each technologist. Scattered radiation dose rate can be estimated from published air-kerma rate isodose curves of the DXA manufacturer, third-party publications (e.g., #20, App. 8) or preferably by direct measurement. From

these data, the cumulative acquired dose of each technologist, principally from scatter, can be calculated. Collectively, these actions will inform the long term work practices of staff members, including their optimal habitual location within the scanning room. Further recommendations supporting these objectives are in App. 7.

- Doses acquired by individual staff members (based initially at least on personal radiation monitoring) on an hourly and yearly basis must comply with limits set by the Radiation Regulator. Usually, these are "<20 μSv effective dose/hour" (virtually impossible to exceed in bone densitometry practice) and "<1 mSv/year" (#15, 19, 21 & 22; App. 8). In the very unlikely event that any limit is predicted to be exceeded or actually exceeded, staff work practices shall be altered to avoid these thresholds.
- Staff shall have attended a course on radiation safety pertaining to bone densitometry, endorsed by the Radiation Regulator. Base-grade training for nuclear medicine technologists and medical imaging technologists ("radiographers") qualifies as equivalent to such a course.
- Staff routinely and frequently operating versions of DXA with higher radiation flux (e.g. iDXA or wide-angle fan beam units) or performing QCT shall wear radiation monitoring devices. Records of radiation exposure shall be kept and be available for review. For pencil-beam units, narrow-angle fan-beam DXA scanners, HRpQCT or pQCT systems the likely possibility of relaxing personal radiation monitoring will depend on the requirements of the Radiation Regulator. (Nuclear medicine technologists and medical imaging technologists would automatically wear personal monitors, because of the scope of their other duties and regulations pertaining to their work practices.)

  Ideally, a case presented to the Radiation Regulator as to whether or not staff should wear personal radiation monitors should include; (i) quantitative findings from an initial monitoring period of, say, one year to establish a reliable habitual occupational baseline; (ii) current and expected patterns of patient referrals, and (iii) input from staff themselves.

  An additional check is the deployment of thermoluminescence dosimeter (TLD) badges around the scanning room at critical locations such as the technologist's chair. Each badge will integrate total dose over (say) three months and establish an upper bound for cumulative dose. (In low-dose environments this is often the detection threshold for the device.)
- Other accountable factors include staff pregnancy and working with children and infants. The recommended limit for effective dose to the embryo/foetus during pregnancy is < 1 mSv (#23; App. 8), and this is effectively impossible to achieve with DXA. However, concerns of pregnant staff should be dealt with sensitively. The wearing of a personal monitor may assuage anxiety.
- Units scanning infants and children shall be aware of their enhanced radiosensitivity (3-5 times that of an adult; #23; App. 8), the possible need for staff to be more physically engaged with the child during scanning and to be particularly aware of economising on dose to the patient. It is strongly recommended that technologists scanning children habitually wear personal radiation monitors. (Personal shielding apparel such as lead-rubberised aprons are effective but are cumbersome and unpopular.)
- Staff shall be aware of the radiation effective doses (in units of millisieverts [mSv] or usually microsieverts [μSv]) encountered in bone densitometry plus the long term relevance of these doses to the normal population, pregnant women and to children. The distinction between "effective dose" (relating to calculation of long term radiobiological

effects) and "absorbed dose" (relating to purely physical phenomena) should be understood, at least qualitatively. Staff shall also be aware of, and be able to comparatively interpret radiation effective doses from natural radiation sources *versu*s those from complementary medical investigations (e.g., chest and spinal radiographs).

4.2 *Other Safety Issues*

These include laser, electrical and mechanical safety, which would be governed by relevant Australian and New Zealand Standards, plus institutional requirements and State or Federal regulations. For example, it would be expected that the Unit or its governing institution would mandate a course for patient manual handling, including lifting and manoeuvring disabled patients, even if the host environment provides specialised personnel. Also, that a mock evacuation in the event of fire would be practiced regularly and be appropriately documented.

STANDARD 5: Patient Management

Units shall have staff who are able to handle the unique challenges of patients presenting for bone densitometry.

Commentary

- Staff shall be aware of the unique challenges experienced by some patients during bone densitometry scanning (e.g., those who are disabled, or with chronic airways disease, joint prostheses, potential cardiac complications, arthritis and so on).
- Staff shall be aware of the unique problems of patients with osteoporosis, including pain due to previous fractures plus the risk of further fractures from even the minor trauma incurred during positioning and scanning.
- Staff shall possess the necessary interpersonal skills in order to interview patients, to place them at ease and instruct them in correct procedure. This may also include access to interpreters or suitable software.
- Staff shall be aware of, and be formally trained in the appropriate procedures for moving and lifting patients (e.g., using hoist), particularly those with recent fractures or who are confined to bed, or who have significant disabilities (such as spinal injury or stroke). Such procedures shall be safe for both staff and patient. However, whenever feasible, such actions shall be undertaken by specialist staff employed by the Unit or its host institution, specifically for this purpose.
- Staff should have relevant legal clearances for managing paediatric and vulnerable patients, as legislated within the service jurisdiction.

STANDARD 6: Equipment and Related Procedures & Work Instructions

All equipment must be suitable for the range of diagnostic investigations performed and be in good and compliant working order. A comprehensive compendium of manuals describing procedures, work instructions, forms and records must be readily accessible.

Commentary

- On installation of equipment and from time-to-time, as defined in Standard 8 and Appendices 3-7, QC testing and compliance testing shall be performed as components of a comprehensive and integrated QA program.
- Some of these tests may be performed by an engineer, either provided by the manufacturer or their agent, or a manufacturer-accredited independent contractor.
- The engineer shall be suitably qualified and will meet all requirements of the relevant State and possibly Federal regulatory authorities, particularly the Radiation Regulator.
- Current manufacturer- and (where relevant) Unit-compiled operating manuals for equipment shall be readily available in written or electronic form. Technologists shall be readily able to refer to manufacturer-recommended scanning and analysis procedures plus related information (App. 8.1).
- The compendium of manuals must comprehensively define the integrated QA program, including all QC procedures. The manuals shall also include all communications with the manufacturer and their agent, (including technical updates), subsequent to installation of the machine.
- The supervising technologist or their delegate shall review the content of the compendium of manuals at least annually, to verify their current validity, including incorporation of any updates from the manufacturer.
- All received software updates shall be implemented as soon as practicable, and their installation documented.
- All records of calibration, QC outcomes plus maintenance and repair of each item of equipment shall be kept in a legible and readily accessible form for the entire operational life of that item.

Broad directives pertaining to the QA program and embedded QC requirements are described in Standard 8.

STANDARD 7: Bone Densitometry Competencies & Continuing Professional Development

Only properly documented, clinically-authenticated and compliant bone densitometry techniques shall be used for clinical purposes. A program of continuing professional development, satisfactory for bone densitometry, should be implemented for technologists, preferably through engagement with the relevant professional body.

Commentary

- Only those techniques will be performed for which there are established reference intervals for the population to be studied, with authenticated procedures published in the peer-reviewed literature; demonstrating the efficacy of the technique in fracture prediction and prevention, or in body composition determination (#24; App. 8).
- The exception is where a particular technique is incorporated in a research study which has the current approval of the appropriate institutional research ethics committee (#16; App. 8).
- In any event, each investigation performed by the Unit, whether in the context of screening, routine clinical scanning on request, an approved research study or a QC procedure must follow a fully-documented protocol with each step carefully defined. Appendix 9 provides guidelines for a comprehensive routine clinical report.
- Bone densitometry is an evolving field; a program of continuing professional development (CPD) for technologists, satisfactory for bone densitometry, or at least adaptable to it, is central to maintaining high standards. Those practitioners not yet obliged to be registered with the Australian Health Practitioner Regulation Agency (AHPRA) should anticipate this eventuality and expect that CPD would ultimately be a component requirement. Ideally, advice on CPD should be sought through the specific professional organisation representing the individual.
- Technologists and other Unit staff shall have access to online and/or printed resources including key scientific journals, to supplement equipment technical manuals incorporating periodic updates from the manufacturer (App. 8).
- Through their knowledge, skills and actions all stakeholders in the provision of the bone densitometry service shall aspire to clinical Best Practices (e.g., #25 & #26; App. 8 & App. 9).

STANDARD 8: Quality Assurance Program; Quality Control & Compliance Testing

An efficient and effective rigorously-documented QA program that integrates engineering interventions (planned & unplanned), QC procedures and regular compliance testing shall be followed; ensuring that results provided by the Unit meet acceptable professional and regulatory standards, aiming always for Best Practice.

Commentary

This Standard plus Appendices 3 & 7 prescribe minimum requirements for the major components of a comprehensive QA/QC program relating to the Best Practice management of DXA equipment, including its whole-of-life operations; illustrated in Figure 1 below. However it is accepted that wherever this Standard is at odds with the mandatory requirements of the relevant Regulations, these latter requirements take precedence.

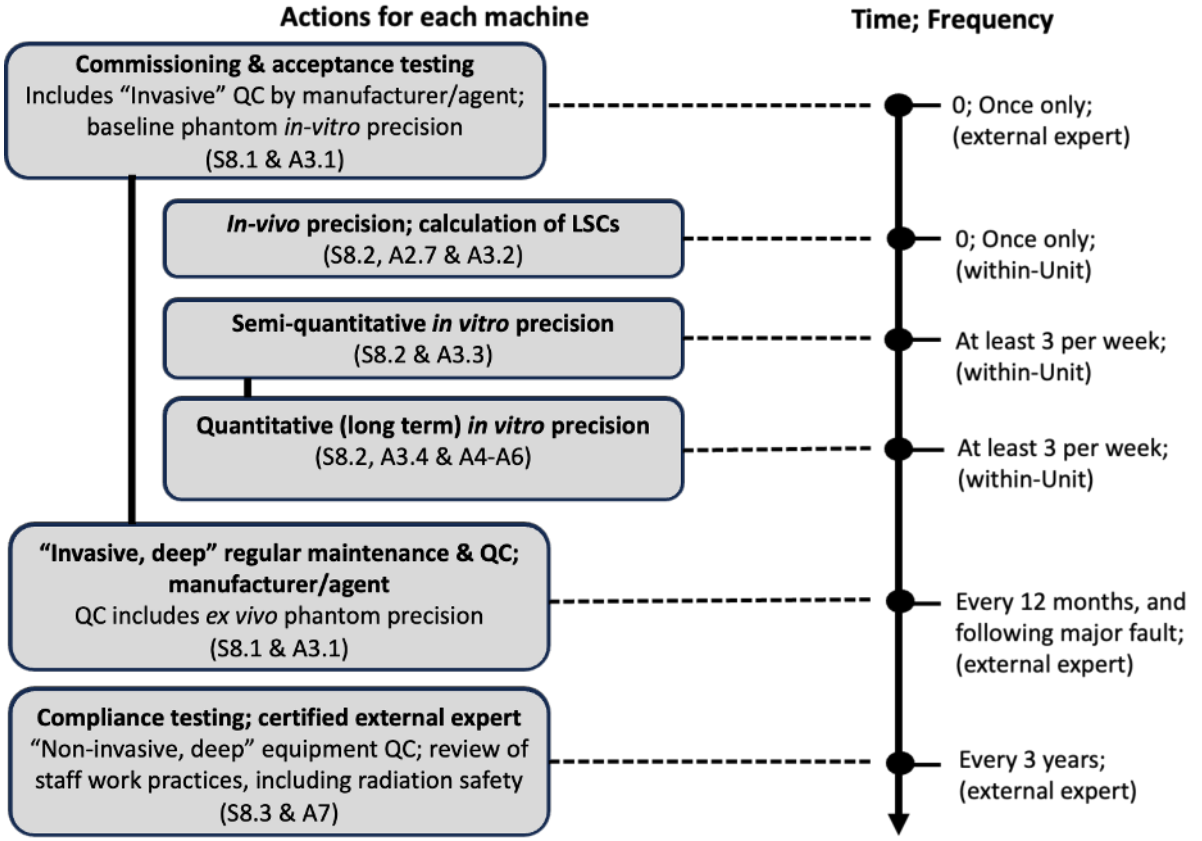

Figure 1: Major elements of a Best Practice QA/QC program for management of DXA equipment, including its whole-of-life operations. Relevant sections of Standards (S) and Appendices (A) of this document are shown in brackets.

An integrated and rigorously-documented QA program, supervised by a formally appointed QA manager (who is also likely to be the supervising technologist) shall span the *full operational lifetime of each item of bone densitometry equipment*. It incorporates equipment commissioning/acceptance testing, frequent QC procedures - including each day that DXA clinical scans are performed, regular authorised engineering preventative maintenance, periodic unplanned engineering interventions and a regular compliance testing program (see Sect. 8.3 below). Normally, only the daily QC procedures are performed by Unit staff.

8.1 *Commissioning/acceptance testing, engineering maintenance & interventions plus related periodic "invasive" QC measurements; performed by manufacturer or representative*

This Standard does not specifically address initial commissioning/acceptance testing of DXA equipment, requiring "invasive" measurements; particularly relating to the X-ray tube, its output plus its beam alignment and collimation. It also does not include details of regular authorised engineering preventative maintenance or unplanned engineering interventions. These are considered to be the responsibility of the manufacturer or their authorised representative.

In addition to adherence to their own established Best Practice procedures, usually devised with awareness of the requirements of multiple national jurisdictions, the manufacturer will be obliged to comply with all mandatory requirements of State and Federal regulations, as these pertain to bone densitometry equipment. For example, in Australasia these would be the relevant subset of requirements defined by AS/NZS 3200.1.0 1998; AS/NZS 3200.1.3:1996; AS/NZS 3200.2.7:1999 and AS/NZS 3200.2.28:1994.

During the operational lifetime of a machine, a manufacturer-authorised field engineer, accredited by the Radiation Regulator, shall when required periodically perform "invasive" QC measurements, made initially at commissioning and acceptance, of key parameters and settings of the X-ray tube and its assembly. These may include X-ray tube leakage, patient-free air surface entrance exposure, beam energy profile, beam collimation, beam quality (kVp[s], filtering), output (mAs), beam-on safety interlocks and hazard labels. Such occasions would include:

- regular planned preventative maintenance, recommended to be annually.
- Repair of significant faults identified by QC procedures, plus testing following hardware upgrades or following relocation of the machine or other possible physical trauma.

On all such occasions, the engineer shall provide the Unit QA Manager with a full description of all repairs, hardware and software alterations plus post-interventional validatory QC measurements. Such records shall be kept for the operational lifetime of the machine.

8.2 *Quality control procedures; performed by the Unit (App. 3)*

The slow rate of bone mineral loss in the ageing general population (~1-2% per year over decades) necessitates that bone densitometry equipment is operating as precisely as possible in the long term and that areal bone mineral density (aBMD, hereafter written more conventionally as BMD) and other relevant measurements of a standard reference object such as a partly-anthropomorphic phantom remain exquisitely stable over the entire operational lifetime of the machine.

Importance of good precision
Precision[1] is expressed quantitatively as the "least significant change" (LSC; App. 2), modified where necessary by the intuition and experience of the physician. Thus the precisional error of a technique, *as applied to a patient scan*, is never less than the statistically calculated LSC.

The *within-Unit-derived* (*in vivo*) LSC is specific for each scan type and each DXA machine, and shall be calculated from a set of repeated measurements on individuals presenting to the Unit who well represent the referred patient population (App. 2.7). The LSC, which may at the discretion of the Unit be stated on the patient's report, should never simply be adapted from a manufacturer's or literature reference.

Good precision (reproducibility) means that two serial measurements of a patient's BMD or other body composition component will agree very closely when the measured variable is in reality unchanged. How closely these measurements actually concur depends strongly on the LSC for that type of scan on that specific machine. Best Practice LSC for the spine or hip is typically ~4.5 - 5% of the mean BMD[2]. Thus, accord of the difference between two serial measurements and their relevant LSC represents an "aspirational" result, obtainable by a skilled technologist when the serial scans are not confounded by complications such as patient movement, unusual anatomy, skeletal changes wrought by ageing or very low BMD.

The LSC is the primary global *statistically derived* key performance indicator (KPI) of the value of a BMD measurement for monitoring real skeletal changes. High measurement stability means that a patient can be monitored over many years without suspicion that a detected long term systematic change is merely a machine-generated artefact.

Role of QC

An efficient and effective set of embedded QC procedures within the integrated QA program will include "non-invasive" tests able to be performed by Unit staff, to quantify real variations in instrument performance that can compromise a specific "one-off" BMD measurement, or the short or long term precisional errors of a patient's serial BMD measurements, at the chosen skeletal site. The following general principles apply.

- One of the final steps in the commissioning/acceptance of a new machine is a QC procedure collecting N = 10 - 20 replicate scans of a manufacturer-recommended or approved phantom. The standard deviation (SD) of the distribution of these measurements should be $\leq$ the value recommended by the manufacturer and likely have a CV% < 0.4% (App. 2). Ninety-five percent of individual measurements should lie within the interval BMD $\pm$ 2SD, where BMD is the phantom "calibration" value and SD is the standard deviation of the replicate measurements. If these criteria are not met, the machine shall be recalibrated and the QC test repeated.
- QC and equipment maintenance procedures shall be performed regularly, as recommended by the manufacturer.
- If a machine fails any of the QC procedures the instrument shall be evaluated. With repeated failures, scanning of patients shall be suspended until the machine is more thoroughly evaluated. If there is a suspicion that certain previous results may be inaccurate, a retrospective re-analysis of patient data shall be performed following rectification of the problem.
- A vital component of QC is regular maintenance of equipment. A regular maintenance program, at least annually, shall be in place and all relevant aspects of the bone densitometer performance shall be checked according to the manufacturer's specifications, by a manufacturer-authorised engineer. All faults discovered must be remedied, and the fault and remedial action recorded permanently in a manner available for inspection, as described under "Commissioning/acceptance testing..." (Sect. 8.1) above. A reliable remedy will very likely require the services of a manufacturer-accredited engineer.
- In addition to semi-quantitative day-by-day routine calibration and QC monitoring of densitometry equipment using a phantom, at least one additional quantitative QC procedure, aimed at more accurate and timely identification and prediction of machine "out-of-control" behaviour shall be performed, to the standards outlined in Appendix 3. A comprehensive, free-of-charge Excel-based statistical calculator for recording all QC measurements and for identifying and predicting "out-of-control" events, can be accessed

from the ANZBMS website (#27; App. 8). It is strongly recommended that this software platform or a similar one be implemented by the Unit.

8.3 *Compliance testing; performed by independent accredited assessor (App. 7)*

Compliance testing shall be performed regularly but relatively infrequently, *at least* once per three years, or as mandated by the Radiation Regulator. The compliance tester is an independent expert who shall be appropriately accredited by the Radiation Regulator.

A DXA machine incorporates an X-ray tube and thus might be expected to require regular "non-invasive" compliance testing of multiple parameters, settings and indicators such as mains power, ready-to-exposure and energised X-ray tube interlocks, hazard indicator labels (machine, room entrance), tube-housing radiation leakage, minimum focal-spot to skin distance (FSD), beam quality (kVp[s], HVL), air kerma beam outputs, limits on collimated field size, plus accuracy of kVp and tube current (mA) settings.

However in DXA FSD is fixed, while air kerma outputs, beam central axis, collimation and field sizes (beam geometry) are fixed or severely restricted, as are kVp & mA settings. Exposure time is automatically dictated by scan type and scanned area. Radiation surface exposure and therefore effective dose to patient and staff is also low compared with other diagnostic radiological modalities, usually less than about 25% of a standard PA chest radiograph.

Because of these highly restricted settings, the nature of dual-beam technology and the inherently low-dose output, it is challenging for the compliance tester to non-invasively measure factors such as output kerma or kVp(s). HVL cannot be measured if there is automatic exposure control. Furthermore, the requirement for rigorous, thrice-weekly (preferably daily) QC that directly monitors key machine KPIs, renders the technology inherently safe for both the technologist and the patient, as well as tightly governing the long term precision of measurements derived from its output.

This has led, over the approximately thirty years of DXA deployment, to different interpretations of adequate requirements for DXA compliance testing, expressing varying degrees of rigour (App. 7). Usually, a pragmatic subset of those measurements normally required for conventional diagnostic X-ray technology is agreed upon by the Unit and its Radiation Regulator. Thus a key step in devising a compliance testing program is an accord with the Regulator, preferably in close collaboration with the relevant professional medical and medical-physics societies. Recommended minimum elements of a compliance testing program, that would likely match or may exceed the requirements of the Regulator, are described in Appendix 7.

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[1] In order to avoid confusion the definition of "precision" used in these Standards is given as a footnote of Standard 2.

[2] If appearing in clinical reports LSC should be expressed in absolute units (g/cm^2), not as a percentage (App. A2.9).

STANDARD 9: Bone Densitometry Reporting

Reports of results, within the context of available information on the patient, shall be furnished to the requesting person with a minimum of delay, commensurate with good patient care.

Accepted guidelines for bone densitometry reports are set out in Appendix 9.

Commentary

- Urgent reports may be communicated by telephone or the like to responsible medical or other authorised staff, with due care to prevent errors, but shall always be followed by a written report.
- No person by virtue of his/her office or employment in the Unit shall disclose information on patients or the results of investigations thereon, except in the performance of his/her duties.
- All reports shall be checked and signed by the reporting medical specialist before release.

STANDARD 10: Records Keeping

The Unit shall maintain a complete record of all QC and patient measurements and this shall include complete identifying details of each patient. Records relating to patients, scan data & derived measurements, QC records plus reports sent to referring practitioners shall be kept in readily accessible form, subject to appropriate effective security, in compliance with privacy law.

Commentary

- The written referral requests shall be retained as long as considered useful, with a conservative bias, at least as long as required by a statutory authority.
- A Unit shall maintain a complete record of all scans performed and this shall include complete identifying details of the patient, the name of the referring medical practitioner, the date the test was performed and investigations required.
- The raw data from all scans shall be stored using appropriate long term electronic storage media, allowing re-analysis when necessary. QC data relevant for the validation of scans shall also be stored for the operational lifetime of a DXA machine.
- Unlike for some clinical investigations, bone densitometry data increase in utility the longer the serial record is maintained. Thus copies of reports released by the Unit shall be retained for a minimum of twenty years, or in compliance with any statutory requirement, whichever is longer.
- Results of investigations are normally confidential to the requesting medical practitioner and patient, but past Unit records may be made available to a clinician currently caring for the patient. Requests from a researcher for access to data must be approved by the appropriate institutional human ethics committee, and all identifying information must be removed from the data, except with the specific written consent of the patient.
- Storage conditions for Unit records shall be adequate for their security, legal data privacy obligations, physical preservation and data retrieval.

Appendix 1: Education & Training for Technologists in Clinical Bone Densitometry

A baseline education, training and skills set for clinical bone densitometry technologists is:

- Tertiary qualifications in a health science, general science or nursing. Practicing nuclear medicine technologists or medical imaging technologists ("radiographers") are automatically assumed to have the required academic qualifications.
- Patient meeting, recording, preparation for scanning and positioning on DXA scanning platform.
- The scanning sites available for each patient examination, including variation in site with body size.
- For each scan site, the anatomic landmarks used for positioning the scanner.
- Acceptable scan margins, which may be partly dictated by manufacturer's instructions.
- A detailed, (including Unit-specific) knowledge of scan acquisitions & analysis. Also, applicable patient reference intervals provided by the manufacturer or from the peer-reviewed literature.
- Knowledge and understanding of the derivation and discretionary clinical application of the "least significant change" (LSC).
- Compilation of a patient's report, to be reviewed and approved by the medical specialist.
- Management of all complications encountered in bone densitometry scanning, plus related image interpretation during analysis, including:

  - extremes of body habitus (height, girth, weight), including in whole-body scanning

  - soft tissue calcification

  - osteoarthritis

  - genetic skeletal malformations

  - fractures

  - scoliosis

  - prior surgery

  - prosthetic devices

  - artefacts

  - uncommon anatomy (e.g., 6 L vertebrae)

  - recent nuclear medicine scans or contrast radiology

  - unusual patient movement

  - managing the fragile and the elderly

  - (if relevant) special aspects of managing paediatric patients.
- Relevant safety issues, including radiation & laser safety of patients, carers & staff, and patient lifting & manoeuvring.

- Knowledge and understanding of QC procedures to be applied within a comprehensive QA program that includes contributions by external expertise for equipment maintenance, fault finding and compliance testing,
- Knowledge of the roles and requirements of regulatory authorities (including the Radiation Regulator) and the host institution.

Appendix 2: Basic Statistical Methods for Bone Densitometry QC & Reporting

A proper interpretation of bone mineral density measurements requires some understanding of the statistical methods used and factors which affect the confidence placed on a measured value of BMD or a related variable. These notes provide a basic introduction to some of the terms and parameters, plus statistical techniques used in the interpretation of bone densitometry results.

However, in the event of any uncertainty as to how to apply statistical techniques, advice from a professional statistician is strongly encouraged.

A2.1 *Accuracy (absolute & relative) and precision*

Accuracy is defined as the ability of a technique to measure the true value of a descriptive variable, by comparison with an absolute ("gold") standard. In bone densitometry, *absolute* accuracy is usually assessed *in vitro* by measuring phantoms of known elemental composition and physical density, or *ex vivo* in cadaveric sections. (In the latter case the measured value is compared to a chemical analysis [ash weight] of the scanned bone; mainly nowadays of historical interest only.)

In vivo, accuracy is affected by *systematic errors* in the measuring technique caused by (e.g.,) incorrect machine calibration or software algorithms for handling varying thicknesses of lean tissue, fat and bone mineral simultaneously during scanning, particularly intra- and extra-osseous fat. *Ceteris paribus*, systematic errors cause the measured value to be offset by a set amount from the "true" value; this offset ("bias") is virtually constant in repeat measurements made under identical conditions.

Accuracy is less crucial than precision in routine BMD measurements since it does not affect conclusions based on comparison of a patient's BMD with a reference interval, or serial changes in BMD measured on the same machine with the same software, since all such measurements (including those contributing to the reference interval) are relative. However, accuracy would become important when comparing bone density values measured using different modalities (e.g., DXA *vs* QCT) or when comparing values obtained on DXA machines from different manufacturers.

For example, the *relative* accuracy of different machines can be assessed by an anthropomorphic "travelling phantom" such as the European Spine Phantom (ESP). This has revealed up to 7% difference in BMD values between different machines (#28; App. 8). However, these concerns are usually outside the scope of routine bone densitometry.

Precision (reproducibility) is calculated from the spread of results obtained when a measurement is repeated under (apparently) identical conditions (#29; App. 8). That is, it is an index of the real significance of differences in repeated measurements when the physical variable being measured is not actually changing.

Precision is affected by *random errors* in the measurement technique. These are caused by fluctuations in the operating characteristics of the machine over time, operator errors in positioning patients and analysing results, or patient movement. When repeated measurements are made, random errors cause each measured value to vary about a mean, usually obeying a bell-shaped ("Normal" or "Gaussian") distribution. The magnitude of random errors *in vivo* must be determined within a sufficiently small timeframe that excludes any true biological changes in the measured variable. Precision can be easily calculated from a knowledge of these random errors.

Measurement precision is the most important factor influencing the clinical efficacy of routine bone densitometry measurements. Better precision allows smaller significant changes in BMD to be detected at any selected statistical confidence level and hence permits any real change in BMD status over time to be detected sooner. In contrast, accuracy is more relevant in research laboratories, when developing and comparing different modalities for BMD measurement.

Ideally, measurements should be highly precise and reasonably accurate. Figure 2 is a cartoon showing the relationship between precision and accuracy.

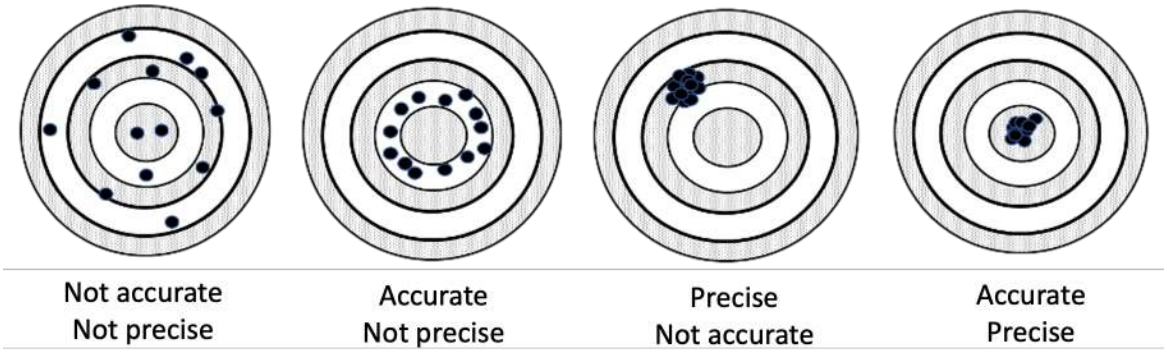

Figure 2. Graphical illustration of the relationship between measurement accuracy and precision (reproducibility).

A2.2 *Standard deviation, coefficient of variation & root mean squared deviation*

Measurement precision is illustrated by the dispersion of the values of repeated measurements of a clinical variable such as BMD around its mean, when it is known that the variable is actually invariant over the period of the measurements. If the frequency of each measured value is plotted, a bell-shaped (Normal) curve is generally obtained. This is characterised by its mean (the average value of the repeated measurements) and a parameter called the standard deviation (SD), which is an index of the spread of the measured values. The smaller the SD, the more precise is the measurement. The result of repeated measurements is usually quoted in terms of their mean and SD, as follows:

$$Mean \pm Standard\ Deviation;\ written\ as\ \mu \pm \sigma \qquad (1)$$

Alternatively, the result may be quoted in terms of a percentage deviation from the mean, a parameter called the coefficient of variation (CV). The CV is simply the SD divided by the mean, often expressed as a percentage. That is:

$$Coefficient\ of\ Variation\ (CV) = \frac{Standard\ Deviation}{Mean} \times 100\% \qquad (2)$$

When duplicate measurements (x_{ai}, x_{bi}; i=1,...,n) are made on an n-sample patient group (from the larger x-population of patients) to assess the precision of a technique, the set of differences ($d_i = x_{ai} - x_{bi}$) represents a (sampled) random variable d which is approximately Normally- distributed and with a mean of zero. The appropriate metric for the dispersion of the d-distribution is the *root mean squared deviation* (*RMSD*), which differs from the conventional SD that would be calculated from the d-data without concern for the origin of the d_i. This distinction arises because of the correlation between each x_{ai} and x_{bi} pair (#18;

App. 8). That is, once the x_a data set has been selected by the first measurement on n patients, the duplicate x_b data set is not simply another random n-sample from the same general x-population, but is pairwise linked to the x_a data set (Sect. A2.7).

A2.3 *Standard Normal probability distribution & z-statistic; confidence limits*

In order to carry out statistical analyses it is often convenient to normalise the measured Normal distribution of data to express deviations from its mean in units of "number of standard deviations". This is done by transforming the measured values of a variable (such as BMD) into its z-*statistic, z,* according to:

$$z = (x - \mu)/\sigma \qquad (3)$$

where x is the measured value to be transformed, so that it may be compared with the Standard Normal probability distribution (SND); μ is the mean of the original Normal distribution to which the random variable x belongs, and σ is the SD of that distribution.

The z-statistic is canonical with the SND for which the mean is zero, the total area under the curve (AUC) is unity and the abscissa axis is expressed in units of SDs. Any Normal distribution of a random variable x can be converted to this form to facilitate statistical analysis (Figure 3). The probability of a given value of z exceeding a given limit, or falling within a specified range, can then be easily calculated (usually automatically). Thus, a "raw" result may be classified in terms of its rarity by examining the position of its calculated z-value within the SND. The table below lists critical z-values for the most important recognised confidence limits.

Confidence Limit Displacement of z from $\mu = 0$ (units of SD)	**Confidence Level** Values lying within range $-z\sigma \leq \mu \leq +z\sigma$ (%)	***p*-value (2-tailed)** Probability that a value will lie outside range $-z\sigma \leq \mu \leq +z\sigma$	**Common Qualitative Classification of Significance**
1	68	0.32	Not significant
1.96	95	0.05	Probably significant
2.58	99	0.01	Significant
3.29	99.9	0.001	Highly significant

Table 1**.** Use of the derived z-statistic to assess the probability that a specific value of a random variable x (i.e., BMD) is an outlier within its hypothesised Gaussian (Normal) distribution.

For example, suppose we have a distribution of replicate BMD values of 1.164 ± 0.010 (i.e., expressed as $\mu \pm \sigma$). Then 99% of all individual measurements contributing to this distribution will lie within 2.58 SDs of the mean, in the range 1.138 to 1.190 (1.164 ± 0.026). That is, we can be 99% sure that the true value will lie in this range. Only1% of values (0.5% higher than 1.190 and 0.5% lower than 1.138) will lie outside this range.

The p-value is an indication of the rarity of events lying outside the selected confidence limits, and usually has a significance classification associated with it. For example, if the BMD value for a particular patient is more than 3.29 SDs lower than the mean for his/her

matched age, gender and ethnic group, this indicates an event which is extremely rare (probability less than 0.0005) which would be classed statistically as "highly significant" and worthy of further investigation. The "degree of suspicion" that this was an abnormal clinical finding would be very high.

A2.4 *Type I & Type II statistical errors*

The statistical significance of a measurement relates to the risk we are willing to take of making an error in accepting, as real, a measured difference which could in fact be due merely to a statistical fluctuation. In statistical terms, this is called a "false-positive" or Type I error. The larger the absolute value of the *z*-value (and thus the lower the corresponding *p*-value), the less likely we are to make such an error. That is, the risk of declaring a "false positive" is smaller.

It should be noted that a measurement may be statistically significant, but may not actually be clinically significant. For example, a small but normal seasonal change in BMD measured in a large enough group of patients may be detectable at a statistically significant level but of little clinical (as distinct from biological) interest.

Alternatively, a real change in BMD (usually measured over a short time interval) may be declared as statistically insignificant when the precision of the technique is (correctly) accounted for, because the measured precisional error was relatively high compared with this change. This effect can be exacerbated for example when the DXA machine has poor QC. This is known statistically as a "false negative" result or a Type II statistical error; again illustrating the crucial importance of good measurement precision.

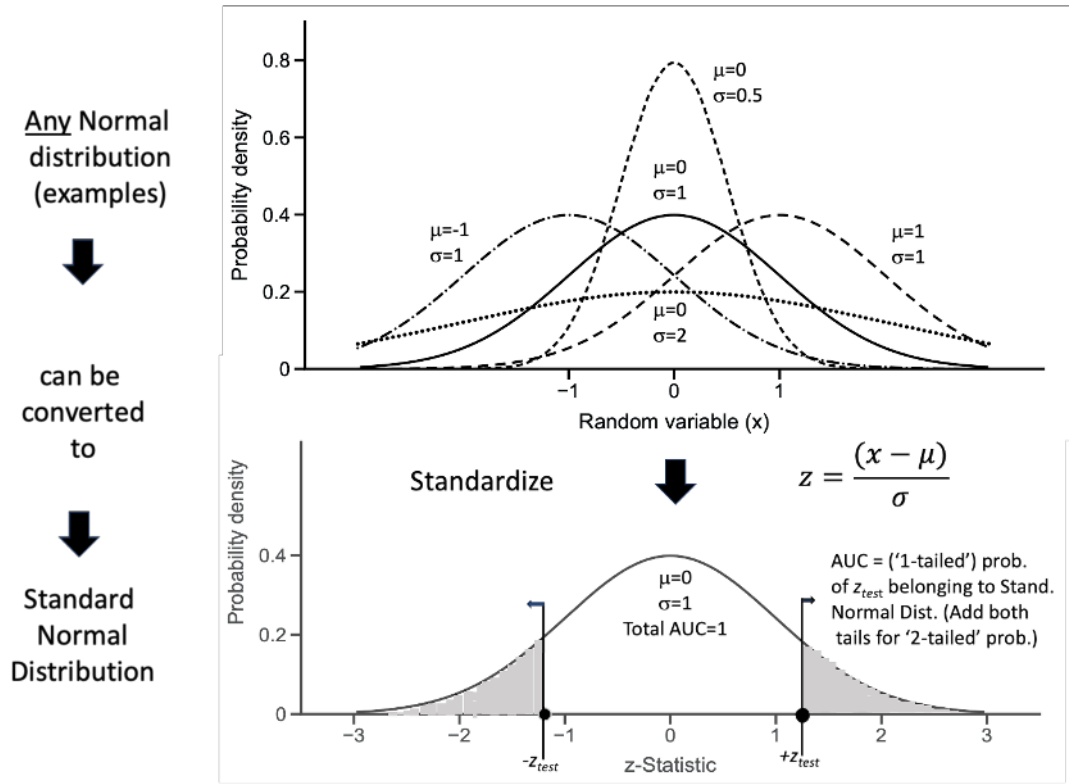

Figure 3. The Standard Normal probability distribution (SND) and the *z*-statistic. Transformation of different Gaussian (Normal) distributions to a SND for ease of statistical comparisons. A test *z*-value (z_{test}) links to the shaded area on its right tail, giving the (single-tailed) probability that z_{test} belongs to

the SND. If a (more rigorous) 2-tailed test is applied (as is usual), shaded areas on both tails are summed.

A2.5 *Z-scores and T-scores in bone densitometry*

In close analogy with the *z*-statistic and Table 1, BMD results are often characterised in terms of a "Z-score", which facilitates comparison with a reference population. The Z-score is simply the number of SDs by which the patient's BMD value differs from the mean BMD of a matched peer reference group (age and gender) selected for comparison.

Statistically significant changes identified by the BMD Z-score may contribute to identifying a specific underlying clinical concern (e.g., corticosteroid-induced osteoporosis). The statistical significance of this difference may be quantified as follows.

***Z*-score Range**	***p* -value** Probability a patient *Z*-score lies within a specified Z-score range derived from reference group	**Common Qualitative Classification of Significance**
$Z > +2.58$	$p < 0.005$ (1-tailed)	Highly significant
$+1.96 < Z \leq +2.58$	$p < 0.025$ (1-tailed)	Significant
$-1.96 \leq Z \leq +1.96$ (i.e., within reference interval)	$p \geq 0.05$ (2-tailed)	Not significant
$-1.96 > Z \geq -2.58$	$p < 0.025$ (1-tailed)	Significant
$Z < -2.58$	$p < 0.005$ (1-tailed)	Highly significant

Table 2. Use of the Z-score in bone densitometry to assess significance of comparison with a peer age- and gender-matched reference group.

Again in analogy with the *z*-statistic, in bone densitometry the "T-score" expresses, in units of SDs, the difference between the patient's BMD and the mean BMD of a young normal reference population of the same gender. (The latter condition may not apply for certain applications of the T-score.) The statistical significance of this difference may also be assessed using the above table. For older persons including some members of the older reference ("normal") population themselves, the T-score will very likely be negative, and often statistically significantly low. The clinical significance of the T-score relates to its use as an indicator of absolute, age-independent fracture risk in the individual patient.

A2.6 *Assessing clinical significance of BMD changes over time: precision & least significant change*

Measurement of the RMSD of the distribution of difference errors

If a patient's BMD has been measured twice the key question is whether the difference is clinically significant and represents a real biological change, or is merely a result of statistical chance. This question is answered from an estimate of the *routine precision* of the entire measurement technique, including the analysis of the scan data. This must be determined by

the Unit *for each scan type on each machine*; not simply accepted from the manufacturer or the published literature.

A routine precisional error estimate starts with repeated measurements on a group, within a sufficiently short time interval (i.e., within about a month) that the BMD of each individual has not changed. The group is chosen to represent the typical patient referred to the Unit, and thus is usually not comprised of healthy young volunteers. The distribution of random errors in these duplicate measurements is approximately Normal. Dahlberg's formula is used to calculate the root mean squared deviation (RMSD) of the dispersion of the distribution of differences (Sect. A2.2 & #18; App.8):

$$RMSD_d = \sqrt{\frac{\sum d_i^2}{2n}} \quad (4)$$

where $d_i = x_{2i} - x_{1i}$ is the difference in the *duplicate* measurements of the *i*th individual and *n* is the number of individuals in the group. $RMSD_d$ is often expressed, mainly for purposes of qualitative comparisons (Sect. A2.9), as a CV, as in Eq. (2):

$$RMSD_d\ (CV\%) = \frac{RMSD_d}{\bar{x}}\ 100 \quad (5)$$

where $\bar{x}$ is the mean of the 2*n* measurements, expressed as $\bar{x} = \sum(x_{1i} + x_{2i})/2n$.

$RMSD_d$ is not *"precision"*
It is important to note that "*$RMSD_d$*" which is usually <0.5% for phantoms and ~1-3 CV% *in vivo* (when expressed as a CV), is *not* the measurement precision as defined in the footnote of Standard 2. It is however the key statistically-derived input to calculate the LSC which in turn is a mathematical guide to the *real* precision of the reported BMD (difference required to declare significant change), determined through review by the reporting physician of *all* factors including the LSC. (See A2.7.)

Measurement of in vivo *short-term precision*
Why must human subjects, rather than repeated measurements on a phantom be used for precision determination, given that the former requires more effort and time, and may require ethical approval? The variations seen in phantom measurements at best only reflect variations in the electro-mechanical performance of the machine. Scanning and analysis is virtually automated. Examined over time, analysis of these variations is indeed vital for judging the quality of machine QC (e.g., Figure 6[a]).

However, random errors introduced by scanning humans are 6 to 10 times greater than seen in phantom studies, being dependent on the patient (habitus, age, movement etc.) and on the skill and reproducible actions of an individual technologist (patient positioning, scanning arm positioning, image analysis etc). Even when manufactured to contain segments that may superficially resemble real bone sections (e.g., lumbar spine), such phantoms are poor analogues of the real skeleton, particularly in comparison with osteoporotic and osteoarthritic patients.

Thus the Unit must report its results judged against an accurate estimate of its own within-Unit *in vivo* precisional error, for each scan type. On the positive side, a demonstrated low within-Unit precisional error is a strong public statement of the clinical merit of the results reported by the Unit.

How might a cohort of patients for duplicate scans be recruited? For example, when acquiring baseline data for a patient likely to be seen in the future, it is important that these measurements have high reliability. Then the patient could be measured twice during the first

referral and thus could contribute to a precision data set. If the Unit contributes to the conduct of a clinical trial, they will likely be required to perform duplicate scans on each patient when first seen.

In any event, repositioning between duplicate scans is essential. The patient should alight completely from the scanning bed between examinations. Statisticians recommend that a satisfactory estimate of $RMSD_d$ (Eq. [4]) requires that at least 30 individuals to be measured in duplicate. (If in the unlikely event that each individual is measured more than twice, the group can be smaller, according to a simple formula. However, this is not recommended as the anatomical diversity of the cohort is an important contributor to the robustness of the precision estimate.)

Measurement of *in vivo* short term precision shall occur following installation of the machine *plus* completion of the training of scanning staff.

In view of the issues raised below (Sects A2.7 & A2.8), it is at the discretion of the Unit as to whether the LSC appears in the clinical report. If included, ideally LSC shall be expressed in absolute units of "g/cm^2" and not as a percentage, for reasons given in Sect. A2.9.

Note that the establishment of a precision value for each scan type, and its utility in aiding the physician to compile the final report, is an important indicator of the quality of the service provided by the Unit, and will be of informed interest to most referring practitioners.

A2.7 *Calculation of the least significant change*

Establishing a reliable value for $RMSD_d$ through duplicate measurements of a reference group of representative patient*s* in the Unit is the first step towards answering the key question of *whether the difference in two serial measurements of a patient's BMD over time (say, about one year) is "real" and not simply an artefact of measurement imprecision*. To achieve this, we compute the *least significant change* (LSC), which is the minimum difference in two BMD measurements over time required to declare that the change is "real".

Calculation of the LSC depends on $RMSD_d$ plus the level of statistical confidence we impose on the estimate (i.e., $p < 0.05$, $p < 0.01$ etc). It can be shown that LSC is expressed as:

$$LSC = z_{\alpha/2}\sqrt{2}\ RMSD_d \qquad (6)$$

where $z_{\alpha/2}$ is the two-tailed z-statistic at the chosen significance level α (i.e., rejection of Type I error). Since the p-value is often chosen as $p < 0.05$, (see Table 1) and thus $z_{\alpha/2} = 1.96$ the LSC is often expressed simply as $LSC \sim 2.8 \times RMSD_d$. This means for example that if the Unit's measured $RMSD_d$-value when expressed as a CV as in Eq. (5) is (realistically) about 1.8% for (say) a PA lumber spine scan, then the LSC for that scan type is 5%, and a patient's BMD must have changed by at least 5% between two measurements for the change to be clinically significant.

As mentioned above, there are two important caveats with use of LSC; (i) the inherent and unavoidable limitations in derivation of the LSC, and (ii) expression of LSC as a *percentage*, which overestimates importance of an absolute change at low BMD and underestimates importance of a change at a high BMD. These limitations are discussed in the next two sections.

A2.8 *Limitations in derivation of the LSC*

Despite the annealing effect of a large statistical sample and the mathematical rigour of its derivation, the LSC remains an idealised estimate of the *lower bound* for precisional error. Several factors conspire to undermine reliance on its unique authority for assessing real changes, particularly when applied in a busy routine clinical setting. These include;

- unconscious "care bias" in scanning those patients contributing to its derivation;
- the "training effect" on such patients for the second scan;
- the "short-cut" of acquiring duplicate scans on the same day, with negligible changes in potential confounders such as body composition and agility;
- its dependence on only two time points for each patient, whereas significant trends will often only be detected after several serial scans;
- "outlier" patients who confound a purely mathematical estimate of "real" significant change;
- changes in behaviour of technologists determining precision who, by the nature of the test, are aware of the importance of their task.

Thus the LSC should be seen as an important, but limited, guide to the intuition and experience of the clinician, who would also take into account pre-scan expectations; changes seen concurrently at other scanning sites; weight, mobility, attention compliance and medication changes; comorbidities, and so on. For these reasons, the LSC is not mandated in the clinical report; however it can be added at the discretion of the Unit.

A2.9 *Correct units for expressing the LSC*

There is a natural tendency to express an error margin as a percentage of the mean (i.e., CV%), since this facilitates an intuitive grasp of its magnitude. However the differences d_i in Eq. (4) above used to derive the LSC are not dependent on BMD magnitude (#30; App. 8). This means that if the LSC is expressed as a CV% it will tend to underestimate real precisional error when the BMD is low; i.e., in patient groups particularly dependent on its veracity. Conversely, when BMD is high the LSC will overestimate precisional error. Therefore the LSC should always be expressed in absolute units of g/cm^2.

A2.10 *Assessing clinical significance of BMD rates of change*

Sometimes, at a slightly more sophisticated level it is useful to compare the patient's measured *rate-of-change of BMD* with an *expected* (reference) rate-of-change (usually loss); the latter obtained for example from a longitudinal study of a reference group of normal postmenopausal women. This aims to assess whether a patient is losing bone (abnormally) faster than their matched peer group.

Basically, the task is to compare rates of bone mineral loss or gain. Using a version of Eq. (6) above, the *z*-statistic is applied to a comparison of a rate-of-change in BMD obtained from two serial measurements of a patient, with that of the equivalent mean value for their reference group, sufficiently large in number of participants that the SEM of the change rate for the group << SD of the patient's change rate. The *z*-value is:

$$z = \Delta T \frac{1}{\sqrt{2}} \frac{(\%Patient\ BMD\ change\ rate - \%mean\ BMD\ ref.\ group\ change\ rate)}{RMSD_d(CV\%)} \qquad (7)$$

where ΔT is the time interval between the first measurement and the followup (for both the patient and the reference group) and $RMSD_d(CV\%)$ *is* from Eq. (5). At the 95% confidence level $z = 1.96$; then the *minimum* rate of BMD change which would be considered statistically significant is given by a version of Eq. (7):

$$Stat.Sig.\%Pat.BMD\ change\ rate\ -\ \%mean\ BMD\ ref.\ group\ change\ rate\ >\ \frac{1.96\sqrt{2}\,RMSD_d(CV\%)}{\Delta T} \quad (8)$$

For example, if we take the reference rate of bone mineral loss to be zero, $RMSD_d(CV\%)$ = 1.8% (Eq. [5]) and the observational time interval to be one year then a rate of bone mineral loss of ≥5% per annum will be required in order to be statistically significant at the 95% confidence level. As expected, this is effectively the same calculation as when the LSC is used directly (see above section).

Minimum time for significant difference (patient) & monitoring time interval (group)
Note that if the measurements are taken over a shorter time interval, a larger rate of loss will be needed if we are to be confident of the result. The *minimum* time taken to obtain a statistically significant difference in BMD between an individual patient and their reference group at the 95% confidence level can be derived easily from Eq. (8):

$$\Delta T_{min}\ >\ \frac{1.96\sqrt{2}\,RMSD_d(CV\%)}{(\%Patient\ BMD\ change\ rate\ -\ \%mean\ BMD\ ref.\ group\ change\ rate)} \quad (9)$$

Note that the numerator of the above equation is the LSC expressed as a CV.

A closely related concept arising from Eq. (9) is the *monitoring time interval* (MTI; #31; App. 8). The MTI is an estimate of the observational time-period after which at least half of the group of patients will have exceeded a detectable change, according to the LSC of the method.

$$MTI(units\ of\ yr) = \frac{LSC}{Annualised\ median\ change} \quad (10)$$

Equations (8) - (10) clearly show that the smaller the difference in bone mineral loss rates we wish to detect, the longer we have to wait between measurements. The way in which an increased time interval between measurements improves the precision with which the rate of BMD loss can be determined is illustrated graphically in Figure 4.

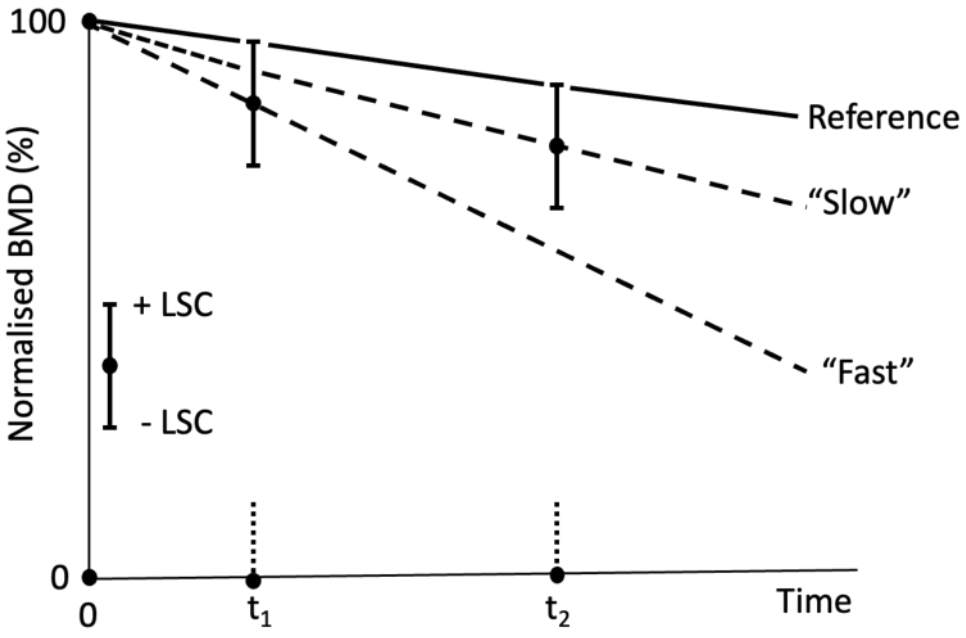

Figure 4**.** The effect of time between measurements on assessing the significance of BMD relative loss-rate determinations. Two measurements are made on a "fast-losing" patient at t=0 and t_1. The error bar

is $\pm$ LSC. Because the measurement at t_1 differs from the (sloping) reference line by the LSC, the estimated loss rate for this patient (though based on only two measurements) is statistically significantly faster than "normal". The same is true for a "slow-losing" patient at time t_2. However the slower rate of loss experienced by this patient required a greater time between baseline (t=0) and second measurement ($t_2 > t_1$). (The reference loss rate, assumed linear for simplicity, might for example be for normal postmenopausal women and is assumed to have minimal error because it is derived from a large enough population sample.)

Clearly the above analysis has been simplified by considering only two serial measurements. In reality, significant changes (and rates of change) may only become apparent following review of a suite of serial studies, together with review of such changes at more than one scanning site.

Appendix 3: DXA-specific Quality Control Procedures

QC procedures are embedded within an integrated QA program, components of which are described in Standard 8 and Apps 3-7. A version is shown in Figure 1.

A3.1 In vitro *(short term) precision following significant engineering intervention, including commissioning/acceptance & software upgrades*

Embedded within an integrated QA program, at the time of commissioning/acceptance, and implemented after any planned maintenance or unplanned repair procedure, following relocation of the machine or after a major software upgrade.

As described in Standard 8, the ongoing QA program must include a regular manufacturer-approved maintenance schedule, with periodic testing of relative accuracy following each maintenance/upgrade outcome (planned or unplanned) using the recommended external QC phantom. Scan the phantom 10-20 times. This phantom is applied in addition to any internal calibration checks automatically performed by the machine at each start-up. It is usually an anthropomorphic (or partly-anthropomorphic) phantom recommended by (or at least acceptable to) the manufacturer. From these measurements, calculate the mean BMD of the phantom and the CV of the results. (See App. 2, Eq. [2].)

All interventions by the maintenance/repair provider shall be recorded so that variations in calibrated QC parameters may be correlated with breakdowns and repairs if necessary; partly to facilitate retrospective analysis and correction of BMD data, if this should with hindsight be deemed necessary.

A3.2 In vivo *(short-term) precision of patient scans*

Normally performed only once in the operational lifetime of a machine, following machine commissioning/acceptance and completion of staff training. If volunteers are recruited, this will require institutional ethics approval and informed consent. The justification for these vital measurements and realistic strategies for recruiting patients is discussed in App. 2.

For each machine, obtain follow up scans within a short timeframe (maximum one month); for example, duplicate scans on the same day on at least 30 subjects. (A smaller number of subjects is possible, but not recommended; see App. 2.) The patients (preferably) or volunteers should be in an age range and with a medical status reflecting the predominant patient population seen by the Unit (i.e., *not* a "sample of convenience" such as young healthy "normal" individuals). From these duplicate data the *in vivo* short-term precision is calculated for BMD (and for body composition components if reportable whole-body scans are to be performed), for each scan type reported by the Unit. (See App. 2.)

A3.3 In vitro *regular routine QC; detecting "out-of-control" machine behaviour*

QC data shall be recorded according to manufacturer's specifications. The bone densitometer daily external QC phantom shall be scanned at least thrice weekly (and preferably daily) using the same scanning procedure as described in Sect. A3.1, but without replicate scans. This allows a semi-quantitative visual presentation of serial phantom BMD or BMC data. (Other variables that may predict "out-of-control" behaviour better may also be followed, based on manufacturer's advice and Unit lived experience.) An example is shown in Figure 6(a).

The simplest method for detecting changes in precisional error is to examine the time development of these data as calculated by the densitometry software. Any form of drift,

systematic (i.e., in one direction) or random from the baseline ("control") value will cause the SD of random errors about the mean (usually < 0.5% when expressed as CV%; see Eq. [2], App. 2) to increase. However this surveillance relies on "eye-balling" and is only semi-quantitative.

A3.4 *Longer term routine* in vitro *QC; detecting trends & their implications*

QC phantom data shall also be analysed in a more quantitative manner for medium-term precisional error and systematic bias using the appropriate statistical analysis. This analysis should include at least one quantitative predictive "out-of-control" test such as a Multi-rule Shewhart Chart (App. 4), Moving Average Plot (App. 5) or CUSUM Plot (App. 6). Further information to assist in the choice of statistical methods, including in reporting of results, is given in Apps 2 & 4-6.

Examination of trends in QC parameters (particularly BMD) over a period of years is a necessary precaution for establishing the integrity of long term studies of individual patients, or for the reporting of results from clinical trials. The statistical methods used to examine long term trends are the same as those used for short- and medium-term studies (see above). However, it should be noted that statistical analyses become more powerful and illuminating with the acquisition of larger data groups. Therefore analyses are worth periodically repeating, as the QC history of a machine accumulates.

Each machine has specific operating characteristics which lead to some QC parameters being more important (i.e., more sensitive) than others, depending on the circumstances. For example, variations in certain machine-dependent parameters (random or systematic) used to calculate clinical outcome variables may be more sensitive to the onset of malfunctions than are BMD, BMC or Area. Individual manufacturers may be able to advise on this topic. Such information should be incorporated into the locally-sourced section of the operations manual for a machine.

A3.5 *Transfer of patients between DXA machines over time, within same Unit; the GLSC*

Ideally, a patient should be measured throughout their clinical history on one DXA machine, only. However, if a patient has to be transferred between DXA machines then some form of cross-calibration is necessary if scans are to be compared between the two systems. The simplest method for "bridging the data gap" with high reliability is to obtain precise *final* measurements for *each scan type*, for *each relevant patient*, on machine 1 (preferably with duplicate scans), so that these (and if relevant, any previous scans) may be retrospectively adjusted by calibration with equivalent concurrent *baseline* measurements for each scan type on the same patient, on machine 2.

However depending on the overlap time for dual operation of the machines, this may not be possible for all patients who ultimately return, having originally been scanned on machine 1. A Unit might choose to regard a returned patient as "new" and wait for a second scan on machine 2 before commenting on any apparent change in BMD, using the "new" LSC acquired on the second DXA.

An alternative method is to calculate the *generalized least significant change* (GLSC), which is used to compare two scans from a patient when measured on two different DXA systems, where these measurements need not have been concurrent. However, to calculate the GLSC it is necessary to have done (for each scan type) an *in vivo* cross-calibration assessment on the two machines, as well as *in vivo* precision assessments on both systems. The latter two assessments would have been required anyway to establish LSCs for both machines, and the cross-calibration could be performed using patients who present as very likely to be followed

over time, while both machines are still operational. The scan-specific GLSC will be larger than the equivalent LSC for either machine because it incorporates the extra error incurred by a patient transferring between systems. (Note that such patients need not have participated in the initial cross-calibration.) In any event, it can be applied to assist the physician to assess the significance of an apparent change in BMD that has occurred "across the data bridge".

Once a serial scanning history has been established on machine 2 for that patient, the (new) scan-specific LSCs for machine 2 alone can be used. The straightforward formulae to calculate GLSC are not given here; the algorithm and formulae are described in #24 (pp69-70; App. 8). The ISCD provides a GLSC calculator for its members (#32; App. 8).

A3.6 *Use of an anthropomorphic "travelling" standard phantom in multi-centre QC comparisons; sBMD (optional)*

It is possible that some form of multi-centre participatory QC will eventually be recommended or required. For example, this will usually be required if the Unit participates in a multi-centre clinical trial. The use of such standards allows the BMD of a particular centre to be expressed as a version of a machine- and location-independent "standardised" BMD (sBMD, usually expressed in units of mg/cm^2), which is more amenable to allowing comparisons between centres in multi-centre studies. An example is the use of the European Spine Phantom (ESP) in cross-calibrations between centres and between modalities (#33, App. 8).

However, in the routine clinical context sBMD is currently not recommended to compare *serial* measurements of the same patient between different Units, whether or not the machines are derived from the same manufacturer, or even between different machines within the same Unit. The methods to be applied for such a comparison are described in Sect. A3.5 above.

Appendix 4: Detecting "Out-of-control" Behaviour: The Multi-rule Shewhart Chart

The QC parameters obtained from serial phantom measurements can be analysed in various ways to determine drifts, changes in precisional error and other factors that may affect machine performance over time.

Well-established statistical techniques are available for this purpose, usually involving the generation of a "control chart" with appropriate control limits. The actual techniques chosen by a Unit will depend on its resources, and to some extent on its particular preferences. Choice of control limits is a critical issue, requiring that sensitivity to "out-of-control" events are balanced against the "false alarm" rate. If uncertain as to how to proceed, advice should be sought from a statistician. The following (plus Apps 5 & 6) is an introduction to common approaches.

The simplest method for detecting changes in precision is to examine the time development of the precisional error for the densitometer daily external QC phantom, as calculated by the densitometry software. Any form of drift, systematic (i.e., in one direction) or random, will cause the SD of random variations about the mean (usually < 0.5% when expressed as CV%; see Eq. [2], App. 2) to increase. This "first line" QC procedure is discussed in Appendix 3. However, since this method relies mainly on visualisation, at least one other independent and more quantitative method should also be applied.

A traditional and popular method which can be set to acceptably balance the "false alarm" rate against the "out-of-control" rate, and which is statistically straightforward is *multi-rule Shewhart charting*. Depending on the rules adopted (see below) Shewhart charting can identify the growth of both random and systematic errors.

Construction of a Shewhart chart begins with the assembly of 10-20 consecutive phantom QC measurements of BMD, or another chosen QC parameter to be followed over time. These data are used to derive the mean and SD for further evaluation. A selection of the following rules may then be applied, to determine the significance of variations in the time-development of the chosen QC parameter. Depending on choice of the combination of rules, either systematic or random errors will be highlighted (or a combination of both).

1. ***Warning rule:*** A single control (phantom) measure exceeds the mean ± 2SD of the baseline phantom mean measure. This occurrence should prompt additional inspection of control data with further rules.

2. ***Three SD rule:*** A single control measure, that exceeds the baseline mean ± 3SD would indicate the need for instrument evaluation.*

3. ***Two SD twice rule:*** Two consecutive control measures that exceed the mean ± 2SD interval would dictate instrument evaluation.*

4. ***Range of 4SD rule:*** When the difference between two consecutive control measures exceeds 4SD (specifically when one measure exceeds + 2SD and another lies below - 2SD) the instrument requires evaluation.*

5. ***Four ± 1SD rule:*** When four consecutive measures exceed the same limit (either + 1SD or - 1SD), then evaluation* is required.

6. ***Mean x 10 rule:*** When 10 consecutive control measures fall on the same side of the mean (regardless of the magnitude of the divergences), then instrument evaluation* is necessary.

An example of a serial data set, suitable for Shewhart charting, and revealing an "out-of-control" event is shown in Figure 6(a).

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* Instrument evaluation shall involve repeated (10-20) control measures. With repeated failure, patient scans shall be suspended until the instrument is more thoroughly evaluated.

Appendix 5: Detecting "Out-of-Control" Behaviour: The Moving Average Plot

Experience with bone densitometry QC data suggests that Shewhart charting may not detect changes rapidly enough, given the layered rules required for interpretation. Also, CUSUM plots (App. 6) may be overly sensitive to change. Therefore, an analysis that is both sensitive to small changes in the mean trends (but not overly sensitive) while remaining easy to interpret is worth considering. As applied in other fields requiring analysis of trending data, the moving average techniques (particularly the EWMA; Sect. A5.2) are generally believed to satisfy these requirements.

A5.1 *Simple Moving Average*

A moving average (MA or "running mean") allows the small daily changes in the phantom scans to be smoothed, and removes large but isolated random fluctuations. It is useful in plotting phantom QC results prior to their incorporation in a Shewhart chart or CUSUM plot. It can also be used standalone for plotting violation of tolerance limits. More data points in the moving average will make the test more discriminating, but display a slower response to drift. The aim is to determine iteratively the mean of a subset of the whole dataset, plot it, and then repeat the procedure by determining the mean of the next subset, while shifting ahead by one time point, and so on.

The formula for computing the *"simple"* moving-average BMD at time t_0 is:

$$MABMD(t_0) = \sum_{i=0}^{-k} BMD(t_i)/(k+1) \qquad (11)$$

where $BMD(t_i)$, i = -1, -2, ... , $-k$ has already been measured prior to time t_0 at the i^{th} retrospective time point and then added to the current measurement $BMD(t_0)$ at t_0. Typical values for k are 10 or 20. Sequential time points are separated by a time interval $\Delta t = BMD(t_i) - BMD(t_{i-1})$. Δt is often constant for all i but need not be. MABMD (t_0) is then added to the moving-average chart plot. The algorithm is then repeated, with a new measurement $BMD(t_1)$ made at the next time increment, and so on.

When a machine is "in-control", the moving ("rolling") average should vary randomly about the target mean (established similar to T for the CUSUM; see App. 6) and within the constraints of the set tolerance limits. These may be for example "tramlines", set (say) ±1SD from the target value. If the MABMD breaches these limits, or drifts systematically in one direction the bone densitometer may be "out-of-control".

The *centred moving average* is a variation that sums an equal number of measurements before and following the measurement BMD (t_0) that is to be plotted.

A5.2 *Weighted moving averages; arithmetic & exponential*

A limitation of the "simple" moving-average methods is that significant trends may not always be demonstrated in a timely way. A *weighted moving average* is a variation on the moving average described above, with arithmetic weights applied to each BMD value over time. These weights appear as the set α_i, prefixing the $BMD(t_i)$ in Eq. (11). Usually, more weight is applied to the most recent data by adjusting the α_i accordingly. Experience shows that weighted moving averages respond more elastically and promptly to data trends.

A popular and effective version of the weighted moving average (particularly in the financial sector) is the *exponentially weighted moving average* (EWMA). The EWMA replaces the

arithmetic weights with exponentially changing factors, granting much greater importance to the most recent measurements and generally improving the timeliness of detection of a trend. Formulae, including those for setting of control limits, will not be discussed here.

The bottom frame of Figure 5 shows the scatterplot of a segment of real data derived from repeated QC phantom measurements on a DXA machine in a busy clinical environment. These data were collected across the time interval of an "out-of-control" event that caused a DXA machine calibration failure. Comparison of the three frames shows how the "simple" moving average (MA) statistic reflects a machine fault and is perhaps more visually interpretable than a simple scatterplot; also that the EWMA may further amplify the anomalous behaviour in a timely way.

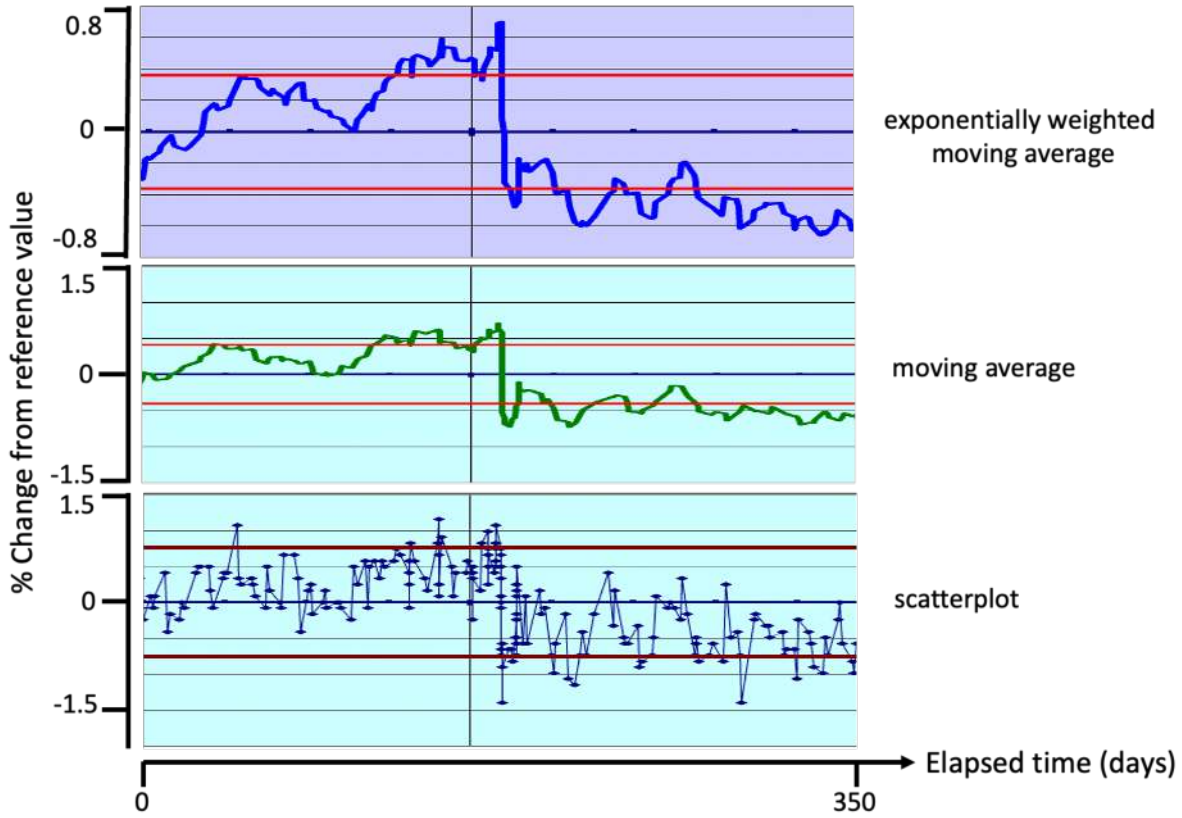

Figure 5. Relative visual effectiveness of a scatterplot (bottom frame) of phantom BMD measurements (identical to the data shown in Figure 6[a]), compared with moving average (MA) or exponentially weighted moving average (EWMA) techniques, for identifying onset of a calibration failure. (Data courtesy of Christopher Schultz, Royal Adelaide Hospital).

Appendix 6: Detecting "Out-of-Control" Behaviour: The CUSUM Plot

A CUSUM plot is a sensitive visual and (with appropriate embedded "trigger" criteria) quantitative indicator of "out-of-control" behaviour of a measured variable, but may be less useful for identifying the specific cause. It is not recommended in favour of moving average techniques (App. 5). However, it is recognised as superior to simply "eyeballing" plots of serial data collected over time, and may be favoured by those already familiar with its use.

Specifically, CUSUM is a method for the sensitive detection of *systematic drift* in a measured QC variable, and may be particularly useful for monitoring of long term) "constant" QC variables such as the BMD or BMC of a phantom; over several months or even years. Note that an increase in *random* errors (e.g., mean error ~ zero; degradation of precision due to failure of electrical circuitry, or wear in a mechanical component) may not be readily detected by a CUSUM plot.

Prior to deriving a CUSUM plot a "target" value is required. The mean of (say) the first 10-20 phantom scans can be used as the initially established *target value* (or "in-control mean"), denoted as T, which is effectively measured at time $t_{i=0}$. In general, let $X(t=t_i)$ denote phantom BMD measurements at times t_i, *where* $i = 0, 1, 2, ...$ is the index of incremental time-spaced measurements. The variable $X(t_i)$ may be the sample mean of (say) k values obtained at the particular time point t_i. The deviation (d_i) of X from the target value is $d_i = X(t_i) - T$. At any specific elapsed time (t_j), the cumulative sum of deviations, $CUSUM(t_j)$ is calculated by summing all the prior values of d_i (positive and negative) up to the current measurement at t_j. The simplest application of CUSUM (see the literature for more sophisticated versions; e.g., #34; App. 8) is expressed as:

$$CUSUM(t_j) = \sum_{i=1}^{j} d_i = \sum_{i=1}^{j} (X(t_i) - T) \qquad (12)$$

The CUSUM is plotted against time to provide a cumulative sum representation. A suitable vertical scale for BMD is (say) one unit per 0.005 g/cm^2 and a suitable horizontal (elapsed time) scale is (say) one unit per 30 days, or more frequently. If each X is a sample mean, CUSUM may be normalised by the representative SD of these means, or the SD of the sample values contributing to calculating the target value T, as shown in Figure 6.

Since any variations of the phantom BMD from the target value T should be randomly positive or negative, the CUSUM should not deviate significantly from zero over time. A persistent deviation of the plot away from zero (identified by a suitable pre-set "out-of-control" criterion) indicates a potential instrument problem. This will occur in particular if a systematic error (persistent shift) in BMD measurement is occurring over time.

Figure 6 analyses the same real phantom QC data set (excerpt from a long term scattergram) as displayed in Figure 5. Here, the onset of a calibration failure seems more predictable, prior to intervention, when viewing the CUSUM plot (b) than for the "raw" data scattergram (a). (The event was build-up and movement of lead swarf in the collimator/shutter assembly of the X-ray tube.)

The CUSUM plot relies on remaining close to the 'true' long term average and because of its sensitivity this is usually only partially achieved. Thus, the CUSUM plot may sometimes seem to unavoidably deviate from the ideal, with the deviation difficult to interpret. Therefore CUSUM can be overly sensitive to change and thus possibly less discriminating than methods based on a moving average. Also, (as with all QC surveillance techniques) the CUSUM algorithm should be reset, following any rectifying intervention (Figure 6).

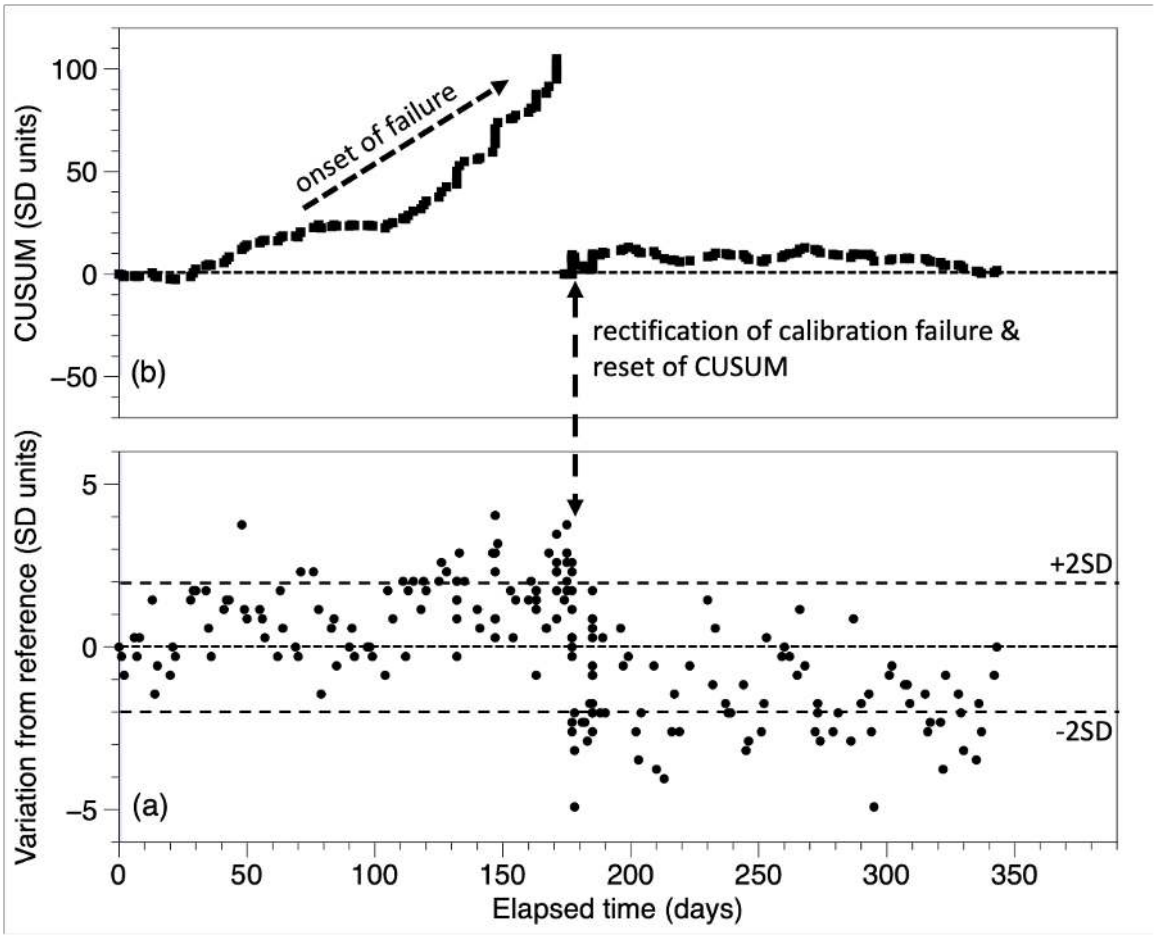

Figure 6. (a) Adaptation of a real QC scattergram of daily variations in BMD from the calibration spinal phantom reference value (same data as shown in Figure 5), here normalised for SD, showing a machine calibration failure. (b) SD-normalised QC CUSUM plot showing evidence of the failure; onset of a monotonic trend. Note the recalibration of CUSUM statistic following rectification of the fault. (Data courtesy Christopher Schultz, Royal Adelaide Hospital.)

The "quality team" of the Unit is strongly encouraged to explore the relative performances of the methods described in Apps 4-6, using an automated spreadsheet-based calculator/plotter such as that available free of charge from the ANZBMS website (#27, App. 8), and to implement in their QA/QC program one or more of those methods they find useful.

Appendix 7: DXA-specific Compliance Testing

Measurements of parameters such as output air kerma from a DXA machine are challenging because of the low dose rates. Details of the techniques and technologies used in compliance testing are not described here in detail because these shall be applied by a trained professional (for example, a medical physicist or engineer specialising in X-ray technology) accredited by the Radiation Regulator.

As noted in Standard 8, the historical development of DXA technologies has been matched by a range of recommendations for QA and compliance testing (e.g., #35; App. 8). The Standard recognises that a DXA machine incorporates an X-ray tube. However in DXA the parameters and settings defining the X-ray beam that are normally required to be tested for compliance in conventional radiology are either fixed or severely restricted in their operational scope. Furthermore, radiation surface entrance exposure and therefore effective dose to the patient (direct beam) is low compared with kindred diagnostic radiological modalities; usually less than about 25% of a standard PA chest radiograph. This translates also to a relatively modest lateral radiation scattered dose impacting on the technologist or (occasionally) on an accompanying carer, despite their usually unshielded proximity; unlike in conventional radiology.

It is challenging for the compliance tester using conventional testing equipment to non-invasively measure factors such as DXA output kerma, kVp or HVL, complicated by the dual energies. Also, the requirement for rigorous, regular QC (App. 3) that directly monitors key machine KPIs facilitates the inherent safety and accuracy of the technology for both the technologist and the patient, as well as tightly governing the long term precision of its measurements.

A7.1 *Design factors of a scanning room impacting on radiation safety*

Getting the layout and construction of a scanning room correct "up-front" greatly assists in establishing long term operational compliance later on. There is a strong relationship between intelligent design & construction of a scanning room and subsequent compliant work practices prescribed for technologists, which would be reviewed by scheduled compliance testing. Elements of a rigorous design concept for a scanning room that inform its construction and subsequent validation (including by compliance testing) are:

- *radiation-scatter air-kerma rate isodose profile of a DXA machine* may be available from the manufacturer, published literature or measured directly by ionization-chamber dosimetry. It is machine-, scan-type- and directionally-specific. Units of physical measurement are those of air kerma rate (μGy/hr), the preferred unit. (Results are often expressed as μSv/hr though this requires assumptions to convert a physical measurement to a radiobiological predictive estimate.) Investigations generally confirm that (in the plane of the scanning platform) for the commonly performed scans the direction perpendicular to the long axis of the scanner and projecting from the centre front of the machine delivers the highest dose rate. Example air-kerma rate isodose curves for three anatomical scan sites performed on two DXA machines are described in Ref #20 (App. 8) and utilised below.
- *Maximum projected long term work load* for each scanning room should be calculated for each scan type; also how scans will be approximately allocated to staff technologists. For example, a full workload might require a single technologist to scan 20 patients (hip, PA spine plus VFA scan sites) each day for the year's 260 working days. As a target

guideline (using this conservative example), total effective dose per scan should not exceed 0.06 μSv, so that the effective dose to a single technologist does not exceed 1 mSv in a full year.

- *Calculation of "protection by distance" for technologist from air-kerma rate isodose profiles & workload*. A review of isodose curves data for two popular, representative machines representing major manufacturers, for each of the three assumed scan sites applied to the conservative workload scenario in the above paragraph, suggests that a single technologist would receive 0.4 - 1.0 mSv/yr effective dose at 2 metres from the front of the DXA machine. (#20; App. 8). (This example is provided as a guideline only and is not a universal indicator.)

  Thus for fan-beam or cone-beam systems the isodose curves generally suggest that the operator's console be located at least two metres from the nearest edge of the machine, preferably facing toward the head or foot of the scanning platform.

- *Within-Unit validation: establishing reference scattered dose rates for subsequent comparisons*. Tantamount to a within-Unit validation of assumed isodose curves for an installed machine, scattered dose can be determined by phantom measurements made at (at least) three defined positions in the scanning room, (say, at 100 cm in front of and from either end of the scanner) at the time of commissioning/acceptance of the machine. These data could then be used subsequently by the compliance tester as baseline comparators. Dose rate to any other point in the room, including the operator seat, could be determined from the inverse square law. However, dose rates within a radius of two metres from the scanned object should be adjusted using a factor of "inverse 1.5-squared" (#36; App. 8).

- *Adjacent occupied spaces*. If the Unit expects to be busy over a long period, dose-rate measurements and calculations to occupied rooms adjacent to the planned scanning room(s) should be performed. No member of the general public, including Unit non-DXA workers shall receive more than the effective dose mandated by the Radiation Regulator, which will not exceed, and may actually be less than 1 mSv per year.

A7.2 *Elements of compliance testing program (I); equipment & scanning room*

A compliance testing program shall be agreed upon by the relevant professional medical society and its governing Radiation Regulator, preferably in close collaboration with representatives of DXA providers. Thus, a key first step in devising a compliance testing program for a DXA machine is an accord with the Regulator. It is recommended that compliance testing be performed at least once every three years. The compliance tester shall be accredited for the task by the Radiation Regulator.

The following suggested investigations by the compliance tester are either DXA-specific or a pragmatic subset of measurements traditionally performed on a clinical diagnostic X-ray system, based on requirements stated in Standards 4 & 8, plus comments above.

- *Labelling of scanning room*. Compliant ionizing radiation and laser warning signs shall be displayed on the outside of the entry door of each room housing a bone densitometer.

- *Layout of scanning room; functional space & geometry.* Sufficient space shall be available for a hospital gurney to be easily manoeuvred adjacent to the scanning platform, for disabled patient transfers. DXA machine to be positioned so that under no circumstances would the scanning arm or platform accidentally hit a wall. Sufficient space around the machine be allocated to allow for maintenance, without the machine having to be moved.

- *Layout of scanning room; radiation doses*. For fan or cone-beam DXA systems, operator to be seated at least 2 m from nearest edge of the scanning platform; preferably facing the foot or head of the scanner, as described in Sect. A7.1. If this is not possible (rarely), then depending on the calculated workload and isodose curves (see Sect. A7.1) radiation shielding (likely 0.25 mm-equivalent lead glass) must be considered (#28 & #37; App. 8).
- *Labelling of X-ray generator, X-ray tube assembly & scanning arm*. X-ray generators and tube assemblies must each be permanently marked in English and the marking must be clearly visible, for unique tracking. Usually, they are each assigned a unique tracking number by the Radiation Regulator, linking to fully compliant descriptive data. The scanning arm shall be appropriately labelled to indicate the housing of a laser.
- *Verification of compliant scattered dose & dose rate to technologists.* By scanning a trunk-sized phantom (e.g., proprietary, or 20-30 cm-diameter solid acrylic or water-filled cylinder or equivalent cube; the larger dimension better approximating the trunk), determine the laterally scattered surface entrance exposure 1 m in front of the centre of the near edge of the scanning platform, and to either side. A calibrated instrument such as a *sensitive* ionization chamber, with appropriate background correction (e.g., #35, App. 8) should be used, with measured air kerma rate (μGy/hr; primary physical measurement) subsequently converted for convenience to effective-dose rate (μSv/hr; radiobiological risk measurement), for easier interpretation by Unit staff. Separate measurements shall be performed for each scan type (and if relevant, scan speed) performed on that machine. These data to be compared with baseline reference measurements made at commissioning/acceptance, as discussed above, and thus where possible with data provided by the manufacturer.

  Scattered dose from a whole-body scan need not be measured directly since it is expected to be much lower than for the spine or hip, due to low surface entrance exposure. The whole-body scattered dose may be estimated from (say) the spine PA dose and the ratio of the patient-free air exposures for the PA spinal and whole-body scans (e.g., available from the manufacturer).

  Because of the inherently low doses arising from DXA, dose rate may need to be integrated by the detector over several identical sequential scans of the same type.

  If the dose to the technologist in their seated position (or for any other location within or outside the scanning room) is required then the inverse square law of dose decrease with distance may be applied. (For close separations less than 2 metres from radiation source, the conservative "inverse 1.5-squared" law should be applied [#36; App. 8].)
- *Dose-area-product meter for patient dose monitoring*. For modern DXA systems, the machine may incorporate a dose-area-product (DAP; μGy cm^2) meter between the X-ray tube and the patient, the serial data of which can be monitored using the statistical tools described in App. 2. This provides a semi-quantitative check on the history of primary-beam dose delivery to patients, and (indirectly) scattered dose to technologists.

  For machines without a built-in DAP, or as an extra verification, such measurements can be made with a sensitive ionization chamber on top of the scanning platform, with the anthropomorphic trunk phantom located 1 cm above it, to account for backscatter (#35, App. 8).

  Such measurements can if desired (in a sophisticated working environment) be used to estimate reference absorbed doses to exposed organs for subsequent patient effective-dose estimations, likely using Monte Carlo (MC) methods. However, such calculations

may not be straightforward. DXA is a variation of "slot-scanning" radiography for which (e.g.,) PCXMC the popular MC computational platform for diagnostic radiology is not suitable (#38; App. 8).

A7.3 *Elements of compliance testing program (II); staff work practices verification*

- *Personal radiation monitoring.* Verification that all staff assigned to scanning are wearing personal radiation monitors that are regularly processed and the data permanently stored; or that the lack of monitoring (for any staff member) is formally approved by their radiation safety officer, in agreement with the Radiation Regulator.
- *Machine QC (embedded within an integrated QA program; Figure 1).* Verification that at least thrice-weekly QC measurements of BMD (and preferably additional QC parameters) of each machine in the Unit are being performed using a manufacturer-approved phantom and protocol, and that each machine is currently within specifications. A typical result is a CV of 0.30 - 0.5% for random errors (Eq. [2]; App. 2), within a chosen control limit of (say) $<\pm$2SD or (say) 1.5%.
- *Additional quantitative & predictive QC*. In addition to the manufacturer-recommended basic QC a more quantitative QC procedure (if not already manufacturer-recommended) such as one of those described in Apps. 4-6 shall be implemented and be available for verification by the compliance tester.
- *Record-keeping*. Verification that continuous, accessible, complete and secure written or electronic records are being kept of all QC and maintenance procedures on each machine. This includes regular, scheduled preventative maintenance by the manufacturer-approved representative, strongly recommended to be applied annually.

Appendix 8: Elements of a Reference Library

Online, or printed copies of relevant reference library items, shall be readily available to staff and should ideally include most of the following resources. Note that most of the material on the recommended websites is accessible without charge.

A8.1 *Equipment- & work-practice-specific documents (obligatory)*

- Operator manuals for each DXA machine.
- An up-to-date compendium of all communications and technical notes published by the manufacturer for each machine. Includes any communications from the Unit to the manufacturer.
- All standard operating procedures (SOPs) created by the Unit. Collectively, these should be regularly reviewed by the QA manager (e.g., once per year) and comprise a component of the integrated QA system, within which are embedded all QC procedures, forms and records that traceably and indestructibly document the daily operations of each DXA machine plus the related data analyses, reports preparation, reporting specialist validations and finally transmission to (& feedback from) referring practitioners.
- In addition to patient-scan data (including archived copies), permanently-retained, clearly-documented data including radiation monitoring for staff, equipment QC & compliance testing, maintenance interventions and equipment & software upgrades.
- Depending on the technical sophistication of the Unit and level of responsibility ceded by the manufacturer to local non-manufacturer technical backup, some elements of "invasive" maintenance manuals may also be included.
- The Medical Benefits Schedule (MBS) plus explanatory notes, the Australian Govt Dept of Health & Aged Care, pertaining to bone densitometry (#17, this appendix).
- Position papers periodically published by international bone-focussed learned societies. Note in particular the International Society for Clinical Densitometry (ISCD); https://iscd.org/learn/official-positions/ (PDFs downloadable); including adult, paediatrics, comprehensive recommendations in routine clinical practice plus DXA-based fracture assessment). (Accessed July 2024.)

A8.2 *Specialist peer-reviewed scientific journals*

1. *Journal of Clinical Densitometry* (strongly recommended)
2. *Osteoporosis International* (strongly recommended)
3. *British Journal of Radiology*
4. *Journal of Bone and Mineral Research*
5. *Calcified Tissue International*
6. *Progress in Osteoporosis*
7. *Bone*

A8.3 *Websites & references, including radiation safety regulations & practices*

8. International Society of Clinical Densitometry: https://iscd.org/ (accessed July 2024)

9. International Osteoporosis Foundation: https://www.osteoporosis.foundation/ (accessed July 2024)

10. Bone Health & Osteoporosis Foundation: https://www.bonehealthandosteoporosis.org/ (accessed July 2024)

11. Australian & New Zealand Bone & Mineral Society: https://www.anzbms.org.au/ (accessed July 2024)

12. Healthy Bones Australia: https://healthybonesaustralia.org.au/about-us/bone-health-australia/ (accessed Nov.2024)

13. Osteoporosis New Zealand: https://osteoporosis.org.nz/ (accessed Dec.2024)

14. ARPANSA 2016 *Statement on the Use of Dual Energy X-ray Absorptiometry:* https://www.arpansa.gov.au/sites/default/files/legacy/pubs/rhc/rhc_dexa.pdf (accessed July 2024)

15. NZ Government Ministry of Health 2018 *Code of Practice for Diagnostic and Interventional Radiology (ORS C1)*: https://www.health.govt.nz/system/files/documents/publications/code-of-practice-diagnostic-and-interventional-radiology-nov18_0.pdf (accessed July 2024)

16. ARPANSA 2005 *Code of Practice: Exposure of Humans to Ionizing Radiation For Research Purposes*: https://www.arpansa.gov.au/sites/default/files/legacy/pubs/rps/rps8.pdf (accessed July 2024)

17. Australian Dept of Health & Aged Care, MBS Online, *Medical Benefits Schedule - Note DN.1.18* https://www9.health.gov.au/mbs/fullDisplay.cfm?type=note&qt=NoteID&q=DN.1.18 (accessed July 2024)

18. Kallner A & Theodorsson E 2019 Repeatability imprecision from analysis of duplicates of patient samples and control materials. *Scand J Clin & Lab Invest* 80: 210-214

19. ICRP 2007 *Recommendations of the ICRP* (International Commission for Radiation Protection, Vienna, Publication 103): https://journals.sagepub.com/doi/pdf/10.1177/ANIB_37_2-4 (accessed July 2024)

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A8.4 *Recommended texts*

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Appendix 9: Standard Adult DXA Report: 2023 Minimum Requirements (AANMS, ANZBMS, ESA & RANZCR)

(Ref. #39, App. 8)

Patient and Scan Details

- Demographics (name, medical record number, date of birth, gender)
- Indications for the test and test date.
- Manufacturer of DXA, model of scanner used and software version.

Bone Mineral Density Results

- The skeletal sites, ROI, and, when appropriate, the side that was scanned.
  Standard sites: Lumbar spine: L1-L4 or L2-L4.
  Proximal femur: femoral neck and total proximal femur.
  Additional sites: Bilateral hips: additional diagnostic sensitivity, improved precision.
  Radius (see * below).
- Technical limitations of the study including rationale of changing standard ROIs (e.g., spinal osteoarthritic changes).
- BMD in g/cm^2 at each site.
- The T-score and/or Z-score where appropriate for each site.
- A general statement if medical evaluation for secondary causes of low BMD is appropriate, based on gender- and race-specific Z- scores.
- WHO classification for postmenopausal females and men aged 50 and over.

Fracture Risk

- Risk factors including information regarding previous non-traumatic fractures.
- Absolute fracture risk estimate (FRAX may be preferred due to general accessibility on DXA machine. The FRAX estimate should be adjusted with TBS if available).

DXA Report: Optional Items

- Suggestions for the necessity and timing of the next BMD study.
- Recommendation for further non-BMD testing, eg X-ray, computed tomography, etc.
- Identifying when the results meet guidelines for pharmacological and/or non-pharmacological intervention (e.g. current guidelines Healthy Bone Australia /RANZCGP).

LVA / VFA Report

LVA/VFA assessment is a useful ancillary measure for screening of asymptomatic vertebral fractures. When performed, this should be alongside DXA of the spine and hip(s).

- VFA reports should comment on the following:
  - Vertebral deformities and whether or not such deformities are consistent with vertebral fracture.
  - Unexplained vertebral and extra-vertebral pathology.

Follow-Up DXA Report

- Indication which previous or baseline study and ROI is being used for comparison.
- Significance or otherwise of change in BMD between the current and previous study or studies.

- Comments on comparison with any previous external study, including DXA machine on which previous studies were performed, plus any limitations of that comparison.

*The 33% radius (of the non-dominant forearm) may be used if; hip and/or spine cannot be measured, hyperparathyroidism or in patients exceeding the weight limit for the DXA scanning platform.