SELF ASSESSMENT QUESTIONNAIRE

ACCREDITATION GUIDELINES FOR BONE DENISTOMETRY

This self assessment questionnaire is to be used by medical practices performing bone densitometry offered by endocrinologists, nuclear medicine physicians and other non-radiological medical specialists.

The questionnaire has been prepared to be used as a checklist to determine compliance with the *Accreditation Guidelines for Bone Densitometry.* These guidelines have been prepared for the Australian & New Zealand Bone & Mineral Society (ANZBMS), the Australian & New Zealand Association of Physicians in Nuclear Medicine (ANZAPNM), the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM) and the Royal Australian and New Zealand College of Radiologists (RANZCR).

STANDARD 1 – STAFF

There shall be sufficient professional and support staff with adequate training and experience to supervise and conduct the work of the unit.

		YES	NO
	Qualifications		
1.	Are technologists tertiary educated (degree or diploma) in the field of radiography, nuclear medicine, science or nursing?	☐	☐
2.	Do these staff have additional post-graduate training in bone densitometry?	☐	☐
	Training		
3.	Are bone densitometers only operated by staff trained in densitometry?	☐	☐
4.	Do these staff perform only scans for which they have been specifically trained?	☐	☐
5.	In addition to tertiary qualifications, does the training of technologists include at least:		
	i) radiation safety (hazard analysis, regulations, patient advice, licensing);	☐	☐
	ii) patient management (reception, advising, lifting, etc);	☐	☐
	iii) DXA scanning training;	☐	☐
	iv) DXA quality assurance and equipment performance;	☐	☐
	v) relevant statistical analysis & report generation?	☐	☐
6.	Is documentation available to demonstrate the education, training received and experience of staff for the following:		
	i) patient preparation & positioning;	☐	☐
	ii) the scanning mode used for all scans performed and variation in mode with body size;	☐	☐
	iii) the anatomic landmarks used for positioning the scanner;	☐	☐
	iv) acceptable scan margins;	☐	☐

		YES	NO
v)	a detailed, unit specific, knowledge of acquisition, analysis and QC procedures and applicable reference intervals taken from the peer reviewed literature;	☐	☐
vi)	management of all problems encountered in densitometry scanning including;	☐	☐

- extremes of body habitus;
- soft tissue calcification;
- osteoarthritis;
- fractures;
- scoliosis;
- prior surgery;
- prosthetic devices;
- artefacts;
- uncommon anatomy (eg. 6 L vertebrae);
- recent nuclear medicine scans and contrast radiology;
- unusual patient movement;
- relevant safety issues;
- radiation safety?

Duties

7. Do the duties of the technologist include:

i)	patient scanning;	☐	☐
ii)	reviewing analysis;	☐	☐
iii)	reviewing results;	☐	☐
iv)	performance or supervision of quality control procedures and review of these results?	☐	☐

STANDARD 2 – CONSULTATION

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

		YES	NO
1.	Does the unit offer a consulting service to referring clinicians?	☐	☐
2.	Does this service include the unit medical specialist(s) or technologist(s) providing authoritative advice on the following:		
	i) the precision and accuracy of methods used in the unit, including in-vivo and in-vitro precision estimates for all scans performed in the unit;	☐	☐
	ii) the statistical significance of results and their relation to reference intervals (this includes data on the source of the reference interval used for the scan interpretation);	☐	☐
	iii) the scientific basis and the clinical significance of the results;	☐	☐
	iv) the suitability of the requested procedure to solve the clinical problem in question;	☐	☐
	v) further procedures which may be helpful?	☐	☐
3.	Is the unit's medical specialist contactable to provide advice when not present on-site?	☐	☐

STANDARD 3 – FACILITIES

Each densitometry unit shall provide sufficient space and facilities for the satisfactory provision of service.

		YES	NO
1.	Does the unit environment allow for the optimum performance of personnel and equipment?	☐	☐
2.	Are facilities adequate for patient comfort and privacy, and safety and efficacy of operation?	☐	☐
3.	i) Is there sufficient space around the x-ray unit such that densitometry staff and persons accompanying the patient are out of the radiation hazard zone of the machine?	☐	☐
	ii) If necessary, is appropriate shielding provided?	☐	☐
4.	If relevant, is the safety of staff and patients occupying space adjacent to the unit considered?	☐	☐
5.	Are communication facilities adequate for proper consultation, patient interviews and reporting?	☐	☐

STANDARD 4 – HEALTH AND SAFETY

Effective levels of control with respect to health and safety must be maintained.

		YES	NO
	Radiation Safety		
1.	Does the unit ensure the protection of personnel, hospital employees, patients and the community at large, taking into account the NHRMC, Radiation Health Series No. 39 *Recommendations for limiting exposure to ionising radiation (1995) and national standard for limiting occupational exposure to ionising radiation* and the New Zealand National Radiation Laboratory, Code C5 *Code of safe practice for the use of x-rays in medical diagnosis*?	☐	☐
2.	Does the unit comply with relevant state safety and occupational health regulations?	☐	☐
3.	Has the unit appointed a radiation safety officer, or have access to one, for consultation on radiation safety issues?	☐	☐
4.	Have staff attended a recognised course on radiation safety as it pertains to bone densitometry?	☐	☐
5.	Do all staff operating DXA fan beam units wear radiation monitoring devices?	☐	☐
6.	Are records of radiation exposure kept and available for review at any time, unless exemption is given by the state radiation regulatory authority? Note: For pencil beam units, the issue of personal monitoring may depend on the local regulatory authority.	☐	☐
7.	Are staff aware of the effective radiation doses involved in densitometry and the clinical relevance of these doses to the normal population, pregnant women and to children?	☐	☐
8.	Are staff also aware of, and be able to clinically interpret, the effective radiation dose of complimentary tests (eg. chest and spinal radiographs)?	☐	☐
	Other Safety Issues		
9.	Does the unit comply with electrical and mechanical safety issues in accordance with Australian and New Zealand Standards and institutional and state regulations?	☐	☐

STANDARD 5 – PATIENT MANAGEMENT

Units shall have staff who are able to handle the particular problems of patients presenting for densitometry.

		YES	NO
1.	Are staff aware of the particular problems which may be experienced during densitometry such as:		
	i) chronic airways disease, joint prostheses, cardiac failure, arthritis, etc by some patients;	☐	☐
	ii) pain due to previous fractures and the risk of further fractures from trauma incurred during the scanning in patients with osteoporosis?	☐	☐
2.	Do staff possess the necessary interpersonal skills in order to interview patients and to place them at ease?	☐	☐
3.	Are staff aware of the appropriate procedure for moving and lifting patients particularly those with recent fractures or who are confined to bed?	☐	☐

STANDARD 6 – EQUIPMENT AND INSTRUMENTATION

The equipment must be suitable for the range of test performed and be in good working order.

		YES	NO
	On installation of equipment and at defined intervals, quality control (QC) and compliance testing shall be performed. Some of these tests will be performed by an engineer either provided by the supplier or independent.		
1.	Is this engineer qualified and meets any requirements established by the state or national regulatory authorities? Note: Ideally, the engineer should be certified by the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM).	☐	☐
	DXA Quality Control *At the time of installation or after any major maintenance procedure or major software upgrade*		
2.	Is the machine calibrated and tested by the supplier for accuracy and precision?	☐	☐
3.	*In vitro: short-term precision* Is the manufacturer's recommended QC phantom scanned 10-20 times and the mean BMD and coefficient of variation (CV) calculated?	☐	☐
4.	*In vivo: short-term precision* Are voluntary follow-up scans within a short timeframe (≤ 1 month), or duplicate scans on the same day on at least 28 subjects performed to determine the precision for BMD?	☐	☐
5.	Is the precision expressed as the CV? Note: Repositioning between scans is essential (the patient shall alight completely from the bed between scans). This rescanning shall occur at installation and after major service or repair, or every 2 years, whichever comes first. The volunteers should be in an age range appropriate to the generally scanned population and should give informed consent.	☐	☐

		YES	NO
	Ongoing quality control procedures		
6.	Is a QC phantom (in accordance with the manufacturer's specifications) scanned at least twice weekly (preferably daily) using the same scanning parameters? Note: This phantom is not the daily calibration, but is an anthropomorphic (or quasi-anthropomorphic) phantom recommended by (or at least acceptable) to the manufacturer.	☐	☐
7.	Is the phantom data recorded?	☐	☐
8.	Is the phantom data checked for medium term precisional error and systematic bias using appropriate analysis? Note: The analysis may include one or more of multi-rule Shewart charting, CUSUM plots and running means.	☐	☐
9.	Does the ongoing QC program include a regular maintenance schedule, with periodic testing of accuracy using a suitable QC phantom as recommended by the manufacturer? Note: This phantom may be the same as that used for the regular QC.	☐	☐
10.	Is a record kept of all interventions by the manufacturer/repair provider so that variations in QC parameters may be correlated with breakdowns and repairs if necessary? Note: This process is to facilitate retrospective analysis and correction of BMD data.	☐	☐
	Long term quality control		
11.	Does the unit review the QC data for trends over a period of years to establish the integrity of long term studies of individual patients, or for the reporting of results from clinical trials? Note: Each machine has specific operating characteristics which leads to some QC parameters being more important than others, depending on the circumstances. For example, experience with Hologic pencil beam systems has shown that variations in the parameters "k" and "d0" are frequently more sensitive to the onset of malfunctions than are BMD, BMC or Area. Such information should be incorporated into the operations manual for a machine.	☐	☐

	YES	NO
Use of internationally accepted anthropomorphic standards in ongoing multi-centre quality control studies		
12. Does the unit have access to an appropriate phantom, for Quality Control studies?	☐	☐

Note: The use of such standards (eventually to be strongly recommended or mandatory) allows the BMD of a particular centre to be expressed as a machine- and location-independent "standardised" BMD (sBMD), which is much more amenable to allowing comparisons between centres in multi-centre clinical trials.

Compliance Testing

13. Is compliance testing performed at the time of commissioning the equipment and after major equipment repair thereafter?	☐	☐

Note: The questions covering compliance testing listed below serve as guidance only and are based in part on a protocol developed by the Department of Medical Physics of the New England Medical Centre, Tufts University, MA, USA.

BMD reproducibility

14. Are daily quality assurance (QA) results for array (PA and lateral lumbar spine) and pencil beam (if relevant) modes reviewed to determine whether the repeatability of the areal BMD results for the phantom have fallen within the manufacturer's limits of ± 1.5% of mean BMD?	☐	☐
15. Are long term QA results reviewed using multi-rule Shewart charting, CUSUM plots or running means?	☐	☐

Accuracy of laser light positioning

(only necessary at commissioning, or after major service or X-ray tube replacement, and usually performed by the manufacturer/installer)

16. To assess the accuracy of the laser light position indicator, two wires meeting at right angles are positioned approximately 1 mm to the right (facing the table) of where the point beam of laser light intercepts the scanning cushion. A PA array spine is carried out to where the wires lie in the field of view. The wires may be imaged on the computer monitor and ideally should lie at the centre of the transverse scan lines and at the starting point of the longitudinal scan motion. A reasonable positioning accuracy is within 5 mm of the start point.	☐	☐

		YES	NO
	Accuracy of scan line spacing and step spacing		
	(only necessary at commissioning and usually performed by the manufacturer/installer)		
17.	To test the accuracy of the scan line spacing and step spacing, two rulers of set lengths are placed at right angles on the scanning table and an AP lumbar spine scan performed to image them. The incremental distances in each direction can be determined from this image by noting the scan length and width, the number of required scan lines, and the number of scan steps within one line. The calculated line spacing and step spacings should be within 2%.	☐	☐
	Accuracy of indicated scan time		
	(only necessary at commissioning and usually performed by the manufacturer/installer)		
18.	The timing of the scan is measured twice from when the X-ray beam light first comes on to when it goes out. The measurements should agree to within 3%.	☐	☐
	Patient free air entrance exposures		
	(only necessary at commissioning, or after major service or X-ray tube replacement and usually performed by the manufacturer/installer)		
19.	Is patient free entrance exposures measured directly for standard PA scans by placing a calibrated radiation monitor ion chamber directly on the table and scanning the chamber?	☐	☐
20	For lateral scans (in some models), is the entrance exposure calculated from the PA exposure values using the "inverse squared distance" correction (provided that the generator technique is the same for the PA and lateral scans)?	☐	☐
	X-ray scatter measurements: exposure from individual scans		
	(only necessary at commissioning, or after major service or X-ray tube replacement and usually performed by the manufacturer/installer)		
21.	Is an appropriate phantom (approximately 17cm cubic), block of perspex or equivalent used to measure scatter:		
	i) 1 metre from the front edge of the patient table;	☐	☐
	ii) at the position where the technologist sits when operating the unit?	☐	☐
22.	Is a calibrated integration radiation survey meter used to make these measurements?	☐	☐

Note: Measurements should be made in the AP and lateral aspects (if both are relevant).

		YES	NO
23.	With the X-ray beam switched off:		
	i) are three background exposure measurements made using the survey meter in integration mode;	☐	☐
	ii) are these measurements averaged?	☐	☐

Note: These measurements include both the actual background radiation plus readings due to any current leakage from the survey instrument itself. The result is deducted from any measurements taken with the X-rays on, or else the monitor zero reading is adjusted to account for "background".

24.	With the X-ray beam on are scatter measurements from the phantom (under scanning conditions) made for PA spine (and lateral spine if relevant) clinical protocols:		
	i) at the operator's seat;	☐	☐
	ii) at 1 metre from the front edge of the table closest to the phantom?	☐	☐

Note: The PA hip integrated dose from the scatter is assumed to be the same per unit as that of the spine. If this is thought not to be the case, then the hip scan scatter measurement should be made as well. Note that for equipment with multiple scan modes representing different scan resolutions, data should be collected from each scan. The exception is the whole body scan.

Scatter dose from the whole body scan need not be measured directly since the scatter is expected to be much lower than for the spine and hip protocols, due to the very low entrance exposures. The whole body scatter dose may be estimated from the spine AP doses and the ratio of the patient free air exposures for the PA spinal and the whole body scans.

X-ray exposure measurements: weekly and annual doses to staff

25.	Is the exposure for each relevant staff member estimated?	☐	☐

Note: This may be achieved by taking into account doses from individual scans performed, the number of scans of each type performed each week and year, and the work practices of the staff member (eg. their normal location within the scanning room).

26.	Do the doses acquired by individual staff members on an hourly and yearly basis comply with the limits established by the state regulatory authority?	☐	☐

Note: Usually these are "<20μSv per hour" and "<1mSv per year".

27.	Are staff practices altered on advice from the unit's radiation safety officer when the regulatory established limits are exceeded?	☐	☐
28.	Are staff aware of radiation safety regulations and recommendations as they pertain to pregnancy?	☐	☐

		YES	NO
	Operating Manuals		
29.	Are operating manuals for equipment readily available?	☐	☐
30	Are staff handling equipment able to check the critical operating characteristics as detailed in the manuals?	☐	☐
31.	Are these characteristics checked at appropriate intervals for the type of equipment and workload?	☐	☐
32.	Do the manuals include all criteria used for assessment of quality assurance procedures?	☐	☐
33.	Are records included in the manuals of all communications with the manufacturer subsequent to installation?	☐	☐
34.	Are all software updates implemented as soon as practicable?	☐	☐
	Records		
35.	Are records kept for the life of each item of equipment including:		
	i) calibration;	☐	☐
	ii) quality control;	☐	☐
	iii) repair and maintenance?	☐	☐

STANDARD 7 – DENSITOMETRY METHODS

Only properly authenticated bone densitometry shall be used for clinical purposes. This shall include only those techniques for which there are established reference intervals for the population to be studied, and data published in peer-reviewed literature demonstrating the efficacy of the technique in fracture predication. Manuals containing all methods and procedures authorised for use in the unit shall be available in the appropriate work areas, and such manuals to be reviewed at least annually.

		YES	NO
1.	Is each procedure performed by the unit (eg. screening, clinical testing, reference densitometry service, QC procedures) fully documented with all steps carefully outlined?	☐	☐
2.	Do the manuals include information covered in Standard 1, question 6?	☐	☐
3.	Are textbooks and journals, relevant to densitometry, available to supplement the unit's manuals?	☐	☐

Note: The increasing usefulness of the world wide web as a source of reference material is noted.

One element from each of the following groups should be available:

Journals

- British Journal of Radiology
- Calcified Tissue International
- Journal of Bone and Mineral Research
- Journal of Clinical Densitometry
- Osteoporosis International

Textbooks

- Blake GM, Wahner HW, Fogelman I, editors. The evaluation of osteoporosis: dual energy x-ray absorptiometry and ultrasound in clinical practice. 2nd ed. London: Martin Dunitz Ltd; 1999.
- Favus MJ, editor. Primer on the metabolic bone diseases and disorders of mineral metabolism (official publication of the American society for bone and mineral research). 4th ed. Philadelphia: Lippincott Williams & Wilkins; 1999.
- Genant HK, Jergas M, Van Kuijk C, editors. Vertebral fractures in osteoporosis. San Francisco: Radiology Research and Education Foundation; 1996.
- Genant HK, Guglielmi G, Jergas M, editors. Bone densitometry and osteoporosis. New York: Springer Verlag; 1997.
- Marcus R, Feldman D, Kelsey J, editors. Osteoporosis. 2nd ed. San Diego: Academic Press; 2001.
- Meunier PJ. Osteoporosis: diagnosis and management. 1st ed. London: Martin Dunitz Ltd; 1998.
- Rosen CJ, Glowacki J, Bilezikian JP, editors. The aging skeleton. San Diego: Academic Press; 1999.

STANDARD 8 – QUALITY ASSURANCE/QUALITY CONTROL

An efficient and effective quality assurance and quality control program shall be followed, ensuring the results provided by the unit meet acceptable standards.

		YES	NO
1.	Are quality assurance and quality control procedures able to detect real changes in instrument performance that will affect the measured BMD value or the short or long term precision of the patient measurements?	☐	☐
2.	Are QC and equipment maintenance procedures performed regularly and in accordance with the manufacturer's recommendations?	☐	☐
3.	Is QC monitoring performed in accordance with Standards 6?	☐	☐
4.	Is the equipment evaluated when QC procedures fail?	☐	☐
5.	When ongoing QC failures are detected, are further patient measurements suspended until the equipment is more thoroughly evaluated?	☐	☐
6.	If there is suspicion that previous patient results may be inaccurate, is a retrospective re-analysis of the data performed?	☐	☐
7.	Is a maintenance program in place for checking all aspects of the densitometer performance in accordance with the manufacturer's specifications?	☐	☐
8.	Are any faults identified during equipment maintenance rectified?	☐	☐
9.	Is a record kept of equipment faults and the remedial action taken?	☐	☐
10.	Is compliance testing of equipment performed on a regular basis in accordance with Standard 8?	☐	☐

STANDARD 9 – REPORTING

Reports and results shall be furnished to the requesting person with a minimum of delay commensurate with good patient care.

		YES	NO
1.	Do test reports include the following:		
	i) unit name;	☐	☐
	ii) patient's name;	☐	☐
	iii) type of densitometer as well as the scan mode and software version;	☐	☐
	iv) type of scan performed;	☐	☐
	v) date the scan was performed;	☐	☐
	vi) quantitative results;	☐	☐
	vii) reference intervals;	☐	☐
	viii) source of reference intervals;	☐	☐
	ix) reference to previous studies;	☐	☐
	x) date of report;	☐	☐
	xi) name of the reporting specialist?	☐	☐
2.	Are urgent reports communicated by telephone or by other means followed by a written report?	☐	☐
	Note: Urgent results should only be communicated to the responsible medical practitioner (or other authorised staff) with due care to prevent errors in communication.		
3.	Are all unit staff members aware not to disclose information on patients or results of investigations, except in the performance of their duties?	☐	☐
4.	Are all reports checked by the reporting medical specialist?	☐	☐

STANDARD 10 – RECORD KEEPING

All units shall maintain a complete record of all tests performed and this shall include complete identifying details of the patient. Records relating to patients, results and quality control shall be kept in readily accessible forms.

		YES	NO
1.	Is the written request retained as long as required by a statutory authority or as long as considered useful?	☐	☐
2.	Do records of scans performed include the following:		
	i) patient identification details;	☐	☐
	ii) name of the referring medical practitioner;	☐	☐
	iii) date the test was performed;	☐	☐
	iv) investigations required?	☐	☐
3.	Is raw data from all scans stored long term electronically to allow reanalysis if necessary?	☐	☐
4.	Is QC relevant for the validation of scans stored?	☐	☐
5.	Are copies of reports retained for a minimum of 10 years, or in accordance with regulatory requirements (whichever is longer)?	☐	☐
6.	Are requests from a researcher for access to data approved by the appropriate institutional ethics committee?	☐	☐
	Note: Results of investigations are normally confidential to the requesting medical practitioner and patient, however, past records may be made available to clinicians currently caring for the patient.		
7.	Is all identifying information removed from data (except with the specific consent of the patient) which is made available to researchers?	☐	☐
8.	Are record storage conditions adequate for to allow preservation and retrieval?	☐	☐