



BREASTSCREEN AUSTRALIA

NATIONAL ACCREDITATION STANDARDS

March 2022

NAS Commentary Version History

| Release Date | Detail |
|---------------|---|
| October 2015 | The NAS were developed by the Accreditation Review Committee through a Review process undertaken in 2011-2014 and subsequently endorsed by the Standing Committee on Screening (SCoS). |
| April 2017 | Non-material amendments, approved by NQMC March 2017 |
| June 2018 | Non-material amendments, approved by NQMC May 2018 |
| January 2019 | Non-material amendments, approved by NQMC May & August 2018 Material amendments, approved by SCoS July 2018 |
| February 2021 | Non-material amendments, approved by NQMC March 2019 |
| February 2021 | Non-material amendments, approved by NQMC November 2019 |
| February 2021 | Non-material amendments, approved by NQMC August 2020 |
| February 2021 | Non-material amendments, approved by NQMC November 2020 |
| March 2022 | Non-material amendments, approved by NQMC August 2021 and Material amendments, approved by NQMC in May 2021 and by Commonwealth Department of Health Chief Medical Officer in October 2021. |

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ACRONYMS USED IN THIS DOCUMENT

| Acronym | Description |
|---------------|---|
| 3 D | Three Dimensional |
| ACPSEM | Australasian College of Physical Scientists and Engineers in Medicine |
| AEC | Automatic Exposure Control |
| AHMAC | Australian Health Ministers Advisory Committee |
| AIR | Australian Institute of Radiography |
| ALARA | As low as reasonably achievable |
| ARC | Accreditation Review Committee |
| BREAST | Breast Reader Assessment Strategy |
| CIMS | Client Management System |
| CIS | Carcinoma in Situ |
| CIS | Client Information System |
| CLE | Complete Local Excision |
| CNR | Contrast to Noise Ratio |
| CR | Computed Radiography |
| CRR | Computed Radiography Reader |
| DBT | Digital Breast Tomosynthesis |
| DCIS | Ductal Carcinoma in Situ |
| DICOM | Digital Imaging and Communications in Medicine |
| DMIST | The Digital Mammography Imaging Study |
| DQE | Detective Quantum Efficiency |
| DR | Digital Radiography |
| FFDM | Full Field Digital Mammography |
| FNA | Fine Needle Aspiration |
| FNAB | Fine Needle Aspiration Biopsy |
| FNB | Fine Needle Biopsy |
| HL7 | Health Level 7 |
| IHE | Integrating the HealthCare Enterprise |
| ISO | International Organization for Standardization |
| LAN | Local Area Network |
| LCIS | Lobular Carcinoma in Situ |
| MPV | Mean Pixel Value |
| MRI | Magnetic Resonance Imaging |
| MTF | Modulation Transfer Function |

| Acronym | Description |
|--------------|---|
| NAF | NAS Accountability Framework |
| NAS | National Accreditation Standards |
| NATA | National Association of Testing Authorities |
| NBCC | National Breast Cancer Centre |
| NQMC | National Quality Management Committee |
| OSI | Open System Interconnection |
| PACS | Picture Archiving and Communication System |
| PGMI | Perfect, Good, Moderate, Inadequate |
| PIS | Patient Information System |
| QA | Quality Assurance |
| QC | Quality Control |
| RANZC | Royal and New Zealand College of Radiologists |
| RCPA | Royal College of Pathologists of Australasia |
| RIS | Radiology Information System |
| ROI | Region of Interest |
| SCoS | Standing Committee on Screening |
| SCU | State Coordination Unit |
| SDNR | Signal Difference to Noise Ratio |
| SNR | Signal to Noise Ratio |
| SQC | State Quality Committee |

GLOSSARY

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| Aboriginal and Torres Strait Islander | A person of Aboriginal or Torres Strait Island descent who identifies as an Aboriginal or Torres Strait Islander and is accepted as such by the community with which he or she is associated. |
| Accreditation Survey | An external review of a Service and/or SCU performance against the national Program standards, based on the NAS Measures, and undertaken by a team of professional peers and the National Surveyor. |
| Acquisition Workstation | A computer used to view images at the point of acquisition of the image. An acquisition workstation may be used by radiographers to review and the check quality of an acquired image. The computer usually incorporates a single monitor with at least 3 megapixel resolution. |
| AEC (Automatic Exposure Control) | A device designed to determine the exposure (mAs) needed to produce an adequately penetrated X-ray image. With digital mammography equipment this is typically done by sampling the X-ray intensity after it passes through the patient and interacts with the image receptor. The AEC may, in some circumstances, also choose the kVp and target filter combination. |
| Aspiration | The insertion of a hypodermic needle into the tissue or area of concern and drawing back on the syringe to obtain fluid or cells. |
| Assessment centre/clinic | The centre or clinic where women are recalled for diagnostic work-up due to an abnormality detected as a result of the screening visit, signs/symptoms reported at the screening visit, or for other reasons, either within or outside the Program. |
| Assessment-only episode | When a client attends a Service for assessment without having had a screening episode with that Service. |
| Assessment visit | Any visit by a woman to an assessment centre or clinic for the purpose of all follow-up investigative procedures arising from a woman's attendance for screening up to and including cytological or histological diagnosis. This does not include attending the assessment clinic for the purpose of receiving results. |
| Axillary lymph nodes | Lymph nodes found in the armpit area. |
| Benign | Not malignant, not cancer. |
| Benign diagnostic open biopsy | An open biopsy recommended by the Service for diagnostic purposes and where the histopathology was not of invasive cancer or DCIS; examples include atypical hyperplasia, radial scar or LCIS. |
| Biopsy | Removal of a sample of tissue or cells from the body to assist in diagnosis of a disease. |
| BRCA1 and BRCA2 | Human genes that produce tumour suppressor proteins. |

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| Breast cancer symptom | Any evidence of disease apparent to the patient. The AIHW states that symptoms refer to a self-reported breast lump and/or blood-stained or watery nipple discharge. |
| Breast conserving surgery | Surgery where the cancer is removed, together with a margin of normal breast tissue. The whole breast is not removed. |
| BreastScreen Australia | The national population based screening program for breast cancer. BreastScreen Australia services are delivered by state and territory governments, through dedicated, accredited Screening and Assessment Services, which provide breast screening in over 600 locations nationwide. |
| BreastScreen Australia Data Dictionary | The authoritative source of data definitions used by BreastScreen Australia to meet the need for national consistency in the data collected for program monitoring and evaluation. |
| Client Management System | The central database, which stores a client's personal, demographic and clinical outcome data. The system will function centrally with the CMS networked at each BreastScreen Service. It may also be integrated with the PACS. This may also be referred to as the 'BreastScreen Registry' in some instances. |
| Calcification | The deposition of calcium salts in body tissues. In the breast, calcification can be seen in normal and abnormal ducts and in association with some carcinomas, both invasive and in situ. |
| Calendar year | Defined by BreastScreen Australia as 365 days and 366 days in a leap year |
| Cancer | A malignant growth. Also see carcinoma. |
| Carcinoma | A malignant tumour arising from epithelial cells, which are cells lining the external or internal surfaces of the body. Carcinomas spread to nearby tissues. They may also spread to distant sites such as lung, liver, lymph nodes and bone. Also see metastasis. |
| Carcinoma in situ (CIS) | A non-invasive lesion in which neoplastic cells are confined by the basement membrane. Carcinoma in situ has an increased risk of becoming an invasive carcinoma if untreated. See also ductal carcinoma in situ and lobular carcinoma in situ. |
| Catchment area | A geographic region based on service size in relation to the population, accessibility and the location of other services. It is uniquely defined for each service based on postcode or Statistical Local Area. |
| Client Record | The record that comprises all clinical and non-clinical information stored electronically relating to an individual client, together with all forms, images and other documentation relating to the client's progress through the screening and assessment pathway. A record includes all documents, images, X-rays, register and electronic data. |
| Clinical breast examination | The physical examination of the breast and axilla by a health professional. |

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| Clinical Director | The person responsible for the provision of high standards of clinical care to BreastScreen clients through the oversight of clinical services in accordance with BreastScreen Australia National Accreditation Standards (NAS). |
| Clinician | A medically trained doctor and member of the multidisciplinary assessment team. The term is used in this document to refer to a doctor/medical practitioner |
| CNR (Contrast to Noise Ratio) | The difference in the mean pixel values of two objects divided by noise, if an image contains two objects differing in contrast. Signal Difference to Noise Ratio (SDNR) is now the preferred terminology. |
| Combined recall to assessment | Recall to assessment for a mammographic abnormality as well as non-mammographic abnormality. |
| Complete local excision | The complete removal of a tumour with a surrounding margin of normal breast tissue. Also known as CLE and breast conserving surgery. |
| Consensus reading | The consideration of a mammogram by two screen readers to reach agreement over discordant reads. |
| Core biopsy | The sampling of breast tissue with a cutting needle, 14 gauge or larger, to obtain a tiny cylinder of tissue for histological examination. This technique may involve the use of vacuum assistance. |
| Criterion | A key service component that comprise the standard; a statement of what is required to achieve the standard. |
| CR (Computed Radiography) | The use of phosphor plate cassettes that are 'read' or 'scanned' by a CR Reader and converted to a digital image. |
| CR Reader (Computed Radiography Reader) | Equipment that receives the phosphor plate cassettes, 'reads' or 'scans' the plate and converts to a digital image. |
| Cyst | A fluid-filled sac. |
| Cytological diagnosis | A diagnosis based on the examination of cells. |
| Cytology | Assessment of cellular detail and abnormalities in a preparation of cells, obtained by fine needle aspiration (FNA), or by other methods, such as imprint or duct discharge cytology. |
| Data Governance and Management Assessment | An independent assessment of the policies and processes that are in place in a Service and/or SCU to ensure effective governance and management of BreastScreen data. These policies and processes must meet the requirements outlined in the National Accreditation Standards (NAS). |
| Decision Tool | The tool developed to assist the NQMC to make accreditation decisions. The tool describes a tiered accreditation system, allocates Measures to one of three risk levels and links accreditation decisions to performance against the NAS Measures. |

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| Dense breast | The American Cancer Society explains dense breasts in the following way. “Breasts are made up of a mixture of lobules, ducts and fatty and fibrous connective tissue. Breasts are considered dense if they have a lot of fibrous or glandular tissue but not much fatty tissue”. |
| Digital Breast Tomosynthesis (DBT) | A technology that combines the use of tomography (multiple images taken through an arc) and 3-D reconstruction, to improve breast lesion visibility. |
| DCIS (Ductal carcinoma in situ) | A form of carcinoma in situ with no invasive component, diagnosed by its characteristic histopathologic features. It is frequently associated with mammographic abnormalities including calcification. There is an increased risk of progression to invasive carcinoma at the same site as the DCIS if not treated adequately. |
| Definitive outcome | The end point of an assessment episode that is complete for the woman. The outcome is definitive when one of three recommendations is made; return for routine rescreening, either yearly or two yearly; a histological result and referral for definitive treatment; or a recommendation for diagnostic open biopsy. |
| Diagnostic mammography | Mammography that is performed when a woman has signs or symptoms of disease. |
| Double reading | The independent reading of screening images by two readers with the readers whereby the readers are blinded to the other reader’s results. |
| DICOM (Digital Imaging and Communication in Medicine) | A standard that enables communication of digital image information between systems on a network. |
| DQE (Detective Quantum Efficiency) | An indicator of combined effect of noise and contrast performance of an imaging system. It is the most complete description of the system’s performance. |
| DR (Digital Radiography) | A system for direct digital capture of an X-ray image. There are several different technologies able to produce images in a digital format. |
| Early review | Early review is the recall of a woman for further assessment within 12 months of the screening date and following an equivocal assessment visit (where a decision cannot be made). Early review within six months of the screening date is considered to be part of the screening episode and cancers found as a result of the review are considered to be screen-detected. Early review carried out at six months or more from the date of screening (but less than 24 months), occurs after the screening visit is complete, and cancers found are considered to be interval cancers. |
| Early rescreen | Early rescreen is defined as a rescreen with a date of attendance less than 24 months after the date of attendance of a woman’s previous screening episode for women on two-yearly screens, or a rescreen with a date of attendance less than 12 months after the date of attendance of a woman’s previous screening episode for women on annual screens. |
| Eligible women | All women aged 40 years or over. |

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| FFDM (Full Field Digital Mammography) | A mammography unit able to produce digital images with an image receptor capable of imaging a field size comparable to film-screen systems i.e. at least 18cm x 24cm or 24cm x 30cm. |
| First screen | The first mammogram taken on a woman who is attending for the first screen in the National Program regardless of the Service in which it is taken. This is also known as the initial screen. |
| Fixed site | A screening and/or assessment clinic that is permanent and does not relocate to alternative locations. |
| Flat Panel Detector | A technology used for digital radiography. It is the part of a mammography unit that captures the X-rays to create a digital image. X-rays may be captured directly or indirectly. |
| FNA (Fine Needle Aspiration, FNAB, FNB) | The sampling of cells from breast tissue for examination by a pathologist. Also known as fine needle aspiration biopsy (FNAB), or fine needle biopsy (FNB). |
| Frozen section | The freezing of a tissue biopsy to facilitate the cutting of a thin tissue section which is stained and examined microscopically. Frozen section is usually used to obtain a tissue diagnosis at or during an operation. |
| Grade | The degree of similarity of the cancer cells to normal cells. A grade one carcinoma is well differentiated and is associated with a good prognosis. A grade 2 carcinoma is moderately differentiated and is associated with an intermediate prognosis. A grade 3 carcinoma is poorly differentiated and is associated with a poor prognosis. Tumour grade is assigned by an assessment of microscopic features of the tumour by a histopathologist. |
| Hard Copy Reading | The reading of digital mammograms that have been printed onto an X-ray film like medium, and displayed as analogue images on multiviewers. |
| Histology | The study of body tissue by a pathologist using a microscope. |
| Histopathology | The microscopic study of diseased tissue, usually performed by a histopathologist. |
| HL7 (Health Level 7) | A standard for electronic patient data exchange. HL7 refers to the highest level of the International Organization's for Standardization (ISO) communications model for Open System Interconnection (OSI) – the application level. |
| IHE (Integrating the HealthCare Enterprise) | An initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information. IHE promotes the coordinated use of establish standards such as DICOM and HL7 to address specific clinical needs in support of optimal patient care. |
| Impalpable | Not able to be felt on a clinical examination. |
| Indigenous | A person of Aboriginal and/or Torres Strait Islander descent who identifies as an Aboriginal and/or Torres Strait Islander and is accepted as such by the community with which he or she is associated. |

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| Informed consent: | The process of communication between a patient and their medical officer that results in the patient's authorisation or agreement to undergo a specific medical intervention. This communication will need to ensure the patient has an understanding of all the available options and the expected outcomes such as the success rates and/or side effects for each option. |
| Initial screen | The first mammogram taken on a woman who is attending for the first screen in the National Program regardless of the Service in which it is taken. This is also known as first screen. |
| In situ | Non invasive |
| Interval cancer – invasive | <p>Interval cancers are invasive breast cancers that are diagnosed in the interval between the completion of a negative screening episode and the commencement of the next screening episode.</p> <p>Interval cancers are defined as:</p> <ul style="list-style-type: none"> • Invasive cancers diagnosed outside BreastScreen Australia in screened women less than 24 months (less than 12 months for women on annual screens) after the date of attendance of a previous negative screening episode. • Invasive cancer detected through BreastScreen Australia at early rescreen less than 24 months (less than 12 months for women on annual screens) after the date of attendance of a previous negative screening episode where the woman presents with a breast lump and/or clear or blood stained nipple discharge in the breast in which the cancer was diagnosed. • Invasive cancers detected through BreastScreen Australia at early review more than 6 months and less than 12 months after the date of attendance of a previous screening episode. |
| Interval cancer – non-invasive | <ul style="list-style-type: none"> • A ductal carcinoma in situ (DCIS) diagnosed outside BreastScreen Australia in screened women less than 24 months (less than 12 months for women on annual screens) after the date of attendance of a previous negative screening episode. • A DCIS detected through BreastScreen Australia at early rescreen less than 24 months (less than 12 months for women on annual screens) after the date of attendance of a previous negative screening episode where the woman presents with a breast lump and/or clear or blood stained nipple discharge in the breast in which the cancer was diagnosed. • A DCIS detected through BreastScreen Australia at early review more than 6 months and less than 12 months after the date of attendance of a previous screening episode. |
| Invasive cancer | A tumour, the cells of which have invaded healthy or normal tissue. |
| LAN (Local Area Network) | A network that allows communication in a restricted area for example, within one department. |
| LCIS (Lobular carcinoma in-situ) | An atypical epithelial process characterised by an increased risk of progression to invasive carcinoma. It is difficult to detect by mammography. |

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| Lesion | An area of abnormal tissue change. A lump or abscess that may be caused by injury or disease, such as cancer. |
| Localisation | The method used to locate/mark an impalpable lesion for surgical removal with wire marker or carbon. |
| Lumpectomy | The surgical removal of a lump from the breast. Also see complete local excision. |
| Lymph node | A lymphoid organ comprising specialised white cells or lymphocytes and related cells. They have a filtering function and are the site development of antibody producing (B) lymphocytes and plasma cells, and cytotoxic and memory (T) lymphocytes. Lymph nodes are found along lymphatic channels, particularly in the axillae, neck and inguinal regions. Axillary lymph nodes are a common site for metastatic breast carcinoma. |
| Malignant tumour | A tumour having the capacity to invade and destroy tissue locally, and spread (metastasise) via the bloodstream or lymphatics, to distant sites (metastasis) and cause death. |
| Mammogram | A soft tissue X-ray of the breast. See also diagnostic mammography and screening mammography. |
| Mammography | The process of taking a mammogram. |
| Mammographic recall | A recall due to a suspicious (screening) mammogram. |
| Metastasis | The spread of a cancer from the primary site to somewhere else via the bloodstream or lymphatic system. |
| Modality | The type of technology used to acquire an image for diagnostic purposes e.g. ultrasound, MRI, CR, DR etc. |
| Morbidity | A measure of illness when referring to ill health in an individual or ill health in a population group. In the broadest sense morbidity is any departure, subjective or objective, from a state of physiological or psychological wellbeing. |
| MPV (Mean Pixel Value) | The mean (average) value of all the pixels in a specified region of interest within an image. |
| MTF (Modulation Transfer Function) | An indicator of equipment system resolution. More formally it defines the ability of the imaging system to transfer object contrast as a function of spatial frequency. |
| Multidisciplinary approach to assessment | The assessment of a woman where the radiologist and the other designated examining medical doctor in the multidisciplinary team, correlate and evaluate the clinical, imaging and pathology findings and decide on further investigations or management. |
| Multi-Service Jurisdiction | A state or territory that has more than one Service operating in the jurisdiction, and where the Services and the SCU have differing management, governance and service delivery responsibilities. These jurisdictions currently include NSW, QLD and VIC. |

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| NAS Accountability Framework (NAF) | The framework document that is required in multi-service jurisdictions, to document responsibilities and to ensure appropriate accountability at the Service and SCU levels for components of the NAS. The NAF ensures that each level is assessed against those accreditation Measures for which they are responsible. |
| NAS Annual Data Report | A report provided annually to the NQMC by Services and/or SCUs, outlining performance against the quantitative NAS Measures. |
| NAS Data Measures | The quantitative NAS Measures defined by a required minimum or maximum performance level, as listed in the NAS data report form. |
| National Quality Improvement Framework | A framework which outlines the process through which quality issues identified within BreastScreen Australia are managed to drive continuous quality improvement at a national, state and service level. |
| New technologies | Technologies that have not yet been used or approved for the screening and assessment of women within the BreastScreen Australia program |
| Non-mammographic Recall | Recall to assessment for reasons other than a mammographic abnormality, for example signs or symptoms. |
| Open biopsy | A surgical procedure performed under local or general anaesthetic in which a sample of breast tissue is obtained for histological examination, using an open incision (i.e.. A conventional surgical procedure). |
| PACS (Picture Archiving and Communication System) | The management and archiving of digital images over a computer network. |
| Pathologist | A medical practitioner who specialises in examining tissue and diagnosing disease. |
| Pathology | The branch of medicine treating the essential nature of disease, especially of the changes in body tissues and organs that cause or are caused by disease. Pathology also refers to the structural and functional manifestations of a disease. |
| Percutaneous needle biopsies | The collective term that refers to fine needle aspiration (FNA) cytology and core biopsy modalities. It does not differentiate the technique used. |
| PGMI – Perfect, Good, Moderate, Inaccurate | A method of evaluation of clinical image quality |
| Preoperative diagnosis of cancer | A malignant result on FNA or core biopsy (including DCIS and invasive cancer) which is consistent with suspicious or malignant imaging findings. |
| Primary breast tumour | A tumour arising in the breast, and derived from breast tissue. |
| Primary treatment | All treatment modalities initiated within six months of diagnosis. This does not include treatment for recurrence or metastases. |

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| Program, or the Program | The BreastScreen Australia Program. The national, organised population based screening program for the early detection of breast cancer that commenced in 1991. |
| Protocol | The document and process that determine the policies, procedures and principles that need to be implemented by BreastScreen Services and/or SCUs to underpin high quality service delivery and support the achievement of the BreastScreen NAS. |
| QA / QC (Quality Assurance/ Quality Control) | The activities that are implemented to monitor, maintain and improve the quality of systems and services. |
| Radical mastectomy | The total removal of the breast, including all lymph nodes from the armpit and removal of muscles of the chest. This operation is obsolete and should be performed rarely. Also known as a Halsted mastectomy. |
| Radiographic | Pertaining to an X-ray. |
| Radiotherapy | The use of radiation, usually X-rays or gamma rays, to kill tumour cells. |
| Reading Workstation | A workstation connected to the PACS used by screen readers for reading digital mammograms. Usually comprised of two 5 megapixel monitors (for reading the images) and a standard computer screen for managing the worklist in the PACS. |
| Research | Any project which involves the use of breast screening data. |
| Review Workstation | A separate workstation usually used by radiographers for reviewing and annotating digital images. This is most often the acquisition workstation. |
| RIS / CIS/ PIS (Radiology/ Client/ Patient Information System) | A computer database that manages demographic information, appointment scheduling and medical reports, which may be integrated with the PACS. |
| ROI (Region of Interest) | A whole or part of a digital image that may be used for image analysis, for example, in the calculation of the SNR or the SDNR. |
| Satellite service | A BreastScreen service that provides only screening. No assessment occurs at a satellite |
| Scanning Photon Counting System | A type of digital radiography technology that is used instead of a flat panel detector which discretely captures the X-ray photons depending on their energy and utilises a scanning slot. |
| Screen detected abnormalities | Abnormalities that are observed on a screening test. |
| Screen-detected cancer | Any invasive breast cancer or DCIS diagnosed during the index screening episode. |
| Screening | The presumptive identification of unrecognised disease or defect by the application of tests, examinations or other procedures which can be applied rapidly. Screening tests distinguish apparently well persons who probably have a disease, from those who probably do not. |

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| Screening and Assessment Service | An integrated service consisting of an assessment centre/service and its associated screening units. |
| Screening Episode (synonymous with Screening Round) | <p>A screening episode commences with an initial attendance for screening and includes any attendances for technical repeat screening images and assessment investigations for breast cancer related to abnormalities detected on the screening mammogram. A screening episode is completed when:</p> <ul style="list-style-type: none"> i) A recommendation is made to return the woman to routine rescreening (either from screening, assessment or after open biopsy); or iii) A diagnosis of cancer is made. <p>Unless one of these occurs, the episode remains incomplete. An incomplete screening episode should be closed when:</p> <ul style="list-style-type: none"> • The woman fails to attend for technical recall or assessment within 6 months • The woman dies. |
| Screening mammography | Mammography that is performed when a woman does not have signs or symptoms of disease. |
| Screening unit | A unit used for breast screening, which is usually one site, fixed or mobile. |
| Second or subsequent screen | The attendance of a woman for any screen in the Program, other than her first screen. |
| Size of tumour | The greatest dimension of the tumour in millimetres. This is ideally determined from the fresh specimen or, if appropriate from histopathologic slides. |
| Single Service Jurisdiction | A state or territory that has only one Service operating to cover the whole jurisdiction, and where the Service and the SCU have shared management, governance and service delivery responsibilities. These jurisdictions currently include the ACT, NT, TAS, SA and WA. |
| Small invasive cancer | An invasive cancer less than or equal to 15mm in diameter. |
| SDNR (Signal Difference to Noise Ratio) | The difference in the mean pixel values of two objects divided by noise, if an image contains two objects differing in contrast. SDNR was previously referred to as the contrast to noise ratio (CNR). SDNR terminology is now preferred. |
| SNR (Signal to Noise Ratio) | The ratio of the signal strength to the underlying noise. In a digital image it is usually defined as the ratio of the mean pixel value to the standard deviation in a ROI. |
| Soft Copy Reading | Reading the digital mammograms directly from the monitors. This enables manipulation and magnification of the images. |
| Staff | Any person employed by the Service. They include full-time, part-time and casual employees. |

| | |
|--------------------------------------|---|
| State Coordination Unit (SCU) | The unit that provides state level stewardship of the Program and undertakes a range of functions that provide the infrastructure to manage and support high quality delivery of the BreastScreen Australia Program within a jurisdiction, in accordance with national policies, to ensure the achievement of the Program aims and objectives. |
| State Quality Committee (SQC) | The committee established in a jurisdiction to drive quality improvement at the jurisdictional level by monitoring the performance of its BreastScreen Services, advising on best practice principles, learning from adverse incidents, systematically addressing areas of risk across the jurisdiction and recommending strategies that will achieve continuous enhancement of breast screening services provided to women within that jurisdiction. |
| Stereotaxis | A radiological technique used to accurately localise a lesion in the breast. It is used to allow precise insertion of a needle in order to obtain material for cytology (fine needle) or histology (core biopsy) or as an aid to surgical excision of an impalpable lesion. |
| Surgical unit | A BreastScreen Australia identifier for the surgical unit attended by the woman for local excision of a lesion, unique within a state or territory. |
| Symptom | Any evidence of disease apparent to the patient. The AIHW states that symptoms refer to a self-reported breast lump and/or blood-stained or watery nipple discharge. |
| Target group | Women aged between 50 and 74 years. |
| Technical repeat | The taking of further images initiated by the radiographer or screen reader due to technically unsatisfactory images at the screening visit. |
| Torres Strait Islander | A person of Torres Strait Islander descent who identifies as a Torres Strait Islander and is accepted as such by the community with which he or she is associated. |
| Total mastectomy | The surgical removal of the entire breast, including the nipple and areola. |
| Tumour | An abnormal growth of tissue. Tumours may be benign or malignant. If malignant they may be primary or secondary (metastatic). |
| Two standard views | The cranio-caudal and medio-lateral oblique views in mammography. |
| Ultrasound | The production of a visual image of a part of the body by recording the echoes of sound waves directed into the body. |

INTRODUCTION

PURPOSE OF THIS DOCUMENT

The purpose of this document is to provide the BreastScreen Australia National Accreditation Standards (NAS) to be used by all BreastScreen Australia Services across Australia.

These standards are the basis upon which the BreastScreen Australia Accreditation program is based.

The suite of companion documents that provides all information about the BreastScreen Australia Accreditation program comprises:

- The National Accreditation Standards 2022
- The National Accreditation Handbook 2021
- The National Accreditation Program Forms 2015
- The BreastScreen Australia Data Dictionary 2019

AIMS AND OBJECTIVES OF THE BREASTSCREEN AUSTRALIA PROGRAM

The BreastScreen Australia Program aims to reduce morbidity and mortality from breast cancer through an organised systematic approach to the early detection of breast cancer using screening mammography. Screening mammography detects unsuspected cancer at an early stage in order that early treatment will reduce illness and death from breast cancer.

This population based approach encourages asymptomatic women in the target population to have regular mammograms. It is distinctly different from the use of mammography used to investigate symptoms in an individual woman, which is a diagnostic procedure. A central tenet of the success of BreastScreen Australia is the maximisation of the benefits of early breast cancer detection while minimising potential harm to women.

Women with symptoms of breast cancer or those at high risk of breast cancer may need individualised care and services that are different from those provided through the screening program.

The objectives of the BreastScreen Australia program are to:

1. Reduce the mortality and morbidity attributable to breast cancer;
2. Maximise early detection of breast cancer in the target population;
3. Maximise the proportion of women in the target population who are screened every two years;
4. Provide high quality services that are equitable, acceptable and appropriate to the needs of the population and equally accessible to all women in the target age group;
5. Provide screening services in accredited Screening and Assessment Services as part of the BreastScreen Australia program;
6. Provide high standards of program management, service delivery, monitoring, evaluation and accountability.

BREASTSCREEN AUSTRALIA ACCREDITATION PROGRAM

BreastScreen Australia's accreditation system is designed to drive continuous quality improvement in the delivery of breast screening services to ensure women receive safe, effective, appropriate, accessible and acceptable care.

Accreditation is the independent review of a Service's and/or the State Coordination Unit's (SCU) performance, and provides a means of assessing and informing the quality improvement program within a Service and/or the SCU. The accreditation process includes an external four-yearly assessment of the extent to which the Service and/or SCU is meeting minimum standards of practice. As such, it can provide women with confidence that the care they receive is of a high standard.

A Service's and/or SCU's approach to accreditation will be integrated into its overall quality improvement program. Continuous review of performance against the standards throughout the four-year interval between accreditation surveys is required. Together with the process of preparing for accreditation, the ongoing review will help the Service and/or SCU identify aspects of service provision where additional quality improvement may be required.

The accreditation system has several components.

- The National Accreditation Standards for the provision of screening and assessment within BreastScreen Australia¹
- The NAS Protocols outlined in this document¹
- Self-assessment by the Service and/or SCU against the NAS²
- The accreditation survey of the Service and/or SCU against the NAS at least once every four years to verify performance²
- Annual data reports detailing a Service's and/or SCU's performance in the period between accreditation surveys²
- Quality improvement plans, which are developed, implemented and reviewed at each level of governance².

The NAS set targets for Services to achieve, which aim at maintaining a high quality screening program and that are achievable by most BreastScreen Services and/or SCUs. Australian data have been analysed and used to set the targets to ensure that Services and/or SCUs are challenged to provide the highest quality of service possible, whilst also being achievable.

The National Quality Management Committee (NQMC) is the national body responsible for reviewing applications for accreditation and annual data reports from BreastScreen Services and SCUs and making a final decision about whether a Service and/or SCU is accredited. The NQMC is also responsible for facilitating quality improvement within BreastScreen Australia.

The NQMC recognises that on occasion individual Services and/or SCUs may be unable to meet a small number of the NAS. The NQMC is mindful of the differences between Services and does not intend that the inability to meet one or several NAS Measures will necessarily preclude a service from achieving accreditation. Rather, the Service and/or SCU will be able to demonstrate that it is implementing a quality improvement program to move towards meeting the Measure over time.

In preparing its application for accreditation, the Service and/or SCU will be expected to identify clearly those Measures that it is unable to meet and to indicate for each:

- the particular circumstances that have resulted in non-achievement of the Measure;

¹ Refer to Section 2 and [Appendix A](#) of this document

² Refer to the National Accreditation Handbook

- the quality improvement processes and targeted strategies in place to ensure that the Service and/or SCU is working towards meeting the Measure in the future; and
- trend data that demonstrate, where appropriate, progress towards meeting the Measure.

POSITION STATEMENTS, POLICIES AND GUIDELINES

A range of position statements, policies and guidelines relevant to the BSA accreditation program can be found on the [Department of Health's website](#).

NATIONAL PROGRAM FEATURES

BreastScreen Australia Services will be delivered in accordance with the following national program features.

ACCESS and PARTICIPATION

Appropriate levels of access and participation in the target and eligible populations:

- women are eligible and invited for screening on the basis of age alone. That is, women aged 40 years and above are eligible to participate and recruitment strategies are targeted at women aged 50–74 years;
- the screening interval is every two years;
- screening is provided at minimal or no cost to the women, and free of charge to eligible women who would not attend if there were a charge; and
- patterns of participation should be representative of the socioeconomic, ethnic and cultural profiles of the target population.

CANCER DETECTION

Breast cancer detection is maximised and harm is minimised:

- screening employs mammography as the primary screening method;
- all women are screened with two view mammography. Reasons for any variation from this policy are documented;
- all mammograms are taken by a mammography practitioner or radiographer appropriately trained in screening mammography;
- all mammographic images are read and reported independently, in a blind relationship, by two or more readers, at least one of whom shall be a radiologist; and
- all mammography results are combined into a single recommendation, which indicates whether or not further assessment for the presence of breast cancer is required.

ASSESSMENT

Assessment and diagnosis of breast cancer is appropriate, safe and effective:

- a comprehensive approach is employed in the assessment of breast abnormalities;
- a multidisciplinary team is involved in the assessment of women recalled from screening;
- the pre-operative diagnosis of breast cancer is maximised, and recommendations for surgery for benign lesions are minimised;

- the outcomes for all women recommended for surgery are collected, reviewed and utilised in continuing professional education for members of the multidisciplinary team; and
- women's general practitioners are kept informed of the results of screening and assessment, unless a woman requests otherwise.

TIMELINESS

Screening and assessment services are provided to women in a timely and efficient manner:

- women have timely access to screening;
- the time from screening to assessment is minimised; and
- the results of screening and assessment are provided promptly and directly to the woman concerned in ways that are sensitive to her possible anxiety.

DATA MANAGEMENT AND INFORMATION SYSTEMS

Effective data and information management systems:

- data are collected, stored and managed using secure, quality, contemporary data management and communication systems that comply with relevant state and national standards, and that enable valid, reliable system and service performance analysis and evaluation;
- data are used for strategic purposes, quality improvement of services and for clinical and service management;
- data are collected in line with the requirements of the BreastScreen Australia Data Dictionary; and
- data are to be submitted annually to the Australian Institute of Health and Welfare, for use in a national program monitoring report, and annual performance data reports for review by the National Quality Management Committee.

CLIENT FOCUS

Services are of high quality and client focused:

- high quality information is provided to inform women, and women feel appropriately engaged and supported;
- screening services are provided in a manner which is acceptable to women in accessible, non-threatening and comfortable environments;
- women and health care providers are given comprehensive and easily understood information about the Program, from screening up to and including diagnosis of breast cancer;
- counselling and information are an integral part of the Program;
- women are advised of the benefits and risks of mammography; and
- women are provided with written information and actively involved in decisions about their management, particularly in relation to further assessment and treatment.

GOVERNANCE AND MANAGEMENT

Effective structures and processes are in place to ensure high quality governance and management:

- Screening and assessment are carried out at BreastScreen Australia accredited services; and

- Key stakeholders and stakeholder groups participate in the monitoring and management of the Program.

NAS STANDARDS STRUCTURE

The National Accreditation Standards contain a hierarchy of detail in order that their intent is clear and Services understand what is required to achieve the standards. There are three levels to each standard plus accompanying Protocols.

- The Standard – the goal relating to a specific component of the program, which needs to be achieved in order to reach the objectives of the Program;
- The Criteria – the key service components that comprise the standard; a statement of what is required to achieve the standard (previously known as performance objectives);
- NAS Measures – the individual components of a Criterion, which have a quantitative target and describe the requirement for accreditation (previously known as data items);
- NAS Protocols – the policies, procedures and principles that need to be implemented by BreastScreen Services and/or SCUs in order to achieve the BreastScreen NAS.

The NAS consist of 7 Standards, 12 Criteria, 42 NAS Measures and 61 Protocols. The details of the NAS are provided, in Section 2 of this document.

MEASURING PERFORMANCE

Performance against the NAS Measures will be used by the NQMC to determine appropriate accreditation ratings for Services and SCUs. Services and SCUs will use the most recent 12-month period for which data are available, which will be no more than 18 months old, when presenting information and data for accreditation. The same 12 month period will be used for the calculation of all NAS Measures. The exceptions to this are the participation, rescreen and interval cancer criteria. More detailed information about the NAS Measures can be obtained from the BreastScreen Australia Data Dictionary.

PROTOCOLS

Protocols determine the policies, procedures and principles that need to be implemented by BreastScreen Services and/or SCUs to underpin high quality service delivery and support the achievement of the BreastScreen NAS. Evaluation of both the protocols and the effectiveness of their implementation, will facilitate the review by Services and/or SCUs of the components that underpin the service and therefore should result in improvement. This will be most beneficial to SCUs and Services in the event of declining performance or difficulty achieving or maintaining the respective NAS Measures. The Protocols are not measured or assessed when determining accreditation. The exception is the Standard 5 Protocols, which are assessed for compliance under the Data Governance and Management Assessment.

Protocols were previously known as ‘non-data measures’. The review of the BreastScreen Australia accreditation system recognised that the previous NAS data and non-data standards could be separated. The SCoS recommended moving the non-data items to a policy document, and re-naming these, ‘Protocols’. The Protocols will be used by Services and/or SCUs to guide the development and implementation of rules, policies and procedures that will ensure the delivery of quality services and the achievement of the standards required. The non-data NAS standards have been merged into a set of Protocols that give overall direction to planning and development of a Service, and can be used to guide and assist with remediation of poor performance.

The SCoS also recommended that the assessment of accreditation of Services and/or SCUs will be made only against the NAS Measures. The survey team will therefore not assess performance

against the protocols, with one exception. The protocols listed within Standard 5 – Data management and Information Systems, will be assessed by the survey team

A full list of the Standards, Criteria, Measures and Protocols can be found at [Appendix A](#) of this document. A summary of the National Accreditation Standards and system review can be found at [Appendix B](#).

THE NATIONAL ACCREDITATION STANDARDS

1

STANDARD 1: ACCESS AND PARTICIPATION

Appropriate levels of access and participation in BreastScreen Australia are achieved in the target and eligible populations

INTRODUCTION

BreastScreen Australia aims to achieve substantial reductions in mortality from breast cancer among Australian women by maximising the participation of women in the target age group of 50–74 years. A high participation rate also helps maximise the efficient use of the physical infrastructure and specialist staff resources required for the population based breast cancer screening program.

Participation in the BreastScreen Australia Program can be assessed by measuring the overall number of the target population (as determined by ABS population data) and the proportion of those in the target population who are screened in a two-year period.

From 1991 to 2013, the target age range for BreastScreen Australia was women aged 50–69 years. In 2013–14, BreastScreen Australia's target age range was expanded to include women aged 50–74 years. This was a priority recommendation of the BreastScreen Australia Evaluation (2009), which recommended changes to the target age group for the Program, based on evidence of the greatest mortality benefit.

To transition to the expanded target age group and to allow comparison with previous data, the participation and rescreening accreditation Measures will be reported for both the 50–74 year age group and the 50–69 year age group for a four year period. During the period required for all Services to become accredited under the revised accreditation system (by the end of 2019), the Program will collect data for women aged 50–74 years. However BreastScreen Services and State Coordination Units (SCUs) will only be assessed against accreditation Measures for women aged 50–69 years. After this period, a target will be set for accreditation Measures for women 50–74 years, which will be used to assess the performance of Services and/or SCUs. Measures for women aged 50–69 years will then be removed.

It is the responsibility of Services and SCUs to provide all women in the target age group with equitable access to screening and assessment services across the state wide Program. This will ensure that the benefits of the Program can be achieved at a population level and for individual women at risk of developing breast cancer. This is currently achieved by the use of mobile and satellite services within a BreastScreen Service catchment, particularly for women in rural and remote areas, Aboriginal and Torres Strait Islander communities and for those living in lower socioeconomic areas. A key part of providing high quality breast cancer screening services is to ensure that all services are provided in an acceptable and appropriate manner that enables and encourages eligible women to participate.

To maximise participation in the Program, evidence based recruitment strategies need to be developed and implemented, which focus on reaching all women in the target age group. A comprehensive approach may include strategies undertaken at national, state and local levels. This approach needs to include specific strategies that are aimed at encouraging women from

Indigenous, culturally and linguistically diverse, rural/remote and lower socioeconomic backgrounds, to participate in the Program.

STANDARD 1

Access and Participation Standard: *Appropriate levels of access and participation to BreastScreen Australia are achieved in the target and eligible populations.*

| Criterion | NAS Measure | Risk Level | Data Dictionary Measure |
|--|--|------------|---|
| 1.1 The Service and/or SCU maximises the participation of women in the target age groups for screening and rescreening. | 1.1.1 a) The Service and/or SCU monitors and reports the participation rate of women aged 50–74 years who participate in screening in the most recent 24-month period. b) $\geq 70\%$ of women aged 50–69 years participate in screening in the most recent 24-month period. | 2 | a) The percentage of women aged 50–74 years in the Service and/or SCU catchment area who are screened by BreastScreen Australia during the most recent 24-month period. b) The percentage of women aged 50–69 years in the Service and/or SCU catchment area who are screened by BreastScreen Australia during the most recent 24-month period. <i>Calculation: See Data Dictionary</i> |
| | 1.1.2 a) The Service and/or SCU monitors and reports the proportion of women aged 50–72 years who attend for their first screening episode within the Program who are rescreened within 27 months. b) $\geq 75\%$ of women aged 50–67 years who attend for their first screening episode within the Program are rescreened within 27 months. | 2 | a) The percentage of women aged 50–72 years who are rescreened within 27 months of their first screening episode. b) The percentage of women aged 50–67 years who are rescreened within 27 months of their first screening episode. <i>Calculation: See Data Dictionary</i> |

| Criterion | NAS Measure | Risk Level | Data Dictionary Measure |
|---|--|------------|---|
| | <p>1.1.3 a) The Service and/or SCU monitors and reports the proportion of women aged 50–72 years who attend for their second and subsequent screen within the Program who are rescreened within 27 months of their previous screening episode.</p> <p>b) ≥90% of women aged 50–67 years who attend for their second and subsequent screens within the Program are rescreened within 27 months of their previous screening episode.</p> | 2 | <p>a) The percentage of women aged 50–72 years who attend for subsequent rescreens within 27 months of their previous screening episode.</p> <p>b) The percentage of women aged 50–67 years who attend for subsequent rescreens within 27 months of their previous screening episode.</p> <p><i>Calculation: See Data Dictionary</i></p> |
| 1.2 BreastScreen services are accessible to the target and eligible populations, especially women from Indigenous; culturally and linguistically diverse; rural/remote; and lower socioeconomic backgrounds and women with a disability. | <p>1.2.1 a) The Service and/or SCU monitors and reports participation of women aged 50–74 years from special groups and where rates are below that of the overall population, implements specific strategies to encourage their participation in screening. Consideration of equitable participation rates of at least the following groups is made: women from Indigenous, culturally and linguistically diverse, rural/remote and lower socioeconomic backgrounds.</p> <p>b) The Service and/or SCU monitors and reports participation of women aged 50–69 years from special groups and where rates are below that of the overall population, implements specific strategies to encourage their participation in screening. Consideration of equitable participation rates of at least the following groups is made: women from Indigenous, culturally and linguistically diverse, rural/remote and lower socioeconomic backgrounds.</p> | 2 | <p>a) i) <u>Indigenous women:</u> The percentage of women aged 50–74 years who are screened by BreastScreen Australia during the most recent 24-month period disaggregated by Indigenous status.</p> <p>ii) <u>Women from culturally and linguistically diverse backgrounds:</u> The percentage of women aged 50–74 years who are screened by BreastScreen Australia during the most recent 24-month period by women with a language other than English spoken at home.</p> <p>iii) <u>Women residing across different remoteness areas:</u> The percentage of women aged 50–74 years who are screened by BreastScreen Australia during the most recent 24-month period disaggregated according to the level of remoteness of the area in which a woman resides.</p> <p>iv) <u>Women residing across different socioeconomic locations:</u></p> |

| Criterion | NAS Measure | Risk Level | Data Dictionary Measure |
|-----------|-------------|------------|---|
| | | | <p>The percentage of women aged 50–74 years who are screened by BreastScreen Australia during the most recent 24-month period disaggregated according to the socioeconomic profile of the area in which a woman resides.</p> <p><i>Calculations: See Data Dictionary</i></p> <p>b) i) <u>Indigenous women</u></p> <p>The percentage of women aged 50–69 years who are screened by BreastScreen Australia during the most recent 24-month period disaggregated by Indigenous status.</p> <p>ii) <u>Women from culturally and linguistically diverse groups:</u></p> <p>The percentage of women aged 50–69 years who are screened by BreastScreen Australia during the most recent 24-month period by women with a language other than English spoken at home.</p> <p>iii) <u>Women residing across different remoteness areas:</u></p> <p>The percentage of women aged 50–69 years who are screened by BreastScreen Australia during the most recent 24-month period disaggregated according to the level of remoteness of the area in which a woman resides.</p> <p>iv) <u>Women residing across different socioeconomic locations:</u></p> <p>The percentage of women aged 50–69 years who are screened by BreastScreen Australia during the most recent 24-month period disaggregated</p> |

| Criterion | NAS Measure | Risk Level | Data Dictionary Measure |
|-----------|---|------------|--|
| | | | <p>according to the socioeconomic profile of the area in which a woman resides.</p> <p><i>Calculations: See Data Dictionary</i></p> |
| | <p>1.2.2 a) The Service and/or SCU monitors the proportion of all women screened aged 40–49 years and 75 years and over.</p> <p>b) The Service and/or SCU monitors the proportion of all women recalled for assessment aged 40–49 years and 75 years and over.</p> | 3 | <p>a) <u>The proportion of women screened aged 40–49 years and 75 years and over in the most recent 12-month period for which data are available.</u></p> <p>b) <u>The proportion of women recalled for assessment aged 40–49 years and 75 years and over in the most recent 12-month period for which data are available.</u></p> <p><i>Calculations: See Data Dictionary</i></p> |

COMMENTARY

ACCESS

The BreastScreen Australia Program aims to provide equitable access to all eligible women in Australia.

ACCESS TO AND PARTICIPATION OF WOMEN FROM SPECIAL GROUPS

The Service and/or SCU will aim to achieve the same participation rates for groups of women with special or differing needs, as for women from the general population. The Program collects data about participation of special groups including women from culturally and linguistically diverse, Indigenous, rural/remote and lower socioeconomic backgrounds.

Lower participation rates have been reported for women from special groups compared to the overall participation rate for women aged 50–69 years of 54.6% in 2011–2012.³ During this period, the BreastScreen Australia participation rate for women who reported that they speak a language other than English at home was 49.9% and the participation rate for Indigenous women was 37.8%. Participation was highest in outer regional areas (59.1%) and lowest in very remote areas (46%). There was little variation in participation across socioeconomic groups with all socioeconomic groups recording participation rates between 52.7% and 55.8%.³

Participation rates for women from special groups will be identified by the Service and/or SCU and documented separately. The special groups may differ between Service catchments relevant to the demographic profile of each Service. The Service and/or SCU will identify and implement specific approaches to recruit these women where participation rates fall below those of women in the general population.

Tailored strategies may also be required for other groups such as women with a low level of literacy and women with physical or intellectual disabilities. Women with a disability are as much at risk of breast cancer as other women and every effort will be made to ensure that services are acceptable to and appropriate for these women. The Service and/or SCU must be able to demonstrate the strategies they have implemented to encourage participation by women from special groups.

PARTICIPATION

In Australia, the overall participation rate for women aged 50–69 years for the 24-month period 2011–2012 was 54.6%.³ When reporting commenced in the Program in 1996–1997, the age-standardised rate of participation for women aged 50–69 years was 51.5%. This increased to a peak of 57.1% in 2001–2002 and thereafter remained steady at about 56% before decreasing slightly to approximately 55% from 2007–2008.³

The 2009 BreastScreen Australia Evaluation concluded that the Program had been successful in reducing mortality from breast cancer at the participation rate of 56% in the target age group, by approximately 21–28%.⁴

The participation target of 70% for women aged 50–69 years was set at the commencement of the BreastScreen Australia Program, based on international trials that indicated a high participation rate was necessary to maximise the mortality benefits of population based breast cancer screening in a

³ AIHW 2014, *BreastScreen Australia Monitoring Report 2011 – 2012*

⁴ BreastScreen Australia 2009, *BreastScreen Australia Evaluation Final Report*

cost-effective manner. While this has not been achieved, the actual number of women aged 50–69 years participating in the Program has increased from 845,143 women in 1996–1997 to 1,407,065 in 2011–2012.³

Although the 70% participation rate has not been achieved for the target age group in Australia, evidence supports this target as providing the greatest mortality benefit. Maintaining the standard will continue to support strategies to achieve the target in the future. Analysis of the mortality reduction associated with participation in the Program indicates that increasing the participation rate will maximise the mortality reduction from breast cancer as a result of screening.⁴

RESCREENING

If the Program is to achieve its potential in terms of mortality benefit, women in the target age group must be rescreened on a regular basis to maximise the opportunity for breast cancers to be detected as early as possible. The screening interval needs to be short enough to detect cancers before they are clinically apparent so they can be treated earlier, providing improved survival. The interval needs to be long enough so that any potential harms of the screening program are minimised for participants.⁴

The long-term effectiveness of the breast cancer screening programs depends on women in the target age group continuing to be screened at regular intervals. Unless high rescreening rates are maintained, overall participation rates will decline. Achieving high rates of rescreening is important in achieving a 70% overall participation rate across the target age group, maximising early detection of breast cancer and reducing mortality.

Based on current evidence, a screening interval of two years seems to be appropriate and is in line with most international screening mammography programs.⁴

PROPORTION OF WOMEN SCREENED AND RECALLED FOR ASSESSMENT AGED 40–49 YEARS AND 75 YEARS AND OVER

To achieve the required participation rates for women in the target age group, it is essential that the Service and/or SCU make the most efficient use of their equipment and staff. Therefore, Measure 1.2.2 (a) and (b) is intended to monitor the proportion of women screened and rescreened outside the target age group, to gauge the impact on the overall screening capacity of the Service and/or SCU. The Service and/or SCU will provide these data to the National Quality Management Committee (NQMC) so they can consider if the capacity of the Service and/or SCU is being used appropriately to maximise the participation of women in the target age group, and to enable monitoring of the screening data for women outside the target age range.

It is also important to monitor the proportion of women recalled for assessment in the 40–49 and 75 years and over age groups to assess the clinical impacts on the assessment service and the clinical outcomes, as this information will be required for future policy decisions for the Program.

ACCESS AND PARTICIPATION PROTOCOLS

The protocols that Services are to develop and maintain in relation to Standard 1 are:

1.1 The Service and/or SCU implements appropriate policies and protocols to:

- a) Recruit women for participation;
- b) Send invitations for screening and rescreening;
- c) Follow-up women who do not respond to invitations; and
- d) Deliver services to women in the target age group and enable equitable participation of women in special groups as outlined in Measure 1.2.1.

APPROPRIATE POLICIES AND PROTOCOLS FOR RECRUITMENT

The BreastScreen Australia Evaluation Final Report (2009) identified the following four factors that positively influence women to participate in breast cancer screening:

- An understanding of the benefits of breast cancer screening;
- Exposure to communication from BreastScreen Australia, including direct correspondence and mass marketing;
- Encouragement from family and friends;
- Recommendation or referral from a doctor or Aboriginal and Torres Strait Islander health worker.

The Service and/or SCU will implement a range of strategies based on available evidence to encourage women to participate in the BreastScreen Australia Program.

RECRUITMENT PLAN

Given the demographic, cultural and geographic diversity of the Australian population, it is likely that each Service and/or SCU will be faced with different challenges in recruiting women to participate in the Program. Therefore, each Service and/or SCU will develop a detailed recruitment plan, including a budget, and review this on an annual basis. The recruitment plan will:

- Document strategies for encouraging participation in screening and rescreening in the defined catchment;
- Outline the communication strategies and health education resources to be used at the local level to meet the information needs of the women in their catchment;
- Include strategies that will be effective in ensuring that general practitioners and other relevant health and community service providers understand the Program and encourage women in the target age group to participate;
- Analyse participation data and identify areas or groups that require additional strategies;
- Include a range of strategies to reach women from special groups;
- Identify barriers to screening;
- Be developed in consultation with relevant consumer groups, general practitioners and other health professional groups;
- Be reviewed annually in consultation with the SCU and/or State Quality Committee (SQC) and relevant local stakeholder groups.

The recruitment plan will also take into account the capacity of the Service and/or SCU to provide screening and assessment services.

COMMUNICATION STRATEGIES AND HEALTH EDUCATION RESOURCES

Communication strategies and health education resources can encourage women to attend BreastScreen Services. Women who have high levels of knowledge and understanding of breast cancer screening using mammography, are more likely to participate in the Program.

The BreastScreen Australia Evaluation 2009 found that Australian women have high levels of knowledge about breast cancer screening and the Program. However, continued use of effective communication strategies will remain important in encouraging participation, particularly for women moving into the target age group. It is important that information is widely available in the community in relation to the location of Services, including mobile services, to ensure that women are aware of where they can access Services locally.

Informed participation in population based screening programs requires an explicit sharing of information about risks and benefits. Health education resources will provide sufficient information about the benefits and potential harms of breast cancer screening to enable woman to make an informed choice about participation in the Program. In particular these resources will be consistent with BreastScreen Australia policy and provide accurate, consistent, honest and evidence based information to women.

Consumer resources can be downloaded from the Australian Government Department of Health's cancer screening website and from State and Territory BreastScreen Australia websites. These resources provide information about the BreastScreen Australia program and may assist women in making an informed decision about participating in screening

The language and format of the health education resources will be appropriate to the intended audience in order to encourage participation in the Program. These resources will be developed in consultation with women from the relevant population group, including consultation with consumer groups and special groups of women as appropriate.

GENERAL PRACTITIONERS AND OTHER RELEVANT HEALTH PROFESSIONALS

General practitioners can be effective in encouraging women to participate in breast cancer screening. Women who were interviewed for the Participation Qualitative Study, as part of the BreastScreen Australia Evaluation, reported that general practitioners are skilled at communicating screening information because they are widely trusted, can provide women with information about the relevance of screening and can direct women to local services.⁵

Services need to develop and adopt strategies that inform general practitioners about the Program and support them in encouraging women to participate. These may include the delivery of relevant continuing education and software prompts to general practitioners in the Service catchment area. They may be developed in conjunction with other health and community service providers, such as women's health nurses and community, Aboriginal and Torres Strait Islander and cross-cultural health workers. These service providers may be particularly important in encouraging the participation of women who are difficult to reach through other means.

SENDING INVITATIONS FOR SCREENING AND RESCREENING

The BreastScreen Australia Evaluation (2009) found that direct marketing including materials sent with invitation letters, is an effective method of encouraging participation in breast cancer screening.

⁵ BreastScreen Australia 2009, *BreastScreen Australia Evaluation Final Report*

Strategies that encourage women to return for second and subsequent screens will be different from those used to gain initial participation. They are likely to rely more heavily on prompts than on information about the value of breast cancer screening. As a woman's first screening experience can leave a lasting impression, service delivery strategies need to address the importance of a positive first-time screening experience to encourage women to return for rescreening.⁵

Therefore, each Service and/or SCU will:

- Send written invitations (which may include via electronic means) to women aged 50–74 years who reside in the service catchment and who have not previously attended, inviting them to participate in the Program;
- Send written invitations to each woman aged 50–74 years at the time they are due for rescreening;
- Implement a protocol for following up women who do not respond to the initial invitation to take part in the Program;
- Implement a protocol for following up women who do not respond to invitations for rescreening.

DELIVERING SERVICES TO WOMEN IN SPECIAL GROUPS

WOMEN FROM INDIGENOUS BACKGROUNDS

Each Service and/or SCU will develop and implement protocols for service delivery to women from Indigenous backgrounds, that:

- have been developed in collaboration with relevant organisations or women's groups;
- include culturally appropriate information;
- allocate block bookings and enables an Aboriginal and Torres Strait Islander Women's Health Worker to attend if appropriate.

WOMEN FROM CULTURALLY AND LINGUISTICALLY DIVERSE BACKGROUNDS

Each Service and/or SCU will develop and implement a protocol for service delivery to women from culturally and linguistically diverse backgrounds. The protocol will:

- have been developed in collaboration with relevant organisations or women's groups;
- include information in the common community languages represented in the service catchment area for women attending for screening and assessment;
- ensure that women are able to request an interpreter if required;
- ensure that a gender appropriate interpreter is available for women attending for screening and assessment whenever possible;
- ensure that a telephone interpreter service is used if an interpreter cannot attend in person;
- allocate block bookings for women from culturally and linguistically diverse backgrounds to attend with a community worker if appropriate.

WOMEN WITH A DISABILITY

Each Service and/or SCU will develop and implement a protocol to ensure the appropriate provision of services and management of women with a disability. The protocol will:

- have been developed in consultation with relevant organisations or community groups;
- ensure that appropriate information and support is available to women with an intellectual disability and/or a low level of literacy;
- ensure that appropriate information and support is available for women with a sight or hearing disability;

- ensure that physical access is provided for women in wheelchairs or with a physical disability that limits their mobility;
- ensure that appropriate consent is obtained.⁶
- ensure that all staff of the Service are adequately trained and equipped to provide care for women with a disability.
- ensure that additional staff and longer appointment times are made available if necessary.
- ensure that, with the woman's or her carer's consent, her nominated general practitioner is informed if a woman seeks advice about participating in, or if she attends for screening or assessment, and the service is unable to be provided as a result of the woman's disability.

WOMEN FROM RURAL/REMOTE AND LOWER SOCIOECONOMIC BACKGROUNDS

Each Service and/or SCU will develop and implement a protocol for the appropriate provision of services and management of women from rural/remote and lower socioeconomic backgrounds. The protocol will:

- have been developed in consultation with relevant organisations or community groups;
- ensure the availability of accessible mobile and/or satellite breast cancer screening services;
- ensure appropriate use of communication strategies and health education resources so women are informed when the mobile and/or satellite breast cancer screening services are available;
- ensure that appropriate information and support are delivered to women according to health literacy guidelines in line with the Australian Commission on Safety and Quality in Health Care principles;
- ensure equitable access to all eligible women from rural/remote and lower socioeconomic backgrounds;
- ensure provision of services at minimal or no charge, and free to eligible women who would not attend if there were a charge.

⁶ In circumstances where the woman herself cannot give informed consent because of intellectual disability and/or low level of literacy, the relevant State and Territory guidelines about the provision of consent by another individual should be followed.

2

STANDARD 2: CANCER DETECTION

Breast cancer detection is maximised in the target population and harm is minimised

INTRODUCTION

The BreastScreen Australia Program aims to achieve significant reductions in morbidity and mortality attributable to breast cancer by maximising the early detection of breast cancer in the target population. Early detection will lead to better treatment options and improved chances of survival for women screened in the Program. This can only be achieved if each step in the screening and assessment pathway is of high quality and the performance standards for the Program are met.

The Program must maintain high standards of clinical practice and technical quality in breast cancer screening. It must also consistently achieve high quality breast imaging, screen reading and reporting. Population screening is different from diagnostic imaging services, as it is offered to a well population of women with the aim of detecting asymptomatic breast cancer at an early stage. Therefore, the Program must also balance maximising cancer detection, particularly small cancer detection, with minimising the potential harm that may be caused to the women screened, by unnecessary recall to assessment or investigations.

Mortality rates are the key outcome measure of the BreastScreen Australia Program. However, mortality rates are unsuitable as an indicator to measure whether the Program is likely to meet the desired outcome because there is a considerable time delay between screening and any measurable impact on deaths from breast cancer. In addition, complex analysis is required to establish the proportion of any observed changes in mortality rates attributable to the screening program as the outcome can be affected by other factors such as the demographic profile of the population including age, region of residence, socioeconomic factors, and screening coverage in the population at risk,⁷ as well as advances in treatment.

Internationally, population based breast cancer screening programs use the interim performance indicators of: invasive breast cancer detection rate; small invasive breast cancer detection rate; ductal carcinoma in situ (DCIS) detection rate; and interval breast cancer rate, to measure and monitor whether the Program is reducing mortality from breast cancer. These indicators also provide more timely information about the performance of Services in providing high quality breast cancer screening, to standards that are known to underpin the achievement of reductions in mortality rates.

The monitoring of these performance indicators, contained in the Criteria and Measures in this Standard, allow Services and SCUs to assess the quality of screening and assessment being provided. It also enables quality improvement strategies to be implemented so that the desired outcomes of a reduction in deaths and the impact of breast cancer are achieved by the Program.

⁷ BreastScreen Australia 2009, *BreastScreen Australia Evaluation Final Report*

MONITORING BREAST CANCER DETECTION RATES FOR WOMEN AGED 70 TO 74 YEARS

In 2013, the target age group for BreastScreen Australia was expanded from women aged 50–69 years to women aged 50–74 years. This was a priority recommendation of the BreastScreen Australia Evaluation (2009), which recommended changes to the target age group for the Program based on evidence of the greatest mortality benefit.

Women aged 70–74 have not previously been included in the target age group. Therefore, new Measures have been developed to monitor and report breast cancer detection rates separately for a period of time, until sufficient women have been screened in this additional cohort, to establish appropriate targets for the expanded age group (women aged 50–74 years).

Over the four-year period that is required for all Services and/or SCUs to be accredited under the revised system, they will not be assessed against the full 50–74 accreditation Measures. During this period the existing Measures for women aged 50–69 years will continue to be used to assess performance. Services will be required to report separately against measures for women in the 70 – 74 age cohort, to accumulate sufficient data to enable the development of appropriate performance measures and targets.

Based on the fact that breast cancer incidence increases with age, and trends that all size invasive and small invasive breast cancer detection rates have increased over time, it can be expected that rates for women aged 50 – 74 would exceed those targets set for women aged 50 – 69 years.

STANDARD 2

Cancer Detection Standard: *Breast cancer detection is maximised in the target population and harm is minimised.*

| Criterion | NAS Measure | Risk Level | Data Dictionary Measure |
|---|--|------------|---|
| 2.1 The Service and/or SCU maximises the detection of invasive breast cancer in the target population. | 2.1.1 a) The Service and/or SCU monitors and reports the proportion of women aged 50–74 years who attend for their first screening episode who are diagnosed with invasive breast cancer. b) ≥50 per 10,000 women aged 50–69 years who attend for their first screening episode are diagnosed with invasive breast cancer. | 1 | a) The number of women aged 50–74 years who attend for their first screening episode who are diagnosed with invasive breast cancer per 10,000 women screened. b) The number of women aged 50–69 years who attend for their first screening episode who are diagnosed with invasive breast cancer per 10,000 women screened. <i>Calculation: See Data Dictionary</i> |
| | 2.1.2 a) The Service and/or SCU monitors and reports the proportion of women aged 50–74 years who attend for their second or subsequent screening episode who are diagnosed with invasive breast cancer. b) ≥35 per 10,000 women aged 50–69 years who attend for their second or subsequent screening episode are diagnosed with invasive breast cancer. | 1 | a) The number of women aged 50–74 years who attend for their second or subsequent screening episode who are diagnosed with invasive breast cancer per 10,000 women screened. b) The number of women aged 50–69 years who attend for their second or subsequent screening episode who are diagnosed with invasive breast cancer per 10,000 women screened. <i>Calculation: See Data Dictionary</i> |
| | 2.1.3 a) The Service and/or SCU monitors and reports the proportion of women aged 50–74 years who attend for their first screening episode who are diagnosed with small (≤15mm) invasive breast cancer. b) The Service and/or SCU monitors and reports the proportion of women aged 50–74 years who attend for their second or subsequent screening episode who are diagnosed with small (≤15mm) invasive breast cancer. | 1 | a) The number of women aged 50–74 years who attend for their first screening episode who are diagnosed with small (≤15mm) invasive breast cancer per 10,000 women screened. b) The number of women aged 50–74 years who attend for their second or subsequent screening episode who are diagnosed with small (≤15mm) invasive breast cancer per 10,000 women screened. |

| Criterion | NAS Measure | Risk Level | Data Dictionary Measure |
|---|---|------------|--|
| | c) ≥ 25 per 10,000 women aged 50–69 years who attend for screening are diagnosed with small ($\leq 15\text{mm}$) invasive breast cancer. | | c) The number of women aged 50–69 years who attend for screening who are diagnosed with small ($\leq 15\text{mm}$) invasive breast cancer per 10,000 women screened. <i>Calculation: See Data Dictionary</i> |
| | 2.1.4 a) The Service and/or SCU monitors and reports the proportion of women aged 50–74 years who attend annually for screening, who are diagnosed with invasive breast cancer. b) The Service and/or SCU monitors and reports the proportion of women aged 50–74 years who attend annually for screening, who are diagnosed with small ($\leq 15\text{mm}$) invasive breast cancer. c) The Service and/or SCU monitors and reports the proportion of women aged 40–49 years who attend annually for screening, who are diagnosed with invasive breast cancer. | 2 | a) The number of women aged 50–74 years who attend annually for screening who are diagnosed with invasive breast cancer per 10,000 women screened. b) The number of women aged 50–74 years who attend annually for screening who are diagnosed with small ($\leq 15\text{mm}$) invasive breast cancer per 10,000 women screened. c) The number of women aged 40–49 years who attend annually for screening who are diagnosed with invasive breast cancer per 10,000 women screened. <i>Calculation: See Data Dictionary</i> |
| | 2.1.5 The Service and/or SCU monitors and reports the proportion of women aged 40–49 years and 75 years and over who are diagnosed with invasive breast cancer. | 2 | The number of women aged 40–49 years and 75 and over who are diagnosed with invasive breast cancer per 10,000 women screened. |
| | 2.1.6 The Service and/or SCU monitors and reports the proportion of women aged 40–49 years and 75 years and over who are diagnosed with small ($\leq 15\text{mm}$) invasive breast cancer. | 2 | The number of women aged 40–49 years and 75 and over who are diagnosed with small ($\leq 15\text{mm}$) invasive breast cancer per 10,000 women screened. |
| 2.2 The Service and/or SCU maximises the detection of ductal carcinoma in situ (DCIS). | 2.2.1 a) The Service and/or SCU monitors and reports the proportion of women aged 50–74 years who attend for their first screening episode who are diagnosed with DCIS. | 2 | a) The number of women aged 50–74 years who attend for their first screening episode who are diagnosed with DCIS per 10,000 women screened. |

| Criterion | NAS Measure | Risk Level | Data Dictionary Measure |
|---|---|------------|---|
| | b) ≥ 12 per 10,000 women aged 50–69 years who attend for their first screening episode are diagnosed with DCIS. | | b) The number of women aged 60–69 years who attend for their first screening episode who are diagnosed with DCIS per 10,000 women screened. <i>Calculation: See Data Dictionary</i> |
| | 2.2.2 a) The Service and/or SCU monitors and reports the proportion of women aged 50–74 years who attend for their second or subsequent screening episode who are diagnosed with DCIS. b) ≥ 7 per 10,000 women aged 50–69 years who attend for their second or subsequent screening episode are diagnosed with DCIS. | 2 | a) The number of women aged 50–74 years who attend for their second or subsequent screening episode who are diagnosed with DCIS per 10,000 women screened. b) The number of women aged 50–69 years who attend for their second or subsequent screening episode are diagnosed with DCIS per 10,000 women screened. <i>Calculation: See Data Dictionary</i> |
| | 2.2.3 The Service and/or SCU monitors and reports the number of women aged 50–74 years who attend annually for screening, who are diagnosed with DCIS. | 3 | The number of women aged 50–74 years who attend annually for screening who are diagnosed with DCIS per 10,000 women screened. <i>Calculation: See Data Dictionary</i> |
| | 2.2.4 The Service and/or SCU monitors and reports the proportion of women aged 40–49 years and 75 years and over who are diagnosed with DCIS. | 2 | The number of women aged 40–49 years and 75 and over are diagnosed with DCIS per 10,000 women screened. |
| 2.3 The Service and/or SCU minimises the number of invasive interval breast cancers. | 2.3.1 a) The Service and/or SCU monitors and reports the proportion of women aged 50–74 years who attend for screening who are diagnosed with an interval invasive breast cancer in the first calendar year following a negative screening episode. b) < 7.5 per 10,000 women aged 50–69 years who attend for screening are diagnosed with an interval invasive | 2 | a) The number of women aged 50–74 years who are diagnosed with an interval invasive breast cancer between 0 and 364 days following a negative screening episode per 10,000 women screened. b) The number of women aged 50–69 years who are diagnosed with an interval invasive breast cancer between 0 and 364 days following a |

| Criterion | NAS Measure | Risk Level | Data Dictionary Measure |
|--|--|------------|---|
| | breast cancer in the first calendar year following a negative screening episode. c) The Service and/or SCU monitors and reports the proportion of women aged 40–49 years and 75 years and over who attend for screening who are diagnosed with an interval invasive breast cancer in the first calendar year following a negative screening episode. | | negative screening episode per 10,000 women screened. c) The number of women aged 40–49 years and 75 years and over who are diagnosed with an interval invasive breast cancer between 0 and 364 days following a negative screening episode per 10,000 women screened. <i>Calculation: See Data Dictionary</i> |
| | 2.3.2 a) The Service and/or SCU monitors and reports the proportion of women aged 50–74 years who attend for screening who are diagnosed with an interval invasive breast cancer in the second calendar year following a negative screening episode. b) ≤15 per 10,000 women aged 50–69 years who attend for screening are diagnosed with an interval invasive breast cancer in the second calendar year following a negative screening episode. c) The Service and/or SCU monitors and reports the proportion of women aged 40–49 years and 75 years and over who attend for screening who are diagnosed with an interval invasive breast cancer in the second calendar year following a negative screening episode. | 2 | a) The number of women aged 50–74 years who are diagnosed with an invasive interval breast cancer between 365 and 729 days following a negative screening episode per 10,000 women screened. b) The number of women aged 50–69 years who are diagnosed with an interval invasive breast cancer between 365 and 729 days following a negative screening episode per 10,000 women screened. c) The number of women aged 40–49 years and 75 years and over who are diagnosed with an interval invasive breast cancer between 365 and 729 days following a negative screening episode per 10,000 women screened. <i>Calculation: See Data Dictionary</i> |
| 2.4 The Service and/or SCU ensures high quality screen reading. | 2.4.1 All screen readers read at least 2,000 mammographic screening cases within the Program per year. | 2 | The number of mammographic screening cases read by readers per year. <i>Calculation: See Data Dictionary</i> |
| 2.5 The Service and/or SCU ensures high quality imaging. | 2.5.1 The Service and/or SCU monitors and reports the percentage of women who have up to 4 images per screen, including technical repeats. | 3 | The percentage of women in any 12-month period who have up to 4 images per screen, including technical repeats. |

| Criterion | NAS Measure | Risk Level | Data Dictionary Measure |
|--|---|------------|--|
| | | | <i>Calculation: See Data Dictionary</i> |
| | 2.5.2 The overall technical repeat rate for the Service and/or SCU is $\leq 2\%$ of all screening images. | 3 | The percentage of the total number of screening images used in any 12-month period which are for repeat images. However, the Service and/or SCU will demonstrate that this is also calculated on a monthly basis. <i>Calculation: See Data Dictionary</i> |
| 2.6 Investigations and recall for assessment of non-malignant lesions is minimised. | 2.6.1 a) The Service and/or SCU monitors and reports the proportion of women aged 50–74 years who attend for annual screening. b) $\leq 10\%$ of women aged 50–69 years attend for annual screening. | 2 | a) The percentage of women aged 50–74 years who attend for annual screening. b) The percentage of women aged 50–69 years who attend for annual screening. <i>Calculation: See Data Dictionary</i> |
| | 2.6.2 The Service and/or SCU monitors and reports the proportion of women who attend for annual screening, aged 40–49 years and 75 years and over. | 3 | The percentage of women who attend for annual screening, aged 40–49 years and 75 years and over. <i>Calculation: See Data Dictionary</i> |
| | 2.6.3 a) The Service and/or SCU monitors and reports the proportion of women aged 50–74 years who attend for their first screening episode and are recalled for assessment. b) $<10\%$ of women aged 50–69 years who attend for their first screening episode are recalled for assessment. c) The Service and/or SCU monitors and reports the proportion of women aged 40–49 years and 75 years and over who attend for their first screening episode and are recalled for assessment. | 2 | a) The percentage of women aged 50–74 years who attend for their first screening episode and are recalled for assessment. b) The percentage of women aged 50–69 years who attend for their first screening episode are recalled for assessment. c) The percentage of women aged 40–49 years and 75 years and over who attend for their first screening episode and are recalled for assessment. <i>Calculation: See Data Dictionary</i> |
| | 2.6.4 a) The Service and/or SCU monitors and reports the proportion of women aged 50–74 years who attend for | 2 | a) The percentage of women aged 50–74 years who attend for their second or subsequent |

| Criterion | NAS Measure | Risk Level | Data Dictionary Measure |
|-----------|--|------------|---|
| | <p>their second or subsequent screening episode and are recalled for assessment.</p> <p>b) <5% of women aged 50–69 years who attend for their second or subsequent screening episode are recalled for assessment.</p> <p>c) The Service and/or SCU monitors and reports the proportion of women aged 40–49 years and 75 years and over who attend for their second or subsequent screening episode and are recalled for assessment.</p> | | <p>screening episode and are recalled for assessment.</p> <p>b) The percentage of women aged 50–69 years who attend for their second or subsequent screen and are recalled for assessment.</p> <p>c) The percentage of women aged 40–49 years and 75 years and over who attend for their second or subsequent screening episode and are recalled for assessment.</p> <p><i>Calculation: See Data Dictionary</i></p> |
| | <p>2.6.5 The Service and/or SCU monitors and reports the positive predictive value of a recall to assessment for detecting invasive breast cancer or DCIS in women aged 50–74 years who attend for their first screening episode.</p> | 2 | <p>The percentage of women aged 50–74 years recalled for assessment at their first screening episode who receive a definitive diagnosis of invasive breast cancer or DCIS.</p> <p><i>Calculation: See Data Dictionary</i></p> |
| | <p>2.6.6 The Service and/or SCU monitors and reports the positive predictive value of a recall to assessment for detecting invasive breast cancer or DCIS in women aged 50–74 years who attend for their second or subsequent screening episode.</p> | 2 | <p>The percentage of women aged 50–74 years recalled for assessment at their second or subsequent screening episode who receive a definitive diagnosis of invasive breast cancer or DCIS.</p> <p><i>Calculation: See Data Dictionary</i></p> |
| | <p>2.6.7 <0.2% of women who attend for screening are recommended for early review for further assessment.</p> | 2 | <p>The percentage of women who attend for screening who are recommended for early review for further assessment.</p> <p><i>Calculation: See Data Dictionary</i></p> |

COMMENTARY

DETECTION OF INVASIVE BREAST CANCER

The detection of early breast cancer is a key performance indicator for the BreastScreen Australia Program. It is a critical measure that is used at a State and National level to monitor the performance of the Program. It is also used at the local level to monitor the performance of the Service, as well as individual screen readers.

Detection of breast cancer is disaggregated into first and subsequent screening episodes because a woman is more likely to have a breast cancer detected the first time she attends for screening than at subsequent visits. This is due to the likelihood that for the woman's first visit, a prevalent breast cancer that may have been present for some time is detected, rather than an incident breast cancer that has developed between her screening visits.

DETECTION OF SMALL INVASIVE BREAST CANCER

In addition to the invasive breast cancer detection rate, the small invasive cancer detection rate is a key indicator of the likely impact of the Program on mortality. The BreastScreen Australia Program aims to reduce mortality from breast cancer by detecting cancers while they are still small and localised to the breast.

The size of the breast cancer at diagnosis is an independent prognostic indicator of survival, as the smaller the size of the breast cancer at diagnosis the better the chance of effective treatment. The five-year survival rate from breast cancer in Australia has increased from 72% (1982–1987) to 89% (2006–2010).⁸ The small breast cancer measure is a subset of the all size invasive breast cancers, and is defined as a breast cancer with a diameter of less than or equal to 15 mm.

The analysis of Service level data for the period 2007 to 2010 found that the mean small breast cancer detection rate for women 50–69 years was 30.19 per 10,000 women screened.⁹

Measure 2.1.3 c) requires that the small cancer detection rate for women aged 50–69 years who attend for all screening episodes to be equal to or greater than 25 per 10,000 women screened. This is consistent with the levels achieved or exceeded for this Measure following a review of longitudinal BreastScreen Australia accreditation data.⁹

DETECTION OF BREAST CANCER FOR WOMEN SCREENED ANNUALLY

A small proportion of women at increased risk of breast cancer, as described in Criterion 2.1 will be screened annually. It is therefore important to monitor and report on the proportion of women who are screened annually who are diagnosed with invasive breast cancer and small invasive breast cancer. This analysis will allow the Service and SCU to monitor the outcomes of the Program for women at increased risk.

Women aged 40–49 years are more likely to have dense breasts. High breast density is a known factor that increases the risk of breast cancer. Evidence suggests that digital mammography is more sensitive for this particular group of women. Following the introduction of digital technology within BreastScreen Australia services, monitoring breast cancer detection rates for these women may help

⁸ Cancer Australia 2012, *Report to the nation – breast cancer*

⁹ BreastScreen Australia, 2012 *BreastScreen Australia National Accreditation Standards, National Data unpublished report*

inform future policy on the appropriate screening interval for women at increased risk.¹⁰ This is not to suggest that these women should be screened annually, but that should they be screened, the outcomes can inform future services.

DETECTION OF DUCTAL CARCINOMA IN SITU (DCIS)

Prior to the establishment of organised population based breast cancer screening programs, ductal carcinoma in situ (DCIS) was infrequently diagnosed. In the majority of cases, DCIS is asymptomatic and is usually detected by mammography or as an incidental finding on a surgical breast biopsy. DCIS is defined as a form of carcinoma in situ with no invasive component, diagnosed by its characteristic histopathological features, frequently associated with mammographic abnormalities, including calcification as described in the BreastScreen Australia Data Dictionary.¹¹

Women who have DCIS detected are at increased risk of developing invasive breast cancer.^{12 13} It is not currently possible to predict which DCIS cases will progress to invasive breast cancer. However, given the increased risk of invasive breast cancer after a diagnosis of DCIS, and that the detection and subsequent treatment of high grade DCIS is likely to prevent deaths from invasive breast cancer, BreastScreen Australia aims to maximise the detection of DCIS.

DETECTION OF DCIS FOR WOMEN SCREENED ANNUALLY

A small proportion of women at increased risk of breast cancer will be screened annually. It is important to monitor and report on the proportion of these women who are diagnosed with DCIS. Analysing data for these women in accordance with Measure 2.2.3 will allow the Service and/or SCU to monitor the outcomes of the Program for women at increased risk.

INTERVAL INVASIVE BREAST CANCER

BreastScreen Australia aims to maximise early detection and minimise the number of cancers detected outside the program, in the interval after a negative screen. A cancer is defined as 'interval' if it is diagnosed in the interval between the completion of a negative screening episode and the commencement of the next screening episode.

Interval cancers can be detected outside BreastScreen Australia, or through BreastScreen Australia either at early rescreen—where a woman rescreens within 24 months of her previous screen (in which case the woman is required to present with a breast lump and/or clear or blood-stained nipple discharge for a cancer to be categorised as interval rather than screen-detected) or at early review—where a woman is recalled within a year of her screen following an equivocal assessment visit.

Interval cancer rates are a key performance indicator of the likely success of the Program to reduce mortality from breast cancer. Women who have their cancer diagnosed as an interval cancer may have a poorer outcome compared to women who have their cancer detected at their screening episode. If too many breast cancers are missed at screening and are found in the interval between screening episodes, the benefit of the screening program in reducing morbidity and mortality attributable to breast cancer is compromised. It is therefore important to monitor the rate of

¹⁰ BreastScreen Australia 2009, *BreastScreen Australia Evaluation Final Report*

¹¹ Australian Institute of Health and Welfare 2015, *BreastScreen Australia Data Dictionary*

¹² AIHW 2010, *Risk of invasive breast cancer in women diagnosed with ductal carcinoma in situ in Australia between 1995 and 2005*

¹³ IARC 2002 *IARC handbook on cancer prevention*

interval cancers by the Program at a national, state and territory level. The interval cancer rate will also be monitored at Service level, as it is a strong indicator of the quality and performance of individual Services and screen readers in particular (refer to [Appendix H](#)).

The calculation of the interval cancer rate relies on accurate and timely provision of data from the jurisdictional cancer registry to match against the BreastScreen Client Management System. Each Service and/or SCU will ensure that the latest available interval cancer data are included in its application for accreditation.

NAS Measures 2.3.1 (a), (b) and (c) and 2.3.2 (a), (b) and (c) refer to monitoring and reporting on the proportion of women who are diagnosed with interval invasive breast cancer in the first and second 'calendar years' following a negative screening episode. A 'calendar year' is defined as 365 days (366 in a leap year) that commences from the 'negative screening episode' and not on 1st January that year.

The Service and/or SCU must have a protocol in place to review all interval cancers, as detailed in [Appendix H](#).

INTERPRETING VARIATIONS FROM THE BREAST CANCER DETECTION MEASURES

It is recognised that there will be variations from the minimum performance measures for monitoring invasive breast cancer and small invasive breast cancer detection rates as a result of chance. This is particularly the case at Services or the SCU where the number of women screened in a specified time period may be relatively small. The smaller the number of women screened the greater the likelihood that the detection rate will differ by chance alone, artificially indicating that performance has met or not met the relevant target when the reverse is actually true.

In considering whether or not a Service and/or the SCU has met the target level of breast cancer detection required for accreditation, the influence of chance needs to be taken into account. To assist Services in determining whether their breast cancer detection rates are truly different from the performance measures, Services and/or the SCU are asked to submit a series of funnel plots with their application for accreditation, based on the Poisson distribution for each of the Measures. These plots will indicate whether or not their breast cancer detection rates are within acceptable bounds of the required performance measure. Services and/or the SCU should not necessarily be satisfied if their performance lies within the confidence bounds of the funnel, especially if it is close to the lower bound. One or several results that lie close to the lower bound may indicate that performance warrants close review and that further analysis of their performance is warranted.

In evaluating performance in a quality improvement context, Services and/or the SCU will need to consider groups of Criteria and Measures together, to provide an integrated view of the quality of the Service. For example, if the invasive breast cancer detection rates, small cancer detection rates and the interval cancer rates all just meet the required levels, the Service and/or the SCU should be concerned, and carefully analyse these outcomes. If, on the other hand, the cancer detection rates and the small cancer detection rates are higher than the required level and the interval cancer rate was also high for the same period, there may be a greater chance variation reflected in the funnel plot, and therefore the Service and/or the SCU might be more confident that the interval cancer rate is of lesser significance or an indicator of poor performance.

The DCIS detection rate should not be viewed in isolation but rather will need to be interpreted in conjunction with other indicators, including invasive breast cancer detection and small breast cancer detection rates.

The interval cancer rate should also not be viewed in isolation but rather will need to be interpreted in conjunction with other Measures. For example, a high interval cancer rate and low invasive breast cancer detection and small breast cancer detection rates may indicate the need for further

investigation by the Service and/or the SCU. If interval cancer rates are not met, and screen-detection rates are low in comparison with the comparable period in the previous year, the Service and/or the SCU will need to implement an extensive review process to understand any contributory factors.

Services and/or the SCU will review performance against the Measures in a quality improvement context on a regular basis, not just in preparation for the accreditation process. If an indicator is relatively low, and falling nearer the lower confidence bounds on the funnel plot over a period of time, then it is more likely that this value accurately reflects the performance of the Service rather than being accounted for by an incidental chance variation.

Services and/or the SCU will need to take care to seek an integrated picture of performance across Measures and over time rather than simply considering whether an individual Measure has been met. Where a pattern of only just meeting the target is apparent, the Service and/or SCU will analyse the reasons for this and if necessary, instigate quality improvement strategies to improve the Service or SCU. As part of the accreditation process, the Service may be asked to provide evidence of this analysis and its outcome.

HIGH QUALITY SCREEN READING - NUMBER OF READS PER READER

The early detection of breast cancer in population screening requires the perception and accurate interpretation of any breast abnormalities on the mammographic images by the screen readers. A significant difference in cancer detection rates has been reported between those readers who read less than 2,000 and those who read 2,000 or more screens per year.¹⁴

The United Kingdom (UK) National Health Service (NHS) Breast Screening Programme requires each radiologist to read a minimum of 5,000 screening and/or symptomatic cases per year.¹⁵ However, in Australia while the major metropolitan Services have sufficient throughput to reach the UK standard of 5,000 screening cases per year, it may not be possible for screen readers to read this number of cases in the smaller States and Territories or in rural or regional areas. The analysis of the national data found that screen readers in most Services (88%) in Australia could feasibly read 2,000 screening cases within the Program per year.¹⁶ Therefore to ensure high quality screen reading the requirements of Measure 2.4.1 is that all screen readers will read at least 2,000 mammographic screening cases within the Program per year. In circumstances where a reader undertakes screen reading across multiple BreastScreen Services and/or SCUs, their reads at each BreastScreen Service and/or SCU will be aggregated to give their annual total.

HIGH QUALITY BREAST IMAGING - IMAGES TAKEN FOR EACH SCREEN

BreastScreen Australia uses two view mammography, consisting of cranio-caudal and medio-lateral oblique images as the screening protocol. This is based on evidence that this is the most effective test for the early detection of breast cancer in a population based screening program.¹⁷

A routine screening examination would consist of four images for each client (2 cranio – caudal and 2 medio-lateral oblique). For women with larger breasts more images may be required. BreastScreen Australia Services will implement a protocol for the examination of women with internal breast

¹⁴ Buist DSM, Anderson ML, Hanesuse SJPA, et al 2011. 'Influence of annual interpretive volume on screening mammography performance in the United States'. *Radiology* 2011: 259:72-84.

¹⁵ NHS 2011, *Quality assurance guidelines for breast cancer screening radiology*

¹⁶ BreastScreen Australia 2012, *BreastScreen Australia National Accreditation Standards, National Data unpublished report*

¹⁷ Smallenburg et al 2011, *Two-view versus single-view mammography at subsequent screening in a region of the Dutch breast screening program*

prostheses to allow adequate visualisation of the breast tissue. This will include the number and type of views, such as push back or implant displacement views.

Taking additional images may increase discomfort for the woman, the radiation dose and also, screening costs. It is important to minimise unnecessary imaging at both screening and assessment. If, during screening, there is any deviation from the standard two views, or more than four images for each client are taken, the reasons will be documented.

Measure 2.5.1 has been established to monitor the number of women who receive up to four images per screen, including technical repeats. Monitoring this Measure over time will assist in developing an appropriate target for the future. Ongoing review of the data for this Measure may also assist in developing quality improvement activities for the Service, or support targeted training for radiographers.

TECHNICAL REPEAT RATE

The overall technical repeat rate has been reviewed using BreastScreen Australia data collected from annual data reports for the period 2007 to 2010 to provide an indication of overall performance patterns within Australia.¹⁸ The average measure recorded for all Services was 1.39%. The requirement set for Measure 2.5.2 is that the overall technical repeat rate for the Service and/or SCU is $\leq 2\%$ of all screening images. This measure is consistent with the European Commission guidelines that recommend that the technical repeat rate should be $< 3\%$ (acceptable) and $< 1\%$ (desired).¹⁹

Measure 2.5.2 requires the overall technical repeat rate to be reported for a 12 month period but this measure will also be calculated and monitored on a monthly basis as part of ongoing quality assurance processes within the Service and/or SCU.

INVESTIGATIONS AND RECALL FOR ASSESSMENT

ANNUAL SCREENING

Within a population based breast cancer screening program it may be appropriate to have a different screening interval for some sub groups of women in the population who have an increased risk of developing breast cancer.

All women are at risk of developing breast cancer over a lifetime. However, a woman's personal risk of developing breast cancer is dependent on the cumulative impact of different factors that increase or reduce the woman's individual risk.

It is possible to identify some sub groups of women at higher than average population risk of developing breast cancer, who may benefit from a shorter screening interval. Apart from increasing age, the relative risk of developing breast cancer is more than twice the population risk for women with identified high breast density, a strong family history, and previous history of breast cancer. The BreastScreen Australia Evaluation recommended that women be screened at the appropriate interval according to their level of risk.

The BreastScreen Australia Evaluation (2009) recommended that the following sub groups of women be offered annual screening in the Program:

¹⁸ BreastScreen Australia 2012 *BreastScreen Australia National Accreditation Standards, National Data unpublished report*

¹⁹ European Commission 2006, *European guidelines for quality assurance in breast cancer screening and diagnosis*

- Women with a previous history of invasive breast cancer or ductal carcinoma in situ (women may be re-admitted to the screening program five years after their diagnosis);
- Women with a history of atypical hyperplasia (atypical ductal hyperplasia or atypical lobular hyperplasia) or lobular carcinoma in situ (LCIS), for at least 15 years following diagnosis.²⁰

Key recommendations in the BreastScreen Australia Final Evaluation Report (2009) relate to the development and implementation of consistent policies for women at increased risk of breast cancer. Work is currently underway to progress toward a national policy on annual screening in the Program. The Service will have clearly defined protocols and procedures that reflect national policy where it exists, for offering women screening more frequently than every two years.

The Measure 2.6.1 b) target has been set at <10% of women aged 50–69 years attending for annual screening. This requirement level takes into account the expected proportion of women in these sub groups of elevated breast cancer risk in the population. This is consistent with the Service level analysis of data from 2007 to 2010 that found the average annual screening rate was approximately 7% (6.99%).²¹ It must be noted that annual screening policies vary across jurisdictions.

Women with a strong family history and women with identified high-risk genetic mutations, such as BRCA1 or BRCA2 require specialised surveillance that is tailored to their individual needs. Tailored screening protocols are not currently part of BreastScreen Australia policy. Women with a recent diagnosis of invasive breast cancer or ductal carcinoma in situ (< 5years) are generally undergoing management by a treating specialist. In some situations where access to mammography is very limited, these women may only have access to a BreastScreen Service. Ongoing clinical surveillance should be recommended in addition to mammography for these women.

For women screened outside the Program target population, being women aged 40–49 years and over 75 years, it is important to monitor the proportion of these women who attend for annual screening to manage Service capacity and to minimise any potential harm of unnecessary recall for these groups of women.

RECALL FOR ASSESSMENT

Population based breast cancer screening is offered to a well population of women with the aim of detecting asymptomatic breast cancer at an early stage. It is important that the Program balances maximising cancer detection, particularly small cancer detection, with minimising the potential harm that may be caused to the women screened, by unnecessary recall to assessment for investigations. An effective breast cancer screening program will limit any unnecessary investigations by minimising the proportion of women recalled for further assessment without affecting the achievement of high breast cancer detection rates.

The Service must achieve an appropriate balance between cancer detection and recall for assessment. Women recalled for assessment experience a degree of anxiety related to the procedures and concern that they will have a diagnosis of breast cancer. A number of studies suggest that women who have been recalled to assessment and are then subsequently found not to have breast cancer, experience heightened anxiety about screening and may be reluctant to return for their routine rescreen when it is due, or require additional encouragement to attend.^{22, 23}

²⁰ BreastScreen Australia 2009, *BreastScreen Australia Evaluation Final Report*

²¹ BreastScreen Australia 2012, *BreastScreen Australia National Accreditation Standards, National Data unpublished report*

²² Roman R, Sala M, De La Vega M, Natal C, et al 2011. Effect of false-positives and women's characteristics on long-term adherence to breast cancer screening. *Breast Cancer Research and Treatment* 2011; 130 (2): 543-552.

²³ Solbjør M, Forsmo S, Skolbekken J and Saetnan AR 2011. Experiences of recall after mammography screening – a qualitative study. *Health Care for Women International* 2011;32:1009-27.

In 2012 the national average recall to assessment rate for women attending for their first screening round was 10.8% however, there was a wide range of performance between State and Territory Programs of 6.6% to 12.8% (AIHW 2014, *BreastScreen Australia Monitoring Report 2011 – 2012*). In 2012 the recall to assessment rate for women attending for their subsequent screening rounds was 3.4%. This was similar across most State and Territory Programs but the range was from 1.9% to 4.0%.²⁴

Measures 2.6.3 b) and 2.6.4 b) maintain the requirements for the recall to assessment rate for women who attend for their first, second and subsequent screening episodes at <10% and < 5% respectively for women 50-69 years. This is consistent with the standards set for the UK NHS Breast Screening Programme of a recall to assessment rate for the first screening round of <10% and <7% for the subsequent screening round for women aged 50–70 years.²⁵ The European Guidelines also have similar recall to assessment requirements of <7% for the first screening round and <5% for the subsequent screening rounds.²⁶

POSITIVE PREDICTIVE VALUE OF RECALL TO ASSESSMENT

The positive predictive value is a measure of the accuracy of a recommendation to recall women to assessment that results in a diagnosis of breast cancer or DCIS. Measures for women attending for their first or second and subsequent screening episodes are designed to monitor and report on the likelihood that women recalled to assessment will have a confirmed breast cancer or DCIS. This will indicate to the Service and/or the SCU the number and proportion of women who may have been recalled to assessment for potentially unnecessary investigations. This will assist the Service and/or the SCU to balance the benefits and potential harms of the screening Program for individual women and the target population.

Measures 2.6.5 and 2.6.6 will be reviewed over time to achieve a benchmark for Services and/or the SCU to use in the future for continuous quality improvement.

EARLY REVIEW

On rare occasions, it may be necessary for a woman to return for further review of the same screen-detected abnormality within 12 months of completion of an assessment as part of her screening episode. This is known as early review, which may be recommended if a definitive diagnosis has not been achieved after all investigations are performed, yet the level of concern is low and does not warrant a recommendation for surgery. The majority of the women recommended for early review are invited to attend assessment within 12 months from completion of their assessment episode. Analysis of Service level data for the period 2007 to 2010 of the proportion of women who attended for early review found that the mean proportion was 0.18%.²⁷

The UK NHS Breast Screening Programme standard for short-term recall, which is similar to early review, is set at less than 0.25% of women screened.²⁸ Measure 2.6.7 requires <0.2% of women who attend for screening are recommended for early review for further assessment. For these women, there must be an outcome from the early review assessment; either a recommendation for diagnostic open biopsy or return for routine rescreening at the appropriate interval.

Early review will only be recommended in exceptional circumstances and with the woman's full understanding of the reasons and with her consent. There are likely to be significant adverse

²⁴ AIHW 2014, *BreastScreen Australia Monitoring Report 2011 – 2012*

²⁵ NHS 2011, *Quality assurance guidelines for breast cancer screening radiology*

²⁶ European Commission 2006, *European guidelines for quality assurance in breast cancer screening and diagnosis*

²⁷ BreastScreen Australia 2012, *BreastScreen Australia National Accreditation Standards, National Data unpublished report*

²⁸ NHS 2011, *Quality assurance guidelines for breast cancer screening radiology*

psychological consequences for the individual woman recommended for early review and her family that will be minimised.

CANCER DETECTION PROTOCOLS

The protocols that Services are to develop and maintain in relation to Standard 2 are:

- 2.1** Where there is discordance between the two independent screen readers on whether further assessment for the presence of breast cancer is required, the Service and/or SCU implements a protocol to achieve a single recommendation, through either:
- a) a third reader where that reader is a radiologist with a high level of expertise in screen reading, or
 - b) consensus reads by the original two or more readers.
- 2.2** The Service and/or SCU ensures the following quality and safety measures:
- a) The ALARA principle (As Low As Reasonably Achievable - a radiation safety principle for minimising radiation exposure) is applied and monitored;
 - b) The mammographic screening examinations consist of the two standard views (they are, cranio-caudal and medio-lateral oblique);
 - c) There is documentation of the reasons for any deviation from the standard two views or more than 4 images for each client; and
 - d) A protocol for adequate examination of women with internal breast prostheses is in place.
- 2.3** The Designated Radiographer implements a process for providing ongoing assessment and feedback to radiographers in all units about the quality of screening images using criteria such as those used in the PGMI evaluation system as outlined in [Appendix G](#).
- 2.4** The Service and/or SCU demonstrates annually that each radiographer achieves 50% or greater P or G ratings in a PGMI evaluation of 50 randomly selected image sets as outlined in [Appendix G](#).
- 2.5** Image identification complies with relevant radiation licensing regulations and complies with the RANZCR 'Standards of Practice for Diagnostic and Interventional Radiology, 2014' and the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM) Position Paper 'Recommendations for a Digital Mammography Quality Assurance Program, 2012' and as updated from time to time.
- 2.6** The Service and/or SCU implements a protocol for:
- a) identifying all interval invasive breast cancers and interval cases of DCIS;
 - b) reviewing and investigating all interval invasive breast cancers and interval cases of DCIS within the Service and/or SCU; and
 - c) identifying and implementing changes to improve practice where necessary.
- 2.7** The Service and/or SCU provides audit and timely feedback which advises each individual reader of:
- a) their individual rate of detection, including small invasive breast cancers in all screens, in initial and subsequent screens (see [Appendix H](#)).
 - b) any interval invasive breast cancers not detected in images read by the reader (see [Appendix H](#)); and
 - c) any invasive breast cancers not detected as an abnormality by an individual reader at screen reading.

- 2.8** The Service and/or SCU implements a timely review process, and where necessary, implements strategies to address the individual reader's performance.
- 2.9** The Service and/or SCU implements a protocol for the management of women who report breast symptoms.

HIGH QUALITY SCREEN READING

Population based breast cancer screening must be underpinned by high quality screen reading if the greatest possible number of breast cancers and small breast cancers are to be detected. In each Service and/or SCU, the Designated Radiologist has primary responsibility for all aspects of quality assurance in screen reading. The roles and responsibilities of the Designated Radiologist are outlined in [Appendix C](#).

The quality of screen reading depends on a number of interrelated factors. These include:

- Double blind reading of each screening examination;
- The comparison of the current screen with a previous screen (where available) as standard operating procedure;
- The qualifications, training and experience of the readers;
- The volume of screens read per year by each reader; and
- Continuous quality monitoring and feedback of reading outcomes to individual readers

QUALIFICATIONS, TRAINING AND EXPERIENCE OF SCREEN READERS

Screen reading for the BreastScreen Australia Program requires a sound knowledge of breast imaging using digital mammography and an understanding of the requirements of reading in the context of a population based screening program. Skill in interpreting mammograms alone is not sufficient to be a screen reader in the BreastScreen Australia Program.

All international breast cancer screening programs use medical officers with specialist radiological qualifications for screen reading. Radiologists are generally trained in diagnostic breast imaging, which involves the use of mammography and ultrasound in the diagnosis of breast symptoms in women of all ages. However, the BreastScreen Australia program requires the interpretation of mammograms from asymptomatic women who are actively invited from a well population of women with the aim of detecting unsuspected breast cancer at an early stage. This necessitates an added degree of skill and training for the screen readers to meet the standards required for the Program. With special training and experience, non-radiologists can perform to the same standards expected of all readers by BreastScreen Australia. Many Services, both within Australia and internationally, employ breast physicians, general practitioners and radiographers as screen readers.

It is, however, not appropriate for two non-radiologist readers to read together. For both medical and legal acceptance of the BreastScreen Australia Program, it is necessary that at least one reader be a radiologist.

The qualifications, training and experience required for radiologist and non-radiologist screen readers in the BreastScreen Australia Program are outlined in [Appendix C](#).

DOUBLE READING OF IMAGES

International best practice in organised population breast cancer screening programs such as the UK, Sweden, the Netherlands and New Zealand, is that all screening images be read independently by two readers. Even among experienced radiologists, there can be a wide range of accuracy in

reporting of mammograms. The BreastScreen Australia Evaluation showed that double reading leads to a higher overall, as well as small breast cancer detection rates.²⁹ This supports the policy of BreastScreen Australia that every screening image will be independently read by two or more readers, at least one of whom is a radiologist. The readers must read in a 'blind' relationship, such that they have no knowledge of the other reader's results.

READER QUALITY ASSURANCE

Continuous quality monitoring and feedback of reading outcomes to individual readers is an essential component of achieving consistent, high quality screen reading. Services will have established quarterly reporting of individual screen reader's performance. This information will be available in a systematic and timely way so that the individual reader has the opportunity to assess their performance and address any issues.

This quarterly Quality Assurance (QA) report will include the reader's recall to assessment rate, small and all breast cancer detection rates, and one reader missed cancers. This individualised report is provided to the individual reader and in confidence to the Designated Radiologist and the Clinical Director of the Service. It is the responsibility of the Designated Radiologist to discuss the reader's QA report and recommend action if required, to address any issues related to the reader's performance. The Service and/or SCU may also conduct regular independent reviews of individual reader performance under protected Quality Assurance Committee processes. The method for the audit of cancer detection rates for individual screen readers is described in detail in [Appendix H](#).

READING OUTCOMES COMBINED INTO A SINGLE RECOMMENDATION

The purpose of breast cancer screening using mammography is not to determine the cause of all lesions identified on imaging, but to exclude any signs of breast cancer or detect any abnormalities that may indicate the likely presence of breast cancer. Each screen reading should result in a clear decision about whether the screening images show no evidence of breast cancer, or that the woman requires further assessment of a screen detected abnormality to determine the presence or otherwise of breast cancer.

In the BreastScreen Australia Program the reading outcomes of each of the screen readers is usually directly entered into the jurisdictional Program's Clinical Information System. The two independent screen readers will use the National Breast Cancer Centre (NBCC) Synoptic Breast Imaging Report³⁰ endorsed by the Royal Australian and New Zealand College of Radiologists (RANZCR) to record their reading outcome. This is a lesion based synoptic reporting system that uses a five-point imaging classification with agreed standard language and descriptions of the imaging findings. The use of this system, in the screening context, allows for tracking of individual lesions, to guide further assessment and can be used to systematise the correlation of the two reading outcomes into a single non-narrative recommendation for the screening episode for the woman. The business rules for correlation of the reading outcomes will be standardised and agreed in consultation with the readers and approved by the SCU.

This combined reading outcome and recommendation will indicate whether the woman has had a normal screening outcome with no signs of breast cancer detected or that further assessment is required to determine the presence or otherwise of breast cancer. For women with a recommendation for routine rescreening the system will automatically be scheduled to send a "well woman" letter to the woman advising her of the outcome and that she will be reinvited for her next

²⁹ BreastScreen Australia 2009, *BreastScreen Australia Evaluation Final Report*

³⁰ NBCC 2007, *Synoptic breast imaging report*

screen, usually in two years. For women who are recommended for recall to assessment the system will generate a collated list that will be acted on by the relevant staff to contact the woman to organise her recall for assessment in accordance with the protocols and procedures of the Service and/or SCU.

DISCORDANT READS

The use of double blind screen reading in the Program will mean that on occasion there will be different reading outcomes from different screen readers. The Service and /or SCU will have a protocol in place for reconciling discordant reads that result in a single recommendation about whether or not the woman will be recalled for further assessment, to exclude or detect the presence of breast cancer.

One of two approaches can be used to reconcile the reads into a single recommendation; either:

1. by using a third reader to decide between the two screen reading outcomes; or
2. through a consensus read, where the two original screen readers consider the mammogram together through discussion to reach agreement on the outcome.

If the Service and/or SCU chooses to use a third reader, it must be a radiologist with a high level of expertise in screen reading. A Service and/or SCU may choose to have more than one 'third reader' review the images, however this is a local decision for the individual Service and /or SCU.

HIGH QUALITY BREAST IMAGING

High quality breast imaging is a fundamental component and a critical prerequisite of a breast cancer screening program to enable the detection of early breast cancer, particularly small breast cancers.

High quality mammography requires highly developed skills and knowledge in radiography and specific training in screening mammography. Requirements to ensure mammography practitioners and radiographers working in the Program are appropriately qualified, and have relevant experience and training are outlined in [Appendix C](#).

Radiographers and mammography practitioners will produce high quality mammography images using the 'As Low As Reasonably Achievable' (ALARA) principle that is an established radiation safety principle for minimising the radiation dose from imaging examinations. Radiographers and mammography practitioners will be aware of the equipment settings for digital mammography and ensure that the woman receives a radiation dose as low as reasonably achievable whilst minimising the number of images taken to produce a quality screening examination.

CLINICAL IMAGE QUALITY

To demonstrate clinical image quality and provide a tool for continuous quality improvement, BreastScreen Australia uses the criteria of perfect, good, moderate or inadequate images (PGMI) as outlined in detail in [Appendix G](#). The Australian Institute of Radiography (AIR) has modified the criteria for PGMI to assess clinical image quality in the digital environment.

A digital PGMI test set has been developed by the AIR to assist with consensus and consistency in the application of the PGMI grading criteria.³¹ The test set is available on the [AIR website](#)

³¹ AIR 2011, *PGMI Digital Image Reference Set Version 1*

(www.air.asn.au). This test set will be regularly reviewed and updated with input from radiographers and radiologists working in the BreastScreen Australia Program. The use of alternative systems or changes to the PGMI criteria will require the endorsement of the AIR.

The number of screens performed by a radiographer or mammography practitioner cannot be used as a measure of clinical image quality. The only valid measure is the systematic evaluation of screening images using the PGMI criteria for assessing clinical image quality. This method of evaluation allows a consistent approach for all radiographers and mammography practitioners, including those working part-time or in primarily administrative roles, to demonstrate they meet the requirements for clinical image quality. Although no formal system is available for evaluating images taken by radiographers and mammography practitioners employed in assessment only, evaluation of basic views can be undertaken using the PGMI criteria as a guide. Radiographers and mammography practitioners employed in assessment only will attend screening sessions to ensure they have an up-to-date knowledge of screening mammography.

Radiographers and mammography practitioners will be encouraged to evaluate their own images at the time of screening using the PGMI ratings. However, a Senior Radiographer with appropriate training in mammography, either within or external to the Service will conduct an independent review of clinical image quality.

Protocol 2.3 requires the Designated Radiographer to implement a process for providing ongoing assessment and feedback to all radiographers and mammography practitioners in all units about the quality of screening images using criteria such as those used in the PGMI evaluation system. This will be a timely formal process with the outcomes documented and incorporated into quality improvement and training activities as required.

The Designated Radiographer at the Service is responsible for all aspects of breast imaging quality within the Service. A description of the roles and responsibilities of the Designated Radiographer is included in [Appendix C](#).

Protocol 2.4 requires the Service to demonstrate annually that each radiographer and/or mammography practitioner achieves 50% or greater P or G ratings in a PGMI evaluation of 50 randomly selected image sets. This must be based on the evaluation of a Senior Radiographer.

IMAGE IDENTIFICATION

All images including soft or hard copy, must be clearly identified according to relevant radiation licensing regulations and comply with the RANZCR 'Standards of Practice for Diagnostic and Interventional Radiology (2014)' and the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM) Position Paper 'Recommendations for a Digital Mammography Quality Assurance Program (2012)' and as updated from time to time.

To meet clinical needs and medico-legal standards, there must be sufficient information to identify the client and enable correct interpretation. This applies to both mammography and ultrasound images. For mammography, the radiographer or mammography practitioner and the mammography unit used must also be recorded. All identifying information for every individual image must be visible on: the soft copy images, printed hard copy images, hard copy images that have been digitised; and on all images that are transferred electronically. It is important to evaluate soft copy images as well as any hard copies made, as hard copy images do not always display all the information contained on soft copy files, for example Digital Imaging and Communication in Medicine (DICOM) Headers.

REVIEW OF INTERVAL CANCERS

Interval invasive breast cancers or DCIS are identified by matching the screening outcomes for women on the jurisdictional Client Management System with the jurisdictional cancer registry data. This process determines whether an interval invasive breast cancer or DCIS has been diagnosed for women with a previous negative screening episode.

All interval invasive cancers and DCIS identified must be investigated. As this will rely on accurate and timely provision of data from the jurisdictional Client Management System, those cases of interval invasive breast cancer or DCIS that are reported ad hoc to the Service, will also be investigated.

The Service will develop and implement a standard protocol and procedure to assess each interval invasive breast cancer or DCIS diagnosed following a negative screening episode. All interval cancers will be reviewed by the Designated Radiologist or other senior radiologist of the Service. Individual readers will be provided with feedback on interval cancers, especially those interval cancers where they were the screen-readers. Review of interval cancers will involve an examination of the screening images, with the diagnostic images if they are available, to determine whether the interval invasive breast cancer or DCIS was a true interval or a failure of the screening process. A true interval may be an aggressive breast cancer that emerges and grows in the period between scheduled screening episodes, or a breast cancer, that due to the characteristics of the cancer or the breast tissue, was not visible on the screening images and therefore not able to be detected. A breast cancer or DCIS that can be detected retrospectively on the previous screening image represents a failure of the screening process. In the BreastScreen Australia Program more than 80% of interval invasive breast cancers are found to be true intervals (AIHW Monitoring Report 2009-2010).

After reviewing and investigating all invasive breast cancers and DCIS, within the context of continuous quality improvement, the review process will be used to determine whether there is a need to change clinical protocols or improve skills. Review of interval cancers is an important part of any multidisciplinary education and quality improvement program.

INDIVIDUAL READER AUDIT AND FEEDBACK

The performance of individual BreastScreen Australia screen readers can be compared using as the benchmark, the Criterion set for invasive breast cancer detection and small cancer detection, detection of DCIS, and interval invasive breast cancers, as part of a quality improvement program. These data need to be interpreted with some caution so that individual Measures are not assessed in isolation, but as an overall measure of reader performance. Services and/or SCUs are to provide audit and timely feedback to assist all screen readers to evaluate their individual performance and identify any areas where intervention by the Service and/or SCU may be required.

Each screen reader will be advised of their individual rate of detection of invasive breast cancer and small breast cancer detection, for both first and subsequent screening episodes. Individual screen readers will also be informed of any invasive breast cancer cases that they did not detect, but were detected by the other reader; "one reader misses". The reader Quality Assurance reports will be provided in a timely way and include data from both the previous 12 months and cumulative data over the previous 24 months.

In interpreting whether a screen reader's cancer detection rates truly differ from the required level for that Criterion, or whether this is due to chance alone, Services and/or SCUs will use the funnel plot method contained in the accreditation application and outlined in [Appendix H](#). Where the detection rates for individual readers fall below the 95% confidence bounds based on the numbers of screening images read, the Service and/or SCU will implement strategies to address individual reader performance.

The Service and/or SCU will have protocols in place for reviewing individual screen reader's performance and for implementing strategies to address and manage performance for screen readers where necessary. This review process may be undertaken by a protected Quality Assurance Committee and include recommended periods of supervised reading by experienced radiologist readers and the use of test image sets for individual screen readers to use for self-paced revision and up-skilling. The BreastScreen Reader Assessment Strategy (BREAST), developed by the University of Sydney, is one quality assurance tool which can be used to enhance reader performance. The BREAST initiative uses digital screen reading test sets designed to assess the performance of screen-reading radiologists and radiology registrars. BREAST provides immediate feedback to individual readers and BreastScreen Services on their performance on a set of 60 clinically relevant test cases.

Each Service and/or SCU has a Designated Radiologist who oversees all aspects of quality assurance in screen reading. The roles and responsibilities of the Designated Radiologist position are described in [Appendix C](#).

WOMEN WITH BREAST SYMPTOMS

The policy of BreastScreen Australia is to screen women on the basis of age alone. Since population based breast cancer screening is provided for women in the target and eligible age groups without breast symptoms, women with breast symptoms at the time of screening are actively discouraged from attending the BreastScreen Australia Program.

A recommendation of the BreastScreen Evaluation was that the Program not include women with breast symptoms, as women with breast symptoms require individualised assessment in a diagnostic setting. The Evaluation also recommended a nationally consistent approach to the management of women with breast symptoms.³² However, for a range of reasons, such as access to mammography services in rural and remote areas, women may present for screening and then indicate that they have breast symptoms. In these circumstances the Service must have a protocol in place for managing these women.

The Service will ensure that the protocol implemented for the management of women who present with breast symptoms, is based on a clear rationale.

WOMEN WITH AN INCREASED RISK

The BreastScreen Australia Evaluation (2009) notes that within a population-based breast cancer screening program, it may be appropriate to apply different screen policies or to use different screening technologies for some sub-groups of women. All women face some risk of breast cancer over their lifetime. However, a woman's personal risk of developing breast cancer is dependent on the cumulative impact for her of the different factors that increase or reduce her individual levels of risk.

A wide range of factors has been examined in relation to the risk of breast cancer. Meta-analyses of existing clinical trials and research reveal inconsistent findings on many factors posited as breast cancer risk factors. Risk differentiation is commonly ascribed as average, moderate or high. While this categorisation is usually used for family history, it could also be used to place other risk factors into context.

Apart from increasing age, the following factors increase the relative risk of developing breast cancer of greater than two times the population risk:

³² BreastScreen Australia 2009, *BreastScreen Australia Evaluation Final Report*

- High breast density;
- A family history of breast cancer in a first degree relative; and
- Previous history of breast cancer.

There is no position statement or consistent national policy for the management of women at increased risk. In the Australian Health Ministers' Advisory Councils (AHMAC) response to the Evaluation in 2012, AHMAC supported further work in this area.³³ The SCoS is responsible for providing advice on existing screening programs. As part of its role in monitoring emerging cancer screening evidence, the SCoS will consider the results of international and local research on breast cancer risk factors.

³³ AHMAC 2012, *Response to the BreastScreen Australia Evaluation Report 2009*

3

STANDARD 3: ASSESSMENT

Assessment and diagnosis of breast cancer are appropriate, safe and effective

INTRODUCTION

Breast cancer, like cancer more generally, is a complex disease. Multidisciplinary care is acknowledged as evidence based best practice in the assessment, diagnosis and care of women who have an abnormality detected through breast cancer screening.

In the BreastScreen Australia Program, multidisciplinary care involves the relevant specialist Service staff working together as a team to ensure that all women who are recalled for assessment of a screen detected abnormality receive an outcome, based on the combined skills and knowledge of the multidisciplinary team. This multidisciplinary approach is critically important to ensuring that these women have all the necessary clinical, imaging and pathology investigations when they attend for assessment. It also helps ensure that they receive a timely outcome to minimise any anxiety experienced. This is an essential component of the BreastScreen Australia Program that aims to maximise the benefits and minimise any potential harm to women screened.

The use of a multidisciplinary approach to the assessment of recalled women is not only clinical best practice, but an effective use of highly specialised clinical resources. The attendance of the relevant specialist staff at assessment leads to more efficient and effective communication. This also reduces the time and effort for busy clinicians and costs to the Service and/or State Coordination Unit (SCU).

This multidisciplinary approach to assessment enables women to be either reassured that they do not have breast cancer or to confirm a diagnosis of breast cancer or suspected breast cancer and provide the appropriate level of care and counselling to support the woman's referral for treatment, diagnostic open biopsy, or occasionally, further diagnostic investigation (such as MRI).

STANDARD 3

Assessment Standard: Assessment and diagnosis of breast cancer are appropriate, safe and effective.

| Criterion | NAS Measure | Risk Level | Data Dictionary Measure |
|---|---|------------|---|
| 3.1 The Service and/or SCU maximises the efficacy of assessment. | 3.1.1 <5% of all percutaneous needle biopsies of malignant breast lesions are classified as benign or inadequate/insufficient. | 2 | The number of percutaneous needle biopsies with a benign or inadequate result and malignant result on final histology as a percentage of all lesions sampled through percutaneous needle biopsy and returning a malignant result on final histology plus all cases called malignant on percutaneous needle biopsy and never confirmed by final histology but were clinically presumed to be malignant. <i>Calculation: See Data Dictionary</i> |
| | 3.1.2 a) 0% of benign lesions assessed by percutaneous needle biopsy have a false positive cancer diagnosis, when the definitive needle biopsy result is achieved after performance of the final needle biopsy at an assessment episode(s). A false positive FNA which is followed by a true negative core biopsy, prior to recommendation for surgery or treatment, is not considered to be a false positive "percutaneous needle biopsy" for the purpose of this standard. b) Where part a) is not met, a root cause analysis on 100% of false positive cancer diagnoses is conducted by the Service and/or SCU. | 2 | The number of lesions assessed by percutaneous needle biopsy with a malignant result on biopsy and a non-malignant result on final histology as a percentage of all lesions biopsied returning a non-malignant result on final histology. <i>Calculation: See Data Dictionary</i> |

| Criterion | NAS Measure | Risk Level | Data Dictionary Measure |
|-----------|--|------------|---|
| | 3.1.3 The absolute sensitivity of a diagnosis of breast cancer based on percutaneous needle biopsy is >90%. | 2 | The number of percutaneous needle biopsies with a malignant biopsy result and returning a malignant result on final histology plus all cases called malignant on biopsy and never confirmed by final histology but were clinically presumed to be malignant, as a percentage of all percutaneous needle biopsies returning a final malignant histology result plus all procedures where the lesion was called malignant on biopsy and never confirmed by final histology but were clinically presumed to be malignant. <i>Calculation: See Data Dictionary</i> |
| | 3.1.4 ≤0.35% of women who attend for their first screening episode are found not to have invasive breast cancer or DCIS after diagnostic open biopsy. | 1 | The percentage of the total number of women who attend for their first screening episode who are found not to have invasive breast cancer or DCIS after diagnostic open biopsy. <i>Calculation: See Data Dictionary</i> |
| | 3.1.5 ≤0.16% of women who attend for their second or subsequent screening episode are found not to have invasive breast cancer or DCIS after diagnostic open biopsy. | 1 | The percentage of the total number of women who attend for their second or subsequent screening episode who are found not to have invasive cancer or DCIS after diagnostic open biopsy. <i>Calculation: See Data Dictionary</i> |
| | 3.1.6 All women with impalpable lesions undergoing excision have specimen imaging recorded.. | 3 | The percentage of women with impalpable lesions at assessment undergoing excision who had specimen imaging recorded. <i>Calculation: See Data Dictionary</i> |
| | 3.1.7 ≥95% of all lesions are correctly identified at first excision. | 1 | The percentage of all lesions which are correctly identified at first excision through correlation of |

| Criterion | NAS Measure | Risk Level | Data Dictionary Measure |
|-----------|--|------------|---|
| | | | final pathology with specimen radiography findings and with screening assessment results. <i>Calculation: See Data Dictionary</i> |
| | 3.1.8 a) $\geq 85\%$ of invasive breast cancers or DCIS are diagnosed without the need for excision. b) Where part a) is not met, the Service and/or SCU provides the proportion of breast cancers that are diagnosed as invasive and DCIS without the need for excision. | 1 | a) The total number of invasive breast cancers or DCIS diagnosed without the need for excision expressed as a percentage of total breast cancers or DCIS diagnosed. b) The proportion of breast cancers that are diagnosed preoperatively that are invasive breast cancer and DCIS. <i>Calculation: See Data Dictionary</i> |

COMMENTARY

PERCUTANEOUS NEEDLE BIOPSIES

Image guided percutaneous needle biopsy has been the mainstay of preoperative diagnosis of breast cancer in the BSA program. The techniques available are core biopsy (CB), vacuum-assisted core biopsy (VACB), and fine needle aspiration (FNA).

In April 2020, following a lengthy consultation process, Cancer Australia released an evidence based [Position Statement on the use of fine needle aspiration \(FNA\) and core biopsy of the breast in the BreastScreen Australia Program](#). The Position Statement recommends that core biopsy, including vacuum assisted core biopsy, is the procedure of choice for the assessment of the majority of screen-detected breast abnormalities. It provides additional information not available with FNA, in particular assessment of receptor/biomarker status (ER/PR and HER2) as recommended by the Royal College of Pathologists of Australia 2018. FNA is appropriate for simple cysts, some complex cystic lesions, axillary lymph nodes and rare situations where core biopsy is not possible, e.g. a lesion close to an implant capsule (see table 1). The guidance further recommends that needle biopsy be performed using imaging guidance. In addition, all needle biopsies should be reviewed and documented in the context of a multidisciplinary meeting (BSA Protocol 3.3).

Whilst core biopsy or VACB are the preferred methods of needle biopsy, it is recognised that in a few cases FNA maybe appropriate (see table 1). In view of this, the measures for the efficacy of needle biopsy (NAS 3.1.1, 3.1.2, 3.1.3, 3.1.8) require the same level of performance regardless of which technique is chosen. Where FNA is used and a follow-up core biopsy is performed within the BSA service, or following core biopsy a VACB is performed within the BSA service, the final result of the needle biopsy that determines the woman's management should be used for the calculation of the NAS measure. (For example, if the FNA was reported as malignant but the service proceeded to a core biopsy which was non-malignant and the surgical specimen was non-malignant, this case should not be reported as a false positive needle biopsy.)

Furthermore, if FNA is chosen as a first procedure for "cystic" lesions, the operator should be prepared to proceed to core biopsy if the lesion proves to be solid.

The Service is responsible for all work-up and diagnostic procedures that are provided up to and including pathological diagnosis of breast cancer. The reporting of needle biopsies will be consistent with current professional standards, as updated periodically by the Royal College of Pathologists of Australasia (RCPA) Full information for the reporting of invasive breast cancer and DCIS is available in the protocol on the [RCPA website](#).

Percutaneous needle biopsy samples should provide sufficient material for pathology assessment. Measure 3.1.1 requires that <5% of all percutaneous needle biopsies of malignant breast lesions are classified as benign or inadequate/insufficient. "Inadequate" is defined as a sample of insufficient yield for pathologic diagnosis of the screen detected lesion. In cases of core biopsies for micro calcifications this includes samples without calcium in the tissue, calcium should ideally be in the sections but at least on the specimen x-ray. Unless there is a concordant pathologic diagnosis, which is consistent with the imaging findings and ratified by the MDM from a management perspective, an insufficient/non-diagnostic result mandates further needle biopsy / or excision. A multidisciplinary approach to the management of cases that are classified as inadequate/insufficient is essential, especially when the pathological findings do not correlate with the imaging and/or clinical findings. This is also the case when the pathologic findings are benign in the context of suspicious clinical or imaging findings.

FALSE NEGATIVE PERCUTANEOUS NEEDLE BIOPSIES

BreastScreen Australia Services will ensure high quality pathology in the performance and interpretation of percutaneous needle biopsies. A high false negative or false positive rate may indicate that these aspects of assessment are ineffective for client care. As percutaneous needle biopsies are highly operator and interpreter dependent procedures, clinicians performing and reporting these procedures will have adequate training and experience and maintain their clinical skills.

FALSE POSITIVE PERCUTANEOUS NEEDLE BIOPSIES

It is acknowledged that there are inherent risks with any diagnostic test, and in line with this, false positive results may occasionally occur. However, the threshold for false positive cancer diagnoses has been set at zero for the purposes of client safety, transparency and accountability, and the need for such events to be reported and reviewed whenever they occur within the Program. As a consequence of a zero threshold, should a false positive biopsy diagnosis of cancer occur within the Service and/or SCU, measure 3.1.2(a) will be unmet, and will be subsequently reported to the NQMC through the Services response to unmet Measures (refer BSA005) using specific documentation provided by the NQMC.

A false positive diagnosis requires action and notification to the SCU and State Quality Committee (SQC). Some services working within the framework of other health units outside of BSA, may need to notify their health unit's incident monitoring and safety committees of these adverse events. The SCU and SQC will work with the Service to ensure that effective quality improvement strategies are implemented to ensure these results are minimised within the Program.

In May 2018 the NQMC clarified that a false positive event does not necessarily constitute a Level 1 adverse event and should be classified at the discretion of the jurisdiction bearing in mind as noted above, that where there is a responsible health service the classification is actually at the discretion of the clinical governance body.

ABSOLUTE SENSITIVITY OF PERCUTANEOUS NEEDLE BIOPSIES

Services will collect and review data related to the absolute sensitivity of percutaneous needle biopsies. Absolute sensitivity is a measure of the number of cases diagnosed accurately as malignant on the basis of needle biopsy, that are ultimately categorised as malignant (mostly by surgical specimens). Absolute sensitivity is related to the inadequate rates, as high rates of inadequate/non-diagnostic needle biopsies will decrease sensitivity. The target for Measure 3.1.3 requires the absolute sensitivity of a diagnosis of breast cancer, based on percutaneous needle biopsies to be >90%. The requirement for this Measure has been set to reflect the results of core biopsies in the collation of BreastScreen Australia National Accreditation Standards Data³⁴ where the average across all jurisdictions was >92%.

³⁴ BreastScreen Australia 2012, *BreastScreen Australia National Accreditation Standards, National Data unpublished report*

GUIDELINES FOR INVESTIGATION OF POSSIBLE FALSE POSITIVE NEEDLE BIOPSY DIAGNOSES OF BREAST MALIGNANCY IN BREASTSCREEN AUSTRALIA ACCREDITED SERVICES

Guidelines for investigation of possible false positive needle biopsy diagnoses of breast malignancy in BreastScreen Australia accredited Services have been developed to provide guidance to BreastScreen Services on when a needle biopsy result is to be classified as a false positive and for assisting services to investigate these cases. The NQMC Biopsy Quality Assurance Initiative Review Committee has provided a Flowchart and Proforma. These documents highlight specific exclusions of situations that are not to be classified as false positives needle biopsy diagnoses. Once cases are identified as possible false positive diagnoses, appropriate multidisciplinary review and analysis of the root causes of the event is required. Services are encouraged to use the structure of this proforma tool when reporting their investigation of false positive diagnoses to the NQMC. The NQMC has the responsibility for accrediting BSA services and this level of information is what the NQMC requires for assessing service performance in such adverse events.

The guidelines do not cover:

- Case management; and
- Procedures for Root Cause Analysis.

The Guidelines, Flowchart and Proforma are available at [Appendix I](#).

DIAGNOSTIC OPEN BIOPSY

Where open biopsy is performed as part of the Program, the Service must ensure that it is performed by specialists with the appropriate expertise and facilities available.

A woman may be referred for her open diagnostic biopsy outside the BSA program either through her general practitioner privately or publicly, or directly to a public sector surgical facility. Regardless of the referral process, the duty of care of the Service extends to the point of being able to demonstrate that the client has been appropriately advised and referred. For example, the Service may include a recommendation in the letter or through verbal advice to the general practitioner, about the facilities and expertise that are required as a minimum, for the adequate performance of a diagnostic open biopsy for a woman with a screen detected abnormality.

The Service must endeavour to minimise the unnecessary investigations for women recalled for assessment to minimise the morbidity associated with surgical procedures. In particular, the number of women who undergo diagnostic open biopsy for a benign lesion will be minimised, while ensuring that the detection of cancer is not compromised.

BENIGN DIAGNOSTIC OPEN BIOPSY

A benign diagnostic open biopsy is defined as an open biopsy recommended by the Service and/or SCU for diagnostic purposes, where the histopathology finding was not of invasive cancer or DCIS. For example, a diagnostic open biopsy with a benign finding may be a diagnosis of:

- atypical ductal hyperplasia;
- radial scar; or
- lobular carcinoma in situ (LCIS).

The rate of benign diagnostic open biopsies per total number of women screened provides an indication of the effectiveness of the Program in minimising unnecessary diagnostic open biopsies. Separate measures have been set for women who attend for their first screening episode and women who attend for their second or subsequent screening episode. Measures 3.1.4 and 3.1.5 use the number of women screened as the denominator, so that the measure is independent of the effect of a variation in the rate of women recalled for assessment.

EXCISION OF IMPALPABLE LESIONS

Breast cancer screening using mammography will identify small, impalpable lesions that require excision by image guidance for diagnosis or treatment. The excision of small, impalpable lesions requires specialist skills in radiology, surgery and histopathology. To maximise the number of cancers detected, excision of these lesions will need to be referred to specialists who work in a multidisciplinary team setting with the skills and facilities to perform such procedures.

Specimen imaging permits a degree of certainty that the lesion detected by mammography and/or sonography has been satisfactorily removed. The requirement for this Measure is for the image to be retained rather than just taken. The surgical specimen will be imaged according to standard protocols to allow the surgeon and pathologist to assess the adequacy of the excision. Although a verbal report by a radiologist can be received, it is desirable that the specimen image be available for the surgeon to review for intraoperative decisions. The orientation of the specimen and copy of the specimen image will also allow the pathologist to assess the location of the lesion within the specimen and margins of resection. It is a requirement that specimen imaging be undertaken and recorded for; a screen detected abnormality that is impalpable pre operatively; any localised procedure; and if a lump becomes palpable during an operation.

Measure 3.1.7 requires ≥95% of all lesions to be correctly identified at first excision, to ensure the anxiety and physical consequences for women are minimised. This is a critical measure of patient safety and therefore, has a level 1 risk level. This Measure applies to all lesions identified at assessment, not just those impalpable lesions that undergo preoperative localisation.

PREOPERATIVE DIAGNOSIS

The ability to provide an accurate diagnosis for the majority of women without the need for diagnostic open biopsy reduces the number of women who require further, more invasive and often unnecessary investigations. Although it is recognised that some women will require evaluation through surgery, the preoperative diagnosis rate is an indicator of the Service effectiveness in minimising the number of investigations that women require for an outcome to be determined.

Breast surgeons should be prepared to proceed with definitive surgery based on a preoperative histopathological diagnosis of cancer. This is defined as a malignant result on a percutaneous needle biopsy, including DCIS and invasive cancer, which is consistent with suspicious or malignant imaging findings. Cancers diagnosed at surgery, as a result of a suspicious percutaneous needle biopsy result, are not considered a preoperative diagnosis.

The preoperative diagnosis of breast cancer reduces the physical and psychological harm to women. It also allows for preoperative discussion with the woman about her treatment options. In the vast majority of cases, it enables a one stage surgical procedure to be planned and will lead to timely, direct referral and commencement of treatment.

The Service and/or SCU will aim to provide a preoperative diagnosis of cancer for the majority of women whilst ensuring a balanced consideration of the diagnostic options for each individual woman assessed. Based on analysis of the BreastScreen Australia National Accreditation Data,³⁵ the target for Measure 3.1.8 has been set at ≥85% of invasive breast cancers or DCIS are diagnosed without the need for excision.

This target is also consistent with the United Kingdom National Health Service (NHS) Breast Screening Programme that has a minimum standard of 90% (invasive) and 85% (non-invasive) rates

³⁵ BreastScreen Australia 2012 *National Accreditation Standards, National Data unpublished report*

for preoperative diagnosis of breast cancer.³⁶ If a Service and/or SCU is not achieving the target for Measure 3.1.8, it will provide the proportion of breast cancers that are diagnosed pre-operatively as invasive and DCIS.

In addition, the reasons for not meeting this Measure will be analysed and targeted quality improvement strategies implemented. Services that do not meet the Measure will provide the rationale for the Measure being unmet, demonstration of quality improvement processes, and trend data, if applicable, to indicate that preoperative diagnosis is increasing over time. This information will be required to accompany an application for accreditation and annual data report.

ASSESSMENT PROTOCOLS

The protocols that Services are to develop and maintain in relation to Standard 3 are:

- 3.1** The Service and/or SCU ensures that the multidisciplinary team involved in the assessment of women recalled from screening has expertise in:
- a) breast examination;
 - b) mammographic image interpretation and work-up;
 - c) ultrasound performance and interpretation;
 - d) percutaneous needle biopsy;
 - e) pathology technique and interpretation;
 - f) surgical planning; and
 - g) supportive care.
- 3.2** The Service and/or SCU implements a protocol that ensures that the radiologist and other designated examining medical doctor from the multidisciplinary team, correlate and evaluate the clinical, pathological and imaging findings and decide on further investigations or management.
- 3.3** The Service and/or SCU ensures that all cases of percutaneous needle biopsy are reviewed by a radiologist and at least one other designated medical doctor of the multidisciplinary team, before giving the results to the woman. Where results of radiology and pathology are inconclusive or inconsistent, the case is reviewed at a minimum by a radiologist in consultation with a pathologist.
- 3.4** The Service and/or SCU implements a protocol for reviewing and correlating the clinical, radiological and pathological findings for all lesions detected as a result of screening for which surgery was performed.
- 3.5** Where there is discordance between assessment and post-surgical results the Service and/or SCU implements a protocol for the follow-up of these women which may include:
- a) notification of the surgeon;
 - b) notification of the general practitioner;
 - c) notification of the woman for review and assessment at the Service; or
 - d) any combination of these.

³⁶ NHS 2010, *Clinical Guidelines for Breast Cancer Screening Assessment*

- 3.6** The Service and/or SCU has systems in place to ensure that screening unit staff work closely with a specific assessment unit to provide an integrated service.
- 3.7** The Service and/or SCU implements protocols for the evaluation of all women recalled to assessment which incorporate, as required:
- a) clinical examination;
 - b) mammography/ultrasound; and
 - c) percutaneous needle biopsy.
- 3.8** A Service or SCU that plans to implement remote radiology must establish and implement a protocol for delivering those remote radiology services to assessment clinics that includes and complies with all of the Remote Radiology Guidelines and utilises appropriate technology/telehealth facilities that meet the minimum technical requirements and quality control procedures in [Appendix G](#).

MULTIDISCIPLINARY TEAM

The assessment of women with a screen detected abnormality and the diagnosis of breast cancer relies on a number of specialist clinical skills. The Service will ensure the availability of an appropriately skilled multidisciplinary team for the evaluation of all women recalled for assessment. In a multidisciplinary approach, members of the team contribute their different expertise to ensure that the appropriate investigations are undertaken and interpreted collaboratively to achieve a definitive outcome for the woman. The multidisciplinary team will appropriately consider all approaches to the management of women with a diagnosis of breast cancer or suspected breast cancer.

The multidisciplinary assessment team will have expertise as outlined in Protocol 3.1, with each member having the relevant skills and appropriate training as outlined in [Appendix C](#).

The Service will implement a protocol that ensures that the radiologist and the other designated examining medical practitioner in the multidisciplinary team correlate and evaluate the clinical, radiological and pathological findings and decide on further investigations or management. However, it is recognised that different Services will provide this expertise in different ways. For example, clinical examination may be undertaken by a surgeon in some Services and in other Services by another appropriately trained member of the assessment team. It is not considered imperative for a surgeon to be physically in attendance at assessment if a medical practitioner is present to provide the detail of the 'next steps', and has an understanding of the surgical management of breast cancer. Surgical input could instead be undertaken by video/teleconferencing where required. However, surgeon's involvement and expertise at this stage of the assessment process is considered clinical best practice.

Where a screen detected abnormality persists after imaging work up, or where there is a breast symptom at assessment, the radiologist and the surgeon or other examining medical practitioner, will discuss, evaluate and correlate the findings and decide on further investigations and management as required. Counselling will be available at assessment to ensure the provision of psychosocial care to the woman and her support person as appropriate.

A medical practitioner in an assessment team who has the appropriate expertise and clinical knowledge will provide all non-benign radiology and percutaneous needle biopsy results to the woman. This is critically important so that the implications of these results can be fully and accurately explained to the woman in a way that ensures she understands the outcome of the assessment investigations. It also enables the woman to ask questions and be clear about the next

step in her screening pathway, whether it is to return for a rescreen, referral for treatment or further diagnostic investigations.

Benign assessment results may be delivered by a suitably trained and experienced medical practitioner, breast care nurse or nurse counsellor, on the conditions that:

- the multi-disciplinary team recommendation is for routine re-screening;
- the woman is offered the opportunity for further discussion with a medical officer.

MULTIDISCIPLINARY MEETINGS

REVIEW OF ASSESSMENT CASES:

The Service and/or SCU will implement a protocol for review and correlation of clinical, radiological and pathological findings of all women who had percutaneous needle biopsy. Where biopsy results are not available at the assessment clinic, the multidisciplinary team who were involved in each case will agree on a management plan for the woman, pending the biopsy results.

The biopsy results must be reviewed as soon as possible after they become available and before the outcome of assessment is given to the woman or her doctor. This review is to be undertaken by a radiologist, and at least one other designated medical member of the multidisciplinary team. This assessment case review will confirm the outcome of the assessment process for the majority of women who have had a percutaneous needle biopsy.

Where results are inconclusive or inconsistent, case review must be performed at a minimum by a radiologist in consultation with a pathologist, to determine the appropriate further investigations or management. The Designated Surgeon should be available to provide input to the review and management of such cases where necessary. All members of the multidisciplinary assessment team will be encouraged to participate in this case review process where possible.

Where women have been recalled for assessment by the Service and/or SCU but have elected to be assessed outside the Program, the Service and/or SCU may advise the woman and her general practitioner about appropriate referral for the assessment of screen detected abnormalities that support a multidisciplinary team approach. In addition, Services and/or SCUs may extend their care to follow-up and review of these assessment outcome results. Where results are available, these cases will be reviewed, at a minimum, by a radiologist and where necessary by other members of the multidisciplinary team.

FOLLOW-UP OF POST-SURGICAL CASES:

The Service and/or SCU will implement a protocol for the review of the histopathology reports of all women who have surgery, for a lesion detected as a result of screening. All members of the multidisciplinary assessment team will be encouraged to participate in multidisciplinary review meetings. The Designated Surgeon should be available to provide input into the review of surgical cases where necessary. All relevant clinical notes; imaging and pathology reports, will be available to facilitate correlation of results and case discussion.

Where the results of surgery are not found to be in accord with the assessment findings, a protocol will be implemented for the follow-up of these women. This may include: notifying the woman and inviting her for review and further assessment at the Service, notifying the treating surgeon, notifying the general practitioner or any combination of these. The Service and/or SCU will ensure that there is a protocol in place that ensures that contact can be made with these women in order that appropriate follow up takes place.

Meetings for the review of assessment cases include the follow up of post-surgical cases, and other educational multidisciplinary meetings, assist in fostering a multidisciplinary team approach. These

meetings enable the sharing of knowledge and expertise between different disciplines, and they function both as a strategy for improving assessment clinic protocols and as an approach to providing continuing professional education for the multidisciplinary team.

SCREENING AND ASSESSMENT PATHWAY

The facilities within a BreastScreen Australia Service must constitute an integrated service that includes operational management of all screening and assessment units. All screening units within the Service must be linked to a specific assessment centre. It is essential that there are clear governance and management mechanisms for the Service, and clinical leadership and liaison between staff in the screening units and the assessment centre.

COMPREHENSIVE APPROACH TO ASSESSMENT

High quality assessment is essential if the BreastScreen Australia Program is to detect breast cancer early while minimising the number of unnecessary investigations. The development of evidence based clinical protocols is important in guiding the appropriate assessment of women with screen detected abnormalities. The Service and/or SCU will implement protocols for the evaluation of all women recalled to assessment. Protocols will incorporate clinical examination and the woman's medical history and will specify:

- the appropriate investigations to be undertaken for different types of lesions;
- the equipment that must be available; and
- the procedures to perform mammographic work-up of screen detected abnormalities, breast ultrasound and percutaneous needle biopsy.

The effective use of imaging using mammography, with or without ultrasound, is a vital aspect of breast assessment. In some cases, appropriate imaging eliminates the need to proceed with further investigations. Targeted imaging and the use of additional special mammographic views for the evaluation of lesions detected at screening may add to the radiology information available from the standard two view mammography.

The use of ultrasound in evaluating breast abnormalities requires advanced skills and knowledge. All ultrasound examinations are to be performed by suitably qualified and experienced radiologists or by a sonographer under the supervision of a suitably qualified and experienced radiologist. Reporting of imaging findings will be standardised within each Service and/or SCU. Standardised imaging reports will be consistent with *Breast Imaging—A Guide for Practice* (NBCC 2002) and *Synoptic Breast Image Report* (NBCC 2007) available on the [Cancer Australia](http://www.canceraustralia.gov.au) website (www.canceraustralia.gov.au).

It is important that the findings of each modality are collated, reviewed and interpreted, taking into account the findings of all other investigations.

Based on this approach, the Service and/or SCU will implement an assessment protocol that ensures that the majority of abnormalities are diagnosed without the need for excision while maintaining a high accuracy in detecting cancer. In cases where cancer is detected, such an approach allows for both pre-operative discussion of treatment options and counselling of the woman, and assists in the planning of single stage surgery. In cases where a benign diagnosis is confirmed and where the need for further investigation or excision is eliminated, the woman can be reassured and appropriate further management can be discussed.

REMOTE RADIOLOGY ASSESSMENT - MINIMUM TECHNICAL REQUIREMENTS AND QUALITY CONTROL PROCEDURES

The current standard of care for the assessment of breast cancer used by BSA Services is face-to-face assessment clinics with the radiologist present.

Remote radiology is where the radiologist is not physically present at the assessment clinic, but attends via an appropriate telehealth system. The telehealth system can be used by the radiologist to view in real time ultrasound taken at the assessment clinic.

When a Service or SCU implements remote radiology for assessment clinics, it will need to meet the minimum technical requirements and quality control procedures set out in [Appendix G](#). These requirements and procedures relate to the telehealth systems necessary to enable remote radiology to be used for assessment in Breast Screen Australia services.

Importantly, the telehealth system is not to be used for the assessment of mammography images. Rather, the assessment team must have direct access to the patient's current imaging (screening and assessment mammograms) and prior imaging (mammograms and ultrasound if relevant), and patient history via PACS and RIS systems that meet the minimum performance standards specified in this NAS commentary.

REMOTE RADIOLOGY ASSESSMENT – GUIDING PRINCIPLE AND NOTIFICATION

Service or SCUs will implement remote radiology for assessment **where and/or when there is a genuine need established to do so**. In relation to **where** there is a genuine need, this will most likely relate to where a Service is in a rural or remote location. A genuine need however may be established in a regional or metropolitan location, **when** “emergency circumstances” exist.

Some examples of such “emergency circumstances” where this remote service may be appropriate, include:

- A pandemic environment, where services that routinely use interstate radiologists face to face, may be heavily impacted by border closures or restrictions and therefore need to pivot to a remote model to ensure service provision.
- The sudden illness or resignation of a key assessment radiologist.
- Regional Radiologist workforce availability/shortages.
- Where/when local staff are not available or not yet appropriately trained.

This list is not exhaustive.

Where a Service determines there is a genuine need to implement remote radiology for assessment, it must **notify the NQMC of its decision**, including advice on how the Service will progress with safe and effective implementation.

4

STANDARD 4: TIMELINESS

Screening and assessment services are provided to women in a timely and efficient manner

INTRODUCTION

For the BreastScreen Australia Program to be acceptable to women, it is critical that there be a timely progression through the screening and assessment pathway. Timeliness is an important quality component of a screening program as it ensures that the results of screening are provided in a timely and appropriate manner for women and, if required, further assessment is carried out promptly. Timely progression through the screening and assessment pathway will assist in minimising any anxiety the woman may experience in relation to screening.³⁷

Timely provision of screening and assessment services is a key indicator of workforce and infrastructure capacity. Appropriate service planning and effective use of specialist staff that matches the demand and target population requirements for breast cancer screening services in each Service and/or State Coordination Unit (SCU) catchment is essential. Excess demand over Service capacity is likely to impact negatively on timeliness for the woman, especially if she is recalled for assessment.

Timely service provision is likely to support high rates of participation in screening. If women are able to organise a prompt appointment and move through the screening and assessment process without undue delay, they will be better able to integrate screening with other aspects of their lives.

Timeliness in relation to the notification of results is an important measure of a quality Service. The decision to participate in the Program is likely to engender some level of anxiety for women about the possible outcome and the process. A positive and supportive experience with the minimum possible waiting time between each part of the screening and assessment pathway will help ensure that the service is acceptable to women and encourage their attendance for rescreening. In addition, this experience may assist in the promotion of the Service to other women and be an important means of encouraging eligible women to participate in the Program.

³⁷ BreastScreen Australia 2009, *BreastScreen Australia Evaluation Final Report*

STANDARD 4

Timeliness Standard: Screening and assessment services are provided to women in a timely and efficient manner.

| Criterion | NAS Measure | Risk Level | Data Dictionary Measure |
|--|---|------------|---|
| 4.1 The Service and/or SCU ensures that women progress through the screening pathway in a timely manner. | 4.1.1 a) ≥90% of women aged 50–74 years attend for a screening appointment within 28 calendar days of their booking date (fixed sites only). b) Where part a) is not met, the Service and/or SCU records and reports the time taken to achieve 90% from booking to screening (fixed sites only). | 2 | a) The percentage of women who attend for a screening appointment within 28 calendar days of their booking date. b) The number of days taken between booking and attending for 90% of women. <i>Calculation: See Data Dictionary</i> |
| | 4.1.2 ≥90% of women have a documented notification of the results of screening within 14 calendar days of the date of screening. | 2 | The percentage of women who have documented notification of the results of screening within 14 calendar days of the date of screening. <i>Calculation: See Data Dictionary</i> |
| 4.2 The Service and/or SCU ensures that women progress through the assessment pathway in a timely manner. | 4.2.1 a) ≥90% of women requiring assessment attend an assessment visit within 28 calendar days of their screening visit. b) Where part a) is not met, the Service and/or SCU records and reports the number of days the Service and/or SCU takes to achieve 90%. c) Where part a) is not met, the Service and/or SCU records and reports the percentage of women who were offered assessment within 28 calendar days of their screening visit. | 1 | a) The percentage of women requiring assessment who attend for an assessment visit within 28 calendar days of their screening visit. b) The number of days the Service and/or SCU takes to achieve 90%. c) The percentage of women who were offered assessment within 28 calendar days of their screening visit. <i>Calculation: See Data Dictionary</i> |

| Criterion | NAS Measure | Risk Level | Data Dictionary Measure |
|-----------|--|------------|---|
| | 4.2.2 ≥95% of women not requiring percutaneous needle biopsy at assessment receive a definitive recommendation at their first assessment visit. | 2 | The percentage of women attending assessment who do not require percutaneous needle biopsy who receive a definitive outcome at their first assessment visit. <i>Calculation: See Data Dictionary</i> |
| | 4.2.3 ≥95% of women require no more than two procedural assessment visits to receive a definitive recommendation from assessment. | 2 | The percentage of women attending assessment who receive a definitive recommendation from assessment in no more than two visits. <i>Calculation: See Data Dictionary</i> |
| | 4.2.4 ≥85% of women are verbally given the results of percutaneous needle biopsy within seven calendar days of the assessment procedure. | 2 | The percentage of women who have percutaneous needle biopsy at assessment who are verbally given the results within seven calendar days. <i>Calculation: See Data Dictionary</i> |
| | 4.2.5 ≥95% of women complete all assessment within 15 calendar days. | 2 | The percentage of women attending assessment who receive a definitive outcome of assessment within 15 calendar days. <i>Calculation: See Data Dictionary</i> |
| | 4.2.6 All women are notified of the results of their assessment in writing within 14 calendar days of the date of completion of assessment. | 2 | The percentage of women assessed who have a letter sent notifying them of the results of assessment within 14 calendar days of the date of completion of assessment. <i>Calculation: See Data Dictionary</i> |

COMMENTARY

TIME FROM BOOKING TO APPOINTMENT

The Service and/or SCU will ensure that women are able to attend for screening within a reasonable period from the time they make an appointment. This is an important measure of the capacity of the Service and/or SCU to provide timely screening appointments as a long delay may result in women being discouraged from screening.

Measure 4.1.1 requires that $\geq 90\%$ of women attend for screening within 28 calendar days of their booking date. This Measure relates to fixed screening sites only, as it can be difficult for mobile units to meet this Measure, as appointments are based on the travelling schedule of the mobile. A fixed site is defined as a screening and/or assessment clinic that is permanent and does not relocate to alternative locations. If this Measure is not met, the Service and/or SCU will report the time taken to achieve 90% from booking to screening (fixed sites only).

RESULTS OF SCREENING

The period waiting for results is likely to cause some anxiety for women. Therefore, the Service and/or SCU will ensure women receive documented notification of the results of their screening visit as promptly as possible, to minimise this period of anxiety.

Documented notification refers to contact with the woman, for example, by a phone call in which the woman is directly spoken TO, or via letter or email. The date of notification is the date the woman is contacted or the date the result letter or email is sent. This information is noted in her record.

For women who require assessment, the Service and/or SCU may choose to arrange for an appropriate clinical staff member such as a nurse to contact the woman verbally prior to them receiving their written results, to arrange for them to attend the Service for assessment of their screen detected abnormality. This allows the clinical staff member to provide some explanation of the assessment process and enables the woman to ask questions about the screening outcome.

The commitment to timely service provision must not compromise the provision of high quality screening and assessment services. The challenges of providing high quality services in some rural and remote areas because of their geographic isolation may need to be taken into account in meeting the timeliness requirements.

Given the anxiety resulting from a delay in receiving results, the Service and/or SCU will seek to ensure that at least 90% of women receive documented notification of their results within 14 calendar days of screening.

TIME FROM SCREENING TO ASSESSMENT

Recall for assessment is associated with significant anxiety, particularly as the majority of women have no previous indication that they have a breast problem. For this reason, when women are

required to attend for assessment of a screen detected abnormality, the time between her screening visit and her attendance for assessment will be as short as is practically possible.³⁸

Measure 4.2.1 requires that ≥90% of women requiring assessment attend an assessment visit within 28 calendar days of their screening visit. There must be enough assessment capacity to ensure that assessment takes place well within this period.

There are several reasons why it may not be possible to provide assessment for some women within 28 calendar days of their screening visit. These include:

- Some women may be unable or unwilling to attend an available appointment within this time frame;
- In rural and remote areas there may be less frequent assessment clinics;
- There may be delays in finalising the results of screening; and
- There may be special difficulties for some groups of women, such as delays in organising interpreters for women from culturally and linguistically diverse backgrounds.

Nonetheless, the Service and/or SCU will work towards ensuring that the time between screening and the assessment visits is as short as possible. Where the proportion of women requiring assessment within 28 calendar days of their screening visit is less than 90%, the Service and/or SCU will record and report the number of days the Service and/or SCU takes to achieve 90%.

The Service and/or SCU will also record and report the percentage of women who were offered an assessment appointment within 28 calendar days of their screening visit. This allows the Service and/or SCU to demonstrate that it is sometimes the woman's choice not to attend for an assessment appointment within the 28 calendar days.

To assist the NQMC in its decision making processes, the NQMC has requested that all Services and/or SCUs present month-by-month data on this Measure. The month-by-month data will relate to the period from when the data reporting period is completed, up to the most recent month of data available. For example if a Service and/or SCU is submitting an application for accreditation using data from the calendar year 2015 and the NQMC is considering this at its August 2016 meeting, the NQMC requests that data are provided for 2015 and then month-by-month up until the most recent month in 2016 for which data are available, which will be for women assessed up to the end of June.

NUMBER OF ASSESSMENT VISITS

The assessment process will involve as few visits as possible for the woman while providing a high quality service. Women recalled to assessment experience an increase in their level of anxiety, and repeated attendances for assessment during a single screening episode are likely to be associated with higher anxiety. Every effort will be made to ensure that all assessment procedures are performed on the day of assessment and, where possible, results given as well. This will ensure that participation in the Program maximises the benefits and minimises any potential harms for the woman.

WOMEN WHO DO NOT REQUIRE PERCUTANEOUS NEEDLE BIOPSY

The vast majority of women who do not require percutaneous needle biopsy will receive a definitive outcome at their first assessment visit. However, there are circumstances where the need to complete assessment in one day will need to be balanced against the need to provide a high quality service. In a small number of cases it may be necessary to discuss imaging findings further, or seek a

³⁸ NHS 2010, *Clinical Guidelines for Breast Cancer Screening Assessment*

second opinion about the interpretation of the findings. The BreastScreen Australia program is a client centred model of service delivery, and women will be informed, engaged and supported in their decision making. Some women may not be willing or able to progress to a stage 2 assessment for a variety of reasons. Women's choices will be respected, whilst ensuring any potential harm to the woman in delaying investigations is minimised.

A first assessment visit also refers to step-down assessment where further views only are undertaken, but clinical assessment, ultrasound or biopsy are not included. Step-down assessment may be undertaken at a screening only fixed or mobile unit, or at an assessment centre at a time outside of an assessment clinic.

WOMEN WHO REQUIRE PERCUTANEOUS NEEDLE BIOPSY

Women recalled for assessment who require a percutaneous needle biopsy will receive a definitive recommendation after attending for no more than two procedural assessment visits. This allows for the woman to have her percutaneous needle biopsy scheduled for another day for reasons of convenience or preference and in the case where a procedure needs to be repeated for clinical reasons this can be scheduled at a second visit. Procedural assessment visits do not include visits for the sole purpose of giving results. This requirement aligns with the United Kingdom National Health Service Breast Screening Programme clinical guidelines that *"no more than two needle biopsy procedures, carried out on separate occasions, should normally be needed to achieve a non-operative diagnosis"*.³⁹ For women who need to travel long distances, every effort will be made to minimise the number of visits required.

A definitive recommendation for the majority of women will be obtained over the course of only a few days. However, women who are taking certain medications, such as aspirin and warfarin, may need to stop these medications for a period of time before investigative procedures are undertaken and therefore may require a longer time to complete their assessment.

COMPLETION OF ASSESSMENT

The results of assessment must clearly indicate a recommendation for the woman in the shortest possible time, without compromising the quality of the assessment process. The Service and/or SCU will ensure that women who are recalled for assessment are followed up until their assessment is complete and a review and correlation of all investigations confirms a definitive recommendation. An assessment is complete for the woman when there is one of three recommendations:

1. Return for routine rescreening, either yearly or two yearly;
2. An histological result and referral for definitive treatment; or
3. A recommendation for diagnostic open biopsy;
4. A recommendation for early review.

To minimise anxiety, Measure 4.2.5 requires that ≥95% of women complete all assessment within 15 calendar days of their first attendance at assessment.

RESULTS OF ASSESSMENT

Once the woman has had a percutaneous needle biopsy, every effort will be made to minimise the time for her to receive the results of this procedure. The Service and/or SCU will ensure that all women receive their results verbally as soon as possible. In accordance with Measure 4.2.4, ≥85% of women must be given verbal results of percutaneous needle biopsy within seven calendar days of the assessment procedure.

³⁹ NHS 2010, *Clinical Guidelines for Breast Cancer Screening Assessment*

After completing an assessment episode, all women must be notified of the results of their assessment, in writing, within 14 calendar days in accordance with Measure 4.2.6.

Note that there are no Protocols associated with this Standard.

5

STANDARD 5: DATA MANAGEMENT AND INFORMATION SYSTEMS

Data and information management systems and processes ensure the safe and effective use of data for strategic, clinical management and service improvement purposes.

INTRODUCTION

A unique and important component of an organised population based breast cancer screening program is the collection of consistent data for every individual woman screened and for every episode of screening. The BreastScreen Australia data provided by the state/territory program Client Management Systems are used to:

- organise and manage screening and assessment services through letters of invitation, appointment scheduling and generate results and follow up requirements;
- inform the screening pathway for the woman, and record her clinical management;
- monitor clinical and program outputs and outcomes, and quality management processes;
- develop service improvement strategies;
- assess the Service and/or State Coordination Unit (SCU) for accreditation; and
- undertake service planning and research.

BreastScreen Australia also uses these data at the state/territory and national levels to monitor the implementation of the Program, evaluate its effectiveness and efficiency, and provide the basis for future policy development. It is therefore critical that Services and/or SCU collect high quality data consistent with the BreastScreen Australia Data Dictionary to allow data analysis and reporting of comparative data and performance measures at Service, state/territory and national levels.

The collection of high quality data is also essential for ensuring the appropriate clinical management of individual women and the quality and safety of the screening and assessment services. Data collected are used to monitor quality along every component of the screening and assessment pathway. BreastScreen Australia Services and/or SCUs are required to adhere to BreastScreen Australia, State /Territory and national policies for the collection and management of client information to ensure that the accuracy, confidentiality and security of this information is maintained at all times.

The introduction of digital mammography across BreastScreen Australia has seen changes in work practices away from predominantly manual systems and processes. It has created opportunities in efficiency with the interoperability of Client Management Systems and systems that manage the digital images. The use of digital technology requires the digital mammography images to be managed by a Picture Archive and Communication System (PACS) with screening and assessment workflow managed through a Client Management System. These can be separate systems or ideally, an integrated system where data are shared and distributed across systems. The challenge for the Service and/or SCU is to ensure that adequate quality assurance is in place to verify data consistency and data integrity across systems, and to ensure appropriate security, disaster recovery and back up processes are in place, as there is a high level of dependency on the systems to operate the Services.

The Measures and Protocols in this section are designed to ensure that the data and information management systems and processes are safe, and make effective use of the data for strategic, clinical management and service improvement purposes.

STANDARD 5

Data Management and Information Systems Standard: *Data and information management systems and processes ensure the safe and effective use of data for strategic, clinical management and service improvement purposes.*

| Criterion | NAS Measure | Risk Level | Data Dictionary Measure |
|---|---|------------|--|
| 5.1 The Service and/or SCU ensures the collection of treatment information about women with breast cancer. | 5.1.1 ≥95% of data dictionary compliant surgical histopathology information is received by the Service and/or SCU. | 2 | The percentage of surgical histopathology information received by the Service and/or SCU. <i>Calculation: See Data Dictionary</i> |
| | 5.1.2 ≥95% of data dictionary compliant primary treatment information is received by the Service and/or SCU. | 3 | The percentage of primary treatment information received by the Service and/or SCU. <i>Calculation: See Data Dictionary</i> |

COMMENTARY

COLLECTION OF TREATMENT INFORMATION

Breast cancer screening aims to detect breast cancer early to improve treatment outcomes. Women with a diagnosis of breast cancer are referred outside the Program for management and treatment. While the scope of BreastScreen Australia only extends to the point of diagnosis or referral for diagnostic open biopsy, facilitation of a successful pathway to treatment services is critical if desired positive health outcomes are to be achieved.

There is a range of treatments for breast cancer, including surgery (breast conservation or mastectomy), radiotherapy, chemotherapy and hormonal therapy. Treatment options depend on the type and extent of the cancer. Smaller cancers require less invasive surgery and less aggressive adjuvant treatments.

BreastScreen Australia collects histological outcome data and the primary treatment received by women diagnosed through the screening program.

Histopathology data are used by the Program to assess whether quality standards have been maintained for screening and assessment, and the Program is on track for reducing deaths from breast cancer.

Information about the cancers detected in the screening program and their treatment is also necessary for the radiological and pathological correlation of screen-detected abnormalities, and the implementation of relevant quality improvement strategies.

The Service and/or SCU will implement a protocol to request information from the treating surgeons of all women diagnosed with breast cancer. If the information is not provided by the surgeon, efforts will be made to collect the information from other sources, including the pathology laboratory and/or the woman's general practitioner.

However, there is a point at which efforts to obtain information will cease. This will be at any stage at which the woman indicates that she does not consent, or withdraws consent, to the transfer of such information to BreastScreen Australia. In addition, Services and/or SCUs may stop seeking information if documented unsuccessful attempts have been made to retrieve this information from the surgeon, the pathology laboratories and the general practitioner. Services and/or SCUs will not make contact with the woman solely for the purpose of gaining access to information about treatment.

DATA MANAGEMENT AND INFORMATION SYSTEMS PROTOCOLS

The protocols that Services are to develop and maintain in relation to Standard 5 are:

- 5.1** The Service and/or SCU conforms with requirements of the BreastScreen Australia Data Dictionary, with regard to:
 - a) collection of all required data items; and
 - b) the definitions and methods used by the Service and/or SCU in the calculation of performance measures.
- 5.2** The Service and/or SCU undertakes ongoing quality control procedures for data throughout the screening and assessment process, including:
 - a) review of the completeness and legibility of clinical records;
 - b) review of the consistency between paper and computer records where required and
 - c) verification of the accuracy of the output of system generated reports.
- 5.3** All relevant staff are instructed in procedures to ensure the quality of the data at all levels of the screening and assessment pathway.
- 5.4** The Service and/or SCU ensures effective policies, procedures and protocols to achieve a high level of data security, accuracy, integrity and organisation and systems management.
- 5.5** The Service and/or SCU ensures the integrity and reliability of the file tracking system used.
- 5.6** Each client has one unique identifier within any State and Territory program.
- 5.7** All client records held by all units in the Service and/or SCU are dated and identifiable to the relevant health professional for that part of the screening and/or assessment pathway.
- 5.8** The Service and/or SCU complies with relevant state/territory legislation for the retention and storage of client records.
- 5.9** The Service and/or SCU has disaster recovery systems that address the risk of network failure and data loss from Picture Archiving Communication System (PACS) and Client Management Systems.
- 5.10** The Service and/or SCU has policies, procedures and guidelines for the development and maintenance of high quality Information, Communication and Technology systems.

BREASTSCREEN AUSTRALIA DATA DICTIONARY REQUIREMENTS

The BreastScreen Australia Data Dictionary has been developed as the authoritative source of data definitions used by the BreastScreen Australia Program to meet the need for national consistency in the data collected for program monitoring and evaluation. It was developed to ensure standardisation and comparability of data across the Program. It was also designed to make data

collection activities more efficient, by reducing duplication of effort, and to be more effective, by ensuring that the information collected is appropriate to its purpose.⁴⁰

The objectives of the BreastScreen Australia Data Dictionary are to:

- establish a core set of uniform definitions relating to the full range of BreastScreen screening and assessment services and a range of population parameters;
- promote uniformity, availability, reliability, validity, consistency and completeness in the data;
- accord with nationally and internationally agreed protocols and standards, wherever possible;
- promote the national standard definitions by being readily available to all individuals and organisations involved in the generation, use and/or development of breast cancer screening services information.

The BreastScreen Australia Data Dictionary outlines data items to be collected at the Service and/or SCU level for monitoring and evaluation purposes and for the purposes of client care. However, from time to time there may be additional State and Territory and national data requirements. The use of standard definitions and agreed methods for calculating screening performance measures facilitates comparisons between Services, States and Territories and international breast cancer screening programs.

Each state/territory is required to provide data to the Australian Institute of Health and Welfare on an annual basis in order that AIHW can prepare the BreastScreen Australia Monitoring Report. This report is publicly available and is used to measure the performance of the state/territory programs through a set of key performance indicators. It is therefore critically important that such comparative data are accurate and consistent.

Protocol 5.1 requires the Service and/or SCU to conform to the requirements of the BreastScreen Australia Data Dictionary, with regard to the collection of all required data items and the definitions and methods used by the Service and/or SCU in the calculation of performance measures.

QUALITY CONTROL PROCEDURES

The Service and/or SCU is responsible for ensuring that high quality data are collected for every woman screened in the Program and for every screening episode of care. High quality data will be achieved and maintained through ongoing quality control procedures and appropriate training of all staff.

All States/Territories operate networked Client Management Systems that require ongoing systems and database administration, maintenance and development. Program data must be stored in a secure Client Management System with well maintained, secure, and highly efficient IT infrastructure that ensures data backup and disaster recovery systems are in place.

The Client Management System should have inbuilt validation checks to minimise incorrect data entry and wherever possible the data will be entered at the point of care by the relevant administrative and clinical staff. These safeguards minimise data inaccuracies and potential misinterpretation of data items and are especially critical for the accuracy of clinical information. In a paperless environment, data capture at point of care also increases efficiency and timeliness of data capture.

⁴⁰ AIHW 2015, *BreastScreen Australia Data Dictionary*

Where paper client records are being maintained, all records will be checked for completeness and legibility and quality control procedures will include a review of the consistency between paper and computer records.

The Service and/or SCU will undertake specific verification and quality control procedures to validate the accuracy of the output for any reports generated by the Client Management System. The algorithms used for generating performance measure reports must be consistent with the data items and definitions for the measures contained in the National Accreditation Standards and the BreastScreen Australia Data Dictionary.

Protocol 5.2 requires that the Service and/or SCU undertake ongoing quality control procedures for data throughout the screening and assessment process, including the review of the completeness and legibility of clinical records and of the consistency between paper and computer records where required. In addition the Protocol requires Services and/or SCU to ensure the verification of the accuracy of the output of any system generated reports.

STAFF TRAINING

Services and/or SCUs must provide appropriate training for all relevant staff in the processes and quality control procedures to ensure the quality and integrity of data at all levels of the screening and assessment pathway. This will include having available an up-to-date Data Manual that outlines the processes, data forms (electronic and paper), and that clearly identifies the data items, consistent with the BreastScreen Australia Data Dictionary, to be entered into the Client Management System.

DESIGNATED DATA PERSON

Information is the key driver for maintaining quality and monitoring performance to provide safe high quality screening and assessment services for women. Each BreastScreen Service and/or SCU will have a designated staff member responsible and accountable for the management and governance of data, to ensure the security, accuracy, integrity and organisation of the information captured within the Service and/or SCU. A qualified and specially trained health information manager would generally undertake this role and allocated responsibility. An appropriately authorised person with the necessary knowledge and skills will also be given responsibility for approving data access, use and data analysis (e.g. a qualified cancer epidemiologist may undertake this role).

Protocol 5.4 requires that the Service and/or SCU has appropriate policies, protocols and procedures in place to achieve good data governance and management. The Service and/or SCU will ensure compliance with this Protocol by developing and implementing appropriate quality improvement strategies to address any issues identified by the Data Governance and Management Assessment.

PROTOCOL FOR MANAGEMENT OF CLIENT RECORDS

The client record comprises all information stored electronically relating to an individual client, together with all forms, images and other documentation relating to the client's progress through the screening and assessment pathway. It comprises both clinical and non-clinical client information. The word 'records' means all administrative, financial and health care/medical client records whether in paper or digital form. 'Records' include all documents, images, X-rays, register and electronic data. Accurate client information and data provide the basis for effective and efficient Service and Program management and reliable calculation of performance measures.

In the BreastScreen Australia Program both clinical and non-clinical information is critical for the safe management of women throughout the screening pathway. Clear protocols will be in place in the

Service and/or SCU to manage the movement of the client's record efficiently and effectively along the screening pathway.

Most of these functions are managed and maintained by the Client Management System. This system will need to have the appropriate business rules built into it to ensure each step is undertaken in the correct sequence, and information is available for the next step in the process, as required for each individual woman. This movement of information, including electronic client records and digital images, may be completely electronic or paper based or a combination of both. The protocols will reflect the form of client record and the movement and file tracking system required, that ensures that the right information, for the right woman, is in the right place at the right time for appropriate clinical care to be provided, and the screening and assessment services to be safe and of high quality.

Where multiple screening and/or assessment units, including mobiles, are part of the Service, the protocol will reflect the methods and processes for transfer of client records. These may include among others, electronic transfer, inter or intranet, DVD, paper forms and hard copy images. The protocol will also clearly identify staff responsibilities for every aspect of client record management that may include multiple staff having responsibility for different steps in the screening and assessment service pathway.

UNIQUE IDENTIFIER

The population based breast screening program is underpinned by a register of individual women screened and of every episode of screening. This enables the Program to maintain quality services; to monitor program outcomes at a population level, such as participation rates and at the individual level, by being able to track a woman's screening history, based on her attendance for multiple screening episodes. The Client Management System for each state/territory Program therefore needs to maintain a unique identifier for every individual woman screened in that jurisdiction so that there is no duplication of client records, and information can be accurately analysed and compared across the national Program. A unique identifier is also required to ensure that there is no potential for mismatching client information with the wrong client. This may lead to inappropriate clinical management and clinical and medico legal risk.

CLIENT RECORD IDENTIFICATION

The Service and/or SCU will ensure that all electronic and paper client records include the name and date of the relevant administrative or health professional responsible for the various components of the screening pathway. Electronic records may identify the relevant health professional through authorised individual numerical codes and electronic signatures, for example for the readers. Where paper records are used, the record must be signed by the relevant clinical staff member responsible for that component of the screening and/or assessment pathway.

Client Management Systems should have inbuilt audit checks and the ability to produce an audit trail if required, to identify any authorised or unauthorised changes made to the data. This is important for quality management and any potential medico legal matters.

STORAGE AND RETENTION OF CLIENT RECORDS

Each state/territory has legislative requirements for the storage and retention of all client records held in that jurisdiction. These legislative requirements are prescriptive and usually linked to access to information regulations for the disclosure of clinical information for medico legal matters, government inquiries and reviews. All clinical services are covered by this legislation, which is similar

but not uniform across states/territories. In some cases specific requirements may be set for BreastScreen Services to allow for sufficient episodes of screening to be retained for a clinically appropriate screening history to be established if necessary.

Legislation covers both electronic and paper client records and provides guidelines about the methods that are acceptable for the storage of these records.

The Service and/or SCU will comply with relevant state/territory legislation for the retention and storage of client records.

APPROPRIATE DATA SECURITY

The implementation of digital technology in the BreastScreen Australia Program has transformed the process of image capture and management to the extent that most mammography images and client information are now in an electronic form. This electronic information requires specific standards and guidelines to ensure that the clinical and client information is maintained at a high quality for reading, reporting, assessment and transfer to other clinicians as required. These data, held in electronic form, must be stored securely so that they cannot be deliberately or accidentally altered and so that they are backed up routinely, to protect the loss of information through system failure or corruption.

The PACS administrator is responsible for ensuring that there is a failsafe protocol in place for the timely retrieval of any image that is lost after acquisition. Regular data integrity reports will also be run and checked by the PACS administrator with any systemic errors identified and corrective actions promptly undertaken.

Where data are transmitted across a wide area network through the health system intranet and/or the internet, they must be encrypted or protected by a username and password.⁴¹ The confidentiality of the woman's information must be maintained at all times.

DISASTER RECOVERY SYSTEMS AND BACK-UP PROCEDURES

Each Service and/or SCU must have a disaster recovery system that addresses the risk of network failure and data loss from the PACS and Client Management System.

The transition of the BreastScreen Australia Program to digital technology has led to a greater need for robust processes and risk management to be in place to ensure that the systems are fail safe and that the provision of services is not disrupted or compromised through data loss. The security and integrity of data must be maintained during transmission and storage, and managed so that information is available, accurate and timely to ensure that the woman receives quality care at all points along the screening and assessment pathway. Risk management processes will include an off-site disaster recovery system with redundancy and a back-up system that will protect the integrity of the system functionality and data in the event of a network failure.

The Service and/or SCU will have a disaster recovery system that addresses the risk of network failure and data loss from the PACS and Client Management System. This will be part of an overall quality assurance and risk management approach that includes a business continuity plan that ensures no loss of information or disruption to the delivery of services.

⁴¹ RANZCR 2014 *Standards of Practice for Diagnostic and Interventional Radiology*

HIGH QUALITY INFORMATION, COMMUNICATION AND TECHNOLOGY SYSTEMS

The SCU has responsibility for the central Client Management System in place in the BreastScreen Services. These systems are complex and require designated and specifically qualified staff to manage the system hardware and software applications to ensure that Program data is stored in a secure Client Management System within a properly maintained, secure and highly efficient Information, Communication and Technology (ICT) system. These roles include database administration, maintenance and development and where the system is integrated with the PACS a multi-disciplinary approach will be needed including medical IT system management, PACS administration and medical IT infrastructure support.

Responsible and appropriate information management practice is critical to the success of the BreastScreen Australia Program and to ensure the Program meets legislative and monitoring requirements. There are industry standards for the development of ICT systems such as the PRINCE2 project management approach or state endorsed modified versions of this method and project management approach. Where applicable, the Service and/or SCU will use industry standards to inform the development of policies, procedures and guidelines to ensure the maintenance of a high quality Information, Communication and Technology system in accordance with Protocol 5.10.

6

STANDARD 6: CLIENT FOCUS

High quality information is provided to inform women, and women feel appropriately engaged and supported

INTRODUCTION

A client focussed, high quality service is critical to ensuring that women have a positive screening experience and respond to their invitation to be screened and rescreened at the appropriate intervals. Equally important is the need to provide appropriate information and support to women, to reduce any anxiety a woman might experience at any stage of her screening and assessment pathway.

The Australian Population Based Screening Framework principles, which are based on international experience and research, recommend that the Program be designed to develop and provide information and support for participants across all aspects of the screening pathway.⁴² Best practice ensures that women who participate in the BreastScreen Australia Program are fully informed about breast cancer screening, including the likely benefits and possible harms, as well as any risks or uncertainties related to the screening process. The information provided will need to be sufficient to enable women to give their informed consent to participate in screening and to undergo any assessment investigations that may be required.

In 2013, a national consumer information resource was developed for BreastScreen Australia, to assist women in making an informed decision about participating in screening. The resource, [*BreastScreen and You*](#), can be downloaded from the Department of Health's [website](#).

The involvement of key stakeholders, particularly consumers, in the design and delivery of the Program, also contributes to the provision of a client focused high quality service.

High quality information and availability of counselling are essential if a woman is required to return for assessment, especially if a diagnosis of cancer is made. The way in which a clinician communicates with a woman diagnosed with breast cancer, can have significant impacts for the woman and her family. The provision of appropriate information to assist in decision-making about treatment options, appropriate referral and provision of written information about the woman's status in relation to the Program in future years, all have an impact on women's satisfaction with the care they receive.

Breast Cancer Network Australia (BCNA) has free information resources for women diagnosed with invasive early breast cancer, metastatic breast cancer and DCIS. The My Journey online tool is tailored to support an individual's specific needs. It offers high-quality, evidence-based information and insights from others. Women can be referred via myjourney.org.au/hp. The printed My Journey Early Breast Cancer Guide is available for women diagnosed with early breast cancer who cannot access the Internet. The guide can be ordered at bcna.org.au.

⁴² Commonwealth of Australia 2008, *Privacy Act*

In addition, Cancer Australia provides evidence-based information for women diagnosed with breast cancer which is available on the Cancer Australia website <http://canceraustralia.gov.au>

Note that there are no Criteria or Measures associated with this Standard.

CLIENT FOCUS PROTOCOLS

The protocols that Services are to develop and maintain in relation to Standard 6 are:

6.1 Evidence based written information, which has been approved by the State Coordination Unit (SCU) and is consistent with state and national policies, is available to all women as appropriate throughout the screening and assessment pathway, and includes:

- a) purpose of screening;
- b) likelihood of recall;
- c) possibilities of false positive and false negative results;
- d) uncertainties and risks;
- e) rescreening;
- f) the investigations that may be required;
- g) the benefits, limitations and risks of the investigations; and
- h) the possible outcomes of assessment.

6.2 Women are provided with information on waiting times at each step of the screening and assessment pathway.

6.3 All non-benign assessment results are given to the woman by a medical practitioner of an assessment team. Women diagnosed with breast cancer or recommended for diagnostic open biopsy are additionally:

- a) told their results by a medical practitioner and with a member of staff responsible for providing counselling present, unless the woman specifically asks them not to be, in accordance with the recommendations in the 'Clinical practice guidelines for the psychosocial care of adults with cancer. A summary guide for health professionals (NBCC/NCC I 2005)'; and
- b) encouraged to discuss treatment options with their preferred medical practitioner such as a family doctor or treating surgeon.

Benign assessment results may be delivered by a suitably trained and experienced medical practitioner, breast care nurse or nurse counsellor, on the conditions that:

- the multi-disciplinary team recommendation is for routine re-screening;
- the woman is offered the opportunity for further discussion with a medical officer.

6.4 The Service and/or SCU implements a protocol, consistent with relevant State and Territory policies for a woman to have access to her own records, including copies of images.

6.5 The Service and/or SCU implements a strategy to encourage participation of key stakeholders, including consumers, in its structure, processes and activities.

6.6 The Service and/or SCU actively seeks feedback from women about the acceptability and appropriateness of screening and assessment.

6.7 Women are offered the opportunity to ask questions in private before giving consent for any procedure. Health care providers are available to answer clinical questions.

- 6.8** The consent process provides a record that information has been given and understood, to the woman's satisfaction. This process clearly indicates that the woman may decline or request discontinuance of a procedure at any time.
- 6.9** In accordance with Commonwealth and state and territory legislation, consent is obtained from all women for:
- a) the screening mammogram;
 - b) investigations at the assessment visit;
 - c) her general practitioner, or other doctor to whom she is referred, to be notified of her results;
 - d) the Service and/or SCU to request information about procedures and treatment from doctors to whom she is referred;
 - e) data that identify the woman being transferred for clinical, research and monitoring purposes or released in any form; and
 - f) an invitation to be sent to her for rescreening.
- 6.10** Women with confirmed breast cancer are given the option of referral to a treatment clinic specialising in the treatment of screen detected breast cancer or returning to their nominated general practitioners for referral to an appropriate surgeon.
- 6.11** The Service and/or SCU implements a protocol for the referral of all women with a diagnosis of breast cancer for subsequent management. The Service and/or SCU ensures that all referrals to treating medical doctors include complete and accurate information to enable appropriate management, and include a request for appropriate follow-up information.
- 6.12** The Service and/or SCU ensures that all women with a diagnosis of breast cancer, which has been diagnosed within the Program, are advised in writing of their status, in relation to the Program in future years.

PROVISION OF EVIDENCE-BASED WRITTEN INFORMATION

Providing women attending for breast cancer screening with the appropriate information and support will help to ensure that they have a positive screening experience and reduce any anxiety they may have about the procedures used for screening and assessment. In addition the community recognises that clients of all health services are entitled to make their own decisions about their health care. In order to do so, they must have enough information about their condition, investigation options, treatment options, benefits, possible adverse effects of investigations or treatment, and the likely result if treatment is not undertaken.⁴³

The NHMRC also recommends that information be provided in a form and manner that help patients understand the problem and treatment options available, and that are appropriate to the person's circumstances, personality, expectations, fears, beliefs, values and cultural background.⁴⁴ This implies that different amounts and types of information may be needed by different women attending for screening and assessment. Women who are referred for diagnostic open biopsy or receive a diagnosis of breast cancer will also have different information, counselling and support needs.

⁴³ NHMRC 2004, *General guidelines for medical practitioners on providing information to patients*

Information provided to women who attend a BreastScreen Australia Service for *screening* will include the following:

- The purpose of screening;
- The likelihood of recall;
- The possibilities of experiencing a false positive or false negative result;
- The uncertainties and risks associated with the procedure; and
- The circumstances of rescreening.

The information provided will also advise women of what to expect during the screening process, the process used by the Service to provide results, and of opportunities to provide feedback about the Service.

Information for women who attend a BreastScreen Australia Service for *assessment* will include the following:

- The investigations that may be required;
- The benefits, limitations and risks of the investigations; and
- The possible outcomes of assessment.

The information provided will also advise women of the process used by the Service to provide results following assessment, the availability of counselling and of opportunities to provide feedback about the Service.

Information for women *diagnosed with breast cancer* will include a copy of the relevant consumer guides that have been developed and are available on the [Cancer Australia website](http://www.canceraustralia.gov.au) at www.canceraustralia.gov.au.

In addition, Breast Cancer Network Australia's (BCNA) My Journey Kit is a free resource for women newly diagnosed with breast cancer. The Kit, which has been developed by women with breast cancer, includes a comprehensive Information Guide and a Personal Record. The Kit can be ordered online at the [BCNA website](http://www.bcna.org.au) (www.bcna.org.au).

It is anticipated that Services will use information resources produced by the SCU. If Services produce their own information resources they will be approved by the SCU, be accurate and appropriate, and consistent with state and national policies.

WAITING TIMES

It is widely acknowledged that women experience a level of anxiety when waiting for their screening results. The expected waiting time for screening results must be included in the information resources made available to women at the Service. Staff will also provide this information at the completion of the woman's examination. The Service and /or SCU will ensure that women are notified in writing of their screening results within 14 calendar days in accordance with Measure 4.1.2.

Waiting for an assessment appointment and waiting for the results from assessment are highly stressful periods for women and their support person/s. Measure 4.2.1 sets the requirements for the time periods within which women should attend for assessment. Every effort will be made to meet or exceed these requirements. Women must be informed of the expected waiting time when they are contacted for their recall to assessment.

The waiting time for assessment results will vary based on the investigations undertaken for each individual woman. A woman who does not require a percutaneous needle biopsy will be informed of her results on the day of her assessment visit, in accordance with Measure 4.2.2. A woman who

does have a percutaneous needle biopsy will receive her results verbally within seven days, in accordance with Measure 4.2.4, and in writing within 14 calendar days, in accordance with Measure 4.2.6.

PROVISION OF RESULTS AND CLIENT FOCUSED SUPPORT

All assessment results will be given to the woman by a medical practitioner of an assessment team. The medical practitioner will provide the results, in person to the woman, of the radiological findings and any percutaneous needle biopsy performed as part of assessment within the Program. This will ensure that the implications of these results can be fully and accurately explained to the woman in a way that ensures that she understands the outcome of the assessment investigations. It also enables the woman to ask questions and to be clear about the next steps in her screening pathway, whether it is to return for a rescreen, referral for treatment or further diagnostic investigations. Sometimes a woman may request to receive her results from her family doctor if she is unable to return to the assessment clinic. In these circumstances it is appropriate for a woman's general practitioner to provide the results, however the Service and/or SCU must ensure that the offer is made for her to return to the assessment clinic in the first instance.

The way in which a diagnosis of cancer is delivered affects not only the person's understanding of the illness, but can also impact on their longer-term psychological adjustment (NBCC 2003). Therefore, particular care will be taken in informing a woman of a diagnosis of breast cancer, as her need for emotional support is likely to be more acute. Protocol 6.3 requires that these women are provided with their results in accordance with recommendations from the *Clinical practice guidelines for the psychosocial care of adults with cancer: A summary guide for health professionals* (NBCC/NCCI 2005). The summary provides an overview of the key emotional issues to consider when treating patients with cancer and is available on the [Cancer Australia website](http://www.cancer australia.gov.au) (www.cancer australia.gov.au).

Given the likely distress that the woman will experience by being informed of a diagnosis of breast cancer, every effort will be made to ensure that the woman has a support person with her and that the consultation is conducted in uninterrupted privacy. The woman will also be provided access to a trained counsellor and relevant information materials as identified above. It is likely to be equally distressing for the small number of women who don't receive a definitive outcome recommendation as a result of their assessment investigations and require a diagnostic open biopsy. These women will need clear information, support and counselling, as they will have an extended period of anxiety until they have a definitive histological result that may or may not be breast cancer.

CLIENT FOCUSED SUPPORT

As a client focused BreastScreen Service, it is important to recognise that women may require counselling and support at any time throughout the screening and assessment process. Counselling can assist women in managing anxiety resulting from screening, assessment or a diagnosis of breast cancer.

The Service and/or SCU will implement appropriate policies and protocols to ensure the following:

- All women who attend for screening, and their support persons, have access to counselling.
- All women who attend for assessment or to receive histological results, and their support persons, have access to counselling on site.
- Counselling for women and their support persons is provided in uninterrupted privacy and is appropriate for a screening program.
- If a woman decides to have her results given over the telephone, information about the availability of counselling is provided and counselling is available over the telephone if requested.

- Counselling within the screening and assessment context is aimed at referring women with specific needs for further support to other agencies and assisting this transition.

Counselling may be provided by a nurse, counsellor or other appropriately qualified staff member. However, the specialised knowledge and skill to provide appropriate counselling is best gained through study and supervised clinical practice. Staff providing counselling will have, or be working towards, completing formal recognised/accredited training in counselling. Appropriate training programs exist in most States and Territories.

Professional support is important, including being provided with the opportunity for debriefing staff who provide counselling, to support work practices and to help ensure a high standard of care is provided to women in the Program. It is recommended that all staff providing counselling have access to professional support given by an appropriate counsellor on an as-needs basis.

TREATMENT OPTIONS

When a diagnosis of breast cancer is given, women will be encouraged to discuss treatment options with their preferred medical practitioner such as a family doctor or treating surgeon. Women will be provided with information about treatment options and where to access additional information. The NHMRC's *General guidelines for medical practitioners on providing information to patients* state that women are entitled to make their own decisions about treatments or procedures and will be given adequate information on which to base those decisions.⁴⁴

The following principles form the basis for BCNA's policy work. They can be drawn upon when considering almost any breast cancer policy issue:

- Every woman will be able to access a range of treatment choices so that together with her doctors she can make the best decision for her in her circumstances.
- Women need information to make good choices about their treatment and care.
- Women need to be at the centre of the breast cancer (or health service) system, not an afterthought ([BCNA website](http://www.bcna.org.au) at www.bcna.org.au).

The NHMRC Guidelines recognise that general practitioners have a key role in providing information and support for women to participate in screening and if required through the assessment process.⁴⁵ This supportive role is particularly important if the woman is diagnosed with breast cancer. The general practitioner's ability to provide relevant information and appropriate medical and supportive care for the woman is dependent upon being promptly notified of the results of screening and assessment for their patients.

The Service and/or SCU will implement appropriate policies and protocols to ensure the following:

- All women who attend for screening or who are recalled for assessment are asked to confirm or nominate a general practitioner to whom their results will be forwarded;
- The nominated general practitioner is notified of all results in writing on the same day as the woman;
- All reasonable efforts are made to notify a woman's nominated general practitioner on the day of any diagnosis of cancer or recommendation for diagnostic open biopsy to ensure that support and information can be provided, if required.

A number of other health care providers may play a role in the provision of support to women in some communities. For example, Indigenous health worker, a rural community health worker or an ethnic health worker may be the first person called for information and support by some women. In

⁴⁴ NHMRC 2004, *General guidelines for medical practitioners on providing information to patients*

these cases, at the woman's request, the Service will notify these health care providers of the woman's results as well as her general practitioner.

Further, timely access to a breast care nurse can greatly assist women going through treatment for breast cancer. Breast care nurses improve the continuity of care for women, and provide important information, support and referral for a wide range of needs experienced by women.⁴⁵

ACCESS TO RECORDS, INCLUDING COPIES OF IMAGES

All women who attend a BreastScreen Australia Service have the right to seek access to their personal information including all information held on the Client Management System, hard copy client records and radiological images. This information may be requested for their own personal use and needs or for the transfer of this information to other health care providers. States and Territories have their respective legislation for the provision of personal information to individuals with which BreastScreen Services must comply.

PARTICIPATION OF KEY STAKEHOLDERS, INCLUDING CONSUMERS

Good corporate governance of health services dictates the existence of an effective management or advisory structure with relevant stakeholder representation. The involvement, in the Service and/or SCU, of key stakeholders such as general practitioners or representatives from the relevant professional colleges will provide invaluable, independent and expert advice that will enhance the quality of services delivered.

The inclusion of consumers in the Service and/or SCU structure will help maintain a clear client focus in the delivery of services to women who participate in the Program. This involvement also helps to ensure that the Service's and/or SCU's processes meet the needs and expectations of consumers. The strategy for encouraging key stakeholders, in particular consumers, could be through a formal committee arrangement and/or other formal or informal consultative processes.

Consumer participation is encouraged by developing and implementing a consumer engagement strategy, which may include:

- having representation on policy and/or advisory committees;
- offering access to training and development opportunities to consumers; or
- having a designated member of staff to support consumers.

FEEDBACK FROM WOMEN

A key part of the Service and/or SCU quality improvement approach is ensuring that the standards of service provision meet the needs of women. Feedback will be sought from women about the acceptability and appropriateness of the screening and assessment services. This feedback can be used to identify any issues of concern to women and where improvements could be made in the quality of, and accessibility to, screening services. Feedback could be sought from women through regular client surveys administered at the point of service delivery, or online, and will be anonymous in order to elicit constructive, and where necessary, critical responses.

Examples of the issues that could be covered within client surveys are as follows:

- The acceptability and appropriateness of the written and verbal information provided;

⁴⁵ Further information can be found at the [BCNA website](http://www.bcna.org.au) at www.bcna.org.au

- Waiting times for each component of the screening and assessment pathway;
- The physical environment;
- Satisfaction with the staff, in particular the level and appropriateness of their communication;
- Pain and discomfort experienced during any part of the services provided; and
- An opportunity for women to make comments or suggestions for improvements in the quality of the Service and/or SCU and the opportunity to offer praise as appropriate.

Other methods of seeking feedback from women could be the use of a web based comments or quality rating system that provides an ongoing system for receiving feedback.

INFORMED CONSENT

Informed consent is a person's voluntary decision about medical care that is made with knowledge and understanding of the benefits and risks involved.⁴⁶ Under common law legally competent patients can make their own decision and grant, withhold or withdraw consent before or during examination or treatment. It is considered best-practice that all healthcare providers obtain the client's consent before an examination or providing healthcare.

The *Australian Safety and Quality Framework for Healthcare* (endorsed in 2010) specifies three core principles for safe and high-quality care. These are that care is consumer centred, driven by information and organised for safety. 'Consumer centred care' means that healthcare staff respect and respond to patient choices, needs and values. This means that consumers will have sufficient information that they can understand, and that helps them to make decisions about their healthcare. For BreastScreen Australia, women, their family members and other involved persons will be encouraged to share decision making about their care with the health care providers.

The 'consent to healthcare' process involves the provision of information, discussion and decision making, all of which involve the consumer and the healthcare provider. All these parts of the consent process form part of 'seeking consent'; a signature on a consent form may be one of the end points of the consent process. Consent may be indicated non-verbally (implied consent), orally, or in writing. Consent is the overall process of information provision and decision making, rather than the act of signing a form. Distinction is made in the health literature between the concepts of informed consent and written consent. The UK guidelines for 'Good practice in consent' suggest that a signature on a form is evidence, but ultimately not proof of consent.

There is no legal requirement for consent in healthcare to be in writing. Consent may also be given verbally or implied. Written consent is recommended where there are known significant risks or potential complications associated with the procedure.

In September 2011, Australian Health Ministers endorsed *the National Safety and Quality Healthcare Standards* (NSQHS), which are now the contemporary best practice and national standards for Australian healthcare. Standard 1 "Governance for Safety and Quality in Health Service Organisations" identifies the following principle for informed consent:

Informed consent: A process of communication between a patient and their medical officer that results in the patient's authorisation or agreement to undergo a specific medical intervention. This communication will ensure the patient has an understanding of all the available options and the expected outcomes, such as the success rates and/or side effects for each option.

Standard 1.18 regarding informed consent states that health services will implement processes to enable partnership with patients in decisions about their care, including informed consent to treatment. The processes will ensure that:

⁴⁶ Medical Board of Australia 2010, *Good Medical Practice: A Code of Conduct for Doctors in Australia*

- patients and carers are partners in the planning for their treatment (1.18.1);
- mechanisms are in place to monitor and improve documentation of informed consent (1.18.2);
- mechanisms are in place to align the information provided to patients with their capacity to understand (1.18.3).

It is important for clients attending BreastScreen services to appropriately consent to their participation in the screening program. The principles of providing information to facilitate informed consent are outlined in the NHMRC *General guidelines for medical practitioners on providing information to patients*.⁴⁷ This publication suggests that women considering participating in breast cancer screening services would have the following information about screening to enable them to make a properly informed decision about participating. This information will include:

- The purpose of screening;
- The likelihood of positive and negative findings and possibility of false positive/negative results;
- The uncertainties and risks attached to the screening process;
- Any significant medical, social or financial implications of screening for the particular condition or predisposition; and
- Follow-up plans, including the availability of counselling and support services.

Presenting at the service for a mammogram is evidence of implied consent for the procedure. Consent for storage, the potential use and exchange with other health professionals of health information is another part of the consent process for BreastScreen clients. In addition, a suitable consent process is also needed for women who are undergoing extra investigations for a screen detected abnormality as part of the assessment processes. The consent process for assessment will be consistent for all women and sufficiently detailed to demonstrate the woman was informed of the potential risks and harms as well as the need for the various procedures, that she was provided the opportunity to ask any questions, and understands what tests she will be undergoing.

In accordance with Protocol 6.9, the Service and/or SCU will implement appropriate policies and protocols consistent with Commonwealth and State and Territory legislation to ensure that consent is obtained from all women for the following:

- The screening mammogram;
- Investigations at the assessment visit;
- Notification of results to her general practitioner, or other doctor to whom she is referred;
- Permission for the Service and/or SCU to request information about procedures and treatment from doctors to whom she is referred; and
- The issue to her of an invitation when her next screen is due.

For any research projects where women's identified data are to be accessed and used, the appropriate ethics approvals and consent processes must be observed.

APPROPRIATE REFERRAL

Following a diagnosis of breast cancer, the woman's care will include appropriate treatment and follow-up and access to other specialist facilities, primary care providers and support services. The same approach to ensuring appropriate referral and management will be taken for both invasive breast cancer and DCIS.

⁴⁷ National Health and Medical Research Council (NHMRC) 2004. *General guidelines for medical practitioners on providing information to patients*. Commonwealth of Australia, Canberra.

The woman has the right to choose the health providers to whom she is referred. She may choose to be referred to her nominated General practitioner or a surgeon or treatment clinic with known expertise in the treatment of breast cancer. This may include liaison between the BreastScreen Service nurse/counsellor and a breast care nurse to facilitate continuity of care for the woman.

The Service will facilitate the provision of relevant information resulting from screening and assessment, to assist in planning of the woman's ongoing care. This information may be provided in hard copy or electronic form and, in the case of images, must be in a format consistent with the RANZCR 'Standards of Practice for Diagnostic and Interventional Radiology' for transmitting images.

The Service will implement appropriate protocols to ensure that all referrals to treating medical doctors include the information as outlined within Protocol 6.11. This information will be provided as soon as possible after diagnosis so that the treating clinicians can discuss treatment options with the woman based on her test results.

FUTURE STATUS IN RELATION TO THE BREASTSCREEN AUSTRALIA PROGRAM

Protocol 6.12 requires that all women diagnosed with breast cancer within the Program, and advised in writing by the Service and/or SCU advises them in writing, of their future screening needs and status in relation to the Program. It is not a requirement for Services and/or SCUs to advise women of their status in relation to the Program if they have been diagnosed with breast cancer outside of BreastScreen.

7

GOVERNANCE AND MANAGEMENT

Effective structures and processes are in place, evaluated and continuously improved, to ensure high quality governance and management of the Service and/or State Coordination Unit

INTRODUCTION

A key objective of the BreastScreen Australia Program is: “to achieve high standards of Program management, service delivery, monitoring, evaluation and accountability.” Effective population screening programs depend heavily on governance and management arrangements to guide, support and deliver the program to a high standard. This is to ensure that screening and any follow up assessment services are delivered in a way that will minimise any potential harms arising from screening a well population of eligible women and maximise the benefits of detecting breast cancer early.

The governance structure that has been developed for the quality management of the BreastScreen Australia Program has four key areas of responsibility, which are based on Tricker’s model of governance.⁴⁸ They are: strategic planning and quality improvement; monitoring compliance; reporting; and policy oversight.

This model of governance has been adopted for each level of the Program’s quality management structure:

- The National Quality Management Committee (NQMC);
- The State Quality Committees (SQCs);
- The State Coordination Units (SCUs); and
- The Screening and Assessment Services.

Each level has a defined role in these four key areas of responsibility to ensure a consistent approach across the BreastScreen Australia Program. These roles and responsibilities are outlined in detail in the Accreditation Handbook.

In accordance with the Tricker model, the roles and responsibilities of the Services and the relevant SCU in relation to the NAS will be articulated in a jurisdictional NAS Accountability Framework. This will facilitate a clear understanding of the governance and management structure for the Program in each jurisdiction. The roles and responsibilities of staff in the Service and SCU will also be clearly delineated in a protocol that is consistent with this Framework and covers all the components of the screening and assessment pathway.

The Protocols in this section aim to ensure high quality governance and management of the Service and /or SCU to support the delivery of a high standard of breast cancer screening services in Australia.

⁴⁸ Tricker RI 1994, *International Corporate Governance: Text Readings and Case Studies*, New York: Prentice Hall

Note that there are no Criteria or Measures associated with this Standard.

GOVERNANCE AND MANAGEMENT PROTOCOLS

The protocols that Services are to develop and maintain in relation to Standard 7 are:

- 7.1** The Service and/or SCU implements appropriate position descriptions which describe staff roles and responsibilities.
- 7.2** All staff meet the relevant expertise, experience and training standards outlined in [Appendix C](#).
- 7.3** All staff are trained to ensure an understanding of the policies, protocols and procedures of the Service and/or SCU.
- 7.4** All staff participate in regular clinical breast specific professional development activities.
- 7.5** The Designated Pathologist and deputy/ies:
 - a) participate in the Royal College of Pathologists of Australasia (RCPA) Anatomical Quality Assurance Programs Breast Diagnostic Module; and
 - b) implement the recommendations for quality assurance and uniform reporting of breast FNA cytology and core biopsy in 'Breast fine needle aspiration cytology and core biopsy—a guide for practice (National Breast Cancer Centre 2004)' and 'Invasive breast cancer structured reporting protocol (Royal College of Pathologists of Australasia 2012)', as amended from time to time.
- 7.6** The Service and/or SCU ensures that all screening and assessment units operate in a space, which is clearly identifiable as a BreastScreen Australia service:
 - a) and that screening and assessment of screen-detected abnormalities are exclusively performed at a given time; and
 - b) with dedicated staff and resources.
- 7.7** The Service and/or SCU continually review, assess and implement a detailed quality improvement plan.
- 7.8** For any research projects using screening and/or assessment data, the Service and/or SCU has evidence of Institutional Ethics Committee approval where appropriate and that they have advised the SCU, and the relevant state or territory health department. Where data are to be published, the SCU and state or territory health department is advised and an independent final review is undertaken.
- 7.9** The Service and/or SCU has a management or advisory structure which has representation from all key stakeholder groups.
- 7.10** Where the Service and/or SCU are separate, there is a written contract detailing their respective responsibilities and accountabilities, including compliance with the NAS.
- 7.11** The Service and/or SCU implements financial management systems that maximise efficiency and accountability.
- 7.12** The Service and/or SCU implements, monitors and continually evaluates infection control processes to meet relevant state, territory and national standards.
- 7.13** The Service and/or SCU implements, and continually evaluates, an incident management process that includes the identification, reporting, investigation, analysis, action, feedback and open disclosure of incidents that occur in the

Service and/or SCU.

- 7.14** The Service and/or SCU has an up-to-date Policy, Protocols and Procedures Manual that is maintained and updated regularly, and underpins all aspects of service delivery.
- 7.15** The Service and/or SCU ensures that all the policies, protocols and procedures outlined in the Policy, Protocols and Procedures Manual are implemented, continuously reviewed and improved.
- 7.16** The Service and/or SCU implements an audit schedule to monitor compliance with all policies, protocols and procedures, and where necessary, develops strategies for improving compliance.
- 7.17** The Service and/or SCU has access to appropriate equipment to maximise breast cancer diagnoses.
- 7.18** X-ray systems, premises and users meet radiation protection regulations.
- 7.19** Breast imaging systems, including ancillary items, meet:
 - a) manufacturer's specifications;
 - b) imaging system performance and standards for quality control as specified in Appendices D, E and F; and
 - c) standards relating to storing, retrieving, displaying and transmitting images, in accordance with the RANZCR 'Standards of Practice for Diagnostic and Interventional Radiology'.
- 7.20** Preventative maintenance and repair of imaging equipment meets manufacturer's recommendations or other appropriate standards.
- 7.21** The Service and/or SCU uses pathology laboratories that maintain RCPA National Association of Testing Authorities accreditation.
- 7.22** For new technologies being introduced at the Service and/or SCU the following apply:
 - a) Introduction is in accordance with State and Territory and/or national policies;
 - b) Where relevant, evaluation of the technology is undertaken;
 - c) A protocol for the safe and effective introduction exists;
 - d) Quality assurance protocols are in place and monitored regularly;
 - e) Relevant staff receive appropriate training in the use of such technologies prior to commencing their use; and
 - f) Appropriate information is provided to the client about the new technology and when it is to be used at assessment or screening.

STAFF ROLES AND RESPONSIBILITIES

All BreastScreen Australia Services must operate as an integrated service that includes the operational management of all aspects of the Service and staff. Each component of the screening and assessment pathway requires staff with particular skills and expertise, and clearly delineated roles and responsibilities. Together, these service components form part of a continuum of care for women. It is therefore critical that all staff have a sound knowledge and understanding of all the components of the screening and assessment pathway. This is important so that all staff appreciate the contribution of their role, and their responsibility in providing an optimum quality service to women through the screening and assessment process.

A whole of Service leadership and management approach will be in place to ensure that all staff work collaboratively; as a team. This is particularly important for staff working solely in a screening unit, such as a mobile unit, or in the assessment clinic.

An integrated Service will have formal leadership and management structures that support clear and consistent communication between the staff working in the screening unit/s and the assessment clinic staff. This is particularly critical for the radiography and administrative staff, where liaison and overlap between staff in the screening units and assessment clinic is encouraged and supported.

It is also important that the assessment clinical team includes radiologists who are screen readers, to ensure the appropriate clinical leadership of the radiological component of the service. The clinical skills and expertise required for the multidisciplinary team involved in assessment, is included in Protocol 3.1.

The Service Clinical Director (however named) will have a key role that provides oversight of all aspects of the Screening and Assessment Service and provides overall clinical leadership for the Service. In addition, there are designated clinical leadership roles and responsibilities for radiography, radiology, surgery and pathology that are outlined in [Appendix C](#).

Within the Service there will be formal management processes that support clear lines of communication between staff; and opportunities for clinical and administrative staff to engage in service governance and management, service planning, quality assurance activities and monitoring of Service performance outcomes. These structural arrangements will enhance continuous quality improvement in the provision of breast cancer screening services.

STAFF MANAGEMENT

Routine individual performance appraisal is an essential part of effective staff management. It is best practice to conduct an annual performance appraisal, where every member of staff has the opportunity to discuss their individual work performance with their supervisor or clinical leader. The objective of the appraisal is to ensure that the individual's performance is viewed from a continuous quality improvement perspective, any training needs are identified, and a plan is agreed to address the training or professional development needs of each member of staff.

It is also important that all new staff understand their responsibilities and obligations in relation to confidentiality of an individual's information. Each state/territory will have legislative requirements related to confidentiality and privacy that will determine the content and form of their confidentiality agreements or forms for staff. The Service and/or SCU have a responsibility to ensure that all staff understand and sign the appropriate form on commencement of their employment that complies with the relevant legislation in their jurisdiction.

When employing new staff in the Service and/or SCU, it is essential that they are made aware of the code of conduct expected of them. Services and SCUs are expected to use the local or state health service code of conduct; these may differ across Australia but are likely to be based on similar principles that support a positive work culture free from discrimination and inappropriate behaviour, such as bullying; promote mutual respect and trust among staff; and expect staff to be honest and fair.

EXPERTISE, EXPERIENCE AND TRAINING STANDARDS

All BreastScreen Australia Services are required to ensure that screening and assessment services are provided by qualified staff who have the appropriate expertise and experience and meet the training standards specified by the relevant college or professional organisation. The training standards required by each of the clinical disciplines are outlined in [Appendix C](#). Staff will be

appropriately qualified in their clinical discipline to work in the Program and specifically trained in breast cancer screening. It is essential that training opportunities and programs are available for all new clinical staff to complete as part of their probationary period, or as soon as practicable after commencing their role in the Service and/or SCU.

BreastScreen Australia has agreed standards for minimum training requirements for relevant clinical disciplines such as radiographers, mammography practitioners and radiologists. Training programs that are currently operating in Australia, are offered as part of the state/territory BreastScreen Program, and may be based within the Service, at a University, or a combination of both. These training programs have been endorsed or supported by the relevant professional organisations, being the Australian Institute of Radiography (AIR) and the Royal Australian and New Zealand College of Radiologists (RANZCR).

SERVICE AND/OR SCU POLICIES, PROTOCOLS AND PROCEDURES

The Service and/or SCU will ensure the delivery of consistently high quality breast cancer screening services, irrespective of where a woman attends for screening. This is achieved through the implementation of standard, evidence based policies, protocols and procedures across the Program that underpin the services delivered⁴⁹. This also allows quality assurance processes to accurately monitor and measure the performance of all aspects of the Service so that high standards of care are maintained and improvements can be made as necessary. All Service and SCU staff must receive training in the Program policies, protocols and procedures; to ensure that they have a clear understanding of their importance for the delivery of consistent quality breast cancer screening services; how they apply to the screening and assessment pathway and their relevance to the individual's role and responsibilities.

All new staff in the Service and/or SCU will be provided with orientation and induction training programs. These will include:

- an introduction to population screening principles;
- an introduction to the BreastScreen Australia Program; its aims and objectives; and
- information about all aspects of the delivery of high quality breast cancer screening and assessment services, including policies, protocols and procedures, and the relevant quality management plan.

These programs will specifically include training in client focused communication, which recognises the importance of helping women to understand the information with which they are provided, particularly given that many women may be somewhat anxious about initiating contact with the Program or attending the Service.

In some situations an orientation and /or induction program will be available as part of the local or state health service to cover generic employment arrangements, conditions and entitlements and may include consumer rights and cultural awareness training. The Service and SCU will arrange for the appropriate orientation and induction to be provided, either as an internal or combined external and internal program, to ensure that all the relevant areas of training are covered.

It is also important to provide all new staff with information about the relevant disability and interpreter services and occupational health and safety requirements.

As part of ongoing training and continuing education, all staff are required to maintain and improve their skills and knowledge and to ensure that the Service and/or SCU delivers up-to-date, high

⁴⁹ Commonwealth of Australia 2008, *Privacy Act*

quality services for women. All staff will participate in ongoing training, continuing education and quality improvement programs. In order to maintain a focus on quality improvement the Service and/or SCU will provide at least six hours of appropriate in-service training annually. In-service training will be arranged by the Service and/or SCU but may be provided by and conducted at the Service or by an external training provider.

PROFESSIONAL DEVELOPMENT

The Service and SCU will develop and implement a planned approach to ongoing professional development for both clinical and administrative staff. This will be linked to the individual's performance appraisal and the relevant professional organisation. Due to the multidisciplinary nature of the Program, it is important that continuing education programs foster both unidisciplinary and multidisciplinary education.

CLINICAL STAFF

When unidisciplinary education occurs for the specific clinical disciplines, it will be conducted in conjunction with the relevant professional college or organisation. Each of the colleges of radiology, surgery and pathology has a special interest group that provides or promotes ongoing professional education and recognition of specific skills in breast imaging, breast cancer diagnosis, management and treatment. These professional colleges offer both unidisciplinary and multidisciplinary professional development opportunities that may include conferences, seminars, workshops, clinical audits, communication and information sharing portals and networking.

Clinical staff will be encouraged to participate regularly in these groups and attend educational programs offered in addition to the in-service training provided by the Service and/or SCU. Continuing professional development is required to maintain and improve their knowledge, expertise and competence and is an obligation of a registered health practitioner.

Overall clinical leadership in the Service and/or SCU will be enhanced through inclusive professional development and educational programs that encourage all clinical staff to participate, on a regular basis, in the assessment component of the service, case reviews and multidisciplinary educational meetings. This allows all staff to understand and gain knowledge about:

- the various components of the screening and assessment pathway;
- the clinical outcomes that the Service is delivering;
- participation in the development and implementation of local quality improvement processes.

NON-CLINICAL STAFF

For non-clinical staff in the Service and/or SCU, in-service training will be linked to their performance appraisal and tailored to meet their professional development needs, either through the appropriate professional organisation for their discipline or a recognised training provider. In-service training may also include programs developed by the Service and/or SCU that are designed to enhance individual or whole of Service performance, such as communications workshops or updates on business processes. These programs may be provided internally or externally by appropriately qualified personnel and will be part of an overall focus on quality improvement.

DEDICATED PROVISION OF BREASTSCREEN AUSTRALIA SERVICES

One of BreastScreen Australia's aims is "to ensure that screening for breast cancer in Australia is provided in dedicated and accredited Screening and Assessment Services as part of the BreastScreen Australia Program". This program model was based on international experience and the findings of the original pilot studies undertaken prior to the establishment of the Program in Australia. This

model has been found to be acceptable to women, effective in achieving the aims of the Program and cost efficient.⁵⁰

Services and/or SCUs will ensure that all facilities operating as part of the integrated screening and assessment service are clearly identifiable as a BreastScreen Australia Service. This recognises that the facility is part of an accredited BreastScreen Service that has achieved the quality standards required for the Program, and provides reassurance to women that the services provided are of a high quality and routinely monitored. The identification of the Service facility with clear signage, also enables women attending the Service to easily locate the Service, particularly if it is provided in a co-located setting with other health services.

BreastScreen Australia is a population based screening program provided for well women and most women who participate in the Program will not have breast cancer. Therefore these well women should be screened and assessed separately from women attending for diagnostic investigations or for the management of an identified breast cancer. This is critically important for women participating in the Program for two reasons; the organisation of screening services requires a rapid throughput of well women to ensure the most efficient use of the equipment; and the shortest possible time to be taken for the woman to attend for her routine screening appointment, is preferable. This encourages many busy women in the target age group to attend.

Women attending for screening have very different expectations from women undergoing diagnostic investigations for symptoms or management of their breast cancer. While the women attending for screening may be somewhat anxious, this will differ from the level of anxiety experienced by women with suspected or identified breast cancer. Providing these services separately is better for both groups of women and will ensure that the level of anxiety about the outcome for women attending for screening is not unduly increased. This is important as increased anxiety may discourage women from returning for future screening.

Other important differences that support the need for screening and assessment services to be separated in space and/or time from diagnostic imaging and/or breast cancer management services are:

- The differing information needs of the women;
- The differing data collection and consent processes;
- The time that is required for a woman undergoing diagnostic investigations or the management of her breast cancer; and
- The level of counselling and support that is required by individual women.

All screening and assessment units must operate either in a dedicated facility, or within a facility at a dedicated time allocated for the exclusive use of women attending for screening or assessment as part of a BreastScreen Service. Staff, equipment and other resources must be dedicated to the provision of screening or assessment services in the dedicated facility, or for a dedicated time in a facility. The space available for the dedicated provision of screening or assessment services must include an appropriate separate waiting area for women. The screening and assessment services may be co-located and provided as part of a breast care service and/or other health service, such as a screening service located in an Aboriginal and Torres Strait Islander Health Service.

QUALITY IMPROVEMENT PLAN

BreastScreen Australia has a comprehensive quality management program supported at the national, state and territory and Service level. The roles and responsibilities of each level of the

⁵⁰ BreastScreen Australia 2009, *BreastScreen Australia Evaluation Final Report*

Program's quality management structure are outlined in detail in the Accreditation Handbook. Compliance with the BreastScreen Australia NAS is a critical component of the quality management program.

The Service and/or SCU will develop and implement a quality improvement plan that includes clear lines of clinical and management responsibility. The quality improvement plan will identify strategies for each component of the screening and assessment pathway that will support and enhance the quality of breast cancer screening services for women.

All staff will be aware of, and involved in the development of the quality improvement plan. This will help ensure high levels of compliance with the implementation of strategies that support a continuous quality improvement approach for the delivery of breast cancer screening services. The quality improvement plan will include as a minimum:

- incident and complaints management;
- case review;
- review of missed cancers and interval cancers;
- educational meetings;
- review of comments from consumers and other key stakeholders such as general practitioners;
- provision of unidisciplinary and multidisciplinary professional development activities; and
- review of Service protocols and procedures.

Staff will be supported and encouraged to participate in the relevant quality improvement activities and be actively informed about national and state directions in quality improvement.

The quality improvement plan will maintain a focus on continuous quality improvement within the Service and/or SCU by monitoring the Service and Program performance against the NAS. The review of the program data will be undertaken every 6 months and used to identify any current and emerging issues. Analysis of these data will inform the need to develop and implement quality improvement strategies to address any issues identified.

Service and/or SCU quality improvement plans must be reviewed annually and copies provided to the SQC and NQMC respectively and as part of any application for accreditation. A template quality improvement plan is available for use by Services and/or SCUs (refer BSA006).

Many services routinely audit all breast pathology reports for clients undergoing surgery. In the event that a Service and/or SCU identifies a quality issue, 300 consecutive pathology reports over a two year period should be audited, in order to review pathology reporting practice in accordance with *Invasive breast cancer structured reporting protocol* (RCPA 2012) and provide a basis for instituting quality improvement measures in pathology reporting. This will be conducted by a pathologist within or outside the Program.

USE OF SCREENING AND ASSESSMENT DATA

The BreastScreen Australia Program collects and collates a significant number of clinical and non-clinical data that are valuable for researchers across a range of disciplines. However, the use of these valuable data is governed by confidentiality and privacy legislation and must only be used for ethical purposes and ideally, to advance knowledge related to breast cancer screening or breast cancer management and treatment. Therefore for any research project that uses Program data, the Service and/or SCU must have Institutional Ethics Committee approval and/or comply with state/territory level ethics approval requirements as appropriate, including for the use of non-identifiable data. Where the research project is Service based, the SCU must be advised and as appropriate the relevant state or territory health department. Where data are to be published, including on any web

based publication site, the SCU and the state or territory health department must be advised prior to publication, and an independent final review undertaken.

MANAGEMENT AND ADVISORY STRUCTURES

The implementation and operational management of the national BreastScreen Australia Program is the responsibility of the states/territories. The Program must operate within national policies, in accordance with the National Health Reform Agreement (2012) and direction from the COAG Council on Health as appropriate.

SCUs have state level stewardship and management responsibility for the Program and undertake a range of functions, as outlined in the SCU roles and responsibilities in section 2.4 of the Accreditation Handbook. It is an important component of good corporate governance to establish an effective advisory structure, with relevant stakeholder representation, to provide advice on policy and strategic planning and to oversee the management of the Program, the SCU functions and the delivery of high quality breast cancer screening Services. Therefore the Service and/or SCU will have a management or advisory structure that has representation from all key stakeholder groups to provide this independent and expert advice.

Key stakeholder groups that may be included in a management or advisory structure are:

- the professional colleges or specialties of radiology, surgery, pathology and general practice;
- the Australian Institute of Radiography;
- relevant non-government organisations and agencies, such as the Cancer Council;
- women's health groups, including women with special needs; and
- consumers.

NATIONAL ACCREDITATION STANDARDS ACCOUNTABILITY FRAMEWORK (NAF)

There are differing business and service delivery models in place across Australia for the BreastScreen Australia Program. Consequently, Services and SCUs within each jurisdiction are likely to have different levels of accountability and responsibility for the Measures within the NAS. Some Measures may have shared responsibility between the Service and SCU, whereas other Measures may be wholly the responsibility of the Service or the SCU.

A key focus of the accreditation system is to ensure that the appropriate accountability is recognised when assessing the Service and SCU performance against the NAS. To achieve this, in multi-service jurisdictions where the SCU and Service are separate, these jurisdictions must develop a state level agreement with each Service in the jurisdiction, known as the NAS Accountability Framework. The (NAF) will clearly outline the Standards, Criteria and Measures that are the responsibility of the SCU and those that are the responsibility of the individual Service in that jurisdiction.

An SCU may need to establish a NAS Accountability Framework for each Service within a State, to reflect differing arrangements for service delivery such as mixed models of public and private sector providers. The NAS Accountability Framework will be developed by the SCU collaboratively with the Services and in consultation with stakeholders such as the Local Health Services. Throughout this document the responsibilities of the Service and those of the SCU are not differentiated. In all instances they are documented as the Service and/or SCU. The differentiation will be made in the NAF.

The NQMC will refer to the NAF in its consideration of an application for accreditation. This document will inform the NQMC in awarding individual Services and SCUs with an accreditation

status in accordance with the agreed Decision Tool. The details of the Decision Tool are included in the Accreditation Handbook.

FINANCIAL MANAGEMENT SYSTEMS

The state/territory SCU has overarching responsibility for the jurisdictional Program and the quality of all aspects of the screening and assessment services provided by the Services. This line of responsibility helps to ensure that high standards are maintained across the state/territory using the available Program resources efficiently and effectively to achieve consistent, high quality service delivery.

To maximise the efficient use of Program funds, it is appropriate for the SCU to implement a funding system with Services, consistent with other models of health service funding that use a payment for outcomes. This approach will provide positive incentives for achieving the desired annual screening throughputs for the Service catchment.

In addition, the Service and/or SCU is responsible for the efficient management of financial resources to ensure that the aims and objectives of the Program are met within the agreed budget. A sound financial management system will be in place that has clear lines of financial delegation and monitoring systems to ensure accountability for funding and the services delivered.

INFECTION CONTROL

Infection control is accepted as best practice in the provision of quality health care services. The Australian Commission on Safety and Quality in Health Care has national infection control standards that guides clinical practice in relation to infection control in BreastScreen Australia Services. In addition, Services must comply with the relevant state/territory and national legislation governing infection control and occupational health and safety.

The Service and/or the SCU will implement and continually evaluate the infection control system in the Service, and ensure that review of the relevant protocols and procedures is included in the quality improvement plan. This is an important aspect of Service management, as it will help ensure the safety of both the staff and the women attending the Service. Implementing these protocols and procedures requires a clear understanding of their importance and a strong commitment from all staff.

INCIDENT AND COMPLAINT MANAGEMENT

A continuous quality improvement approach to the provision of breast cancer screening services is critical to ensuring that the BreastScreen Australia Program is provided in a way that balances the known benefits and potential harms of population screening for breast cancer.

A key part of this approach is ensuring that all incidents, adverse events and complaints are managed well. This requires that they are identified, reported, prioritised, investigated and analysed, and that lessons are learnt and improvements are implemented in order to mitigate or eliminate the risk of such events recurring in the future. Each jurisdiction must develop and implement an incident and complaints management process in accordance with the national recommendations for managing adverse events, as outlined in Section 9 of the Accreditation Handbook.

POLICY, PROTOCOL AND PROCEDURES MANUAL

For the BreastScreen Australia Program to be implemented consistently across Australia, it is important that the state/territory responsible for the implementation and management of the Program in their jurisdiction develops and implements a Policy, Protocols and Procedures Manual. The Manual will be consistent with national and state/territory Program policies and based on:

- current research evidence or evaluation outcomes;
- relevant national clinical guidelines; and
- best practice principles for delivery of quality breast cancer screening services, that may be established through benchmarking achievement against current NAS.

The development of the Manual will translate the national and state/territory policies into operational protocols and procedures that will be implemented in the Service and/or SCU as appropriate.

Protocols will state the evidence based best practice that needs to be used in a particular situation. The procedures define the staff responsible, the actions and the processes to be undertaken to comply with the protocol.

Procedures are usually locally based and may vary from Service to Service to take account of the resources available and the local needs and circumstances of each Service. All screening and assessment units within a Service must operate under the same set of procedures, and the policies and protocols in the Manual will be common across all Services and/or SCU in that jurisdiction, so meaningful monitoring of performance measures can be made across the jurisdictional program.

IMPLEMENTATION, CONTINUOUS REVIEW AND IMPROVEMENT

For consistent best practice to be achieved in the delivery of breast cancer screening services, strategies will be developed to ensure that the Policy, Protocols and Procedures Manual is effectively implemented and reviewed. All staff will undergo training to gain an understanding of the policies, protocols and procedures of the Service and/or SCU to better support their implementation. Self-paced learning tools that are made available on the web or in digital form, could also be used to provide orientation to new staff about the Manual and its use, or when there are changes made to the policy, protocol or procedures.

Regular review and improvement of the Policy, Protocols and Procedures Manual is an important strategy in continuous quality improvement for the Service and/or SCU, as it allows for new evidence or information to be incorporated, which could enhance the quality of services, and improve the effectiveness and efficiency for the Program. This review will be undertaken at the jurisdictional level in consultation with the Services and relevant stakeholders, as well as national organisations as appropriate, such as Cancer Australia.

To ensure that implementation and continuous review occur, it would be appropriate for a designated member of the Service and SCU staff to be responsible for the implementation and review of the Policy, Protocols and Procedures Manual.

AUDIT OF COMPLIANCE WITH THE POLICY, PROTOCOLS AND PROCEDURES MANUAL

To ensure that the Service and/or SCU complies with the implementation of the Policy, Protocols and Procedures Manual, an internal audit schedule will be in place that actively monitors compliance with the policies, protocols and procedures.

The audit schedule could be undertaken for different components of the screening and assessment pathway and be the responsibility of the relevant designated clinical leaders or management.

The audit schedule will also be included in the Service and/or SCU quality improvement plan, with designated time periods for the audits to be undertaken. Any lack of compliance would need to be addressed and strategies implemented to rectify the lapse, such as re-training of the relevant staff and/or performance appraisal and management of individuals. The audit process will take a continuous quality improvement approach.

The value of auditing compliance with the Policy, Protocols and Procedures Manual is to enable a Service and/or SCU to demonstrate to women that the service they receive is operating in accordance with evidence based policies, protocols and procedures that will achieve the NAS. In the case of a medico legal claim or complaint, a well-documented audit process will potentially enable the Service and/or SCU to demonstrate that these policies, protocols and procedures were being complied with, the designated time period that policies, protocols and procedures were in place and if there have been changes made to the policies, protocols and procedures.

HIGH QUALITY SCREENING AND DIAGNOSTIC EQUIPMENT

BreastScreen Australia aims to maximise the number of cancers detected while minimising the number of unnecessary recalls and investigations. This can only be achieved if each step in the screening and assessment pathway is of high quality.

The BreastScreen Australia Program has transitioned to digital technology following international trends in breast cancer screening programs to the exclusive use of digital mammography for image acquisition and Picture Archiving and Communication Systems (PACS) for soft copy reading. The Digital Mammography Imaging Study (DMIST), undertaken by the United States of America Cancer Institute⁵¹ found that digital mammography was as effective as film screen mammography in overall breast cancer detection and may have particular benefits for younger women and women with denser breasts.

The Service and/or SCU will ensure that digital mammography systems are available, to provide high quality screening images in the Service including mobile units. The minimum acceptable technology to be used by BSA Services is Digital Radiography technology. Services must not use Computed Radiography (CR) mammography systems.

All assessment units within the Service must have the digital equipment available to undertake stereotactic-guided percutaneous needle biopsy and specialist breast ultrasound equipment. Ultrasound equipment must meet the specific requirements for breast ultrasound, be appropriately calibrated, maintained and subject to quality control procedures as outlined in [Appendix F](#). This equipment will also need to have sufficient capability to accurately provide ultrasound guided percutaneous needle biopsy when clinically indicated. Breast ultrasound equipment must be fit for purpose and ideally be a stand-alone unit specifically designed for breast investigations and not used for other ultrasound investigations.

It is important to optimise the use of digital technology for the Program through the use of digital mammography to maximise screening capacity. Wherever possible secure intranet or internet will be used to move images from the point of acquisition to the PACS. An effective use of these structural resources can also be made by integrating the Client Management System with the PACS to enable seamless management of the screening images linked to the woman's clinical information to achieve efficiencies and improve timeliness along the screening and assessment pathway. This

⁵¹ Pisano 2005, *Diagnostic Performance of digital Versus film Mammography for Breast Cancer Screening*

integrated system allows for the transition to paperless data capture and will enhance the accuracy and timeliness of information, as it is entered at the point of care by the relevant staff and/or clinician.

RADIATION PROTECTION LEGISLATION

All states and territories have radiation protection legislation that regulates the use of radiation equipment and systems, the facility using the equipment and the staff who operate the equipment. The Service and/or SCU must meet the relevant radiation protection regulatory requirements in their jurisdiction.

QUALITY CONTROL FOR BREAST IMAGING SYSTEMS

Digital mammography equipment requires a high level of quality assurance to ensure that the image captured and presented for reading is of the highest standard. All breast imaging systems including mammography and ultrasound equipment must be configured appropriately and operate in accordance with the manufacturer's specifications.

Digital mammography equipment operates through vendor specific software and algorithms that determine the parameters to achieve the final digital image for reading. The optimal mammogram for screening is to achieve the best image with the minimum dose of radiation. This is important as women are screened every two years. There is a high level of variability in the appearance of mammograms produced by the different mammography equipment offered by vendors. It is therefore important that the Designated Radiologist and the readers agree on the standard algorithm to be used by the Service to ensure the optimal image is consistently produced for the readers.

READING WORKSTATIONS

Quality assurance procedures are also needed for the reading workstations. These must be comprehensive and include daily checks, cleaning and inspection and weekly testing of the monitors used for reading. The ambient light in the reading room is critically important in optimising the reading environment. Specific standards for the optimal digital reading environment have been developed by the ACPSEM and are contained in [Appendix D](#). These standards are congruent with those endorsed by RANZCR.

IMAGE STORAGE, RETRIEVAL AND TRANSMISSION

Adherence to standards for storing, retrieving, displaying and transmitting images is critical to ensuring the consistency of appearance of the mammographic images produced. The optimal image must be stored, retrieved and displayed appropriately, using consistent standardised hanging protocols. These standards also ensure that retrieved and transmitted images are of diagnostic quality and that image compression for storage and transmission does not compromise the images. Services and/or SCUs must therefore ensure that protocols are developed and implemented for the standardised storing, retrieving, displaying and transmission of images that comply with the RANZCR 'Standards of Practice for Diagnostic and Interventional Radiology'.

QUALITY ASSURANCE TESTING

Testing of breast imaging equipment must be performed in accordance with the latest ACPSEM Position Paper: 'Recommendations for Digital Mammography Quality Assurance Program'.

All breast imaging equipment and ancillary items will meet these minimum performance standards to ensure clinical safety and quality for all women screened and assessed. The equipment

performance shall be confirmed at acceptance, annually and following major maintenance by, or under the close supervision of a suitably qualified and experienced medical physicist as specified in [Appendix C](#). At acceptance, more extensive testing of breast imaging equipment will be performed in accordance with the ACPSEM recommendations.

Each Service and/or SCU must have access to a medical physics service that can perform imaging system performance evaluations and provide advice on quality control, equipment selection, optimisation of image quality and radiation dose, and general radiation protection matters.

PREVENTATIVE MAINTENANCE

The quality of the breast screening image, the assessment procedures and the ability of the Program to maximise the detection of early breast cancer is dependent on the quality of the equipment used. It is therefore not only important to implement stringent quality control measures as outlined above but to ensure that all imaging and PACS equipment used in the Service have ongoing checks and regular maintenance and repair so that the equipment is safe and effective. This regular maintenance will be undertaken in accordance with the manufacturer's recommendations or other appropriate standards.

USE OF ACCREDITED PATHOLOGY LABORATORIES

The BreastScreen Australia Program requires the highest standards of pathology to provide accurate definitive clinical outcomes for women screened and assessed in the Program. Therefore the Service and/or SCU must only use those pathology laboratories that maintain accreditation through the Royal Australasia National Association of Testing Authorities.

SAFE INTRODUCTION OF NEW TECHNOLOGIES

There is currently a rapid expansion of new technologies for the detection and diagnosis of breast abnormalities. BreastScreen Australia needs to be up-to-date with recent developments and ensure that the most appropriate high quality screening and assessment services are being provided to women. BreastScreen Australia has a duty of care to clients to ensure that any new diagnostic technique introduced into the program for screening and assessment has undergone appropriate evaluation of client safety, diagnostic efficiency and a formal economic evaluation of cost effectiveness. It is important that safety and quality are carefully assessed by the Service and/or SCU and/or NQMC in considering when, how, and if to introduce new technologies.

It is the responsibility of the Service and/or SCU to consider the introduction of new technologies within the context of national and state and territory policies as well as the NAS and other relevant national standards. In this context, 'new technologies' are technologies that have not yet been used or approved for the screening and assessment of women within the BreastScreen Australia program.

Before a new technology is introduced into the Service, there must be evidence that it is safe and effective in the screening and assessment setting. Before introducing a new technology, the Service and/or SCU will seek advice from the SQC and/or NQMC and conduct an appropriate evaluation of the technology. The introduction of the new technology by the Service and /or SCU will be considered based on a number of factors. These include:

- The cost effectiveness of the technology;
- The cost implications for the Program including replacement and recurrent costs;
- The clinical benefits and any potential harms of the technology for women;
- Acceptability of the new technology to women; and

- Results of past or ongoing evaluation studies.

State services intending to introduce a new or novel diagnostic procedure or process that is significantly different from current clinical practice will provide a submission of intent to utilise, to the NQMC for oversight.

The evaluation of any new technology will include clinical outcomes and client acceptance as key criteria for determining the introduction of the technology. Reviews by the Medicare Services Advisory Committee and the Therapeutic Goods Administration may help inform the decision making process for determining whether a new technology will need to be evaluated, for consideration of the technology for use in breast cancer screening and assessment.

The introduction of any new technology will require a clear protocol for its safe and effective introduction. New technologies may require configuration with existing equipment, an assessment by a medical physicist and relevant staff to ensure that images are of an appropriate standard and able to be transferred without loss of quality to the PACS. Quality control procedures will need to be developed and documented prior to commencing the use of the new technology.

The safe and effective introduction of new technology requires a high level of practical clinical skills and competence. Services require adequate resources and appropriate infrastructure to ensure client safety and clinical procedural effectiveness for patients. Before a new technology is introduced, training (including change management training) will be provided to all relevant staff.

The effectiveness of newly introduced technologies will be monitored by the Service and/or SCU as part of their quality improvement program. Services that experience any serious adverse clinical outcomes of the utilisation of any new technology or new techniques will report this expediently to the NQMC who will notify the Standing Committee on Screening of any significant adverse clinical outcomes.

APPENDICES

APPENDIX A:

LIST OF NATIONAL ACCREDITATION STANDARDS, CRITERIA, MEASURES AND PROTOCOLS

STANDARD 1: ACCESS AND PARTICIPATION

Appropriate levels of access to and participation in BreastScreen Australia are achieved in the target and eligible populations.

Criterion 1.1 – The Service and/or SCU maximises the participation of women in the target age groups for screening and rescreening.

Measures

- 1.1.1** a) The Service and/or SCU monitors and reports the participation rate of women aged 50–74 years who participate in screening in the most recent 24-month period.
b) $\geq 70\%$ of women aged 50–69 years participate in screening in the most recent 24-month period.
- 1.1.2** a) The Service and/or SCU monitors and reports the proportion of women aged 50–72 years who attend for their first screening episode within the Program who are rescreened within 27 months.
b) $\geq 75\%$ of women aged 50–67 years who attend for their first screening episode within the Program are rescreened within 27 months.
- 1.1.3** a) The Service and/or SCU monitors and reports the proportion of women aged 50–72 years who attend for their second and subsequent screen within the Program who are rescreened within 27 months of their previous screening episode.
b) $\geq 90\%$ of women aged 50–67 years who attend for their second and subsequent screens within the Program are rescreened within 27 months of their previous screening episode.

Criterion 1.2 – BreastScreen services are accessible to the target and eligible populations, especially women from Indigenous; culturally and linguistically diverse; rural/remote; and lower socioeconomic backgrounds and women with a disability.

Measures

- 1.2.1** a) The Service and/or SCU monitors and reports participation of women aged 50–74 years from special groups and where rates are below that of the overall population, implements specific strategies to encourage their participation in screening. Consideration of equitable participation rates of at least the following groups is made: Indigenous, women from culturally and linguistically diverse, rural/remote and lower socioeconomic backgrounds.

b) The Service and/or SCU monitors and reports participation of women aged 50–69 years from special groups and where rates are below that of the overall population, implements specific strategies to encourage their participation in screening. Consideration of equitable participation rates of at least the following groups is made: women from Indigenous, culturally and linguistically diverse, rural/remote and lower socioeconomic backgrounds.

- 1.2.2** a) The Service and/or SCU monitors the proportion of all women screened aged 40–49 years and 75 years and over.
b) The Service and/or SCU monitors the proportion of all women recalled for assessment aged 40–49 years and 75 years and over.

STANDARD 2: CANCER DETECTION

Breast cancer detection is maximised in the target population and harm is minimised.

Criterion 2.1 – The Service and/or SCU maximises the detection of invasive breast cancer in the target population.

Measures

- 2.1.1** a) The Service and/or SCU monitors and reports the proportion of women aged 50–74 years who attend for their first screening episode who are diagnosed with invasive breast cancer.

b) ≥ 50 per 10,000 women aged 50–69 years who attend for their first screening episode are diagnosed with invasive breast cancer.
- 2.1.2** a) The Service and/or SCU monitors and reports the proportion of women aged 50–74 years attend for their second or subsequent screening episode who are diagnosed with Invasive breast cancer.

b) ≥ 35 per 10,000 women aged 50–69 years who attend for their second or subsequent screening episode are diagnosed with invasive breast cancer.
- 2.1.3** a) The Service and/or SCU monitors and reports the proportion of women aged 50–74 years who attend for their first screening episode who are diagnosed with small ($\leq 15\text{mm}$) invasive breast cancer.

b) The Service and/or SCU monitors the proportion of women aged 50–74 years who attend for their second or subsequent screening episode who are diagnosed with small ($\leq 15\text{mm}$) invasive breast cancer.

c) ≥ 25 per 10,000 women aged 50–69 years who attend for screening are diagnosed with small ($\leq 15\text{mm}$) invasive breast cancer.
- 2.1.4** a) The Service and/or SCU monitors and reports the proportion of women aged 50–74 years who attend annually for screening, who are diagnosed with invasive breast cancer.

b) The Service and/or SCU monitors and reports the proportion of women aged 50–74 years who attend annually for screening, who are diagnosed with small ($\leq 15\text{mm}$) invasive breast cancer.

c) The Service and/or SCU monitors and reports the proportion of women aged 40–49 years who attend annually for screening, who are diagnosed with invasive breast cancer.

2.1.5 The Service and/or SCU monitors and reports the proportion of women aged 40–49 years and 75 years and over who are diagnosed with invasive breast cancer.

2.1.6 The Service and/or SCU monitors and reports the proportion of women aged 40–49 years and 75 years and over who are diagnosed with small ($\leq 15\text{mm}$) invasive breast cancer.

Criterion 2.2 – The Service and/or SCU maximises the detection of ductal carcinoma in situ (DCIS).

Measures

2.2.1 a) The Service and/or SCU monitors and reports the proportion of women aged 50–74 years who attend for their first screening episode who are diagnosed with DCIS.

b) ≥ 12 per 10,000 women aged 50–69 years who attend for their first screening episode are diagnosed with DCIS.

2.2.2 a) The Service and/or SCU monitors and reports the proportion of women aged 50–74 years who attend for their second or subsequent screening episode who are diagnosed with DCIS.

b) ≥ 7 per 10,000 women aged 50–69 years who attend for their second or subsequent screening episode are diagnosed with DCIS.

2.2.3 The Service and/or SCU monitors and reports the number of women aged 50–74 years who attend annually for screening, who are diagnosed with DCIS.

2.2.4 The Service and/or SCU monitors and reports the proportion of women aged 40–49 years and 75 years and over who are diagnosed with DCIS.

Criterion 2.3 – The Service and/or SCU minimises the number of interval invasive breast cancers.

Measures

2.3.1 a) The Service and/or SCU monitors and reports the proportion of women aged 50–74 years who attend for screening who are diagnosed with an interval invasive breast cancer in the first calendar year following a negative screening episode.

b) < 7.5 per 10,000 women aged 50–69 years who attend for screening are diagnosed with an interval invasive breast cancer in the first calendar year following a negative screening episode.

c) The Service and/or SCU monitors and reports the proportion of women aged 40–49 years and 75 years and over who attend for screening who are diagnosed with an interval invasive breast cancer in the first calendar year following a negative screening episode.

2.3.2 a) The Service and/or SCU monitors and reports the proportion of women aged 50–74 years who attend for screening who are diagnosed with an interval invasive breast cancer in the second calendar year following a negative screening episode.

b) ≤ 15 per 10,000 women aged 50–69 years who attend for screening are diagnosed with an interval invasive breast cancer in the second calendar year following a negative screening episode.

c) The Service and/or SCU monitors and reports the proportion of women aged 40–49 years and 75 years and over who attend for screening who are diagnosed with an interval invasive breast cancer in the second calendar year following a negative screening episode.

Criterion 2.4 – The Service and/or SCU ensures high quality screen reading.

Measures

2.4.1 All screen readers read at least 2,000 mammographic screening cases within the Program per year.

Criterion 2.5 – The Service and/or SCU ensures high quality imaging.

Measures

2.5.1 The Service and/or SCU monitors and reports the percentage of women who have up to 4 images per screen, including technical repeats.

2.5.2 The overall repeat rate for the Service and/or SCU is $\leq 2\%$ of all screening images.

Criterion 2.6 – Investigations and recall for assessment of non-malignant lesions is minimised.

Measures

2.6.1 a) The Service and/or SCU monitors and reports the proportion of women aged 50–74 years who attend for annual screening.

b) $\leq 10\%$ of women aged 50–69 years attend for annual screening.

2.6.2 The Service and/or SCU monitors and reports the proportion of women who attend for annual screening, aged 40–49 years and 75 years and over.

2.6.3 a) The Service and/or SCU monitors and reports the proportion of women aged 50–74 years who attend for their first screening episode and are recalled for assessment.

b) $< 10\%$ of women aged 50–69 years who attend for their first screening episode are recalled for assessment.

c) The Service and/or SCU monitors and reports the proportion of women aged 40–49 years and 75 years and over who attend for their first screening episode and are recalled for assessment.

2.6.4 a) The Service and/or SCU monitors and reports the proportion of women aged 50–74 years who attend for their second or subsequent screening episode and are recalled for assessment.

b) $< 5\%$ of women aged 50–69 years who attend for their second or subsequent screening episode are recalled for assessment.

- c) The Service and/or SCU monitors and reports the proportion of women aged 40-49 years and 75 years and over who attend for their second or subsequent screening episode and are recalled for assessment.
- 2.6.5** The Service and/or SCU monitors and reports the positive predictive value of a recall to assessment for detecting invasive breast cancer or DCIS in women aged 50–74 years who attend for their first screening episode.
- 2.6.6** The Service and/or SCU monitors and reports the positive predictive value of a recall to assessment for detecting invasive breast cancer or DCIS in women aged 50–74 years who attend for their second or subsequent screening episode.
- 2.6.7** <0.2% of women who attend for screening are recommended for early review for further assessment.

STANDARD 3: ASSESSMENT

Assessment and diagnosis of breast cancer are appropriate, safe and effective.

Criterion 3.1 – The Service and/or SCU maximises the efficacy of assessment.

Measures

- 3.1.1** <5% of all percutaneous needle biopsies of malignant breast lesions are classified as benign or inadequate/insufficient.
- 3.1.2** a) 0% of benign lesions assessed by percutaneous needle biopsy have a false positive cancer diagnosis, when the definitive needle biopsy result is achieved after performance of the final needle biopsy at an assessment episode(s). A false positive FNA which is followed by a true negative core biopsy, prior to recommendation for surgery or treatment, is not considered to be a false positive 'percutaneous needle biopsy' for the purpose of this standard.

b) Where NAS Measure 3.1.2 is not met, a comprehensive clinical review on 100% of false positive cancer diagnoses is conducted by the Service and/or SCU.
- 3.1.3** The absolute sensitivity of a diagnosis of breast cancer based on percutaneous needle biopsy is >90%.
- 3.1.4** ≤0.35% of women who attend for their first screening episode are found not to have invasive breast cancer or ductal carcinoma in situ (DCIS) after diagnostic open biopsy.
- 3.1.5** ≤0.16% of women who attend for their second or subsequent screening episode are found not to have invasive breast cancer or DCIS after diagnostic open biopsy.
- 3.1.6** All women with impalpable lesions undergoing excision have specimen imaging recorded.
- 3.1.7** ≥95% of all lesions are correctly identified at first excision.
- 3.1.8** a) ≥85% of invasive breast cancers or DCIS are diagnosed without the need for excision.

- b) Where part a) is not met, the Service and/or SCU provides the proportion of breast cancers that are diagnosed as invasive and DCIS without the need for excision.

STANDARD 4: TIMELINESS

Screening and assessment services are provided to women in a timely and efficient manner.

Criterion 4.1 – The Service and/or SCU ensures that women progress through the screening pathway in a timely manner.

Measures

4.1.1 a) ≥90% of women aged 50-74 years attend for a screening appointment within 28 calendar days of their booking date (fixed sites only).

b) Where part a) is not met, the Service and/or SCU records and reports the time taken to achieve 90% from booking to screening (fixed sites only).

4.1.2 ≥90% of women have a documented notification of the results of screening within 14 calendar days of the date of screening.

Criterion 4.2 – The Service and/or SCU ensures that women progress through the assessment pathway in a timely manner.

Measures

4.2.1 a) ≥90% of women requiring assessment attend an assessment visit within 28 calendar days of their screening visit.

b) Where part a) is not met, the Service and/or SCU records and reports the number of days the Service and/or SCU takes to achieve 90%.

c) Where part a) is not met, the Service and/or SCU records and reports the percentage of women who were offered assessment within 28 calendar days of their screening visit.

4.2.2 ≥95% of women not requiring percutaneous needle biopsy at assessment receive a definitive recommendation at their first assessment visit.

4.2.3 ≥95% of women require no more than two procedural assessment visits to receive a definitive recommendation from assessment.

4.2.4 ≥85% of women are verbally given the results of percutaneous needle biopsy within seven calendar days of the assessment procedure.

4.2.5 ≥95% of women complete all assessment within 15 calendar days.

4.2.6 All women are notified of the results of their assessment in writing within 14 calendar days of the date of completion of assessment.

STANDARD 5: DATA MANAGEMENT AND INFORMATION SYSTEMS

Data and information management systems and processes ensure the safe and effective use of data for strategic, clinical management and service improvement purposes.

Criterion 5.1 – The Service and/or SCU ensures the collection of treatment information about women with breast cancer.

Measures

- 5.1.1** ≥95% of data dictionary compliant surgical histopathology information is received by the Service and/or SCU.
- 5.1.2** ≥95% of data dictionary compliant primary treatment information is received by the Service and/or SCU.

STANDARD 6: CLIENT FOCUS

High quality information is provided to inform women, and women feel appropriately engaged and supported

There are no Criteria or Measures associated with this Standard. There are 12 Protocols associated with this Standard.

STANDARD 7: GOVERNANCE AND MANAGEMENT

Effective structures and processes are in place, evaluated and continuously improved, to ensure high quality governance and management of the Service and/or State Coordination Unit

There are no Criteria or Measures associated with this Standard. There are 22 Protocols associated with this Standard.

PROTOCOLS

PROTOCOL 1 – ACCESS AND PARTICIPATION: Appropriate levels of access and participation in BreastScreen Australia are achieved in the target and eligible populations

1.1 The Service and/or SCU implements appropriate policies and protocols to:

- a) Recruit women for participation;
- b) Send invitations for screening and rescreening;
- c) Follow-up women who do not respond to invitations; and
- d) Deliver services to women in the target age group and enable equitable participation of women in special groups as outlined in Measure 1.2.1.

PROTOCOL 2 – CANCER DETECTION: Breast cancer detection is maximised in the target population and harm is minimised

2.1 Where there is discordance between the two independent screen readers on whether further assessment for the presence of breast cancer is required, the Service and/or SCU implements a protocol to achieve a single recommendation, through either:

- a) a third reader where that reader is a radiologist with a high level of expertise in screen reading, or
- b) consensus reads by the original two or more readers.

2.2 The Service and/or SCU ensures the following quality and safety measures:

- a) The ALARA principle (As Low As Reasonably Achievable - a radiation safety principle for minimising radiation exposure) is applied and monitored;
- b) The mammographic screening examinations consist of the two standard views (they are, cranio-caudal and medio-lateral oblique);
- c) There is documentation of the reasons for any deviation from the standard two views or more than 4 images for each client; and
- d) A protocol for adequate examination of women with internal breast prostheses is in place.

2.3 The designated radiographer implements a process for providing ongoing assessment and feedback to radiographers and mammography practitioners in all units about the quality of screening images using criteria such as those used in the PGMI evaluation system outlined in [Appendix G](#).

2.4 The Service and/or SCU demonstrates annually that each radiographer and mammography practitioner achieves 50% or greater P or G ratings in a PGMI evaluation of 50 randomly selected image sets as outlined in [Appendix G](#).

2.5 Image identification complies with relevant radiation licensing regulations and complies with the RANZCR 'Standards of Practice for Diagnostic and Interventional Radiology, 2014' and the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM) Position Paper 'Recommendations for a Digital Mammography Quality Assurance Program, 2012' as updated from time to time.

2.6 The Service and/or SCU implements a protocol for:

- a) identifying all interval invasive breast cancers and interval cases of DCIS;
- b) reviewing and investigating all interval invasive breast cancers and interval cases of DCIS within the Service and/or SCU; and
- c) identifying and implementing changes to improve practice where necessary.

2.7 The Service and/or SCU provides audit and timely feedback which advises each individual reader of:

- a) their individual rate of detection, including small invasive breast cancers in all screens, in initial and subsequent screens (see [Appendix H](#));
- b) any interval invasive breast cancers not detected in images read by the reader ([Appendix H](#)); and
- c) any invasive breast cancers not detected as an abnormality by an individual reader at screen reading.

2.8 The Service and/or SCU implements a timely review process, and where necessary, implements strategies to address the individual reader's performance.

2.9 The Service and/or SCU implements a protocol for the management of women who report breast symptoms.

PROTOCOL 3 – ASSESSMENT: Assessment and diagnosis of breast cancer are appropriate, safe and effective

3.1 The Service and/or SCU ensures that the multidisciplinary team involved in the assessment of women recalled from screening has expertise in:

- a) breast examination;
- b) mammographic image interpretation and work-up;
- c) ultrasound performance and interpretation;
- d) percutaneous needle biopsy;
- e) pathology technique and interpretation;
- f) surgical planning; and
- g) supportive care.

3.2 The Service and/or SCU implements a protocol which ensures that the radiologist and other designated examining medical doctor from the multidisciplinary team, correlate and evaluate the clinical, pathological and imaging findings and decide on further investigations or management.

3.3 The Service and/or SCU ensures that all cases which underwent percutaneous needle biopsy are reviewed by a radiologist and at least one other designated medical doctor of the multidisciplinary team, before giving the results to the woman. Where results of radiology and pathology are inconclusive or inconsistent, the cases are reviewed at a minimum by a radiologist in consultation with a pathologist.

3.4 The Service and/or SCU implements a protocol for reviewing and correlating the clinical, radiological and pathological findings for all lesions detected as a result of screening for which surgery was performed.

3.5 Where there is discordance between assessment and post-surgical results the Service and/or SCU implements a protocol for the follow-up of these women which may include:

- a) notification of the surgeon;
- b) notification of the general practitioner;
- c) notification of the woman for review and assessment at the Service; or
- d) any combination of these.

3.6 The Service and/or SCU has systems in place to ensure that screening unit staff work closely with a specific assessment unit to ensure an integrated service.

3.7 The Service and/or SCU implements protocols for the evaluation of all women recalled to assessment which incorporates, as required:

- a) clinical examination;
- b) mammography/ultrasound; and
- c) percutaneous needle biopsy.

3.8 A Service or SCU that plans to implement remote radiology must establish and implement a protocol for delivering those remote radiology services to assessment clinics that includes and complies with all of the Remote Radiology Guidelines and utilises appropriate technology/telehealth facilities that meet the minimum technical requirements and quality control procedures in Appendix G.

PROTOCOL 5 – DATA MANAGEMENT AND INFORMATION SYSTEMS: Data and information management systems and processes ensure the safe and effective use of data for strategic, clinical management and service improvement purposes

5.1 The Service and/or SCU conforms with requirements of the BreastScreen Australia Data Dictionary, with regard to:

- a) collection of all required data items; and
- b) the definitions and methods used by the Service and/or SCU in the calculation of performance measures.

5.2 The Service and/or SCU undertakes ongoing quality control procedures for data throughout the screening and assessment process, including:

- a) review of the completeness and legibility of paper clinical records;
- b) review of the consistency between paper and computer records where required; and
- c) verification of the accuracy of the output of system generated reports.

5.3 All relevant staff are instructed in procedures to ensure quality of data at all levels of the screening and assessment pathway.

5.4 The Service and/or SCU ensures effective policies, procedures and protocols to achieve a high level of data security, accuracy, integrity and organisation and systems management.

5.5 The Service and/or SCU ensures the integrity and reliability of the file tracking system used.

5.6 Each client has one unique identifier within any State and Territory program.

5.7 All client records held by all units in the Service and/or SCU are dated and identifiable to the relevant health professional for that part of the screening and/or assessment pathway.

5.8 The Service and/or SCU complies with relevant state/territory legislation for the retention and storage of client records.

5.9 The Service and/or SCU has disaster recovery systems that address the risk of network failure and data loss from Picture Archiving Communication System (PACS) and client management systems.

5.10 The Service and/or SCU has policies, procedures and guidelines for the development and maintenance of high quality Information, Communication and Technology systems.

PROTOCOL 6 – CLIENT FOCUS: High quality information is provided to inform women, and women feel appropriately engaged and supported

6.1 Evidence based written information, which has been approved by the SCU and is consistent with state and national policies, is available to all women as appropriate, throughout the screening and assessment pathway, and includes:

- a) purpose of screening;
- b) likelihood of recall;
- c) possibilities of false positive and false negative results;
- d) uncertainties and risks;
- e) rescreening;
- f) the investigations which may be required;
- g) the benefits, limitations and risks of the investigations; and
- h) the possible outcomes of assessment.

6.2 Women are provided with information on waiting times at each step of the screening and assessment pathway.

6.3 All non-benign assessment results are given to the woman by a medical doctor of an assessment team, unless the woman specifically asks for them not to be. Women diagnosed with breast cancer or recommended for diagnostic open biopsy are additionally:

- a) told their results by a medical doctor and with a member of staff responsible for providing counselling present, unless the woman specifically asks them not to be, in accordance with the recommendations in the 'Clinical practice guidelines for the psychosocial care of adults with cancer. A summary guide for health professionals (NBCC/NCCI 2005)'; and
- b) encouraged to discuss treatment options with their preferred medical doctor such as a family doctor or treating surgeon.

Benign assessment results may be delivered by a suitably trained and experienced medical practitioner, breast care nurse or nurse counsellor, on the conditions that:

- the multi-disciplinary team recommendation is for routine re-screening;
- the woman is offered the opportunity for further discussion with a medical officer.

6.4 The Service and/or SCU implements a protocol, consistent with relevant State and Territory policies for a woman to have access to her own records, including copies of images.

6.5 The Service and/or SCU implements a strategy to encourage participation of key stakeholders, including consumers, in its structure, processes and activities.

6.6 The Service and/or SCU actively seeks feedback from women about the acceptability and appropriateness of screening and assessment.

6.7 Women are offered the opportunity to ask questions in private before giving consent for any procedure. Health professionals are available to answer clinical questions.

6.8 The consent process provides a record that information has been given and understood to the woman's satisfaction. This process clearly indicates that the woman may decline or request discontinuation of a procedure at any time.

6.9 In accordance with Commonwealth and state and territory legislation, consent is obtained from all women for:

- a) the screening mammogram;
- b) investigations at the assessment visit;
- c) her general practitioner, or other doctor to whom she is referred, to be notified of her results;
- d) the Service and/or SCU to request information about procedures and treatment from doctors to whom she is referred;
- e) data which identify the woman being transferred for clinical, research and monitoring purposes or released in any form; and
- f) an invitation to be sent to her for rescreening.

6.10 Women with confirmed breast cancer are given the option of referral to a treatment clinic specialising in the treatment of screen detected breast cancer or returning to their nominated general practitioners for referral to an appropriate surgeon.

6.11 The Service and/or SCU implements a protocol for the referral of all women with a diagnosis of breast cancer for subsequent management. The Service and/or SCU ensures that all referrals to treating medical doctors include complete and accurate information to enable appropriate management, and include a request for appropriate follow-up information.

6.12 The Service and/or SCU ensures that all women with a diagnosis of breast cancer, which has been diagnosed within the Program, are advised in writing of their status in relation to the Program in future years.

PROTOCOL 7 – GOVERNANCE AND MANAGEMENT: Effective structures and processes are in place, evaluated and continuously improved to ensure high quality governance and management of the Service and/or SCU

7.1 The Service and/or SCU implements appropriate position descriptions which describe staff roles and responsibilities.

7.2 All staff meet the relevant expertise, experience and training standards outlined in [Appendix C](#).

7.3 All staff are trained to ensure an understanding of the policies, protocols and procedures of the Service and/or SCU.

7.4 All staff participate in regular clinical breast specific professional development activities.

7.5 The designated pathologist and deputy/ies:

- a) participate in the Royal College of Pathologists of Australasia (RCPA) Anatomical Quality Assurance Programs Breast Diagnostic Module; and
- b) implement the recommendations for quality assurance and uniform reporting of breast FNA cytology and core biopsy in 'Breast fine needle aspiration cytology and core biopsy—a guide for practice (National Breast Cancer Centre 2004)' and 'Invasive breast cancer structured reporting protocol (Royal College of Pathologists of Australasia 2012)' as amended from time to time.

7.6 The Service and/or SCU ensures that all screening and assessment units operate in a space, which is clearly identifiable as a BreastScreen Australia service:

- a) and that screening and assessment of screen-detected abnormalities are exclusively performed at a given time; and
- b) with dedicated staff and resources.

7.7 The Service and/or SCU continually review, assess and implement a detailed quality improvement plan.

7.8 For any research projects using screening and/or assessment data, the Service and/or SCU has evidence of Institutional Ethics Committee approval where appropriate and that they have advised the SCU, and relevant state or territory health department. Where data are to be published, the SCU and state or territory health department is advised and an independent final review is undertaken.

7.9 The Service and/or SCU has a management or advisory structure which has representation from all key stakeholder groups.

7.10 Where the Service and/or SCU are separate, there is a written contract detailing their respective responsibilities and accountabilities, including compliance with the National Accreditation Standards.

7.11 The Service and/or SCU implements financial management systems that maximise efficiency and accountability.

7.12 The Service and/or SCU implements, monitors and continually evaluates infection control processes that meet relevant state, territory and national standards.

7.13 The Service and/or SCU implements, and continually evaluates, an incident management process that includes the identification, reporting, investigation, analysis, action, feedback and open disclosure of incidents that occur in the Service and/or SCU.

7.14 The Service and/or SCU has an up-to-date Policy, Protocols and Procedures Manual that is maintained and updated regularly, and underpins all aspects of service delivery.

7.15 The Service and/or SCU ensures that all of the policies, protocols and procedures outlined in the Policy, Protocols and Procedures Manual are implemented, continuously reviewed and improved.

7.16 The Service and/or SCU implements an audit schedule to monitor compliance with all policies, protocols and procedures, and where necessary, develops strategies for improving compliance.

7.17 The Service and/or SCU has access to appropriate equipment to maximise breast cancer diagnoses.

7.18 X-ray systems, premises and users meet radiation protection regulations.

7.19 Breast imaging systems, including ancillary items, meet:

- a) manufacturer's specifications;
- b) imaging system performance and standards for quality control as specified in Appendices D, E, and F; and
- c) standards relating to storing, retrieving, displaying and transmitting images, in accordance with the RANZCR 'Standards of Practice for Diagnostic and Interventional Radiology'.

7.20 Preventative maintenance and repair of imaging equipment meets manufacturer's recommendations or other appropriate standards.

7.21 The Service and/or SCU uses pathology laboratories which maintain RCPA National Association of Testing Authorities accreditation.

7.22 For new technologies being introduced at the Service and/or SCU:

- a) introduction is in accordance with State and Territory and/or national policies;
- b) where relevant, evaluation of the technology is undertaken;
- c) a protocol for the safe and effective introduction exists;
- d) quality assurance protocols are in place and monitored regularly;
- e) relevant staff receive appropriate training in the use of such technologies prior to commencing their use; and
- f) appropriate information is provided to the client about the new technology when it is to be used at assessment or screening.

APPENDIX B:

HISTORY OF THE DEVELOPMENT AND REVIEW OF THE BREASTSCREEN AUSTRALIA NATIONAL ACCREDITATION STANDARDS

1991 – 2008 REVIEWS

In 1991, the National Advisory Committee^{zz} for the National Program for the Early Detection of Breast Cancer (now BreastScreen Australia) developed the first set of Accreditation Guidelines for the Program.

In 1994, the review of the Accreditation Guidelines was endorsed by the National Advisory Committee, which resulted in the newly titled National Accreditation Requirements (NARs) becoming the standards against which BreastScreen Australia Services were assessed.

In 1999, the National Quality Management Committee (NQMC) initiated a review of the NARs, which was undertaken in collaboration with the National Breast Cancer Centre^{aaa}. The resulting National Accreditation Standards (NAS) were endorsed by the National Advisory Committee in July 2001, and became operational throughout BreastScreen Australia in July 2002.

In May 2004, a 'mini review' was conducted by the NQMC to amend seven 'exigent' NAS, which BreastScreen Australia Services had difficulty in achieving. The changes to these NAS were endorsed by the Australian Screening Advisory Committee in November 2004.

In 2006 the Digital Mammography Accreditation Standards Working Group (DMASWG) was established as a working group of the NQMC, to update the NAS for the introduction of digital mammography throughout BreastScreen Australia. This review included: an update of terminology within the NAS to refer to 'image' instead of 'film'; an update of existing appendices; and development of new appendices to support quality assurance processes for digital mammography. The DMASWG's revisions to the NAS were endorsed by the Screening Subcommittee on 7 April 2008.

2011 – 2014 REVIEW

In 2011, the Australian Government Department of Health auspiced a full review of the NAS as part of a broader project to review BreastScreen Australia's accreditation system. In April 2011, the Accreditation Review Committee (ARC) was established to oversee and guide the review of the accreditation system. In December 2011, two subcommittees were established under the ARC to progress specific streams of work for the review, and provide advice to the ARC on the revised components of the BreastScreen Australia accreditation system. The NAS and Data Subcommittee was established to revise the NAS and data requirements for the accreditation system, and the Performance Improvement and Governance Subcommittee was established to review and refine the accreditation process and governance arrangements for the updated system and develop a National Quality Improvement Framework.

^{zz} In 2004, the National Advisory Committee was replaced by the Australian Screening Advisory Committee. In 2006 the Screening Subcommittee was established, and in 2012, it was renamed as the Standing Committee on Screening.

^{aaa} The National Breast Cancer Centre was renamed the National Breast and Ovarian Cancer Centre (NBOCC), and on 1 July 2011, the NBOCC was amalgamated with Cancer Australia.

In November 2012, a third subcommittee, the Pilot and Implementation Subcommittee was established to develop the requirements for the pilot, and develop the project methodology, pilot evaluation plan and the implementation plan for the national roll-out of the revised accreditation system.

Two major phases of stakeholder consultation helped inform the review of the NAS and ensured the ongoing, open and transparent engagement of BreastScreen Australia stakeholders, clinicians, professional colleges and members of the community in revising the BreastScreen Australia NAS.

PHASE 1 CONSULTATION

The first phase of consultation commenced in November 2011, through a series of workshops with BreastScreen Australia Program Managers, accreditation staff and the National Quality Management Committee (NQMC). Stakeholders provided input on the broad approach, direction and priorities for updating the accreditation system and reviewing the NAS.

PHASE 2 CONSULTATION

Woolcott Research was engaged by the Australian Government Department of Health to manage the second phase of consultation. This included a two-staged approach, and commenced with a national forum on 24 May 2012, followed by an online survey (released from 20 June – 11 July 2012).

At the conclusion of this consultation process, approximately two thirds of stakeholders agreed that the changes (including those to the NAS) would reduce duplication, make the system more efficient and increase transparency and accountability.

PILOT OF THE REVISED ACCREDITATION SYSTEM

In May 2013, a pilot of the revised accreditation system was conducted. This involved:

1. A desktop audit of the revised National Accreditation Standards (NAS) in Tasmania; and
2. A full accreditation site visit in Geelong

A Pilot Evaluation Report was developed, following the pilot which identified enablers and barriers of the revised accreditation system, key learnings, and informed development of an implementation plan for and roll-out of the new accreditation system.

2014 REVIEW - SUMMARY OF CHANGES TO THE BREASTSCREEN AUSTRALIA NAS

- The naming conventions in the NAS were amended to align with the nomenclature used within other accreditation programs (including the Australian Commission on Safety and Quality in Health Care), as described in Table 1.
- The NAS were reframed to align the previously titled clusters with outcomes^{BBB}. The original ten clusters under the previous system have been reduced to seven Standards, as described in Table 2.
- The NAS were reviewed and reduced from 173 individual quantitative and qualitative NAS to 42 NAS Data Measures.
 - The NAS Data Measures are supported by a set of qualitative Protocols, which outline the policies, procedures and principles that underpin high quality service delivery and will facilitate the achievement of the NAS. The protocols are intended to facilitate Services and/or SCUs to design, deliver, and improve service delivery and drive quality improvement.

- In the event of declining performance or difficulty achieving the respective Measures, the Protocols will inform quality improvement initiatives.
- To maintain longitudinal data integrity of continuous program monitoring, none of the NAS Data Measures that are reported to the Australian Institute of Health and Welfare were altered.
- NAS Data Measures and Protocols covered by jurisdictional and/or Commonwealth legislation were removed to avoid duplication. Measures that were considered similar in nature were also consolidated.
- A number of new NAS Data Measures and Protocols were inserted to 'future proof' the accreditation system; and collect data to inform development of future policy.
- The previous targets for quantitative NAS (e.g., $\geq 75\%$ of women are given results of biopsy within seven days) were revised in line with longitudinal BreastScreen Australia accreditation data, current evidence and clinical practice. Where necessary, these targets were adjusted to drive continuous quality improvement within the program.
- Following a review of the literature and longitudinal national accreditation data, the NAS and Data Subcommittee agreed that the revised accreditation standards for BreastScreen Australia will no longer separate standards for FNA cytology and core biopsy. Rather than focus on the technique used, BreastScreen Australia will adopt an outcomes based approach, requiring minimum performance targets for percutaneous needle biopsy, and leaving it to each BreastScreen Service to determine which approach would be implemented in their setting to achieve the desired goals.
- New NAS Data Measures for the expanded target age range of 50–74 were developed following the announcement in the 2013–14 Federal Budget to expand BreastScreen Australia's target age range, from women aged 50–69 years to women aged 50–74 years.

TABLE 1: REVISED NAS TERMINOLOGY

| Previous Terminology | Revised Terminology | Description |
|-----------------------|---------------------|---|
| Aims and outcomes | Objectives | High level statements that describe the goals which aim to be achieved by BreastScreen Australia. For example: <ul style="list-style-type: none"> • Reduce morbidity and mortality attributable to breast cancer. |
| Cluster | Standard | Goals relating to specific components of the program, which need to be achieved in order to reach the objectives. For example: <ul style="list-style-type: none"> • Breast cancer detection is maximised in the target population and harm is minimised. |
| Performance Objective | Criterion | Key components that make up each Standard. For example: <ul style="list-style-type: none"> • The Service maximises the detection of invasive breast cancer; and • The Service maximises the detection of DCIS. |
| Data NAS | NAS Data Measure | Individual components of a Criterion, which have a quantitative target and describe the requirement for accreditation. For example: <ul style="list-style-type: none"> • ≥ 50 per 10,000 women aged 50–69 years who attend for their first screening episode are diagnosed with invasive breast cancer. • ≥ 35 per 10,000 women aged 50–69 years who attend for their second or subsequent screening episode are diagnosed with invasive breast cancer. |
| Non-data NAS | Protocol | Individual components of a Standard, which describe the policies, procedures and principles that underpin high quality service delivery and support achievement of the NAS Data Measures. |

TABLE 2: REVISED STANDARDS

| Previous Cluster | Revised Standard | Rationale |
|------------------------------------|---|--|
| Participation | 1. Access and Participation | Combined the former 'Participation' and 'Access' clusters. Access is central to the BreastScreen Australia objective of providing a population based screening program for all women in the target and eligible age groups. |
| Access | | Participation rates are directly impacted by access issues and it was therefore considered appropriate to combine these two areas. |
| Cancer Detection | 2. Cancer Detection | The former 'Unnecessary Recall' cluster was combined with the Cancer Detection Standard as it is directly impacted by the quality of imaging and screen reading Measures. |
| Unnecessary Recall | | |
| Assessment | 3. Assessment | Remained unchanged at the Standard level. |
| Timeliness | 4. Timeliness | Remained unchanged at the Standard level. |
| Data Management | 5. Data Management and Information Systems | Remained unchanged at the Standard level. |
| Continuity Counselling and Support | 6. Client Focus | Combined the former 'Continuity, Counselling and Support' and 'Information' clusters. <i>Protocols</i> under both existing clusters relate to the provision of information and support to clients within the program. |
| Information | | |
| Management | 7. Governance and Management | Refocused the existing 'Management' cluster. |

APPROVAL BY THE INTERGOVERNMENTAL STANDING COMMITTEE ON SCREENING

The Standing Committee on Screening (SCoS), a committee of the Australian Health Ministers' Advisory Council's Community Care and Population Health Principal Committee, was responsible for providing the final endorsement of the revised BreastScreen Australia accreditation system, including the NAS.

The final, revised set of BreastScreen Australia NAS was submitted for approval by the SCoS on 31 July 2014. At this meeting, the SCoS approved the revised BreastScreen Australia NAS in full.

The following committees played a pivotal role in the review of the accreditation system.

BREASTSCREEN AUSTRALIA ACCREDITATION REVIEW COMMITTEE (ARC)

The ARC was established in April 2011 to oversee and guide the review of the BreastScreen Australia accreditation system.

| Members | Representation |
|-------------------------------------|--|
| Dr Heather Buchan (Chair) | Director, Australian Commission on Safety and Quality in Health Care |
| Dr Tracey Bessell | Director, Screening Section, Department of Health |
| Ms Louise Galloway | Manager, Department of Health VIC |
| Ms Susan Garner | Director, Susan J Garner and Associates |
| Associate Professor Rosemary Knight | Principal Adviser, Department of Health |
| Ms Val Lang | Consumer |
| Associate Professor Warwick Lee | State Radiologist, BreastScreen NSW |
| Professor Bruce Mann | Specialist Breast Surgeon and Surgical Oncologist, Royal Women's Hospital, Melbourne |
| Ms Linda O'Connor | Executive Director, Australian Council on Healthcare Standards |
| Ms Maureen Robinson | Director, Quorus |
| Ms Lou Williamson | General Manager, BreastScreen SA |

BREASTSCREEN AUSTRALIA PERFORMANCE IMPROVEMENT AND GOVERNANCE SUBCOMMITTEE

The Performance Improvement and Governance Subcommittee of the BreastScreen Australia ARC was established to streamline the BreastScreen Australia accreditation process and governance arrangements.

| Members | Representation |
|---|---|
| Associate Professor Rosemary Knight (Chair) | Principal Adviser, Department of Health |
| Dr Tracey Bessell | Director, Screening Section, Department of Health |
| Dr Jane Brazier | Medical Director, BreastScreen QLD Brisbane Northside Service |
| Dr Jill Evans | State Radiologist, BreastScreen VIC |

| Members | Representation |
|-------------------------|---|
| Ms Louise Galloway | Manager, Department of Health VIC |
| Ms Susan Garner | Director, Susan J Garner and Associates |
| Ms Val Lang | Consumer |
| Ms Linda O'Connor | Executive Director, Australian Council on Healthcare Standards |
| Ms Maureen Robinson | Director, Quorus |
| Mr Mathivanan Sakthivel | Director, South Eastern Sydney Illawarra BreastScreen Service |
| Ms Gail Ward | State Manager, BreastScreen Tasmania, Department of Health and Human Services |

BREASTSCREEN AUSTRALIA NATIONAL ACCREDITATION STANDARDS (NAS) AND DATA SUBCOMMITTEE

The BreastScreen Australia NAS and Data Subcommittee of the BreastScreen Australia ARC was established to refine the 173 BreastScreen Australia NAS and data requirements for the accreditation system.

| Members | Representation |
|-------------------------------------|---|
| Dr Tracey Bessell (Chair) | Director, Screening Section, Department of Health |
| Ms Rosa Cameron | Chief Medical imaging Technologist, BreastScreen WA |
| Associate Professor Gelareh Farshid | Clinical Director, BreastScreen SA |
| Associate Professor Warwick Lee | State Radiologist, BreastScreen NSW |
| Professor Bruce Mann | Specialist Breast Surgeon and Surgical Oncologist, Royal Women's Hospital, Melbourne |
| Mr Warwick May | Accreditation Manager, Cancer Institute NSW |
| Ms Maureen Robinson | Director, Quorus |
| Mr Dylan Sutton | Project Manager for Digital Imaging, BreastScreen Tasmania, Department of Health and Human services |
| Ms Sue Viney | Consumer |
| Ms Fleur Webster | Acting Manager, Breast Cancer, Cancer Australia |
| Ms Lou Williamson | General Manager, Department of Health SA |
| Past members | Representation |
| Dr Gordana Culjak | Manager of Health Informatics, Cancer Institute NSW |

BREASTSCREEN AUSTRALIA PILOT AND IMPLEMENTATION SUBCOMMITTEE

The Pilot and Implementation Subcommittee of the BreastScreen Australia ARC was established to oversee the pilot of the revised accreditation system, evaluate the pilot and develop an implementation plan for the national roll-out of the revised system across BreastScreen Australia.

| Members | Representation |
|-------------------------|---|
| Ms Susan Garner (Chair) | Director, Susan J Garner and Associates |
| Dr Tracey Bessell | Director, Screening Section, Department of Health |
| Mr Warwick May | Accreditation Manager, Cancer Institute NSW |
| Ms Linda O'Connor | Executive Director, Australian Council on Healthcare Standards |
| Mr Dylan Sutton | Project Manager for Digital Imaging, BreastScreen Tasmania, Department of Health and Human Services |
| Ms Jules Wilkinson | Manager, BreastScreen Victoria |
| Ms Lou Williamson | General Manager, Department of Health SA |

APPENDIX C:

STAFF QUALIFICATIONS, EXPERIENCE AND TRAINING STANDARDS, INCLUDING ROLES AND RESPONSIBILITIES OF DESIGNATED PERSONNEL

All staff employed or contracted by BreastScreen Australia will have qualifications, experience and training relevant to the positions held in the Program.

Staff expertise, experience and training standards have been developed since the commencement of the Program in conjunction with relevant colleges and other professional organisations and representatives.

All designated clinicians (radiologists, surgeons, pathologists, and radiographers) have responsibility and accountability for all aspects of quality assurance for the BSA Service that is relevant to their respective discipline.

The Service and/or State Coordination Unit (SCU) will develop and implement a planned approach to continuing professional development (CPD) for both clinical and administrative staff to ensure the best outcomes for women attending the Program. Specific CPD activities will be identified through annual individual performance appraisals.

In, addition, the Service and/or SCU has the responsibility to ensure all staff are aware of their obligations to comply with; their local and/or professional codes of conduct and requirements to sign confidentiality forms.

CLINICAL DIRECTOR

The role of Clinical Director may be filled by a clinical specialist in any of the disciplines involved in the BreastScreen Australia program (radiology, pathology, surgery), or by a Medical Officer with significant expertise in breast cancer screening.

The Clinical Director is responsible for the provision of high standards of clinical care to BreastScreen clients through the oversight of clinical services in accordance with BreastScreen Australia National Accreditation Standards (NAS).

The position provides leadership, supervision, support and direction to clinicians employed by the BreastScreen Program to ensure the professional and clinical service delivery standards are of the highest quality and that BreastScreen Australia NAS are met.

Clinical Directors are sometimes also referred to as Service Directors.

RADIOLOGISTS

Radiologists must hold a fellowship of the Royal Australian and New Zealand College of Radiologists, or equivalent, be currently registered with the Medical Board of Australia through the Australian Health Practitioners Regulation Agency (AHPRA).

Registrars in training with the Royal Australian and New Zealand College of Radiologists may meet the experiential requirements of the RANZCR Radiodiagnosis Curriculum through BreastScreen Australia Services. Registrars will be under the direct supervision of the Service Designated Radiologist.

Radiologists commencing as screen readers in the Program are closely supervised by a senior radiologist/radiologists

Radiologists commencing as an unsupervised assessment radiologist will have attained a high level of competency in digital screening mammography and diagnostic imaging, interventional procedures and assessment.

It is desirable that all radiologists be involved in both screen reading and assessment.

All screen readers and assessment clinic radiologists will be subject to review by the Service Designated Radiologist, based on clinical audit as detailed in [Appendix H](#).

TRAINING FOR NEW SCREEN READERS AND ASSESSMENT RADIOLOGISTS

- New screen readers and assessment radiologists will be expected to have already obtained a high level of theoretical knowledge related to mammographic screening by processes such as attendance at formal mammography training courses which contain a screening component and/or participation in Breast Imaging Fellowships.
- The training protocol for new readers and assessment radiologists is based on experiential training in digital screening mammography and mentoring by an experienced BreastScreen Radiologist, under the supervision of the Service Designated Radiologist.
- The Service will facilitate formation of digital mammographic libraries to assist training of new readers in the digital environment.
- Unless a new screen reader has documentary evidence of a high level of digital mammographic screen reading performance from other jurisdictions, new readers will be required to demonstrate or develop appropriate screen reading skills before commencing independent reads by methods such as:
 - Undertaking screen-read test sets
 - Undertaking a number of trainee reads, subsequently reviewed by the supervising radiologist or Designated Radiologist
 - The number of trainee reads will depend on the reader's previous experience and level of competence, as assessed by the supervising radiologist. The number of trainee reads may typically range from 500 to 2000 reads.
 - Satisfactory performance following audit of trainee reads, under the direction of the Designated Radiologist, must be demonstrated before independent screen reading commences.
- New Assessment Clinic Radiologists will initially attend assessment clinics as observers, then as supervised radiologists. The supervising senior radiologist will ensure that the new assessment clinic radiologist has the knowledge and skills to make appropriate clinical decisions and work as part of a BreastScreen multidisciplinary assessment clinic.

The new radiologist's competence in performing breast ultrasound and image guided biopsies will be assessed by the designated or supervising radiologist. Any deficiencies in these skills need to be addressed during the period of supervision.

THE DESIGNATED RADIOLOGIST

The role of the Designated Radiologist is to oversee the provision of high quality breast cancer screening and assessment services relating to radiology in the Service and/or SCU in accordance with the BreastScreen Australia National Accreditation Standards (NAS), as well as implementing quality improvement strategies for radiologists/readers as detailed in the Service Quality Improvement (QI) Plan. This requires the Designated Radiologist to work closely with the Designated Radiographer and

the Clinical Director/Program Manager to deal with issues of quality. Close liaison with the Designated Pathologist, Designated Surgeon and medical physicist is also required.

QUALIFICATIONS AND EXPERIENCE

In addition to the prerequisite qualifications, registration and licensing (if applicable) the Designated Radiologist requires:

- extensive experience in screening mammography, diagnostic mammography, breast ultrasound and image-guided interventional procedures of the breast.
- excellent knowledge of breast imaging technical quality assurance.
- well developed knowledge of the BreastScreen Australia Program and the NAS.

RESPONSIBILITIES

The responsibilities of the Designated Radiologist include, but are not limited to:

- Orientation and supervision of training of radiologists new to the Service.
- Direct supervision of registrars in training.
- Undertaking quarterly assessment of radiologists' performance in screening and assessment and providing feedback of this assessment to individual radiologists. As a minimum, this includes analysis of the Service and/or SCU's and the individual radiologist's recall rates, cancer detection rates, missed cancer detection rates and interval cancers. Assessment performance, such as pre-operative diagnosis of breast cancers and adequacy of percutaneous biopsies, will also be included. This individualised, identifiable information is confidential to the Designated Radiologist, the individual radiologist, the Clinical Director/Program Manager and the data manager.
- Ensuring regular radiology/pathology/surgery review of biopsies is undertaken.
- Encouraging radiologists to participate in continuing education programs. This will include, but not limited to, multidisciplinary review meetings in the Service.
- Undertaking quarterly formal reviews of mammographic quality and equipment performance with the Designated Radiographer. Although the Designated Radiographer is responsible for the performance of technical quality assurance, the Designated Radiologist needs to be aware of the standards and testing procedures for mammographic and ultrasound equipment and to be certain that these are being met. The Designated Radiologist also needs to communicate with the Designated Radiographer regarding radiation dose measurements.
- The Designated Radiologist will assist in the development and implementation of documented quality assurance protocols on:
 - Radiation dose measurement
 - Equipment
 - Radiation protection
 - Mammogram and ultrasound quality evaluation.
- Contribute to the development of clinical protocols and procedures for screening and assessment in collaboration with the Clinical Director/Program Manager and other designated personnel.
- Contribute to the selection and replacement of appropriate breast imaging equipment if required.

RADIOGRAPHERS

Radiographers must hold qualifications in diagnostic radiography (medical imaging), be currently registered with the Australian Health Practitioners Regulation Agency and hold relevant state or territory licensing.

Radiographers will be appropriately trained and supervised. Radiographers are required to complete an Australian Institute of Radiography (AIR) accredited mammography training program with academic and clinical components, ideally within 12 months of commencing employment in the Program, or have previously completed an international equivalent course. Radiographers will be encouraged to seek recognition through the AIR Certificate of Clinical Proficiency in Mammography (CCPM) or Advanced Breast Imaging Certificate.

Radiographers are required to possess mammography knowledge and skills in both screening and assessment. Screening radiographers are required to attend assessment and radiographers employed in assessment only are required to attend screening to maintain their clinical proficiency.

In-service training will be made available to all radiographers to ensure they participate in continuing professional development to maintain, improve and broaden their knowledge, expertise and competence as required for registration renewal. The Designated Radiographer is responsible for the supervision of all radiographer training requirements.

THE DESIGNATED RADIOGRAPHER

The role of the Designated Radiographer is to oversee the provision of high quality breast cancer screening and assessment services in relation to radiography in the Service and/or SCU in accordance with the BreastScreen Australia NAS. Further, the role of the Designated Radiographer is to implement quality improvement strategies for radiographers and sonographers (where employed) as detailed in the Service QI Plan. This requires the Designated Radiographer to work closely with the Clinical Director/Program Manager/Service Director and Designated Radiologist to deal with issues of quality. Close liaison with the medical physicist is also required.

The Designated Radiographer is usually the radiographer-in-charge (chief radiographer) in a Service. However, in large Services, components of the roles and responsibilities may be allocated to other appropriate radiographers.

QUALIFICATIONS AND EXPERIENCE

In addition to the prerequisite qualifications, registration and licensing (if applicable) the Designated Radiographer will have:

- Current Certificate of Clinical Proficiency in Mammography (CCPM).
- Extensive knowledge and experience in screening mammography and/or diagnostic mammography.
- Excellent knowledge of technical quality assurance.
- Experience in staff supervision.
- Well developed knowledge of the BreastScreen Australia Program and an understanding of the NAS.
- Excellent knowledge of the role of sonography in the BreastScreen assessment pathway

RESPONSIBILITIES

The responsibilities of the Designated Radiographer include, but are not limited to:

- Orientation and supervision of training of radiographers and mammography practitioners new to the Service.
- Ensuring a continuing education program for radiographers, mammography practitioners and sonographers.
- Ensuring the ALARA principle is implemented and radiation safety requirements are met.
- Ensuring the technical aspects of breast imaging quality assurance are implemented as per Appendices D, E and F.
- Ensuring the annual PGMI evaluation of images taken by all radiographers and mammography practitioners is undertaken.
- Implementing a process for providing ongoing assessment and feedback to radiographers and mammography practitioners in all units about the quality of screening images using criteria such as those used in the PGMI evaluation system outlined in [Appendix G](#) and quality control requirements in [Appendix E](#).
- Implementing quality improvement strategies for radiographers and mammography practitioners as detailed in the Service Quality Improvement Plan.
- Consulting with the Designated Radiologist on mammographic quality assurance, including undertaking quarterly formal reviews of image quality and equipment performance.
- Liaising with the medical physicist on technical quality and equipment issues.
- Contributing to the development of clinical policies and procedures for screening and assessment relating to radiographers, mammography practitioners and sonographers.
- Awareness of emerging technologies in breast imaging.

SONOGRAPHERS

Sonographers must hold relevant and postgraduate qualifications in breast ultrasound or medical ultrasound, or be a student sonographer, accredited by and on the register of the Australian Sonographer Accreditation Registry (ASAR). Accredited Medical Sonographers will be appropriately trained and supervised in the examination and correlation of screen detected lesions. Sonographers are also required to maintain accreditation by documenting their continuing professional development (CPD) activities with one of the ASAR recognised CPD programs.

MAMMOGRAPHY PRACTITIONERS

The mammography practitioner performs mammography screening, diagnostic and further assessment imaging at BreastScreen Australia Services. Mammography practitioners are required to possess mammography knowledge and skills in both screening and assessment. Screening mammography practitioners are required to attend assessment and mammography practitioners employed in assessment only are required to attend screening to maintain their clinical proficiency. Mammography practitioners may operate as the sole practitioner at a screening-only site. The Designated Radiographer at each Service is responsible for monitoring the activity and performance of all radiographers and mammography practitioners. The mammography practitioner is a member of the multidisciplinary team whose duties include: Performing routine mammography screening and assessment;

- Maintaining and operating imaging equipment and accessories in accordance with radiation protection and safety, infection control guidelines and best practice standards;
- Maintaining an up-to-date knowledge of new techniques and advances in mammography and breast screening.

SURGEONS

Surgeons must hold a fellowship of the Royal Australasian College of Surgeons, or equivalent and be currently registered with the Medical Board of Australia.

Surgeons are encouraged to be members of Breast Surgeons of Australia and New Zealand (BreastSurg ANZ).

Surgeons have evidence of post-fellowship training and experience in breast surgical techniques.

Surgeons can demonstrate appropriate training and expertise in the clinical assessment and surgical management of benign and malignant breast disease, including:

- the clinical assessment of women with screen-detected abnormalities.
- surgical management of benign and malignant breast lesions detected in the BreastScreen Australia Program.

Surgeons are encouraged to participate in the Royal Australasian College of Surgeons continuing medical education program and be involved in audits of short-term and long-term outcomes for their patients, such as BreastSurg ANZ Quality Audit.

THE DESIGNATED SURGEON

The role of the Designated Surgeon is to oversee all issues of quality assurance relating to surgery for the Service. This requires the Designated Surgeon to work closely with the Designated Radiologist, the Designated Pathologist and the Clinical Director in dealing with all issues of clinical quality. Close liaison with all other members of the multidisciplinary assessment team, including staff providing counselling, is also required.

QUALIFICATIONS AND EXPERIENCE

In addition to the prerequisite qualifications, registration and membership of BreastSurg ANZ, the Designated Surgeon requires extensive experience in:

- The diagnosis and management of symptomatic and screen detected breast abnormalities.
- Multidisciplinary assessment.
- Well developed knowledge of the BreastScreen Australia Program and a sound understanding of the NAS.

RESPONSIBILITIES

The responsibilities of the Designated Surgeon include, but are not limited to:

- Orientation of surgeons new to the Service.
- Represent Service affiliated surgeons.
- Facilitate the involvement of surgeons in continuing educational activities and multidisciplinary meetings relevant to their work in the BreastScreen Australia Program.
- Participate in the review of cases where surgical input is deemed necessary, particularly where the results of radiology and pathology are inconsistent or inconclusive.
- Oversee the development and implementation of quality assurance Service protocols for those elements of the Program relevant to their clinical discipline.

PATHOLOGISTS

Pathologists will hold a fellowship of the Royal College of Pathologists of Australasia or recognised equivalent and are currently registered with the Medical Board of Australia through AHPRA.

Pathologists will have sufficient experience to have attained a high level of competency in breast cytology and histopathology. Documentary evidence of their experience will be provided to the Clinical Director/Program Manager.

Registrars in training are registered with the Royal College of Pathologists of Australasia. Registrars are under the direct supervision of the Designated Pathologist or deputy/ies.

The laboratory responsible for the reporting of breast specimens is accredited by the National Association of Testing Authorities (NATA). The pathologist also participates in quality assurance programs in cytopathology and/or histopathology such as the program run by the Royal College of Pathologists of Australasia.

THE DESIGNATED PATHOLOGIST

The role of the Designated Pathologist is to oversee all issues of quality assurance relating to pathology for the Service. The deputy/deputies are there to assist him/her in their task.

RESPONSIBILITIES

Responsibilities of the Designated Pathologist and deputy/ies include, but are not limited to:

- Pathology training and continuing education at the Service level.
- Where pathology registrars are being trained in the Program, the Designated Pathologist will be responsible for their training and for overseeing other pathologists associated with the Service.
- Being part of the assessment team and being responsible for reporting or review of all biopsies and FNAs of lesions detected by screening.
- Providing pathology input at multidisciplinary team meetings. Either the Designated Pathologist or deputy/deputies will attend and present pathology results at each meeting.
- Being available for consultation and advice regarding specimen handling and histological and cytological diagnosis.
- Analysis of the pathological and cytological data in a manner suitable for quality control, reports and publications.

MEDICAL OFFICERS

Medical officers hold current registration with the Medical Board of Australia through AHPRA. Medical officers may perform a number of varied roles in different Services depending on local requirements and the expertise of the Medical Officer. These may include the giving of results to women, communicating with general practitioners about results, referral for follow-up, performing clinical breast examinations, answering client questions about assessment tests and coordinating assessment.

The roles that a medical officer plays in screening and assessment need to be identified by the Service and/or SCU. Medical officers will be able to demonstrate competence in the areas in which they are involved e.g. percutaneous needle biopsies. Medical officers employed as screen readers will have appropriate training and demonstrated experience and expertise in reading screening mammograms and will participate in the regular audit process detailed in [Appendix H](#) to evaluate their performance in the detection of invasive cancers and small invasive cancers.

An appropriate period of in-service training is required of all medical officers, either under the direct supervision of an experienced radiologist, a surgeon or other relevant medical practitioner on the screening and assessment team.

NURSES

Nurses hold current registration as a nurse with the Nursing and Midwifery Board of Australia through AHPRA. Eligibility for membership of the Breast Interest Group of the Royal College of Nursing Australia is desirable.

Nurses are to have training in the screening and detection of breast cancer. Where nurses are involved in breast examination and interventional breast procedures, they be able to demonstrate competence in these areas.

All nurses commencing employment with the BreastScreen Program will undertake appropriate in-service training.

STAFF PROVIDING COUNSELLING

Staff providing counselling will have completed, or be working towards completing, formal recognised/accredited training in counselling. Experience/competency in women's health and/or breast/oncology nursing is desirable.

A range of modules to support health professionals have been developed by Cancer Australia to implement evidence-based communication skills. These modules are relevant for all cancer types. Attendance at ongoing training is highly recommended for all staff who provide counselling. It is recommended that all staff providing counselling have access to professional support provided by an appropriate counsellor on an as needs basis.

MEDICAL PHYSICISTS (OR EQUIVALENT)

The role of the medical physicist is to ensure high quality digital mammographic images are consistently acquired and also to ensure that all aspects of radiation safety practice are adhered to. The medical physicist is the qualified expert in matters pertaining to the technical aspects of image acquisition, quality, optimisation and radiation safety. Close liaison with the Designated Radiologist and Designated Radiographer and other members of the multi-disciplinary team in matters related to the quality of radiographic digital imaging is a key aspect of his/her function.

QUALIFICATIONS AND EXPERIENCE

Medical physicists (or equivalent) must hold Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM) Certification in Mammography Equipment Testing (DR and CR) to the standard defined by the Royal Australian and New Zealand College of Radiologists Accreditation Requirements.

ACPSEM Registration in Diagnostic Imaging Medical Physics, specialising in Diagnostic Radiology or Mammography, is highly desirable.

RESPONSIBILITIES

- Specification of new equipment performance.
- Acceptance testing and performance verification.

- Supervision of calibration, preventive maintenance, repair of equipment and documentation of all relevant information.
- Development and oversight of a quality assurance program for all imaging equipment to facilitate the production of digital mammography images of optimum quality while minimizing radiation doses to clients.
- Determination and monitoring of doses from mammographic procedures.
- Optimization of imaging procedures, e.g. radiographic techniques, collimation, radiation protection, efficient utilization of imaging equipment.
- Establishing, and maintaining a radiation safety program.
- Consultation with BreastScreen staff regarding concerns about client radiation exposure.
- Continued education of the diagnostic imaging staff to ensure the efficient implementation of new and existing technology.
- Continued education in radiation safety for all employees working with ionizing radiation in the BreastScreen Australia Program.

PACS ADMINISTRATORS

The role of the PACS Administrator will vary depending on whether it is a SCU or Service based position. The role is usually undertaken by a radiographer, but may also be undertaken by professionals with information technology, medical physicist or biomedical engineering expertise.

The PACS Administrator will have the knowledge and skills relevant to their role and responsibilities and will access area specific in-service training as required. Some examples of the responsibilities of the PACS Administrator, based on the BreastScreen Aotearoa Interim Digital Mammography Quality Standards – [NSU website](http://www.nsu.govt.nz) (www.nsu.govt.nz) are:

- Responsible for day-to-day operation of mammography PACS equipment including image workflow, archiving, auto routing, and prefetching and other related activities
- Ensures timely and complete capture of DICOM digital image data into the PACS system as well as network transmission, RIS validation, and exceptions handling
- Oversees activities of vendors in all phases of installation and maintenance of PACS
- Responsible for diagnosing, maintaining and upgrading all PACS associated hardware and software while ensuring its optimal performance
- Responsible for disaster recovery and data backup
- Ensures all procedures related to PACS are documented and current
- Identifies future needs and efficient workflow processes
- Provides application support via training sessions
- Involved in strategic planning of breast screening service.

The role of PACS administration is sometimes combined with the role of Client Management System manager.

DATA MANAGEMENT STAFF

Data management staff can demonstrate skills in the collection and monitoring of data including ensuring that quality assurance activities are undertaken for data accuracy and in the use of computer systems for the management, analysis and reporting of data.

Data management will have specialist knowledge of relevant requirements regarding information privacy, client confidentiality and security issues.

Relevant qualifications in data management are highly desirable.

EPIDEMIOLOGISTS

The role of the epidemiologist is to analyse and interpret the breast cancer data. Cancer epidemiology is concerned with the study of the distribution of the disease in populations. The ultimate goal is to identify risk factors that may lead to early introduction of effective preventive measures.

HEALTH PROMOTION

The role of health promotion staff is to use a mix of health promotion strategies and methods, based on current evidence and research, to:

- Increase the number of women aged 50–74 years joining the BreastScreen Australia Program.
- Increase the number of women returning for rescreening within the BreastScreen Australia Program.
- Inform general practitioners and other health professionals about breast cancer screening in order to increase clinician recommendations for breast cancer screening.
- Inform the community and key stakeholders about the risks and benefits of breast cancer screening.
- Encourage equitable participation especially amongst women from culturally and linguistically diverse, Indigenous, rural/remote and lower socioeconomic backgrounds.

QUALIFICATIONS AND EXPERIENCE

Tertiary qualifications in public health/health promotion/education and demonstrated skills and experience in health promotion strategies are highly desirable.

Health promotion staff will have the knowledge and ability to promote the BreastScreen Australia Program using a range of strategies and methods including media liaison, health education and community development.

Health promotion staff require high level communication and interpersonal skills demonstrating a proven ability to negotiate, liaise and work with a range of groups. These include the general public, the media, health professionals, community groups and women's groups.

ADMINISTRATION AND OTHER SUPPORT STAFF

Administration and other support staff will have knowledge and skills relevant to their current positions and will have access to area specific in-service training as required.

Communication skills training for administration staff with direct client interaction is highly desirable.

APPENDIX D:

STANDARDS FOR MAMMOGRAPHY IMAGING SYSTEM PERFORMANCE

All mammography imaging system equipment shall meet the minimum performance standards specified in Tables D.1 to D.3 and relevant radiation protection regulatory requirements. The equipment shall meet the minimum standards and shall be confirmed by testing performed at acceptance, annually and following major maintenance (for example, X-ray tube replacement) unless indicated otherwise. This testing shall be performed by, or under the close supervision of suitably qualified and experienced persons as specified in [Appendix C](#).

Procedures used shall be consistent with the latest recommendations of the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM) Position Paper Recommendations for a Digital Mammography Quality Assurance Program. Tables D.1 to D.3 must be read in conjunction with the relevant sections of this paper.

At acceptance, more extensive testing shall be performed as per the Australasian College of Physical Scientists and Engineers in Medicine recommendations (see ACPSEM Position paper).

TABLE D.1: DIGITAL (DR) MAMMOGRAPHY IMAGING SYSTEM PERFORMANCE STANDARDS (2D AND DBT)

| Item | Minimum standards |
|---|---|
| Mammography Unit Assembly Evaluation | <ul style="list-style-type: none">• Mechanical stability, correct and safe function of system components.• All moving parts move smoothly, without obstructions to motion.• Image receptor assembly is free from vibrations.• Appropriate operator technique control charts are posted.• Thickness display accuracy within ± 5 mm and reproducible to 2 mm for each breast support platform in use. Note: Flexi paddles will not comply (manufacturer recommendation varies ~ 11-12 mm for flexi paddles).• Verify DICOM image header for correct display of parameters.• Power compression less than 200 N.• Manual compression less than 300 N. |
| Collimation and Alignment Assessment | <p>Assess for each target/geometry/acquisition (2D & DBT)/breast support platform combination.</p> <ul style="list-style-type: none">• <i>Missed tissue at the chest wall (acceptance/ tube/ image receptor change only)</i> Width of missed tissue at chest wall ≤ 5 mm in contact mode (2D and DBT) and ≤ 7 mm in magnification mode. Additionally for DBT mode, the full thickness of tissue must be imaged.• <i>X-ray field / Image receptor alignment</i> The x-ray field shall irradiate the image receptor fully in contact mode and to chest wall in magnification mode. The x-ray field must not extend beyond the breast support on the chest wall edge of the image receptor by more than 2 mm; and must not extend beyond the breast support platform on the other three margins. |

| Item | Minimum standards |
|--|---|
| <ul style="list-style-type: none"> <i>Paddle / Image alignment</i> | <p>The chest wall edge of the compression paddle shall be aligned just beyond the chest wall edge of the image receptor such that it does not appear in the image. In addition, the compression paddle shall not extend beyond the chest wall edge of the image by more than 1% of the SID.</p> |
| <p>Distance Calliper Accuracy (acceptance or software upgrade, annual for DBT)</p> | <p>Distance callipers must agree to within $\pm 2\%$ of true values when allowance made for manufacturer's calibration plane.</p> <p>Requirement applies to both contact (2D and DBT) and magnification modes.</p> |
| <p>System Resolution/ MTF</p> | <p>Assess for 2D contact and magnification modes.</p> <p>Resolution in 2D contact mode should be >5 lp/mm but may be limited by the Nyquist frequency to a slightly lower value.</p> <p>Compare to baseline values, variation must be $< 10\%$.</p> |
| <p>Automatic Exposure Control (AEC) & SDNR Performance</p> | |
| <ul style="list-style-type: none"> <i>Reproducibility</i> | <p>Coefficient of variation (COV) for both absorbed dose to detector (MPV) and mAs for at least three phototimed exposures of a test object shall be better than or equal to 0.05.</p> |
| <ul style="list-style-type: none"> <i>Compensation and SDNR System Performance Assessment</i> | <p>For 2D contact and magnification modes:</p> <p>Compare SDNR values to baseline and to the minimum acceptable values for 4 cm PMMA ($SDNR_{accept}$):</p> <ul style="list-style-type: none"> $SDNR_{2cm} > 1.1 \times SDNR_{accept}$ $SDNR_{4cm} > SDNR_{accept}$ $SDNR_{6cm} > 0.9 \times SDNR_{accept}$ <p>For DBT mode:</p> <p>mAs = baseline $\pm 10\%$ given the same kVp/target/filter combination for each thickness of PMMA.</p> |
| <ul style="list-style-type: none"> <i>Density control (if applicable)</i> | <p>The density control should be capable of changing the mAs from the value used normally by -25% to +50</p> |
| <ul style="list-style-type: none"> <i>Back-up timer / security cut-out</i> | <p>Security cut-out mechanisms shall be present & terminate the exposure within 50 ms or within 5 mAs, otherwise the back-up timer should terminate the exposure at ≤ 500 mAs and must terminate the exposure at ≤ 800 mAs; or less as dictated by regulatory requirements.</p> |

| Item | Minimum standards | | | | | | | | | |
|--|---|----------------------------------|---------|----------|-------------|---|----------------------------------|----------------|----------------------------------|----------------------------------|
| Full Field Image Uniformity and Artefact | <p>There must be no evidence of clinically significant structures that are more conspicuous than the objects in the phantom used for weekly testing, blotches or regions of altered noise appearance, observable grid lines or breast support structures, bright or dark pixels, dust artefacts mimicking calcifications or significant stitching or registration artefacts.</p> <p>For 2D contact and magnification modes:</p> <ul style="list-style-type: none">Maximum deviation of MPV < ±10% of MPV for central ROI.Maximum deviation in SNR of central ROI as a function of time is < ±10%. <p>For DBT mode:</p> <ul style="list-style-type: none">Visual assessment of the projections and reconstructions must appear uniform.The mAs must be within baseline ±10% (given the same kVp/target/filter combination). | | | | | | | | | |
| Detector Element Failure | <ul style="list-style-type: none">Limits must meet manufacturer’s recommendations.Bad pixel map must be available for inspection at any time, independent of manufacturer. | | | | | | | | | |
| Image Quality Evaluation | <p>Use clinically relevant radiographic settings (kVp, target/filter) under AEC.</p> <p>In an image of an ACR accreditation phantom must clearly visualise at least:</p> <table><tr><td></td><td>2D mode</td><td>DBT mode</td></tr><tr><td>ACR phantom</td><td>5 fibres 3.5 specks (4 is desirable) 4 masses</td><td>4 fibres 3 specks 3 masses</td></tr><tr><td>ACR DM Phantom</td><td>4 fibres 3 specks 3 masses</td><td>2 fibres 1 specks 2 masses</td></tr></table> <p>Note: There are no minimum requirements for synthesised images. Comparisons with baseline should be made.</p> <ul style="list-style-type: none">The image quality score must not vary by more than 0.5 from baseline.The mAs must not vary by more than 10% from baseline (given the same kVp/target/filter).The plane of focus in DBT mode must not vary by more than 1 mm from baseline.Additionally, with the ACR DM phantom in 2D mode, the SDNR with the contrast object must be ≥2.0. | | 2D mode | DBT mode | ACR phantom | 5 fibres 3.5 specks (4 is desirable) 4 masses | 4 fibres 3 specks 3 masses | ACR DM Phantom | 4 fibres 3 specks 3 masses | 2 fibres 1 specks 2 masses |
| | 2D mode | DBT mode | | | | | | | | |
| ACR phantom | 5 fibres 3.5 specks (4 is desirable) 4 masses | 4 fibres 3 specks 3 masses | | | | | | | | |
| ACR DM Phantom | 4 fibres 3 specks 3 masses | 2 fibres 1 specks 2 masses | | | | | | | | |
| Ghost Image Evaluation | “Ghost image” factor < 2.0. | | | | | | | | | |

| Item | Minimum standards |
|---|---|
| System Linearity and Noise Analysis | <ul style="list-style-type: none"> Plot of MPV versus ESAK: $R^2 > 0.99$ Plot of SD^2 versus MPV: $R^2 > 0.99$ Noise parameters: Compare to baseline results |
| Generator Performance (optional) | |
| <ul style="list-style-type: none"> <i>kVp, output, and timer reproducibility</i> | COV ≤ 0.02 for a minimum of three exposures. |
| <ul style="list-style-type: none"> <i>kVp accuracy</i> | Measured kVp shall be within $\pm 5\%$ of the specified value over the clinically relevant range. |
| Beam Quality | HVL $> [(kVp/100) + 0.03]$ mm Al and is not excessively high. |
| Mean Glandular Dose | <ul style="list-style-type: none"> ≤ 2.0 mGy for the ACR accreditation phantom or the ACR DM phantom (4.2 cm 50% adipose, 50% glandular breast). < 1 mGy for 2D mode and < 1.2 mGy for DBT mode for 2.0 cm PMMA (2.3 cm 50% adipose, 50% glandular breast). < 4.5 mGy for 6.0 cm PMMA, (6.5 cm 50% adipose, 50% glandular breast). The difference between calculated and displayed MGD must be $< 25\%$. MGDs should be within 10% of baseline. <p>Note that additional output and HVL measurements may be required for the purpose of evaluating diagnostic reference levels.</p> |
| Exposure Time | <p>The maximum exposure time when irradiating 6 cm PMMA should be less than 3.5 seconds and 2 seconds for fine and broad focus, respectively.</p> <p>Criteria does not apply for the scanning slot technologies.</p> |
| Evaluation of Site QC | Confirm site QC is being carried out in accordance with Appendix E . |

| Item | Minimum standards |
|---|---|
| Monitor Luminance and Viewing Conditions | <p>Monitors used for interpretation:</p> <ul style="list-style-type: none"> • Must not be < 5 megapixels per image at full resolution. • Maximum pixel pitch of 0.2 mm. • Luminance ratio > 250 and ideally ~350. • Minimum luminance preferably ≥ 1 cd/m². • Maximum luminance ≥ 450 cd/m². • The maximum luminance of paired monitors must be matched to $\leq 5\%$. • Luminance response deviates from the Greyscale Standard Display Function by $\leq 10\%$. • Ambient light < 20 lux. • No specular reflections. <p>Acquisition monitor:</p> <ul style="list-style-type: none"> • Must not be < 3 megapixels. • Luminance dynamic range > 250:1. • Maximum luminance >250 cd/m². |
| Monitor Performance | <ul style="list-style-type: none"> • No smearing artefact, ramps without terracing. • Lines straight, boxes square, active display centred, borders complete • Squares of different shades from black to white must be distinct and small squares in corners of each clearly discernible. • 0-5% visible, 95-100% visible. • All high contrast line pairs and the two pixel low contrast line pairs visible in all four corners and the centre. • No artefacts. • The number of letters visible in the phrase "Quality Control" for the dark, mid-grey and light renditions must be ≥ 11. |
| Printer (Hardcopy only) | <ul style="list-style-type: none"> • B+F = baseline ± 0.03 and ≤ 0.25 OD. • Mid density and density difference should be close to baseline values. • Dmax = baseline ± 0.10 and ≥ 3.4 OD. • The number of letters visible in the phrase "Quality Control" for the dark, mid-gray and light renditions must be ≥ 11. <p>Note: If hardcopy is used for reference only, then OD measurements are only required at initial printer set-up and the printed films must be clearly annotated that they are not for diagnosis.</p> |

TABLE D.2: DIGITAL STEREOTACTIC IMAGING SYSTEM PERFORMANCE STANDARDS

| Item | Minimum standards |
|--|--|
| Mammographic Unit Assembly Evaluation | <ul style="list-style-type: none"> • Mechanical stability, correct and safe function of system components and alarms. • DICOM image header (if present) correctly displays parameters. • Technique charts are confirmed to be in place. This applies to units both with and without AEC. • The X-ray tube angular locations are positively locked and inadvertent movement from them cannot take place. • The image receptor and compression plate biopsy window is free of wobble. • The vernier table drive and needle guide is rigid and is free of wobble. • The localisation system zeroes coordinates properly. • The biopsy device is properly immobilised to prevent recoil. |
| Collimation and Alignment Assessment | <p>The X-ray field defined by the biopsy window:</p> <ul style="list-style-type: none"> • shall be aligned centrally with digital image receptor, and • may extend beyond the edge of the image receptor by no more than 5 mm on all four sides, where all distances are referred to the plane of the image receptor. |
| Distance Calliper Accuracy (acceptance or software upgrade) | Distance callipers must agree to within $\pm 2\%$ of true values when allowance made for manufacturer's calibration plane. |
| System resolution/MTF | Resolution should be >5 lp/mm but may be limited by the Nyquist frequency to a slightly lower value. Compare to baseline values, variation must be $< 10\%$. |
| Automatic Exposure Control (AEC) Performance | |
| <ul style="list-style-type: none"> • <i>Reproducibility</i> | Coefficient of variation for both absorbed dose to detector (MPV) and mAs for at least three phototimed exposures of a test object shall be better than or equal to 0.05. |
| <ul style="list-style-type: none"> • <i>Compensation and SDNR System Performance Assessment</i> | <p>The equipment vendor must provide the manufacturer's recommended target pixel values and allowable tolerance for a range of PMMA absorber thicknesses. In most old biopsy systems, the AEC is designed to maintain an essentially constant mean pixel value (MPV) over the thickness range, in which case a single target value is appropriate.</p> <p>The MPV and the SDNR, in those instances where it can be measured, should be within $\pm 10\%$ of the previously measured value for the respective PMMA thickness.</p> |
| <ul style="list-style-type: none"> • <i>Density control (if applicable)</i> | The density control should be capable of changing the mAs from the value used normally by -25% to $+50\%$ |

| Item | Minimum standards | | | | |
|---|--|----------------------------------|------------------------------------|------------------|------------------------------------|
| <ul style="list-style-type: none"> <i>Back-up timer / security cut-out</i> | <p>Security cut-out mechanisms shall be present & terminate the exposure within 50 ms or within 5 mAs, otherwise the back-up timer should terminate the exposure at ≤ 500 mAs and must terminate the exposure at ≤ 800 mAs; or less as dictated by regulatory requirements.</p> | | | | |
| Image Uniformity and Artefact | <ul style="list-style-type: none"> Maximum deviation of MPV in any ROI $\leq \pm 10\%$ of MPV for central ROI. Maximum deviation in SNR of central ROI as a function of time is $\leq \pm 10\%$. <p>Note: Some separate image receptor systems do not allow the placement of ROIs on the image so that a visual inspection using an appropriately adjusted level and narrow window is all that may be possible.</p> <ul style="list-style-type: none"> There must be no evidence of clinically significant structures that are more conspicuous than the objects in the phantom used for weekly testing, blotches or regions of altered noise appearance, observable grid lines or table top structures, bright or dark pixels, dust artefacts mimicking calcifications or significant stitching or registration artefacts. | | | | |
| Image Quality Evaluation | <p>Use clinically relevant radiographic settings (kVp, target/filter) under AEC.</p> <p>In an image of an ACR accreditation phantom must clearly visualise at least:</p> <table border="1"> <tbody> <tr> <td>ACR mini phantom (e.g. NA 18-25)</td><td>3 fibres 3 specks 2.5 masses</td></tr> <tr> <td>RMI 156S Phantom</td><td>3 fibres 2 specks 1.5 masses</td></tr> </tbody> </table> <ul style="list-style-type: none"> Images shall be free of clinically significant artefacts. The image quality score must not vary by more than 0.5 from baseline. The mAs must not vary by more than 10% from baseline given the same kVp/target/filter. | ACR mini phantom (e.g. NA 18-25) | 3 fibres 3 specks 2.5 masses | RMI 156S Phantom | 3 fibres 2 specks 1.5 masses |
| ACR mini phantom (e.g. NA 18-25) | 3 fibres 3 specks 2.5 masses | | | | |
| RMI 156S Phantom | 3 fibres 2 specks 1.5 masses | | | | |
| Ghost Image Evaluation | "Ghost image" factor < 2.0. | | | | |
| System Linearity Evaluation | <ul style="list-style-type: none"> Plot of MPV versus ESAK: $R^2 > 0.99$ Plot of SD^2 versus MPV: $R^2 > 0.95$ | | | | |
| Generator Performance (optional) | | | | | |
| <ul style="list-style-type: none"> <i>kVp, output, and timer reproducibility</i> | COV ≤ 0.02 for a minimum of three exposures. | | | | |

| Item | Minimum standards |
|---|--|
| <ul style="list-style-type: none"> <i>kVp accuracy</i> | Measured kVp shall be within $\pm 5\%$ of the specified value over the clinically relevant range. |
| Beam Quality | HVL > [(kVp/100) + 0.03] mm Al and is not excessively high. |
| Mean Glandular Dose (MGD) | <ul style="list-style-type: none"> ≤ 2.0 mGy for the ACR mini accreditation phantom (4.2 cm 50% adipose, 50% glandular breast). < 1 mGy for 2.0 cm PMMA (2.3 cm 50% adipose, 50% glandular breast). < 4.5 mGy for 6.0 cm PMMA, (6.5 cm 50% adipose, 50% glandular breast). MGDs should be within 10% of baseline. |
| Exposure Time | The maximum exposure time when irradiating 6 cm PMMA should be less than 2 seconds. |
| Accuracy of stereotactic localisation^{CCC} | Localisation within ± 1 mm. |
| Evaluation of Site QC | Confirm site QC is being carried out in accordance with Appendix E . |
| Monitor Luminance and Viewing Conditions | <p>Monitors used for interpretation:</p> <ul style="list-style-type: none"> Must not be < 5 megapixels per image at full resolution. Maximum pixel pitch of 0.2 mm. Luminance ratio > 250 and ideally ~350. Minimum luminance preferably ≥ 1 cd/m². Maximum luminance ≥ 450 cd/m². The maximum luminance of paired monitors must be matched to $\leq 5\%$. Luminance response deviates from the Greyscale Standard Display Function by $\leq 10\%$. Ambient light < 20 lux. No specular reflections. <p>Acquisition monitor:</p> <ul style="list-style-type: none"> Must not be < 3 megapixels. Luminance dynamic range > 250:1. Maximum luminance > 250 cd/m². |

^{CCC} As verification of stereotactic accuracy is performed regularly by facility staff this test may be omitted from annual testing.

| Item | Minimum standards |
|--------------------------------|---|
| Monitor Performance | <p>If possible using TG18-QC pattern establish:</p> <ul style="list-style-type: none"> • No smearing artefact, ramps without terracing. • Lines straight, boxes square, active display centred, borders complete. • Squares of different shades from black to white must be distinct and small squares in corners of each clearly discernible. • 0-5% visible, 95-100% visible. • All high contrast line pairs and the two pixel low contrast line pairs visible in all four corners and the centre. • No artefacts. • The number of letters visible in the phrase "Quality Control" for the dark, mid-grey and light renditions must be ≥ 11. |
| Printer (hardcopy only) | <ul style="list-style-type: none"> • $B+F = \text{baseline} \pm 0.03$ and ≤ 0.25 OD. • Mid density and density difference should be close to baseline values. • $D_{\text{max}} = \text{baseline} \pm 0.10$ and ≥ 3.4 OD. • The number of letters visible in the phrase "Quality Control" for the dark, mid-gray and light renditions must be ≥ 11. <p>Note: If hardcopy is used for reference only, then OD measurements are only required at initial printer set-up and the printed films must be clearly annotated that they are not for diagnosis.</p> |

APPENDIX E:

STANDARDS FOR MAMMOGRAPHY QUALITY CONTROL PROCEDURES

This Appendix is based on the recommendations of the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM) Position Paper [Recommendations for a Digital Mammography Quality Assurance Program](#).

The Royal Australian and New Zealand College of Radiologists Guidelines for Quality Control Testing for Digital (CR DR) Mammography align the Radiographer quality control procedures with those recommended by the ACPSEM Position Paper. It is recommended that Tables E.1 to E.5 be read in conjunction with these two papers.

The Designated Radiographer is responsible for:

- Ensuring that all relevant staff are aware of their responsibilities with respect to mammography quality control.
- Allocating responsibility for quality control procedures to facility staff.
- Ensuring relevant staff receive training in these procedures.
- Ensuring quality control test equipment meeting the minimum standards specified in Table E.1 is readily available to facility staff.

Facility quality control procedures shall meet the minimum requirements specified in Tables E.2 to E.5.

Unless otherwise indicated or to meet regulatory requirements:

- Baseline values shall be determined from an average of five results from tests performed on different days.
- All quality control records (written or electronic) shall be retained for a minimum of 12 months.
- Phantom images used to assess image quality should be retained for a minimum of six months.

TABLE E.1: QUALITY CONTROL TEST EQUIPMENT FOR MAMMOGRAPHY

| Item | Minimum Standards |
|---|--|
| Breast phantom | Shall allow assessment of background optical density, if applicable, image quality and contrast. The ACR or ACR DM mammography accreditation phantom must be used for this purpose. |
| Polymethylacrylate (PMMA) or tissue equivalent material | Able to provide, at least, 2, 4 and 6 cm thicknesses. Should be at least 18 x 24 cm in size and preferably be 24 x 30 cm. |
| Densitometer (if film used for reporting) | Accuracy of at least: <ul style="list-style-type: none">• ± 0.03 in the optical density range 0 to 3.0• $\pm 3\%$ in the optical density range 3.0 to 4.0 |

TABLE E.2: QUALITY CONTROL PROCEDURES AND STANDARDS FOR ALL MAMMOGRAPHY SYSTEMS

| Procedure | Control-Limits/Requirements | Minimum Frequency | Required Procedure Elements | Minimum Record Requirements |
|--|--|-------------------|---|---|
| Infection control of breast imaging equipment | Clean equipment | As required | <ul style="list-style-type: none"> All cleaning as per manufacturer's recommendations and/or suitable infection control advice. Cleaning of breast support and compression paddle between each examination. | Documented procedures. |
| Viewing conditions | Appropriate viewing conditions | Daily | Visual inspection of ambient lighting conditions to ensure conformance with acceptable viewing condition configuration. Refer to corresponding text in the ACPSEM Position Paper for detail. | Records confirm: <ul style="list-style-type: none"> Date performed. Person performing task. |
| Monitor cleaning | Monitor screens must be free of dust, fingerprints and other marks that might interfere with image interpretation. | Weekly | Clean all monitor screens gently with lint-free cloth as per manufacturer's instructions. | Records confirm: <ul style="list-style-type: none"> Date performed. Person performing task. |

| Procedure | Control-Limits/Requirements | Minimum Frequency | Required Procedure Elements | Minimum Record Requirements |
|---|---|-------------------|---|---|
| Monitor QC (monitors used for interpretation and attached to the acquisition workstation) | <p>Borders must be visible, lines must be straight, squares must appear square, the ramp bars must appear continuous without any contour lines (not applicable to older GE acquisition monitors), there must be no smearing or bleeding at black-white transitions, all corner patches must be visible, squares of different shades from black to white must be distinct, all high contrast resolution patterns and two low contrast patterns must be visible in all four corners and in the centre, the 5% and 95% pixel value squares must be clearly visible, pattern should be centred in the active area and no disturbing artefacts should be visible on the displayed TG18-QC test pattern.</p> <p>The number of letters visible in the phrase "Quality Control" for the dark, mid-grey and light renditions must be ≥ 11.</p> | Weekly | <p>Display the TG18-QC test pattern.</p> <ul style="list-style-type: none"> • Ensure viewing conditions are acceptable. • Use window-width set to maximum and window-level set to half of maximum. • Check visibility and distortion of several items used for evaluating the quality of the image. • Check for disturbing artefacts. | <p>Records showing:</p> <ul style="list-style-type: none"> • Date test performed. • Person performing test. • Monitor identification. • Monitor settings (window and level). • Test results. |
| Printer area cleanliness (if applicable) | Clean and dust free environment. | Monthly | <ul style="list-style-type: none"> • Wet cleaning of printer area floor and open shelves. • Inspect and clean air intake filters on the film printer. | <p>Records confirm:</p> <ul style="list-style-type: none"> • Date performed. • Person performing task. |

| Procedure | Control-Limits/Requirements | Minimum Frequency | Required Procedure Elements | Minimum Record Requirements |
|------------------------------|--|-------------------|--|---|
| Mechanical inspection | <ul style="list-style-type: none"> Indicated breast thickness accurate to ± 5 mm for each breast support platform. No hazardous, inoperative, out of alignment or improperly operating items on the system. All items listed on the visual check list (see RANZCR QA and QC Guidelines) have received a pass. <p>Additionally for Stereotactic biopsy systems:</p> <ul style="list-style-type: none"> The image receptor and compression plate biopsy window is free of wobble. The vernier table drive and needle guide is rigid and is free of wobble. The localisation system zeroes coordinates properly. The biopsy device is properly immobilised to prevent recoil. | Monthly | <ul style="list-style-type: none"> Confirm accuracy of thickness indication. Visual inspection of the system to ensure safe and optimum operation. | <p>Records showing:</p> <ul style="list-style-type: none"> Date performed. Person performing test. Inspection results. |

| Procedure | Control-Limits/Requirements | Minimum Frequency | Required Procedure Elements | Minimum Record Requirements |
|-----------------------------------|---|--|--|---|
| Printer QC (if applicable) | <p>Borders must be visible, lines must be straight, squares must appear square, the ramp bars must appear continuous without any contour lines, there must be no smearing or bleeding at black-white transitions, all corner patches must be visible, squares of different shades from black to white must be distinct, all high contrast resolution patterns and the two pixel low contrast patterns must be visible in all four corners, the 5% and 95% pixel value squares must be clearly visible, and no disturbing artefacts should be visible on the printed TG18-QC pattern.</p> <p>The number of letters visible in the phrase "Quality Control" for the dark, mid-grey and light renditions must be ≥ 11.</p> <p>If reporting from hardcopy, the following OD measurements are required:</p> <ul style="list-style-type: none"> • The mid density (MD) and density difference (DD) = baseline ± 0.15. • Base + fog (B+F) = baseline ± 0.03 and ≤ 0.25. • D_{\max} = baseline ± 0.10 and ≥ 3.4. | Monthly for dry lasers and daily or as used for wet lasers | <ul style="list-style-type: none"> • Print the TG18-QC test pattern. • Check visibility and distortion of several items used for evaluating the quality of the image. • Check for disturbing artefacts. • If reporting from hardcopy, measure MD, DD, B+F and D_{\max}. | <p>Records showing:</p> <ul style="list-style-type: none"> • Date test performed. • Person performing test. • Printer identification. • Test results. • Clearly marked control limits. • Baseline values. • Remarks regarding corrective actions and baseline changes. |

| Procedure | Control-Limits/Requirements | Minimum Frequency | Required Procedure Elements | Minimum Record Requirements |
|--|--|-------------------|--|--|
| Film Digitiser QC (if applicable) | <p>Digitised images are produced that consistently and accurately reproduce hard copy images.</p> <ul style="list-style-type: none"> A plot of MPV versus OD should be linear over full range of OD from B+F to D_{\max} with $R^2 > 0.95$ <p>Note: If the plot of MPV versus OD is not linear, it could be due to the wrong LUT being selected by the equipment. This should be rectified by service personnel.</p> | Monthly | <ul style="list-style-type: none"> Produce an analogue film with a step wedge pattern. This may be generated automatically by a laser printer, for example. Measure the Optical Densities (OD) for each step. Digitise the image. Measure the mean pixel value (MPV) at a convenient place in each step. Plot the MPV versus OD using an EXCEL spreadsheet. This should be linear if the correct look up table (LUT) is used. <p>Note: The LUT is part of the software in the digitiser or workstation it is attached to.</p> <ul style="list-style-type: none"> Obtain the value of the correlation coefficient (R^2) using EXCEL for this plot. | <p>Records showing:</p> <ul style="list-style-type: none"> Date test performed. Person performing test. The R^2 value for the plot of MPV versus OD. |
| Compression | <p>Maximum motorised compression force in range 150 - 200 newtons and manual compression force less than 300 newtons.</p> <p>Once the compression has stabilised, it must remain unchanged.</p> | Six monthly | <ul style="list-style-type: none"> Confirm machine indicated compression force meets requirements. | <p>Records showing:</p> <ul style="list-style-type: none"> Date test performed. Person performing test. Test results. |

| Procedure | Control-Limits/Requirements | Minimum Frequency | Required Procedure Elements | Minimum Record Requirements |
|---|---|-------------------|---|---|
| Test equipment quality control Densitometer calibration check (If applicable) | Optical density measurement accurate to within: <ul style="list-style-type: none"> • ± 0.03 for (0 to 3.0 OD) and • $\pm 3\%$ for (3.0 to 4.0 OD) | Six monthly | Verification of accuracy using an OD calibration strip traceable to an accepted standard. | Records showing: <ul style="list-style-type: none"> • Date test performed. • Person performing test. • Test results. |
| Maintenance and fault logging | Records for each imaging system, including diagnostic monitors and film printer if relevant | As required | Recording of equipment faults, incidents and occasions of maintenance (preventative and corrective) as they occur | Dated records that identify the occasion type (maintenance/fault), time, the person making the entry, equipment the occasion occurred on, actions leading up to any fault, occasion description, any machine error code displayed, action taken and follow-up result of action. |

TABLE E.3: QUALITY CONTROL PROCEDURES AND STANDARDS FOR DR (2D & DBT) MAMMOGRAPHY SYSTEMS

| Procedure | Control-Limits/Requirements | Minimum Frequency | Required Procedure Elements | Minimum Record Requirements |
|---------------------------------------|---|-------------------|--|---|
| Full field artefact evaluation | <p>mAs = baseline \pm 10%</p> <p>Mean pixel value in image = baseline \pm 10% (2D Only)</p> <p>There must be no evidence of:</p> <ul style="list-style-type: none"> Structures that are more conspicuous than the objects in the phantom used for weekly testing. Blotches or regions of altered noise appearance. Observable grid lines or breast support structures. Bright or dark pixels Dust artefacts mimicking calcifications. Significant stitching or registration artefacts. Any processing artefacts (if applicable). | Daily | <ul style="list-style-type: none"> Assess for both 2D and DBT mode. Expose a uniform thickness of PMMA using clinically relevant technique factors. Image should be acquired in “raw” or “for processing” form. Measure mean pixel value in 4 cm² ROI positioned centrally along long axis of image and 6 cm from chest wall (2D only). View images (both the central projection and central reconstruction in DBT mode) on the acquisition monitor using zoom and roam to check for possible detector faults. Print image if interpretation performed using hard copy. | <p>Records showing:</p> <ul style="list-style-type: none"> Date test performed. Person performing test. X-ray system identification. Acquisition mode (2D or DBT). Radiographic settings (kVp, target/filter combination, AEC mode, AEC detector position and density setting (if applicable)). Plots of mAs and MPV (if applicable). Clearly marked control limits. Baseline values. Remarks regarding corrective actions and baseline changes. |

| Procedure | Control-Limits/Requirements | Minimum Frequency | Required Procedure Elements | Minimum Record Requirements | | | | | | | |
|---|---|----------------------------------|--|--|-----|-------------|------------------------------------|----------------------------------|----------------|----------------------------------|----------------------------------|
| Image Quality Evaluation - Phantom images | mAs = baseline ± 10% | Weekly | Assess for both 2D and DBT mode. | Records showing: | | | | | | | |
| | Clearly visualize in an image: | | Obtaining the phantom image: | <ul style="list-style-type: none">Date test performed.Person performing test.X-ray system identification.Phantom model.Acquisition mode (2D or DBT).Radiographic settings (kVp, target/filter combination, AEC mode, AEC detector position and density setting (if applicable)).Plots of mAs, image quality scores, OD (if applicable) and position of reconstructed slice used for scoring (DBT only).Clearly marked control limits.Baseline values.Remarks regarding corrective actions and baseline changes. | | | | | | | |
| | <table><tr><td></td><td>2D</td><td>DBT</td></tr><tr><td>ACR phantom</td><td>5 fibres 3.5 specks 4 masses</td><td>4 fibres 3 specks 3 masses</td></tr><tr><td>ACR DM Phantom</td><td>4 fibres 3 specks 3 masses</td><td>2 fibres 1 specks 2 masses</td></tr></table> | | | 2D | DBT | ACR phantom | 5 fibres 3.5 specks 4 masses | 4 fibres 3 specks 3 masses | ACR DM Phantom | 4 fibres 3 specks 3 masses | 2 fibres 1 specks 2 masses |
| | 2D | DBT | | | | | | | | | |
| ACR phantom | 5 fibres 3.5 specks 4 masses | 4 fibres 3 specks 3 masses | | | | | | | | | |
| ACR DM Phantom | 4 fibres 3 specks 3 masses | 2 fibres 1 specks 2 masses | | | | | | | | | |
| | Position of the reconstructed slice used for scoring the phantom must not change by more than ± 1 mm (DBT only). | | Evaluating the phantom image (preferably on reading workstation or on printed copy (if hardcopy reporting used) at least once a month): | | | | | | | | |
| | For hard copy reporting, optical density (OD) in the background must be in the range of 1.6 to 2.0 and the contrast between the PMMA disc and the background must be ≥ 0.40 OD (see also SDNR test below). | | <ul style="list-style-type: none">Use “for presentation” image with zoom and modest adjustment of window/level functions to score fibres and specks.Use consistent viewing conditions that reflect those used to read actual mammograms.For DBT, scroll through the reconstructed images until the slice displaying the speck details most clearly is reached.Image quality scoring by the same person, if possible.Measure optical density in reproducible part of phantom image if hardcopy reporting.Use of a control chart to record results. | Dated phantom images from at least the last six months showing X-ray system and radiographic settings. | | | | | | | |

| Procedure | Control-Limits/Requirements | Minimum Frequency | Required Procedure Elements | Minimum Record Requirements |
|--|-------------------------------|--|--|---|
| Detector Calibration – Flat Field Test | Test passes | Weekly or as per manufacturer's requirements | Follow manufacturer's specific procedure. | Records confirm: <ul style="list-style-type: none"> • Date test performed. • Person performing test. |
| Signal Difference to Noise Ratio (SDNR) | SDNR = baseline \pm 20% | Weekly | <p>Assess for 2D mode only.</p> <p>Use manufacturer's protocol and test block if available or otherwise:</p> <ul style="list-style-type: none"> • Use the 2D "for presentation" image obtained with ACR (with PMMA disc on paddle) or ACR DM phantom for image quality purposes. • Measure the mean pixel value (MPV₁) and SD in a small ROI next to PMMA disc (or negative contrast disc in the ACR DM phantom). • Measure mean pixel value (MPV₂) in ROI centred in disc. • Calculate SDNR = (MPV₁ – MPV₂)/SD. | Records showing: <ul style="list-style-type: none"> • Date test performed. • Person performing test. • X-ray system identification. • Radiographic settings (kVp, target/filter combination, AEC mode, AEC detector position and density setting (if applicable)). • Test results. |
| Repeat analysis | Overall repeat rate \leq 2% | Quarterly | Analysis of the proportion of repeats attributable to positioning, a range of equipment faults and other reasons for the quarter or from at least 250 consecutive client examinations. | Records showing: <ul style="list-style-type: none"> • Date analysis performed. • Person performing analysis. • X-ray system identification. • Results of analysis and any corrective actions taken. |

| Procedure | Control-Limits/Requirements | Minimum Frequency | Required Procedure Elements | Minimum Record Requirements |
|-----------------------------------|--|---|---|---|
| Image receptor homogeneity | <ul style="list-style-type: none"> Maximum deviation in MPV in ROI < $\pm 10\%$ of MPV in central ROI. Maximum variation of the MPV in central ROI between successive quarterly images < $\pm 10\%$. | Quarterly or more frequently if recommended by the manufacturer | <p>Assess for 2D mode only.</p> <p>Use manufacturer's protocol and test block if available or otherwise:</p> <ul style="list-style-type: none"> Image a standard test block at clinical settings. On the "for processing" image, draw 100 mm² square or circular ROIs in the centre and four corners. If the mean pixel value of a ROI deviates by more than 10% from the mean pixel value in the central ROI, the detector gain map may require re-calibration. If required, to exclude failure due to non-uniformities in the standard test block, rotate latter by 180° and repeat measurement. | <p>Records showing:</p> <ul style="list-style-type: none"> Date test performed. Person performing test. X-ray system identification. Radiographic settings (kVp, target/filter combination, AEC mode, AEC detector position and density setting (if applicable)). Test results. |
| AEC calibration test | <p>The AEC shall be able to maintain:</p> <ul style="list-style-type: none"> Mean pixel value (MPV) to within $\pm 10\%$ of the baseline MPV for each 2, 4 and 6 cm thickness of PMMA (2D contact and magnification modes). mAs to within $\pm 10\%$ of the baseline mAs for each 2, 4 and 6 cm thickness of PMMA given the same target/filter combination (DBT only). | Quarterly | <ul style="list-style-type: none"> Assess for 2D and DBT contact modes and magnification mode. Use PMMA thicknesses of 2, 4 and 6 cm covering complete image receptor. Use clinical AEC settings (kVp, target/filter and mode). Measure mean pixel value in 4 cm² ROI positioned centrally along axis and 6 cm from chest wall (2D contact and magnification modes). Examine image for clinically significant artefacts. | <p>Records showing:</p> <ul style="list-style-type: none"> Date test performed. Person performing test. X-ray system identification. Acquisition mode (2D, DBT or Magnification). Radiographic settings (kVp, target/filter combination, AEC mode, AEC detector position and density setting (if applicable) and mAs for each phantom thickness). Test results. |

TABLE E.4: QUALITY CONTROL PROCEDURES AND STANDARDS FOR DIGITAL STEREOTACTIC UNITS

Three different configurations of digital stereotactic biopsy units may be encountered in the field; (i) 'integrated', where the same detector is used for mammography and biopsy use, (ii) 'separate image receptor' where an X-ray system common to mammography but with a different image receptor assembly is used, and (iii) 'stand alone' where full testing must be completed e.g. prone biopsy tables. As such, it must be anticipated that in some cases little or no additional QC testing may be required for biopsy units (e.g. category (i)), whilst in other instances variations to the basic tests outlined below may be expected.

| Test | Applies to | | | Notes |
|--------------------------------|------------|------|-------|------------------------|
| | (i) | (ii) | (iii) | |
| Infection Control | • | • | • | See E.2 |
| Stereotactic Accuracy | • | • | • | See test outline below |
| Viewing Conditions | | | • | See E.2 |
| Image Quality Evaluation | | • | • | See test outline below |
| Monitor QC | | | • | See E.2 |
| Monitor Cleaning | | | • | See E.2 |
| Full Field Artefact Evaluation | • | • | • | See test outline below |
| Mechanical Inspection | • | • | • | See E.2 |
| Image Receptor Homogeneity | | • | • | See test outline below |
| AEC Calibration | | • | • | See test outline below |
| Repeat Analysis | • | • | • | See test outline below |
| Compression | | | • | See E.2 |
| Maintenance and Fault-logging | • | • | • | See E.2 |

| Procedure | Control-Limits/Requirements | Minimum Frequency | Required Procedure Elements | Minimum Record Requirements | | | | | | |
|--|--|-------------------|-----------------------------|-----------------------------|------------------------------------|----------|------------------------------------|--------|---|--|
| Image Quality Evaluation - Phantom images | <p>Clearly visualize in an image:</p> <table border="1"><tr><td></td><td>Contact</td></tr><tr><td>ACR mini</td><td>3 fibres 3 specks 2.5 masses</td></tr><tr><td>RMI 156S</td><td>3 fibres 2 specks 1.5 masses</td></tr></table> <p>mAs = baseline ± 10%</p> | | Contact | ACR mini | 3 fibres 3 specks 2.5 masses | RMI 156S | 3 fibres 2 specks 1.5 masses | Weekly | <p>Obtaining the phantom image:</p> <ul style="list-style-type: none">• Use an ACR mini mammography accreditation phantom or equivalent.• Light contact between the compression paddle and the phantom surface.• Consistent positioning of the phantom.• Consistent selection of a clinically relevant kVp and target/filter combination.• Selection of the density setting in current clinical use (if applicable). <p>Evaluating the phantom image:</p> <ul style="list-style-type: none">• Use of consistent viewing conditions that reflect those used to read clinical images.• Image quality scoring by the same person, if possible.• Use of a control chart to display results. | <p>Records showing:</p> <ul style="list-style-type: none">• Date test performed.• Person performing test.• X-ray system identification.• Phantom model.• Radiographic settings (kVp, target/filter combination, AEC mode, AEC detector position and density setting (if applicable)).• Plots of mAs and image quality scores.• Clearly marked control limits.• Baseline values• Remarks regarding corrective actions and baseline changes. <p>Dated phantom images from at least the last six months showing X-ray system and radiographic settings.</p> |
| | Contact | | | | | | | | | |
| ACR mini | 3 fibres 3 specks 2.5 masses | | | | | | | | | |
| RMI 156S | 3 fibres 2 specks 1.5 masses | | | | | | | | | |

| Procedure | Control-Limits/Requirements | Minimum Frequency | Required Procedure Elements | Minimum Record Requirements |
|---------------------------------------|---|---|---|---|
| Full field artefact evaluation | <p>There must be no evidence of:</p> <ul style="list-style-type: none"> Structures that are more conspicuous than the objects in the phantom used for weekly testing. Blotches or regions of altered noise appearance. Observable grid lines or breast support structures. Dust artefacts mimicking calcifications. Significant stitching or registration artefacts. | Monthly | <p>Expose a uniform thickness of PMMA using clinically relevant technique factors.</p> <p>View image on acquisition monitor using zoom and roam to check for possible detector faults.</p> <p>Print image if interpretation performed using hard copy.</p> | <p>Records showing:</p> <ul style="list-style-type: none"> Date test performed. Person performing test. X-ray system identification. Test results. |
| Image receptor homogeneity | <ul style="list-style-type: none"> Maximum deviation in MPV in ROI $< \pm 10\%$ of MPV in central ROI. Maximum variation of the MPV in central ROI between successive images $< \pm 10\%$. | Quarterly or more frequently if recommended by the manufacturer | <p>Use manufacturer's protocol if available or otherwise:</p> <ul style="list-style-type: none"> Image a standard test block at clinical settings. Note the MPV in centre ROI and each of the four corner ROIs. If the MPV of a ROI deviates by more than 10% from the MPV in the central ROI, the detector gain map may require re-calibration. Note that ROIs should be placed 1 cm in from corners due to small field of view. If it is not possible to position ROIs, a visual inspection will suffice. | <p>Records showing:</p> <ul style="list-style-type: none"> Date test performed. Person performing test. X-ray system identification. Radiographic settings (kVp, target/filter combination, AEC mode, AEC detector position and density setting (if applicable) and mAs. Test results. |

| Procedure | Control-Limits/Requirements | Minimum Frequency | Required Procedure Elements | Minimum Record Requirements |
|---|---|---|---|---|
| AEC calibration test | The AEC shall be able to maintain mean pixel value (MPV) to within $\pm 10\%$ of the baseline MPV for each 2, 4 and 6 cm thickness of PMMA. | Quarterly | <ul style="list-style-type: none"> • Use PMMA thickness of 2, 4 and 6 cm covering complete image receptor. • Use clinical AEC settings (kVp, target/filter and mode). • Measure mean pixel value in 4 cm² ROI positioned centrally in the image. • Examine image for clinically significant artefacts. <p>Note: If it is not possible to position a ROI in the centre of the image, use the MPV from the entire image or note the default greyscale value at which the image is displayed.</p> | <p>Records showing:</p> <ul style="list-style-type: none"> • Date test performed. • Person performing test. • X-ray system identification. • Radiographic settings (kVp, target/filter combination, AEC mode, AEC detector position and density setting (if applicable) and mAs for each phantom thickness). • Test results. |
| Stereotactic accuracy confirmation | Localisation within ± 1 mm | Prior to first use on day of procedures | Procedure as per manufacturer's recommendations. | <p>Records showing:</p> <ul style="list-style-type: none"> • Date test was performed. • Person performing test. • X-ray system identification. • Test results. |
| Repeat analysis | Overall repeat rate <20% (ACR, 1999) | Six monthly | Analysis of the proportion of repeats attributable to positioning, a range of equipment faults and other reasons for 6 months or from at least 150 consecutive stereotactic examinations. | <p>Records showing:</p> <ul style="list-style-type: none"> • Date analysis performed. • Person performing task. • Results and any corrective actions. |

APPENDIX F:

STANDARDS FOR ULTRASOUND QUALITY CONTROL PROCEDURES

The standards specified below are based on the recommendations of the *American Association of Physicists in Medicine (AAPM) Ultrasound Taskgroup* (Goodsitt, 1998).

Tests specified to be performed at six monthly intervals are easily performed by routine users or service engineer of the ultrasound system under the supervision of a medical physicist. The tests specified to be performed annually may require the direct assistance of a medical physicist or ultrasound service engineer.

The method of testing will be documented in depth in the Radiographer or Service procedure manual. For all procedures it is essential that system settings are well described and reproducible. Minimum settings that will be recorded are dynamic range, grey level map, power level, gain and Time Gain Control settings.

Ultrasound tissue mimicking phantom/s suitable for performing measurements as specified in Table F.1 shall be available.

TABLE F.1: ULTRASOUND SYSTEM QUALITY CONTROL AND PERFORMANCE STANDARDS

| Procedure ^{DDD} | Minimum Frequency | Required Procedure Elements | Control Limits/ Requirements |
|---|-------------------|--|--|
| Physical and mechanical inspection | Six-monthly | Inspection of transducers, power cords, controls and system cleanliness | Satisfactory operation and condition |
| Display monitor setup and fidelity | Six-monthly | <ul style="list-style-type: none"> • Verification that contrast and brightness settings are in baseline positions • Evaluation of number of grey scale test pattern steps visible • Evaluation of clarity of displayed text | Number of grey scale test pattern steps visible should not decrease by more than 2 steps |
| Image uniformity | Six-monthly | Evaluation of a uniform region of tissue-mimicking phantom and identification of deviation from smooth tissue texture | No significant non-uniformities |
| Depth of penetration/visualisation | Six-monthly | Evaluation of maximum depth of either ultrasound speckle or object perception | < 6 mm change in depth of penetration/visualisation measurement from baseline value |

^{DDD} Procedure should be repeated for each transducer (excluding Display Monitor Setup).

| Procedure ^{DDD} | Minimum Frequency | Required Procedure Elements | Control Limits/ Requirements |
|---|-------------------|---|--|
| Hard copy fidelity | Six-monthly | <ul style="list-style-type: none"> Comparison of on-screen image and hard copy image Verification that the weakest echoes visible on the display are visible in the hard copy image Comparison with baseline image | Number of grey levels in the hard copy image should not change from the baseline value by more than 2. |
| Distance Accuracy | Six-monthly | <ul style="list-style-type: none"> Measurement of known distances in vertical and horizontal directions | <ul style="list-style-type: none"> Vertical measurement error less than 1.5 mm or 1.5% Horizontal measurement error less than 2 mm or 2% |
| Anechoic object imaging ^{EEE} | Annually | <ul style="list-style-type: none"> Evaluation of image quality Comparison with baseline images | No major distortion or change from baseline performance |
| Axial resolution | Annually | <ul style="list-style-type: none"> Evaluation of full-width-half-maximum (FWHM) from profile; <u>OR</u> Evaluation of filament targets in an axial resolution grouping | <ul style="list-style-type: none"> Resolution ≤ 1 mm for > 4 megahertz (MHz) transducer) No significant change from baseline values |
| Lateral resolution or response width | Annually | <ul style="list-style-type: none"> Measurement of filament image width <u>OR</u> Evaluation of FWHM from image profile <u>OR</u> Evaluation of filament targets in a lateral resolution grouping | <ul style="list-style-type: none"> FWHM < 0.8 mm for > 4 megahertz (MHz) transducer) Image width or spacing between targets < 1.5 mm No major change from baseline values |
| Ring down or dead zone | Annually | <ul style="list-style-type: none"> Imaging of filament targets near scanning window <u>OR</u> Evaluation of image texture features | Dead zone < 3 mm (for > 7 megahertz (MHz) transducer) |

^{EEE} It may be desirable for these procedures to be performed by or with the assistance of a medical physicist or ultrasound service engineer.

APPENDIX G:

PGMI EVALUATION OF CLINICAL IMAGE QUALITY

Quality mammography requires dedication, enthusiasm and self-appraisal on the part of the radiographer or mammography practitioner. The United Kingdom (UK) Mammography Trainers Group with the support of the College of Radiographers originally devised the PGMI (Perfect, Good, Moderate, Inadequate) method of evaluation of clinical image quality (NHS 1994). This enabled an ongoing critical evaluation of each mammographic examination within a quality improvement framework.

The PGMI criteria from the UK model has been adapted and used in Australian Institute of Radiography (AIR) accredited training programs, to assess clinical image quality. These criteria have been modified by the AIR for use in the digital environment. The aims of continuing to use this method of evaluation are to ensure the maintenance of a high standard of mammography in BreastScreen Australia and to facilitate a consistent method of external audit.

CRITERIA FOR IMAGE ASSESSMENT

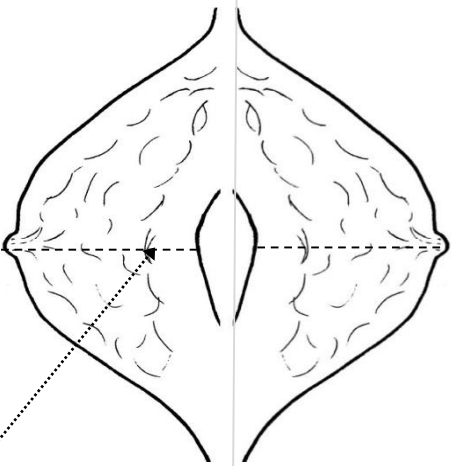
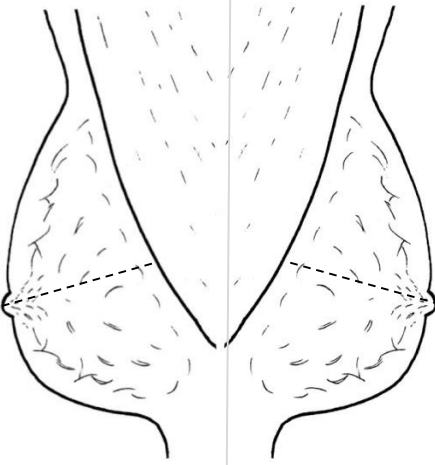
1. All breast tissue imaged (fat visualised posterior to glandular tissue)
2. Correct image identification clearly shown:
 - date of examination
 - client identification—name and (number and/or date of birth)
 - side markers
 - positional markers
 - radiographer or mammography practitioner identification
3. Correct exposure for modality
4. Good compression
5. Absence of movement
6. Correct image processing
7. Absence of artefacts
8. No skin folds
9. Symmetrical images

NAS MEASURE:

2.5.2 The overall repeat rate for the Service and/or SCU is $\leq 2\%$ of all screening images.

PROTOCOL:

- 2.4 The Service and/or SCU demonstrates annually that each radiographer and mammography practitioner achieves 50% or greater P or G ratings in a PGMI evaluation of 50 randomly selected image sets

| | |
|---|---|
| <p>Rcc</p>  <p>Lcc</p> | <p>Rmlo</p>  <p>Lmlo</p> |
| <p><i>Cranio-caudal view (CC)</i> <i>Specific positioning criteria</i></p> <ol style="list-style-type: none"> 1. All breast tissue imaged <ul style="list-style-type: none"> ○ medial border well demonstrated ○ nipple in profile or skin edge seen transecting nipple (retro-areolar tissue well separated) ○ nipple in midline of imaged breast ○ posterior nipple line (PNL) within 1cm of PNL on MLO view) | <p><i>Medio-lateral oblique view (MLO)</i> <i>Specific positioning criteria</i></p> <ol style="list-style-type: none"> 1. All breast tissue imaged <ul style="list-style-type: none"> ○ pectoral muscle shadow to nipple level ○ full width of pectoral muscle ○ nipple in profile or skin edge seen transecting nipple (retro-areolar tissue well separated) ○ infra-mammary angle well demonstrated ○ PNL within 1cm of PNL on CC view |
| <p><i>Classification of CC images</i></p> | <p><i>Classification of MLO images</i></p> |
| <p>P = Perfect images Both CC and MLO images meet criteria for image assessment 1–9</p> | |
| <p><i>G = Good images</i></p> <ol style="list-style-type: none"> 1. All breast tissue imaged* <ul style="list-style-type: none"> ○ all postero-medial tissue visualised (*axillary portion of breast not to be included at expense of medial portion) ○ nipple in profile or skin edge seen transecting nipple ○ nipple in midline of imaged breast | <p><i>G = Good images</i></p> <ol style="list-style-type: none"> 1. All breast tissue imaged <ul style="list-style-type: none"> ○ pectoral muscle well demonstrated ○ nipple in profile or skin edge seen transecting nipple ○ infra-mammary angle (IMA) well demonstrated |

| | |
|--|--|
| <p>M = Moderate images</p> <p>(Acceptable for diagnostic purposes)</p> <ol style="list-style-type: none"> 1. Most breast tissue imaged (<i>however, all breast tissue must be imaged on MLO image</i>). <ul style="list-style-type: none"> ○ nipple not in profile but clearly distinguishable from retro-areolar tissue- (however, nipple must be in profile on MLO image) ○ nipple not in midline <p>(significant bias)</p> | <p>M = Moderate images</p> <p>(Acceptable for diagnostic purposes)</p> <ol style="list-style-type: none"> 1. Most breast tissue imaged. <ul style="list-style-type: none"> ○ Pectoral muscle not to nipple level but posterior breast tissue adequately shown ○ nipple not in profile but clearly distinguishable from retro-areolar tissue (however, nipple must be in profile on CC image) ○ IMA not clearly demonstrated but breast tissue adequately shown |
| <ol style="list-style-type: none"> 2. Correct(ed) image identification 3. Correct exposure for modality 4. Adequate compression 5. Absence of movement 6. Correct image processing 7. Artefacts which do not obscure the image 8. Skin folds which do not obscure the breast tissue 9. Asymmetrical images | |
| <p>I = Inadequate images (applies to both CC and MLO images)</p> <ol style="list-style-type: none"> 1. Significant part of the breast not imaged 2. Incomplete or incorrect identification 3. Incorrect exposure 4. Inadequate compression which hinders diagnosis 5. Blurred image 6. Incorrect processing 7. Overlying artefacts 8. Skin folds which obscure the image | |

MINIMUM TECHNICAL REQUIREMENTS AND QUALITY CONTROL PROCEDURES – USE OF REMOTE RADIOLOGY FOR ASSESSMENT

These requirements and procedures related to the telehealth systems necessary to enable remote radiology to be used for assessment in BreastScreen Australia Services. In addition, when establishing and operating remote radiology for assessment clinics, BreastScreen Australia Services should have regard to the teleradiology technical requirements and quality assurance processes contained in Standard 8 of the [‘Standards of Practice for Clinical](#)

[Radiology](#)’ published by the Royal Australian and New Zealand College of Radiologists (RANZCR) and as updated from time to time.

The aim of this initiative is the remote assessment of breast ultrasound images, in conjunction with already available resources. The telehealth system is not to be used for the assessment of mammography images. The assessment team must have direct access to the patient’s current imaging (screening and assessment mammograms) and prior imaging (mammograms and ultrasound if relevant), and patient history via PACS and RIS systems that meet the minimum performance standards specified in this NAS commentary. This access must be on a dedicated mammography workstation(s) meeting the standards defined in [Appendix D](#) of the NAS commentary, including viewing conditions.

A. MINIMUM TECHNICAL REQUIREMENTS

There are various technologies that are available to deliver a remote radiology solution. Table G.1 specifies the high-level minimum technical requirements that should be considered when designing the remote radiology solution. These focus on image acquisition at the ultrasound to image display at the remote location.

TABLE G.1: BREASTSCREEN AUSTRALIA REMOTE RADIOLOGY TECHNICAL REQUIREMENTS

| Item | Minimum Technical Requirements |
|---|---|
| Ultrasound Secondary Video Output | Supports at minimum High Definition 720p. |
| Image aspect ratio, between Ultrasound Primary display and transmitted image | 1:1 or if this cannot be achieved, clinical scoring and evaluation of deviation and impact to clinical image will be required. |
| Available Network Bandwidth | Minimum 1Mbps. |
| Network Latency | Less than 100ms (end-to-end) – based on 30fps (3 frames latency). |
| Network QoS | Quality of Service network settings for connected Video Conferencing devices should be configured to allow Video data as highest priority. |
| Other considerations | <ul style="list-style-type: none"> • Access to Video Conference call number of VC devices sending images should be limited as to not inadvertently breach any patient privacy. • Cyber/Information Security Risk Assessment of final solution. • Solution meets local state/territory ICT eHealth design standards. • Solution meets local state/territory privacy policies. • Change Management process for both Ultrasound device and/or Video Conferencing devices. For any change introduced to the end-to-end image transmission ‘ecosystem’ appropriate change control must be delivered to assess the impact of change to the solution. |

B. PERFORMANCE AND QUALITY CONTROL PROCEDURES

This section outlines the performance and quality control procedures to achieve acceptable diagnostic quality for use in remote radiology (remote telesonography) scenarios for BreastScreen assessment clinics only. These procedures relate to the processes for assessing the performance quality of audio and visual equipment required to deliver remote radiology – particularly in relation to transmitted ultrasound video.

The performance and quality control criteria described herein are the minimum criteria to be achieved, to ensure that the transmitted medical video is not diagnostically “inferior” to the primary (source) ultrasound video.

The successful implementation of remote radiology requires awareness of the limitations of teleradiology when used as a diagnostic tool in the assessment clinic.

One of the main limitations of remote telesonography is video latency. Two key points for clinicians, to offset latency effects are:

1. A good professional relationship between the sonographer performing the ultrasound and the radiologist viewing the live (transmitted) ultrasound video.
2. Ultrasound imaging is highly operator-dependent, and the successful outcome of the examination is dependent on the technical skills of the sonographer. The sonographer must take extra care during the ultrasound assessment, to image the patient with the transducer moving more slowly than usual; whilst maintaining good communication and listening to instruction provided by the radiologist.

BreastScreen Services must develop face-to-face in-house training with the clinical team to discuss and develop strategies to encourage optimisation of the entire remote radiology service, and to gain or retain competence in the application of systems and equipment used in the remote radiology service. Training must be documented and competence assessed and recorded.

The purpose of this section is to describe remote radiology performance and Quality Control (QC) tests for BreastScreen assessment clinics, to be performed by or under the supervision of a medical physicist. There are specific tests for sonographers and radiologists.

Test results must not be considered in isolation and the judgement of whether or not the system is fit for the clinical task is the decision of the radiologist in charge.

STANDARDS FOR MAMMOGRAPHY TELESONGRAPHY SYSTEM PERFORMANCE (ASSESSMENT CLINIC)

Table G.2 specifies the high-level system performance minimum standards that need to be applied when assessing the remote radiology solution.

TABLE G.2: MAMMOGRAPHY REMOTE RADIOLOGY (TELESONOGRAPHY) VIDEO SYSTEM PERFORMANCE MINIMUM STANDARDS

| Item | Minimum standard |
|--|---|
| Remote radiology (telesonography) system | The transmitted medical video must not be diagnostically “inferior” to the primary (source) ultrasound video. |
| Ultrasound machine | Meets all BreastScreen Australia National Accreditation Standards requirements |
| Ultrasound machine | The Ultrasound machine must have video output capabilities that faithfully reproduce the ultrasound video as displayed on the ultrasound machine. |
| Telehealth video transmission [§] | The video signal resolution must not be less than the ultrasound output signal (should ideally match). |
| Telehealth video transmission | The frame rate must not be less than the ultrasound video frame rate (should ideally match). |
| Display monitor used to view the video transmission* | Should match the ultrasound video matrix, pixel pitch and refresh rate. |
| Display monitor used to view the video transmission* | Must be calibrated to the DICOM Greyscale Standard Display Function (GSDF) [#] . |
| The remote display viewing environment | Existing standards for ambient lighting conditions must be maintained. |

§ The telehealth system software must not apply any scaling to the final video signal such that reporting and interpretation is only carried out on video displayed at full resolution.

* The reporting and interpretation must only be performed using monitors facilitating full resolution display of the ultrasound video.

GSDF ensures adequate distribution of grey scale values applicable to medical applications. Specifically, for its application in breast imaging, the ability to control and aid visualisation of low contrast detail to help facilitate the visualisation of subtle masses in breast tissue.

STANDARDS FOR MAMMOGRAPHY TELESONOGRAPHY QUALITY CONTROL PROCEDURES (ASSESSMENT CLINIC)

Quality control (QC) frequency is provided in the tables below. Further testing must be performed if there are any changes to the imaging chain that will affect image quality.

The imaging chain is every aspect of the technology used for remote radiology including the ultrasound system, the telehealth equipment and the display used to view the videos.

Examples of items that may affect the quality of the image are firmware or software updates, display replacement, ultrasound repairs/replacements, and transducer repairs/replacements. If in doubt contact your medical physics support service.

The QC requirements provided in Table G.3 are only valid at the time of testing. Due to technology limitations the image quality could deteriorate during patient assessment as a result of, for example, reduced bandwidth or high latency. Therefore, the sonographer and radiologist must remain vigilant during the ultrasound assessment; if any significant deterioration is suspected the radiologist must decide whether to terminate the examination and seek medical physics support.

QUALITY CONTROL TEST EQUIPMENT FOR REMOTE RADIOLOGY

Existing QC equipment already required for BreastScreen sites can also be utilised for the remote radiology quality control. Additional test patterns are freely available from the American Association of Physicists in Medicine (AAPM).

TABLE G.3: QUALITY CONTROL PROCEDURES AND STANDARDS FOR REMOTE RADIOLOGY ASSESSMENT CLINICS

| Procedure | Control limits/ requirements | Minimum frequency | Required procedure elements | Minimum record requirements |
|--|---|--|---|--|
| Ultrasound display ^s TG18-QC (static) | <p>Borders must be visible, lines must be straight, squares must appear square, the ramp bars must appear continuous without any contour lines, there must be no smearing or bleeding at black-white transitions, all corner patches must be visible (optional), squares of different shades from black to white must be distinct, all high contrast resolution patterns and two low contrast patterns must be visible in all four corners and in the centre, the 5% and 95% pixel value squares must be clearly visible, pattern should be centred in the active area and no disturbing artefacts should be visible on the displayed TG18-QC test pattern.</p> <p>The number of letters visible in the phrase “Quality Control” for the dark, mid-grey and light renditions must be ≥ 11.</p> | Acceptance/ commissioning annually | <p>Display the TG18-QC test pattern. Ensure viewing conditions are acceptable. Check visibility and distortion of several items used for evaluating the quality of the image. Check for disturbing artefacts.</p> | <ul style="list-style-type: none"> • Date test performed. • Person performing test. • Ultrasound identification. • Ultrasound monitor settings. • Test results. |
| Video Transmission viewed and tested on remote display monitor TG18-QC (static) | <p>Borders must be visible, lines must be straight, squares must appear square, the ramp bars must appear continuous without any contour lines, all corner patches must be visible (optional), squares of different shades from black to white must be distinct, all high contrast resolution patterns and two low contrast patterns must be visible in all four corners and in the centre, the 5% and 95% pixel value squares must be clearly visible, pattern should be centred in the active area and no disturbing artefacts should be visible on the displayed TG18-QC test pattern.</p> <p>There must be no significant blurring at black and white transitions/edges of the squares NB. This may be due to suboptimal setup of the telehealth system not the LCD display.</p> <p>The number of letters visible in the phrase “Quality Control” for the dark, mid-grey and light renditions must be ≥ 11.</p> | Acceptance/ commissioning annually | <p>Display the TG18-QC test pattern. Ensure viewing conditions are acceptable. Check visibility and distortion of several items used for evaluating the quality of the image. Check for disturbing artefacts that will impact the diagnostic image.</p> | <ul style="list-style-type: none"> • Date test performed. • Person performing test. • Remote display settings and identification. • Codec (Teleradiology) settings. • Test results. |
| Video Transmission viewed and tested on remote display monitor | <p>Second row squares visible in black/grey/white regions. Borders are visible, lines are straight, squares are not distorted. All squares should be similar to those horizontally adjacent, and distinct from those vertically adjacent.</p> | Acceptance/ commissioning annually | <p>Display the TG18-270TR test pattern. Ensure viewing conditions are acceptable.</p> | <ul style="list-style-type: none"> • Date test performed. • Person performing test. |

| Procedure | Control limits/ requirements | Minimum frequency | Required procedure elements | Minimum record requirements |
|---|---|------------------------------------|---|--|
| TG18-270TR (moving pattern) | Horizontal nominal count of 6 squares per row. No significant blurring at the edges of squares. No significant pixilation or artefacts. | | Record the image or view directly on the remote display. Check visibility and distortion of several items used for evaluating the quality of the image. Check for disturbing artefacts. | <ul style="list-style-type: none"> • Remote display settings and identification. • Codec (Teleradiology) settings. • Test results. |
| *Anechoic object imaging seen on video transmission (see below) Sonography | Agree with ultrasound and no change from baseline | Acceptance/ commissioning annually | Evaluation of image quality. | <ul style="list-style-type: none"> • Date test performed. • Person's performing test. • Ultrasound identification. • Ultrasound settings • Codec (Teleradiology) settings. • Test results. |
| Remote display luminance response | DICOM (GSDF) tolerance of +/- 20%. | Acceptance/ commissioning annually | Display the TG18-LN or TG18-QC test pattern. Ensure conformance with DICOM GSDF and JDNs are uniformly spaced. | <ul style="list-style-type: none"> • Date test performed. • Person's performing test. • Remote display identification. • Remote display settings. • Test results. |

| Procedure | Control limits/ requirements | Minimum frequency | Required procedure elements | Minimum record requirements |
|--------------------------------|------------------------------|------------------------------------|---|---|
| Clinical video self-evaluation | Agree with ultrasound | Acceptance/ commissioning annually | Five clinical test videos displayed simultaneously on both the ultrasound system and the remote display | <ul style="list-style-type: none"> • Date test performed. • Person's performing test. • Ultrasound and remote display identification. • Ultrasound settings • Codec (Teleradiology) settings. • Test results. |

§ The ultrasound display is considered an integral component of the telehealth system and must be setup appropriately for optimal performance of the telehealth system; consequently tests are required.

* Ultrasound tissue mimicking phantom.

ASSESSMENT STANDARDS FOR MAMMOGRAPHY TELESONOGRAPHY QUALITY CONTROL PROCEDURES (ASSESSMENT CLINIC)

Due to new QC process for optimising (telehealth system) diagnostic videos, the following additional commentary is provided to assist the implementation of the QC standards.

1. TEST PATTERN TG18 QC

View and score the test pattern on the ultrasound display and on the remote display. These are absolute measures, and comparison with each display is not necessary.

TABLE G.4: TG18-QC TEST CRITERION

| TG18 QC Criterion | | |
|---|------------|----------------|
| | Ultrasound | Remote display |
| Aspect ratio should be 1:1 | Yes | Yes |
| Letters visible in the dark, mid-grey and light renditions | 11 | 11 |
| Borders are visible | Yes | Yes |
| Lines are straight | Yes | Yes |
| Squares appear square | Yes | Yes |
| The ramp bars should appear continuous without any contour lines | Yes | Yes |
| All corner patches are visible | *Optional | *Optional |
| Squares of different shades from black to white are distinct | Yes | Yes |
| There should be no significant blurring at the edges of the squares or at black and white transitions | Yes | Yes |
| All high contrast resolution patterns and at least two low contrast patterns are visible in all four corners and the centre | Yes | Yes |
| The 5% and 95% pixel value squares are clearly visible | Yes | Yes |
| The pattern is centred in the active area | Yes | Yes |
| Artefacts visible | No | No |

*Some systems will not have the ability to zoom the test pattern on the remote display in order to assess the corner patches.

2. TEST PATTERN TG18-270TR

View and score the test pattern on the remote display. This is an absolute measure and comparing the test pattern on the ultrasound display is not necessary.

Many video compression algorithms use interframe prediction to reduce the bandwidth to transmit a series of frames. One frame is compared with a reference frame and only pixels that have changed with respect to the reference frame are coded. Therefore, animated test patterns provide a means to test the influence of the algorithm on the integrity of the video quality.

TG18-270TR contains five background regions, each of which contains several contrast levels of temporal patches. These contrast differences are similar to the TG18-QC. The test pattern can be configured to match the frame rate of the ultrasound video, typically 30fps.

The TG18-270TR can be loaded onto the ultrasound system or directly connected to the teleradiology system via a laptop. These tests are in addition to those described by AAPM TG270 (see references). Physicists are encouraged to also perform testing as described by AAPM. However, the method has been modified to test the influence of the codecs algorithm on the video quality. The test pattern can be treated like a moving TG18-QC test pattern.

METHOD

- Connect the pattern to the telehealth system either via the ultrasound system or a laptop.
- Record the image at the remote display using one of the following methods:
 - Direct screen capture, such as with windows snipping tool
 - Photography with a high frame rate/slow motion camera
 - Capture the image via a USB video converter, and perform the test on one of the captured frames.

Alternatively, the test pattern can be configured to slow to a comfortable speed to facilitate a direct visual assessment of the transmit/receive video at the remote display.

Assess the image according to the following criteria:

TABLE G.5: TG18-270TR TEST CRITERION

| TG18-270TR Criterion |
|--|
| The top three background regions are likely to be of most importance |
| Second row squares are visible in black/grey/white regions |
| Borders are visible, lines are straight, squares are not distorted |
| Contrast visibility: all squares should be similar to those horizontally adjacent, and distinct from those vertically adjacent |
| Appearance of shadow squares: horizontal nominal count of six squares per row |

| TG18-270TR Criterion |
|--|
| There is no significant blurring at the edges of squares |
| There is no significant pixilation or artefacts (e.g. clearly visible artefacts due to lossy compression) |

This test does not make any specific recommendations for limits when assessing the video. However, in cases where there is significant blurring or loss of squares, the medical physicist must assess the potential impact on the clinical video.

For example, if the second rows in the background regions cannot be seen this will impact clinical video quality. The system should be evaluated (using information from all the QC tests described in this section) and optimised before clinical use.

3. ANECHOIC OBJECT IMAGING

The number of objects seen at depth must be baselined at the ultrasound unit.

During the usual ultrasound assessment (with the transducer typically used clinically) view and score the target objects seen at depth on the ultrasound system and simultaneously scored on the remote display. Communication between the operator (evaluating the objects on the ultrasound unit) and the individual viewing and scoring the objects at the remote display must be maintained. The depth of visualisation for different diameter targets should agree.

The number and size of objects at each depth is phantom dependent. Each object seen at depth on the remote display should agree with that seen at depth on the ultrasound display and compared with baseline.

4. REMOTE DISPLAY PERFORMANCE AND VIEWING ENVIRONMENT

Evaluation can be performed in conjunction with usual BreastScreen display and environmental tests.

The remote display used for viewing the transmit/receive ultrasound video must have a minimum standard of performance as described in Part 14 of the DICOM standard, the DICOM Grayscale Standard Display Function (GSDF). The test patterns TG18-LN12-01 through to TG18-LN12-18 are used to determine this function using a photometer. The TG18-QC pattern may also be used but each grayscale square should be zoomed and centred. It is recommended to use the existing (GSDF) testing method already established in BreastScreen and described in ACPSEM mammography position paper or AAPM Display Quality Assurance report. Calibration of a display's luminance response helps to ensure suitable contrast over a range of displayed grey levels.

AAPM (Display Quality Assurance report) recommends ultrasound displays used for image acquisition, procedure guidance, or patient diagnosis meet the criteria for diagnostic displays. The suggested maximum and minimum luminance limits are only suggested values.

The evaluation of the performance of the remote display should be left to the medical physicist or other qualified personnel. The recommendations are:

- minimum luminance ≥ 1.0 cd/m²
- maximum luminance ≥ 300 cd/m²
- luminance ratio = 350; acceptable range 250 - 450

It is important to highlight that inappropriate minimum and maximum luminance values may result, for example, suboptimal visualisation of breast masses. This should be evident from the test results described in this report.

Existing standards and practices should be maintained with regards to the environmental ambient lighting conditions when viewing and reporting clinical mammographic images and ultrasound videos.

TELESONOGRAPHY VIDEO QUALITY SELF-AUDIT

This test should be performed by a sonographer and a radiologist. Sites can develop their own template or use Table G.6. However, the clinical features described in Table G.6 must be incorporated.

BreastScreen Services must create and record a minimum of five ultrasound clinical videos. The clinical videos must contain varying breast types, breast densities and features as described in the self-audit template. As ultrasound system characteristics vary, test sets should be created for each different make and model. The test sets should be uncompressed and ideally DICOM format.

Commonly, telehealth video compression algorithms compare each frame with a reference frame and only pixels that have changed with respect to the reference frame are coded. Thus, when evaluating the test sets the videos should be slowed but never stationary.

The evaluation must be performed by sonographer and a radiologist. At each site the clinical videos will be scored simultaneously, and the results compared. If there is significant discrepancy between the source ultrasound video and the transmitted video it is the decision of the radiologist whether to continue with the telesonography examination or to terminate the session. "General and Comments" sections on the self-audit template can be used to describe the sub-optimal video quality. Contact your medical physics team for support and advice.

TABLE G.6: QUALITY SELF-AUDIT TEMPLATE

| Item | Ultrasound video visible (yes/no) | | | | | | Transmit/receive video visible (yes/no) | | | | |
|---------------|-----------------------------------|---|---|---|---|--|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | | 1 | 2 | 3 | 4 | 5 |
| Image # | | | | | | | | | | | |
| Image Quality | | | | | | | | | | | |

| Item | Ultrasound video visible (yes/no) | | | | | | Transmit/receive video visible (yes/no) | | | | |
|--|---|---|---|---|---|--|---|---|---|---|---|
| Image # | 1 | 2 | 3 | 4 | 5 | | 1 | 2 | 3 | 4 | 5 |
| Solid and cystic lesions differentiation | | | | | | | | | | | |
| Posterior acoustic shadowing | | | | | | | | | | | |
| Posterior acoustic enhancement | | | | | | | | | | | |
| Demonstration of low-contrast lesions | | | | | | | | | | | |
| Lesion and tissue echogenicity | | | | | | | | | | | |
| Shape and margin of a lesion | | | | | | | | | | | |
| Visibility of calcification (if present) | | | | | | | | | | | |
| Visibility of microcalcification clusters (if present) | | | | | | | | | | | |
| Sonographic anatomy | | | | | | | | | | | |
| Visibility of skinline | | | | | | | | | | | |
| Visibility Mammary zone | | | | | | | | | | | |
| Visibility Subcutaneous fat | | | | | | | | | | | |
| Visibility Retromammary fat space | | | | | | | | | | | |
| Visibility Pectoralis muscle | | | | | | | | | | | |
| Visibility Copper's ligaments | | | | | | | | | | | |
| General | This section may be used to highlight the cause of any differences (above) seen by the two observers to help troubleshoot potential causes. | | | | | | | | | | |
| Overall image quality | | | | | | | | | | | |
| Noise content | | | | | | | | | | | |
| Image contrast | | | | | | | | | | | |

| Item | Ultrasound video visible (yes/no) | | | | | | Transmit/receive video visible (yes/no) | | | | |
|----------|-----------------------------------|---|---|---|---|--|---|---|---|---|---|
| Image # | 1 | 2 | 3 | 4 | 5 | | 1 | 2 | 3 | 4 | 5 |
| | | | | | | | | | | | |
| Comments | | | | | | | | | | | |

APPENDIX H:

AUDIT OF CANCER DETECTION RATES FOR INDIVIDUAL SCREEN READERS AND REVIEW OF INTERVAL CANCERS PROTOCOL

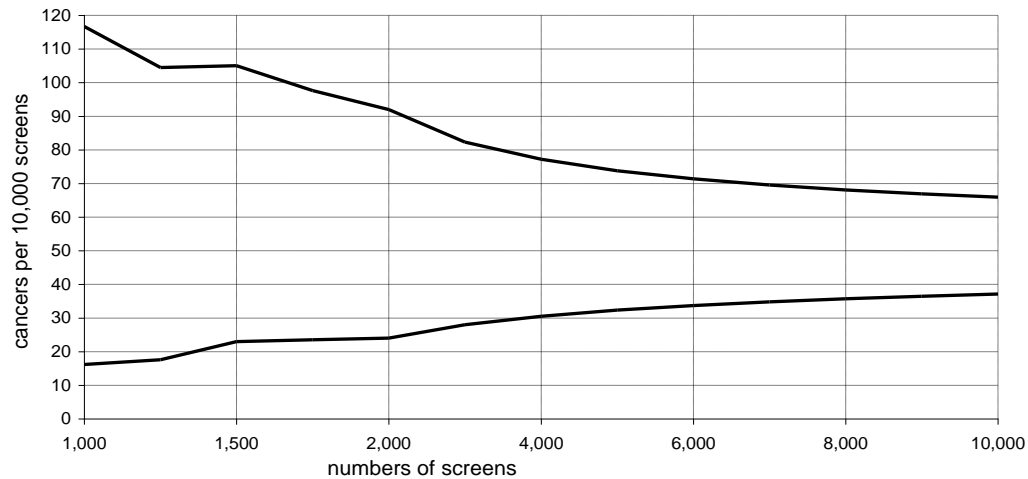
All BreastScreen screen readers will be required to participate in an audit and feedback to evaluate their performance in the detection of invasive cancers and small invasive cancers.

Individual readers will be informed of their cancer detection rates. In considering the performance of an individual reader during the 24-month period, the likelihood of chance needs to be taken into account. A reader will have detected cancers at a rate compatible with the Service and/or State Coordination Unit (SCU) standard if their cancer detection rate is above the value of the *lower* 95% confidence bound. The (upper and lower) 95% confidence bounds are the limits of the range of indicator values on either side of the measure that will include 95% of values that are exactly meeting the measure on average. By chance, 2.5% will fall above the upper bound and 2.5% will fall below. That is, 5% will fall outside the bounds and 95% will fall within them.

A screen reader is required to read a minimum of 2,000 screens a year and the cancer detection rate for individual readers will take into account the number of screens read over a consecutive 24-month period.

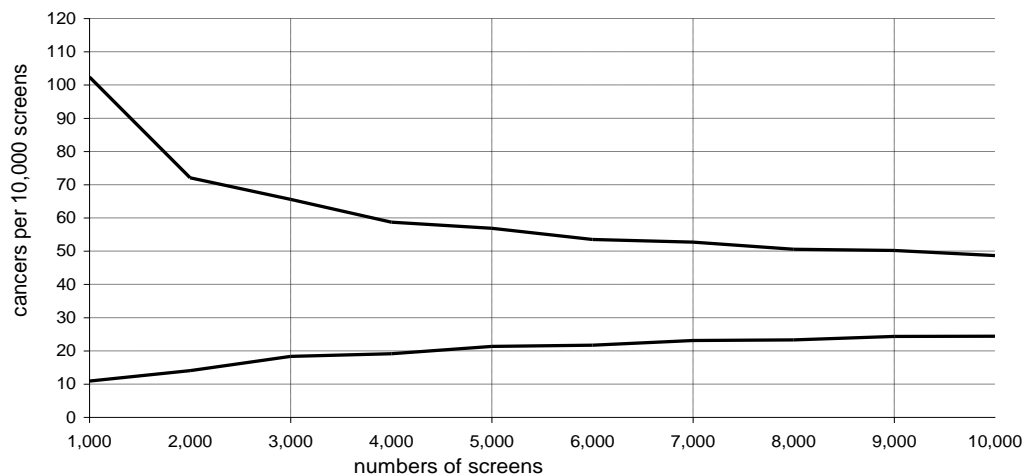
For invasive breast cancers at initial screens, the Service standard is 50 per 10,000 screens (see Figure H1). For an individual reader who detects 5 cancers and has completed 2,000 initial screens, this is the equivalent of 25 per 10,000 screens. The lower bound at 2,000 initial screens is 24 per 10,000. Therefore, they will be considered to have achieved the standard

Figure H.1: *Detection of invasive breast cancers at initial screens in women aged 50–69 years in a 24-month period: confidence bounds around the required rates (50 per 10,000) at 1,000 to 10,000 initial screens*



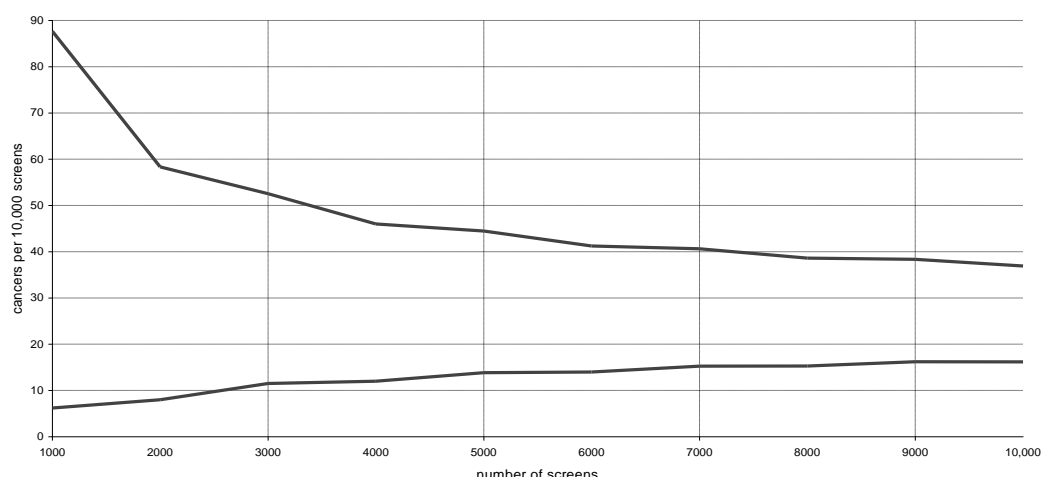
For invasive breast cancers at subsequent screens, the Service standard is 35 per 10,000 screens (see Figure H2). For an individual reader who detects 5 cancers and has completed 2,000 subsequent screens, this is the equivalent of 25 per 10,000 screens. The lower bound at 2,000 subsequent screens is 14 per 10,000. Therefore, they will be considered to have achieved the standard.

Figure H.2: *Detection of invasive breast cancers at subsequent screens in women aged 50–69 years in a 24-month period: confidence bounds around the required rates (35 per 10,000) at 1,000 to 10,000 subsequent screens*



For small invasive breast cancers, the Service standard is 25 per 10,000 screens (see Figure H3). For an individual reader who detects 4 cancers and has completed 2,000 screens, this is the equivalent of 20 per 10,000 screens. The lower bound of cancers detected at 2,000 screens is 8 so they have surpassed the standard. On the other hand, if the reader had completed 10,000 screens, they would have just equalled the lower bound of 20 at 10,000 screens.

Figure H.3: *Detection of small invasive cancers in women aged 50–69 years in a 24-month period: confidence bounds around the required rates (25 per 10,000) at 1,000 and 10,000 screens*



In addition, the Designated Radiologist is responsible for undertaking quarterly assessment of radiologists' performance in screening and assessment and providing feedback of this assessment to individual radiologists. As a minimum, this includes analysis of the Service and/or SCU's and the individual radiologist's recall rates, cancer detection rates, missed cancer detection rates and interval cancers. Assessment performance, such as pre-operative diagnosis of breast cancers and adequacy of percutaneous biopsies, should also be included. This individualised, identifiable information is confidential to the Designated Radiologist, the individual radiologist, the Clinical Director/Program Manager and the data manager.

REVIEW OF INTERVAL CANCERS PROTOCOL

Each jurisdiction is responsible for developing and implementing a protocol for reviewing interval cancers. All interval cancers are to be reviewed by the Designated Radiologist or other senior radiologist. Individual readers will be provided with feedback on interval cancers, especially for those interval cancers where they were a screen reader. The review of interval cancers will include a system to classify the woman's previous images, to determine the presence or otherwise of an abnormality on the screening mammogram, and subsequently whether the interval cancer was considered True or False. An example of such a classification system can be found in the UK NHS Breast Screening Programme *Quality Assurance Guidelines for Breast Cancer Screening Radiology* (2011).

APPENDIX I

GUIDELINES FOR INVESTIGATION OF POSSIBLE FALSE POSITIVE NEEDLE BIOPSY DIAGNOSES OF BREAST MALIGNANCY IN BREASTSCREEN AUSTRALIA ACCREDITED SERVICES

NAS Measure

- 3.1.2 a) 0% of benign lesions assessed by percutaneous needle biopsy have a false positive cancer diagnosis, when the definitive needle biopsy result is achieved after performance of the final needle biopsy at an assessment episode(s). A false positive FNA which is followed by a true negative core biopsy, prior to recommendation for surgery or treatment, is not considered to be a false positive “percutaneous needle biopsy” for the purpose of this standard.
- b) Where part a) is not met, an analysis of the root causes of 100% of false positive cancer diagnoses is conducted by the Service and/or SCU.

Data Dictionary Measure

The number of lesions assessed by percutaneous needle biopsy with a malignant result on biopsy and a non-malignant result on final histology as a percentage of all lesions biopsied returning a non-malignant result on final histology.

Calculation: See Data Dictionary

The intent of this standard is to identify instances where an erroneous pathological diagnosis of malignancy has been made on the basis of a needle biopsy of a lesion that is ultimately proven to be non-malignant in the final analysis.

Although there are a number of diagnostic pitfalls and mimics of cancer, misclassification of benign lesions as malignant on the basis of needle core biopsies is a rare event, estimated to account for 2 out of 100,000 cases cored^{58, 59}. As such, and in view of the potential harms to clients, in the revised NAS, any confirmed false positive assessment based on the final results of needle biopsy (or biopsies) diagnosis is to be notified by the relevant Clinical Director to the responsible health service or auspice, the appropriate State Quality Committee and the NQMC. The NQMC is to be notified as soon as a false positive needle biopsy diagnosis is identified, even if this is not at time of the routine ADR or accreditation reporting to the NQMC. This notification maybe a simple email or letter to the NQMC Secretariat. More detailed reporting is required once investigation of the case is complete (see below).

Once cases are identified as possible false positive diagnoses, appropriate multidisciplinary review and analysis of the root causes of the event is required. The NQMC has developed a proforma to assist in the clinical investigation and reporting of such events. Services must use the structure of this proforma tool when reporting their investigation of false positive diagnoses to the NQMC. The NQMC has the responsibility for accrediting BSA services and this level of information is what the NQMC requires for assisting services and identifying national trends in such adverse events.

⁵⁸ Rakha EA, El-Sayed ME, Reed J, Lee AH, Evans AJ, Ellis IO. Screen-detected breast lesions with malignant needle core biopsy diagnoses and no malignancy identified in subsequent surgical excision specimens (potential false-positive diagnosis). *Eur J Cancer* 2009;45(7): 1162- 7.

⁵⁹ Farshid G, Sullivan T, Jones S, Roder D. Performance Indices of Needle Biopsy Procedures for the Assessment of Screen Detected Abnormalities in Services Accredited by BreastScreen Australia. *Asian Pac J Cancer Prev* 2014;15(24): 10665-73.

DATA REVIEW

The BreastScreen Australia Data Dictionary specifies that NAS Measure 3.1.2 be measured as the number of lesions assessed by percutaneous needle biopsy with a malignant result on biopsy and a non-malignant result on final histology as a percentage of all lesions biopsied returning a non-malignant result on final histology.

This definition will capture a range of scenarios. Each case identified through a data review should be reviewed by a medical doctor before final designation as a false positive diagnosis can be confirmed. For the purposes of data reporting, only cases medically confirmed as false positive diagnoses should be discussed.

MEDICAL REVIEW

Before classifying a case as a false positive diagnosis, alternative explanations for the failure to find a malignant lesion in the final specimen should be sought. There are a range of well-characterized situations, outlined below, that even though breast cancer is not found in the final specimen, do not fit with the intent of the standard and should be excluded from the false positive diagnosis category. Each of these scenarios is more common than a genuine false positive diagnosis. The case is not regarded as a false positive in the following circumstances:

CIRCUMSTANCES NOT REGARDED AS FALSE POSITIVE DIAGNOSES OF CANCER

- Complete removal of the cancer by needle biopsy
- Failure to remove the intended screen detected lesion through surgery
- Surgical specimen lost or destroyed
- Complete pathologic response of cancer after neoadjuvant chemotherapy or neoadjuvant hormonal therapy
- Client unable or unwilling to undergo definitive surgery
- Pleomorphic lobular carcinoma in situ on the core biopsy and/or in the resection specimen

INVESTIGATION OF CASES OF POSSIBLE FALSE POSITIVE CANCER DIAGNOSIS ON PERCUTANEOUS NEEDLE BIOPSY

1. REVIEW OF THE INITIAL SLIDES

In all cases of a possible FP needle biopsy diagnosis of malignancy, the first step is verification of the diagnosis of malignancy by review of the initial biopsy by a pathologist.

Ideally, the case will be reviewed not only by the original pathologist but also by at least one other experienced, breast pathologist. The aim of the review is to determine if the diagnosis of malignancy can be verified, in the light of the information that the subsequent specimen has not identified a malignancy. If necessary, slides from the subsequent resection should be made available to the reviewing pathologist for comparison with the core needle biopsies. If required, additional work up may be undertaken at this point, for example performance of additional immunohistochemical stains for myoepithelial cells.

It is important for the pathologists to be clear that the aim of this review is not to establish whether a reasonable pathologist would classify the needle biopsy as malignant, but rather, knowing that to

date no malignancy has been found in the resection specimen, to determine if further investigation is needed to find an as yet elusive cancer in the patient.

If this review of the needle biopsy confirms malignancy, the case is highly unlikely to constitute a false positive diagnosis and alternative explanations for the finding of no malignancy should be sought, e.g. complete lesion removal.

2. COMPARISON OF THE IMAGING FEATURES BEFORE AND AFTER SURGERY

Comparison of the preoperative images with the post-operative imaging and specimen x-ray will be a key step in determining the nature of each case.

EXCLUSION CRITERIA FOR FALSE POSITIVE NEEDLE BIOPSY DIAGNOSIS

1. COMPLETE REMOVAL OF THE MALIGNANT LESION BY THE CORE NEEDLE BIOPSY

Complete removal of the malignant lesion by the core needle biopsy procedure is an uncommon though not rare scenario, particularly when small lesions are assessed by vacuum assisted biopsies.

This can be assessed by comparing the screening and assessment and post-biopsy images with the resection specimen imaging and the post-operative mammogram.

The size of the area of imaging abnormality should correlate with the extent of lesional tissue on the needle biopsies. The histologic finding of biopsy site changes, clips, markers or carbon tattoos in the surgical specimen should be documented in the pathology report, as they permit evaluation of the likelihood of removal of the target area of the breast tissue. Examination of the subsequent breast imaging allows assessment of the presence of a persisting lesion. If no residual lesion is identified on these images, complete lesion removal by core biopsy is a plausible explanation.

In cases of invasive cancer on the core biopsy, the grade, subtype and biomarker profile should be assessed on the basis of the core biopsies. The extent of the lesion should be based on the imaging estimates as well as histological assessment of the core biopsy. As the entire lesion has been removed by the biopsy, margins are assumed to be clear^{60,61}.

Such circumstances are not regarded as false positive tissue diagnoses.

2. INTENDED LESION NOT REMOVED DURING THE INITIAL SURGERY

The small size of screen detected breast cancers makes localisation and removal challenging on occasion.

To minimize these issues, post-procedure imaging should be performed following marker clip insertion and accurate clip placement confirmed or any deviations documented. Even where a clip has not been inserted, post biopsy imaging may be helpful to confirm the position and extent of the residual lesion prior to the needle localisation procedure

In these cases the review of the biopsy will confirm malignancy. However comparison of the pre and post-operative imaging will reveal a persisting lesion. The specimen imaging is important in that it

⁶⁰ Farshid G, Downey P, Pieterse S, Gill PG. Effectiveness of core biopsy for screen-detected breast lesions under 10 mm: implications for surgical management. ANZ J Surg 2015

⁶¹ Casey M, Rosenblatt R, Zimmerman J, Fineberg S. Mastectomy without malignancy after carcinoma diagnosed by large-core stereotactic breast biopsy. Mod Pathol 1997;10(12): 1209-13

will not identify the intended lesion. Multi-disciplinary review may be required to determine the optimal approach to post-operative imaging.

Such circumstances are not regarded as false positive tissue diagnoses.

3. SPECIMEN LOST OR DESTROYED

Rarely the surgical specimen is lost or destroyed inadvertently after removal and before final histopathology assessment can take place.

In this scenario, review of the core biopsy will confirm malignancy but there is no final specimen for comparison.

Such circumstances are not regarded as false positive tissue diagnoses. Specimen x-rays and post-operative imaging will be important in determining the completeness of removal and the core biopsy will be the basis for the pathologic information required to determine management.

4. COMPLETE PATHOLOGIC RESPONSE AFTER NEOADJUVANT CHEMOTHERAPY OR HORMONAL THERAPY

When chemotherapy is used prior to definitive surgery, 10-15% of cancers respond completely, such that no residual tumour is identified in the surgical specimen. This outcome is more common in high grade cancers.

Such circumstances are not regarded as false positive tissue diagnoses.

5. CLIENT UNABLE OR UNWILLING TO UNDERGO DEFINITIVE SURGERY

Some women may be unable to withstand breast cancer surgery due to co-morbidities. Others may decline surgical intervention.

Hormonal treatment may be used for these patients.

There will be no surgical specimen in such cases.

Such circumstances are not regarded as false positive tissue diagnoses.

6. PLEOMORPHIC LOBULAR CARCINOMA IN SITU

Pleomorphic LCIS is distinguishable from classic LCIS by its high nuclear grade. It is also often associated with comedonecrosis and microcalcifications and may be florid and extensive or of limited volume.

While there is little evidence to support consensus on its management, many authorities treat PLCIS at margins of a surgical specimen as a surgical disease, akin to high grade DCIS. This is not the case for classic LCIS in the surgical specimen, which although a marker of increased risk for the subsequent development of breast cancer, often has a more dispersed distribution and is not amenable to surgical extirpation, short of mastectomy. The 2020 WHO Classification of Tumours Editorial Board recognise PLCIS and florid LCIS (specific histologic diagnostic criteria apply) as variants of classic LCIS. For lack of a substantial evidence base, they only make a specific recommendation supporting excision to clear margins for PLCIS.

If the needle biopsy diagnosis of malignancy led to the finding of PLCIS in the surgical specimen, these cases are not regarded as false positive tissue diagnoses, since a surgically treatable disease has been managed.

Approach to Investigation of Possible False Positive Biopsy Diagnoses

Final percutaneous needle biopsy of breast or axillary lesion reported as malignant, final histology does not confirm malignancy

Pleomorphic LCIS

Not a FP diagnosis

Complete response to neoadjuvant therapy

Not a FP diagnosis

Patient unable or unwilling to have surgery

Not a FP diagnosis

Independent review of needle biopsy

Malignant needle biopsy diagnosis confirmed

Malignant needle biopsy diagnosis NOT confirmed

MDT Review

Complete lesion removal by needle biopsy

Not a FP diagnosis

Intended lesion not removed at surgery

Not a FP diagnosis

Surgical specimen lost or destroyed

Not a FP diagnosis

Likely FP

- These cases are not considered false positive diagnoses by the NQMC
- Services may amend their ADR accordingly
- No need to notify the NQMC

- Follow local protocol for reporting and management of adverse events, including disclosure to the relevant local clinical governance agency
- Notify the NQMC in a 2 step process:
 - 1) Prompt, brief, initial notification to the NQMC,
 - 2) Perform a multidisciplinary clinical investigation of the root causes, using the **BSA false positive investigation proforma**. Report the completed findings to the NQMC.

DRAFT PROFORMA FOR THE CLINICAL INVESTIGATION AND REPORTING OF FALSE POSITIVE BIOPSIES

Clinical Data Proforma

1. Background information

| | |
|--|-----------------|
| Jurisdiction: | |
| SAS: | |
| Client age: | |
| Side: | |
| Lesion imaging grade: | |
| Lesion imaging morphology: | Choose an item. |
| Lesion imaging size, mm: | |
| Strong FHX indicated/known: | |
| Findings on Clinical Breast Examination: | |

2. Biopsy

| | |
|---|-------------------------------|
| Guidance: | Choose an item. |
| Equipment technical issues: | Choose an item. |
| | If Other, please explain: |
| Issues: | |
| Method: | Choose an item. |
| Biopsy clip placed: | Choose an item. |
| | If Other, please explain: |
| Position: | |
| Biopsy pathology diagnosis: (copy and paste from the pathology report) | |
| | |
| Date of Biopsy: | Click or tap to enter a date. |
| Original needle biopsy report and slides reviewed: | Choose an item. |
| | If Other, please explain: |

| | |
|--|---------------------------|
| | |
| Needle biopsy and slide review outcome: | |
| Original needle biopsy reviewed and no longer definitive for malignancy: | Choose an item. |
| | If Other, please explain: |
| Any further needle biopsy (with result)? | |

3. BSA Service Recommendation

| | |
|------------------------|---------------------------|
| Service Recommendation | Choose an item. |
| | If Other, please explain: |

4. Client Consultation

| | |
|---|-----------------|
| What was the woman told regarding the nature of her screen detected lesion at the time? | Choose an item. |
|---|-----------------|

5. Surgery

| | |
|---|--|
| Nature of surgery: | Choose an item. |
| Was any image guided or surgical axillary procedure performed? (Choose all relevant options) | <div>FNA <input type="checkbox"/></div> <div>Core <input type="checkbox"/></div> <div>SN Biopsy <input type="checkbox"/></div> <div>Axillary Sampling <input type="checkbox"/></div> <div>Axillary Dissection <input type="checkbox"/></div> |
| Findings on surgical pathology: (copy and paste from the pathology report) | |
| Biopsy site seen in pathology report: | Choose an item. |
| Date of Surgical pathology report: | Click or tap to enter a date. |

6. Timelines

| | |
|---|--|
| What was the time interval between the initial diagnosis and the final pathology result being known at the Service? | |
|---|--|

7. Service Clinical Review After the Incident, led by Clinical Director

| | |
|--|-----------------|
| Was a clinical review of the incident undertaken? | Choose an item. |
| What was the nature of the review? | |
| Was there multidisciplinary input into the review? | Choose an item. |
| Outcome of review: | |

8. Notification

| | |
|---|-----------------|
| Were the clinical and risk oversight committees notified? | Choose an item. |
| Was the NQMC notified? | Choose an item. |
| How was the patient notified of the adverse event? | |

9. Authorisation

| | |
|--------------------|-------------------------------|
| Clinical Director: | |
| Signature: | |
| Date: | Click or tap to enter a date. |

APPENDIX J

Not used

APPENDIX K:

BREASTSCREEN AUSTRALIA GUIDELINES FOR USE OF REMOTE RADIOLOGY AT ASSESSMENT CLINICS

A Service or SCU that wishes to implement remote radiology must establish and implement, under **Protocol 3 - Assessment**, a protocol for delivering those remote radiology services to assessment clinics that includes and complies with all of the following:

1. The assessment clinic and the radiologist must have immediate and direct access to the necessary technology/tele-health facilities that can enable the real time transmission and reading of high-quality radiology images and to support real-time communications between the radiologist and the clinical team.
2. The remote radiologist and the facility in which they operate must meet any protocol or standard that applies to radiologists operating at a BreastScreen Service site.
3. Women participating in assessments involving remote radiology, must have the process explained to them and must consent to the assessment being undertaken on that basis.
4. Remote radiology is not to be used in all assessment clinics as a matter of routine. A radiologist where possible should be present at alternate assessment clinics or at least on a regular basis to participate in any assessments that require the onsite presence of a radiologist. The appropriate frequency of assessment clinics with an onsite radiologist is at the discretion of the jurisdiction and should be determined collaboratively between the Service and SCU.
5. The radiologist must be known to the staff of the Service and vice versa and steps must be taken to establish mutual confidence of the clinical assessment team in their competence and the conduct of assessments.
6. The radiologist must be fully engaged in remote assessment whilst participating in the assessment clinic, and not participate in other radiology service delivery at his or her practice setting.
7. All mammographic images and ultra-sounds undertaken during the assessment clinic must be made available to the radiologist in real time and the radiologist must be able to monitor the progress of the clinic in real time.
8. Appropriate communication devices must be used for the examination, to ensure satisfactory communications with the clinical assessment team, and being mindful of client comfort and appropriate communication of findings.
9. Good governance of the remote radiology arrangements must be established at the Service to ensure rigorous scrutiny of participating staff experience and qualifications, particularly Medical Practitioners and Sonographers.
10. Good governance must also be established at the State Quality Committee level prior to the commencement of the remote radiology clinic.
11. The Service must document the business and clinical processes of the remote radiology clinic.

12. A report on the performance of remote radiology clinics must be included in Service accreditation applications and Annual Data Reports to the NQMC.

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