MINISTRY OF HEALTH
MANATŪ HAUORA
newzealand.govt.nz

BreastScreen Aotearoa National Policy and Quality Standards

2013

Revised November 2022

National Screening Unit,
Ministry of Health

National Screening Unit

Revision history

Version	Description of changes
June 2016	Review of document and corrections made New element (8.18.12) added
December 2016	Review of document and corrections made
September 2020	Review of document and corrections made
November 2022	Review of document and corrections made. Refer to supplementary document for the full list of changes.

Citation: Ministry of Health. 2013. *BreastScreen Aotearoa National Policy and Quality Standards*. Wellington: Ministry of Health.

Published in December 2013 *(revised November 2022)*
by the
Ministry of Health
PO Box 5013, Wellington 6145, New Zealand

ISBN 978-0-478-41584-1 (online)
HP 5784

This document is available at www.nsu.govt.nz

National ID: 18571

Acknowledgements

The Ministry of Health would like to acknowledge the individuals and groups who have contributed to the development of the BreastScreen Aotearoa National Policy and Quality Standards in their current and previous versions.

We are grateful to the BreastScreen Aotearoa Advisory Group, unidisciplinary group members and their staff, service providers and consumers for their generous and thoughtful involvement in the review process.

In addition, we acknowledge the importance of BreastScreen Australia in allowing the use of their National Accreditation Standards to inform the structure and format of this document.

Abbreviations used in the Standards

ACPSEM	Australasian College of Physical Scientists and Engineers in Medicine
ACR	American College of Radiology
AEC	Automatic exposure control
BSA	BreastScreen Aotearoa
BreastSurgANZ	Breast Surgeons of Australia and New Zealand
CAD	Computer aided detection
CNR	Contrast to noise ratio
CPD	Continuing professional development
DCIS	Ductal carcinoma in situ
DDP	Default display protocol
DICOM	Digital Imaging and Communications in Medicine
DR	Digital radiography
FFDM	Full field digital mammography
FTE	Full-time equivalents
GP	General practitioner
GP/PCP	General practitioner / primary care provider
IANZ	International Accreditation New Zealand
IPA	Independent Practitioner Association
MQA	Mammographic quality assurance
MIT	Medical imaging technologist
NHI	National Health Index
NHSBSP	National Health Service Breast Screening Programme
NPQS	National Policy and Quality Standards
NZIMRT	New Zealand Institute of Medical Radiation Technology
PACS	Picture archiving and communication system
PCP	Primary care provider
QHP	Qualified Health Physicist
RACS	Royal Australasian College of Surgeons
RANZCR	Royal Australian and New Zealand College of Radiologists
RHA	Regional health authority
RIS	Radiology Information System
RN	Registered nurse
ROI	Region of interest
SDNR	Signal difference to noise ratio
SNR	Signal to noise ratio
UDG	Unidisciplinary group
VAB	Vacuum-assisted biopsy
VAE	Vacuum-assisted excision

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Introduction

The development of breast screening in New Zealand

Breast cancer

Breast cancer is an important health concern in New Zealand, where it is the leading cause of non-tobacco-attributable cancer deaths for women. Approximately 2800 women are diagnosed with breast cancer in New Zealand every year.

Breast cancer screening initially inflates this incidence by diagnosing cancers that would otherwise have been detected in later years. After an initial increase with the implementation of BreastScreen Aotearoa (BSA) to 97.2 breast cancers per 100,000 women in 2000, age-standardised registration rates declined to 88.5 per 100,000 women in 2004. There was also an increase in the rate of breast cancer registrations following the age extension in 2004, for the same reason.

Survival for women diagnosed with breast cancer increased between 1998/99 and 2008/09. The increased survival was seen for both Māori and non-Māori women, although Māori women have a significantly lower survival rate than non-Māori women.

Any reduction in breast cancer mortality attributable to BSA would not be expected to be detected for a minimum of 10 years from the start of the national programme. In December 2015 the National Screening Unit published the Cohort and Case Control Analyses of Breast Cancer Mortality: BreastScreen Aotearoa 1999-2011. The study was commissioned by the National Screening Unit and carried out by researchers from the University of New South Wales. The study found that:

- for women ever screened by BSA, the death rate from breast cancer is reduced by a third, compared to women never screened by the programme
- for women who take part in regular BSA screening, there is an even greater reduction in the rate of breast cancer deaths
- for women with a BSA screen-detected cancer, outcomes are more favourable, as the cancer is found earlier.

Although Māori women had low average participation in screening through the study, it was clear that they would benefit from a similar reduction in the death rate as other New Zealand women if participation can be increased.

Early detection of breast cancer

Mammographic screening is able to identify cancers at an early stage, thereby improving the probability of a positive outcome. This is because survival after diagnosis and treatment is directly related to the stage at which the cancer is diagnosed. In addition, early-stage small tumours are more amenable to treatment with breast conserving surgery (that is, complete local excision), which is known to have some important psychological and practical advantages over mastectomy.

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Mammographic screening as a cancer control strategy has been introduced in a number of countries, including New Zealand. International evidence has shown that breast screening delivered through a properly organised programme reduces mortality from breast cancer in women screened aged 50–69 years by 30 percent.

An organised approach to screening

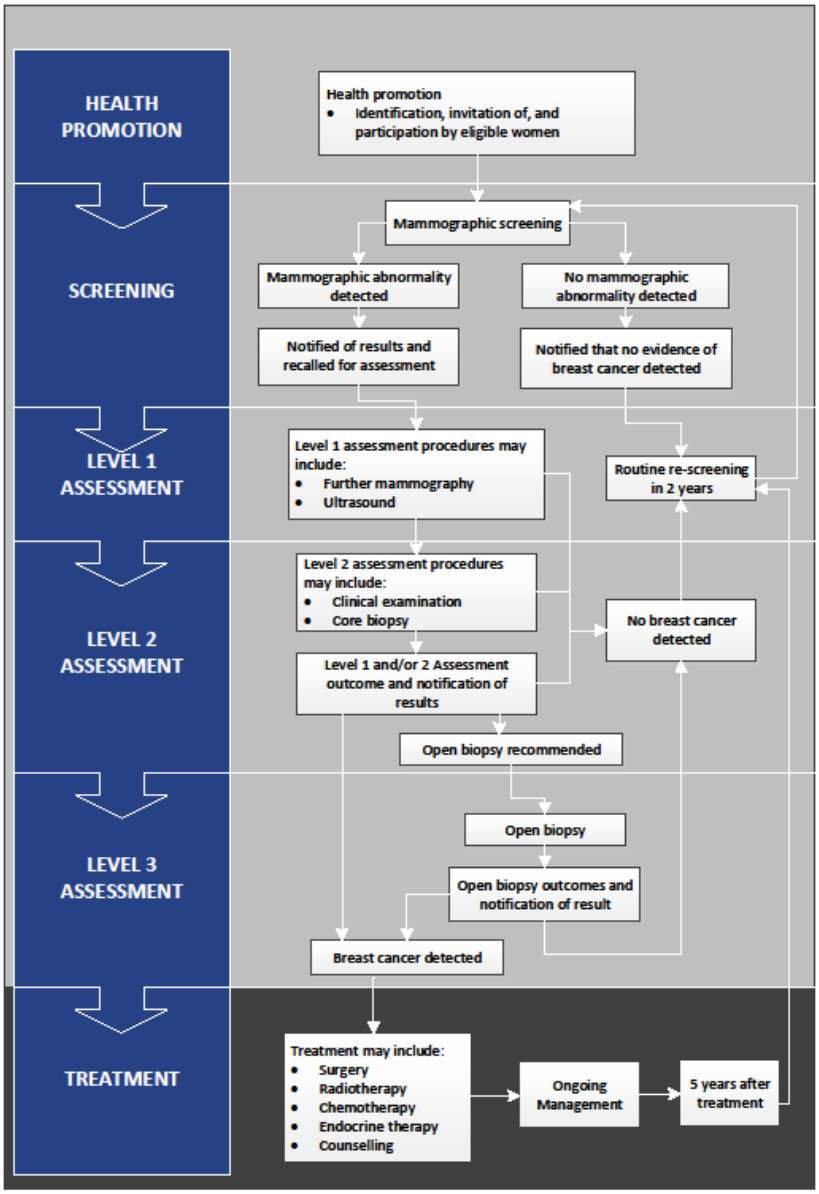
Organised breast screening programmes aim to reduce breast cancer mortality by routinely screening an entire defined population at regular intervals (ie, women with no symptoms of breast cancer). A reduction in mortality at a population level depends on high levels of coverage of the population, along with high quality screening and follow-up services.

For screening to be effective in meeting its aim of reducing mortality, it is important that a programme is well organised and focused. For this reason, an organised approach to screening on a national basis is more successful at reducing the incidence and mortality from breast cancer than *ad hoc* screening.

The key difference between an *ad hoc* screening approach and an organised population-based screening approach is that *ad hoc* screening does not always include the following essential components of an effective screening programme:

- a central agency to lead and coordinate the screening pathway
- clinical leadership
- infrastructure and systems to manage a screening programme
- quality management
- monitoring and evaluation.

The screening pathway is depicted below



The development of organised breast screening in New Zealand is summarised below.

History of BreastScreen Aotearoa

During the 1980s a number of countries implemented local, regional and national population-based breast screening programmes. In 1987, on the basis of early international evidence, the Cancer Society of New Zealand and the then Department of Health invited a working group to make recommendations on breast screening by mammography. The resulting report, now known as the Skegg Report, concluded that New Zealand had a shortage of professionals skilled in the specialised techniques required for the screening of asymptomatic women. It recommended that decisions about routine screening be delayed until pilot programmes were established and an assessment made of their effectiveness, economic efficiency and social acceptability.

The pilot programmes

As a result of the Skegg Report, the Government agreed to fund two pilot mammography screening programmes (in Waikato and Otago/Southland). These were established and began screening in 1991. Initially the pilots were set up to complete one-and-a-half rounds of screening by June 1994. In December 1993 the Minister of Health approved the extension of the pilots to December 1996 to allow for the completion of two full rounds of screening.

During 1995 the Government was faced with two options for the future direction of breast screening services:

- develop and implement an organised population-based breast screening programme
- coordinate an organised approach to the existing *ad hoc* opportunistic screening approach.

The two pilot programmes were based on an organised population-based screening model. They actively identified, invited and recalled eligible women in the community, provided a screening service at both mobile and fixed units, ensured follow-up assessment services, and informed the community about breast screening. Dedicated information systems enabled organised monitoring and auditing of the pilots, and the entire process provided an opportunity to establish close links with treatment services.

Outside the two pilot programme areas an *ad hoc* approach was taken to breast screening. Women who were aware of the importance of mammography screening, and those who could afford it, sought out those services if they were available in their region. While some private providers actively promoted their services, there was generally no systematic identification and invitation of women for screening outside of the pilot programmes.

A nationwide programme

In June 1995 the Minister of Health announced that the Government would be introducing a 'nationwide' breast cancer screening programme (note the term 'nationwide' rather than 'national') for women aged 50–64 years. The reasons given for this decision were as follows.

- Breast cancer was a significant health issue in New Zealand.
- There was clear evidence of the efficacy of mammographic screening in reducing mortality from breast cancer among women aged 50–64 years.
- Studies confirmed that breast cancer screening was better value for money than other available health interventions.
- The early results from the pilot programmes demonstrated that mammographic screening (as delivered in those pilot programmes) could be done effectively and efficiently in New Zealand.
- The health sector had the capacity to accommodate a screening programme for women aged 50–64 years.

Following this announcement, the Minister of Health appointed a Breast Cancer Screening Policy Advisory Group in July 1995 to provide policy advice on the establishment of a population-based screening programme in New Zealand. Key recommendations of the group were that:

- the programme should be an organised, population-based screening programme as part of a strategic approach to breast cancer detection and management
- there should be central planning, coordination, monitoring and evaluation of the programme
- the service specifications should be based on those of the pilot programmes, but modified according to the lessons learned

- national quality standards should be developed
- all women aged 50–70 years without symptoms should be eligible
- there should be no charge to women for access to the programme.

Further planning and policy development were required before any implementation of a national breast screening programme could occur. Between 1996 and 1998 work was undertaken on the development of national targets and indicators, a national monitoring and evaluation system, and an information system to support the programme.

The major changes made to health service delivery policy in 1991 affected the development of breast screening services from the pilot programmes into the national breast screening programme when it was extended nationwide. Delivery of the BSA services across New Zealand through six Lead Provider organisations was chosen as the method of administering the programme. This resulted in a partially centralised programme, with national policy but regional administration through contracts with the six Lead Provider organisations.

The Breast Cancer Screening Policy Advisory Group had originally recommended two-yearly and two-view mammography for asymptomatic women aged 50–69 years, but the Government of the day decided to limit the programme to women aged 50–64 years and to review the age range at a later date.

This decision was in response to concerns that the then health service may not have had sufficient trained staff (ie, medical imaging technologists and radiologists) to operate a breast screening programme. There were also concerns that the programme may have had major flow-on effects for breast surgery and radiation oncology departments. However, the Minister of Health reiterated that the Government would seek further advice from a Ministry of Health advisory group on whether the programme should be extended to older and/or younger women.

In 1997 the former regional health authorities (RHAs) entered into a tendering process with interested parties in order to identify and select appropriate providers from which to purchase breast screening services. A decision was made whereby the RHAs would enter into an agreement with a defined provider to cover the bulk of breast screening services within a geographic region. Providers were required to meet the *Interim National Quality Standards* in determining the configuration and delivery of their services within that region. In 1998 contracts were entered into with six main Lead Providers. This number increased to eight in 2006 with the reconfiguration of the Auckland and Northland region.

Following the restructuring of the New Zealand health services, the former Health Funding Authority established independent service providers (ISPs), which were contracted during 1997 and 1998 to provide health promotion and support services for Māori and Pacific Island women. The *Interim National Operations Manual* was completed in 1998 and implemented to complement the *Interim National Quality Standards* in delivering breast screening services. BreastScreen Aotearoa was launched nationally in December 1998, with services offered in each of the regions from that time.

Age extension

On 23 February 2004 the Government announced that from 1 July 2004 the breast screening programme would be extended to include women aged 45–49 years, and women aged 65 years and over until their 70th birthday. This meant that BSA breast screening services became available to an additional 216,000 women, in addition to the more than 328,000 women aged 50–64 who were already covered by the programme before July 2004.

Digital mammography

In 2007 the National Screening Unit endorsed the use of digital mammography for women enrolled in BSA. This was based on strong evidence that digital mammography achieves a diagnostic accuracy in screening that is equivalent to traditional film screen mammography. The decision had benefits for medical imaging technologists (MITs) using the new systems and enabled the use of teleradiography to read images across different locations. At the time, digital mammography was used in the National Health Service Breast Screening Programme (NHSBSP) and in some European breast screening programmes, and it has subsequently become the international standard. Since 2007 Lead Providers across New Zealand gradually adopted digital mammography and the programme was fully digital by the end of 2013.

Breast screening in New Zealand today

National policy

The aim of screening is to reduce morbidity or mortality from a specific health condition. It reduces the risk of the development of, or dying from, a disease, but it is not a guarantee of prevention, or diagnosis and cure. Screening has its benefits, costs and potential harm, and so there is an ethical obligation to minimise harm and maximise benefits at a reasonable cost.

The National Screening Unit has adopted a definition of 'screening' based on that of the National Screening Committee of the United Kingdom and adapted by the New Zealand National Health Committee:

> Screening is a health service in which members of a defined population, who either do not necessarily perceive they are at risk of, or are already affected by a disease or its complications, are asked a question or offered a test, to identify those individuals who are more likely to be helped than harmed by further tests or treatment to reduce the risk of a disease or its complications.[1]

In order for a screening programme to be successful, a coordinated approach is required. The essentials of such an approach include clear lines of accountability, high quality service provision, effective monitoring of defined policy and quality standards, the timely availability and appropriate integration of screening services with diagnostic and treatment services, and high levels of programme enrolment and participation. It is also important to identify priority groups who are most likely to benefit from screening and to ensure the programme is accessible to these groups.

Three principal factors in influencing how much benefit can be obtained in any population are the proportion of the eligible women who are screened, the sensitivity of the screening test (mammography) in detecting invasive cancers at an early stage, and the adequacy of treatment provided for the screen-detected cancers.

Eligibility

Currently, BreastScreen Aotearoa offers free mammography every two years to women who:

- are aged 45–69 years
- have not had mammography within the previous 12 months
- are not pregnant or breastfeeding – breastfeeding women who meet the other criteria are able to have a mammogram within BSA no sooner than three months after lactation has ceased

[1] 2003.

- are free from breast cancer – women previously diagnosed with breast cancer are eligible for screening at least five years after diagnosis
- are asymptomatic
- are eligible for public health services in New Zealand.

(Refer to www.health.govt.nz/new-zealand-health-system/eligibility-publicly-funded-health-services. for further information.)

Eligibility for treatment

Regardless of an individual's participation in BSA, free treatment services for individuals diagnosed with cancer are only available to those who are eligible for publicly funded health services in New Zealand. A number of private services also provide treatment, but there is a cost to the woman or her insurance company.

Scope

BSA provides a national screening programme, which includes:

- promotion of screening
- education about breast cancer, screening and treatment
- identification and invitation of women eligible for screening
- invitation and recall of women eligible for screening at two-yearly intervals
- screening mammography for eligible women
- multidisciplinary assessment for screened women, including clinical examination, ultrasound, percutaneous needle biopsy, open surgical excision biopsy, vacuum-assisted excision, and pathology services
- communication of the screening results to women and their primary health care provider
- support and counselling for women undergoing assessment procedures
- referral to treatment for those women identified with breast cancer
- an information system to support the screening programme
- quality assurance, audit, monitoring and evaluation.

Configuration

The National Screening Unit sits within the National Health Board, National Services Purchasing group of the Ministry of Health and is responsible for:

- national management and oversight of BSA
- funding of BSA providers
- national coordination of providers
- national recruitment and retention activities (including the development of standardised resources and national promotions)
- national strategy and policy development
- national monitoring, evaluation and audit.

BreastScreen Aotearoa providers

BSA is delivered to women on both a national and a regional basis. For the purposes of this document, a provider is defined as any Lead, subcontracted or Screening Support Service Provider that delivers services on behalf of BSA.

Each Lead Provider is responsible for providing, either directly or by subcontracting another provider, all services (except those provided by Screening Support Service Providers) throughout their region. This includes:

- recruitment and retention
- invitation
- screening
- assessment
- referral to treatment
- quality assurance.

Screening is provided at both fixed and mobile sites throughout each Lead Provider's region, while assessment is usually provided at centralised locations. The Lead Provider and Screening Support Service Provider remain responsible for ensuring that all services within their area, either provided directly or through a subcontract with another provider, are delivered according to the National Policy and Quality Standards contractually required of them.

Screening Support Service Providers are contracted by the National Screening Unit to provide support services directly to specific groups of women who might otherwise not be reached by Lead Providers (ie, Māori/iwi and Pacific women). Each Screening Support Service Provider is responsible for providing services throughout their region. Screening Support Service Providers and Lead Providers work in partnership with each other while being accountable to the National Screening Unit.

Incorporating the Treaty of Waitangi

The BreastScreen Aotearoa National Policy and Quality Standards (BSA NPQS) acknowledge the Treaty of Waitangi as the founding document of New Zealand, and both recognise and respect the principles of the Treaty. BSA is committed to working with Māori in good faith, with mutual respect, cooperation and trust.

This commitment is reflected in the Government's strategic objectives for Māori health, which focus on:

- building the capacity for Māori participation at all levels of the health and disability sector
- enabling Māori communities to identify and provide for their own health needs
- recognising the importance of relationships between Māori and the Crown in health services, both mainstream and those provided by Māori
- ensuring accessible and appropriate services for Māori
- fostering Māori health workforce development.

Reducing inequalities for all New Zealanders, including Māori and Pacific peoples

The Ministry of Health paper *Reducing Inequalities in Health* articulates the Crown's broader responsibilities to all New Zealanders under the Treaty of Waitangi. Furthermore, Durie has

said that the Treaty speaks about citizenship for non-Māori as well as Māori,[2] which infers ensuing Crown obligations towards the non-Māori population.

The main non-Māori ethnic groups in New Zealand are:

- NZ European
- Pacific peoples
- Asian peoples.

The NSU is committed to reducing inequalities and effecting improvements across all population groups that participate in screening programmes, particularly Māori and Pacific peoples.

BreastScreen Aotearoa priority groups for screening

The National Screening Unit will ensure that strategies are developed that ensure priority is given to groups of women known to be at increased risk of developing breast cancer and/or who are likely to be under-screened. Groups identified as a priority for invitation, screening, rescreening and treatment within BSA are:

- Māori women
- Pacific women
- unscreened women (women who have either never been screened or have not been screened for five years)
- under-screened women (groups of women whose participation is well below those of the total eligible population).

Health and Disability Commissioner's Code of Consumers' Rights

Compliance with the NPQS will help services to meet their obligations under the Code of Health and Disability Services Consumers' Rights 1996 (the Code), a regulation under the Health and Disability Commissioner Act 1994. The NPQS should be interpreted in a manner that is consistent with consumers' rights and providers' obligations under the Code. Every individual or organisation subject to the NPQS should be knowledgeable about the Code and comply with its obligations.

Ethical issues

Screening can be an effective way of identifying early signs of disease so that progression can be halted, and treatment provided. However, screening does have limitations and uncertainties and no screening test can be 100 percent accurate. Furthermore, healthy and asymptomatic people could be subjected to unnecessary interventions and distress as a result of the screening process.

It is also important that personnel involved with a screening programme understand the difference, from an ethical perspective, between providing services to an individual seeking medical help or treatment and actively inviting and encouraging people to participate in screening procedures.

Some consequences of screening can have a major impact on people's lives, and the failure to clearly explain the limitations of screening can result in a lack of confidence in the entire

[2] Durie 1998.

programme. It is also important to provide an accurate assessment of the risks of the disease being screened for so that individuals do not overestimate their personal risk of the disease.

It is therefore very important to ensure that women considering participation in the breast screening programme are provided with full, fair and balanced information in order to make a fully informed choice based on understanding the screening process inclusive of the benefits and harms (refer to Criterion 2.1 and 2.2).

The National Policy and Quality Standards

The NPQS apply to all providers (Lead Providers, their subcontractors and Screening Support Service Providers) who provide services to BSA. Providers are contractually obliged to meet the NPQS, which also provide the basis for the National Screening Unit's ongoing programme monitoring and provider compliance audit.

This version of the NPQS replaces the 2008 version and the *Interim Digital Mammography Standards for Full Field Digital Mammography and CR Systems* (2013), which had previously determined the operational and quality standards and level of service required for the national programme.

As well as meeting the NPQS, it is expected that each provider will meet its legal obligations, including recognition of and adherence to health legislation and any legislation related to the privacy of health information; in particular, the:

- Health Act 1956
- Medicines Act 1981
- Cancer Registry Act 1993
- Privacy Act 2020
- Health Information Privacy Code 2020
- Health and Disability Commissioner Act 1994
- New Zealand Public Health and Disability Act 2000.

Background to the standards

Standards New Zealand, on behalf of the Ministry of Health, facilitated the initial development of the NPQS. They were developed in line with internationally recognised processes, while working with representatives from the health sector and key stakeholders, and were published in 2004. They replaced the *Interim BSA National Quality Standards* (1996) and the *Interim BSA National Operations Manual* (1998).

Subsequently, a decision was made to move this process in-house to the Ministry of Health with the inception of the National Screening Unit and the establishment of a dedicated BSA team. A revised NPQS was published in 2008, following a collaborative process between the National Screening Unit, BSA Lead Providers, ISPs, key stakeholders and consumers.

The 2008 version of the NPQS also contained an addendum with the *Interim Digital Mammography Standards for Full Field Digital Mammography and CR Systems*. The addendum was regularly updated as technical requirements advanced; the fourth revision was published early in 2013.

During the review that led to the current version of the NPQS, BSA considered a number of options that would meet the current and future needs of the maturing screening programme. In consultation with stakeholders, the structure and format of the Australian *National Accreditation Standards* was adopted in order to achieve a clear, streamlined and quality improvement-focused document. The *National Accreditation Standards* were comprehensively reviewed in 2012 and provided a foundation aligned with international best practice.

In consultation with providers and consumers, the review process identified areas that needed to be updated to reflect changes in best practice or technology, along with incorporating the *Interim Digital Mammography Standards* addendum into the body of the standards. A crucial part of the review was ensuring that the strength of previous NPQS – the focus on well women in the New Zealand context – was retained.

Document maintenance of National Policy and Quality Standards

The NPQS are published online and are available from the National Screening Unit's website (www.nsu.govt.nz) and the Ministry of Health's website (www.health.govt.nz). It is intended that the NPQS remains a dynamic document reflecting the challenges and changes within the screening sector. In order to achieve this, regular updates of the NPQS are required to ensure the standards remain both appropriate and applicable.

The process for maintaining this document involves reviewing particular elements based on evidence-informed findings and in accordance with international practice. Once the updates are posted on the website, providers and other relevant stakeholders listed on the database held by the National Screening Unit will be notified by email.

Monitoring and audit of the National Policy and Quality Standards

BSA providers are monitored against a number of key national evaluation targets on a regular basis. It is expected that each BSA provider will have systems in place, including internal audit processes, that ensure their ongoing adherence to the NPQS. Ultimate responsibility for this process occurring rests with the contracted Lead Provider or Screening Support Service Provider. There is an expectation that where shortcomings are identified as a result of internal auditing, steps will be taken (and documented) to meet the required standard and relevant elements.

In addition, an audit framework provides the basis for external provider audits. The external audit process enables a verification of adherence to each of the standards.

The quality framework

Providers are also expected to align quality processes with the screening programme's quality framework. The quality framework is the National Screening Unit's response to the *New Zealand Health and Disability System Quality Improvement Strategy for Screening Programmes in New Zealand*. It articulates high-level quality expectations and sets the strategic foundation for New Zealand's screening programmes.

Underlying the quality framework are eight principles:

- the principles of the Treaty of Waitangi: partnership, protection and participation
- people centred

- continuous improvement
- building on the knowledge base
- accountability for and clarity of roles and processes
- bridging the expectation gap
- coherence throughout the programme
- partnership with programme staff and participants.

The quality framework helps support the National Screening Unit's strategic vision of 'high quality, equitable and accessible national screening programmes. It applies to BSA as well as the other national screening programmes coordinated by the National Screening Unit: the National Cervical Screening Programme, Antenatal HIV Screening, Antenatal screening for Down syndrome and other conditions, the Newborn Metabolic Screening Programme, and the Universal Newborn Hearing Screening Programme. The framework is also generally applicable to other organised and opportunistic screening in New Zealand.

Explanation of the NPQS structure and terminology

Standard

The standard is the goal relating to specific components of the programme that need to be achieved to reach the overall objectives for the BSA programme. For example:

- The programme is well women centred and all women are appropriately informed and supported.

The standard is achieved when all criteria and elements associated with it are met. There are eight standards in the NPQS.

Criterion

The criteria are the key components that make up each standard. For example:

- The provider provides evidence based and consistent information and resources to women
- Screening, assessment and referral for treatment are continuous and women are kept informed throughout the pathway.

Element

The individual components of a criterion are called elements, which describe the specific requirements for the Lead Provider, subcontracted providers and Screening Support Service Providers to meet. For example:

- Women will be advised of waiting times when attending appointments
- Protocols that outline communication and presentation expectations of staff who have personal contact with each woman, her family/whānau and other members of the public are followed.

Appendices

The referenced appendices included in the document are considered part of the NPQS.

Standard 1: Access and participation

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

Criterion 1.1: The provider maximises the participation of women in the target age groups for screening and rescreening

Elements

1.1.1 ≥70% of women aged 45–69 years participate in screening in the most recent 24-month period.

1.1.2 ≥75% of women aged 45–67 years who attend for their first screen within the programme are rescreened within 20 to 27 months.

1.1.3 Of women aged 45–67 years participating in their subsequent rescreens within the programme, ≥85% are rescreened within 20 to 27 months of their previous screening episode.

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Criterion 1.2: BreastScreen Aotearoa services are accessible to the eligible population, including women from culturally and linguistically diverse backgrounds and women with a disability, and especially tangata whenua

Elements

1.2.1 The provider monitors and reports on the coverage of women 45–69 years of age from priority groups, and where rates are below 70% implements specific, evidence-informed strategies to encourage their participation in screening. Consideration of equitable coverage among at least the following priority groups will be made:

- Māori women
- Pacific women
- unscreened women (women who have either never been screened or have not been screened for five years)
- under-screened women (groups of women whose participation is well below those of the total eligible population).

1.2.2 Women are eligible to participate in BSA who:

- are aged 45–69 years
- are asymptomatic
- have not had a mammogram in the last 12 months
- are not pregnant or breastfeeding – breastfeeding women who meet the other criteria are able to have a mammogram within BSA no sooner than three months after lactation has ceased
- are eligible for public health services in New Zealand[3]
- are more than five years since diagnosis if they have a history of previous breast cancer.

1.2.3 Barriers experienced or reported by women are acted on and subsequently taken into consideration for future planning (refer to Appendix 1: Known Barriers to Screening).

1.2.4 Mammograms are provided at fixed or mobile sites to ensure:

- 90% of eligible women will be within 60 minutes' travelling time of a screening unit (mobile or fixed)
- 95% of eligible women will be within 90 minutes' travelling time of a screening unit (mobile or fixed)
- 99% of eligible women will be within 120 minutes' travelling time of a screening unit (mobile or fixed).

[3] www.health.govt.nz/new-zealand-health-system/eligibility-publicly-funded-health-services/guide-eligibility-publicly-funded-health-services-0

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Criterion 1.3: The provider ensures that their services are responsive to the needs of Māori women and their whānau

Elements

1.3.1 The provider ensures that all staff recognise and understand the principles and articles of the Treaty of Waitangi, and that these are reflected every day in their practice.

The principles of the Treaty of Waitangi are as follows.

- Partnership: Māori and the Crown will have a relationship of good faith, mutual respect and understanding and shared decision-making.
- Participation: The Crown and Māori will work together to ensure Māori (including whānau, hapū, iwi and communities) participate at all levels of decision-making around health and disability issues. Participation includes the right to self-determination and self-management.
- Protection: The Crown actively contributes to improving the wellbeing of Māori, including support for independent living and the protection of Māori property and identity, in accordance with Māori values. Māori have the same rights and privileges as other citizens.

1.3.2 The provider:

- recognises and respects the unique identity of Māori as tangata whenua in the planning and provision of services
- assists each Māori woman to access relevant services, support and resources such as 'for Māori, by Māori' services, where these exist
- consults iwi and Māori in order to meet the needs of Māori women during service provision
- partners with iwi and Māori to establish appropriate monitoring and evaluation processes.

1.3.3 The provider ensures that all staff understand the holistic framework of Te Whare Tapa Whā as being central to the wellbeing of Māori. The four dimensions of Te Whare Tapa Whā are:

- te taha hinengaro – mental wellbeing
- te taha tinana – physical wellbeing
- te taha wairua – spiritual wellbeing
- te taha whānau – family wellbeing.

Te Whare Tapa Whā is a well-recognised and endorsed health concept for Māori (Durie 1998). It is a holistic approach in which health and wellbeing are described in relation to the four walls of a house. A person is considered unwell if any one of these supports is weak, and healthy if all four walls are strong. If the strength of the whānau, for example, is disrupted by insensitive practices, this affects all of the supports.

Criterion 1.4: The provider ensures that the cultural needs of each woman and her family and whānau are recognised

Elements

1.4.1 For all women, and with particular consideration of Māori and Pacific women, the provider ensures that all staff:

- recognise the impact that diversity of cultural practices and beliefs may have on the breast screening process
- practise in a manner that respects the identity of each woman and her family and whānau who accompany her, and that upholds their right to personal beliefs and values
- assist each woman to gain appropriate support and representation from those who understand her culture, needs and preferences
- recognise their own beliefs, values and prejudice that may arise in relation to each woman's ethnicity, culture, beliefs, sexual orientation, health status and/or disability
- provide alternative arrangements when cultural appropriateness is undermined
- validate that their own practice is culturally appropriate, particularly when providing direction or supervision to other staff.

1.4.2 The provider seeks feedback and relevant cultural advice or guidance to ensure both the practice and maintenance of cultural appropriateness.

1.4.3 The provider respects the views and expectations of Māori and Pacific women in relation to the collection and use of breast screening information.

Criterion 1.5: The provider establishes relationships with local general practices and primary care providers

Elements

1.5.1 The provider supports the process of matching general practitioner (GP) registers with lists of BSA-screened women. This must be carried out with adherence to confidentiality principles.

1.5.2 Where a woman has given consent, the provider informs her GP or primary care provider (PCP) of the outcomes of screening and assessment within the specified timeframes (refer to Appendix 2: Communication Matrix, and Appendix 3: Proforma Letters and Forms).

1.5.3 The provider supports GPs/PCPs in their role in the programme, particularly in terms of:

- outlining the benefits and limitations of screening mammography to eligible women
- identification and invitation of eligible women (with GP/PCP support of the invitation)
- result reporting
- confirming a woman's eligibility and contact details, as required
- encouraging women to attend further rounds of screening
- providing information and support for women.

1.5.4 The provider ensures:

- GPs/PCPs are informed about the programme, and their active support is encouraged and maintained
- GPs/PCPs are provided with the opportunity for upskilling in relation to BSA so that they may actively promote the programme
- the distribution of appropriate promotional and educational resources to relevant providers and practitioners
- there are effective working relationships and support for iwi/Māori and Pacific PCPs to achieve equitable coverage
- information seminars for GPs/PCPs include information on how best and most appropriately to inform, support and recruit Māori women, Pacific women and other ethnic groups
- sufficient information is available for GPs/PCPs, featuring information on how best and most appropriately to inform, support and recruit women with disabilities
- information is provided about inappropriate referrals and the differences between screening and diagnostic mammography
- GPs/PCPs receive feedback about the number of women from their practice participating in the programme (eg, regular reports of women screened, outcomes)

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1.5.5 An identified provider staff member has designated responsibility for maintaining regular contact (at least annually) and liaison with GPs/PCPs and provider groups in their region (this may be through face-to-face contact, newsletters, etc)

1.5.6 Women presenting without a current GP/PCP (or not wishing to nominate a GP/PCP) are encouraged to nominate one, and if required, are offered contact details of the local primary health organisation(s).

Criterion 1.6: There is regional collaboration to promote informed participation in BreastScreen Aotearoa

Elements

1.6.1 The provider ensures that strategies:

- are evidence-based, and follow best-practice standards and ethical requirements
- focus on priority women
- align with models of health relating to Māori and Pacific health
- are developed and implemented to include family and whānau, from a community development approach
- consider the whole screening pathway
- recognise the diversity of cultural practices
- are respectful of a woman's choice to make an informed decision not to participate in the programme.

1.6.2 The provider ensures:

- the use of appropriate public forums to provide accurate information about screening
- liaison and collaboration with key organisations, stakeholders, community representatives and others to support them in encouraging eligible women and families and whānau to facilitate the community ownership of BSA
- the identification of appropriate key organisations, groups and communities to assist in promoting key messages to women is undertaken using a community development approach
- the distribution of BSA health education resources[4] to women at BSA sites and other community facilities.

4 For a list of available BSA resources, see www.nsu.govt.nz/health-professionals/1839.aspx

Criterion 1.7: Lead Providers and Screening Support Service Providers work together in partnership to deliver BreastScreen Aotearoa services

Elements

1.7.1 BSA Lead Provider Managers and Screening Support Service Providers must:

- meet to discuss relevant issues at least six-monthly
- undertake joint planning sessions annually, with a particular focus on mobile scheduling, recruitment and retention issues and programme performance data.

1.7.2 Screening Support Service Providers should be actively involved with Lead Provider services to contribute to the success of the programme and maintain the confidence of women, including:

- providing support to services for women identified by the Screening Support Service Provider as requiring support, or as requested by the Lead Provider
- engaging with and supporting women who have not attended appointments or have not responded to invitation, as requested by the Lead Provider.

Criterion 1.8: The provider has protocols and procedures to manage appointment-making and recall

Elements

1.8.1 The appointment-making process is initiated after the woman has been identified through the mechanisms outlined in the regional coordination plan and the provider has recorded the woman's interest in the programme.

1.8.2 Providers ensure the appointment-making process includes:

- obtaining information to register the woman within the programme, including any special needs
- informing the woman of the name of the provider, where the service is provided, and any relevant information she requires before attending for a screening mammogram
- making an appointment (or confirming an appointment) and providing information about how to change her appointment time, if required
- providing consent and notification forms, as applicable
- providing the national information brochure about the programme (HE10102).

1.8.3 For women transferring between Lead Providers, the provider ensures:

- current *Data Management Manual* requirements are met
- there is direct contact between Clinical Directors for women transferring during the assessment phase of a screening episode
- women who are within five years of a BSA breast cancer diagnosis are not transferred until they return to the programme.

1.8.4 The provider ensures each woman is no longer recalled for routine rescreening or assessment, when she:

- has a positive diagnosis of breast cancer and is referred for treatment
- actively requests not to be recalled by BSA
- falls outside the eligible age range
- is deceased
- fails or refuses to attend or complete an assessment
- repeatedly (at least three times) does not attend confirmed screening appointments, if in the opinion of the Lead Provider further attempts to schedule an appointment would be futile
- cannot be contacted by the provider after all reasonable efforts have been made using the range of means available to that Lead Provider.

The provider must ensure that, where possible, women are informed of the implications of no longer being recalled for routine rescreening or assessment.

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Standard 2: Client focus

The programme is well-women centred and all women are appropriately informed and supported.

Criterion 2.1: The provider provides women with information and resources that are evidence-based and consistent

Elements

2.1.1 Written information that has been approved by the National Screening Unit and is consistent with national policies and key messages (refer to Appendix 2: Key Messages for BreastScreen Aotearoa) is available to all women in a format best suited to the needs of the woman and her family and whānau, throughout the screening and assessment pathway, and includes:

- the purpose of screening
- rescreening
- the likelihood of recall for assessment
- the risks of false positive results, false negative results or over-diagnosis
- the investigations that may be required
- the benefits, limitations and risks of the investigations
- the possible outcomes of assessment.

2.1.2 Providers ensure that:

- regional/local radio and print media strategies complement any national media activities
- while there may be some paid advertising, regionally the emphasis will be on unpaid coverage, including interviews and media releases
- priority is given to effective media coverage for women from BSA priority groups
- BSA media issues are discussed with the National Screening Unit to ensure effective management
- any communication with the media initiated by providers about the programme (eg, a media release) requires prior written approval by the National Screening Unit, who will review it within 48 hours where possible
- where agreed, routine or repeated operational notices may be placed without additional approval (eg, the mobile schedule).

2.1.3 The provider is required to ensure all communications issued as a result of activities of BSA (including educational materials, advertising media communications and signage, but excluding letters on BSA letterhead):

- comply with the brand guidelines *(Provider toolkit – a guide to using the BreastScreen Aotearoa resources)* and include the BSA logo – other logos will not be

placed on them except where specific approval has been given by the National Screening Unit

- use the standard design 'shell' when developing print advertisements relating to BSA
- are approved by the National Screening Unit, who will review the material within 10 working days where possible.

Criterion 2.2: The provider ensures client consent throughout the screening pathway

Elements

2.2.1 The provider ensures informed consent is obtained according to the following principles:

- Consent is obtained in compliance with the Code of Health and Disability Services Consumers' Rights – Rights 5, 6 and 7
- Full, fair and balanced information is provided so that a woman is able to make a 'fully' informed choice
- Consent is given voluntarily
- The woman has the capacity to consent
- Women should be aware they have the right to 'informed dissent' and withdrawal of consent at any time.

2.2.2 The provider ensures written consent is obtained from all women for:

- her first screening mammogram
- invasive diagnostic procedures
- her GP/PCP to be notified of her participation in and results for her first screening mammogram
- the provider to request relevant clinical information from other health care providers
- participation in research (if required by an ethics committee and/or the National Screening Unit)
- mammograms for women with breast implants.

Refer to Appendix 3: Proforma Letters and Forms.

2.2.3 The provider ensures verbal consent is obtained and recorded from all women for:

- subsequent screening mammograms
- her GP/PCP to be notified of her participation in and results for her subsequent screening mammograms
- level 1 assessment
- trainees to perform or observe procedures.

2.2.4 The provider notifies all women in writing (called 'use of information notification ') of the purpose, use and recipients of information that is collected about them and any consequences of not supplying such information, in accordance with the Health Information Privacy Code 2020 (refer to Appendix 3: Proforma Letters and Forms).

2.2.5 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 and all women receive a copy of the most recent version of the BSA-approved information pamphlet(s) prior to every screen.

Criterion 2.3: The provider ensures each woman is supported to access and participate in the programme to an extent that can be reasonably expected, whatever her particular culture, needs and preferences

Elements

2.3.1 The provider informs each woman participating in BSA of her right to have one or more support persons present, except where safety may be compromised, in accordance with the Code of Health and Disability Services Consumers' Rights.

2.3.2 The provider ensures staff help any woman who requires assistance to obtain support or advocacy.

2.3.3 Māori and Pacific women are given the option to access Māori and Pacific Screening Support Service Providers, where this service is available.

2.3.4 Providers ensure that during the appointment-making process the woman is asked if she has an impairment, disability or special need/requirement that will need to be accommodated at the time of her screen, so that:

- interpreters and any other additional services required to assist a woman are organised prior to her attending
- disabled women are encouraged to attend a fixed site that is better equipped to provide access and additional time, and can accommodate carers
- women who have breast implants have additional time scheduled.

2.3.5 The breast care nurse liaises with each woman being recalled for assessment and ensures:

- on-site support and assistance with any practical arrangements required is provided for all women recalled for assessment
- follow-up for women who require support – where follow-up availability is limited to telephone links, the breast care nurse must be able to demonstrate knowledge and linkages with local support networks
- all nursing support provided is documented in the woman's records.

2.3.6 The provider ensures a private area is available for discussions with the breast care nurse, and this must include access to a telephone.

Criterion 2.4: Screening, assessment and referral for treatment are continuous, and women are kept informed throughout the pathway

Elements

2.4.1 Women are advised of waiting times when attending appointments.

2.4.2 Protocols that outline the communication and presentation expectations of staff who have personal contact with each woman, her family/whānau and other members of the public are followed.

2.4.3 Each woman receives a full explanation of the procedure before commencement of the screening mammogram, including the need for adequate compression and the advantages in terms of enhancing image quality and reducing radiation dose.

2.4.4 Each woman has the method and timeframe of result notification discussed with her at the completion of the screen.

2.4.5 Providers ensure, at the time of screening, that eligible women are advised that they will be re-invited.

2.4.6 Providers ensure, at the time of screening, that each woman is advised that if they develop breast symptoms prior to their next scheduled screening mammogram they should see their family doctor.

2.4.7 Each woman recalled to assessment is notified of the need to attend the assessment clinic by the breast care nurse as soon as possible after screening.

2.4.8 For women diagnosed with cancer, the surgeon or other appropriate doctor must discuss treatment and provider options with the involvement of the breast care nurse. BSA-approved consumer material must be available.

2.4.9 A list of names of local surgeons with expertise in management of breast cancer is available to women.

2.4.10 The service implements a protocol for the referral of all women with a diagnosis of breast cancer for subsequent management. The service ensures that all referrals to treating clinicians include:

- results of tests and a diagnosis
- access to images
- access to pathology reports
- access to multidisciplinary team meeting recommendations or assessment sheet
- a request for appropriate follow-up information.

Criterion 2.5: The personal privacy of each woman receiving services is respected at all times

Elements

2.5.1 The provider has policies and protocols that ensure the protection of personal privacy for each woman participating in the programme.

2.5.2 Providers have protocols for telephone conversations, sending information by text message (SMS) or email, and/or personal contact with women, which take into consideration the principles of respect, sensitivity and cultural appropriateness.

2.5.3 When sending information by text message or email, the provider representative must:

- ensure that information is only sent in relation to non-clinical notifications, which may include appointment reminders, confirmation of appointments, and follow-up of missed appointments or Return to Routine Screening results where consent has been obtained from the women prior.
- not send information relating to results or clinical information

2.5.4 When having a conversation by telephone, information is given only to the woman concerned and the provider representative must:

- identify the woman by full name
- if asked by a third party, advise them that the call is 'personal'
- identify themselves by name, role and workplace
- confirm the woman's date of birth.

Family members may be used as interpreters for non-clinical information for women who do not speak English.

2.5.5 If staff representing BSA leave personal written messages for women with family, they should be left in an envelope marked 'Confidential'.

2.5.6 All women are offered a gown or korowai during screening and assessment.

2.5.7 The provider has a protocol to manage each woman's access to her personal records.

Standard 3: Timeliness

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

Criterion 3.1: The provider ensures women progress through the screening pathway in a timely manner

Elements

3.1.1 Target: ≥90% of eligible women, once enrolled, are offered an available appointment for a screening mammogram within 60 working days (fixed sites only).

3.1.2 Target: >90% of women have a documented notification generated of the results of screening within 10 working days of the screening mammogram where the result is return to screening.

Criterion 3.2: The provider ensures women progress through the assessment pathway in a timely manner

Elements

3.2.1 Target: ≥90% of women are offered an assessment appointment date that is within 15 working days of their final mammogram. For the purposes of data entry in the Radiology Information System (RIS), an offer is a minimum of three telephone calls followed by a letter, where contact is not initially made.

3.2.2 Target: all women who do not require biopsy at assessment receive final results within five working days of their visit.

3.2.3 Target: ≥90% of percutaneous needle biopsies (level 2 assessment) are performed within five working days of the first assessment visit.

3.2.4 Target: ≥90% of women requiring level 3 assessment (that is open surgical excision biopsy or vacuum-assisted excision) will have their operation performed within 20 working days of being notified of the need for this operation.

3.2.5 Target: ≥80% of percutaneous needle biopsy (level 2 assessment) results are reported to the Lead Provider within three working days of the reporting pathology laboratory receiving the specimen.

3.2.6 Target: ≥90% of written histology reports for percutaneous needle biopsy (level 2 assessment) and open surgical excision biopsy or vacuum-assisted excision (level 3 assessment) are received by the Lead Provider within five working days of the pathology laboratory receiving the specimen.

3.2.7 Target: ≥90% of women receive the results within seven working days of their final percutaneous needle biopsy.

3.2.8 Target: where the diagnosis is cancer, ≥90% of women have their initial treatment performed within 31 calendar days of the final decision to treat (treatment is defined as an MDT decision).[5]

5 National Breast Cancer Tumour Standards Working Group (2013).

Standard 4: Cancer detection

Cancer detection is maximised in the target population and harm is minimised.

Criterion 4.1: The provider ensures high quality imaging

Elements

4.1.1 Although the Clinical Director in the screening programme has ultimate responsibility for image quality, it is the role and function of all MITs to produce images of the highest quality for reading. The Clinical Director, or a designated radiologist as directed by the Clinical Director, meets with MITs at least quarterly.

4.1.2 The service monitors and reports the percentage of women who have four or fewer images per screen.

4.1.3 Providers ensure that:

- all screening mammograms have a cranio-caudal and medio-lateral oblique view of each breast
- MITs are permitted to use their professional discretion to decide any additional views required to image the entire breast, with unnecessary exposure to radiation kept to a minimum
- any deviation from the standard protocol is recorded by the MIT performing the screen
- for each screening examination, the total number of images taken is recorded
- for each screening examination, the total number of images rejected is recorded
- the name of the MIT performing the screen is recorded.

4.1.4 The provider ensures that the following nationally consistent protocols are used within the programme:

- breast implants
- mastectomy.

(Refer to Appendix 4: National Screening Protocols.)

4.1.5 The provider has a local protocol for screening women with medical devices (eg, pacemakers).

4.1.6 Providers ensure there is accurate recording of any factors, including techniques, which assist in the production of high-quality images for future screens.

4.1.7 The Lead MIT provides professional leadership to MITs within their region and is responsible for ensuring:

- a high standard of mammographic image quality is achieved by all MITs in the Lead Provider region
- individual MIT performance is monitored, and feedback is provided to each MIT in the team.

4.1.8 For the reading radiologist to evaluate minute structures within the breast, the MIT must image the breast by paying attention to the following areas:

- quality control
- positioning
- exposure factors.

4.1.9 Before images are displayed, it is the responsibility of the MIT to check all images for:

- positioning
- sharpness
- contrast
- correct exposure
- compression
- correct annotation
- woman's details
- absence of artefacts
- completeness of examination according to the MIQ classification, and to document the grading (refer to Appendix 5: Mammographic Image Quality Classification).

4.1.10 Another MIT, other than the one performing the examination, may review the images prior to them being read, and this will usually occur with mammograms performed offsite.

4.1.11 The technical reject rate for the provider is ≤3% of all screening images.

4.1.12 The technical recall rate for the provider is ≤0.5%.

4.1.13 Image identification complies with relevant regulations and with the Royal Australian and New Zealand College of Radiologists (RANZCR) *Standards of Practice for Diagnostic and Interventional Radiology*, including standards relating to storing, retrieving and transmitting images.

4.1.14 The provider has a disaster recovery system that addresses the risk of network failure and also takes into consideration PACS (picture archive and communication system) and image failure.

Criterion 4.2: The provider ensures high quality screen reading so that cancer detection is maximised, and harms are minimised

Elements

4.2.1 Images are read independently by two radiologists, both of whom meet the radiology training requirements as specified in this document.

4.2.2 Providers ensure there is uninterrupted time scheduled for reading screening mammograms.

4.2.3 Providers ensure the system supports independent reading where the second radiologist cannot view or alter the results entered by the first reader.

4.2.4 All primary reading of digitally acquired examinations must be conducted through soft copy reading. The printing of hard-copy films for primary reading is not permitted within the programme.

4.2.5 All image readers must read at least 3000 screening mammograms within the programme per year.

4.2.6 The final outcome of imaging is reported as either:

- return to routine screening (which may also have 'but has symptoms' or 'not complete') or
- 'for assessment' (refer for further mammographic or clinical work-up at an assessment clinic).

4.2.7 A written protocol is followed for resolving cases in which consensus between the blind reads is not reached. This may include interpretation by a third reader or a consensus process. The result of this process will be a final single recommendation: either 'return to routine screening' or 'for assessment' (as above).

Criterion 4.3: Unnecessary investigations and recall for assessment are minimised

Elements

4.3.1 <10% of women aged 45–69 who attend for their first screen are recalled for assessment.

4.3.2 <5% of women aged 45–69 who attend for their second or subsequent screen are recalled for assessment.

4.3.3 The provider monitors the positive predictive value of the screening mammogram for women aged 45–69 for those who attend for their first screen.

4.3.4 The provider monitors the positive predictive value of the screening mammogram for women aged 45–69 for those who attend for their second or subsequent screens.

4.3.5 <2% of women are recommended for extended assessment following their initial assessment.

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Criterion 4.4: The provider has policies and protocols in place that are essential for high quality cancer detection

Elements

4.4.1 For invasive interval cancers identified through Cancer Registry data, the provider implements a protocol for:

- reviewing and investigating all invasive interval cancers within their 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.

4.4.2 The service implements a protocol for the management of women who report symptoms either at booking or at attendance (refer to Appendix 6: Symptomatic Women). Significant symptoms are:

- a new lump or thickening (a lump the woman can feel that has arisen in the last 12 months)
- puckering or dimpling of the skin
- any change in one nipple such as:
  - a turned-in nipple
  - a watery or bloodstained discharge, which persists without squeezing.

4.4.3 All women screened must have breast history recorded, which is available to the reading radiologist. This should include:

- the date and place of previous mammogram(s)
- previous breast surgery or treatment
- any family history of breast cancer
- scars, moles and other 'signs' (position recorded)
- current symptoms
- the use of hormone replacement therapy (HRT).

Criterion 4.5: The provider maximises the detection of invasive breast cancer in the target population

Elements

4.5.1 Target: Initial screen (prevalent): The invasive breast cancer detection rate for women aged 50-69 years who attend for their first screen is ≥ 6.1 per 1,000 women screened and >50% of these breast cancers were small (≤15 mm).

4.5.2 Target: Subsequent screens (incident): The invasive breast cancer detection rate for women aged 50-69 years who attend for subsequent screens is ≥ 3.4 per 1,000 women screened, and >50% of these breast cancers were small (≤15 mm).

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Criterion 4.6: The provider monitors the detection of ductal carcinoma in situ

Element

4.6.1 Target: 10–25% of women aged 50–69 years who have cancer detected by the programme are diagnosed with ductal carcinoma in situ (DCIS).

Criterion 4.7: The provider minimises the number of invasive interval breast cancers

Elements

4.7.1 Target: ≤7.1 per 10,000 women aged 50–69 years who attend for screening are diagnosed with an invasive interval breast cancer within one calendar year of a negative screening episode.

4.7.2 Target: ≤15.0 per 10,000 women aged 50–69 years who attend for screening are diagnosed with an invasive interval breast cancer in the second calendar year following a negative screening episode or before their next screening mammogram.

Standard 5: Assessment

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

Criterion 5.1: The provider demonstrates a multidisciplinary approach to assessment

Elements

5.1.1 The provider ensures that the multidisciplinary team involved in the assessment of women recalled from screening has documented training and expertise in:

- breast examination
- mammographic performance
- mammographic image interpretation and work-up
- ultrasound performance and interpretation
- percutaneous needle biopsy
- vacuum-assisted excision
- pathology technique and interpretation
- surgical planning
- supportive care.

5.1.2 The provider implements a protocol which ensures that the multidisciplinary team correlate and evaluate the clinical, imaging and/or pathology findings and decide on further investigations or management for all cases that underwent percutaneous needle biopsy or diagnostic surgical excision biopsy, or vacuum-assisted excision biopsy.[6] Multidisciplinary team meetings will:

- occur preferably weekly but at least fortnightly
- keep a register of attendees
- give special consideration to pathologically indeterminate lesions (B3) or where microcalcifications are not identified in samples as expected
- review all cases of extended assessment
- review all staged assessment results at the initial assessment site.

5.1.3 Final results are only communicated to women by a health professional after all clinical review processes are completed. The method and timeframe of result notification are discussed with the woman at the completion of her assessment visit.

5.1.4 There is a local protocol for correlating treatment pathology slides with percutaneous needle biopsy diagnosis and imaging at a multidisciplinary team meeting, and discordant results must be investigated.

[6] A useful reference is Ministry of Health (2013) *Guidance for Implementing High-quality Multidisciplinary Meetings*.

Criterion 5.2: The provider maximises the efficacy of assessment

Elements

5.2.1 The provider implements protocols for the evaluation of all women recalled to assessment, which incorporates:

- level 1 assessment – further mammographic views, magnification or ultrasound
- level 2 assessment – clinical examination or percutaneous needle biopsy, as required
- level 3 assessment – diagnostic excision biopsy (either open surgical excision biopsy or vacuum-assisted excision), as required.

5.2.2 The provider ensures that during breast ultrasound examination of any significant lesion(s), the size, side, clockface position and an indication of distance from the nipple is recorded on the image.

5.2.3 The provider ensures that all radiological lesions are categorised as follows:

- category 1: normal/benign – return to routine rescreening
- category 2: probably benign – may require biopsy diagnosis for confirmation
- category 3: indeterminate – biopsy diagnosis required
- category 4: probably malignant – biopsy diagnosis required
- category 5: malignant – biopsy diagnosis required.

5.2.4 All women who require level 2 or level 3 assessment must have a clinical examination prior to their procedure.

5.2.5 Target: <5% of all percutaneous needle biopsies are classified as false negative or inadequate.

5.2.6 Target: <0.5% of benign lesions assessed by percutaneous needle biopsy have a false positive result.[7]

5.2.7 Target: The absolute sensitivity of a diagnosis of breast cancer based on percutaneous needle biopsy is >90%.

5.2.8 Target: The complete sensitivity of percutaneous needle biopsy in the assessment of breast lesions is >95%.

[7] A useful reference is NHS Cancer Screening Programmes (2007) *Good Practice Guide No 9: Reporting, recording and auditing B5 core biopsies with normal/benign surgery*.

Criterion 5.3: The provider ensures that accurate information is provided to the reporting pathologist

Elements

5.3.1 The provider has a written protocol for labelling pathology specimens that ensures:

- all specimens have double identifiers (that is, name and date of birth, or name and National Health Index number)
- all specimens or request forms are clearly identified as originating from within BSA
- where multiple lesions are sampled, each sample is clearly differentiated and consistently labelled and tracked
- the same screening lesion number on the request form is maintained in the pathology laboratory, pathology and radiology reports, and woman's notes
- the clinician performing the test is responsible for checking the correct labelling of specimens.

5.3.2 For all specimens, the radiologist or surgeon provides full clinical information to the reporting pathologist, including:

- the exact location of the lesion(s)
- mammographic/sonographic findings and the radiological grade of the abnormalities
- the findings of the clinical examination
- the nature of the biopsy procedure, whether percutaneous needle biopsy or vacuum-assisted biopsy
- any previous pathology results
- a guide to the location of any orientation sutures/clips.

5.3.3 Percutaneous needle biopsies taken from areas of microcalcification are X-rayed and have the sites of calcification documented for the pathologist before being transported to the pathology laboratory.

Criterion 5.4: The provider follows protocols and procedures to ensure accurate diagnosis and reporting of pathology specimens

Elements

5.4.1 Separately labelled specimens should be processed as separate specimens.

5.4.2 The provider ensures percutaneous needle biopsy specimens are processed as for a routine surgical biopsy. A minimum of three levels must be obtained from all core percutaneous needle biopsies. Additional levels must be performed as required to try to achieve concordance.

5.4.3 Frozen section examination must not be undertaken on impalpable breast lesions.

5.4.4 For open surgical excision biopsies or vacuum-assisted excision diagnostic excision biopsies, unless there is a very definite correlation between the radiographic abnormality in the specimen radiograph and the macroscopic findings, additional radiography of the sliced specimen should be performed. This second-stage radiography can be undertaken either in the screening suite, an alternative radiology facility, or with specially designed equipment located in the pathology suite. The radiologist should be consulted if the pathologist has any doubt as to the presence of the lesion in the sliced specimen radiographs.

5.4.5 The reporting pathologist will:

- include the radiologist's description of the lesion in the report
- confirm that surgical specimen(s) is (are) correctly oriented if orientation clips are used
- follow the reporting terminology and diagnostic categories used for screen-detected breast specimens in the current *National Health Service Breast Screening Programme Guidelines* (National Health Science Breast Screening Programme 2001)
- adopt the criteria for the classification of DCIS set out in *The Pathology Reporting of Breast Cancer* (National Breast and Ovarian Cancer Centre and Australian Cancer Network 2008).

5.4.6 In addition to any specific diagnostic categories used, the reporting pathologist should also categorise the core biopsy, as follows:

- B1: inadequate sample or normal breast tissue
- B2: benign breast lesion
- B3: uncertain malignant potential
- B4: suspicious of malignancy
- B5: malignant breast lesion.

5.4.7 At a minimum, percutaneous needle biopsies categorised as B3, B4 or B5 are required to be independently second read by another BSA-accredited pathologist.

5.4.8 The report and the slides of the specimen must be made available to the treatment service for review at the pre-operative multidisciplinary team meeting in a timely manner to avoid delay in surgery.

5.4.9 All BSA pathologists are encouraged to forward difficult-to-diagnose or uncertain cases to Lead Pathologists or recognised overseas pathologists for second opinions. Any

potential delay in diagnosis must be communicated to the Lead Provider Manager, Clinical Director and the woman at the earliest opportunity.

Criterion 5.5: The provider minimises the number of open surgical excision biopsies (level 3 assessment) performed for benign disease

Elements

Equivalent targets for vacuum-assisted excision are likely to be amended following formal monitoring and evaluation of the use of vacuum-assisted excision within BSA

5.5.1 The number of open surgical excision biopsies performed for benign disease is ≤3.5 per 1000 women who attend for their first screen.

5.5.2 The number of open surgical excision biopsies performed for benign disease is ≤1.6 per 1000 women who attend for their second or subsequent screens.

Criterion 5.6: The provider minimises the harms of open surgical excision biopsies (level 3 assessment)

Elements

5.6.1 100% of tissue specimens from impalpable lesions are appropriately imaged perioperatively and reported by a radiologist.

5.6.2 >90% of biopsies that prove to be benign will weigh <30 grams.

5.6.3 >95% of impalpable lesions are excised at the first biopsy operation.

5.6.4 >90% of screen detected cancers are diagnosed pre-operatively.

Criterion 5.7: The provider minimises the adverse effects for women recalled to assessment clinics

Elements

5.7.1 Women who do not require biopsy at assessment must receive provisional results, at least, at their visit. Final results are only given after second reading by another radiologist of assessment images and outcome.

5.7.2 Women are kept informed at all times about the outcome of their assessment. Possible outcomes of the first assessment visit are:

- return to routine screening
- percutaneous biopsy
- staged assessment
- vacuum-assisted excision
- open surgical excision biopsy
- extended assessment (early recall) for category 2 lesions where it is not possible to undergo biopsy (note: category 2 lesions managed by extended assessment should have a risk of malignancy of ≤2%).

5.7.3 Where written approval has been given by the National Screening Unit, the provider monitors effective management of staged assessment as per their written protocol, ensuring:

- women are informed about the process
- women are provided with a choice of travelling to an alternative centre from the outset
- the radiologist initially assessing the woman obtains feedback on the results of the further assessment.

5.7.4 The provider monitors timely and appropriate follow-up if a woman does not complete assessment according to their protocol, ensuring:

- if the woman does not complete assessment (with BSA or elsewhere) this means:
  - further rescreening within the programme becomes irrelevant
  - the woman is allocated 'opt out permanently' in BSA and is advised to see her GP/PCP about any concerns
  - the woman is sent a letter as a final sign-off of responsibility – this should be done in accordance with the Code of Health and Disability Consumers' Rights, and the letter should be sent by courier where a residential address is supplied
  - the woman's GP/PCP is advised
- if the woman chooses to have her assessment with a private provider, the results of that private assessment will be recorded, where available. If the woman's results are benign, she should be invited for rescreening when that is next due.

5.7.5 Women are eligible for travel and accommodation assistance for themselves and a support person, as specified by the National Screening Unit, if they hold a Community Services Card and have 80 km or more to travel by road distance from the nearest screening centre (including mobile site) to the relevant assessment centre.

- Accommodation and transport assistance may be increased at the provider's discretion, as resources allow. This must not be done to the detriment of a Lead Provider's screening service.
- Meals will be at the expense of the individual.
- Payment will be made by full reimbursement upon receipts being presented to the provider, except in special cases where the provider deems it necessary to provide support payment up-front. In such cases, this is done at the provider's discretion.

Standard 6: Management and governance

Effective structures and processes are in place, evaluated and continuously improved to ensure high quality management and governance of the service.

Criterion 6.1: Staff employed or subcontracted by the provider are appropriately managed to ensure high quality services

Elements

6.1.1 All staff are trained to ensure an understanding of the policies, protocols and procedures of the service.

6.1.2 The provider ensures all staff have an understanding of BSA and the breast screening pathway to a level that allows them to fulfil their role effectively.

6.1.3 The provider documents the accountability, responsibilities, authority, functions and outcomes to be achieved in each position.

6.1.4 The provider ensures all new and/or transferred staff receive orientation/induction programmes that cover the essential components of the services provided.

6.1.5 All staff sign a confidentiality form outlining their responsibilities and obligations upon commencement of employment and comply with the relevant Code of Conduct.

6.1.6 The provider ensures human resource management processes are conducted in accordance with good employment practice and meet the legislative requirements.

6.1.7 Each provider has a clearly documented management structure, which includes:

- identification of the person who has designated responsibility for the management of all aspects of the service, and clarification of roles where there is joint accountability
- responsibilities and accountabilities of specific individuals, groups and/or committees and the relationship between them
- clear delineation of the relationships and responsibilities of medical and non-medical staff.

6.1.8 Management multidisciplinary team meetings are held to discuss:

- coordination between the Lead Provider and subcontractor
- coordination of mobile scheduling and recruitment and retention activities
- peer review and exchange of information
- process and systems reviews
- complaints review

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- review of feedback from internal and external monitoring, quality assurance and audit activities
- communicating changes in policy, protocols or procedures
- review of consumer feedback
- ensuring fail-safe mechanisms are in place and operating routinely.

6.1.9 Management multidisciplinary team meetings:

- must be held regularly (at least six-monthly)
- are required at both the level of Lead Providers and subcontractor sites that perform assessment
- must have minutes recorded, including a record of those who attended
- require mandated team members to attend at least 50 percent of management multidisciplinary meetings – team members must nominate a delegate to attend on their behalf when they are unable to attend
- may be by teleconference if appropriate.

6.1.10 Management multidisciplinary team meetings at the Lead Provider site must be attended by:

- the Lead Provider Manager
- the Clinical Director
- the Data Manager
- lead clinicians, as agreed with the provider (eg, Lead Radiologist, Lead Pathologist, Lead Surgeon, Lead MIT)
- a recruitment and retention representative
- a quality coordinator
- at least one representative from each subcontract assessment site (six-monthly)
- others working in the programme, as appropriate.

6.1.11 Management multidisciplinary team meetings at the subcontracted provider assessment sites may be attended by:

- the Lead Provider Manager or Clinical Director from the Lead Provider site
- others working at the subcontract site.

Criterion 6.2: BreastScreen Aotearoa facilities are of a high quality

Element

6.2.1 The provider ensures that all screening and assessment units operate in a space that is clearly identifiable as a BSA service, with dedicated (but not necessarily exclusive) time, staff and resources.

Criterion 6.3: The service implements quality organisational systems

Elements

6.3.1 The BSA provider has a documented quality and risk management system that:

- reflects continuous quality improvement principles
- clearly identifies in detail all quality improvement processes that will be undertaken, and when they will be undertaken, and staff responsibilities
- includes an internal audit plan
- regularly assesses all practices to ensure the NPQS are maintained and carried out by staff
- ensures that quality improvement information is collected, analysed and evaluated and the results are communicated to providers and (where appropriate) consumers as part of the quality improvement process
- ensures there is a process informing programme management and the National Screening Unit about continuous quality improvement activities and findings
- ensures there is a process for notifying the National Screening Unit of any matters relating to a significant risk
- ensures a corrective action plan is developed and implemented addressing areas requiring improvement in order to meet the specified standard or requirement
- ensures satisfaction surveys and questionnaires are in the standardised format or have been approved by the National Screening Unit prior to use
- is reviewed by management at regular intervals to ensure compliance
- ensures written evidence of routine quality assurance is available for audits and site visits
- ensures information and experience gained from the continuous quality improvement processes are shared within the provider organisation and, where appropriate, through the BSA programme manager and clinical leader to unidisciplinary groups and to other providers.

6.3.2 The provider has a documented policy for the identification, management and resolution of complaints and ensures:

- all complaints are managed in accordance with the provider's local policy and specified timeframes
- consumers of BSA services are aware of the right to complain, and the procedure for complaining, to the provider of the service and/or the Health and Disability Commissioner and/or independent advocacy services
- resolution of complaints at the lowest possible level
- the complaint management process complies with legislative and contractual requirements
- all complaints and any relevant comments and suggestions are recorded in a specific service logbook, file or database
- the complaint is dealt with in accordance with the requirements of the Code of Health and Disability Services Consumers' Rights (SR 1996/78)

- the requirements of the Privacy Act 1993 will be complied with and supported by written protocols to deal with requests for access to clinical records, where this information is requested by the woman as part of the complaint investigation
- specific personnel are identified and are responsible for ensuring the complaint management process is effective and efficient
- each woman who accesses the complaint process will be assured of anonymity and confidentiality
- the complaints management process links to the service's quality and risk management systems in order to facilitate feedback and improvements.

6.3.3 Research applications and research projects (including clinical trials and studies) involving breast screening participants and/or their data are managed in accordance with ethical principles, current legislation, professional standards and the Health and Disability Commissioner's Code of Rights and must be:

- approved by the appropriate ethics committee
- approved by the National Screening Unit.

6.3.4 The provider implements an incident management process that includes the identification, reporting, investigation, analysis, action, feedback and open disclosure of incidents, and ensures:

- the clinical care of an individual who has been placed at unnecessary risk is made a priority
- implementation is timely, complete and signed off
- processes are reviewed to ascertain the effectiveness of corrective action
- the Clinical Director and Lead Provider Manager are fully informed
- serious adverse/sentinel events are reported to the National Screening Unit within 2 working days and in writing,[8] including:
  - events compromising the quality of the service
  - failure to meet the needs of women
  - failure to meet the overall aims of the programme
  - events that may attract negative media attention.
- where the National Screening Unit, or entity designated by the National Screening Unit, determines that the quality of screening performed by a facility is inconsistent with the NPQS and presents a significant risk to individual or public health, the provider will notify each woman who has received mammograms at that facility, and her GP/PCP, of the deficiencies presenting such risk, the resulting potential harm, appropriate remedial measures, and other relevant information as the National Screening Unit may require
- where a review of the Provider is stipulated:
  - the National Screening Unit, or an entity approved by the National Screening Unit, is responsible for performing the review undertaken in conjunction with the provider concerned
  - the review may be conducted as an on-site audit at the facility or may be performed through the review of images and/or other materials.

[8] National Screening Unit Policy Framework: Adverse Event Management Policy, see https://www.nsu.govt.nz/publications/national-screening-unit-policy-framework-adverse-event-management-policy-nsu-01

Incidents include:

- poor mammographic image quality
- failure to send screening results in a timely manner
- employment of personnel who do not meet the necessary requirements
- accidents, incidents, near misses and clinical events
- complaints and suggestions
- infections/notifiable diseases
- other reportable serious events and/or sentinel events, as indicated by legislation, regulation, professional practice standards and contracts.

Criterion 6.4: The provider ensures that all screening and assessment units have current policies, protocols and procedures

Elements

6.4.1 Providers maintain written policies, procedures, guidelines, systems or plans that ensure compliance with the NPQS and all relevant standards they must comply with, such as the Radiation Safety Act and Regulations 2016, International Accreditation New Zealand (IANZ) and Infection Control.

6.4.2 Providers update or formulate procedures and processes whenever it is found that there is an absence of documentation that could potentially affect the safety and/or quality of service delivery.

6.4.3 The provider ensures all copies of the NPQS and other BSA documentation are kept up to date.

6.4.4 The day-to-day operation of the programme complies with the principles and details of relevant legislation and standards (refer to Appendix 7: Legislation and Standards).

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Criterion 6.5: The provider ensures high quality screening and diagnostic equipment are used

Elements

6.5.1 The provider has available the diagnostic equipment to perform:

- a complete mammographic work-up
- breast ultrasound examinations
- percutaneous needle biopsy.

The provider may choose to provide the diagnostic equipment to perform:

- Vacuum-assisted biopsy
- Vacuum-assisted excision

6.5.2 X-ray systems, the provider and authorised users meet current radiation safety requirements.

6.5.3 Providers must use digital mammography at all sites, including mobile and subsites, which must be accredited for digital mammography by the National Screening Unit (refer to Appendix 8: Site Accreditation for Digital Mammography).

6.5.4 If prior mammograms are analogue, the provider must digitise at least one episode for comparison and ensure:

- a minimum resolution of 50 microns is used, to provide maximal spatial information
- digitised image quality is checked using the TG 18-QC test pattern, as with the printer testing (refer to Appendix 9: Recommendations for Medical Physicist Testing of Digital Mammography Units)
- patient demographic data, including patient side (right or left), view (MLO or CC), patient name, date of birth and image size are automatically included in the DICOM header, to allow accurate retrieval and automation of the DDP
- the original prior films, and a viewer with luminance greater than 3000 cd/m^2, is available and nearby.

6.5.5 All digital mammography equipment used in BSA, including biopsy attachments, must be DICOM compliant.

6.5.6 All digital mammography equipment must comply with the Integrating the Healthcare Enterprise (IHE) Framework.[9]

6.5.7

6.5.8 All digital mammography equipment must comply with the DICOM Greyscale Standard Display Function to ensure that digital mammograms appear similar on different viewing systems.

6.5.9 All images used within BSA must comply with default display protocols (DDP) that standardise the way the images are displayed and hung on the image displays in the PACS. For examples, refer to Appendix 10: Digital Default Display Protocols.

9 Refer to www.ihe.net/Technical_Frameworks/#radiology

6.5.10 Providers must ensure that protocols are in place to ensure that digitally acquired and reported images are available in an accessible format, fit for purpose, for:

- surgeons to view in theatre
- pathology departments
- comparative purposes in other mammography providers.

6.5.11 All displays in clinical use must comply with relevant quality control measures.

6.5.12 The acquisition displays for BSA screening mammograms are required to:

- be a minimum of 3 megapixels
- meet all quality control requirements and meet DICOM 3.4.
- have display quality control that complies with quality control procedures under elements 6.6.5 and 6.6.8 and Appendices J, L, M, N and O
- have ambient lighting minimised while not compromising client comfort or safety
- be capable of ≥300 cd/m^2 luminance (existing displays) or ≥450 cd/m^2 luminance (new displays)
- comply with DICOM 3.4 for luminance response.

6.5.13 A reporting workstation must have high-specification, high-resolution medical displays arranged suitably for clinical use by the reader and with no reflected highlights on the screen(s):

- single or dual monitor display suitable for mammographic viewing, 4096 x 2160 pixel or higher.
- where a single display is used to view paired images, it will be tested in the same way as a pair of displays.
- pixel size of about 0.2 mm.
- be used with low ambient lighting (<40 lux).
- be calibrated to the DICOM 3.14 Grayscale Standard Display Function[1] plus or minus 10%. This applies to all displays used clinically including the quality control display (MIT) and image review display (radiologist).
- be adjusted to ≥300 cd.m^{-2} maximum luminance (existing displays) or ≥450 cd.m^{-2} luminance (new displays) and a minimum between 1 and 1.2 cd.m-2.

6.5.14 Pre-set parameters for viewing all digital mammograms are required as a minimum, with window and levelling maximised for detection of both calcifications and low-density asymmetries. The reading radiologist may manually employ additional tools for problem solving while reading, including:

- invert
- window width/level
- zoom
- magnify and roam
- edge enhancement
- region of interest (ROI)
- measurement
- statistics.

(For details, see Glossary.)

6.5.15 BSA providers ensure that all laboratories involved in the programme are IANZ accredited for histopathology.

Criterion 6.6: The provider complies with quality assurance protocols for mammographic and other equipment used

Elements

6.6.1 The provider ensures that the RANZCR Mammographic Quality Assurance (MQA) Programme 2012 or subsequent versions are complied with.

6.6.2 The provider ensures that:

- the MQA committee, which, in association with a designated individual from each screening site, will ensure there is a comprehensive continuous quality improvement process
- they own or access appropriate and adequate test equipment.

6.6.3 Every screening unit must recognise that these Standards for Digital Mammography are minimum standards. Site-specific additions, either to tests or to frequencies, may be required to deal with particular vendor compliances for specific digital mammography machines. A collaborative approach between BSA, MITs, radiologists and medical physicists will ensure an appropriate quality control programme is undertaken.

6.6.4 Where vacuum-assisted technologies are employed, it is expected that this equipment will meet the equivalent standards and that the provider complies with quality assurance protocols appropriate to these technologies

6.6.5 Documentation of all tests using the appropriate template and protocol must be carried out (refer to Appendix 15: Templates and Instructions – Quality Control Procedures for Digital Mammography).

6.6.6 The Quality Control MIT has oversight for ensuring that the following daily/weekly full-field digital mammography quality control tests are performed (refer to Appendix 11: Facility Quality Control Procedures for Digital Radiography Units)

Test name	FFDM system	Minimum frequency
Viewing conditions	All	Daily
Display cleaning	All	Daily
AEC constancy test	All	Daily
Laser printer sensitometry test (if applicable)	All hard copy	Weekly
Phantom image quality (SDNR and artefact evaluation)	All	Weekly
Review workstation display	All	Weekly
Acquisition display	All	Weekly
Viewbox cleanliness (if applicable)	All hardcopy	Weekly
Modulation transfer function	All with moving parts in the imaging chain	Monthly
Mechanical inspection	All	Monthly
Film digitiser	All	Monthly
Laser printer artefacts	All hard copy	Monthly
Repeat analysis	All	Quarterly
Laser printer – TG18 pattern	All hard copy	Quarterly
Compression force	All	Six monthly

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6.6.7 MITs must carry out the image quality evaluation phantom test and any other tests recommended by the manufacturer once the mobile van is at a new site.

6.6.8 The ultrasound quality assurance tests are complied with (refer to Appendix 16: Ultrasound System Performance and Quality Control).

6.6.9 The medical physicist ensures the following tests are performed (refer to Appendices 9, 13, 14 and 17).

Test name	FFDM system	Minimum frequency
Mammographic unit assembly evaluation	All	Six monthly and yearly
Artefact evaluation	All	Yearly
Ghost image evaluation	All	Yearly, after replacement of detector
Breast entrance exposure and mean glandular dose	All	Six monthly and yearly
Chest wall missed tissue	All	Six monthly, detector replacement
Spatial resolution measurement	All	Six monthly and yearly
Collimation assessment	All	Yearly
Beam quality assessment – HVL	All	Yearly
AEC evaluation (SDNR)	All	Six monthly and yearly
Noise and linearity	All	Yearly
Spatial linearity and geometric distortion of the detector	All	Yearly
Display resolution	All soft copy	Yearly
Display luminance response and viewing conditions	All soft copy	Yearly
Viewbox luminance response (if applicable) and viewing conditions	All hard copy	Yearly
Laser printer evaluation	All hard copy	Yearly
Image quality evaluation	All	Six monthly and yearly
Image homogeneity	All	Yearly

6.6.10 Medical physics tests are conducted within 20 working days of the due date.

6.6.11 Medical physicists forward copies of reports to the relevant Lead MIT, Charge MIT and Quality Control MIT and the national coordinator of mammography physics, within 20 working days of the medical physics audit.

6.6.12 If any quality control test fails, the problem must be identified, and corrective action taken. Other test failures must be corrected within 30 days of the test date.

6.6.13 Where the equipment fails the image quality or mean glandular tests, it is withdrawn from use.

Criterion 6.7: The service introduces new technologies in a planned and safe manner

Elements

6.7.1 BSA providers ensure that:

- Any new technologies or medical devices for use within the BSA programme must meet contemporary Medsafe requirements for medical devices and must comply with the requirements set out in the Medicines (Database of Medical devices) Regulations 2003, the Medicines Act 1981 and the Medicines Regulations 1984
- BSA also requires any new technology or medical device to meet approval standards set by at least one of the following regulatory bodies: the United States Food and Drug Administration; the Australian Therapeutic Goods Administration, or the European Union Conformitè Europëenne marking system.
- the introduction of interventional procedures is strictly controlled and undertaken after an appropriate period of training, and the development and implementation of appropriate policies and protocols
- monitoring and evaluation of new technologies is undertaken and reported to the National Screening Unit.

Standard 7: Information management

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

Criterion 7.1: The provider ensures that high quality data are collected and reported

Elements

7.1.1 The provider conforms with requirements of the *BreastScreen Aotearoa Data Management Manual* with regard to:

- the collection of all required data elements
- the definitions and methods used by the provider in calculating screening indices.

7.1.2 Providers ensure that sufficient data are collected and analysed to:

- regionally and nationally monitor the BSA programme
- evaluate the programme's effectiveness and efficiency
- support effective business processes
- invite, manage and track women throughout the programme
- enable ongoing improvement of the programme's performance
- inform future policy and programme development decisions.

7.1.3 Quality procedures for data management are documented and undertaken at all levels of the screening and assessment pathway to ensure:

- data is captured in a complete, timely and accurate manner
- checks are implemented to identify any errors that may arise during data entry
- data are validated against the business rules documented in the current *Data Management Manual*
- definitions and edit rules are understood and followed
- inconsistencies are investigated and rectified.

7.1.4 The provider has protocols that clearly describe staff responsibilities for data entry and ensure:

- the individual responsible for entering information is unambiguously identified
- non-clinical staff are not permitted to interpret individual clinical data
- clinical data are never assimilated into a clinical record without the involvement of a clinician, who takes legal responsibility for that inclusion: 'automatic' amendments by computer systems are not acceptable to clinical users.

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7.1.5 Staff involved in data entry have adequate time to correctly use the system, interruptions are minimised, and the environment is conducive to detailed data entry.

7.1.6 A designated individual is responsible for the overall information system management, security, data integrity and availability, in line with the current *Data Management Manual*.

7.1.7 All external requests for aggregate data are forwarded to the Programme Manager and Clinical Leader, BreastScreen Aotearoa, National Screening Unit.

7.1.8 The provider utilises BSA information systems and notifies the NSU if the computer recording system does not meet data management requirements.

Criterion 7.2: The provider ensures that clinical records (which include all paper and electronic records, including images, slides and reports, at all stages of the screening pathway) are well managed

Elements

7.2.1 All BSA and other relevant documentation pertaining to an individual woman's breast health record are integrated and up to date. This includes multidisciplinary meeting documentation and treatment data, where relevant, being available and complete.

7.2.2 The National Health Index (NHI) is used as the unique identifier across all records.

7.2.3 Women self-identify their ethnicity, in line with the Ethnicity Data Protocols for the Health and Disability Sector (refer to Appendix 18: Collecting Ethnicity Data).

7.2.4 There are documented policies, procedures and protocols to ensure client records:

- have an identified author and signature
- are dated
- are legible
- are written in blue or black ink, produced electronically, or in other media acceptable under the Health Information Privacy Code 2020
- use common abbreviations
- are not defaced or obliterated by correction fluid.

7.2.5 Systems are in place to electronically and/or manually track and retrieve clinical records when they are removed from the main record management area, ensuring records are readily accessible.

7.2.6 Failsafe processes are in place to ensure all screening processes and episodes are completed and have been managed appropriately.

7.2.7 A documented process is implemented to ensure that clinical records are complete, and all appropriate actions have been taken prior to filing or archiving.

7.2.8 The provider ensures clinical records of women screened during the previous month are audited at each screening and assessment site and:

- all standards are met
- variances/trends in record keeping are responded to
- records are objective and factual.

(Refer to Appendix 19: Monthly Records Audit.)

Criterion 7.3: The provider ensures that digital images are well managed

Elements

7.3.1 Where images are transferred between services other than through Central PACS, the RANZCR *Position on Teleradiology* (Royal Australian and New Zealand College of Radiologists 2001) must be followed.

7.3.2 A failsafe protocol is in place to ensure timely retrieval of any image that is lost after acquisition.

7.3.3 Regular data integrity reports are run and checked by the PACS administrator. Systemic errors are identified, and corrective actions are promptly taken.

7.3.4 Redundancy and back-up systems to protect the integrity of the transfer and storage of the information are implemented.

7.3.5 Lossless image compression may be used for primary archive and for intermediary steps such as transfer over networks.

7.3.6 BSA digital mammography images may not be compressed using lossy image compression techniques.

Criterion 7.4: The provider ensures the accurate and timely collection of treatment information about women with breast cancer

Elements

7.4.1 ≥90% of screening and surgical data are collected and entered within six months of diagnosis.

7.4.2 ≥90% of oncology data are collected, entered and audited within nine months of diagnosis.

7.4.3 The treatment data collector is responsible for collecting and entering treatment data and maintaining a paper record for accuracy and completeness (refer to Appendix 20: Breast cancer synoptic report).

7.4.4 All treatment data collected are checked by a clinician for clinical accuracy.

7.4.5 The Data Manager is responsible for all entered treatment data being checked for data accuracy against the paper record, and for any discrepancies being forwarded to the treatment data collector for investigation.

Criterion 7.5: The provider meets the requirements of appropriate legislation and relevant professional and sector standards

Elements

7.5.1 Women's personal information and data are collected, stored, accessed and destroyed to a standard that complies with the Health Information Privacy Code 2020 and Public Records Act 2005.

7.5.2 Timeframes for retention of information, including previous films, are known and met, and subsequently meet the relevant guidelines (National Screening Unit 2012; Archives New Zealand 2013).

7.5.3 Timeframes for the retention of pathology (histology and cytology) slides are known and meet the relevant guidelines (National Pathology Accreditation Advisory Council 2009).

7.5.4 Women's personal information and data are managed in such a way that they meet the standards set out in the *Code of Practice for Information Security Management* (AS/NZS ISO/IEC 27002:2006) and *The Health Network Code of Practice* (SNZ HB 8169:2002).

Criterion 7.6: The provider respects each woman's health information

Elements

7.6.1 There are written protocols to ensure the privacy of each woman's clinical information.

7.6.2 Access to clinical records (either in use or in storage) is limited to those with authorisation.

7.6.3 Data and software that are maintained by the provider will be safeguarded against tampering and made secure against illegitimate use and unintentional destruction. These access protocols demand both system and data security measures.

- When updating records, it must not be possible to alter or erase previous entries without an audit trail being maintained.
- All information updates in the database must have an audit trail that identifies the change, author and date.
- Where the record is to be used by a large number of health professionals for different purposes, it must be possible to withhold certain information from general viewing.

7.6.4 Transfer of data must be as secure as possible, and references to external data must be maintained on transmission.

7.6.5 Electronic back-up of information that is maintained by the provider is secure, protected from loss, corruption, inappropriate alteration or miscalculation.

7.6.6 Retained/archived clinical records are securely maintained in a suitable order and condition.

Standard 8: Professional requirements

The provision of a quality breast screening service requires an expert multidisciplinary team.

Criterion 8.1: The provision of an expert multidisciplinary team requires mandatory key roles to be appointed

Elements

8.1.1 The Lead Provider, subcontractors and Screening Support Service Providers must maintain an up-to-date list of all personnel filling mandated BSA roles (detailed in this Standard) within their region.

8.1.2 The BSA provider may choose to provide additional expertise in addition to the mandatory roles listed in this section in order to meet the specific needs of women receiving their services.

8.1.3 All professional requirements listed in Standard 8 are included in job descriptions and are subject to performance appraisals.

8.1.4 The provider ensures attendance by the relevant team member at national UDG meetings as per schedule (refer to Appendix 21: Schedule of Uni- and Multidisciplinary Group Meetings.)

8.1.5 Prior to performing clinical work in the breast screening programme, all radiologists, surgeons, pathologists and medical physicists intending to practise in BSA must be accredited to ensure they meet the programme's requirements (refer to Appendix 22: Accreditation Protocols).

8.1.6 The provider ensures there are opportunities for all staff with frontline contact with women (eg, telephone and reception staff) to be trained to:

- provide a well women-centred approach
- provide accurate information
- understand the eligibility criteria for the programme
- meet privacy and confidentiality requirements
- know when and where to refer each woman
- provide and maintain appropriate communication and listening skills
- respond effectively to difficult situations
- address, at the earliest opportunity, unsatisfactory experiences reported by women
- recognise their own knowledge limitations.

Criterion 8.2: Each provider has a designated Clinical Director

Elements

8.2.1 The Clinical Director is ultimately responsible for the overall clinical performance of the BSA programme in the detection and diagnosis of breast cancer in the geographical area defined by the Lead Provider contract, including any and all subcontractors. In undertaking their respective roles, the Clinical Director and Lead Provider manager are responsible for implementing the operation of BSA within their lead provider region.

8.2.2 The Clinical Director is medically qualified, registered to practise in New Zealand, holds relevant vocational registration, and is active professionally within the programme.

8.2.3 Mammographic screening for breast cancer is a radiological procedure and it is appropriate for the Clinical Director of a BSA Lead Provider to be a radiologist.

8.2.4 The Clinical Director may also undertake the role of the Lead Radiologist.

8.2.5 Responsibilities of the Clinical Director include:

- the implementation of a high-quality mammography and assessment service, subject to adequate resources
- direct leadership of the clinical team throughout the lead provider region (including associated subcontractors)
- ensuring all screening staff receive adequate clinical training and regular updates, subject to adequate funding/resources
- oversight of clinical performance monitoring with the lead clinicians
- ensuring that fail-safe mechanisms are in place so that women with radiological abnormalities are recalled to assessment
- ensuring the NPQS are implemented, monitored and evaluated through a continuous quality improvement process in relation to technical, radiological and clinical services, subject to the availability of adequate resources
- overall responsibility for the accuracy of internal data audits
- ongoing review of programme performance data, with particular attention paid to cancer detection and the review of interval cancers
- ensuring advertising and publicity material is clinically correct via feedback to the National Screening Unit
- active involvement in the assessment clinics
- regular attendance at Clinical Directors' unidisciplinary meetings.

8.2.6 The Clinical Director has responsibility for the clinical performance of positions with a clinical aspect within the Lead Provider region, including:

- lead radiologist, pathologist and surgeon (and through them, all BSA radiologists, pathologists and surgeons)
- the Lead MIT (and through them, all BSA MITs)
- other positions with a clinical component to their work, eg, medical physicist, breast care nurse, data manager (if inputting or coding clinical data).

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8.2.7 The Clinical Director must visit each subcontracted screening site and each assessment site at least annually and liaise with those at the clinical multidisciplinary meeting.

8.2.8 The Clinical Director must submit an annual return to the National Screening Unit showing the number of image review meetings attended in the year by each radiologist, regardless of whether they work in the main site or a subcontracted site.

8.2.9 Participating Clinical Directors must provide documented evidence that they have attended national and/or international meetings with a breast screening component. This should demonstrate that they have participated in breast screening components for at least 10 educational hours during the preceding three years.

8.2.10 Continuing professional development must include all the requirements of the appropriate speciality within the programme. It is expected that the Clinical Director will also actively participate in regional and national quality assurance activities (eg, interval cancer review).

Criterion 8.3: Each provider has a designated Lead Provider Manager

Elements

8.3.1 The Lead Provider Manager ensures the provision of effective operational management, leadership, planning and coordination for the service. In undertaking their respective roles, they have joint responsibility with the Clinical Director for the operation of the BSA programme within their lead provider region.

8.3.2 The Lead Provider Manager's areas of responsibility include:

- advocating for adequate resources being available within funding allocations to meet the requirements of the NPQS
- ensuring effective use of available resources
- ensuring all non-clinical aspects of the NPQS are implemented, monitored and evaluated
- ensuring the organisational quality plan is developed, implemented, monitored and evaluated, including overseeing the internal quality improvement activities and ensuring corrective actions where standards are not met
- overseeing the recruitment, education, training, professional development and ongoing quality of staff involved in the programme, in partnership with the Clinical Director
- ensuring recommendations from the BSA Independent Monitoring Group Report are acted upon
- facilitating a close working relationship between members of a multidisciplinary group
- ensuring adequate policies and procedures are in place to meet the requirements of the NPQS and the current *Data Management Manual*
- distributing any amendments to national documents
- communicating and liaising regularly with the Clinical Director to ensure the success of the service
- regular attendance at the Lead Provider Managers' UDG.

8.3.3 The Lead Provider Manager is responsible for the performance of all non-clinical staff, including:

- the Data Manager
- reception staff
- clerical staff
- recruitment and retention staff
- the Quality Coordinator.

8.3.4 The Lead Provider Manager visits each screening and assessment site in their region annually. This could be timed to coincide with the management multidisciplinary meeting.

8.3.5 Lead Provider Managers will have previous management skills and experience appropriate to the position, and should have or be working towards relevant tertiary qualifications, preferably in a health-related area.

8.3.6 Continuing professional development must include service-specific training (eg, the Diploma of Public Health, breast screening courses/conferences) in addition to management training, multidisciplinary courses and support to travel to other providers in New Zealand and internationally.

8.3.7 The Lead Provider Manager's expertise includes:

- an understanding of the philosophy and operations of a breast screening programme
- strong leadership skills
- planning for service provision
- working within budgets and financial allocations
- an understanding of working with the community
- managing people, bringing together a team and liaising with other professions.

8.3.8 The provider has processes in place to ensure that during the temporary absence of the manager there are appropriate resources, expertise or equipment to meet normal volumes/activities.

8.3.9 Orientation for a new Lead Provider Manager ensures exposure to the relevant facets of the programme and may include:

- visiting other sites within the programme
- visiting subcontractor sites
- liaison with other Lead Provider Managers within the programme
- attendance at regular national programme management meetings.

Criterion 8.4: Each provider has a designated Lead Radiologist

Elements

8.4.1 The Lead Radiologist is ultimately responsible for the quality of images, subsequent reports produced under his/her direction, the clinical performance of BSA radiologists and the overall imaging performance of the programme within their Lead Provider area.

8.4.2 The Lead Radiologist is responsible for the operation of the mammographic and associated mammographic quality assurance (MQA) programmes at all sites within the Lead Provider contract, and hence must liaise well with designated MQA radiologists at subcontractor sites.

8.4.3 The Lead Radiologist may also undertake the role of Clinical Director.

8.4.4 Specific responsibilities of the Lead Radiologist include:

- selecting a medical physicist (or more than one medical physicist) who will administer the MQA programme, perform the physicist quality control tests and oversee the work of the Quality Control MITs
- ensuring the NPQS standards relevant to imaging are implemented, monitored and evaluated
- ensuring all imaging equipment is performing satisfactorily
- ensuring GPs/PCPs are kept fully informed of the screening outcomes for women registered with their practices
- reviewing radiologist performance data by site and by individual radiologist, as per the NPQS – an individual's data are confidential to the radiologist concerned, the Lead Radiologist and the Clinical Director
- active involvement as a screening and assessment radiologist within the programme
- ensuring BSA radiologists receive adequate training and regular updates.

8.4.5 The Lead Radiologist, Lead MIT and medical physicist are responsible for coordinating regular (eg, six-monthly) MQA meetings within their Lead Provider region. These meetings are to ensure that site-specific MQA programmes are in place and reviewed, and that fail-safe mechanisms are in place and operating routinely. These meetings must involve the medical physicist, either through a presence at the meeting, by teleconference or during the planning stage.

8.4.6 The Lead Radiologist is responsible for coordinating regular (at least six-monthly) radiologist meetings with all BSA radiologists in their Lead Provider region. These are to ensure that monitoring of activities and data occurs, a regional interval cancer review is performed, and fail-safe mechanisms are in place and operating routinely.

8.4.7 The Lead Radiologist is required to visit each assessment site to coordinate a clinical multidisciplinary meeting at least annually.

Criterion 8.5: There is a designated Mammographic Quality Assurance (MQA) Radiologist at each site

Elements

8.5.1 The specific responsibilities of the designated MQA Radiologist include but are not limited to:

- ensuring that an effective MQA programme exists for all mammography performed at the site
- selecting, in consultation with the Lead or Charge MIT, a single MIT to be the QC MIT, responsible for ensuring the prescribed quality control tests are performed at the site.

8.5.2 The designated MQA Radiologist reviews the MQA programme annually with the medical physicist for that site and ensures compliance with CSP-5.

8.5.3 The MQA Radiologist may also undertake the role of Lead Radiologist.

Criterion 8.6: Each provider has a designated Lead Pathologist

Elements

8.6.1 The Lead Pathologist provides professional leadership for all BSA-accredited pathologists in the pathological aspects of the programme, within their Lead Provider region.

8.6.2 The specific responsibilities of the Lead Pathologist include: but are not limited to:

- facilitating an effective quality assurance programme for all pathologists within their Lead Provider region
- facilitating processes whereby accredited pathologists receive adequate clinical training and regular updates
- confirming that processes are in place to implement, monitor and evaluate the relevant NPQS standards
- confirming that processes are in place to monitor the accuracy of pathology data
- ensuring there is a designated BSA-accredited pathologist from each contributing laboratory responsible for the quality of work at that site
- monitoring and assuring the provision of reports and slides to the assessment centre and treatment providers to meet the specified timeliness requirements
- regular attendance at pathologist unidisciplinary meetings.

8.6.3 The Lead Pathologist is responsible for monitoring the BSA-audited clinical performance of BSA pathologists.

8.6.4 The Lead Pathologist facilitates regular communication and pathology meetings, at least annually, with all BSA pathologists in their Lead Provider region.

Criterion 8.7: Each provider has a designated Lead Surgeon

Elements

8.7.1 The Lead Surgeon provides professional leadership on the surgical aspects of the programme in their Lead Provider region.

8.7.2 The specific responsibilities of the Lead Surgeon include but are not limited to:

- facilitating an effective quality assurance programme for all surgery (diagnostic biopsy and hook wire) performed within the programme
- facilitating, where necessary, the implementation and evaluation of the relevant NPQS standards
- facilitating the return of surgical treatment data via synoptic forms/reporting
- encouraging BSA surgeons to receive adequate opportunities for clinical training and regular updates
- being actively involved in the development of, as well as having an operational role within, the assessment process in their region
- regular attendance at surgeons' unidisciplinary meetings.

8.7.3 The Lead Surgeon is responsible for monitoring the BSA-audited clinical performance of BSA surgeons.

8.7.4 The Lead Surgeon facilitates the coordination of regular communication with all BSA-accredited surgeons in the Lead Provider region. This is to ensure that monitoring of activities and data occurs and that quality assurance processes are in place and operating routinely.

Criterion 8.8: Each provider has a designated Data Manager

Elements

8.8.1 The Data Manager is responsible for:

- the overall data quality and consistency of information recorded in the Lead Provider databases and for ensuring the data comply with all the National Screening Unit standards documented in the BSA documents
- ensuring data is forwarded to the national monitoring database as per the agreed timetable
- the use of information systems supplied by the National Screening Unit.

8.8.2 To ensure that activity and results are accurately monitored on a regular basis, the Data Manager liaises with:

- members of the multidisciplinary team
- service providers
- other BSA Data Managers
- the National Screening Unit, including attendance at BSA IT user groups
- key stakeholders.

8.8.3 Data Managers participate in ongoing professional development in areas including:

- database management skills
- quality assurance
- data analysis
- breast screening issues (eg, site visits)
- attendance at a data management/audit course every three years.

8.8.4 It is essential that the Data Manager demonstrates:

- a minimum of two years' experience managing a 'business critical' information system
- experience in data management and analysis, including report generation
- interpretation of report data
- experience in managing data quality.

8.8.5 The expertise of Data Managers should include:

- an understanding of audit, monitoring and evaluation requirements
- an understanding of the data management responsibilities (eg, audit and quality issues for manual and computer records)
- monitoring and facilitating the maintenance of appropriate information systems and database housekeeping activities
- appropriate knowledge and adequate training in the information system/database that captures and stores the information
- a thorough knowledge of the relationships with other information systems and interfaces
- the provision of accurate and meaningful *ad hoc* reports to the Clinical Director and other staff when required, as resources allow

- well-developed written and oral communication skills
- the identification of problem areas and possible areas of improvement and implementation of solutions, following authorisation by the Lead Provider Manager
- good working relationships with the other staff and stakeholders to ensure targets are met and the data are accurate
- project management
- understanding of user acceptance testing (UAT).

8.8.6 New Data Managers and staff in training must receive adequate supervision until they reach a level of competence that satisfies their immediate manager. New staff and staff in training must limit their data management activities to the areas they have been deemed competent in by their immediate manager.

8.8.7 The provider must establish contingencies to manage episodes of extended leave, sickness or the resignation of the Data Manager to ensure the continuity of data management and reporting.

Criterion 8.9: Each provider has a designated Lead Medical Imaging Technologist (MIT)

Elements

8.9.1 The Lead MIT provides professional leadership to MITs within their region and is responsible for:

- ensuring site visits occur at least every six months
- ensuring a high standard of mammographic image quality is achieved by all MITs in the lead provider region
- ensuring individual MIT performance is monitored and feedback is provided to each MIT in the team
- ensuring all MITs participate in the monthly peer review process using mammographic image quality criteria
- identifying any training needs of MITs and ensuring any appropriate training occurs
- overseeing the overall performance of the MQA programme within the Lead Provider region.

8.9.2 The Lead MIT is responsible for the clinical performance of the following within their region:

- all BSA MITs (including ensuring the quality for those working on fixed term and locum basis)
- the designated QC MIT (if other than a BSA MIT).

8.9.3 The Lead MIT will:

- be actively involved in performing a minimum of 700 screening mammograms annually within the programme
- demonstrate a high standard of mammography and maintain a strong clinical focus
- retain responsibilities as below, but be able to delegate
- meet all the professional and continuing professional development requirements of an MIT.

In addition, continuing professional development relevant to the managerial aspects of the lead role will be undertaken.

Criterion 8.10: There is a designated Charge MIT at each screening site

Elements

8.10.1 The Charge MIT is responsible for:

- ensuring MQA at that site occurs
- technical/support staff who support MITs
- reviewing the MQA programme annually with the QC MIT, the designated MQA Radiologist and the medical physicist to ensure compliance with NRL-C548
- ensuring all MITs at their site meet the minimum entry and ongoing requirements for screening MITs within the programme.

8.10.2 The designated Charge MIT:

- is actively involved in the programme
- demonstrates a high standard of mammography and maintains a strong clinical focus
- retains responsibilities as below, but is able to delegate
- meets all the professional and continuing professional development relevant to the managerial aspects of the role.

Criterion 8.11: Each provider has a designated Quality Control (QC) MIT at each screening and/or assessment site

Elements

8.11.1 The QC MIT may be the Charge MIT or another designated MIT for each screening site.

8.11.2 The designated QC MIT is responsible for:

- ensuring the mammographic quality assurance (MQA) programme occurs at that site
- ensuring all quality control tests are performed, data collection is adequate and current, and any corrective action is initiated as required
- ensuring the accuracy of the quality control data.

8.11.3 The designated QC MIT:

- is actively involved in the programme
- demonstrates a high standard of mammography and maintains a strong clinical focus
- retains responsibilities as above, but is able to delegate
- meets all the professional and continuing professional development relevant to the managerial aspects of the role.

Criterion 8.12: Each provider has a designated PACS administrator

Elements

8.12.1 The PACS administrator has training to fulfil the following competencies:

- being responsible for the day-to-day operation of mammography PACS equipment, including image workflow, archiving, auto-routing, pre-fetching and other related activities
- ensuring timely and complete capture of DICOM digital image data into the PACS system, as well as network transmission, Radiology Information System (RIS) validation and exceptions handling
- overseeing the activities of vendors in all phases of installation and maintenance of PACS
- overseeing and coordinating diagnosis, and maintaining and upgrading all PACS-associated hardware and software while ensuring its optimal performance
- overseeing and coordinating disaster recovery and data backup
- ensuring all procedures related to PACS are documented and current
- identifying future needs and efficient workflow processes
- coordinating application support via training sessions
- involvement in strategic planning of breast screening services, as appropriate.

Criterion 8.13: Each provider has a designated Quality Coordinator

Elements

8.13.1 The Quality Coordinator, on behalf of the Clinical Director and Lead Provider manager, coordinates the operation of the quality management systems within their Lead Provider region. This is expected to be a part-time role and can be combined with another role, provided there is no conflict of interest.

8.13.2 The Quality Coordinator helps ensure that the systems and protocols within Lead Providers and subcontracted sites meet quality requirements.

8.13.3 The Quality Coordinator assists professional groups, the manager and Clinical Director to:

- ensure the NPQS are met
- coordinate corrective actions when standards are not met
- ensure the organisation's quality plan is current, implemented, monitored and evaluated
- ensure the recommendations stemming from the BSA Independent Monitoring Group reports are responded to
- ensure all relevant information, policies and procedures remain current
- facilitate internal quality improvement activities
- organise quality-related meetings on a regular basis and maintain a record of these, including attendance and outcomes
- manage internal document control of NPQS across all sites, including subcontractors.

8.13.4 The Quality Coordinator liaises with the Clinical Director and Lead Provider Manager to:

- document protocols and processes and plan for or timetable all internal audit requirements
- provide comparisons of provider data with external audit, with a focus on BSA Independent Monitoring Group reports
- ensure the effective provision of clinical performance information
- develop and facilitate the monitoring of the quality plan on a quarterly basis.

8.13.5 The Quality Coordinator liaises with the lead clinicians to ensure analysis of individual staff performance measures. Such information is confidential within the respective professional group(s).

8.13.6 The Quality Coordinator liaises with the Charge MIT to:

- review MQA data to monitor the effective operation of the screening process
- ensure analysis of individual staff performance measures – such information remains confidential within the professional group.

8.13.7 The Quality Coordinator liaises with the data manager to:

- verify protocols for determining all audit and performance data
- review all programme data for anomalous results

- ensure analysis of performance data by individual sites, where appropriate
- ensure the resolution of all missing, erroneous or suspicious data on a case-by-case basis.

8.13.8 The Quality Coordinator will have demonstrated an ability in implementing quality and audit systems, and will have experience in a health-related field and/or a qualification in quality management such as the Certificate of Quality Assurance.

8.13.9 The provider ensures there is appropriate training and orientation for staff new to the Quality Coordinator role.

8.13.10 Orientation and ongoing training may include but is not limited to:

- visiting sub-contractor sites within their region
- visiting other sites within the programme
- liaison with other Quality Coordinators within the programme
- attendance at regular Unidisciplinary National Quality Management meetings
- courses, including summer schools, etc.

8.13.11 The Quality Coordinator will have a close working relationship with the Clinical Director and the Lead Provider Manager, particularly when new in the role.

Criterion 8.14: Each provider has qualified breast care nurses

Elements

8.14.1 The breast care nurse primarily provides information, education, support and counselling services for women undergoing assessment, but is available to assist women at any stage of the screening process, if required.

8.14.2 All women participating in BSA are entitled to services from the breast care nurse which:

- comply with legal, professional, ethical and other standards relevant to the profession of nursing, minimising any potential harm to and optimising the quality of life of that individual
- are delivered in a professional manner, consistent with the physical, psychological, spiritual and cultural needs of the individual.

8.14.3 The breast care nurse works as a member of a multidisciplinary team in partnership with women, their families and whānau to empower each woman to make informed choices and optimise her health and wellbeing.

8.14.4 The role of the breast care nurse includes, but is not limited to:

- empathetically providing support to women and their family/whānau
- acting as advocate for the woman and her supporters
- providing education and information with a particular emphasis on facilitating informed decision-making for women prior to attending assessment and after a diagnosis of cancer
- promoting awareness of psychosocial issues of concern to well women participating in screening
- referring women (where appropriate) to other support services
- facilitating communication between other health professionals and services (particularly GPs/ PCPs) regarding the care of individual women
- providing nursing support for clinicians during all stages of assessment
- ensuring there are appropriate infection control protocols in place
- facilitating appropriate handling and pathways for pathology specimens
- facilitating access to clinical supplies for assessment days.

8.14.5 The role of a BSA breast care nurse is undertaken by a registered nurse with a current practising certificate and a minimum of two years' postgraduate work experience as a registered nurse and a strong commitment to the provision of a high standard of care.

8.14.6 The registered nurse will have demonstrated an understanding of and a commitment to meeting the NPQS.

8.14.7 Within the first year of employment the BSA nurse must have attended/or be attending a breast care nurse course where one is available. Where possible the course should be accredited by the New Zealand Nursing Council.

8.14.8 The breast care nurse, in consultation with the manager, must develop both short-and long-term strategies relating to personal career development within the programme. In order to provide a specialist service for women, the breast care nurse must have access to ongoing breast-specific training.

8.14.9 The breast care nurse must follow the New Zealand Nurses Organisation Professional Development and Recognition Programme's requirements for nursing study, planned educational programmes and self-directed study, including attending:

- 50% of clinical multidisciplinary in-house sessions for case review, or 15 meetings annually, whichever is the greater
- nationally recognised education programmes,
- regional, national or international seminars, conferences or courses (at least three in any five-year period)

Clinical supervision, if requested by the breast care nurse, is available.

8.14.10 The breast care nurse demonstrates advanced knowledge of nursing theory and practice, with an emphasis on:

- anatomy and physiology of the breast
- signs and symptoms of breast disorders
- pathology of breast cancer
- diagnostic procedures/interventions and potential complications
- therapeutic interventions and potential complications
- treatment options and/or trial protocols
- self-help groups/support services and community networks
- issues relating to population screening of well women
- principles and processes of research and quality assurance
- professional ethics
- Health Information Privacy Code (2020)
- Health and Disability Service Consumers' Rights (SR 1996/78)
- the Treaty of Waitangi and the subsequent impact on Māori health.

8.14.11 The breast care nurse will demonstrate expertise in:

- breast awareness
- nursing and health assessment
- client information and educational needs assessment
- assessment and support
- determining when the woman requires referral to relevant health professionals for additional specialised psychological care
- written and verbal communication
- communication/listening
- evaluation and feedback
- support and advocacy
- participation as a member of a multidisciplinary team
- quality improvement activities
- clinical breast examination, where mandated and appropriately trained.

Criterion 8.15: Each provider has a qualified diagnostic medical physicist

Elements

8.15.1 The medical physicist's areas of responsibility include, but are not limited to:

- ensuring the quality assurance (MQA) programme is of the required standard and is operating effectively
- ensuring all imaging and ancillary equipment is covered by the MQA programme (eg, X-ray equipment, reporting stations, CR plate readers, localisation devices, ultrasound imagers and hard-copy devices)
- being a member of the breast screening site MQA committee, which will meet six-monthly to review results and annually to review the QA programme
- performing the medical physics quality control tests
- ensuring the performance and calibration of quality control test equipment
- performing acceptance testing on new imaging and associated equipment prior to its use on women
- assisting the quality control MIT in the review of MIT quality control test data
- advising the quality control MIT on all matters concerning image quality and the MQA programme
- advising the designated MQA radiologist, specifically in the areas of image quality and all aspects of the MQA programme, safety and equipment purchase
- advising the Lead Provider Manager and/or Clinical Director and source license holder specifically in the areas of safety, quality control analysis and equipment purchase, including the preparation of equipment specifications
- co-operating with all others involved in the programme
- co-operating with other medical physicists working in BSA
- providing radiation protection advice to the screening unit, particularly the authorised users, and ensuring the radiation safety of the women, staff and members of the public
- enabling regulatory compliance.

8.15.2 Where a lead provider is served by more than one medical physicist, there must be a designated lead medical physicist who will liaise with the others.

8.15.3 All medical physicists accredited and active in the programme are members of the Medical Physicists Unidisciplinary Group (UDG) and are required to take part in these meetings and associated activities. The Medical Physicists' UDG will seek to cooperate with the ACPSEM NZ branch and/or NZ Qualified Health Physicist (QHP) group in professional matters related to mammography physics practice and education.

8.15.4 Medical physicists seeking accreditation to BSA must satisfy the following criteria.

- They must be vocationally trained in the physics of diagnostic imaging.
- They must be explicitly trained in the physics of mammography and in the philosophy of breast screening.
- Approved mammography courses agreed by the Royal Australian and New Zealand College of Radiologists (RANZCR) and the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM), and practices are provided by the ACPSEM.

Other internationally recognised courses (eg, those provided in the USA by the American Association of Physicists in Medicine / American College of Radiology (ACR) and in the UK by the Institute of Physics and Engineering in Medicine) are acceptable.

- To be acceptable, a mammography course must contain a minimum of 20 contact hours of documented, specialised training in conducting surveys of digital mammography facilities. Time must also be spent visiting established screening units in order to gain practical experience working with physicists in the field.
- Take part in activities organised for them by the Medical Physicists UDG. This may involve attendance as observers for part of UDG meetings.

Applicants must also:

- be an appropriately licensed medical physicist under the Radiation Safety Act 2016. hold a master's degree or higher qualification in physics
- have recognised, documented, specialised training in conducting surveys of mammography facilities as per American College of Radiology (ACR) or RANZCR standards
- have experience of conducting surveys of at least six machines over a 12-month period (ie, six machines, two tests per machine, each six months apart within BSA) – experience conducting surveys must be acquired under the direct supervision of a medical physicist who meets all the requirements of the NPQS.

Where applicants have extensive mammography experience that has been gained practicing overseas, at least two supervised surveys are required as part of the orientation to BSA protocols and standards.

The medical physics UDG will give advice on the attainment of these requirements, and will seek the advice of those sponsoring the applicant and of the ACPSEM NZ branch spokesperson and/or NZ QHP group.

8.15.5 To maintain accreditation to BSA, medical physicists will participate in continuing professional development (CPD) in the area of mammography physics. Some CPD is external, for example attendance at conferences, reading/reviewing published work, visiting colleagues overseas. Some CPD is internal, ensuring and maintaining a common standard of practice within BSA. A medical physicist's CPD must include:

- attendance at one (minimum) scientific meeting or refresher course, with content specific to the clinical practice of mammography physics, every two years – only time spent on mammography physics may count towards the 15 hours of CPD
- attendance at relevant multidisciplinary or peer review and audit meetings
- review of current journals and authoritative material relevant to mammography physics.

The medical physicist must meet the RANZCR/ACR standard of 15 hours' CPD in mammography physics during the 36 months immediately preceding any facility survey. A record of medical physicists practising in New Zealand who meet this standard, and are accredited to BSA will be kept by the National Screening Unit and be reviewed annually by the Medical Physicists UDG. The national physics coordinator, in conjunction with the Medical Physicists UDG, will give advice on the attainment of CPD requirements.

8.15.6 To achieve and maintain an adequate awareness of current technology, techniques and clinical practice within BSA, the medical physicist must:

- during the 24 months immediately preceding any survey, conduct two full facility surveys, including the review of the facility MQA programme, and either:
  - perform the MQA surveys on six BSA mammography units in the previous 12 months, or
  - perform the MQA surveys on four BSA mammography units, plus
  - have extensive experience, and
  - work in general diagnostic radiology
- participate in the review of MQA data from surveys on at least six mammography units at least once a year, and have access to such data when necessary
- liaise with other mammography physicists and attend national meetings on mammography physics organised by the medical physicists UDG, and support practical inter-comparison sessions associated with the UDG meetings
- undertake visits to other accredited BSA mammography physicists to compare techniques at least every two years ('buddy visits').

8.15.7 Staff in training can perform medical physics duties under the direct supervision of an accredited medical physicist currently practising within BSA. Staff in training must undertake the full range of tasks under the direct supervision of the accredited medical physicist. Trainees must undertake duplicate surveys and be directly supervised for any procedure conducted within the programme. Until a medical physicist is accredited to BSA, the NPQS survey remains the responsibility of the supervising medical physicist and must be performed by them.

8.15.8 The medical physicist must participate in a planned, coordinated MQA programme covering all imaging equipment that will be used in achieving a diagnosis, as well as ancillary equipment. The MQA programme must also include the test and calibration of the MQA test equipment itself and the provision of the medical physics service. The service must be specified in a written agreement between a breast screening unit and the designated medical physicist.

8.15.9 The physics QA tests must be performed in a standardised manner and to the national protocols in order to facilitate the exchange of data. A national protocol of tests, based on those recommended by RANZCR, has been agreed, and will be continually reviewed by the medical physicists UDG. Other additions to the RANZCR tests may be necessary for regulatory compliance.

8.15.10 In accordance with the UK National Health Service Breast Screening Programme guidelines, there is a programme of dose measurements on women.

8.15.11 There must be an internal quality system to ensure that:

- all critical test failures are identified to the facility on the day testing is completed
- 95% of final reports are provided to the unit within 20 working days of the day testing is completed
- defects are reviewed when identified and the medical physicist specifies the timeframe in which they must be resolved in consultation with the Clinical Director.

8.15.12 The medical physicist must send medical physics quality assurance survey results to the national physics coordinator in a timely manner, to enable the annual collation of results.

8.15.13 The medical physicists UDG must ensure the efficient exchange of information to ensure national protocols are maintained and revised on the basis of current evidence.

Criterion 8.16: Each provider has qualified medical imaging technologists (MITs)

Elements

8.16.1 MITs require skills that will make mammography an acceptable experience for women by minimising anxiety at all stages of the screening pathway.

8.16.2 The MIT has two main areas of responsibility:

- provision of an acceptable screening experience for women who participate in BSA
- the provision of medical images of high quality to ensure the detection of small cancers – the detection of such cancers will demonstrate the benefits of screening mammography for women.

8.16.3 All MITs performing screening mammography within BSA must be trained and qualified as MITs. They must be registered with the NZ Medical Radiation Technologists Board and hold a current annual practising certificate. All MITs must also have enrolled for a Post Graduate Certificate or a Clinical Competence in Mammography (New Zealand Institute of Medical Radiation Technology – NZIMRT), or a recognised equivalent within one year of commencing employment with the programme. Any overseas mammography qualifications must be endorsed by the Lead MIT UDG and BSA clinical leader.

8.16.4 To assist in maintaining the necessary skill level and expertise, MITs should:

- remain up to date with advances in clinical practice and mammography techniques
- be conversant with current methods of early detection and treatment of breast disease.

These should be achieved by regular attendance (no less than one every three years) at validated update courses, conferences or seminars. These may be regional, national or international and it is desirable that one event contain a clinical component. Within each screening centre, ongoing education must occur through regular in-house study programmes, journal reviews and peer teaching sessions.

All continuing education should be of a quality that would enable it to be included in the continuing professional development programme (CPD) endorsed by NZIMIT.

8.16.5 All new MIT staff requiring training will be supervised by an MIT who holds a mammography qualification recognised by NZIMIT. Mentoring of the MIT in training must occur until the level of competency reached enables the MIT to function with a technical reject rate of less than 3%. Staff under training must progressively become involved in all relevant aspects of the screening programme as their competency levels develop.

8.16.6 MITs must complete a minimum of eight hours' training in digital mammography.

8.16.7 All MITs performing screening mammograms in BSA must assess each examination using the mammographic image quality (MIQ) classification criteria. These MIQ classification criteria are to be used in all training situations and whenever conducting peer review. Images that fall into the inadequate category are to be recorded as such. While these may be recorded as rejects, there may be instances when they are retained if they assist in the comprehensiveness of an examination.

8.16.8 All MITs participate in peer review of images monthly. The Lead MIT may determine the times and method used. However, the peer review process must utilise the MIQ criteria and must support the Lead MIT's responsibility to maintain overall image quality.

8.16.9 All permanently employed MITs involved in BSA (except Lead MITs) must be performing no less than 1000 mammograms per year, or 80 per month within BSA.

8.16.10 All MITs or sonographers working in either fixed or mobile sites are to attend a minimum of three assessment clinics and three clinical multidisciplinary meetings per year.

8.16.11 All MITs must attend regular sessions (at least monthly) reviewing images for technical quality.

Criterion 8.17: Each provider has qualified pathologists

Elements

8.17.1 A pathologist involved in BSA will be medically qualified and registered to practise in New Zealand. All BSA pathologists should hold recognised postgraduate qualifications in pathology and be enrolled on the New Zealand Medical Council's Vocational Register in anatomic or general pathology.

8.17.2 Participating pathologists must be enrolled in the Royal College of Pathologists of Australasia's CPD scheme and complete the appropriate requirements for participation in the programme.

8.17.3 Every three years participating pathologists must submit evidence to the Unidisciplinary Pathologists Group that they have attended national and/or international pathology meetings or conferences with a component on breast pathology. They should demonstrate that they have participated in the breast pathology components for a total of at least six educational hours over the preceding three years.

8.17.4 BSA pathologists must report on a minimum of 50 patient biopsy episodes from assessment clinics or open diagnostic biopsies within the programme per annum. Each tissue sample is counted as a separate episode and, if double signed, counts as an episode for each signing pathologist.

8.17.5 BSA pathologists must attend a minimum of eight BSA multidisciplinary meetings each year while ensuring that a BSA-accredited pathologist is present at each multidisciplinary meeting to present and comment on relevant pathology.

8.17.6 Pathologists in training may undertake gross and microscopic descriptions of screen-detected lesions, but the material must be reviewed and signed out by a BSA pathologist.

8.17.7 Pathologists reporting on screen-detected lesions should have sufficient exposure to relevant material to develop and maintain competence in the reporting of such cases. The lead pathologist should endeavour to make material from larger assessment centres available to pathologists working with smaller volumes as a teaching/learning resource.

8.17.8 All BSA pathologists must be enrolled and participate in the Royal College of Pathologists of Australasia's Quality Assurance Programme (QAP). BSA pathologists must participate on an individual rather than a laboratory basis and complete five surveys every two years. The results of participation in the QAP scheme must be recorded and provided to the programme by the lead pathologist and be available for external audit as required.

8.17.9 All participating laboratories should be enrolled in the Royal College of Pathologists of Australasia Anatomical Pathology quality assurance programme.

Criterion 8.18: Each provider has qualified radiologists

Elements

8.18.1 Radiologists involved in BSA will be medically qualified, have a basic qualification in radiology, such as Fellowship of RANZCR and be registered to practise in New Zealand or have provisional registration and be under supervision. . They will also hold vocational registration in diagnostic radiology. While on the provisional registration pathway radiologists should be supervised by a BSA radiologist, if they come off the provisional pathway they must cease reading screening mammograms.

8.18.2 BSA radiologists must undertake further training prior to commencing screening mammography within the programme. This should include, as a minimum:

- reporting of a minimum of 2000 mammograms within the 12 months prior to commencement
- completion of 300 dummy third reads within the three months prior to commencement (a recall rate of not more than 12% is required)
- demonstration of reader sensitivity of 80% from the cancer seeded set of images known as the National Accreditation Set
- participation as an observer at the full clinical multidisciplinary team meetings, and the process of resolution of discordant readings during the period of training as a third reader
- attendance at one teaching course currently recognised by RANZCR within the last two years.

8.18.3 Prior to commencing unsupervised assessment, radiologists must satisfy the Clinical Director that they are competent in the following:

- supervising and interpreting mammographic work-up
- performing and interpreting breast ultrasound
- performing invasive procedures available in their assessment clinic
- Where vacuum-assisted technologies are offered, those radiologists employed to provide either vacuum-assisted biopsies or vacuum-assisted excisions must satisfy the Clinical Director that they are competent in these procedures
- attendance and supervised participation during the 12 months prior to commencement in 10 assessment sessions within an established national population-based screening programme, either in New Zealand or overseas, at a screening facility approved by RANZCR.

8.18.4 All radiologists must participate in CPD that includes:

- attending at least one scientific meeting or refresher course specific to breast imaging every two years. In exceptional circumstances the Clinical Director may approve substitution of an online course.
- attending multidisciplinary review and audit meetings
- reviewing current journals and material on relevant radiological websites.

8.18.5 Every radiologist involved in the screening programme must read a minimum of 3000 screening mammograms within the provider region-each year.

8.18.6 An individual radiologist's reading statistics must fall within 95% confidence intervals for rates of cancer detection and detection of small cancers (Criteria 4.5, 4.6 and 4.7) (refer to Appendix 24: Funnel Plots). Where an individual fails to meet these criteria, the Clinical Director will ensure strategies for improving performance are implemented.

8.18.7 BSA radiologists must:

- Review cases that they have recalled to assessment
  - When a radiologist's performance is satisfactory, as decided by the Clinical Director, Lead Radiologist or Radiologist Quality Assurance Panel, this may be adequately achieved by regular attendance at multidisciplinary meetings and radiologist review meetings
  - When a radiologist's performance is unsatisfactory (below 80% sensitivity) all false negative reads must be reviewed (images and pathology)
  - When a radiologist's performance is unsatisfactory (high recall rate or low PPV) all false positive cases should be reviewed, including those that did not result in a recall
- attend at least 30 screening multidisciplinary review meetings a year (using video conferencing if necessary). Or pro-rata if a radiologist is working a part year**.**
- participate in the programme's interval cancer review and other audit sessions.

Radiologists who perform ultrasound, biopsy and localisation techniques at an assessment clinic must be competent at these procedures. To achieve this, it is recommended that these radiologists have a regular weekly commitment to breast imaging, which may include diagnostic, screening, assessment clinic and audit sessions.

BSA radiologists must also read screening mammograms and participate in assessment clinics. It is recognised that this may be difficult to achieve while still allowing assessment clinic radiologists to develop and maintain sufficient expertise. For this reason, it is desirable for screening radiologists to be performing assessment in diagnostic clinics outside the programme.

BSA radiologists must continuously monitor the technical quality of mammograms and provide constructive feedback to the lead MIT. This is particularly important in situations where MITs do not have direct contact with the radiologist who reports the images.

8.18.8 Radiologists must attend regular radiology review sessions to allow:

- interval cancer review and internal classification
- review of reading or assessment procedures and protocols
- review of literature
- review of interesting cases or third reads.

8.18.9 All BSA radiologists must complete training in digital mammography. Education for radiologists in digital mammography consists of the following.

- Supervised reading of digital mammography images must be performed with an experienced radiologist at a digital mammography accredited site.
- Digital images will ideally be viewed on a workstation identical to the one the radiologist will be using at his/her own site.
- Sufficient time should be spent at the workstation so that the radiologist is comfortable with altering windowing, levelling, zoom and inversion pre-sets as necessary to optimally visualise calcifications or subtle asymmetries.

Education should also include:

- a minimum reading of 3000 digital mammograms in the preceding twelve months, including reading the national BSA accreditation set.
- quality control for digital mammography (such as vendor-specific quality control).

8.18.10 It is desirable for radiology registrars to rotate through a breast screening unit, and trainees may participate in BSA under supervision from a BSA radiologist, with:

- time spent in the screening unit divided between reading screening mammograms and assessment
- direct supervision for any procedure conducted within the programme
- trainees performing dummy reads – these reads should not influence outcomes for women.

8.18.11 The screening unit's data management system must allow regular monitoring of an individual radiologist's performance and feedback of information. At a minimum this will include the number of screening mammograms read, the total referral rate, and small invasive cancer and overall cancer detection rates. This information must be provided every six months, will be cumulative and must include performance criteria for assessment.

De identified performance data will be reviewed by a Radiologist Quality Assurance Panel and where concern about radiologist performance is identified this will be communicated to the region's Clinical Director and Lead Radiologist.

Individual performance data is confidential but continuing performance issues may be notified to the line manager and Lead Provider manager, if different. Individual performance data will also be available for scrutiny by the visiting BSA radiologist auditor.

8.18.12 To assist small reading sites to maintain services, off site screening is desirable but all readers must meet other BSA criteria and be monitored. Feedback must be provided.

To enable optimal management of the process:

- At least one read must be performed by a BSA radiologist at the assessing site.
- Each BSA radiologist must designate a primary Lead Provider where they will attend multidisciplinary meetings or radiology review meetings. Radiologists must perform at least 60% of reads for this Lead Provider (measured per calendar year). If greater than 40% of reads are performed for secondary sites the radiologist must attend multidisciplinary meetings or radiology review meetings at the secondary site (this may be by video conference) and meet attendance requirements.
- The Clinical Director or Lead Radiologist of the secondary sites will make available reading statistics to the Clinical Director or Lead Radiologist of the primary Lead Provider for inclusion in monitoring statistics. Any issues or concerns should be discussed, as the Clinical Director of the primary Lead Provider has ultimate responsibility for the performance of the readers.
- Secondary sites must have a mechanism to provide feedback to reading radiologists. This will include missed cancers (non-concordant reads), and outcome of cases recalled to assessment.

Criterion 8.19: Each provider has staff who are employed to undertake the role of recruitment and retention

Elements

8.19.1 All recruitment and retention staff employed or subcontracted in the programme must be able to demonstrate a good understanding of the theory and practice of public health approaches.

8.19.2 Recruitment and retention staff employed in the programme will:

- advocate for community and individual understanding of screening at all levels
- promote an understanding of the need for, and the adoption of, community health development practices based on the Treaty of Waitangi and other health promotion models
- demonstrate the full range of knowledge and skills required for competent practice
- demonstrate accountability and effectiveness to a range of stakeholders
- model and support consultative ways of working with other key public health principles.

8.19.3 The provider ensures that recruitment and retention staff demonstrate competencies relevant to their role outlined in:

- *Nga Kaiakatanga Hauora mo Aotearoa: Health Promotion Competencies for Aotearoa–New Zealand*
- National Screening Unit competencies, including cultural competencies
- Ministry of Health public health competencies.

8.19.4 The provider ensures that recruitment and retention staff have a professional development plan and are supported in continuing education which:

- promotes and demonstrates sound public health principles and practice
- demonstrates an understanding of practice management systems and the primary care environment
- maintains professional knowledge and skills relating to breast cancer and screening in addition to health promotion
- develops and maintains cultural knowledge and skills
- identifies, develops and maintains community and professional networks
- involves critically reflecting on and evaluating their own work
- involves participation in peer review processes.

8.19.5 The provider must ensure there is access to accurate and current information to allow staff to fulfil their role.

8.19.6 Recruitment and retention staff in a leadership role:

- actively develop the recruitment and retention workforce
- demonstrate strategic leadership
- facilitate strategic regional coordination planning, including writing, implementing and evaluating recruitment and retention activities
- contribute to organisational decisions that promote public health practice
- facilitate robust critical debate and reflection on recruitment and retention activities
- access and provide opportunities for quality training for staff
- develop and implement quality assurance and quality improvement strategies.

8.19.7 Staff in training must:

- become familiar with the BSA resources, and develop a comprehensive understanding of the screening pathway and the range of health professional roles in the programme
- undertake an individualised orientation programme with the guidance of an experienced team member to observe and participate as their skills develop
- present health education sessions under guidance and supervision until deemed competent by an experienced team member.

Criterion 8.20: Each provider has qualified surgeons

Elements

8.20.1 The role of the surgeon commences during the assessment phase and continues through treatment and follow-up.

8.20.2 It is expected that surgeons in the programme will be closely involved with the assessment and surgical aspects of the diagnosis of and therapy for cancers detected. In addition, the surgeon will contribute to setting standards, and to audit and administrative aspects of the programme, as required.

8.20.3 BSA surgeons:

- have registration to practise in New Zealand with a current annual practising certificate
- hold a qualification in general surgery and are vocationally registered in general surgery with the Medical Council of New Zealand.
- participate in a re-certification programme in general surgery by their own college
- are credentialed to an accredited hospital
- are a member of BreastSurgANZ (Breast Surgeons of Australia and New Zealand);

Where a surgeon has an overseas qualification, accreditation will be considered on a case-by-case basis by the Surgeons Unidisciplinary Group and BSA clinical leader.

8.20.4 A surgeon in the programme, in addition to training and experience in general surgery should have specialist surgical expertise and a major interest in breast cancer management. Surgeons ensure they have acquired the necessary skills in the management of screen detected lesions by attending approved multidisciplinary training activities, such as those organised by the Royal Australasian College of Surgeons (RACS) and by spending time in a breast screening unit.

8.20.5 All surgeons must enter all cases of breast cancer into Breast Surgeons of Australia and New Zealand Quality Audit.

8.20.6 BSA surgeons should maintain an ongoing level of specialist expertise in diagnosis and management of screen detected breast lesions and must meet the Breast Surgeons of Australia and New Zealand requirements, which are:

- full participation in the Breast Surgeons of Australia and New Zealand Quality Audit, with information on entered cases assessed against the RACS average for a number of clinical indicators – the clinical indicators will be determined and reviewed by the executive of the section after consideration by an accreditation sub-committee
- meeting audit and CPD criteria as for full membership of Breast Surgeons of Australia and New Zealand – the CPD requirements include an ongoing commitment to CPD activities in breast disease.

Each year breast screening surgeons will be asked to complete three questions that specifically relate to breast disease. These questions will be included in the annual RACS CPD form distributed by the College. This form is to be made available to surgeons who are not fellows of the RACS for a fee. The questions will relate to:

- attendance at significant breast related CPD meetings (eg, Breast Surgeons of Australia and New Zealand lectures, ANZ Breast Cancer Trials Group Meetings, international breast meetings)

- attendance at specific breast related multidisciplinary meetings (including hospital meetings, BSA and private breast clinics)
- reading of journal articles related to breast disease or computer-based and/or distance learning
- attendance at 20 screening and/or symptomatic breast multidisciplinary meetings each year, which must include at least 10 screening meetings.

8.20.7 Surgical trainees may participate in BSA under supervision from an established BSA surgeon.

8.20.8 BSA surgeons are subject to regular peer review at the multidisciplinary meetings.

8.20.9 BSA surgeons receive regular reports on their compliance with programme quality targets and requirements.

8.20.10 BSA surgeons should receive all quality assurance monitoring reports on the breast screening programme and should participate in regular meetings to review these reports and programme performance in general.

8.20.11 It is expected that BSA surgeons will:

- participate in a regular multidisciplinary audit of quality assurance outcomes and morbidity data, including review of records for those women with interval cancers
- participate in the training of staff involved with the screening programme.

8.20.12 Any new surgical technologies or treatment procedures to be used in consultation for women in BSA should meet at least one of the following criteria:

- is being used in accordance with Breast Surgeons of Australia and New Zealand policy
- is being evaluated under the appropriate assessment process for New Zealand (for example, ASERNIPS)
- has ethics committee approval, or is part of research protocol.

Any new or innovative mode of treatment funded by BSA must be approved by BSA, or by any national body established with ethical approval, or by the local ethical committee.

Glossary

Term	Definition
Absolute sensitivity	A measure of cancer detection, with the number of carcinomas that were indeterminate, suspicious or malignant (B3, B4 or B5) on diagnostic needle biopsy expressed as a percentage of the total number of carcinomas sampled.
Active display area	The part of the display used for displaying images, applications and desktop.
Age-standardised rate	A summary rate of disease, or death, in a population, that takes into account differences in the age structure of different populations. Age-standardised rates are used because so many diseases are more common at some ages than others (usually more common as people get older). It gives a better indication than crude or age-specific mortality rates of the 'true' burden of disease in a population, presented as a single figure.
Assessment	All the follow-up examination and investigations arising from a woman's attendance for a screening mammogram, up to and including histological or cytological diagnosis. Assessment is a multidisciplinary process.
Assessment – level 1	Further mammographic views and/or magnification and/or ultrasound.
Assessment – level 2	Clinical examination and diagnostic percutaneous needle biopsy, as required.
Assessment – level 3	Diagnostic excision biopsy, either open surgical excision biopsy or vacuum-assisted excision, as required.
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.
Asymptomatic women	Women who do not have a symptom that may be due to breast cancer.
Atypical hyperplasia	A growth of abnormal duct epithelial cells in the breast. Women with this diagnosis are at an increased risk of developing breast cancer.
Axillary (armpit) dissection	A surgical procedure that incises the axilla (armpit) to identify and remove lymph nodes.
Background incidence rate	The expected incidence of a disease in the absence of screening. It is usually calculated from the incidence before screening began, combined with the change in incidence that was occurring before screening began, adjusted for other factors such as population changes.
Bad pixel map	A map (either an image or a table) which defines the position of all pixels of which the pixel value is not based on its own del reading.

National ID: 18571

Benign tumour	An abnormal growth that is not a cancer. A benign tumour is not capable of spreading and usually does not recur after being completely removed.
Biopsy	Removal of a sample of tissue from the body for examination under a microscope by a pathologist to assist with the diagnosis of a disease.
Bit-depth	The number of values that can be assigned to a pixel in a certain digital system, expressed in bits.
Breast awareness	Involves a woman knowing what her breasts are like normally, including understanding how her breasts change at different times of the month and as she grows older. A woman should consult a doctor if any changes that seem different from usual are noted.
Breast cancer	A pathologically proven malignant lesion that is classified as ductal carcinoma *in situ* or invasive breast cancer.
Breast cancer classification	Breast cancers are classified in terms of tumour type, grade, size, nodal involvement and stage, as specified in the current TNM Classification of Breast Cancer.
Breast cancer incidence rate	The rate at which new cases of breast cancer occur in a population. The numerator is the number of newly diagnosed cases of breast cancer that occur in a defined time period. The denominator is the population at risk of being diagnosed with breast cancer during this defined period, sometimes expressed in person-time.
Breast cancer mortality rate	The rate at which deaths of breast cancer occur in a population. The numerator is the number of breast cancer deaths that occur in a defined time period. The denominator is the population at risk of dying from breast cancer during this defined period, sometimes expressed in person-time.
Breast compression	The application of pressure to the breast during mammography so as to immobilise the breast and to present a lower and more uniform breast thickness to the X-ray beam, thereby maximising image quality and minimising radiation dose.
Breast conserving surgery	A type of surgery that involves removing a breast cancer, together with a margin of normal breast tissue. The whole breast is not removed.
Breast implant	A round or teardrop-shaped sack inserted into the chest in order to restore or enhance the shape of the breast. A breast implant may be filled with saline, silicone or a synthetic material.
Breast reconstruction	The formation or re-creation of breast shape after a total mastectomy.
BreastScreen Aotearoa (BSA)	New Zealand's free national breast-screening programme. The programme offers free mammograms every 2 years to eligible women aged 45–69 years who have no symptoms of breast cancer.
Cancer	A general term for a large number of diseases that all display uncontrolled growth and spread of abnormal cells. Also called a malignant tumour. Cancer cells have the ability to continue to grow, invade and destroy surrounding tissue, and leave the original site and travel via the lymph or blood systems to other parts of the body, where they may establish further cancerous tumours.

Cancer detection rate	The number of people who have cancer detected within a screening programme, usually expressed as a rate per 1000 people screened. The rate is influenced by the incidence of cancer in the population: all other things being equal, the higher the incidence in the background population, the higher the cancer detection rate will be. A low cancer detection rate signifies that more people will have to be screened to detect the same number of cancers.
Carcinoma	A cancer consisting of malignant epithelial cells that may infiltrate surrounding tissues and spread to other parts of the body via the blood or lymph system.
Code of Health and Disability Consumers' Rights	A regulation under the Health and Disability Commissioner Act 1994.
Complete sensitivity	A measure of cancer detection, with the number of carcinomas diagnosed as B5 on diagnostic needle biopsy, expressed as a percentage of the total number of carcinomas sampled.
Computer aided detection (CAD)	Software to aid the radiologists' detection of suspicious areas in the breast image.
Continuous quality improvement process	Ongoing collection and evaluation of information about important aspects of a process to identify and rectify problems, control unintended variations and identify and manage opportunities for improving the process.
Contrast to noise ratio (CNR)	See *Signal difference to noise ratio (SDNR)*.
Coverage rate	The percentage or proportion of eligible women screened by the programme, calculated as the number of women screened, divided by the number of those who are eligible by age and domicile according to the Census. The Māori coverage rate is calculated as the number of self-identified Māori women screened, divided by the number of Māori women, as identified by the Census.
Cytology	An examination of a sample of cells by a pathologist.
Del	Discrete element in a digital radiography detector.
Delay time	The time between when a cancer could be detected by a screening programme and the time it actually is detected.
Detection rate	See *Cancer detection rate*.
Detective quantum efficiency (DQE)	A function which describes the transfer of SNR as a function of spatial frequency when recording an X-ray image. The DQE gives the efficiency with which the device uses the available quanta.
Detector correction	A correction in digital radiography systems whereby the pixel value of the defective detector elements is reconstructed, and pixel values are corrected for individual detector element sensitivity variations and electronic gain of the read-out.
Diagnosis	The process of identifying a disease by its characteristic signs, symptoms and findings on investigation.
Diagnostic needle biopsy	Sampling of breast tissue with a needle to obtain a sample of tissue for examination by a pathologist to diagnose the lesion sampled.
Diagnostic open surgical excision biopsy	A surgical biopsy recommended for diagnostic purposes.

Digital Imaging and Communications in Medicine (DICOM)	A standard for the interconnection of medical digital imaging devices, developed and sponsored by the American College of Radiology and the National Electrical Manufacturers Association. It addresses the integration of information produced by various specialty applications. It also defines the network and media interchange services allowing storage and access to DICOM objects. The conversion of the digitised image information in an appropriate DICOM format is necessary in order to automatically hang the scanned images according to pre-defined hanging protocols, to enable calculation of the dose used for any examination, and also to enable storage, query and retrieval on the Picture Archiving and Communication System.
Digital radiography (DR)	Digital radiology technology using sealed units mounted on a radiography system, which captures X-rays and produces a digital image by sampling the X-ray image.
Direct supervision	The person supervising is physically present and actively involved in the process, takes ultimate responsibility and signs the report.
Ductal carcinoma in situ (DCIS)	A form of breast cancer, which spreads along the ducts of the breast but has not invaded the duct wall.
Early recall	Early recall occurs when a woman is asked to return earlier than the usual screening interval for a range of further investigations at an assessment centre.
Early rescreen	Early rescreen occurs when a woman is asked to return earlier than the usual screening interval for further screening mammography.
Edge enhancement	In relation to tools for digital mammography reading, this can improve edge differentiation and conspicuity of calcifications; however, it may also have the effect of amplifying noise and reducing the visibility of low-contrast objects. A range of levels of edge enhancement is normally provided.
Effectiveness	The effectiveness of an intervention is used to describe the impact in everyday practice.
Eligible age group	For BreastScreen Aotearoa this is currently 45–69 years.
Eligible population	The adjusted target population. In practice this is the target population, minus those who are excluded according to screening policy on the basis of eligibility criteria other than age, sex and geography (ie, women who have had breast cancer within the last 5 years are not eligible for screening in Breast Screen Aotearoa, nor are women currently breastfeeding).
Enrolment	This occurs when a woman gives her name, or allows her name to be given, to BreastScreen Aotearoa to begin the registration process.

Ethnicity	In New Zealand, ethnicity is based on self-identification. People can belong to more than one ethnic group. At different times in their lives, they may wish to identify with other groups. The current official (Statistics New Zealand) definition of an ethnic group is a social group whose members: • share a common origin • claim a common and distinctive history and destiny • possess one or more dimensions of collective and cultural individuality such as unique language, religion, customs, mythology or folklore feel a sense of unique collective solidarity.
Evidence-informed	• Decisions based on the best available evidence.
Extended assessment	The term 'extended assessment' has been used in the literature to include a range of practices. These include early rescreen, which occurs when a woman is asked to return earlier than the usual screening interval for further screening mammography; and early recall, which occurs when a woman is asked to return earlier than the usual screening interval for a range of further investigations at an assessment centre. Extended assessment may be offered as a suitable option when the lesion has a low probability of being cancer, is (or has proven) difficult to biopsy, and when re-biopsy would cause unnecessary morbidity to the woman. Within BreastScreen Aotearoa, only early recall is permitted.
False negative	A negative screening test in a person who does have the condition being screened for. People with false negative tests are falsely reassured that they do not have the disease in question, and as a result may delay seeking help if symptoms develop later.
False positive	A positive screening test in a person who does not have the condition being screened for. The higher the proportion of false positives, the more people are referred for unnecessary further assessment. A test with a false positive rate of 0% will mean that no one is referred for further assessment unnecessarily.
False positive rate for screening mammograms	The proportion of women who do not have cancer but are given an abnormal mammogram result (false positives), calculated as the number of false positive results divided by the total number of women screened.
Fine needle aspiration	The procedure to remove cells or fluid from tissues using a fine needle.
First screening episode of the programme	This is a woman's first mammogram in the screening programme. It should occur at least 12 months after a previous mammogram taken outside the screening programme.
Further assessment	These are the extra investigations carried out to clarify the nature of an abnormality detected at screening. In BreastScreen Aotearoa, this includes further mammograms, ultrasound and biopsy.
Ghost image	The residual of a previous image visible on the current image.

Grayscale	The number of different shades of levels of grey that can be stored and displayed by a computer system. The number of grey levels is directly related to the number of bits used in each pixel: 6 bits = 64 grey levels, 7 bits = 128 grey levels, 8 bits = 256 grey levels, 10 bits = 1024 grey levels, and 12 bits = 4096 grey levels.
Health Information Privacy Code 2020	This code of practice applies rules to agencies in the health sector to better ensure the protection of individual privacy. The rules in the Code are enforceable by complaining to the Privacy Commissioner and, if necessary, later to the Complaints Review Tribunal. The Code is available at the Privacy Commission's website.
Histology	The study of the structure and composition of tissues.
Identification rate	The percentage of eligible women who are identified for the purposes of being invited to the screening programme. This measure is calculated as: the total invitation roll at the end of a screening round, divided by the population of eligible women, as defined by the Census. This measure should also be calculated by the source or method of identifying eligible women.
Incidence	The number of new cases of a disease in a given population during a given period of time. Incidence is usually expressed per 100,000 people per year.
Initial screen	The screening episode of a woman who has never had a mammogram before, or who has not had a mammogram within the past 5 years within the Breast Screen Aotearoa programme.
Integrating the Healthcare Enterprise (IHE) framework	An initiative for developing a 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.

Interval cancer

A cancer that is diagnosed between a negative screen and the time the next screen would have occurred. In Breast Screen Aotearoa, this is a cancer diagnosed within two years of a negative screen. All interval cancers should be classified according to the standard classification. Interval cancers should also be categorised as:

Category	Radiological	Action warranted
Satisfactory	Normal or benign mammographic features	No reason to recall
Satisfactory, with learning points	Seen with hindsight, difficult to perceive. Not obviously malignant	May provide learning Not all readers would recall
Unsatisfactory	Appearance is obviously malignant	Should have been recalled All readers reviewing the images agree that they would recall.

Interval cancer rate

The number of interval cancers diagnosed in a given population during a given period of time. The interval cancer rate is usually expressed per 1000 people per year. The interval cancer rate should be calculated by 12-month intervals from the time of the last screen, and by using the entire time interval from the previous screening.

Invasive procedure

A procedure that involves the introduction of instruments into the body, or body cavities.

Invert

In relation to tools for digital mammography reading, the image grey scale is inverted (black to white / white to black), which may assist the visualisation of certain tissues.

Lead provider

One of eight service providers that contract with the National Screening Unit to provide breast-screening services. The Lead Provider has the overall responsibility for the provision of the programme in a defined geographical area, although it will not necessarily provide all components and may enter into subcontracts with other providers.

Lesion	An area of tissue damaged by disease or injury. Within BreastScreen Aotearoa, lesions are categorised as follows: • Category 1: normal/benign – return to routine rescreening • Category 2: probably benign – may need assessment to confirm • Category 3: indeterminate – needs assessment to elucidate • Category 4: probably malignant – requires assessment and a tissue diagnosis Category 5: malignant – requires assessment and a tissue diagnosis.
Magnify and roam	• In relation to tools for digital mammography reading, a selected area of the image is magnified (magnifying glass effect), and the magnified area can be moved about the image field.
Mammogram	A soft tissue X-ray of the breast, which may be used to evaluate a lump, or as a screening test in women with no signs or symptoms of breast cancer.
Mammography	The process of taking a mammogram.
Māori	The indigenous people of New Zealand.
Mastectomy	Surgical removal of the breast. A mastectomy may be total (all of the breast) or partial.
Measurement	In relation to tools for digital mammography reading, a measurement of distance in real space. The image is a projection image and therefore the measurement plane must be specified.
Modulation transfer function (MTF)	A function that describes how the contrast of image components is transmitted as a function of their spatial frequency content.
Mortality rate	The number of deaths from a disease in a given population during a given period of time. The mortality rate is usually expressed per 100,000 people per year.
Multidisciplinary	An approach whereby a range of health professionals work together as a team, with the woman as the focus.
National Screening Unit	A business unit of the Ministry of Health, which is responsible for BreastScreen Aotearoa, and the authority that funds the programme, its agents, nominee or successor.
Negative mammogram	A mammogram that has been classified as normal during a routine screening.
Negative predictive value	The proportion of those who are healthy among those with a negative test.
Negative screening result	The final diagnosis of 'no cancer' after screening and assessment procedures.
National Health Index (NHI)	A unique identifier allotted to people who have contact with health services in New Zealand. The NHI is administered by the New Zealand Health Information Service on behalf of the Crown.
Noise	Fluctuations in pixel values, which are unrelated to the imaged object. The standard deviation in a region of interest in the output image is taken as a measure of noise.

Non-operative diagnosis rate	The percentage of women diagnosed with cancer who have a confirmed diagnosis prior to any surgical procedure. Calculated as: the total number of women with a confirmed diagnosis prior to open surgery, divided by the total number of women with cancer diagnosed. This is a measure of the quality of the assessment part of the screening programme.
Number needed to screen (NNS)	The number needed to screen (NNS) is an easily understood measure of the absolute benefit of being screened, and is literally the number of people who would need to be screened (for a given period of time) in order to prevent a single event (ie, death from breast cancer). The NNS often varies markedly with risk factors such as age: the smaller the NNS, the fewer people who need to be screened to prevent an event (ie, death from breast cancer).
Open surgical excision biopsy rate	The percentage of screened women who undergo open surgical excision biopsy procedures. This is calculated as: the number of screened women who undergo open surgical excision biopsy procedures, divided by the total number of women screened.
Open surgical excision diagnostic biopsy	Surgery performed under a local or general anaesthetic in which a sample of tissue is removed to be examined by a pathologist.
Opportunistic screening	Screening outside an organised screening programme. The key feature that distinguishes opportunistic screening from screening within a screening programme is the lack of a quality process, including routine monitoring and evaluation. Opportunistic screening usually occurs when a person who is presenting to the health system for another reason is asked a question or offered a test in order to detect the presence or confirm the absence of a specific condition. Opportunistic screening may be organised to a greater or lesser degree. However, because there are no attendant quality processes, its safety, effectiveness and cost-effectiveness cannot be assessed and/or guaranteed.
Pacific women	Women of Pacific Island ethnic origin (eg, Tongan, Niuean, Fijian, Samoan, Cook Islands Māori and Tokelauan). Includes women of Pacific Island ethnic origin born in New Zealand as well as those born overseas
Pixel	A picture element, the smallest unit in the image.
Pixel value	A discrete value assigned to a pixel. In mammography systems the pixel value ranges from 1024 (10 bits) to 16,384 (14 bits), depending on the detector.
Population-based screening programme	A screening programme in which screening is systematically offered by invitation to a defined, identifiable population: this requires a means of identifying and inviting the target population (eg, through a population register).

Positive predictive value (PPV) of screening mammogram	The proportion of people having the outcome in question (ie, a cancer) if the screening test is abnormal, usually expressed as a percentage. The higher the positive predictive value, the more likely it is that the person has the outcome in question (ie, a cancer) when their test is positive. A screening test with a high positive predictive value is beneficial, since it will reduce the proportion of people having unnecessary further investigations. It is calculated as: the number of women with cancer and an abnormal mammogram result, divided by the total number of women with an abnormal screening mammogram result both with and without cancer.
Pre-operative diagnosis of cancer	A malignant result on needle biopsy (including both ductal carcinoma in situ and invasive cancer), which is consistent with suspicious or malignant imaging findings.
Percutaneous core needle biopsy	Sampling of breast tissue with a needle to obtain a tiny cylinder of tissue for examination by a pathologist.
Presentation value	The pixel value after value of interest look-up table (VOI LUT) or window width and window level settings have been applied.
Prevalent screen (changed to 'initial screen')[10]	The screening episode of a woman who has never had a mammogram before (as part of BreastScreen Aotearoa), or who has not had a mammogram within the past five years within the BreastScreen Aotearoa programme.
Primary class display device	A display device that is used for diagnosis, with $L_{max} \geq 450$ cd/m² when new and $L_{max} \geq 300$ cd/m² when in use LR is > 250.
Processed image	The image after image processing, ready for presentation on the display or printout.
Programme (the programme)	The National Breast Screening Programme, also known as BreastScreen Aotearoa.
Quality assessment	Performance measurement against standards.
Quality assurance	The detection of problems through external or internal inspection, and their correction through systematic activity.
Quality improvement	The prevention of problems and the control of unintended variations in processes through total quality management.
Radiotherapy	The use of radiation, usually X-rays or gamma rays, to kill tumour cells.
Raw image	See *Unprocessed image*.
Reference region of interest	The region of interest (≈ 4 cm² either circular or square) in which mean pixel values and standard deviation are measured. The centre of the region of interest is positioned 60 mm perpendicular to the chest wall edge of the table and centred laterally.
Referral to assessment	The referral of a woman in order to clarify a perceived abnormality detected at screening, by performing an additional procedure.
Referral to assessment rate	The number of individuals recalled to assessment, expressed as a proportion of all those screened.

[10] Ministry of Health 2002.

Region of interest (ROI)	In relation to tools for digital mammography reading, the ROI allows a specific region of the image to be selected. Numerical data referring to the ROI may be provided.
Routine rescreening	Routine rescreening is for women with a 'normal' screening mammogram, or who have been assessed as having 'no evidence of cancer' after assessment, who are re-invited for a repeat screening mammogram every two years until they are no longer eligible.
Screen-detected cancer	Any invasive breast cancer or ductal carcinoma in situ diagnosed during a screening episode.
Screening	The examination of asymptomatic people in order to classify them as likely or unlikely to have the disease that is the object of screening. The aim of screening is to detect disease before it is clinically apparent, and for this to improve the outcome for people with the disease.
Screening episode	A woman's attendances for screening and assessment relating to a particular round of screening. A screening episode is complete when a definitive diagnosis is made, or the woman is returned to routine screening. This includes extended assessments.
Screening interval	The fixed interval between routine screens, specific to the screening programme and dependent on the screening policy. In BreastScreen Aotearoa the screening interval is two years.
Screening pathway	The screening process from a participant's perspective. It includes: • an invitation to be screened • being given information about the purpose of the screening, the likelihood and possibility of false positive/negative results, the uncertainties and risks associated with the screening process, any significant medical, social or financial implications of screening for the particular condition or predisposition, and follow-up plans, including the availability of counselling and support services • being questioned or offered a test • having the test • receiving test results • assessment and diagnosis if the test is positive • possible treatment understanding that there are activities to monitor and evaluate at all of these stages.
Screening policy	• The specific policy of a screening programme, which dictates the targeted age and gender group, the geographic area to target, the screening interval, and other key features.
Secondary class display device	A display device used for viewing the images, but not for diagnosis, with specification L_{max} >170 cd/m², LR' is >100.

Sensitivity	The likelihood that a test will detect a cancer when one is present, calculated as the number with cancer detected during a screening episode (X) as a percentage of X plus the number with cancer detected within one year of a clear screen. The higher the sensitivity, the better the test is at detecting cancer. A test with a low sensitivity will miss a lot of cancers. A test with a sensitivity of 100% will detect all cancers present. It should be calculated for both the screening mammogram alone and for the screening programme (ie, both screening and assessment). Also see *Absolute Sensitivity* and *Complete Sensitivity*.
Signal difference to noise ratio (SDNR)	The SDNR is calculated for a specific test object (eg, 0.2 mm Al thickness on 40 mm PMMA). $\text{SDNR} = \frac{Mean\ pixel\ value(signal) - mean\ pixel\ value(background)}{\sqrt{\frac{std\ deviation(signal)^2 + std\ deviation(background)^2}{2}}}$
Signal to noise ratio (SNR)	The SNR is calculated for a specific region of interest as follows: $\text{SNR} = \frac{Mean\ pixel\ value - offset}{standard\ deviation}$
Site	The identified physical location at which BreastScreen Aotearoa services are provided.
Specificity	The likelihood that a test will exclude a cancer when one is not present, calculated as the number with true negative screening results (Y) as a percentage of Y plus the number of false positive screening results. The higher the specificity, the better the test is at excluding cancers when they are not present. A test with a low specificity will mean that a lot of people are referred for further assessment unnecessarily. A test with a specificity of 100% will mean that no one is referred for further assessment unnecessarily.
Staged assessment	Where a woman's assessment occurs on separate occasions over a number of sites. Staged assessment may be used in peripheral areas where a woman would be required to travel a considerable distance in order to access complete assessment services.
Standardised detection ratio (SDR)	A measure of cancer detection that takes into account what the age- specific incidence of breast cancer would be if no screening took place. BreastScreen Aotearoa detection rates are compared against the rates for the 'gold standard' Swedish Two Counties (S2C) Trial detection rates. The SDR is BreastScreen Aotearoa's surrogate mortality indicator that most closely approximates BreastScreen Aotearoa's potential mortality reduction rates.
Standard test block	A PMMA test object to represent approximately the average breast (although not an exact tissue substitute) so that the X-ray machine operates correctly under automatic exposure control and the dose metre readings may be converted into dose to glandular tissue. The thickness is 40 ± 3 mm, or as agreed by your medical physicist.
Statistics	In relation to tools for digital mammography reading, numerical data such as pixel count and histograms.

Stereotactic needle biopsy	A biopsy carried out while the breast is compressed under mammography. This technique is used when a mammographic abnormality is unable to be biopsied by alternative methods. A series of pictures locate the lesion, and information is entered into a computer. The computer calculates the three-dimensional coordinates of the lesion within the breast and helps position a needle-holder over the lesion. A needle is inserted into the lesion, and pieces of tissue are removed and sent to the laboratory for analysis.
Subsequent screen	Any screen that is not an initial screen.
Symptomatic women	Women reporting breast symptoms at the screening examination.
Technical recall rate	The number of women who have to return to a screening unit (either fixed or mobile) for further images to complete their screening episode, expressed as a percentage of the number of women screened.
Technical reject rate	The number of films rejected as a percentage of the number of films taken.
The Code	The Code of Health and Disability Consumers' Rights.
True negative	The screening test correctly identifies a person without the disease.
True positive	The screening test correctly identifies a person with the disease.
Tumour	An abnormal growth of tissue. A breast tumour may be: localised without potential to spread (benign), malignant and growing inside the milk ducts (DCIS), malignant and invading nearby tissues (invasive), or malignant and invading distant tissues (metastatic).
Ultrasound	The use of high frequency sound waves to study an organ or tissue. Ultrasound helps to determine if a breast abnormality is likely to be benign or malignant, and is particularly useful for distinguishing fluid-filled structures from solid lesions.
Under-screened women	Groups of women for whom there is evidence that they are less likely to be screened regularly.
Unprocessed image	The image of a DR system after flat-fielding and detector corrections but before other image processing has been applied. For a DR system the pixel value is, in general, related linearly to exposure. In CR systems the pixel value is usually logarithmically related to exposure. In the DICOM file the value of tag Pixel Intensity Relationship (0028, 1040) is 'for processing'. International Electrotechnical Commission (IEC) Maintenance Team (MT) 31 refers to the unprocessed image as 'raw data'.
Unscreened women	Women who have either never been screened or have not been screened for five years.
Vacuum-assisted excision	Removal of a lesion or an imaging with the aim of excising the lesion of concern. May be used as an alternative to an open surgical excision.
Value Of Interest Look-Up Table (VOI LUT)	This defines the (non-linear) transformation of pixel values into values meaningful for presentation (presentation values).

Window width/level	In relation to tools for digital mammography reading, the brightness/contrast of the image is altered to optimise visualisation of the data displayed.
Zoom	In relation to tools for digital mammography reading, the complete image is magnified; varying degrees of magnification may be provided.

References

ACR. 1999. *Stereotactic Breast Biopsy Quality Control Manual*. Reston, Virginia: American College of Radiology.

ACR. 2013. *Ultrasound Accreditation Programme*. Reston, Virginia: American College of Radiology. URL: www.acr.org.

Archives New Zealand. 2013. *Authority to Retain Digitised Public Records in Electronic Form Only*. Wellington: Archives New Zealand.

Barrows GH, Anderson TJ, Lamb JL, et al. 1986. Fine needle aspiration of breast cancer: relationship of clinical factors to cytology results in 689 primary malignancies. *Cancer* 58: 1493–98.

Durie M. 1998. *Whaiora: Māori Health Development*. Auckland: Oxford University Press.

Goodsitt MM, Witt S, Hykes DL, et al. 1998. Real-time B-mode ultrasound quality control test procedures: report of AAPM Ultrasound Task Group No. 1. *Medical Physics* 25: 1385–406.

Ministry of Health. 2002. Outcomes of the treatment provider data indicators review (TPDIR). Wellington: Ministry of Health.

Ministry of Health. 2004. *Ethnicity Data Protocols for the Health and Disability Sector*. Wellington: Ministry of Health.

Ministry of Health. 2013. *Guidance for Implementing High-quality Multidisciplinary Meetings*. Wellington: Ministry of Health.

National Breast and Ovarian Cancer Centre and Australian Cancer Network. 2008. *The Pathology Reporting of Breast Cancer: A guide for pathologists, surgeons, radiologists and oncologist*s (3rd edition). Surry Hills, NSW: National Breast and Ovarian Cancer Centre.

National Breast Cancer Tumour Standards Working Group. 2013. Standards of Service Provision for Breast Cancer Patients in New Zealand - Provisional. Wellington: Ministry of Health.

National Pathology Accreditation Advisory Council. 2009. *Requirements for the Retention of Laboratory Records and Diagnostic Material* (5th edition). Canberra, Australia: The Department of Health.

National Screening Unit. 2012. *National Screening Unit Retention and Disposal Schedule Appraisal Report: V11. Approved as DA539.*

NHSBSP. 2000. *Quality Assurance Guidelines for Radiographers*. Sheffield, UK: National Health Science Breast Screening Programme NHS Cancer Screening Programmes. Publication number 30.

NHSBSP. 2001. *Guidelines for Non-operative Diagnostic Procedures and Reporting in Breast Cancer Screening*. Sheffield, UK: National Health Science Breast Screening Programme. Publication number 50.

NHS Cancer Screening Programmes. 2007. *Good Practice Guide No 9: Reporting, recording and auditing B5 core biopsies with normal/benign surgery*. Sheffield, UK: National Health Science Breast Screening Programme.

RANZCR. 2001. *Position Statement on Teleradiology*. Sydney, NSW: Royal Australian and New Zealand College of Radiologists.

Further information

ACPSEM. 2007. *Interim Recommendations for a Digital Mammography Quality Assurance Programme*. Mascot: Australia: Australasian College of Physical Scientists and Engineers in Medicine.

ACR. 1999. *Mammography Quality Control Manual*. Reston, Virginia: American College of Radiology.

ACR–AAPM–SIIM. 2012. *Practice Guideline for Determinants of Image Quality in Digital Mammography*. Reston, Virginia: American College of Radiology, American Association of Physicists in Medicine and the Society for Imaging Informatics in Medicine.

ACR–AAPM–SIIM. 2012. *Technical Standard for Electronic Practice or Medical Imaging*. Reston, Virginia: American College of Radiology, American Association of Physicists in Medicine and the Society for Imaging Informatics in Medicine.

BCSPAG. 1995. *A Summary of Interim Recommendations to the Director-General of Health from the Breast Cancer Screening Policy Advisory Group*. Recommendation 6.

Blanks S, Moss R. 1996. Monitoring the performance of breast screening programmes. *Journal of Medical Screening* 3(2): 79–84.

BreastScreen Australia. 2013. *National Accreditation Standards*. Canberra, Australia: BreastScreen Australia.

Britton PD, McCann J. 1999. Needle biopsy in the NHS Breast Screening Programme 1996/1997: how much and how accurate? *The Breast* 8: 5–11.

Brunton M, Jordon C, Campbell I. 2005. Anxiety before, during, and after participation in a population-based screening mammography programme in Waikato Province, New Zealand. *New Zealand Medical Journal* 118(1209).

DICOM. 2005. *DICOM Strategic Document v5.1*. Rosslyn, Virginia: Digital Imaging and Communication in Medicine.

Heggie J, McLean ID, Herley J, et al. 2012. *ACPSEM Position Paper: Recommendations for a Digital Mammography Quality Assurance Programme, v3*. Mascot, Australia: Australasian College of Physical Scientists and Engineers in Medicine.

HQSC. 2012. *New Zealand Health and Disability Services: National reportable events policy 2012*. Wellington: Health Quality and Safety Commission New Zealand.

Health and Disability Services Act 1993, section 25.

Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996.

Health (Retention of Health Information) Regulations 1996, sections 5 and 6(1).

HPFNZ. 2012. *Nga Kaiakatanga Hauora mo Aotearoa: Health Promotion Competencies for Aotearoa–New Zealand*. Auckland : Health Promotion Forum of New Zealand – Runanga Whakapiki ake i te Hauora o Aotearoa.

IARC. 2002. *Breast Cancer Screening*. Lyon: International Agency for Research on Cancer, WHO.

IARC. 2002. *IARC Handbooks of Cancer Prevention: Volume 7 – Breast cancer screening*. Lyon: International Agency for Research on Cancer, WHO.

Ministry of Health. 2002. *Reducing Inequalities in Health*. Wellington: Ministry of Health.

Ministry of Health. 2003. *New Zealand Health and Disability System Quality Improvement Strategy*. Wellington: Ministry of Health.

Ministry of Health. 2012. *Cancer Patient Survival Change over Time Update*. Wellington: Ministry of Health.

Ministry of Health. 2012. *Cancer: Selected sites 2009, 2010, 2011*. Wellington: Ministry of Health.

Ministry of Health. 2013. *Guide to Eligibility for Publicly Funded Personal Health and Disability Services in New Zealand*. Wellington: Ministry of Health. URL: www.health.govt.nz/new-zealand-health-system/eligibility-publicly-funded-health-services/guide-eligibility-publicly-funded-health-services-0 (accessed May 2013).

Ministry of Health, University of Otago. 2010. *The Burden of Cancer: New Zealand 2006*. Wellington: Ministry of Health.

National Health Committee. 2003. *Screening to Improve Health in New Zealand: Criteria to assess screening programmes*. Wellington: National Health Committee.

National Panel to Review Breast Biopsy Errors. 2012. *Report of the National Panel to Review Breast Biopsy Errors*. Wellington: Ministry of Health

NEMA. 2006. *Manufacturers of Displays and Workstations Labeled for Final Interpretation and Template for Manufacturers of Hardcopy Output Devices Labeled for Final Interpretation in Full Field Digital Mammography*. Rosslyn, Virginia: National Electrical Manufactures Association.

National Screening Unit. 2005. *Improving Quality: A framework for screening programmes in New Zealand*. Wellington: National Screening Unit.

National Screening Unit. 2010. *National Screening Unit: Incident management*. Wellington: National Screening Unit.

National Screening Unit. 2010. *National Screening Unit: Strategic plan 2010 to 2015*. Wellington: National Screening Unit.

New Zealand Guidelines Group. 2009. *Management of Early Breast Cancer: Evidence-based best practice guidelines*. Wellington: New Zealand Guidelines Group.

New Zealand Health Information Service. *Guide to Data Requirements*. Wellington: Ministry of Health.

NHSBSP. 2005. *Guidelines for Pathology Reporting in Breast Disease*. Sheffield, UK: National Health Science Breast Screening Programme. Publication number 58.

NHSBSP. 2005. *Quality Assurance Guidelines for Mammography*. Sheffield, UK: National Health Science Breast Screening Programme. Publication number 63.

NHSBSP. 2005. *Quality Assurance Guidelines for Medical Physics Sciences*. Sheffield, UK: National Health Science Breast Screening Programme. Publication number 33.

NHS Cancer Screening Programmes. 2007. *Good Practice Guide No 9: Reporting, recording and auditing B5 core biopsies with normal/benign surgery*. Sheffield, UK: NHS Cancer Screening Programmes.

ORS. 2010. *Code of Safe Practice for the Use of X-rays in Medical Diagnosis (CSP-5)*. Christchurch: Office of Radiation Safety.

Perry NM, Broeders M, de Wolf C, et al (eds). 2006. *European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis* (4th edition). Luxembourg: European Communities.

RANZCR. 2012. *Guidelines for Quality Control Testing for Digital (CR DR) Mammography, v 3*. Sydney, NSW: Royal Australian and New Zealand College of Radiologists.

RANZCR. 2012. *Standards of Practice for Diagnostic and Interventional Radiology, v 9.2*. Sydney, NSW: Royal Australian and New Zealand College of Radiologists.

Skegg DC, Paul C, Benson-Cooper D, et al. 1988. Mammographic screening for breast cancer: prospects for New Zealand. *New Zealand Medical Journal* 101: 531–3.

Wells CA. 1995. Quality assurance in breast cancer screening cytology: a review of the literature and a report on the UK National Cytology Scheme. *European Journal of Cancer* 31A: 273–80.

Wells CA, Perera R, White FE, et al. 1999. Fine needle aspiration cytology in the UK Breast Screening Programme: a national audit of results. *The Breast* 8: 261–6.

WHO. 1986. *Ottawa Charter for Health Promotion: First International Conference on Health Promotion.URL: http://www.who.int/healthpromotion/conferences/previous/ottawa/en/ (accessed May 2013)*.

Appendices

Abbreviations used in the appendices

ACPSEM	Australasian College of Physical Scientists and Engineers in Medicine
ACR	American College of Radiology
AEC	Automatic exposure control
Al	Aluminium
AS	Absolute sensitivity
B+F	Base and fog
BSA	BreastScreen Aotearoa
BreastSurgANZ	Breast Surgeons of Australia and New Zealand
CC	Cranio-caudal
CNR	Contrast to noise ratio
COV	Coefficient of variation
CPD	Continuing professional development
CS	Complete sensitivity
DD	Density difference
DDP	Default display protocol
DICOM	Digital Imaging and Communications in Medicine
Dmax	Maximum density
DMCX	Dimethoxychromenoxanthenium
Dmin	Minimum density
DR	Digital radiography
DRS	Director of Radiation Safety
ESAK	Entrance surface air Kerma
F+	False positive
FRACS	Fellow of the Royal Australasian College of Surgeons
FRANZCR	Fellow of the Royal Australian and New Zealand College of Radiologists
FRCPA	Fellow of the Royal College of Pathologists of Australasia
GP	General practitioner
GP/PCP	General practitioner / primary care provider
HVL	Half value layer
kVp	Kilovoltage peak
LCC	Left cranio-caudal
LMLO	left medio-lateral oblique

LMP	Licensed medical physicist
LUT	Look-up table
lp/mm	Line pairs per millimeter
MAP	Mammography accreditation phantom
mAs	Milliampere seconds
MD	Mid density
MDT	Multidisciplinary team
MGD	Mean glandular dose
mGy	milligray
MIQ	Mammographic image quality
Mo	Molybdenum
MPV	Mean pixel value
MIT	Medical imaging technologist
NHI	National Health Index
NZMC	New Zealand Medical Council
OD	Optical density
PACS	Picture Archiving and communication system
PMMA	Poly(methyl methacrylate)
PV	Predictive value
QAP	Quality assurance programme
QC	Quality control
RANZCR	Royal Australian and New Zealand College of Radiologists
RCC	Right cranio-caudal
RCPA	Royal College of Pathologists of Australasia
Rh	Rhodium
RMLO	Right medio-lateral oblique
ROI	Region of interest
S#	“S” value /
SD	Standard deviation
SDNR	Signal difference to noise ratio
SID	Source to image distance
TG18	Technical Group 18
UDG	Unidisciplinary group
VOI LUT	Value of interest look-up table
W	Tungsten

Appendix 1: Known barriers to screening

These barriers include, but are not limited to:

- health literacy
- costs associated with attending appointments, including opportunity costs
- shyness/whakamā
- concern about the health professional's attitude to a woman's sensitivity about her body
- previously painful or unpleasant experiences
- fear of having cancer
- access to public transport
- child-care availability
- clinic opening hours
- distance to providers.

Appendix 2: Communication matrix and key messages

Table B.1: Communication requirements in BSA

Scenario	Contact	Within	Method
Appointment confirmation	Woman	Five working days prior to appointment	By telephone, letter, SMS/text or email
Did not attend screening appointment	Woman and/or GP/PCP	Woman – 10 working days of appointment GP – after three appointments not attended	By telephone and follow-up letter/email
Requests not to be part of the screening programme	GP/PCP		By letter
Negative screening results	Woman	10 working days of screen date	By letter
Negative screening results	GP/PCP	10 working days of screen date	By letter – by mail or electronic delivery
Screen-detected abnormalities recall for assessment	Woman	Following the final reading of the mammogram and offered appointment within 15 working days of final screening mammogram	By telephone and follow-up letter
Screen-detected abnormalities recall for assessment	GP/PCP	As soon as possible following the final reading of the mammogram	Letter – by electronic delivery
Assessment appointment confirmation	Woman	1–2 working days before assessment	By telephone or text/email
Did not attend assessment appointment	Woman and GP/PCP	Woman – one day (next working day) GP – after three attempts	By telephone and follow-up letter
Diagnosis of cancer	Woman	Informed at results clinic	Face-to-face consultation
Diagnosis of cancer	Women (rural or provincial)	If requested, informed by their GP who must have spoken with a BSA radiologist or surgeon	Face-to-face consultation
Diagnosis of cancer	GP/PCP	Immediately after speaking with the woman	Telephone and letter

Key messages for BreastScreen Aotearoa

- The risk of developing breast cancer increases with age.
- Free mammograms (breast X-rays) are available for women aged 45 to 69 years through the National Breast Screening Programme (BreastScreen Aotearoa).
- Screening mammograms detect breast cancer before you can feel or notice anything unusual.
- Early detection and treatment can save lives.
- Mammograms need to be repeated every two years.
- Most women who have two-yearly mammograms will be informed they have no evidence of breast cancer.
- Most women who develop breast cancer have no relatives with the disease.
- Women of any age who feel or notice anything unusual about their breast should seek advice from their doctor.

Appendix 3: Proforma letters and forms

The following pro forma letters and forms cover:

- consent for mammography
- women with implants
- assessment
- use of information notification
- technically inadequate result
- results of screening.

Deviation from these standard texts should be checked with the BSA Clinical Leader.

Consent for mammography

Scenario

Written consent is required prior to the first screening mammogram. This is to ensure each woman has been given adequate information and has had the opportunity to ask questions and feel they are fully informed about the procedure, the risks and benefits of a screening mammogram, and the possible outcomes of participation in the programme.

Written consent must be asked for as part of the registration process, but should be on a separate form so that the consent process, the registration and notification about the use of information are not confused.

Standard text

BreastScreen Aotearoa needs to ensure that you agree to the following before you have a breast-screening mammogram as part of the free national programme. If you have any concerns regarding this, please telephone us so we may discuss these with you, or if you prefer, telephone your General Practitioner (GP) or Primary Care Provider to discuss further.

I [consent/wish/agree*] to have a screening mammogram. I have been provided with information about the screening programme. I understand that mammograms do not find all breast cancers nor do they prevent breast cancer.

I authorise BreastScreen Aotearoa to obtain relevant images and/or clinical information regarding any mammograms or breast procedures I have had or will have elsewhere. This will enable a more accurate assessment of my mammograms and contribute to monitoring the quality of the programme.

Signed:
Date:

* Providers may use any such wording.

Women with implants

Scenario

This form may be used to record the informed consent to screening of a woman who has (a) breast implant(s) in place. Women should be given appropriate information so that they understand the additional risks associated with screening mammography where implants are in place.

These include a greater risk of cancer not being detected because of reduced coverage of breast tissue, and a minimal risk of rupture of the implant at mammography. Women should also be informed that they will need more views and what will happen if damage to the implant is discovered. As the implant ages there is an increased likelihood of unsuspected rupture, and mammography may indicate this.

Standard text

BreastScreen Aotearoa needs to ensure that you agree to the following before you have a breast-screening mammogram as part of the free national programme. If you have any concerns regarding this, please telephone us so we may discuss these with you, or if you prefer, telephone your General Practitioner (GP) or Primary Care Provider to discuss further.

I have a breast implant(s) in place, and I understand that while the Medical Imaging Technologists (MITs) have been trained in the appropriate examination methods to obtain the best possible views of the breast, implants can interfere with the detection of early cancer and may 'hide' suspicious lesions.

I also understand that since the breast is compressed during mammography, it is possible, although very unusual, for an implant to rupture.

Signed:
Date:

Assessment

Scenario

This form may be used to record a woman's informed consent to an assessment procedure that does not involve an anaesthetic.

Standard text

BreastScreen Aotearoa needs to ensure that you agree to the following before you have a breast-screening assessment procedure as part of the free national programme.

I understand that my mammogram findings require further investigation.

I have had adequate opportunity to ask questions about the procedure(s) and I have been given the information I require.

I agree to the following assessment procedure(s):

Signed:
Dated:

Use of information notification

Scenario

The following text is included in the general pamphlet, which must be provided to all women enrolling in the programme. It ensures compliance with the legal requirement to notify women, and therefore additional notification on enrolment forms is no longer required.

Standard text

As with all health services, your rights are protected by the Code of Health and Disability Services Consumers' Rights.

The programme also has a legal obligation under the Health Information Privacy Code. Your clinical record and breast X-rays will be kept confidential and stored securely.

To assess the effectiveness and quality of the programme, BreastScreen Aotearoa wishes to notify you that the following information may be collected:

- any information relating to the treatment you have received for your breasts in the past and may require in the future
- any relevant clinical information, your mammograms, and reports.

The information will be collected from public and private providers by the Ministry of Health or its agents; for example, another entity designated by the National Screening Unit or BreastScreen Aotearoa, the NZ Health Information Service or the Cancer Registry through your National Health Index number (NHI).

As a result of collecting this information, your mammograms will be able to be assessed more accurately, BreastScreen Aotearoa will be able to provide you with any necessary follow-up assessment, and you will be invited to attend your next mammogram.

You will receive more information about your rights when you attend a BreastScreen Aotearoa centre.

Technically inadequate result

Scenario

Women whose mammography was technically inadequate but cannot be improved upon (eg, due to physical immobility problems) should be sent a normal result letter including the following standard text or similar approved wording.

Standard text

Due to problems with positioning, this examination does not show all the breast tissue. However, there was no evidence of breast cancer in the areas imaged. Despite these limitations, continued screening is recommended. Accordingly, we will recall you for a further screen in two years' time.

Results of screening

Scenario

The following results letters should be sent to all women and their GP/PCP (if the woman consents) as appropriate for the result.

Note: any signatory to a clinical report is deemed to have reviewed the clinical information (eg, films) and agreed with the content of the report. Clearly this is not the case for every set of mammography films for which a generic normal result letter is sent out.

Generic letters do not require the signature of the Clinical Director in addition to their name. Lead Providers who are already appending a signature to these letters may continue to do so.

No evidence of cancer was detected (return to routine screening): Letter to woman

Your mammogram (breast X-ray) has been reported by two qualified radiologists (doctors who report mammograms) and I am pleased to inform you that they found NO EVIDENCE OF BREAST CANCER.

Mammography can miss cancers. It is therefore important to see your doctor promptly if you notice any changes in your breasts.

Women who have a regular two-yearly mammogram reduce their chances of dying from breast cancer.

BreastScreen Aotearoa, the National Breast Screening Programme, provides free screening mammography every two years for women aged 45 to 69 years.

You will be recalled in two years' time if you are still eligible. Should you change your address, please notify us to ensure that your next appointment for breast screening reaches you.

Please consult your doctor if you have been previously advised to have more frequent breast screening.

No evidence of cancer was detected (return to routine screening): Letter to GP

[Name's] mammogram has been reviewed by two qualified radiologists and they found NO EVIDENCE OF BREAST CANCER.

Mammography can miss breast cancers. If she does report a breast symptom, further investigations may be required, and we would appreciate being notified of the results.

Your patient will be informed of this and advised that BreastScreen Aotearoa, the National Breast Screening Programme, provides free screening mammography every two years for women aged 45 to 69 years. Your patient will be recalled in two years if she is still eligible.

No evidence of cancer but has a symptom (return to routine screening with symptom): Letter to woman

When your recent mammogram (breast X-ray) was performed, either you mentioned a change in your breast or the radiographer who performed your mammogram noticed a possible change.

Results of your mammogram have been reported by two qualified radiologists (doctors who report mammograms). We are pleased to inform you that they found NO EVIDENCE OF BREAST CANCER.

Although there was no evidence of breast cancer, due to the possible change that was noticed in your breast PLEASE SEE YOUR DOCTOR WITHOUT DELAY. This is important because not all breast cancers show up on a mammogram. Your doctor will advise you if further care is required.

BreastScreen Aotearoa, the National Breast Screening Programme, provides free screening mammography every two years for women aged 45 to 69 years. Breast screening is for women who are well and have no symptoms.

You will be recalled in two years' time if you are still eligible. Should you change your address, please notify us to ensure that your next appointment for breast screening reaches you.

No evidence of cancer but has a symptom (return to routine screening with symptom): Letter to GP

[Name's] mammogram has been reviewed and reported by two qualified radiologists and there is NO EVIDENCE OF BREAST CANCER.

However, your patient mentioned a symptom, or the radiographer who performed the mammogram noticed a possible abnormality at the time of her recent screening mammogram.

Please arrange an appointment to see your patient and review her breast symptoms and/or changes in her breast. It is recognised that a normal screening mammogram does not completely exclude breast cancer.

Your patient may require further mammography, ultrasound, or surgical opinion and these are not covered by BreastScreen Aotearoa in the presence of a normal screening mammogram. BreastScreen Aotearoa has advised this woman to consult you.

BreastScreen Aotearoa, the National Breast Screening Programme, provides free screening mammography every two years for women aged 45 to 69 years. Your patient will be recalled in two years if she is still eligible.

Appendix 4: National screening protocols

Protocol for imaging women with breast implant(s)

Objective

To produce high-quality mammograms and maximise coverage of breast tissue in women with breast implants.

Rationale

Mammographic screening is more difficult in women with breast implants and requires additional mammographic views. Despite extra views, an unknown portion of breast tissue will not be imaged.

Screening versus diagnosis

Mammography is the screening procedure of choice, and the normal screening interval applies as for the current eligible age group.

When making an imaging appointment for a woman with implants, the screening unit should be made aware of the implants so that they can allow additional time for mammography.

Clinical and ultrasound examinations of the breast are diagnostic procedures and should be reserved for symptomatic women or for assessment of mammographic abnormalities.

Although ultrasound is sometimes used to assess the integrity of an implant prior to mammography, it has a low negative predictive value when used for this purpose.

Timetabling

Processes should be in place to identify women with breast implants at the initial contact to enable appropriate scheduling. Mammography in these women requires additional time and mammographic expertise.

Consent

Specific informed consent must be obtained, usually by the MIT performing the examination. Women should be given appropriate information, so they understand the additional risks associated with screening mammography where implants are in place. These include a greater risk of cancer not being detected because of reduced coverage of breast tissue, and a minimal risk of rupture of the implant at mammography.

Women should also be informed that they will need more views and what will happen if damage to the implant is discovered. As the implant ages there is an increased likelihood of unsuspected rupture, and mammography may indicate this.

Mammographic views

Standard four views

This is medio-lateral oblique and cranio-caudal of both breasts with the implants in place. These views enable the posterior part of the breast to be evaluated.

Modified positioning technique

The implant is displaced posteriorly against the chest wall and the breast tissue is pulled over and in front of the implant. This allows compression of the breast tissue with improved visualisation.

90˚ medio-lateral view

The true lateral view of the breast may be included as well as the medio-lateral oblique view, especially if the implant is rigidly encapsulated.

Spot compression views

Compression spot views may also be necessary to image all of the breast tissue satisfactorily.

Photocell AEC sensor (CR only)

The photocell may need to be repositioned or a manual exposure used to obtain correct exposure. For any one examination, five views of each breast may be necessary, thus increasing the radiation dose.

After screening, if the examination has failed to show sufficient breast tissue to be of diagnostic value, the woman must be informed of this and advised to exit the programme and discuss her options with her GP/PCP. The outcome must be documented, and appropriate outcome data provided to BreastScreen Aotearoa.

Mastectomy protocol

Women who have had a mastectomy with or without reconstruction are eligible for routine two-view mammography of the unaffected breast, within the programme, after five years following the diagnosis of breast cancer. Routine screening of the mastectomy flap is not indicated.

Appendix 5: Mammographic image quality (MIQ) classification

Using the MIQ classification

All mammographic images are to be assessed for acceptability prior to reading. The tool for this assessment is the mammographic image quality (MIQ) criteria, as stated below in Table F.1.[11] This assessment may be made by the MIT performing the mammogram or by another MIT with the appropriate level of competency.

The MIQ criteria apply to all images, irrespective of the subject, from easy to extremely difficult anatomical types.

Regular monthly peer review should also be carried out using the MIQ criteria. The appropriate sample size provides a balance of these representations. A random sample is used to represent the total unit output, so the size of that sample must be determined by complex statistical arguments to ensure a valid result. The sample sizes required to give an acceptable accuracy level (± 5%) are given in Table F.2 and the target levels in Table F.3.

Best practice is >80% of women screened have four or fewer images taken.

Table F.1: Mammographic image quality (MIQ) classification

Excellent images	Good images
Maximum breast tissue imaged: • cranio-caudal position • breast and nipple positioned centrally • nipple in profile • medial aspect shown • as much axillary tail as possible • pectoral muscle shadow at chest wall	Maximum breast tissue imaged: • nipple profiled in one view only Cranio-caudal position: • as for Excellent category, except pectoral muscle not shown but breast tissue imaged well back to chest wall.
Medio-lateral oblique position: • pectoral muscle shadow to nipple level • pectoral muscle at appropriate angle • nipple in profile • infra-mammary angle clearly demonstrated.	Medio-lateral oblique position: • pectoral muscle well demonstrated (but not meeting Excellent criteria) • infra-mammary angle clearly demonstrated.
Correct annotation clearly shows: • woman's identification label • positioned markers • date of examination	Correct annotation clearly shown
Appropriate exposure	Appropriate exposure
Appropriate compression	Appropriate compression
Absence of movement / geometric blur	Absence of movement / geometric blur
Correct processing	Correct processing
Absence of artefacts	Artefacts – a minor degree will be acceptable
Skin fold free	Skin folds (not obscuring breast tissue) to a minor degree
Symmetrical images	Asymmetrical images – to a minor degree will be acceptable

[11] NHSBSP 2000.

Moderate images	Inadequate images
Maximum breast tissue imaged: • nipple profiled in one view only Cranio-caudal position: • as for Good category Medio-lateral oblique position: • pectoral muscle well demonstrated • infra-mammary angle not clearly • demonstrated, but minor tissue overlap	Any of the following criteria will determine inadequate imaging: • part of breast not imaged
Correct annotation, clearly shown	Inadequate identification/annotation
Appropriate exposure	Incorrect exposure
Appropriate compression	Inadequate compression
Absence of movement / geometric blur	Movement / geometric blur
Correct processing	Incorrect processing
Minimal artefacts, but not obscuring breast tissue Skin folds but not obscuring breast tissue	Overlying artefacts

Table F.2: Required sample size to give accuracy of ±5% for different sizes of screening unit

Average monthly examinations	Required monthly sample size
250	125
500	150
750	200
1000 and above	250

Measurements must be followed by analysis and comparison with the performance targets given below as well as with previous MIQ results.

Table F:3: MIQ classification target levels

Classification	Target level (% appraised)
Excellent	5%
Excellent and Good	>70%
Moderate	<27%
Inadequate	<3%

Analysis must be followed by feedback. It is imperative that results, recommendations and feedback are communicated promptly to the MITs performing the imaging.

Appendix 6: Symptomatic women

Signs and symptoms

Significant signs and symptoms are:

- a new lump or thickening (a lump that the woman can feel that has arisen in the last 12 months)
- puckering or dimpling of the skin
- any change in one nipple such as:
  - a turned-in nipple
  - a watery or bloodstained discharge which persists without squeezing.

When symptoms are identified prior to attendance

If the woman indicates the presence of significant signs and symptoms, it is then appropriate for the booking staff to recommend that the woman make an appointment to see her GP/PCP to have this assessed prior to enrolment, unless:

A new lump or thickening that can be felt now:	has been present and unchanged for 12 months or more *or* was previously investigated by mammogram/ultrasound +/- biopsy and found to be benign
Puckering or dimpling of the skin:	has been present and unchanged for 12 months or more *or* was previously investigated and found to be benign
One nipple turned in:	which has been present and unchanged for 12 months or more *or* was previously investigated and found to be benign
Nipple discharge:	which has been present and unchanged for 12 months or more *or* which is bilateral (both sides) and *not* blood stained or it persists without squeezing

If the woman has any old mammograms, staff will request that they be brought to screening.

Signs and symptoms identified during the screening visit

Where signs or symptoms are identified that may require further investigation, the woman and her nominated GP/PCP (provided consent has been obtained) must be notified in writing, using the standard letters in Appendix 3.

Where the result of the screening mammogram is negative the provider, with the woman's consent, will refer her (in order of priority) to:

- her GP/PCP
- a specialist diagnostic clinic through the public hospital service, or
- a private provider.

The National Screening Unit recommends the first referral option is the most appropriate option for these women unless there are specific reasons for not doing so. The reasons for not doing so should be documented in the woman's file.

Women who declare they have breast pain, either in writing or verbally, must be given the BSA breast pain pamphlet.

Appendix 7: Legislation and standards

Legislation and standards that must be complied with include:

- Building Act 1991
- Building Regulations 1992
- Cancer Registry Act 1993
- Cancer Registry Regulations 1994
- Code of Practice for Information Security Management (AS/NZS ISO/IEC17799:2006)
- Health Act 1956, and any subsequent amendments to the Act
- Health and Disability Commissioner Act 1994, and any subsequent amendments to that Act
- Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996
- Health and Disability Sector Standards Health Information Privacy Code 2020 (NZS 8134:2001)
- Health and Disability Services (Core) Standards (NZS 8134:2008)
- Health Network Code of Practice (SNZ HB 8169:2002)
- Health Practitioners Competence Assurance Act 2003
- Health Records Standard (NZS 8153:2002)
- Health (Retention of Health Information) Regulations 1996
- Health and Safety in Employment Act 1992Human Rights Act 1993
- Infection Control (NZS 8142:2000)
- Management of Clinical and Related Wastes (AS/NZS 3816:1998)
- Medical Electrical Equipment (AS/NZS 3200.1.3:1996)
- Medical Radiation Technologists Regulations 1995
- Medicines Act 1981
- Medicines Regulations 1984
- New Zealand Public Health and Disability Act 2000
- Official Information Act 1982
- Privacy Act 2020
- Public Records Act 2005
- Risk Management – Principles and guidelines (AS/NZS ISO 31000:2009)
- Radiation Safety Act 2016
- Radiation Safety Regulations 2016.

Appendix 8: Site accreditation for digital mammography

All sites must be accredited for digital mammography by the NSU. This is to ensure:

- the equipment complies with the standards and has passed acceptance testing
- appropriate digital training of MITs, medical physicists and radiologists prior to screening BSA women
- standardised default display protocols (DDP) for digital mammographic images for radiologist reading of screening mammograms are in place
- protocols have been developed for failsafe acquisition, storage, retrieval, transmission and reporting of images
- protocols are in place to ensure documentation and compliance with (a) digital mammography quality standards and (b) vendor-specific quality assurance activities, and staff are trained to undertake appropriate corrective actions.

Purchasing and commissioning of digital mammography equipment

The designated medical physicist must be involved in the selection process of all digital mammography equipment intended for use by BSA. All digital mammography equipment, including biopsy equipment, must undergo acceptance testing by an authorised BSA medical physicist prior to the commencement of routine breast screening (in accordance with Appendix 13: Recommendations for Medical Physicist Testing at Acceptance or Equipment Upgrade) and for routine six-monthly testing (refer to Appendix 9: Recommendations for Medical Physicist Testing of Digital Mammography Units).

Mammography image acquisition subsystems must:

- be approved by MedSafe
- be in use in other organised breast screening programmes, and/or
- be permitted for use in BSA at this time, and
- comply with the dose and image quality standards in the RANZCR requirements, but others will be considered by the NSU on a case-by-case basis in collaboration with medical physicists and Clinical Directors.

The Radiology Information System (RIS) must be capable of:

- registration of women
- management of the woman's invitation
- management and rescheduling of individual screening appointments
- client registration in the screening unit
- generation of bar codes and labels that are needed at the screening visit
- recording of the client questionnaire
- recording of MIT comments or graphical information such as markings and annotations of breast sketches
- recording of reading results

- recording of consensus conference results
- generation of recall and result information letters
- recording of performed procedures and results of further assessment in case of recall
- recording of pathological information in case of biopsies.

Display acceptance testing

All displays must pass acceptance testing by the designated BSA medical physicist prior to use within BSA. In order to test the performance of displays, the TG18 test patterns must be available, and the following conditions need to be met.

- The correct version of these tools must be matched to the spatial resolution of the display under evaluation.
- The patterns must be displayed at full resolution (one display pixel for each pixel in the digital image).
- A suitable photometer with a narrow acceptance angle should be used for the luminance measurements.

Appendix 9: Recommendations for medical physicist testing of digital mammography units

Procedure	Performance requirements/guidelines	Routine testing guidelines	Acceptance and additional tests
Mammography unit assembly evaluation	• Correct and safe function of system components • Thickness display accuracy within ± 5 mm • Reproducible to 2 mm Note: Flexi paddles will not comply (manufacturer recommendation varies ~ 11–12 mm for flexi paddles). Verify DICOM image header for correct display of parameters.	• Confirm function of all motorised components, warning lights, displays, etc. • Evaluate system for any miscellaneous safety risks etc. • DICOM verification required after software upgrades.	As per routine tests.
Spatial resolution	Resolution should be greater than 5 lp/mm but may be limited by the Nyquist to a slightly lower value.	Measure using line pair test pattern, as per RANZCR.	Establish baseline values.
Collimation and alignment assessment			
Light field / X-ray field alignment	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 SID.	Assess alignment for largest collimator in clinical use for each target/geometry combination.	As per routine tests.
X-ray field / image receptor alignment	The X-ray field shall extend to the chest wall edge of the image receptor but not extend by more than 2% of the SID beyond it.	Assess alignment for each target/geometry combination.	As per routine tests.
Paddle/image alignment	The chest wall edge of the compression paddle shall be aligned just beyond the chest wall edge of the image receptor such that it does not appear in the image. In addition, the compression paddle shall not extend beyond the chest wall edge of the image by more than 1% of the SID.	Assess alignment for all clinically relevant bucky/paddle/target/ geometry combinations.	As per routine tests.

Appendix 9: Recommendations for medical physicist testing of digital mammography units (continued)

Procedure	Performance requirements/guidelines	Routine testing guidelines	Acceptance and additional tests
AEC system performance assessment			
Reproducibility	Coefficient of variation (COV) for both absorbed dose and mAs for at least four photo-timed exposures of a test object shall be better than or equal to 0.05.	Use a 4 cm PMMA block or MAP.	As per routine tests.
Compensation and SDNR system performance assessment	Compare SDNR values to IAEA Achievable values[12]: (Achievable = RANZCR target x 1.5) • ratio $SDNR_{2cm}$ /$SDNR_{4cm}$ > 1.1 • ratio $SDNR_{6cm}$ /$SDNR_{4cm}$ > 0.9	Assess the most commonly used AEC modes for contact and magnification geometry. Use 0.2 mm Al foil as contrast test tool and measure SDNR for at least 2, 4, 6 and 7 cm PMMA (also see section on glandular dose).	Establish baseline values. Assess all available AEC modes for contact and magnification geometries.
Density control (if applicable)	The difference in mAs should typically be between 5% and 10% for adjacent density control steps.	Assess change in mAs for at least two density settings either side of the usual clinical setting using 4 cm of PMMA.	Assess change in mAs across full range of density settings.
Back-up timer/security cut-out	Security cut-out mechanisms shall be present and terminate the exposure within 50 ms or within 5 mAs, or with an entrance absorbed dose for the ACR accreditation phantom of less than 0.44 mGy.	Assess change in mAs for at least two density settings either side of the usual clinical setting using 4 cm of PMMA.	Assess change in mAs across full range of density settings.
	In absence of security cut-out, a back-up timer shall terminate exposure at ≤600 mAs.	Confirm that the back-up timer/ security cut-out is functioning in the typical fashion.	Confirm that the security cut-out functions within the limits specified.
Image homogeneity and artefact	Maximum deviation of mean pixel value < ± 10% of mean pixel value for central ROI. Maximum deviation in SNR < ± 15% of mean SNR for all ROIs. Maximum deviation in SNR as a function of time is ± 10% in a year. There must be no evidence of blotches or regions of altered noise appearance. Observable grid lines or tabletop structures, bright or dark pixels.	Assess for 40 mm PMMA covering complete detector. Test both contact and mag modes. Use five ROIs (one central, with the other four approximately 20 mm from any edge) each of 1 cm^2 measurements performed on unprocessed image.	Test all target/filter combinations
Detector element failure	Limits currently not established. Must monitor independent of manufacturer. Inspect bad pixel map.	A mammographic screen-film mesh can be used to determine if correction for bad columns successful.	Bad pixel map must be available at any time, independent of manufacturer.
Image quality evaluation	The ability to clearly visualise five fibres, four speck groups and four masses in an image of an ACR accreditation phantom.	Use typical clinical settings.	As per routine testing.

[12] https://www.iaea.org/publications/8560/quality-assurance-programme-for-digital-mammography

Appendix 9: Recommendations for medical physicist testing of digital mammography units (continued)

Procedure	Performance requirements/guidelines	Routine testing guidelines	Acceptance and additional tests
System linearity evaluation	Compare to baseline results.	Use standard test block (eg, 4 cm PMMA) at typical clinical beam settings. Measure mean pixel value and SD. Calculate SNR and SNR^2 and plot mean pixel value and SNR^2 as a function of ESAK.	Baseline measurements at clinical kVp; also at maximum and minimum clinical kVps for all target filter combinations.
Ghost image evaluation	Ghost image factor < 2.	Not required unless change made to image receptor system.	Measure ghost image using 4 cm PMMA block.
Generator performance			
kVp, output, and timer reproducibility	COV ≤ 0.02 for a minimum of four exposures.	Assess at least kVp reproducibility at typical clinical kVp.	Assess kVp, output and timer reproducibility.
kVp accuracy	Measured kVp shall be within ± 1 of the specified value over the clinically relevant range.	Assess kVp accuracy over the clinically relevant range in, at most, 2 kVp increments. Note: the kVp need only be verified for one target filter combination per kVp; however, the kVp meter must be calibrated for that particular target/filter combination.	Assess kVp accuracy over clinically relevant range in 1 kVp increments.
Beam quality	[(kVp/100) + 0.03] ≤ 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	Measure the HVL required for mean glandular dose calculations.	As per routine tests plus measure HVL at 28 kVp for all target/filter combinations with the compression paddle removed.
Mean glandular dose	≤ 1.5 mGy. ACR mammography accreditation Phantom: representing a 4.2 cm 50% adipose, 50% glandular breast. < 0.6 mGy for 2.0 cm PMMA < 3.6 mGy for 6.0 cm PMMA	Assess for an AEC controlled exposure using typical clinical settings using ACR phantom and also for 20 mm and 60 mm PMMA.	As per routine tests.
Radiation output rate	For all clinically relevant SID settings the maximum exposure time when irradiating 6 cm PMMA should be less than 2 seconds.	• Assess for both contact and magnification modes. • Use 6 cm of PMMA. • Use clinically relevant technique factors for this PMMA thickness consistent with SDNR and MGD measurements. • Record mAs and infer the exposure time from specified mA.	As per routine tests

Appendix 9: Recommendations for medical physicist testing of digital mammography units (continued)

Procedure	Performance requirements/guidelines	Routine testing guidelines	Acceptance and additional tests
Viewbox luminance and room illuminance (hard copy only)	Viewing area illuminance ≤ 50 lux Viewbox luminance ≥ 3000 cd/m²	Assess viewing conditions for all viewers.	As per routine tests
Display luminance and viewing conditions	Luminance ≥ 300 cd/m^2 in clinical use Luminance dynamic range > 250:1. Paired displays matched Ambient light < 10 lux.	Measure dynamic range under clinical lighting conditions.	As per routine testing. Maximum luminance ≥450 cd/m^2 when new. Display or workstation shall have a comprehensive quality assurance programme.
Display performance	No smearing, artefact, ramps without terracing contour lines, lines straight, boxes square, active display centred, borders complete. All steps visible, 5% and 95% squares visible. > 11 letters visible in dark, mid-grey and white.	Test patterns to be displayed at full resolution. Test under clinical lighting conditions use TG18 test pattern.	As per routine testing. Display or workstation may have comprehensive quality assurance programme.
Printer (hard copy only)	Dmin <0.25 OD-, Dmax >3.4 OD.	Print TG18-QC test pattern as per weekly printer quality control test.	As per routine tests.

National ID: 18571

Appendix 10: Digital default display protocols

Display protocol: exam types

Overview

Display protocols define how digital images are displayed during a radiologist's reading session. They define the orientation and position of each display, and the order in which the images are displayed. There is a default display protocol for each exam type.

Default display protocols (DDPs) are important because additional views may be missed if their location is not predictable. Default protocols exist to protect women, and readers, from the possibility that additional views may not be read because they are not in a standard location. Where the software permits and does not permanently change the record, individual readers should use personalised display protocols as long as these meet the minimum requirements. It is important for individuals who do this to remember when reporting cases elsewhere, or when someone else is logged on, that there may be additional images in other locations.

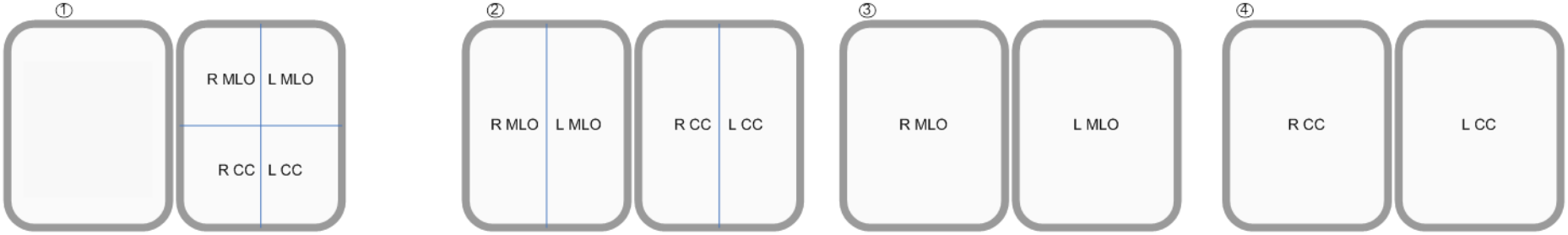
The following DDPs are the minimum to be available:

- routine screening no priors/priors
- implants no priors/priors
- eight images no priors/priors
- mastectomy.

Below are examples of possible display protocols, based on Sectra PACS.

First screening (four views)

Image types
RMLO
LMLO
RCC
LCC

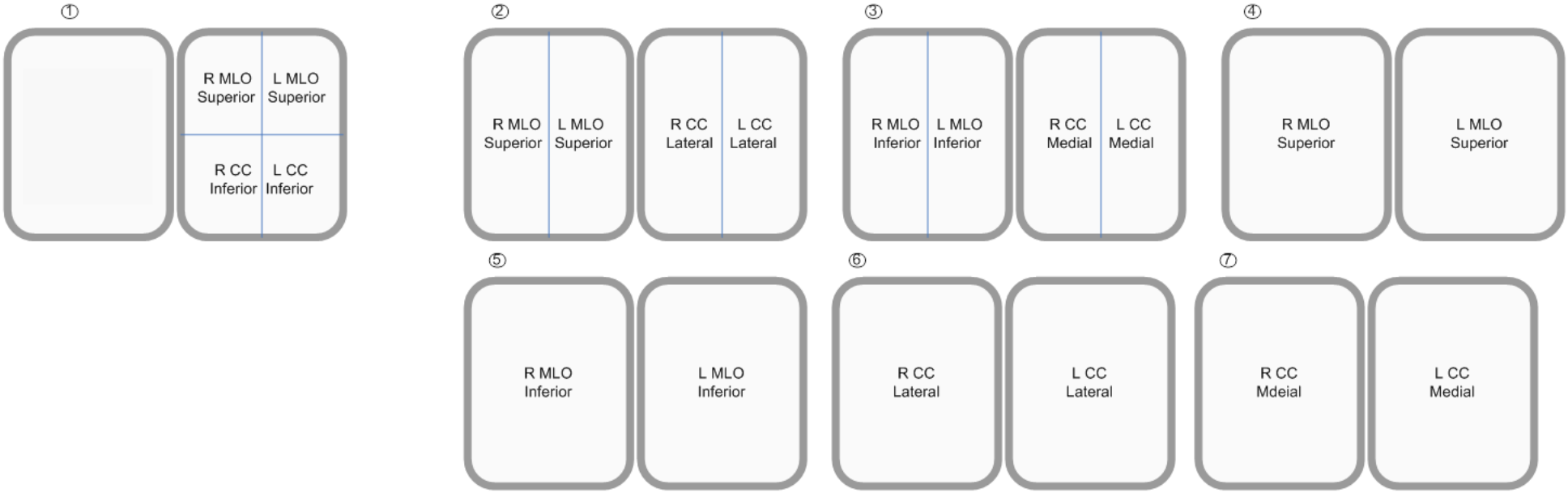


First screening (four views) with priors

Image types	Priors (digitised)
RMLO	Image 1
LMLO	Image 2
RCC	Image 3
LCC	Image 4

First screening (eight views)

Image types
RMLO (superior)
LMLO (superior)
RCC (lateral)
LCC (lateral)
RMLO (inferior)
LMLO (inferior)
RCC (medial)
LCC (medial)

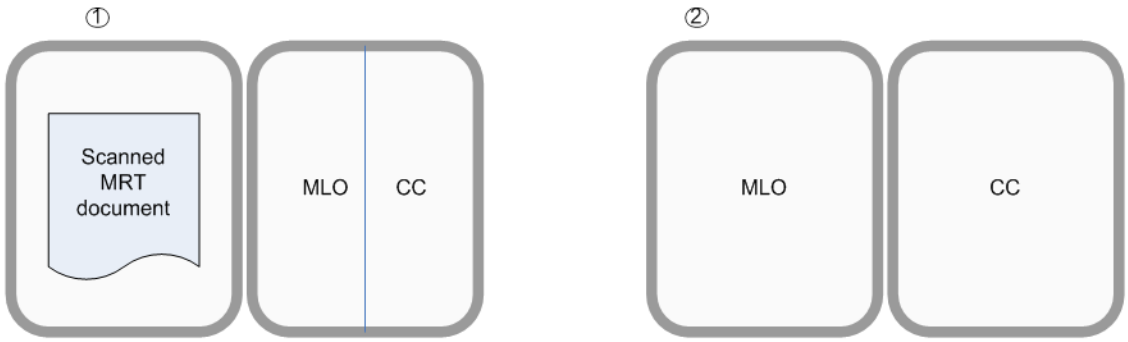


First screening (eight views) with priors

Image types	Priors (digitised)	Image types	Priors (digitised)
RMLO (superior)	Image 1	RCC (lateral)	Image 5
LMLO (superior)	Image 2	LCC (lateral)	Image 6
RMLO (inferior)	Image 3	RCC (medial)	Image 7
LMLO (inferior)	Image 4	LCC (medial)	Image 8

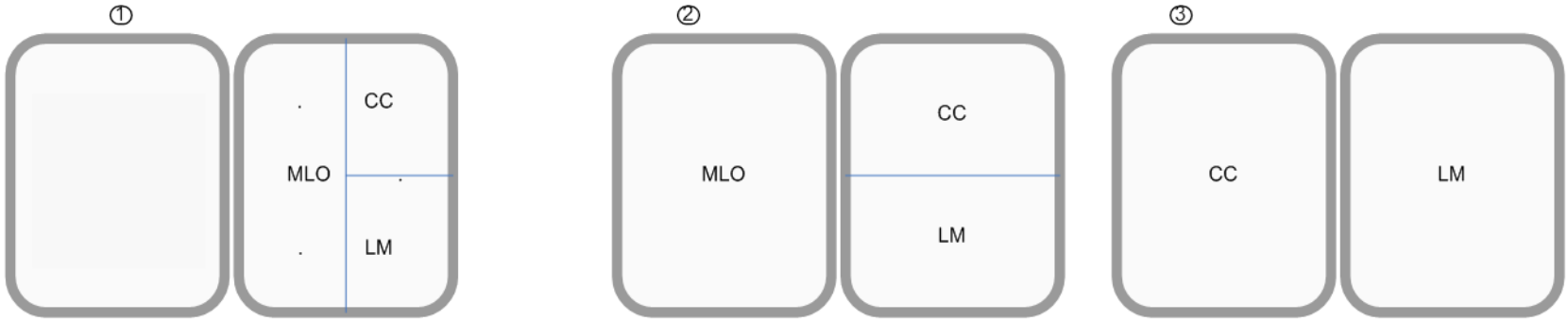
Mastectomy, right/left breast (two views)

Image types
R/L MLO (m)
R/L CC (m)



Mastectomy, right/left breast (three views)

Image types
R/L MLO (m)
R/L CC (m)
R/L LM (m)



Mastectomy right/left breast (two views) with priors

It is assumed that there will only be digitised images for one side.

Image types	Priors (digitised)
R/L MLO (m)	Image 1
R/L CC (m)	Image 2

Mastectomy right/left breast (three views) with priors

It is assumed that there will only be digitised images for one side.

Image types	Priors (digitised)
R/L MLO (m)	Image 1
R/L CC (m)	Image 2
R/L LM (m)	Image 3

Normal screening with uplift (six views)

When infra-mammary angle not imaged.

Image types
RMLO
LMLO
RCC
LCC
RMLO (inferior)
LMLO (inferior)

Normal screening with extra CC (six views)

When nipple not in profile in original views.

Images taken
RMLO
LMLO
RCC
LCC
RCC (nipple)
LCC (nipple)

Implant with pushback (10 views)

Image types
RMLO implant visible
LMLO implant visible
RCC implant visible
LCC implant visible
RMLO implant pushback
LMLO implant pushback
RCC implant pushback (medial)
LCC implant pushback (medial)
RCC implant pushback (lateral)
LCC implant pushback (lateral)

Normal screening L (12 views)

Image types
RMLO (superior)
LMLO (superior)
RCC (lateral)
LCC (lateral)
RMLO (nipple)
LMLO (nipple)
RCC (nipple)
LCC (nipple)
RMLO (inferior)
LMLO (inferior)
RCC (medial)
LCC (medial)

Appendix 11: Facility quality control procedures for digital radiography units

Procedure	Recommended control limits/requirements	Minimum frequency	Key procedure elements	Recommendations for record keeping[13]
Display cleaning	Display screens must be free of dust, fingerprints and other marks that might interfere with image interpretation.	Daily	Clean all display screens gently with lint-free cloth.	Checklist/logbook entry showing: • date performed • person performing task.
Viewing conditions	Appropriate viewing conditions (ie, no glare from other displays, light boxes or windows).	Daily	Visual inspection of ambient lighting conditions around both the acquisition and review displays to ensure conformance with acceptable viewing condition configuration, as outlined in sections 5.2.1 and 5.2.2.	Checklist/logbook entry showing: • date performed • person performing task.
Daily constancy test	mAs = baseline ± 10%. Mean pixel value (MPV) in image = baseline ± 10%. Alternatively, use an equivalent automated test provided by the manufacturer.	Daily	Use standard test block. Use clinical exposure conditions as agreed with your medical physicist. Record the exposure parameters (kV target filter mAs). Measure the mean and standard deviation (SD) of pixels in an ROI at the centre of the imaged block.	Record numerical mAs, MPV, SD values. Control charts showing: • plot of mAs • plot of MPV • ≥ 25 results • baseline values • remarks (eg, corrective action) • clearly marked control limits.
Image quality evaluation	mAs = baseline ± 10%. Mean pixel value in image = baseline ± 10%. NB: Control limits for detail visibility are dependent on the scoring scheme used. The ability to visualise five fibres, four speck groups and four masses in an image of an ACR accreditation phantom.	Weekly	Obtaining the phantom image: • use American College of Radiology (ACR) mammography accreditation phantom • use a consistent automatic exposure control (AEC) detector position where this is manually selected • ensure light contact between the compression paddle and the phantom surface in order to trigger the AEC or manufacturer's recommendations • ensure consistent positioning of the phantom • use clinical exposure conditions as agreed with your medical physicist • select the density setting in current clinical use (if applicable).	Record numerical mAs values and image quality scores. Control chart showing: • plots of mAs, and • image quality score/s • ≥ 25 results • clearly marked • control limits • baseline values. Also, record radiographic settings (kVp, target/filter combination, density setting and SID) remarks (eg, corrective action), identity of tester.

[13] Unless otherwise indicated, all QC records and relevant images should be retained for a minimum of two years and at least since the last BSA audit.

Appendix 11: Facility quality control procedures for digital radiography units (continued)

Procedure	Recommended control limits/requirements	Minimum frequency	Key procedure elements	Recommendations for record keeping[14]
Image quality evaluation (continued)			Evaluating the phantom image: • use consistent (baseline) viewing conditions that reflect those used to read actual mammograms • ensure image quality scoring by the same person, if possible • measure mean pixel value in are producible ROI	Phantom images identifying: • date • X-ray system • technique factors.
Printer quality control (if applicable)	• Borders must be visible; lines must be straight. • All corner patches must be visible. • Squares of different shades from black to white must be distinct. • The finest horizontal and vertical line pairs must be visible in all four corners. • The 5% and 95% pixel value squares must be clearly visible. • The 10 cm line must be between 9.5 cm and 10.5 cm long. • No disturbing artefacts should be visible on the printed TG18-QC test pattern. • The mid density (MD) and density difference (DD) = baseline ± 0.15. Base + fog (B+F) = baseline ± 0.03. • Check low-contrast resolution by counting the number of letters you can see in the words on the printout. The number of letters visible in the phrase 'Quality Control' for the dark, mid-grey and light renditions should be at least 11.	Weekly	• 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. • Measure MD, DD and B+F.	Records showing: • date test was performed • person performing test • printer identification • test results.

[14] Unless otherwise indicated, all QC records and relevant images should be retained for a minimum of two years and at least since the last BSA audit.

Appendix 11: Facility quality control procedures for digital radiography units (continued)

Procedure	Recommended control limits/requirements	Minimum frequency	Key procedure elements	Recommendations for record keeping[14]
Display quality control (primary and secondary). Displays used for image assessment or interpretation.	• Borders must be visible, lines must be straight, squares must appear square. • There should be no smearing or bleeding at black–white transitions. • All corner patches must be visible. • Squares of different shades from black to white must be distinct. • The finest horizontal and vertical line pairs must be visible in all four corners. • The 5% and 95% pixel value squares must be clearly visible. • The resolution at all corners and in the middle should be uniform. • The pattern should be centred in the active area. • No disturbing artefacts should be visible on the displayed TG18-QC test pattern. • The number of letters visible in the phrase 'Quality Control' for the dark, mid-grey and light renditions should be at least 11.	Weekly	Display TG18-QC test pattern. Ensure viewing conditions are acceptable. TG-18 QC must be displayed at the native resolution of the display. Use window-width set to maximum and window-level set to half of maximum. Automated tests using the display manufacturer's software are usually the best way of performing and recording these tests.	Records showing: • date test was performed • person performing test • display identification • test results.
Display/ viewboxes cleaning	Display screens and view boxes must be free of dust, fingerprints and other marks that might interfere with image interpretation.	Daily	Clean all display screens and view boxes gently with lint-free cloth.	Checklist/logbook entry showing: • date performed • person performing task.
Full field artefact evaluation	There must be no evidence of: • 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 tabletop structures • bright or dark pixels • stitching or registration artefacts.	Monthly	Expose a uniform thickness of PMMA so that the mean pixel value is within 10% of the weekly phantom value. View and assess the image on a primary display. Use a narrow greyscale window.	Records showing: • date test was performed • person performing test • test results.
Mechanical inspection	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.	Checklist/logbook entry showing: • date performed • person performing task.

Appendix 11: Facility quality control procedures for digital radiography units (continued)

Procedure	Recommended control limits/requirements	Minimum frequency	Key procedure elements	Recommendations for record keeping[14]
Repeat analysis	Repeat rate < 3% (< 2% preferred).	Quarterly	Inclusion of images from at least 250 consecutive client examinations. The ability to determine repeat rates attributable to a range of equipment faults and positioning errors.	Worksheet/logbook entries showing all results and calculations.
Image receptor homogeneity	Use the manufacturer's protocol if available.			
AEC calibration test	Mean pixel value for each of 2, 4 and 6 cm PMMA within 10% of baseline values.	Quarterly	• Use PMMA blocks agreed with the medical physicist. • Use clinical AEC settings (kVp, target/filter and mode). • Measure mean pixel value and SD in 4 cm^2 ROI positioned centrally along axis and 6 cm from chest wall. • Calculate SNR from ratio of pixel value to SD.	Records showing: • date test was performed • person performing test • X-ray system identification • kVp, target/filter, AEC mode and mAs • test results.
Compression	Maximum motorised compression force in the range of 150–200 N.	Six-monthly	Measurement of compression force using a suitable measuring device (eg, analogue bathroom scales).	Checklist/logbook entry showing: • date test performed • test results • person performing • test.
Test equipment quality control. Densitometer calibration check.	Optical density measurement accurate to within: • ± 0.03 (0–3.0 OD) • ± 3% (3.0–4.0 OD).	Annually	Verification of accuracy using an optical density calibration strip traceable to an accepted standard.	Checklist/logbook entry showing: • date test performed • test results • person performing • test.
Maintenance and fault logging	Separate logbooks for each imaging system, including diagnostic displays and film printer if relevant.	As required	Dated entries describing fault encountered and/or maintenance performed.	Logbooks with dated and initialled entries.
Infection control of breast-imaging equipment	Clean equipment.	Before each examination	Clean using alcohol swipes, or as per manufacturer's recommendations and/or suitable infection control advice.	Nil

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Appendix 11: Facility quality control procedures for digital radiography units (continued)

Procedure	Recommended control limits/requirements	Minimum frequency	Key procedure elements	Recommendations for record keeping[14]
Stereotactic accuracy confirmation	Localisation within ±1 mm.	Prior to first use on day of procedure	Procedure as per manufacturer's recommendations and/or ACR manual.	Checklist/logbook entry showing: • date test performed • test results • person performing test • any action taken.
Film digitiser (if applicable)	Plot of MPV should be linear over full range of OD from B + F to DMCX. A linear regression should have an R^2 >0.95.	Monthly	• Produce a film with a step wedge pattern. This could be a test print from a laser printer. • Measure the OD for each step. • This film may be preserved for future tests • Digitise the film. • Measure the mean pixel value (MPV). • Plot MPV vs OD using an Excel spreadsheet. • Obtain the value of the correlation coefficient for a linear regression (R^2).	Checklist/logbook entry showing: • date test performed • test results • person performing test.

Appendix 12: Deleted

Previously “Facility quality control procedures for computed radiography units”. Removed as Computed Radiography (CR) units were previously allowed in the programme however are no longer approved for use in BreastScreen Aotearoa. Placeholder - Full review of NQPS scheduled for 2023.

Appendix 13: Recommendations for medical physicist testing at acceptance or equipment upgrade

Procedure	Performance requirements/guidelines	Routine testing guidelines	Key procedure elements
Leakage radiation	• ≤ 1 mGy/hr at 1 m from focus • ≤ 0.01 mGy/100 mAs @ 30 kVp and 30 cm from focus.	Not required unless tube has been changed or system relocated.	As per AS/NZS 3200.1.3.[15]
Transmission through breast support	≤ 0.001 mGy @ max kVp and mAs.	Not required unless change made to image receptor system.	As per AS/NZS 3200.1.3.[10, 16]
Missed tissue at chest wall	Width of missed tissue at chest wall ≤ 5 mm.	Not required unless tube has been changed or change made to image receptor system or system relocated.	Some units will not comply with this test (see text).
Plate fogging (CR only)	Image of coin should not be visible.	Not required unless changes in storage of cassettes have occurred.	Monitor during acceptance testing.
Spatial resolution	Benchmark testing, compare to manufacturer's specification.	Not required unless tube has been changed or a change made to image receptor system.	As per IEC 62220-1-2.
Spatial linearity and geometric distortion	Measured dimensions of ruler in image should be within 2% of true dimensions.	Not required unless a change made to image receptor system.	Use wire mesh tool and/or steel rulers. Determine dimensions in image.

[15] Standards Australia & Standards New Zealand, Approval and test specification – Medical electrical equipment – General requirements for safety – collateral Standard: Requirements for radiation protection in diagnostic X-ray equipment No. AS/NZS 3200.1.3:1996,1996.

[16] International Electrotechnical Commission, Medical Electrical Characteristics of Digital X-ray imaging devices – Part 1–2: Determination of the quantum detection efficiency – mammography detectors, International Electrotechnical Commission Report No. 62220-1-2,2004 [draft].

Appendix 14: Deleted

Previously “Recommendations for medical physicist testing of computed radiography units”. Removed as Computed Radiography (CR) units were previously allowed in the programme however are no longer approved for use in BreastScreen Aotearoa. Placeholder - Full review of NPQS scheduled for 2023

Appendix 15: Templates and instructions – quality control procedures for digital mammography[17]

Infection control of breast-imaging equipment

Before each examination

There is a local protocol for image plate cleaning before each examination.

Maintenance and fault logging

As required

Dedicated logbooks for each imaging system, including diagnostic displays and film printer if relevant, must be kept for recording faults and maintenance and should be retained for the life of the equipment.

Viewing conditions

Daily test

Carry out visual inspection of ambient lighting conditions to ensure conformance with acceptable viewing condition configuration.

Check for reflections on displays and light from doorways and windows.

Checklist/logbook entry showing:

- date performed
- person performing task
- any action taken/required.

Display cleaning

Daily test

Display screens must be free of dust, fingerprints and other marks that might interfere with image interpretation.

Clean all display screens gently with a lint-free cloth.

Checklist/logbook entry showing:

- date performed
- person performing task.

[17] Modified from Breast Screen Victoria 2007.

Daily constancy

Obtaining the image

1. Use the standard test block (4 cm).
2. Apply the minimum compression necessary for exposure.
3. Consistently position the phantom flush with the chest wall edge.
4. Expose using the standard clinical AEC setting.
5. Select the density setting in current clinical use (if applicable).
6. For CR, process the plate after a fixed delay (30 seconds) to avoid image fading issues.
7. All images should be identified by:
   - date and person performing task
   - the X-ray system
   - the technique factors
   - action taken/required.

Note: for CR, use a designated test cassette and an imaging plate that is in routine clinical use.

Example of data recorded

Date					
kVp					
mAs					
Indicated MGD or exposure indicator (CR)					
MPV of ROI centre of the imaged block					
SD of pixels in the centre of the imaged block					

Image quality evaluation

Weekly test

Obtaining the phantom image

1. Use the ACR mammography accreditation phantom (MAP) (eg, RMI 156).
2. Use a consistent AEC detector position where this is manually selected.
3. Place the MAP on the breast support and position it with the chest-wall edge of the MAP aligned with the chest-wall side of the breast support. Centre the MAP left to right. Consistent positioning is important.
4. Lower the compression paddle so that it just touches the phantom. Be aware that compression may damage the paddle, or cause a 'flexi'-type paddle to indicate a false breast thickness, which may then lead to an inappropriate technique. On some units some compression is required to enable exposure.
5. Set the exposure technique used clinically for a 4.2 cm compressed breast of average density. Consistent selection of clinically relevant kVp and target/filter combinations is critical to this test.
6. Select the density setting in current clinical use (if applicable).
7. For CR, use a designated plate that is in routine clinical use and process the plate after a fixed delay (eg, 30 seconds) to avoid image-fading issues.
8. All phantom images should be retained and identified by:
   - date
   - X-ray system
   - technique factors.
9. Images should be recorded and post-processed using the technique recommended by the manufacturer for such images.
10. Record radiographic technique on the control chart.
11. Measure the mean pixel value (MPV) of three regions of interest (ROIs) on the image: one in the centre, one over the perspex disc, and one adjacent to it. The ROIs should be a consistent size and shape and must not be near the edge of the perspex disc. The basic methodology is as described in the RANZCR *Mammography Quality Control Manual*. The results are recorded on the control chart.
12. If a CR system used both 18 x 24 and 24 x 30 screens, then this test must be performed on both formats. If the system is used for magnification mammography, the magnified MAP images should be taken and analysed in the same way.
13. Images will be assessed on the reporting display used clinically, employing the scoring methodology described in the RANZCR *Mammography Quality Control Manual*.
14. Ensure consistent viewing conditions (these should reflect conditions used to read clinical mammograms). A 1:1 zoom setting should be used to score the speck groups. Minimum acceptable scores are:
   - at least five fibres
   - at least four speck groups
   - at least four masses.

15. Record the image scores on the control chart.

Date							
Target:filter							
kVp							
mAs							
Exposure indicator or MGD							
MPV of centre ROI							
MPV of disc ROI							
MPV of ROI next to disc							
MPV difference (background – disc)							
Fibres							
Specks							
Masses							
Comments/actions							

For limits/explanations, see below.

Exposure indicator, Air Kerma (dose), relates to CR systems and should not change by greater than:

- ±10% with respect to the baseline value
- Fuji CR S# of ±10%.

ROI area 1: measure and record the region of interest (mean pixel value) next to the Perspex dot (high-density measure).

ROI area 2: measure and record the region of interest (mean pixel value) of the Perspex dot (low-density measure). Subtract these two values to get a contrast measurement.

Please note: both ROI measurements should be the same and of consistent size.

Visual scoring

Ensure consistent viewing conditions (these should reflect the conditions used to read clinical mammograms):

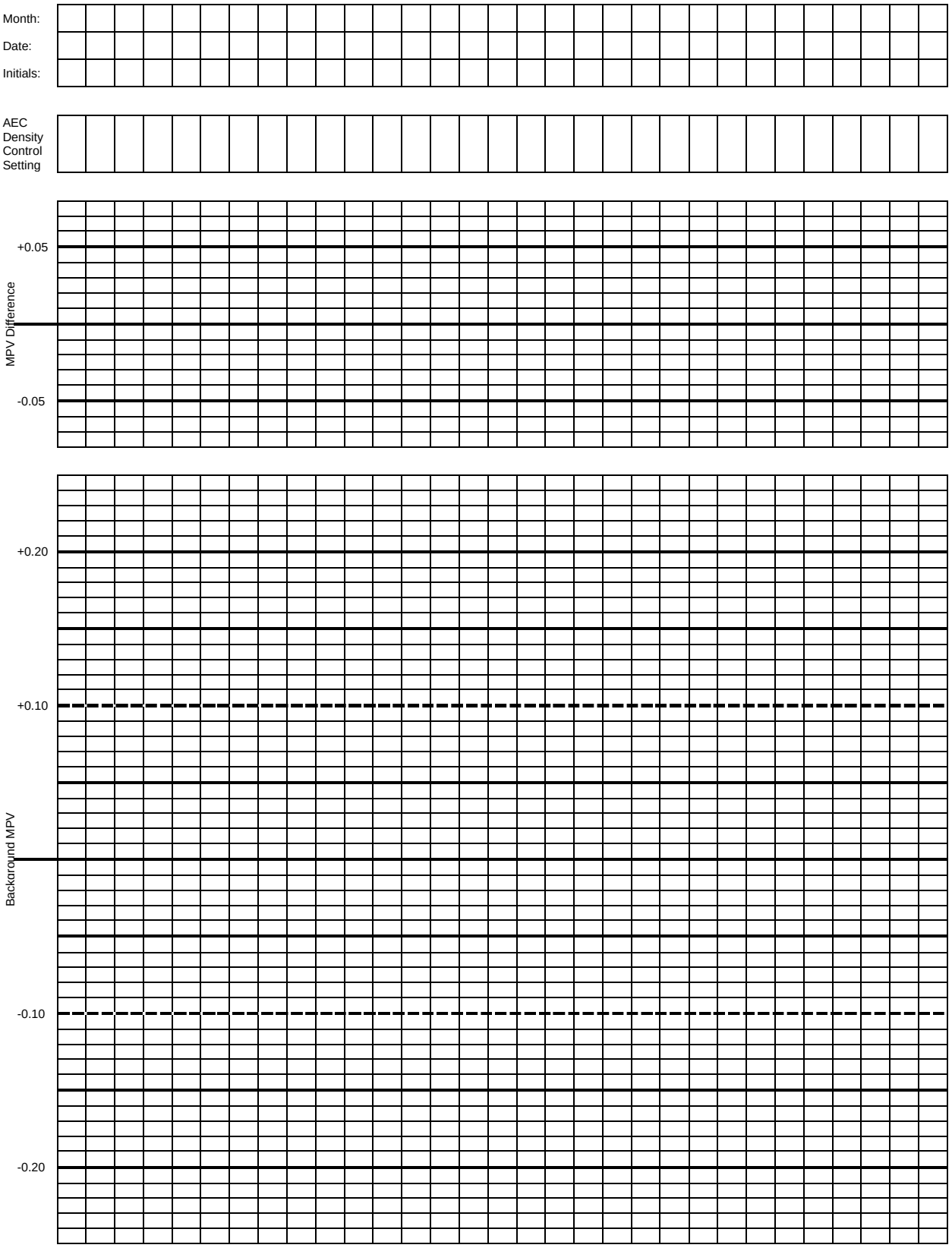
- at least five fibres
- at least four speck groups
- at least four masses.

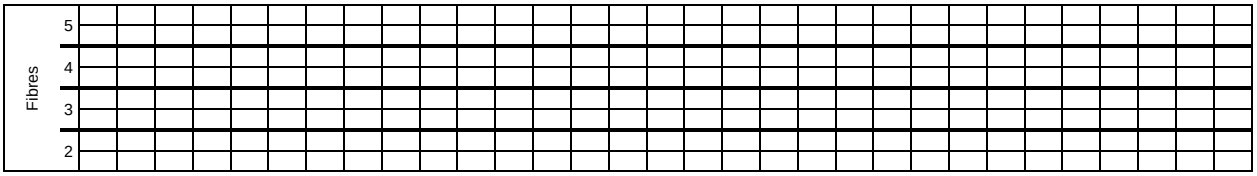
Please note: you may need to use the magnification and roam factors to assess the images. A suitable display should be used to make this analysis.

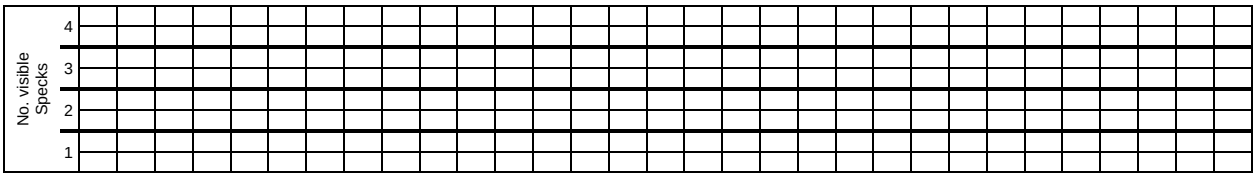
Map digital control chart

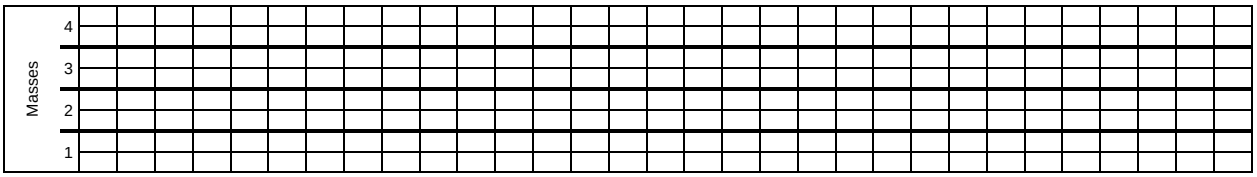
BREASTSCREEN AOTEAROA

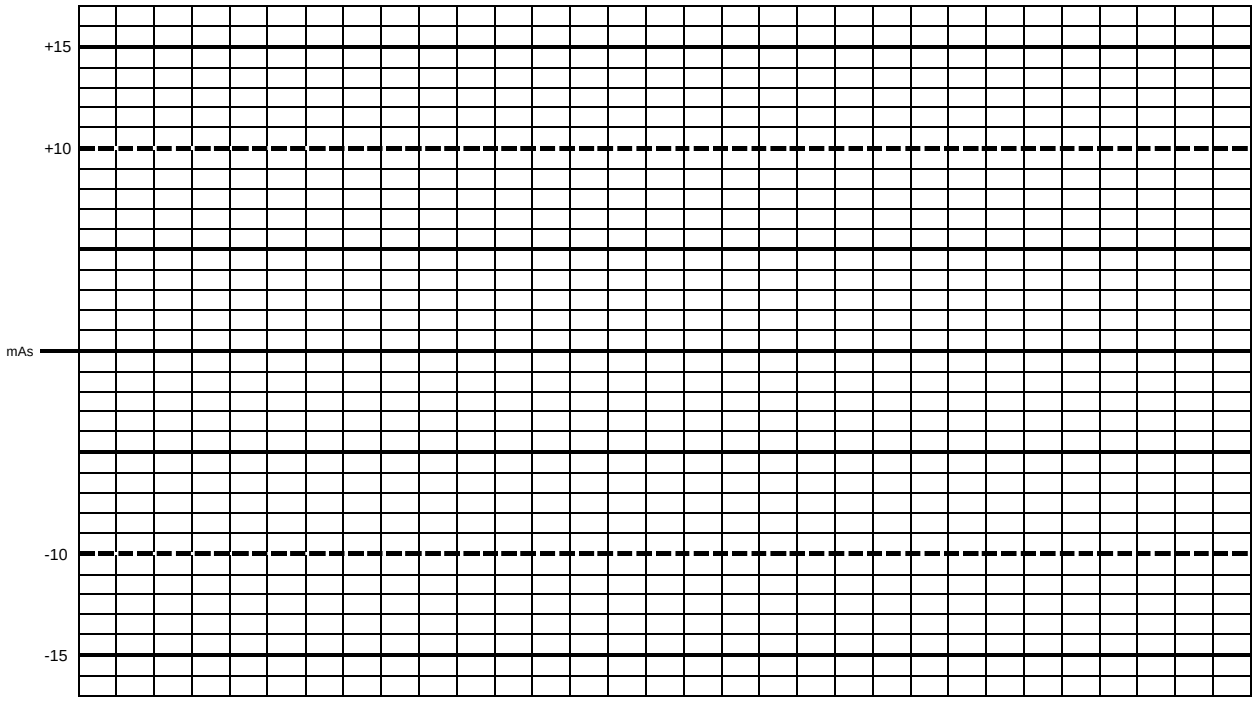
Room: _____ kVp: _____ Target:filter _____ : _____ Yr _____




Fibres
5
4
3
2


No. visible Specks
4
3
2
1


Masses
4
3
2
1


+15
+10
mAs
-10
-15

Phantom control chart

CR plate log (if required)

Date	Size	Plate number

Date	Size	Plate number

Remarks

Date	Action

Display QC

Weekly test

This test is for displays used for interpretation and attached to the acquisition workstation.

Procedure

- Display the TC18-QC test pattern.
- Ensure viewing conditions are acceptable.
- Use window-width set to maximum and window-level set to half of maximum.

Record

Record the following:

- date test was performed
- person performing test
- display identification
- display settings
- test results.

Limits

- Borders are visible.
- Lines are straight.
- Squares appear square.
- There is no smearing or bleeding at black–white transitions.
- All corner patches are visible.
- Squares of different shades from black to white are distinct.
- The finest horizontal and vertical line pairs are visible in all four corners and in the centre.
- The 5% and 95% pixel value squares are clearly visible.
- The resolution at all corners and in the middle is uniform.
- The pattern is centred in the active area.
- No disturbing artefacts are visible.
- The number of letters visible in the phrase ‘Quality Control’ for the dark, mid-grey and light renditions is ≥ 11.

Display QC record sheet

Weekly test

Date							
Initials							
Display ID							
Display settings							
Test results, comments, actions							

Printer QC (if applicable)

Weekly test (as per ACPSEM guidelines)

Please note: although BreastScreen Aotearoa will not be printing films for primary reporting, it will be important to make sure the printed images are of a relatively high standard if being sent as a client's record.

The test should be performed at installation to establish a baseline, then regularly (eg, quarterly), for assurance.

Procedure

- Print the TG18-QC test pattern.
- Check visibility and distortion of several items used for evaluation of the quality of the image.
- Check for disturbing artefacts.
- Measure MD, DD and B+F.

Record

Record the following:

- date test was performed
- person performing test
- printer identification
- test results.

Limits

- Borders are visible.
- Lines are straight.
- All corner patches are visible.
- Squares of different shades from black to white are distinct.
- The finest horizontal and vertical line pairs are visible in all four corners and in the centre.
- The 5% and 95% pixel value squares are clearly visible.
- The 10 cm line is between 9.5 cm and 10.5 cm long.
- No disturbing artefacts are visible.
- MD (mid density) and DD (density difference) are within ± 0.15 OD of their baseline values.
- B+F (base and fog) and D max (maximum density) are within ± 0.03 OD of their baseline values.

Please note:

- MD (mid-density) should be measured at 50%.
- DD (density difference) should be measured at 60% and 40%.

Image plate erasure – CR only

Daily/weekly

CR image plates are sensitive to scattered and naturally occurring radiation sources and if left unused for long periods of time will store energy absorbed from these sources. It is recommended that all CR image plates be subjected to secondary and primary erasure procedures on a daily and weekly basis, as per the manufacturer's instructions.

Daily: secondary erasure

Weekly: primary erasure

Please note: primary erasure should also be performed following prolonged non-use (eg, on Monday or after a holiday period).

Mammography quality control check list

CR units

These tests are performed daily and weekly.

Site: ..... Year:..... Month: .....

Date	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Initials																															
Daily																															
Display cleaning																															
Viewing conditions																															
Image plate erasure (secondary)																															
Weekly																															
Image quality evaluation																															
Display QC																															
Image plate erasure (primary)																															

DR units

These tests should be performed daily and weekly.

Site: ..... Year:..... Month: .....

Date	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Initials																															
Daily																															
Display cleaning																															
Viewing conditions																															
AEC test																															
Weekly																															
Image quality evaluation																															
Display QC																															
Printer QC																															

Mechanical inspection

Monthly test

As in screen/film mammography, the facility staff must perform an overall mechanical inspection of the digital mammography system and associated components. The test should be carried out monthly to ensure there are no hazardous, inoperative, out-of-alignment or improperly operating items on the system.

Procedure

- Carry out visual inspection of the system to ensure safe and optimal operation.

Record

Record the following:

- date inspection performed
- inspection results
- person performing test.

Film digitiser QC (if applicable)

Monthly test

Please note: this test is performed to ensure the film digitiser is producing consistently accurate reproductions of a hard-copy image.

The test should be performed at installation to establish a baseline, then regularly for quality control purposes.

Procedure

- Produce an analogue film with a step wedge pattern. This may be generated automatically by a laser printer, for example.
- Measure the optical densities (OD) for each step.
- Digitise the image.
- Measure the mean pixel value (MPV) at a convenient place in each step.
- Plot the MPV versus OD using an EXCEL spreadsheet. This should be linear if the correct look-up table (LUT) is used.
- Note: a look-up table is part of the software in the digitiser or workstation it is attached to.
- Obtain the value of the correlation coefficient (R^2) using EXCEL for this plot.

Record

Record the following:

- date test was performed
- person performing test
- the R^2 value for the plot of MPV versus OD.

Limits

- The plot of MPV versus OD should be linear over the full range of OD, from B+F to Dmx with $R^2 > 0.95$.
- Note if the plot of MPV versus OD is not linear: it could be due to the wrong LUT being selected by the equipment.
- This should be rectified by service personnel.

Full field artefact evaluation: DR system

Monthly test

Procedure

- Expose a uniform thickness of perspex that covers the entire image receptor.
- Measure the mean pixel value (MPV) in a central 1 cm square ROI as per the homogeneity test and confirm the MPV is within 10% of the weekly phantom value.
- View the image on a display used for interpretation of digital mammography images.
- Print the image if interpretation is performed using hard copy.

Record

Record the following:

- date test was performed
- person performing test
- X-ray system identification
- kVp, target/filter
- AEC mode (if applicable)
- exposure (mAs)
- test results.

Limits

There must be no evidence of:

- 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
- stitching or registration artefacts.

Please note: use a narrow window to roam the image to assess for any variations in noise etc.

Full field artefact evaluation: DR system

Record sheet

Monthly

Date:..... Machine ID: .....

Date	kVp	Target/filter	mAs	Artefact Y/N	Comment	Initials

AEC calibration – CR

Quarterly test

Procedure

- Use perspex blocks with thicknesses of 2 cm, 4 cm and 6 cm.
- Position the blocks consistently (eg, flush with the chest wall edge of the detector).
- Expose each thickness of the blocks using factors you would use in a clinical setting (ie, kVp, target/filter, mode used for corresponding thickness of breast).
- Use a designated test cassette and record the exposure indicator.
- Process the plate after a fixed delay (30 seconds) to avoid image-fading issues.
- Measure the mean pixel value (MPV) in a specified ROI in each image using a 4 cm^2 ROI positioned centrally along the long axis of the image receptor and 6 cm in from the chest wall.
- Record the exposure and exposure indicator.

Record

Record the following:

- date test was performed
- person performing test
- X-ray system identification
- kVp, target/filter, AEC mode and mAs
- test results.

Limits

- The MPV for each of the 2, 4, and 6 cm perspex blocks should be within 10% of baseline values.
- The variation in MPV as a function of thickness should be < ±20%.
- For CR units, the basic requirement is that the average dose to the plate for each of the three thicknesses of perspex should be within ±10% of the baseline value.
- Fuji S# for 2, 4, and 6 cm blocks should be within ±10% of the baseline value, and the variation as a function of thickness should be less than ±20%.
- The variation as a function of thickness should be less than ±80.

AEC calibration – CR

Record sheet

Quarterly test

Date:.....

Machine: .....

AEC detector position:.....

Test completed by:.....

Phantom thickness	kVp	Target and filter	AEC density setting	mAs	Mean pixel value (ROI)	Exposure indicator (eg, S# if applicable)
2 cm						
4 cm						
6 cm						

Baseline mean pixel value

2 cm <x> =
4 cm <x> =
6 cm <x> =

Limits

Mean pixel value for each of 2, 4, and 6 cm should be ±10% of baseline values.

AEC calibration – DR

Quarterly test

Procedure

- Use perspex blocks with thicknesses of 2 cm, 4 cm and 6 cm.
- Position the blocks consistently (eg, flush with the chest wall edge of the detector).
- Choose a digital detector/algorithm that will cover the perspex (eg, CC).
- Expose each thickness of the blocks using factors you would use in a clinical setting (ie, kVp, target/filter, mode used for corresponding thickness of breast).
- Record the exposure.
- Measure the MPV in a specified ROI in each image using a 4 cm^2 ROI positioned centrally along the long axis of the image receptor and 6 cm in from the chest wall.

Record

Record the following:

- date test was performed
- person performing test
- X-ray system identification
- kVp, target/filter, AEC mode and mAs
- test results.

Limits

- The mean pixel value for each of 2, 4, and 6 cm perspex should be within 10% of baseline values.

AEC calibration – DR

Record sheet

Quarterly test

Date:.....

Machine: .....

AEC detector position:.....

Test completed by:.....

Phantom thickness	kVp	Target and filter	AEC density setting	mAs	Mean pixel value (ROI)	Indicated MGD
2 cm						
4 cm						
6 cm						

Baseline mean pixel value

2 cm <x> =
4 cm <x> =
6 cm <x> =

Limits

Mean pixel value for each of 2, 4, and 6 cm should be ±10% of baseline values.

Repeat analysis

Quarterly

This procedure remains the same as in existing mammography recommendations.

However, some new categories for repeat causes may need to be created to reflect the digital environment (eg, software failures, blank images, non-appearance of images on the acquisition station although an exposure was made, etc).

Limits

Repeat rate < 3%.

Cassette image plate condition and interplate sensitivity variation – CR only

Annual

This test is analogous to the uniformity of screen speed test of screen-film mammography.

Procedure

- Visually examine the condition of cassettes and image plates.
- Secondary erase image plates as per the manufacturer's recommendations.
- Image a standard test block using consistent clinical settings (including the relevant AEC mode).
- Image the quality control 'test' cassette/plate on three separate occasions to confirm repeatability of the X-ray tube output.
- Repeat with each imaging plate.
- Evaluate for artefact.

Record

Record the following:

- date test was performed
- person performing test
- kVp, target/filter, AEC mode
- exposure indicator and mAs for each plate.

Limits

- Fuji:
  - the S# for any image plate should differ from the mean S# for that size by less than ±5%
  - the mean S# of different sizes should differ by less than ±20%
- clean and dust-free cassettes
- no major inhomogeneities on the images.

Cassette/image plate condition and interplate sensitivity variation – CR only

Record sheet

Annual

Date: ..... Machine ID:.....

AEC detector: ..... AEC density setting: .....

Cassette number	kVP	mAs	Exposure indicator (S#)	Artefact

Test performed by: .....

Please note: the quality control test cassette/plate should be irradiated three times to confirm repeatability of the X-ray output.

Compression test

Six-monthly

Although adequate compression is required for optimal mammography, it is important the unit does not allow the application of unnecessarily high levels of force in either manual or power-driven modes. This also protects the paddle from undue pressure, leading to possible damage.

The maximum manual compression force should be equal to or less than 20 kg (200 Newtons). The compression device should provide a maximum power-driven compression force of between 15 kg (150 N) and 20 kg (200 N).

Measurement of the compression force is done by using a set of bathroom scales (analogue). The scales are placed on the bucky, and a rolled-up towel used to compress, allowing a reading to be taken of the resultant maximum motorised compression force. The value should be recorded and dated on the compression form.

If the value is outside the recommended values, then the engineers should be contacted to make appropriate adjustments.

Machine ID: .....

Date	Compression value (manual)	Compression value (motorised)	Pass/fail	Action	Initials

The compressed breast thickness display accuracy should be within ±5 mm (when present on unit). For digital units this is particularly important because the measured thickness is used to select the technique factors. This is checked by checking the compression readout for 4 cm perspex with the paddle in light contact with the perspex on the bucky. If the values are outside the limits, engineers should adjust the device.

Date	Compression value	Thickness accuracy ±5 mm	Action	Initials

Please note: for digital units the amount of compression used for the testing should reflect clinical use (eg, OPCOM for Siemens units).

Mammography quality control checklist: CR only

Site: ..... Machine ID:.....

Year												
Month	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**
Full field artefact evaluation (monthly)												
Repeat analysis (quarterly)												
Image receptor homogeneity (quarterly)												
AEC calibration test (quarterly)												
Mechanical inspection (monthly)												
Printer quality control (dry) (monthly)												
Compression (half-yearly)												
Cassette/image plate condition and inter-plate sensitivity variation (annual)												
Physicist's check (half-yearly)												

Mammography quality control checklist: DR only

Site: ..... Machine ID:.....

Year												
Month	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**
Full field artefact evaluation (monthly)												
Repeat analysis (quarterly)												
Image receptor homogeneity (quarterly)												
AEC calibration test (quarterly)												
Printer quality control (quarterly for BreastScreen Aotearoa)												
Film digitiser (monthly)												
Mechanical inspection (monthly)												
Compression (half-yearly)												
Physicist's check (half-yearly)												

Appendix 16: Ultrasound system performance and quality control

Quality assurance is crucially important in breast screening, and this applies just as much to the ultrasound equipment used in assessment as it does to the mammographic X-ray units. The requirements for quality assurance specified below are based on the American Association of Physicists in Medicine recommendations (Goodsitt et al 1998) and the American College of Radiology Breast Ultrasound Accreditation Programme (ACR 2013).

Ultrasound user tests

The tests to be performed are as detailed below (Table Q.1).

Table Q.1: Ultrasound user tests

Procedure	Frequency	Description
Visual inspection	Monthly	Check all cables for signs of damage and/or wear and tear. Check each transducer and its cable for similar signs or cracks, chips and so on.
Hard-copy device	Annually	Use the ACR stereotactic hard-copy protocol (ACR 1999), or similar manufacturer's protocol, preferably employing a TG18 or SMPTE (or similar) pattern.

Ultrasound acceptance testing / baseline readings

These tests will be performed by a medical physicist with training and experience in diagnostic ultrasound. The initial visit to an ultrasound scanner is to:

1. compile the machine performance profile (baseline measurements) for both the user and the medical physicist's tests
2. determine compliance with the manufacturer's declared performance and the radiologists' National Quality Standards document.

All the tests described below (Table Q.2) should be performed and recorded in a standardised manner. Locally it may be considered appropriate, perhaps because of the availability of test objects, to extend the range of tests (eg, to include power output).

Table Q.2: Ultrasound system quality control and performance requirements

Procedure*	Minimum frequency	Procedure elements	Control limits/ requirements
Physical and mechanical inspection	Annually	Inspection of transducers, power cords, controls and system cleanliness.	Satisfactory operation and condition
Display monitor set-up and fidelity	Annually	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	Annually	Evaluation of a uniform region of tissue-mimicking phantom and identification of deviation from smooth tissue texture.	No significant non-uniformities.
Depth of penetration/ visualisation	Annually	Evaluation of maximum depth of either ultrasound speckle or object perception.	< 6 mm change in depth of penetration or visualisation.
Hard copy fidelity	Annually	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 images.
Distance accuracy	Annually	Measurement of known distances in vertical and horizontal directions.	Vertical measurement error less than 1.5 mm or 1.5%. Horizontal measurement error less than 2 mm or 2%.
Anechoic object imaging	Annually	Evaluation of image quality. Comparison with baseline images.	No major distortion or change from baseline performance.
Axial resolution	Annually	Evaluation of full-width half-maximum (FWHM) from profile, or evaluation of filament targets in an axial resolution grouping.	Resolution ≤ 1 mm. No significant change from baseline values.
Lateral resolution or response width	Annually	Measurement of filament image width, or evaluation of FWHM from image profile, or evaluation of filament targets in a lateral resolution grouping.	FWHM < 0.8 mm. Image width or spacing between targets < 1.5 mm. No major change from baseline values.
Ring down or dead zone	Annually	Imaging of filament targets near scanning window, or evaluation of image texture features.	Dead zone < 4 mm (for > 7 MHz transducer).
Review of user quality control	Annually		

* Procedure should be repeated for each transducer (excluding display monitor set-up and hard copy fidelity).

Ultrasound performance assessment tests

These tests shall be performed by a medical physicist with training and experience in diagnostic ultrasound. The National Screening Unit makes tissue-equivalent phantoms available for these tests. The Medical Physicists UDG produces and maintains a set of protocols.

For all procedures it is essential that system settings are well described and reproducible. Settings that should be recorded are:

- transducer model / serial number
- dynamic range
- grey-level map (where available)
- power level
- gain
- time gain control (TGC) settings
- mode (where relevant)
- set focal length (may be multiple focal zones)
- depth of tissue (range).

Appendix 17: Medical physicist testing for biopsy units

Procedure	Performance requirements/guidelines	Routine testing guidelines	Acceptance and additional tests
Focal spot	If film-based: • ≥ 11 lp/mm for line-pair bars perpendicular to anode–cathode axis, and • ≥ 13 lp/mm for line-pair bars parallel to anode–cathode axis, or • complies with AS/NZS 4274, or • if direct digital then as per digital tests.	Not required unless tube has been changed.	As per section 4.2.3 OR AS/NZS 4274.
Leakage radiation	• ≤ 1 mGy/hr at 1 m from focus, and • ≤ 0.01 mGy/100 mAs @ 30 kVp and 30 cm from focus.	Not required unless tube has been changed.	Measure leakage radiation.
Mammography unit assembly evaluation*	Correct and safe function of system components. Thickness display accuracy within ± 5 mm.	• Confirm function and stability of all components, warning lights, displays, etc. • Ensure technique charts are posted. • Evaluate system for any miscellaneous safety risks, etc.	Confirm presence of all documentation.
Collimation assessment*	**Film systems** X-ray field should be contained by image receptor on three sides. No more than 2% of SID extension at chest wall. **Digital systems** X-ray field should not extend beyond image receptor more than 5 mm.		Assess collimation.
System resolution*	Manufacturer's specification or baseline.	Use line-pair gauge.	Establish baseline system resolution as required.

Appendix 17: Medical physicist testing for biopsy units (continued)

Procedure	Performance requirements/guidelines	Routine testing guidelines	Acceptance and additional tests
Generator performance			
• kVp reproducibility	• COV ≤ 0.02 for a minimum of four exposures.	• Assess at least kVp reproducibility at typical clinical kVp.	Assess kVp reproducibility.
• kVp accuracy	• Measured kVp shall be within ±1 of the specified value over the clinically relevant range.	• Assess kVp accuracy over the clinically relevant range in, at most, 2kVp increments.	Assess kVp accuracy over clinically relevant range in 1 kVp increments.
Beam quality	[(kVp/100) + 0.03] ≤ HVL < [(kVp/100) + C] where C = • 0.12mm Al for Mo/Mo • 0.19mm Al for Mo/Rh • 0.22mm Al for Rh/Rh • 0.30mm Al for W/Rh • 0.32mm Al for W/Al	Measure the HVL required for mean glandular dose calculations.	As per routine tests.
AEC system performance assessment*	Digital: • SNR ±20% of mean value for 2 cm, 4 cm and 6 cm • ideally exposure times should be < 2 seconds.	Use 2, 4, 6, 8 cm PMMA blocks at clinical kVps.	As per routine tests.
Digital image uniformity and artefact	• Maximum deviation of mean pixel value < ±15% of mean pixel value for all ROIs. • Maximum deviation in SNR < ±15% of SNR in whole image.	• Assess for 40 mm PMMA covering complete detector • Use five ROIs each of 1 cm^2	Assess also at 20 mm and 60 mm.
Mean glandular dose*	≤ 1.5 mGy for a 4.2 cm 50% adipose, 50% glandular breasts (ie, ACR accreditation phantom).	Assess for an AEC-controlled exposure using typical clinical settings.	As per routine tests; also for 20 mm and 60 mm PMMA.
Image quality evaluation	Digital: the ability to clearly visualise five fibres, four speck groups and four masses in an image of an ACR accreditation phantom or three fibres, three speck groups and 2.5 masses in an image of the ACR mini phantom.	Use typical clinical settings.	As per routine testing.
Artefact*	Inspection for artefacts.	Use uniform PMMA block with typical clinical settings.	As per routine testing.

* Tests required on all types of biopsy units. Other tests may already be covered in FFDM testing.

Appendix 17: Medical physicist testing for biopsy units (continued)

Procedure	Performance requirements/guidelines	Routine testing guidelines	Acceptance and additional tests
Display luminance and viewing conditions	Luminance dynamic range > 250:1 Ambient light < 10 lux.	Measure dynamic range under clinical lighting conditions.	As per routine testing. Display or workstation may have comprehensive quality assurance programme.
Display performance	No smearing artefact, ramps without terracing, lines straight, boxes square, active display centred, borders complete and free from artefact.	• Test patterns to be displayed at full resolution. • Test under clinical lighting conditions. • Use TG18 test pattern, SMPTE pattern may be applicable to older units.	As per routine testing. Display or workstation may have comprehensive quality assurance programme.
Localisation accuracy test	Test performed by MIT performing stereotactic biopsies and observed by physicist.	As per manufacturer's recommendations.	As per routine tests.

National ID: 18571

Appendix 18: Collecting ethnicity data

In New Zealand, ethnicity is based on self-identification. You can belong to more than one ethnic group. At different times of your life, you may wish to identify with other groups. Ethnicity is not the same as the country you were born in, the country you live in, or your ancestry.

This is the standard ethnicity question for the health and disability sector. It mirrors the Statistics New Zealand 2001 Census ethnicity question (Ministry of Health 2004):

- Which ethnic group do you belong to?
- Mark the space or spaces which apply to you.
  - NZ European
  - Māori
  - Samoan
  - Cook Island Māori
  - Tongan
  - Niuean
  - Chinese
  - Indian
  - Other (such as Dutch, Japanese, Tokelauan).
    Please state:

Why do people need to ask this question?

This information helps to develop appropriate services and policies for everyone and ensures that people's needs are met.

The best way to collect ethnicity data is to ask women to fill in the ethnicity question. Deciding from appearance or guessing is not reliable, so the best way is to ask. It is the woman's decision which ethnic group(s) she belongs to.

Appendix 19: Monthly records audit

The following table shows how many records need to be manually checked per site each month. This is the minimum number of records. Further records must be checked if errors are found.

Table T.1: Minimum number of records to be checked per site

	Number records to be checked		
	< 150 screens per month at the site	**< 750 screens per month at the site**	**> 750 screens per month at the site**
Screening records	5	20	30
Assessment records	5	10	20
Cancer records	All cancer records should be checked		

Appendix 20: Breast cancer synoptic report

The following data are for use in a synoptic form that has been developed by the National Screening Unit in consultation with pathologists and other interested parties. The aim is for the form to be used by pathologists for recording treatment data on screen- and non-screen-detected breast cancer.

The form includes 'mandatory data', which are all the pathology treatment data that are required to be collected on screen-detected breast cancer for BSA. This information is vital for monitoring the success of breast cancer screening in New Zealand. Data from patients with cancer detected through BSA will be collected by data collectors and forwarded to the National Screening Unit for analysis. It is hoped that synoptic reporting will improve the quality and quantity of pathology data collected.

Data from patients with non-screen-detected cancers will not be collected for the National Screening Unit. However, recording the same information for both screen- and non-screen-detected cancer may encourage consistency in the synoptic reporting of screen-detected cases. Furthermore, the data from non-screen-detected cases are forwarded to the Cancer Registry and used in calculating the interval cancer rate. This means that synoptic reporting of screen- and non-screen-detected cancers will improve the quality of the analysis of interval cancer rate because the analysis would be based on comparable data. Synoptic reporting for non-screen-detected cancers is also the first step towards the possibility of an in-depth analysis of data on screen- versus non-screen-detected cases in the future.

Along with the 'mandatory data' from the BSA *Data Management Manual*, there are questions on the form for recording data for purely clinical purposes. Such data are designated 'non-mandatory'. It is hoped that the form will not be altered significantly at the regional level, but we acknowledge that different regions may wish to add more 'non-mandatory' fields.

Because pathologists enter data in a variety of ways, a selection of synoptic forms have been developed, including a prompt card for dictation, a one-page synoptic form for handwritten results, and a word document for direct computer entry.

To ensure that synoptic reporting for pathology treatment data is successful, it is imperative that involved parties provide feedback on a regular basis. There will be regular forums for discussion in the form of UDG meetings. It is also important that communication is held on a regional level between pathologists, data collectors, and other interested parties (such as surgeons and oncologists).

For screen- and non-screen-detected breast cancer

One form per breast

- If there is a lesion in each breast, use two forms: for screen-detected cancers, data collectors will decide which lesion is the most significant clinical lesion (based on the Nottingham Prognostic Index formula, or NPI).
- If there is more than one lesion in a breast, use one form. For multiple tumours, record elements marked with an asterisk (*) for the most clinically significant tumour as per the NPI.
- NPI = (Size in cm x 0.2) + Grade (1–3) + Nodes (1–3; 1 = node negative, 2 = 1–3 nodes positive, 3 = > 3 nodes positive, or the apical node positive)

Note: Elements marked with this symbol (•) are mandatory fields.

Data	Value
•NHI number	
•Name	
•Date of birth	
•Date	
Pathologist	
•Breast: L = Left; R = Right	
•Source of pathology data 1 = Cytology 2 = Standard core (non-vacuum) 3= Vacuum-assisted biopsy 4= Vacuum-assisted excision 5 = Open surgical excision, including excision biopsy 6 = Autopsy U = Not available / unknown / unsure	
•Re-excision: Y = Yes; N = No	
•Histopathology of invasive lesions: 00 = No invasive component 01 = Invasive duct not otherwise specified 02 = Invasive tubular (primary) 03 = Invasive cribriform 04 = Invasive mucinous (colloid) 05 = Invasive medullary 06 = Invasive lobular classical 07 = Invasive lobular variants 08 = Mixed invasive ductal/lobular 09 = Other invasive malignancy (primary) 10 = Other invasive malignancy (secondary) U = Not available / unknown / unsure If 9 or 10 specify type in writing DCIS with microinvasion is classified as 01 = invasive duct not otherwise specified. Microinvasion is ≤ 1mm.	
•Histopathology of CIS lesions: 00 = No DCIS 11 = Low nuclear grade 12 = Intermediate nuclear grade 13 = High nuclear grade 14 = Lobular carcinoma in situ (LCIS) = Pleomorphic LCIS 19 = Other DCIS U = Not available / unknown / unsure LCIS is not recorded unless it is in association with invasive disease.	
EIC: P = Positive; N = Negative	
Calcification: P = Present; A = Absent. Give size.	
Central duct necrosis: P = Present; A = Absent	
*•Size: Give size in mm to 1 decimal point (00.0) U = Not available / unknown / unsure If multiple tumours, record size of largest invasive lesion – refer to TMN 2002	
- Invasive component	
- Entire lesion (invasive and DCIS component)	
*•pT staging: pTX = Primary tumour cannot be assessed histologically pTO = No histological evidence of primary tumour pTis = Carcinoma in situ Tmic = < 1mm PTIa = > 0.1 to 0.5 cm pT 1c = > 1 to 2 cm pT2 = > 2 to 5 cm pT3 = > 5 cm pT4 = Chest wall /skin/ inflammatory carcinoma.	
•Histological grade as per the Bloom, Richardson and Elston system: 0 = No grading 1 = Grade 1 2 = Grade 2 3 = Grade 3 U = Not available / unknown / unsure	

Data	Value
•Regional nodes Includes sentinel, intramammary, subscapular, supraclavicular and regional nodes. U = Not available / unknown / unsure	
- Number of nodes examined by pathologist	
- Number of nodes found positive	
Sentinel node involvement 1 = Node(s) negative 2 = Node(s) positive 3 = Sentinel node biopsy attempted but no sentinel node identified 4 = Sentinel nodes positive on immunohistochemistry (note micro-metastasis 0.2–2mm) 5 = ITC < 0.2mm on immunohistochemistry U = Not available / unknown / unsure *2 = Sentinel nodes positive on histology* *4 = Only positive on immunohistochemistry*	
•N staging pNX = Regional lymph nodes cannot be assessed pN0 = No regional lymph node metastasis pN1mi = Micrometastasis, > 0.2 mm M 2 mm pN1a = 1–3 axillary nodes pN1b = Internal mammary nodes with microscopic metastasis by sentinel node biopsy but not clinically apparent pN1c = 1–3 axillary nodes and internal mammary nodes with microscopic metastasis by sentinel node biopsy but not clinically apparent pN2a = 4–9 axillary nodes pN2b = internal mammary nodes, clinically apparent, without axillary nodes pN3a = N 10 axillary nodes or infraclavicular mode(s) pN3b = Internal mammary nodes, clinically apparent, with axillary node(s) or > 3 axillary nodes and internal mammary nodes with microscopic metastasis by sentinel node biopsy but not clinically apparent pN3c = Supraclavicular *Isolated tumour cells (ITC) < 0.2 mm are not considered true metastases for this classification.*	
•Multiple tumours Y = Yes N= No U = Not available / unknown / unsure	
•Clearance from margins *Margins are to be reported in mm to 1 decimal point (00.0). An involved margin would be 00.0.* *If value is U please record reason. If > 99.9, record as 99.9*	
- Invasive. Radial	
- Invasive. Subcutaneous or pectoral fascia	
- Invasive. Unoriented sample	
- Non-invasive. Radial	
- Non-invasive. Subcutaneous or pectoral fascia	
- Non-invasive. Unoriented sample	
- Comments	
•Lymphovascular invasion 1 = present; 2 = absent; 3 = suspicious; U = unsure	
•Hormone receptor assay requested Y = Yes; N = No; P = Pending	
ER: P = Positive; N = Negative Percentage of nuclei stained Predominant intensity of staining	
PR: P = Positive N = Negative Percentage of nuclei stained Predominant intensity of staining	
HER2 testing requested Y = Yes; N = No; P = Pending	
HER2 results P = Positive; E = Equivocal; N = Negative; U = Unknown	
Other findings or comments: Add any information that is not covered in the synoptic report categories (eg, Paget's disease of the nipple). There may be particular features that are specific to a given case and that need to be recorded or details that need to be expanded or further reinforced.	
Diagnostic summary	

Appendix 21: Schedule of uni- and multidisciplinary group meetings

Table V.1: Unidisciplinary group meetings schedule

Unidisciplinary group meetings	Frequency
Breastcare nurses / treatment data collectors*	1 face to face per year
Data Managers	1 face to face per year
Lead Provider Managers	3 face to face per year
Medical physicists	1 face to face per year
Medical imaging technologists	1 face to face per year 1 teleconference
Pathologists	1 face to face per year 1 teleconference (if required)
Clinical Directors	2 face to face per year 1 teleconference (if required)
Surgeons	1 face to face per year 1 teleconference (if required)

Table V.2: Multidisciplinary group meetings schedule

Meeting	Location	Required attendees	Weekly	Fortnightly	Monthly	Quarterly	Six-Monthly	Annually
Liaison meeting/phone or written contact	Lead Provider site GP/PCP sites	Lead Provider GP liaison GPs/PCPs						X
Lead and Screening Support Service Provider coordination	Lead Provider site Screening Support Service Providers	Lead Provider Manager, recruitment and retention staff, Screening Support Service Providers					X	
Joint planning sessions	Lead Provider site Screening Support Service Providers	Lead Provider Manager, recruitment and retention staff, Screening Support Service Providers						X
Management multidisciplinary team	Lead Provider site	Lead Provider Manager, Clinical Director, Data Manager, Lead MIT, lead clinicians, recruitment and retention representative, Quality Coordinator					X	
Management multidisciplinary team	Subcontracted sites (performing assessments)	Subcontracted Provider MITs, clinicians, and manager					X	
Review films for technical quality	Lead Provider site	MITs Clinical Director or a designated radiologist			X	X		
Clinical multidisciplinary team	Lead Provider assessment site	Clinical MDT	X	X				
Clinical multidisciplinary team	Subcontracted assessment site	Clinical Director/Lead Radiologist Clinical MDT	X	X				X
Regional radiologists meeting	Lead Provider region	Lead Radiologist Regional BSA radiologists					X	
Regional MQA committee: review of all sites quality assurance results	Lead Provider region	Lead Radiologist Lead MIT, medical physicist					X	
Regional pathology meeting	Lead Provider region	Lead Pathologist Regional BSA pathologist						X
Regional surgical meeting	Lead Provider region	Lead surgeon Regional BSA surgeons						X
Sites visits (could coincide with clinical MDT at assessment sites)	Lead Provider region	Clinical Director						X
Sites visit	Lead Provider region	Lead MIT					X	
Sites visits (could coincide with management MDT)	Lead Provider region	Lead Provider Manager / QC MIT						X
MQA committee quality assurance programme review	Screening or assessment sites	Medical physicist / designated radiologist						X

Appendix 22: Accreditation protocols

Prior to performing clinical work in BSA, all radiologists, surgeons, pathologists and medical physicists intending to practise in BSA must be accredited to ensure they meet the programme's requirements, as follows.

1. The applicant must complete, in full, the relevant accreditation template electronically. The Clinical Director will verify the information before it is submitted to the NSU.

2. The NSU will allocate a non-identifiable pseudonym from the central register (eg, BSSL 5).

3. The clinical leader will review the template for consistency, content, etc, and if necessary additional information will be sought. Note: the pathologists have delegated responsibility to the Clinical Leader, BSA, to make the decision as to whether the pathologist meets the criteria. Where a decision cannot be made by the Clinical Leader, the pathologist will be referred to the UDG for follow-up and discussion.

4. The accreditation template will be included as an agenda item at the next radiologist, surgeon, pathologist or medical physicist UDG meeting.

5. Where the timeframes from receipt of the template to the date of the next UDG meeting are deemed protracted by the clinical leader, and where they may subsequently disadvantage the Lead Provider in the provision of services, the clinical leader may request email/ correspondence or a teleconference to review the application, and make a decision. Alternatively, the application may be presented at the radiologists, surgeons, pathologists, or medical physicists UDG meeting, where it is subsequently discussed. During the teleconference or UDG, each Clinical Director, Lead Surgeon, Lead Pathologist or medical physicist will complete their panel evaluation template.

6. Once agreement has been reached on the status of the application, all documentation circulated to UDG members (eg, template, evaluation template) is to be destroyed or deleted.

7. A quorum of five radiologists, surgeons or pathologists, or three medical physicists (members of the UDG), is required to participate and the sponsoring clinician is excluded from both the quorum and the final decision-making process.

8. Following the UDG/teleconference, a letter is sent to the applicant and their Clinical Director and copied to the Lead Provider Manager concerned, notifying them of the outcome.

Application for accreditation to work in the BSA programme: Radiologist

Lead Provider	
Code identifier	
Pre-employment criteria (statutory requirements): Clinical Director to confirm	
NZMC registration	
Annual practising certificate	
References/performance appraisal	
Qualifications	
Basic radiology qualifications (eg, FRANZCR), including where and when received	
Mammography experience	
Where worked	
Amount of time spent there	
Whether involved in screening or diagnostic / ad hoc screening	
If this was an organised screening programme, approximately how many women were screened there per annum	
Role in screening unit (eg, observing/reading, involvement in MDT meetings and assessment	
Estimations of the volume of mammograms read (eg, weekly/ monthly)	
Volume of mammograms read in the last 12 months	
Breast fellowship?	
Pre-entry requirements (Clinical Director to complete)	
A minimum of 2000 dummy reads within the last 12 months	
Results of the last 1000 dummy reads	
-Recall rate (less than 12%, as per the NPQS standard)	
-False negative rate (provide narrative if required)	
Adequate sensitivity from the national cancer seeded set (at least 80%, as per the NPQS standard)	
Number of local assessment clinics attended	
Number of local MDMs attended	
Observed/competency	
Ultrasound	
Ultrasound guided biopsy	
Stereotactic core biopsy	
Vacuum assisted biopsy (if provided)	
DBT (if available)	
Localisation for open biopsy	
Training and experience	
Screening mammography courses attended, including online (eg, Tabar or RANZCR multidisciplinary meetings attended, and when)	
Additional meetings/courses attended relevant to mammography	
BreastScreen Aotearoa	
Please outline your current/planned involvement (eg, working with Lead Provider, subcontracted, working in one centre or more).	

General Please make any other comments relating to mammography experience that are not summarised elsewhere. Include publications/presentations.	

Panel evaluation for accreditation to work in the BSA programme: Radiologist

Lead Provider name/code	
Pre-employment requirements • NZ qualifications • Overseas qualifications • NZ registration • APC	
Pre-entry requirements • Dummy reads (300) • Sensitivity • Specificity • Recall rate	
Mammography experience • Sufficient • Borderline • Insufficient	
Training and courses attended • Sufficient • Borderline • Insufficient	
Overall grading • Sufficient • Borderline • Insufficient	
Recommendation • Suitably qualified: – digital screening – assessment • Requiring a specific set of defined training activities • Not eligible to practise as a principle	
For example: a specific set of activities • May continue working in the programme. • Recommend working under supervision as a third reader for three to six months while completing courses. • Exposure to a major multidisciplinary course within 12 months. • Attendance at a Tabar course required.	

Application for accreditation to work in the BSA programme: Pathologist

Lead Provider	
Code identifier	
Pre-employment criteria (statutory requirements]) – lead pathologist to confirm	
NZMC registration	
Annual practising certificate	
References / performance appraisal	
Qualifications	
Basic pathology qualifications (eg, FRCPA), including where and when	
Enrolled on the NZMC vocational register in anatomic or general pathology	
Enrolment in the RCPA's Continuing Professional Development Programme [CPDP]	
Enrolment in the RCPA Quality Assurance Programme (QAP) (Breast Diagnostic)	
Pathology experience with breast screening Relevant experience with breast screening	
Training and experience	
Courses attended (eg, FRCPA multidisciplinary meetings attended, and when)	
Additional meetings/courses attended relevant to breast pathology	
BreastScreen Aotearoa	
Please outline your potential involvement	
Is your laboratory IANZ accredited for histopathology?	
Assessment – percutaneous needle biopsy and/or open biopsy	
Will your individual BSA patient biopsy episodes be less than 50 per annum?	
General Please make any other comments relating to breast pathology that are not summarised elsewhere. Include publications / presentations.	

Panel evaluation for accreditation to work in the BSA programme: Pathologist

Lead Provider name/code	
Pre-employment requirements • NZ registration • APC • References	
Qualifications • NZ • Overseas • Vocational enrolment • CPDP enrolment • RCPA QAP enrolment	
Pathology experience • Sufficient • Borderline • Insufficient	
Training and courses attended • Sufficient • Borderline • Insufficient	
Overall grading • Sufficient • Borderline • Insufficient	
Recommendation • Suitably qualified • Requiring a specific set of defined training activities • Not eligible to practise as a principle	
For example: a specific set of activities • Recommend working under supervision while completing courses. • Recommend exposure to a major multidisciplinary course within 12 months.	

Application for accreditation to work in the BSA programme: Surgeon

Lead Provider	
Code identifier	
Pre-employment criteria (statutory requirements)	
NZMC registration	
Vocationally registered in general surgery with NZMC	
Annual practising certificate	
Evidence of hospital credentialing	
References/performance appraisal	
Qualifications (applicant to complete)	
Basic surgery qualifications (eg, FRACS), including where and when	
Post FRACS diploma, including when and where	
Training and experience	
Surgical experience with breast screening	
Participation in a re-certification programme in general surgery	
Meetings/courses attended relevant to breast surgery	
Meets criteria for full membership of Breast Surgeons of Australia and New Zealand	
Enters all cases of breast cancer in Breast Surgeons of Australia and New Zealand Quality Audit	
Meets CPD requirements for breast disease (including attendance at national and international meetings on breast disease	
BreastScreen Aotearoa Please outline your proposed involvement	
General Please make any other comments relating to breast surgery that are not summarised elsewhere. Include publications/ presentations.	

Panel evaluation for accreditation to work in the BSA programme: Surgeon

Lead Provider/code identifier	
Pre-employment requirements • NZ qualifications • Overseas qualifications • Requires NZ registration • APC	
Pre-entry requirements	
Training and courses attended • Sufficient • Borderline • Insufficient	
Breast surgery experience • Sufficient • Borderline • Insufficient	
Overall grading • Sufficient • Borderline • Insufficient	
Recommendation • Suitably qualified • Requiring a specific set of defined training activities • Not eligible to practise as a principle	
For example: • Recommend working under supervision while completing courses • Recommend attendance at a major multidisciplinary course within 12 months	

Application for accreditation to work in the BSA programme: Medical physicist

Lead Provider	
Code identifier	
Pre-employment criteria (statutory requirements)	
Hold a use license under the Radiation Safety Act (2016) as a diagnostic imaging medical physicist (LMP)	
References / performance appraisal	
Qualifications	
Basic qualifications Master's degree or higher in physics Vocational training in diagnostic imaging medical physics Where and when?	
Specialist training in mammography physics (eg, ACPSEM) When and where?	
Mammography experience • Where worked • Amount of time spent there • Experience in conducting surveys of mammography facilities • Machine testing on six machines over a 12-month period (ie, six machines, two tests per machine, each six months apart) with supervision from a programme-accredited medical physicist (including survey reports, name of supervisor) • Review of quality assurance programmes at two sites	
Continuing professional development • Attendance at scientific meetings • Where and when? • Attendance at multidisciplinary meetings, peer review or audit meetings • Where and when? • Additional meetings/courses attended relevant to mammography physics • Where and when? • Review of current journals and authoritative material	
BreastScreen Aotearoa • Please outline your current/planned involvement • How many facilities and mammography machines do you expect to test per annum? • Where? • When? • How often?	
General Please make any other comments relating to mammography experience that are not summarised elsewhere Include publications/presentations	

Panel evaluation for accreditation to work in the BSA programme: Medical physicist

Name	
Pre-employment requirements • NZ qualifications • Overseas qualifications	
Pre-entry requirements	
Mammography physics experience • Sufficient • Borderline • Insufficient	
Training and courses attended • Sufficient • Borderline • Insufficient	
Continuing professional development • Training within 36 months of undertaking surveys or 15 hours of CPD or pro rata	
Overall grading • Sufficient • Borderline • Insufficient	
Recommendation • Suitably qualified • Requiring a specific set of defined training activities • Not eligible to practise	
For example: a specific set of activities • May continue working in the programme	

Appendix 23: Percutaneous needle biopsy quality assurance

Suggested thresholds for percutaneous needle biopsy performance are shown in Table X.1. These figures will obviously depend on sampling techniques and the experience and care of the clinician (see Barrows et al 1986), and will vary widely between units.

The performance measures are inter-related, and a strategy to improve one aspect of performance will affect others. Thus, attempts to improve sensitivity are likely to increase the false positive rate, attempts to improve the specificity will increase the false negative rate, and so on.

Table X.1: Suggested thresholds for core biopsy performance

Performance indicator	Target (%)
Absolute sensitivity (AS)	> 90
Complete sensitivity (CS)	> 95
Specificity (full) (SPEC) (including non-biopsied cases)	> 85
Positive predictive value (+PV)	> 99.5
False positive rate (F+)	< 0.1
Miss rate (B1 + B2) from cancer	< 10%
Suspicious rate	< 5

Appendix 24: Funnel plots

The funnel plots allow comparison of programme, subcontractor and individual (de-identified) reader performance by allowing for statistical variation due to sample size. The 95% confidence interval limits indicate action points at which the NSU, audit teams or Clinical Directors will institute corrective actions to ensure an improvement in screening performance. Exceeding the 95% confidence intervals, however, should not serve as the only indication for action, and root cause analysis should be initiated if trend data shows the lower limits are being approached over time.

How to use the funnel plots

Users of the funnel plots should insert the relevant cancer detection rate, given the number of women screened in that period, into the graph. All funnel plots are for women aged 50–69 years. For example, for subsequent (incident) screen cancers detected in a six-month period of 27 from 8700 screened women:

rate 27/8700 x 10,000 = 31.0.

Use the funnel plot for subsequent (incident) screen cancers.

Plot 31 on the y axis and 8700 along the x axis. If the point of intersection lies between the limits of the credible interval, it is likely that the target is being met. As noted above, however, a trend of reducing rates should be investigated before limits are reached.

Figure Y.1: Invasive cancers detected on first screen

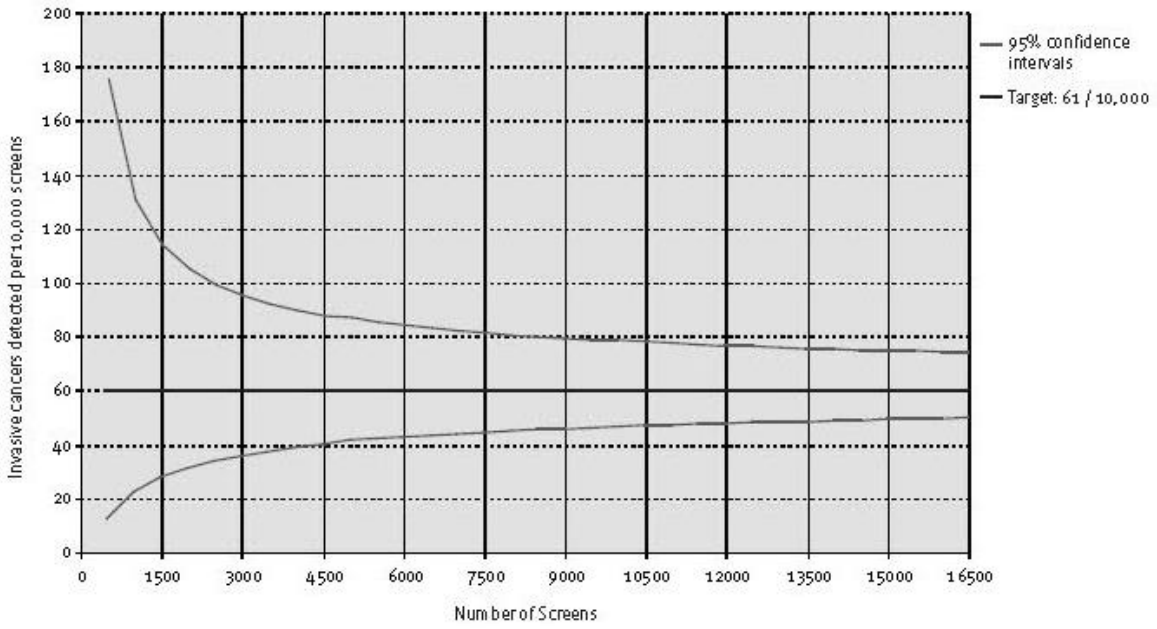


Figure Y.2: Invasive cancers detected on second or subsequent screen

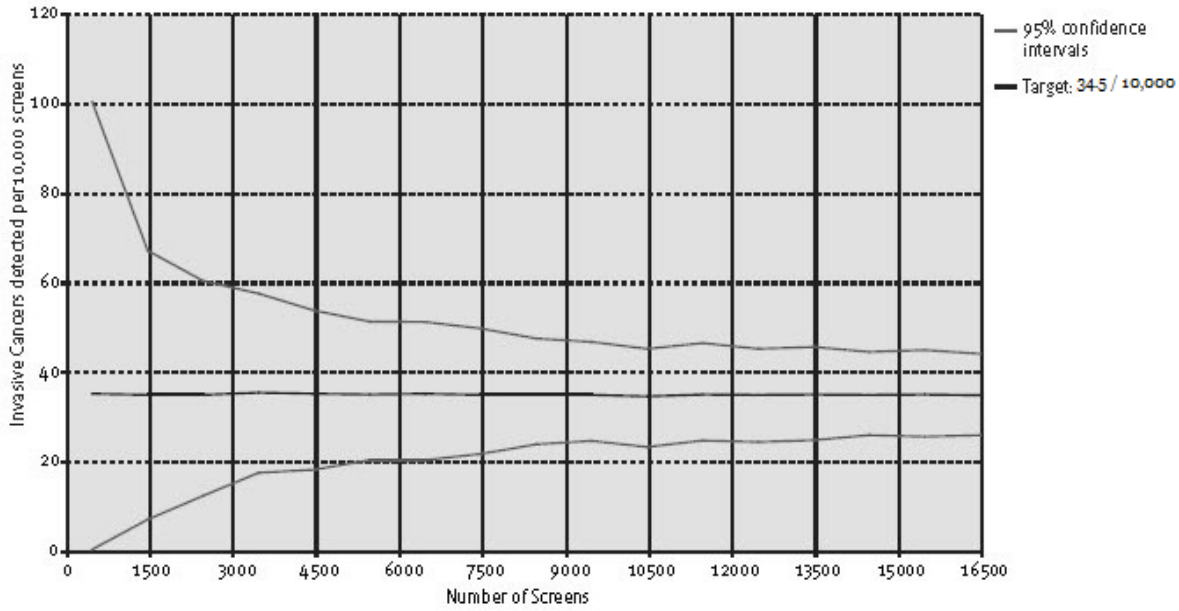


Figure Y.3: Small invasive cancers detected on first screen (< 15 mm)

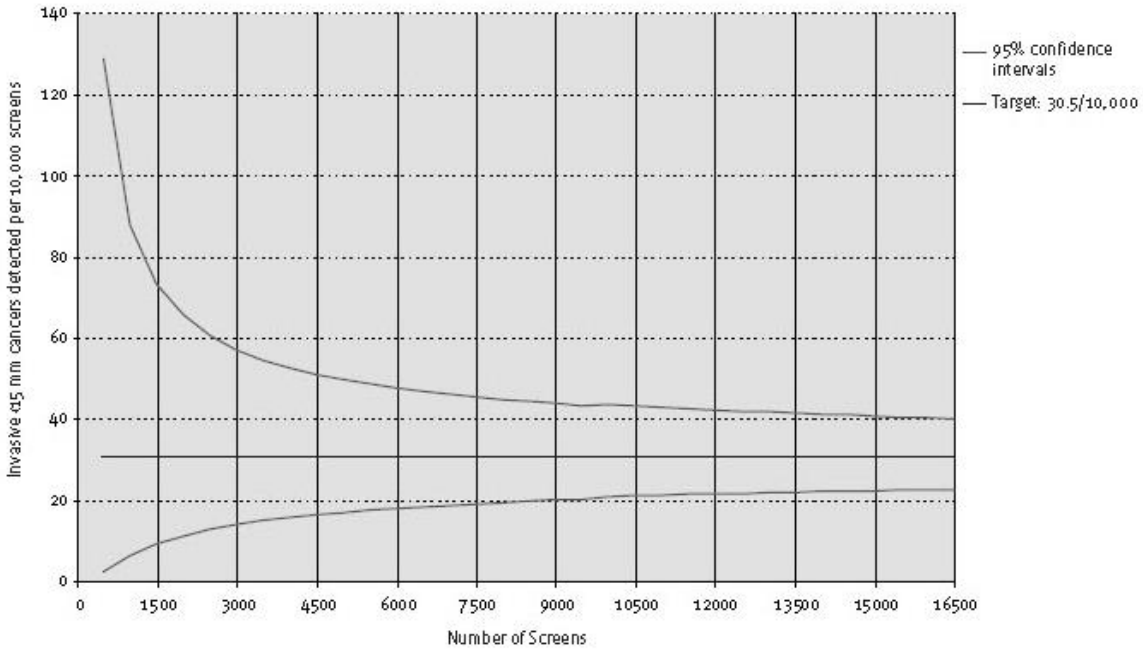


Figure Y.4: Small invasive cancers detected on second or subsequent screen (< 15 mm)

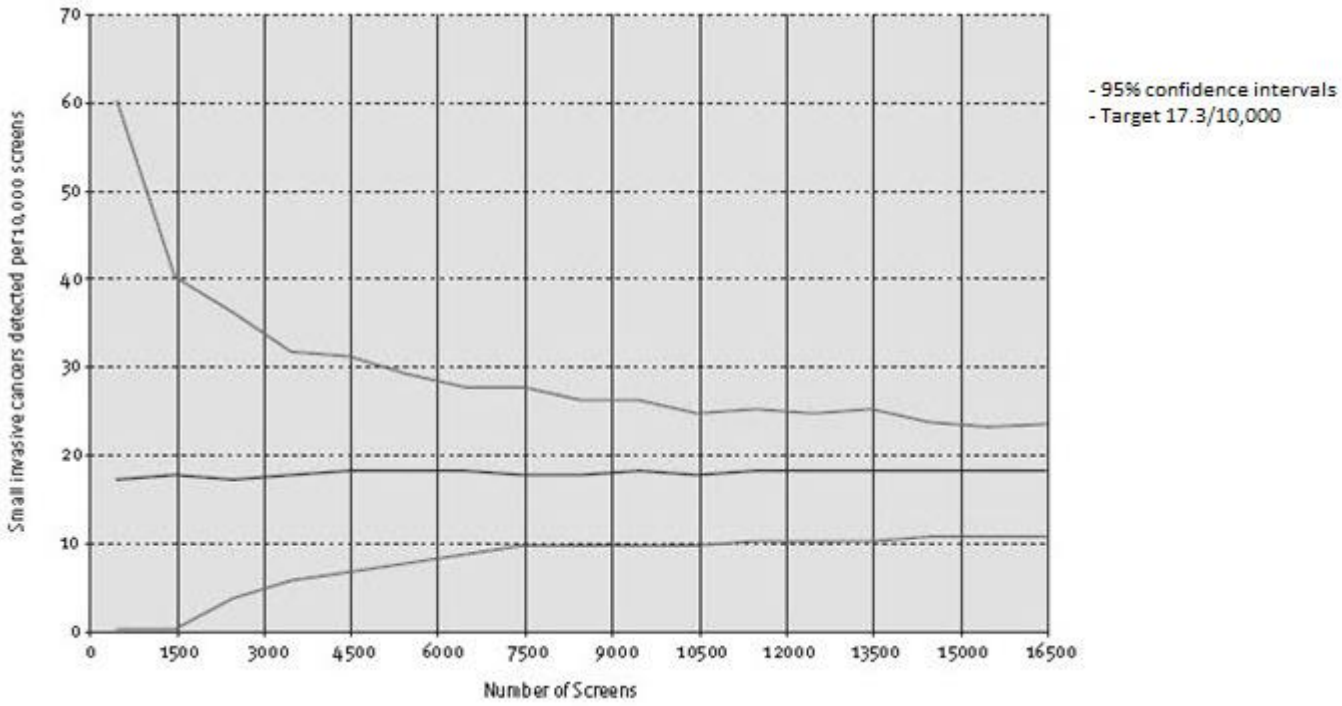


Figure Y.5: Invasive interval cancers within one calendar year of a negative screening episode

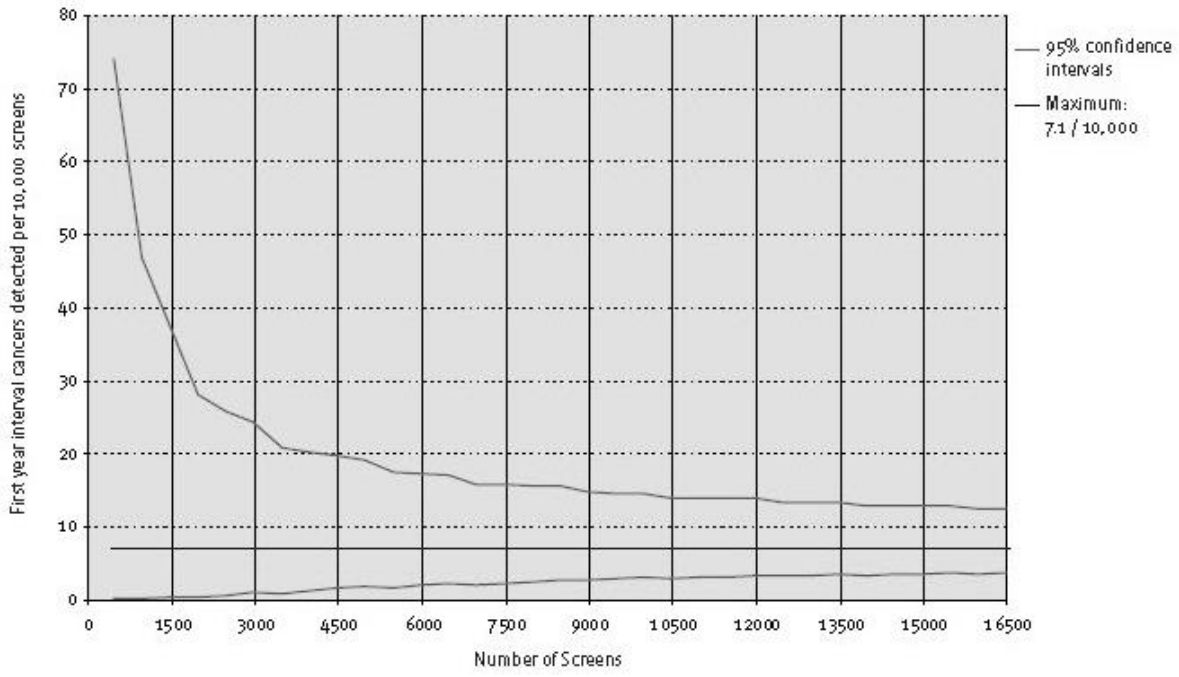
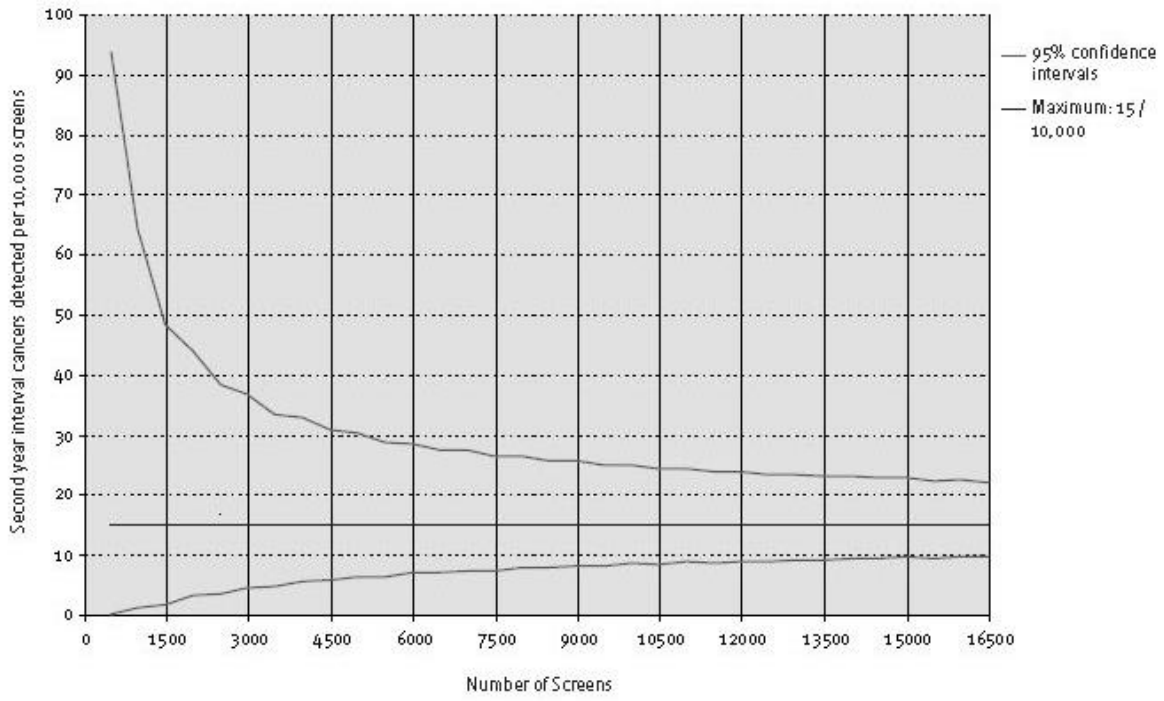


Figure Y.6: Invasive interval cancers in the second calendar year following a negative screening episode



Appendix 25: Reading the Screening Mammogram - Radiologist Specific Targets

Quality Indicator

The reading of the screening mammogram shall occur in such a manner as to maximise detection of any mammographic abnormality that could be cancer.

Evaluation Process

1. Individual radiologists must receive performance feedback, as specified in Criterion 8.18. These records are made available for external audit as de-identified data.
2. Information is collected through the National Minimum Data Set for monitoring and evaluation purposes. (Refer: Current Data Management Manual.)
3. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

Evaluation Target

These quantitative targets apply to women aged 50-69 years. Individual radiologists' reading statistics must lie within 95% confidence intervals for rates of cancer detection and detection of small cancers. Where an individual fails to meet these criteria, the Clinical Director will ensure strategies for improving performance are implemented. This will be monitored by visiting audit teams.

1. Positive Predictive Value of screening mammogram: >9%
2. False positive rate:
    - Initial (Prevalent) Screening Examination < 9% minimum
    - Initial (Prevalent) Screening Examination < 6% desired
    - Subsequent (Incident) Screening Examination < 4% minimum
    - Subsequent (Incident) Screening Examination < 3% desired
3. Referral to assessment:
    - Initial (Prevalent) Screening Examination < 10% minimum
    - Initial (Prevalent) Screening Examination < 7% desired
    - Subsequent (Incident) Screening Examination < 5% minimum
    - Subsequent (Incident) Screening Examination < 4% desired
4. Invasive cancer detection rate (including DCIS) per 10,000 women screened:
    - Initial (Prevalent) Screening Examination = 61.0
    - Subsequent (Incident) Screening Examination = 34.5
5. Small invasive screen-detected cancers (≤ 10 mm) per 10,000 women screened:
    - Initial (Prevalent) Screening Examination ≥ 25% (of invasive cancers) = 15.2
    - Subsequent (Incident) Screening Examination ≥ 30% (of invasive cancers) = 10.45
6. Small invasive screen-detected cancers (< 15 mm) per 10,000 women screened:
    - Initial (Prevalent) Screening Examination > 50% (of invasive cancers) = 30.5
    - Subsequent (Incident) Screening Examination > 50% (of invasive cancers) = 17.3
7. Node-negative invasive screen-detected cancers:
    - Initial (Prevalent) Screening Examination > 70% (of invasive cancers)
    - Subsequent (Incident) Screening Examination > 75% (of invasive cancers)
8. Ductal carcinoma in situ (DCIS): (of all cancers detected by the programme) 10–25%
9. Interval cancers (including DCIS):

- Per 10,000 women screened within one calendar year of previous screen: Goal 5.0, maximum 7.1
- Per 10,000 women screened within the second calendar year of previous screen: Goal 10.65, maximum 15.0

Programme Evaluation Targets
In addition to the above evaluation of the Programme will include:

10. Specificity of screening mammogram (actual) *: > 93%
11. Specificity of Programme (approximate): > 93%
12. Standardised Detection Ratio
    > 0.75 minimum
    > 1% desired
13. Sensitivity of screening mammogram* no target (EU guidelines)

* NOTE: (Refer: Glossary)