

BreastScreen

AUSTRALIA

A joint Australian, State and Territory Government Program

**BREASTSCREEN AUSTRALIA
NATIONAL ACCREDITATION STANDARDS**

**BreastScreen Australia
Quality Improvement Program**

Developed by the National Quality Management Committee of
BreastScreen Australia

Endorsed by the
National Advisory Committee
To BreastScreen Australia
July 2001

Revisions endorsed by the
Australian Screening Advisory Committee
November 2004

Revisions recommended by the
Digital Mammography Accreditation Standards Working Group
and the National Quality Management Committee endorsed by the
Screening Subcommittee
April 2008

TABLE OF CONTENTS

FOREWORD	vii
INTRODUCTION	1
AIMS, OBJECTIVES AND POLICIES OF THE BREASTSCREEN AUSTRALIA PROGRAM	11
1 SECTION 1	15
To maximise the proportion of women aged 50–69 years who are screened every two years, and to ensure equitable access for women in this age group	
2 SECTION 2	27
To maximise the number of small cancers and cancers detected, while minimising the number of unnecessary recalls and investigations	
3 SECTION 3	73
To ensure that services are acceptable and appropriate to the needs of the eligible population	
4 SECTION 4	97
To ensure that services are managed effectively and efficiently	
APPENDIX A: Committee Members	115
APPENDIX B: BreastScreen Australia National Accreditation Requirements review process	121
APPENDIX C: Interpreting variations from the cancer detection standards	125
APPENDIX D: Data from Services and States and Territories used in developing the standards	131
APPENDIX E: Tool for assessing whether a woman is at increased risk of breast cancer due to family history	143
APPENDIX F: International cancer detection standards	145

APPENDIX G:	Determining cancer detection rates: some procedural notes	149
APPENDIX H:	Standards for ultrasound quality control procedures	151
APPENDIX I:	Standards for mammography imaging system performance	153
APPENDIX J:	Staff expertise, experience and training standards	165
APPENDIX K:	Standards for mammography quality control procedures	169
APPENDIX L:	Standards for quality control test equipment	193
APPENDIX M:	PGMI evaluation of clinical image quality	195
APPENDIX N:	Roles and responsibilities of the designated radiographer	199
APPENDIX O:	Roles and responsibilities of the designated radiologist	201
APPENDIX P:	Audit of cancer detection rates for individual screen readers	203
APPENDIX Q:	Roles and responsibilities of the designated pathologist	205
APPENDIX R:	Pathology reporting of breast cancer: breast fine needle aspiration cytology and core biopsy reports	207
APPENDIX S:	Handling of specimens and pathology reporting	209
APPENDIX T:	Roles and responsibilities of the designated surgeon	211
APPENDIX U:	Recommendations for providing results to women diagnosed with breast cancer	213
APPENDIX V:	List of protocols to be included in the Policy and Procedures Manual	215
APPENDIX W:	Information Technology standards for digital mammography	217
GLOSSARY		219
REFERENCE LIST		227

LIST OF TABLES

TABLE 1	Relationship between the overall outcomes and the aims of the BreastScreen Australia Program	9
TABLE 2.1	Detection rates for invasive cancer in BreastScreen Australia in 1997: number detected per 10,000 screens	29
TABLE 2.2	Detection rates for small invasive cancers in BreastScreen Australia in 1997: number detected per 10,000 screens	31
TABLE 2.3	DCIS in BreastScreen Australia in 1997: number detected per 10,000 screens	33
TABLE 2.4	Recall for assessment for first and subsequent screens in Australia and internationally	36
TABLE F.A	Standards per 1,000 women screened in United Kingdom National Health Service Breast Screening Program ¹⁰ and Scottish Breast Screening Program ¹⁵⁶ in women aged 50–64 years	145
TABLE F.B	Observed numbers of cancers (invasive breast cancer and DCIS) detected in the Netherlands and Canada	146
TABLE F.C	Standards and achievements for small cancer detection rates in women aged 50–64 in Great Britain and Scottish programs	146
TABLE F.D	Standards for detection of DCIS in the Great Britain and Scottish programs in women aged 50–64	147
TABLE H.A	Ultrasound system quality control and performance standards	151
TABLE I.A	Screen/film mammography imaging system performance standards	153
TABLE I.B	Digital (DR) mammography imaging system performance standards	155
TABLE I.C	Computed Radiography (CR) mammography imaging system performance standards	158
TABLE I.D	Digital stereotactic imaging system performance standards	161

TABLE K.A	Quality control procedures and standards for screen/film mammography	170
TABLE K.B	Quality control procedures and standards for DR mammography	176
TABLE K.C	Quality control procedures and standards for CR mammography	181
TABLE K.D	Quality control procedures and standards for digital stereotactic units	186
TABLE L.A	Quality control test equipment for mammography	193
TABLE U.A	Recommended steps for informing women that they have a diagnosis of breast cancer	213

FOREWORD

The BreastScreen Australia Program aims to reduce mortality and morbidity from breast cancer. The BreastScreen Australia National Accreditation Standards (NAS) are designed to ensure that the national mammographic screening program is offering a high quality service to women attending for screening and assessment.

The NAS assist Services to incorporate into everyday practice the essential principles of a quality improvement program. The site visit, conducted every two to four years, is the external verification by expert peers of how well the Service is using the advice of the standards and continually improving the quality of the care it provides.

To achieve a high quality service requires leaders to recognise the value of standards and quality improvement and to create an environment where staff are encouraged and supported to identify opportunities to improve. It also requires staff to make changes that will improve their daily practice and the outcomes for the women who attend their Service. Accreditation is recognition of the commitment of staff in providing a high quality service.

The current NAS are an outcome of a major review of the National Accreditation Requirements (NARs) that had been in existence since the inception of the Program. In 2004, the National Quality Management Committee (NQMC) reviewed six exigent NAS. This was an interim measure to identify ways to manage NAS that were of concern to the Program and problematic for some services to achieve within the accreditation process. The NQMC agreed that a full review would be conducted when there was sufficient Australian data available to support a full review of the NAS.

The NAS were developed in a predominantly film-based mammography environment. The emergence of digital technology necessitated a review of the NAS to ensure services using digital technology are well positioned to undertake assessment and be accredited against the NAS.

The Digital Mammography Accreditation Standards Working Group (DMASWG) was established as a working group of the NQMC which exists under the auspices of the Australian Population Health Development Principal Committee Screening Subcommittee.

The role of the DMASWG has been to recommend modifications to the existing NAS and develop any new NAS relating to digital mammography as required. This has been done with reference to current literature, expert opinion, overseas experience, and consulting with the relevant professional organisations and medical colleges as required.

The introduction of digital technology across BreastScreen Australia is an exciting opportunity for the national program to face the current challenges and embrace the latest technology.

We hope that everyone involved in the BreastScreen Australia Program sees the NAS as a key element of an ongoing national quality improvement program and continues to strive to improve the quality of the services they deliver to women.

Ms Lou Williamson
Chair
National Quality Management Committee (2004-present)

ABBREVIATIONS IN TEXT

ACPSEM	Australian College of Physical Scientists and Engineers in Medicine
AHMAC	Australian Health Ministers' Advisory Council
AIHW	Australian Institute of Health and Welfare
AIR	Australian Institute of Radiography
APHDPC	Australian Population Health Development Principal Committee
ASAC	Australian Screening Advisory Committee
CI	Confidence interval
DCIS	Ductal carcinoma in situ
DMASWG	Digital Mammography Accreditation Standards Working Group
FNA	Fine needle aspiration
LCIS	Lobular carcinoma in situ
NARS	National Accreditation Requirements
NAS	National Accreditation Standards
NHMRC	National Health and Medical Research Council
NHS	National Health Service
NQMC	National Quality Management Committee
PGMI	The United Kingdom Mammography Trainers Group/College of Radiographers—devised PGMI method of radiographer performance evaluation (Perfect, Good, Moderate, Inadequate)
the Program	The BreastScreen Australia Program
the Service	An individual BreastScreen Australia site, or group of sites, which provides BreastScreen Australia services to a geographical region within a state or territory.
RANZCR	Royal Australian and New Zealand College of Radiologists
Screening Subcommittee	The Screening Subcommittee of The Australian Population Health Development Principal

ABBREVIATIONS USED IN APPENDICES

ACR	American College of Radiology
AEC	automatic exposure control
ASR	age standardised rates
CC	Cranio-caudal view
CCPM	Certificate of clinical proficiency in mammography
cd/m²	candela per square metre
CI	contrast index
CNR	contrast to noise ratio
CR	computed radiography
DICOM	digital imaging and communication in medicine
Dmax	maximum density
DR	digital radiography
DRL	diagnostic reference level
FWHM	full-width-half-maximum
IMF	infra-mammary fold
IS	information system
lp/mm	line pairs per millimetre
kVp	kilovolts peak
mAs	milli-ampere seconds
mGy	milligray
MLO	medio-lateral oblique view
Mo	molybdenum
MPV	mean pixel value
MTF	modulation transfer function
N	newton
OD	optical density
PACS	Picture Archiving and Communication System
PNL	posterior nipple line
QC	quality control
Rh	rhodium
ROI	region of interest
SI	speed index
SID	source to image distance
SNR	signal to noise ratio
W	tungsten

INTRODUCTION

BREASTSCREEN AUSTRALIA

During the 1970s and 1980s the results of a number of randomised trials were published which demonstrated that mammographic screening could reduce deaths from breast cancer among women aged 50–69 years.

In response to the results of these trials, it was decided to explore the feasibility of a national mammographic screening program in Australia. The program was piloted in 11 sites over a three-year period between 1987–1990. The results of this evaluation guided the Australian Health Ministers' Advisory Council (AHMAC) in establishing a strategy for a national breast cancer screening program.

The BreastScreen Australia Program (the Program) for national mammographic screening was established in 1991. The implementation of the Program was guided by the report *Breast cancer screening in Australia: future directions*.¹

The Australian Screening Advisory Committee (ASAC), incorporating the former National Advisory Committee (NAC) to BreastScreen Australia was disbanded following changes to the committee structure under AHMAC in 2006. The Screening Subcommittee of the Australian Population Health Development Principal Committee (APHDPC) is now the national body which coordinates policy for the Program and integrates feedback from individual States and Territories, the Australian Government and relevant professional and consumer bodies into the policy process. Within each State and Territory, a State Coordination Unit has responsibility for implementation of the Program within its jurisdiction. States and Territories have established Screening and Assessment Services in ways that meet the needs of their different populations. Each Service screens between 1,000 and 95,000 women each year.

There were 33 Services operating across Australia in 2007.

QUALITY IMPROVEMENT IN BREASTSCREEN AUSTRALIA

It was recognised from the outset that all aspects of screening and assessment must be of high quality in order to achieve reductions in mortality and morbidity from breast cancer.

A comprehensive quality improvement program was implemented to improve screening outcomes for women, minimising the potential adverse effects of mammographic screening and maximising benefits.

A population-based screening program like BreastScreen Australia must be implemented with stronger control and guidance than is customary in health service development. The report, *Breast cancer screening in Australia: future directions*¹ emphasised the need for a highly integrated, systematic and coordinated quality improvement program, which includes standardised accreditation processes, specialised training, quantitative performance criteria, ongoing monitoring and evaluation, and national and state-level coordination mechanisms.

The quality improvement program within BreastScreen Australia includes education and training, review and accreditation programs. At the national level, the approach to quality improvement is summarised in the document *Quality Improvement for BreastScreen Australia*.² In each State and Territory, a State Accreditation Committee oversees the development and implementation of a quality improvement program within the broad national framework. In some jurisdictions, discipline-specific quality groups assist in this process.

The focus of the quality improvement program is to ensure that minimum standards are maintained and to pursue excellence by continually developing strategies to review and improve care. The Program strives for continual improvement through self-review, feedback, acquisition of new knowledge and skills and change in practice. As part of its overall approach to quality improvement, BreastScreen Australia also includes a formal accreditation program.

ROLE OF THE ACCREDITATION PROCESS

Accreditation is an independent review of Service performance and a way of assessing and informing the quality improvement program within a Service. The accreditation process provides an external three-yearly assessment of the extent to which the Service is meeting minimum standards for practice in a two to four-year period. As such, it provides women attending the Service with confidence that the care they receive is of an agreed high standard.

A Service's approach to accreditation should be integrated into its overall quality improvement program. There should be continuous review of performance against the standards throughout the two to four-year interval between site visits. Together with the process of preparing for an accreditation visit, the ongoing review should help the Service identify aspects of service provision where additional quality improvement may be required.

The accreditation program has several components, as follows:

- Minimum standards for the provision of screening and assessment within BreastScreen Australia outlined in this document.
- Data auditors who conduct an independent data audit prior to the site visit.
- Site visitors who conduct a review of the Service against the standards.
- Annual data reports detailing a Service's performance in the period between site visits.

- State Coordination Units, with the State Accreditation Committees, which are responsible for working with Services to ensure that they meet the standards and coordinating the process of accreditation of the Service. State Accreditation Committees make a recommendation regarding the accreditation of the Service to the NQMC.
- The NQMC, which reviews the applications for accreditation with advice from the site visitors and the comments of the State Accreditation Committee. The NQMC is responsible for making a final decision about whether a Service is accredited.

Further details of the accreditation process can be found in the *BreastScreen Australia Accreditation Handbook*.³

REVIEW OF THE NATIONAL ACCREDITATION REQUIREMENTS (NARS)

National Accreditation Guidelines were established at the outset of the Program. The Guidelines were reviewed and then ratified as the NARs by the NAC for the Early Detection of Breast Cancer (now BreastScreen Australia) in March 1994.

The second review was initiated in 1999 by the NQMC, the membership of which is in Appendix A. The review process was undertaken in consultation with the State and Territory programs, as well as consumers and representatives of the disciplines/areas involved in the Program. The review process utilised expertise from across Australia by forming six teams to assist with the review. The membership of the review teams is in Appendix A. The work of the review teams was informed by the comments raised in the national consultation process. A detailed account of the review process is outlined in Appendix B. During the review process it was proposed the NARs be renamed the National Accreditation Standards (NAS). This proposal was endorsed by the National Advisory Committee to BreastScreen Australia in July 2001.

Several principles guided the review of the requirements:

Quality improvement, core standards and targets

The accreditation process is designed to foster a continuous quality improvement approach within BreastScreen Australia.

To assist Services, the text accompanying the performance objectives refers to targets which the Program should strive to meet where these are relevant. It is not expected that Services meet all of these for accreditation purposes, but the NQMC anticipates that discussion of targets will assist Services in developing a continuous quality improvement approach.

However, the accreditation process should also provide clients with assurance that the Services meet agreed standards. The NQMC believes that all of the performance objectives reflect key aspects of the provision of a high quality program. It is therefore not possible to identify core standards. Services should seek to meet all of the standards although special factors affecting individual Services will be taken into account in determining accreditation status.

Achievable by most services

The NQMC has set standards which maintain a high quality screening program and which are achievable by most Services within the Australian context. Australian data have been considered in setting the standards where available to ensure that they are achievable by most Services.

However, the NQMC was also mindful of the need to ensure that Services were challenged to provide as high a quality program as possible. The standards were therefore set to ensure that the Program was of high quality rather to enable every Service to meet them.

Recognition of factors affecting individual Services

The NQMC recognises that on occasion individual Services may be unable to meet a small number of the standards. This may be because of factors relating to geography, workforce, demographics or other considerations.

The NQMC is mindful of the differences between Services and does not intend that the inability to meet one or several standards will necessarily preclude accreditation. Rather the Service should be able to demonstrate that it is implementing a quality improvement program to move towards meeting the standard over time.

In developing its application for accreditation, the Service will be expected to clearly identify those standards that it is unable to meet and to indicate for each:

- the particular circumstances that make it unable to meet the standard;
- the quality improvement processes and targeted strategies in place to ensure that the Service is working towards meeting the standard in the future; and
- data about trends over time to demonstrate, where appropriate, progress towards meeting the standard.

Evidence based

Where ever possible, the standards are based on evidence. In some cases, studies or data from overseas have been used. It is now possible to base many of the standards on what appears to be achievable within the Australian context; Australian data have in many instances been used to establish the standards.

However, in some areas there are few data to guide the establishment of standards; if the issue was perceived as important to ensuring quality in the Program, a standard was still included and a consensus approach (level IV evidence) was used in establishing the standard.

The standards have been made consistent with other nationally agreed guides, where appropriate.

Any draft documents referred to in the revised National Accreditation Standards which has not been endorsed by the ASAC, incorporating the former NAC, will remain inactive until the final document is endorsed and Services are given an appropriate period of time to put the principles and practices of the document into place before they are assessed against related standards.

Clear rationale

In revising the NARS, the NQMC sought to clearly identify the relationship between the Aims and Objectives of the Program and each of the performance objectives. The Performance Objectives are grouped into four broad outcomes reflecting the Program's Aims and Objectives. The text provides the rationale for including each performance objective in relation to achieving the broad outcome.

Concrete and measurable

The NQMC has sought to define the standards to ensure that they are concrete and measurable. This ensures that any decision about whether a standard has been achieved are transparent. It also assists Services, State Accreditation Committees, site visitors and the NQMC in achieving a common understanding of the standards.

Context of decision making process within NQMC

The NQMC recognises that the standards will be viewed in the context of the approach it takes to decision making. A decision tool has been developed by the NQMC to assist with accreditation decision making against the National Accreditation Standards. The Decision Tool was endorsed by the National Advisory Committee in February 2003 and updated by the NQMC in November 2004. Strategies will be put in place to ensure that membership of the NQMC is regularly reviewed.

At the 21 May 2004 NQMC meeting it was agreed to conduct a mini review of the NAS. This was an interim measure to identify ways to manage standards that had been causing concern to Program Managers and that some services had difficulties in meeting within the accreditation process. The NQMC agreed that a full review would be conducted when there was sufficient data available to support reconsideration of the NAS.

REVIEW FOR THE INCLUSION OF DIGITAL MAMMOGRAPHY

The Digital Mammography Accreditation Standards Working Group (DMASWG), under the auspice of the NQMC undertook a review of the BreastScreen Australia NAS to incorporate standards for digital mammography in screening and assessment.

Digital mammography encompasses imaging acquisition using either computed radiography or digital radiography (see Glossary).^A

In the main body of the document, the word 'film' has been replaced with 'image' or 'screen' (as appropriate). More significant changes appear in the appendices I through to M.

A Computed and digital radiography are also further defined in the *ACPSEM Position Paper Interim Recommendations for a Digital Mammography Quality Assurance Program*⁴

A GUIDE TO THE DOCUMENT

The standards address all aspects of the screening and assessment pathway, including recruitment, management, technical quality assurance, education and counselling, assessment, data management and training. Although the standards primarily focus on women in the target age group (that is, women aged 50–69 years), the principles of quality apply to all women eligible for mammographic screening (that is, women aged 40 years and over). The Program should monitor the standards for women aged 40–49 years and 70 years and over.

BreastScreen Australia aims to reduce mortality and morbidity from breast cancer. However, the impact on deaths from breast cancer of the introduction of a screening program or of changes in the quality of that program will not be evident for some time. In a quality improvement and accreditation context, it is therefore also important to measure other aspects of performance which indicate whether the Program is likely to be on track to reduce mortality from breast cancer. For example, if the Program is not finding small cancers, it is unlikely that changes in mortality will be observed. The standards are therefore based on these performance indicators.

BreastScreen Australia recognises the need to achieve the best possible outcomes for individual women within the context of a population screening program. The needs of individual women in service delivery must therefore be met, and their participation in decision making and rights and needs as consumers acknowledged. The screening process should minimise anxiety and ensure that the services are acceptable and appropriate to women. The possible adverse effects of screening which must be minimised may include anxiety, radiation exposure, over-diagnosis and under-diagnosis and unnecessary intervention (including unnecessary open biopsy). Some groups of women have special needs, and appropriate and equitable access should be provided for all women as far as possible.

Appropriate organisational structures and management systems will exist to ensure the efficiency and effectiveness of the Program. BreastScreen Australia recognises the need for effective monitoring and evaluation of clinical activities, recruitment, resource management, data collection and training activities.

Outcomes

The standards were developed to assist in achieving four overall outcomes critical to a high quality program:

- To maximise the proportion of women aged 50–69 years who are screened every two years, and to ensure equitable access for women in this age group.
- To maximise the number of small cancers and cancers detected, while minimising the number of unnecessary recalls and investigations.
- To ensure that Services are acceptable and appropriate to the needs of the eligible population.
- To ensure that Services are managed effectively and efficiently.

These outcomes are derived from the aims of the Program, as shown in Table 1.

Within each outcome there is a series of performance objectives with linked standards and measures. The performance objectives make an essential contribution to the achievement of the relevant outcome. The site visitors will use the measures to determine whether the standards have been met by a Service.

The standards and quality improvement

Services should strive to continually improve their performance. The standards can be used as a tool to improve the quality of the service that is delivered.

In analysing their performance, Services should note that the standards represent the **minimum standards** to be achieved. It is anticipated that most Services will perform above the standard. If a Service is **just** meeting the minimum standards, careful analysis should be undertaken about how performance may be improved.

The document includes some tools to assist Services in considering their performance:

- **Targets:** Several standards include ‘targets’. The targets are based on what is achievable in Services in Australia and/or what has been achievable overseas. While a Service might meet the minimum standard, it should not be satisfied with this level of performance but strive towards achieving the target.
- **Funnel plots** accounting for variation based on numbers screened: If a Service is screening small numbers of women, its performance may vary from the standard as a result of chance. The document includes funnel plots outlining the 95% confidence bounds based on the Poisson Distribution to assist Services in judging whether their performance truly differs from the standard or differs as a result of chance variation. This is described in detail in Appendix C. However, a Service should not necessarily be satisfied if its performance lies within the confidence bounds or 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 should be improved and should indicate to the Service that further analysis of their approach is warranted.

In evaluating their performance in a quality improvement context, Services should consider clusters of standards or performance objectives together to provide an integrated view of the quality of care being provided. For example, if the cancer detection rates, small cancer detection rates and the interval cancer rates all **just** meet the standards, the Service should be concerned and carefully analyse its performance. If, on the other hand, the cancer detection rates and the small cancer detection rates are much higher than the standard and the interval cancer rate is also a little high, the Service might be more confident in thinking that the interval cancer rate is due to chance variation.

Services should also review their performance against the indicators on a regular basis, not just in preparation for the accreditation process. If performance in relation to a standard is relatively low, over time then the Service should review its approach even if it is meeting the standards.

In summary, in using the accreditation standards as a quality improvement tool, Services should take care to seek an integrated picture of their performance across indicators and over time rather than simply considering whether an individual standard has been met. Where a pattern of only just meeting the standards is apparent, the Service will analyse the reasons for this and if necessary instigate strategies to improve care. As part of the accreditation process, the Service may be asked to provide evidence of this analysis and its outcome.

Measures

Services should use the most recent 12-month period for which data are available when presenting information and data for accreditation. The **same** 12-month period should be used for the calculation of all measures. The exceptions to this are the participation, rescreen and interval cancer standards. More detailed information about the measures can be obtained from the BreastScreen Australia Data Dictionary.

Table 1 Relationship between the overall outcomes and the aims of the BreastScreen Australia Program

Outcome 1	To maximise the proportion of women aged 50–69 years who are screened every two years, and to ensure equitable access for women in this age group.	<p>Aim 2 To maximise the early detection of breast cancer in the target population.</p> <p>Aim 4 To ensure equitable access for women aged 50–69 years to the Program.</p>
Outcome 2	To maximise the number of cancers and small cancers detected, while minimising the number of unnecessary recalls and investigations.	<p>Aim 1 To ensure that the Program is implemented in such a way that significant reductions can be achieved in morbidity and mortality attributable to breast cancer.</p> <p>Aim 2 To maximise the early detection of breast cancer in the target population</p>
Outcome 3	To ensure that services are acceptable and appropriate to the needs of the eligible population.	<p>Aim 5 To ensure that services are acceptable and appropriate to the needs of the eligible population.</p>
Outcome 4	To ensure that services are managed effectively and efficiently.	<p>Aim 4 To ensure equitable access for women aged 50–69 years to the Program.</p>
		<p>Aim 3 To ensure that screening for breast cancer in Australia is provided in dedicated and accredited Screening Assessment Services as part of the BreastScreen Australia Program.</p> <p>Aim 6 To achieve high standards of program management, service delivery, monitoring and evaluation, and accountability.</p>

AIMS, OBJECTIVES AND POLICIES OF THE BREASTSCREEN AUSTRALIA PROGRAM

AIMS

1. To ensure that the Program is implemented in such a way that significant reductions can be achieved in morbidity and mortality attributable to breast cancer.
2. To maximise the early detection of breast cancer in the target population.
3. 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.
4. To ensure equitable access for women aged 50–69 years to the Program.
5. To ensure that services are acceptable and appropriate to the needs of the eligible population.
6. To achieve high standards of program management, service delivery, monitoring and evaluation, and accountability.

OBJECTIVES

1. To achieve, after five years, a 70 per cent participation rate in the BreastScreen Australia Program by women in the target group (women aged 50–69 years) and access to the Program for women aged 40–49 years and 70–79 years.
2. To rescreen all women in the Program at two-yearly intervals.
3. To achieve agreed performance outcomes which minimise recall rates, retake images, invasive procedures, ‘false negatives’, and ‘false positives’, and maximise the number of cancers detected, particularly the number of small cancers.
4. To refer to appropriate treatment services and collect information about the outcome of treatment.

5. To fund through State Coordination Units only Screening and Assessment Services which are accredited according to agreed National Accreditation Standards, and to ensure that those standards are monitored and reviewed by appropriate State Accreditation Committees.
6. To recognise the real costs to the women of participation in the Program, and to minimise those costs. This includes the provision of services at minimal or no charge, and free to eligible women who would not attend if there was a charge.
7. To make information about mammographic screening and the BreastScreen Australia Program available in easily comprehensible and appropriate forms in a variety of forums, and to women and health-care providers in particular.
8. To achieve patterns of participation in the Program which are representative of the socioeconomic, ethnic and cultural profiles of the target population.
9. To provide services in accessible, non-threatening and comfortable environments by staff with appropriate expertise, experience and training.
10. To provide appropriate service in that: the provision of counselling, education and information is an integral part of the Program; sensitive procedures for notification of recall are in place; and the time between the initial screen and assessment is minimised.
11. To achieve high levels of participation in the development and management of the Program by members of significant professional and client groups.
12. To collect and analyse data sufficient to monitor the implementation of the Program, to evaluate its effectiveness and efficiency, and to provide the basis for future policy and program development decisions.

POLICIES OF THE BREASTSCREEN AUSTRALIA PROGRAM

Services accredited under BreastScreen Australia are expected to operate according to the national policies and information statements of BreastScreen Australia, and to ensure that these policies and information statements are freely available to staff and consumers.

BreastScreen Australia policies are regularly reviewed by the APHDPC Screening Subcommittee and its working groups and by State and Territory Program Managers.

MAJOR POLICY FEATURES OF THE BREASTSCREEN AUSTRALIA PROGRAM

The key agreed national BreastScreen Australia policy statements are:

1. BreastScreen Australia selects women for screening on the basis of age alone. Women aged 40 years and above are eligible. Recruitment strategies will be targeted at women aged 50–69 years. The age for screening will be monitored and reviewed as new data become available.

2. The screening interval will be every two years and will be reviewed as new data become available.
3. Screening will be at minimal or no cost to the women, and free of charge to eligible women who would not attend if there were a charge.
4. Comprehensive and easily understood information, emotional support and counselling will be provided as appropriate. Women will be advised of the effectiveness and risks of mammography and on the maintenance of a regime of breast care to reinforce the message that a negative mammographic screen does not preclude a diagnosis of breast cancer prior to the next screening.
5. Screening services will be provided in a manner which is acceptable to women in the target group and in accessible, non-threatening and comfortable environments.
6. General practitioners will be kept informed of the results of screening and of any further work-up required, unless a woman directs otherwise. Although a doctor's referral is not a prerequisite for attendance, a letter from the woman's doctor is welcome.
7. Screening will employ mammography as the initial screening method.
8. All women will be screened with two view mammography. At a subsequent rescreening one view may be used if previous mammograms have indicated that two views are not required.
9. All mammograms will be taken by a radiographer appropriately trained in screening mammography.
10. All mammographic images will be read and reported independently by two or more readers, at least one of whom shall be a radiologist. Both readers must be specially trained in screening mammography and both meet the same performance criteria. Reports will be combined into a single recommendation.
11. The results of screening will be provided promptly and directly to the woman who is the subject of screening in a way which is sensitive to her possible anxiety.
12. Women will be actively involved in decisions about their management, particularly in relation to further assessment and treatment, and written information will be provided.
13. Screening and assessment will be carried out at accredited centres/services.
14. The Program will take a woman from screening up to and including histological or cytological diagnosis of breast cancer.
15. Women with histologically or cytologically confirmed breast cancer will be 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.

1

TO MAXIMISE THE PROPORTION OF WOMEN AGED 50–69 YEARS WHO ARE SCREENED EVERY TWO YEARS, AND TO ENSURE EQUITABLE ACCESS FOR WOMEN IN THIS AGE GROUP

A high participation rate among women aged 50–69 years is necessary to achieve substantial reductions in mortality from breast cancer across the Australian community. A high participation rate will also ensure that mammographic screening resources are used efficiently.

INDICATORS

Participation in the Program can be assessed by measuring both the overall proportion of the target population who attend in a two-year period, and the proportion of women who attend for rescreening.

PARTICIPATION IN MAMMOGRAPHIC SCREENING

Participation rates in the overseas randomised trials of mammographic screening ranged between 67% and 89%.⁵⁻⁷ In these trials, reductions in mortality of up to 30% were achieved among those populations offered screening.

Based on the evidence from the trials, BreastScreen Australia aims to screen at least 70% of women aged 50–69 years every two years. A lower participation rate will result in a smaller benefit in terms of deaths prevented in the population. As a public health measure, the cost-effectiveness of mammographic screening was based on achieving up to a 30% reduction in mortality.⁸ A lower participation rate may affect judgements about the cost-effectiveness of the BreastScreen Australia Program.

There will be variations in participation rates between countries because of different cultures and health service delivery systems. Programs overseas have achieved participation rates of 70% or more. For example, programs have reported participation rates as follows: 71% (Denmark, women aged 50–69 years in 1991–93);⁹ 73% (United Kingdom, women aged 50–64 years in 1997–98);¹⁰ 78% (Netherlands, women aged 50–69 years in 1991–97);¹¹ 81% (Sweden, women aged 40–74 years in 1995–96);¹² 89% (Finland, women aged 50–59 years in 1987–97).^{13, B}

In Australia, the overall participation rate for women aged 50–69 years for the 24-month period

B These data need to be interpreted with some caution as participation rates are calculated differently across countries.

1997–98 was 54.3%.¹⁴ Based on the rates of participation in 1997–98, additional recruitment programs will be required.

It is recognised that many Services are currently below the standard for participation. However, a 70% participation rate is crucial if the Program is to have the desired public health impact. If a Service is not achieving a 70% participation rate, the reasons for lower participation should be analysed and targeted strategies for increasing participation implemented. The NQMC will consider accrediting Services who do not meet the participation standard based on: the reasons provided for not meeting the standard; demonstration of quality improvement processes and targeted strategies for increasing participation; and trend data to indicate that participation rates are increasing over time.

The evidence of a benefit from mammographic screening in terms of reductions in mortality is strongest for women aged 50–69 years. Standards have therefore been set only for the target age group (50–69 years) in the BreastScreen Australia Program. For women 40–49 years and 70 years and older, Services will monitor the proportion of women screened. Services may be asked to provide these data to enable the NQMC to consider whether participation rates among women aged 50–69 years could be increased by reducing screening among women outside of the target age group.

Performance objective 1.1:

The Service maximises the proportion of women aged 50–69 years who are screened every two years.^c

PARTICIPATION IN RESCREENING

If the Program is to achieve its potential in terms of mortality benefit, women aged 50–69 years should be rescreened on a regular basis to increase the likelihood that breast cancers are found as early as possible. The long-term effectiveness of the screening program 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.

There is evidence that screening intervals of longer than two years will reduce the mortality benefit from screening.^{15–17} For example, the Swedish Two County Study found an increase in interval cancer rates as the screening interval increased past two years.¹⁸

The trials of mammographic screening on which the BreastScreen Australia Program was based used a screening interval of two years.⁵ Most established mammographic screening programs have also used a two-yearly screening interval, including those in Finland, Sweden, the Netherlands and Canada.¹

^c All performance objectives in this document, unless stated otherwise, refer to women resident in the Service catchment area

For these reasons, BreastScreen Australia policy states that the screening interval will be two-yearly.

Overseas population-based programs have reported high rates of rescreening in first and subsequent rescreening rounds. In the United Kingdom, which has a three-yearly screening interval, in 1997–98, 87% of women aged 50–64 years who had previously been screened at least once accepted an invitation to reattend for rescreening.¹⁰ In Denmark in 1995–97, 90% of those women aged 50–69 years screened in the first and second rounds participated in a third round of screening.⁹ However, there will be variations in rescreening rates between countries because of different health service delivery systems and differences in how screening programs are organised.

To assist in estimating rescreening rates in Australia, data were provided by State and Territory programs about individual Services (Appendix D). Services reported that between 55% and 83% of women who had attended for a first screen within the Program returned for the second screen. At subsequent rescreens, between 79% and 91% of women screened by the Program in the previous rounds reattended.

The standard is that 75% of women aged 50–67 years participating in their first screen in the Program will attend for rescreening within 27 months, and that 90% of women aged 50–67 years attending for their second or subsequent rescreens in the Program will be screened within 27 months of their previous screen. This standard has been amended from women aged 50–69 years to women aged 50–67 years to take into consideration the varying policies of the State and Territory programs with respect to the age at which women are no longer sent an invitation to attend for rescreening. These rates of rescreening will be important in achieving a 70% overall participation rate across the target age group. First screen attenders are defined as those women who are attending for their first screen within the Program regardless of the Service.

However, given that maintaining a high rate of rescreening is of vital importance to the success of the Program, Services should seek to achieve the following targets: 85% of women participating in their first screen in the Program will be rescreened within 27 months and 90% of women attending for their second or subsequent rescreens in the Program will be rescreened within 27 months of their previous screen.

It is recognised that not all Services will meet the rescreening participation standards. If a Service is not achieving the rescreening standards, the reasons for lower participation should be analysed and targeted strategies for increasing participation implemented. The NQMC will consider accrediting Services who do not meet the rescreening standards based on: the reasons provided for not meeting the standard; demonstration of quality improvement processes and targeted strategies for increasing participation; and trend data to indicate that rescreening rates are increasing over time.

Performance objective 1.2:

The Service maximises the proportion of women aged 50–67 years who are rescreened every two years.

STRATEGIES

Services will implement a range of strategies to encourage women to participate in the screening program.

SYSTEMATIC APPROACH TO RECRUITMENT

Given the demographic, cultural and geographic diversity of the Australian population, it is likely that each Service will be faced with different challenges in recruiting women to participate in screening.

Therefore, each Service will develop a detailed recruitment plan, including budget, and review this on an annual basis. The plan will document the approach to encouraging women aged 50–69 years to participate in mammographic screening. It will cover all approaches to recruitment including: strategies to provide information to the community about mammographic screening; the use of invitation letters; and approaches to informing general practitioners and other health professionals. The plan will also outline strategies to encourage women to attend for second and subsequent screens. Women from the relevant population should be involved in the development of the recruitment plan.

The plan will analyse current participation rates among different groups and in different parts of the catchment. Depending upon the demographics of the catchment, it may be necessary, for example, to assess participation rates among women from culturally and linguistically diverse, indigenous and rural/remote and/or lower socioeconomic backgrounds.

The plan will identify barriers to screening and include special strategies to reach groups of women who have low participation rates. Specific strategies to reach these women, developed in consultation with relevant health providers and/or community groups, will be outlined in the recruitment plan.

The plan will also take into account the capacity of the Service to provide screening and assessment to meet the participation standards in terms of facilities, workforce and infrastructure.

Performance objective 1.3:

The Service demonstrates a systematic approach to maximising participation in screening.

STRATEGIES FOR ENCOURAGING ATTENDANCE

There is evidence that a range of strategies can be effective in encouraging women to participate in mammographic screening, including: mass media programs;¹⁹ community-based programs;²⁰ general practitioner programs;²¹ and personal invitation,²² especially with fixed appointments.²³

Most active recruitment strategies for inviting women into community breast cancer screening have been shown to be effective.²⁴ The Service will use relevant local strategies to encourage participation including the following:

Invitation letters

Invitation letters are a simple and potentially effective method of encouraging attendance at breast screening.²⁵ The Cochrane Collaboration recently conducted a review of the evidence about strategies for increasing the participation of women in community breast cancer screening and found invitation letters to be an effective strategy for encouraging attendance. For example, in the United Kingdom 71% of women attended for screening following receipt of an invitation letter.²⁶ These rates are lower in Australia, where two trials of the impact of letters generated from the electoral roll found that 33%²⁷ and 40%²³ of women attended for screening.²⁸

Community information programs

Community information programs can encourage women to attend for screening. Women who have high levels of knowledge of, and understanding about, mammographic screening are more likely to participate in the Program.^{28,29} Informed participation in population-based screening programs requires an explicit sharing of information about risks and benefits.³⁰ Information materials should be consistent with National Health and Medical Research Council (NHMRC) guidelines and BreastScreen Australia policy by providing accurate, consistent, honest and sensitive information to women^{31,32} so that they can make an informed choice about whether or not to participate in the Program. Australian women have high levels of knowledge about screening mammography.³³ However, continued community information programs will remain important in encouraging participation, particularly for women moving into the screening age group.

The States and Territories and national Program set the framework for the activities undertaken by the Services. In general, it is more cost-effective to produce community information at a state level. However, there may be instances where Services produce their own information materials. Any information produced at a Service level must be consistent with state and national policies and be approved by the State Coordination Unit. Any information produced should be consistent with the BreastScreen Australia National Information Statements.

The recruitment plan will outline the types of information resources needed by the Service to encourage participation. These resources might include printed information and videos and will be dependent upon the planned strategies.

The language and format will be appropriate to the intended audience in order to encourage participation in the Program. Women from the relevant population should be involved in the development of information resources, perhaps through consultation with local consumer groups.

Performance objective 1.3(a):

The Service implements strategies to disseminate accurate and consistent community information.

General practitioners and other relevant health professionals

General practitioners can be very effective in encouraging women to participate in mammographic screening. Australian studies have shown that between 68%²⁰ and 91%³⁴ of women will attend for screening following a recommendation from their general practitioner.

However, only about one-third of Australian women surveyed in 1996 reported that their general practitioner had suggested that they have a mammogram as part of the Program.³³

This highlights the need for continuing programs to inform general practitioners about the Program and to support them in encouraging women to participate. Strategies used to help inform general practitioners may include the delivery of relevant continuing medical education to general practitioners. These strategies should at least involve local Divisions of General Practice.

Depending upon the local context and the recruitment plan, strategies may also 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. There is evidence both from within Australia³⁵ and internationally^{36,37} that these service providers can be effective in encouraging women to participate in screening and may be particularly important in encouraging the participation of women who are difficult to reach through other strategies.

The recruitment plan will include approaches to 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. These programs will be coordinated with any national or state strategies.

All programs will be based on an understanding of the information needs of the different health and community service providers and developed in close consultation with their relevant professional associations.

Performance objective 1.3(b):

The Service includes strategies to inform general practitioners and other relevant health professionals about breast cancer screening.

Women from special groups

The Program seeks to provide equitable access to all eligible women in Australia. Services should aim to achieve the same participation rates for special groups as for the general population. Special groups include women from culturally and linguistically diverse, Aboriginal and Torres Strait Islander, rural/remote and lower socio-economic backgrounds. Relevant special groups will differ between Services.

There is evidence that women from some of these groups may be less likely to participate in mammographic screening in certain areas of Australia. Data from five States and Territories indicate that participation rates among Aboriginal and Torres Strait Islander women aged 50–69 years ranges from 14% to 85% in different Services.³⁸ Data from the same Services show that participation rates among women from culturally and linguistically diverse backgrounds range from 17% to 132%^D in different Services.³⁸ In some Services, these groups and others may require special strategies to encourage attendance.^{23,35}

Special groups should be identified within the recruitment plan, and their participation rates documented separately. The plan should identify general approaches to recruitment and where participation rates fall below those of the general population, special recruitment strategies should be identified and implemented. Women from different cultural and linguistic backgrounds may require different strategies.

It is recognised that not all Services will meet this standard for special groups. If a Service is not achieving a 70% participation rate among all of the special groups identified, the reasons for lower participation should be analysed and targeted strategies for increasing participation implemented. The NQMC will consider accrediting Services who do not meet the participation standard based on: the reasons provided for not meeting the standard; demonstration of quality improvement processes and targeted strategies for increasing participation; and trend data to indicate that participation rates in these groups are increasing over time.

Performance objective 1.3(c):
The Service includes strategies for women from special needs groups.

STRATEGIES FOR ENCOURAGING HIGH RATES OF RESCREENING

Strategies will be required to encourage women to return for second and subsequent screens. These strategies will be different from those used to encourage initial participation and are likely to rely more heavily on prompts than on information about the value of screening. The woman's experience of screening at her initial visit will also be a determinant of whether or not she returns for subsequent visits.

There is some evidence that invitation letters can be an effective strategy for encouraging women to participate in rescreening.^{39,40} This approach will be supplemented by other strategies described in the recruitment plan.

Follow-up strategies targeted at women who do not respond to invitation letters for rescreening should be implemented.^{41,42}

Performance objective 1.4:
The Service implements a planned approach to encouraging rescreening.

D Percentage greater than 100 results from the lack of updated population estimates for this group.

PARTICIPATION IN SCREENING OF WOMEN AT SUBSTANTIALLY INCREASED RISK OF DEVELOPING BREAST CANCER

Women may be classified as at increased risk of developing breast cancer for several reasons, including a significant family history or previously diagnosed atypical hyperplasia or lobular carcinoma in situ.

Further research is needed to assess whether or not there is benefit in more frequent screening among women at high risk. As yet the benefit of more frequent screening has not been demonstrated for any group. Therefore, Services should seek to minimise the numbers of women being rescreened more frequently than every two years. However, in the absence of data to either support or refute benefit, some States and Territories may judge that more frequent screening should be offered to some women at high risk. The standard has been set at not more than 10% of women to be screened annually—assuming that 1% of women have a significant family history,⁴³ 4% have a moderate family history⁴³ and 5% of women are considered to require early rescreen for other reasons such as a diagnosis of lobular carcinoma in situ. A tool for assessing whether a woman is at increased risk of developing breast cancer due to family history is provided in Appendix E. It is recommended that Services use this tool or an equivalent.

The reasons for offering women screening more frequently than every two years should be documented clearly in the Policy and Procedures Manual, and reflect national policy where it exists. It is recognised that there will be exceptions and that annual screening will be offered to some women. The national policy on screening some women more frequently than every two years will be reviewed.

Performance objective 1.5:

Annual screening is offered only to women at substantially increased risk of developing breast cancer.

PERFORMANCE INDICATORS

Performance Objective	Standard	Measure
1.1	1.1.1	<p>The percentage of women aged 50–69 years in the Service catchment area who are screened by BreastScreen Australia during the most recent 24-month period.</p> <p>Calculation: <i>See Data Dictionary</i></p>
	1.1.2	<p>Evidence of monitoring the proportion of women aged 40–49 years and 70 years and over screened in the most recent 12-month period for which data are available.</p>
1.2	1.2.1	<p>The percentage of women aged 50–67 years who are rescreened within 27 months of their first screen.</p> <p>Calculation: <i>See Data Dictionary</i></p>
	1.2.2	<p>The percentage of women aged 50–67 years who attend for subsequent rescreens within 27 months of their previous screening episode.</p> <p>Calculation: <i>See Data Dictionary</i></p>

PERFORMANCE INDICATORS

Performance Objective	Standard	Measure
1.3	<p>The Service demonstrates a systematic approach to maximising participation in screening, and implements strategies:</p> <p>(a) to disseminate accurate and consistent community information</p> <p>(b) to inform general practitioners and other relevant health professionals about breast cancer screening</p> <p>(c) to recruit women from special needs groups</p>	<p>Evidence of implementation of an appropriate recruitment plan which reflects local needs and relevant consultation and is reviewed annually.</p>
	<p>1.3.1</p> <p>The Service implements a recruitment plan which:</p> <ul style="list-style-type: none"> documents strategies for encouraging participation in screening and rescreening in the defined catchment; analyses participation data and identifies areas or groups where additional strategies are required; is developed in consultation with relevant consumer, general practitioner and other health professional groups; and is reviewed annually in consultation with the State Coordination Unit and relevant local stakeholder groups. 	
	<p>1.3.2</p> <p>The Service disseminates information resources which are:</p> <ul style="list-style-type: none"> developed by the State Coordination Unit; or approved by the State Coordination Unit and consistent with state and national policies and with the resource <i>Facts about Breast Cancer and Screening</i>. 	<p>Evidence of dissemination of appropriate information.</p>
	<p>1.3.3</p> <p>Invitation letters are sent to women aged 50–69 years who are resident in the Service catchment and who have not previously attended, inviting them to participate in the Program.</p>	<p>Evidence of a process for sending letters inviting women aged 50–69 years to take part in the Program.</p>
	<p>1.3.4</p> <p>The Service implements a protocol for following up women who do not respond to initial letters inviting them to take part in the Program.</p>	<p>Evidence of:</p> <ul style="list-style-type: none"> implementation of a protocol for follow up of women who do not respond to initial letters inviting them to take part in the Program strategies to review and evaluate the implementation of the protocol.
	<p>1.3.5</p> <p>The Service monitors participation of women from special groups and where rates are below 70%, implements specific strategies to encourage their participation in screening. Consideration of at least the following groups will be made: women from culturally and linguistically diverse, indigenous, rural/remote and lower socio-economic backgrounds.</p>	<p>Evidence of:</p> <ul style="list-style-type: none"> ongoing review of participation in screening of women in special groups and a breakdown of the participation for individual special groups. <p>Calculation: See Data Dictionary</p> <ul style="list-style-type: none"> Implementation of specific strategies to encourage participation of women in identified special groups.

PERFORMANCE INDICATORS

Performance Objective	Standard	Measure
1.4 The Service implements a planned approach to encourage rescreening.	1.4.1 Invitation letters are sent to each woman aged 50–69 years at the time they are due for rescreening.	Evidence of a process for sending invitation letters to all women aged 50–69 years at the time they are due for rescreening.
	1.4.2 The Service implements a protocol for following up women who do not respond to invitation letters for rescreening.	Evidence of: <ul style="list-style-type: none"> • implementation of a protocol to follow up women who do not respond to invitation letters for rescreening • strategies to review and evaluate the implementation of the protocol.
1.5 Annual screening is offered only to women at substantially increased risk of developing breast cancer.	1.5.1 The Service offers annual screening for ≤ 10% of women aged 50–69 years.	The percentage of women aged 50–69 years who are recommended for annual screening. Calculation: See Data Dictionary
	1.5.2 The Service monitors the proportion of women aged 40–49 years and 70 years and over who are offered annual screening.	Evidence of monitoring the proportion of women aged 40–49 years and 70 years and over who are offered annual screening.

2

TO MAXIMISE THE NUMBER OF SMALL CANCERS AND CANCERS DETECTED, WHILE MINIMISING THE NUMBER OF UNNECESSARY RECALLS AND INVESTIGATION

High quality screening and assessment is necessary to ensure that as many cancers, in particular small cancers, are found while at the same time minimising the number of unnecessary investigations.

INDICATORS

BreastScreen Australia aims to reduce deaths from breast cancer through the early detection of invasive breast cancers in women aged 50–69 years. Although mortality rates are the main long-term indicator of the impact of the Program, they are unsuitable for measuring quality improvement because there is a considerable time delay between screening and any measurable impact on deaths from breast cancer. In addition, it is very difficult to establish the proportion of any observed changes in mortality rates attributable to the screening program rather than to other factors such as changes in treatment.⁴⁴

MAXIMISING CANCER DETECTION

To provide more timely information about whether or not the Program is on track to reducing mortality from breast cancer, screening programs therefore use the following short-term measures:

- invasive cancer detection rate
- small invasive cancer detection rate
- ductal carcinoma in situ (DCIS) detection rate
- interval cancer rate.

In calculating standards for these measures, Australian data from all States and Territories was used as outlined in Appendix D.

It is recognised that there will be variations from these standards as a result of chance; this is particularly the case at the Service level where the numbers of women screened may sometimes be relatively small. The smaller the number of women contributing to the estimate, the greater the likelihood that the detection rate will differ from the standard, by chance alone.

In considering whether or not a Service has met the standard required for accreditation, the play of chance needs to be taken into account. To assist Services in determining whether their cancer detection rates are truly different from the standards, a series of funnel plots based on the Poisson distribution have been developed. Appendix C shows these funnel plots for each of the measures and explains how they can be used to judge whether a Service's cancer detection rates are within acceptable bounds of the standard.

However, a Service should not necessarily be satisfied if its performance lies within the confidence bounds or 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 should be improved and should indicate to the Service that further analysis of their approach is warranted.

In evaluating their performance in a quality improvement context, Services should consider clusters of standards or performance objectives together to provide an integrated view of the quality of care being provided. For example, if the cancer detection rates, small cancer detection rates and the interval cancer rates all **just** meet the standards, the Service should be concerned and carefully analyse its performance. If, on the other hand, the cancer detection rates and the small cancer detection rates are much higher than the standard and the interval cancer rate is also a little high, the Service might be more confident in thinking that the interval cancer rate is acceptable.

Likewise, Services should review their performance against the indicators in a quality improvement context on a regular basis, not just in preparation for the accreditation process. If an indicator is relatively low, say falling near the lower confidence bounds on the funnel plot, over a couple of years, then it is more likely that this value accurately reflects the performance of the Service rather than being accounted for by chance variation.

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

Invasive cancers

When BreastScreen Australia was established, the expected cancer detection rate included both invasive cancer and DCIS and in the absence of relevant Australian data, was calculated on the basis of the international randomised trials.

However, the NAS are based on the number of invasive breast cancers detected by BreastScreen Australia over recent years. The standards also exclude DCIS, in line with programs overseas and therefore reflect the underlying incidence of invasive breast cancer in

the Australian population. Data from State and Territory programs were used in the estimates, as outlined in Appendix D.

The cancer detection rates were examined to determine whether or not there was evidence of substantial variation among States and Territories in the proportion of age groups in the population that were screened; the proportions of women screened at first and subsequent screens; rates of detection of cancers; cancer detection rates by size (≤ 10 mm and ≤ 15 mm); and differences in the proportions of cancers detected at first and subsequent screens.

There was little substantial variation among State and Territory programs in cancer detection rates in women aged 50–69 years. The lack of variation meant that the national cancer detection rate could be used to develop the standard since it was similar to the expected cancer detection rate in each State and Territory.

However, there was substantial variation between States and Territories when rates included women in their 40s. In addition, the evidence of a benefit from mammographic screening in terms of reductions in mortality is strongest for women aged 50–69 years. Standards have therefore been set only for the target age group (women aged 50–69 years) in the BreastScreen Australia Program. For women 40–49 years and 70 years and older, Services will monitor the rates of invasive cancer, small invasive cancer and DCIS.

Age standardisation was considered but has not been incorporated as analysis of national data suggests that there will be little impact on rates of cancer detection among women aged 50–69 years. The use of Standardised Detection Ratios to control for the impact of cancer incidence on detection rates was not considered to be feasible at this time.

In 1997, the crude cancer detection rates for Australia for women aged 50–69 years were 51.1 per 10,000 at first screen and 36.6 per 10,000 at subsequent screens, as shown in Table 2.1.

Table 2.1 *Detection rates for invasive cancer in BreastScreen Australia in 1997: number detected per 10,000 screens*

	Women aged 50–69 years	Women aged 40+ years
First screens		
Invasive cancers per 10,000	51.1	48.9
Subsequent screens		
Invasive cancers per 10,000	36.6	36.8

The standards have therefore been set at ≥ 50 invasive cancers per 10,000 first screens and ≥ 35 per 10,000 subsequent screens. In considering whether their invasive cancer detection rates differ from the standard, Services should consult Appendix C.

As shown in Appendix F, the proposed standards are compatible with the standards and performance of the programs in Great Britain and Scotland, both of which examine invasive cancer rates separately from DCIS. At the first screen, the United Kingdom program detects 50 cancers per 10,000 women screened and the Scottish program detects 48. In subsequent screening rounds, the United Kingdom program detects 38 cancers per 10,000 women screened and the Scottish program detects 42. Appendix F also shows cancer detection rates observed in the Netherlands and Canada; however, these include both invasive breast cancer and DCIS.

Performance objective 2.1:
The Service maximises the detection of invasive cancer.

Small invasive cancers

Along with the invasive cancer detection rate, the small invasive cancer detection rate is a key indicator of the likely impact of the Program.

A breast screening 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;⁴⁵⁻⁴⁷ the smaller the size of the breast cancer diagnosis, the better the change of effective treatment. Women whose breast cancer is localised to the breast at diagnosis have a 5-year survival rate of 90%.⁴⁸

At the establishment of BreastScreen Australia, the standard for the detection of small invasive cancers was developed for cancers less than or equal to **10mm**. In the revised NARs, the standard refers to cancers less than or equal to **15mm**. There is little evidence of important biological or prognostic differences between cancers that are $\leq 10\text{mm}$ at diagnosis and those that are 11–15mm. There are two additional advantages of increasing the standard for small cancers to 15mm; a standard of less than or equal to 15mm will increase the number of cancers contributing to the estimate and therefore decrease the variability. It will also enable international comparisons to be made more readily.

The standards were developed based on data from all States and Territories as outlined in Appendix G. Table 2.2 shows that the crude annual cancer detection rates in 1997 for women aged 50–69 years for BreastScreen Australia were: $\leq 10\text{mm}$: 15.3 cancers per 10,000 first screens and 14.0 cancers per 10,000 subsequent screens; and $\leq 15\text{mm}$: 29.8 cancers per 10,000 first screens and 24.7 cancers per 10,000 subsequent screens.

The rates for first and subsequent screens for 15mm are very similar with confidence intervals almost touching: first round 29.8 (26.9–32.8) and subsequent screens 24.7 (23.0–26.4). The confidence intervals for first and subsequent screens overlap for every State and Territory; therefore one standard has been set for all rounds.

When cancers were totalled for the first and subsequent screens, the rate for cancers $\leq 15\text{mm}$ was calculated as 26.3 per 10,000 screens in women aged 50–69 years and 25.7 per 10,000 in women 40 years and older.

The standard has therefore been set at more than 25 cancers of 15mm or less per 10,000 women screened. As shown in Appendix F, this standard is comparable to the small cancer detection rate achieved in the Scottish program in 1996–97, which was 26 invasive cancers of less than 15mm per 10,000 women screened in the first round, and 24 in subsequent rounds.

Table 2.2 *Detection rates for small invasive cancers in BreastScreen Australia in 1997: number detected per 10,000 screens*

	Women aged 50–69 years	Women aged 40+ years
First screens		
Invasive cancers ≤ 15mm per 10,000	29.8	27.6
Invasive cancers ≤ 10mm per 10,000	15.3	14.4
Subsequent screens		
Invasive cancers ≤ 15mm per 10,000	24.7	24.8
Invasive cancers ≤ 10mm per 10,000	14.0	14.1

As with invasive cancer detection rates, there will be variation around this number at a Service level. In considering whether their small invasive cancer detection rates differ from the standard, Services should consult Appendix C.

Performance objective 2.2:
The Service maximises the detection of small invasive breast cancer.

Ductal carcinoma in situ

In the majority of cases, DCIS is asymptomatic and is usually detected as a change on a mammogram or as a chance finding on a breast biopsy for another condition. Prior to the establishment of mammographic screening programs, DCIS was infrequently diagnosed. DCIS is defined as in situ cancer **alone** with no invasive component as in the Australian Cancer Network *Pathology Reporting of Breast Cancer: a guide for pathologists, surgeons, radiologists*.⁴⁹ Women who develop DCIS while on early review are **not** included in the DCIS detection rates if it occurs in the period 6–12 months after the completion of the screening episode.

The natural history of DCIS is still not well understood. However, there is evidence that women with DCIS are at increased risk of subsequent development of invasive breast cancer.

Two small series have suggested that 20–30% of women with unrecognised DCIS will develop invasive breast cancer within 15 years.^{50,51} Other studies have shown that when DCIS is treated with breast conserving therapy alone rates of subsequent invasive breast cancer at eight years are between 7% and 13%.^{52,53} For this reason, current practice is to treat DCIS with the aim of reducing the woman's risk of developing invasive disease.

The risk of developing subsequent invasive disease is much greater if the DCIS is high grade.⁵⁴ In Australia, DCIS detected through the screening program is primarily of high or intermediate grade ranges. For example, BreastScreen Victoria reported in 1999 that 50% of DCIS was high grade and 27% intermediate grade. BreastScreen NSW reported that in 1998–1999, 53% of cancers where grade was known were high and 31% intermediate grade.

The early detection of high grade DCIS through the screening program, and its treatment, is very likely to prevent deaths from breast cancer.^{50,E} Therefore, no upper limit for the detection of DCIS has been set. However, the benefits of diagnosing and treating low grade DCIS are less clear. Existing evidence is not sufficient to prove that treatment is or is not of value in low grade DCIS, particularly in the longer term. Research is needed to monitor the grade of DCIS which is being detected over time.

Relatively little is known about the patterns of occurrence of DCIS in the population. The extent to which there may be true differences in rates between different catchment areas is unknown. Work to further delineate the different subtypes of DCIS and their definition in relation to other changes in the breast such as atypical hyperplasia is still underway. Further improvements in technology may result in increasing numbers of women being diagnosed with DCIS over time. There may therefore be a need to regularly review this standard as more data become available.

As described in Appendix D, standards have been based on data from the State and Territory programs. All programs have crude annual DCIS detection rates of between 11 and 15 per 10,000 at first screen and between 6 and 11 at subsequent screens for women aged 50–69 years. Rates for Australia are given in Table 2.3.

Table 2.3 indicates that, in 1997 among women aged 50–69 years, DCIS was diagnosed at a rate of 11.3 cases per 10,000 first screens, which is equivalent to 22% of all cancers found at first screens. Likewise, 6.4 cases of DCIS per 10,000 subsequent screens is equivalent to 17.5% of all cancers diagnosed at subsequent screens. This is comparable to the United Kingdom rates in 1997–98 which were 23.9% of all cancers found at first screening were DCIS and 20.9% of cancers at rescreening.¹⁰

E Personal communication: Dr Robin Wilson; Consultant Radiologist, Breast Screening Training Centre; National Health Service Breast Screening Programme, United Kingdom

Table 2.3 DCIS in BreastScreen Australia in 1997: number detected per 10,000 screens

	Women aged 50–69 years	Women aged 40+ years
First screens		
DCIS per 10,000	11.3	10.3
Subsequent screens		
DCIS per 10,000	6.4	6.1

The standard for the detection of DCIS is ≥ 12 per 10,000 at first screen and ≥ 7 per 10,000 at subsequent screens. As described for invasive cancer, there will be variation around this standard at a Service level. In considering whether their DCIS detection rates differ from the standard, Services should consult Appendix C.

The DCIS detection rate should not be viewed in isolation but rather should be interpreted in conjunction with other indicators. Detection of DCIS must not be disproportionately high at the expense of the invasive cancer detection and small invasive cancer detection rates for a particular Service.

Performance objective 2.3:
The Service maximises the detection of DCIS.

Interval cancers

Interval cancer rates are a key indicator of the likely success of a screening program in reducing mortality from breast cancer. Women whose cancers are detected as interval cancers have poorer outcomes compared to women whose cancers are found at screening.^{55,56} If too many cancers are missed at screening and are only found between screening rounds, the opportunity to prevent death is compromised. For these reasons, interval cancer rates should be monitored by the Program at the State and Territory and national levels.

Women with interval cancers have similar survival to women who have not participated in screening.⁵⁶⁻⁵⁸

The United Kingdom standards were based on the results of the Swedish Two County Study and were set by calculating expected rates after adjustment for the underlying incidence in England and Wales. The rates were revised after the United Kingdom National Health Service Breast Screen Programme published much higher than expected interval cancer rates.⁵⁹

In BreastScreen Australia, an interval cancer is ‘an invasive breast cancer diagnosed in the interval following a negative screening episode and before the next scheduled screening examination’. This includes women diagnosed with cancer at early review or in the interval between screening and early review where the recommendation for early review is six months

or more from the screening date, and women who present for early rescreening who have a symptom in the breast in which the cancer is subsequently diagnosed. This definition excludes women with DCIS only or with a personal history of breast cancer.⁶⁰ Cancers found in women who are on a 12-month screening interval are included as interval cancers if it occurs in the first 12 months after their last screen. Cancers found in women on early review are included as interval cancers, if early review is carried out at six months or more from the date of screening. All interval cancers must be investigated. Within the context of quality improvement, the review process should be used to minimise the interval cancer rate in the future. All interval cancers should be identified by matching Service records with the cancer registry to determine whether any interval cancers have occurred.

All interval cancers should then be carefully investigated by the Service to determine whether there is a need to change protocols or improve skills. Investigation should include consideration of whether the cancer was visible on the screening mammogram. It might also include review of diagnostic mammograms if they are available. Review of interval cancers is an important part of any multidisciplinary education and quality improvement program.

In addition to the process of exploring all interval cancers, Services should consider their interval cancer rate. The calculation of this rate may occur at the State and Territory or Service level but should be available on a Service basis at the time of accreditation.

The interval cancer rate will increase as time since screening increases.⁶⁰ The upper threshold of acceptability was set at 6.5 per 10,000 screens up to 12 months after completion of a negative screening episode and was based on the national interval cancer rate which has been reported for BreastScreen Australia in 1996 by the Australian Institute of Health and Welfare (AIHW).¹⁴ However, interval cancer rates were not reported for State and Territory programs in 1996 for the period 12–24 months following a negative screen.¹⁴ Interval cancer rate data provided by the States and Territories have subsequently been reviewed by the AIHW as the NQMC considered that the original data used to derive the rate of < 6.5 was insufficient and hence the performance measure was set too low for the Australian context and needed to be reviewed. The AIHW reviewed five years of national data and results showed an overall Australian average interval cancer rate of 7.5 per 10,000 women. This change was agreed to by the NQMC in November 2004 and endorsed by ASAC in November 2004.

There are not sufficient data at this time on which to base a standard for interval cancers for either 0–24 or between 12 and less than 24 months following a negative screen. Services will collect data for the two consecutive 12-month periods following screening. The data for the first 12 months following a negative screen will be reviewed in relation to the standard set at 7.5 per 10,000 screens.

However, the small number of interval cancers occurring at the Service level means that there will be substantial variation around this rate. This makes it difficult to determine whether an interval cancer rate which is very different from the standard is attributable to variation resulting from small numbers or to a performance issue in the Service.

It is therefore unlikely that the interval cancer rate will be useful as a standard at the Service level for less than 20,000 screens. For larger Services with greater than 20,000 screens per year, the rate of interval cancers which occurred in women who were screened in a 12-month

period and followed for 12 months is the performance measure. For smaller Services, however, data will be collected over consecutive 12-month periods to increase the number of women screened for the calculation of the rate.

In considering whether their interval cancer rates differ from the standard, Services should consult Appendix C and aggregate their data, use funnel plots and report confidence intervals.

The interval cancer rate should not be viewed in isolation but rather should be interpreted in conjunction with other indicators. For example, a high interval cancer rate and low invasive cancer detection and small invasive cancer detection rates may indicate the need for further investigation by the Service.

If interval cancer rates are higher than the standard, the Service should implement more extensive review processes.

Performance objective 2.4:

The Service minimises the number of interval cancers and ensures that all interval cancers are reviewed and investigated.

Interval cases of DCIS

It will also be useful for Services to investigate interval cases of DCIS. All interval cases of DCIS should be identified by matching Service records with the cancer registry to determine whether any cases of DCIS have occurred. All interval cases of DCIS should then be carefully investigated to determine whether there is a need to change protocols or improve skills. Investigation should include consideration of whether the DCIS was visible on the screening mammogram. It might also include diagnostic mammograms if they are available.

Performance objective 2.5:

The Service ensures that all interval cases of DCIS are reviewed and investigated.

MINIMISING UNNECESSARY INVESTIGATIONS

The detection of breast cancer within the Program must be achieved with minimal physical, psychological and economic harms associated with unnecessary recalls and investigations in asymptomatic women. As well as achieving high cancer detection rates, an effective screening program must limit unnecessary investigations.

Indicators of the extent to which the screening and assessment process minimises unnecessary investigations include:

- recall for assessment rate
- pre-operative diagnosis rate
- benign open biopsy rate.

Recall for assessment

In achieving a high cancer detection rate, it is not appropriate for Services to recall a large proportion of women to assessment. The Service must achieve an appropriate balance between cancer detection and recall for assessment.

Table 2.4 shows the actual recall to assessment rates in Australia for first and subsequent screens, based on State and Territory data from 1997. In 1997, most States and Territories were meeting the 1994 NAR of < 10% women recalled for first screens, and all States and Territories were meeting the requirement of < 5% women recalled for subsequent screens.

Table 2.4 also compares the requirements for the percentage of women screened who were recalled to assessment in Australia with those in programs overseas. In Europe it is acceptable for the recall rate for first screen to be less than 7%, although the target is less than 5%.⁶¹ For subsequent screens, it is considered acceptable for the recall rate to be less than 5%, with the target set at less than 3%.⁶¹ In the United Kingdom, the minimum standards are less than 10% (first screen) and less than 7% (subsequent screens), while the targets are less than 7% and 5% respectively.⁶²

Table 2.4 *Recall for assessment for first and subsequent screens in Australia and internationally*

	First screen recall rates as a percentage of women screened	Subsequent screen recall rates as a percentage of women screened
Australia		
Minimum (1994 requirements)	< 10	< 5
Actual (1997)	6.5	3.5
Europe (1996 requirements)		
Minimum	< 7	< 5
Target	< 5	< 3
United Kingdom (1997 requirements)		
Minimum	< 10	< 7
Target	< 7	< 5

In 1997, States and Territories were meeting the United Kingdom minimum requirements for first and subsequent screen recall rates. States and Territories were also meeting the United Kingdom target for subsequent screen recall rates. However, not all States and Territories could meet the United Kingdom target for first screen recall rates.

The recall to assessment standard for first screens has been set at < 10% of women recalled to assessment because of a screen detected abnormality or other reasons which is equivalent to the minimum standard in the United Kingdom and achievable by most Services. The standard for subsequent screens is < 5% of women recalled to assessment because of a screen detected abnormality or other reasons which is equivalent to the European minimum and the target for the United Kingdom. This is achievable by most Services.

Services will be able to report separately the proportion of women recalled to assessment for (a) screen-detected abnormalities and (b) women who present with breast symptoms at screening.

If a Service is not achieving the recall to assessment standard, the reasons should be analysed and targeted strategies for improving implemented. The NQMC will consider accrediting Services who do not meet the recall to assessment standard based on: the reasons provided for not meeting the recall to assessment standard; demonstration of quality improvement processes and targeted strategies for improving; and trend data to indicate that the recall to assessment standard is increasing over time.

Performance objective 2.6:
The Service minimises recalls for assessment.

Preoperative diagnosis

The increasing experience and extensive use of fine needle aspiration (FNA) cytology and core biopsy in the assessment of screen-detected abnormalities has resulted in an increasing preoperative diagnosis of cancer and a decrease in the total number of cases going to diagnostic open biopsy.⁶³ The ability to provide an accurate diagnosis in the majority of cases without the need for diagnostic open biopsy reduces the number of cases which require further, more invasive and often unnecessary investigations. Although it is recognised that some cases will require evaluation by open biopsy, the preoperative diagnosis rate is an indicator of the extent to which Services are effective in minimising investigations.

Most surgeons would be prepared to proceed with definitive surgery based on a preoperative diagnosis of cancer, defined as a malignant result on FNA or core biopsy (includes DCIS and invasive cancer) which is consistent with suspicious or malignant imaging findings. Cancers diagnosed at surgery as a result of a suspicious FNA cytology or core biopsy result are not considered as a preoperative diagnosis. The preoperative diagnosis of cancer therefore has two main advantages. First, it allows for preoperative discussion with the woman about her treatment options. Second, in the vast majority of cases, it enables a one-stage surgical procedure to be planned and performed. The United Kingdom National Health Service Breast Screening Programme has a minimum standard of > 70% preoperative diagnosis of cancer as

an accreditation requirement. The United Kingdom National Health Service Breast Screening Programme's data show a steady increase in preoperative diagnosis over recent years; 62% of cancers were diagnosed preoperatively in 1996–97; 71% in 1997–98 and 80% in 1998–99.⁹ The 1999–2000 United Kingdom National Health Service Breast Screening Programme's data indicate that over 90% of Programmes were meeting the 70% minimum requirement.^F

Services should aim to provide a preoperative diagnosis of cancer in the majority of cases whilst ensuring a balanced consideration of the diagnostic options in each individual assessment case. The median percentage of women whose cancers were diagnosed without the need for diagnostic open biopsy for all States and Territories using 1999–2000 Service level data was 75.4%. Some individual Services achieved a preoperative diagnosis rate for cancer of > 90%. Based on these data and on the evidence of continuing improvement in the preoperative diagnosis rate with the increasing use of core biopsy both in Australia and overseas, the standard for the proportion of cancers diagnosed without the need for diagnostic open biopsy has been set at $\geq 75\%$. This is an area of changing practice and Service data will help inform the setting of this standard in the future.

If a Service is not achieving the preoperative diagnosis standard, the reasons should be analysed and targeted strategies for improving implemented. The NQMC will consider accrediting Services who do not meet the preoperative diagnosis standard based on: the reasons provided for not meeting the preoperative diagnosis standard; demonstration of quality improvement processes and targeted strategies for improving; and trend data to indicate that the preoperative diagnosis standard is increasing over time.

Performance objective 2.7:
***The Service maximises the preoperative
diagnosis of cancer.***

Diagnostic open biopsy

Services must endeavour to minimise the unnecessary investigations for women recalled for assessment and particularly the morbidity associated with a surgical procedure. The number of women who undergo diagnostic open biopsy for a benign lesion as part of the BreastScreen Australia assessment process should be minimised.

A benign diagnostic open biopsy is defined as an open biopsy recommended by the Service for diagnostic purposes and where the histopathology was not of invasive cancer or DCIS; for example, a benign diagnostic open biopsy in a diagnosis of atypical ductal hyperplasia, radial scar or LCIS.

^F Personal communication: Dr Robin Wilson; Consultant Radiologist, Breast Screening Training Centre; National Health Service Breast Screening Programme, United Kingdom.

The increasing use of FNA and core biopsy should result in a smaller proportion of women requiring diagnostic open biopsy to provide a diagnosis. With the introduction of more accurate and minimally invasive diagnostic procedures, fewer cases overall will go to diagnostic open biopsy and fewer cases will require a diagnostic open biopsy to confirm malignancy. However, the assessment of difficult lesions requires a balanced approach which ensures women do not undergo a number of unnecessary percutaneous biopsies. Therefore, while the total number of cases going to diagnostic open biopsy is decreasing there will always be some lesions whose radiology or pathology findings will require open biopsy for further evaluation. Services will minimise the proportion of women who undergo a diagnostic open biopsy for a benign lesion while ensuring that the detection of cancer is not compromised.

The rate of benign open biopsy per number of women **screened** provides an indication of the effectiveness of the Program in minimising unnecessary diagnostic open biopsies; the rate per women **assessed** provides an indication of the ability of the assessment process to confirm a benign diagnosis without the requirement for open biopsy. Standards have therefore been set for benign diagnostic open biopsy rates for both the number of women screened and the number of women assessed.

The United Kingdom National Health Service Breast Screening Programme standard for the benign diagnostic open biopsy rate for the first screening round is < 2.7 per 1,000 women screened and < 2.0 per 1,000 women screened in second and subsequent rounds.⁶² In Australia, Service level data for 1999–2000 for the percentage of women screened and assessed who had a benign result following a diagnostic open biopsy recommended at assessment in the BreastScreen Australia Program showed considerable variation between Services.⁶⁴

The benign diagnostic open biopsy rates for women screened and for women assessed were very different between first and subsequent screens.⁶⁴ The standards for women screened and women assessed have therefore been set separately for first and subsequent screens.

Less than or equal to 0.34% of women attending for their first **screen** will undergo a benign diagnostic open biopsy and less than or equal to 0.16% of women attending for subsequent screens will undergo a benign diagnostic open biopsy. These rates are comparable to those of the United Kingdom National Health Service Breast Screening Programme. The 1999–2000 data indicate that these rates for benign diagnostic open biopsy are achievable by 71% of Services in Australia.

Less than or equal to 4.0% of women undergoing **assessment** following their first screen will undergo a benign diagnostic open biopsy and less than or equal to 3.2% of women attending for assessment following their second or subsequent screen will undergo a benign diagnostic open biopsy. The 1999–2000 data indicate that these rates for benign diagnostic open biopsy are achievable by 65% of Services in Australia.

Performance objective 2.8:
The Service minimises the proportion of benign open biopsies for diagnostic purposes.

STRATEGIES

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

Therefore, Services must implement strategies to ensure high quality breast imaging, screen reading and reporting, effective assessment, quality pathology and the follow-up and continuity of care of women diagnosed with breast cancer. These strategies will ensure that cancer detection, particularly small cancer detection is maximised, while minimising the harm caused by unnecessary recalls or investigations.

BREAST IMAGING

It is essential that the breast image is of sufficient technical quality to maximise the effectiveness of mammography as a screening tool for cancer.

The need for high technical quality should be balanced against the need to minimise both the impact on the woman and the cost to the screening program. Mammographic screening should not result in unnecessary discomfort.

In ensuring the quality of breast imaging, several issues are of importance:

Safety and quality control

X-ray systems, premises and users must meet relevant radiation protection regulatory requirements in the appropriate jurisdiction.

Equipment shall meet minimum performance standards to offer maximum benefit to the client. Requirements for imaging system performance are specified in Appendices H and I. The equipment performance shall be confirmed at acceptance, annually and following major maintenance by suitably qualified and experienced persons. For mammography systems this testing shall be performed by a medical physicist (or equivalent) as specified in Appendix J.

Appropriate quality control procedures, as outlined in Appendices K and H, are required to ensure that imaging systems achieve and maintain high quality performance. Quality control test equipment must be appropriate for the intended application and meet the standards as outlined in Appendix L. In addition, regular maintenance of imaging equipment is required to ensure that equipment is safe and effective.

Each Service should 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.

Performance objective 2.9:
*The Service ensures high quality of
breast imaging systems.*

Radiographer skills

High quality mammography requires highly developed skills and knowledge in radiography. The training and supervision standards for radiographers working in the Program are outlined in Appendix J.

A widely used measure of radiographer image quality is the PGMI evaluation outlined in Appendix M. Other systems may be used if they have the endorsement of the Australian Institute of Radiography. An evaluation system allows those radiographers working part-time or in primarily administrative roles to meet the standards. Although no formal system is available for evaluating images taken by radiographers employed in assessment only, evaluation of basic views can be undertaken using the stated criteria in the PGMI evaluation. Radiographers employed in assessment only should attend screening sessions regularly to ensure they have an up-to-date knowledge of screening mammography. The PGMI evaluation should be conducted by an appropriately trained radiographer (as outlined in Appendix J), either within or external to the Service.

There should be a designated radiographer who implements quality assurance measures and is responsible for all aspects of imaging within the Service. A description of the roles and responsibilities of the designated radiographer is included in Appendix N.

Quality imaging

Two view mammography is used in BreastScreen Australia, based on research demonstrating that this is the most effective method in the detection of breast cancer in a population-based screening program.⁶⁵⁻⁶⁸

The technical requirements for mammography in women with internal breast prostheses are different. BreastScreen Australia Services will implement a protocol for examination of women with internal breast prostheses to allow adequate visualisation of the breast tissue. This will include the number and type of views, such as push back or pinch views.

Repeat mammograms increase discomfort for the client, radiation dose and screening costs. Therefore the rate of repeated mammograms is to some extent an indicator of imaging quality. As agreed by the Australian Institute of Radiography Mammography Advisory Panel, less than 3% of mammograms will be repeats. However, Services should aim to ensure that repeat rates are as low as possible and the American College of Radiology recommends that the overall repeat rate ideally should be approximately 2% or less.⁶⁹

Performance objective 2.10:
The Service ensures high quality imaging.

Adequate documentation

The images must be clearly identified according to relevant radiation licensing regulations. To meet clinical needs and medico-legal standards, there must be sufficient information to identify the client and enable correct interpretation. This standard applies to both mammography and ultrasound images/hardcopies. All identifying information must be transferred onto copied images.

For the purposes of evaluating the quality of the screening mammogram and identifying equipment faults, the radiographer, X-ray machine and cassette/screen number where appropriate should be recorded (including rejected images). This information may appear on the image or be available in other documentation.

Performance objective 2.11:
*The Service ensures the adequate identification
of all images.*

HIGH QUALITY SCREEN READING AND REPORTING

A mammographic screening program must be underpinned by high quality screen reading, if the greatest possible number of cancers and small cancers are to be detected. In each Service, 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 O.

In ensuring the quality of screen reads, there are several issues to be considered:

Number of screen readers

Double reading, where the screening images are independently read by two readers, is practised in Australia and Sweden. Even among experienced radiologists, there can be a wide range of accuracy in reporting of mammograms.^{70,71} Double reading results in a higher cancer detection rate⁷⁰⁻⁷⁴ and is therefore the policy of BreastScreen Australia. To be of most value, double reading should consist of two truly independent reads; the readers should be in a 'blind' relationship such that they have no knowledge of the other reader's results.

Qualifications of screen readers

The basic requirements for mammographic screen reading are knowledge of mammography and an understanding of the requirements of a population health screening program. Radiologists are specifically trained to interpret images (see Appendix J) and all international screening programs base their reading upon medical officers with radiological qualifications.

Skill in interpreting mammograms alone is not sufficient to be a screen reader with BreastScreen. Radiologists are generally trained in diagnostic breast imaging, which involves

the use of mammography and ultrasound in the diagnosis of the causes of breast symptoms in women of all ages. However, BreastScreen Australia requires the interpretation of mammograms principally from asymptomatic women aged 40 years or older. This necessitates an added degree of skill and training on the part of the readers. Because of their long training in mammography, radiologists adapt most easily to the additional demands of breast cancer screening. However with special training and experience, non-radiologists can perform to the standards expected of all readers by BreastScreen Australia.

Australia should endeavour to maintain a screen reading practice consistent with internationally accepted best practice. BreastScreen Australia should maintain some degree of flexibility to ensure that, if the need arises and screening numbers outstrip the current available workforce of radiologists, specifically trained non-radiologist readers could be employed to read alongside the radiologists (see Appendix J). It is, however, inappropriate that two non-radiology readers read together. For both medical and legal acceptance of the BreastScreen Australia program, it is necessary that at least one reader be a radiologist.

Quality of screen reads

The early detection of breast cancer using mammographic screening requires the perception and accurate interpretation of mammographic abnormalities by screen readers. Two approaches have been adopted to ensure high quality screen reading and these are reflected in the standards for BreastScreen Australia.^{70,75}

First, a minimum number of reads over a given period has been used to promote competency. Screen reading experience increases the detection of cancers.⁷⁶ A significant difference in cancer detection ratios has been reported between those who read less than 2,000 and those who read 2,000 or more screening mammograms per year.⁷⁵ However, the minimum number of mammograms that a reader must examine to be regarded as competent varies between different countries. The United States Food and Drug Authority requires a reader to examine 960 mammographic examinations per 24-month period in order to be accredited to read mammograms, either screening or diagnostic.⁷⁷ The United Kingdom National Health Service Breast Screening Programme requires each radiologist to read a minimum of 5,000 screening and/or symptomatic cases per year.⁶²

In Australia, the 1994 NAR was that each screen reader should examine 2,000 screening cases within the Program per year. While the major metropolitan Services have sufficient throughput to reach the United Kingdom standard of 5,000 screening cases per year, it may not be possible for a radiologist to read this number of cases in the smaller States and Territories or in rural or regional areas and some metropolitan Services of the larger States. Most Services in Australia have found that radiologists can feasibly read 2,000 screening cases within the Program per year. These cases can be from either digital or film modalities.

Second, quality of screen reading can also be assessed against agreed standards for mammographic screening. For example, the United Kingdom National Health Service Breast Screening Programme requires each reader to perform adequately in examining a set of quality assurance images. This approach is still being evaluated and has not yet been adopted by other programs such as those in the Netherlands and Sweden.

In Australia, the performance of individual BreastScreen Australia screen readers can be compared with agreed benchmarks in relation to standards for cancer detection and small cancer detection as part of a quality improvement program. Services will provide audit and feedback to assist readers to evaluate their individual performance and identify any areas where intervention by the Service may be required.

Each reader will be advised of the individual number of invasive cancers and the number of small invasive cancers in both first and subsequent screens which they detected in both the previous 12 months and cumulated over the previous 24 months. In interpreting whether a reader's cancer detection rates truly differ from the standard or whether this is due to chance alone, Services should refer to the funnel plots in Appendix P; see Appendix C for interpretation of the funnel plots. Where the detection rates for individual readers fall below the 95% confidence bounds based on the numbers of screens read, the Service will implement strategies to address individual reader performance. Services should develop protocols for implementing interventions around performance management where necessary, such as a period of supervised reading by experienced radiologist readers and the development of test image sets for individual radiologist use.

In addition, feedback will be provided to readers at least every three months on any cases where they did not recall a subsequently diagnosed cancer. For example, if one reader of a team perceives an abnormality on mammography which is later found to be a cancer, which is not seen by the other reader, or if a woman is diagnosed with an invasive cancer in the interval following a negative screening episode and before the next scheduled screening examination (an interval cancer) the reader will be informed. Individual readers will be provided with the opportunity to review all relevant images, where possible. An appropriate figure for this measure has not been established. Studies evaluating the benefit of double reading have proposed alternative measures but there have been methodological flaws and small sample sizes.⁷⁸ Services should collect this data to inform the future development of an appropriate standard.

Given the small numbers, it is inappropriate to compare interval cancer rates of individual readers with the standards. Feedback about such cases provides the opportunity for ongoing review and may reveal reading trends which could benefit from early recognition and intervention. The minimal three-month period for providing feedback may therefore be useful in highlighting issues for continuing quality improvement or identifying poor individual reader performance which may require investigation.

Each Service has a designated radiologist who oversees all aspects of quality assurance in radiology. The roles and responsibilities of this position are described in Appendix O.

The Service should ensure that any data which can be identifiable to any individual reader are confidential to the Director, the individual reader, the Service designated radiologist and the data manager.

Performance objective 2.12:
The Service ensures high quality screen reading.

Quality of reporting

Each screen reading should result in a clear decision about whether the woman requires further assessment to determine the presence of a breast cancer. The purpose of screening mammography is not to determine the cause of all lesions identified on imaging, but either to exclude the likelihood of breast cancer or confirm its presence.

The reports of the independent screen readers are combined into a single recommendation which is provided in a non-narrative form. The report does not describe the appearances of a normal/benign mammographic image but only those features that are suspicious of malignancy.

A recommendation for routine rescreening or recall is required in the report and any subsequent client/doctor correspondence.

Double reading will mean that on occasion there will be different results from different screen readers. No evidence about the relative impact of different approaches to reconciling discordant reads could be located. Services must have in place a protocol for reconciling discordant reads that results in **a single** recommendation about whether or not further assessment for the presence of breast cancer is required.

Larger Services which utilise multiple readers find the most efficient method of handling discordant reads is to use a third reader to decide between the two screen reading decisions.⁷⁹ The third reader should be a radiologist with a high level of expertise in screen reading.

In smaller Services, where there are fewer readers with less experience, it may be more appropriate that discordant reads are dealt with by 'consensus reading', where the screen readers consider the mammogram together through discussion to reach agreement.

Performance objective 2.13:
The Service ensures high quality reporting of breast images.

Symptomatic women

The policy of BreastScreen Australia is to screen women on the basis of age alone. Since population based mammographic screening is directed at women without symptoms, women with symptoms are actively discouraged from attending the BreastScreen Australia Program.

However, due a range of factors, between 2.3% and 5.3%⁸⁰ of women presenting to the Program have breast symptoms. In response to this finding, the National Advisory Committee to BreastScreen Australia, through its Policy Review Working Group, identified the need to review the national policy in relation to symptomatic women. The review was conducted from January–June 2001.

The objectives of the review were:

- to provide a framework for updating the BreastScreen Australia Program’s current policy on symptomatic women, to best meet the needs of women accessing the Program;
- to consult with a range of stakeholders to scope current practice, issues and considerations; and
- to develop a national approach to symptomatic women.

The results of the review process revealed that the majority of stakeholders consulted believed that it was important that the Program develop a policy that allowed for the flexibility to meet the wide diversity of needs of women accessing the Program. This resulted in the development of a National Policy Framework^G in relation to symptomatic women. This Framework sets the broad parameters within which all BreastScreen services are required to respond to symptomatic women. It does not prescribe local policy, practices or protocols, which are the jurisdiction of the State and Territory service providers, but rather, provides an overall and consistent framework within which these can be developed.

The Framework comprises a set of National Policy Principles and a set of National Policy Options. The development of these have been guided by the BreastScreen Australia Policy Review Working Group and consultation with State and Territory Program Managers, service providers and consumers to best reflect the needs of women. The Principles are a critical element of the policy framework and underpin the national policy options.

The Service should ensure the implementation of a protocol for the management of women who present with symptoms, based on clear rationales and within the parameters of the National Policy Framework for the Management of Women with Symptoms by BreastScreen Australia Services.

Several issues are relevant in relation to women who present with symptoms at screening.

- Women aged over 50 years with breast symptoms are more likely to be diagnosed with breast cancer than those without symptoms. A detailed review of research about breast symptoms by Irwig and Macaskill concluded that the probability of cancer in women over 50 years who report a breast lump or a nipple discharge is 10–50%.⁸¹
- These data are confirmed by experience within the breast screening program in Australia. BreastScreen Victoria analysed data from 1996 and 1997 from women with a suspicious symptom (defined as a breast lump present less than 12 months and not investigated by a doctor or a current blood stained or watery nipple discharge) and found that breast cancer was diagnosed in 13.7% and 11.4% respectively of these women (irrespective of mammographic findings).^H

G Endorsed by the National Advisory Committee to BreastScreen Australia in 2002.

H Personal communication: Ms Cathy Krishnan, Data Manager, BreastScreen Victoria.

- The Irwig and Macaskill review demonstrated that mammograms may fail to detect up to 10% of cancers in symptomatic women. This is illustrated by data from a United Kingdom National Health Service Breast Screening Programme study conducted between 1989 and 1995 in Newcastle, United Kingdom, which reported a cancer detection rate of 8 from 448 or 17.8 per 1,000 in symptomatic women with normal mammograms.⁸²

Services should report invasive cancer, small invasive cancer, DCIS and interval cancer rates separately for screen-detected and symptomatic women once there is an agreed definition of breast symptoms.

Performance objective 2.14:

The Service implements a protocol for the management of women who report breast symptoms consistent with the National Policy Framework for the Management of Women with Symptoms.

HIGH QUALITY ASSESSMENT

High quality assessment is essential if the BreastScreen Australia Program is to detect cancers while minimising the number of unnecessary investigations. Several strategies will be important:

Comprehensive approach to assessment

The Service will implement protocols for the evaluation of all women recalled to assessment; the protocols will incorporate clinical examination and medical history, imaging (mammography and/or ultrasound) and percutaneous biopsy (FNA cytology or core biopsy) as required. Each woman does not necessarily require all of the tests.

The effective use of imaging tests (mammography with or without ultrasound) is a vital aspect of breast assessment. In some cases, appropriate imaging eliminates the need to proceed with further tests. Targeted imaging and the use of additional special mammographic views may add to the radiological information available from the standard two view mammography in the evaluation of screen-detected lesions. The use of ultrasound in evaluating breast abnormalities requires advanced skills and knowledge. All ultrasound examinations are to be performed by suitability qualified and experienced radiologists or by a sonographer with a radiologist available on site during the conduct of examinations. Reporting of imaging results should be standardised within each Service. For examples of imaging reporting see *Breast Imaging—A guide for practice*⁸³ and *Synoptic breast imaging report*⁸⁴ available from the National Breast and Ovarian Cancer Centre.

It is important that the results of each of the tests are collated, reviewed and interpreted in light of all other test results.

Based on this approach, the Service will implement an assessment protocol which ensures that the majority of abnormalities are diagnosed without the need for open biopsy 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 with 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 open biopsy is eliminated, the woman can be reassured and appropriate further management options discussed.

Performance objective 2.15:
The Service implements a comprehensive approach to the assessment of breast abnormalities.

Training and relevant staff and facilities

The Service will have a multidisciplinary team with all of the relevant skills and appropriate training as outlined in Appendix J. This must include expertise in the following: breast examination; reading and mammographic work-up of images; ultrasound performance and interpretation; FNA and core biopsy; pathology and supportive care. It is recognised that different Services will provide this expertise in different ways. For example, clinical examination may be undertaken in some Services by a surgeon and in others by another member of the assessment team.

The Service must ensure that clinicians have access to all relevant work-up and diagnostic equipment at the assessment visit. Assessment services should have the equipment available to perform mammographic work-up, breast ultrasound, FNA cytology (including ultrasound and stereotactic guided biopsy) and core biopsy.

From time to time, new modalities to assess screen-detected abnormalities will become available. Training and quality improvement practices will be developed for new technologies as they are introduced.

Performance objective 2.16:
The Service ensures that all members of the multidisciplinary team involved in the assessment of women are appropriately trained and qualified and have access to all relevant diagnostic equipment.

Multidisciplinary approach to assessment

The diagnosis of breast cancer relies upon a number of specialist skills. The Service should ensure the availability of an appropriately skilled multidisciplinary team for the evaluation of all women recalled for assessment. In a multidisciplinary approach, all relevant members of the team contribute their different expertise to ensure that all approaches to management have been appropriately considered. The multidisciplinary team will have expertise in: breast examination; mammographic screen reading and work-up; ultrasound performance and

interpretation; biopsy (FNA and core); pathology technique and interpretation and supportive care. A multidisciplinary team with expertise in all these areas will be available at each assessment clinic.

Where a screen detected abnormality persists after imaging work-up or where there is a breast symptom at assessment, the radiologist, the surgeon, and other examining clinician, will discuss, evaluate and correlate test results and decide on further investigations and management as required. Where the examining clinician is a qualified member of staff other than a surgeon, they will discuss and evaluate all assessment findings with the surgeon and radiologist. Counselling will be available to ensure the provision of psychosocial care to women as appropriate.

Performance objective 2.17:
The Service demonstrates a multidisciplinary approach to assessment.

Fine needle aspiration and core biopsy

The Service is responsible for all work-up and diagnostic procedures provided as part of the Program up to and including cytological and/or histological diagnosis of breast cancer. The approach to taking FNA and core biopsy samples should be consistent with the guide *Breast fine needle aspiration cytology and core biopsy: a guide for practice*.⁸⁵

FNA and core biopsy samples should provide sufficient material for pathological assessment. Adequacy/sufficiency rates of FNA cytology and core biopsy are, in part, a measure of operator competence and the quality of the selection of the lesion for sampling.⁶² 'Inadequate' indicates either poor preparation or scanty or acellular specimen and may result from poor cellularity, preparative artefacts or excessive blood.⁸⁶ There is very little Australian data about adequacy rates in FNA cytology and core biopsy. The United Kingdom National Health Service Breast Screening Programme requires that less than 25% of FNA sampling procedures performed at assessment are inadequate or insufficient for a diagnosis (NHS, 2001). However for core biopsy, it is not appropriate to provide a standard for inadequacy rates as there is no definition which applies here. Instead, the 'miss rate' for core biopsy has been adopted as a better measure of the effective use of this technique (see Performance objective 2.19).

Performance objective 2.18:
The Service demonstrates the effective use of FNA cytology and core biopsy in assessment.

Pathology

High quality pathology is vital for the accurate diagnosis of in situ and invasive breast cancer.

Breast cancer screening offers several challenges for pathologists. For example, many of the lesions will be impalpable and will need specimen radiography. This requires the availability of appropriate equipment and radiological expertise and will add to the time and cost of evaluating the specimen. A greater proportion of screen-detected lesions will be DCIS, small lesions and borderline atypical lesions when compared to lesions detected because of symptoms.

The Service will have a designated pathologist who is appropriately qualified, to oversee the implementation of quality assurance measures in pathology. At least one deputy is desirable though not essential. The roles and responsibilities of the designated pathologist and any deputies are set out in Appendix Q.

It is important that Services use pathology laboratories which maintain Royal College of Pathologists of Australasia/National Association of Testing Authorities accreditation.

Pathologists have led the multidisciplinary development of two documents to practice in the reporting of breast specimens: *The pathology reporting of breast cancer: a guide for pathologists, surgeons and radiologists*⁴⁹ and *Breast fine needle aspiration cytology and core biopsy—a guide for practice*.⁸⁵ The recommendations in these documents will be used to guide reporting for BreastScreen Australia. The key recommendations in these documents and the use of standardised reporting for invasive disease are outlined in Appendices R and S. To review practice in accord with these guides and provide a basis for instituting quality improvement measures in pathology reporting, Services will audit 300 consecutive pathology reports every two years. This should be conducted by a pathologist within or outside of the Program.

A number of standards are identified which, when reviewed together, will provide a measure of the quality of pathology in assessment. Performance against individual standards should be reviewed cautiously as they may reflect performance in clinical and imaging aspects of assessment. The accuracy of FNA and core biopsy depends on the experience and skill of the aspirator, the nature of the lesions, the localisation technique used, and the interpretative skills and experience of the pathologist.⁸⁶

The BreastScreen Australia program should ensure high quality pathology in the performance and interpretation of FNA cytology and core biopsy. A high false negative or false positive rate for FNA cytology or core biopsy may indicate that these aspects of assessment are ineffective in providing an accurate diagnosis.

The United Kingdom National Health Service Breast Screening Programme has suggested that less than 6% of FNA cytology procedures should have a false negative result and less than 1% a false positive result.⁸⁷

For core biopsy, the rate of normal or benign results which subsequently turn out to be cancer, provides a measure of biopsy technique. This cancer miss rate, which includes a false negative rate combined with an inadequate rate, has been adapted from the United Kingdom National

Health Service Breast Screening Programme. The NHS standards do not include a stand-alone false negative rate on core biopsies. As this standard has been adapted, a benchmark will not be established until sufficient data have been collected to review this standard. The false positive rate for core biopsy should be less than 0.5%, in accordance with the United Kingdom National Health Service Breast Screening Programme.⁸⁷

Services should also collect and review data relating to absolute sensitivity, complete sensitivity and positive predictive value of FNA and core biopsy. The United Kingdom National Health Service Breast Screening Programme has suggested that the absolute sensitivity of FNA cytology be greater than 60% and the complete sensitivity greater than 80%.⁸⁷ For core biopsy, the United Kingdom National Health Service Breast Screening Programme suggests the absolute sensitivity be greater than 70% and the complete sensitivity greater than 80%.⁸⁷ Absolute sensitivity is a measure of the number of cases diagnosed accurately, ie categorised as malignant. Complete sensitivity is a measure of the proportion of cancers that have produced an abnormal cytologic appearance, ie categorised as atypia/indeterminate, suspicious of malignancy or malignant.⁸⁶ Both absolute and complete sensitivity, are related to the inadequate rates, as high rates of inadequacy will decrease the sensitivity.

Positive predictive value of a malignant diagnosis is a direct measure of diagnostic accuracy; the percentage of correctly identified cancers out of the total number of malignant diagnoses.⁸⁶ The United Kingdom National Health Service Breast Screening Programme suggests the standards for positive predictive value be greater than 98 and 99% for FNA cytology and core biopsy procedure respectively.⁸⁷

In the absence of Australian data on which to base these standards, the United Kingdom standards have been adopted for the BreastScreen Australia program. The collection of Australian Service data will help inform the future revision of these standards for pathology.^{88,89}

Performance objective 2.19:
The Service demonstrates high quality pathology.

OUTCOME OF THE ASSESSMENT EPISODE

The results of assessment must clearly indicate an outcome for the woman in the shortest possible time without compromising the quality of the assessment process. The Service will ensure that women who are recalled for assessment are followed up until their assessment episode is complete and a review and correlation of all test results confirms a definitive outcome. An assessment **episode** is complete when there is one of three outcomes: return for routine rescreening (either yearly or two yearly); a histological result at referral for definitive treatment or recommendation for early review.

For those women referred for surgery, correlation of results from the individual tests at assessment with results of histopathology is vital to the process of ensuring an accurate diagnosis and appropriate treatment.

Number of assessment visits

The assessment process should involve as few a visits as possible for the woman while providing a high quality service.

Women recalled to assessment experience an increase in their level of anxiety,⁹⁰ and repeated attendances for assessment during a single screening episode are likely to be associated with unnecessary anxiety.⁶² Every effort should therefore be made to ensure that all assessment procedures are performed on the day of assessment and, where possible, results given as well.⁹¹ The vast majority of women who do not require FNA cytology or core biopsy should receive a definitive outcome at their first assessment visit.

However, there are many circumstances where the need to complete assessment in one day should be balanced against the need to provide a high quality service. In some cases, for example, it may be necessary to discuss results further or seek a second opinion about the interpretation of test findings. In addition, it will not always be possible to obtain an FNA cytology result on the day of the procedure, and core biopsy results require longer for adequate preparation and reporting. The woman may therefore have to return for a second visit to receive her results. The majority of women who do not receive their results at the first assessment visit will receive a definite outcome on the second assessment visit. However in a very small number of cases, more visits will be required—for example, where repeat biopsy is required due to the insufficiency of the sample. For women who need to travel long distances, every effort should be made to minimise the number of visits required.

A definitive outcome 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 have to stop these medications for a period of time before investigative procedures are undertaken and will require a longer assessment period.

Performance objective 2.20:

The Service minimises the number of visits and time required to achieve an outcome of assessment.

Open biopsy

Mammographic screening will identify small, impalpable lesions which require excision by image guidance for diagnosis or treatment. The excision of small, impalpable lesions requires special radiological, surgical and histopathological skills, and to maximise the number of cancers detected, should be referred to specialists who work in a multidisciplinary team setting with the skills and facilities to perform these excisions.

Program policy stipulates that ‘women with histologically or cytologically confirmed breast cancer will be 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’. Open biopsy within the Program can be defined as open

biopsy solely funded by BreastScreen Australia and not requiring onward referral. Where open biopsy is performed within the Program, the Service must ensure that it is performed by specialists with expertise and with appropriate facilities available. Where clients are referred to, or choose, outside providers, 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 might include a recommendation in the letter to the general practitioner about the facilities and expertise which are minimally required for the adequate performance of an operative procedure in a woman with a screen-detected abnormality.

In cases of impalpable lesions, specimen radiography permits a degree of certainty that the mammographic lesion has been satisfactorily removed.⁹² In addition, specimen radiography may be helpful in determining the completeness of the mammographically detected lesions.⁹³ The surgical specimen submitted for specimen X-ray should be orientated and marked according to standard local protocols to allow the surgeon and pathologist to assess the adequacy of excision.⁹⁴ Although a verbal report by a radiologist can be received, it is desirable that the specimen X-ray be available for review if the surgeon requires it for intraoperative decision making. The orientation of the specimen and copy of the specimen X-ray will also allow the pathologist to assess the location of the lesion within the specimen and margins of resection.⁹⁵

The percentage of all impalpable lesions which are correctly identified at first open biopsy is affected by the process of lesion localisation by mammographic or ultrasound guidance and by the surgeon's capacity to remove impalpable lesions. Specimen radiography assists the radiologist and the surgeon in the accurate localisation and surgical excision of impalpable lesions. The vast majority of women with impalpable lesions will have them correctly identified at first open biopsy, ensuring that the anxiety and physical consequences for women are minimised.⁹⁶ At this time, large core devices are regarded as diagnostic procedures and are therefore part of the assessment process when appropriately used either within or outside the Program. However, there may be a need for this standard to be revised in the future if large core biopsy devices are used in the treatment setting.

Performance objective 2.21:
The Service maximises the operative identification of lesions requiring open biopsy.

Early review

Occasionally, it may be necessary for women to return for a further review of the same screen-detected abnormality within 12 months of completion of the assessment episode—that is, to be recommended for early review (sometimes known as 'short-term recall' or 'early recall'). For example, early review 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 placed on early review are invited to attend assessment at an interval of up to 12 months from completion of their assessment episode.

Early review should only be employed in exceptional circumstances and with fully informed consent.⁶² Women placed on early review have significantly higher adverse psychological consequences than those women who have a false-positive mammographic result after assessment.^{97,98}

The United Kingdom National Health Service Breast Screening Programme standard is currently set at less than 1% of women **screened** to be placed on short-term recall.⁹⁶ The mean percentage of women placed on early review for Australian States and Territories in 1999 was 0.19% as shown in Appendix D2. The Australian standard is that up to 0.2% of women who attend for screening may be recommended for early review of the same screen-detected abnormality within 12 months of the screening visit. For these women, there must be an outcome from the early review assessment; either a recommendation for open biopsy or return for routine rescreening at an interval appropriate to her risk factors.

Performance objective 2.22:
The Service minimises the proportion of women on early review.

Appropriate referral

Following a diagnosis of breast cancer, the woman’s care should include appropriate treatment and follow-up and access to other specialist facilities, primary care providers and support services.^{99,100} The same approach to ensuring appropriate referral and management should be taken for both invasive cancer and DCIS.

It is the woman’s choice as to whom she is referred. She may chose to be referred to her nominated general practitioner or a surgeon or treatment clinic with known expertise in the treatment of breast cancer. The Service should facilitate the provision of relevant information resulting from screening and assessment to assist in planning of the woman’s ongoing care. Therefore, where possible, the referral letter to the general practitioner or other treating clinician should include relevant test results, copies of images, pathology results and a clear diagnosis. This information should 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.

The Service should advise women diagnosed with breast cancer in writing of their future screening needs and status in relation to the Program.

Performance objective 2.23:
The Service ensures that women diagnosed with breast cancer are appropriately referred for treatment.

Treatment information

BreastScreen Australia monitors the treatment received by women diagnosed through the screening program to promote best practice. Relevant 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 assurance measures.

The Service will implement a protocol for the request of relevant information from the treating clinician of all women diagnosed with breast cancer. Where information is not provided by the surgeon, efforts should be made to collect the information from other sources. This might include contacting pathology laboratories and setting up arrangements whereby pathology laboratories routinely provide follow-up information. Further efforts might also be directed at general practitioners.¹⁰¹

The Service will receive relevant surgical histopathology for 95% or more of the women diagnosed with breast cancer and at least 80% of primary treatment information. This includes women undergoing open diagnostic biopsy and/or surgery. The Service should strive to receive 95% of all primary treatment information requests.

However, there is a point at which efforts to obtain information will cease. This should 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 may stop seeking information if documented unsuccessful attempts have been made to retrieve this information through the surgeon, the pathology laboratories and the general practitioner. Services should not make contact with the woman solely for the purpose of gaining access to information about treatment.

Performance objective 2.24:
The Service ensures the collection of treatment information about women with breast cancer.

Multidisciplinary meetings

For review of assessment cases:

The Service will implement a protocol for review and correlation of clinical, radiology and pathology results of all women who underwent FNA or core biopsy. Where results of cytology or core biopsy are not available at the assessment clinic, the multidisciplinary team who were involved in each case should agree a management plan pending the biopsy results. The biopsy results must be reviewed as soon as is possible after the pathology results become available and before the result of assessment is given to the woman or her doctor. These results must be reviewed by a radiologist, where possible, together with a pathologist and other members of the multidisciplinary team. These assessment case review meetings confirm the conclusion of the assessment process for the majority of cases. Where results are inconclusive

or inconsistent, case review must be performed minimally by a radiologist together with a pathologist to determine appropriate further investigations or management. The designated surgeon should be available to provide input into the review and management of such cases where necessary. The roles and responsibilities of the designated surgeon are outlined in Appendix T. Members of the multidisciplinary assessment team should be encouraged to participate in this case review process where possible.

Where women recalled by the Service have elected to be assessed outside the Service, the Service may advise the woman and her general practitioner about appropriate referral for the assessment of screening abnormalities which supports a multidisciplinary team approach. In addition, Services may extend their care to follow-up and review these assessment results. Where results are available, these cases should be reviewed minimally by a radiologist and where necessary by other members of the multidisciplinary team.

For follow-up of surgical cases:

In addition, the Service will implement a process for the review of the histopathology reports of all women who undergo surgery for a lesion detected as a result of screening. All clinical members of the multidisciplinary assessment team will be encouraged to participate in multidisciplinary review meetings to ensure that discussion involves appropriate expertise for the correlation of clinical, imaging, cytological and histopathological findings of individual cases. 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 by clinicians.

Where the results of surgery are not found to be in accord with the preoperative test findings, a protocol will exist for the follow-up of these women. This may include; notifying the woman for review and assessment by the Service, notifying the treating surgeon, notifying the general practitioner or any combination of these. The Service should ensure that there is a protocol in place for ensuring that contact is made in order that further follow up of these women takes place.

For professional education:

Attendance at professional educational meetings by all members of the multidisciplinary team is important in ensuring the delivery of best care by the Service. Such professional educational meetings may be provided by the Service to enable the opportunity to review Service data, develop local protocols or to discuss cases of interest or around specific topic areas. Other opportunities for participation in relevant ongoing professional education are provided, for example, by individual medical colleges and a number of multidisciplinary breast cancer groups who hold meetings both within Australia and internationally.

Each Service will ensure that all members of the multidisciplinary team participate in at least five professional education activities per year relevant to their work in BreastScreen Australia which can be either within or outside the Service. A target of eight professional education activities per year should be strived for. The Service should provide such meetings wherever possible to ensure that all members of the multidisciplinary team are able to comply with this standard.

Both case review and educational meetings will assist in fostering a multidisciplinary approach, as they enable the sharing of expertise from different disciplines and function both as a strategy for improving assessment protocols and an approach to providing multidisciplinary continuing education.

Performance objective 2.25:

The Service implements strategies for multidisciplinary case review, follow-up of individual cases and professional education

PERFORMANCE INDICATORS

Performance Objective	Standard	Measure
2.1 The Service maximises the detection of invasive breast cancer.	2.1.1 ≥ 50 per 10,000 women aged 50–69 years who attend for their first screen are diagnosed with invasive breast cancer.	The number of women diagnosed with invasive ¹ breast cancer for every 10,000 women aged 50–69 years who attend for their first screen. Calculation: See Data Dictionary
	2.1.2 ≥ 35 per 10,000 women aged 50–69 years who attend for their second or subsequent screen are diagnosed with invasive breast cancer.	The number of women diagnosed with invasive breast cancer for every 10,000 women aged 50–69 years who attend for their second or subsequent screen. Calculation: See Data Dictionary
	2.1.3 The Service monitors the rates of invasive breast cancer among women aged 40–49 years and 70 years and over.	Evidence of monitoring the rates of invasive breast cancer among women aged 40–49 years and 70 years and over in the most recent 12-month period for which data are available. Calculation: See Data Dictionary
2.2 The Service maximises the detection of small invasive breast cancer.	2.2.1 ≥ 25 per 10,000 women aged 50–69 years who attend for screening are diagnosed with small (≤ 15mm) invasive breast cancer.	The number of women diagnosed with small (≤ 15mm) invasive breast cancer for every 10,000 women aged 50–69 years who attend for screening. Calculation: See Data Dictionary
	2.2.2 The Service monitors the rates of small (≤ 15mm) invasive breast cancer among women aged 40–49 years and 70 years and over.	Evidence of monitoring the rates of small (≤ 15mm) invasive breast cancer among women aged 40–49 years and 70 years and over in the most recent 12-month period for which data are available. Calculation: See Data Dictionary
2.3 The Service maximises the detection of DCIS.	2.3.1 ≥ 12 per 10,000 women aged 50–69 years who attend for their first screen are diagnosed with DCIS.	The number of women diagnosed with DCIS for every 10,000 women aged 50–69 years who attend for their first screen. Calculation: See Data Dictionary
	2.3.2 ≥ 7 per 10,000 women aged 50–69 years who attend for their second or subsequent screen are diagnosed with DCIS (see Appendix C).	The number of women diagnosed with DCIS for every 10,000 women aged 50–69 years who attend for their second or subsequent screen. Calculation: See Data Dictionary
	2.3.3 The Service monitors the rates of DCIS among women aged 40–49 years and 70 years and over.	Evidence of monitoring the rates of DCIS among women aged 40–49 years and 70 years and over in the most recent 12-month period for which data are available. Calculation: See Data Dictionary

¹ Lesions should be recorded and sized as invasive cancers, if they include any invasive component, for performance objectives 2.1, 2.2, 2.3, & 2.4.

PERFORMANCE INDICATORS

Performance Objective	Standard	Measure
2.4	<p>2.4.1 The Service implements a protocol for:</p> <ul style="list-style-type: none"> • identifying all invasive interval cancers through cancer registry data • reviewing and investigating all invasive interval cancers within the Service on an annual basis • identifying and implementing changes to improve practice where necessary, particularly when the invasive interval cancer rate is greater than the standard. <p>2.4.2 The Service will collect data about invasive interval breast cancers.</p> <p>(a) < 7.5 per 10,000 women aged 50–69 years who attend for screening are diagnosed with an invasive interval breast cancer between 0 and less than 12 months following a negative screening episode.</p> <p>(b) The number per 10,000 women aged 50–69 years who attend for screening and who are diagnosed with an invasive interval breast cancer in the period between 12 and less than 24 months following a negative screening episode.</p>	<p>Evidence of implementation of a protocol for the identification and investigation of all invasive interval cancers on an annual basis and implementing changes where necessary.</p> <p>The number of women who are diagnosed with an invasive interval breast cancer in the period between 0 and less than 12 months following a negative screening episode for every 10,000 women aged 50-69 years who attend for screening in a defined 12-month period.</p> <p>Calculation: See Data Dictionary</p> <p>The number of women who are diagnosed with invasive interval breast cancer in the period between 12 and less than 24 months following a negative screening episode for every 10,000 women aged 50-69 years who attend for screening in the 12-month period defined in part (a).</p> <p>Calculation: See Data Dictionary</p>
2.5	<p>2.4.3 The Service monitors the number of women aged 40–49 years and 70 years and over diagnosed with an invasive interval breast cancer.</p> <p>2.5.1 The Service implements a protocol for:</p> <ul style="list-style-type: none"> • identifying all interval cases of DCIS through cancer registry data • reviewing and investigating all interval cases of DCIS within the Service on an annual basis • identifying and implementing changes to improve practice where necessary. 	<p>Evidence of monitoring the number of women aged 40-49 years and 70 years and over diagnosed with an invasive interval breast cancer.</p> <p>Calculation: See Data Dictionary</p> <p>Evidence of implementation of a protocol for the identification and investigation of all interval cases of DCIS on an annual basis and implementing changes where necessary.</p>

PERFORMANCE INDICATORS

Performance Objective	Standard	Measure
2.6 The Service minimises recalls for assessment.	2.6.1 < 10% of women who attend for their first screen are recalled for assessment.	The percentage of women aged 50-69 years who attend for their second or subsequent screen and who are recalled for assessment. Calculation: See Data Dictionary
	2.6.2 < 5% of women who attend for their second or subsequent screen are recalled for assessment.	The percentage of women aged 50-69 years who attend for their second or subsequent screen and who are recalled for assessment. Calculation: See Data Dictionary
	2.6.3 The Service monitors the rates of recall among women aged 40- 49 years and 70 years and over.	Evidence of monitoring the rates of recall among women aged 40-49 years and 70 years and over in the most recent 12-month period for which data are available.
2.7 The Service maximises the preoperative diagnosis of invasive cancer and DCIS.	2.7.1 ≥ 75% of invasive cancers or DCIS are diagnosed without the need for diagnostic open biopsy.	The percentage of the total number of invasive cancers or DCIS diagnosed without the need for diagnostic open biopsy. Calculation: See Data Dictionary
2.8 The Service minimises the proportion of benign open biopsies for diagnostic purposes.	2.8.1 ≤ 0.35% of women who attend for their first screen are found not to have invasive cancer or DCIS after a diagnostic open biopsy.	The percentage of the total number of women who attend for their first screen who are found not to have invasive cancer or DCIS after a diagnostic open biopsy. Calculation: See Data Dictionary
	2.8.2 ≤ 0.16% of women who attend for their second or subsequent screen are found not to have invasive cancer or DCIS after a diagnostic open biopsy.	The percentage of the total number of women who attend for their second or subsequent screen who were found not to have invasive cancer or DCIS after a diagnostic open biopsy. Calculation: See Data Dictionary
2.8.3 ≤ 4.0% of women assessed after their first screen are found not to have invasive cancer or DCIS after a diagnostic open biopsy.	2.8.3 ≤ 4.0% of women assessed after their first screen are found not to have invasive cancer or DCIS after a diagnostic open biopsy.	The percentage of the total number of women who are assessed as a result of being recalled after their first screen, who are found not to have invasive cancer or DCIS after a diagnostic open biopsy. Calculation: See Data Dictionary
	2.8.4 ≤ 3.2% of women assessed after their second or subsequent screen are found not to have invasive cancer or DCIS after a diagnostic open biopsy.	The percentage of the total number of women who are assessed as a result of being recalled after their second or subsequent screen, who are found not to have invasive cancer or DCIS after a diagnostic open biopsy. Calculation: See Data Dictionary

PERFORMANCE INDICATORS		
Performance Objective	Standard	Measure
2.9 The Service ensures high quality of breast imaging systems.	2.9.1 X-ray systems, premises and users meet radiation protection regulations.	Evidence of licence and/or registration documentation from the relevant regulatory authority responsible for radiation control legislation.
	2.9.2 Breast imaging quality control test equipment meets the minimum standards specified in Appendix L.	Evidence that breast imaging quality control test equipment meets the standards specified in Appendix L.
	2.9.3 Quality control procedures that meet the standards specified in Appendices K and H are implemented.	Evidence of implementation of quality control procedures.
	2.9.4 Breast imaging systems, including ancillary items, meet: <ul style="list-style-type: none"> • manufacturer's specifications • performance standards as specified in Appendices H and I. 	Evidence that breast imaging systems meet manufacturer's specifications and performance standards at acceptance, annual testing and following major maintenance.
	2.9.5 Acceptance and annual testing of mammography systems is performed by, or under the close supervision of suitably qualified and experienced persons as specified in Appendix J.	Evidence that persons performing mammography system testing are suitably qualified and experienced or are closely supervised by suitable qualified and experienced persons as specified in Appendix J.
	2.9.6 Preventative maintenance and repair of imaging equipment meets manufacturer's recommendations or other appropriate standards.	Evidence that maintenance is performed in accordance with manufacturers' recommendations or other justified alternative standards.

PERFORMANCE INDICATORS

Performance Objective	Standard	Measure
2.10 The Service ensures high quality imaging.	2.10.1 Mammography is performed by diagnostic radiographers who are appropriately trained and supervised as specified in Appendix J.	Evidence that each radiographer has appropriate training and supervision as specified in Appendix J.
	2.10.2 The Service ensures: <ul style="list-style-type: none"> • that mammographic screening examinations consist of the two standard views (that is, cranio-caudal and medio-lateral oblique); • documentation of reasons for any deviation from the standard two views; • implementation of a protocol for adequate examination of women with internal breast prostheses. 	Examination of a random sample of screening images which demonstrate: <ul style="list-style-type: none"> • two view mammography as the standard mammographic screening examination • documentation of reasons for any deviation from the two standard views • implementation of a protocol for adequate examination of women with internal breast prostheses.
	2.10.3 The overall repeat rate for the Service is < 3% of all screening images.	The percentage of the total number of screening images used in any 12-month period which are for repeat images. However, the Service will demonstrate that this is also calculated on a monthly basis. Calculation: See Data Dictionary
	2.10.4 The Service 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 M.	Evidence for each radiographer in the Service of the percentage of P or G ratings in a PGMI grading of 50 randomly selected image sets as outlined in Appendix M.
	2.10.5 The Service has a designated radiographer who is appropriately qualified and who is responsible for all aspects of quality assurance in radiography as outlined in Appendix N.	Evidence of a designated radiographer who is appropriately qualified. Evidence that the designated radiographer implements quality assurance measures in radiography and fulfils the responsibilities as outlined in Appendix O.
	2.10.6 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.	Evidence that the designated radiographer provides ongoing feedback to radiographers in all units about the quality of screening images using criteria such as those used in the PGMI evaluation system outlined in Appendix M.
2.11 The Service ensures the adequate identification of all images.	2.11.1 Image identification complies with relevant radiation licensing regulations. Each image (soft or hard copy) is clearly marked with the date and sufficient information to identify the client and enable correct interpretation. All identifying information is on the image and is transferred to each copied image.	Examination of random sample of images which are marked with the relevant identifying information.
	2.11.2 The Service demonstrates the identification of the radiographer and X-ray machine used for each screening mammogram.	Examination of a random set of records which identify the radiographer and the X-ray machine for each screening mammogram.

PERFORMANCE INDICATORS		
Performance Objective	Standard	Measure
2.12	2.12.1	<p>Two readers read all screening images independently, in a 'blind' relationship.</p> <p>Evidence of:</p> <ul style="list-style-type: none"> individual reader identification for two readers for all screening cases a protocol for screen reading in an independent and 'blind' relationship.
	2.12.2	<p>The Service demonstrates that at least one reader of screening images is a radiologist.</p> <p>Evidence that at least one reader of a random sample of screening records is a radiologist.</p>
	2.12.3	<p>All screen readers read at least 2,000 mammographic screening cases within the Program per year.</p> <p>The number of mammographic screening cases read by readers within the Program per year.</p> <p>Calculation: See Data Dictionary</p>
	2.12.4	<p>The Service provides audit and feedback which advises each reader of:</p> <p>(a) their individual rate of detection of small invasive cancers in all screens and their invasive cancer detection rate in initial and subsequent screens (see Appendix P); and</p> <p>(b) timely feedback about:</p> <ul style="list-style-type: none"> any interval invasive cancers not detected in cases read by the reader; and any invasive cancers not detected as an abnormality by an individual reader at screen reading <p>Evidence of processes for providing feedback to each reader about:</p> <p>(a) their small invasive cancer detection rate in all screens and invasive cancer detection rate in initial and subsequent screens over both the previous 12-month and 24-month period.</p> <p>(b) any interval invasive cancers not detected as an abnormality by an individual reader at screen reading in the preceding three-month period.</p>
	2.12.5	<p>The Service implements a review process, and where necessary, implements strategies to address the individual reader's performance.</p> <p>Evidence of implementation of strategies developed to address individual poor reader performance.</p>
	2.12.6	<p>The Service ensures that a designated radiologist who is appropriately qualified is responsible for all issues of quality assurance and undertakes the roles and responsibilities related to radiology as outlined in Appendix O.</p> <p>Evidence of a designated radiologist who is appropriately qualified.</p> <p>Evidence that the designated radiologist implements quality assurance measures in radiology and fulfils the responsibilities as outlined in Appendix O.</p>

PERFORMANCE INDICATORS

Performance Objective	Standard	Measure
2.13 The Service ensures high quality reporting of breast images at screening.	2.13.1 The reports of the independent screen readers are combined into a single recommendation for every woman, which indicates whether or not further assessment for the presence of cancer is required.	Evidence from a random sample of screening reports of an agreed outcome of screening between the two independent screen readers provided in a single, unambiguous recommendation.
	2.13.2 The recommendation is provided in a non-narrative form approved by the State Coordination Unit.	Evidence from a random sample of screening reports of an outcome of screening provided in a non-narrative form approved by the State Coordination Unit.
	2.13.3 Where there is discordance between the two independent screen readers on whether further assessment for the presence of cancer is required, the Service implements a protocol to achieve a single recommendation, through either: <ul style="list-style-type: none"> • a third reader where that reader is a radiologist with a high level of expertise in the screening modality used, or • consensus reads by the two readers. 	Evidence of implementation of a protocol for dealing with discordant reads, either through an appropriate third reader or through consensus reads by the two readers.
2.14 The Service implements a protocol for the management of women who report breast symptoms consistent with the National Policy Framework for the Management of Women with Symptoms.	2.14.1 The Service implements a protocol for the management of women who report symptoms in accordance with the National Policy Framework for the Management of Women with Symptoms by BreastScreen Australia Services.	Evidence of implementation of a protocol for the management of women who report symptoms in accordance with the National Policy Framework for the Management of Women with Symptoms by BreastScreen Australia Services.
2.15 The service implements a comprehensive approach to the assessment of breast abnormalities.	2.15.1 The service implements protocols for the evaluation of all women recalled to assessment which incorporates: <ul style="list-style-type: none"> • clinical examination; • mammography/ultrasound; and • FNA cytology/core biopsy as required. 	Evidence of the implementation of processes for: <ul style="list-style-type: none"> • Evaluating women recalled to assessment using a comprehensive approach • Regularly reviewing and evaluating compliance with these procedures

PERFORMANCE INDICATORS

Performance Objective	Standard	Measure
2.16	<p>2.16.1 The Service demonstrates that all members of the multidisciplinary team involved in the assessment of women recalled from screening have the relevant training and qualifications as outlined in Appendix J.</p> <p>2.16.2 The Service ensures that the multidisciplinary team involved in the assessment of women recalled from screening has expertise in:</p> <ul style="list-style-type: none"> • breast examination; • mammographic screen reading and work-up; • ultrasound performance and interpretation; • biopsy (FNA and core); • pathology technique and interpretation; and • supportive care. <p>2.16.3 The Service will have available the diagnostic equipment to perform:</p> <ul style="list-style-type: none"> • complete mammographic work-up; • breast ultrasound examinations; • FNA cytology (including ultrasound and stereotactic guided biopsy); and • core biopsy (including ultrasound and stereotactic guided biopsy). <p>2.16.4 Ultrasound examinations are performed by suitably qualified and experienced radiologists as specified in Appendix J or by a sonographer with a radiologist available on site during conduct of examinations.</p>	<p>Evidence of relevant training and qualifications of all members of the multidisciplinary team involved in the assessment of women as outlined in Appendix J.</p> <p>Evidence that all the relevant expertise is available for women recalled to assessment.</p> <p>Evidence of the availability of all diagnostic equipment required to provide adequate evaluation of all women recalled to assessment, as outlined in the standards.</p> <p>Evidence of relevant qualifications and experience of the radiologist(s) performing ultrasound examinations as specified in Appendix J.</p> <p>Evidence that where sonographers perform ultrasound examinations, a radiologist is available on site during conduct of examinations.</p>
2.17	2.17.1 The Service implements a protocol which ensures that the radiologist and the surgeon and other designated examining clinician from the multidisciplinary team, are in attendance together at assessment to correlate and evaluate the clinical and imaging findings and to decide on further investigations or management. Where the medical officer is the initial examining clinician, the medical officer discusses and evaluates all patient findings with the surgeon and radiologist.	<p>Evidence of implementation of a protocol for the correlation and evaluation of the clinical and imaging findings by relevant clinicians of the multidisciplinary team at assessment and for deciding on further investigations or management.</p>

PERFORMANCE INDICATORS

Performance Objective	Standard	Measure
2.18	<p>The Service demonstrates the effective use of FNA cytology and core biopsy in assessment:</p> <p>2.18.1 < 25% of all lesions assessed by FNA are classified with the result inadequate/insufficient.</p> <p>2.18.2 The proportion of core biopsy procedures with a false negative or inadequate result. Note: RCPA has recommended that no benchmark be set for this standard but data collected against it for a period of time. The standard, with associated data, will be reviewed at a later time and a benchmark established.</p>	<p>The percentage of all lesions assessed by FNA is classified with the result inadequate/insufficient. Calculation: See Data Dictionary</p> <p>The number of lesions sampled through core biopsy with a benign or inadequate result and malignant result on final histology as a percentage of all lesions sampled through core biopsy and returning a malignant result on final histology but were clinically presumed to be malignant. Calculation: See Data Dictionary</p>
2.19	<p>The Service demonstrates high quality pathology.</p> <p>2.19.1 The Service ensures that a designated pathologist is appropriately qualified and responsible for all issues of quality assurance related to pathology, as specified in Appendix Q.</p> <p>2.19.2 The designated pathologist and any deputy/ies participate in the Royal College of Pathologists of Australasia Quality Assurance Program Breast Pathology Module.</p> <p>2.19.3 The Service uses pathology laboratories which maintain Royal College of Pathologists of Australasia National Association of Testing Authorities accreditation.</p> <p>2.19.4 The designated pathologist and deputy/ies implement the recommendations for quality assurance and uniform reporting of breast FNA cytology and core biopsy in <i>Breast fine needle aspiration cytology and core biopsy – a guide to practice</i>⁸⁵ as amended from time to time.</p> <p>2.19.5 < 6% of malignant lesions assessed by FNA have a false negative result.</p>	<p>Evidence of a designated pathologist who is appropriately qualified and who implements quality assurance measures, as specified in Appendix Q.</p> <p>Evidence that the designated pathologist and any deputy/ies participate in the Royal College of Pathologists of Australasia Quality Assurance Program Breast Pathology Module at least every three years.</p> <p>Evidence that the Service only uses pathology laboratories which maintain Royal College of Pathologists of Australasia National Association of Testing Authorities accreditation.</p> <p>Evidence of an audit of 300 consecutive pathology reports in the Service in the most recent two calendar years; to review pathology reporting practice in line with <i>Breast fine needle aspiration cytology and core biopsy – a guide for practice</i>⁸⁵ as amended from time to time as outlined in Appendix R and S.</p> <p>The number of lesions assessed by FNA with a benign result on cytology and a malignant result on histology, as a percentage of all lesions aspirated returning malignant histology plus all cases called malignant on cytology and never confirmed by histology but were clinically presumed to be malignant. Calculation: See Data Dictionary</p>

PERFORMANCE INDICATORS

Performance Objective	Standard	Measure
2.19 The Service demonstrates high quality pathology (continued).	2.19.6 (a) < 1% of lesions reported as malignant by FNA have a false positive result.	The number of lesions assessed by FNA with a malignant result on cytology and a non-malignant result on histology, as a percentage of all lesions aspirated returning malignant histology plus all cases called malignant on cytology and never confirmed by histology a but were clinically presumed to be malignant. Calculation: See Data Dictionary
	2.19.6 (b) The proportion of non-malignant lesions assessed by FNA with a false positive result.	The number of lesions assessed by FNA with a malignant result on cytology and a non-malignant result of histology, as a percentage of all lesions assessed by FNA returning a non-malignant result on histology. Calculation: See Data Dictionary
	2.19.7 < 0.5% of lesions sampled through core biopsy have a false positive result.	The number of lesions sampled through core biopsy with a malignant core biopsy result and non-malignant result on final histology, as a percentage of all lesions sampled through core biopsy returning a final malignant on core biopsy and never confirmed by final histology but were clinically presumed to be malignant. Calculation: See Data Dictionary
	2.19.8 The absolute sensitivity of a diagnosis of breast cancer based on FNA cytology is > 60%.	The number of lesions assessed by FNA with a malignant cytology result and confirmed as malignant on histology plus all cases called malignant on cytology and never confirmed by histology but were clinically presumed to be malignant, as a percentage of all lesions assessed by FNA returning malignant histology plus all cases called malignant on cytology and never confirmed by histology but were clinically presumed to be malignant. Calculation: See Data Dictionary

PERFORMANCE INDICATORS

Performance Objective	Standard	Measure
2.19 The Service demonstrates high quality pathology (continued).	2.19.9 The complete sensitivity of FNA biopsy in the assessment of breast lesions is > 80%.	The number of lesions assessed by FNA with a malignant, suspicious or atypical cytology result and confirmed as malignant on histology plus all cases called malignant on cytology and never confirmed by histology but were clinically presumed malignant, as a percentage of all lesions aspirated returning malignant histology plus all cases called malignant on cytology and never confirmed by histology but were clinically presumed malignant. Calculation: See Data Dictionary
2.19.10	The absolute sensitivity of core biopsy in the assessment of breast lesions is > 70%.	The number of lesions sampled through core biopsy with a malignant core biopsy result and returning a malignant result on final histology plus all cases called malignant on core biopsy and never confirmed by final histology but were clinically presumed to be malignant, as a percentage of all lesions sampled through core biopsy returning a final malignant histology result plus all cases called malignant on core biopsy and never confirmed by final histology but were clinically presumed to be malignant. Calculation: See Data Dictionary
2.19.11	The complete sensitivity of core biopsy in the assessment of breast lesions is > 80%.	The number of lesions sampled through core biopsy with a malignant, suspicious or atypical core biopsy result and returning a malignant result on final histology plus all cases called malignant on core biopsy and never confirmed by final histology but were clinically presumed to be malignant, as a percentage of all lesions sampled through core biopsy returning a final malignant histology result plus all cases called malignant on core biopsy and never confirmed by final histology but were clinically presumed to be malignant. Calculation: See Data Dictionary

PERFORMANCE INDICATORS

Performance Objective	Standard	Measure
2.19 The Service demonstrates high quality pathology (continued):	2.19.12 The positive predictive value of a malignant FNA diagnosis is > 98%.	The number of lesions assessed by FNA with a malignant cytology result minus the number of lesions assessed by FNA with a malignant cytology result shown to be non-malignant on histology, as a percentage of all lesions assessed by FNA with a malignant cytology result. Calculation: See Data Dictionary
	2.19.13 The positive predictive value of a malignant core biopsy diagnosis is > 99%.	The number of lesions sampled through core biopsy with a malignant result minus the number of lesions sampled through core biopsy with a malignant result shown to be non-malignant on final histology, as a percentage of all lesions sampled with a malignant result. Calculation: See Data Dictionary
	2.19.14 The designated pathologist and deputy/ies implement the recommendations for reporting DCIS and invasive breast cancer in the <i>Recommendations for the pathology reporting of breast cancer</i> as amended from time to time as outlined in Appendix 5.	Evidence of an audit of 300 consecutive pathology reports in the most recent two calendar years, to review practice in line with Recommendations for the pathology reporting of breast cancer as amended from time to time as outlined in Appendix 5. Calculation: See Data Dictionary
2.20 The Service minimises the number of visits and time required to achieve an outcome of assessment.	2.20.1 ≥ 95% of women require no more than two assessment visits to receive a definitive outcome.	The percentage of women attending assessment who receive an outcome of assessment in either one or two assessment visits. Calculation: See Data Dictionary
	2.20.2 ≥ 95% of women complete all assessment within a two week period.	Percentage of women attending assessment who receive a definitive outcome of assessment within a two week period. Calculation: See Data Dictionary
	2.20.3 ≥ 95% of women not requiring FNA cytology or core biopsy at assessment receive a definitive outcome at their first assessment visit.	The percentage of women attending assessment who do not require FNA cytology or core biopsy who receive a definitive outcome at their first assessment visit. Calculation: See Data Dictionary

PERFORMANCE INDICATORS

Performance Objective	Standard	Measure
2.21	<p>The Service maximises the operative identification of lesions requiring open biopsy.</p> <p>2.21.1</p> <p>The Service refers women for open biopsy to facilities which are fully equipped to provide:</p> <ul style="list-style-type: none"> • image-guided localisation (mammographic or ultrasound); • specimen radiography; and • specialist histopathological techniques. <p>2.21.2</p> <p>All women with impalpable lesions undergoing open biopsy have specimen radiography performed.</p> <p>2.21.3</p> <p>≥ 95% of all impalpable lesions are correctly identified at first open biopsy.</p>	<p>Evidence that the Service refers women for open biopsy to appropriately equipped facilities.</p> <p>The percentage of women with impalpable lesions undergoing open biopsy who had specimen radiography performed.</p> <p>Calculation: See Data Dictionary</p> <p>The percentage of all impalpable lesions which are correctly identified at first open biopsy through correlation of final pathology with specimen radiography findings and with screening assessment results.</p> <p>Calculation: See Data Dictionary</p>
2.22	<p>The Service minimises the proportion of women on early review.</p> <p>2.22.1</p> <p>< 0.2% of women who attend for screening are recommended for early review for further assessment. <i>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, occurs after the screening visit is complete and cancers found are considered to be interval cancers.</i></p>	<p>Percentage of women who attend for screening who are recommended for early review within 12 months of the screening visit and following an equivocal assessment outcome.</p> <p>Calculation: See Data Dictionary</p>

PERFORMANCE INDICATORS

Performance Objective	Standard	Measure
2.23 The Service ensures that women diagnosed with breast cancer are appropriately referred for treatment.	2.23-1 The Service implements a protocol for the referral of all women with a diagnosis of breast cancer to the person of their choice, either their nominated general practitioner or to a surgeon or treatment clinic with known expertise in the treatment of breast cancer.	Evidence that: <ul style="list-style-type: none"> • there is a protocol for referral of women with a diagnosis of cancer to the person of their choice • the protocol is implemented and regularly reviewed.
	2.23-2 The Service ensures that all referrals to treating clinicians for women diagnosed with breast cancer include: <ul style="list-style-type: none"> • results of tests and a diagnosis; • copies of images; • copies of pathology reports; and • a request for appropriate follow-up information. 	Examination of a random sample of referral letters for women with breast cancer which include appropriate information and test results, as well as a request for appropriate follow-up information.
	2.23-3 The Service ensures that all women with a diagnosis of breast cancer are advised in writing of their status in relation to the Program in future years.	Evidence of a process for advising women with a diagnosis of breast cancer in writing of their relationship to the Program in future years.
	2.24-1 The Service implements a protocol for: <ul style="list-style-type: none"> • the collection of information from treating clinicians, which satisfies BreastScreen Australia Data Dictionary requirements, about the surgical histopathology and primary treatment of all women diagnosed with breast cancer; and • following up those clinicians who do not respond to the initial request for information. 	Evidence of implementation of processes for requesting appropriate treatment information from relevant clinicians of all women diagnosed with breast cancer. Evidence of implementation of processes for the follow-up of clinicians who do not respond to the initial request for information.
2.24 The Service ensures the collection of treatment information about women with breast cancer.	2.24-2 All surgical histopathology and primary treatment information is requested by the Service.	Evidence of all surgical histopathology and primary treatment information being requested by the Service for all women who have been diagnosed with breast cancer by the Service.
	2.24-3 ≥ 95% of surgical histopathology information is received by the Service.	The percentage of women diagnosed with breast cancer by the Service for whom information about surgical histopathology is received by the Service. Calculation: See Data Dictionary
	2.24-4 ≥ 80% of primary treatment information is received by the Service.	The percentage of women diagnosed with breast cancer by the Service for whom information about primary treatment information is received by the Service. Calculation: See Data Dictionary

PERFORMANCE INDICATORS

Performance Objective	Standard	Measure
2.25	<p>2.25.1 The Service ensures that all cases which underwent FNA cytology or core biopsy are reviewed by a radiologist and at least one other clinician before giving the results to the woman. Where results of radiology and pathology are inconclusive or inconsistent, the cases must be reviewed minimally by a radiologist together with a pathologist.</p> <p>2.25.2 The Service implements a protocol for reviewing and correlating the clinical, radiological, cytological and histopathological findings for all lesions detected as a result of screening which required surgery.</p> <p>2.25.3 Where there is discordance between these results the Service implements a protocol for the follow-up of these women which may include:</p> <ul style="list-style-type: none"> • notification of the surgeon; • notification of the general practitioner; • notification of the woman for review and assessment at the Service or any combination of these. <p>2.25.4 Each member of the multidisciplinary assessment team attends at least five professional educational meetings per year either within or outside the Service.</p>	<p>Evidence of implementation of a protocol for the timely review of all cases which underwent FNA cytology or cor biopsy by a radiologist and at least one other clinician, and where results are inconsistent or inconclusive, by a radiologist and a pathologist.</p> <p>Evidence of processes for reviewing and correlating the clinical, radiological, cytological and histopathological findings for all lesions detected as a result of screening which required surgery.</p> <p>Evidence of appropriate follow-up of all cases where there is discordance of results.</p> <p>Evidence of attendance at least five appropriate professional educational meetings per year.</p>

3

TO ENSURE THAT SERVICES ARE ACCEPTABLE AND APPROPRIATE TO THE NEEDS OF THE ELIGIBLE POPULATION

Screening and Assessment Services will be acceptable and appropriate to all women eligible for the Program. The care provided will be appropriate for well women and will ensure: informed participation; equity of services for all eligible women; timely provision of screening and assessment; appropriate provision of results; and adequate counselling and support.

If the Service provides care which is acceptable and appropriate to the needs of the eligible population, it is more likely that women will wish to return and that high rates of rescreening will be achieved. Clients who are satisfied with the care will be more likely to provide positive comments to their friends and colleagues; the acceptability of the Service may therefore also impact on initial participation rates.

INDICATOR

The extent to which care is acceptable and appropriate to the needs of the eligible population can only be assessed by exploring the views of women themselves. The Services will therefore seek to encourage client feedback and monitor the extent to which it is perceived as acceptable and appropriate.

The Service will seek feedback from women at each of its screening sites in order to assess satisfaction with information, waiting time, the physical environment, pain and discomfort and interactions with staff. A process for reviewing, evaluating and incorporating feedback will be documented and implemented where appropriate.

While there may be many aspects of care which can be assessed by a client survey, because of the diversity of their experience, it is more difficult to assess the views of women undergoing assessment using this method. The smaller numbers of women with disabilities or from linguistically diverse or indigenous backgrounds attending the Service will make it difficult to explore issues for these groups. Likewise, there are many aspects of care which may be important to women but which cannot be included in a client survey.

For these reasons, the Service will encourage women to provide comment on the acceptability and appropriateness of care at each step in the screening pathway. Women will be actively encouraged to comment and assured of the confidentiality of their comments. Invitations to comment will be included in information material and means for confidential comment (for example, a confidential suggestion box) will be readily available. The Service will also record any key verbal comments made by women to staff members to help inform quality improvement initiatives. Consumers will also be able to provide feedback through the BreastScreen Australia web site www.cancerscreening.gov.au

Client comments will be regularly reviewed, and where necessary, strategies to improve service provision will be implemented.

Performance objective 3.1:

The Service monitors and responds to women's views about the appropriateness and acceptability of screening and assessment.

STRATEGIES

The Service will implement a range of strategies to ensure that its services are acceptable and appropriate. This will include processes to ensure:

- Informed participation
- Equity of services for all eligible women
- Timely provision of screening and assessment
- Appropriate provision of results
- Adequate counselling and support.

INFORMED PARTICIPATION

Women participating in population health programs such as mammographic screening must be fully informed about the procedure, the likely benefits and possible costs. The information provided should be sufficient to enable women to give their informed consent to participation.

If women are well informed about health services, they will be more likely to be satisfied with the care that they receive^{102,103} and to experience less emotional distress.⁹⁹ In turn, women who are satisfied with the Service will be more likely to return for subsequent screening rounds and to encourage their friends to participate. Research about patient satisfaction with medical care suggests that patient dissatisfaction leads to both delay in seeking care and non-compliance with instructions.^{104,105}

There is a growing recognition of the rights of health care consumers to information about their care.^{106,107} It is widely accepted that all individuals being screened:

- Should receive full and accurate information about the procedure and give their informed consent
- Be made aware of uncertainty where it exists, as well as side effects¹⁰⁷
- Have a right to decide what health care, if any, they will receive.¹⁰⁸

The principles of providing information to facilitate informed patient consent are outlined in the NHMRC *General guidelines for medical practitioners on providing information to patients*³¹ and suggest that women considering participating in mammographic screening services should have the following information about screening to enable them to make a properly informed decision about attendance:

- the purpose of the 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
- follow-up plans, including the availability of counselling and support services.

Information

The NHMRC recommends that women be given adequate information to fully participate in decision making.¹⁰⁹ The NHMRC also states that to make clinical decisions, consumers need quite detailed information including that related to treatment or diagnostic options, risks and benefits, their own risk level and ways to incorporate their values and cultural preferences into their deliberations.¹⁰⁹ This implies that different amounts and types of information may be needed by different women attending for screening and assessment.

Women will require specific information as they move through the screening and assessment pathway. A series of surveys of satisfaction of women participating in screening in the United Kingdom found that women emphasised that the information about screening must spell out clearly and honestly what is involved in the screening process, even at the risk of discouraging women from attending.¹⁰⁷ The information that the Service provides to women attending for screening will include the issues identified in the NHMRC *General guidelines for medical practitioners on providing information to patients*.³¹ The information provided will also advise women about what to expect during the screening process, about the process used by the Service to provide results and about opportunities to provide comment on the Screening and Assessment Services. The information should include the percentage of women likely to be recalled.

Information for women attending for assessment will include: investigations which may be required; the benefits, limitations and risks of the investigations; the possible outcomes of assessment and the process used by the Service to provide results. It will also include advice about the availability of counselling and of opportunities to provide comment on the Service. The timely provision of appropriate information will also contribute to reducing anxiety.¹¹⁰

In general, it is anticipated that Services will use information resources produced by the State Coordination Unit. If Services produce their own information resources they will be approved by the State Coordination Unit, accurate, and consistent with state and national policies, and with the BreastScreen Australia National Information Statements.

Performance objective 3.2:

The Service ensures that all women are provided with information to make informed decisions about their participation in screening and assessment.

Obtaining consent

In Australia, no medical or dental services can be carried out without the consent of the individual concerned. For consent to be valid, it must be a voluntary choice, free of coercion and given after receiving adequate and appropriate information at the individual's level of comprehension.

The role of informed consent is widely recognised in Australia. The New South Wales Government Privacy and *Personal Information Protection Act 1998*¹¹¹ emphasises that:

- Before care is provided, health services staff must obtain consent. In the case of some treatments, such as surgery, written consent must be obtained. For other types of care, verbal consent is sufficient.
- Before consent is given, health services staff will clearly explain the proposed care, significant risks and alternatives to the proposed approach in a way the patient can understand.
- Enough time should be available for the woman to ask questions about the care that is being suggested, the risks, and other options and for consultation with family/friends.

Legislation requires that written consent be obtained for all biopsy procedures.¹¹² However, it is best practice that separate written consent be obtained for each screening and assessment procedure to be undertaken. BreastScreen Australia requires that written consent is obtained from all women before the screening mammogram and before investigations at the assessment visit. All staff have a role and responsibility for ensuring that consent is based on adequate information and understanding.

The written consent form should be sufficiently detailed to cover the key aspects of consent.¹¹¹ For example, a consent form should ask for: consent to a particular procedure; consent to any other procedure considered necessary; patient acknowledgment that the procedure has been fully explained to them and that they understand. It might be helpful to have someone witness the signature. The consent process must make it clear to women that they can refuse or withhold consent to any aspect of the screening and assessment process at any point in time.

When seeking consent, the woman must be warned about any risks involved with the procedure or test. Known risks should be disclosed when an adverse outcome is common

even though the detriment is slight, or when an adverse outcome is severe even though the occurrence is rare.

In Australian law, if the client experiences an adverse consequence of the procedure about which she has not been informed, the care provider could be found to be negligent. The level of information required has been established by the High Court decision in *Rogers vs Whitaker* (1992) in which the Court noted that:

*The law should recognise that a doctor has a duty to warn a patient of a material risk inherent in the proposed treatment; a risk is material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should be reasonably aware that the particular patient, if warned of the risk would be likely to attach significance to it.*¹⁰⁸

The key issue in informed consent is that the woman has truly understood the procedure, its benefits and risks when signing a consent form. Neither a signed consent form nor the provision of written information is likely to be accepted on their own as sufficient evidence of disclosure of risk by a doctor.¹⁰⁸ There also needs to be evidence that the woman had an adequate opportunity to ask questions and to read and understand any written information and the consent form.¹⁰⁸ This can be achieved by the implementation of protocols for obtaining consent from a client.

Performance objective 3.3:
*All women provide written consent prior to screening
and to assessment procedures.*

Transfer of information or data

Within BreastScreen Australia, identified data are collected about individuals. Identified personal data contain name in full or part and street address. These data are used for a number of purposes, including providing a clinical record about the woman for the Service and for other doctors involved in the care of the woman and monitoring the quality of the Service. Performance objective 4.11 outlines the approach used by Services to ensure confidentiality and privacy.

However, there are also issues of consent in relation to the data and information held by BreastScreen, particularly where the data and information are to be transferred. The most common types of data and information transfer are the provision of results to doctors to whom women are referred and the request of information from these or other doctors. These data and information transfers are primarily to assist in the clinical care of the woman. Data transfer may also occur for monitoring purposes; for example, identified data may be transferred for the purpose of identifying interval cancers. The woman's data will also be used to generate the invitation letter for screening. Deidentified data are also used for the purposes of State and Territory and national reporting.

Services need to comply with State and Territory legislation. The *Privacy Act 1988*¹¹¹⁻¹¹⁴ requires that individuals are advised of the purpose for which information is being collected before the information is collected, or if that is not practical, as soon as possible after the information is collected. The *Privacy Act 1988* and complementary State and Territory legislation also stipulate that personal information shall not be disclosed unless the individual concerned has consented to the disclosure, or unless the disclosure is required by law or the record-keeper believes it is necessary to prevent or lessen a serious threat to the individual concerned or another person.¹¹¹⁻¹¹⁴

The *Privacy Act 1988* also outlines a sequence of steps to obtain consent from individuals to the disclosure of information. These aim to minimise the disclosure of personal health information and to protect as fully as possible the confidentiality of personal health information.

While consent must be sought before information is transferred, women must not be refused screening or assessment if they do not consent to the transfer of data.

Performance objective 3.4:
The woman's consent is obtained before identified information or data is transferred for clinical or monitoring purposes.

EQUITY OF SERVICES FOR ALL ELIGIBLE WOMEN

The Service will provide screening and assessment in an acceptable and appropriate manner that enables all women in the eligible age group to participate. However, recruitment into the Program is focused on women in the target age group.

Women from Aboriginal and Torres Strait Islander, culturally and linguistically diverse, rural and lower socio-economic backgrounds, those with a low level of literacy and with physical or intellectual disabilities may require special strategies to ensure that screening and assessment are appropriate. Depending upon the catchment, special strategies may also be required for other groups.

Australia's Charter of Public Service in a Culturally Diverse Society¹¹⁵ recognises that access and equity policies should aim to ensure that government services meet the needs of people from diverse cultural and linguistic backgrounds so that they can participate fully in economic, social and cultural life. This document has been recognised at the Australian Government, State and Territory and local government levels. The Charter identifies seven principles for delivering services in a culturally and linguistically diverse society. Several of these principles are of special relevance to BreastScreen Australia, including:

- Access: Government services should be available to everyone who is entitled to them and should be free of any form of discrimination irrespective of a person's country of birth, language, culture, race or religion

- Equity: Government services should be developed and delivered on the basis of fair treatment of clients who are eligible to receive them
- Communication: Government service providers should use strategies to inform eligible clients of services and their entitlements and how they can obtain them. Providers should also consult with their clients regularly about the adequacy, design and standard of government services
- Responsiveness: Government services should be sensitive to the needs and requirements of clients from diverse linguistic and cultural backgrounds and responsive as far as practicable to the particular circumstances of individuals.

Women from culturally and linguistically diverse backgrounds

Twenty-three per cent of the Australian population is born overseas and 66% of these people were born in a country in which English is not the first language.¹¹⁶ In the 1996 Census, approximately 154,000 women aged 55–64 years and a further 130,000 aged 65–74 years indicated that they spoke a language other than English at home.¹¹⁶ Unfortunately, the Australian Bureau of Statistics does not have a category for women aged 50–69 years. Approximately 50,000 women aged 55–64 years and a further 101,000 women aged 65–74 years indicated that they were not proficient in English.¹¹⁶ In order, the most common community languages spoken by women who are not proficient in English are: Chinese, Italian, Greek, Arabic, Vietnamese and German.¹¹⁶

Women from linguistically diverse backgrounds may face language difficulties while attending for screening and assessment. Since the proportion of women speaking languages other than English will vary by Service catchment, each Service will ensure that written information about screening and assessment is available in locally common community languages. Special attention will be paid to ensuring that consent is understood, and this may include the use of translated consent forms or an appropriate interpreter.

The Service will ensure that appropriate interpreter services are available. It will have in place a protocol to ensure that women are asked when they book about whether or not an interpreter is required. It is not advisable to use a friend or family member as an interpreter, since only qualified interpreters can ensure that all of the information is fully translated.

Women from different cultural backgrounds may also have different beliefs, attitudes, feelings and emotions stemming from underlying cultural perceptions of illness and well being. Such issues must be taken into account for the Service to provide screening and assessment which is appropriate to the different groups in the catchment area.

Consultation with relevant ethnic community groups and involvement of cross-cultural health workers will assist in ensuring that services are appropriate and provided in a manner which is culturally appropriate to the different groups within the catchment.

The Service will offer women attending screening and assessment an interpreter appropriate to the needs of the individual. Ethnic health workers, if present, will also be able to assist women attending for screening and assessment; strategies will be in place to encourage their involvement.

Women from Aboriginal and Torres Strait Islander backgrounds

Based on 1996 Census data, there are approximately 12,000 Aboriginal and Torres Strait Islander women aged 55–64 years in Australia and a further 5,300 aged over 65 years.¹¹⁶ However, this is likely to be a conservative estimate due to the difficulties surrounding accurate reporting among indigenous Australians.

Collaboration with Aboriginal and Torres Strait Islander community representative bodies will assist in ensuring that services are appropriate and provided in a manner which is culturally appropriate to the different groups within the catchment. Collaboration with Aboriginal Community Controlled Health Services has played a significant role in enhanced participation rates and should be continued. Partnerships with these services can ensure that mammographic screening is approached in a holistic primary health care framework through the support of Aboriginal Health Workers. Collaborative efforts should be appropriately acknowledged and reported as part of Performance objective 1.3c.

The provision of an appropriate service will also be assisted by encouraging staff to participate in cultural awareness training on a regular basis. This should involve training about indigenous cultural issues as well as other cultures. All staff, including clinical staff, should attend at least one cultural awareness training course as it enables participants to explore cultural assumptions and to increase their understanding of different cultures. It assists in understanding cultural differences in communication and provides skills to remove cultural barriers to communication. Staff should maintain their skills in this area.

Performance objective 3.5:

The Service meets the needs of women from indigenous and culturally and linguistically diverse backgrounds by recognising linguistic, cultural and socio-economic diversity.

Women with a disability

Since women with a disability are as much at risk of breast cancer as other women, every effort should be made to ensure that services are acceptable to and appropriate for these women.

The Australian Bureau of Statistics 1993 report estimated that there were approximately 95,000 profoundly or severely handicapped women aged 50–69 years and a further 280,000 moderately or mildly handicapped.¹¹⁷ Moderately handicapped women may experience difficulty or need help in performing some tasks such as using stairs, public transport or walking 200 metres or more.¹¹⁷

Several strategies will be implemented to ensure that screening and assessment is acceptable and appropriate for women with a disability and these will be outlined in a written protocol. All staff of the Service will be adequately trained and equipped to provide care to people with a disability.¹¹⁸ Depending upon the needs of the woman, protocols will be in place to allow for the provision of longer appointment times, additional staff, and access to a nurse/counsellor. Where appropriate, Services will endeavour to facilitate transport for women with a disability.¹¹⁹

All women with disabilities, and with their agreement, their families and carers, will have full access to information about the services available and about how their particular needs will be met. The support and information offered will focus on the needs of the individual woman.

Some women with intellectual disability and/or low level of literacy may need a different type of information in order to provide fully informed consent. This information might best be developed by the State Coordination Unit; if it is developed by the Service it will be approved by the State Coordination Unit.

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. These guidelines will vary slightly in different jurisdictions. For example, New South Wales Health¹¹¹ recommends that if someone is incapable of deciding for themselves about participation in health care, consent will be asked of their guardian if they have one, or of the patient's spouse or de facto partner. If there is no partner or carer, consent can be asked of a close personal friend or relative. If there is no one to give consent or if there is dispute over who should give consent, then health professionals will seek advice from the relevant Guardianship Authority. The Service should have a protocol for such circumstances.

For women with a physical disability, appropriate physical access will be provided as outlined in the Australian Standard 1428, which outlines appropriate environmental specifications such as the provision of ramps, width of corridors, design of toilets and doors. Each Service will have at least one screening unit and one assessment unit that complies with Australian Standard 1428.

A woman's nominated general practitioner will be informed if a woman seeks advice about participating in or attends for screening or assessment and the service cannot be provided as a result of her disability.

Performance objective 3.6:

The Service meets the needs of women with disabilities.

TIMELY PROVISION OF SCREENING AND ASSESSMENT

If the Program is to be acceptable to women, there will be a timely progression through the screening and assessment pathway.

Timely service provision is likely to encourage high rates of participation in screening, since there is some evidence that practical difficulties in arranging times for appointments discourages women from attending for both first screening¹²⁰ and for rescreening.^{39,121} If women are able to organise a prompt appointment and to move through the screening and assessment process without undue delay, they will be better able to integrate screening within the other aspects of their lives.

Timely progression through the screening and assessment pathway will also contribute to reducing anxiety.^{96,122}

However, the commitment to timely service provision must not be allowed to compromise the provision of high quality screening and assessment. The special challenges of providing high quality services in some rural and remote areas because of their geographic isolation must be recognised in considering appropriate standards as well as workforce shortages in some Services.

It is recognised that not all Services will meet all of the standards about timely progression through the screening and assessment pathway. If a Service is not achieving a standard, the reasons should be analysed and targeted strategies for improving implemented. The NQMC will consider accrediting Services who do not meet a standard based on: the reasons provided for not meeting the standard; demonstration of quality improvement processes and targeted strategies for improving; and trend data to indicate that the standard is increasing over time.

Booking to appointment

The Service will ensure that women are able to attend for screening within a reasonable period from the time they make an appointment. There is some evidence from the United Kingdom that waiting intervals of greater than 14 calendar days to obtain mammography appointments may decrease participation in screening.¹²³

Women should attend for screening within 28 calendar days of their booking date at a fixed site. A fixed site is defined as a screening or assessment clinic that is permanent and does not relocate to alternative locations. However, it can be difficult for mobile units to meet this standard, as appointments are based on the travelling schedule.

Screening to assessment

There is considerable evidence that women experience anxiety when recalled for assessment.¹²⁴⁻¹²⁹

In the 1994 NARs, the standard was that 90% of women should attend for assessment within 10 days of screening. However, of the 24 Services for which data were available (see Appendix D), only one Service provided assessment within 10 working days of screening for 90% of women or more. Six Services reported attendance within 10 working days for between 70–89% of women, six Services between 60–69% of women and 11 Services did not meet the standard at less than 60% of women. Most Services were therefore unable to meet or come close to meeting this standard.

There are several reasons why it may not be possible to provide assessment within 10 working days of screening: 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 linguistically diverse backgrounds.

Nonetheless, given the anxiety generated by a recall to assessment, the Service will work towards ensuring that the delay between screening and the assessment appointment is

as short as possible. The Service will therefore aim for at least 90% of women requiring assessment to attend an appointment date within 28 calendar days of their screening visit. Future Service data will help inform the monitoring and review of this standard over time.

Assessment to open biopsy where relevant

Minimising the waiting time between the recommendation for, and performance of, open biopsy reduces anxiety and psychological impact.^{96,122}

For most women, open biopsies can occur within 14 calendar days of the assessment visit. However, it is recognised that there will be some exceptions which will result in delays beyond the control of the Service. These include: patient preference or deferment; hospital waiting lists; medical indications to exclude or defer surgery; and non-availability of surgeons.

The number of women experiencing delays other than those due to patient preference will be minimised. The Service will examine cases where the time between the recommendation for, and performance of, an open biopsy exceeds 14 calendar days and implement a plan to reduce waiting times. Where open biopsy is performed outside of the Program, it is recognised that the Service has less control over the timing. However, the Service still has a responsibility to ensure that all care is provided in a timely manner and should work with external service providers to ensure that open biopsies are performed promptly.

Information will be provided to women about waiting times. This will be in accordance with the National Information Statement, under development, on this issue.

Performance objective 3.7:

The Service ensures that women progress through the screening and assessment pathway in a timely manner.

APPROPRIATE PROVISION OF RESULTS

Women report considerable anxiety while waiting for the results of screening and assessment.^{130,131} Informing the woman of the results of her screening and assessment promptly will help ensure that any period of anxiety is as brief as possible. Prompt provision of results will also improve satisfaction and possibly influence the likelihood of returning for rescreening.

However, the special challenges of providing high quality services in some rural and remote areas because of their geographic isolation must be recognised in considering appropriate standards. It is recognised that not all Services will meet all of the standards about the appropriate provision of results. If a Service is not achieving a standard, the reasons should be analysed and targeted strategies for improving implemented. The NQMC will consider accrediting Services who do not meet a standard based on: the reasons provided for not meeting the standard; demonstration of quality improvement processes and targeted strategies for improving; and trend data to indicate that the standard is increasing over time.

During a screening episode, women may receive the results of screening or assessment, which may include FNA and core biopsy. While the majority of women who are assessed will not be found to have breast cancer, the communication of a breast cancer diagnosis will require special care.

Provision of results of screening and assessment

RESULTS OF SCREENING

Women will receive a letter informing them of the results of screening. Adequate time needs to be allowed for the processing and reporting of mammograms. Although this is achievable for most women within 14 calendar days of screening, the reporting of images may take a little longer for a small number of women. For example, the radiologist may need to re-examine previous images and remote Services may face challenges in transporting images over long distances for reading and infrequent assessment.

Given the anxiety resulting from a delay in receiving results, the Service will seek to ensure that at least 90% of women receive a letter informing them of their results within 14 calendar days of screening and that **all** women receive their results within 28 calendar days. For some women who require assessment, a verbal contact will be made prior to them receiving their written results to arrange for them to attend an assessment clinic.

Women come from a diverse range of backgrounds; results of screening and assessment need to be delivered in a way that is sensitive and appropriate to the needs of the woman. Women need to be offered ample opportunity to ask questions.

RESULTS OF ASSESSMENT—NOT REQUIRING BIOPSY

Women experience considerable stress and anxiety during assessment.¹³⁰ There is some evidence that most women with a benign diagnosis have their anxiety lessened by receiving the result on the day.¹³¹

Almost all women who do not require biopsy as part of the work-up of a screen-detected abnormality can be provided with a definitive outcome of assessment on the day (see Section 2 for a definition of definitive outcome of assessment). However, this may not be possible for a small number of women. For example, additional time may be required if the woman has had previous breast surgery which resulted in scarring—in this case, previous mammograms may need to be obtained from outside the Service for review.

RESULTS OF ASSESSMENT—REQUIRING FINE NEEDLE ASPIRATION OR CORE BIOPSY

As women move through the assessment pathway, their anxiety will increase. A small proportion of women will have an FNA or core biopsy and these results may not be available on the day of assessment.

The Service will provide most women who have an FNA or core biopsy with their results verbally within seven calendar days of the assessment procedure. For a small number of women, it may take longer to provide the results. For example, if more core samples are taken it may take longer to process, the pathologist may wish to seek a second opinion or there may be delays in reporting due to exceptional pathology workload.

All histological and cytological results will be given by a clinical member of the assessment team. All women who have FNA or core biopsy will be provided with an opportunity to ask questions of a clinician about the meaning of the results, regardless of whether the test result is or is not indicative of cancer. The woman should have the opportunity to ask questions about the results and the next steps.

A benign diagnosis will still require discussion with the woman; for example, if the diagnosis is a fibroadenoma the woman may have questions about the significance of the condition, the options for management and whether it may develop into cancer.

Women who are diagnosed with breast cancer will be told in person by a clinician. A member of staff responsible for providing counselling will also be present (unless the woman requests not), so that they have all of the information available to them that has been provided to the woman. Women should be encouraged to return to receive their results in person. However, it may be the woman's preference to be given her results over the telephone or by her local general practitioner and if so, this should be negotiated at the time of biopsy and documented. All women, including those told their results over the telephone or by their local general practitioner, should have access to counselling.

In addition, all women who have an FNA or core biopsy will be told their results and receive **written** notification of their results within 14 calendar days.

Performance objective 3.8:

The Service ensures that the results of screening and assessment are provided to women in a timely and appropriate manner.

A diagnosis of breast cancer

PROVIDING THE RESULTS

Particular care will be taken in informing a woman of a diagnosis of breast cancer. The way in which this information is relayed can affect a woman's understanding of her illness and can also impact on her longer term psychological adjustment.^{132,133}

Consensus guidelines about the recommended approach to informing women of a diagnosis of breast cancer have been published by the NHMRC.³² These guidelines have been agreed by clinicians and consumers and endorsed by the NHMRC. The key recommendations from these guidelines are outlined in Appendix U.

INFORMATION ABOUT TREATMENT OPTIONS

When a diagnosis of breast cancer is given, the woman should be provided with information about treatment options and where to access additional information.

The NHMRC *Clinical practice guidelines for the management of early breast cancer* state that:

*Women are entitled to make their own decisions about treatments or procedures and should be given adequate information on which to base those decisions.*¹³⁴

The majority of women want to be involved in decisions about their treatment,¹³⁵ and the NHMRC recommends that consumers are provided with appropriate information based on relevant clinical guidelines. The NHMRC notes that information for consumers should be as rigorously prepared, evidence-based and as broad-ranging as information for health professionals. It should focus on outcomes and be based on the best available evidence.

Evidence-based consumer guides have been developed from the NHMRC *Clinical practice guidelines for the management of early breast cancer*,¹³⁴ *Clinical practice guidelines for the management of advanced breast cancer*¹³⁶ and *The clinical management of ductal carcinoma in situ, lobular carcinoma in situ and atypical hyperplasia of the breast*.¹³⁷ These guides are entitled *A guide for women with early breast cancer*,¹³⁸ *A guide for women with metastatic breast cancer*,¹³⁹ *Ductal carcinoma in situ: Understanding your diagnosis and treatment*¹⁴⁰ and *Lobular carcinoma in situ and atypical hyperplasia of the breast: understanding your diagnosis*.¹⁴¹

Women should be provided with a copy of these consumer guides.

Performance objective 3.9:

Women are informed of a diagnosis of breast cancer in an appropriate manner and provided with information about their treatment options.

ADEQUATE COUNSELLING AND SUPPORT

Women may require counselling and support at any time throughout the screening and assessment process. However, the need for emotional support is likely to be more acute if the woman is diagnosed with breast cancer.

Counselling

Counselling can assist women in managing anxiety resulting from screening, assessment or a diagnosis of breast cancer.

Although most women are not unduly anxious during screening, a small minority may be concerned, perhaps because of previous personal or family experiences. More women will experience increased anxiety when they are recalled to assessment.¹²⁴⁻¹²⁸ For these women,

the opportunity to talk with a counsellor may provide more information about screening and assessment and a chance to discuss any concerns.¹⁴² Counselling must be provided in uninterrupted privacy. As women who are attending for assessment or to receive pathology results are likely to be more anxious, they will have access to counselling on site. Women should be encouraged to ask questions at the assessment session or at any other time. If women decide to have their results given over the telephone, information about the availability of counselling will be provided and counselling will be available over the telephone if requested. The counselling should offer an opportunity to explore the woman's concerns and provide immediate support. Counselling within the screening and assessment context should aim to refer women with needs for further support to other agencies and to assist 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 (see also Appendix J).¹⁴³ Staff providing counselling should 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 in offering the opportunity for debriefing of 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 provided by an appropriate counsellor on an as needs basis.

Performance objective 3.10:
***Appropriate counselling is offered to women and
their support person/s.***

General practitioners

General practitioners provide information and support for women throughout the screening and assessment process, and this is particularly important if the woman is diagnosed with breast cancer.¹⁴⁴ NHMRC guidelines³² stress the key role played by general practitioners in ensuring support and continuity of care for women 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.

All women who attend for screening or who are recalled for assessment will be given the opportunity to nominate a general practitioner who will be informed of their results. The nominated general practitioner will be sent the results at the same time as the woman.

If a woman is diagnosed with breast cancer or recommended for open biopsy, the Service will ensure that all reasonable efforts are made to inform the woman's nominated general practitioner on that day 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, Aboriginal health workers, rural community health workers and ethnic health workers may be the first port of call for information and support for some women. In these cases and at the woman's request, the Service will notify these health care providers of the woman's results in addition to her general practitioner.

Performance objective 3.11:

The Service assists general practitioners and other health care providers to support women through all stages of the screening and assessment pathway.

PERFORMANCE INDICATORS

Performance Objective	Standard	Measure
3.1	<p>3.1.1 The Service actively seeks feedback from women about the acceptability and appropriateness of screening and assessment. For example, but not limited to:</p> <ul style="list-style-type: none"> • information; • waiting time; • physical environment; • staff; and • pain and discomfort. <p>A process for reviewing, evaluating and incorporating feedback is documented and implemented.</p>	<p>Evidence of:</p> <ul style="list-style-type: none"> • strategies to encourage and record client feedback at each step of the screening and assessment pathway • monitoring, review and evaluation of client feedback • implementation of processes to improve service based on consumer feedback, where appropriate.
3.2	<p>3.2.1 Written information, which has been approved by the State Coordination Unit and is consistent with state and national policies is available to all women attending for screening, and includes:</p> <ul style="list-style-type: none"> • purpose of screening; • likelihood of recall; • possibilities of false positive and false negative results; • uncertainties and risks; • rescreening. 	<p>Evidence that appropriate written information is available to all women attending for screening.</p>
	<p>3.2.2 Written information, which has been approved by the State Coordination Unit and is consistent with state and national policies, is available to all women attending assessment. It includes:</p> <ul style="list-style-type: none"> • the investigations which may be required; • the benefits, limitations and risks of the investigations; • the possible outcomes of assessment. 	<p>Evidence that appropriate written information is available to all women who attend assessment.</p>

PERFORMANCE INDICATORS

Performance Objective	Standard	Measure	
3-3	3-3.1 All women provide written consent prior to screening and assessment procedures.	<p>Women are offered the opportunity to ask questions in private before giving consent for any procedure. Health care providers are available to answer any clinical questions.</p>	<p>Evidence that there are strategies to ensure that:</p> <ul style="list-style-type: none"> women are offered the opportunity to ask questions in private staff understand the importance of encouraging questions health care providers are available to respond to clinical questions
	3-3.2 The consent forms provide a record that information has been given and understood to the woman's satisfaction. The forms clearly indicate that the woman may decline or request discontinuance of a procedure at any time.	<p>Evidence that the consent forms provide an appropriate record that information has been understood and that the woman can decline or request discontinuance of a procedure at any time.</p>	
	3-3.3 Written consent is obtained from all women before:	<ul style="list-style-type: none"> the screening mammogram; investigations at the assessment visit. 	<p>Evidence that separate and prior consent is obtained for screening and for any assessment procedure.</p>
3-4	3-4.1 The woman's consent is obtained before identified information or data are transferred for clinical or monitoring purposes.	<p>Written consent is obtained from the woman before:</p> <ul style="list-style-type: none"> her general practitioner, or other doctor to whom she is referred, is notified of her results the Service requests information about procedures and treatment from doctors to whom she is referred data, including identifying details, are transferred for clinical and monitoring purposes or released in any form she is sent an invitation letter for rescreening. 	<p>Evidence that:</p> <ul style="list-style-type: none"> there are processes for ensuring that transfer and use of information or data occurs only when prior consent has been given by the woman these procedures are reviewed and implemented.

PERFORMANCE INDICATORS

Performance Objective	Standard	Measure
3.5 The Service meets the needs of women from indigenous and culturally and linguistically diverse backgrounds by recognising linguistic, cultural and socio-economic diversity.	3.5.1 The Service has protocols for service delivery to women from (a) indigenous and (b) culturally and linguistically diverse backgrounds, which have been developed in collaboration with relevant organisations that reflect the socio-demographics of the Service.	Evidence that: <ul style="list-style-type: none"> • there are protocols to ensure appropriate service delivery to women from (a) indigenous and (b) culturally and linguistically diverse backgrounds • the protocols are implemented and reviewed
	3.5.2 Information in the common community languages represented in the Service catchment are available for women attending for screening and assessment.	Evidence of information in the common community languages for women attending for screening and assessment.
	3.5.3 The Service ensures that: <ul style="list-style-type: none"> • women are asked when they book if an interpreter is required • a gender appropriate interpreter is available for women attending for screening and assessment whenever possible • a telephone interpreter service is used if an interpreter cannot attend in person. 	Evidence that appropriate interpreters are used.
	3.5.4 All staff attend at least one cultural awareness training course.	Documentation of the staff who have attended cultural awareness training.

PERFORMANCE INDICATORS

Performance Objective	Standard	Measure
3.6	The Service meets the needs of women with disabilities.	Evidence of the implementation of a protocol to ensure the appropriate management of women with a disability who undergo screening and/or assessment.
3.6.1	<p>The Service has a protocol to ensure the appropriate management of women with a disability, which:</p> <ul style="list-style-type: none"> • has been developed in consultation with relevant organisations; • requires that appropriate information and support is available to women with an intellectual disability and/or a low level of literacy; • requires that appropriate consent is obtained; • requires that additional staff and longer appointment times be made available if necessary; • requires that, with the woman's consent, her nominated general practitioner is informed if a woman seeks advice about participating in or attends for screening or assessment and the service is unable to be provided as a result of the woman's disability. 	Evidence of compliance with AS1428 for at least one screening unit and one assessment unit within a Service.
3.6.2	The Service complies with AS1428 for at least one screening unit and one assessment unit.	Evidence of compliance with AS1428, or documentation of barriers to compliance, for new sites or sites undergoing refurbishment.
3.6.3	New units and units undergoing refurbishment comply with AS1428, wherever possible.	Evidence of compliance with AS1428, or documentation of barriers to compliance, for new sites or sites undergoing refurbishment.

PERFORMANCE INDICATORS		
Performance Objective	Standard	Measure
3.7 The Service ensures that women progress through the screening and assessment pathway in a timely manner.	3.7.1 ≥ 90% of women attend for a screening appointment within 28 calendar days of their booking date (fixed sites only).	The percentage of women who attend for a screening appointment within 28 calendar days of their booking date. Calculation: See Data Dictionary
	3.7.2 (a) ≥ 90% of women requiring assessment attend an assessment visit within 28 calendar days of their screening visit.	The percentage of women requiring assessment who attend for an assessment visit within 28 calendar days of their screening visit. Calculation: See Data Dictionary
	3.7.2 (b) All women will be provided with information on waiting times.	Evidence of information being provided to women who have not attended their assessment visit within three months of the screening visit about the reasons for the delay.
	3.7.2 (c) Programs will collect data on: <ul style="list-style-type: none"> • date of screening; • date of screening result notification; • date of offered assessment appointment; • date of attendance at assessment; and be able to calculate the time taken for all women to attend assessment.	Evidence that these data are routinely collected and that the waiting times are regularly monitored.
3.7.3 ≥ 70% of open biopsies are performed within 14 calendar days of the recommendation for the procedure.	The percentage of women who undergo open biopsy within 14 calendar days of the recommendation for the procedure. Calculation: See Data Dictionary	
3.7.4 Where ≥ 70% of open biopsies are not performed within 14 calendar days of the recommendation, the Service implements a plan to reduce waiting times.	Evidence of the implementation of a plan to reduce waiting times.	

PERFORMANCE INDICATORS

Performance Objective	Standard	Measure
3.8 The Service ensures that the results of screening and assessment are provided to women in a timely and appropriate manner.	3.8.1 ≥ 90% of women have a letter sent notifying them of the results of screening in writing, within 14 calendar days of the date of screening.	The percentage of screening episodes where women have a letter sent notifying them of the results of screening, within 14 calendar days of the date of screening. Calculation: See Data Dictionary
	3.8.2 All women are notified of the results of their screening in writing, within 28 calendar days of the date of screening.	The percentage of screening episodes where women have a letter sent notifying them of the results of screening within 28 calendar days of the date of screening. Calculation: See Data Dictionary
	3.8.3 ≥ 70% of women are verbally given the results of: (a) FNA biopsy within seven calendar days of the assessment procedure. (b) core biopsy within seven calendar days of the assessment procedure.	(a) The percentage of women who have FNA biopsy at assessment who are verbally given the results of cytology within seven calendar days. Calculation: See Data Dictionary (b) The percentage of women who have core biopsy at assessment who are verbally given the results of histology within seven calendar days. Calculation: See Data Dictionary
	3.8.4 All women receive the results of FNA biopsy or core biopsy in writing within 14 calendar days of the assessment procedure.	The percentage of women who have FNA biopsy at assessment who are given the results in writing within 14 calendar days. Calculation: See Data Dictionary
	3.8.5 All histological and cytological results are given by a clinical member of the assessment team.	Evidence that: there is a protocol to ensure that an appropriate member of the assessment team provides results the protocol is implemented and reviewed.
	3.8.6 All women are notified of the results of their assessment in writing within 14 calendar days of the date of completion of assessment.	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. Calculation: See Data Dictionary

PERFORMANCE INDICATORS

Performance Objective	Standard	Measure
3.9 Women are informed of a diagnosis of breast cancer in an appropriate manner and provided with information about their treatment options.	3.9.1 All women diagnosed with breast cancer are told their results by a clinician in accord with the recommendations in Appendix U and with a member of staff responsible for providing counselling present, unless the woman specifically asks them not to be.	Evidence that: there is an appropriate protocol for informing women of a diagnosis of breast cancer the protocol is implemented and reviewed.
	3.9.2 All women diagnosed with breast cancer are: <ul style="list-style-type: none"> • provided with the consumer guide based on NHMRC clinical practice guidelines • encouraged to discuss options with their clinician. 	Evidence that: <ul style="list-style-type: none"> • there is a protocol for provision of appropriate information • the protocol is implemented and reviewed.
3.10 Appropriate counselling is offered to women and their support person/s.	3.10.1 All women who attend for screening and their support persons have access to counselling.	Evidence of the availability of a counsellor for women who attend for screening.
	3.10.2 All women who attend for assessment or to receive pathology results and their support persons have access to counselling <u>on-site</u> .	Evidence of the availability for at least one counsellor on site at assessment and pathology results sessions.
	3.10.3 Counselling for women and their support persons is provided in uninterrupted privacy and is appropriate for a screening program.	Evidence that: <ul style="list-style-type: none"> • there are protocols providing appropriate counselling to women and their support persons • the protocol is implemented and reviewed. Evidence of a private area available for counselling women and their support persons.
3.10.4 All counselling is provided by staff who have specialist knowledge of breast screening and assessment and relevant counselling skills and training (see Appendix J).	3.10.4 All counselling is provided by staff who have specialist knowledge of breast screening and assessment and relevant counselling skills and training (see Appendix J).	Evidence that staff providing counselling have specialist knowledge of breast screening and assessment and relevant counselling skills and training (see Appendix J).
	3.10.5 All staff who provide counselling have access to professional support provided by an appropriate counsellor.	Evidence that staff providing counselling have access to professional support by an appropriate counsellor.
3.11 The Service assists general practitioners and other health care providers to support women through all stages of the screening and assessment pathway.	3.11.1 All women screened are asked to nominate a general practitioner to whom their results will be forwarded.	Evidence of implementation of a protocol which ensures that all women screened are asked to nominate a general practitioner to receive a copy of the results of screening.

PERFORMANCE INDICATORS

Performance Objective	Standard	Measure
3.11.2	All women recalled for assessment are asked to confirm or nominate a general practitioner to whom their results will be forwarded.	Evidence that all women recalled to assessment are routinely asked to confirm or nominate a general practitioner.
3.11.3	The Service has a protocol to ensure that the nominated general practitioner is notified of all results in writing on the same day as the woman.	Evidence of implementation of a protocol for notifying both the woman and her nominated general practitioner on the same day and by letter of the outcome of screening or assessment.
3.11.4	The Service has a protocol to ensure that all reasonable efforts are made to notify a woman's nominated general practitioner on the day of any diagnosis of cancer or recommendation for open biopsy.	Evidence that: <ul style="list-style-type: none"> there is a protocol for ensuring that all reasonable efforts are made to notify a woman's nominated general practitioner on the day a cancer is diagnosed or a recommendation for open biopsy is made the protocol is implemented and reviewed.
3.11.5	The Service allows women to nominate a health care provider, in addition to their general practitioner, to receive their results if they request to do so.	Evidence that: <ul style="list-style-type: none"> there is a protocol for allowing women to nominate a health care provider, in addition to their general practitioner, if they request to do so and for ensuring that results are forwarded the protocol is implemented and reviewed.

4

TO ENSURE THAT SERVICES ARE MANAGED EFFECTIVELY AND EFFICIENTLY

High standards of care for women and efficient use of resources depend upon effective management of all aspects of the Service.

STRATEGIES

The Service will implement a range of strategies to ensure the delivery of high standards of care for women and the efficient use of resources. These strategies aim to ensure:

- Effective and appropriate service management
- Staff effectiveness
- Commonly implemented policies, protocols and procedures
- Appropriate facilities for effective data management.

EFFECTIVE AND APPROPRIATE MANAGEMENT STRUCTURE

The Service is responsible for the delivery of high quality screening and assessment to the eligible women in its catchment area. The Service should therefore ensure that it operates within the Service agreement with the relevant State and Territory coordinating bodies and that its management structure encourages the participation of all key stakeholders, including consumers.

Ensuring accountability and efficient use of resources

The Service is responsible to its relevant State and Territory coordinating body for all aspects of screening and assessment. This line of responsibility helps to ensure that high standards are maintained using the resources available and that clients experience consistency of service delivery. The standards in this document are the benchmarks by which every BreastScreen Australia Service must operate, and this should be reflected in the contractual agreements with state coordinating bodies.

In addition, the Service 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. Processes must be in place to ensure that the Service's financial management systems are accountable and transparent. The Service and the State Coordination Unit are also responsible for ensuring that units set up for screening reach a minimum annual throughput. The planning of where to set up screening sites needs to be considered in light of the resources to ensure an adequate throughput of women.

It is important that units screen a minimum number of women to help ensure that resources are used efficiently and staff gain adequate experience.

A screening unit can be either a fixed or mobile/relocatable service. A mobile unit or relocatable unit operating in different locations is considered to be a screening site.

In urban areas and major provincial towns the screening unit will screen a minimum of 4,000 women per year. In rural or remote areas, the screening unit will screen a minimum of 3,000 women per year. Screening units should be linked to the Screening and Assessment Service and have quality improvement processes in place.

Screening units that can demonstrate that the radiographers are employed, managed and professionally linked (ie attendance at two assessment sessions per year, participating in radiography quality assurance activities) to the Screening and Assessment Service are not required to meet the throughput standards. Screening units that have radiographers who are only professionally linked are required to meet the throughput standards. This standard avoids the potential for small sites to operate in isolation.

The Service Director is responsible for reporting to relevant State and Territory and national bodies about how the Service is managed, delivered and monitored on a regular basis and according to written agreements.

Performance objective 4.1:
The Service ensures that requirements for accountability of service management are met.

Involvement of key stakeholders

The Service should actively encourage and support representation of key stakeholders on committees or reference groups. Participation of key stakeholders in the management structure of Services helps ensure that the service provided is appropriate and of high quality.

There is currently a growing level of support for increased consumer participation in decision making at all levels of the health care system.¹⁴⁵ The principle of consumer participation in the planning and implementation of health care is increasingly being recognised as critical to the development of health systems which promote the health and wellbeing of communities.¹⁴⁶ The Australian Government has developed a strategic plan to strengthen the focus on consumers in health service planning, delivery, monitoring and evaluation in Australia.¹⁴⁷

Consumer participation should be encouraged by ensuring that there are at least two consumer representatives on any policy or advisory committees at a Service or State Coordination Unit level, which may be established. In this context, a consumer representative can be defined as a woman, aged 40 years or older, who has experienced screening and/or assessment in the BreastScreen Australia Program or has a keen interest in the Program or women's health service provision in general. A consumer representative should be able to represent the views of women attending the Program.

Consumer participation may be fostered by ensuring consumer representatives have access to training and support opportunities in order that they are familiar with the policies, protocols and procedures of the Service and adequately equipped with advocacy skills. A designated member of the Service staff will have responsibility for providing access to these opportunities and supporting consumer representatives. In addition, all staff at the Service will receive specific training about the rights of consumers and their roles and responsibilities, so that an active relationship between the Service and consumers is fostered at all levels. The State Coordination Unit should provide support for the effective involvement of consumers by assisting with the identification and training of representatives.

Performance objective 4.2:
The Service encourages participation of key stakeholders in its structure, processes and activities.

MAXIMISING STAFF EFFECTIVENESS

Services should ensure that screening and assessment services are provided by staff with appropriate training and expertise and who participate in ongoing training, continuing education and quality improvement programs.

Staff training and development

Staff will be appropriately trained and qualified in their discipline/area prior to beginning work in the Program. The expertise, experience and training standards for staff are outlined in Appendix J. However, within a quality improvement framework, ongoing training and continuing education for all staff is necessary to maintain and improve staff skills and knowledge and to ensure the delivery of an up-to-date, high quality service for women.

In Australia, there are agreed standards for minimum training at entry for many disciplines/areas, although the ways in which these are achieved may be different from jurisdiction to jurisdiction and for different disciplines/areas. Training programs in Australia and overseas have been established in different ways. For example, some countries have used national training centres; others have created infrastructure and responsibilities for training at the regional/local level; others have focused on unidisciplinary training.

The Service will develop and implement a planned approach to ongoing training. Continuing education programs will foster both unidisciplinary and multidisciplinary education.

When unidisciplinary education occurs, it will be conducted in conjunction with the relevant professional colleges. Multidisciplinary educational meetings will be held by Services on a regular basis to facilitate continuing education and implementation of local quality improvement processes (see Performance objective 2.25.4).

In-service training will be offered to all staff and cover at least an introduction to all aspects of screening and assessment of women, knowledge of disability services, occupational health and safety, cultural awareness and the importance of helping women to understand the information with which they are provided. In-service training is arranged by the Service but may, or may not be, physically conducted at the Service.

Performance objective 4.3:
All staff employed by the Service have appropriate expertise, experience and training.

Integrated screening and assessment

Service staff will be part of an integrated Screening and Assessment Service. The various aspects of the screening and assessment pathway require staff with particular skills and expertise, and clearly delineated roles and responsibilities. However, these individual aspects form part of a continuum of care for women. All staff must have a working appreciation of all aspects of the pathway so they feel well supported in their role and can provide optimum support to women through the screening and assessment process.

The potential exists for screening unit staff in particular to work in isolation. Services should implement processes to ensure that screening and assessment unit staff work in a collaborative relationship as part of a team. This will require liaison and exchange between the screening staff and the assessment centre staff. In particular, at least one of the screen readers should be part of an assessment team to ensure radiological liaison. Likewise, liaison and overlap between staff in the screening units and assessment centre should be ensured. This may be through shared education programs or by encouraging screening staff to spend time at the assessment centre.

Performance objective 4.4:
The Service ensures that all staff of screening units are an integrated part of the assessment unit.

Comprehensive quality improvement program

Quality improvement programs have been shown to result in improvements in care¹⁴⁸ and in greater provider and consumer satisfaction.^{149,150} BreastScreen Australia has a comprehensive quality improvement program supported at the national, State and Territory and Service levels.

The Service will implement a number of strategies which support a quality improvement program in the screening setting including: individual case review; review of missed cancers and interval cancers; provision of educational meetings; review of comments from consumers and other key stakeholders; provision of unidisciplinary and multidisciplinary continuing education activities; review of Service policies and procedures; and review of program data to identify current and emerging issues in service delivery.

Staff will be supported and encouraged to participate in such activities and will be actively informed about national directions in quality improvement and opportunities for quality improvement activities within the Service. The Service can implement quality improvement programs across a number of areas of service delivery. Areas for quality improvement could include the auditing of pathology reports, reviewing consumer satisfaction with information provision, and communication with general practitioners. The Service can also nominate areas which require particular attention at a particular time.

Quality improvement activities should be reviewed annually and be in accord with national and State and Territory policies.

Performance objective 4.5:
The Service implements an effective quality improvement program.

EFFECTIVE POLICIES AND THEIR IMPLEMENTATION

The policies of BreastScreen Australia are based on the best available evidence and agreed by the ASAC. They are designed to provide the highest quality mammographic screening program with the resources available. National policies will be made operational at the State and Territory and Service levels through the development of more detailed operational policies, protocols and procedures.

Common policies, protocols and procedures

All screening and assessment units within a Service will operate under the same set of policies, protocols and procedures where possible; however, varying local needs and circumstances may necessitate some variation. An up-to-date Policy and Procedures Manual will assist in ensuring that practice is in accord with State and Territory and national policies. It will also contribute to ensuring that the duty of care responsibilities of the Service are fully discharged.

Strategies will be developed to ensure that policies and procedures outlined in the Policy and Procedures Manual are implemented and reviewed. All staff will undergo training to gain an understanding of the policies, protocols and procedures of the Service to better support their implementation. A designated member of staff will be responsible for keeping the Policy and Procedures Manual up-to-date, for monitoring its implementation and for identifying aspects where additional activities are required to ensure full implementation. Where relevant, the policies and procedures included in the Policy and Procedures Manual will be consistent with national and State and Territory policies. It will include the protocols outlined in Appendix V.

Performance objective 4.6:

The Service ensures that all screening and assessment units use common policies, protocols and procedures.

PROTOCOLS AND PROCEDURES FOR INFECTION CONTROL AND OCCUPATIONAL HEALTH AND SAFETY

Infection control standards are primarily determined by legislation governing individual clinicians. Examples of relevant state-based infection control acts and regulations include the New South Wales Nurses (General) Regulation (1997)—Section 12; the New South Wales Medical Practice Regulation (1998)—Section 18; the New South Wales Day Procedure Centres Regulation (1996)—Section 23 and the Australian Capital Territory Medical Practitioners Registration Act (1996)—Section 85. In addition, there are national standards for infection control which will be relevant to Services (for example, AS4187 *Sterilizer tests and test frequencies* and AS1079 *Sterilized packaging*).

Occupational health and safety standards are also determined by both State and Territory and national legislation. Examples of relevant occupational health and safety acts and regulations in different States and Territories include the *New South Wales Occupational Health and Safety Act (1983)*; the Victorian Occupational Health and Safety Regulations (1998); the *Australian Capital Territory Occupational Health and Safety Act (1989)* and the South Australian Occupational Health, Safety and Welfare Regulations (1995). These acts and regulations cover areas such as the duties of the staff and managers in making the workplace safe and healthy, and procedures to be put in place as part of a complete occupational and health safety system. In addition, there are national standards for occupational health and safety in the workplace which will be relevant to Services (for example AS2569.2 *Guide to the lifting and moving of patients*, AS1670 *Fire detection, warning, control and intercom systems* and AS1319 *Safety signs for the occupational environment*).

The Service will use relevant State and Territory and national legislation about infection control and occupational health and safety to develop local protocols and procedures. 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. The Service is required by law to meet the relevant standards set out by State and Territory and national bodies. Implementing these protocols and procedures requires a strong commitment from all staff.

Performance objective 4.7:

The Service ensures that relevant infection control and occupational health and safety standards are met.

APPROPRIATE FACILITIES

Effective service management includes ensuring that appropriate facilities are available. Several standards elsewhere in this document note the need for appropriate screening and assessment facilities. However, there are several aspects of the organisation of the Service which are important if appropriate facilities are to be available:

Dedicated services

Women should be screened and assessed separately from women in a diagnostic or cancer management setting.⁸

Most women participating in mammographic screening will not have breast cancer and it may therefore be inappropriate for them to be part of the same service as women with identified disease. The separation of screening and diagnostic services is advocated because the organisation of a screening clinic requires a rapid throughput of well women with very different expectations from the patients undergoing diagnostic investigation.¹⁵¹ The separation of services is also intended to reduce women's anxiety about the outcomes of screening, as increased anxiety may discourage women from returning for future screening.^{2,151,152} There are other important differences between screening services for well women and those for women diagnosed with cancer which support the need for separate services: for example, the type of written information available, the time spent with individual women, and the level of counselling and support which is required.

The Service can ensure that each of the screening and assessment units is dedicated in space and time through a number of strategies, including: appropriate signage; a dedicated telephone line for bookings and enquiries; and a separate waiting area appropriate for well women. Women should be aware that they are attending an accredited BreastScreen Australia Service which is for mammographic screening and assessment of asymptomatic women. This can be achieved through written information, contact with staff, promotional material at the Service and by separating the screening and assessment units either physically in time from those designed to investigate breast symptoms. Depending upon local conditions, BreastScreen Australia Services may be provided in designated facilities. However, separation of services can also occur by providing mammographic screening and assessment of screen-detected abnormalities in facilities which are dedicated to screening at that time, but operate as diagnostic facilities at other times. This may require special arrangements to ensure that the accreditation standards are met. It is also important that staff and facilities are dedicated to providing a BreastScreen Australia Service at any given time.

Performance objective 4.8:

The Service ensures that all screening and assessment units operate in a dedicated space, at a dedicated time and with dedicated staff and facilities.

Linked screening and assessment facilities

The facilities within a BreastScreen Australia Screening and Assessment Service must constitute an integrated service. There is the potential for screening services to work separately from assessment centres. However, an effective screening program relies on the integration of screening and assessment to ensure better utilisation of resources, implementation of common policies and protocols and continuity of service delivery.

All screening units within the Service must be linked to a specific assessment centre.

Performance objective 4.9:
The Service provides integrated facilities.

Introducing 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 and high quality screening and assessment service is being provided to women. During this phase, the Service will need to consider when, how, and if to introduce new technologies.

It is the responsibility of the Service to consider the introduction of new technologies within the context of national and State and Territory policies as well as national standards. In this context, 'new technologies' are technologies which have not yet been used by the Service for the screening and assessment of women.

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 will seek advice from its State Coordination Unit and/or State Accreditation Committee. The introduction of the new technology at the Service will be considered based on a number of factors, including: throughput of women; cost implications including recurrent costs; need; and results of past or ongoing evaluation. The evaluation should include clinical outcomes as one of the key criteria for determining introduction of the technology. Reviews by the Medicare Services Advisory Committee and the Australian Safety and Efficacy Register of New Interventional Procedures may be useful in determining whether to adopt a new technology. The ASAC Policy Review and New Technologies Working Group and the National Breast and Ovarian Cancer Centre are also a source of information about new technologies for breast cancer screening.

Before a new technology is introduced, staff training will be required and documentation of quality control procedures. The effectiveness of newly introduced technologies should be evaluated by the Service as part of the quality improvement program.

Performance objective 4.10:
The Service introduces new technologies in a planned and appropriate manner.

EFFECTIVE DATA MANAGEMENT

BreastScreen Australia requires that Services collect and analyse sufficient high quality data in order to monitor the implementation of the Program and evaluate its effectiveness and efficiency. The data may also provide the basis for future policy decisions. Services adhere to State, Territory and national policies for the collection and management of client information, and ensure that confidentiality and security of this information is maintained at all times.

Confidentiality, security and data integrity of client information

The Service will maintain high standards in the management of client information, consistent with State and Territory and national policies. Privacy principles have been legislated in the Federal *Privacy Act (1988)*¹¹² and in complementary State and Territory legislation.

Confidentiality and security of client information is paramount, as women attending the Service must be assured that their personal information will be treated confidentially. All staff will be aware of their responsibilities and obligations with regard to client information and will sign a confidentiality agreement at the commencement of their employment and undertake annual re-signing. Procedures will be followed by staff to ensure security of client information. Client records should be securely stored and, according to the principles outlined in the Federal *Privacy Act (1988)*,¹¹² access restricted to certain personnel only.

All staff employed by the Service are liable for breaches in confidentiality and need to be aware of the importance of confidentiality at all times. Annual signing of confidentiality forms can be an opportune way to remind staff of their responsibilities and obligations in maintaining confidentiality of client information.

Individual women have the right to seek access to their personal information.¹⁵³ This may be for their own needs or for the transfer of this information to other medical service providers. The Service will ensure that there is a process, consistent with relevant State and Territory protocols which enables women to access their own records or images if they request them.

Research projects are undertaken using breast screening and assessment data; they may help provide answers to many of the questions in screening and assessment, such as the sensitivity of tests and acceptability of tests. The Service is responsible for ensuring that such research projects receive institutional ethics committee approval where appropriate and that the State Coordination Unit or State Accreditation Committee is advised of the research. Such research projects will be monitored closely in accordance with NHMRC guidelines^{154,155} and the Service must play a role in this monitoring process. Where data are to be published, the State Coordination Unit or State Accreditation Committee should be advised and an independent final review undertaken.

The introduction of digital mammography creates additional complexity with client information systems. Generally digital mammography images are managed by a Picture Archive and Communication System (PACS), digital mammography reporting is managed by a radiology information systems (RIS), and screening and assessment workflow is managed through a client information management system (CIMS). These can be separate systems or integrated to a level where data is shared and distributed across systems. The challenge for the Service is to ensure that adequate quality assurance is in place to verify data consistency and data integrity across systems.

Performance objective 4.11:

The Service ensures that confidentiality, security and data integrity of client information is maintained.

Data collection

It is important that the data collected be sufficient to provide clinical records and support key aspects of quality improvement, monitoring and evaluation.

Data are collected for clinical purposes and to ensure that the Service and the Program are operating effectively to meet their aims and objectives. Data might also be collected for research purposes.

National and State and Territory agreements and policy determine the type of data to be collected by BreastScreen Australia Services. Services will contribute to statewide data collection processes outlined in a statewide data practice manual and in accordance with the BreastScreen Australia Data Dictionary.

The BreastScreen Australia Data Dictionary outlines data items to be collected at the Service level for monitoring and evaluation purposes and for the purposes of client care; however, from time to time there will be additional State and Territory and national data requirements. The use of standard definitions and agreed methods for calculating screening indices facilitates comparisons between Services, States and Territories and other programs overseas.

High quality data will be collected and maintained through appropriate training and ongoing quality control checks. The data will be stored in a secure and appropriate information system within a properly maintained, secure and highly efficient computer system.

The quality control procedures will include review of the completeness and legibility of paper clinical records. The paper clinical records must be dated and identifiable to the relevant health professional for that segment of the screening and assessment pathway. The quality control procedures should also include a review of the consistency between paper and computer records and verification of the accuracy of the output from the programs. The quality controls in place must also include verification of data consistency across systems. A designated person at each Service will be responsible for data integrity and maintenance of computer hardware and software. Additional procedures will be used to maintain high quality data. For example, a cross match with data from all Services within the State will be conducted at least annually to ensure that an individual woman is only counted once in calculations.

Performance objective 4.12:

The Service ensures that sufficient and high quality data are collected.

PERFORMANCE INDICATORS		
Performance Objective	Standard	Measure
4.1	<p>4.1.1 Where the Service and State coordination Unit are separate, there is a written contract detailing their responsibilities and the need for the Service to comply with the national standards.</p> <p>4.1.2 The Service implements a protocol for managing finances to maximise efficiency and accountability, including a delegation schedule.</p> <p>4.1.3 The Service demonstrates a minimum annual throughput for each independent screening unit of:</p> <ul style="list-style-type: none"> • 4,000 women for urban units; and • 3,000 women for rural/remote units. 	<p>Evidence of an appropriate written agreement where appropriate.</p> <p>Evidence of a protocol for managing finances, including a delegation schedule.</p> <p>Number of women screened by each screening unit by urban and rural/remote classification in the most recent 12-month period for which data are not available. Calculation: See Data Dictionary</p>
4.2	<p>4.2.1 The Service implements a strategy to encourage participation of key stakeholders in its structure, processes and activities:</p> <ul style="list-style-type: none"> • ways to encourage participation of key stakeholders • representation of key stakeholders on committees or reference groups. <p>4.2.2 The Service has a management or advisory structure which has representation from all key stakeholder groups.</p> <p>4.2.3 The Service encourages consumer participation by:</p> <ul style="list-style-type: none"> • having appropriate representation with a minimum of at least two consumer representatives on any policy or advisory committee; • offering access to training and development opportunities to consumers • having a designated member of staff to support consumers. 	<p>Evidence that the Service implements an appropriate strategy to encourage participation of key stakeholders in its structure, processes and activities.</p> <p>Evidence of a clearly documented management or advisory structure which supports involvement from all key stakeholder groups.</p> <p>Evidence that consumers are represented by at least two members on any policy or advisory committee.</p> <p>Evidence that consumer representatives are offered access to training and development opportunities.</p> <p>Evidence that support of consumers participating in the Service is part of the job description of a designated member of staff.</p>
4.2.4	A consumer rights module is included in the education and training of staff at the Service	Evidence of staff training in consumer rights.

PERFORMANCE INDICATORS

Performance Objective	Standard	Measure
4-3 All staff employed by the Service have appropriate expertise, experience and training.	4-3-1 All new and existing staff meet the relevant expertise, experience and training standards outlined in Appendix J.	Evidence that all new and existing staff meet the standards relevant to their discipline/area outlined in Appendix J.
	4-3-2 All professional staff undertake continuing education and meet the continuing requirements of the professional bodies which represent their discipline.	Evidence that all professional staff undertake continuing education and meet the continuing education requirements of the professional bodies which represent their discipline.
	4-3-3 The Service implements a plan for training.	Evidence of implementation of a training plan.
	4-3-4 All staff receive appropriate orientation and training within three months of commencement of employment at the Service.	Evidence that all staff receive appropriate orientation and training within three months of commencement of employment at the Service.
	4-3-5 In-service training, of at least six hours, is provided to all staff annually	Evidence that adequate in-service training is provided to all staff annually.
	4-3-6 All staff undergo annual performance appraisal, where they have the opportunity to identify any training needs that have not been met and agree to a plan for addressing these needs.	Evidence that all staff undergo annual performance appraisal. Evidence that staff have the opportunity to identify any training needs which have not been met. Evidence that any training needs that have not been met are documented and that a plan for addressing these is developed.
4-4 The Service ensures that all staff of screening units are an integrated part of the assessment unit.	4-4-1 The Service has systems in place to ensure that screening unit staff work closely with the assessment unit to ensure an integrated service, including: <ul style="list-style-type: none"> • at least one of the screen readers will be part of an assessment team in the Program • there will be liaison between staff in the screening units and assessment centre. 	Evidence that there are systems in place to ensure that screening unit staff work closely with the assessment unit to ensure an integrated service.
	4-4-2 The Service implements a protocol which delineates staff roles and responsibilities between the various components of screening and assessment.	Evidence that the Service: <ul style="list-style-type: none"> • implements a protocol which delineates staff roles and responsibilities between the various components of screening and assessment. • informs staff about the protocol • regularly reviews and evaluates compliance with the protocol.

PERFORMANCE INDICATORS

Performance Objective	Standard	Measure
4-5	<p>4-5.1 The Service implements an effective quality improvement program.</p>	<p>The Service implements a detailed quality improvement plan which includes case review, review of missed and interval cancers, educational meetings, review of comment from consumers and other key stakeholder, unidisciplinary and multidisciplinary activities, review of policies and procedures and review of program data. The plan will:</p> <ul style="list-style-type: none"> • include all staff; • include strategies for improving care in areas of need or focus; and • be reviewed annually.
4-6	<p>4-6.1 The Service ensures that all screening and assessment units use common policies, protocols and procedures.</p>	<p>The Service has an up-to-date Policy and Procedures Manual which:</p> <ul style="list-style-type: none"> • is consistent with State and Territory and national policies; • contains common protocols as outlined in Appendix V; • is maintained and updated by a designated member of staff.
4-7	<p>4-7.1 The Service ensures that relevant infection control and occupational health and safety standards are met.</p>	<p>The Service ensures that all of the policies and procedures outlined in the Policy and Procedures Manual are implemented, monitors compliance and where necessary develops strategies for improving compliance.</p>
		<p>4-6.2 All staff are trained to ensure an understanding of the policies, protocols and procedures of the Service.</p>
	<p>4-7.2 The Service implements protocols to meet relevant State and Territory and national occupational health and safety standards.</p>	<p>The Service implements protocols to meet relevant State and Territory and national infection control standards.</p>

PERFORMANCE INDICATORS

Performance Objective Standard Measure

4-8	The Service ensures that all screening and assessment units operate in a dedicated space, at a dedicated time and with dedicated staff and facilities.	<p>4-8.1</p> <p>The Service ensures that all screening and assessment units operate in:</p> <ul style="list-style-type: none"> • a dedicated space, which is clearly identifiable as a BreastScreen Australia Service; • at a dedicated time, so that screening and assessment of screen-detected abnormalities is exclusively performed at a given time; • with dedicated staff and facilities.
4-9	The Service provides integrated facilities.	<p>4-9.1</p> <p>All screening units within the Service are linked to a specific assessment centre.</p>
4-10	The Service introduces new technologies in a planned and appropriate manner	<p>4-10.1</p> <p>New technologies in use at the Service are introduced only if there is evidence of safety and effectiveness.</p> <p>4-10.2</p> <p>For new technologies being introduced at the Service:</p> <ul style="list-style-type: none"> • a protocol for introduction exists; • relevant staff receive appropriate training in the use of such technologies prior to commencing their use; • quality assurance protocols are in place; • where relevant, introduction is in accord with State and Territory and national policies; • where relevant, evaluation of the technology is undertaken.

PERFORMANCE INDICATORS		
Performance Objective	Standard	Measure
4.11 The Service ensures that confidentiality and security of client information is maintained.	4.11.1	The Service implements protocols to ensure that information collected about a woman is treated in a confidential manner, consistent with State and Territory and national requirements.
	4.11.2	All staff sign a confidentiality form outlining their responsibilities and obligations upon commencement of employment at the Service and each year thereafter.
	4.11.3	For any research projects using screening and/or assessment data, the Service has evidence of Institutional Ethics Committee approval where appropriate and that they have advised the State Coordination Unit/State Accreditation Committee. Where data are to be published, the State Coordination Unit/State Accreditation Committee is advised and an independent final review is undertaken.
	4.11.4	All client records are securely stored, using an accepted method of medical record filing, and access is restricted to appropriate persons only
	4.11.5	The Service implements a protocol, consistent with relevant State and Territory protocols for a woman to have access to her own records, including copies of images.
	4.11.6	Where multiple systems are in place to manage data, such as client information system, radiology information system, PACS etc the Service ensures that adequate quality assurance checks are in place to verify data consistency across systems.

PERFORMANCE INDICATORS

Performance Objective	Standard	Measure
4.12	4.12.1	The Service collects all data detailed in the BreastScreen Australia Data Dictionary and as agreed from time to time between the States and Territories and the Australian Government.
	4.12.2	The Service cooperates with the State Coordination Unit to ensure that State and Territory and national reporting requirements are met.
	4.12.3	The Service implements a protocol for data collection and any movement of client records which includes staff responsibilities, the transfer of records between units and the file tracking system used.
	4.12.4	The definitions and methods used by the Service in the calculation of screening indices conform to the definitions and methods specified in the national standards and BreastScreen Australia Data Dictionary.
	4.12.5	Each client has one unique identifier within each State and Territory program.
	4.12.6	All paper clinical records held by all units in the Service are dated and identifiable to the relevant health professional for that part of the screening and/or assessment pathway.
	4.12.7	<p>The Service undertakes ongoing quality control procedures for data throughout the screening and assessment process, including:</p> <ul style="list-style-type: none"> • review of the completeness of all clinical records and legibility of paper clinical records; • review of the consistency between paper and computer records; • verification of the accuracy of the output; and • data consistency across systems.

PERFORMANCE INDICATORS		
Performance Objective	Standard	Measure
4.12 The Service ensures that sufficient and high quality data are collected (continued):	4.12.8 All relevant staff are instructed in procedures to ensure quality of data at all levels of the screening and assessment pathway.	
	4.12.9 The Service has a designated person responsible for data management, security and integrity.	
	4.12.10 The Service has standard procedures for the maintenance of computer hardware and software	

APPENDIX A

COMMITTEE MEMBERS

FORMER NATIONAL ADVISORY COMMITTEE TO BREASTSCREEN AUSTRALIA

Professor Sally Redman (Chair)	National Breast Cancer Centre (now National Breast and Ovarian Cancer Centre)
Dr Chris Bayley	Royal Australian and New Zealand College of Obstetrics and Gynaecology
Ms Judy Blazow	Australian Government
Ms Judy Bursle	Australian Institute of Radiography
Assoc Professor Robert Carter	Health Economist
Ms Cynthia Croft	Program Manager, NT
Professor Mark Elwood	National Cancer Control Initiative
Ms Valerie Gardner	Program Manager, Tasmania
Ms Lilly Geraghty-Madsen	Aboriginal and Torres Strait Islander Representative
Dr Paul Glasziou	Epidemiologist
Dr Julienne Grace	Royal College of Pathologists of Australasia
Dr Paul Jelfs	Australian Institute of Health and Welfare
Ms Alice Jones	Program Manager, ACT
Dr Barbara Jones	Royal Australian College of General Practice
Ms Sue Lockwood	Consumer
Ms Sarah Major	Australian Government
Ms Jennifer Mitchell	NSW Department of Health
Ms Jennifer Muller	Program Manager, QLD
Dr Marjorie Pawsey	Chair, National Quality Management Committee
Dr Mary Rickard	Royal Australian and New Zealand College of Radiologists
Ms Onella Stagoll	Program Manager, Victoria
Mr Neil Wetzig	Royal Australasian College of Surgeons
Ms Lou Williamson	Program Manager, SA
Dr Liz Wylie	Program Manager, WA
Ms Andriana Koukari	Australian Government
Mr John Harding	Australian Institute of Health and Welfare
Ms Karen Finch	Acting Program Manager, NT

NATIONAL QUALITY MANAGEMENT COMMITTEE

The NQMC is a sub-committee of the National Advisory Committee. Past and present members are listed, as well as past and present proxies.

Dr Marjorie Pawsey	(Chair) Australian Council on Healthcare Standards
Ms Angela Beitz	Recruitment Officer, QLD
Ms Pam Brackman	Australian Institute of Radiography
Ms Jenny Brogan	Program Manager, ACT
Mr John Buckingham	Royal Australasian College of Surgeons (proxy)
Dr Julie Burn	Royal College of Pathologists of Australasia (proxy)
Ms Judy Bursle	Australian Institute of Radiography (proxy)
Mr Terry Callaghan	Data Manager, NSW
Mr John Collins	Royal Australasian College of Surgeons
Dr Bridget Cooke	Royal College of Pathologists of Australasia
Mr Tony Craig	Medical Physicist (ex officio)
Dr Christine Crane	Royal Australian and New Zealand College of Radiologists (proxy)
Mr Damien Davidson	Data Manager, TAS
Ms Frances Diver	Recruitment Officer, Victoria
Dr Gelareh Farshid	Royal College of Pathologists of Australasia
Mr Andrew Field	Royal College of Pathologists of Australasia
Ms Valerie Gardner	Program Manager, Tasmania
Ms Roberta Higginson	Consumer (proxy), NSW
Ms Angela Hill	Recruitment Officer, VIC
Ms Bindi Hill	Nurse/Counsellor (proxy), QLD
Dr Paul Jelfs	Epidemiologist (proxy), SA
Mr Alan Keith	Australian Government
Ms Andriana Koukari	Australian Government
Ms Sue Lockwood	Consumer, VIC
Ms Sarah Major	Australian Government
Mr Warwick May	Accreditation Officer, NSW
Ms Jennifer Muller	Program Manager (proxy), QLD
Dr Jonothan Osborne	Royal Australian and New Zealand College of Radiologists (proxy)
Ms Prue Playford	Data Manager, SA
Ms Helen Porritt	Counsellor, ACT
Ms Gail Raw	Program Manager (proxy), TAS
Dr Mary Rickard	Royal Australian and New Zealand College of Radiologists
Dr David Roder	Epidemiologist
Ms Gervaise Sellers	Counsellor, TAS

Ms Leonie Short	Behavioural Scientist, NSW
Ms Onella Stagoll	Program Manager, Victoria
Ms Helen Sutherland	Program Manager (proxy), ACT
Mr Richard Tewson	Recruitment Officer (proxy), NSW
Ms Della Thomas	Data Manager, ACT,
Ms Jan Tresham	Data Manager (proxy), WA
Mr Owen Ung	Royal Australasian College of Surgeons
Ms Fleur Webster	Secretariat, National Breast and Ovarian Cancer Centre
Mr Neil Wetzig	Royal Australasian College of Surgeons
Ms Jules Wilkinson	Accreditation Officer (proxy), VIC
Ms Lou Williamson	SA and NQMC Chair (2004 to present)
Dr Liz Wylie	Royal Australian and New Zealand College of Radiologist

REVIEW TEAM MEMBERS

Dr Christine Baker	Service Director
Ms Angela Beitz	Recruitment Officer
Dr Virginia Billson	Pathologist
Ms Carol Bishop	Consumer
Mr Christopher Boundy	Lawyer
Ms Louise Bowen	Service Director
Ms Judy Bursle	Radiographer
Ms Penny Button	Consumer
Ms Bronwyn Chapple	Program Manager
Dr Frieda Cheok	Epidemiologist
Dr Alexandra Clavarino	Social Scientist
Ms Carmel Coleman	Counsellor
Mr Tony Craig	Medical Physicist
Dr Dallas English	Epidemiologist
Ms Karen Finch	Consumer
Ms Valerie Gardner	Program Manager
Mrs Ann Goves	Clinical Nurse Consultant
Dr Janet Hiller	Epidemiologist
Dr Robin Jenkins	Clinical Coordinator
Mr James Kollias	Surgeon
Dr Marjorie Kossoff	Radiologist
Dr Anne Kricker	Epidemiologist
Mr David Oliver	Surgeon
Assoc Professor Jon Osborne	Radiologist
Ms Helen Porritt	Nurse Counsellor
Ms Sue Richardson	Radiographer
Ms Margaret Rose	Radiographer
Dr Angela Rutherford	General Practitioner
Dr Patricia Shepherd	General Practitioner
Ms Sharon Sweeney	Consultant
Assoc Professor Richard Taylor	Epidemiologist
Mr Owen Ung	Breast Surgeon
Dr Jane Vallentine	Service Director
Ms Maria Wright	Consumer
Dr Elizabeth Wylie	Radiologist
Miss Amanda Young	Surgeon

DIGITAL MAMMOGRAPHY ACCREDITATION STANDARDS WORKING GROUP MEMBERS

Ms Lou Williamson (Chair)	National Quality Management Committee
Ms Pam Brackman	Australian Institute of Radiography
Dr John Buckingham	Royal Australasian College of Surgeons
Mr Mark Costello	Program Manager, NSW and NSW Digital Technologies User Group
Dr Bronwen Harvey	Australian Government
Dr John Heggie	Australasian College of Physical Scientists and Medicine
Mr Alan Keith	Australian Government
Dr Darren Lockie	Radiologist
Ms Gill Miller	Radiographer
Ms Gail Raw	Program Manager, TAS
Mr John Siddham	Information Technology expert
Ms Margaret Tassell	Consumer
Dr Madeleine Wall	NZ Digital Advisory Group
Dr Liz Wylie	Royal Australian and New Zealand College of Radiologists and Breast Imaging Reference Group

APPENDIX B

BREASTSCREEN AUSTRALIA NATIONAL ACCREDITATION REQUIREMENTS REVIEW PROCESS

The NARs for the national mammographic screening program were last reviewed in 1994 by the former National Accreditation Committee. The revised standards were produced by the NQMC of BreastScreen Australia, with the support of the National Breast Cancer Centre (now the National Breast and Ovarian Cancer Centre). The NQMC was reconstituted in November 1998 and is the national committee responsible for quality improvement in the program. The NARs were ratified by the National Advisory Committee to the National Program for the Early Detection of Breast cancer (now BreastScreen Australia). Membership of the NQMC and the National Advisory Committee are shown in Appendix A.

The revised standards take into account the levels of performance achieved by the program since the NARs were revised (in March 1994), as well as other available research and data from within Australia and overseas.

The review process was undertaken in consultation with the State and Territory programs, BreastScreen Australia Screening and Assessment Services, representatives of various disciplines involved in the Program, representatives of relevant professional groups and organisations and consumers across Australia. Formal consultations were conducted with each of the State and Territory programs in early 1999. These involved staff of the State Coordination Units, members of the State Accreditation Committees as well as various discipline, Service and consumer representatives and sought to determine their views on the current NARs and areas for improvement. One-day meetings were held at each State and Territory program with the relevant people from the State and Territory as well as NQMC and National Breast Cancer Centre representatives. Discussion centred around how the 1994 NARs were being met by the Services and how they could be improved to take account of the diverse practice across Australia while maintaining a high quality service. The outcomes of the consultations were summarised and collated into a document which was used to inform the review process.

In undertaking the review, international recommendations and guidelines were considered. The review also built on Australian experience and sought to ensure that the revised standards were relevant and workable within the Australian setting, taking into account the diversity of practice and geography which exists.

REVIEW TEAMS

To ensure that the review utilised expertise from across Australia from all relevant disciplines and areas, State and Territory programs were asked to nominate individuals to assist with the review. Approximately 35 individuals were subsequently selected to join one of six review teams, based on their expertise in a particular discipline or area. Where possible, the NQMC attempted to ensure balanced representation from each State and Territory in Australia.

The review teams sought to develop a national consensus by seeking wide consultation with peers and colleagues and considering the comments raised in the consultation process. Wherever possible, the review teams were encouraged to base their recommendations on data. On occasion, specific analyses of data were requested and received from the State and Territory programs. These analyses are referred to throughout the document as 1997 or 1999–2000 State and Territory data and are also summarised in Appendix D.

To keep the process as transparent as possible, the review teams were required to clearly document their reasons for making changes to the NARs and their responses to issues raised during the consultation process. Their response to issues raised in the consultations and the response of the NQMC are contained in a separate document, Results of the consultation and review process: a summary (made available at the time of public consultation).

CONSIDERATION BY THE NATIONAL QUALITY MANAGEMENT COMMITTEE

The NQMC held two extraordinary meetings to consider the draft performance objectives developed by the review teams. Those performance objectives which were unable to be considered at these meetings, were considered during ordinary meetings of the NQMC.

Based on comments made by members of the NQMC, the draft standards were revised accordingly. Relevant review team members as well as other relevant people were contacted to assist with the revisions, as required.

CONSIDERATION BY RELEVANT PROFESSIONAL COLLEGES/ORGANISATIONS

As part of the review process, the section of the document dealing with staff expertise, experience and training was circulated to relevant professional colleges/organisations for comment. These included the Royal Australasian College of Surgeons, Australian Institute of Radiography, Royal Australian and New Zealand College of Radiologists, Royal College of Pathologists of Australasia, Australasian Society of Breast Physicians and Australasian College of Physical Scientists and Engineers in Medicine. In addition, the Australasian College of Physical Scientists and Engineers in Medicine received the sections of the document relating to medical physics for comment.

PUBLIC CONSULTATION

The draft revised NARs were circulated for public consultation in mid November 2000. Comments were requested by mid February 2001.

The draft document was circulated to relevant professional colleges/organisations, State and Territory BreastScreen Programs, nominated working groups of the National Advisory Committee, consumer groups and review team members.

The comments received were arranged for the NQMC according to the area of the document they pertained to. The NQMC considered the comments during two extraordinary workshops and one extraordinary teleconference. Some additional data were requested and received from the State and Territory programs at this time to help inform the review process. State and Territory program managers were invited to attend part of the first workshop to discuss their overall comments and concerns with the current draft document. These comments were also used to inform the decisions made by the NQMC.

The document was reviewed based on the comments received and the recommendations made by the NQMC. It was then circulated to nominated working groups of the National Advisory Committee as well as State and Territory program managers for their consideration. The Monitoring and Evaluation Working Group were asked to review the calculations used in the revised document in light of the BreastScreen Australia Data Dictionary in particular.

The second round of comments received were also arranged for the NQMC according to the area of the document they pertained to. The NQMC considered the comments during one face-to-face meeting of the NQMC and one extraordinary teleconference. Each comment received was considered and a recommendation made by the NQMC. The draft standards were revised based on these recommendations.

CONSIDERATION BY THE NATIONAL ADVISORY COMMITTEE

The June draft of the revised NARS document, renamed the National Accreditation Standards, was completed and forwarded to members of the National Advisory Committee to BreastScreen Australia for their consideration at their July 2001 meeting.

The National Advisory Committee ratified the revised National Accreditation Standards with minor changes.

CONSIDERATION BY THE MONITORING AND EVALUATION WORKING GROUP

The changes suggested by the National Advisory Committee were completed and a September 2001 draft forwarded to the Monitoring and Evaluation Working Group for special consideration of the measures and calculations contained in the document.

A sub-group of the Monitoring and Evaluation Working Group subsequently developed Segment J—National Accreditation Standards Specifications Segment to be included in the BreastScreen Australia Data Dictionary.

REVIEW OF EXIGENT BREASTSCREEN AUSTRALIA NATIONAL ACCREDITATION STANDARDS (NAS)

At its 21 May 2004 meeting the NQMC agreed to conduct a mini review of some NAS as interim measure to identify ways to manage standards that had been causing concern to Program Managers given some services had difficulties in meeting certain NAS in the accreditation process. The NQMC agreed that a full review will be conducted when there is sufficient data available to support reconsideration of the NAS. The NQMC considers a sufficient quantum of data for this purpose will be available in around two years time.

All Program Managers were contacted to identify exigent NAS for consideration by a small working group established by the NQMC comprising members from both the NQMC and the former Monitoring and Evaluation Working Group, a sub group of the National Advisory Committee.

Seven exigent NAS (2.4.2a, 2.8.3, 2.8.4, 2.18.1, 3.1.1, 3.7.2 and 3.8.3) were considered in full as well as accompanying Appendices S and T. Changes to NAS 3.1.1 and 2.18.1, 3.8.3 and part of 3.7.2 were agreed at the 3 September 2004 NQMC meeting. The remaining exigent NAS were referred for further consideration to a second small working group with members from the NQMC, the Department and the Australian Institute of Health and Welfare (AIHW).

The AIHW undertook further analysis and provided a report on service data related to the outstanding exigent NAS. The working group agreed on recommendations for changes to NAS 2.4.2a, and 3.7.2 and sought further advice from an epidemiologist adviser to BreastScreen Victoria and the AIHW prior to making recommendations to the NQMC on NAS 2.8.3 and 2.8.4.

Accompanying appendices to the above NAS were also considered. It was agreed to remove Appendix Q and that Appendices S and T (pathology and related issues) be updated. The updating of appendices S and T (now R and S) was undertaken by the Royal College of Pathologists of Australasia.

The recommendations of the various working groups were considered by the NQMC at its 3 September 2004 meeting as well as out of session in October/November. Changes to NAS 2.4.2a, 2.18.1, 3.1.1, 3.7.2 and 3.8.3 were approved by the NQMC to go to ASAC for final endorsement out of session. It was agreed NAS 2.8.3 and 2.8.4 would remain unchanged. In considering changes to the exigent NAS, the NQMC applied the risk management framework of the Decision Tool to the proposed changes and determined that the risk levels of all the exigent NAS will remain as they are if the changes are implemented

ASAC endorsed the changes to the exigent NAS out of session in November 2004.

INTERPRETING VARIATIONS FROM THE CANCER DETECTION STANDARDS

It is recognised that there will be variations from the cancer detection standards as a result of chance; this is particularly the case at the Service level where the numbers of women screened may be relatively small. The smaller the number of women contributing to the estimate, the greater the chance that the detection rate will appear to differ from the standard.

In considering whether or not a Service has met the standard required for accreditation, the play of chance needs to be taken into account. To assist Services in determining whether their cancer detection rates are truly different from the standards, a series of funnel plots based on the Poisson distribution have been developed.

This appendix outlines the reasons for considering chance variation in relation to cancer detection rates and the approach used to calculating the funnel plots. It also outlines how the funnel plots can be used by Services to consider their cancer detection rates and how the plots will be considered by the NQMC in determining accreditation status. Funnel plots for each of the cancer detection standards are also included along with detailed tables to aid calculation (the tables will be produced when the document is agreed).

VARIATION FROM THE STANDARDS

Indicator values vary by chance as well as in response to variation in performance. The number of observations (for example, screens) on which a value is based determines the range over which variation by chance is likely to occur. The smaller the number, the wider is the range. In practice, this means that small Services with small numbers of screens in a measurement period will be more likely to have an indicator value that is widely different from the standard simply by chance. Hence, we see the confidence bounds around a standard get narrower as the throughput of the Service increases (see Figure C.A and C.B). Equally, however, the difference may mean that the Service is performing much better or much worse than the standard.

The probability that a particular indicator value is different from the standard by chance can be represented by use of a probability distribution (the Poisson Distribution) for the standard value, given the number of screens on which the indicator is based. For example, if the Service achieves the requirement of 35 invasive cancers per 10,000 subsequent screens and it has performed 20,000 subsequent screens in a particular year, it would have detected 70 invasive cancers in these screens.

In considering whether or not a Service has met the standard required for accreditation during the year's performance on which accreditation is based, the play of chance needs to be taken into account. For example, it cannot be decided that a Service that should detect at least 70

invasive cancers in a year would fail to meet the standard if it detected only 69 (a number that would be reached by only 48% of Services performing exactly according to the standard). Therefore, what probability of declaring failure to meet a standard should be accepted when, in practice, a Service is really performing at a level that meets the standard? The question is when is a Service considered not to be performing at a level that meets the requirement.

There is no simple answer to this question. For the NAS, it has been set at a level where only 2.5% (or 1 in 40) would be performing accordingly by chance. That is, a Service will be considered to meet the standard if its performance in the year on which the indicator value is based is above the lower 95% confidence bound for the standard value of the indicator, given the number of screens the Service did in the measurement year.

The (upper and lower) 95% confidence bounds are the limits of the range of indicator values on either side of the standard that will include 95% of values from Services that are exactly meeting the standard on average. By chance, 2.5% of these Services 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.

USING THE FUNNEL PLOTS TO CONSIDER ACCREDITATION

Figures have been prepared to determine whether the cancer detection rates of a Service exceed the lower 95% confidence bounds. For example, Figure C.A shows the 95% confidence bounds around the standard. Detailed tables are available to assist services in determining their cancer detection rates in relation to the standard and confidence bounds.

Services can compare their cancer detection rates in women aged 50–69 based on the number of women screened on the graph in Figure C.A. A Service is considered not to fall significantly short of the standard if the crude annual cancer detection rate does not fall below the lower confidence bounds, given the number of screens carried out in the specified time interval.

However, a Service should not necessarily be satisfied if its performance lies within the confidence bounds or 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 should be improved and should indicate to the Service that further analysis of their approach is warranted.

In evaluating their performance in a quality improvement context, Services should consider the pattern of their detection rates. This will be taken into account in considering accreditation status. Services should consider:

- Clusters of indicators: The Service should consider clusters of accreditation requirements or performance objectives together to provide an integrated view of the quality of care being provided. For example, if the cancer detection rates, small cancer detection rates and the interval cancer rates all just meet the accreditation requirements, the Service should be concerned and carefully analyse its performance. If, on the other hand, the cancer detection rates and the small cancer detection rates are much higher than the accreditation requirement and the interval cancer rate is also a little high, the Service might be more confident in thinking that the interval cancer rate is acceptable.

- Over time: Services should review their performance against the indicators in a quality improvement context on a regular basis, not just in preparation for the accreditation process. If an indicator is relatively low, say falling near the lower confidence bounds on the funnel plot, over a couple of years, then it is more likely that this value accurately reflects the performance of the Service rather than being accounted for by chance variation.

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

THE FUNNEL PLOTS AND TABLES FOR EACH OF THE CANCER DETECTION INDICATORS

Figure C.A *Detection of invasive breast cancers in women aged 50–69 years: 50 per 10,000 at first screen in a 12-month period*

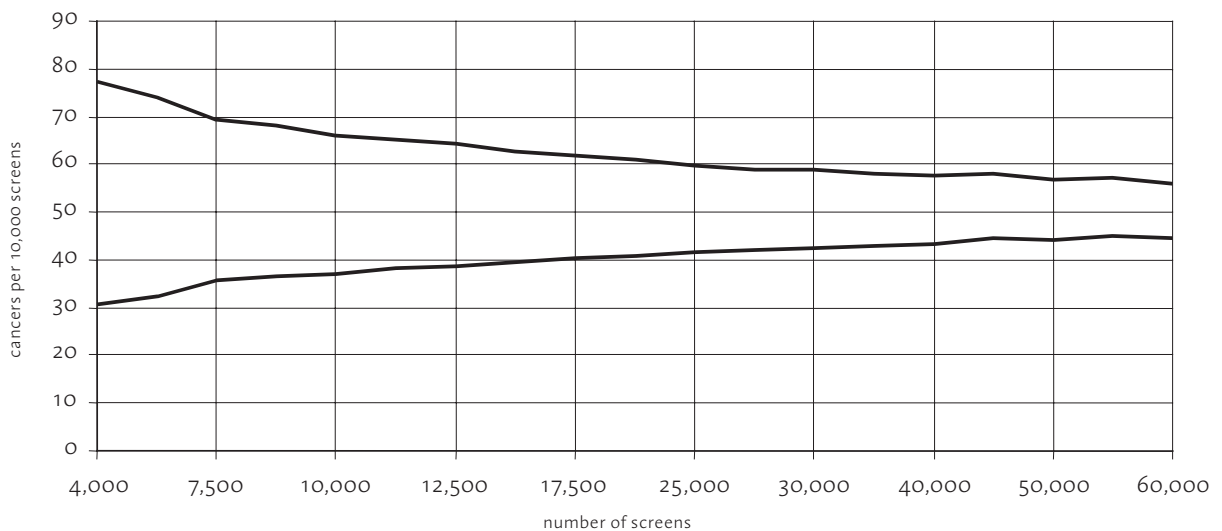


Figure C.B *Detection of invasive breast cancers in women aged 50–69 years: 35 per 10,000 at subsequent screens in a 12-month period*

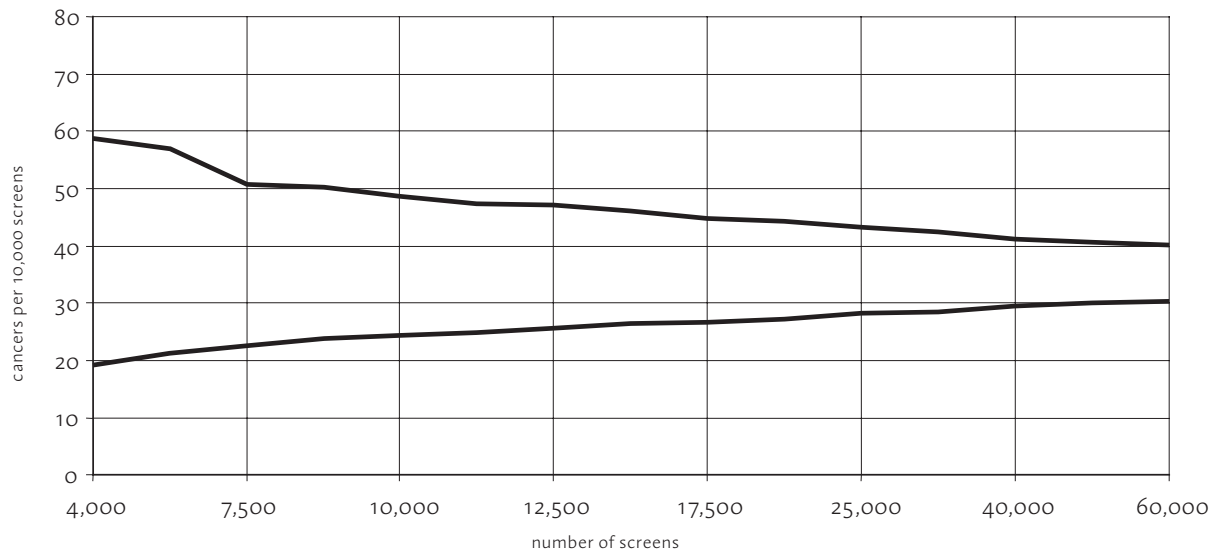


Figure C.C *Detection of small invasive breast cancers (< 15mm) in women aged 50–69 years: 25 per 10,000 screens*

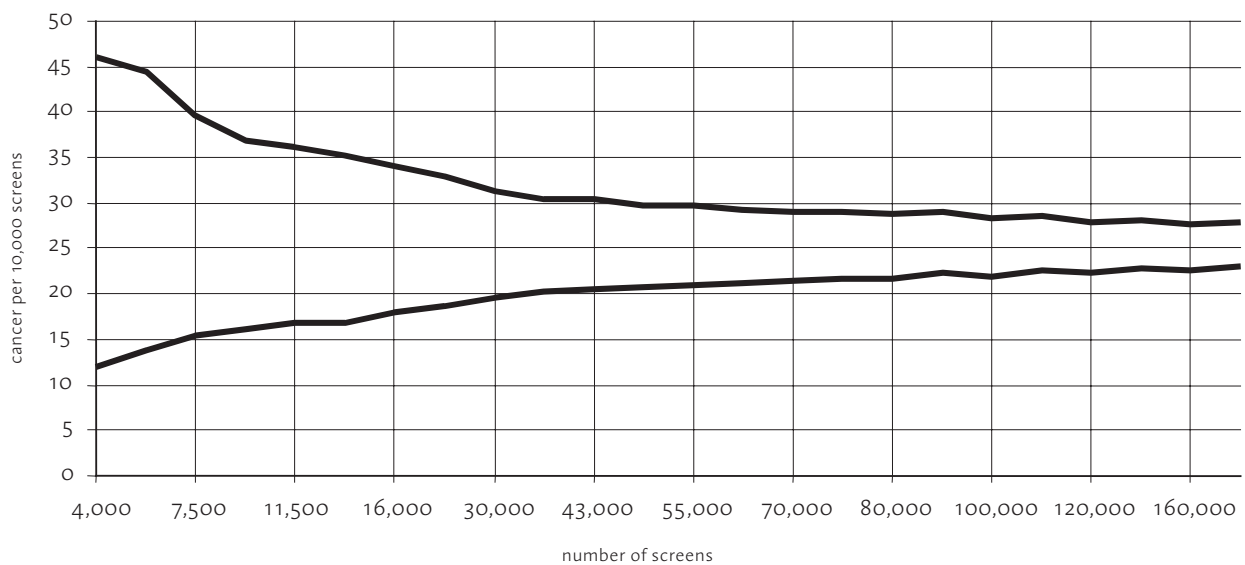


Figure C.D *Detection of DCIS in women aged 50–69 years: 12 per 10,000 at first screen in a 12-month period*

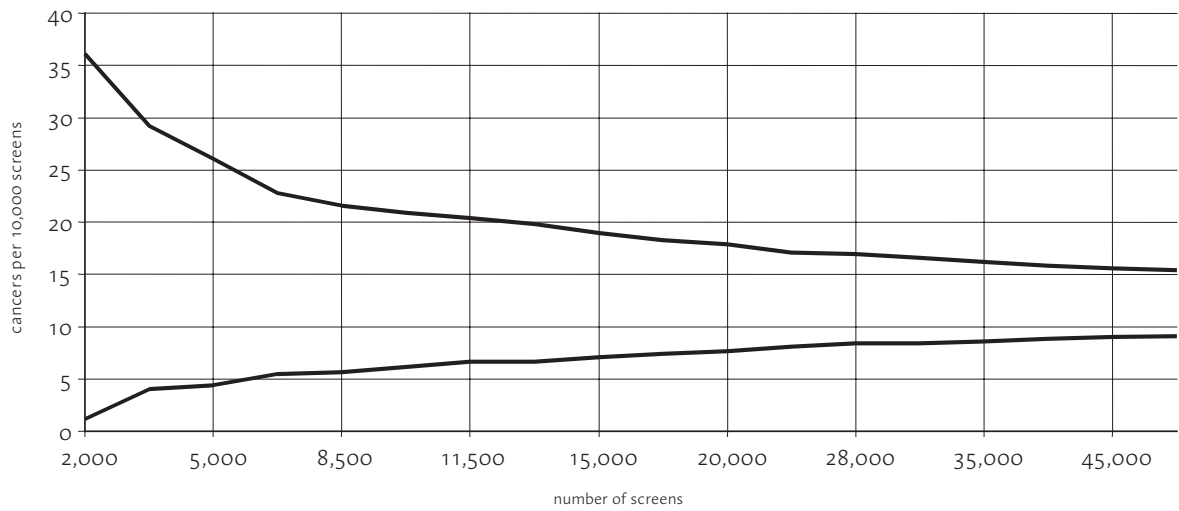
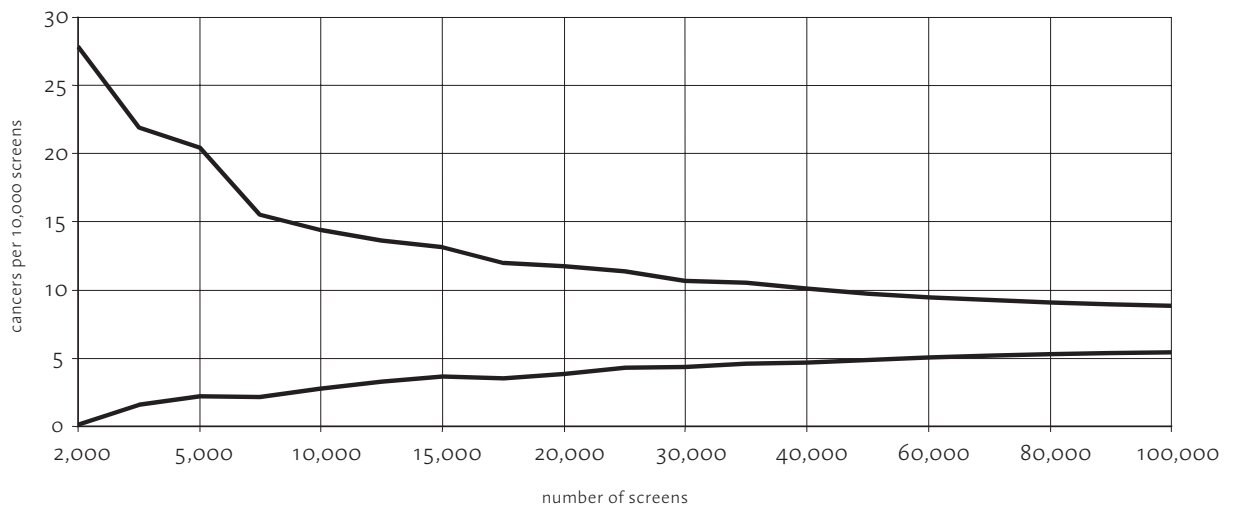


Figure C.E *Detection of DCIS in women aged 50–69 years: 7 per 10,000 at subsequent screens in a 12 month period*



APPENDIX D.A

DATA FROM SERVICES AND STATES AND TERRITORIES USED IN DEVELOPING THE STANDARDS

In order to help ensure that the standards are appropriate and relevant in the Australian context, State and Territory Programs were asked to provide data about a number of aspects of practice. Data were received from seven States and Territories.³⁸ A summary of these data and the NAS to which they relate is attached.

STATE AND TERRITORY DATA

Data collected	Number of States and Territories contributing data ^J	Range	Median	Purpose
Attendance	6	First screen: 3,989 to 47,183 Subsequent screens: 10,812 to 107,391	First screen: 16,588 Subsequent screens: 39,838	Denominator for the calculation of rates per women screened
Number of women who attended, in 5 year age groupings by screening round				
<i>Related NAS</i>				
1.1.1 ≥ 70% of women aged 50-69 years participate in screening in the most recent 24-month period.				
1.1.2 The Service monitors the proportion of women aged 40-49 years and 70 years and over screened.				

^J Data were received from VIC, TAS, WA, SA, NT, ACT, and QLD, however not all data contributed from each State/Territory for certain aspects of practice was in a format appropriate for analysis.

STATE AND TERRITORY DATA

Data collected	Number of States and Territories contributing data ¹	Range	Median	Purpose
<p>Recall to assessment</p> <p>Number of women who were recalled to assessment, in 5 year age groupings by screening rounds by reason (suspicious mammogram, sign/symptoms or both)</p> <p><i>Related NAS</i></p> <p>2.6.1 < 10% of women who attend for their first screen are recalled for assessment.</p> <p>2.6.2 < 5% of women who attend for their second or subsequent screen are recalled for assessment.</p> <p>2.6.3 The Service monitors the rates of recall among women aged 40-49 years and 70 years and over.</p>	5	First screen: 282 to 3,931 Subsequent screens: 321 to 4,385	First screen: 505 Subsequent screens: 902	Denominator for the calculation of rates per women assessed Numerator for the calculation of recall rates
<p>Referral for diagnostic open biopsy</p> <p>Number of women who were referred for open biopsy, in 5 year age groupings by screening rounds</p> <p><i>Related NAS</i></p> <p>2.8.1 ≤ 0.35% of women who attend for their first screen are found not to have invasive cancer or DCIS after a diagnostic open biopsy.</p> <p>2.8.2 ≤ 0.16% of women who attend for their second for subsequent screen are found not to have invasive cancer or DCIS after a diagnostic open biopsy.</p>	5	First screen: 12 to 321 Subsequent screen: 9 to 339	First screen: 62 Subsequent screen: 78	Numerator for the calculation of open biopsy referral rates

STATE AND TERRITORY DATA

Data collected	Number of States and Territories contributing data¹	Range	Median	Purpose
<p>Diagnostic open biopsies performed</p> <p>Number of women who underwent an open biopsy, in 5 year age groupings by screening round</p> <p><i>Related NAS</i></p> <p>2.8.1 $\leq 0.35\%$ of women who attend for their first screen are found not to have invasive cancer or DCIS after a diagnostic open biopsy.</p> <p>2.8.2 $\leq 0.16\%$ of women who attend for their second or subsequent screen are found not to have invasive cancer or DCIS after a diagnostic open biopsy.</p>	5	<p>First screen: 11 to 337</p> <p>Subsequent screen: 9 to 367</p>	<p>First screen: 62</p> <p>Subsequent screen: 77</p>	<p>Used in conjunction with benign: malignant biopsy ratios to calculate pre-operative diagnosis rates and benign open biopsy rates</p>
<p>Diagnostic open biopsies performed in the Program</p> <p>Percentage of open biopsies performed in the Program</p>	5	None to 100%		<p>Informed discussion regarding the responsibility of the Program for open biopsies performed in and outside the Program</p>

STATE AND TERRITORY DATA

Data collected	Number of States and Territories contributing data ¹	Range	Median	Purpose
<p>Invasive cancers detected</p> <p>Number of invasive cancers detected, in 10 year age groupings by screening round and size of largest cancer detected</p> <p><i>Related NAS</i></p> <p>2.1.1 <i>≥ 50 per 10,000 women aged 50-69 years who attend for their first screen are diagnosed with invasive breast cancer.</i></p> <p>2.1.2 <i>≥ 35 per 10,000 women aged 50-69 years who attend for their second or subsequent screen are diagnosed with invasive breast cancer.</i></p> <p>2.1.3 <i>The Service monitors the rates of invasive breast cancer among women aged 40-49 years and 70 years and over.</i></p>	6	First screen: 12 to 246 Subsequent screen: 34 to 435	First screen: 86 Subsequent screen: 305	Numerator for calculation of invasive cancer detection rates
<p>Invasive Cancer Detection Rates</p> <p>Number of invasive cancers detected in women aged 50-69 yrs per 10,000 screens</p> <p><i>Related NAS</i></p> <p>2.1.1 <i>≥ 50 per 10,000 women aged 50-69 years who attend for their first screen are diagnosed with invasive breast cancer.</i></p> <p>2.1.3 <i>≥ 35 per 10,000 women aged 50-69 years who attend for their second or subsequent screen are diagnosed with invasive breast cancer.</i></p>	6	First screen: 30-64 Subsequent screen: 35-40	First screen: 49 Subsequent screen: 37	Informed discussion regarding invasive cancer detection rates

STATE AND TERRITORY DATA

Data collected	Number of States and Territories contributing data ¹	Range	Median	Purpose
<p>Invasive Cancer Detection Rates</p> <p>Number of invasive cancers detected in women aged 40+ years per 10,000 screens</p> <p><i>Related NAS</i></p> <p>2.1.3 <i>The Service monitors the rates of invasive breast cancer among women aged 40-49 years and 70 years and over.</i></p>	6	<p>First screen: 30-64</p> <p>Subsequent screen: 25-41</p>	<p>First screen: 50</p> <p>Subsequent screen: 38</p>	<p>Informed discussion regarding invasive cancer detection rates</p>
<p>Small Invasive Cancer Detection Rates</p> <p>Number of small invasive cancers (less than or equal to 15mm) detected in women aged 50-69 yrs per 10,000 screens</p> <p><i>Related NAS</i></p> <p>2.2.1 <i>≥ 25 per 10,000 women aged 50-69 years who attend for screening are diagnosed with small (≤ 15mm) invasive breast cancer.</i></p>	6	All Screens: 16-29	All screens: 27	<p>Informed discussion regarding small invasive cancer detection rates</p>
<p>Small Invasive Cancer Detection Rates</p> <p>Number of small invasive cancers (less than or equal to 15mm) detected in women aged 40+ yrs per 10,000 screens</p> <p><i>Related NAS</i></p> <p>2.2.2 <i>The Service monitors the rates of small (< 15mm) invasive breast cancer among women aged 40-49 years and 70 years and over.</i></p>	6	All Screens: 15-30	All screens: 26	<p>Informed discussion regarding small invasive cancer detection rates</p>

STATE AND TERRITORY DATA

Data collected	Number of States and Territories contributing data ¹	Range	Median	Purpose
<p>DCIS detected</p> <p>Number of DCIS detected in the absence of invasive cancer, in 10-year age groupings by screening round</p> <p><i>Related NAS</i></p> <p>2.3.1 ≥ 12 per 10,000 women aged 50-69 years who attend for their first screen are diagnosed with DCIS.</p> <p>2.3.2 ≥ 7 per 10,000 women aged 50-69 years who attend for their second or subsequent screen are diagnosed with DCIS.</p> <p>2.3.3 The Service monitors the rates of DCIS among women aged 40-49 years and 70 years and over.</p>	6	First screen: 5 to 52 Subsequent screen: 8 to 81	First screen: 22 Subsequent screen: 28	Numerator for calculation of DCIS detection rates
<p>DCIS Detection Rate</p> <p>Number of DCIS detected in the absence of invasive cancer in women aged 50-69 years per 10,000 screens</p> <p><i>Related NAS</i></p> <p>2.3.1 ≥ 12 per 10,000 women aged 50-69 years who attend for their first screen are diagnosed with DCIS.</p> <p>2.3.2 ≥ 7 per 10,000 women aged 50-69 years who attend for their second or subsequent screen are diagnosed with DCIS.</p>	6	First screen: 11-15 Subsequent screen: 6-11	First screen: 14 Subsequent screen: 7	Informed discussion regarding DCIS detection rates
<p>DCIS Detection Rate</p> <p>Number of DCIS detected in the absence of invasive cancer in women aged 40+ years per 10,000 screens</p> <p><i>Related NAS</i></p> <p>2.3.3 The Service monitors the rates of DCIS among women aged 40-49 years and 70 years and over.</p>	6	First screen: 9-17 Subsequent screen: 5-10	First screen: 12 Subsequent screen: 8	Informed discussion regarding DCIS detection rates

STATE AND TERRITORY DATA

Data collected	Number of States and Territories contributing data ¹	Range	Median	Purpose
Abnormal mammograms diagnosed as cancer Number of women who attended for assessment on the basis of a suspicious mammogram who were subsequently diagnosed as having cancer (invasive and/or DCIS), in 5 year age groupings by screening round	5	First screen: 18 to 263 Subsequent screen: 48 to 470	First screen: 108 Subsequent screen: 210	Informed discussion regarding pre-operative diagnosis rates

SERVICE DATA

Data collected	Number of Services contributing data	Range	Median and mean	Purpose
Participation rates Women aged 40–49 years as a percentage of total number of women screened Related NAS 1.1.2 <i>The Service monitors the proportion of women aged 40–49 years and 70 years and over screened.</i>	24	10.0 to 35.2%	Median: 23.9% Mean: 21.9%	Informed discussion regarding participation rate standards
Women aged 50–69 years as a percentage of total number of women screened Related NAS 1.1.1 <i>≥ 70% of women aged 50–69 years participate in screening in the most recent 24-month period.</i>	24	55.0 to 77.0%	Median: 67.0% Mean: 67.0%	

SERVICE DATA			
Data collected	Number of Services contributing data	Range	Median and mean
Participation of women aged 50–69 years as a percentage of the population <i>Related NAS</i> 1.1.1 ≥ 70% of women aged 50–69 years participate in screening in the most recent 24-month period.	24	39.4 to 69.8%	Median: 58.8% Mean: 58.3%
Participation of women aged 40–49 years as a percentage of the population <i>Related to Performance Indicator 1 - Participation</i>	22	9.0 to 46.3%	Median: 25.1% Mean: 24.1%
Participation of women aged 70+ years as a percentage of the population <i>Related to Performance Indicator 1 - Participation</i>	22	9.4 to 33.0%	Median: 26.0% Mean: 24.2%
Participation of Aboriginal and Torres Strait Islander women as a percentage of the population – Services reporting women aged 40+ years <i>Related NAS</i> 1.3.5 <i>The Service monitors participation of women from special groups and where rates for women aged 50–69 years are below 70% implements specific strategies to encourage their participation in screening. Consideration of at least the following groups will be made:</i> (b) Indigenous women	9	14.0 to 36.0%	Median: 22.0% Mean: 23.1%
Participation of Aboriginal and Torres Strait Islander women as a percentage of the population – Services reporting women aged 50–69 years only <i>Related NAS – as above</i>	22	14.0 to 84.7%	Median: 55.6% Mean: 40.9%

SERVICE DATA			
Data collected	Number of Services contributing data	Range	Median and mean
Participation of non-English-speaking background women as a percentage of the population – Services reporting women aged 40+ years <i>Related NAS</i> 1.3.5) <i>The Service monitors participation of women from special groups and where rates for women aged 50-69 years are below 70% implements specific strategies to encourage their participation in screening. Consideration of at least the following groups will be made:</i> (a) Women from culturally and linguistically diverse backgrounds.	9	17.0 to 40.0%	Median: 33.0% Mean: 30.1%
Participation of non-English-speaking background women as a percentage of the population – Services reporting women aged 50–69 years only <i>Related NAS – as above</i> Rescreening rates	22	17.0 to 131.7%	Median: 63.5% Mean: 56.8%
Rescreening rates for all screening rounds Related to Performance Indicator 6	23	55.3 to 89.6%	Median: 82.3% Mean: 80.9%
Rescreening rates for the first rescreen <i>Related NAS</i> 1.2.2 > 75% of women aged 50-67 years who attend for their first screen within the Program are rescreened within 27 months.	21	55.0 to 82.9%	Median: 71.4% Mean: 71.0%

^k A percentage greater than 100 results from the lack of updated population estimates for this group.

SERVICE DATA				
Data collected	Number of Services contributing data	Range	Median and mean	Purpose
<p>Rescreening rates for the second and subsequent rescreen</p> <p><i>Related NAS</i></p> <p>1.2.2 <i>Of women aged 50-67 years participating in their second and subsequent screen within the Program, ≥ 90% are rescreened within 27 months of their previous screening episode.</i></p>	21	78.6 to 91.2%	Median: 84.0% Mean: 84.0%	
<p>Multidisciplinary team meetings</p> <p>Percentage of staff attending at least 60% of multidisciplinary team meetings</p>	9	32.0 to 100.0%	Median: 50.0% Mean: 60.0%	Informed discussion of appropriateness of existing standard as a measure of multidisciplinary activity
<p>Interval between screening and assessment</p> <p>Percentage of women recalled for assessment for whom the interval between the screening and initial assessment visit was no more than 10 days</p> <p><i>Related NAS</i></p> <p>3.7.2 (a) <i>≥ 90% of women requiring assessment attend for an assessment visit within 28 calendar days of their screening visit.</i></p> <p>3.7.2 (b) <i>All women will be provided with information on waiting times.</i></p>	23	15.2 to 92.4%	Median: 60.0% Mean: 61.2%	Informed discussion of the appropriateness of the existing standard
<p>Completion of primary treatment forms</p> <p>Percentage of primary treatment forms completed</p> <p><i>Related NAS</i></p> <p>2.25.4 <i>≥ 80% of primary treatment information are received by the Service.</i></p>	13	10.0 to 100.0%	Median: 100.0% Mean: 87.1%	Informed discussion of the appropriateness of the existing standard as a measure of effective follow-up

APPENDIX D.B

DATA FROM SERVICES AND STATES AND TERRITORIES USED IN DEVELOPING THE STANDARDS

In order to help ensure that the standards are appropriate and relevant in the Australian context, State and Territory Programs were asked to provide additional data about certain aspects of practice. Data were received from all States and Territories.⁶⁴

STATE AND TERRITORY DATA^L

Data collected	Number of States and Territories contributing data	Range	Median	Mean	Purpose
Early review Percentage of women screened placed on early review for assessment	8	0.02% - 0.26%	0.215	0.19	Informed discussion regarding early review standards

^L 1999–2000 data year.

TOOL FOR ASSESSING WHETHER A WOMAN IS AT INCREASED RISK OF DEVELOPING BREAST CANCER DUE TO FAMILY HISTORY

The Family History Tool was endorsed by the National Advisory Committee in 2001 as a valid mechanism for the collection and analysis of data regarding patterns and prevalence of family history. It is not compulsory to use the tool to meet the requirements of the NAS.

QUESTIONS ABOUT BREAST CANCER IN YOUR FAMILY

Your answers to these questions will help us to work out if you may have an increased risk of breast cancer. By family we are referring to your blood relatives, your mother, sisters and daughters, and your grandmothers, aunts and nieces. You should be aware that your family history can change over time. Please see your doctor if you have any concerns in the future about breast cancer in your family.

Instructions

- Please tick the boxes that are most appropriate to your family.
- If you are unsure or don't know, please tick NO.

1. Have any of the following blood relatives—your mother, sisters, daughters, grandmothers, aunts and nieces, ever had breast cancer?

YES Please go to question 2.

NO Thank you. You have finished. There is no need to answer any more questions. Please read **BOX 1** over page page.

2. Have your mother, sisters or daughters had breast cancer?

YES Please go to question 3.

NO Please do not answer questions 3 or 4 and go directly to question 5.

3. Were any of the women in Question 2 diagnosed with breast cancer before the age of 50?

NO Please go to question 4.

YES Thank you. There is no need to answer any more questions. Please read **BOX 2** over page page.

4. How many women in question 2 developed breast cancer?

- One only** Please go to question 5. **Two or more** Thank you. There is no need to answer any more questions. Please read **BOX 2** at the bottom of this page.

5. Have your grandmothers, aunts or nieces on either your mother's or your father's sides of the family ever had breast cancer?

- YES** Please go to question 6. **NO** Thank you. There is no need to answer any more questions. Please read **BOX 1** at the bottom of this page.

6. Please tick **ONE** of the following statements that describes all your relatives who have had breast cancer: (Note: for statements c and d, your daughters and sisters can be counted on either side of the family).

- a. I have **one relative** with breast cancer.
*Thank you. Please read **BOX 1** at the bottom of this page.*
- b. I have **one relative** on each side of my family with breast cancer.
*Thank you. Please read **BOX 1** at the bottom of this page.*
- c. I have **two or more relatives on my mother's side** of the family who have had breast cancer.
*Thank you. Please read **BOX 2** at the bottom of this page.*
- d. I have **two or more relatives on my father's side** of the family who have had breast cancer.
*Thank you. Please read **BOX 2** at the bottom of this page.*

BOX 1 Currently, based on the history of breast cancer in your close relatives, your risk of breast cancer is about the same as that of the great majority of women in the general population.

BOX 2 Currently, based on the history of breast cancer in your close relatives, you may have an increased risk of developing breast cancer. Please see your doctor for more information.

APPENDIX F

INTERNATIONAL CANCER DETECTION STANDARDS

Table F.A: Standards per 1,000 women screened in United Kingdom National Health Service Breast Screening Program¹⁰ and Scottish Breast Screening Program¹⁵⁶ in women aged 50–64 years

	Great Britain 1997–98		Scotland 1996–97	
	Standard	Achieved	Expected	Achieved
First screens				
Invasive cancer detection rate per 1,000	> 3.6	5.0	> 3.6 ^M	4.8
In situ rate (%)	10–20	23.9	–	–
Invasive cancers < 15 mm	50%	48.9%	> 1.8	2.6
Invasive cancers < 10 mm	–	–	> 0.9	1.0
Standardised detection ratio	≥ 1.0	1.22	> 1.0	1.2
Subsequent screens				
Invasive cancer detection rate per 1,000	> 4.0	3.8	> 4.0	4.2
In situ rate (%)	10–20	20.9	–	–
Invasive cancers < 15 mm	50%	55.2%	> 2.0	2.4
Invasive cancers < 10 mm	–	–	> 1.0	1.2
Standardised detection ratio	≥ 1.0	0.98	> 1.0	1.1
All screens				
In situ (%)	–	–	10–20	18.1

^M 50–54 years only.

Table F.B: Observed numbers of cancers (invasive breast cancer and DCIS) detected in the Netherlands and Canada

	Year	Age group	Initial screens per 1,000 screens	Subsequent screens Per 1,000 screens
Ontario Breast Screen ¹⁵⁷	Website, no date	All ages screened	9.6	5.3
Canadian Breast Cancer Screening	1996	50–59 years	5.9	3.2
Programs, 1999 ¹⁵⁸	1996	60–69 years	9.0	4.5
Netherlands ¹⁵⁹	1990–1992	50–59 years	6.9	3.5
Netherlands ¹⁶⁰	1990–1993	All ages screened	6.57	3.46
Limberg, Netherlands ¹⁶¹	1986–1995	All ages screened	5.1	2.4

Table F.C: Standards and achievements for small cancer detection rates in women aged 50–64 in Great Britain and Scottish programs

	United Kingdom National Health Service 10 1997–98		Scottish Breast Screening Program 156 1996–97	
	Standard	Achieved	Expected	Achieved
First screens				
Invasive cancers < 15 mm	50%	48.9%	> 1.8	2.6
Invasive cancers < 10 mm	–	–	> 0.9	1.0
Subsequent screens				
Invasive cancers < 15 mm	50%	55.2%	> 2.0	2.4
Invasive cancers < 10 mm	–	–	> 1.0	1.2

Table F.D: Standards for detection of DCIS in the Great Britain and Scottish programs in women aged 50–64

	United Kingdom National Health Service ¹⁰ 1997–98		Scottish Breast Screening Program ¹⁵⁶ 1996–97	
	Women aged 50–64		Women aged 50–64	
	Standard	Achieved	Expected	Achieved
First screens				
Invasive cancer detection rate per 1,000 women screened	> 3.6	5.0	> 3.61	4.8
In situ rate (%)	10–20	23.9	–	–
Subsequent screens				
Invasive cancer detection rate per 1,000 women screened	> 4.0	3.8	> 4.0	4.2
In situ rate (%)	10–20	20.9		
Standardised detection ratio	≥ 1.0	0.98	> 1.0	1.1
All screens				
In situ (%)	–	–	10–20	18.1

DETERMINING CANCER DETECTION RATES: SOME PROCEDURAL NOTES

1. PROPORTION OF WOMEN SCREENED

In 1997 screening covered 28% of women aged 50–69 years in Australia. Coverage varied substantially between states, from 25% of women aged 50–69 years in one state to 27–30% in the majority of states and 48% in a small population. Nationally, 40% of invasive breast cancers in this age group were detected in BreastScreen. BreastScreen detected between 30% and 39% of cancers in individual states, although in two populations BreastScreen detected high percentages, 47% and 69%.

2. DIFFERENCES BETWEEN INITIAL AND SUBSEQUENT SCREENS

Focusing on screening round, initial screens in women aged 50–69 years in each state ranged between 17% and 36% of all screens and the invasive breast cancers detected at initial screens were between 20% and 45% of all invasive cancers detected in BreastScreen.

3. NUMBER OF SCREENS

The number of screens in the Australian programs covered a large range. In 1997, the lowest number of initial screens in women aged 50–69 years in a state was 2,000, intermediate numbers were around 10,000 and the highest number was 48,000. Subsequent screens covered a range between 8,000 and 112,000 screens. The probability of detecting cancers and cancers of a certain size is greatest in populations with the greatest number of screens. The standard for cancer and small cancer detection needs to take into account variation in individual estimates caused by differences in number of screens carried out. To address this issue, we have suggested confidence limits that are based on the number of screens done. The standard would require achievement above the lower 95% confidence limit based on the number of screens.

4. THE USE OF A STANDARDISED DETECTION RATIO IN THE UNITED KINGDOM

In its standards, the United Kingdom program uses a standardised detection ratio. This measure requires knowledge of the incidence rates expected in the absence of screening and application of the prevalence to incidence ratio from the Swedish Two County Study. There is considerable uncertainty in knowing the expected incidence and in applying the Swedish rates to the Australia screening program.

We have estimated incidence in the absence of screening by applying standard annual increases (0.5% a year was the increase in breast cancer mortality rates in the 1980s; and 1.5% a year as calculated by Harmer et al in Victoria to rates from 1986 on) and also by projecting trendlines to rates in 1982–86.¹⁶² Expected incidence rates in women 50–59 years range from 18.1 to 22.8 per 10,000 and in women aged 60–69 years from 21.8 to 27.0 per 10,000. In 1987, incidence was higher than in 1986 in all age categories. If included in the baseline for predictions, expected rates in 1997 are higher by around five points or so.

5. CALCULATION OF VARIATION AMONGST STATES AND TERRITORIES

The steps taken to calculate rates for examination of variation among the states and territories were: first, calculate crude cancer detection rates and test the overall variation against the chi-square distribution. Second, calculate age-standardised rates (ASRs) using two different, suitable populations, (1) the 1997 Australian female population and (2) the population of women who were screened by BreastScreen in 1997. These rates can be used to see if any one state had 95% CIs around the ASR that did not overlap with the CI for the Australian ASR. Third, calculate standardised detection ratios using overall Australian rates for different age groups as the expected rates in each state to see if any states had rates that departed from the overall rate.

APPENDIX H

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*.¹⁶³

Tests specified to be performed at six monthly intervals are easily performed by routine users of the ultrasound system. The tests specified to be performed annually may require assistance from a medical physicist or ultrasound service technician.

The method of testing should be documented in depth in the Radiographer or Service procedure manual. For all procedures it is Essen level map, power level, gain and Time Gain Control settings.

Table HA: *Ultrasound system quality control and performance standards*

Procedure ^N	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
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

^N Procedure should be repeated for each transducer (excluding Display Monitor Setup).

Procedure ^N	Minimum frequency	Required procedure elements	Control limits/requirements
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
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 	No significant change from baseline image
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 ⁷	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 ^o	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 \leq 1 mm • No significant change from baseline values
Lateral resolution or response width ^o	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 • Image width or spacing between targets < 1.5 mm • No major change from baseline values
Ring down or dead zone ^o	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)

^N Procedure should be repeated for each transducer (excluding Display Monitor Setup).

^o It may be desirable for these procedures to be performed by or with the assistance of a medical physicist or ultrasound service technician.

APPENDIX I

STANDARDS FOR MAMMOGRAPHY IMAGING SYSTEM PERFORMANCE

All mammography imaging system equipment shall meet the minimum performance standards specified in Table I.A to I.D 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 J. Procedures used shall be consistent with the recommendations of the Australasian College of Physical Scientists and Engineers in Medicine mammography quality assurance position papers.^{4,164} At acceptance, more extensive testing shall be performed as per the Australasian College of Physical Scientists and Engineers in Medicine recommendations.

Table I.A: Screen/film mammography imaging system performance standards

Item	Minimum standards
General mammographic unit condition	Mechanical stability, correct and safe function of system components and alarms.
Breast compression facility	<ul style="list-style-type: none"> • Maximum compression force ≤ 300 Newtons (N) • Maximum power-driven compression force in range 150–200 N • Force display accurate to within ± 20 N (when present) • Compressed breast thickness display accuracy within ± 5 mm (when present)
Collimation and alignment	<p>The X-ray field shall:</p> <ul style="list-style-type: none"> (a) extend to the chest wall edge of the film (b) not extend beyond the edge of the primary beam stop for those edges not adjacent to the patient's chest wall (c) not extend by more than 2% of the source to image distance (SID) beyond any edge of the film and (d) for standard contact views, extend to the non-chest wall edges of the film^P <p>The lack of alignment between any boundary of the light beam and the equivalent boundary of the X-ray beam in the plane of the image receptor shall not exceed 1% of the distance between the focus of the X-ray tube and the plane of the image receptor (ie. SID).</p> <p>The chest wall edge of the compression paddle shall:</p> <ul style="list-style-type: none"> • be aligned just beyond the chest wall edge of the image receptor such that the chest-wall edge of the compression paddle does not appear in the mammogram • not extend beyond the chest-wall edge of the image receptor by more than 1% of the SID with the paddle at 4.5 cm above the breast support

^P This requirement shall not apply to systems in the Program prior to July 2001

Item	Minimum standards
System resolution ^Q	<p>For both contact and magnification geometries, system resolution shall be:</p> <ul style="list-style-type: none"> • ≥ 11 line pairs per millimetre (lp/mm) for line-pair bars perpendicular to anode-cathode axis; and • ≥ 13 lp/mm for line-pair bars parallel to anode-cathode axis
Automatic exposure control (AEC) system performance	<p>An AEC shall be present and meet the following requirements:</p> <p>Reproducibility:</p> <ul style="list-style-type: none"> • Coefficient of variation for both absorbed dose and milli-ampere seconds (mAs) for four phototimed exposures of a test object shall be better than or equal to 0.05 <p>Mean Optical Density:</p> <ul style="list-style-type: none"> • Mean optical density shall be within ± 0.2 of the nominated optical density baseline for quality control phantom images. <p>For a given imaging geometry, mean optical density is defined as the mean of optical density measurements made at 4 cm from the chest wall edge on the mid-line of the film for images of 2, 4 and 6 cm of perspex (or tissue mimicking material) obtained using clinically relevant AEC, kilovolts peak (kVp) and target/filter selections, the 18 by 24 cm film format and a single density setting.</p> <p>Compensation:</p> <ul style="list-style-type: none"> • For photo-timed imaging of 2, 4 and 6 cm phantom thicknesses using a single density setting and clinically relevant kVp and target/filter selections the AEC shall be able to maintain optical density to within ± 0.15 of the mean optical density for contact geometry and ± 0.20 of the mean optical density for magnification geometry (if used) <p>Density Control:</p> <ul style="list-style-type: none"> • The difference in film optical density produced by adjacent density control settings should not be less than 0.10 and shall not exceed 0.20 except for units in the Program as of date of this document's publication, when it shall not exceed 0.25. <p>Security Cut-Out and Back-up Timer:</p> <ul style="list-style-type: none"> • Security cut-out mechanisms should be present and terminate the exposure within 50 ms or within 5 mAs or with an entrance absorbed dose for the American College of Radiology (ACR) accreditation phantom of less than 0.44 mGy. In the absence of security cut-out a back-up timer shall terminate exposure at ≤ 600 mAs.
Uniformity of cassette/screen response	<p>The optical density produced for a photo-timed exposure of a suitable phantom should be within ± 0.10 and shall be within ± 0.15 of the average optical density for all cassettes of the same size^R</p>
Image quality	<p>The ability to clearly visualise 4 fibres, 3 speck groups and 3 masses in an image of an American College of Radiology (ACR) accreditation phantom for a phototimed exposure using typical clinical settings at a MGD of ≤ 2 mGy.</p> <p>Images shall be free of clinically significant artefacts</p>
kVp accuracy	<p>Measured kVp shall be within $\pm 5\%$ of the specified value over the clinically relevant range</p>
kVp reproducibility	<p>Coefficient of variation ≤ 0.02 for a minimum of four exposures</p>

^Q For systems that meet manufacturer's focal spot size specifications and are operating in the Program as of the date of this document's publication this requirement shall only apply from the time of the next x-ray tube replacement.

^R Annual testing of uniformity of cassette/screen response may be performed by facility staff with results reviewed by the person performing annual system testing.

Item	Minimum standards
Beam quality	The half value layer (HVL) shall satisfy relationship: $[(kVp/100) + 0.03] \leq HVL < [(kVp/100) + C]$ where C = 0.12 mm Al for Mo/Mo = 0.19 mm Al for Mo/Rh = 0.22 mm Al for Rh/Rh = 0.30 mm Al for W/Rh = 0.32 mm Al for W/Al
Mean glandular dose (MGD)	MGD for contact imaging (with grid) of a 4.2 cm 50% adipose, 50% glandular breast (ie. American College of Radiology accreditation phantom) shall be \leq 2.0 milligray (mGy) for exposures made using typical clinical settings. The 2 mGy value shall be considered not as a dose limit but as a Diagnostic Reference Level (DRL) as defined by the International Commission on Radiological Protection in their Publication 73
Radiation output rate	For all clinically relevant SID settings the average rate of absorbed dose to air measured with the paddle in the beam shall be: <ul style="list-style-type: none"> • \geq 7.0 mGy/s at 4.5 cm above the breast support surface for a three-second, 28 kVp, Mo/Mo, large focus exposure; and • \geq 1.5 mGy/s at 4.5 cm above the upper surface of the film cassette for a three second, 28 kVp, Mo/Mo, small focus exposure
Accuracy of stereotactic localisation ⁵	Localisation within \pm 1 mm
Film viewer luminance	Viewers used for interpreting mammograms shall be capable of producing a luminance of at least 3,000 candela per square meter (cd/m ²).
Viewing area illuminance	\leq 50 lux
Film viewer masking	Shall be present and effectively restrict light to the exposed area of the film
X-ray tube leakage radiation [†]	The leakage radiation shall not exceed: <ul style="list-style-type: none"> • 1 mGy in one hour at 1 metre from the focal spot with the x-ray tube operating at the maximum rated voltage and the maximum rated continuous tube current • 0.01 mGy/100 mAs at 30 cm from the focal spot at 30 kVp

Table I.B: Digital (DR) mammography imaging system performance standards

Item	Minimum standards
General mammographic unit condition	<ul style="list-style-type: none"> • Mechanical stability, correct and safe function of system components and alarms. • DICOM image header correctly displays parameters
Breast compression facility	<ul style="list-style-type: none"> • Maximum compression force \leq 300 Newtons (N) • Maximum power-driven compression force in range 150–200 N • Force display accurate to within \pm 20 N • Compressed breast thickness display accuracy within \pm 5 mm

⁵ As verification of stereotactic accuracy is performed regularly by facility staff this test may be omitted from annual testing.

[†] At acceptance testing and following x-ray tube replacement

Item	Minimum standards
Collimation and alignment	<p>The X-ray field shall:</p> <p>extend to the chest wall edge of the image receptor, and</p> <p>not extend beyond the edge of the primary beam stop for those edges not adjacent to the patient's chest wall by more than 2% of the source to image distance (SID).</p> <p>The lack of alignment between any boundary of the light beam and the equivalent boundary of the X-ray beam in the plane of the image receptor shall not exceed 1% of the distance between the focus of the X-ray tube and the plane of the image receptor (ie. SID).</p> <p>The chest wall edge of the compression paddle shall:</p> <ul style="list-style-type: none"> • be aligned just beyond the chest wall edge of the image receptor such that the chest-wall edge of the compression paddle does not appear in the mammogram • not extend beyond the chest-wall edge of the image receptor by more than 1% of the SID with the paddle at 4.5 cm above the breast support
Missed tissue at chest wall ^u	Extent of missed tissue at chest wall ≤ 5 mm
System resolution	For both contact and magnification geometries, system resolution shall meet the manufacturer's specification. This may be established by measuring the Modulation Transfer Function (MTF) at acceptance.
Automatic exposure control (AEC) system performance	<p>An AEC shall be present and meet the following requirements:</p> <p>Reproducibility:</p> <ul style="list-style-type: none"> • Coefficient of variation for both absorbed dose and milli-ampere seconds (mAs) for four phototimed exposures of a test object shall be better than or equal to 0.05 <p>Compensation & Contrast to Noise Ratio (CNR):</p> <p>The equipment vendor must provide the manufacturer's recommended target pixel values and allowable tolerance for a range of PMMA absorber thicknesses. In some systems, the AEC is designed to maintain an essentially constant MPV over the thickness range, in which case a single target value is appropriate.</p> <p>The MPV should be within $\pm 10\%$ of the baseline value for the respective PMMA thickness.</p> <p>When a 0.2 mm Al foil is used as a contrast test tool the CNR for 2, 4 and 6 cm PMMA may be measured and the provisional requirement is that:</p> <ul style="list-style-type: none"> • The ratio $CNR_{2cm} / CNR_{4cm} > 1.1$ and ratio $CNR_{6cm} / CNR_{4cm} > 0.9$ <p>For systems that use hardcopy for reporting the OD should comply with the standards for film screen mammography.</p> <p>Density Control (if applicable):</p> <ul style="list-style-type: none"> • The difference in mAs should typically be between 5% and 10% for adjacent density control steps. <p>Security Cut-Out and Back-up Timer:</p> <ul style="list-style-type: none"> • Security cut-out mechanisms should be present and terminate the exposure within 50 ms or within 5 mAs or with an entrance absorbed dose for the American College of Radiology (ACR) accreditation phantom of less than 0.44 mGy. In the absence of security cut-out a back-up timer shall terminate exposure at ≤ 600 mAs.

^u At acceptance testing and following x-ray tube replacement.

Item	Minimum standards
Image uniformity and artefact	<p>Maximum deviation of MPV in any ROI $\leq \pm 15\%$ of MPV for central ROI</p> <p>Maximum deviation in SNR $\leq \pm 15\%$ of mean SNR for central ROI.</p> <p>Maximum deviation in SNR as a function of time is $\leq \pm 10\%$.</p> <p>There must be no evidence of blotches or regions of altered noise appearance, observable grid lines or table top structures, bright or dark pixels</p>
Detector element failure	The manufacturers should provide a “bad pixel map” which indicates which del values are not based on their own reading. This should be inspected by the medical physicist at each visit and compared to earlier maps.
Image quality	<p>The ability to clearly visualise 5 fibres, 4 speck groups and 3.5 masses in an image of an American College of Radiology (ACR) accreditation phantom for a photo timed exposure using typical clinical settings at a MGD of ≤ 2 mGy.</p> <p>Images shall be free of clinically significant artefacts</p>
Spatial linearity and geometric distortion ^v	Measured dimensions in image should be within 2% of true dimensions.
Ghost image evaluation	<p>Assessed using 40 mm PMMA and 0.1 mm Al foil:</p> <p>ghost image factor < 0.3</p>
System linearity evaluation	<ul style="list-style-type: none"> Plot of MPV versus the absorbed dose should have $R^2 > 0.99$ Plot of noise or standard deviation squared (SD^2) versus the absorbed dose should have $R^2 > 0.95$
kVp accuracy	Measured kVp shall be within $\pm 5\%$ of the specified value over the clinically relevant range
kVp reproducibility	Coefficient of variation ≤ 0.02 for a minimum of four exposures
Beam quality	<p>The half value layer (HVL) shall satisfy relationship:</p> $[(kVp/100) + 0.03] \leq HVL < [(kVp/100) + C]$ <p>where C</p> <ul style="list-style-type: none"> = 0.12 mm Al for Mo/Mo = 0.19 mm Al for Mo/Rh = 0.22 mm Al for Rh/Rh = 0.30 mm Al for W/Rh = 0.32 mm Al for W/Al
Mean glandular dose (MGD)	<p>MGD for contact imaging of a 4.2 cm 50% adipose, 50% glandular breast (ie. American College of Radiology accreditation phantom) shall be ≤ 2.0 milligray (mGy) for exposures made using typical clinical settings.</p> <p>The 2 mGy value shall be considered not as a dose limit but as a Diagnostic Reference Level (DRL) as defined by the International Commission on Radiological Protection in their Publication 73</p> <p>Additionally the MGD shall be:</p> <ul style="list-style-type: none"> ≤ 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)
Exposure time	<p>For clinically relevant techniques and SID settings the maximum exposure time when irradiating 6 cm PMMA should be:</p> <ul style="list-style-type: none"> ≤ 3.5 seconds for fine focus, and ≤ 2 seconds for broad focus.
Film viewer luminance	Viewers used for interpreting hardcopy images shall be capable of producing a luminance of at least 3,000 candela per square meter (cd/m^2).

^v At acceptance testing and following x-ray tube replacement

Item	Minimum standards
Viewing area illuminance	≤ 50 lux (hardcopy only)
Film viewer masking	Shall be present and effectively restrict light to the exposed area of the film (hardcopy only)
Monitor luminance and viewing conditions	<ul style="list-style-type: none"> • Monitors used for interpretation must not be < 5 megapixels and that for acquisition must not be < 1.3 megapixels • Luminance dynamic range > 250:1 • Ambient light ≤ 10 lux
Monitor performance	<p>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 • Resolution patterns resolved • All shades of grey visible • Free from artefact
X-ray tube leakage radiation ^w	<p>The leakage radiation level shall not exceed:</p> <ul style="list-style-type: none"> • 1 mGy in one hour at 1 metre from the focal spot with the x-ray tube operating at the maximum rated voltage and the maximum rated continuous tube current • 0.01 mGy/100 mAs at 30 cm from the focal spot and 30 kVp
Printer (hardcopy only)	$D_{\min} < 0.25 \text{ OD}$ and $D_{\max} > 3.4 \text{ OD}$

Table I.C: Computed Radiography (CR) mammography imaging system performance standards

Item	Minimum standards
General mammographic unit condition	<ul style="list-style-type: none"> • Mechanical stability, correct and safe function of system components and alarms. • DICOM image header correctly displays parameters
Breast compression facility	<ul style="list-style-type: none"> • Maximum compression force ≤ 300 Newtons (N) • Maximum power-driven compression force in range 150–200 N • Force display accurate to within ± 20 N • Compressed breast thickness display accuracy within ± 5 mm

^w At acceptance testing and following x-ray tube replacement

Item	Minimum standards
Collimation and alignment	<p>The X-ray field shall:</p> <ul style="list-style-type: none"> extend to the chest wall edge of the image receptor not extend beyond the edge of the primary beam stop for those edges not adjacent to the patient's chest wall, and not extend by more than 2% of the source to image distance (SID) beyond any edge of the image <p>The lack of alignment between any boundary of the light beam and the equivalent boundary of the X-ray beam in the plane of the image receptor shall not exceed 1% of the distance between the focus of the X-ray tube and the plane of the image receptor (ie. SID).</p> <p>The chest wall edge of the compression paddle shall:</p> <ul style="list-style-type: none"> be aligned just beyond the chest wall edge of the image receptor such that the chest-wall edge of the compression paddle does not appear in the mammogram not extend beyond the chest-wall edge of the image receptor by more than 1% of the SID with the paddle at 4.5 cm above the breast support
Missed tissue at chest wall ^x	Extent of missed tissue at chest wall ≤ 5 mm
System resolution	For both contact and magnification geometries, system resolution shall meet the manufacturer's specification. This may be established by measuring the Modulation Transfer Function (MTF) at acceptance.
Automatic exposure control (AEC) system performance	<p>An AEC shall be present and meet the following requirements:</p> <p>Reproducibility:</p> <ul style="list-style-type: none"> • Coefficient of variation for both absorbed dose and milli-ampere seconds (mAs) for four phototimed exposures of a test object shall be better than or equal to 0.05 <p>Compensation^y:</p> <ul style="list-style-type: none"> • The absorbed dose to the image plate should be within $\pm 10\%$ of the baseline value for the respective PMMA thickness. • Variation of the absorbed dose to the image plate as a function of thickness (2 cm to 6 cm PMMA) should be less than $\pm 20\%$ for both contact and magnification modes (if applicable). <p>For systems that use hardcopy for reporting the OD should comply with the standards for film screen mammography.</p> <p>Density Control:</p> <ul style="list-style-type: none"> • The difference in mAs should typically be between 5% and 10% for adjacent density control steps. • Security Cut-Out and Back-up Timer: Security cut-out mechanisms should be present and terminate the exposure within 50 ms or within 5 mAs or with an entrance absorbed dose for the American College of Radiology (ACR) accreditation phantom of less than 0.44 mGy. In the absence of security cut-out a back-up timer shall terminate exposure at ≤ 600 mAs.

^x At acceptance testing and following x-ray tube replacement

^y These specifications in terms of the exposure indicator depend on the CR manufacturer (see ACPSEM Position Paper⁴)

Item	Minimum standards
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 $\leq \pm 15\%$ of mean SNR for central ROI. • Maximum deviation in SNR as a function of time is $\leq \pm 10\%$. • There must be no evidence of blotches or regions of altered noise appearance, observable grid lines or table top structures, bright or dark pixels
Uniformity of cassette/image plate response	<ul style="list-style-type: none"> • Maximum mAs variation $\leq \pm 10\%$ between all plates • Coefficient of variation (COV) of absorbed dose to QC plate < 0.05 • Absorbed dose to individual plate should differ from mean for that size by $< \pm 5\%$. • Difference in mean absorbed dose to plates of different sizes $< \pm 20\%$.^z
Image quality	<p>The ability to clearly visualise 5 fibres, 4 speck groups and 3.5 masses in an image of an American College of Radiology (ACR) accreditation phantom for a phototimed exposure using typical clinical settings at a MGD of ≤ 2 mGy.</p> <p>Images shall be free of clinically significant artefacts</p>
Spatial linearity and geometric distortion ^{AA}	Measured dimensions in image should be within 2% of true dimensions.
Ghost image evaluation	<p>Assessed using 40 mm PMMA and 0.1 mm Al foil:</p> <ul style="list-style-type: none"> • ghost image factor < 0.3
System linearity evaluation	<ul style="list-style-type: none"> • Appropriate plot of exposure indicator versus the absorbed dose should have $R^2 > 0.99$
kVp accuracy	Measured kVp shall be within $\pm 5\%$ of the specified value over the clinically relevant range
kVp reproducibility	Coefficient of variation ≤ 0.02 for a minimum of four exposures
Beam quality	<p>The half value layer (HVL) shall satisfy relationship:</p> $[(kVp/100) + 0.03] \leq HVL < [(kVp/100) + C]$ <p>where C</p> <ul style="list-style-type: none"> = 0.12 mm Al for Mo/Mo = 0.19 mm Al for Mo/Rh = 0.22 mm Al for Rh/Rh = 0.30 mm Al for W/Rh = 0.32 mm Al for W/Al
Mean glandular dose (MGD)	<p>MGD for contact imaging of a 4.2 cm 50% adipose, 50% glandular breast (ie. American College of Radiology accreditation phantom) shall be ≤ 2.0 milligray (mGy) for exposures made using typical clinical settings.</p> <p>The 2 mGy value shall be considered not as a dose limit but as a Diagnostic Reference Level (DRL) as defined by the International Commission on Radiological Protection in their Publication 73</p> <p>Additionally the MGD shall be:</p> <ul style="list-style-type: none"> • ≤ 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)

^z These specifications in terms of the exposure indicator depend on the CR manufacturer (see ACPSEM Position Paper⁴)

^{AA} At acceptance testing and following x-ray tube replacement

Item	Minimum standards
Exposure time	For clinically relevant techniques and SID settings the maximum exposure time when irradiating 6 cm PMMA should be: <ul style="list-style-type: none"> • ≤ 3.5 seconds for fine focus, and • ≤ 2 seconds for broad focus.
Film viewer luminance	Viewers used for interpreting hardcopy images shall be capable of producing a luminance of at least 3,000 candela per square meter (cd/m ²).
Viewing area illuminance	≤ 50 lux (hardcopy only)
Film viewer masking	Shall be present and effectively restrict light to the exposed area of the film (hardcopy only)
Monitor luminance and viewing conditions	<ul style="list-style-type: none"> • Monitors used for interpretation must not be < 5 megapixels and those for acquisition must not be < 1.3 megapixels • Luminance dynamic range > 250:1 • Ambient light ≤ 10 lux
Monitor performance	Using TG18-QC pattern: <ul style="list-style-type: none"> • No smearing artefact, ramps without terracing. • Lines straight, boxes square, active display centred, borders complete • Resolution patterns resolved • All shades of grey visible • Free from artefact
X-ray tube leakage radiation ^{BB}	The leakage radiation level shall not exceed: <ul style="list-style-type: none"> • 1 mGy in one hour at 1 metre from the focal spot with the x-ray tube operating at the maximum rated voltage and the maximum rated continuous tube current • 0.01 mGy/100 mAs at 30 cm from the focal spot and 30 kVp
Printer (hardcopy only)	$D_{\min} < 0.25 \text{ OD}$ and $D_{\max} > 3.4 \text{ OD}$

Table I.D: Digital stereotactic imaging system performance standards

Item	Minimum standards
General mammographic unit condition	<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.

^{BB} At acceptance testing and following x-ray tube replacement

Item	Minimum standards
Breast compression facility	<ul style="list-style-type: none"> • Maximum compression force \leq 300 Newtons (N) • Maximum power-driven compression force in range 150–200 N • Force display accurate to within \pm 20 N • Compressed breast thickness display accuracy within \pm 5 mm
Collimation and alignment	<p>The X-ray field defined by the biopsy window:</p> <p>(c) shall be aligned centrally with digital image receptor, and</p> <p>(d) 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.</p>
System resolution	<p>The system resolution shall meet the manufacturer's specification. This may be established by measuring the Modulation Transfer Function (MTF) at acceptance.</p>
Automatic exposure control (AEC) system performance	<p>The AEC shall meet the following requirements:</p> <p>Reproducibility:</p> <ul style="list-style-type: none"> • Coefficient of variation for both absorbed dose and milli-ampere seconds (mAs) for four phototimed exposures of a test object shall be better than or equal to 0.05 <p>Compensation & Contrast to Noise Ratio (CNR):</p> <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> <ul style="list-style-type: none"> • The MPV should be within \pm10% of the baseline value for the respective PMMA thickness. <p>If the contrast to noise ratio (CNR) is measured using a 0.2 mm Al foil as a contrast test tool the CNR for 2, 4 and 6 cm PMMA the provisional requirement is that:</p> <ul style="list-style-type: none"> • The ratio $CNR_{2cm} / CNR_{4cm} > 1.1$ and ratio $CNR_{6cm} / CNR_{4cm} > 0.9$ <p>For systems that use hardcopy for reporting the OD should comply with the standards for film screen mammography.</p> <p>Density Control (if applicable):</p> <ul style="list-style-type: none"> • The difference in mAs should typically be between 5% and 10% for adjacent density control steps. <p>Security Cut-Out and Back-up Timer:</p> <ul style="list-style-type: none"> • Security cut-out mechanisms should be present and terminate the exposure within 50 ms or within 5 mAs or with an entrance absorbed dose for the ACR mini-accreditation phantom of less than 0.44 mGy. In the absence of security cut-out a back-up timer shall terminate exposure at \leq 600 mAs.

Item	Minimum standards
Image uniformity and artefact	<ul style="list-style-type: none"> • Maximum deviation of MPV in any ROI $\leq \pm 15\%$ of MPV for central ROI • Maximum deviation in SNR $\leq \pm 15\%$ of mean SNR for central ROI. • Maximum deviation in SNR as a function of time is $\leq \pm 10\%$. • There must be no evidence of blotches or regions of altered noise appearance, observable grid lines or table top structures, bright or dark pixels
Image quality	<p>The ability to clearly visualise 3 fibres, 2 speck groups and 1.5 masses in an image of an ACR mini-accreditation phantom for a phototimed exposure using typical clinical settings at a MGD of ≤ 2 mGy.</p> <p>Images shall be free of clinically significant artefacts</p>
Spatial linearity and geometric distortion ^{CC}	Measured dimensions in image should be within 2% of true dimensions.
Ghost image evaluation ^{DD}	<p>Assessed using 40 mm PMMA and 0.1 mm Al foil:</p> <ul style="list-style-type: none"> • ghost image factor < 0.3
System linearity evaluation ^{EE}	<p>Plot of MPV versus the absorbed dose should have $R^2 > 0.99$</p> <p>Plot of noise or standard deviation squared (SD^2) versus the absorbed dose should have $R^2 > 0.95$</p>
kVp accuracy	Measured kVp shall be within $\pm 5\%$ of the specified value over the clinically relevant range
kVp reproducibility	Coefficient of variation ≤ 0.02 for a minimum of four exposures
Beam quality	<p>The half value layer (HVL) shall satisfy relationship:</p> $[(kVp/100) + 0.03] \leq HVL < [(kVp/100) + C]$ <p>where C</p> <ul style="list-style-type: none"> = 0.12 mm Al for Mo/Mo = 0.19 mm Al for Mo/Rh = 0.22 mm Al for Rh/Rh = 0.30 mm Al for W/Rh = 0.32 mm Al for W/Al
Mean glandular dose (MGD)	<p>MGD for imaging of a 4.2 cm 50% adipose, 50% glandular breast (i.e. ACR mini accreditation phantom) shall be ≤ 2.0 milligray (mGy) for exposures made using typical clinical settings.</p> <p>The 2 mGy value shall be considered not as a dose limit but as a Diagnostic Reference Level (DRL) as defined by the International Commission on Radiological Protection in their Publication 73</p> <p>Additionally the MGD shall be:</p> <ul style="list-style-type: none"> • ≤ 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)
Exposure time	<p>For clinically relevant techniques and SID settings the maximum exposure time when irradiating 6 cm PMMA should be:</p> <ul style="list-style-type: none"> • ≤ 2 seconds
Accuracy of stereotactic localisation ^{FF}	Localisation within ± 1 mm

^{CC} At acceptance testing and following x-ray tube replacement

^{DD} For *image receptor* systems, that do not allow positioning of ROIs on the image, a quantitative measure of ghosting cannot be undertaken.

^{EE} This test can be performed on units where the MPV for part or all of image can be extracted. However, the detector used to monitor the absorbed dose may influence the measurement so it may be necessary to employ mAs as a surrogate for absorbed dose.

^{FF} As verification of stereotactic accuracy is performed regularly by facility staff this test may be omitted from annual testing.

Item	Minimum standards
Film viewer luminance	Viewers used for interpreting hardcopy images shall be capable of producing a luminance of at least 3,000 candela per square meter (cd/m ²)
Viewing area illuminance	≤ 50 lux (hardcopy only)
Film viewer masking	Shall be present and effectively restrict light to the exposed area of the film (hardcopy only)
Monitor luminance and viewing conditions	<ul style="list-style-type: none"> • Monitors used for interpretation must not be < 2 megapixels and that for acquisition must not be < 1.3 megapixels (note that where the acquisition and interpretation monitors may well be one and the same the higher specification applies unless the unit predates 2008, in which case the lower specification applies) • Luminance dynamic range > 250:1 • Ambient light ≤ 10 lux
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 • Resolution patterns resolved • All shades of grey visible • Free from artefact
X-ray tube leakage radiation ^{GG}	<p>The leakage radiation level shall not exceed:</p> <ul style="list-style-type: none"> • 1 mGy in one hour at 1 metre from the focal spot with the x-ray tube operating at the maximum rated voltage and the maximum rated continuous tube current • 0.01 mGy/100 mAs at 30 cm from the focal spot and 30 kVp
Printer (hardcopy only)	D _{min} < 0.25 OD and D _{max} > 3.4 OD

^{GG} At acceptance testing and following x-ray tube replacement

STAFF EXPERTISE, EXPERIENCE AND TRAINING STANDARDS

Staff expertise, experience and training standards are based on the 1994 BreastScreen Australia NARs, the relevant United Kingdom National Health Service Breast Screening Programme guidelines^{62,165,166} and appropriate clauses of the United States of America Department of Health and Human Services Food and Drug Administration Quality Mammography Standards; Final Rule.⁷⁷

Consultation regarding these standards has been undertaken with relevant colleges and with other professional organisations and representatives.

RADIOGRAPHERS

Radiographers hold diagnostic accreditation issued by the Australian Institute of Radiography and relevant registration or licensing.

Radiographers are appropriately trained and supervised. Radiographers will be eligible to hold a current Certificate of Clinical Proficiency in Mammography (CCPM) or be undertaking Australian Institute of Radiography accredited training, ideally within 12 months of commencing employment in the Program.

Screening radiographers attend an assessment clinic at least twice per year. Where radiographers are employed in assessment only, they attend a screening clinic at least twice per year.

In-service training is available to all radiographers to ensure they participate in continuing professional development. The designated radiographer supervises radiographer training.

RADIOLOGISTS

Radiologists hold a fellowship of the Royal Australian and New Zealand College of Radiologists, or equivalent.

Registrars in training are registered with the Royal Australian and New Zealand College of Radiologists. Registrars are under the direct supervision of the designated radiologist.

Radiologists commencing as screen readers in the Program are closely supervised by a senior radiologist.

Radiologists commencing as an unsupervised assessment radiologist should have attained a high level of competency in diagnostic imaging, interventional procedures and assessment.

It is desirable that all radiologists should be involved in both screen reading and regular assessment.

In-service training is available to all radiologists to ensure they participate in continuing professional development. Radiologist training is directly supervised by the designated radiologist.

SURGEONS

Surgeons hold a fellowship of the Royal Australasian College of Surgeons, or equivalent.

Surgeons are members of the Breast Section of the Royal Australasian College of Surgeons. Full membership is desirable, however, employment of associate members is acceptable where no full members are available in the Service's geographic area.

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
- guided biopsy of impalpable lesions
- surgical management of benign and malignant breast lesions detected in the screening program

Surgeons participate in the Royal Australasian College of Surgeons continuing medical education program and are involved in audits of short-term and long-term outcomes for their patients, such as the Royal Australasian College of Surgeons Section of Breast Surgery National Audit.

PATHOLOGISTS

Pathologists hold a fellowship of the Royal College of Pathologists of Australasia or recognised equivalent.

Pathologists have sufficient experience to have attained a high level of competency in breast cytology and histopathology. Documentary evidence of their experience has been provided to the Director.

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/s.

The laboratory responsible for the reporting of breast specimens is accredited by the National Association of Testing Authorities. 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.

MEDICAL OFFICERS

Medical officers hold a current registration as a medical officer in the relevant State or Territory.

Medical officers may perform a number of varied roles in different Services. These may include the giving of result to women, communicating with general practitioners about results, referral for follow-up, performing clinical breast assessment, answering patient questions about assessment tests and coordinating assessment.

The roles which a medical officer plays in screening and assessment need to be identified by the Service. Medical officers should be able to demonstrate competence in the areas in which they are involved.

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 clinician on the screening and assessment team.

MEDICAL PHYSICISTS (OR EQUIVALENT)

Medical physicists (or equivalent) hold Australasian College of Physical Scientists and Engineers in Medicine Accreditation in Radiological Physics or Certification in Mammography Equipment Testing to the standard defined by the Royal Australian and New Zealand College of Radiologists Accreditation Requirements or equivalent.

Tertiary qualifications in medical physics are desirable.

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 desirable.

NURSES

Nurses hold current registration as a nurse with the relevant state regulatory body. 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 should be able to demonstrate competence in these areas.

All nurses commencing employment with the BreastScreen Program will undertake appropriate in-service training.

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 staff have specialist knowledge of relevant requirements regarding information privacy, client confidentiality and security issues.

Relevant qualifications in data management are highly desirable.

PROMOTIONS AND RECRUITMENT STAFF

Promotions and recruitment staff can demonstrate skills and experience in health promotion.

Relevant formal qualifications in health promotion/education are highly desirable.

Promotions and recruitment staff should 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.

Promotions and recruitment 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.

APPENDIX K

STANDARDS FOR MAMMOGRAPHY QUALITY CONTROL PROCEDURES

Much of the content of this Appendix is based on the recommendations of the Australasian College of Physical Scientists and Engineers in Medicine.^{4, 164} It is recommended that these tables be read in conjunction with these Position 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.

Radiographer quality control shall meet the minimum standards specified in tables K.A to K.D. Quality control test equipment meeting the minimum standards specified in Appendix L shall be readily available to facility staff.

The method of testing shall be documented in depth, and relevant staff should receive training in these procedures (see performance objective 4.6, standard 4.6.3).

Unless otherwise indicated:

- Baseline values shall be determined from an average of five results from tests performed on different days.
- All quality control records shall be retained for a minimum of 12 months (unless indicated otherwise in the tables).

Table K.A: Quality control procedures and standards for screen/film mammography

Procedure	Control-Limits/Requirements	Minimum Frequency	Required Procedure Elements	Minimum Record Requirements
Darkroom cleanliness	Clean and dust free environment	Daily (darkroom processing) Weekly (daylight processing)	Cleaning of counter tops, darkroom floor and processor feed tray	Records that confirm the procedure has been performed for a given date
Film processor quality control				
<ul style="list-style-type: none"> Establishing processor quality control operating levels 	Sensitometric performance including average gradient ^{†††} and maximum density (D_{max}) as per manufacturer's specifications	At acceptance and to set new baselines as required. Thereafter for troubleshooting purposes	<ul style="list-style-type: none"> Confirmation that developer temperature, developer dwell time, developer and fixer replenishment rates, developer and fixer^{††} Confirmation that developer and fixer specific gravities are as per manufacturer's recommendations 	Dated records of all measurements

^{†††} Average gradient is very dependent on the particular sensitometer used. This should be taken into account when comparing measured values of average gradient with manufacturer's specifications.

^{††} If superior performance can be obtained using operating levels other than the manufacturer's specifications these operating levels may be used.

Procedure	Control-Limits/Requirements	Minimum Frequency	Required Procedure Elements	Minimum Record Requirements
<ul style="list-style-type: none"> Daily processor quality control 	<p>Speed Index (SI) = $baseline \pm 0.15$</p> <p>Contrast Index (CI) = $baseline \pm 0.15$</p> <p>Base + fog = $baseline \pm 0.03$</p>	When changing to a new box of control film	<ul style="list-style-type: none"> Monitoring of SI, CI and base + fog where: <ul style="list-style-type: none"> SI is defined as the optical density of the step with an optical density closest to, but above, 1.2. CI is defined as the difference in optical density between the step with an optical density closest to, but above, 2.2 and the step with an optical density closest to but not less than 0.45. Use of a dedicated box of film of the type in current clinical use (control film) Averaging of 5 results from different days to determine baseline values Immediate processing of the sensitised quality control film Evaluation of results prior to processing of clinical films Consistency in orientation and placement of the film when feeding into the processor Use of a control chart to record results 	<p>Control chart showing:</p> <ul style="list-style-type: none"> Plots against date of SI, CI and base plus fog A record of at least the last 25 results Clearly marked control limits Baseline values Step numbers used for calculation of CI and SI Dated remarks regarding corrective actions and baseline changes
<ul style="list-style-type: none"> Cross-over procedure 		When changing to new box of control film	<ul style="list-style-type: none"> Ensuring that the processor is operating within control limits Determination of the average CI, SI and base plus fog for film from the old and new boxes of control film using a minimum of three films Adjustment of CI, SI and base plus fog baseline values by the differences in these average values 	Dated records of cross-over results and calculations

Procedure	Control-Limits/Requirements	Minimum Frequency	Required Procedure Elements	Minimum Record Requirements
Screen cleanliness	Clean and dust free cassettes and screens	Weekly and more frequently if required	<ul style="list-style-type: none"> Screen cleaning as per manufacturer's recommendations <p>In the case of wet cleaning:</p> <ul style="list-style-type: none"> Removal of excess screen cleaner using a lint-free cloth Air-drying of cassettes standing vertically, on edge and partially open 	Records that confirm the procedure has been performed at least weekly
Phantom images	<p>Optical density (OD) = baseline \pm 0.20ⁱⁱ</p> <p>mAs = baseline \pm 20%</p> <p>Contrast = baseline \pm 15%</p> <p>Control limits for detail visibility are dependent on the phantom selected and the scoring method applied</p> <p>The baseline optical density for phantom images shall be consistent with an OD range of 1.6 to 2.0 for measurements made centred laterally at 4cm in from the chest wall edge of the film.</p>	Weekly	<p>Obtaining the phantom image:</p> <ul style="list-style-type: none"> Use of a suitable mammography image quality phantom Use of a designated test cassette that is in routine clinical use Use of a consistent automatic exposure control (AEC) detector position Light contact between the compression paddle and the phantom surface Consistent positioning of the phantom Use of the film in current clinical use Consistent selection of a clinically relevant kVp and target/filter combination Selection of the density setting in current clinical use <p>Evaluating the phantom image:</p> <ul style="list-style-type: none"> Optical density measurements at consistent points on the film Use of constant 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>Control chart showing:</p> <ul style="list-style-type: none"> Plots against date of mAs, optical density, contrast and image quality scoresⁱ A record of at least the last 25 results Clearly marked control limits Baseline values Radiographic settings (kVp, target/filter combination, AEC detector position, density setting and focus to film distance). Dated remarks regarding corrective actions and baseline changes Dated phantom images from at least the last six months showing x-ray system and radiographic settings

ⁱⁱ For phantom imaging a nominated baseline is used for optical density in preference to a baseline determined by averaging. The nominated optical density baseline shall be selected by the radiologist and be the same for all x-ray systems at a facility.

Procedure	Control-Limits/Requirements	Minimum Frequency	Required Procedure Elements	Minimum Record Requirements
Darkroom fog	Increase in optical density \leq 0.05 for 2 minutes exposure to safelight	Six monthly	<ul style="list-style-type: none"> Use of a mammography film exposed to between 1.4 and 2.0 optical density Partial exposure of the film to safelight conditions for two minutes 	Records of test date, measured fog level and any corrective actions
Screen-film contact	Areas of poor contact shall not be greater than 10 mm in diameter	Six monthly	<ul style="list-style-type: none"> Use of a 40 mesh film/screen contact test tool. Allowing 15 minutes or the cassette manufacturer's recommended time following loading of film before exposure Use of mesh images with an average optical density of approximately 0.7 - 0.8 (or test-tool manufacturer's recommendations) Viewing of mesh images from approximately 1 metre 	Records of test date, the identity of each cassette tested and the corresponding result (pass or fail)
Compression	Maximum motorised compression force in range 150 - 200 newtons	Six monthly	<ul style="list-style-type: none"> Protection of the compression paddle to prevent damage Measurement of the maximum motorised compression force using a suitable measuring device (eg. Analogue bathroom scales) 	Records of test date, maximum motorised compression force and any corrective actions
Repeat analysis	Overall repeat rate < 3%	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 of date analysis was performed, analysis results and any corrective actions
Viewboxes and viewing conditions	Appropriate viewing conditions	Quarterly	<ul style="list-style-type: none"> Cleaning of viewers Visual inspection of uniformity of viewer brightness and colour Confirmation of presence and operation of masking devices Visual inspection of ambient lighting conditions 	Records of the date the procedure was performed and any corrective actions taken

Procedure	Control-Limits/Requirements	Minimum Frequency	Required Procedure Elements	Minimum Record Requirements
Analysis of fixer retention in film	≤ 0.05 g/m ²	Quarterly	Procedure as per recommendations of the test kit manufacturer	Records of the date the test was performed and test results
Maintenance & fault logging	Records for each imaging system and film processor	As required	Recording of equipment faults, incidents and occasions of maintenance (preventative and corrective) as they occur	Dated records that identify the person reporting the event
X-ray system constancy check	mAs = baseline ± 10%	Daily, prior to system use	<ul style="list-style-type: none"> Completion of x-ray system manufacturer's recommended warm-up procedure prior to testing Use of a suitable phantom equivalent to 4 - 5 cm perspex Use of a designated test cassette that is in routine clinical use Use of a consistent AEC detector position Light contact between the compression paddle and the phantom surface Consistent positioning of the phantom Consistent selection of kVp, target/filter combination and density setting Use of a control chart to display results 	<ul style="list-style-type: none"> A control chart showing: <ul style="list-style-type: none"> A plot against date of mAs results A record of at least the last 25 results Clearly marked control limits Baseline values Radiographic settings (kVp, target/filter combination, AEC detector position, density setting and focus to film distance) X-ray system identification Dated remarks regarding corrective actions and baseline changes
Stereotactic accuracy confirmation	Localisation accuracy within ±1 mm	Prior to first use on day of procedures	Procedure as per manufacturer's recommendations	Records that confirm the procedure has been performed for a given date and describe any corrective actions

Procedure	Control-Limits/Requirements	Minimum Frequency	Required Procedure Elements	Minimum Record Requirements
AEC calibration test	The AEC shall be able to maintain optical density to within: <ul style="list-style-type: none"> ± 0.15 of the mean optical density for contact geometry ± 0.20 of the mean optical density for magnification geometry 	Quarterly	<ul style="list-style-type: none"> Use of a designated test cassette that is in routine clinical use Use of a consistent AEC detector position Light contact between the compression paddle and the phantom surface Use of the film in current clinical use Imaging of 2, 4 and 6 cm phantom thicknesses Selection of clinically relevant kVp, target/filter combination and density setting Measurement of optical density at 4 cm in from the chest wall edge on the mid-line of the film 	Records showing: <ul style="list-style-type: none"> Date test was performed X-ray system identification and focus to film distance kVp, target/filter, density setting, mAs and optical density for each phantom thickness Mean optical density (ie. average for 2, 4 and 6 cm images) for each geometry Maximum difference in optical density above and below the mean value for each geometry
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
Test equipment quality control	Accurate to within: <ul style="list-style-type: none"> ±0.03 for the OD range 0 to 3.0; and ±3% for the optical density range 3.0 to 4.0 	Annually	Verification of accuracy using an OD calibration strip traceable to an accepted standard	Records of test date and result (pass or fail)
Densitometer calibration check				
Thermometer calibration check	Measurement accurate to within ± 0.1 °C for the applicable temperature range	Annually	<ul style="list-style-type: none"> Single point validation against a thermometer with a current calibration traceable to an accepted standard OR Calibration of thermometer to an accepted standard 	Records of test date and result (pass or fail)

Table K.B: *Quality control procedures and standards for DR mammography*

Procedure	Control-Limits/Requirements	Minimum Frequency	Required Procedure Elements	Minimum Record Requirements
Monitor cleanliness	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 that confirm the procedure has been performed for a given date
Viewing conditions	Appropriate viewing conditions	Weekly	Visual inspection of ambient lighting conditions to ensure conformance with acceptable viewing condition configuration.	Records that confirm the procedure has been performed for a given date
Printer QC (if applicable)	Borders in TG18-QC pattern must be visible, lines must be straight, 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, the 10cm line must be between 9.5cm and 10.5cm long, and no disturbing artefacts should be visible. <ul style="list-style-type: none"> The speed index (SI) = baseline \pm 0.15 contrast index (CI) = baseline \pm 0.15 Base + fog (B+F) = baseline \pm 0.03 	Weekly	<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. Monitoring of SI, CI and base + fog where: <ul style="list-style-type: none"> SI is defined as the optical density of the step with an optical density closest to, but above, 1.2. CI is defined as the difference in optical density between the step with an optical density closest to, but above, 2.2 and the step with an optical density closest to but not less than 0.45. 	<p>Control chart showing:</p> <ul style="list-style-type: none"> Plots against date of SI, CI and base plus fog A record of at least the last 25 results Clearly marked control limits Baseline values Step numbers used for calculation of CI and SI Dated remarks regarding corrective actions and baseline changes

Procedure	Control-Limits/Requirements	Minimum Frequency	Required Procedure Elements	Minimum Record Requirements
<p>Monitor QC (monitors used for interpretation and attached to the acquisition workstation)</p>	<ul style="list-style-type: none"> Borders in TG18-QC pattern must be visible, lines must be straight, 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, the 10cm line must be between 9.5cm and 10.5cm long, and no disturbing artefacts should be visible. The number of letters visible in the phrase “Quality Control” for the dark, mid-grey and light renditions should = baseline values. 	<p>Weekly</p>	<ul style="list-style-type: none"> Display the TG18-QC test pattern. 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>Control chart showing:</p> <ul style="list-style-type: none"> Monitor identification Monitor settings (window and level) A record of at least the last 25 results Baseline values Dated remarks regarding corrective actions and baseline changes

Procedure	Control-Limits/Requirements	Minimum Frequency	Required Procedure Elements	Minimum Record Requirements
Phantom images	<ul style="list-style-type: none"> • Mean pixel value (MPV) in image = baseline \pm 10% • mAs = baseline \pm 10% • Signal to noise ratio (SNR) = baseline \pm 10% <p>Clearly visualize in ACR phantom:</p> <ul style="list-style-type: none"> • 5 fibres • 4 speck groups • 3-5 masses 	Weekly	<p>Obtaining the phantom image:</p> <ul style="list-style-type: none"> • Use of an ACR accreditation mammography image quality phantom • Use of a consistent automatic exposure control (AEC) detector position where manually selected • 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 • Measure MPV and noise (SD) in reproducible ROI • Calculate the SNR by dividing MPV by the SD • Use of a control chart to display results 	<p>Control chart showing:</p> <ul style="list-style-type: none"> • Plots against date of mAs, MPV, SNR, and image quality scores • A record of at least the last 25 results • Clearly marked control limits • Baseline values • Radiographic settings (kVp, target/filter combination, AEC detector position, density setting and source to image distance (SID)). • Dated remarks regarding corrective actions and baseline changes • Dated phantom images from at least the last six months showing x-ray system and radiographic settings
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 table top structures. • Bright or dark pixels. • Significant stitching or registration artefacts 	Monthly	<ul style="list-style-type: none"> • Expose a uniform thickness of PMMA so that MPV is within 10% of weekly phantom value. • View image on a monitor used for interpretation of digital mammography images • Print image if interpretation performed using hard copy. 	<p>Records showing:</p> <ul style="list-style-type: none"> • Date test was performed. • Listing of significant artefacts • Person performing test

Procedure	Control-Limits/Requirements	Minimum Frequency	Required Procedure Elements	Minimum Record Requirements
Mechanical inspection	<ul style="list-style-type: none"> No hazardous, inoperative, out of alignment or improperly operating items on the system. All items listed on the visual check list have received a pass. 	Monthly	Visual inspection of the system to ensure safe and optimum operation.	Records showing: <ul style="list-style-type: none"> Date inspection performed Inspection results Person performing test
Repeat analysis	Overall repeat rate < 3%	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 of date analysis was performed, analysis results and any corrective actions
Image receptor homogeneity	<ul style="list-style-type: none"> Maximum deviation in MPV in ROI < $\pm 15\%$ 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	Use manufacturer's protocol if available or otherwise: <ul style="list-style-type: none"> Image a standard test block at clinical settings. Run the flat field programme (if applicable) on the unprocessed (raw) image using 100 mm² square or circular ROI Note 1: If the MPV of a ROI deviates by more than 15% from the MPV in the central ROI, the detector gain map may require re-calibration Note 2: If required, to exclude failure due to non uniformities in the standard test block, rotate latter by 180° and repeat measurement.	Records showing: <ul style="list-style-type: none"> Date test was performed. X-ray system identification. kVp, target/filter, density setting and mAs. Test results Person performing test.

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 thickness.	Quarterly	<ul style="list-style-type: none"> Use of a consistent AEC detector position (if applicable) Light contact between the compression paddle and the phantom surface Imaging of 2, 4 and 6 cm phantom thicknesses Selection of clinically relevant kVp, target/filter combination and mode Measurement of MPV in a ROI of area 4 cm² at 6 cm in from the chest wall edge on the mid-line of the image 	<p>Records showing:</p> <ul style="list-style-type: none"> Date test was performed X-ray system identification and source to image distance (SID) kVp, target/filter, mode, mAs and MPV for each phantom thickness Note departure from tolerance in MPV for each thickness of PMMA
Compression	Maximum motorised compression force in range 150 - 200 newtons	Six monthly	<ul style="list-style-type: none"> Protection of the compression paddle to prevent damage Measurement of the maximum motorised compression force using a suitable measuring device (eg. Analogue bathroom scales) 	Records of test date, maximum motorised compression force and any corrective actions
Test equipment quality control	Optical density measurement accurate to within: <ul style="list-style-type: none"> ± 0.03 for the OD range 0 to 3.0; and $\pm 3\%$ for the optical density range 3.0 to 4.0 	Six monthly	Verification of accuracy using an OD calibration strip traceable to an accepted standard	Records of test date and result (pass or fail)
Maintenance & 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 person reporting the event
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

Table K.C: *Quality control procedures and standards for CR mammography*

Procedure	Control-Limits/Requirements	Minimum Frequency	Required Procedure Elements	Minimum Record Requirements
Monitor cleanliness	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 that confirm the procedure has been performed for a given date
Viewing conditions	<ul style="list-style-type: none"> • Appropriate viewing conditions • All viewbox lamps must be operational and appropriate masking available^{kk} 	Weekly	<ul style="list-style-type: none"> • Visual inspection of ambient lighting conditions to ensure conformance with acceptable viewing condition configuration. • Visual inspection of viewboxes for uniformity of brightness. • Confirmation of presence and operation of masking for viewboxes. 	Records that confirm the procedure has been performed for a given date
Printer area cleanliness (if applicable)	Clean and dust free environment	Weekly	<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. 	Records that confirm the procedure has been performed for a given date

^{kk} If applicable

Procedure	Control-Limits/Requirements	Minimum Frequency	Required Procedure Elements	Minimum Record Requirements
Phantom images	<ul style="list-style-type: none"> mAs = baseline \pm 10% Absorbed dose to image plate = baseline \pm 10%¹¹ Mean pixel value (MPV) = baseline \pm 10% OD = baseline \pm 20% (hardcopy only) <p>Clearly visualize in ACR phantom:</p> <ul style="list-style-type: none"> 5 fibres 4 speck groups 3-5 masses 	Weekly	<p>Obtaining the phantom image:</p> <ul style="list-style-type: none"> Use of an ACR accreditation mammography image quality phantom Use a designated QC test cassette and imaging plate that is in routine clinical use. Use of a consistent automatic exposure control (AEC) detector position where manually selected 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 Consistent time delay between plate irradiation and readout <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. This applies to both soft and hardcopy Image quality scoring by the same person, if possible Measure MPV in reproducible ROI or measure OD in reproducible part of phantom image (hardcopy only) Use of a control chart to display results 	<p>Control chart showing:</p> <ul style="list-style-type: none"> Plots against date of mAs, MPV, and image quality scores A record of at least the last 25 results Clearly marked control limits Baseline values Radiographic settings (kVp, target/filter combination, AEC detector position, density setting and source to image distance (SID)). Dated remarks regarding corrective actions and baseline changes Dated phantom images from at least the last six months showing x-ray system and radiographic settings

¹¹ See ACPSEM Position Paper⁴ for interpretation of absorbed dose to image plate in terms of exposure indicator.

Procedure	Control-Limits/Requirements	Minimum Frequency	Required Procedure Elements	Minimum Record Requirements
Printer QC (if applicable)	<p>Borders in TG18-QC pattern must be visible, lines must be straight, 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, the 10cm line must be between 9.5cm and 10.5cm long, and no disturbing artefacts should be visible.</p> <ul style="list-style-type: none"> The speed index (SI) = baseline ± 0.15 contrast index (CI) = baseline ± 0.15 Base + fog (B+F) = baseline ± 0.03 	Weekly	<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. Monitoring of SI, CI and base + fog where: <ul style="list-style-type: none"> SI is defined as the optical density of the step with an optical density closest to, but above, 1.2. CI is defined as the difference in optical density between the step with an optical density closest to, but above, 2.2 and the step with an optical density closest to but not less than 0.45. 	<p>Control chart showing:</p> <ul style="list-style-type: none"> Plots against date of SI, CI and base plus fog A record of at least the last 25 results Clearly marked control limits Baseline values Step numbers used for calculation of CI and SI Dated remarks regarding corrective actions and baseline changes
Monitor QC (monitors used for interpretation and attached to the acquisition workstation)	<ul style="list-style-type: none"> Borders in TG18-QC pattern must be visible, lines must be straight, 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, the 10cm line must be between 9.5cm and 10.5cm long, and no disturbing artefacts should be visible. The number of letters visible in the phrase "Quality Control" for the dark, mid-grey and light renditions should = baseline values 	Weekly	<ul style="list-style-type: none"> Display the TG18-QC test pattern. 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>Control chart showing:</p> <ul style="list-style-type: none"> Monitor identification Monitor settings (window and level) A record of at least the last 25 results Baseline values Dated remarks regarding corrective actions and baseline changes

Procedure	Control-Limits/Requirements	Minimum Frequency	Required Procedure Elements	Minimum Record Requirements
Mechanical inspection	<ul style="list-style-type: none"> No hazardous, inoperative, out of alignment or improperly operating items on the system. All items listed on the visual check list have received a pass. 	Monthly	Visual inspection of the system to ensure safe and optimum operation.	Records showing: <ul style="list-style-type: none"> Date inspection performed Inspection results Person performing test
Repeat analysis	Overall repeat rate < 3%	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 of date analysis was performed, analysis results and any corrective actions
Image receptor homogeneity	<ul style="list-style-type: none"> Maximum deviation in MPV in any two ROIs < $\pm 10\%$ Maximum variation of the MPV in central ROI between successive images < $\pm 10\%$. 	Quarterly or more frequently if recommended by the manufacturer	<ul style="list-style-type: none"> Image a standard test block at clinical settings. Perform measurements on the unprocessed (raw) image using 100 mm² square or circular ROI if possible Note 1: If the MPV of any two ROIs deviates by more than 10% from each other the CR unit's shading correction may require re-calibration	Records showing: <ul style="list-style-type: none"> Date test was performed. X-ray system identification. kVp, target/filter, density setting and mAs. Test results Person performing test.
AEC calibration test	The AEC shall be able to maintain: <ul style="list-style-type: none"> the absorbed dose to the plate for each of the three thicknesses of PMMA to within $\pm 10\%$ of the baseline value ^{MM} The variation as a function of thickness to less than $\pm 20\%$ 	Quarterly	<ul style="list-style-type: none"> Use of a consistent AEC detector position Light contact between the compression paddle and the phantom surface Use designated QC imaging plate Imaging of 2, 4 and 6 cm phantom thicknesses Selection of clinically relevant kVp, target/filter combination and density control Consistent time delay between plate irradiation and readout 	Records showing: <ul style="list-style-type: none"> Date test was performed X-ray system identification and source to image distance (SID) kVp, target/filter, density control, mAs and exposure indicator for each phantom thickness Note departure from tolerance in MPV for each thickness of PMMA

^{MM} See ACPSEM Position Paper⁴ for interpretation of absorbed dose to image plate in terms of exposure indicator

Procedure	Control-Limits/Requirements	Minimum Frequency	Required Procedure Elements	Minimum Record Requirements
Compression	Maximum motorised compression force in range 150 - 200 newtons	Six monthly	<ul style="list-style-type: none"> Protection of the compression paddle to prevent damage Measurement of the maximum motorised compression force using a suitable measuring device (eg. Analogue bathroom scales) 	Records of test date, maximum motorised compression force and any corrective actions
Test equipment quality control	Optical density measurement accurate to within: <ul style="list-style-type: none"> ±0.03 for the OD range 0 to 3.0; and ±3% for the optical density range 3.0 to 4.0 	Six monthly	Verification of accuracy using an OD calibration strip traceable to an accepted standard	Records of test date and result (pass or fail)
Cassette/Image plate condition and inter plate sensitivity variation	<ul style="list-style-type: none"> Clean and dust free cassettes & image plates No major inhomogeneities or artefacts on the images Coefficient of variation (COV) of absorbed dose to QC plate < 0.05 Absorbed dose to individual plate should differ from mean for that size by less than ±5% Difference in mean absorbed dose to plates of different sizes < 20%^{NN} 	As required	<ul style="list-style-type: none"> Cassette/image plate cleaning as per manufacturer's recommendations Image a standard test block at clinical settings. Pre-processing should be turned off as much as possible and no post processing should be applied. Evaluate for artefact on both monitor and hard copy (if applicable) 	Records showing: <ul style="list-style-type: none"> Date test was performed. Person performing test. kVp, target/filter, AEC mode. Exposure indicator and mAs for each plate.
Image plate erasure	Erasure of energy absorbed from scattered radiation or naturally occurring radiation by CR image plates before they are used.	Daily/Weekly	<ul style="list-style-type: none"> On a daily basis or if left unused for more than 8 hours, all CR image plates should be subjected to a secondary erasure (following manufacturer's instructions). On a weekly basis all CR image plates should be subjected to a primary erasure (following manufacturer's instructions). 	Dated records that identify the person reporting the event
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 person reporting the event

^{NN} See ACPSEM Position Paper⁴ for interpretation of absorbed dose to image plate in terms of exposure indicator

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

Table K.D: *Quality control procedures and standards for digital stereotactic units*

Three different configurations of digital stereotactic 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. 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.

Procedure	Control-Limits/Requirements	Minimum Frequency	Required Procedure Elements	Minimum Record Requirements
Monitor cleanliness	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 that confirm the procedure has been performed for a given date
Viewing conditions	Appropriate viewing conditions	Weekly	Visual inspection of ambient lighting conditions to ensure conformance with acceptable viewing condition configuration.	Records that confirm the procedure has been performed for a given date

Procedure	Control-Limits/Requirements	Minimum Frequency	Required Procedure Elements	Minimum Record Requirements
Printer QC (if applicable)	<p>Borders in TG18-QC pattern must be visible, lines must be straight, 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, the 10cm line must be between 9.5cm and 10.5cm long, and no disturbing artefacts should be visible.</p> <ul style="list-style-type: none"> The speed index (SI) = baseline \pm 0.15 contrast index (CI) = baseline \pm 0.15 Base + fog (B+F) = baseline \pm 0.03 	Weekly	<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. Monitoring of SI, CI and base + fog where: <ul style="list-style-type: none"> SI is defined as the optical density of the step with an optical density closest to, but above, 1.2. CI is defined as the difference in optical density between the step with an optical density closest to, but above, 2.2 and the step with an optical density closest to but not less than 0.45. 	<p>Control chart showing:</p> <ul style="list-style-type: none"> Plots against date of SI, CI and base plus fog A record of at least the last 25 results Clearly marked control limits Baseline values Step numbers used for calculation of CI and SI Dated remarks regarding corrective actions and baseline changes
Printer area Cleanliness (if applicable)	Clean and dust free environment	Weekly	Wet cleaning of printer area floor and open shelves. Inspect and clean air intake filters on the film printer.	<p>Checklist/logbook entry showing:</p> <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)	<ul style="list-style-type: none"> Borders in TG18-QC pattern must be visible, lines must be straight, 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, the 10cm line must be between 9.5cm and 10.5cm long, and no disturbing artefacts should be visible. The number of letters visible in the phrase "Quality Control" for the dark, mid-grey and light renditions should = baseline values 	Weekly	<ul style="list-style-type: none"> Display the TG18-QC test pattern. 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>Control chart showing:</p> <ul style="list-style-type: none"> Monitor identification Monitor settings (window and level) A record of at least the last 25 results Baseline values Dated remarks regarding corrective actions and baseline changes
Phantom images	<p>Clearly visualize in ACR mini-phantom:</p> <ul style="list-style-type: none"> 3 fibres 2 speck groups 1.5 masses 	Weekly	<p>Obtaining the phantom image:</p> <ul style="list-style-type: none"> Use of an ACR mini accreditation mammography phantom 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>Control chart showing:</p> <ul style="list-style-type: none"> Plots against date of mAs and image quality scores A record of at least the last 25 results Clearly marked control limits Baseline values Radiographic settings (kVp, target/filter combination, density setting. Dated remarks regarding corrective actions and baseline changes 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
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 table top structures. Bright or dark pixels. Significant stitching or registration artefacts 	Monthly	<ul style="list-style-type: none"> Expose a uniform thickness of PMMA so that MPV is within 10% of weekly phantom value. View image on a monitor used for interpretation of digital mammography images Print image if interpretation performed using hard copy. 	<p>Records showing:</p> <ul style="list-style-type: none"> Date test was performed. Listing of significant artefacts Person performing test
Mechanical inspection	<ul style="list-style-type: none"> No hazardous, inoperative, out of alignment or improperly operating items on the system. All items listed on the visual check list have received a pass. The image receptor & compression plate biopsy window is free of wobble The vernier table drive & 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	<p>Visual inspection of the system to ensure safe and optimum operation.</p>	<p>Records showing:</p> <ul style="list-style-type: none"> Date inspection performed Inspection results Person performing test
Repeat analysis	Overall repeat rate < 20%	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 client examinations	Records of date analysis was performed, analysis results and any corrective actions

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 < $\pm 15\%$ 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 <p>Note: If the MPV of a ROI deviates by more than 15% from the MPV in the central ROI, the detector gain map may require re-calibration</p>	<p>Records showing:</p> <ul style="list-style-type: none"> Date test was performed. X-ray system identification. kVp, target/filter, density setting and mAs. Test results Person performing test.
AEC calibration test	The AEC shall be able to maintain mean pixel value (MPV) to within $\pm 10\%$ of the baseline MPV for each thickness.	Quarterly	<ul style="list-style-type: none"> Light contact between the compression paddle and the phantom surface Imaging of 2, 4 and 6 cm phantom thicknesses Selection of clinically relevant kVp, target/filter combination and mode Measurement of MPV in a ROI of area 4 cm² centred in image <p>Note: Some image receptor systems, do not allow positioning of ROIs on the image. In that case, it is suggested that the MPV from the entire image area meet the specification.</p>	<p>Records showing:</p> <ul style="list-style-type: none"> Date test was performed kVp, target/filter, mode, mAs and MPV for each phantom thickness Note departure from tolerance in MPV for each thickness of PMMA
Compression	Maximum motorised compression force in range 150 - 200 newtons	Six monthly	<ul style="list-style-type: none"> Protection of the compression paddle to prevent damage Measurement of the maximum motorised compression force using a suitable measuring device (e.g. Analogue bathroom scales) <p>Verification of accuracy using an OD calibration strip traceable to an accepted standard</p>	<p>Records of test date, maximum motorised compression force and any corrective actions</p>
Test equipment quality control	Optical density measurement accurate to within: <ul style="list-style-type: none"> ± 0.03 for the OD range 0 to 3.0; and $\pm 3\%$ for the optical density range 3.0 to 4.0 	Six monthly		Records of test date and result (pass or fail)

Procedure	Control-Limits/Requirements	Minimum Frequency	Required Procedure Elements	Minimum Record Requirements
Stereotactic accuracy confirmation	Localisation within ± 1 mm	Prior to first use on day of procedures	Procedure as per manufacturer's recommendations	<p>Checklist/logbook entry showing:</p> <ul style="list-style-type: none"> • Date test performed • Test results • Person performing test
Maintenance & 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 person reporting the event
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

STANDARDS FOR QUALITY CONTROL TEST EQUIPMENT

Table LA: *Quality control test equipment for mammography*^{4,69,164}

Item	Minimum Standards
Breast phantom	Shall allow assessment of background optical density, image quality and contrast.
Polymethylacrylate (PMMA) or tissue equivalent material	Able to provide, at least, 2, 4 and 6 cm thicknesses
Sensitometer	21 step sensitometer
Densitometer	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 3.4 to 4.0
Digital thermometer	$\pm 0.1^{\circ}\text{C}$ accuracy
Hydrometer	Suitable for measuring specific gravity of processing chemicals
Fixer retention test kit	Includes hypo estimator and hypo test solution
Film screen contact test tool	40 mesh
Ultrasound phantom/s	Tissue mimicking phantom suitable for performing measurements as specified in Appendix H
Photometer or luxmeter	Designed to measure ambient lighting

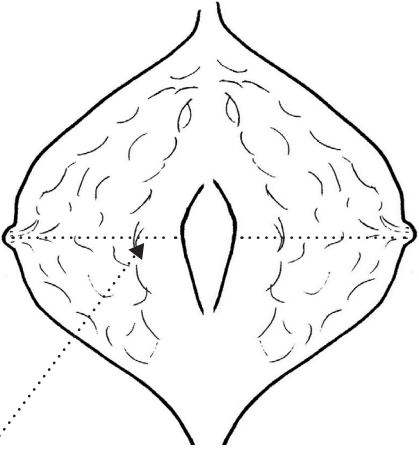
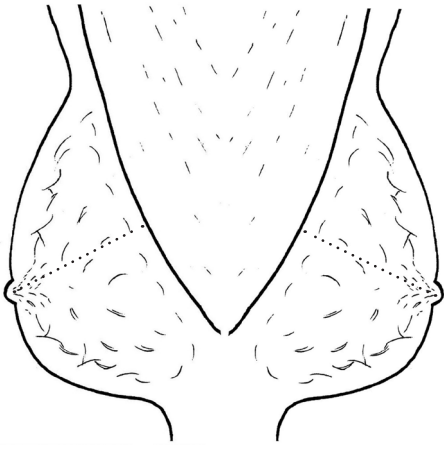
PGMI EVALUATION OF CLINICAL IMAGE QUALITY

Quality mammography requires dedication, enthusiasm and self-appraisal on the part of the radiographer. The United Kingdom Mammography Trainers Group with the support of the College of Radiographers devised the PGMI (Perfect, Good, Moderate, Inadequate) method of evaluation of clinical image quality.¹⁶⁵ Ongoing evaluation critically looks at each mammographic examination within a quality improvement framework.

The PGMI criteria adapted from the United Kingdom model, are used in Australia in Australian Institute of Radiography accredited training programs to assess clinical image quality. 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 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 identification
3. Correct exposure according to workplace requirements
4. Good compression
5. Absence of movement
6. Correct processing
7. Absence of artefacts
8. No skin folds
9. Symmetrical images

<p>Rcc</p>  <p>Lcc</p> <p>PNL</p>	<p>Rmio</p>  <p>Lmio</p>
<p><i>Cranio-caudal view (CC)</i> <i>Specific positioning criteria</i></p> <ol style="list-style-type: none"> All breast tissue imaged <ul style="list-style-type: none"> medial border well demonstrated nipple in profile-(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"> All breast tissue imaged <ul style="list-style-type: none"> pectoral muscle shadow to nipple level full width of pectoral muscle nipple in profile - (retro-areolar tissue well separated) infra-mammary fold 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</p> <ul style="list-style-type: none"> Both CC and MLO images meet criteria for image assessment 1–9 	
<p><i>G = Good images</i></p> <ol style="list-style-type: none"> 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 nipple in midline of imaged breast 	<p><i>G = Good images</i></p> <ol style="list-style-type: none"> All breast tissue imaged <ul style="list-style-type: none"> pectoral muscle well demonstrated nipple in profile infra-mammary fold (IMF) well demonstrated
<p>2 - 6. Both CC and MLO images meet criteria for image assessment 2–6 inclusive for categorisation as G</p> <p>7 - 9. Both CC and MLO images displaying minor degrees of variation in criteria for imaging assessment 7, 8 and 9 will be accepted for categorisation as G</p>	

<p>M = Moderate images (Acceptable for diagnostic purposes)</p> <p>1. Most breast tissue imaged (<i>however, all breast tissue must be imaged on MLO image</i>)</p> <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 (significant bias) 	<p>M = Moderate images (Acceptable for diagnostic purposes)</p> <p>1. Most breast tissue imaged.</p> <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) • IMF not clearly demonstrated but breast tissue adequately shown
<ol style="list-style-type: none"> 2. Correct(ed) image identification 3. Correct exposure 4. Adequate compression 5. Absence of movement 6. Correct 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 	

RECOMMENDED STANDARD:

A minimum of 50% of an audit of 50 randomly selected cases should be graded in the P or G categories (75% desirable).

REPEAT RATE:

< 3% of consecutive images to be classified 'Inadequate'.

ROLES AND RESPONSIBILITIES OF THE DESIGNATED RADIOGRAPHER

The designated radiographer is responsible for overseeing all issues relating to breast imaging for the Service

QUALIFICATIONS AND EXPERIENCE

- Holder of a Statement of Accreditation from the Australian Institute of Radiography
- Certificate of Clinical Proficiency in Mammography
- Licence to operate Radiation Equipment in the state or territory
- Extensive experience in screening mammography and 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 National Accreditation Standards

ROLES AND RESPONSIBILITIES

Roles of the designated radiographer include, but are not limited to:

- Orientation and supervision of training of radiographers new to the Service
- Work with the designated radiologist on quality assurance, including undertaking quarterly formal reviews of mammographic quality and equipment performance
- Liaises with the medical physicist (or equivalent)
- Attending State Radiographer meetings
- Ensuring a continuing education program for the radiographers
- Keeping up-to-date on latest developments in breast imaging
- Works in a multi-disciplinary team and liaises with other personnel as required

Responsibilities of the designated radiographer include aspects of:

- Technical aspects of breast imaging quality assurance
- Performance of the radiographers in screening and assessment
- Service delivery
- Training and continuing education at the Service level
- Occupational health and safety
- Radiation dose
- Equipment
- Radiation protection
- Image processing
- Mammogram and ultrasound quality evaluation
- Contribute to the development of clinical policies and procedures for screening and assessment

ROLES AND RESPONSIBILITIES OF THE DESIGNATED RADIOLOGIST

The designated radiologist is responsible for overseeing all issues of quality assurance relating to radiology for the Service. This requires the designated radiologist to work closely with the chief radiographer and the Service Director to deal with issues of quality. Close liaison with the designated pathologist, designated surgeon and medical physicist is also required.

QUALIFICATIONS AND EXPERIENCE

- Fellowship in the Royal Australian and New Zealand College of Radiologists
- Licence from the appropriate State Medical Board
- Licence from the Radiation Protection Authority
- Extensive experience in screening mammography, diagnostic mammography, breast ultrasound and image-guided interventional procedures for the breast
- Excellent knowledge of technical quality assurance
- Well developed knowledge of the BreastScreen Australia Program and an understanding of the National Accreditation Standards

ROLES AND RESPONSIBILITIES

Roles of the designated radiologist include, but are not limited to:

- Orientation and supervision of training of radiologists new to the Service.
- Encouraging radiologists to participate in continuing education programs. This would include, but is not limited to, multidisciplinary review meetings in the Service.
- 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 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 radiologist who completed the reading, the Service Director and the data manager at 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
 - Image Processing
 - Mammogram and ultrasound quality evaluation
 - Developing clinical policies and procedures for screening and assessment with the Service Director, designated radiographer, designated surgeon and designated pathologist
 - Ensuring regular radiology/pathology/surgery review of biopsies
 - Contribute to the selection and replacement of appropriate mammography and ultrasound equipment if required.

Responsibilities of the designated radiologist include:

- Quality assurance aspects in radiology
- Radiologist performance in screening and assessment
- Radiologist training and continuing education at the Service level
- Screening and assessment protocols
- Breast imaging equipment selection and maintenance
- Involvement in radiographer training and continuing education at the Service level.

AUDIT OF CANCER DETECTION RATES FOR INDIVIDUAL SCREEN READERS

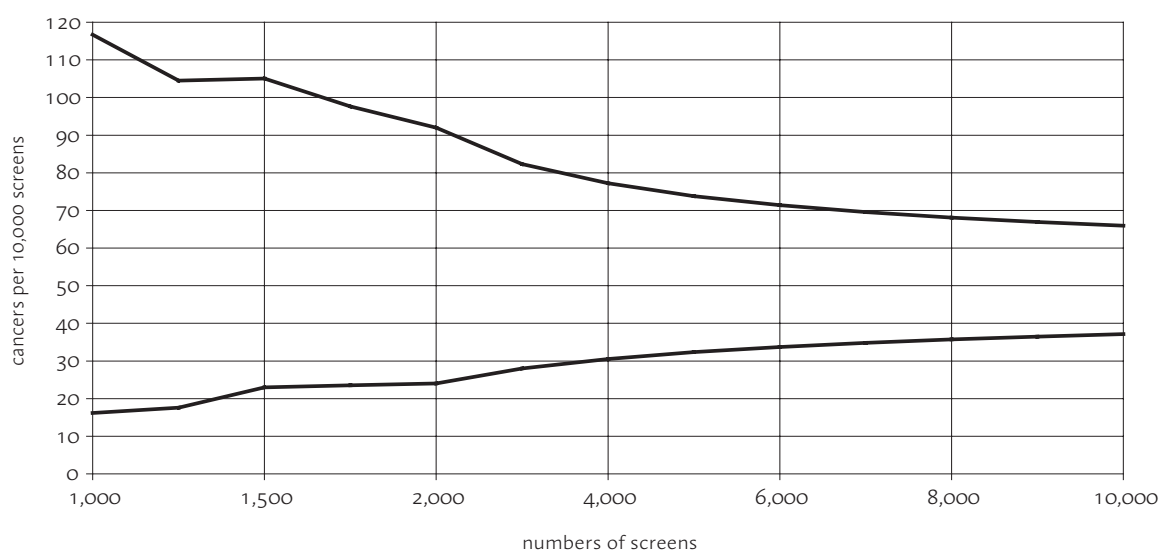
All BreastScreen screen readers will be required to participate in an audit and feedback to evaluate their performance in the detection of invasive cancers and small invasive cancers.

Individual readers will be informed of their cancer detection rates. In considering the performance of an individual reader during the 24-month period, we need to take the play of chance into account. A reader will have detected cancers at a rate compatible with the Service standard if their cancer detection rate is above the value of the *lower* 95% confidence bound. See Appendix C for a fuller description.

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.

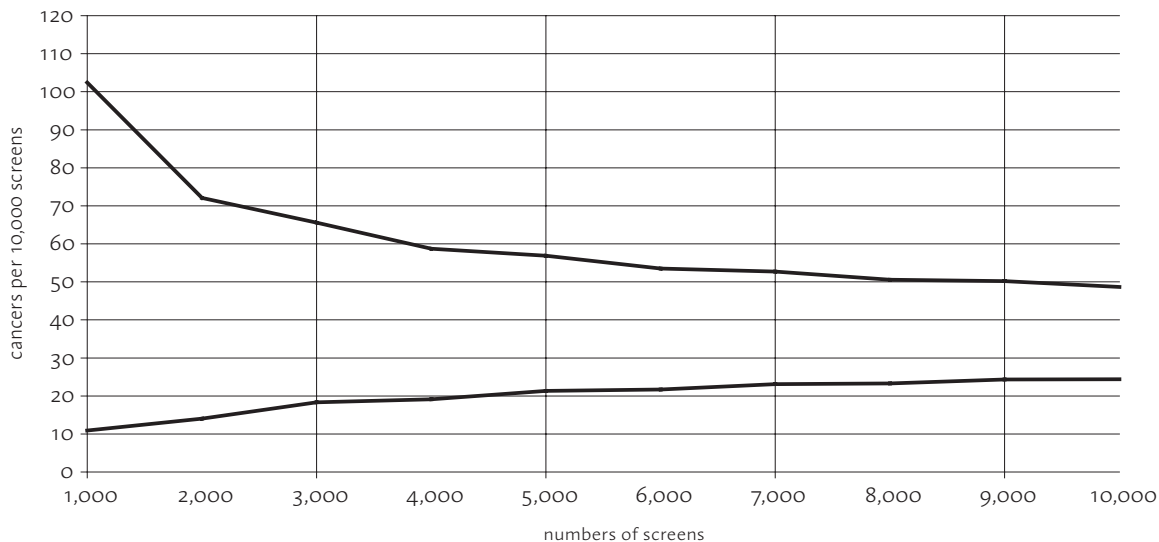
For invasive breast cancers at initial screens, the Service standard is 50 per 10,000 screens (see Figure P1). For an individual reader who detects 5 cancers and has completed 2,000 initial screens, this is the equivalent of 25 per 10,000 screens. The lower bound at 2,000 initial screens is 24 per 10,000. Therefore, they will be considered to have achieved the standard

Figure P1: *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*



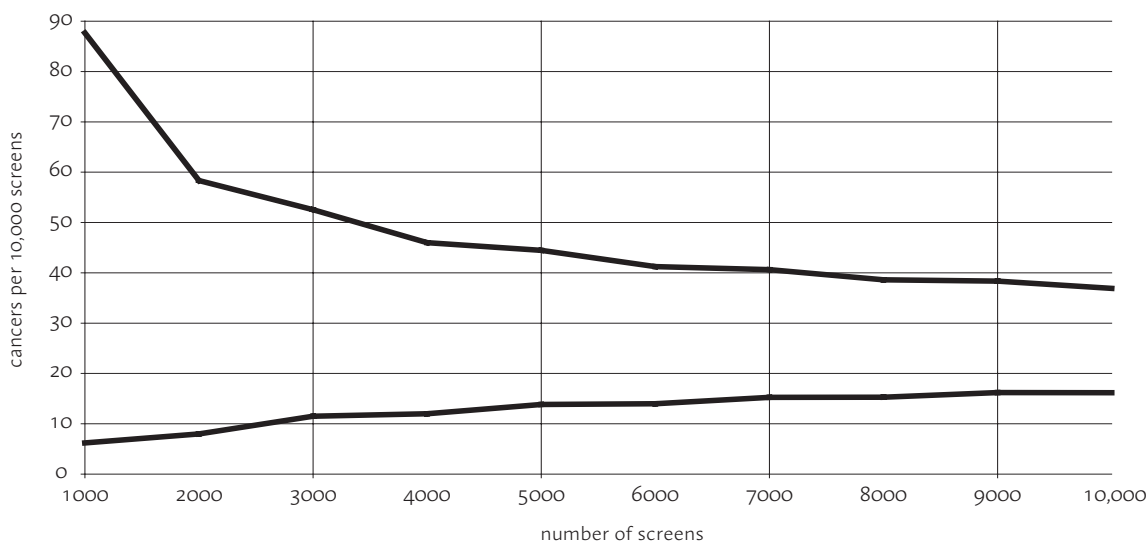
For invasive breast cancers at subsequent screens, the Service standard is 35 per 10,000 screens (see Figure P2). For an individual reader who detects 5 cancers and has completed 2,000 subsequent screens, this is the equivalent of 25 per 10,000 screens. The lower bound at 2,000 subsequent screens is 14 per 10,000. Therefore, they will be considered to have achieved the standard.

Figure P2: *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 P3). 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 P3: *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*



ROLES AND RESPONSIBILITIES OF THE DESIGNATED PATHOLOGIST

The designated pathologist is responsible for overseeing all issues of quality assurance relating to pathology for the Service. The deputy/deputies are there to assist him/her in their task.

QUALIFICATIONS AND EXPERIENCE

- Fellowship of the Royal College of Pathologists of Australasia, or an equivalent academic qualification in pathology should be held by the designated pathologist and deputy deputies.
- Attendance at an internationally recognised mammographic screening unit or recognised training centre in Australia, either to participate in a course, or spend sufficient time to acquire the necessary skills.
- Attendance should be within the first 12 months of commencement of appointment to the program for the designated pathologist, and within the first 24 months for the deputy/deputies.
- Well developed knowledge of the BreastScreen Australia Program and an understanding of the National Accreditation Standards.

ROLES AND RESPONSIBILITIES

Roles of the designated pathologist and deputy/s include, but are not limited to:

- 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 should attend and present pathology results at each meeting.
- 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 available for consultation and advice regarding specimen handling and histological and cytological diagnosis.
- Ensuring optimum handling of mammographically detected lesions, including: receipt of mammogram with biopsy; specimen radiography for confirmation of excision and clearance of the lesion, and for guidance in selection of tissue sections; and analysis of the pathological and cytological data in a manner suitable for quality control, reports and publications.

It is desirable that the designated pathologist and deputy/s attend the following quality improvement activities:

- Meetings with other designated pathologists in other Services within their state on a six monthly basis.
- Educational activities relevant to breast pathology, including the Royal College of Pathologists of Australasia Breast Pathology Module as well as local, interstate and international meetings and workshops with a view to providing feedback to those working at the Service.
- National meeting to present pathology data from the Service.

Responsibilities of the designated pathologist and deputy/deputies include:

- Technical aspects of pathology quality assurance.
- Pathology training and continuing education at the Service level.

PATHOLOGY REPORTING OF BREAST CANCER: BREAST FINE NEEDLE ASPIRATION CYTOLOGY AND CORE BIOPSY REPORTS

The following recommendations cover key aspects to be included in FNA cytology and core biopsy reports⁰⁰.

A report for breast FNA cytology should include:

- Patient's identification details—the report should include:
 - Name and date of birth.
 - Unit Medical Record Number if hospital based.
 - A unique pathology accession number.
 - Preferably the patient's address.
 - Name of the referring doctor.
- Description of material received, including:
 - Number of air-dried and wet-fixed slides.
 - If material received is cyst fluid, this should be stated along with a statement of the volume received, in the report.
 - Statement as to whether material received for cell block preparation.
- A statement about the adequacy of the specimen, with regard to correlation with the clinical and imaging findings supplied on the request form.
- All of the clinical/imaging notes provided by the clinician or radiologist on the request form or subsequently, including:
 - Side of lesion (whether left or right).
 - Site of lesion (o'clock position and distance from the nipple).
 - Nature of the lesion, including clinical and imaging features.
 - The method by which the specimen was obtained (eg palpation, ultrasound or mammographically directed).
 - Name of the clinician or radiologist performing the aspirate.
- Diagnosis—including clear description of the cytological features, specific diagnoses where possible, and statement whether findings consistent with the clinical/imaging findings.
- Description of cell block findings where available, and whether specific immunoperoxidase studies performed.
- Diagnostic category/code—the report should include one of the following diagnostic categories:
 - Insufficient/inadequate material.
 - Benign.

⁰⁰ Modified version of NBCC, *Breast fine needle aspiration (FNA) cytology and core biopsy: a guide for practice*. 2004.

- Atypical/indeterminate.
- Suspicious of malignancy.
- Malignant.
- Name of reporting cytopathologist.
- Date of report.

A report for breast core biopsy should include:

- Patient’s identification details—the report should include:
 - Name and date of birth.
 - Unit Medical Record Number if hospital based.
 - An unique pathology accession number.
 - Preferably the patient’s address.
 - Name of the referring doctor.
- Description of material received, including:
 - Number of cores or tissue fragments and their size and nature eg fat, fibrous tissue.
 - Whether or not a specimen radiograph is attached to the specimen, if the biopsy has been performed for microcalcification/s.
- All clinical/imaging notes provided by the clinician or radiologist on the request form or subsequently, including:
 - Side of lesion (whether left or right).
 - Site of lesion (o’clock position and distance from the nipple).
 - Nature of the lesion including clinical and imaging features; a report as to how many core biopsies contain microcalcifications if there is a specimen radiograph.
 - The method by which the specimen was obtained (eg palpation, ultrasound or mammographically directed).
 - Name of the clinician or radiologist performing the aspirate.
- A microscopic description of the histological features including a statement of the adequacy of the specimen, and whether the material received is consistent with the clinical and imaging diagnosis/findings.
- Specific Diagnosis—If carcinoma is present, the type and grade of invasive carcinoma, and the presence or absence of DCIS and vascular invasion should be stated.
- If the core biopsy was for microcalcifications, a statement of the presence or absence of microcalcifications should be made and whether they are consistent with the specimen radiograph findings.
- Diagnostic category—the report should include one of the following diagnostic categories:
 - Insufficient/inadequate.
 - Benign.
 - Atypical/indeterminate.
 - Suspicious of malignancy.
 - Malignant.
- Name of reporting pathologist.
- Date of report.

HANDLING OF SPECIMENS AND PATHOLOGY REPORTING

The following recommendations cover key aspects of handling of breast specimens and pathology reporting for invasive breast cancer and DCIS. They are based on the guide *The pathology reporting of breast cancer*,⁴⁹ published in 2001 by the Australian Cancer Network as amended from time to time. Full information for the reporting of invasive breast cancer and DCIS is available in the guide.

HANDLING OF BREAST SPECIMENS

When handling breast specimens, the following recommendations should be applied:

- The surgical specimen should be orientated and marked by the surgeon using clips and/or sutures, following an agreed protocol established between the surgeon and the pathologist.
- If the excision is of a clinically impalpable, mammographically detected lesion, specimen radiography should be performed to ensure the lesion is within the specimen, especially if the lesion consists of microcalcifications. The radiograph also assists the pathologist to identify the position of the lesion within the specimen and must be received by the pathologist. The original mammographic features should be detailed on the request form or the original mammography report should accompany the specimen.
- The type of specimen (eg mastectomy and axillary clearance, wide local excision, sentinel lymph node biopsy, hook wire localization excision) should be stated.
- Specimens should be measured in three dimensions. X-ray of the specimen or slices of the specimen can be used to direct tissue sampling, especially if the lesion contains microcalcifications and/or no mass lesion can be detected macroscopically.
- Frozen section examinations of breast specimens have a limited role in the management of the patient with a mammographically detected or palpable breast lesion. They are rarely indicated in the management of patients with a clinically impalpable lesion. FNA and core biopsies are widely available for preoperative diagnosis and have been shown to be as accurate as frozen sections.

PATHOLOGY REPORTING OF BREAST CANCER

Standardised reporting of both invasive breast cancer and DCIS is essential for optimal patient management. Synoptic reporting is advocated in the guide.⁴⁹

The pathology report should include:

- Diagnosis summary: summary of findings as needed.
- Location: the site of FNAB or core biopsy (o'clock and distance from the nipple) should be correlated with the surgical specimen, and the site of the lesion in the pathological specimen recorded similarly, or as central, upper outer quadrant (UOQ), upper inner quadrant (UIQ), lower outer quadrant (LOQ), lower inner quadrant (LIQ) or not known.
- Tumour type: state the histological type. If 'ductal not otherwise specified (NOS)' or 'no special type (NST)' this should be indicated.
- Histological grade: use the Elston modification of the Bloom and Richardson system.¹⁶⁷
- Tumour size: the maximum diameter or dimensions of the invasive carcinoma should be recorded in millimetres (macroscopic size to be checked microscopically if less than or equal to 15mm and the larger dimension taken as the correct size). If tumour size is not assessable, state size as 'indeterminate'.
- Resection margins: the margins of both invasive breast cancer and DCIS should be assessed. State if margins are free or involved, which margins are involved if known, and the extent of involvement in millimetres. If margins are free of tumour, the distance from the edge of the invasive breast cancer and the DCIS to the nearest margin(s) (if < 10mm) should be recorded in millimetres. If the margins cannot be assessed, the reason(s) should be clearly stated.
- Vessel or perineural invasion: state whether present or absent and if present, whether intratumoral or peritumoral.
- Degree of DCIS in the tumour: this is to be assessed and expressed as an actual percentage.
- Extent of DCIS in the tumour and overall if DCIS extends outside the invasive component: in millimetres.
- Nuclear grade of DCIS: use the Elston modification of the Bloom and Richardson grading system for invasive breast cancer.¹⁶⁷
- Architecture of DCIS: identify the type. In tumours showing more than one type, identify the dominant pattern and any other pattern(s).
- Necrosis and calcification associated with the DCIS: State whether present or absent.
- DCIS in adjacent breast tissue: state whether present or absent.
- Non-neoplastic breast: a statement regarding the presence or absence of changes and their significance should be included. Any features such as fibrocystic change, epithelial hyperplasia, sclerosing adenosis or other should be reported.
- Oestrogen and progesterone receptor immunoperoxidase studies should be routinely performed and HER2 studies can be performed at this time. If the specimen has been sent to another laboratory for these studies then the report should state which laboratory.
- Sentinel and axillary lymph nodes: the number, size and description of lymph nodes should be reported, as well as the size and number of metastases in individual nodes, the overall number of positive nodes and total number of examined nodes, and the method of microscopic analysis (eg intraoperative, paraffin fixed, protocols used such as the number of levels and use of immunoperoxidase stains).
- Other findings or comments: as required.
- The name of the reporting pathologist.
- Date of report.

ROLES AND RESPONSIBILITIES OF THE DESIGNATED SURGEON

The designated surgeon is responsible for overseeing 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 Service Director in dealing with all issues of quality. Close liaison with all other members of the multidisciplinary assessment team, including staff providing counselling, is also required.

QUALIFICATIONS AND EXPERIENCE

- Fellowship of the Royal Australasian College of Surgeons and membership of its breast section
- Licence from the appropriate State Medical Board
- Extensive experience in:
 - the diagnosis and management of symptomatic and screen detected breast abnormalities
 - image guided localisation procedures
 - multidisciplinary assessment
 - well developed knowledge of the BreastScreen Australia Program and understanding of the national standards

ROLES AND RESPONSIBILITIES

Roles and 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 BreastScreen
- 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 in surgery.

RECOMMENDATIONS FOR PROVIDING RESULTS TO WOMEN DIAGNOSED WITH BREAST CANCER

The way a clinician communicates with a woman diagnosed with breast cancer can have significant benefits for the woman and her family. These benefits potentially include improvements in psychological adjustment, decision-making, treatment compliance and satisfaction with care. Women with cancer repeatedly report a desire to be well-informed. Effective communication, however, involves more than the provision of information; it requires a process of individually tailored explanation, problem-solving and acknowledgment of the woman's feelings. There are a number of communication skills that are relevant to any clinical situation and should be considered whenever a clinician is providing information to a woman with breast cancer.

Further information on general interactional skills is available in the *Psychosocial clinical practice guidelines: providing information, support and counselling for women with breast cancer*.³² Recommendations for providing information to women with a diagnosis of breast cancer are presented in Table U.A. These recommendations also apply when providing information to women who are experiencing a recurrence or metastases. It should be noted that these steps are recommended for use in conjunction with the set of general interactional skills discussed in section 2.1 of the *Psychosocial clinical practice guidelines: providing information, support and counselling for women with breast cancer*.³²

Table U.A. ***Recommended steps for informing women that they have a diagnosis of breast cancer***

1. *Prior to discussing diagnosis, recurrence or metastases*

- Ensure the news is given in person, in a quiet, private place and allow enough uninterrupted time
- Encourage a second person to be present if appropriate
- Arrange to provide other methods to convey the information (for example, written materials, video tapes, tapes of consultations, etc.)

2. *When providing the information*

- Assess the woman's understanding of her condition and the woman's personal preference for information
- Briefly explain the process by which the diagnosis was reached
- Provide information simply and honestly, using lay terms without using euphemisms
- Avoid the notion that 'nothing can be done'
- Clearly indicate that the woman will have the final decision regarding her care

3. *Emotional and supportive role*

- Encourage the woman to express her feelings (for example by crying freely, talking about concerns, fears, anger, anxieties, etc) and respond to her feelings with empathy
- Address disturbing or embarrassing topics directly, and with sensitivity
- Assess the type and level of assistance that may be required, such as financial, transport or childcare assistance
- Provide information about support services

4. *Concluding the discussion*

- Summarise main points of the consultation and assess the woman's understanding
- Ask if there is anything further the woman would like to discuss
- Offer assistance to tell others difficult news
- Indicate your availability for contact to address any questions or concerns

5. *After discussing a diagnosis, recurrence or metastases*

- Document information given to the woman and family members
- Let others, particularly the woman's general practitioner, know the extent of information given and your perception of the woman's understanding

Reproduced from the NHMRC *Psychosocial clinical practice guidelines: providing information, support and counselling for women with breast cancer* (National Health and Medical Research Council, National Breast Cancer Centre, 2000)

APPENDIX V

LIST OF PROTOCOLS TO BE INCLUDED IN THE POLICY AND PROCEDURES MANUAL

Standard	Protocol
Section 1	
1.3.4	Follow-up of women who do not respond to initial letters inviting them to take part in the Program.
1.4.2	Follow-up of women who do not respond to invitation letters for rescreening.
Section 2	
2.4.1	Identification and investigation of interval cancers.
2.5.1	Identifying, reviewing and investigating interval cases of DCIS.
2.10.2	Imaging of women with internal breast prostheses.
2.12.1	Screen reading in an independent and 'blind' relationship.
2.13.3	Achievement of a single recommendation where there is discordance between the two independent screen readers on whether further assessment for the presence of breast cancer is required.
2.14.1	Management of women who report in accordance with the National Policy Framework for the Management of Women with Symptoms by BreastScreen Australia Services.
2.15.1	Evaluation of all women recalled to assessment using the triple test approach.
2.17.1	Correlation and evaluation of the clinical and imaging findings by relevant clinicians at assessment and for deciding on further investigations or management.
2.23.1	Referral of all women with a diagnosis of breast cancer.
2.24.1	Collection of treatment information about women with a diagnosis of breast cancer.
2.25.1	Review of all cases which underwent FNA cytology or core biopsy.
2.25.2	Reviewing and correlating the clinical, radiological, cytological and histopathological findings for all lesions detected as a result of screening which required surgery.
2.26.3	Follow-up of women where there is discordance between the result of surgery and the preoperative clinical and radiological findings.

Standard	Protocol
Section 3	
3.5.1	Service delivery to women from indigenous and culturally and linguistically diverse backgrounds.
3.6.1	Appropriate management of women with a disability.
3.8.5	Provision of all histological and cytological results by an appropriate member of the assessment team.
3.9.1	Informing women of a diagnosis of breast cancer.
3.9.2	Provision of appropriate information to women with a diagnosis of breast cancer.
3.10.3	Providing appropriate counselling to women and their support persons.
3.11.1	Asking all women to nominate a general practitioner to receive a copy of the results of screening.
3.11.3	Notifying the nominated general practitioner of all results in writing at the same time as the woman.
3.11.4	Making all reasonable efforts to notify a woman's nominated general practitioner on the day of any diagnosis of cancer or recommendation for open biopsy.
3.11.5	Inviting relevant women to nominate a health care provider in addition to their general practitioner and ensuring that results are forwarded.
Section 4	
4.1.2	Managing finances to maximise efficiency and accountability, which includes a delegation schedule.
4.4.2	Delineating staff roles and responsibilities between the various components of screening and assessment.
4.6.1	Policy and procedure manual containing protocols listed in this appendix.
4.6.2	Implementation of policy and procedure manual
4.6.3	Staff training on policy and procedures
4.7.1	Meeting relevant state and national infection control requirements.
4.7.2	Meeting relevant state and national occupational health and safety requirements.
4.10.2	Introduction of new technologies at the Service.
4.11.1	Information collected about a woman is treated in a confidential manner, consistent with state and national requirements.
4.11.5	Access by women to their own records, including copies of images.
4.12.3	Data collection and movement of records within the Service which includes staff responsibilities, the transfer of records between units and the file tracking system used.

APPENDIX W

INFORMATION TECHNOLOGY STANDARDS FOR DIGITAL MAMMOGRAPHY

The introduction of digital mammography creates additional complexity with client information systems. Generally, digital mammography images are managed by a Picture Archive and Communication System (PACS), digital mammography reporting is managed by Radiology Information Systems (RIS), and screening and assessment workflow is managed through a Client Information Management System (CIMS). These can be separate systems or integrated to a level where data is shared and distributed across systems. The challenge and the requirement for the Service is to ensure that adequate quality assurance is in place to verify data consistency and data integrity across systems.

When acquiring imaging modalities or software systems Services will have to ensure that the systems comply with the following standards to ensure interoperability.

HEALTH LEVEL 7

Health Level 7 is a messaging standard to transfer clinical information between different systems. It is now a recognised standard that is widely used all over the world. The National E-Health Transition Authority (NEHTA) has now endorsed HL7 as the national standard for secure electronic messaging. Some systems such as CIMS and RIS have been integrated with PACS using HL7 messaging standard. HL7 standards continue to evolve with newer versions. Vendors may claim that their systems are HL7 compliant however the Service needs to ensure that all the systems are compliant to the similar version.

DICOM

Digital Imaging and Communications in Medicine (DICOM) standard is used in the field of medical informatics to exchange digital information between medical imaging modalities and other medical image management systems. The function of DICOM is to ensure interoperability between these systems. It was originally developed by the National Electrical Manufacturers Association (NEMA) and the American College of Radiology. It is now controlled by the DICOM Standards Committee, and supports a wide range of medical images across the fields of radiology, cardiology, pathology and dentistry. Imaging modalities and image management systems have to be DICOM compliant. The DICOM message that carries information about the DICOM image must carry the required minimum national data set for screening mammograms, assessment mammograms and ultrasounds. This minimum national data set includes the client's full name and identification number, the date and time of the mammographic and/or ultra sound examination, the name of who performed the examination, the practice where it was performed. For mammography images the DICOM message must also include technical examination details including compressed breast thickness, side markers, positional markers, kVp, anode and filter type, tube-current-time product (mAs) and an estimate of dose.

INTEROPERABILITY FRAMEWORK

Interoperability Framework (IF) version 2.0 has been released by NEHTA. This framework provides the basis for development and implementation of new systems that can take advantage of the organisational, information and technical perspective of interoperability. Where applicable the systems specifications must comply with the IF to enable exchange of information across jurisdictions and systems.

INTEGRATING THE HEALTHCARE ENTERPRISE (IHE) FRAMEWORK

The IHE Framework is an initiative aimed at developing seamless exchange of information across applications and systems. The IHE uses the existing standards of HL7 and DICOM in addressing specific needs and optimising solutions that offer better patient care. There are technical frameworks and integration profiles that can benefit systems integration.

Aboriginal and Torres Strait Islander	A person of Aboriginal or Torres Strait 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.
Acquisition Workstation	Computer for viewing images at the point of acquisition of the image. An acquisition workstation may be used by radiographers to review and check quality of acquired image. Usually incorporates a single monitor with at least 1.3 megapixel resolution.
AEC (Automatic Exposure Control)	A device designed to determine the exposure (mAs) needed to produce an adequately penetrated X ray image. This is typically done by sampling the X ray intensity after it passes through the patient and image receptor. The AEC may, in some circumstances, also choose the kVp and target filter combination.
Aspiration	Putting 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 episode	An assessment episode includes all attendances for assessment during a particular screening episode. An assessment episode is complete when there is one of three outcomes: return for routine rescreening, referral for definitive treatment or a recommendation for early review.
Assessment visit	Any visit by a woman to an assessment 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 includes attending the assessment clinic for the purpose of receiving results.
Axillary dissection	Surgical excision of the axillary contents (fat and lymph nodes) en bloc with mastectomy or as an independent procedure. The extent of the axillary dissection is further defined in the following way: <ul style="list-style-type: none"> Level 1 – excision of the axillary contents up to the inferior border of the pectoralis minor muscle. Level 2 – excision of the axillary contents up to the superior border of the pectoralis minor muscle. Level 3 – excision of the axillary contents up to the apex of the axilla.
Axillary lymph node dissection	Surgical removal of lymph nodes found in the armpit region. See axillary dissection.
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.
Breast conserving Surgery	Surgery where the cancer is removed, together with a margin of normal breast tissue. The whole breast is not removed.
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.
Cancer	A malignant growth. See also 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	Catchment area is 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.
Clinical examination of breast	The physical examination of breast and axilla by a health professional.
Clinician	A medical doctor and member of the multidisciplinary assessment team.
CNR (Contrast to Noise Ratio)	If an image contains two objects differing in contrast the CNR represents the difference in the mean pixel values of the two objects divided by the noise.
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	Where the screen readers consider the mammogram together 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 a mechanical device to drive the cutting needle.
CR (Computed Radiography)	Uses phosphor plate cassettes which are 'read' or 'scanned' by a CR Reader and converted to a digital image
CR Reader (Computer Radiography Reader)	Equipment which receives the phosphor plate cassettes, 'reads' or 'scans' the plate and converts to a digital image.
Cyst	Fluid-filled sac.
Cytological diagnosis	A diagnosis based on looking at 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. ¹³⁴
DCIS (Ductal carcinoma in situ)	A form of carcinoma in situ with no invasive component, diagnosed by its characteristic histopathologic features. 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 adequately treated.
Definitive outcome	An assessment recommendation of 1. Routine rescreen at 2 years; at assessment; 2. Routine rescreen at 1 year; 3. Definitive treatment at assessment; 2. Routine rescreen at 1 year; 3. Definitive treatment for cancer.
Definitive result	Whether the lesion is malignant or non-malignant. No definitive result applies where the sample obtained does not permit definitive diagnosis and where further biopsy will not be performed. The decision not to perform further biopsy may be the woman's or the surgeon's.
Diagnostic mammography	Mammography which is performed when a woman has signs or symptoms of disease.
Double reading	Where the screening images are independently read by two readers.

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 performance.
DR (Digital Radiography)	A system for direct digital capture of an x-ray image – there are a number of 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, occurs after the screening visit is complete and cancers found are considered to be interval cancers.
Eligible women	Any woman aged 40 years or over without symptoms.
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	Women who are attending for their first screen within the National Program, including the pilot phase and regardless of the Service. Also known as initial screen.
Flat Panel Detector	One of the technologies used for DR. Relates to the part of a mammography unit which 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 FNB.
Frozen section	Freezing of a tissue biopsy to facilitate cutting a thin tissue section which is stained and examined microscopically. 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	Reading digital mammograms that have been printed onto an x-ray film like media, and hung as analogue images on multiviewers
Histology	An examination of the body tissue by a pathologist using a microscope.
Histopathology	Microscopic study of diseased tissue, usually performed by a histopathologist.
HL7 (Health Level 7)	A standard for patient electronic data exchange. HL7 refers to the highest level of the International Organization's of 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 need 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.

Initial screen	Women who are attending for their first screen within the National Program, including the pilot phase and regardless of the Service. Also known as first screen.
Interval cancer invasive	<ul style="list-style-type: none"> • An interval breast cancer is any invasive breast cancer (including Paget’s disease of the nipple only if there is an underlying invasive tumour) diagnosed in the interval following a negative screening episode and before the next scheduled screening examination. • A case of invasive breast cancer that is diagnosed at early review or in the interval between assessment and early review, where the recommendation for early review is six months or more from the screening date. • A case of invasive breast cancer that is diagnosed at diagnostic open biopsy if the date of diagnosis is six months or more from the screening date. • Invasive breast cancers diagnosed at early rescreen are classified as interval breast cancers if the woman presents at early rescreen with a breast lump and/or clear or blood-stained nipple discharge in the breast in which the breast cancer was diagnosed. • Invasive breast cancers diagnosed during the interval between a negative screening episode and next screening episode of women who are on annual rescreen are only included as interval breast cancers for year of screening > 0 < 12 months. • Invasive breast cancers diagnosed between six and 24 months after a recommendation for further assessment is made and a woman fails to attend for assessment. • Invasive cancer that is diagnosed at diagnostic open biopsy if the date of diagnosis is six months or more from the date of screening.
Interval cancer non-invasive	As for interval cancer invasive, but replace ‘invasive breast cancer’ with ‘DCIS’.
Invasive cancer	The tendency of a malignant process or growth to spread into healthy tissue ¹⁶⁸ . Invasion occurs when cancer cells push between and break through other surrounding cells and structures ¹⁶⁹ . An invasive cancer is greater than 15mm (as compared to a small invasive cancer which is less than or equal to 15mm). Tumours demonstrating micro-invasion should be reduced and sized as invasive cancers and not as DCIS. Invasive cancer excludes DCIS.
LAN (Local Area Network)	A network that allows communication in a restricted area (e.g. within one department)
LCIS (Lobular carcinoma in situ)	Atypical epithelial process characterised by an increased risk of progression to invasive carcinoma. It is difficult to detect by mammography.
Lesion	An area of abnormal tissue change. A lump or abscess that may be caused by injury or disease, such as cancer.
Localisation	Method used to locate/mark an impalpable lesion for surgical removal with wire marker or carbon.
Lumpectomy	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 the axillae, neck and inguinal regions. Axillary lymph nodes are a common site for metastatic breast carcinoma.
Malignant	A tumour having the capacity to invade and destroy tissue locally, and metastasise via the bloodstream or lymphatics to distant sites (metastasis) and cause death.
Mammogram	A soft tissue x-ray of the breast which may be used to evaluate a lump or which may be used as a screening test in women with no signs or symptoms of breast cancer.
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 the 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	Where the radiologist and the surgeon, or other designated examining clinician, are in attendance together at assessment to correlate and evaluate the clinical and imaging findings and to decide on further investigations or management.
Non-mammographic Recall	Recall to assessment for reasons other than a mammographic abnormality, eg signs or symptoms.
Open biopsy	A surgical procedure performed under local or general anaesthetic in which a sample of breast tissue for histological examination is obtained in a conventional surgical procedure, using an open incision.
PACS (Picture Archiving and Communication System)	The management and archiving of digital images over a computer network.
Pathologist	Doctor who specialises in examining tissue and diagnosing disease.
Pathology	Scientific study of the alterations produced by disease.
Preoperative diagnosis of cancer	A malignant result on FNA or core biopsy (includes DCIS and invasive cancer) which is consistent with suspicious or malignant imaging findings.
Primary breast tumour	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.
QA/ QC (Quality Assurance/ Quality Control)	Ensuring processes are in place to monitor, maintain and improve the quality of systems and services.
Radical mastectomy	Total mastectomy with removal of 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 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 radiologists 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	Research is considered to include 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.

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 which may be used for image analysis. For example, in the calculation of the SNR or the CNR.
Scanning Photon Counting System	Another type of DR technology 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 which are observed on a screening test.
Screen-detected cancer	A screen-detected breast cancer is 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 sort out apparently well persons who probably have a disease from those who probably do not.
Screening and Assessment Service	An integrated service consisting of an assessment centre/service and its associated screening units.
Screening Episode	A screening episode includes all attendances for screening and assessment within 6 months relating to a particular round of screening. It commences at the date of attendance for screening. It is completed when: <ul style="list-style-type: none"> i) A recommendation is made to return the woman to routine rescreening ii) A recommendation is made for early review iii) A diagnosis of cancer is made iv) The woman fails to attend for technical recall or assessment within 6 months v) The woman dies.
Screening mammography	Mammography which is performed when a woman does not have signs or symptoms of disease.
Screening unit	A screening unit is usually one site, fixed or mobile.
Send/ Receive Workstation	A workstation, usually at a remote site, used for either transmitting images via a LAN or WAN or for downloading images to or from an interchangeable hard-drive for transfer to the PACS.
Size of tumour	The greatest dimension of the tumour in mm. This is ideally determined from the fresh specimen or, if appropriate, from histopathologic slides.
Small invasive cancer	An invasive cancer less than or equal to 15mm.
Second or subsequent screen	Women who are attending for any screen in the Program, other than their first screen.
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	Staff refers to any person employed by the service, which includes full-time, part-time and casual staff.
Stereotaxis	A radiological technique to accurately localise a lesion in the breast. Used to permit 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 and Territory.

Target group	Women aged between 50 and 69 years.
Technical repeat	The taking of further images initiated by the radiographer or radiologist due to technically unsatisfactory images at the screening visit.
Torres Strait Islander	A person of Torres Strait Islander descent who identifies as an Torres Strait Islander and is accepted as such by the community with which he or she is associated.
Total mastectomy	Surgery to remove 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	Production of a visual image of a part of the body by recording the echoes of sound waves directed into the body.
WAN (Wide Area Network)	A network that allows communications between institutions and or many departments.

REFERENCE LIST

1. Australian Health Ministers' Advisory Council Breast Cancer Screening Evaluation Committee. *Breast cancer screening in Australia: future directions. Prevention Program Evaluation Series No 1*. Canberra: Australian Government Publishing Services, 1990.
2. National Quality Management Committee of BreastScreen Australia. *Quality Improvement in BreastScreen Australia*. Unpublished. BreastScreen Australia, 1999.
3. BreastScreen Australia. *National Accreditation Handbook, 2005*
4. McLean D, Heggie J, Herley J, Thomson F, Grewal R. Interim Recommendations for a digital mammography quality assurance program. *Australasian Physical Engineering Scientists in Medicine* 2007;30.
5. Andersson I, Aspegren K, Janzon L, Landberg T et al. Mammographic screening and mortality from breast cancer: the Malmo mammographic screening trial. *BMJ* 1988;297:943–8.
6. Shapiro S, Strax P, Venet L. Periodic breast cancer screening in reducing mortality from breast cancer. *JAMA* 1971;215:1777–85.
7. Tabar L, Gad A. Screening for breast cancer: the Swedish trial. *Radiology* 1981;138:219–22.
8. Report of the Senate Standing Committee on Community Affairs. *Breast cancer screening and treatment in Australia*. Canberra: Senate Printing Unit, Parliament House, 1994.
9. Lynge E. Mammography screening for breast cancer in Copenhagen April 1991–March 1997. Mammography Screening Evaluation Group. *APMIS Suppl* 1998;83:1–44.
10. NHS Breast Screening Programme. *NHS Breast Screening Programme Review 1999—Meeting new challenges*. Sheffield: NHS Breast Screening Programme, 1999.
11. Fracheboud J, Boer R, van Ineveld B, Verbeek A et al. Nationwide Breast Cancer Screening in the Netherlands (VII). Instituut Maatschappelijke Gezondheidszorg: Erasmus Universiteit Rotterdam, 1999.
12. Olsson S, Andersson I, Karlberg I, Bjurstam N et al. Implementation of service screening with mammography in Sweden: from pilot study to nationwide programme. *J Med Screen* 2000;7:14–8.
13. Dean PB, Pamilo M. Screening mammography in Finland—1.5 million examinations with 97 percent specificity. Mammography Working Group, Radiological Society of Finland. *Acta Oncol* 1999;38 Suppl 13:47–54.
14. Australian Institute of Health and Welfare. *BreastScreen Australia Achievement Report 1997 and 1998*. Canberra: Australian Institute of Health and Welfare, 2000.
15. Chen H, Duffy S, Tabar L, Day N. Markov chain models for progression of breast cancer. Part I: tumor attributes and the preclinical screen-detectable phase. *J Epidemiol Biostat* 1997;2:9–23.
16. Chen H, Duffy S, Tabar L, Day N. Markov chain models for progression of breast cancer. Part II: prediction of outcomes for different screening regimes. *J Epidemiol Biostat* 1997;2:25–35.
17. Duffy S, Chen H, Tabar L, Day N. Estimation of mean sojourn time in breast cancer screening using a Markov chain model of both entry to and exit from the preclinical detectable phase. *Stat Med* 1995;14:1531–43.
18. Tabar L, Faberberg G, Day N, Holmberg L. What is the optimum interval between mammographic screening examinations? An analysis based on the latest results of the Swedish two-county breast cancer screening trial. *Br J Cancer* 1987;55:547–51.
19. Vogel V, Graves D, Coody D, Winn R, Peters G. Breast screening compliance following a statewide low-cost mammography project. *Cancer Detect Prev* 1990;14:573–6.
20. Clover K, Redman S, Forbes J, Sanson-Fisher R, Callaghan T. Two sequential randomized trials of community participation to recruit women for mammographic screening. *Prev Med* 1996;25:126–34.
21. Dorsch M, Cheok F, Ingham H. The effectiveness of invitations from general practitioners in recruiting women to mammographic screening. *Med J Aust* 1991;155:623–5.

22. Schofield P, Cockburn J, Hill D, Reading D. Encouraging attendance at a screening mammography programme: determinants of response to different recruitment strategies. *J Med Screen* 1994;1:144–9.
23. Hurley S, Huggins R, Jolley D, Reading D. Recruitment activities and sociodemographic factors that predict attendance at a mammographic screening program. *Am J Public Health* 1994;84:1655–8.
24. Bonfill X, Marzo M, Pladevall M, Marti J, Emparanza JI. Strategies for increasing women’s participation in community breast cancer screening (Cochrane review). In: The Cochrane Library, 1, 2002. Oxford: Update Software.
25. Sin J, St Leger A. Interventions to increase breast screening uptake: do they make any difference? *J Med Screen* 1999;6:170–81.
26. Banks E, Richardson A, Beral V, Crossley B *et al*. Effect on attendance at breast cancer screening of adding a self administered questionnaire to the usual invitation to breast screening in southern England. *J Epidemiol Community Health* 1998;52:116–9.
27. Turnbull D, Irwig L, Adelson P. A randomised trial of invitations to attend for screening mammography. *Aust J Public Health* 1991;15:33–6.
28. Cockburn J, White V. *Review of Australian research into behavioural aspects of screening mammography*. Carlton South: Centre for Behavioural Research in Cancer, 1994.
29. Slaytor E, Ward J. How risks of breast cancer and benefits of screening are communicated to women: analysis of 58 pamphlets. *BMJ* 1998;317:263–4.
30. Ward J. Population-based mammographic screening: Does ‘informed choice’ require any less than full disclosure to individuals of benefits, harms, limitations and consequences? *Aust N Z J Public Health* 1998;23:301–4.
31. National Health and Medical Research Council. *General guidelines for medical practitioners on providing information to patients*. Canberra: Australian Government Publishing Service, 1994.
32. NHMRC National Breast Cancer Centre. *Psychosocial clinical practice guidelines: providing information, support and counselling for women with breast cancer*. Canberra: Commonwealth of Australia, 2000.
33. Barratt A, Cockburn J, Redman S, Paul C, Perkins J. Mammographic screening: results from the 1996 National Breast Health Survey. *Med J Aust* 1997;167:521–4.
34. Clover K, Redman S, Forbes J, Sanson-Fisher R, Dickinson J. Promotion of attendance for mammographic screening through general practice: a randomised trial of two strategies. *Med J Aust* 1992;156:91–4.
35. Adelson P, Irwig L, Turnbull D. Evaluating the impact of a promotional campaign for screening mammography: who attends? *Aust J Public Health* 1992;16:66–71.
36. Kernohan E. Evaluation of a pilot study for breast and cervical cancer screening with Bradford’s minority ethnic women; a community development approach, 1991–93. *Br J Cancer Suppl* 1996;29:S42–S46.
37. Skinner C, Sykes R, Monsees B, Andriole D *et al*. Learn, share, and live: breast cancer education for older, urban minority women. *Health Educ Behav* 1998;25:60–78.
38. BreastScreen Australia State Programs. Raw data from the State BreastScreen Programs for the 1997 calendar year, 1999.
39. Elwood M, McNoe B, Smith T, Bandaranayake M, Doyle T. Once is enough— why some women do not continue to participate in a breast cancer screening programme. *N Z Med J* 1998;111:180–3.
40. Meldrum P, Turnbull D, Dobson H, Colquhoun C *et al*. Tailored written invitations for second round breast cancer screening: a randomised controlled trial. *J Med Screen* 1994;1:245–8.
41. Stead M, Wallis M, Wheaton M. Improving uptake in non-attenders of breast screening: selective use of second appointment. *J Med Screen* 1998;5:69–72.

42. Wolosin R. Effect of appointment scheduling and reminder postcards on adherence to mammography recommendations. *J Fam Pract* 1990;30:542–7.
43. NHMRC National Breast Cancer Centre. *Advice about familial aspects of breast cancer and ovarian cancer: a guide for health professionals*. Woolloomooloo (NSW): NHMRC National Breast Cancer Centre, 2000.
44. *BreastScreen Australia monitoring report 2001. Draft indicators and data specifications for the 2001 BreastScreen Australia monitoring report*. BreastScreen, 2001.
45. Sauer R, Schauer A, Rauschecker HF, Schumacher M *et al*. Therapy of small breast cancer: a prospective study on 1036 patients with special emphasis on prognostic factors. *International Journal of Radiation Oncology, Biology, Physics* 1992;23:907–14.
46. Toikkanen S, Jeensuu H. Prognostic factors and long-term survival in breast cancers in a defined urban population. *APMIS* 1990;98:1005–14.
47. O'Reilly SM, Camplejohn RS, Barnes DM, Millis RR *et al*. Node-negative breast cancer: prognostic subgroups defined by tumour size and flow cytometry. *Journal of Clinical Oncology* 1990;8:2040–6.
48. Supramaniam R, Smith D, Coates M, Hayes L *et al*. *Breast Cancer Survival in NSW in 1973 to 1995*. Sydney: NSW Cancer Council, 1998.
49. Australian Cancer Network Pathology Working Party. *The pathology reporting of breast cancer*. Sydney: Australian Cancer Network, 2001.
50. Eusebi V, Feudale E, Foschini MP, Micheli A *et al*. Long-term follow-up of in situ carcinoma of the breast. *Semin Diagn Pathol* 1994;11:223–35.
51. Page DL, Dupont WD, Rogers LW, Landenberger M. Intraductal carcinoma of the breast: follow-up after biopsy only. *Cancer* 1982;49:751–8.
52. Fisher B, Dignam J, Wolmark N, Mamounas E *et al*. Lumpectomy and radiation therapy for the treatment of intraductal breast cancer: findings from National Surgical Adjuvant Breast and Bowel Project B–17. *Journal of Clinical Oncology* 1998;16:441–52.
53. Silverstein M, Lagios M, Martino S, Lewinsky B *et al*. Outcome after invasive local recurrence in patients with ductal carcinoma in situ of the breast. *Journal of Clinical Oncology* 1998;16:1367–73.
54. Lampejo O, Barnes D, Smith P, Millis R. Evaluation of infiltrating ductal carcinomas with a ductal carcinoma in situ component: correlation of the histologic type of the in-situ component with grade of infiltrating component. *Seminars in Diagnostic Pathology* 1994;11:215–22.
55. DeGroot R, Rush BF, Milazzo J, Warden MJ, Rocko JM. Interval breast cancer: a more aggressive subset of neoplasias. *Surgery* 1983;94:543–7.
56. Duffy SW, Tabar L, Fagerberg G, Gad A *et al*. Breast screening, prognostic factors and survival—results from the Swedish two county study. *Br J Cancer* 1991;64:1133–8.
57. Shapiro S, Venet W, Strax P, Venet L, Roeser R. Ten to fourteen year effect of screening on breast cancer mortality. *J Natl Cancer Inst* 1982;69:349–55.
58. Holmberg L, Tabar L, Adami HO, Bergstrom R. Survival in breast cancer diagnosed between mammographic screening examinations. *Lancet* 1986;2:27–30.
59. Everington D, Gilbert F, Tyack C, Warner J. The Scottish breast screening programme's experience of monitoring interval cancers. *J Med Screen* 1999;6:27.
60. Kavanagh A, Amos A, Marr G. *The ascertainment and reporting of interval cancers within the BreastScreen Australia Program*. Woolloomooloo (NSW): National Breast Cancer Centre, 1999.
61. European Commission. *European Guidelines for Quality Assurance in Mammography Screening*. 2nd edition. Luxembourg: Office for Official Publications of the European Communities, 1996.

62. NHS Breast Screening Programme. *Quality assurance guidelines for radiologists*. 15. Sheffield: NHS Breast Screening Programme, 1997.
63. Zannis V, Aliano K. The evolving practice pattern of the breast surgeon with disappearance of open biopsy for nonpalpable lesions. *Am J Surg* 1998;176:525–8.
64. BreastScreen Australia State Programs. Raw data from the State BreastScreen Programs for the Year 1999, 2001.
65. Blanks R, Moss S, Wallis M. Use of two view mammography compared with one view in the detection of small invasive cancers: further results from the National Health Service breast screening programme. *J Med Screen* 1997;4:98–101.
66. Blanks R, Moss S, Wallis M. A comparison of two view and one view mammography in the detection of small invasive cancers: results from the National Health Service breast screening programme. *J Med Screen* 1996;3:200–3.
67. Blanks R, Given-Wilson R, Moss S. Efficiency of cancer detection during routine repeat (incident) mammographic screening: two versus one view mammography. *J Med Screen* 1998;5:141–5.
68. Young K, Wallis M, Blanks R, Moss S. Influence of number of views and mammographic film density on the detection of invasive cancers: results from the NHS Breast Screening Programme. *Br J Radiol* 1997;70:482–8.
69. American College of Radiology. *Mammography quality control manual*. Reston, VA: American College of Radiology, 1999.
70. Elmore J, Wells C, Howard D. Does diagnostic accuracy in mammography depend on radiologists experience? *Journal of Women's Health* 1998;7:443–9.
71. Elmore J, Barton M, Mocerri V, Arena P, Fletcher S. Ten-year risk of false positive screening mammograms and clinical breast examinations. *N Engl J Med* 1998;338:1089–96.
72. Blanks R, Wallis M, Moss S. A comparison of cancer detection rates achieved by breast cancer screening programmes by number of readers, for one and two view mammography: results from the UK National Health Service breast screening programme. *J Med Screen* 1998;5:195–201.
73. Anderson E, Muir B, Walsh J, Kirkpatrick A. The efficacy of double reading mammograms in breast screening. *Clin Radiol* 1994;49:248–51.
74. Thurfjell E, Lernevall K, Taube A. Benefit of independent double reading in a population-based mammography screening programme. *Radiology* 1994;191:241–4.
75. Kan L, Olivotto IA, Warren Burhenne L, Sickles E, Coldman A. Standardized Abnormal Interpretation and Cancer Detection Ratios to Assess Reading Volume and Reader Performance in a Breast Screening Program. *Radiology* 2000;215:563–7.
76. Schmidt F, Hartwagner K, Spork E, Groell R. Medical audit after 26,711 breast imaging studies improved rate of detection of small breast carcinomas (classified as Tis or T1a,b). *Cancer* 1998;83:2516–20.
77. Department of Health & Human Services Food and Drug Administration. *Quality mammography standards; Final rule 21 CFR parts 16 & 900*. Federal Register, 1997.
78. Williams L, Hartswood M, Prescott R. Methodological issues in mammography double reading studies. *J Med Screen* 1998;5:202–6.
79. Mucci B, Athey G, Scarisbrick G. Double read screening mammograms: the use of a third reader to arbitrate on disagreements. *The Breast* 1999;8:37–9.
80. BreastScreen Australia. *National Review of Policy on Symptomatic Women. Volume 1: Final Report and Policy Framework*. BreastScreen Australia, 2001.
81. Irwig L, Macaskill P. *Evidence relevant to guidelines for the investigation of breast symptoms*. Woolloomooloo (NSW): NHMRC National Breast Cancer Centre, 1997.
82. Hide I, McLean L, Simpson W, Neilson F. Women with normal mammography describing symptoms at screening. *The Breast* 1999;8:116–9.

83. National Breast Cancer Centre. *Breast Imaging: A Guide for Practice*. NSW: National Breast Cancer Centre, 2002.
84. National Breast Cancer Centre. *Synoptic breast imaging report*. NSW: National Breast Cancer Centre, 2007.
85. National Breast Cancer Centre. *Breast fine needle aspiration (FNA) cytology and core biopsy: a guide for practice*. Woolloomooloo (NSW): National Breast Cancer Centre, 2004.
86. Singh N, Wells, C. Assessment of accuracy in breast cytology. *Cytopathology* 2001;12:211-8
87. NHS Breast Screening Programme. *Guidelines for non-operative diagnostic procedures and reporting in breast cancer screening*. 50. Sheffield: NHS Breast Screening Programme, June 2001.
88. Britton P, McCann J. Needle biopsy in the NHS Breast screening Programme 1996–1997: how much and how accurate? *The Breast* 1999;8:5–11.
89. Britton P. Fine needle aspiration or core biopsy. *The Breast* 1999;8:1–4.
90. Lowe J, Balanda K, Del Mar C, Hawes E. Psychologic distress in women with abnormal findings in mass mammography screening. *Cancer* 1999;85 :1114–8.
91. Commonwealth Department of Human Services and Health. *National program for the early detection of breast cancer: national accreditation requirements*. Canberra: Australian Government Publishing Service, 1994.
92. Weyant M, Carroccio A, Tartter P, Hermann G et al. Determinants of success with spot localization biopsy of the breast. *J Am Coll Surg* 1995;181:521–4.
93. Kollias J, Gill P, Beamond B, Rossi H et al. Clinical and radiological predictors of complete excision in breast-conserving surgery for primary breast cancer. *Aust N Z J Surg* 1998;68:702–6.
94. Dixon J, Ravi SO, Walsh J, Paterson D, Anderson T. Specimen-orientated radiography helps define excision margins of malignant lesions detected by breast screening [see comments]. *Br J Surg* 1993;80:1001–2.
95. Ramsy-Stewart G, Lauer C. Use of a specimen-evaluation device for the diagnosis of impalpable breast lesions detected by mammography. *Med J Aust* 1992;17:244–6.
96. Bull A, Campbell M. Assessment of the psychological impact of a breast screening programme. *Br J Radiol* 1991;64:510–5.
97. Ong G, Austoker J, Brett J. Breast screening: adverse psychological consequences one month after placing women on early recall because of a diagnostic uncertainty. A multicentre study. *J Med Screen* 1997;4:158–68.
98. Lerman C, Trock B, Rimer B, Boyce A et al. Psychological and behavioural implications of abnormal mammograms. *Ann Intern Med* 1991;114:657–61.
99. Health Committee. *Breast cancer services*. 3(1). London: 1995.
100. Richards M, Baum M, Dowsett M, Maguire P et al. *Provision of breast services in the UK: the advantages of specialist breast units*. London: British Breast Group, 1993.
101. NHS Breast Screening Programme. *Guidelines on the collection and use of breast cancer data*. 26. Sheffield: National Health Service Breast Screening Programme, 1993.
102. Girgis A, Foot G. *Satisfaction with breast cancer care: A summary of the literature, 1984–1994*. Sydney: NHMRC National Breast Cancer Centre, 1995.
103. Fallowfield L, Hall A, Maguire G, et al. Psychological outcomes of different treatment policies in women with early breast cancer outside a clinical trial. *BMJ* 1990;301:575–80.
104. Ware J, Davies A. Behavioral consequences of consumer dissatisfaction with medical care. *Eval Program Plann* 1983;6:291–7.
105. Linn M, Linn B, Stein S. Satisfaction with ambulatory care and compliance in older patients. *Med Care* 1982;20:606–14.

106. Tito F, Roche S. *Partnerships in general practice: a discussion paper*. Curtin, ACT: Consumer's Health Forum of Australia, 1999.
107. Austoker J. Gaining informed consent for screening is difficult—but many misconceptions need to be undone. *BMJ* 1999;18:722–3.
108. Tito F and Newby L. *Medicolegal implications of clinical practice guidelines in the diagnosis and treatment of breast cancer and legal implications of clinical practice guidelines (a recommendations paper)*. Woolloomooloo (NSW), National Breast Cancer Centre. 1998.
109. National Health and Medical Research Council. *How to present the evidence for consumers: preparation of consumer publications*. Canberra: Australian Government Publishing Service, 1999.
110. Austoker J, Ong G. Written information needs of women who are recalled for further investigation of breast screening: results of a multicentre study. *J Med Screen* 1994;1:238–44.
111. New South Wales Government. Privacy and Personal Information Protection Act. Act No. 133. Updated 13 July 1999. 1998.
112. Commonwealth of Australia. Privacy Act. Act No.119 of 1998 as amended . 1998.
113. Information Management Branch PCUIPW. *Personal Information Privacy Principles for Queensland Health*. <http://www.health.qld.gov.au/imb/POLQLD19980139v1.htm> Queensland Department of Health, (last updated 1 December 1998).
114. NSW Department of Health. *Information Privacy Code of Practice*. <http://www.health.nsw.gov.au/iasdl/information-privacy/> NSW Health, (last updated 1 September 1999).
115. Department of Immigration and Multicultural Affairs. *Charter of public service in a culturally diverse society*. Canberra: Commonwealth of Australia, 1998.
116. Australian Bureau of Statistics. *1996 Census of population and housing*. Canberra: ABS, 1997.
117. Australian Bureau of Statistics. *Disability, Ageing and Carers Australia: Summary of findings*. Catalogue No: 4430.0. Canberra: Commonwealth of Australia, 1993.
118. BreastScreen Victoria. *Victorian Breast Screening Program Policy and Procedures Manual*. Carlton South: BreastScreen Victoria Inc., 1999.
119. Commonwealth Department of Human Services and Health. *Commonwealth disability strategy: a ten year framework for Commonwealth departments and agencies*. Canberra: Department of Human Services and Health, 1994.
120. McNoe B, Richardson A, Elwood J. Factors affecting participation in mammography screening. *N Z Med J* 1996;109:359–61.
121. Marshall G. A comparative study of re-attenders and non-re-attenders for second triennial National Breast Screening Programme appointments. *J Public Health Med* 1994;16:79–86.
122. Fentiman I. Pensive women, painful vigils: consequences of delay in assessment of mammographic abnormalities. *Lancet* 1988;1:1041–2.
123. Margolis K, Lurie N, McGovern P, Slater J. Predictors of failure to attend scheduled mammography appointments at a public teaching hospital. *J Gen Intern Med* 1993;8:602–5.
124. Brett J, Austoker J, Ong G. Do women who undergo further investigation for breast screening suffer adverse psychological consequences? A multi-centre follow-up study comparing different breast screening result groups five months after their last breast screening appointment. *J Public Health Med* 1998;20:396–403.
125. Gilbert F, Cordiner C, Affleck I, Hood D *et al*. Breast screening: the psychological sequelae of false-positive recall in women with and without a family history of breast cancer. *Eur J Cancer* 1998;34:2010–4.
126. Rimer B, Bluman L. The psychosocial consequences of mammography. *J Natl Cancer Inst Monogr* 1997;131–8.

127. Scaf-Klomp W, Sanderman R, van de Wiel H, Otter R, van den Heuvel W. Distressed or relieved? Psychological side effects of breast cancer screening in The Netherlands. *J Epidemiol Community Health* 1997;51:705–10.
128. Steggles S, Lightfoot N, Sellick S. Psychological distress associated with organized breast cancer screening. *Cancer Prev Control* 1998;2:213–20.
129. Poole K. The emergence of the 'waiting game': a critical examination of the psychosocial issues in diagnosing breast cancer. *J Adv Nurs* 1997;25:273–81.
130. Poole K, Hood D, Monypenny I, Sweetland H *et al*. Psychological distress associated with waiting for results of diagnostic investigations for breast disease. *The Breast* 1999;8:334–8.
131. Harcourt D, Ambler N, Rumsey N, Cawthorn S. Evaluation of a one-stop breast lump clinic: a randomized controlled trial. *The Breast* 1998;7:314–9.
132. Roberts C, Cox C, Reintgen D, Baile W, Gilbertini M. Influence of physician communication on newly diagnosed breast patients' psychologic adjustment and decision-making. *Cancer* 1994;74:336–41.
133. Sardell A, Trierweiler S. Disclosing the cancer diagnosis: procedures that influence patient hopefulness. *Cancer* 1993;72:3355–65.
134. National Health and Medical Research Council. *Clinical practice guidelines for the management of early breast cancer*. Canberra: Australian Government Publishing Services, 1995.
135. Williams P, Davis C, Rankin N, Redman S *et al*. *National Consumer Survey. In preparation*. Woolloomooloo (NSW): National Breast Cancer Centre, 2000.
136. NHMRC National Breast Cancer Centre. *Clinical practice guidelines for the management of advanced breast cancer*. Camperdown (NSW); National Breast Cancer Centre, 2001.
137. NHMRC National Breast Cancer Centre. *Clinical management of ductal carcinoma in situ, lobular carcinoma in situ and atypical hyperplasia of the breast*. Camperdown (NSW); National Breast Cancer Centre, 2003.
138. National Breast Cancer Centre. *A guide for women with early breast cancer*. Camperdown (NSW); National Breast Cancer Centre, 2003.
139. National Breast Cancer Centre. *A guide for women with metastatic breast cancer*. Woolloomooloo (NSW): National Breast Cancer Centre, 2001.
140. National Breast Cancer Centre. *Ductal carcinoma in situ: Understanding your diagnosis and treatment*. Camperdown (NSW): National Breast Cancer Centre, 2004.
141. National Breast Cancer Centre. *Lobular carcinoma in situ and atypical hyperplasia of the breast: understanding your diagnosis*. Camperdown (NSW): National Breast Cancer Centre, 2004.
142. Ong G, Austoker J. Recalling women for further investigation of breast screening: women's experiences at the clinic and afterwards. *J Public Health Med* 1997;19:29–36.
143. Poole K. The evolving role of the clinical nurse specialist within the comprehensive breast cancer centre. *Journal of Clinical Nursing* 1996;5:341–9.
144. National Health Strategy. *The future of general practice. Issues paper no. 3*. Canberra: National Health Strategy, 1992.
145. Silburne K, Johnson A. *Needs assessment* . <http://www.latrobe.edu.au/www/nrccph> National Resource Centre for Consumer Participation in Health, (last updated 1999).
146. National Resource Centre for Consumer Participation in Health. *Feedback, participation and consumer diversity. A literature review*. Canberra: Commonwealth Department of Health and Aged Care, 2000.
147. Consumer Focus Collaboration. *Strategic plan 1997/98–2000/01: strengthening the focus on consumers in health service planning, delivery, monitoring and evaluation in Australia*. Canberra: Commonwealth Department of Health and Aged Care, 2000.

148. Australian Council of Health Care Standards. *Quality initiatives. Second edition*. Sydney: Australian Council of Health Care Standards, 2000.
149. Spoon B, Hamlin A, Lowry J, Reimels E. CQI applications in a community hospital. *Nursing connections* 1996;9:35–42.
150. Forrest P, Working group on breast cancer screening. *Breast cancer screening, report to the health ministers of England, Wales, Scotland and Northern Ireland*. London: Her Majesty's Stationery Office, 1986.
151. Austoker J, Fagger D, Patnick J, (eds.). *Messages about breast screening: Guidelines for health promotion specialists primary care teams and screening unit staff*. 31. Sheffield: NHS Breast Screening Programme, 1995.
152. Cockburn J, Schofield P, White V, Hill D, Russell I. Predictors of returning for second round screening at a population based mammographic screening programme in Melbourne, Australia. *J Epidemiol Community Health* 1997;51:62–6.
153. Commonwealth of Australia. *Freedom of Information Act 1992*. 1992.
154. National Health and Medical Research Council. *National statement on ethical conduct in research involving humans*. Canberra : Commonwealth of Australia, 1999.
155. National Health and Medical Research Council. *Guidelines under section 95 of the Privacy Act 1988*. Canberra: Commonwealth of Australia, 2000.
156. Scottish Breast Screening Programme. *Scottish Breast Screening Programme*. <http://www.show.scot.nhs.uk/nsdl/sbsp/sbsp.htm> Scottish Health on the Web, (last updated 5 May 1999).
157. Ontario Breast Screening Program. *Ontario Breast Screening Program*. <http://www.obsp.on.ca> Ontario Breast Screening Program, (last updated 27 July 2000).
158. Cancer Bureau. *Organised breast cancer screening programs in Canada*. Laboratory Centre for Disease Control, 1999.
159. De Koning H, Fracheboud J, Boer R, Verbeek A *et al*. Nation-wide breast cancer screening in The Netherlands: support for breast-cancer mortality reduction. *Int J Cancer* 1995;60:777–80.
160. Fracheboud J, De Koning H, Beemsterboer P, Boer R *et al*. Interval cancers in the Dutch breast cancer screening programme. *Br J Cancer* 1999;81:912–7.
161. Schouten L, de Rijke J, Schlangen J, Verbeek A. Evaluation of the effect of breast cancer screening by record linkage with the cancer registry, the Netherlands. *J Med Screen* 1998;5:37–41.
162. Harmer C, Staples M, Kavanagh A. Evaluation of breast cancer incidence: is the increase due entirely to mammographic screening? *Cancer Causes Control* 1999;10:333–7.
163. Goodsitt M, Carson P, Witt S, Hykes D, Kofler JJ. Real-time B-mode ultrasound quality control test procedures. Report of AAPM Ultrasound Task Group No. 1 . *Med Phys* 1998;25:1385–406.
164. Craig A, Heggie J, McLean D, Coakley K, Nicoll J. Recommendations for a mammography assurance program. *Australasian Physical Engineering Scientists in Medicine* 2001;24.
165. NHS Breast Screening Programme. *Quality assurance guidelines for radiographers*. 30. Sheffield: NHS Breast Screening Programme, 1994.
166. NHS Breast Screening Programme. *Quality assurance guidelines for nurses in breast cancer screening*. 29. Sheffield: NHS Breast Screening Programme, 1998.
167. Elston C. Grading of invasive carcinoma of the breast. In Page D, Anderson T, (eds). *Diagnostic histopathology of the breast*, Edinburgh: Churchill Livingstone, 1987: 300– 311.
168. Thomas C (ed.) 1997. *Tabers Cyclopaedic Medical Dictionary*, Edition 15. Philadelphia: Davis & Company.
169. Australian Institute of Health and Welfare (AIHW) 2000a. *BreastScreen Australia Achievement Report 1997–1998*. AIHW Cat. No. CAN 8. Canberra: Australian Institute of Health and Welfare (Cancer Series number 13).