National Policy & Quality Standards

National Policy & Quality Standards for BreastScreen Aotearoa
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The National Screening Unit is a separate unit of the Ministry of Health
The National Policy and Quality Standards determine the minimum requirements for any Service Provider of BreastScreen Aotearoa services, be they Independent Service Providers, Lead Providers or Subcontracted Providers working within New Zealand’s National Breast Screening Programme, BreastScreen Aotearoa.

Breast screening has the potential to prevent premature death and disability and to improve the quality of life. However, it also has additional costs and the potential to harm.

Breast screening is a complex process, and for those women participating in the screening pathway the requirement exists for the National Screening Unit and its service providers to reassure women that services are based on quality evidence, and operate within the context of an effective quality assurance programme.

The Interim Standards have been in existence for some time, and following extensive revision, consultation with Providers, Professional Groups, Consumers and Key Stakeholders these National Policy and Quality Standards have been developed. While for some the process to achieve this was initially perceived as straightforward, the task to ensure robust evidence-based Standards was more complex than anticipated and the timeframes were extended to accommodate these requirements.

Our present stage is one of implementing the National Policy and Quality Standards and ongoing work to ensure these Standards remain a dynamic document. The development of additional Standards and/or protocols will be undertaken as required, to ensure they are both appropriate and current.

We would like to thank all those who have worked extremely hard in developing these National Policy and Quality Standards, and we look forward to working with everyone concerned, to ensure New Zealand’s National Breast Cancer Screening Programme, BreastScreen Aotearoa, maintains (or surpasses) a level of quality which is comparable to the best programmes internationally.

Barbara Phillips
Manager
BreastScreen Aotearoa
National Screening Unit

Dr Madeleine Wall
Clinical Leader
BreastScreen Aotearoa
National Screening Unit
National Policy & Quality Standards

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ACKNOWLEDGMENTS

The Ministry of Health would like to acknowledge the individuals and groups who have contributed to the development and subsequent completion of the BreastScreen Aotearoa National Policy and Quality Standards.

We are grateful to the BreastScreen Aotearoa Lead Providers and Independent Services Providers, who gave willingly of their time, and the support from the professional groups involved.

In addition, we acknowledge the importance of the European Guidelines for Quality Assurance in Mammography Screening and the BreastScreen Australia National Accreditation Standards as reference documents which contributed to the completion of the BreastScreen Aotearoa National Policy and Quality Standards.
BACKGROUND TO THE STANDARDS
Standards New Zealand (SNZ), on behalf of the Ministry of Health, facilitated the initial development of the National Policy and Quality Standards (NP&QS) for BreastScreen Aotearoa in line with internationally recognised processes, while working with representatives from the health sector and key stakeholders.
Subsequently, a decision was made to move this process in-house with the inception of the National Screening Unit and the establishment of a dedicated BreastScreen Aotearoa team.
The resulting NP&QS are a collaborative effort between the National Screening Unit, BreastScreen Aotearoa Lead Providers, Independent Service Providers (ISPs), key stakeholders and consumers. They align with those of international breast screening programmes.

A GUIDE TO THE STANDARDS
The NP&QS apply to all Providers (Lead Providers, their subcontractors and Independent Service Providers) who provide services to BreastScreen Aotearoa. It is the responsibility of Lead Providers and Independent Service Providers to ensure that all providers for which they have responsibility meet the NP&QS.
Providers are contractually obliged to meet the NP&QS which also provide the basis for the National Screening Unit’s ongoing programme monitoring and Provider compliance audit.
The NP&QS replace the BreastScreen Aotearoa Interim National Quality Standards (1996) and the Interim BreastScreen Aotearoa National Operations Manual (1998), which had previously determined the operational and quality standards, and level of service required for the national programme.
As well as meeting the NP&QS, it is expected that each Provider will meet its legal obligations, including recognition and adherence to health legislation and any legislation related to the privacy of health information; in particular:
- Health Act 1956
- Medicines Act 1981
- Cancer Registry Act 1992
- Privacy Act 1993
- Health and Disability Services Act 1993
- Health Information Privacy Code 1994

The National Screening Unit, in its leadership role, wishes to share its quality purpose, vision and language and foster a culture within the screening programmes of:
- working together as ‘one programme’
- striving for excellence in a collaborative, learning environment
- encouraging clarity of accountability for quality
- managing quality through a ‘systems approach’
- enhancing co-ordination of quality improvement activities.

In line with the New Zealand Health and Disability System Quality Improvement Strategy the Quality Framework indicates a shift in environment from quality assurance to quality improvement. This does not imply that quality assurance activities are of lesser importance, rather that they become part of a wider quality system which focuses on continual improvement where incremental steps are taken to incorporate new knowledge, changes in technology and changing expectations.

The Quality Framework can be summarised as comprising three key elements:
- principles
- quality requirements
- factors enabling implementation.

EXPLANATION OF TERMINOLOGY

Standard
The Standard is the overall goal, and wherever possible is outcome-focused and relates directly to the woman. The standard will always specify the objective that is expected.
The Standard is achieved when all indicators associated with it are met.

Quality Indicators
The quality indicators in this document should be measurable elements of service provision. Quality indicators will usually relate to the desired outcome or performance of staff or services.

Criteria
The criteria are components of service provision (inputs) that are required to be in place in order to achieve the indicator.

Evaluation Process
The evaluation process is the means through which the criteria are assessed.

Evaluation Target
Targets are only specified where quantitative measures are available. If no target has been set, the expectation is that there will be full compliance with all criteria.

The evaluation target should clearly identify the level of compliance required to meet the specific standard, indicator or criteria.

A The eligible populations the programmes intend to serve includes those people who participate in screening services and any follow-up diagnostic or therapeutic treatments they may access, as well as those persons eligible to participate in the programme who are not currently participating, other than those who have made an active choice (informed decision) not to participate in the screening programme.

INTRODUCTION

Organised breast screening programmes aim to reduce breast cancer mortality by routinely screening an entire, defined population at regular intervals (in these circumstances, women asymptomatic of breast cancer). A reduction in mortality at a population level depends upon high levels of coverage of the population, 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. Furthermore, the initiative is that of the health service and not the women.

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

1. co-ordination of all elements of the service
2. a population-based register (currently no such register is available to BreastScreen Aotearoa)
3. an invitation and recall system
4. a multidisciplinary team approach to screening, assessment and diagnosis
5. close linkages with treatment services
6. specific operational policies, quality standards and ongoing monitoring and quality assurance processes.

BACKGROUND TO BREAST SCREENING

BREAST CANCER IN NEW ZEALAND

Breast cancer is an important health concern in New Zealand. It is the leading cause of cancer registrations and deaths for non-Māori women in New Zealand, and the leading cause of cancer registrations and second leading cause of cancer deaths (after lung cancer) for Māori women. In 1998 (the most recently published data)6, 628 New Zealand women died from the disease, and 2061 were registered as having been diagnosed with breast cancer.

The total breast cancer registration rate has increased by 16 percent from 1993 to 1996 with most of the increase occurring prior to 1994. Rationale for the increase since 1993 may be due to more complete reporting since the introduction of the Cancer Registry Act on 1 July 1994, which made registration a legislative requirement.

Internationally, New Zealand’s annual age-standardised breast cancer incidence rate is among the highest in the world7 and the projections of the cancer burden in New Zealand suggest that breast cancer mortality and incidence can be expected to increase steadily through to the year 20218. Any reduction in breast cancer mortality related to BreastScreen Aotearoa would not be expected to be detected for a minimum of ten years from the start of the programme.

EARLY DETECTION OF BREAST CANCER

Although risk factors for breast cancer have been identified9, primary prevention of breast cancer is not yet possible. However, mammographic screening is able to identify cancers at an early stage, thereby improving the probability of a positive outcome, as 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.

Mammographic screening as a cancer control strategy has been introduced in a number of nations, including New Zealand. International evidence has shown that breast screening delivered through a properly organised programme is efficacious in reducing mortality from breast cancer for women aged 50-69 by 30 percent.10

ORGANISED APPROACH TO SCREENING

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EXPECTED BENEFITS FROM POPULATION-BASED SCREENING

It has been estimated that an organised breast screening programme in New Zealand could save approximately 100 lives per year in the first five years, and up to 175 lives per year after twenty years of screening. It should also be noted that the number of deaths from breast cancer per year is influenced by other factors, including the true incidence of breast cancer and treatment advances.

Therefore, while there is confidence that an organised breast screening programme will result in a reduction in the number of deaths, the actual number will also be influenced by factors other than screening.

HISTORY OF BREASTSCREEN AOTEAROA

During the 1980s a number of nations 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,11 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, with an assessment of their effectiveness, economic efficiency and social acceptability.

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:

1. to develop and implement an organised population-based breast screening programme
2. to co-ordinate 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, there existed an ad hoc approach 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.

References:

7. Asymptomatic women are women who do not have a symptom that may be due to breast cancer. (Refer Appendix A: Glossary)
In June 1995, the Minister of Health announced that the Government would introduce a nationwide breast cancer screening programme (note ‘nationwide’ rather than national) for women aged 50 to 64 years of age. The basis for that decision was:

1. breast cancer was a significant health issue in New Zealand
2. there was clear evidence of the efficacy of mammographic screening in reducing mortality from breast cancer
3. studies confirmed that breast cancer screening was better value for money relative to other available health interventions
4. 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
5. mammographic screening was effective in reducing mortality from breast cancer among women aged 50–64 years
6. 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 (BCSPAG) 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:
1. the programme should be an organised, population-based screening programme as part of a strategic approach to breast cancer detection and management
2. there should be central planning, co-ordination, monitoring and evaluation of the programme
3. the service specifications should be based on those of the pilot programmes, but modified according to lessons learned
4. national quality standards should be developed
5. all women aged 50 to 70 without symptoms should be eligible
6. there should be no charge to women for access to the programme.

Further planning and policy development was 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.

There were major changes in policy that originated in 1991 for the delivery of health services in New Zealand. These 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.

While the BCSPAG had originally recommended two-yearly, and two-view mammography for asymptomatic women aged 50–69 years,8 the Government of the day decided to limit the programme to women aged 50–64 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 (i.e. MRTs, 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.

Furthermore, the Minister 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.9

In June 1996, the Ministry of Health published the Interim National Quality Standards. This document outlined the Standards that would be required to be met by breast screening Providers in order to maximise the quality of the programme to women.

In 1997, the 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 configuration and delivery of their services within that region. Subsequently contracts were entered into with six main Lead Providers in 1998.

Following the restructuring within the New Zealand health services, the former Health Funding Authority (HFA) established Independent Service Providers (ISPs) who 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 being offered in each of the regions from that time. Since then, large numbers of eligible women have participated in BreastScreen Aotearoa.

NATIONAL POLICY

The aim of screening is to reduce morbidity or mortality from a specific health condition. It reduces the risk of development of, or dying from a disease, but is not a guarantee of prevention, or diagnosis and cure. As screening has its benefits, cost and potential harm, 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 upon 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.’

(National Health Committee 2003)10

In order for a screening programme to be successful, a co-ordinated 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. In addition, it is important to identify priority groups who are most likely to benefit from screening and to ensure that 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 aged 50–64 years of age
• women who have not had mammography within the previous 12 months

INTRODUCTION

THE TREATY OF WAITANGI

Groups for screening

The National Screening Unit is a separate unit of the Public Health Directorate of the Ministry of Health and is responsible for:

- national management and oversight of BreastScreen Aotearoa
- funding of BreastScreen Aotearoa Providers
- national co-ordination of Providers
- national health promotion activities (including development of standardised resources and national promotions)
- national strategy and policy development
- national monitoring, evaluation and audit.

BREASTSCREEN AOTEAROA PROVIDERS

BreastScreen Aotearoa is delivered to women on both a national and regional basis. For the purposes of this document, a BreastScreen Aotearoa Provider is defined as being any Lead, subcontracted Provider or Independent Services Provider (ISP) who deliver services on behalf of BreastScreen Aotearoa.

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

- health promotion
- invitation
- screening
- assessment
- referral to treatment
- quality assurance.

Screening is provided at both fixed and mobile sites throughout each Lead Provider region while assessment is provided at a reduced number of locations. The Lead Provider and Independent 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 NP&QS contractually required of them.

Independent Service Providers (ISPs) are contracted by the National Screening Unit to provide health promotion, invitation and support services directly to specific groups of women who might otherwise not be reached by Lead Providers; that is, Māori, non-Māori and Pacific women. Each ISP is responsible for providing services throughout their region. Independent Service Providers and Lead Providers work in partnership with each other while being accountable to the National Screening Unit.

ELIGIBILITY FOR TREATMENT

Regardless of an individual’s participation in this Programme, free treatment services for individuals diagnosed with cancer are only available to those who are eligible for publicly funded health services in New Zealand. (Refer Appendix G: 2003 Direction of the Minister of Health relating to Eligibility for Publicly Funded Personal and Disability 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

BreastScreen Aotearoa provides a national screening programme, which includes:

1. promotion of screening
2. education about breast cancer, screening and treatment
3. identification and invitation of women eligible for screening
4. invitation and recall of women eligible for screening at two-yearly intervals
5. screening mammography for eligible women
6. multidisciplinary assessment for screened women including clinical examination, ultrasound, fine needle aspiration biopsy, core needle biopsy, stereotactic-directed biopsy, open biopsy and pathology services
7. communication of the screening results to women and their primary health care provider
8. support and counselling for women undergoing assessment procedures
9. referral to treatment for those women identified with breast cancer
10. an information system to support the screening programme
11. quality assurance, audit, monitoring and evaluation.

CONFIGURATION

The National Screening Unit is a separate unit of the Public Health Directorate of the Ministry of Health and is responsible for:

- national management and oversight of BreastScreen Aotearoa
- funding of BreastScreen Aotearoa Providers
- national co-ordination of Providers
- national health promotion activities (including development of standardised resources and national promotions)
- national strategy and policy development
- national monitoring, evaluation and audit.

RECALLING INEQUALITIES FOR ALL NEW ZEALANDERS, INCLUDING MĀORI AND PACIFIC PEOPLES

The Ministry of Health paper Reducing Inequalities in Health1 articulates the Crown’s broader responsibilities to all New Zealanders under the Treaty of Waitangi. Furthermore Durie2 has said that the Treaty speaks about citizenship for non-Māori as well as Māori, which imposes ensuing Crown obligations towards the non-Māori population.

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

- NZ European peoples
- 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.

INTEGRATING THE TREATY OF WAITANGI

The BreastScreen Aotearoa National Policy and Quality Standards acknowledge the Treaty of Waitangi as the founding document of New Zealand and both recognise and respect the Principles of the Treaty.

BreastScreen Aotearoa is committed to working with Māori in good faith, with mutual respect, co-operation and trust. This commitment is reflected in the Government’s strategic objectives for Māori health and focuses on:

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

HEALTH AND DISABILITY COMMISSIONER’S CODE OF CONSUMERS’ RIGHTS

Compliance with this Standard will assist services in meeting 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.

Therefore, the NP&QS 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 NP&QS should be knowledgeable about the Code and comply with its obligations.

INTRODUCTION

MONITORING AND AUDIT OF NATIONAL POLICY AND QUALITY STANDARDS

BreastScreen Aotearoa Providers will be monitored comparatively against a number of key national evaluation targets on a regular basis.

It is expected that each BreastScreen Aotearoa Provider will have systems in place, including internal audit processes, which ensure their adherence to the NP&QS on an on-going basis. Ultimate responsibility for this process occurring rests with the contracted Lead Provider or Independent Service Provider.

The evaluation processes outlined in the NP&QS provide specific protocols to follow, where appropriate, in order to assist in this process. 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 targets. Where the evaluation process includes surveys, it is expected that these will be undertaken annually.

In addition, an audit framework will provide the basis for external Provider audits. The external audit process enables a verification of adherence to each of these Standards.

DOCUMENT MAINTENANCE OF NATIONAL POLICY AND QUALITY STANDARDS

The NP&QS are distributed to Lead Providers, subcontracted Providers, Independent Service Providers, professional groups and key stakeholders. It is also available from the National Screening Unit’s website (www.healthywomen.co.nz) and Ministry of Health website (www.moh.govt.nz).

It is intended that the NP&QS remain a dynamic document reflecting the challenges and changes within the screening sector. In order to achieve this, reviews of the NP&QS are required to ensure they remain both appropriate and applicable. The process for maintaining this document is one where particular areas or sections will be reviewed based on evidence informed findings and in accordance with international practice. Any amendments to the NP&QS issued between now and the next review will be sent to those parties listed on the database held by the National Screening Unit as having received the document. The updates will also be posted on the website.

ETHICAL ISSUES

Screening can be an effective way of identifying early signs of disease so progression can be halted and treatment provided. However, screening does have limitations and uncertainties and no screening test offered can be 100% 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 to note 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. The failure to clearly explain the limitations of screening can result in a lack of confidence in the entire 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 sufficient information to make an informed choice. Refer Standard 5: Consent.

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SECTION 1 – Universal Requirements

1. WELL WOMEN-CENTRED SERVICES

Standard — The entire screening pathway and all other activities provided within BreastScreen Aotearoa have a key focus on women and their needs (as they relate to breast screening) to ensure each woman has confidence in the Programme.

1.1 WELL WOMEN-CENTRED SERVICES

Quality Indicator
BreastScreen Aotearoa Providers have a commitment to work collaboratively with women, women’s groups or community organisations or with women and their representatives to ensure the Programme is well women-centred and reflects the particular issues relevant to the screening of asymptomatic women.

Criteria
1. BreastScreen Aotearoa Providers ensure that all women participating in the Programme receive services which are:
   a. delivered in a professional manner consistent with each woman’s physical, emotional, spiritual and cultural needs
   b. provided in line with all relevant standards and legislation and in accordance with:
      i. the Code of Practice and ethics of each profession
      ii. the philosophy of minimising potential harm and optimising the quality of life of that individual.
2. BreastScreen Aotearoa Providers shall encourage each woman to be actively involved in discussions and decisions about procedures to be undertaken.
3. BreastScreen Aotearoa Providers shall ensure that all staff working in the Programme:
   a. undergo culturally consumer-focused training
   b. work as members of a multidisciplinary team in partnership with each woman, with her consent, and her family-whānau
   c. enable each woman to make informed choices about breast screening
   d. demonstrate excellent communication skills and the ability to establish rapport with women
   e. work in a manner that respects consumer rights, and in particular the Code of Health and Disability Services Consumer Rights\(^1\) and the Health Information Privacy Code 1994
   f. are sensitive to both the needs of the age group and a woman’s cultural needs
   g. recognise and respond to the requirements of women with disabilities.

4. BreastScreen Aotearoa Providers shall include well women consumer representatives on any advisory committees it establishes, or those which operate within the region.

Evaluation Process
1. Satisfaction surveys.
2. 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
1. 95% of women surveyed report that the overall service they received is women-centred and meets their needs.
2. All other criteria are met.

1.2 WELL WOMEN-CENTRED SERVICES – BbreastScreen Aotearoa Priority Groups

Quality Indicator
BreastScreen Aotearoa Providers have a commitment to maximise coverage and participation of the women from the BreastScreen Aotearoa Priority Groups from invitation to screening and re-screening through to possible assessment and/or treatment.

Criteria
1. Evidence informed invitation strategies are developed by BreastScreen Aotearoa Providers to ensure that priority is given to the following groups:
   • Māori women
   • Pacific women
   • unscreened women (women who have either never been screened or have not been screened for five years)
   • underscreened women (groups of women whose coverage and participation rates are well below those of the total eligible population).
2. Invitation strategies for these priority groups are based on a regional needs assessment and subsequently developed in collaboration with other relevant providers.

\(^1\) Health and Disability Commissioner (Code of Health and Disability Services Consumers’ Rights) Regulations 1996.
3. Screening, re-screening and assessment services are provided in a manner that ensures the priority groups are encouraged to participate and feel safe in doing so.

4. Known barriers to screening for the priority groups are considered by Providers in the planning and provision of services. These barriers include:
   - lack of appropriate information
   - cost
   - shyness/whakamā
   - embarrassment
   - previously painful or unpleasant experiences
   - fear of having cancer
   - transport and/or childcare difficulties
   - distance to Service Providers and other location issues
   - generational and cultural factors.

**Evaluation Process**
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**
All criteria are met.

2. CULTURAL APPROPRIATENESS

**Standard**
Staff practise in a manner that meets individual cultural needs for each woman and her family and whānau and they are culturally appropriate.

2.1 CULTURAL APPROPRIATENESS – TREATY OF WAITANGI

**Quality Indicator**
Staff practice reflects knowledge of the principles and articles of the Treaty of Waitangi and applicability to the services provided.

**NOTE:** The principles of the Treaty of Waitangi are:
- 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, hapu, 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.
- Recognition: Māori and the Crown will have a relationship of good faith, mutual respect and understanding and shared decision-making.

**Criteria**
BreastScreen Aotearoa Providers will ensure that all staff:
1. recognise and understand the principles and articles of the Treaty of Waitangi, and that this is reflected in their practice.
2. recognise and respect the unique identity of Māori as Tangata Whenua in the planning and provision of services.
3. assist each Māori woman to access relevant services, support and resources such as 'for Māori, by Māori' services where these exist.
4. consult iwi and Māori in order to meet the needs of Māori women during service provision.

**Evaluation Process**
1. Satisfaction surveys.
2. Specific iwi and Māori feedback.
3. Formal cultural evaluation of the service, for example, an external cultural audit.
4. Partnerships made with iwi and Māori to establish appropriate monitoring and evaluation processes.
5. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

**Evaluation Targets**
1. 95% of Māori women surveyed report that their cultural needs were addressed in a manner that was culturally appropriate.
2. All other criteria are met.

2.2 CULTURAL APPROPRIATENESS – TE WHARE TAPA WHA

**Quality Indicator**
Staff recognise the philosophy of Te Whare Tapa Wha in their practice.

**NOTE:** The four dimensions of Te Whare Tapa Wha are:
- Te taha hinengaro – mental wellbeing
- Te taha tinana – physical wellbeing
- Te taha wairua – spiritual wellbeing
- Te taha whānau – family wellbeing.

**Criteria**
BreastScreen Aotearoa Providers ensure that all staff understand the holistic framework of Te Whare Tapa Wha2 as being central to the wellbeing of Māori.

**Evaluation Process**
1. Satisfaction surveys.
2. Specific iwi and Māori feedback.
3. Formal cultural evaluation of the service, for example, an external cultural audit.
4. Partnerships made with iwi and Māori to establish appropriate monitoring and evaluation processes.
5. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

**Evaluation Targets**
1. 95% of Māori women surveyed report that their cultural needs were addressed in a manner that was culturally appropriate.
2. All other criteria are met.

2.3 CULTURAL APPROPRIATENESS – INDIVIDUAL CULTURAL NEEDS

**Quality Indicator**
The individual cultural needs of each woman and her family and whānau during each stage of the Programme are recognised and relevant cultural advice and/or guidance is sought to ensure both the practice and maintenance of cultural appropriateness.

**Criteria**
BreastScreen Aotearoa Providers will ensure that all staff:
1. recognise the impact that diversity of cultural practices and beliefs may have on the breast screening process.
2. practise in a manner that respects the identity of each woman and her family and whānau who accompany her and which upholds their right to personal beliefs and values.
3. identify cultural barriers within their control which reduce access for women.
4. assist each woman to gain appropriate support and representation from those who understand her culture, needs and preferences.
5. 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.
6. provide alternative arrangements when cultural appropriateness is undermined.
7. validate that their own practice is culturally appropriate, particularly when providing direction or supervision to other staff.

**Evaluation Process**
1. Satisfaction surveys.
2. Formal cultural evaluation of the service, for example, an external cultural audit.
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 Targets**
1. 95% of women surveyed report that their cultural needs were addressed in a manner that was culturally appropriate.
2. All other criteria are met.

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2 Te Whare Tapa Wha is a well-recognised and endorsed health concept for Māori. It is an holistic approach in which health and wellbeing is described in relation to four walls of a strong house. A person is considered unwell if any one of these foundations 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 foundations. For further information refer to Durie M. 1998.
2.4 CULTURAL APPROPRIATENESS – PACIFIC WOMEN

Quality Indicator
The individual cultural needs of each Pacific woman and her family during each stage of the Programme are recognised and relevant cultural advice and/or guidance are sought to ensure both the practice and maintenance of cultural appropriateness.

Criteria
BreastScreen Aotearoa Providers will ensure that all staff:
1. recognise the impact that diversity of cultural practices and beliefs may have on the breast screening process
2. practise in a manner that respects the identity of each woman and her family who accompany her and which upholds their right to personal beliefs and values
3. identify cultural barriers within their control which reduce access for women
4. assist each woman to gain appropriate support and representation from those who understand her culture, needs and preferences
5. 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
6. provide alternative arrangements when cultural appropriateness is undermined
7. validate that their own practice is culturally appropriate, particularly when providing direction or supervision to other staff.

Evaluation Process
1. Satisfaction surveys.
2. Formal cultural evaluation of the service, for example, an external cultural audit.
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 Targets
1. 95% of women surveyed report that their cultural needs were addressed in a manner that was culturally appropriate.
2. All other criteria are met.

3. COMMUNICATION

3.1 COMMUNICATION – EFFECTIVE COMMUNICATION

Quality Indicator
Each woman participating in the Programme receives relevant information that maximises the opportunity for understanding and that demonstrates respect and cultural appropriateness.

Criteria
BreastScreen Aotearoa Providers ensure that the key messages about the overall aims of breast screening are communicated to women (Refer to Appendix P: Key Messages for BreastScreen Aotearoa).

• The intent of these messages is to raise the awareness and understanding of participation in the breast screening service provided by BreastScreen Aotearoa and aims to:
  a. provide accurate and appropriate information about the Programme in order to inform and encourage participation
  b. undertake the above in the context of improving, promoting and protecting the health of women in New Zealand.
• The information provided by BreastScreen Aotearoa to women needs to include:
  a. purpose of screening
  b. potential benefits and limitations of screening
  c. role of a mammogram and other procedures when these are indicated
  d. likelihood of false negative or false positive results and what this means
  e. possibility and implications of finding abnormalities that could include cancer
  f. availability of counselling and support services
  g. importance of seeking medical advice if there are any subsequent breast symptoms or concerns, even if a recent screening mammogram was normal
  h. uncertainties and risks associated with the screening pathway.
• BreastScreen Aotearoa Providers will ensure that:
  a. information is provided in a format best suited to the needs of the woman and her family and whānau
  b. all information provided is consistent with the national information and key messages developed by BreastScreen Aotearoa
  c. all staff are well informed about and fully conversant with current methods of early detection and the benefits and possible adverse effects of breast screening. This will ensure that staff are able to respond to each woman’s questions and concerns with confidence, so helping to allay any fears, guilt or anxieties. If the information that is required is outside the jurisdiction or knowledge of the particular team member then referral on to the relevant individual(s) shall occur.

Evaluation Process
1. Satisfaction surveys.
2. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

Evaluation Targets
1. 95% of women surveyed report that they received relevant and easily understood information.
2. All other criteria are met.

3.2 COMMUNICATION – WRITTEN INFORMATION

Quality Indicator
Appropriate written information, approved or developed by the National Screening Unit, is made available to all women explaining breast screening, proposed procedures, interventions and options.

Criteria
BreastScreen Aotearoa Providers shall ensure that appropriate written information is made available for women.

Evaluation Process
1. Satisfaction surveys.
2. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

Evaluation Targets
1. 95% of women surveyed report that written information was made available that was appropriate and accessible to them.

3.3 COMMUNICATION – TELEPHONE AND PERSONAL CONTACT

Quality Indicator
Communication in person, or by telephone, is conducted in a respectful and culturally appropriate manner.

Criteria
1. BreastScreen Aotearoa Providers shall have protocols for telephone and/or personal contact with women, which take into consideration the principles of respect, sensitivity and cultural appropriateness.

2. When making telephone contact, information is given only to the woman concerned and the Provider representative must:
  a. identify the woman by name
  b. identify themselves by name, and not by workplace
  c. confirm the woman’s full name and date of birth
  d. if asked by a third party advise them that the call is ‘personal’
  e. not leave messages on answering machines or with friends or relatives of the woman, unless the woman has given instructions to do so (such instructions must be documented)
  f. if leaving personal written messages for women with family, they should be left in an envelope marked ‘Confidential’.

3. Staff are educated as to why this process is undertaken, including privacy issues and relevant legislative clauses and appropriate levels of management involvement if required.

Evaluation Process
1. Satisfaction surveys.
2. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

Evaluation Targets
1. 95% of all women surveyed report that their privacy was maintained and telephone and/or personal contact was respectful and culturally appropriate.
2. All other criteria are met.
3.4 COMMUNICATION ABOUT BREASTSCREEN AOTEAROA – MEDIA STRATEGIES AND COMMUNICATION

Quality Indicator
All BreastScreen Aotearoa media communication is presented in a nationally consistent and accurate manner.

Criteria
1. BreastScreen Aotearoa Providers ensure that:
   a. regional/local radio and print media strategies complement any national media activities
   b. while there may be some paid advertising, regionally the emphasis will be on unpaid coverage including interviews and media releases
   c. priority should be given to effective media coverage for women from BreastScreen Aotearoa priority groups. This will involve participation of Maori and Pacific Providers and other key stakeholders, for example, organisations involving older women
   d. BreastScreen Aotearoa media issues are discussed with the National Screening Unit to ensure effective management (refer to Standard 1.2 Well Women-Centred Services – Priority Groups)
   e. any communication with the media initiated by Providers about the Programme (for example, media releases) requires prior written approval by the National Screening Unit
   f. where agreed, routine or repeated operational notices may be placed without additional approval, for example, the Mobile schedule.

2. National Screening Unit will review media material and return it to the Provider within 48 hours where possible.

Evaluation Process
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
All criteria are met.

3.5 COMMUNICATION ABOUT BREASTSCREEN AOTEAROA – VISUAL IDENTITY GUIDE

Quality Indicator
All material identifying BreastScreen Aotearoa must comply with the BreastScreen Aotearoa Visual Identity Guide available from Lead Providers or ISP Managers.

Criteria
1. BreastScreen Aotearoa Providers are required to ensure:
   a. all communications issued by Providers as a result of activities of BreastScreen Aotearoa (including educational materials, advertising media communications and signage) comply with the Visual Identity Guide and include the BreastScreen Aotearoa logo. These items should not have other logos placed on them, except where specific approval has been given by the National Screening Unit
   b. use of the standard design ‘shell’ when developing print advertisements relating to BreastScreen Aotearoa

   NOTE: A range of standard design ‘shells’ has been developed for communication about BreastScreen Aotearoa (included in the BreastScreen Aotearoa Visual Identity Guide). Providers may insert their own content within these shells
   c. the National Screening Unit is notified of any material that is developed and final copy must be approved by the National Screening Unit
   d. BreastScreen Aotearoa media issues are discussed with the National Screening Unit to ensure effective management (refer to Standard 1.2 Well Women-Centred Services – Priority Groups)
   e. any communication with the media initiated by Providers about the Programme (for example, media releases) requires prior written approval by the National Screening Unit
   f. where agreed, routine or repeated operational notices may be placed without additional approval, for example, the Mobile schedule.

2. The National Screening Unit approves all Providers’ service advertisements (which must include the BSA logo).

3. The BreastScreen Aotearoa logo is used only in association with documents and resources associated with BreastScreen Aotearoa.
   a. any material developed by Providers on which the logo appears must be approved by the National Screening Unit
   b. letters on BreastScreen Aotearoa letterhead do not require prior approval.

Evaluation Process
1. The internal audit process confirms compliance with the Visual Identity Guide.

2. 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
All criteria are met.

4. ACCESS TO THE PROGRAMME

Standard – There is acceptable access to BreastScreen Aotearoa services for all eligible women.

4.1 ACCESS TO THE PROGRAMME

Quality Indicator
Each woman in the eligible age group has access to BreastScreen Aotearoa services.

Criteria
BreastScreen Aotearoa Providers will ensure that:
1. every endeavour is made to encourage eligible women to access the Programme
2. each woman is supported in accessing the Programme;
3. the national minimum data set for monitoring and evaluation purposes (Refer Current DMM).
4. The BreastScreen Aotearoa logo is used only in association with documents and resources associated with BreastScreen Aotearoa.
   a. any material developed by Providers on which the logo appears must be approved by the National Screening Unit
   b. letters on BreastScreen Aotearoa letterhead do not require prior approval.

Evaluation Process
1. Information is collected through the National Minimum data set for monitoring and evaluation purposes (Refer Current DMM).
2. Review of the provision of access to the Programme and related information, prior to a decision being made to change the configuration, mobile routes or location of fixed sites.
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 Targets
1. >=70% of eligible women receive a screen within the Programme in the most recent 24 months.
2. 90% of eligible women should be within 60 minutes travelling time of a screening unit (mobile or fixed).
3. 95% of eligible women should be within 90 minutes travelling time of a screening unit (mobile or fixed).
4. 99% of eligible women should be within 120 minutes travelling time of a screening unit (mobile or fixed).
5. All other criteria are met.

8 VERSION 1A BreastScreen Aotearoa National Policy and Quality Standards – February 2004

February 2004 – BreastScreen Aotearoa National Policy and Quality Standards VERSION 1A
5. CONSENT

Standard — Each woman is able to make informed choices about having a screening mammogram and any further assessment if necessary through the use of effective information and communication, enabling her to make an informed choice and give informed consent.

Criteria
1. BreastScreen Aotearoa Providers will ensure that:
   a. the requirements of the Health and Disability Code of Rights 5 and 6 are fully met, ensuring women are able to give informed consent to all aspects of the screening pathway
   b. the service clearly identifies and documents when written consent is required and how this is to be recorded
   c. written consent is obtained and a record kept for the following:
      i. a screening mammogram
      ii. ensuring a woman’s GP/PCP is informed of her participation in BreastScreen Aotearoa
      iii. obtaining previous mammograms.
   d. written consent is obtained where a service, treatment or investigation is to be provided under anaesthetic and/or where there is a significant risk of adverse effects e.g. assessment procedures. For all invasive procedures involving an anaesthetic, a standard surgical and anaesthetic consent form should be used.
   REF: Appendix I: Pro Forma Letters and Forms.
2. BreastScreen Aotearoa Providers shall ensure that each woman:
   a. is provided with sufficient and relevant information in an appropriate manner that she understands, and that enables her to give informed consent in accordance with Standard 3.1. This includes form, language and manner
   b. is able to have any questions she has answered by an appropriate person
   c. is aware that she can decline a procedure at any time and is aware of the consequences of that decision
   d. with an implant must be given information regarding the additional risks of mammography for them and additional special consent. (Refer: Protocol for Screening Women with Breast Implants, Appendix J: National Screening Protocols)

6. SUPPORT/ADVOCACY

Standard — Each woman’s right to have support persons and/or advocates present is recognised and upheld.

6.1 RIGHTS

Quality Indicator — Providers respect the woman’s right to a support person or advocate being present.

Criteria
1. The Code of Health and Disability Services Consumers’ Rights gives each woman participating in BreastScreen Aotearoa the right to have one or more support persons present except where safety may be compromised.
2. BreastScreen Aotearoa Providers will ensure that:
   a. each woman is informed of her right to support and/or advocacy throughout the screening pathway
   b. staff will help any woman who requires assistance to obtain support or advocacy
   c. Māori and Pacific women have access to Māori or Pacific Independent Service Providers where these Providers exist
   d. each woman’s right to have one or more support person(s) of her choice present is met, except where safety may be compromised or another woman’s rights may be unreasonably infringed
   e. where the above occurs, the woman and her support persons are provided with a detailed explanation; and/or alternative arrangements are made
   f. policies/procedures are in place that specify advocacy and support processes.
   This may be achieved by, but is not limited to:
   g. involving family and whānau or other representatives when requested by the woman or as appropriate
   h. the use of independent advocate/advocacy services where required
   i. the use of cultural support persons where required
   j. the provision of access to consumer support groups or agencies where requested and/or appropriate
   k. the facilitation of access to advocacy information/material leaflets/brochures etc.

NOTE: Appropriate radiation protection shall be provided for support persons if they are in the room while the mammogram is performed. This will require a protective screen with a thickness equivalent to 2mm of aluminium or 0.1mm of lead. However, where possible, it is preferable for support people to leave the room while exposures are made.

Evaluation Process
1. Satisfaction surveys.
2. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

Evaluation Targets
1. 95% of women report that they were appropriately informed about the processes involved prior to giving consent.
2. 100% of records have appropriate consent documented where informed consent is required to be provided by the woman.
3. All other criteria are met.
7. PERSONAL PRIVACY

8. COMPLAINT MANAGEMENT

9. INFORMATION PRIVACY

SECTION 1 – Universal Requirements

Universal Requirements – SECTION 1

9. the complaints management process links to the service’s quality and risk management systems in order to facilitate feedback and improvements.

9. INFORMATION PRIVACY

Standard – Individual clinical records are unique to each woman, protected from unauthorised access and treated confidentially.

9.1 INFORMATION PRIVACY

Quality Indicator

All staff ensure that the confidentiality and privacy of information is maintained.

Criteria

1. BreastScreen Aotearoa Providers ensure that:
   a. women’s personal information and data about women is collected, stored, accessed and destroyed to a standard that complies with the Health Information Privacy Code 1994
   b. the Code requires that women will be fully informed 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.
   c. this notification needs to be provided to women at any point when information is collected about them.
   d. refer to Appendix I 5: Information Notification
   e. The Code requires that women be fully informed 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.

NOTE: A complaint may be defined as a consumer-based response to an event they have experienced. It is an expression of dissatisfaction that requires a response from the Provider. Complaints may be voiced in person or over the phone, received in writing, emerge from a survey, by a consumer, their family or whanau or alternatively, a third party.

Evaluation Process

1. Satisfaction surveys.
2. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

Evaluation Targets

1. 95% of women participating in the Programme surveyed have received detailed information of the complaint process.
2. 100% of complaints are managed in accordance with the service’s specified policy and timeframes.
3. All other criteria are met.

7. PERSONAL PRIVACY

Quality Indicator – The physical environment and practices at all BreastScreen Aotearoa facilities provide personal privacy for all women participating in the Programme.

7.1 PERSONAL PRIVACY

Criteria

BreastScreen Aotearoa Providers ensure that:

1. there are documented policies and procedures in place that ensure the protection of personal privacy for each woman participating in the Programme
2. consultations and the provision of services occur in an environment that provides for optimum visual and auditory privacy
   a. no personal information, other than a woman’s name, being elicited verbally in waiting rooms
   b. discussions with, and counselling of women are undertaken in a private environment
3. attention is paid to issues such as a woman’s privacy while changing and while in a gown during screening and assessment. Women, if they wish, should be able to be dressed in their own clothes when participating in discussions with health professionals
4. women participating in the Programme have the opportunity to communicate with others in privacy
   a. a visitors’ room
   b. private waiting space
   c. private counselling rooms.

Evaluation Process

1. Satisfaction surveys.
2. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

Evaluation Targets

1. 95% of women surveyed report that their privacy was respected.
2. All other criteria are met.
SECTION 1 – Universal Requirements

10. CLINICAL RECORD

Evaluation Process
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
All criteria are met.

10.1 CLINICAL RECORD KEEPING

Quality Indicator
Each woman's clinical records (including films, slides and reports) are accurate, accessible, authorised and complete.

Criteria
BreastScreen Aotearoa Providers ensure that:

1. clinical records meet the requirements of appropriate legislation and relevant professional and sector standards where these exist
2. there are documented and implemented policies, procedures and protocols for each step of the screening pathway, that clearly identify the recording requirements of staff (for example, role, responsibility, level of detail, frequency, etc.)
3. clinical records are reviewed regularly to ensure:
   a. identified standards are met
   b. variances/trends in record keeping are responded to
   c. records are objective and factual
4. the woman’s access to her personal records is appropriately managed
5. clinical records are up to date and reflect the current status of the woman
   This may be achieved by, but is not limited to policies and procedures that ensure all:
   a. records indicate which Lead Provider provided the referral
   b. records are current and reflect current status
   c. ethnicity and ethnic groups are recorded
   d. historical records are accessible and an effective record tracking system exists
   e. recent test/investigation/assessment information is accessible or indicated as pending
   f. records contain appropriate information and documentation for all actions taken.
6. women self-identify their ethnicity and their ethnic group(s) at any time
   NOTE: Ethnicity categories will be determined by the National Screening Unit and will be updated in accordance with New Zealand Census categories.
   (Refer Appendix H: Collecting Ethnicity Data)

Criteria
BreastScreen Aotearoa Providers ensure that:

1. all records are legible and all entries are identifiable
   This may be achieved by, but is not limited to ensuring:
   a. all entries are written clearly
   b. abbreviations are listed and approved
   c. signature, designation and date (authorisation) are recorded in a legible manner by staff members
   d. entries are made in ink, electronic or other mediums acceptable under statute
   e. entries are readable and not defaced or obliterated by correction fluid
2. all clinical records shall be signed by the relevant health professional, directly responsible for each part of the screening pathway and/or assessment episode
   This may be achieved by, but is not limited to, a system where:
   a. filing processes facilitate timely retrieval
   b. filing is centrally referenced
   c. filing is cross-referenced
d. the destination of removed files is logged.
3. retained/archived clinical records and films are securely maintained in a suitable order and condition so that they may be retrieved when required
   This may be achieved by, but is not limited to ensuring records are:
   a. protected from destructive forces
   b. secure.
4. timeframes for retention of information are known and met, and subsequently meet the relevant guidelines
   (Refer to Health Records Standard NZS 8153:2002)
5. electronic back-up of information is secure, protected from loss, corruption, inappropriate alteration or miscalculation
6. easily retrievable
7. each woman’s record is stored in an individual file.

Evaluation Process
1. Monthly auditing of clinical records for women screened during the previous month at each screening and assessment site (this may occur in conjunction with the Data Quality Plan requirements).
2. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

Evaluation Targets
1. 100% of records audited are complete and accurate.
2. All other criteria are met.

10.2 CLINICAL RECORD MANAGEMENT

Quality Indicator
Each woman’s clinical records (including films, slides and reports) are appropriately referenced, kept secure, tracked and readily accessible.

Criteria
BreastScreen Aotearoa Providers ensure that:

1. a documented process is implemented to ensure that clinical records are complete and all appropriate actions have been taken prior to filing/archiving
2. systems are in place to electronically and/or manually track and retrieve clinical records and films when they are removed from the main record management area
   This may be achieved by, but is not limited to, a system where:
   a. filing processes facilitate timely retrieval
   b. filing is centrally referenced
   c. filing is cross-referenced
d. the destination of removed files is logged.
3. Electronic datasets (including those held in a clinical record management system) and electronic records of other sources referenced in a record (for example, treatment) are cross-referenced and/or traceable.
4. women’s access to her personal records is appropriately managed
5. clinical records are up to date and reflect the current status of the woman
   This may be achieved by, but is not limited to policies and procedures that ensure all:
   a. records indicate which Lead Provider provided the referral
   b. records are current and reflect current status
   c. ethnicity and ethnic groups are recorded
   d. historical records are accessible and an effective record tracking system exists
   e. recent test/investigation/assessment information is accessible or indicated as pending
   f. records contain appropriate information and documentation for all actions taken.
7. each woman’s record is stored in an individual file.

Evaluation Process
1. Monthly auditing of clinical records for women screened during the previous month at each screening unit/assessment site. (This may occur in conjunction with the Data Quality Plan requirements).
2. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

Evaluation Targets
1. 100% of hard copy clinical records audited are referenced, secured, tracked and readily accessible.
2. All other criteria are met.
II. DATA MANAGEMENT

Standard – All data collected is accurate, reliable and reported in a consistent and timely manner ensuring each woman has confidence in the data management of the Programme.

II.1 DATA MANAGEMENT – ELECTRONIC CLINICAL INFORMATION SYSTEM

Quality Indicator
The clinical information system complies with legislative requirements, Government policy on health information, and new policy principles where appropriate.

Criteria
BreastScreen Aotearoa Providers will ensure:

1. the clinical information system is developed with consideration for the following principles:
   a. the use of, and direct access to, national information systems, particularly the unique identifier from the National Health Index (NHI)
   b. sensitivity to the views and expectations of Māori and Pacific women in relation to the collection and use of breast screening information
   c. mandatory collection of accurate ethnicity data
   d. the definition of ethnicity should be updated continually to reflect the current New Zealand Census categories, determined by the National Screening Unit (Refer Appendix C: Ethnicity)
   e. adherence to, and compliance with the current BSA Data Management Manual (DMM), national standards, definitions and guidelines maintaining the integrity and security of the databases and transmission or exchange of data between organisations.

2. the information system will support BreastScreen Aotearoa by:
   a. storing and maintaining information on screening, assessment, and treatment in accordance with the current Data Management Manual (DMM)
   b. ensuring recall of each woman screened and follow-up assessment is appropriate
   c. providing information required to support quality assurance activities
   d. providing information required for routine monitoring and evaluation of programme outcomes and screening processes
   e. providing screening and assessment results for women and their GP/PCP
   f. providing a fail-safe process to ensure all screening processes and episodes are completed and have been managed appropriately
   g. providing appropriate security access controls within the information system to limit access to identified users and/or organisations.

3. information systems used for making decisions about women participating in BreastScreen Aotearoa are designed and maintained to be fail-safe, thereby, ensuring women do not ‘fall through gaps’ in referral processes or health care services provided

4. women’s personal information and data are managed in such a way that it meets the standards set out in the Code of Practice for Information Security Management (AS/NZS ISO/IEC 17799:2001) and The Health Network Code of Practice (SNZ HB 8169:2002)

5. data and software are to be safeguarded against tampering, secured against illegitimate use and unintentional destruction. These access protocols demand both system and data security measures:
   a. when updating records it must not be possible to alter or erase previous entries without an audit trail being maintained
   b. all information updates in the database shall have an audit trail which identifies the change, author and date
   c. 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.

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

7. data must never be assimilated into a clinical record without the involvement of a clinician who is willing to take legal responsibility for that inclusion. ‘Automatic’ amendments by computer systems are not acceptable to clinical users

8. the author of the record (electronic signature) is to be identifiable

9. the individual responsible for the updating of information should be unambiguously identified. If, for example, a secretary were to enter a clinician’s notes into the record, the transactions would be entered by the secretary and confirmed and authorised for entry by the clinician.

Evaluation Process
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
All criteria are met.

II.2 DATA MANAGEMENT – DATA COLLECTION AND MONITORING

Quality Indicator
Sufficient data is collected to enable BreastScreen Aotearoa Providers to operate at the highest standard and to undertake/participate in evaluation at both a regional and national level.

Criteria
BreastScreen Aotearoa Providers will ensure that:

1. sufficient data is collected and analysed to:
   a. regionally and nationally monitor the Programme
   b. evaluate the Programme’s effectiveness and efficiency
   c. support effective business processes
   d. efficiently invite, manage and track women throughout the Programme
   e. enable ongoing improvement of the Programme’s performance
   f. inform future policy and Programme development decisions.

2. data management conforms to relevant legislation and to the guiding principles of data collection and management as described in NZHIS Guide to Data Requirements*

3. collecting and reporting on the data requirements, data quality checks and periodic audits as detailed in the current Data Management Manual and Data Quality Plan are maintained.

4. procedures are implemented to ensure:
   a. data is captured in a complete, timely and accurate manner
   b. checks are implemented for identifying any errors that may arise during data entry
   c. data is validated against the business rules documented in the current Data Management Manual
   d. definitions and edit rules are understood and are followed
   e. inconsistencies are investigated and rectified.

Evaluation Process
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
All criteria are met.

II.3 DATA MANAGEMENT – DATA INTEGRITY

Quality Indicator
The BreastScreen Aotearoa Provider will ensure that captured data is accurate and complete before use.

Criteria
BreastScreen Aotearoa Providers will ensure that:

1. protocols are developed that clearly describe staff responsibilities for accurate, timely and complete data entry

   Protocols include the accurate recording of a woman’s ethnicity according to categories determined by the National Screening Unit and updated in accordance with New Zealand Census categories. Refer: Appendix H: Collecting Ethnicity Data

   NOTE: women must be allowed to self-identify their ethnicity and ethnic group(s) at any time.

2. staff involved in data entry have adequate time, that allows them to correctly use the system, interruptions are minimised and the environment is conducive to detailed data entry

   note: women must be allowed to self-identify their ethnicity and ethnic group(s) at any time.

   NOTE: BreastScreen Aotearoa Providers may collect additional data to assist them in the provision of a comprehensive service to participating women. New core data elements must be advised to the National Screening Unit for inclusion in the Data Management Manual and the manual updated accordingly.
3. staff involved in data entry (including the interpretation and recording of clinical screening, analysis/treatment notes) are adequately trained and supported in the process

- Non-clinical staff members involved in data entry are not permitted to interpret data but are to be given adequate training in the reading of data provided by the clinicians and to subsequently enter it into the IS system

4. clinicians are responsible for recording their own screening and assessment data (either directly into the computer system or as a paper record) and for its accuracy and completeness. If the computer recording system does not allow sufficient detail to be recorded, then a paper record must supplement this

5. the NSU is notified if the computer recording system does not meet data management requirements.

**Evaluation Process**

1. Monthly auditing of clinical records for women screened during the previous month at each screening and assessment site. (This may occur in conjunction with the Data Quality Plan requirements).

2. 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**

1. 100% of records audited were entered correctly into the system.

2. All criteria are met.

**11.4 DATA MANAGEMENT – RELEASE OF DATA**

**Quality Indicator**

The BreastScreen Aotearoa Provider will ensure that women’s personal information and data about women are used in a way that is consistent with BSA overall purpose and goals, protects the interests and privacy of women involved in the Programme, whilst complying with health information and privacy legislation.

**Criteria**

BreastScreen Aotearoa Providers ensure that:

1. procedures for women seeking access to their personal information are consistent with the requirements of the Official Information Act 1987 and the Privacy Act 1993

2. all requests for aggregate data are forwarded to the Manager and Clinical Leader, BreastScreen Aotearoa, the National Screening Unit, Ministry of Health.

**Evaluation Process**

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**

All criteria are met.

**12. QUALITY AND RISK MANAGEMENT**

**Standard** — The safety of the women, staff and others is protected through comprehensive quality and risk management systems.

**12.1 QUALITY MANAGEMENT SYSTEMS**

**Quality Indicator**

The BreastScreen Aotearoa Provider has an established, quality and risk management system that reflects continuous quality improvement principles.

**Criteria**

1. BreastScreen Aotearoa Providers will maintain written policies, procedures, guidelines, systems or plans that ensure compliance with the National Policy and Quality Standards (NP&Qs) and all relevant standards the Service must comply with, such as the National Radiation Laboratory (NRL), IANZ, Infection Control, and others including:

   a. updating or formulating 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

   b. ensuring that staff are adequately informed and regularly updated of the content of these documents.

2. BreastScreen Aotearoa Providers have a current documented quality management system that:

   a. clearly identifies the personnel that are responsible for ensuring the quality management processes are documented and implemented

   b. clearly identifies in detail all quality improvement processes that will be undertaken in the Lead Provider region and includes an internal audit plan

   c. references the quality model or philosophy selected by the organisation, for example, PDCA Cycle (Plan, Do, Check, Act), Accreditation, ISO Certification, etc

   d. is reviewed by the management at regular intervals to ensure compliance

   e. has the commitment and participation of management and staff, and enables consumer participation wherever appropriate.

3. BreastScreen Aotearoa Providers:

   a. implement a system to regularly assess all practices including management systems, policies, procedures and guidelines, to ensure the NP&Qs are maintained and carried out by staff

   b. ensure that changes/advances in practice adopted by the Provider are documented, are communicated to, and implemented by all staff involved in service delivery

   c. ensure that quality improvement information is collected, analysed and evaluated and the results communicated to Providers and, where appropriate, consumers as part of the quality improvement process

   d. ensure that quality improvement information is relevant to the organisation’s needs and its analysis is both accurate and unbiased

   e. ensure that there are appropriate linkages between the Continuous Quality Improvement (CQI) process and the Risk Management process

   f. ensure that there is a process informing Programme management and the National Screening Unit about CQI activities and findings

   g. ensure a corrective action plan, addressing areas requiring improvement in order to meet the specified standard or requirement, is developed and implemented

   h. ensure that satisfaction surveys and questionnaires are in the standardised format or have been approved by the National Screening Unit prior to use

   i. ensure that the use of questionnaires and surveys follows a process approved by the National Screening Unit, that includes pre-testing

   j. ensure written evidence of routine quality assurance is available for audits and site visits

   k. ensure information and experience gained from the CQI processes are shared within the Provider organisation and where appropriate, through the BreastScreen Aotearoa Manager and Clinical Leader to Undisciplinary Groups and to other Providers.

**Evaluation Process**

The internal audit process shall:

1. evaluate documentation and implementation of the quality management plan

2. evaluate compliance of staff in meeting the requirements of the quality management system

3. ensure identified non-compliances are addressed at the earliest opportunity

**Evaluation Target**

All criteria are met.
12.2 CONTINUOUS QUALITY IMPROVEMENT (CQI) – RISK MANAGEMENT SYSTEMS

Quality Indicator

Policies and procedures have a risk management focus to maximise the safety of women, staff and others through the identification and minimisation of preventable and/or avoidable risks throughout the Programme.

Criteria

BreastScreen Aotearoa Providers are to ensure that:

1. significant risks within their control are identified and managed
2. the National Screening Unit is notified of any matters relating to a significant risk within a specified timeframe
3. assessment of risk is based on factual information and informed opinion. Information accuracy is essential and the determinants of this include sufficiency, relevance, competency and timeliness
4. individual staff are aware of their responsibility for implementing the requirements of the organisation’s quality and risk management system in order to minimise potential harm to women, colleagues and others
5. identified risks are monitored and reassessed at a frequency determined by the severity of the risk, and the probability of change in the status of that risk, in line with the organisation’s policies and procedures.

Evaluation Process

The internal audit process shall:

1. ensure the risk management system reflects continuous quality improvement principles
2. evaluate staff compliance in meeting the requirements of the risk management system
3. ensure identified non-compliance issues are addressed at the earliest opportunity.

Evaluation Target

All criteria are met.

13. ADVERSE/SENTINEL EVENTS REPORTING

Standard — There is a robust process for adverse/sentinel event management, which is linked to the Continuous Quality Improvement (CQI) process to ensure the safety of women, staff and others.

13.1 ADVERSE/SENTINEL EVENTS REPORTING

Quality Indicator

The Provider systematically records all adverse/sentinel, unplanned or untoward events.

NOTE: A serious adverse event is one that may significantly compromise screening and/or assessment activities and/or outcomes, and/or an event for which a facility fails to take appropriate corrective action in a timely manner.

A sentinel event is ‘an event that signals something serious has occurred and warrants in-depth investigation.”

Criteria

BreastScreen Aotearoa Providers ensure that:

1. a process to identify and appropriately respond to adverse events exists
2. adverse, unplanned, untoward or sentinel events are reported, recorded, managed and evaluated in order to identify opportunities to improve service delivery

Adverse/sentinel events include but are not limited to:

a. poor mammographic image quality
b. failure to send mammography reports in a timely manner
c. employment of personnel who do not meet the necessary requirements
d. accidents, incidents, near misses and clinical events
e. complaints and suggestions
f. infections/notifiable diseases

g. other reportable serious events and/or sentinel events as indicated by legislation, regulation, professional practice standards and contracts.

3. the adverse/sentinel event reporting system is a planned and co-ordinated process that links to the quality and risk management system where appropriate

This may be achieved by, but is not limited to:

a. investigation
b. analysis
c. identification of trends
d. planned corrective action
e. ensuring implementation is timely, complete and signed off
f. processes are reviewed to ascertain the effectiveness of corrective action.

4. the clinical care of an individual(s) who has/have been placed at unnecessary risk is made a priority. The Clinical Director is fully informed, and has the authority and resources to provide the appropriate care at the earliest opportunity. During the review it may be deemed appropriate and/or necessary to share information with outside agencies, for example, the Accident Compensation Commission (ACC), the Health and Disability Commission (HDC) and professional organisations in view of public health and safety.

5. the Clinical Director shall undertake an internal review of all such cases and outcomes. Those which could contribute to improving BreastScreen Aotearoa will be shared with the National Screening Unit and other Providers. The results of such reviews shall be made available to auditors and may be referred to outside agencies such as ACC, HDC and professional bodies in view of public health and safety.

6. adverse/sentinel events are reported to the National Screening Unit at the earliest opportunity and in writing, these include but are not limited to:

a. events compromising the quality of the service
b. failure to meet the needs of women
c. failure to meet the overall aims of the Programme
d. events that may attract negative media attention.

7. where the screening quality at a facility has been compromised, Providers shall provide clinical images and other relevant information, as specified by the National Screening Unit, for review by another entity designated by the National Screening Unit.

8. 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 NPIAGS and presents a significant risk to individual or public health, the Provider may be required to 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.

9. where a review of the Provider is stipulated:

a. 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
b. the review may be conducted as an on-site audit at the facility or may be performed through the review of films and/or other materials off-site

c. the reports of any reviews shall be made available to the National Screening Unit.
14. GENERAL PRACTICE/PRIMARY CARE PROVIDER LIAISON

Standard – Effective links with General Practitioners and other Primary Care Providers, including Māori or Pacific Providers are established and maintained.

14.1 GENERAL PRACTICE (GP)/PRIMARY CARE PROVIDER (PCP) INVOLVEMENT

Quality Indicator
The importance of strong relations with General Practitioners (GPs) and Primary Care Providers (PCPs), which include Māori and Pacific Providers, is recognised by Lead Providers and ISPs.

NOTE: While many women will self-refer to BreastScreen Aotearoa, GPs and other PCPs are a point of information and access to the Programme. It is essential to establish and maintain good working relationships with all providers of health services.

Criteria

1. BreastScreen Aotearoa Providers recognise the important role that GPs/PCPs fulfil in the Programme, particularly in:
   a. outlining the benefits and limitations of screening mammography to eligible women
   b. co-ordinating ongoing care
   c. encouraging women to attend further rounds of screening
   d. providing information, support and counselling for women.

2. GPs and other PCPs should be actively involved in BreastScreen Aotearoa Provider services to ensure the success of the Programme and maintain the confidence of women including:
   a. identification of eligible women (review of age/sex registers, consultation with women, completion of the BSA GP Enrolment Form)
   b. invitation to eligible women (with GPs/PCPs support of invitation)
   c. result reporting (where the GP/PCP is nominated by the woman, the GP/PCP should be directly informed of the woman’s results)
   d. confirming information prior to woman’s recall (GP/PCPs confirm a woman’s eligibility and contact details before the woman is recalled).

3. BreastScreen Aotearoa Providers ensure:
   a. GPs and other PCPs are informed about the Programme and their active support is encouraged and maintained
   b. GPs and other PCPs are provided with the opportunity for up-skilling in relation to BreastScreen Aotearoa so they may actively promote the Programme
   c. relevant Providers are informed that referrals are only made following the woman’s informed consent and that the principles of confidentiality are adhered to
   d. the distribution of appropriate promotional and educational resources to relevant providers and practitioners
   e. effective working relationships and support for Iwi/Māori and Pacific Primary Care Providers exists to achieve equitable coverage
   f. information seminars for GPs and other PCPs include information on how best and most appropriately to inform, support and recruit Māori women, Pacific women and other ethnic groups
   g. sufficient information is available including seminars for GPs and other PCPs featuring information on how best and most appropriately to inform, support and recruit women with disabilities
   h. Programme education includes information about inappropriate referrals and the differences between screening and diagnostic mammography
   i. information provided by a woman’s GP/PCP is accepted on the understanding that the GP/PCP has satisfied the requirements of the Health Information Privacy Code 1994 regarding the initial collection and disclosure of this information
   j. a comprehensive strategy is maintained to ensure GPs and other PCPs are involved in the Programme.

This may include but is not limited to:
   • researching GP/PCP information requirements in relation to BreastScreen Aotearoa
   • developing resources for GPs, other PCPs and practice nurses in line with key messages.

4. an identified BreastScreen Aotearoa Provider staff member has designated responsibility for maintaining regular contact (at least six-monthly) and liaison with GPs, PCPs and Provider groups in their region (this may be through face to face contact, newsletters, etc.)

5. women presenting to BreastScreen Aotearoa without a current GP/PCP (or wishing to nominate a GP/PCP) should be encouraged to nominate one, and if required, be offered a list of local GPs/PCPs.

Evaluation Process

1. Satisfaction surveys of GPs/PCPs.

2. 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

1. 95% of GPs/PCPs surveyed report that feedback from BreastScreen Aotearoa Lead Providers is prompt and accurate.

2. All other criteria are met.

14.2 GENERAL PRACTICE (GP)/PRIMARY CARE PROVIDER (PCP) LIAISON – COMMUNICATING RESULTS

Quality Indicator
The GP/PCP shall be kept informed of the results pertaining to women from within their practice.

Criteria

1. Where a woman has given prior consent, the GP/PCP shall be informed as follows:
   a. identification of eligible women (review of age/sex registers, consultation with women, completion of the BSA GP Enrolment Form)
   b. invitation to eligible women (with GPs/PCPs support of invitation)
   c. result reporting (where the GP/PCP is nominated by the woman, the GP/PCP should be directly informed of the woman’s results)
   d. confirming information prior to woman’s recall (GP/PCPs confirm a woman’s eligibility and contact details before the woman is recalled).

NOTE: Women do not have to consult with their GP/PCP if they do not want or need to but are encouraged to do so by the Programme

2. With the woman’s consent BreastScreen Aotearoa Providers shall ensure that the timetables specified in Appendix B: Communication Matrix, for communication with GPs/PCPs, are met.

3. Communication with the GPs/PCPs should include feedback about the number of women from their practice participating in the Programme, for example, regular reports of women screened, outcomes, etc.

Evaluation Process

1. Satisfaction surveys of GPs/PCPs.

2. 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

1. 95% of GPs/PCPs surveyed report that feedback from BreastScreen Aotearoa Lead Providers is prompt and accurate.

2. All other criteria are met.

14.3 WORKING RELATIONSHIP BETWEEN LEAD PROVIDERS AND INDEPENDENT SERVICE PROVIDERS

Quality Indicator
Lead Providers and Independent Service Providers work together in partnership to deliver BreastScreen Aotearoa services and have a good understanding of each other’s roles.

BreastScreen Aotearoa Lead Providers understand the role that ISPs fulfil in the Programme such as outlining the benefits and limitations of screening mammography to priority women, co-ordinating ongoing care, encouraging women to attend further rounds of screening and providing information and support for the women.

Criteria

1. ISPs and Lead Providers demonstrate commitment to working collaboratively to identify any issues that arise and resolve them in a collaborative manner.

2. BSA Lead Provider Managers, Health Promoters and ISPs shall:
   a. meet at least quarterly to discuss relevant issues
   b. undertake joint planning sessions annually with a particular focus on Mobile scheduling, health promotion and recruitment issues and programme performance data.

3. ISPs should be actively involved with Lead Provider services to contribute to the success of the Programme and maintain the confidence of women including:
   a. identification of eligible women (review of age/sex registers, consultation with women, completion of the BSA Enrolment Form)
   b. invitation to eligible women
   c. reviewing information prior to women being recalled (for example, GPs/PCPs check a woman’s eligibility and contact details before the woman is recalled).

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**Universal Requirements – SECTION 1**

5. Lead Provider Managers meet with representatives of the multidisciplinary team regularly to discuss both clinical and operational issues. Such meetings will occur in partnership.

a. A regular (at least three-monthly) management multidisciplinary meeting shall be held. This may constitute an extension of the existing regular Clinical multidisciplinary team meetings.

b. Management multidisciplinary team meetings are required at both Lead Providers and subcontracted Provider levels.

c. A minutes register is maintained for all meetings held, including attendees.

6. the management multidisciplinary team meeting at the Lead Provider site shall be attended by:

a. Lead Provider Manager
b. Clinical Director
c. Data Manager
d. Lead Clinicians as agreed (for example, Lead Radiologist, Lead Pathologist, Lead Surgeon, Lead MRT)
e. Health Promotion representative
f. Quality Co-ordinator
g. at least one representative from each subcontract Provider

7. the management multidisciplinary team meeting at the subcontracted Provider sites may be attended by:

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

c. Peer Review and exchange of information
d. process and systems reviews
e. complaints review
f. review of feedback from internal and external monitoring, quality assurance and audit activities
g. communicating changes in policy, protocols or procedures
h. review of consumer questionnaires

8. the purpose of the management multidisciplinary team meetings include:

a. Lead Provider/subcontractor co-ordination
b. co-ordination of mobile scheduling and health promotion activities
c. peer review and exchange of information
d. process and systems reviews
e. complaints review
f. review of feedback from internal and external monitoring, quality assurance and audit activities
g. communicating changes in policy, protocols or procedures
h. review of consumer questionnaires

9. all mandated team members shall attend at least 60 percent of management multidisciplinary meetings. Team members must nominate a delegate to attend on their behalf, when they are unable to attend. Attendance may be by teleconference if appropriate.

10. attendance by relevant team members at national multidisciplinary Group meetings as per schedule (Refer: Appendix X: Schedule of Uni- and Multidisciplinary Meetings).

**Evaluation Process**

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**

All criteria are met.
16. HUMAN RESOURCE MANAGEMENT

Standard — Processes and systems ensure that human resource management complies with good employment practice and legislation.

16.1 HUMAN RESOURCE MANAGEMENT

Quality Indicator
Human resource management processes are conducted in accordance with good employment practice and meet the legislative requirements.

Criteria
BreastScreen Aotearoa Providers ensure that:
1. the accountability, responsibilities, authority, functions and outcomes to be achieved in each position are documented
   These may be included in, but are not limited to:
   a. employment contracts
   b. position descriptions
   c. delegations of authority
   d. human resource/personnel policies
   e. organisation chart/reporting lines
   f. performance appraisal/review process
2. professional qualifications are validated, including evidence of registration where applicable prior to employment
   This may be achieved by, but is not limited to:
   a. sighting and recording of practice qualifications/registration/certificate renewal information
   b. internal processes for evaluating competence
3. appropriately qualified and experienced staff are appointed who can safely meet the needs of each woman
   These processes may include, but are not limited to:
   a. recruitment, selection, appointment and re-appointment processes
   b. recruitment of staff that reflect the eligible population where appropriate
   c. education/qualification checking
   d. reference checking
   e. written declaration in relation to physical health and criminal history.

4. orientation/induction programmes for new and/or transferred staff that cover the essential components of services provided
   This may be achieved by, but is not limited to ensuring staff are familiar with:
   a. the philosophy of breast screening
   b. the roles and responsibilities of the Lead Provider, Subcontracted Provider and ISPs
   c. the nature, authority and responsibilities of the position
   d. quality improvement responsibilities
   e. BreastScreen Aotearoa and Provider policies and procedures
   f. Consumer Code of Rights
   g. cultural appropriateness
   h. confidentiality and privacy requirements
   i. health, safety and emergency procedures.

5. a system to identify, plan, facilitate and record training and education for staff is implemented
   This may be achieved by, but not limited to
   a. a documented plan (organisational and/or individual) to meet identified training needs and associated timeframes to achieve these
   b. training plans with evidence of progress/achievement
   c. appraisal/performance/feedback/development systems to identify and review effectiveness/appropriateness of the training provided
   d. a system to meet supervision requirements.

6. the analysis of staff turnover and exit interview feedback.

Evaluation Process
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
All criteria are met.

17. WOMEN TRANSFERRING BETWEEN LEAD PROVIDERS

Standard — Women who move between regions at any stage during their involvement with BreastScreen Aotearoa will be managed efficiently to ensure continuity of care.

17.1 WOMEN TRANSFERRING BETWEEN LEAD PROVIDERS

Quality Indicator
Each woman is transferred between Lead Providers according to the current Data Management Manual (DMM) requirements.

Criteria
BreastScreen Aotearoa Providers ensure that the policy for transferring women between Lead Providers during a screening episode is complied with (Refer Appendix T: Women Transferring Between Providers Protocol).

Evaluation Process
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
All criteria are met.
18. NEW TECHNOLOGIES

**Standard** — New technologies are utilised in accordance with the National Screening Unit’s Framework For New Technology Assessment.*

18.1 NEW TECHNOLOGIES

**Quality Indicator**

The approval and inclusion of new technologies is managed in accordance with evidence-informed principles and the National Screening Unit’s Framework for New Technology Assessment, relevant policies and procedures and ethical review where required.

**Criteria**

BreastScreen Aotearoa Providers will ensure that:

1. all new technologies considered for use within the Programme are identified using a Pro Forma and submitted to the National Screening Unit for consideration
2. the service establishes a robust process in conjunction with the National Screening Unit to review and subsequently approve the use of new technologies
3. the introduction of interventional procedures should be strictly controlled and undertaken after an appropriate period of training, and the development and implementation of appropriate policies and protocols
4. monitoring and evaluation of new technologies is undertaken and reported to the National Screening Unit.

**Evaluation Process**

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**

All criteria are met.

19. RESEARCH

**Standard** — The Service has established protocols for conducting and/or participating in research activities.

19.1 RESEARCH

**Quality Indicator**

Research applications and approved research projects (including clinical trials and studies) are managed in accordance with the evidence-informed principles, current legislation, the National Screening Unit and BreastScreen Aotearoa Providers policies and procedures for research, the Code of Rights 1996* and ethical review requirements.

**Criteria**

BreastScreen Aotearoa Providers will ensure that:

1. all research proposals comply with legal, professional, ethical and other relevant standards or criteria, and are approved by the appropriate ethics committee
2. prior to commencement of any research activity, the National Screening Unit is notified of:
   a. research activities incorporating breast screening participants and/or their data
   b. publishing of research incorporating breast screening participants and/or their data.
3. all research activities meet the legislative requirements for informed consent, adequate information and confidentiality and the ability of potential participants to say ‘no’ or participants to ‘opt out’
4. the National Screening Unit, or a Provider, has a process to resolve ethical issues in relation to research activities.

**Evaluation Process**

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**

All criteria are met.

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* In production

7 Code of Health and Disability Services Consumers’ Rights [SR 1996/78].
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THE BREAST SCREENING PATHWAY

LEVEL 1 ASSESSMENT

SCREENING

- Mammographic screening
- Film reading and reporting

LEVEL 2 ASSESSMENT

- Level 1 and/or 2 assessment outcome and notification of result

LEVEL 3 ASSESSMENT

TREATMENT

- Surgery
- Radiotherapy
- Chemotherapy
- Counselling
- Ongoing Management

Outcome of Assessment
- No further active recall
- Breast cancer detected
- No breast cancer detected

No further active recall
- Open biopsy recommended
- No breast cancer detected

LEVEL 1 ASSESSMENT

- Clinical
- Imaging the breast at assessment
- Grading of lesions
- Extended assessment
- Clinical examination
- Staged assessment

LEVEL 2 ASSESSMENT

- Non-operative diagnosis
- Minimising delay to needle biopsy
- Needle biopsy tissue sampling of screen-detected lesions
- Core biopsy, including vacuum-assisted biopsy specimens
- Labelling of specimens
- Pathologic examination of core needle biopsy specimen (CNBS)
- Pathologic examination of fine needle aspiration cytology (FNAC) specimens
- Laboratory facilities and processes for reporting on screen-detected material

LEVEL 3 ASSESSMENT

- Surgical biopsy
- Surgical biopsy general principles
- Pre-operative localisation of impalpable lesions
- Orientation of specimen
- Size of specimen
- Specimen radiography
- Pathology reporting of surgical biopsy specimens
- Size of specimen
- Pathology reporting of surgical biopsy specimens

OUTCOME OF ASSESSMENT

- Notification of results
- Referral to treatment
- Ongoing management

- Surgery
- Radiotherapy
- Chemotherapy
- Counselling

25. Assessment

25.1 Assessment – Waiting Times

25.2 Assessment – Education, Information and Consent

25.3 Assessment – Support

25.4 Assessment – Quality Assurance Protocols for Equipment

26. Multidisciplinary Management

26.1 Multidisciplinary Team – Clinical

27. Level 1 Assessment

27.1 Level 1 Assessment – Imaging the Breast at Assessment

27.2 Level 1 Assessment – Grading of Lesions

27.3 Level 1 Assessment – Extended Assessment

27.4 Level 1 Assessment – Clinical Examination

27.5 Level 1 Assessment – Staged Assessment

28. Level 2 Assessment – Non-operative Diagnosis

28.1 Level 2 Assessment – Minimising Delay to Needle Biopsy

28.2 Level 2 Assessment – Work up, Information and Consent

28.3 Level 2 Assessment – Needle Biopsy Tissue Sampling of Screen-detected Lesions – (FNAC), Core Biopsy, including vacuum-assisted biopsy specimens

28.4 Level 2 Assessment – Labelling of Specimens

28.5 Level 2 Assessment – Pathologic Examination of Core Needle Biopsy Specimen (CNBS)

28.6 Level 2 Assessment – Pathologic Examination of Fine Needle Aspiration Cytology (FNAC) Specimens

28.7 Level 2 Assessment – Laboratory Facilities and Processes for Reporting on Screen-detected Material

29. Level 3 Assessment – Surgical Biopsy

29.1 Level 3 Assessment – Surgical Biopsy General Principles

29.2 Level 3 Assessment – Pre-operative Localisation of Impalpable Lesions

29.3 Level 3 Assessment – Orientation of Specimen

29.4 Level 3 Assessment – Size of Specimen

29.5 Level 3 Assessment – Specimen Radiography

30. Outcome of Assessment

30.1 Outcome of Assessment – Notification of Results

30.2 Outcome of Assessment – Referral to Treatment

31. No further active recall

31.1 No further active recall
20. HEALTH PROMOTION

Standard – Health promotion activities are planned and delivered within recognised public health, population-based, health promotion frameworks. This will ensure maximum participation based on evidence-based strategies to increase awareness and informed choice.

20.1 HEALTH PROMOTION – OBJECTIVES

Quality Indicator
Health promotion plans and strategies support the overall objectives of BreastScreen Aotearoa in the reduction of illness, disability and death from breast cancer and meet the key health promotion objectives.

Criteria
Key BreastScreen Aotearoa health promotion objectives include, but are not limited to:
1. improving, promoting and protecting the health of eligible woman in New Zealand
2. ensuring participation by eligible women as a result of informed decision-making and ensuring informed consent underpins all health promotion activities
3. providing accurate, understandable and relevant information in a culturally appropriate manner
4. providing comprehensive information about the purpose of screening, in addition to the potential benefits and limitations
5. increasing the awareness of breast health, breast screening and breast cancer
6. encouraging participation in BreastScreen Aotearoa
7. ensuring health promotion messages do not imply a negative reaction among women who choose not to attend for screening
8. ensuring that strategies are evidence-based, and follow best practice standards and ethical requirements.

Evaluation Process
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
All criteria are met.

20.2 HEALTH PROMOTION – MANAGEMENT

Quality Indicator
Effective health promotion management ensures the implementation of appropriate health promotion principles and practices through the development and support of those involved in health promotion.

Criteria
BreastScreen Aotearoa Providers ensure that those involved in health promotion:
1. understand and work within principles based on the Treaty of Waitangi
2. understand and work within health promotion frameworks based on the Ottawa Charter, Jakarta Declaration, Te Pae Mahutonga and other models of health relating to Māori and Pacific health
3. have sufficient orientation and training to clearly understand the ethics and principles of population-based screening programmes
4. have a sound understanding of breast cancer, breast screening and the breast cancer screening pathway
5. demonstrate the knowledge and skills required for competent practice
6. demonstrate a detailed knowledge of the Code of Rights
7. participate in quality assurance and quality improvement activities
8. provide feedback on issues that constrain or prevent participation in BreastScreen Aotearoa
9. participate in decisions that may constrain or prevent evidence based health promotion
10. develop a close working relationship with the screening and assessment teams
11. have access to accurate and current information enabling them to fulfil their health promotion role.

Evaluation Process
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
All criteria are met.

20.3 HEALTH PROMOTION – GENERAL REQUIREMENTS

Quality Indicator
Health promotion strategies are aligned with the Public Health Services Handbook and the National Health Promotion Framework for the National Screening Unit.

Criteria
1. BreastScreen Aotearoa Providers will:
a. develop and implement health promotion strategies that include family and whānau, from a community development approach
b. work collaboratively with other providers, practitioners and community organisations involved with the programme to implement the health promotion strategies in an appropriate manner
c. ensure BreastScreen Aotearoa promotional materials and resources are used appropriately:
   i. that the full range of BreastScreen Aotearoa resources are available to women at all sites
   ii. resources are distributed to identified groups, agencies and community-based facilities (eg libraries, CABs, churches, women’s centres etc)
   iii. follow the provisions laid out in the Visual Identity Guide when producing/distributing any resources/material.
2. BreastScreen Aotearoa Providers will not endorse or promote products nor will they offer inducements or gifts to encourage participation in BreastScreen Aotearoa, without the prior approval of the National Screening Unit.
3. BreastScreen Aotearoa Providers must handle personal information of participants in a way that is consistent with the Health and Disability Services Act 1993 and the Privacy Act 1993.

Evaluation Process
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
All criteria are met.

20.4 HEALTH PROMOTION – ELIGIBILITY OF WOMEN

Quality Indicator
Only eligible women are invited to participate in BreastScreen Aotearoa.

Criteria
1. All asymptomatic women in the eligible age range, who are entitled to free health and disability services in New Zealand as defined in section 25 of the Health and Disability Services Act 1993 and Amendments, are eligible for inclusion in BreastScreen Aotearoa and should be encouraged to participate. (Refer: Appendix G: 2000 Direction of the Minister of Health relating to the eligibility for publicly funded Personal and Disability Health Services in New Zealand)

BreastScreen Aotearoa eligibility criteria:
• women aged 50-64 years
• asymptomatic women
• women who are New Zealand citizens or ordinarily resident in New Zealand
• women who hold an immigration permit that allows a stay in New Zealand of two or more years.

The following are exceptions to the eligibility criteria:
• pregnant women
• women with a history of previous breast cancer, who are less than five years since diagnosis
• women with significant signs and symptoms suspicious of breast cancer (including GP/PCP referrals due to symptoms). Symptomatic women must be referred to diagnostic services
• women who have had mammography within the last twelve months.

2. BreastScreen Aotearoa Providers shall accept and encourage into the programme all eligible women including:
• women who self refer
• women who are referred by their GP/PCP as a result of a direct request to their GP/PCP
• women whose GP/PCP has sent them an invitation pack as prearranged with the Lead Provider.

3. In those localities serviced by mobile units, the processes used may differ from those used in the main centres.

1 The Health and Disability Commissioner (Code of Health and Disability Services Consumers’ Rights) Regulations 1996.
3 Health and Disability Services Act 1993, section 25.
4. Women with a previous breast cancer who are well, i.e. no recurrence of breast cancer since their initial diagnosis, are five years post-operative and are not receiving surveillance and follow-up are eligible to rejoin the Programme.

5. Women with a previous biopsy of atypical ductal hyperplasia are eligible to participate in the Programme for a screening mammogram every two years.

NOTE: If at any stage after joining the Programme a Provider becomes aware of a woman’s history of recent breast cancer(s) the woman will be unable to continue in the Programme and an appropriate arrangement is made for referral back to the woman’s GP/PCP.

6. A Provider may construct a separate list of ineligible or inactive women who have approached BreastScreen Aotearoa in order to be able to invite and enrol them at a later date when they are eligible.

**Evaluation Process**
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**
All criteria are met.

### 20.6 HEALTH PROMOTION – REGIONAL STRATEGIES

#### Quality Indicator
Health promoters are responsible for including in their plan appropriate regional strategies that raise awareness, encourage participation and inform about BreastScreen Aotearoa.

#### Criteria
BreastScreen Aotearoa Providers ensure that:
1. all strategies used reflect the service specifications in the Provider contract
2. strategies are delivered in the wider context of women’s health
3. strategies include the screening pathway
4. evidence-based/best practice strategies are used
5. strategies are consistent with an informed consent approach to screening
6. there is collaboration between BreastScreen Aotearoa Providers, practitioners and community organisations
7. strategies are developed that include family/whānau and community-based approaches
8. strategies are developed that recognise the diversity of cultural practices.

#### Evaluation Process
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
All criteria are met.
20.9 HEALTH PROMOTION – ADVOCACY

Quality Indicator
The use of appropriate strategies to raise the profile of BreastScreen Aotearoa in the context of women’s health.

Criteria
BreastScreen Aotearoa Providers ensure:
1. the use of appropriate public forums to provide accurate information about screening
2. 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 BreastScreen Aotearoa
3. that the identification of appropriate key organisations, groups and communities to assist in promoting key messages to women is undertaken using a community development approach
4. they encourage the distribution of BreastScreen Aotearoa health education resources to women.

Evaluation Process
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
All criteria are met.

20.10 HEALTH PROMOTION – WORKFORCE DEVELOPMENT

Quality Indicator
Appropriately trained personnel deliver health promotion within BreastScreen Aotearoa.

Criteria
BreastScreen Aotearoa Providers ensure that:
1. the health promotion team has an appropriate skill mix, range of experience, cultural competencies and expertise required to effectively deliver the service
2. adequate supervision and support is available for new or inexperienced health promotion practitioners
3. opportunities for health promotion practitioners to progress through the competency levels outlined in:
   a. Nga Kaiakatanga Hauora mo Aotearoa Health Promotion Competencies for Aotearoa-New Zealand

21. ENTERING THE PROGRAMME

21.1 ENTERING THE PROGRAMME – APPOINTMENT-MAKING

Quality Indicator
All eligible women will receive an appropriate invitation to attend an appointment with BreastScreen Aotearoa.

Criteria
1. the appointment-making process will be initiated after the woman has been identified through the mechanisms outlined in the recruitment plan and the BreastScreen Aotearoa Provider has recorded the woman’s interest in the Programme
2. BreastScreen Aotearoa Providers will ensure that the appointment-making process includes the following:
   a. obtaining information to register the woman within the Programme, including any special needs
   b. the name of the Provider, where the service is provided and any relevant information the woman requires before attending for a screening mammogram
   c. an appointment (or confirmation of an appointment) and information about how to change her appointment time, if required
   d. a comprehensive consent and notification form
   e. the national information brochure about the Programme.

Evaluation Process
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
All criteria are met.

21.2 ENTERING THE PROGRAMME – SPECIAL NEEDS

Quality Indicator
Information relating to special needs is obtained prior to finalising a woman’s appointment.

Criteria
BreastScreen Aotearoa Providers will ensure that:
1. the woman is asked, during the appointment-making process, if she has an impairment, disability or special need that will need to be accommodated at the time of her screen. For example, interpreters, attendant carers, additional time, wheelchair access
2. the woman is asked whether there have been any concerns with previous mammograms she may have had
3. interpreters and any other additional services required to assist a woman are organised prior to her attending
4. disabled women are encouraged to attend a fixed site as they are better equipped to provide access, additional time and accommodate carers
5. women who have implants must attend a fixed site, where their films are processed immediately for checking by the MRT for technical quality.

Evaluation Process
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
All criteria are met.
**SECTION 2 – The Breast Screening Pathway**

**22. FIRST IMPRESSIONS**

**Standard** — Each woman experiences a welcoming and helpful response when first making contact with the Programme.

**22.1 FIRST IMPRESSIONS – FIRST POINT OF ENTRY**

**Quality Indicator**

Telephone and reception staff demonstrate effective communication and listening skills, and respond in a professional and timely manner.

**Criteria**

1. 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.
2. Staff are friendly, welcoming and helpful and take into consideration that each woman may have differing expectations of the Programme.
3. Opportunities are provided for all staff with front-line contact with women, for example, telephone and reception staff, to be trained to:
   a. provide a well women-centred approach
   b. provide accurate information
   c. understand the eligibility criteria for the Programme
   d. meet privacy and confidentiality requirements
   e. know when and where to refer each woman
   f. provide and maintain appropriate communication and listening skills
   g. respond effectively to difficult situations
   h. address, at the earliest opportunity, unsatisfactory experiences reported by women
   i. recognise their own knowledge limitations.

**Evaluation Process**

1. Satisfaction surveys.
2. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

**Evaluation Targets**

1. 95% of women surveyed report that they did not wait unnecessarily.
2. All other criteria are met.

**23. SCREENING**

**Standard** — The screening service is well women-centred and produces timely, reliable and high-quality results.

**23.1 SCREENING – WAITING TIMES**

**Quality Indicator**

The screening unit processes ensure that women are not kept waiting unnecessarily.

**Criteria**

BreastScreen Aotearoa Providers ensure that:
1. screening schedules shall be well planned and documented, and take into account the needs of women requiring additional time (for example, implants, disabilities.)
2. staff resources and training facilitate screening schedules to be kept on target/time.

**Evaluation Process**

1. Satisfaction surveys.
2. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

**Evaluation Targets**

1. 95% of women surveyed report that they did not wait unnecessarily.
2. All other criteria are met.

**23.2 SCREENING – BREAST HISTORY**

**Quality Indicator**

Each woman shall have a specified breast history recorded, and this information will be made available to the reading radiologist.

**Criteria**

BreastScreen Aotearoa Providers ensure that the breast history includes but is not limited to:
1. date and place of previous mammogram(s)
2. any family history of breast cancer
3. previous breast surgery or treatment
4. scars, moles and other ‘signs’ (position recorded)
5. current symptoms, for example, nipple discharge, lump, etc, outlined in Standard 21.3 Entering the Programme – Significant Symptoms Prior to Attendance
6. relevant medication including the use of hormone replacement therapy (HRT)
7. the breast history information is readily available to the radiologist during mammogram reading.

**Evaluation Process**

Monthly auditing of clinical records for women screened during the previous month at each screening unit. (This may be undertaken in conjunction with the Data Management Manual requirements.)

**Evaluation Targets**

1. 100% of women who comply shall have the specified breast history recorded so that it is readily available to the reading radiologist.
2. All other criteria are met.

**23.3 SCREENING – EXPLANATION OF PROCEDURE**

**Quality Indicator**

Each woman receives a full explanation of the procedure before commencement of her screen.

**Criteria**

BreastScreen Aotearoa Providers ensure that:
1. the woman has an understanding of the screening process, including benefits and limitations, in order to make an informed decision to participate in mammography. Refer: Standard 5 – Consent
2. women using HRT should be informed that the accuracy of mammography screening tests may be lower for women using HRT
3. the need for adequate compression and advantages in enhancing image quality and reducing radiation dose is explained before commencement of the screen.

**Evaluation Process**

Satisfaction surveys.

**Evaluation Target**

95% of women surveyed report that they received sufficient information in order to make an informed choice, and understand the process.
### 23.4 SCREENING – MRT COMMUNICATION SKILLS AND RAPPORT

#### Quality Indicator

Each woman finds the mammogram process acceptable, which encourages her return for subsequent re-screening.

#### Criteria

**BreastScreen Aotearoa Providers** ensure that:
1. rapport with the woman is established
2. the woman’s potential fears and anxieties regarding the procedure are acknowledged
3. every effort is made to make the woman comfortable, for example, maintaining her personal privacy and dignity
4. the woman is offered a gown or a korowai during screening
5. the woman is given a sense of control within the procedure, to help alleviate anxiety and discomfort/pain
6. pain is acknowledged if it occurs, and the procedure terminated if the woman requests
7. mechanisms are in place to deal with issues that have occurred during the mammogram

This shall include, but are not limited to:
- a. further discussion
- b. advice on pain relief prior to or subsequent to a mammogram
- c. advice on future mammograms.

#### Evaluation Process

**Satisfaction surveys.**

**Evaluation Target**

95% of women surveyed report finding the MRT reassuring, caring and helpful.

### 23.5 SIGNS AND SYMPTOMS AT SCREENING

#### Quality Indicator

Women who present to a screening appointment with signs and symptoms shall have their mammogram performed, but will be appropriately referred for symptom management irrespective of screening outcome.

**NOTE:** If a woman identifies current signs and symptoms PRIOR to screening. Refer: Standard 21.3 Entering the Programme – Significant Symptoms Prior to Attendance.

#### Criteria

**BreastScreen Aotearoa Providers** must ensure that:
1. a protocol exists to ensure the appropriate referral of each woman in whom signs and symptoms are identified during the screening visit
2. signs and symptoms are:
   - a new lump or thickening (lump that the woman can feel that has arisen in the last 12 months)
   - pain or tenderness
   - 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.
3. the woman and her nominated GP/PCP (provided consent has been obtained) are notified in writing of any signs and/or symptoms that may require further investigation
4. where the result of the screening mammogram is negative the BreastScreen Aotearoa Provider, with the woman’s consent, will refer her (in order of priority) to:
   - a. her GP/PCP
   - b. a specialist diagnostic clinic through the public hospital service, or
   - c. a private provider.

**NOTE:** the National Screening Unit recommends the first referral option is the most appropriate option for these women and all Lead Providers are to refer these women back to their GP/PCP unless there are specific reasons for not doing so. The reasons for not doing so should be documented in the woman’s file.

#### Evaluation Process

**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**

All criteria are met.

### 23.6 SCREENING – ROUTINE VIEWS PERFORMED

#### Quality Indicator

All screening examinations shall be comprehensive and complete with unnecessary exposure to radiation kept to a minimum.

#### Criteria

**BreastScreen Aotearoa Providers** must ensure that:
1. all screening mammograms will have a cranio-caudal and medio-lateral oblique view of each breast. Any deviation from this will be recorded by the MRT performing the screen
2. MRTs 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. The number of these films shall be recorded
3. the name of the MRT performing the screen is recorded
4. for each screening examination the total number of films taken are recorded
5. for each screening examination the total number of films rejected are recorded
6. the MRT performing the examination should check it for completeness and document the MIQ Grading (Refer: Appendix N: Mammographic Image Quality (MIQ) Classification)
7. another MRT, other than the one performing the examination, may review the films prior to them being read and this will usually occur with mammograms performed on the mobile units.

#### Evaluation Process

1. **The MRT monthly peer review process will review films for completeness.** (Refer: Section 4, Professional Requirements: Medical Radiation Technologist and Appendix N: Mammographic Image Quality (MIQ) Classification.)
2. Monthly auditing of clinical records for women screened during the previous month at each screening unit (This may occur in conjunction with the Data Management Manual requirements).
3. Information is collected through the National Minimum Data Set for monitoring and evaluation purposes (Refer: Current DMM).

**Evaluation Target**

All criteria are met.

### 23.7 SCREENING – SPECIAL IMAGING PROTOCOLS

#### Quality Indicator

Specific imaging protocols are used within screening units for women who have large breasts, breast implants, had a mastectomy, breast conservation surgery or are at high risk.

#### Criteria

**BreastScreen Aotearoa Providers** ensure that the following nationally consistent protocols are used within the Programme (Refer: Appendix J: National Screening Protocols):
1. large breasts
2. breast implants
3. mastectomy
4. women treated by breast conservation surgery (wide local excision)
5. high risk women.

#### Evaluation Process

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

All criteria are met.

### 23.8 SCREENING – FILM IDENTIFICATION LABELLING

#### Quality Indicator

Each mammographic image shall have the following information on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures.

#### Criteria

1. there are fail-safe processes in place to ensure that the woman’s details, clinical record and labels are matched.
2. BreastScreen Aotearoa Providers must ensure that the following information is recorded:
   - a. full name of the woman
   - b. date of birth
   - c. NHI number
   - d. date of examination
   - e. view and laterality (This information should be placed on the image near the axilla)
   - f. facility name and location
6. All MRTs will attend regular sessions (at least monthly) reviewing films for technical quality. This shall be attended by the designated radiologist or Clinical Director quarterly ... to inform the other radiologists of the outcomes of this meeting where it impacts on radiologist technical recalls.

7. Each batch of films must be accompanied by a sensitometric strip, which is exposed before the first client in that batch.

23.11 SCREENING – HIGH QUALITY RADIOGRAPHIC TECHNIQUE

Quality Indicator
All screen detectable breast cancers are shown on the mammogram which should include as much breast tissue on the plate as possible.

Criteria
1. While the Clinical Director in the screening programme has ultimate responsibility for image quality it is the role and function of all MRTs to produce images of the highest quality for reading.
2. BreastScreen Aotearoa Providers ensure that there is accurate recording of any factors including technique which assist in the production of quality images for future screens.
3. For the reading radiologist to evaluate minute structures within the breast the MRT must image the breast by paying attention to the following areas:
   - quality control
   - positioning
   - exposure factors.
4. It is the responsibility of the MRT to check all images for:
   - positioning
   - sharpness
   - contrast
   - correct exposure
   - compression
   - processor faults
   - correct annotation
   - women's identification label
   - absence of artefacts
   - completeness of examination according to the MIQ classification.

Evaluation Process
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
All criteria are met.

23.12 SCREENING – MAMMOGRAPHIC QUALITY ASSURANCE (MQA)

Quality Indicator
A Mammographic Quality Assurance (MQA) programme shall be complied with to ensure high quality mammographic imaging.

Criteria
1. BreastScreen Aotearoa Providers ensure that the RANZCR Mammographic Quality Assurance Programme 2002 or subsequent versions are complied with.

Evaluation Process
1. Information is collected through the National Minimum Data Set for monitoring and evaluation purposes (Refer: Current DMM).
2. The internal audit process ensures that the criteria are compiled with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

Evaluation Target
All other criteria are met.
2. BreastScreen Aotearoa Providers ensure that:
   a. the MQA committee, which, in association with a designated individual from each screening site, will ensure there is a comprehensive CQI process. (Refer Appendix K: Mammographic Quality Assurance (MQA) Programme)
   b. they own or access appropriate and adequate test equipment. (Refer: Appendix P: Test Equipment)

3. Individual screening units recognise that these are minimum standards and that often increased frequency (especially for items such as screen cleaning) or additional tests may be necessary to ensure quality. Frequency beyond the minimum requirements is at the discretion of the screening/assessment site:
   a. all tests shall be fully documented
   b. for some tests a standardised report shall be required
   c. test results shall be made available for inter-comparison and the collation of national statistics
   d. to promote high quality imaging for all women and compliance with NRL-CS2, a programme of dose measurements on women shall be included.

4. Current quality test records are held for each X-ray set and processor used within the programme, these shall be kept until after the following NRL audit which authorised disposal

5. Equipment test records show that the equipment parameters are maintained within operating limits, and corrective action has been taken where required

6. Medical Physics tests are conducted within 20 working days of the due date

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

8. Other defects detected by the Medical Physicists tests shall be rectified within 30 working days.

**Evaluation Process**
The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

**Evaluation Targets**
1. 100% compliance with all Medical Physics tests.
2. All other criteria are met.

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3.13 SCREENING – READING THE SCREENING MAMMOGRAM

**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.

**Criteria**
BreastScreen Aotearoa Providers ensure that:
1. there is uninterrupted time scheduled for reading screening mammograms:
   a. the room should be quiet and lights dimmed
   b. an automated viewer is highly desirable and a practical necessity for a screening unit. (Refer: Appendix O: Film View Box)
   c. a bright spotlight is available
   d. magnification glasses are available
2. previous mammograms are obtained, wherever possible, for comparison. Failure to obtain the previous mammograms will be documented in the clinical record
3. radiologists assess all films for:
   a. positioning
   b. sharpness
   c. contrast
   d. density
   e. processor faults
   f. correct labelling
   g. completeness of examination.
4. the mammogram is reported as technically adequate or not
   a. calcifications
   b. spiculated mass
   c. multiple masses
   d. discrete mass with/without calcification
   e. architectural distortion
   f. non-specific density
   g. other.

Where a woman refuses for whatever reason to allow completion of her screening mammograms, the films should be read in the usual manner. A report indicating whether or not there is an abnormality shall be sent to the woman (and her GP/PCP if consented). This report should indicate that the examination was incomplete, that the woman has refused further views and a recommendation has been made which includes either return to screening or recall to assessment.

5. feedback to the MRI's by the Clinical Director should include comments regarding technically adequate mammograms that could be improved upon (for example: skin fold, lack of sharpness in only one view) and when the examination is technically perfect

6. the radiologist should have access to available information when interpreting mammograms, which includes any symptoms, previous breast surgery and hormone replacement therapy. This information should be readily available to the reading radiologist

7. reader fatigue may adversely influence visual perception. It is therefore recommended that the second reader review the films in the reverse order to the first

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

9. lesions for categorisation include:
   a. calcifications
   b. spiculated mass
   c. multiple masses
   d. discrete mass with/without calcification
   e. architectural distortion
   f. non-specific density
   g. other.

10. suggested categorisation of these lesions by reading radiologists are:
   Category 1. Normal/Benign – return to routine re-screening
   Category 2. Probably benign – may need assessment to confirm
   Category 3. Indeterminate – needs assessment to elucidate
   Category 4. Probably malignant – requires assessment and probably a tissue diagnosis

NOTE: Categorisation should allow triage of women to an appropriate assessment centre (where staged assessment is an option) or appropriate appointment scheduling.

11. films are reported as either:
   a. ‘Normal’ (continue two-yearly screening)
   b. ‘For assessment’ (refer for further mammographic or clinical work-up at an assessment clinic)

23.1.3 SCREENING – READING THE SCREENING MAMMOGRAM

**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.

**Criteria**
BreastScreen Aotearoa Providers ensure that:
1. there is uninterrupted time scheduled for reading screening mammograms:
   a. the room should be quiet and lights dimmed
   b. an automated viewer is highly desirable and a practical necessity for a screening unit. (Refer: Appendix O: Film View Box)
   c. a bright spotlight is available
   d. magnification glasses are available
2. previous mammograms are obtained, wherever possible, for comparison. Failure to obtain the previous mammograms will be documented in the clinical record
3. radiologists assess all films for:
   a. positioning
   b. sharpness
   c. contrast
   d. density
   e. processor faults
   f. correct labelling
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   g. other.

Where a woman refuses for whatever reason to allow completion of her screening mammograms, the films should be read in the usual manner. A report indicating whether or not there is an abnormality shall be sent to the woman (and her GP/PCP if consented). This report should indicate that the examination was incomplete, that the woman has refused further views and a recommendation has been made which includes either return to screening or recall to assessment.

5. feedback to the MRI's by the Clinical Director should include comments regarding technically adequate mammograms that could be improved upon (for example: skin fold, lack of sharpness in only one view) and when the examination is technically perfect

6. the radiologist should have access to available information when interpreting mammograms, which includes any symptoms, previous breast surgery and hormone replacement therapy. This information should be readily available to the reading radiologist

7. reader fatigue may adversely influence visual perception. It is therefore recommended that the second reader review the films in the reverse order to the first

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

9. lesions for categorisation include:
   a. calcifications
   b. spiculated mass
   c. multiple masses
   d. discrete mass with/without calcification
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   f. non-specific density
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10. suggested categorisation of these lesions by reading radiologists are:
   Category 1. Normal/Benign – return to routine re-screening
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   Category 3. Indeterminate – needs assessment to elucidate
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NOTE: Categorisation should allow triage of women to an appropriate assessment centre (where staged assessment is an option) or appropriate appointment scheduling.

11. films are reported as either:
   a. ‘Normal’ (continue two-yearly screening)
   b. ‘For assessment’ (refer for further mammographic or clinical work-up at an assessment clinic)

2. BreastScreen Aotearoa Providers ensure that:
   a. the MQA committee, which, in association with a designated individual from each screening site, will ensure there is a comprehensive CQI process. (Refer Appendix K: Mammographic Quality Assurance (MQA) Programme)
   b. they own or access appropriate and adequate test equipment. (Refer: Appendix P: Test Equipment)

3. Individual screening units recognise that these are minimum standards and that often increased frequency (especially for items such as screen cleaning) or additional tests may be necessary to ensure quality. Frequency beyond the minimum requirements is at the discretion of the screening/assessment site:
   a. all tests shall be fully documented
   b. for some tests a standardised report shall be required
   c. test results shall be made available for inter-comparison and the collation of national statistics
   d. to promote high quality imaging for all women and compliance with NRL-CS2, a programme of dose measurements on women shall be included.

4. Current quality test records are held for each X-ray set and processor used within the programme, these shall be kept until after the following NRL audit which authorised disposal

5. Equipment test records show that the equipment parameters are maintained within operating limits, and corrective action has been taken where required

6. Medical Physics tests are conducted within 20 working days of the due date

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

8. Other defects detected by the Medical Physicists tests shall be rectified within 30 working days.

**Evaluation Process**
The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

**Evaluation Targets**
1. 100% compliance with all Medical Physics tests.
2. All other criteria are met.
Evaluation Targets

Radiologist Specific Targets

Individual radiologists’ reading statistics shall lie within 95% confidence intervals for rates of cancer detection and detection of small cancers. Where an individual fails to meet these criteria, the Medical 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. Cancer detection rate (including DCIS) per 10,000 women screened:
   - Initial (Prevalent) Screening Examination ≥ 3 x the background incidence = 69.0
   - Subsequent (Incident) Screening Examination ≥ 1.5 x the background incidence = 34.5

Small invasive screen-detected cancers (≤ 10 mm) per 10,000 women screened:
- Initial (Prevalent) Screening Examination ≥ 25% (of invasive cancers) = 17.3
- Subsequent (Incident) Screening Examination ≥ 30% (of invasive cancers) = 10.45

Small invasive screen-detected cancers (<15 mm) per 10,000 women screened:
- Initial (Prevalent) Screening Examination > 50% (of invasive cancers) = 34.5
- Subsequent (Incident) Screening Examination > 50% (of invasive cancers) = 17.3

Nodule-negative invasive screen-detected cancers:
- Initial (Prevalent) Screening Examination > 70% (of invasive cancers)
- Subsequent (Incident) Screening Examination > 75% (of invasive cancers)

Ductal carcinoma in situ (DCIS): (of all cancers detected by the programme)
- Initial (Prevalent) Screening Examination 10-25%
- Subsequent (Incident) Screening Examination > 9%

Interval cancers (including DCIS): Per 10,000 women screened within one calendar year of previous screen < 6.9

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: Appendix A: Glossary)

23.14 SCREENING – FILM ACCESSIBILITY

Quality Indicator

BreastScreen Aotearoa retains ownership of all original mammogram films taken within the Programme.

Criteria

1. BreastScreen Aotearoa Providers ensure that:
   a. screening films are stored separately from general radiology films
   b. screening films are to be retained by the Lead Provider for four years before the date of the request form retained
   c. original films are to be retained by the Lead Provider to ensure the availability of recent mammograms for comparative purposes
   d. all films are adequately stored and accessible for monitoring and subsequent audit.

2. BreastScreen Aotearoa Providers will ensure that in the event of a woman changing Lead Providers or moving overseas:
   a. films will be released to the new Provider on the receipt of the designated request form from the new Provider or the woman concerned
   b. during transfer of original films to a new Provider, a track and trace system and record of receipt of films must be implemented
   c. a copy of the most recent screen is retained for quality assurance purposes in the event that an interval cancer is detected
   d. the films are then the responsibility of the new Provider.

3. BreastScreen Aotearoa Providers will ensure that:
   a. under most circumstances, film copies, rather than the originals should be sent to other Providers. If these are considered inadequate for comparative purposes, original films may be released on receipt of a written request (letter or fax) from other health professionals for example, surgeons, radiologists
   b. a copy of the films and a note is made in the client file and the request is also retained on file
   c. the films are dispatched following the completion of the tracking requirements

4. Women may:
   a. request their films in writing
   b. be informed not to expect originals to be provided
   c. expect copies to be provided and that the cost will be paid by them or by the Lead Provider
   d. expect that the Lead Provider will inform them that, if undergoing a mammogram with a private provider (radiologist), the radiologist may access the originals, and copies are not required in this situation
   e. expect a note will be placed in their client file indicating that copies have been made and dispatched to them.

Evaluation Process

The internal audit process ensures the criteria are complied with and identified shortfalls are addressed through the Continuous Quality Improvement (CQI) Process.

Evaluation Target

All criteria are met.
**24. OUTCOME OF SCREENING**

**Standard** — Women are told to return appropriately to ensure they either return to routine re-screening or are recalled to assessment.

**24.1 OUTCOME OF SCREENING – NOTIFICATION OF RESULTS OR RECALL**

**Quality Indicator**
Each woman receives timely and accurate notification of her results.

**Criteria**
BreastScreen Aotearoa Providers ensure that:
1. each woman will have the method and timeframe of result notification discussed with her at the completion of the screen
2. the woman’s nominated GP/PCP is also to be advised of the results simultaneously, if the woman has given consent, so that she can contact her GP/PCP for support and advice if required
3. each woman will receive an explanation if she is recalled for technical repeat films. The woman should be offered the opportunity to view her films when recalled for repeats, if appropriate. This may help allay some of the anxiety associated with recall.

**Evaluation Process**
1. Regular reports, which identify women who are outside the target parameters, shall be generated and reviewed by the Clinical Director and Lead Provider Manager or a designated individual.
2. Information is collected through the National Minimum Data Set for monitoring and evaluation purposes. (Refer: Current DMM)

**Evaluation Targets**
1. Films must be read promptly enough so that > 90-95% of women can be notified within 10 working days of the screening mammogram.
2. All other criteria are met.

**24.2 OUTCOME OF SCREENING – ROUTINE RE-SCREENING**

**Quality Indicator**
Each woman eligible for routine re-screening is invited back to the programme in an appropriate timeframe.

**NOTE:** Routine re-screening is for eligible women with a ‘normal’ screening mammogram or women who have been assessed as having ‘no evidence of cancer’ after assessment, and who are re-invited for a repeat screening mammogram every two years until no longer eligible.

**Criteria**
BreastScreen Aotearoa Providers will ensure that:
1. a process is implemented to offer eligible women an appointment for re-screening between 20 and 24 months from the date of previous screen
2. at the time of screening, eligible women will be advised that they will be re-invited
3. GPs/PCPs are encouraged to assist providers to confirm ongoing eligibility of women, for example, if they have moved, are unwell, or have had an interval cancer
4. women contacting the programme with interval symptoms (that is, between routine screening mammograms), are to be advised to see their GP/PCP for a consultation.

**Evaluation Process**
1. Regular reports shall be generated and reviewed by the Lead Provider Manager to ensure scheduling enables women to be screened within the targets and timeframes.
2. Information is collected through the National Minimum Data Set for monitoring and evaluation purposes (Refer: Current DMM)
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 Targets**
1. > 75% of women who return for a screen are re-screened between 20 and 24 months from their previous screen.
2. > 85% of women screened in a Programme round are subsequently (if eligible) re-screened in the next Programme round.
3. All other criteria are met.

**24.3 OUTCOME OF SCREENING – RECALL TO ASSESSMENT**

**Quality Indicator**
All women with mammographic abnormalities that may be malignant are recalled to assessment.

**Criteria**
BreastScreen Aotearoa Providers ensure that:
1. each woman is notified of the need to attend the assessment clinic, by the breastcare nurse, as soon as possible after screening. The breastcare nurse clearly identifies herself, her role and availability at this time
2. where the woman has consented, the GP/PCP is notified of the recall to assessment at the same time as the woman
3. every effort is made to reduce anxiety or uncertainty experienced by the woman
4. where possible, reasonable notice is given to women. Consideration is to be given to reducing the duration of any anxiety by contacting the woman close to the proposed assessment day, for example, not just before a weekend or public holiday.

**Evaluation Process**
1. Reports that identify women who are to be recalled for assessment shall be generated regularly and are reviewed by the Lead Provider Manager, Clinical Director or a designated individual and retained for future audit activities.
2. Information is collected through the National Minimum Data Set for monitoring and evaluation purposes (Refer: Current DMM)
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 Targets**
1. 90% of women are offered an assessment appointment within 15 working days of their final screening mammogram.
2. All other criteria are met.

**24.4 OUTCOME OF SCREENING – FAILURE OR REFUSAL TO ATTEND ASSESSMENT**

**Quality Indicator**
The BreastScreen Aotearoa Provider ensures timely and appropriate follow-up when a woman fails or refuses to attend for assessment.

**Criteria**
The BreastScreen Aotearoa Provider should undertake a minimum of three attempts to contact the woman (via telephone, mail and GP/PCP if consent for this has been given):
1. if the woman attends, no further action is required
2. if the woman does not attend:
   a. the woman is sent a letter as a final sign-off of responsibility, that is, this should be done in accordance with the Code of Health and Disability Consumers’ Rights. The letter should be sent by courier where a residential address is supplied
   b. the woman’s GP/PCP is advised: i. of the screening findings ii. of the woman’s refusal to attend for assessment iii. that the woman has been discharged from BreastScreen Aotearoa
   c. the woman’s GP/PCP is advised:
      i. of the screening findings
      ii. of the woman’s refusal to attend for assessment
      iii. that the woman has been discharged from Programme at her request.
25. ASSESSMENT

Standard — The assessment process provides accurate diagnosis for women with screen-detected lesions and returns those who do not have breast cancer to routine re-screening. This is carried out in an effective and efficient manner that is woman-centred and minimises morbidity.

25.1 ASSESSMENT – WAITING TIMES

Quality Indicator

The multidisciplinary assessment team functions effectively and efficiently in the assessment clinic to ensure that women are not kept waiting unnecessarily.

Criteria

BreastScreen Aotearoa Providers ensure that:
1. a simple, well co-ordinated system through which the woman progresses, with the least chance of confusion or delay, is implemented
2. assessment schedules are planned and documented
3. during assessment the woman is kept informed of any waiting times
4. at each stage of the process the woman shall be fully informed of what is happening
5. staff resources and training ensure assessment schedules are kept on time.

Evaluation Process

1. Satisfaction surveys.
2. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

Evaluation Targets

1. 95% of women surveyed who attended assessment clinics report receiving sufficient information about the assessment process to make informed decisions and provide their consent.
2. All other criteria are met.

25.2 ASSESSMENT – EDUCATION, INFORMATION AND CONSENT

Quality Indicator

The members of the multidisciplinary team ensure that each woman attending assessment receives relevant information in a manner that enables her to make informed choices regarding assessment and any further interventions.

NOTE: Information and understanding enables the woman to make informed choices and contributes to the reduction of anxiety.

Criteria

BreastScreen Aotearoa Providers ensure that:
1. women invited to assessment are provided with approved information prior to attending the assessment clinic
2. sufficient uninterrupted time is available to allow for relevant information to be shared with each woman and with her consent, her family or whanau
3. the woman is greeted and the assessment process is fully explained so that she is able to make an informed decision about proceeding. Ideally this should be undertaken by the breastcare nurse or relevant Clinician
4. there is an appropriate private area for discussion of options
5. the woman’s concerns regarding the assessment procedure, or any other related issues, are discussed and addressed in a manner that ensures the privacy of the individual and any relevant parties
6. with the woman’s consent, follow-up contact is made by the breastcare nurse to assess information retention and further individual needs, in a manner which minimises stress to the woman concerned
7. a wide range of information about breast cancer and treatment, such as the resources produced by the National Screening Unit are available for women attending assessment and their families (Refer: Appendix D: Breast Screening Resources)

Evaluation Process

1. Satisfaction surveys.
2. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.
3. if the woman chooses to 'exit' the Programme and undergoes further 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 re-screening when that is next due.

Evaluation Target

All criteria are met.
6. the woman is informed (verbally and in writing) how to contact the breastcare nurse, or a designated staff member
7. the breastcare nurse documents all nursing support provided in the woman’s records
8. where required, and with a woman’s consent, the woman may be referred to other specialist agencies and this is facilitated by the breastcare nurse in consultation with the woman’s GP/PCH
9. access to counselling support from a suitably trained breastcare nurse or counsellor is available, either on site or via referral to a specialist agency

Evaluation Process

Satisfaction surveys.

Evaluation Target

95% of women surveyed who attended assessment report that they received adequate support and/or appropriate referral where indicated.

25.4 ASSESSMENT – QUALITY ASSURANCE PROTOCOLS FOR EQUIPMENT

Quality Indicator

All equipment used for assessment meets the Standard referred to and/or specified in this document.

Criteria

BreastScreen Aotearoa Providers ensure that the following protocols are complied with:
1. ultrasound scanner (Refer: Appendix M: Ultrasound System Performance and Quality Control)
2. stereotactic localisation device (Refer: Appendix L 2, 3: Stereotactic Breast Biopsy Quality Assurance (Q&A) Programme)
3. appendix K: Mammographic Quality Assurance MQA Programme
4. current quality test records are held for each item of equipment used within the programme
5. equipment test records show that the equipment parameters are maintained within operating limits, and corrective action has been taken as where and when required
6. Medical Physics tests are conducted within 20 working days of being due
7. where any X-ray equipment fails the image quality or mean glandular dose tests it is withdrawn from use immediately and the National Screening Unit is notified concurrently
8. Medical Physicists will forward copies of reports to the relevant Charge MRT and the the National Co-ordinator of Mammography Physics, within 20 working days of the Medical Physics audit
9. other defects detected by the Medical Physicists’ tests shall be rectified within 30 working days.

Evaluation Process

The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

Evaluation Targets
1. 100% of reports are forwarded to the National Co-ordinator of Mammography Physics within 20 working days of the Medical Physics audit.
2. 95% of defects are rectified within the timeframe specified by the Medical Physicist.
3. All other criteria are met.

26. MULTIDISCIPLINARY MANAGEMENT

Standard – Each stage of the programme is co-ordinated in a manner that promotes a multidisciplinary team approach where appropriate.

26.1 MULTIDISCIPLINARY TEAM – CLINICAL

Quality Indicator

A close, co-operative working relationship between all staff involved in the Programme ensures an effective multidisciplinary approach to care.

NOTE: The number of assessment teams are to be limited to ensure the team sees enough cases to maintain their skills and experience, in order to provide a high quality service and a consistent approach to assessment and treatment.

Criteria

BreastScreen Aotearoa Providers will ensure that:
1. co-ordinated specialist intervention from all members of the team results in the optimum care of each woman participating in the screening pathway
2. staff demonstrate good interpersonal skills and work closely with all disciplines to ensure a quality service is delivered
3. each assessment centre must have a clinical multidisciplinary team that includes: a. radiologists (reading and assessing) b. surgeons c. pathologists (reporting both FNAC and core biopsy) d. MRTs e. breastcare nurses f. other professionals as appropriate.
4. clinical multidisciplinary team meetings are required at all assessment sites
5. the clinical multidisciplinary team shall meet preferably weekly but at least fortnightly
6. clinical multidisciplinary team members are required to attend meetings with a frequency as outlined in the relevant Professional Requirements section of this document
7. the purpose of the clinical multidisciplinary team meetings is to ensure that women have completed assessment undertaken by the Lead Provider assessment team, and shall include the following:
   a. ongoing management and review of results of assessment cases
   b. concordance of the radiological, surgical and pathological lesion findings for women undergoing level 2 and 3 assessment at that site
   c. special consideration to ensure appropriate management where needle-biopsy results of ADH, radial scar, papillary lesions and mucocoeles are obtained, or where microcalcifications are not identified in samples as expected
   d. a lesion seen only on one view should not proceed to surgery until its position on an orthogonal plane is determined by further work-up views, ultrasound, CT or MRI
   e. radiological and pathological review of all Level 2 (needle biopsy) and Level 3 (open biopsy) assessments originating from that site
   f. review of all staged assessment results at the initial assessment site
   g. peer review and exchange of information
   h. review of post-assessment interval cancers
   i. correlation of treatment pathology slides with needle biopsy diagnosis
   j. analysis of screening and treatment results
   k. process and systems reviews
   l. review of feedback from internal and external monitoring, quality assurance and audit activities
   m. ongoing management and review of results of all cases of extended assessment
   n. discussion of treatment options for women with cancer.
8. co-ordination and consistency between assessment centres within a Lead Provider region should be promoted by regular visits of personnel for attendance at Lead Provider clinical MDT meetings or vice versa.

Evaluation Process

1. A register of minutes for all these meetings is held, including attendees.
2. 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

All criteria are met.
27. **LEVEL I ASSESSMENT**

**Standard** — Women with abnormal screening mammograms who do not have a screen-detected lesion requiring biopsy diagnosis are returned to routine re-screening.

### 27.1 LEVEL I ASSESSMENT – IMAGING THE BREAST AT ASSESSMENT

**Quality Indicator**
The radiologist must be able to prove a lesion is benign or confirm a malignancy while keeping invasive procedures for benign abnormalities to a minimum. The aim therefore is to increase specificity without compromising sensitivity.

**Criteria**
1. BreastScreen Aotearoa Providers ensure that radiologists performing Level I assessment are competent in all radiological specialised diagnostic techniques available at their assessment clinic.
2. BreastScreen Aotearoa Providers ensure the radiological specialised diagnostic techniques include:
   a. additional mammographic views
   b. magnification.
3. Breast ultrasound examination:
   a. shall be undertaken by or under the direct supervision of the radiologist
   b. which includes hard copy or digital storage of ultrasound images shall be of a quality that permits peer review
   c. of any significant lesion(s) must have the size, side, clock face position and an indication of distance from the nipple recorded on the image.
4. BreastScreen Aotearoa Providers will ensure a second radiologist reviews all specialised diagnostic images for each woman recalled to assessment. This shall occur before the final result is issued.

**Evaluation Process**
The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

**Evaluation Targets**
1. a surgeon shall be present at all assessment clinics for at least part of the time and will examine, or be responsible for ensuring that an experienced clinician examines, each woman with a confirmed abnormality prior to any invasive procedure
2. each woman requiring clinical examination shall be assigned to the rostered surgeon who is responsible for the clinical examination
3. the surgeon responsible and the person performing the examination should be recorded in the woman's records.
4. BreastScreen Aotearoa Providers will ensure a second radiologist reviews all specialised diagnostic images for each woman recalled to assessment. This shall occur before the final result is issued.

### 27.2 LEVEL I ASSESSMENT – GRADING OF LESIONS

**Criteria**
At the completion of Level I Assessment a radiological category will be assigned to all lesions assessed.

**Quality Indicator**

1. BreastScreen Aotearoa Provider ensures that all radiological lesions are categorised as follows:
   - Category 1. Normal/benign – return to routine re-screening
   - 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.

**Evaluation Process**
Monthly auditing of clinical records for women screened during the previous month at each screening unit.

**Evaluation Target**
100% of lesions assessed have their category recorded.

### 27.3 LEVEL I ASSESSMENT – EXTENDED ASSESSMENT

**Criteria**
Individual women may be referred to 'extended assessment' as an alternative to biopsy when they have a Category 2 lesion identified at assessment.

**Quality Indicator**

1. BreastScreen Aotearoa Providers ensure that radiologists performing Level I assessment are competent in all radiological specialised diagnostic techniques available at their assessment clinic.

**Evaluation Process**
2. BreastScreen Aotearoa Providers ensure that radiologists performing Level I assessment are competent in all radiological specialised diagnostic techniques available at their assessment clinic.

**Evaluation Targets**
1. a surgeon shall be present at all assessment clinics for at least part of the time and will examine, or be responsible for ensuring that an experienced clinician examines, each woman with a confirmed abnormality prior to any invasive procedure
2. each woman requiring clinical examination shall be assigned to the rostered surgeon who is responsible for the clinical examination
3. the surgeon responsible and the person performing the examination should be recorded in the woman's records.

### 27.4 LEVEL I ASSESSMENT – CLINICAL EXAMINATION

**Quality Indicator**
All women requiring further invasive intervention (Level 2 Assessment) shall be examined first by a clinician experienced in breast examination. Clinical examination may be offered but is not required for women considered not to have breast cancer on Level 1 Assessment.

**Criteria**
BreastScreen Aotearoa Providers ensure that:
1. a surgeon shall be present at all assessment clinics for at least part of the time and will examine, or be responsible for ensuring that an experienced clinician examines, each woman with a confirmed abnormality prior to any invasive procedure
2. each woman requiring clinical examination shall be assigned to the rostered surgeon who is responsible for the clinical examination
3. the surgeon responsible and the person performing the examination should be recorded in the woman's records.

**Evaluation Process**
The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

**Evaluation Targets**
1. a surgeon shall be present at all assessment clinics for at least part of the time and will examine, or be responsible for ensuring that an experienced clinician examines, each woman with a confirmed abnormality prior to any invasive procedure
2. each woman requiring clinical examination shall be assigned to the rostered surgeon who is responsible for the clinical examination
3. the surgeon responsible and the person performing the examination should be recorded in the woman's records.
4. BreastScreen Aotearoa Providers ensure that:
   a. a surgeon shall be present at all assessment clinics for at least part of the time and will examine, or be responsible for ensuring that an experienced clinician examines, each woman with a confirmed abnormality prior to any invasive procedure
   b. each woman requiring clinical examination shall be assigned to the rostered surgeon who is responsible for the clinical examination
   c. the surgeon responsible and the person performing the examination should be recorded in the woman's records.

### 27.5 LEVEL I ASSESSMENT – EDUCATION, INFORMATION AND CONSENT

**Quality Indicator**
Refer: Appendix I: Proforma letters and forms

**Criteria**
All women referred to assessment are recalled to a full assessment clinic and all necessary diagnostic imaging is performed by staff competent in the procedure and are reviewed by another radiologist.

**Evaluation Target**
1. a surgeon shall be present at all assessment clinics for at least part of the time and will examine, or be responsible for ensuring that an experienced clinician examines, each woman with a confirmed abnormality prior to any invasive procedure
2. each woman requiring clinical examination shall be assigned to the rostered surgeon who is responsible for the clinical examination
3. the surgeon responsible and the person performing the examination should be recorded in the woman's records.

### 27.6 LEVEL I ASSESSMENT – PROGRESS REVIEW

**Quality Indicator**
Refer: Standard 5 Consent and Standard 25.2 Assessment – Education, Information and Consent

**Criteria**
All women requiring further invasive intervention (Level 2 Assessment) shall be examined first by a clinician experienced in breast examination. Clinical examination may be offered but is not required for women considered not to have breast cancer on Level 1 Assessment.

**Evaluation Process**
The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

**Evaluation Targets**
1. a surgeon shall be present at all assessment clinics for at least part of the time and will examine, or be responsible for ensuring that an experienced clinician examines, each woman with a confirmed abnormality prior to any invasive procedure
2. each woman requiring clinical examination shall be assigned to the rostered surgeon who is responsible for the clinical examination
3. the surgeon responsible and the person performing the examination should be recorded in the woman's records.

### 27.7 LEVEL I ASSESSMENT – QUALITY INDICATORS

**Quality Indicator**
Refer: Appendix I: Proforma letters and forms

**Criteria**
1. Following consultation with a woman, an informed decision is subsequently made by the woman and Category 2 lesions shall be managed by either:
   a. cytological or biopsy diagnosis
   b. extended assessment.
   NOTE: Category 2 lesions managed by extended assessment have a risk of malignancy of ≤ 2%.
2. Where assessment results in a lesion classification of ≤ 2% and percutaneous biopsy is not possible. Investigations with dynamic contrast enhanced MRI, Sestamibi or CT Scan should be considered, in order to locate the lesion for hookwire.
   NOTE: BreastScreen Aotearoa does not provide these services, and women would need to be referred accordingly.

### 27.8 LEVEL I ASSESSMENT – CLINICAL MILESTONES

**Quality Indicator**
Refer: Standard 5 Consent and Standard 25.2 Assessment – Education, Information and Consent

**Criteria**
All women referred to assessment are recalled to a full assessment clinic and all necessary diagnostic imaging is performed by staff competent in the procedure and are reviewed by another radiologist.

**Evaluation Process**
The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

**Evaluation Targets**
1. a surgeon shall be present at all assessment clinics for at least part of the time and will examine, or be responsible for ensuring that an experienced clinician examines, each woman with a confirmed abnormality prior to any invasive procedure
2. each woman requiring clinical examination shall be assigned to the rostered surgeon who is responsible for the clinical examination
3. the surgeon responsible and the person performing the examination should be recorded in the woman's records.

### 27.9 LEVEL I ASSESSMENT – CLINICAL OUTCOMES

**Quality Indicator**
Refer: Appendix I: Proforma letters and forms

**Criteria**
All women referred to assessment are recalled to a full assessment clinic and all necessary diagnostic imaging is performed by staff competent in the procedure and are reviewed by another radiologist.

**Evaluation Process**
The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

**Evaluation Targets**
1. a surgeon shall be present at all assessment clinics for at least part of the time and will examine, or be responsible for ensuring that an experienced clinician examines, each woman with a confirmed abnormality prior to any invasive procedure
2. each woman requiring clinical examination shall be assigned to the rostered surgeon who is responsible for the clinical examination
3. the surgeon responsible and the person performing the examination should be recorded in the woman's records.

### 27.10 LEVEL I ASSESSMENT – CLINICAL OUTCOMES

**Quality Indicator**
Refer: Appendix I: Proforma letters and forms

**Criteria**
All women referred to assessment are recalled to a full assessment clinic and all necessary diagnostic imaging is performed by staff competent in the procedure and are reviewed by another radiologist.

**Evaluation Process**
The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

**Evaluation Targets**
1. a surgeon shall be present at all assessment clinics for at least part of the time and will examine, or be responsible for ensuring that an experienced clinician examines, each woman with a confirmed abnormality prior to any invasive procedure
2. each woman requiring clinical examination shall be assigned to the rostered surgeon who is responsible for the clinical examination
3. the surgeon responsible and the person performing the examination should be recorded in the woman's records.
**27.5 LEVEL 1 ASSESSMENT – STAGED ASSESSMENT**

**Quality Indicator**

Staged assessment is where a woman’s assessment occurs on separate occasions over a number of sites.

NOTE: 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, or where a local clinic does not have specialised staff and/or equipment for second level assessment, for example, digital stereotactic equipment.

**Criteria**

1. BreastScreen Aotearoa Providers may only provide staged assessment with prior written approval of the National Screening Unit.
2. At centres which have staged assessment, all women recalled for assessment must be:
   a. advised that they may be required to travel elsewhere or return on another day for part of their assessment
   b. provided with a choice of travelling to an alternative centre from the outset thereby, ensuring all assessment procedures may be completed in the one visit.
3. Centres involved in staged assessment must clearly document the protocols for managing this process effectively.
4. The radiologists initially assessing the woman must obtain feedback (including pathology and subsequent radiology) on all cases that have been referred for further assessment.

**Evaluation Process**

1. Satisfaction surveys.
2. The internal audit process ensures that the criteria are complied with and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

**Evaluation Targets**

1. 95% of surveyed women affected by staged assessment report receiving sufficient information about the assessment process to make an informed choice about which centre to attend.
2. All other criteria are met.

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**28. LEVEL 2 ASSESSMENT – NON-OPERATIVE DIAGNOSIS**

**Standard** — The non-operative diagnosis of screen-detected abnormalities in maximised by obtaining accurate needle biopsy specimens of palpable and impalpable lesions.

**28.1 LEVEL 2 ASSESSMENT – MINIMISING DELAY TO NEEDLE BIOPSY**

**Quality Indicator**

The delay between the decision to perform a needle biopsy and it being undertaken should be minimised.

NOTE: Actual and appropriate needle biopsy utilisation has been identified as the most effective and least morbid pathway to definitive cancer surgery and minimises the need for open surgical biopsy (and attendant morbidity) for benign abnormalities.

**Criteria**

BreastScreen Aotearoa Providers ensure that:

1. processes are in place to ensure that the assessment clinic is appropriately resourced to allow for timely needle biopsy
2. Fine Needle Aspiration Cytology (FNAC) and/or core biopsy are offered at the same assessment appointment where possible.

**Evaluation Process**

1. Regular reports which identify women who are to be recalled for needle biopsies are reviewed by the Lead Provider Manager or a designated individual.
2. Information is collected through the National Minimum Data Set for monitoring and evaluation purposes. (Refer: Current DMM)

**Evaluation Target**

90% of needle biopsies are performed within five working days of the first assessment visit.

**28.2 LEVEL 2 ASSESSMENT – WORK UP, INFORMATION AND CONSENT**

**Quality Indicator**

Women shall be given both appropriate information and work-up prior to invasive breast procedures (Level 2 and Level 3 assessment) being performed.

Criteria

BreastScreen Aotearoa Providers ensure:

1. written consent is obtained from the woman before any Level 2 assessment is undertaken, including all biopsies. Refer: Standard 5 Consent and Standard 25.2 Assessment – Education, Information and Consent (Refer: Appendix I: Pro Forma letters and forms)
2. invasive procedures are only carried out after those performing the radiological work-up and clinical examination have completed their assessment and the woman has been fully informed and has provided consent.

**Evaluation Process**

Monthly auditing of clinical records for women screened during the previous month at each screening unit.

**Evaluation Targets**

1. 100% of records audited show women provided written consent before a Level 2 assessment was carried out.
2. All other criteria are met

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**28.3 LEVEL 2 ASSESSMENT – NEEDLE BIOPSY TISSUE SAMPLING OF SCREEN-DETECTED LESIONS – FINE NEEDLE ASPIRATION CYTOLOGY, CORE BIOPSY, INCLUDING VACUUM-ASSISTED BIOPSY SPECIMENS**

**Quality Indicator**

Needle biopsies are used to maximise preoperative diagnosis of cancer and non-operative diagnosis of benign abnormalities requiring further work-up.

NOTE: In this section, core biopsy includes vacuum-assisted biopsy.

**Criteria**

BreastScreen Aotearoa Providers ensure that:

1. screen detected cancers are diagnosed preoperatively:
   a. advised that they may be required to travel elsewhere or return on another day for part of their assessment
   b. provided with a choice of travelling to an alternative centre from the outset thereby, ensuring all assessment procedures may be completed in the one visit.
2. all women requiring needle biopsy for diagnosis are assessed and biopsied by Clinicians who are competent in needle biopsy techniques as follows:
   a. all image guided needle biopsies of impalpable or palpable lesions shall be performed by a radiologist
   b. needle biopsy of palpable lesions shall be performed by either a radiologist, pathologist or surgeon
   c. all Clinicians performing needle biopsies must be recognised members of the multidisciplinary team.
3. appropriate equipment is available at assessment to carry out any of the necessary needle biopsy techniques
4. radiologists performing assessment must be competent in all image-guided tissue sampling techniques available at their assessment site and be able to advise which is the most appropriate for each woman
5. the appropriate image guided tissue sampling technique for each woman should be agreed upon by members of the multidisciplinary team. Intervention should be carried out in a manner that causes the least discomfort to the woman (for example, ultrasound), and maximises accurate preoperative diagnosis
6. there is a possibility of removing the entire mammographic lesion a marker should be left to allow accurate localisation, should further excision be required.
7. where a marker is to be left for this or other reasons, these must be explained to the woman and informed consent must be obtained.

**Evaluation Process**

1. The Clinical Director shall ensure that the sensitivity and specificity according to the operator, biopsy technique, mode and reporting pathologist are measured and monitored.
2. Information is collected through the National Minimum Data Set for monitoring and evaluation purposes (Refer: Current DMM).
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 Targets**

1. Screen detected cancers are diagnosed preoperatively:
   a. > 70% minimum
   b. > 90% desired
2. Image-guided FNAC procedures with an inadequate/insufficient result should be:
   a. < 25% minimum
   b. < 15% desired.
3. Other suggested thresholds for cytology and core biopsy performance (Refer: Appendix W: FNAC Quality Assurance)
4. All other criteria are met.
3. if a cytotechnologist attends the assessment clinic they should carry cytological material in the assessment clinic setting, adequate space and equipment must be provided for preparation and staining, together with a good quality microscope.

5. in addition to any specific diagnostic categories used, the reporting cytopathologist should also categorise the FNAC findings in one of the following groups:

2. All other criteria are met.

28.4 LEVEL 2 ASSESSMENT – LABELLING OF SPECIMENS

Quality Indicator
A written protocol for the labelling of pathology specimens exists.

Criteria
BreastScreen Aotearoa Providers ensure that:
1. there is a written protocol for the labelling of pathology specimens. This will ensure that the same screening assessment clinic from which the specimen originated is to其中有 from within the Programme.
2. where multiple lesions are sampled, each sample is clearly differentiated and consistently labelled and tracked.
5. all specimens require double identifiers, that is, name and date of birth, or name and NZI number.

Evaluation Process
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
All criteria are met.

28.5 LEVEL 2 ASSESSMENT – PATHOLOGIC EXAMINATION OF CORE NEEDLE BIOPSY SPECIMEN (CNBS)

Quality Indicator
Successful pathologic readings of specimens.

Criteria
BreastScreen Aotearoa Providers ensure that:
1. the radiologist or surgeon provides full clinical information to the reporting pathologist. The latter shall include the exact location of the lesion(s), the mammographic/sonographic findings, the radiological grade of the abnormalities and the findings of clinical examination. A standardised and dedicated request form may facilitate adequate communication.
2. specimens taken from areas of microcalcification shall be X-rayed before they are transported to the pathologist.
3. a copy of this radiograph should accompany the specimen.
4. the radiologist shall indicate to the reporting pathologist whether they consider calcifications are present in the core biopsy specimen X-ray.
5. it is recommended that core biopsies containing microcalcification are submitted in separately labelled specimen containers from the other cores.
6. core specimens are processed as for a routine surgical biopsy, with sections from at least six levels in the tissue block examined.
7. separately labelled specimens should be processed as separate specimens.
8. reporting terminology and diagnostic categories used for screen-detected breast specimens should follow the current National Health Service Breast Screening Programme guidelines.
9. in an attempt to improve diagnostic concordance on classification of DCIS, reporting pathologists should adopt the criteria as set out in The Reporting of Breast Cancer. (Refer Appendix X: Microscopic Reporting of Ductal Carcinoma In Situ)
10. in addition to any specific diagnostic categories used, the reporting pathologist should also categorise the core biopsy (Refer: Appendix W: FNAC Quality Assurance):
B1: Inadequate sample or normal breast tissue
B2: Benign breast lesion
B3: Uncertain malignant potential
B4: Suspicious of malignancy
B5: Malignant breast lesion.
11. core needle biopsy and FNAC specimens from the same woman should be read in the same department/laboratory and the findings correlated. Where this is not possible, mechanisms for co-operation and combined review of the two modalities must be put in place, with the findings correlated prior to the multidisciplinary meeting.

12. all BreastScreen Aotearoa pathologists are encouraged to forward difficult-to-diagnose, issues/uncertain cases in consultation, either to Lead pathologists or recognised overseas pathologists for second opinions. It needs to be acknowledged that this will delay the final diagnosis in such cases by a period of one to three weeks. Any potential delay in diagnosis shall be communicated to the Lead Provider Clinical Director/Manager and the woman at the earliest opportunity.

Evaluation Process
The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

Evaluation Targets
1. > 80% of core biopsy results are reported to the assessment centre within 3 working days of a core or vacuum assisted biopsy being performed.
2. All other criteria are met.

28.6 LEVEL 2 ASSESSMENT – PATHOLOGIC EXAMINATION OF FINE NEEDLE ASPIRATION CYTOLOGY (FNAC) SPECIMENS

Quality Indicator
All Fine Needle Aspiration Cytology (FNAC) specimens shall be appropriately reported.

Criteria
BreastScreen Aotearoa Providers ensure that:
1. handling and reporting of screen-detected breast specimens should follow the National Health Service Breast Screening Programme (NHSBSP) guidelines.
2. it is desirable but not mandatory for a cytopathologist or cytotechnologist to attend the assessment clinic to report on FNAC material. However, if adequacy of specimens does not achieve the specified targets then a cytopathologist or a cytotechnologist shall be present at the assessment clinic:
   a. the period of time which the cytopathologist or cytotechnologist shall attend assessment clinics after a drop in adequacy is at the discretion of the Clinical Director.
   b. a record of this and the rationale for reducing the cytopathologists or cytotechnicians shall be maintained.
3. if a cytotechnologist attends the assessment clinic they may render an opinion as to the adequacy of the material obtained but they are not to give either a verbal or written cytological diagnosis.
4. if a cytopathologist or cytotechnologist is to access cytological material in the assessment clinic setting, adequate space and equipment must be provided for preparation and staining, together with a good quality microscope.
5. in addition to any specific diagnostic categories used, the reporting cytopathologist should also categorise the FNAC findings in one of the following groups:
   C1: Inadequate sample
   C2: Benign breast lesion
   C3: Atypical or indeterminate changes
   C4: Suspicious of malignancy
   C5: Malignant breast lesion.
6. FNAC specimens and core biopsy specimens should be read in the same department/laboratory and the findings correlated. Where this is not possible, mechanisms for co-operation and combined review of the two modalities shall be put in place, with the findings correlated prior to the multidisciplinary meeting. A written report of FNAC results is received by the screening unit within 2 working days.

Evaluation Process
The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

Evaluation Targets
1. 100% of written reports containing FNAC results are received by the screening assessment unit within 2 working days.
2. All other criteria are met.

28.7 LEVEL 2 ASSESSMENT – LABORATORY FACILITIES AND PROCESSES FOR REPORTING ON SCREEN DETECTED MATERIAL

Quality Indicator
Pathologists and laboratories participating in the programme must demonstrate that there are adequate facilities and processes for reporting on screen-detected material.

20 NHSBSP 1993 Guidelines for Cytology Procedures and Reporting in Breast Cancer Screening – Cytology Subgroup of the National Co-ordinating Group for Breast Screening Pathology NHSBSP Publication 22.
Section 2 – The Breast Screening Pathway

Evaluation Targets

29. Level 3 Assessment – Surgical Biopsy

Quality Indicator

The aim of the open surgical biopsy is to successfully identify and remove mammographically detected lesion(s) for pathological assessment with the minimum of morbidity for the woman.

Criteria

BreastScreen Aotearoa Providers ensure that:

1. The number of women requiring an open surgical biopsy for the diagnosis of cancer is minimised

2. The number of women undergoing open surgical biopsy for benign lesions is minimised

NOTE: On occasion a woman may need to undergo an open surgical biopsy to make a diagnosis. This may be due to a number of reasons – the nature of the lesion, failure of previous interventional biopsy (FNAC or core), a mammographic lesion may be difficult to image, too small, or the woman may request an open biopsy.

3. Open surgical biopsy should be carried out by the surgeon who will be responsible for ongoing surgical management, should cancer be diagnosed.

4. Women are given information to enable their decision about whether to have their surgery undertaken in the public sector and the implications of these options for future management

5. The delay between the surgical decision to operate and the operation being performed is minimised

Evaluation Process

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

All criteria are met.

29.1 Level 3 Assessment – Surgical Biopsy General Principles

Quality Indicator

Lesions are successfully localised preoperatively.

Criteria

BreastScreen Aotearoa Providers ensure that:

1. Radiologists performing preoperative localisations are competent in these techniques, which must all be available on-site at the assessment clinic

2. Localisation of impalpable lesions is performed before surgery. The approach and method of localisation for each woman should be decided in discussion between the surgeon and radiologist. If several methods of localisation are possible, the one chosen should be the most comfortable for the woman (for example, if the lesion is visible under ultrasound, this would probably be the quickest and most comfortable means of guidance for localisation).

Other methods that use X-ray guidance include:

- Stereotactic localisation
- Manual localisation using co-ordinates

3. The marker used will generally be a hookwire or carbon fibre wire

4. Whichever localisation method is used, sufficient views of the marker placement (with skin markers if necessary) should be obtained at the end of the procedure, to aid surgical planning. It is helpful if these films are reviewed with the surgeon prior to surgery, particularly if the marker placement is not ideal

5. The radiologist will document in writing the method of localisation and position of the marker in relation to the mammographic lesion. An accompanying diagram is important, and should be included with the woman’s notes.

Evaluation Targets

1. Open biopsies performed for benign disease per 1,000 women screened

2. > 90% of markers should be within 10 mm of the correct position

3. All other criteria are met.

Evaluation Process

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

All criteria are met.

29.2 Level 3 Assessment – Preoperative Localisation of Impalpable Lesions

Quality Indicator

Lesions are successfully localised preoperatively.

Criteria

BreastScreen Aotearoa Providers ensure that:

1. Radiologists performing preoperative localisations are competent in these techniques, which must all be available on-site at the assessment clinic

2. Localisation of impalpable lesions is performed before surgery. The approach and method of localisation for each woman should be decided in discussion between the surgeon and radiologist. If several methods of localisation are possible, the one chosen should be the most comfortable for the woman (for example, if the lesion is visible under ultrasound, this would probably be the quickest and most comfortable means of guidance for localisation).

Other methods that use X-ray guidance include:

- Stereotactic localisation
- Manual localisation using co-ordinates

3. The marker used will generally be a hookwire or carbon fibre wire

4. Whichever localisation method is used, sufficient views of the marker placement (with skin markers if necessary) should be obtained at the end of the procedure, to aid surgical planning. It is helpful if these films are reviewed with the surgeon prior to surgery, particularly if the marker placement is not ideal

5. The radiologist will document in writing the method of localisation and position of the marker in relation to the mammographic lesion. An accompanying diagram is important, and should be included with the woman’s notes.

Evaluation Targets

1. Open biopsies performed for benign disease per 1,000 women screened

2. > 90% of markers should be within 10 mm of the correct position

3. All other criteria are met.

Evaluation Process

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

All criteria are met.

29.3 Level 3 Assessment – Orientation of Specimen

Quality Indicator

Localisation and position of the marker in relation to the mammographic lesion are accurately recorded.

Criteria

BreastScreen Aotearoa Providers ensure that:

1. The surgeon taking the specimen(s) ensures that all criteria are met.

2. The number of women undergoing open surgical biopsy for benign lesions is minimised

3. All other criteria are met.

Evaluation Process

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

All criteria are met.

29.4 Level 3 Assessment – Size of Specimen

Quality Indicator

The adverse impact of diagnostic surgical biopsy on breast appearance, contour or shape shall be minimised.

Criteria

BreastScreen Aotearoa Providers ensure that:

1. The number of women requiring an open surgical biopsy for the diagnosis of cancer is minimised

2. The number of women undergoing open surgical biopsy for benign lesions is minimised

NOTE: On occasion a woman may need to undergo an open surgical biopsy to make a diagnosis. This may be due to a number of reasons – the nature of the lesion, failure of previous interventional biopsy (FNAC or core), a mammographic lesion may be difficult to image, too small, or the woman may request an open biopsy.

3. Open surgical biopsy should be carried out by the surgeon who will be responsible for ongoing surgical management, should cancer be diagnosed.

4. Women are given information to enable their decision about whether to have their surgery undertaken in the public sector and the implications of these options for future management

5. The delay between the surgical decision to operate and the operation being performed is minimised

Evaluation Process

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

All criteria are met.


18. European Guidelines for Quality Assurance in Mammography Screening. 3rd Ed.
3. before the open biopsy is completed, if the lesion has not been fully excised, the radiologist may be able to indicate to the surgeon in which direction further tissues should be removed, by reviewing the specimen radiograph in conjunction with post-localisation check films. This is facilitated if the surgeon has used radiopaque markers and sutures to indicate the orientation of the specimen within the breast, and if the specimen has been orientated in an anatomical position prior to radiography.

4. occasionally, an impassable lesion may not be visible on mammography or specimen radiography. If ultrasound was used for preoperative localisation, ultrasound of the specimen may be necessary to confirm removal of the lesion.

5. specimen radiography should be performed using magnification, without a grid, and with the specimen centred over the automatic exposure control (AEC) chamber. Compression may be useful to aid detection of ill-defined, low density lesions but may also distort margins of the specimen, making pathological evaluation difficult. Use of compression should therefore be according to a documented protocol agreed to by the multidisciplinary team.

6. at least two radiographs should be obtained of the specimen, one shall accompany the specimen to the Pathology Department and the other be retained in the woman’s screening record.

7. further radiology of the sliced specimen may be performed to improve efficiency of pathological diagnosis and should be performed for lesions containing calcifications. The radiologist should mark the mammographic abnormality on this film, so that the appropriate slices can be examined by the pathologist.

8. all tissue specimens from impassable lesions should be appropriately imaged perioperatively.

**Evaluation Process**

1. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

2. In 90% of cases a written histology report is received by the screening unit within 5 working days of the pathology laboratory receiving the specimen.

3. 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 (Refer: Level 3 Assessment – Specimen Radiography). 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 there is any doubt by the pathologist as to the presence of the lesion in the sliced specimen radiographs.

4. frozen section examination shall not be undertaken on impassable breast lesions.

5. reporting terminology, diagnostic categories used and the recording of routine prognostic variables for screen-detected breast specimens shall follow the National Health Service Breast Screening Programme guidelines.

6. reporting pathologists should adopt the criteria as set out in The Pathology Reporting of Breast Cancer, in an attempt to improve diagnostic concordance on classification of DGS.

7. this report and the slides of the specimen must be made available to the treatment service in a timely manner to avoid delay in surgery.

**Evaluation Targets**

1. 100% of tissue specimens from impassable lesions are appropriately imaged perioperatively and reported by a radiologist.

2. >95% of specimen images and/or verbal reports should be received in less than 15 minutes of the specimen being sent from the operating theatre.

3. >95% of impassable lesions are excised at the first biopsy operation.

4. All other criteria are met.
30. OUTCOME OF ASSESSMENT

Standard — Each woman is notified of her assessment results, and if required, is referred to treatment in a manner that is unbiased and cognisant of her informed decision.

30.1 OUTCOME OF ASSESSMENT – NOTIFICATION OF RESULTS

Quality Indicator

Each woman receives timely and accurate assessment result notification.

Criteria

BreastScreen Aotearoa Providers ensure that:

1. final results are only communicated to women after all clinical review processes are completed (that is, after the multidisciplinary meeting). The method and timeframe of result notification is discussed with the woman at the completion of her assessment visit
2. wherever possible, provisional results are to be given on the day of assessment
3. if the woman can be returned to two yearly recall after the radiological assessment (that is, if further views with or without ultrasound, the results are to be given by the radiologist at assessment.
4. where it is not possible to give results on the day of assessment, the woman is to be informed of when to expect the results (allowing for a second read by a radiologist, pathology results and clinical multidisciplinary team meeting), and an arrangement made for her to return to the centre for this
5. if the woman has to travel a long distance, consideration will be given to other arrangements for results (for example, if consent has been given, a woman’s GP/PCP will provide her with her results following discussions with the surgeon.) The breastcare nurse will follow up in a timely manner
6. if the diagnosis is cancer, the breastcare nurse shall be present when the diagnosis is explained (Refer: Standard 25.3: Assessment – Support)
7. if consent has been obtained, the results will also be given to the woman’s GP/PCP or practice nurse.

- where this is a diagnosis of cancer, the GP/PCP (or if not available, the practice nurse), is to be advised immediately by telephone, and followed up with a letter
- where the diagnosis is not cancer the GP/PCP is to be advised by letter
- where the result of the assessment is ‘no evidence of cancer’ eligible women are placed on the routine re-screen list (Refer: Standard 24.2: Outcome of Screening – Routine Re-screening)
- assessments are reported according to the recommendations in Breast Imaging – A Guide to Practice22 – EXCEPT for lesion classification where the NPI&Q5 grading of lesions will be used. (Refer section 27.2)

Evaluation Process

1. Regular reports, which identify women who have not been notified of their results, are reviewed by the Lead Provider Manager or a designated person and the reason for the delay is documented.
2. Information is collected through the National Minimum Data Set for monitoring and evaluation purposes (Refer: Current DMM).
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

1. Time taken from final diagnostic needle biopsy to reporting results to the woman – 90% of women receive results within 5 working days of final diagnostic needle biopsy.
2. All other criteria are met.

30.2 OUTCOME OF ASSESSMENT – REFERRAL TO TREATMENT

Quality Indicator

Comprehensive information relevant to her situation, provided within a supportive environment, allows the woman to make an informed decision regarding her treatment options and the process of a woman’s referral to treatment.23

Criteria

BreastScreen Aotearoa Providers ensure that:

1. the surgeon or other relevant clinician shall discuss treatment and provider options with the woman in conjunction with the breastcare nurse
2. the breastcare nurse shall also be available to the woman during or immediately after she has been informed of her treatment and provider options
3. the information regarding the treatment and provider options shall not be given solely by any person, as it may be interpreted as biased
4. information about appropriate treatment options are provided to the woman. This includes but is not limited to:
   a. the Treatment and Support Services for Women with Breast Cancer Broker (Refer: Appendix D: Breast Screening Resources)
   b. all available options for treatment provision, their advantages and disadvantages (including benefits, costs where relevant and actual waiting times)
   c. the full consequences of all treatment options (including adjuvant therapy)
   d. a list of names of surgeons who are eligible for full membership of the Breast Section of the Royal College of Surgeons is available to women
   e. the possibility of requiring radiotherapy and the implications of this regardless of whether surgery is provided in the private or public sector (for example, travel to a main centre, attending a public hospital).

5. the woman is advised of the option to discuss her choices of treatment option with her GP/PCP but must be advised that the cost of the GP/PCP visit is not covered by the Programme
6. each woman is actively involved in the decision making process and should be provided with options for accessing information regarding treatment and treatment providers such as her GP/PCP or the Cancer Society and any other appropriate local support agencies
7. where a woman has decided to attend the public system for free treatment she may choose:
   a. the nearest public hospital to her residence, or
   b. the nearest high-volume public provider.
8. if a woman chooses a private provider she needs to be informed that she will be required to pay for any surgical treatment.

---

31. NO FURTHER ACTIVE RECALL

Standard — Women have a clear understanding of the reasons for no longer being eligible for the programme, the process of no further active recall to BreastScreen Aotearoa or choosing not to participate in BreastScreen Aotearoa.

31.1 NO FURTHER ACTIVE RECALL

Quality Indicator
Each woman is informed that she will no longer be actively recalled for routine re-screening when the eligibility criteria are no longer met, or she chooses to leave BreastScreen Aotearoa.

Criteria
1. BreastScreen Aotearoa Providers will ensure that the woman is no longer recalled for routine re-screening with BreastScreen Aotearoa when she:
   a. has a positive diagnosis of breast cancer, and is referred for treatment
   b. actively requests not to be recalled by BreastScreen Aotearoa
   c. falls outside the eligible age range
   d. has died
   e. fails or refuses to attend assessment (Refer: Standard 24.4: Outcome of Screening – Failure or Refusal to Attend Assessment).

DMM Field Codes
0 = Not Specified
1 = Stopped – Woman Transferred to Other Lead Provider
2 = Stopped – Unable to Contact Woman
3 = Stopped – Woman Refused Assessment
4 = Stopped – Woman Declined to Complete Assessment
5 = Stopped – Woman unable to Complete Assessment due to ill health
9 = Stopped – Other

2. with the woman’s permission, the GP/PCP is also informed that she is not to be recalled, and the reasons for this.

Evaluation Process
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
All criteria are met.
**SECTION 3 MANDATORY LEADERSHIP POSITIONS**

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32. MANDATORY LEADERSHIP POSITIONS IN BREAST SCREENING

Breast screening is a team activity and success depends on leadership and teamwork from all participants. At any stage in the pathway, only part of the team is involved, but few of the boundaries are rigid and co-operation and understanding is vital. This team approach cannot be achieved passively; rather it requires an ongoing effort. Identified individuals must fill the leadership positions outlined in this section. The positions identified here will require a clear allocation of time to fulfil their roles. There may be circumstances where some of the roles can be undertaken by one individual, eg Lead MRT and designated QC MRT.

All individuals must fulfil the qualifications and continuing professional development requirements of the relevant profession and/or position within the Programme.

33. CLINICAL DIRECTOR

33.1 THE ROLE OF THE CLINICAL DIRECTOR

Mammographic screening for breast cancer is a radiological procedure and it is appropriate that the Clinical Director of a BreastScreen Aotearoa Lead Provider is a radiologist and, in these circumstances, the Clinical Director may also undertake the tasks of the Lead Radiologist as described in this document.

The Clinical Director is ultimately responsible for the overall clinical performance of the 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 BreastScreen Aotearoa within their Lead Provider region.

Responsibilities of the Clinical Director include:
1. the implementation of a high-quality mammography and assessment service subject to adequate resources
2. direct leadership of the clinical team throughout the Lead Provider region, (including associated subcontractors)
3. ensuring all screening staff receive adequate clinical training and regular updates subject to adequate funding/resources
4. oversight of clinical performance monitoring, with the Lead Clinicians
5. ensuring that fail-safe mechanisms are in place so that women with radiological abnormalities are recalled to assessment
6. ensuring that the National Policy and Quality Standards are implemented monitored and evaluated through a continuous quality improvement (CQI) process in respect to technical, radiological and clinical services and subject to the availability of adequate resources
7. overall responsibility for the accuracy of internal data audits
8. ongoing review of Programme performance data, with particular attention to cancer detection and the review of interval cancers
9. ensuring advertising and publicity material is clinically correct via feedback to the National Screening Unit
10. active involvement in the assessment clinics
11. regular attendance at Clinical Directors unidisciplinary meetings

33.2 PROFESSIONAL STANDARDS

The Clinical Director will be medically qualified, registered to practice in New Zealand, hold vocational registration, and be active professionally within the Programme. They must also meet all the professional requirements of their relevant profession within the Programme (refer Section 4 – Professional Requirements). They should demonstrate participation in breast radiology components for a total of at least fifteen educational hours during the preceding three years, in keeping with the RANZCR Mammography Continuing Professional Development (CPD) programme.

Continuing professional development

Every three years, participating Clinical Directors must submit to the Clinical Directors’ Unidisciplinary Group evidence that they have attended national and/or international meetings with a component on breast screening. They should demonstrate that they have participated in breast screening components for a total of at least ten educational hours during the preceding three years.

CPD shall include all the requirements of the appropriate specialty within the Programme. It is expected that the Clinical Director will also actively participate in regional and national quality assurance activities (for example, interval cancer review).

34. LEAD RADIOLOGIST

34.1 THE ROLE OF THE LEAD RADIOLOGIST

The Lead Radiologist is ultimately responsible for the quality of films, subsequent reports produced under his/her direction and the overall imaging performance of the Programme within their Lead Provider area.

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

Responsibilities of the Lead Radiologist are:
1. to select a medical physicist(s) who will administer the MQA programme, perform the physicist(s) QC tests and oversee the work of the QC MRTs
2. to ensure that the NP&QS Standards relevant to imaging are implemented, monitored and evaluated [Reference: Standards 23.7-14, 27.1-27.5]
3. to ensure that all imaging equipment is performing satisfactorily
4. to ensure that GP/PCPs are kept fully informed of the screening outcomes for women registered with their practices
5. to review radiologist performance data by site and individual radiologist, as per the NP&QS. Individual data is confidential to the radiologist concerned, the Lead Radiologist and the Clinical Director
6. actively involved as a screening and assessment radiologist within the Programme
7. to ensure BreastScreen Aotearoa radiologists receive adequate training and regular updates.

Responsibility

The Lead Radiologist is responsible for the clinical performance of BreastScreen Aotearoa radiologists in their region.

Co-ordination

The Lead Radiologist, Lead MRT and medical physicists are responsible for co-ordinating regular (for example, quarterly) MQA meetings within their Lead Provider region. These 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 with a presence at the meeting, by teleconference, or during the planning stage.
35. LEAD PATHOLOGIST

35.1 THE ROLE OF THE LEAD PATHOLOGIST

The Lead Pathologist is ultimately responsible for providing professional leadership and ensuring compliance with the National Policy and Quality Standards (NP&QS) for all pathologists in the Lead Provider region. The specific responsibilities of the Lead Pathologist include:

1. ensuring that the agreed BreastScreen Aotearoa CQI programme is implemented at all sites
2. ensuring that process are in place to implement, monitor and evaluate the relevant NP&QS standards
3. ensuring that processes are in place to monitor the accuracy of pathology data (for example, the correct use of the pathology synoptic forms. Refer: Appendix S: Synoptic Form)
4. ensuring there is a designated pathologist from each contributing laboratory responsible for the quality of work at that site
5. active involvement with pathology assessment assessment of BreastScreen Aotearoa women within their region
6. monitoring and assuring provision of reports and slides to the assessment centre and treatment providers while meeting the specified timeliness requirements.
7. regular attendance at pathologist interdisciplinary meetings

Responsibility

The Lead Pathologist is responsible for overseeing the clinical performance of the following within their region:

1. BreastScreen Aotearoa pathologists
2. Cytotechnologists
3. Laboratory staff.

36. LEAD SURGEON

36.1 THE ROLE OF THE LEAD SURGEON

The Lead Surgeon is responsible for overseeing the clinical performance of the following within their region:

1. BreastScreen Aotearoa surgeons
2. the designated QC MRT (if other than a BreastScreen Aotearoa MRT).

Responsibility

The Lead Surgeon is responsible for overseeing the clinical performance of BreastScreen Aotearoa surgeons.

37. LEAD MEDICAL RADIATION TECHNOLOGIST

37.1 THE ROLE OF THE LEAD MEDICAL RADIATION TECHNOLOGIST (MRT)

The Lead MRT provides professional leadership to MRTs within their region. The Lead MRT is responsible for:

1. ensuring site visits occur at least every six months
2. ensuring a high standard of mammographic film quality is achieved by all MRTs in the Lead Provider region
3. ensuring individual MRT performance is monitored and feedback is provided to each MRT in the team
4. ensuring all MRTs participate in the monthly peer review process using MQ criteria
5. identifying any training needs of MRTs and ensuring any appropriate training occurs
6. overseeing the overall performance of the MQA programme within the Lead Provider region.
7. regular attendance at MRTs interdisciplinary meetings

Responsibility

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

1. BreastScreen Aotearoa MRTs
2. the designated QC MRT (if other than a BreastScreen Aotearoa MRT).

37.2 PROFESSIONAL STANDARDS

The Lead MRT will:

1. be actively involved in performing a minimum of 700 screening mammograms within the Programme and is required to comply with Standard 4.2.2
2. demonstrate a high standard of mammography and maintain a strong clinical focus
3. retain responsibilities as below but be able to delegate
4. the Lead, Charge and Charge QC MRT will otherwise meet all the professional and continuing professional development requirements of an MRT detailed in 4.2.2
5. In addition continuing professional development relevant to the managerial aspects of the charge role will be undertaken.
37.3 THE ROLE OF THE CHARGE MRT
A MRT in charge of screening. Charge MRT, is to be appointed at each screening site. They are responsible for:
1. ensuring MQA at that site occurs and is reported back to the Lead MRT/Lead QC MRT
2. technical/support staff who support MRTs
3. reviewing the MQA programme annually with the Lead MRT and Lead QC MRT, designated MQA radiologist and the medical physicist to ensure compliance with NRL-GS. Ensuring that all MRTs at the Lead Provider and subcontractor sites meet the minimum entry and ongoing requirements for screening MRTs within the Programme.

38. LEAD PROVIDER MANAGER
38.1 THE ROLE OF THE LEAD PROVIDER MANAGER
The Lead Provider Manager ensures the provision of effective operational management, leadership, planning and co-ordination for the service. In undertaking their respective roles, they have joint responsibility with the Clinical Director for the operation of the BreastScreen Aotearoa Programme within their Lead Provider region. The Lead Provider Manager’s areas of responsibility include but are not limited to:
1. advocating for adequate resources being available within funding allocations to meet the requirements of the NP&BQS
2. ensuring effective use of available resources
3. ensuring all non-clinical aspects of the NP&BQS are implemented, monitored and evaluated
4. 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
5. overseeing the recruitment, education, training, professional development and ongoing quality of non-clinical staff involved in the Programme
6. ensuring recommendations from the BreastScreen Aotearoa Independent Monitoring Group (BSA IMG) Report recommendations are acted upon
7. facilitating a close working relationship between members of a multidisciplinary group (including health promotion, screening and assessment personnel)
8. ensuring adequate policies and procedures are in place to meet the requirements of the NP&BQS and the current Data Management Manual (DMM)
9. distributing any amendments to national documents
10. communicating and liaising regularly with the Clinical Director to ensure the success of the service
11. regular attendance of the Lead Provider Manager’s Unidisciplinary Group.

Responsibility
1. The Lead Provider Manager is responsible for the performance of all non-clinical staff including the following:
   a. Data Manager
   b. reception staff
   c. clerical staff
   d. Health Promotion staff
   e. Quality Co-ordinator.
2. The Lead Provider Manager will visit each screening and assessment site in their region a minimum of every six months. This could be timed to coincide with the management multidisciplinary meeting.

38.2 MINIMUM QUALIFICATIONS REQUIRED
1. Management skills and experience appropriate to the position.
2. Relevant tertiary qualifications or working towards, preferably in a health related area.

Continuing professional development
Continuing professional development shall include servicespecific training, for example, the Diploma of Public Health, breast screening courses/conferences in addition to management training and multidisciplinary courses.

38.3 LEAD PROVIDER MANAGER EXPERTISE
The Lead Provider Manager’s expertise includes but is not limited to:
1. an understanding of the philosophy and operations of a breast screening programme
2. strong leadership skills
3. planning for service provision
4. working within budgets and financial allocations
5. an understanding of working with the community
6. managing people, bringing together a team, liaising with other professions.

38.4 TRAINING
New Lead Provider Managers in training
There will be appropriate training and orientation for new Managers. The orientation is designed to ensure that a new Lead Provider Manager has exposure to the relevant facets of the Programme to ensure an appropriate level of understanding.
This may include but is not limited to:
1. visiting other sites within the Programme
2. visiting subcontractor sites
3. liaison with other Lead Provider Managers within the Programme
4. attendance at regular national programme management meetings.

39. DATA MANAGER
39.1 THE ROLE OF THE DATA MANAGER
The Data Manager works as a member of a multidisciplinary team providing timely, accurate and reliable data to support all phases of the screening, assessment and treatment processes. The Data Manager is responsible for the overall data quality and consistency of information recorded in the Lead Provider database and that the data is forwarded to the national monitoring database as per the agreed timetable.
The Data Manager needs to understand each phase of the BreastScreen Aotearoa Programme from the identification, screening, assessment, treatment and follow-up of women diagnosed as having breast cancer. The Data Manager should support the different professional groups involved with breast screening in meeting the NP&BQS by providing accurate and timely information.
The Data Manager has the responsibility to ensure that the information system complies with all the National Screening Unit Standards documented in the BreastScreen Aotearoa documents, for example:
1. Data Management Manual (DMM), the current version
2. Breast Screening Compliance Scripts (NZHIS), the current version
3. Breast Screening National Database File Layouts; the current version
4. Breast Screen Aotearoa Data Quality Plan, the current version
5. official clarification documents issued by the National Screening Unit (as required).
This will be facilitated by regular attendance at the Data Manager’s Unidisciplinary Group.

Liaison requirements
To ensure that activity and results are accurately monitored and on a regular basis, the Data Manager liaises with:
1. members of the Multidisciplinary Team
2. the Health Promotion team (if not represented within the multidisciplinary team)
3. software vendors
4. other BreastScreen Aotearoa Data Managers
5. the National Screening Unit
6. key stakeholders.
39.2 PROFESSIONAL STANDARDS

Qualifications
It is essential that the Data Manager demonstrates:
1. experience in data management, including report generation
2. a minimum of two years experience managing a ‘business critical’ information system
3. interpretation of report data
4. experience in managing data quality.

Continuing professional development
Continuing professional development requirements include:
1. database management skills
2. quality assurance
3. data analysis
4. breast screening issues, for example, site visits
5. attendance at a data management/audit course every two years.

39.3 DATA MANAGER’S EXPERTISE
Expertise should include:
1. an understanding of BreastScreen Aotearoa and the breast screening pathway
2. a meticulous and methodical approach to data accuracy and completeness
3. an understanding of audit, monitoring and evaluation requirements
4. an understanding of the data management responsibilities for example, audit and quality issues for manual and computer records
5. the ability to monitor and facilitate the maintenance of appropriate information systems and database housekeeping activities
6. appropriate knowledge and adequate training in the information system/database which captures and stores the information
7. a thorough knowledge of the relationships with other information systems and interfaces
8. the ability to provide ad hoc reports to the Clinical Director and other staff when required
9. the ability to recognise restrictions and exceptions in order to ensure accuracy of these reports
10. the ability to demonstrate well developed written and oral communication skills
11. the ability to identify problem areas and possible areas of improvement and implement solutions as appropriate, following authorisation by the Lead Provider Manager
12. the ability to develop good working relationships with the other staff and stakeholders to ensure that targets are met and the data is accurate.

39.4 STAFF IN TRAINING (NEW AND TRAINEE STAFF)

Supervision requirements
New Data Managers and staff in training shall receive adequate supervision until they reach a level of competence that satisfies their immediate Manager. Due to the pivotal nature of this position, it is essential that contingencies be established to manage episodes of extended leave, sickness or the resignation of the Data Manager to ensure the continuity of data management and reporting.

Practice limitations
New staff and staff in training shall limit their data management activities to the areas they have been deemed competent in by their immediate Manager.
## SECTION 4 PROFESSIONAL REQUIREMENTS

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40. OTHER MANDATORY ROLES WITHIN BREASTSCREEN AOTEAROA

The provision of an expert multidisciplinary team and the provision of a quality breast screening service requires specific key roles which are considered mandatory.

All mandatory roles are detailed in the following section. The requirements of each role in relation to the specific responsibilities, professional standards, continuing professional development (CPD) and quality are specified. All professional requirements should be included in job descriptions and be subject to performance appraisals.

Mandatory roles include:
1. Breastcare nurses
2. Health promoters
3. Medical physicists
4. Medical radiation technologists
5. Pathologists
6. Quality co-ordinator
7. Radiologists
8. Surgeons.

The BreastScreen Aotearoa Lead Provider, subcontractors and ISPs must maintain an up to date list of all personnel filling mandated BreastScreen Aotearoa roles within their region.

The BreastScreen Aotearoa provider may choose to provide additional expertise in addition to the mandatory roles listed above in order to meet specific needs of women receiving their services.

Additional complementary roles (non-mandatory) may include:
1. Counsellors
2. Cytotechnicians
3. GP/PCP liaison
4. Interpreters
5. Medical officers
6. Reception, administration and clerical
7. Sonographers

It is a requirement that all staff undergo culturally consumer focused training, for example, Well Women Customer Service.

41. BREASTCARE NURSE

41.1 THE ROLE OF THE BREASTCARE NURSE

The breastcare 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.

1. All women participating in BreastScreen Aotearoa are entitled to services from the breastcare nurse which:
   a. Comply with legal, professional, ethical and other standards relevant to the profession of nursing
   b. Are delivered in a professional manner consistent with the physical, psychological, spiritual and cultural needs of the individual
   c. Are delivered according to the ethics of the nursing profession, minimising any potential harm to and optimising the quality of life of that individual.

2. The breastcare 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.

The role of the breastcare nurse includes, but is not limited to:
   a. Empathetically providing support to women and their family/whānau
   b. Acting as advocate for the woman and her supporters
   c. 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
   d. Promoting awareness of psychosocial issues of concern to well women participating in screening
   e. Referring women (where appropriate) to other support services
   f. Facilitating communication between other health professionals and services (particularly GPs/PCPs) regarding the care of individual women
   g. Nursing support for women and clinicians during all stages of assessment
   h. Ensuring there are appropriate infection control protocols in place
   i. Facilitating appropriate handling and pathways for pathology specimens
   j. Facilitating access to clinical supplies for assessment days
   k. Regular attendance at the breastcare nurse’s multidisciplinary group.
SECTION 4 – Professional Requirements

4.1.2 PROFESSIONAL STANDARDS

Qualifications

The role of a BreastScreen Aotearoa breastcare nurse is undertaken by a Registered Nurse (RCGN or RCPN) 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.

The registered nurse will have demonstrated an understanding of and a commitment to meeting the NP&QS.

Within the first year of employment, the BreastScreen Aotearoa Nurse must have attended or be attending a breastcare nurse course accredited by the New Zealand Nursing Council.

Enrolled Nurses currently working in the Programme may continue in their role but they will participate in ongoing education/training as specified and have their practice overseen by a registered nurse.

Continuing professional development

In order to provide a specialist service for women, the breastcare nurse shall have access to ongoing professional development.

The breastcare nurse, in consultation with the Manager, shall develop both short and long-term strategies relating to personal career development within the Programme.

The breastcare nurse shall actively update her nursing knowledge and practice while maintaining current knowledge in breast screening through participation in graduate nursing study, planned educational programmes, and self-directed study.

In addition to this, the breastcare nurse shall maintain up to date knowledge and skills by participation in:

1. clinical multidisciplinary in-house sessions for case review, 60% or 15 meetings annually, whichever is the greater
2. programme study sessions
3. nationally recognised education programmes, or
4. regional, national or international seminars, conferences or courses, attending three in any five-year period
5. regular clinical supervision if available and requested by the breastcare nurse.

4.1.3 NURSING EXPERTISE

The breastcare nurse demonstrates advanced knowledge of nursing theory and practice with an emphasis on:

1. anatomy and physiology of the breast
2. signs and symptoms of breast disorders
3. pathology of breast cancer
4. diagnostic procedures/interventions and potential complications
5. therapeutic interventions and potential complications
6. treatment options/trial protocols
7. self-help groups/support services and community networks
8. issues relating to population screening of well women
9. principles and processes of research and quality assurance
10. professional ethics

The breastcare nurse demonstrates excellent skills in:

1. breast awareness
2. nursing and health assessment
3. client information and educational needs assessment
4. assessment and support
5. determining when the woman requires referral to relevant health professionals for additional specialised psychological care
6. written and verbal communication
7. communication/listening
8. evaluation and feedback
9. support and advocacy
10. participation as a member of a multidisciplinary team
11. quality improvement activities.

4.1.4 STAFF IN TRAINING (NEW AND TRAINEE STAFF)

1. The breastcare nurse must have attended or be attending a recognised Breast Care course.
2. The Nurse shall receive an orientation programme to the role and the BreastScreen Aotearoa Programme.
3. The Nurse demonstrates a sound knowledge of nursing theory and practice with a particular emphasis on:
   a. anatomy and physiology of the breast
   b. signs and symptoms of breast disorders
   c. pathology of breast cancer
   d. diagnostic procedures/interventions and potential complications
   e. therapeutic interventions and potential complications

4.2. HEALTH PROMOTION

4.2.1 THE ROLE OF THE HEALTH PROMOTER

Health promotion is the process of enabling people to increase control over, and to improve their health. To reach a state of complete physical, mental and social wellbeing, an individual or group must be able to identify and realise aspirations, to satisfy needs, and to change or cope with the environment. Health is, therefore, seen as a resource for everyday life, not the objective of living. Health is a positive concept emphasising social and personal resources, as well as physical capacities. Therefore, health promotion is not just the responsibility of the health sector, but goes beyond healthy lifestyles to wellbeing.¹

4.2.2 PROFESSIONAL STANDARDS

Qualifications

To maximise effective health promotion and national consistency of messages, all health promotion staff employed in the Programme shall be able to demonstrate a good understanding of the theory and practice of public health and health promotion approaches.

Minimum competency requirements

BreastScreen Aotearoa providers will use:

• Nga Kaiakatanga Hauora mo Aotearoa Health Promotion Competencies for Aotearoa-New Zealand²
• National Screening Unit Competencies, including Cultural Competencies

Continuing professional development

Professional development and continuing education requires that health promotion staff employed or subcontracted by BreastScreen Aotearoa Providers shall:

1. promote and demonstrate sound health promotion principles and practice
2. maintain professional knowledge and skills relating to breast cancer and screening in addition to health promotion
3. develop and maintain cultural knowledge and skills
4. identify, develop and maintain community and professional networks
5. critically reflect on and evaluate own work
6. participate in peer review processes.

¹ WHO, 1986, Ottawa charter for health promotion: First International Conference on Health Promotion, 21 November.
42.3 HEALTH PROMOTION EXPERTISE

In addition to generic health promotion knowledge and skills, a health promoter will be able to:

1. advocate for health promotion at all levels
2. promote an understanding of the need for, and the adoption of health promotion practices based on the Treaty of Waitangi, and health promotion models outlined in the National Screening Unit Health Promotion Strategy
3. demonstrate the full range of knowledge and skills required for competent practice
4. demonstrate accountability and effectiveness to a range of stakeholders
5. model and support consultative ways of working with other key health promotion principles
6. have a recognised, or be working towards, a health promotion or related qualification.

In addition to generic health promotion knowledge and skills, a health promoter in a leadership role will be able to:

1. successfully negotiate or support negotiations of contracts and funding for sustainable services
2. actively develop the health promotion workforce
3. demonstrate strategic health promotion leadership
4. facilitate strategic health promotion planning including writing, implementing and evaluating health promotion plans
5. challenge organisational decisions that constrain or prevent good health promotion practice
6. facilitate robust critical debate and reflection on health promotion practice
7. access and provide opportunities for quality health promotion training for staff
8. develop and implement quality assurance and quality improvement strategies.

42.4 STAFF IN TRAINING (NEW AND TRAINEE STAFF)

Scope of involvement within the Programme

Staff in training shall:

1. become familiar with the BreastScreen Aotearoa health promotion resources, develop a comprehensive understanding of the screening pathway and the range of health professional roles in the Programme
2. undertake an individualised orientation programme with the guidance of an experienced health promoter to observe and participate as skills develop
3. be working towards achieving relevant competencies
   • Nga Kaikatanga Hauora mo Aotearoa Health Promotion Competencies for Aotearoa-New Zealand
   • National Screening Unit Competencies, including Cultural Competencies
4. attend a BreastScreen Aotearoa nationally organised training event within 12 months of joining the Programme.

Supervision requirements

The trainee will present health education sessions under guidance and supervision until deemed competent by an experienced health promoter.

43. MEDICAL PHYSICIST

43.1 THE ROLE OF THE MEDICAL PHYSICIST

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

1. ensure that the quality assurance (MQA) programme is of the required standard and is operating effectively
2. ensure that all imaging and ancillary equipment is covered by the QA programme, for example, X-ray equipment, film processors, film illuminators, localisation devices, ultrasound imagers and hard copy devices
3. be a member of the breast screening site MQA committee which will meet quarterly to review results and annually to review the QA programme
4. perform the physics quality control (QC) tests
5. ensure the performance and calibration of QC test equipment
6. perform acceptance testing on new imaging and associated equipment prior to its use on women
7. assist the QC MRT in the review of MRT QC test data
8. advise the QC MRT on all matters concerning image quality and the MQA programme
9. advise the Designated MQA radiologist, specifically in the areas of image quality, all aspects of the MQA programme, safety and equipment purchase
10. advise the Lead Provider Manager and/or Clinical Director specifically in the areas of safety, QC analysis and equipment purchase, including the preparation of equipment specifications
11. co-operate with all others involved in the Programme
12. co-operate with and support other medical physicists working in BreastScreen Aotearoa
13. provide radiation protection advice to the screening unit, particularly the licensee, ensuring the radiation safety of the women, staff and members of the public
14. ensure regulatory compliance.

All medical physicists working in the Programme are members of the medical physicists Undisciplinary Group (UDG) and are required to take part in these meetings and other activities.

Acceptance testing is required by New Zealand regulations (NRL 1994) and the RANZCR (1994) but not described by them. A list of necessary tests is provided in Appendix K: Mammographic Quality Assurance (MQA) Programme. Additional tests are included within the NHBSBP Standard (IPSM 1994) and in AS/NZS (H84-3.2: 1990). QC tests are required for ultrasound scanners used in assessment. Refer: Appendix M: Ultrasound System Performance and Quality Control.

1. advocate for health promotion at all levels
2. promote an understanding of the need for, and the adoption of health promotion practices based on the Treaty of Waitangi, and health promotion models outlined in the National Screening Unit Health Promotion Strategy
3. demonstrate the full range of knowledge and skills required for competent practice
4. demonstrate accountability and effectiveness to a range of stakeholders
5. model and support consultative ways of working with other key health promotion principles
6. have a recognised, or be working towards, a health promotion or related qualification.

In addition to generic health promotion knowledge and skills, a health promoter in a leadership role will be able to:

1. successfully negotiate or support negotiations of contracts and funding for sustainable services
2. actively develop the health promotion workforce
3. demonstrate strategic health promotion leadership
4. facilitate strategic health promotion planning including writing, implementing and evaluating health promotion plans
5. challenge organisational decisions that constrain or prevent good health promotion practice
6. facilitate robust critical debate and reflection on health promotion practice
7. access and provide opportunities for quality health promotion training for staff
8. develop and implement quality assurance and quality improvement strategies.

43.2 PROFESSIONAL STANDARDS

Qualifications

Medical physicists providing services to BreastScreen Aotearoa must:

1. be explicitly trained in the physics of mammography and in the philosophy of breast screening. Approved courses agreed by the RANZCR and ACPSEM and practices are provided by the ACPSEM. Other internationally recognised courses (for example those provided in the USA by the AAPM/ACRT and in the UK by the IPEM) are acceptable.
2. be licensed under the Radiation Protection Act (1965) to use X-rays to perform tests and measurements as part of the quality assurance programmes in radiation protection
3. be recognised by the National Radiation Laboratory (NRL) as a qualified health physicist within the context of NRL-C5 and mammography
4. hold a Masters Degree or a higher qualification in a physical science
5. have recognised, documented, specialised training in conducting surveys of mammography facilities as per ACR or RANZCR Standards
6. have experience of conducting surveys of at least one mammography facility within BreastScreen Aotearoa and a total of at least ten units. Experience conducting surveys must be acquired under the direct supervision of a medical physicist who meets all the requirements of the NP&QS.

Continuing professional development
Medical physicists providing such services will participate in continuing professional development (CPD) in the area of mammography physics.

Continuing Professional Development (CPD) includes:
1. attendance at, at least one scientific meeting or refresher course, with content specific to mammography physics, every two years. Only time spent on ‘Mammography Physics’ may count towards the 15 hours CPD
2. attendance at relevant multidisciplinary or peer review and audit meetings
3. 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 proceeding any facility survey. A record of medical physicists practising in New Zealand who meet this Standard will be kept by the National Physics Co-ordinator. The National Physics Co-ordinator, in conjunction with the medical physicists Undisciplinary Group, will give advice on the attainment of CPD requirements.

43.4 STAFF IN TRAINING (NEW AND TRAINEE STAFF)
Staff in training can perform medical physics duties under the direct supervision of a qualified medical physicist currently practising with BreastScreen Aotearoa, who meets the requirements of Section 43.2.

Scope of involvement within the Programme
Staff in training shall undertake the full range of tasks under the direct supervision of the medical physicist. Trainees shall undertake duplicate surveys and be directly supervised for any procedure conducted within the Programme.

Supervision requirements
Until a medical physicist meets the requirements of Section 43.2 the survey remains the responsibility of the supervising medical physicist, and must be signed by them.

43.5 QUALITY ASSURANCE

Performance evaluation
The designated Medical Physics service must participate in a planned, co-ordinated MQA programme covering all imaging equipment that will be used in achieving a diagnosis, as well as, ancillary equipment such as film processors and viewing boxes. 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 shall be specified in a written agreement between a breast screening unit and the designated medical physics services.

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 the Royal Australian and New Zealand College of Radiologists (RANZCR) have been agreed, and will be continually reviewed by the medical physicists UDG. Additions to the RANZCR tests are necessary for regulatory compliance.

In accordance with the United Kingdom (UK) NHS Breast Screening Programme guidelines, and to promote compliance with NRL-C5, a programme of dose measurements on women is included. The medical physicists UDG will develop the testing protocol and frequency.

Specific quality targets/requirements

The internal quality system ensures that:
1. all critical test failures must be identified to the facility on the day testing is complete
2. 95% of preliminary reports are provided to the unit on the day testing is completed
3. 95% of final reports are provided to the unit within 20 working days of the day testing is completed
4. defects must be reviewed when identified and the medical physicist shall specify the timeframe in which they shall be resolved in consultation with the Clinical Director.

National co-ordination and sharing
To promote the highest standards of breast screening it is important that the medical physicists involved are able to use their collective experience and knowledge, which requires a mechanism for the collation and exchange of data. The designated medical physicist shall send Medical Physics QA survey results to the National Physics Co-ordinator, who shall collate the results.

The medical physicists UDG shall ensure the efficient exchange of information and furthermore to maintain and revise national protocols to ensure they remain evidence informed.

Reference materials
The medical physicist will require the following documents while performing the tests:
1. RANZCR Mammography Quality Control Manual: 2002 including revisions or
3. National Radiation Laboratory Code of Safe Practice for the use of X-rays in Medical Diagnosis, NRL-C5 1994 or subsequent versions.

Additional supportive documents

NRL 1994.
NHSBSP 1995a.
NHLRC 1994.

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44. MEDICAL RADIATION TECHNOLOGIST (MRT)

44.1 THE ROLE OF THE MEDICAL RADIATION TECHNOLOGIST
Breast screening is a service for well women. For most women attending BreastScreen Aotearoa, the MRT is the only health professional with whom they interact. The quality of this interaction is critical to the woman's decision to re-attend for subsequent screens. MRTs therefore require skills that will make this an acceptable experience for women with minimal anxiety at all stages of the screening pathway.

The MRT has two main areas of responsibility:
1. the provision of an acceptable screening experience for women who participate in BreastScreen Aotearoa
2. 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.

44.2 PROFESSIONAL STANDARDS

Qualifications
A MRT is a trained and qualified health professional employed in the field of medical radiation technology. All MRTs performing screening mammography within BreastScreen Aotearoa must be registered with the medical radiation technologists Board (MRTB) and hold a current practising licence. Additionally all MRTs must have completed a Certificate of Proficiency (NZIMRT, or its recognised equivalent) in Mammography within two years of commencing employment with the Programme. Those who are already working within the Programme, but have not completed the Certificate of Proficiency (or its recognised equivalent) by January 2004, will be reassessed.

Continuing professional development
To assist in maintaining the necessary skill level and expertise, MRTs should:
1. remain up to date with advances in clinical practice and mammography techniques
2. be conversant with current methods of early detection and treatment of breast disease.
These should be achieved by regular attendance (three in any five-year period) at validated update courses, conferences or seminars. These may be at regional, national or international and it is desirable that one event contains a clinical component. Within each screening centre, ongoing education shall 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 NZIMRT.

Supervision requirements
All new MRT staff requiring training will be supervised by an MRT who holds a mammography qualification recognised by NZIMRT. Mentoring of the MRT in training shall occur until the level of competency reached enables the MRT to function with a technical reject rate of less than 3%.

Scope of involvement within the Programme
Staff under training shall progressively become involved in all relevant aspects of the screening programme as their competency levels develop.

44.4 MRT EXPERTISE

Technical reject rate
All MRTs performing screening mammograms in BSA shall examine each examination using the MIQ classification criteria. These MIQ classification criteria are to be used in all training situations and when ever conducting peer review.

All images that fall into the inadequate category must be rejected and recorded as such. The Standard is for all MRTs to have a reject rate of < 3%. This measure should be considered in conjunction with the Standard 23.6: Screening – Routine Views Performed.

Definition: The number of films rejected as a percentage of the number of films taken calculated separately for women screened at a fixed unit and a mobile unit.

Technical recall rate
Technical recalls will occur when the MRT is unable to view the films while the woman is still present (normally for women seen at mobile units) or because a reading radiologist finds the study to be inadequate.

The technical recall rate is defined as the number of women who have to return to a screening unit (either fixed or mobile) for further films to complete their screening episode, expressed as a percentage of the number screened.

The technical recall rate for screening units of women requiring repeat films for technical reasons must be < 3% of the total number of women screened at a mobile unit, and < 0.5% for women screened at a fixed unit.

NOTE: Recalling women to screening units for technically rejected films contributes to increased anxiety levels in the screened population and this should be minimised to enhance service acceptability.

Monthly MRT peer review
Monthly peer review of all MRTs' work using mammographic image quality (MIQ) criteria will occur (refer Appendix M: Mammographic Image Quality (MIQ) Classification). Appropriate and regular feedback will be provided to each MRT to maintain the focus of excellence required for screening mammography. Any training needs will be identified and promptly addressed. It is the responsibility of the Lead MRT to ensure that this is carried out at all screening sites within the Lead Provider region.

Mammography workload
All MRTs involved in BreastScreen Aotearoa must be performing no less than 1,000 mammograms per year or 80 per month or 0.4 FTE within BreastScreen Aotearoa.

Mobile units
MRTs will initially work at a fixed unit with processing facilities and have their skill level assessed before working 'blind' on the mobile.

The skill level of MRTs working on mobile units must be such that their technical reject rate is < 3% before commencing work on the mobile.

Any additional training needs will be identified and addressed before commencing work on the mobile unit.

NOTE: The skill level of the MRT working on mobile units requires special consideration, as they do not receive 'instant feedback' by seeing their films as they work. They must therefore have the opportunity to view their work at a later time and receive regular feedback to maintain their skills. A further consideration is that recalling women to mobile units for repeat films generates higher levels of anxiety and lack of acceptance of the service.

Assessment clinics and multidisciplinary meetings
1. All MRTs working in either fixed or mobile sites are to attend a minimum of 2 assessment clinics and 4 clinical multidisciplinary meetings per year.
2. MRTs should participate fully in the breast care team contributing their expertise as appropriate.
**45.3 PATHOLOGIST EXPERTISE**

Where an individual pathologist is reporting on fifty or fewer patient biopsy episodes from BreastScreen Aotearoa assessment clinics patients per annum, then the pathology material from those episodes must be reviewed and signed out by the Lead pathologist. A patient biopsy episode is defined as all the pathology material derived from an assessment visit for that patient; FNAC alone, core biopsy alone or combined FNAC and core biopsy count as one episode. Each pathologist must attend the greater of 60% or 15 clinical multidisciplinary meetings per annum.

**45.4 STAFF IN TRAINING (NEW AND TRAINEE STAFF)**

Within 24 months of commencing reporting within the Programme, all BreastScreen Aotearoa pathologists must show evidence that they have attended a multidisciplinary training course in breast screening. Such courses are offered on a regular basis in Australia, USA and Great Britain and the UDG should produce a list of approved courses on an annual basis to the National Screening Unit. Pathologists in training may undertake gross and microscopic descriptions of screen-detected lesions however the material must be reviewed and signed out by a BreastScreen Aotearoa pathologist.

**45.5 QUALITY ASSURANCE**

**Performance evaluation**

**Internal**

Pathologists reporting on screen-detected lesions should have sufficient exposure to relevant material to develop and maintain competence in 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.

**External**

All BreastScreen Aotearoa pathologists shall be enrolled and participate in the RCPA Australasian Breast External Quality Assurance Scheme (ABEQAS), which consists of a slide-based circulation EQA scheme based on the United Kingdom model using pro forma reporting and grouped statistical analysis of performance.

BreastScreen Aotearoa pathologists must participate on an individual rather than a laboratory basis and complete at least five of the six surveys per year. The results of participation in EQA scheme must be recorded and provided to the Programme by the Lead pathologist and be available for external audit as required. Participation in this scheme will be recognised by the RCPA Board of Education as an activity for Fellows counting towards continued professional development.

**Quality system recognition**

All laboratories involved in the Programme must be IANZ accredited for histopathology, and where FNAC is undertaken, cytology IANZ accreditation is also required. All participating laboratories should be enrolled in the Royal College of Pathologists of Australasia (RCPA) anatomic pathology external assurance programme and, where appropriate, the cytology quality assurance programme. While these programmes cover all aspects of routine histo- and cytopathology, they also include important components of laboratory practice which impinge on breast pathology.

**46. QUALITY CO-ORDINATOR**

**46.1 THE ROLE OF THE QUALITY COORDINATOR**

The Quality Co-ordinator, on behalf of the Clinical Director and Lead Provider Manager, co-ordinates the operation of the quality management systems within their Lead Provider region. This is expected to be a part-time role and can be one that is combined another role, for example, the breastcare nurse. The Quality Co-ordinator will help ensure that systems and protocols exist with Lead Providers and subcontracted sites to meet quality requirements. The Quality Co-ordinator will assist professional groups, the Manager and Clinical Director to:

1. ensure the National Policy and Quality Standards (NP&QS) are met
2. co-ordinate corrective actions where Standards are not met
3. ensure the organisation’s quality plan is current, implemented, monitored and evaluated
4. ensure BreastScreen Aotearoa Independent Monitoring Group (BSAIMG) Reports’ recommendations are responded to
5. ensure all relevant information, policies and procedures remain current
6. facilitate internal quality improvement activities
7. organise quality-related meetings on a regular basis, maintaining a record of these including attendance and outcomes
8. manage internal document control of NP&QS across all sites including subcontractors.

**Liaison requirements**

The Quality Co-ordinator liaises with Clinical Director and Lead Provider Manager to:

1. document protocols and processes and plan or timetable for all internal audit requirements
2. provide comparisons of Provider data with external audit, with a focus on BSA IMG Reports
3. ensure the effective provision of clinical performance information
4. develop and facilitate the monitoring of the quality plan on a quarterly basis.

The Quality Co-ordinator liaises with the Lead Clinicians to ensure analysis of individual staff performance measures. Such information is confidential within the respective professional group(s).

The Quality Co-ordinator liaises with the Charge MRT to:

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

The Quality Co-ordinator liaises with the Data Manager to:

1. verify protocols for determining all audit and performance data
2. review all Programme data for anomalous results
3. ensure analysis of performance data by individual sites, where appropriate
4. ensure the resolution of all missing/erroneous/suspect data on a case by case basis.

**46.2 PROFESSIONAL STANDARDS**

**Qualifications**

The Quality Co-ordinator will have a quality and/or audit experience and experience in a health-related field.

**Quality Co-ordinator expertise**

It is expected that the Quality Co-ordinator will have demonstrated an ability in implementing quality and audit systems.

**46.3 STAFF IN TRAINING (NEW AND TRAINEE STAFF)**

**New Quality Co-ordinators in training**

There will be appropriate training and orientation for staff new to Quality Co-ordinator role. The orientation will be designed to ensure that the new Quality Co-ordinator has exposure to all relevant facets of the Programme to ensure an appropriate level of understanding. This may include but is not limited to:

1. visiting sub-contractor sites within their region
2. visiting other sites within the Programme
3. liaison with other Quality Co-ordinators within the Programme
4. attendance at regular Undisciplinary National Quality Management meetings.

**Supervision Requirements**

The Quality Co-ordinator will have a close working relationship with the Clinical Director and the Lead Provider Manager.
3. performing all invasive procedures available in their assessment clinic.
4. attendance and supervised participation within the 12 months prior to commencement in ten assessment sessions within an established national population-based screening programme either in New Zealand or overseas, at a screening facility approved by the RANZCR.

Accreditation process:
1. All radiologists working in the BSA Programme require accreditation to do so.
2. Each radiologist will be assessed on their qualification, training and a decision will be made by the Accreditation Committee based on information submitted in the Accreditation Template. Refer: Appendix V: Accreditation Processes.
3. A recommendation will be made by BreastScreen Aotearoa, regarding their ability to work in the Programme. The outcome will be communicated to their Lead Provider Manager, Clinical Director and the radiologist concerned.

47.2 PROFESSIONAL STANDARDS

Qualifications
Radiologists involved in the BreastScreen Aotearoa will be medically qualified, registered to practise in New Zealand, and hold vocational registration in diagnostic radiology. They will also have a basic qualification in radiology, such as the Fellowship of the Royal Australian and New Zealand College of Radiologists (RANZCR).

Minimum Qualification Required/Entry Level Requirements
BreastScreen Aotearoa radiologists must undertake further training prior to commencing screening mammography within the Programme. This should include a minimum of the following:
1. attendance at one teaching course currently recognised by the RANZCR within the last two years
2. completion of 300 dummy third reads within the three months prior to commencement. A recall rate of not more than 12% is required
3. 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
4. demonstration of reader sensitivity of 80% from a cancer seeded set of films such as PERFORMS.

Minimum Qualification Required for Unsupervised Assessments
Prior to commencing unsupervised assessment, radiologists must satisfy the Clinical Director that they are competent in the following:
1. supervising and interpreting mammographic work-up
2. performing and interpreting breast ultrasound
3. radiologists who perform ultrasound, biopsy and localisation techniques at an assessment clinic must be competent at these procedures
4. To achieve this it is recommended that these radiologists have a regular weekly commitment to breast imaging, which must include diagnostic, screening, assessment clinic and audit sessions
5. reading mammograms and should participate in assessment clinics
6. 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.
7. radiologists shall attend regular radiology review sessions to allow:
   a. interval cancer review and internal classification
   b. review of reading or assessment procedures and protocols
   c. review of literature
   d. review of interesting cases or third reads.

47.4 STAFF IN TRAINING (NEW AND TRAINEE STAFF)

Competency
It is desirable for Radiology Registrars to rotate through a breast screening unit and Trainees may participate in BreastScreen Aotearoa under supervision from an BreastScreen Aotearoa Radiologist.

47.5 QUALITY ASSURANCE

Interval cancer review process
Retrieval and review of interval cancers will be undertaken by Lead Providers which includes a monthly interchange of ten sample mammograms. These films may or may not contain any interval cancer(s) and will be blind double read with the receiving Provider’s regular screens. This process will allow classification of interval cancers into ‘miss’ or ‘not miss’. Further classification (occult cancers) shall occur at the original screening unit.

Refer: Appendix Q: Interval Cancer Review Process

Performance feedback
The screening unit’s data management system shall allow regular monitoring of an individual radiologist’s performance and feedback of information. At a minimum this will include the number of films read, total recall rate and small invasive cancer and overall cancer detection rates. This information shall be provided every three months, will be cumulative and shall include performance criteria for assessment (for example, no more than 15% of FNAs are inadequate). Individual performance data shall be confidential to the individual reader and to the Clinical Director, but will be available for scrutiny by the visiting BreastScreen Aotearoa radiologist Auditor.
SECTION 4 – Professional Requirements

48. SURGEON

48.1 THE ROLE OF THE SURGEON

For breast cancer screening to meet its goal of reducing breast cancer mortality, the screening process must include timely and appropriate surgical intervention. The role of the surgeon commences during the assessment phase and continues through treatment and follow-up. BreastScreen Aotearoa surgeons must be trained and skilled in the management of breast diseases. In addition to clinical skills they must be able to communicate effectively with women in the Programme and be able to work as part of a Multidisciplinary Team.

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

General expectations

Surgeons involved within BreastScreen Aotearoa should:
1. contribute to setting standards that a woman in the screening programme may reasonably expect including rapid assessment and surgical opinion, access to timely and appropriate therapy for cancer
2. set quality standards suitable for use in clinical audit including the number of palpable lesions correctly identified and surgically removed at the first localisation biopsy.

48.2 PROFESSIONAL STANDARDS

Qualifications

1. Registration to practise in New Zealand with a current Annual Practising Certificate (APC).
2. Hold a qualification in General Surgery and be Vocationally Registered in General Surgery with the Medical Council of New Zealand.
3. Participate in a re-certification programme in general surgery.

Competency

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.

Accreditation process

1. All surgeons working in BSA Programme require accreditation to do so.
2. Each surgeon will be assessed on their qualifications, training, etc. and a decision will be made by the Accreditation Committee based on information submitted in the Accreditation Template. Refer: Appendix V: Accreditation Processes
3. BreastScreen Aotearoa, regarding their ability to work in the Programme, will make a recommendation. The outcome will be communicated to their Lead Provider Manager, Clinical Director and the surgeon.

Indicators

BreastScreen Aotearoa surgeons should be:
1. vocationally registered in General Surgery
2. credentialled to an accredited hospital.

Criteria

The surgeon should meet these criteria:
1. Re-certification requirements:
   a. participation in audit
   b. credentialled by an accredited hospital
   c. meets CPD requirements.
2. Meets criteria for full membership of Section of Breast Surgery of RACS:
   a. enters all cases of breast cancer into RACS Breast Section Audit
   b. meets CPD requirements for breast disease (this includes attendance at national and international meetings on breast disease).

Continuing professional development and re-certification requirements

BreastScreen Aotearoa surgeons should maintain an ongoing level of specialist expertise in diagnosis and management of screen detected breast lesions.

Criteria

All surgeons (FRACS and non FRACS) must meet the RACS Breast Section requirements which are:
1. full participation in the Breast Section 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.
2. meeting audit and CPD criteria as for full membership of the Breast Section of the College. The CPD requirements include:
   a. an ongoing commitment to CPD activities in breast disease. Each year Breast Screen surgeons will be asked to complete three questions which 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 be:
   i. attendance at significant breast-related CPD meetings including, for example, RACS ASC Breast Section lectures, ANZ Breast Cancer Trials Group Meetings, Leura, Overseas breast meetings, etc
   ii. attendance at specific breast related clinico-pathology and clinico-radiology meetings (including hospital meetings, BreastScreen Aotearoa and private breast clinics)
   iii. reading of journal articles related to breast disease or computer-based and/or distance learning
   iv. attendance at the greater of 60% or 15 of the unit’s clinical multidisciplinary meetings per annum.

48.4 TRAINING

Surgeons involved in the Programme will have extensive training in breast surgery as part of their training in General Surgery.

Indicators

Surgeons will ensure that 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 RACS and by spending time in a breast screening unit.

48.5 STAFF IN TRAINING (NEW AND TRAINEE STAFF)

Competency

It is recognised that it is important for surgical trainees and qualified surgeons to undergo training in breast screening. Trainees may participate in BreastScreen Aotearoa under supervision from an established BreastScreen Aotearoa surgeon.

Criteria

1. Surgical trainees may be involved in the assessment and management of women in the Programme under direct supervision commensurate with their degree of experience and as agreed by the local site multidisciplinary team.
2. Informed consent shall be obtained from the woman for any trainee participating in, or observing her assessment phase (the trainee should not be present whilst this consent is requested).

48.6 QUALITY ASSURANCE

Performance Evaluation

Internal
1. BreastScreen Aotearoa surgeons will be subject to regular peer review at the multidisciplinary meetings.
2. BreastScreen Aotearoa surgeons will receive regular reports on their compliance with programme quality targets and requirements.

External
1. Compliance of BreastScreen Aotearoa surgeons with the standards will be monitored by the NSU.
2. BreastScreen Aotearoa surgeons must meet the ongoing CPD requirements for the RACS Breast Section or its equivalent.
**Performance feedback**

BreastScreen Aotearoa 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.

**Involvement in auditing and training**

It is expected that BreastScreen Aotearoa surgeons will:

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

**New Technologies and New Treatment Procedures**

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

1. the technology or treatment is being used in accordance with RACS Breast Section policy
2. is being evaluated under the appropriate assessment process for New Zealand, for example, ASERNIPS
3. has Ethics Committee approval or is part of research protocol
4. any new or innovative mode of treatment funded by BreastScreen Aotearoa must be approved by:
   a. BreastScreen Aotearoa, or
   b. any national body established with ethical approval, or
   c. the local ethical committee.

Refer to Standard 18: New Technologies

**Research**

Participation in appropriate research protocols such as those co-ordinated by the ANZ Breast Cancer Trials Group or as organised locally with approval of the local Ethics Committee and multidisciplinary team is encouraged.
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49. APPENDIX A: GLOSSARY

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<tr>
<td>Age standardised rate</td>
<td>This is 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, since 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.</td>
</tr>
<tr>
<td>Assessment</td>
<td>Assessment is all the follow-up examination and investigations arising from a woman's attendance for a screening mammogram, up to and including cytological or histological diagnosis. Assessment is a multidisciplinary process.</td>
</tr>
<tr>
<td>Assessment – Level 1</td>
<td>Further mammographic views and/or ultrasound and/or clinical examination.</td>
</tr>
<tr>
<td>Assessment – Level 2</td>
<td>Needle Biopsy</td>
</tr>
<tr>
<td>Assessment – Level 3</td>
<td>Open Biopsy</td>
</tr>
<tr>
<td>Assessment visit</td>
<td>An assessment visit is 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.</td>
</tr>
<tr>
<td>Asymptomatic</td>
<td>Asymptomatic women are women who do not have a symptom that may be due to breast cancer.</td>
</tr>
<tr>
<td>Atypical hyperplasia</td>
<td>An abnormal increase in the number of epithelial cells in the breast. Women with this diagnosis are at a slightly increased risk of developing breast cancer.</td>
</tr>
<tr>
<td>Background incidence rate</td>
<td>This is 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.</td>
</tr>
<tr>
<td>Benign diagnostic open biopsy</td>
<td>An open biopsy that was recommended for diagnostic purposes, and where the histopathology was not of invasive cancer or DCIS; examples include atypical hyperplasia, radial scar or LCIS.</td>
</tr>
<tr>
<td>Benign</td>
<td>A benign tumour is an abnormal growth that is neither malignant, nor a cancer. A benign tumour is not capable of spreading, and usually does not recur after being removed.</td>
</tr>
<tr>
<td>Biopsy</td>
<td>Removal of a sample of tissue from the body, for examination under a microscope, to assist with the diagnosis of a disease.</td>
</tr>
<tr>
<td>Breast awareness</td>
<td>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.</td>
</tr>
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<tr>
<th>Term/Abbreviation</th>
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<tbody>
<tr>
<td>Breast cancer</td>
<td>A pathologically-proven malignant lesion that is classified as ductal carcinoma in situ or invasive breast cancer.</td>
</tr>
<tr>
<td>Breast cancer classification</td>
<td>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.</td>
</tr>
<tr>
<td>Breast cancer incidence rate</td>
<td>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.</td>
</tr>
<tr>
<td>Breast cancer mortality rate</td>
<td>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.</td>
</tr>
<tr>
<td>Breast compression</td>
<td>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.</td>
</tr>
<tr>
<td>Breast conserving surgery</td>
<td>A type of surgery that involves removing a breast cancer, together with a margin of normal breast tissue. The whole breast is not removed.</td>
</tr>
<tr>
<td>Breast Implant</td>
<td>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.</td>
</tr>
<tr>
<td>Breast Reconstruction</td>
<td>The formation or recreation of breast shape after a total mastectomy.</td>
</tr>
<tr>
<td>BreastScreen Aotearoa</td>
<td>BreastScreen Aotearoa is New Zealand’s free national breast screening programme. The programme offers free mammograms every two years to women in the eligible age group who have no symptoms of breast cancer.</td>
</tr>
<tr>
<td>Cancer</td>
<td>A general term for a large number of diseases which 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.</td>
</tr>
<tr>
<td>Cancer detection rate</td>
<td>The cancer detection rate is the number of people who have cancer detected within a screening programme, usually expressed as a rate per 1000 people screened. It 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.</td>
</tr>
<tr>
<td>Term/Abbreviation</td>
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<tr>
<td>Carcinoma</td>
<td>A malignant tumour made up of epithelial cells that may infiltrate surrounding tissues and spread to other parts of the body via the blood or lymph system.</td>
</tr>
<tr>
<td>Code of Health and Disability Consumers’ Rights</td>
<td>The Code is a regulation under the Health and Disability Commissioner Act 1994.</td>
</tr>
<tr>
<td>Continuous Quality Improvement Process</td>
<td>Ongoing collection and evaluation of information about important aspects of a process to identify and rectify problems, control unintended variations and to identify and manage opportunities for improving the process.</td>
</tr>
<tr>
<td>Core Needle Biopsy</td>
<td>Sampling of breast tissue with a needle to obtain a tiny cylinder of tissue, for examination by a pathologist.</td>
</tr>
<tr>
<td>Coverage rate</td>
<td>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.</td>
</tr>
<tr>
<td>Cytology</td>
<td>An examination by a pathologist of a sample of cells.</td>
</tr>
<tr>
<td>DCIS – Ductal carcinoma in situ</td>
<td>A form of breast cancer, which spreads along the ducts of the breast, but has not invaded the duct wall.</td>
</tr>
<tr>
<td>Delay time</td>
<td>The time between when a cancer could be detected by a screening programme, and the time it actually is detected.</td>
</tr>
<tr>
<td>Detection rate</td>
<td>See ‘Cancer detection rate’.</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>The process of identifying a disease by its characteristic signs, symptoms and findings on investigation.</td>
</tr>
<tr>
<td>Direct Supervision</td>
<td>The person supervising is physically present and actively involved in the process, takes ultimate responsibility and signs the report.</td>
</tr>
<tr>
<td>Early Recall</td>
<td>Early recall occurs when a woman is asked to return earlier than the usual screening interval for further investigations at an assessment centre.</td>
</tr>
<tr>
<td>Early Re-screen</td>
<td>Early Re-screen occurs when a woman is asked to return earlier than the usual screening interval for further screening mammography.</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>The effectiveness of an intervention is used to describe the impact in everyday practice.</td>
</tr>
<tr>
<td>Eligible Age Group</td>
<td>Currently 50 – 64 years.</td>
</tr>
<tr>
<td>Eligible population</td>
<td>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, i.e. women who have had breast cancer within the last five years are not eligible for screening in BSA.</td>
</tr>
<tr>
<td>Evidence Informed</td>
<td>Decisions based on the best available evidence.</td>
</tr>
<tr>
<td>Extended assessment</td>
<td>The term ‘extended assessment’ has been used in the literature to include a range of practices. These include: Early Re-screen – occurs when a woman is asked to return earlier than the usual screening interval for further screening mammography. 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. Within BSA, only early recall is permitted.</td>
</tr>
<tr>
<td>False negative</td>
<td>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.</td>
</tr>
<tr>
<td>False positive</td>
<td>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.</td>
</tr>
<tr>
<td>False positive rate for screening mammograms (FPR)</td>
<td>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.</td>
</tr>
<tr>
<td>First screening episode of the programme</td>
<td>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.</td>
</tr>
<tr>
<td>Fine needle aspiration (FNA)</td>
<td>The procedure to remove cells or fluid from tissues using a fine needle.</td>
</tr>
<tr>
<td>Term/Abbreviation</td>
<td>Description</td>
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</tr>
<tr>
<td>FNAC</td>
<td>Fine needle aspiration cytology.</td>
</tr>
<tr>
<td>FTE</td>
<td>Full-time equivalents.</td>
</tr>
<tr>
<td>Further assessment</td>
<td>These are the extra investigations carried out to clarify the nature of an abnormality detected at screening. In BSA, this includes further mammograms, ultrasound and biopsy.</td>
</tr>
<tr>
<td>GP/PCP</td>
<td>GP/PCP is a generic term for a woman’s General practitioner (GP) or other nominated Primary Care Provider (PCP). Includes Iwi, Māori and Pacific providers.</td>
</tr>
<tr>
<td>Health Information Privacy Code 1994</td>
<td>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 Commissioner’s website.</td>
</tr>
<tr>
<td>Histology</td>
<td>The examination of the structure and composition of tissues by a pathologist.</td>
</tr>
<tr>
<td>Identification rate</td>
<td>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.</td>
</tr>
<tr>
<td>Incidence</td>
<td>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.</td>
</tr>
<tr>
<td>Initial Screen</td>
<td>The screening episode of a woman who has never had a mammogram before, or who has not had a mammogram within the past five years within the BSA Programme.</td>
</tr>
<tr>
<td>Interval cancer</td>
<td>This is a cancer that is diagnosed between a negative screen, and the time the next screen would have occurred. In BSA, 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 either a ‘true interval’ (one that cannot be detected in retrospect on screening mammograms), or a ‘missed cancer’ (one that was present at the previous screening, but was not detected). ‘Oncocat’ cancers are a subgroup of ‘true’ interval cancers, which are not detected by mammography at the time of subsequent diagnosis. Refer Appendix Q: Interval Cancer Review Process</td>
</tr>
<tr>
<td>Interval cancer rate</td>
<td>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.</td>
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<tr>
<td>Invasive Procedure</td>
<td>A procedure which involves the introduction of instruments or other objectives into the body, or body cavities.</td>
</tr>
<tr>
<td>IPA</td>
<td>Independent Practitioner Association.</td>
</tr>
<tr>
<td>Lead Provider</td>
<td>One of six service providers who contracts 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.</td>
</tr>
<tr>
<td>Lesion</td>
<td>An area of tissue damaged by disease or injury. Within BSA, lesions are categorised as follows: Category 1 – Normal/Benign – return to routine re-screening Category 2 – Probably benign – may need assessment to confirm Category 3 – Indeterminate – needs assessment to elucidate Category 4 – Probably malignant – requires assessment and probably a tissue diagnosis Category 5 – Malignant – probably requires a tissue diagnosis.</td>
</tr>
<tr>
<td>Mammogram</td>
<td>A soft tissue X-ray of the breast which may be used to evaluate a lump, or which may be used as a screening test in women with no signs or symptoms of breast cancer.</td>
</tr>
<tr>
<td>Mammography</td>
<td>The process of taking a mammogram.</td>
</tr>
<tr>
<td>Māori</td>
<td>The indigenous people of New Zealand.</td>
</tr>
<tr>
<td>Mastectomy</td>
<td>Surgical removal of the breast. A mastectomy may be total (all of the breast) or partial.</td>
</tr>
<tr>
<td>MoH</td>
<td>Ministry of Health.</td>
</tr>
<tr>
<td>Mortality rate</td>
<td>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.</td>
</tr>
<tr>
<td>MRT</td>
<td>Medical Radiography Technologist, or Radiographer.</td>
</tr>
<tr>
<td>Multidisciplinary</td>
<td>An approach where a range of health professionals work together as a team, with the woman as the focus.</td>
</tr>
<tr>
<td>National Screening Unit</td>
<td>A business unit of the Ministry of Health, responsible for BSA. The authority that funds the Programme, its agents, nominee, or successor.</td>
</tr>
<tr>
<td>Negative mammogram</td>
<td>A mammogram that has been classified as normal during a routine screening.</td>
</tr>
<tr>
<td>Negative predictive value</td>
<td>The negative predictive value is the proportion of those who are healthy among those with a negative test.</td>
</tr>
<tr>
<td>Term/Abbreviation</td>
<td>Description</td>
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<tr>
<td>Negative screening result</td>
<td>The final diagnosis of ‘no cancer’ after screening and assessment procedures.</td>
</tr>
<tr>
<td>NHI</td>
<td>National Health Index: 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 (NZHIS) on behalf of the Crown.</td>
</tr>
<tr>
<td>Non-operative diagnosis rate</td>
<td>The percentage of women diagnosed with cancer who have a confirmed diagnosis prior to an open surgical biopsy. Calculated as: the total number of women with a confirmed diagnosis prior to open surgery biopsy, 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.</td>
</tr>
<tr>
<td>NP&amp;QS</td>
<td>National Policy and Quality Standards (i.e. this document).</td>
</tr>
<tr>
<td>Number needed to screen (NNS)</td>
<td>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 (i.e. death from breast cancer). The NNS often varies markedly with risk factors such as age. The smaller the NNS, the fewer people that needs to be screened to prevent an event (i.e. death from breast cancer).</td>
</tr>
<tr>
<td>Open biopsy rate</td>
<td>The percentage of screened women who undergo open biopsy procedures. Calculated as: the number of screened women who undergo open biopsy procedures, divided by the total number of women screened.</td>
</tr>
<tr>
<td>Open surgical biopsy</td>
<td>Surgery performed under a local or general anaesthetic in which a sample of breast tissue is removed to be examined by a pathologist.</td>
</tr>
<tr>
<td>Opportunistic screening</td>
<td>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.</td>
</tr>
<tr>
<td>Optical density (OD)</td>
<td>The optical density is a measure of film density. It is one of the many measures of mammographic quality, and is measured with a test object. It is calculated as: the logarithm of the ratio of the intensity of perpendicularly incident light ($I_0$) on a film to the light intensity ($I$) transmitted by the film: $OD = \log_{10} \left( \frac{I_0}{I} \right)$. Optical density differences should be measured in a line perpendicular to the tube axis to avoid influences by the heel effect.</td>
</tr>
<tr>
<td>Pacific women</td>
<td>Women of Pacific Islands ethnic origins (for example, Tongan, Nuean, Fijian, Samoan, Cook Islands Māori, and Tokelauan). Includes women of Pacific Islands ethnic origin born in New Zealand as well as those born overseas.</td>
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<tr>
<td>Participation rate</td>
<td>This is the number of people who have a screening test, expressed as a proportion of the eligible population. The participation rate is calculated by screening round.</td>
</tr>
<tr>
<td>PCP</td>
<td>Primary Care Provider, (refer also GP/PCP).</td>
</tr>
<tr>
<td>Population-based screening programme</td>
<td>A population-based screening programme is one in which screening is systematically offered by invitation to a defined, identifiable population: this requires a means of identifying and inviting the target population, for example through a population register.</td>
</tr>
<tr>
<td>Positive predictive value (PPV) of screening mammogram</td>
<td>The positive predictive value (PPV) of a screening test is the proportion of screening people having the outcome in question (i.e. 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 (i.e. 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 mammogram result, both with and without cancer.</td>
</tr>
<tr>
<td>Preoperative diagnosis of cancer</td>
<td>A malignant result on FNA or core biopsy (including both DCIS and invasive cancer), which is consistent with suspicious or malignant imaging findings.</td>
</tr>
<tr>
<td>Prevalent screen (changed to 'initial screen' as per TPDIR)</td>
<td>The screening episode of a woman who has never had a mammogram before, or has not had a mammogram within the past five years within the programme.</td>
</tr>
<tr>
<td>Programme (the Programme)</td>
<td>The National Breast Screening Programme, also known as BreastScreen Aotearoa.</td>
</tr>
<tr>
<td>Quality Assessment</td>
<td>Performance measurement against Standards.</td>
</tr>
<tr>
<td>Quality Assurance</td>
<td>Detection of problems through external or internal inspection, and their correction through systematic activity.</td>
</tr>
<tr>
<td>Quality Improvement</td>
<td>Prevention of problems and control of unintended variations in process through total quality management.</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>The use of radiation, usually X-rays or gamma rays, to kill tumour cells.</td>
</tr>
<tr>
<td>Referral to assessment</td>
<td>This is the referral of a woman, in order to clarify a perceived abnormality detected at screening, by performing an additional procedure.</td>
</tr>
<tr>
<td>Referral to assessment rate</td>
<td>The number of individuals recalled to assessment, expressed as a proportion of all those screened.</td>
</tr>
<tr>
<td>RGON</td>
<td>Registered General Obstetric Nurse.</td>
</tr>
<tr>
<td>RCompN</td>
<td>Registered Comprehensive Nurse.</td>
</tr>
<tr>
<td>Term/Abbreviation</td>
<td>Description</td>
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</tr>
<tr>
<td>Routine re-screening</td>
<td>Routine re-screening 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 no longer eligible.</td>
</tr>
<tr>
<td>Screen-detected cancer</td>
<td>A screen-detected cancer is any invasive breast cancer or DCIS diagnosed during a screening episode.</td>
</tr>
<tr>
<td>Specificity</td>
<td>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 aren’t 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.</td>
</tr>
<tr>
<td>Screening</td>
<td>Screening is 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.</td>
</tr>
<tr>
<td>Standardised Detection Ratio</td>
<td>A measure of cancer detection that takes into account what the age-specific incidence of breast cancer would be if no screening took place. BSA detection rates are compared against the rates for the ‘gold standard’ Swedish Two Counties (ST2C) Trial detection rates. The SDR is BSA’s surrogate mortality indicator that most closely approximates BSA’s potential mortality reduction rates.</td>
</tr>
<tr>
<td>Stereotactic Needle Biopsy</td>
<td>A biopsy carried out while the breast is compressed under mammography. This technique is used when a mammographic abnormality is difficult to biopsy by alternative methods. A series of pictures locate the lesion, and a radiologist enters information into a computer. The computer calculates the three dimensional co-ordinates of the lesion within the breast and helps position a needle-holder over the lesion. A needle is inserted into the lesion, and a piece of tissue or sample of cells is removed and sent to the laboratory for analysis.</td>
</tr>
<tr>
<td>True negative</td>
<td>The screening test correctly identifies a person without the disease.</td>
</tr>
<tr>
<td>True positive</td>
<td>The screening test correctly identifies a person with the disease.</td>
</tr>
<tr>
<td>Screening episode</td>
<td>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.</td>
</tr>
<tr>
<td>Screening interval</td>
<td>This is the fixed interval between routine screens, specific to the screening programme, and dependent on the screening policy. In BSA, the screening interval is two years.</td>
</tr>
<tr>
<td>Screening pathway</td>
<td>This is 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 attached to the screening process, any significant medical, social or financial implications of screening for the particular condition or predisposition, follow-up plans, including the availability of counseling and support services • being questioned or offered a test • having the test • receiving of test results • assessment and diagnosis if the test is positive • possible treatment • understanding that there are activities to monitor and evaluate all these stages.</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>Number with cancer detected during a screening episode (X) as a percentage of X plus the number with cancer detected within one year from 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 the screening mammogram alone, and for the screening programme (i.e. both screening and assessment).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Term/Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site</td>
<td>The identified physical location at which BreastScreen Aotearoa services are provided.</td>
</tr>
<tr>
<td>Specificity</td>
<td>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 aren’t 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.</td>
</tr>
<tr>
<td>Standardised Detection Ratio</td>
<td>A measure of cancer detection that takes into account what the age-specific incidence of breast cancer would be if no screening took place. BSA detection rates are compared against the rates for the ‘gold standard’ Swedish Two Counties (ST2C) Trial detection rates. The SDR is BSA’s surrogate mortality indicator that most closely approximates BSA’s potential mortality reduction rates.</td>
</tr>
<tr>
<td>Stereotactic Needle Biopsy</td>
<td>A biopsy carried out while the breast is compressed under mammography. This technique is used when a mammographic abnormality is difficult to biopsy by alternative methods. A series of pictures locate the lesion, and a radiologist enters information into a computer. The computer calculates the three dimensional co-ordinates of the lesion within the breast and helps position a needle-holder over the lesion. A needle is inserted into the lesion, and a piece of tissue or sample of cells is removed and sent to the laboratory for analysis.</td>
</tr>
<tr>
<td>True negative</td>
<td>The screening test correctly identifies a person without the disease.</td>
</tr>
<tr>
<td>True positive</td>
<td>The screening test correctly identifies a person with the disease.</td>
</tr>
<tr>
<td>Tumour</td>
<td>An abnormal growth of tissue. A breast tumour may be: localised without potential (benign), malignant and growing inside the milk ducts (DCIS), malignant and invading nearby tissues (invasive), or malignant and invading distant tissues (metastatic).</td>
</tr>
</tbody>
</table>
APPENDICES

Term/Abbreviation | Description
--- | ---
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.
Unscreened women | Women who have either never been screened or have not been screened for five years.

50. APPENDIX B: BIBLIOGRAPHY

European Guidelines for Quality Assurance in Mammography Screening 3rd Ed.
Health and Disability Commissioner (Code of Health and Disability Services Consumers’ Rights) Regulations 1996.
Health (Retention of Health Information) Regulations 2001.


Ministry of Health. 2000. Direction of The Minister of Health Relaxing To Eligibility For Publicly Funded Personal Health And Disability Services In New Zealand.


### 51. APPENDIX C: COMMUNICATION MATRIX

#### TABLE C:1 COMMUNICATION MATRIX

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Contact</th>
<th>Within</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appointment confirmation</td>
<td>Woman</td>
<td>5 working days prior to appointment</td>
<td>By telephone or letter</td>
</tr>
<tr>
<td>Did not attend screening appointment</td>
<td>Woman and/or GP/PCP</td>
<td>10 working days of appointment</td>
<td>By telephone and follow-up letter</td>
</tr>
<tr>
<td>Negative Screening results</td>
<td>Woman</td>
<td>10 working days of screen date</td>
<td>By letter</td>
</tr>
<tr>
<td>Negative Screening results</td>
<td>GP/PCP</td>
<td>10 working days of screen date</td>
<td>By letter or fax or electronic delivery</td>
</tr>
<tr>
<td>Screen-detected abnormalities recall for assessment</td>
<td>Woman</td>
<td>As soon as possible following the final reading of the mammogram</td>
<td>By telephone and follow-up letter</td>
</tr>
<tr>
<td>Screen-detected abnormalities recall for assessment</td>
<td>GP/PCP</td>
<td>As soon as possible following the final reading of the mammogram</td>
<td>Letter by fax or electronic delivery</td>
</tr>
<tr>
<td>Assessment appointment confirmation</td>
<td>Woman</td>
<td>1-2 working days before assessment</td>
<td>By telephone</td>
</tr>
<tr>
<td>Did not attend assessment appointment</td>
<td>Woman and GP/PCP</td>
<td>1 day (next working day)</td>
<td>By telephone and follow-up letter</td>
</tr>
<tr>
<td>Diagnosis of cancer</td>
<td>Woman</td>
<td>Informed at results clinic</td>
<td>Face to face consultation</td>
</tr>
<tr>
<td>Diagnosis of cancer</td>
<td>GP/PCP</td>
<td>Immediately after speaking with the woman</td>
<td>Telephone and letter</td>
</tr>
</tbody>
</table>
### 52. APPENDIX D: BREAST SCREENING RESOURCES

<table>
<thead>
<tr>
<th>Code No</th>
<th>Title</th>
<th>Resource</th>
</tr>
</thead>
<tbody>
<tr>
<td>10102</td>
<td>BreastScreen Aotearoa General pamphlet in English</td>
<td></td>
</tr>
<tr>
<td>10107</td>
<td>More about Breast Screening Detailed booklet</td>
<td></td>
</tr>
<tr>
<td>10111</td>
<td>BreastScreen Aotearoa Chinese pamphlet</td>
<td></td>
</tr>
<tr>
<td>10112</td>
<td>BreastScreen Aotearoa Hindi pamphlet</td>
<td></td>
</tr>
<tr>
<td>10113</td>
<td>BreastScreen Aotearoa Japanese pamphlet</td>
<td></td>
</tr>
<tr>
<td>10114</td>
<td>BreastScreen Aotearoa Korean pamphlet</td>
<td></td>
</tr>
<tr>
<td>10115</td>
<td>BreastScreen Aotearoa Thai pamphlet</td>
<td></td>
</tr>
<tr>
<td>10116</td>
<td>BreastScreen Aotearoa Vietnamese pamphlet</td>
<td></td>
</tr>
<tr>
<td>10117</td>
<td>Now that you’ve had your mammogram Pamphlet</td>
<td></td>
</tr>
<tr>
<td>10118</td>
<td>When you are called for an assessment Pamphlet</td>
<td></td>
</tr>
<tr>
<td>10119</td>
<td>Information for Women under 50 Pamphlet</td>
<td></td>
</tr>
<tr>
<td>10120</td>
<td>Information for Women over 65 Pamphlet</td>
<td></td>
</tr>
<tr>
<td>10121</td>
<td>It’s time to take care of ourselves A2 poster</td>
<td></td>
</tr>
<tr>
<td>10121A</td>
<td>It’s time to take care of ourselves A3 poster</td>
<td></td>
</tr>
<tr>
<td>10122</td>
<td>Information for General Practice and Primary Health Care Providers A5 question and answer card</td>
<td></td>
</tr>
<tr>
<td>10123</td>
<td>BreastScreen Aotearoa – Māori Pamphlet</td>
<td></td>
</tr>
<tr>
<td>10124</td>
<td>BreastScreen Aotearoa - Māori A2 Poster</td>
<td></td>
</tr>
<tr>
<td>10125</td>
<td>BreastScreen Aotearoa – Samoan Pamphlet</td>
<td></td>
</tr>
<tr>
<td>10126</td>
<td>BreastScreen Aotearoa – Tongan Pamphlet</td>
<td></td>
</tr>
<tr>
<td>10127</td>
<td>BreastScreen Aotearoa – Cook Islands Māori Pamphlet</td>
<td></td>
</tr>
<tr>
<td>10128</td>
<td>BreastScreen Aotearoa – Tokelauan Pamphlet</td>
<td></td>
</tr>
<tr>
<td>10129</td>
<td>BreastScreen Aotearoa – Niuean Pamphlet</td>
<td></td>
</tr>
<tr>
<td>10130</td>
<td>BreastScreen Aotearoa – Fijian Pamphlet</td>
<td></td>
</tr>
<tr>
<td>10131</td>
<td>BreastScreen Aotearoa – Samoan A2 poster</td>
<td></td>
</tr>
<tr>
<td>10132</td>
<td>BreastScreen Aotearoa – Tongan A2 poster</td>
<td></td>
</tr>
<tr>
<td>10133</td>
<td>BreastScreen Aotearoa – Cook Islands Māori A2 poster</td>
<td></td>
</tr>
<tr>
<td>10134</td>
<td>BreastScreen Aotearoa – Tokelauan A2 poster</td>
<td></td>
</tr>
<tr>
<td>10135</td>
<td>BreastScreen Aotearoa – Niuean A2 poster</td>
<td></td>
</tr>
<tr>
<td>10136</td>
<td>BreastScreen Aotearoa – Fijian A2 poster</td>
<td></td>
</tr>
<tr>
<td>10147</td>
<td>BreastScreen Aotearoa Frequently asked questions A5 card similar to 10122</td>
<td></td>
</tr>
<tr>
<td>1201</td>
<td>BreastScreen Aotearoa – Asian A3 poster</td>
<td></td>
</tr>
<tr>
<td>1210</td>
<td>Is BreastScreen Aotearoa for you? Information for women who have breast problems Pamphlet</td>
<td></td>
</tr>
</tbody>
</table>

To order a Ministry of Health publication, you can
Telephone (04) 496 2277
or write to:
Ministry of Health Publications
c/- Wickliffe Press
PO Box 932, Dunedin
email: moh@wickliffe.co.nz

The brochure Treatment and Support Services for Women with Breast Cancer can be obtained directly from the National Screening Unit.

For information on developing additional resources for BreastScreen Aotearoa, Providers must follow the Ministry of Health National Guidelines for Health Education Resource Development in New Zealand, Wellington, June 2002. The document sets out the main steps to be taken, which incorporate planning, financial, cultural and practical issues that need to be considered during the development and production of the resource. It is available on the Ministry of Health website (www.moh.govt.nz).
53. APPENDIX E: KEY MESSAGES FOR BREASTSCREEN AOTEAROA

- Nearly 10% of women in New Zealand develop breast cancer.
- The risk of developing breast cancer increases with age.
- Free mammograms (breast x-rays) are available for women aged 50 – 64 years through the National Breast Screening Programme.
- 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 mammograms will be reassured they do not have 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.

54. APPENDIX F: GUIDELINES FOR BREASTSCREEN AOTEAROA BOOKING STAFF

Women with the following are excluded from the BreastScreen Aotearoa Programme.

<table>
<thead>
<tr>
<th>EXCLUDED (cannot be booked for screening)</th>
<th>EXCEPTIONS (can be booked for screening)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mammogram within last 12 months (may book for screening when 12 months has elapsed)</td>
<td>None</td>
</tr>
<tr>
<td>Breast cancer within the last 5 years (may book for screening 5 years after diagnosis)</td>
<td>None</td>
</tr>
</tbody>
</table>

SYMPTOMS*

- All MUST bring any old mammograms to screening

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Exclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>New breast lump or thickening you can feel now</td>
<td>Present unchanged for 12 months or more. Or Previously investigated by mammogram/ultrasound or biopsy and found to be benign.</td>
</tr>
<tr>
<td>Puckering or dimpling of the skin</td>
<td>Present unchanged for 12 months or more. Or Previously investigated and found to be benign.</td>
</tr>
<tr>
<td>Turned in nipple</td>
<td>Present unchanged for 12 months or more. Or Previously investigated and found to be benign.</td>
</tr>
<tr>
<td>Nipple discharge</td>
<td>Present unchanged for 12 months or more. Or Bilateral (both sides) and NOT blood stained or persists without squeezing.</td>
</tr>
</tbody>
</table>

* If women indicate they have the following symptoms, they must be informed that they need to see their GP to investigate the symptoms fully, before they can be booked at a later date for screening.
55. APPENDIX G: 2003 DIRECTION OF THE MINISTER OF HEALTH RELATING TO ELIGIBILITY FOR PUBLICLY FUNDED PERSONAL HEALTH AND DISABILITY SERVICES IN NEW ZEALAND

Pursuant to section 32 of the New Zealand Public Health and Disability Act 2000, the Minister of Health, after consulting with boards as required by that section, hereby gives the following direction to District Health Boards (DHBs) established under section 32 of that Act:

1. TITLE AND COMMENCEMENT
   1. This direction may be cited as the Health and Disability Services Eligibility Direction 2003.
   2. This direction comes into force on 30 October 2003.

2. INTERPRETATION
   In this direction, unless the context otherwise requires:
   “Commonwealth Scholarship” means a postgraduate university scholarship awarded to a member of the Commonwealth under the Commonwealth Scholarship and Fellowship Plan;
   “Crown Funding Agreement” means an agreement within the meaning of section 10 of the NZPHD Act entered into by a DHB, and for the purposes of clause 4 (12) may include a service agreement entered into under section 301 of the IPRAC Act;
   “DHB” means a District Health Board established under section 19 of the NZPHD Act, and for the purposes of this direction includes the Ministry of Health where the Ministry is acting as purchasing agent for a DHB pursuant to an agency agreement;
   “disability support services” has the same meaning as in section 6 of the NZPHD Act;
   “eligibility” means the right to be considered for receipt of publicly-funded services, but does not equate to an entitlement to receive those services, and eligibility is assessed at the time services are sought (it may not operate retrospectively);
   “eligibility criteria” means the criteria set out in clause 4 of this direction, any of which, as a minimum, must be satisfied before any person may receive any publicly-funded service;
   “guardian” has the same meaning as in section 3 of the Guardianship Act 1968 or any successors to that Act;
   “health care facility” means a hospital, or other facility for the provision of services operated by a DHB (whether or not located in a hospital);
   “IPRAC Act” means the Injury Prevention, Rehabilitation and Compensation Act 2001, and includes any successor to that Act and any Regulations made under that Act;
   “Minister” means the Minister of Health;
   “New Zealand” includes all waters within the outer limits of the territorial sea of New Zealand as defined in section 3 of the Territorial Sea and Exclusive Economic Zone Act 1977, but does not include the Cook Islands, Niue, Tokelau or the Ross Dependency;
   “New Zealand citizen” means a person who has New Zealand citizenship under the Citizenship Act 1977 or the Citizenship (Western Samoa) Act 1982;
   “NZIS” means the New Zealand Immigration Service;
   “NZPHD Act” means the New Zealand Public Health and Disability Act 2000;
   “Ordinary resident in New Zealand” refers to a person who is lawfully present in New Zealand at the time of seeking services and who:
   a. holds a residence permit issued under the Immigration Act 1987, and
   b. is a person exempted, by virtue of being a citizen of the Commonwealth of Australia or by virtue of holding a current resident return visa issued by the Government of Australia, in New Zealand for a period that equals or exceeds two years;
   c. is a person who is in the process of legally adopting that child and that person meets either of the eligibility criteria specified in clauses 4 (1) or (2) or is a person referred to in clause 3 (3);
   d. is a Work Permit Holder;
   “partner” means--
   a. where the parties are legally married, either the husband or the wife, as the case requires; or
   b. a “de facto partner” within the meaning of that term in section 2C of the Property (Relationships) Act 1976;
   “prison” includes a Gazetted police jail, or corrective training institution;
   “publicly-funded services” means personal health, mental health and disability support services funded by a DHB using funds provided by the Crown under a Crown Funding Agreement or section 88 notice and, except in relation to public health acute services, does not include services funded by a DHB using funds provided by any person or agency other than the Crown, whether or not the purchasing of those services results in a part charge to the person receiving the services;
   “public health acute services” has the same meaning as in section 6 of the IPRAC Act;
   “services” means personal health services, mental health or disability support services;
   “Work Permit Holder” means a person who:
   a. holds a work permit issued under section 26 of the Immigration Act 1987:
      i. entitling that person to remain in New Zealand for a period that equals or exceeds two years; or
      ii. entitling that person to remain in New Zealand for a specified period of time which, together with the period of time that person has already been lawfully in New Zealand immediately prior to obtaining the permit, equals or exceeds two years; and
   b. includes a dependent child aged 19 years or under, or of any such person.

3. SCOPE OF THIS DIRECTION
   1. This direction covers all publicly-funded services funded by DHBs, whether in or outside a health care facility, and without limitation includes primary health services;
   2. Except as provided in clause 3(3) below, this direction does not operate retrospectively;
   3. An individual on a student or visitor permit who as at 29 October 2003 would have been eligible under clauses 2 (a) and (f) of the 2000 Direction had it not been revoked, will retain eligibility under the 2000 Direction if he or she is:
      a. a visitor permit holder and is granted consecutive permits to remain in or re-enter New Zealand;
      b. a student permit holder and is granted consecutive permits to remain in or re-enter New Zealand, even where the individual leaves New Zealand for short periods (of up to four months);

4. ELIGIBILITY CRITERIA
   A person is eligible for publicly funded services if he or she is in New Zealand at the time of seeking services and falls into any one or more of the following categories:
   1. A New Zealand citizen;
   2. Ordinarily resident in New Zealand;
   3. A person who has refugee status in New Zealand or is in the process of having an application for refugee status determined by NZIS or a person who is in the process of having an appeal against refusal of refugee status determined by the Refugee Status Appeal Authority;
   4. A student receiving funding under the New Zealand Agency for International Development Official Development Assistance Programme, or is the partner, or dependent child under the age of 18 years, of such a student;
   5. A participant in the Ministry of Education’s Foreign Language Teaching Assistantship Scheme;
   6. The holder of a Commonwealth Scholarship;
   7. In respect only of eligibility for services required to be provided under the agreement referred to in the Schedule to the Health Benefits (Reciprocity with Australia) Act 1986 or any of its successors, a resident of Australia who is in New Zealand on a temporary basis;
   8. In respect only of eligibility for services required to be provided under the agreement set out in the Schedule to the Health Benefits (Reciprocity with the United Kingdom) Act 1982 or any of its successors, a person recognised by the Government of the United Kingdom as a national, who has or her usual place of abode in the United Kingdom, and is in New Zealand on a temporary basis; or
   9. A child under the age of 18 years who is for the time being in the care and control of:
      a. his or her parent or guardian, and his or her parent or guardian meets either of the eligibility criteria specified in clauses 4 (1) or (2) or is a person referred to in clause 3 (3); or
      b. a person who is in the process of legally adopting that child and that person meets either of the eligibility criteria specified in clauses 4 (1) or (2) or is a person referred to in clause 3 (3).

---

1 This Eligibility Direction sets out who is entitled to publicly funded health services in New Zealand. If you do not meet one of the criteria set out in this direction, you are not entitled to free or subsidised services and are liable to be charged for any health services accessed.
2 Eligibility is assessed at the time of seeking services and cannot be backdated, therefore eligibility changes made by this revised direction apply only to persons seeking services after this direction comes into force.
3 This category includes New Zealand citizens living in the Cook Islands, Niue or Tokelau who visit New Zealand on a temporary basis.
10. In respect only of eligibility for compulsory services under the Tuberculosis Act 1948, the Health Act 1956, the Alcoholism and Drug Addiction Act 1966, the Mental Health (Compulsory Assessment and Treatment) Act 1992, or any Regulations made under any of those enactments (together the "enactments"), a person receiving or eligible to receive services under the enactments;

11. In respect only of eligibility for services not available through the prison health services, a prison inmate (including an individual on remand in prison custody);

12. A person who:
   a. in respect only of eligibility for public health acute services required by that person for a personal injury for which that person has cover and entitlement
   b. in respect of eligibility for disability support services, requires those services for a personal injury for which that person has cover and entitlement to treatment under the IPRAC Act, is seeking services covered by a Crown Funding Agreement; or
   c. has cover and entitlement under the IPRAC Act, and seeks primary-referred pharmaceutical and laboratory services.

5. DISPUTES AND PAYMENTS

If any question or dispute arises as to whether or not a person satisfies any of the eligibility criteria, that question or dispute shall be determined by the Ministry of Health.

6. AMENDMENT, REVOCATION AND TERM OF DIRECTION

1. The Minister may from time to time, by notice under section 32 of the NZPHD Act, amend or revoke this direction.
2. The Health and Disability Services Eligibility Direction 2000 is revoked by this direction.
3. This direction (together with any amendments to it made under clause (1) of this section) will remain in force until it is revoked by the Minister. Dated at Wellington this 19th day of September 2003.

Annette King
Minister of Health

56. APPENDIX H: COLLECTING ETHNICITY DATA

In New Zealand, ethnicity is based on self-identification. You can belong to more than 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. Many organisations are now using the 2001 Census question to collect ethnicity information.

This is the question being asked about ethnicity in the 2001 Census.

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 in developing appropriate services and policies for everyone and ensuring that people’s needs are met.

The best way to collect ethnicity data is to ask you to fill in the ethnicity question.

Deciding from appearance or guessing is not reliable, so the best way is to ask. It is your decision which ethnic group(s) you belong to.

Information that you provide to organisations such as those listed above is protected by privacy rules. If you wish, you can ask to see your information and make any changes.

57. APPENDIX I: PRO FORMA LETTERS AND FORMS

I:1 Consent for Mammography
I:2 Women with Implants
I:3 Assessment
I:4 Notification of Collection of Treatment Data
I:5 Information Notification
I:6 Women with Technical Inadequate Result
I:7 Results of screening

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

I:1 CONSENT FOR MAMMOGRAPHY

Scenario
Written consent is required prior to the screening mammogram. This is to ensure each woman has been given adequate information and has had opportunity to ask questions and feel they are fully informed about the procedure, the risks and benefits of a screening mammogram and 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 (wash/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.

---

4 “Entitlement” in clause 4 (12) (a) means a person who has statutory entitlements in terms of section 69 of the IPRAC Act, and who has not been disqualified under sections 118-122 of the IPRAC Act.

5 The services covered by subclause 4 (12) (c) are outlined in the 2000/2001 Crown-ACC funding agreement for primary-referred pharmaceutical and laboratory services between ACC and the Minister of Health.

6 The brochure was developed in 2001 by HURA (Health Utilisation Research Alliance), with funding from the HFA (Health Funding Authority). HURA is a joint project between Te Ropu Rangahau Hauora a Eru Pōmare, Departments of General Practice and Public Health at the Wellington School of Medicine and Health Sciences, and the Wellington Independent Practitioners Association (WIPA).
I authorise BreastScreen Aotearoa to obtain relevant films 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.

I:2 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 they understand the additional risks associated with screening mammmography 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 Radiation Technologists (MRTs) 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.

Signature: Date:

I:3 ASSESSMENT

Scenario
This form may be used to record a woman’s informed consent to an assessment procedure which 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 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: Date:

I:4 NOTIFICATION OF COLLECTION OF TREATMENT DATA

Standard Text
In order to assess its effectiveness and monitor the quality of BreastScreen Aotearoa programme, BreastScreen Aotearoa wish to notify you that relevant clinical information regarding treatment procedures that you may receive will be collected from treatment providers. Some of this information will be forwarded to the Ministry of Health or its agent, e.g. another entity designated by the National Screening Unit of BreastScreen Aotearoa, the New Zealand Health Information Service and the Cancer Registry, by National Health Index Number (NHI).

You have the right to see and correct any information held about you. To do so, please advise BreastScreen Aotearoa.

Date of Notification:

Signature of person providing notification:

Name/position of person providing notification:

I:5 INFORMATION NOTIFICATION

Scenario
This notification should be printed on any form that is used to collect information from women, such as the registration form. The font should be distinct from the main text but no smaller than 9 point. Women should be able to keep a copy of this notification to refer to later.

Standard Text
The text below contains the required components which must be included in any form used for the specified function:

The information you have given on this form and your screening results will be used by the Provider of the breast screening programme, BreastScreen Aotearoa, to provide you with any necessary follow-up assessment including inviting you for your next mammogram.

This information and the X-ray film will be held securely by the Provider of the screening programme, BreastScreen Aotearoa, on their premises and only authorised personnel will have access to your information.

In order to assess the effectiveness of the breast screening programme and monitor the quality of the National breast screening programme, BreastScreen Aotearoa, some information collected about you is also forwarded to the Ministry Of Health or its agents, e.g. another entity designated by the National Screening Unit of BreastScreen Aotearoa, the New Zealand Health Information Service and the Cancer Registry, by National Health Index Number (NHI).

Information about any further assessment or treatment for breast cancer that is necessary for you, will also be collected from both public and private providers by BreastScreen Aotearoa.

It is only by monitoring the care and outcome of all women who have mammograms, that the ongoing quality of the Programme can be properly assessed.

You have the right to see and if necessary correct the information held about you.

☐ Please tick the box if you agree to the General Practitioner or Primary Care Provider you have named on the questionnaire being informed of your screening results. (This is strongly recommended but not a requirement to participate in BreastScreen Aotearoa).

I:6 TECHNICALLY INADEQUATE RESULT

Scenario
Women whose mammography was technically inadequate but cannot be improved upon (for example, physical immobility problems etc.) 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 that is necessary for you, will also be collected from both public and private providers by BreastScreen Aotearoa.

Following your visit to the breast screening centre on (date) we are pleased to inform you that your mammogram has been reviewed and reported by two qualified radiologists and that they found no evidence of breast cancer.

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APPENDICES

J:1 LARGE BREAST PROTOCOL

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

Rationale
There are specific technical issues that must be addressed when imaging women with large breasts. These include: difficulty in obtaining optimum position due to body size; long exposure time; scattered radiation within the breast: potential for injuring fragile skin areas; and physical fatigue of both the MRT and woman.

Criteria
Each screening unit shall have a specific protocol for imaging women with large breasts. This may include:
1. two standard views of each breast using large (24 cm x 30 cm) film format;
2. a combination of large or small film format with minimal overlap, if sufficient coverage is not obtained using a page film format (24 cm x 30 cm).

The MRT should use their professional expertise in deciding which of these techniques is appropriate for an individual woman, taking into account the woman’s previous imaging and other factors, such as body shape, which may necessitate additional films regardless of breast size.

Each fixed and mobile screening unit shall be appropriately equipped to enable them to perform screening mammography according to the protocols above. This includes film/cassette combinations, film reading viewers (or viewing boxes on mobiles) and film storage facilities.

J:2 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 with 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 may 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 a mammographic abnormality.

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.

Photocell:
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 shall be informed of this and advised to exit the programme. The outcome must be documented and appropriate outcome data provided to BreastScreen Aotearoa.

J:3 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.

The National Screening Unit, in conjunction with the Clinical Director’s UDG and Medical Radiation Technologist’s UDG will develop a National Mastectomy Protocol for the Programme.

J:4 BREAST CONSERVATION

Women who have undergone breast conservation therapy are eligible for bilateral screening mammography within the programme, five years following a diagnosis of breast cancer. In the absence of a new mammographic abnormality these women will not be recalled to assessment for clinical examination.

J:5 HIGH RISK WOMEN

Where Atypical Ductal Hyperplasia has been detected within the programme the woman and her GP/CP (with the appropriate consent) will be informed of her increased risk of developing breast cancer.

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 should 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.

CONSENT

Specific informed consent shall be obtained (Refer Appendix 1:2) usually by the MRT 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.

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APPENDICES

59. APPENDIX K: MAMMOGRAPHIC QUALITY ASSURANCE (MQA) PROGRAMME

**K:1 MQA PROGRAMME**

The professions involved have agreed to adopt the protocols and standards of the RANZCR Mammography Accreditation Programme as the basis of the MQA programme used in the BreastScreen Aotearoa Programme. The quality control (QC) tests will be as per the RANZCR manuals (RANZCR (2002) or subsequent versions) with modifications to meet regulatory requirements or New Zealand conditions, implying additional tests without loss of acceptability to the RACR accreditation scheme. (While BreastScreen Aotearoa have agreed on the Standard, it is by no means the intention that all screening units must be accredited to the RANZCR scheme). Where the requirements of the regulations and the RANZCR are different, this will be explained.

**K:2 MQA COMMITTEE**

There shall be a site MQA committee, where the designated MQA radiologist, MQC MRT and Medical Physicist co-ordinate the QC tests and their frequencies, review the results and the MQA programme generally. This committee will convene initially a minimum of every three months, or more frequently until consistency has been achieved, thereafter twice a year.

**K:3 MRT QC CHECKS AND TESTS**

The MRT performing the role of QC MRT must hold either grandparenting status (Refer: Standard 44.2: Professional Standards) with NZIMRT or have completed a mammography course endorsed by NZIMRT. It is desirable that the Charge MRT be the QC MRT, as the maintenance of the comprehensive MQA programme will be one of their major management tasks. The QC MRT need not be the individual who performs every test but they shall ensure that tests are performed, and collate the results and analyse them in consultation with the Charge MRT and the Medical Physicist. The Charge MRT shall also monitor equipment maintenance, which shall be recorded in the QC log and advise, in consultation with the Medical Physicist, when these interventions require the review of QC tests, test intervals, repeat tests and related practices.

It is particularly important that the MRTs and Medical Physicists act co-operatively in their QC tests to ensure appropriate coverage of all aspects of the task. The RANZCR scheme gives an appropriate allocation of duties, the MRT contribution to which is summarised below, with the additions necessary for regulatory compliance. This is recognised as a minimum requirement and inevitably local additions, either to tests or frequencies, will be required to deal with particular circumstances. These shall be agreed with the Medical Physicist. The QC MRT shall supervise the performance of the tests in accordance with the RANZCR Manual. There must be an appropriate allocation of staff time to perform these tests.

A record shall be kept of the test measurements as well as any faults, breakdowns or maintenance of equipment. This should include, for example, any fault messages from on-board computers, even if they resolve themselves.

Individual screening units must recognise that these are minimum standards and that often increased frequency (specifically items such as screen cleaning) or additional tests may be necessary to ensure quality. This will vary from site to site and time to time:

1. All tests must be fully documented using the RANZCR 2002 protocol, but a daily check of the AEC is required by the regulatory authority and documented using Template under K:4.
2. All tests must be fully documented using the appropriate protocol.
3. Test results must be made available for inter-comparison and the collation of national statistics.

**TABLE K:1 MRT QC CHECKS AND TESTS**

<table>
<thead>
<tr>
<th>Test Category</th>
<th>RANZCR Protocol</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DAILY</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Darkroom cleanliness</td>
<td>RANZCR protocol</td>
<td></td>
</tr>
<tr>
<td>Processor quality control</td>
<td>RANZCR protocol</td>
<td>Immediately</td>
</tr>
<tr>
<td>Mobile Unit QC</td>
<td>RANZCR protocol</td>
<td>Immediately</td>
</tr>
<tr>
<td>Automatic exposure control (AEC)</td>
<td>RANZCR protocol</td>
<td>Immediately</td>
</tr>
<tr>
<td>Processor cleaning (crossover rollers)</td>
<td>Follow manufacturer’s protocols and recommendations</td>
<td></td>
</tr>
<tr>
<td><strong>WEEKLY</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clean screens (dry and wet)</td>
<td>RANZCR protocol (may require far more frequent attention)</td>
<td>Immediately (whenever an artefact is identified by an MRT or radiologist)</td>
</tr>
<tr>
<td>View boxes and viewing conditions</td>
<td>RANZCR protocol</td>
<td>As per RANZCR 2002</td>
</tr>
<tr>
<td>Phantom images</td>
<td>RANZCR protocol</td>
<td>Immediately</td>
</tr>
<tr>
<td>Processor: clean racks and rollers</td>
<td>Follow manufacturer’s recommendations and protocols</td>
<td></td>
</tr>
</tbody>
</table>

---

9 RANZCR 2002 or subsequent versions
10 RANZCR (2002) or subsequent versions
11 The failure of any critical test would require immediate suspension from use, for non-critical tests, at the radiologist’s discretion, from 30 days of the test date.
K4. Procedure: Automatic Exposure Control (AEC) Compensation Assessment

**Objective**
To assess the ability of the automatic exposure control system to correct for changes in kVp and breast thickness.

**Frequency**
This test must be carried out quarterly.

**Required Test**
- Mammographic X-ray unit

**Equipment**
- Perspex slabs of 2, 4 and 6 cm thicknesses
- Densitometer
- Test cassette
- Test record sheet

**Test Procedure Steps**
1. Position a 2 cm perspex slab on the breast table, centred laterally, and place loaded cassette in the Bucky.
2. Ensure that the automatic exposure control detector is in the chest wall position and bring the compression paddle into gentle contact with the phantom.
3. Select a phototimed imaging mode that allows manual selection of kVp. Use the kVp that would be used clinically for a breast with radiographic properties equivalent to the perspex thickness being used.
4. Repeat steps 1 – 4 for 4 cm and 6 cm of perspex.
5. If alternative target/filter combinations are available (e.g. Mo/Rh, Rh/Rh, W/Rh), obtain images for 6 cm of perspex using the combination used clinically at the appropriate kVp. Reach an agreement on technique with your medical physicist.
6. Calculate the mean optical density for the above group of films and the maximum variation in optical density from this mean.

**Precautions and Caveats**
The cassette used should be designated for this test and be in routine clinical use. Normal clinical film should be used. See Appendix 1, Section 3.4.14

**Recommended Performance Criteria and Corrective Action**
The optical density of any film must be within +/- 0.15 of the mean optical density. The mean optical density must be within 0.20 of the baseline and greater than 1.40.

---

**Mobile Mammography**
The Lead Provider shall verify that each mobile mammography unit meets the mammography QC standards as stated above. In addition, on arrival at each location the facility shall verify satisfactory performance by performing a phantom test and noting parameters recorded on the machine. If parameters are within acceptable limits, screening can commence. Once the phantom has been processed, if it is found to be outside acceptable limits then screening should cease immediately.

It is expected that once a unit is established at a site Approach B would be sufficient to ensure quality.

---

**TABLE 4.1**

<table>
<thead>
<tr>
<th>Monthly:</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual checklist</td>
<td>RANZCR protocol</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quarterly:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Repeat analysis</td>
<td>RANZCR protocol</td>
</tr>
<tr>
<td>Analysis of fixer retention in film</td>
<td>RANZCR protocol</td>
</tr>
<tr>
<td>AEC Compensation (test to 6cm)</td>
<td>RANZCR protocol</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Six Monthly:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Darkroom fog</td>
<td>RANZCR protocol</td>
</tr>
<tr>
<td>Screen film contact</td>
<td>RANZCR protocol</td>
</tr>
<tr>
<td>Compression</td>
<td>RANZCR protocol</td>
</tr>
</tbody>
</table>

**Note:**
APPENDICES

AEC CALIBRATION TEST
BreastScreen Aotearoa
AEC Calibration test

<table>
<thead>
<tr>
<th>Room:</th>
<th>Film:</th>
<th>Cassette #:</th>
<th>Month:</th>
<th>Yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small Cassette ID:</td>
<td>Large Cassette ID:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Thickness Tracking

<table>
<thead>
<tr>
<th>Image receptor (Small / large)</th>
<th>Grid (yes / no)</th>
<th>Focal Spot (small / large)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AEC sensor position: Density Control</td>
<td>mA</td>
<td></td>
</tr>
</tbody>
</table>

Phantom thickness | Image # | AEC Mode | kVp | Anode & Filter | mAs | OD |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2cm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4cm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6cm (optional)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8cm (optional)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Overall AEC Performance Contact Mode
Site baseline OD (1.6 to 2.0) | Mean OD (2-6 cm) | OD Range | Allowed OD Range |
|-------------------------------|-----------------|-----------|------------------|

**Action Limit:** If the OD range exceeds ±0.15 of mean OD, when thickness is varied from 2 to 6 cm and the kVp is varied over those values clinically relevant, then contact your medical physicist for complete assessment.

**Artefact present?**

K: 5 MEDICAL PHYSICIST’S CHECKS AND TESTS

All tests must be recorded on the approved forms and in the manner described in the RANZCR Manual. Prompt reporting is important. A preliminary report, (Refer: RANZCR 200213 for the format), should be given to the facility on the day that testing is completed. If any equipment fails a critical examination (MGD or Image Quality), then every effort must be made to advise the Licensee, the designated MQA radiologist, and the Charge MRT immediately. A written preliminary report shall be retained by the facility documenting the failure. A final report for all tests shall be sent to the designated Charge MRT and National Physics Co-ordinator within 20 working days.

The base frequency of testing recommended by RANZCR14 is annual, although many authorities suggest some checks be done more frequently. The minimum testing frequency for the Critical Examinations and the AEC tests, is six monthly. The qualified Medical Physicist may decide to increase the frequency of certain tests, perhaps only for a limited period of time, based upon the machine performance. These tests must be performed within 30 days of their due date.

<table>
<thead>
<tr>
<th>Test Frequency</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Mammographic unit assembly evaluation</td>
<td>Within 30 days of test date</td>
</tr>
<tr>
<td>2. Collimation assessment</td>
<td>Within 30 days of test date</td>
</tr>
<tr>
<td>3. Evaluation of focal spot performance</td>
<td>Within 30 days of test</td>
</tr>
<tr>
<td>4. kVp accuracy and reproducibility</td>
<td>Within 30 days of test date</td>
</tr>
<tr>
<td>5. Beam quality assessment (half-value layer)</td>
<td>Within 30 days of test date</td>
</tr>
<tr>
<td>6. Automatic exposure control (AEC) system performance assessment</td>
<td>Within 30 days of test date</td>
</tr>
<tr>
<td>7. Uniformity of screen speed</td>
<td>Within 30 days of test date</td>
</tr>
</tbody>
</table>

**TABLE K: 2 MEDICAL PHYSICIST’S CHECKS AND TESTS**


These tests, performed by the Medical Physicist, provide baseline values for the Physicist’s tests, ensure compliance with NRL-C5\textsuperscript{15} and ensure that equipment performance meets the contract specifications. The tests must be performed prior to the use of the equipment for breast cancer screening.\textsuperscript{16} To facilitate this, ample notice of the installation data must be supplied to the Medical Physicist. A comprehensive description of acceptance tests is given in the UK NHSBSP document.\textsuperscript{17}

Acceptance testing should be done against the following Standards. The first two apply to all equipment used in the Programme, the third and fourth to new equipment, and the remainder are valuable guidance, but allowance must be made for the New Zealand regulations and the purchase conditions.

1. Tests as per Approach B of the document, i.e. modified RANZCR (2002).\textsuperscript{18}
2. For stereotactic breast biopsy units, the ACR Mammography Quality Manual\textsuperscript{19} for stereotactic units should be followed.
3. Code of Safe Practice for the use of x-rays in Medical Diagnosis, NRL-C5.\textsuperscript{20}
4. The purchase contract.
5. The manufacturer’s specifications.

### Resource Materials
1. A list documenting the specific tests that are required to be met for Medical Physicists acceptance testing.
2. Commissioning and Routine Testing of Mammographic X-ray Systems.\textsuperscript{21} This provides very detailed tests. Some allowance must be made for New Zealand regulations. Compliance with some of the tests here would need to be specified at purchase.
3. Acceptance testing prone stereotactic breast biopsy units.\textsuperscript{22}
4. Recommended Specifications for New Mammography Equipment: Report of the ACR-DCD Focus Group on mammography Equipment.\textsuperscript{23}

### Electrical Safety
Under the Electricity Regulations 1993, responsibility for electrical safety lies principally with the owners and operators of medical equipment. Electrical safety will be checked initially by the suppliers at installation, but further checks will normally be made by engineers employed by the Lead Providers or the subcontracted parties. The responsibility for electrical safety checks (both at installation and afterwards) should be clearly laid down, e.g. in the purchase or maintenance contract. QA Medical Physicists normally have no training or experience in this field.

It should be noted that stereotactic localisation equipment, where the normal electrical resistance of the skin is broken by the penetration of the needle, will require ‘body protected’ status.

<table>
<thead>
<tr>
<th>Test Frequency</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. Breast entrance exposure, average glandular dose, and AEC reproducibility</td>
<td>Immediately if &gt;3mGy; * Within 30 days if &gt;2mGy</td>
</tr>
<tr>
<td>9. Image quality evaluation</td>
<td>Immediately</td>
</tr>
<tr>
<td>10. Artfact evaluation**</td>
<td>Within 30 days of test date</td>
</tr>
<tr>
<td>11. Assessment of site’s QC programme</td>
<td>Within 30 days of test date</td>
</tr>
<tr>
<td>12. Measurement of view box luminance and illuminance</td>
<td>Within 30 days of test date</td>
</tr>
<tr>
<td>13. Output linearity</td>
<td>Within 30 days of test date</td>
</tr>
</tbody>
</table>

\textsuperscript{*} It is unusual for the PmGD to the PmAP to exceed 2 mGy. If this occurs then technique and equipment parameters shall be reviewed to prevent it exceeding 2 mGy. If the MGD exceeds 3 mGy then the system shall be suspended from use until MGD is brought under control.

\textsuperscript{**} This test may have to be modified by the Medical Physicist to accommodate daylight loading film processors.

\textsuperscript{15} NRL 1994.
\textsuperscript{16} NRL 1994.
\textsuperscript{17} IPSM Report 59 (2nd Edition) (IPSM 1994).
\textsuperscript{20} NRL 1994.
60. APPENDIX L: STEREOTACTIC BREAST BIOPSY QUALITY ASSURANCE (QA) PROGRAMME

L.1 QA Responsibilities and Relationships
L.2 MRT QC Checks and Tests for Stereotactic Equipment
L.3 Medical Physicist’s Checks and Tests

L.1 QA RESPONSIBILITIES AND RELATIONSHIPS

Responsibilities for the Stereotactic Breast Biopsy QA Programme are the same as for the MQA Programme, Appendix K.

Stereotactic Breast Biopsy QA Programme

This should be as per the ACR Stereotactic Breast Biopsy Accreditation Programme, modified as detailed:

1. when a completely dedicated Stereotactic Breast Biopsy system is used, or where the unit does not otherwise have documented testing to satisfy the requirements of Appendix K then it must be tested, in full, to the ACR Standard.

2. when the Stereotactic Breast Biopsy system is an accessory, attached to a mammography system which has been satisfactorily tested, as per Appendix K then the modified tests tabulated below may be used to avoid duplication.

Individual screening units must recognise that these are minimum standards and that often increased frequency or additional tests may be necessary to ensure quality. This will vary from site to site and time to time. NRL-C5 requires that the MQA programme is approved by the Medical Physicist.

L.2 MRT QC CHECKS AND TESTS FOR STEREOTACTIC EQUIPMENT

The QC MRT shall supervise the performance of the tests in accordance with the RANZCR or ACR Manual. There must be an appropriate allocation of staff time to perform these tests. All MRTs need to be able to perform these tests and notify the QC MRT of any issues. These tests shall be agreed with the Medical Physicist.

There shall be a record kept of the test measurements as well as any faults, breakdowns or maintenance of equipment. This should include, for example, any fault messages from on-board computers, even if they resolve themselves.

If any QC test fails, the problem must be identified and corrective action taken. In some cases, when the test result falls outside action limits, this must be done before any further examinations are made, or any films processed, using the component of the mammography system that failed the test. Other test failures must be corrected within 30 days of the test date.

<table>
<thead>
<tr>
<th>TABLE L.1</th>
<th>MRT QC CHECKS AND TESTS FOR STEREOTACTIC EQUIPMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DAILY</strong></td>
<td></td>
</tr>
<tr>
<td>Localisation Accuracy (in air)</td>
<td>ACR, or manufacturer’s protocol (The needle length shall be identical to that most commonly used clinically)</td>
</tr>
<tr>
<td>Zero Alignment</td>
<td>If required by manufacturer</td>
</tr>
<tr>
<td><strong>WEEKLY</strong></td>
<td></td>
</tr>
<tr>
<td>Phantom images</td>
<td>ACR protocol</td>
</tr>
<tr>
<td><strong>MONTHLY</strong></td>
<td></td>
</tr>
<tr>
<td>Hardcopy Output Quality***</td>
<td>ACR, or manufacturer’s protocol</td>
</tr>
<tr>
<td>Visual checklist</td>
<td>ACR protocol</td>
</tr>
<tr>
<td><strong>SIX-MONTHLY</strong></td>
<td></td>
</tr>
<tr>
<td>Repeat analysis</td>
<td>ACR protocol</td>
</tr>
<tr>
<td>Compression</td>
<td>ACR protocol</td>
</tr>
</tbody>
</table>

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24 ACR. 1999 b.
25 ACR. 1999 b.
APPENDICES

**TABLE L:2 ADDITIONAL TEST FOR SCREEN: FILM SYSTEMS**

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Test Description</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>DAILY*</td>
<td>Processor quality control</td>
<td>ACR protocol. No additional testing required if processor assessed as per Appendix K</td>
</tr>
<tr>
<td></td>
<td>Processor cleaning (crossover rollers)</td>
<td>Follow manufacturer’s protocols and recommendations; not required if covered by Appendix K</td>
</tr>
<tr>
<td></td>
<td>View boxes and viewing conditions</td>
<td>ACR protocol; not required if covered by Appendix K</td>
</tr>
<tr>
<td></td>
<td>Analysis of fixer retention in film</td>
<td>ACR protocol; not required if covered by Appendix K</td>
</tr>
<tr>
<td></td>
<td>Darkroom fog</td>
<td>ACR protocol; not required if covered by Appendix K</td>
</tr>
<tr>
<td></td>
<td>Screen film contact</td>
<td>ACR protocol; not required if covered by Appendix K</td>
</tr>
</tbody>
</table>

**TABLE L:3 ACR STEREOTACTIC CHECKS AND TESTS**

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Test Frequency</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Mammographic Unit assembly evaluation</td>
<td>Six-monthly</td>
<td>Within 30 days of test date</td>
</tr>
<tr>
<td>2. Collimation assessment</td>
<td></td>
<td>Within 30 days of test date</td>
</tr>
<tr>
<td>3. Evaluation of focal spot performance*</td>
<td></td>
<td>Within 30 days of test date</td>
</tr>
<tr>
<td>4. kVp accuracy and reproducibility</td>
<td>Six-monthly</td>
<td>Immediately</td>
</tr>
<tr>
<td></td>
<td>Full test annually</td>
<td>Within 30 days of test date</td>
</tr>
<tr>
<td>5. Beam quality assessment (half-value layer)**</td>
<td></td>
<td>Within 30 days of test date</td>
</tr>
<tr>
<td>6. Automatic exposure control (AEC) system performance assessment</td>
<td>Six-monthly</td>
<td>Within 30 days of test date</td>
</tr>
<tr>
<td></td>
<td>Density control function annually</td>
<td>Note: ACR 1999b explicitly requires AEC testing to a thickness of 8 cm</td>
</tr>
<tr>
<td>7A. Uniformity of screen speed</td>
<td></td>
<td>Within 30 days</td>
</tr>
<tr>
<td>7B. Digital Receptor Uniformity</td>
<td></td>
<td>Within 30 days</td>
</tr>
<tr>
<td>8. Breast entrance exposure, average glandular dose, and AEC reproducibility</td>
<td>Six-monthly</td>
<td>Immediately if &gt;3mGy;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Image quality evaluation</td>
<td>Six-monthly</td>
<td>Immediately</td>
</tr>
<tr>
<td>10. Artefact evaluation</td>
<td></td>
<td>Within 30 days of test date</td>
</tr>
<tr>
<td>11. Localisation Accuracy (Gelatine Phantom Test****)</td>
<td>Six-monthly</td>
<td></td>
</tr>
</tbody>
</table>

**L:3 MEDICAL PHYSICIST’S CHECKS AND TESTS**

All tests must be recorded on the approved forms or a spreadsheet equivalent, in the manner described in the ACR Manual29, with copies sent to the designated MQA radiologist, Charge MRT and National Mammography Physics Co-ordinator. Prompt reporting is important. If any equipment fails a critical examination (MGD, Image Quality or accurate localisation) then every effort must be made to advise the Licensee, the Designated MQA radiologist and the Charge MRT immediately. A written preliminary report shall be left with the facility documenting the failure. A final report for all tests shall be sent to the facility within 15 working days. Except where specified in Table L:2, tests must be performed at least annually. The qualified Medical Physicist may decide to increase the frequency of certain tests, perhaps only for a limited period of time, based upon the machine performance.

29 ACR 1999 b
* Each day that the stereotactic breast biopsy system is used on patients.
** Each week that the stereotactic breast biopsy system is used on patients.
*** It is unusual for the MGD to the MAP to exceed 2 mGy. If this occurs then technique and equipment parameters shall be reviewed to bring it below 2 mGy. If the MGD exceeds 3 mGy then the system shall be suspended from use until MGD is brought under control.
**** This requires phantom availability.
61. APPENDIX M: ULTRASOUND SYSTEM PERFORMANCE AND QUALITY CONTROL

Quality assurance is of the greatest importance in breast screening and this applies no less to the ultrasound equipment used in assessment than 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 (AAPM) recommendations and the American College of Radiology Ultrasound and Ultrasound Guided Breast Biopsy Accreditation Programmes.

**M:1 ULTRASOUND USER TESTS**
The test to be performed are as detailed below.

### TABLE M:1 ULTRASOUND USER TESTS

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Minimum Frequency</th>
<th>Procedure Elements</th>
<th>Control Limits/Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual Inspection:</td>
<td>Monthly</td>
<td>Inspection of transducers, power cords, controls and system cleanliness.</td>
<td>Satisfactory operation and condition.</td>
</tr>
<tr>
<td>Hard copy device:</td>
<td>Monthly (Can be reduced to 6 monthly by the Medical Physicist)</td>
<td>Use the ACR Stereotactic Hardcopy protocol (ACR 1999 b), or similar manufacturer's protocol, preferably employing a SMPTE (or similar) pattern.</td>
<td></td>
</tr>
</tbody>
</table>

**M:2 ULTRASOUND ACCEPTANCE TESTING/BASELINE READINGS**

These tests shall 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 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 (e.g. to include power output).

**M:3 ULTRASOUND PERFORMANCE ASSESSMENT TESTS**

### TABLE M:2 ULTRASOUND SYSTEM QUALITY CONTROL AND PERFORMANCE REQUIREMENTS

<table>
<thead>
<tr>
<th>Procedure*</th>
<th>Minimum Frequency</th>
<th>Procedure Elements</th>
<th>Control Limits/Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical and mechanical inspection</td>
<td>Six-monthly</td>
<td>Inspection of transducers, power cords, controls and system cleanliness.</td>
<td>Satisfactory operation and condition.</td>
</tr>
<tr>
<td>Display monitor set-up and fidelity</td>
<td>Six-monthly</td>
<td>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.</td>
<td>Number of grey scale test pattern steps visible should not decrease by more than 2.</td>
</tr>
<tr>
<td>Image Uniformity</td>
<td>Six-monthly</td>
<td>Evaluation of a uniform region of tissue-mimicking phantom and identification of deviation from smooth tissue texture.</td>
<td>No significant non-uniformities.</td>
</tr>
<tr>
<td>Depth of penetration/visualisation</td>
<td>Six-monthly</td>
<td>Evaluation of maximum depth of either ultrasound speckle or object perception.</td>
<td>&lt;6 mm change in depth of penetration/visualisation.</td>
</tr>
<tr>
<td>Hard copy fidelity</td>
<td>Six-monthly</td>
<td>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.</td>
<td>No significant change from baseline images.</td>
</tr>
<tr>
<td>Distance Accuracy</td>
<td>Six-monthly</td>
<td>Measurement of known distances in vertical and horizontal directions.</td>
<td>Vertical measurement error less than 1.5 mm or 1.5%. Horizontal measurement error less than 2 mm or 2%.</td>
</tr>
<tr>
<td>Anechoic object imaging</td>
<td>Six-monthly</td>
<td>Evaluation of image quality. Comparison with baseline images.</td>
<td>No major distortion or change from baseline performance.</td>
</tr>
<tr>
<td>Axial resolution</td>
<td>Six-monthly</td>
<td>Evaluation of full-width half-maximum (FWHM) from profile. OR Evaluation of filament targets in an axial resolution grouping.</td>
<td>Resolution ≤ 1 mm. No significant change from baseline values.</td>
</tr>
</tbody>
</table>

* Procedure should be repeated for each transducer (excluding Display Monitor Set-up and Hardcopy fidelity).
APPENDICES

Procedure* Minimum Frequency Procedure Elements Control Limits/ Requirements

Lateral resolution or response width Six-monthly 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 Six-monthly Imaging of filament targets near scanning window. OR Evaluation of image texture features. Dead zone < 4 mm (for > 7 MHz transducer).

Review of User QC Six-monthly

62. APPENDIX N: MAMMOGRAPHIC IMAGE QUALITY (MIQ) CLASSIFICATION

USING THE MIQ CLASSIFICATION

All mammographic images are to be assessed for acceptability prior to hanging for reading. The tool for this assessment is the MIQ criteria as stated below in Table N:2. This assessment may be made by the MRT performing the mammogram or another MRT with the appropriate level of competency.

NOTE: MRTs working on mobile units without processing will be dependent on another MRT performing this assessment. Any relevant feedback should be given promptly to the MRT concerned.

The MIQ criteria33 apply to all images, irrespective of the subject, from easy to extremely difficult anatomical types.

Regular monthly peer review should also occur 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%) have been published34 and are given below.

TABLE N:1 REQUIRED SAMPLE SIZE TO GIVE ACCURACY OF ±5% FOR DIFFERENT SIZES OF SCREENING CENTRE.

<table>
<thead>
<tr>
<th>Average Monthly Examinations</th>
<th>Required Monthly sample size</th>
</tr>
</thead>
<tbody>
<tr>
<td>250</td>
<td>125</td>
</tr>
<tr>
<td>500</td>
<td>150</td>
</tr>
<tr>
<td>750</td>
<td>200</td>
</tr>
<tr>
<td>1000 and above</td>
<td>250</td>
</tr>
</tbody>
</table>

Measurements must be followed by analysis and comparison with the performance targets given below as well as with previous MIQ results.

Analysis must be followed by feedback. It is imperative that results, recommendations and positive feedback are communicated promptly to the MRTs performing the imaging.

Classification Target level (% of films appraised)

<table>
<thead>
<tr>
<th>Perfect</th>
<th>≥ 10%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perfect and Good</td>
<td>&gt; 75%</td>
</tr>
<tr>
<td>Moderate</td>
<td>&lt; 22%</td>
</tr>
<tr>
<td>Inadequate</td>
<td>&lt; 3%</td>
</tr>
</tbody>
</table>

34 NHSBSP March 2000 Publication No 30.
TABLE N:2 MAMMOGRAPHIC IMAGE QUALITY (MIQ) CLASSIFICATION

<table>
<thead>
<tr>
<th>Perfect Images</th>
<th>Good Images</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Maximum breast tissue imaged:</strong></td>
<td><strong>Maximum breast tissue imaged:</strong></td>
</tr>
<tr>
<td>Cranio-caudal position</td>
<td>Cranio-caudal position:</td>
</tr>
<tr>
<td>Breast &amp; nipple positioned centrally</td>
<td>As for Perfect category except pectoral muscle not shown but breast tissue</td>
</tr>
<tr>
<td>Nipple in profile</td>
<td>imaged well back to chest wall.</td>
</tr>
<tr>
<td>Medial aspect shown</td>
<td>Medio-lateral oblique position:</td>
</tr>
<tr>
<td>As much axillary tail as possible</td>
<td>Pectoral muscle well demonstrated (but not meeting Perfect criteria)</td>
</tr>
<tr>
<td>Pectoral muscle shadow at chest wall</td>
<td>Infra-mammary angle clearly demonstrated.</td>
</tr>
<tr>
<td>Perfect crieteria</td>
<td><strong>Perfect crieteria</strong></td>
</tr>
<tr>
<td>Medirolateral oblique position:</td>
<td>Medirolateral oblique position:</td>
</tr>
<tr>
<td>Pectoral muscle shadow to nipple level</td>
<td>Pectoral muscle well demonstrated (but not meeting Perfect criteria)</td>
</tr>
<tr>
<td>Pectoral muscle at appropriate angle</td>
<td>Infra-mammary angle clearly demonstrated.</td>
</tr>
<tr>
<td>Retroareolar area well demonstrated</td>
<td>Correct annotation clearly shown.</td>
</tr>
<tr>
<td>Nipple in profile</td>
<td>Woman’s identification label</td>
</tr>
<tr>
<td>Retroareolar area well demonstrated</td>
<td>Positioned markers</td>
</tr>
<tr>
<td>Breast tissue well demonstrated and firmly held compression</td>
<td>Date of examination</td>
</tr>
<tr>
<td>Correct annotation clearly shown:</td>
<td>Correct annotation clearly shown:</td>
</tr>
<tr>
<td>Pectoral muscle and axilla not obscured by skin folds or creases</td>
<td>Correct annotation clearly shown:</td>
</tr>
<tr>
<td>Pectoral muscle at back of the breast demonstrate to the level of the nipple</td>
<td>Correct annotation clearly shown:</td>
</tr>
<tr>
<td>Nipple in profile</td>
<td>Correct annotation clearly shown:</td>
</tr>
<tr>
<td>Retroareolar area well demonstrated</td>
<td>Correct annotation clearly shown:</td>
</tr>
</tbody>
</table>

**Annotations clearly shown**

- NH number
- Name
- Date of birth
- Screening Centre
- Date
- Radiographer I.D.
- Anatomical marker
- Nipple in profile
- Retroareolar area well demonstrated
- Breast tissue well demonstrated and firmly held compression
- Pectoral muscle
- Pectoral muscle and axilla not obscured by skin folds or creases
- Pectoral muscle at back of the breast demonstrate to the level of the nipple
- Nipple in profile
- Retroareolar area well demonstrated
- Breast tissue well demonstrated and firmly held compression
- Pectoral muscle
### Moderate Images

<table>
<thead>
<tr>
<th>Maximum breast tissue imaged:</th>
<th>Inadequate images</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nipple profiled in one view only</td>
<td>Any of the following criteria will determine inadequate imaging: Part of breast not imaged</td>
</tr>
<tr>
<td>Cranio-caudal position:</td>
<td></td>
</tr>
<tr>
<td>As for Good category</td>
<td></td>
</tr>
<tr>
<td>Medio-lateral oblique position:</td>
<td></td>
</tr>
<tr>
<td>Pectoral muscle well demonstrated</td>
<td></td>
</tr>
<tr>
<td>Infra-mammary angle present, but minor tissue overlap</td>
<td></td>
</tr>
<tr>
<td>Correct annotation, clearly shown</td>
<td>Inadequate identification/annotation</td>
</tr>
<tr>
<td>Appropriate exposure</td>
<td>Incorrect exposure</td>
</tr>
<tr>
<td>Appropriate compression</td>
<td>Inadequate compression</td>
</tr>
<tr>
<td>Absence of movement/geometric blur</td>
<td>Movement/geometric blur</td>
</tr>
<tr>
<td>Correct processing</td>
<td>Incorrect processing</td>
</tr>
<tr>
<td>Minimal artefacts, but not obscuring breast tissue</td>
<td>Overlying artefacts</td>
</tr>
<tr>
<td>Skin folds but not obscuring breast tissue</td>
<td></td>
</tr>
</tbody>
</table>

### 63. APPENDIX O: FILM VIEW BOX

A film view box with uniform brightness of at least 3,000 cd.m$^{-2}$ is required for adequate viewing of mammograms; unused areas of viewing screen shall be masked and room-ambient light levels shall be 50 lux or less$^{35}$ to maximise the ability to detect low contrast lesions. A bright spotlight (at least 20,000 cd.m$^{-2}$ over 8 cm diameter) preferably with iris diaphragm$^{36}$ and magnifying glass with magnification of x 2 to x 4 are also essential. Viewing conditions shall be monitored quarterly, with a full Medical Physicist’s quality check annually.

---

64. APPENDIX P: TEST EQUIPMENT

TABLE P:1 FOR MAMMOGRAPHY X-RAY EQUIPMENT:

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Features</th>
<th>Precision</th>
<th>Accuracy</th>
<th>Calibration</th>
</tr>
</thead>
<tbody>
<tr>
<td>kV meter</td>
<td>Suitable mammo</td>
<td>±0.1 kV</td>
<td>±1.0 kV</td>
<td>Biennially</td>
</tr>
<tr>
<td>Ion chamber or ss detector/ dosimeter</td>
<td>Suitable mammo</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exposure timer</td>
<td>Suitable mammo</td>
<td></td>
<td></td>
<td>Biennially</td>
</tr>
<tr>
<td>Aluminium sheets (HVL measurement)</td>
<td>99.5% purity or Type I 100 + correction</td>
<td>±0.01 mm thick</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 cm slit camera</td>
<td>NEMA spec</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High contract resolution pattern</td>
<td>16lp. mm⁻¹; 20 preferred</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Focal spot measurement jig</td>
<td>? made in-house</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnifier + graticule</td>
<td>0.2 mm div; x10 mag</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perspex blocks (for AEC tests)</td>
<td>10 or 20 mm blocks; total 80 mm thick</td>
<td>±1 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spot densitometer</td>
<td>Range = 3.0 OD</td>
<td>±0.01 OD (0-3 OD)</td>
<td>±0.02 OD (0-3 OD)</td>
<td>Annually³⁷</td>
</tr>
<tr>
<td>Image quality phantom/test object</td>
<td>As per RANZCR</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mammography film illuminator</td>
<td>&gt;3000 cd.m⁻²</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Personal computer system for analysis and reporting</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Light meter</td>
<td>Range &gt;3500 cd.m ²</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stereotactic localisation test object</td>
<td>Provided by BSA</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

65. APPENDIX Q: INTERVAL CANCER REVIEW PROCESS

OVERVIEW
The Interval Cancer Review Process is a two-step process aimed at ensuring quality of screen reading within the Programme.

Step 1. Monthly External Review by screen readers from another Lead Provider.
Step 2. Internal Review with the original screen readers.

DEFINITION OF INTERVAL CANCER
This is a cancer that is diagnosed between a negative screen and the time the next screen would have occurred. In BSA, 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 either a 'true interval' (one that cannot be detected in retrospect on screening mammograms), or a 'missed cancer' (one that was present at the previous screening, but was not detected). ‘Occult’ cancers are a subgroup of ‘true’ interval cancers, which are not detected by mammography at the time of subsequent diagnosis.

CLASSIFICATION OF INTERVAL CANCERS

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal audit</td>
<td>Screening films (originals), Diagnostic films and/or report.</td>
</tr>
<tr>
<td>Continual reader improvement</td>
<td></td>
</tr>
<tr>
<td>Identification of individual training requirements.</td>
<td></td>
</tr>
</tbody>
</table>

EXTERNAL REVIEW

Purpose
To classify films by independent peer review into MISS or NOT MISS categories.

Process
1. Each Lead Provider sends 10 original screening films monthly to another Lead Provider. These films may be all normal screening films, all intervals, or a mix. This ‘unknown’ mix ensures readers are less likely to be primed for a certain number of recalls.
2. Films are mounted on viewers duplicating the original reading conditions (i.e., if originally read with previous/old films, these are reviewed as well).
3. Three readers independently record a decision of Recall to Assessment or Return to Screen and document in the usual way (i.e. site, side, lesion type, number and category).
4. Classify original reading as MISS or NOT MISS from consensus of external readers. A consensus decision (two or more external readers) is created for each film reviewed. The consensus decision classifies the original reading as a MISS (Recall to Assessment) or NOT A MISS (Return to Screen).
5. All the films, along with the reader forms and consensus decision for each film, are sent back to the parent Lead Provider.

INTERNAL REVIEW

Purpose
To subclassify readings following External Review and record subject to external audit. Occurs with radiologists who originally read the films. Radiologists review screening films with diagnostic films.

Where External Review was ‘Return to Screen’
Subclassify as follows:
- Occult: If the cancer was not visible on diagnostic films, or the diagnostic film report said ‘normal’.
- True interval: If a new lesion was present on diagnostic film or mentioned in film report.

Minimal sign: If retrospectively, subtle signs on the screening mammogram are present at site of cancer on diagnostic films.

APPENDICES

37 By measurement of a calibration film.
NOTE: This is not a false negative, because to recall all similar lesions would risk elevating recall rates above targets with little gain.

**Unclassified**: Diagnostic films or report not available.

**Films where External Review was 'Recall to Assessment'**
Subclassify as follows:

**True Interval**: If new cancer was visible on diagnostic films and not in site of lesion on screening films for which assessment was recommended by external review.

**False negative**: If the cancer on diagnostic films corresponded to lesion site on screening films.

**Post Assessment Intervals**
(Developed interval cancer after negative assessment)
- These will be included in evaluation of 'programme sensitivity' and usually require review to identify inadequate assessment or pathology misreads. Any 'process' errors should lead to change of internal assessment protocols.
- However, where the subsequent cancer was at a different site to the lesion assessed, the films should proceed through the external review process as above to ensure this was not a screen-reading miss.

---

**FIGURE Q:1 SUBCLASSIFICATION OF INTERVAL CANCER**

1. **Cancer diagnosed <2 years after normal screening**
   - Confirm pathological diagnosis of breast cancer from surgical histopathology (refer next page)
   - **External blinded review of screening mammograms** (see page 49 for process)

2. **Internal review of mammogram at diagnosis**
   - **Abnormality detected**
     - **Unclassified films not available**
       - **Abnormality demonstrated**
         - **Informed review of screening mammograms**
           - **Abnormality visible in retrospect**
             - **Minimal signs**
             - **Occult**
             - **True interval**
           - **No abnormality demonstrated**
         - **New lesion in different site to external review abnormality**
         - **Cancer in different site to external review abnormality and not visible on diagnostic mammogram**
       - **No abnormality detected**
         - **Internal review of mammogram at diagnosis**
   - **No abnormality detected**

3. **Abnormality demonstrated**
   - **Internal review of mammogram at diagnosis**
   - **Informed review of screening mammograms**
   - **Abnormality visible in retrospect**
   - **Occult**
   - **False negative**
Ductal carcinoma in situ (DCIS) has various histological forms with differing growth patterns, nuclear morphology and natural history. There is currently no generally agreed classification of DCIS, but there are several classifications in use, all of which assess the same factors. It is important to record these factors both in an attempt to give prognostic information and to correlate with the radiological findings of a particular case.

A system of reporting pathology findings for pure ductal carcinoma in situ was developed by pathologists from throughout Australia at a consensus workshop held in March 1996 under the auspices of the Australian and New Zealand Breast Cancer Trials Group. This system was subsequently ratified by a multidisciplinary workshop. Both groups reached the consensus that no current classification system for ductal carcinoma in situ should be adopted. In preference, it was agreed that the following characteristics should be recorded for each case of pure ductal carcinoma in situ:

- size
- margins
- nuclear grade
- necrosis
- architecture
- calcification.

**MARGINS**

The distance from each margin should be stated in millimetres when <10 mm, and ‘>10 mm’ stated otherwise. If ductal carcinoma in situ is present at the margin, this should be reported, specifying the margin involved and stating the extent of margin involvement in millimetres.

The phrase ‘excision is complete’ is not recommended for use in reporting, because clear margins do not necessarily mean completeness of excision.

**NUCLEAR GRADE**

Nuclear grade should be reported as low, intermediate or high, based on the criteria advocated by Elston and Ellis for grading invasive carcinoma. The highest grade present in the biopsy should be reported.

**NECROSIS**

Two categories are recognised:
- necrosis not present or minimal (no central duct necrosis is present but focal necrosis and isolated apoptotic cells may be present)
- necrosis present (central necrosis is identified in ducts, i.e. comedo necrosis).

Specify the percentage of involved ducts in comedo necrosis. Some classification systems for ductal carcinoma in situ have used specific cut-off points for the percentage of ducts with comedo necrosis. The inclusion of this information will allow clinicians to apply these systems if necessary.

**ARCHITECTURE**

Many tumours show more than one type. These should be identified as:
- dominant pattern
- other pattern(s).

For both of these, the terms may include solid, cribriform, micropapillary and papillary.

---


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).

**APPENDIX S: BREAST CANCER SYNOPTIC REPORTS**

**S:1 PATHOLOGY SYNOPTIC FORM**

The following data is for use in a synoptic form that has been developed by the National Screening Unit in consultation with pathologists and other interested parties. The intent of the form is that it be used by pathologists for recording treatment data on screen and non-screen detected breast cancer.

The form includes ‘mandatory data’ which is all the pathology treatment data that is required to be collected on screen detected breast cancer for BreastScreen Aotearoa. This information is vital for monitoring the success of breast cancer screening in New Zealand. Data from patients with cancer detected through BreastScreen Aotearoa will be collected by data collectors and forwarded to the National Screening Unit for analysis. It is hoped that synoptic reporting will greatly 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 is forwarded to the Cancer Registry and used in calculating the interval cancer rate; hence, 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 toward 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 is designated ‘non-mandatory’. It is hoped that the form will not be altered significantly at the regional level, but it is acknowledged 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.

---

40 This mandatory data set has been recently revised and will be included in the latest version of the BreastScreen Aotearoa Data Management manual.
### APPENDICES

**BREAST CANCER SYNOPTIC DATA** (Form will be distributed)

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 (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.

**DATA**

<table>
<thead>
<tr>
<th>DATA</th>
<th>VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHI Number</td>
<td></td>
</tr>
<tr>
<td>Name</td>
<td></td>
</tr>
<tr>
<td>Date of birth</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td></td>
</tr>
<tr>
<td>Pathologist</td>
<td></td>
</tr>
<tr>
<td>Breast: L=Left R=Right</td>
<td></td>
</tr>
<tr>
<td>Source of pathology data:</td>
<td></td>
</tr>
<tr>
<td>1 = Cytology</td>
<td>5 = Open excision including excision biopsy</td>
</tr>
<tr>
<td>2 = Standard core</td>
<td>6 = Autopsy</td>
</tr>
<tr>
<td>3 = Large core / suction biopsy</td>
<td>U = not available/unknown/unsure</td>
</tr>
<tr>
<td>i = MammoSite, 6 = Abbr</td>
<td></td>
</tr>
<tr>
<td>Re-section: Y= Yes N= No</td>
<td></td>
</tr>
<tr>
<td>Histopathology of invasive lesion:</td>
<td></td>
</tr>
<tr>
<td>00 = No invasive component</td>
<td>08 = Mixed invasive ductal/lobular</td>
</tr>
<tr>
<td>01 = Invasive duct not otherwise specified</td>
<td>09 = Other invasive malignancy</td>
</tr>
<tr>
<td>02 = Invasive tubular (primary)</td>
<td>10 = Other invasive malignancy (secondary)</td>
</tr>
<tr>
<td>03 = Invasive lobular</td>
<td>11 = Invasive mucinous (colloid)</td>
</tr>
<tr>
<td>04 = Invasive medullary</td>
<td>12 = Invasive medullary U = Not available/unknown/unsure</td>
</tr>
<tr>
<td>05 = Invasive lobular classical</td>
<td>13 = Invasive lobular classical</td>
</tr>
<tr>
<td>06 = Invasive lobular variant</td>
<td>14 = Invasive lobular variant</td>
</tr>
<tr>
<td>07 = Invasive lobular variants 8 or 9 or 10=aplastic type in writing</td>
<td>01 = invasive duct not otherwise specified</td>
</tr>
<tr>
<td>DCS with microinvasion is classified as 01 = invasive duct not otherwise specified</td>
<td></td>
</tr>
</tbody>
</table>

**Histopathology of DCIS lesions:**

- 00 = No DCIS
- 14 = Lobular carcinoma in situ (LCIS)
- 11 = Low nuclear grade
- 19 = Other DCIS
- 12 = Intermediate nuclear grade U = Not available/unknown/unsure
- 13 = High nuclear grade

**Notes:**

- LCIS is not recorded unless it is in association with invasive disease.
- EIC: P= Positive N= Negative
- Ccalcification: P= Present A= Absent: Give size:
- Central duct necrosis: P= Present A= Absent
- Font: 56
- For invasive tumour record size of largest invasive lesion – refer to TNM 2002

**Diagnosis**

- Invasive component
- Entire lesion (invasive and DCIS component)

**Histopathology of invasive lesions:**

- 00 = No invasive component
- 01 = Invasive duct not otherwise specified
- 02 = Invasive tubular (primary)
- 03 = Invasive lobular
- 04 = Invasive mucinous (colloid)
- 05 = Invasive medullary
- 06 = Invasive lobular classical
- 07 = Invasive lobular variants
- 08 = Mixed invasive ductal/lobular
- 09 = Other invasive malignancy
- 10 = Other invasive malignancy (secondary)
- 11 = Invasive mucinous (colloid)
- 12 = Invasive medullary U = Not available/unknown/unsure
- 13 = Invasive lobular classical
- 14 = Lobular carcinoma in situ (LCIS)
- 15 = Low nuclear grade
- 16 = Intermediate nuclear grade
- 17 = High nuclear grade
- 18 = Other DCIS
- 19 = Other DCIS

**Notes:**

- LCIS is not recorded unless it is in association with invasive disease.
- EIC: P= Positive N= Negative
- Ccalcification: P= Present A= Absent: Give size:
- Central duct necrosis: P= Present A= Absent
- Font: 56
- For invasive tumour record size of largest invasive lesion – refer to TNM 2002

**Diagnosis**

- Invasive component
- Entire lesion (invasive and DCIS component)
### APPENDIX U: QUALITY DEVIATION APPLICATION TEMPLATE AND PROCESS

The National Policy and Quality Standards (NP&QS) determine the level and standards of service provided by the Lead Providers. In specific circumstances, where Lead Providers are unable to meet the NP&QS, a Quality Deviation would need to be sought from BSA.

The application for a Quality Deviation would document the request on the attached template, including the reason(s)/rationale for a Deviation, the relevant Standard, any additional information pertaining to the location, monitoring or supervisory mechanisms etc. that could be implemented to ensure quality standards are upheld, while the Deviation remained in force.

Timeliness of applications is an important requirement when Lead Providers apply for a Deviation. Adequate lead time of a minimum of eight weeks is required to ensure the process can be both initiated and completed by both Lead Providers and BSA.

| NSU to complete |
|-----------------|-----------------|
| 7. Date received by the NSU |  
| 8. Action undertaken by BSA |  
| 9. Clinical Leader, BSA |  
| Comment: | Date:  
| 10. Manager, BSA |  
| Comment: | Date:  
| 11. BSA Recommendation |  
| 12. Clinical Leader, BSA |  
| Sign Off: | Dr Madeleine Wall  
| Date: |  
| 13. Manager, BSA |  
| Sign Off: | Barbara Phillips  
| Date: |  

**Receipt of Quality Deviation request from Lead Provider**

<table>
<thead>
<tr>
<th>Acknowledgement of request received by BSA to Lead Provider</th>
<th>Within 5 working days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review of the request by BSA</td>
<td>Within 5 working days</td>
</tr>
<tr>
<td>Consultation Process/Request for additional information etc.</td>
<td>Within 15 working days</td>
</tr>
<tr>
<td>Final consideration by Manager BSA and Clinical Leader</td>
<td>Within 5 working days</td>
</tr>
<tr>
<td>Outcome communicated to Lead Provider</td>
<td>Within 5 working days</td>
</tr>
</tbody>
</table>
### APPENDIX V: ACCREDITATION PROTOCOLS

All radiologists/surgeons/pathologists intending to practise in the national breast screening programme, BreastScreen Aotearoa are required to have undergone an accreditation process which ensures that they are deemed meeting the programme's requirements.

1. The submission of a radiologist/surgeon/pathologist accreditation template to the Clinical Leader, BSA, where both the Lead Provider Clinical Director/Lead Surgeon/Lead Radiologist and radiologist/surgeon/pathologist have completed the relevant sections.

2. The allocation by BSA of a non-identifiable pseudonym, from the central register e.g. BSAN 5.

3. A review of the template by the Clinical Leader – for consistency, content etc., and if necessary additional information being sought.

Note: The pathologists have delegated responsibility to the Clinical Leader, BSA to make the decision 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/discussion.

4. Inclusion as an agenda item at the next radiologist/surgeon/pathologist Unidisciplinary Group (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 Leader 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 presentation of the radiologists/surgeons/pathologists UDG meeting, where it is subsequently discussed. During the teleconference or UDG each Clinical Director/Lead Surgeon/Lead pathologist will complete their own evaluation template.

6. Once agreement has been reached on the status of the application all documentation (e.g. template, evaluation template) is returned to the Clinical Leader, BSA, or destroyed.

7. A quorum of four radiologists/surgeons/pathologists (members of the UDG) is required to participate and the sponsoring Clinical Director is excluded from both the quorum and the final decision-making process.

8. Following the teleconference/UDG, a letter is sent to the Lead Provider/Clinical Director/Lead Surgeon/Lead pathologist and copied to the Lead Provider Manager concerning notifying them of the outcome related to their accreditation application.

---

#### V.1: RADIOLOGIST ACCREDITATION TO WORK IN THE BSA PROGRAMME

<table>
<thead>
<tr>
<th>Lead Provider</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Code Identifier</td>
<td></td>
</tr>
<tr>
<td>Pre-Employment Criteria [Statutory Requirements] (Clinical Director to confirm)</td>
<td></td>
</tr>
<tr>
<td>NZMC Registration</td>
<td></td>
</tr>
<tr>
<td>NRL Licence</td>
<td></td>
</tr>
<tr>
<td>Annual Practising Certificate</td>
<td></td>
</tr>
<tr>
<td>References/Performance Appraisal</td>
<td></td>
</tr>
<tr>
<td>Qualifications</td>
<td></td>
</tr>
<tr>
<td>Basic radiology qualifications e.g. FRACR. Where and when</td>
<td></td>
</tr>
<tr>
<td>Post-FRACR diploma When and where?</td>
<td></td>
</tr>
</tbody>
</table>

**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, e.g. observing/reading, involvement in MDT meetings and assessment
- Estimations of the volume of mammograms read e.g. weekly/monthly
### Pre-Entry Requirements
*(Clinical Director to complete)*

<table>
<thead>
<tr>
<th>Timing and results of a minimum of 300 Dummy reads</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recall Rate</td>
</tr>
<tr>
<td>Adequate sensitivity (from cancer seeded set)</td>
</tr>
</tbody>
</table>

### Observed/Competency

- Ultrasound
- Guided biopsy
- Sterotactic Core Biopsy
- Localisation for Open Biopsy

### Training and Experience

<table>
<thead>
<tr>
<th>Courses attended e.g. Tabar or RANZCR multidisciplinary meetings attended, and when</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional meetings/courses attended relevant to mammography</td>
</tr>
</tbody>
</table>

### BreastScreen Aotearoa

Please outline your current/planned involvement e.g. 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

### RADIOLOGIST ACCREDITATION TO WORK IN THE BSA PROGRAMME

**Panel Evaluation**

<table>
<thead>
<tr>
<th>Lead Provider Name/Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Employment Requirements</td>
</tr>
<tr>
<td>• NZ Qualifications</td>
</tr>
<tr>
<td>• Overseas Qualifications</td>
</tr>
<tr>
<td>• Requires NZ Registration</td>
</tr>
<tr>
<td>• APC</td>
</tr>
<tr>
<td>• NRL Licence</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pre-Entry Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Dummy Reads (300)</td>
</tr>
<tr>
<td>• Sensitivity</td>
</tr>
<tr>
<td>• Specificity</td>
</tr>
<tr>
<td>• Recall Rate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Training and Courses Attended</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Sufficient</td>
</tr>
<tr>
<td>• Borderline</td>
</tr>
<tr>
<td>• Insufficient</td>
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</table>

<table>
<thead>
<tr>
<th>Mammography Experience</th>
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</thead>
<tbody>
<tr>
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</tr>
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<td>• Borderline</td>
</tr>
<tr>
<td>• Insufficient</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Overall Grading</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Sufficient</td>
</tr>
<tr>
<td>• Borderline</td>
</tr>
<tr>
<td>• Insufficient</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Suitably Qualified</td>
</tr>
<tr>
<td>• Requiring a specific set of defined training activities</td>
</tr>
<tr>
<td>• Not eligible to practice as a principle</td>
</tr>
</tbody>
</table>

**For example:**

- May continue working in the programme
- Recommend working under supervision as a third reader for 3 to 6 months while completing courses
- Exposure to a major multidisciplinary course within 12 months
- Attendance at a Tabar course required
V:2 PATHOLOGIST ACCREDITATION TO WORK IN THE BSA PROGRAMME

<table>
<thead>
<tr>
<th>Lead Provider</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Code Identifier</td>
<td></td>
</tr>
<tr>
<td>Pre-Employment Criteria [Statutory Requirements] (Lead Pathologist to confirm)</td>
<td></td>
</tr>
<tr>
<td>NZMC Registration</td>
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<td>Annual Practising Certificate</td>
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<tr>
<td>References/Performance Appraisal</td>
<td></td>
</tr>
<tr>
<td>Qualifications</td>
<td></td>
</tr>
<tr>
<td>Basic pathology qualifications e.g. FRCP Where and when</td>
<td></td>
</tr>
<tr>
<td>Post FRCP Diploma When and where</td>
<td></td>
</tr>
<tr>
<td>Enrolled on the NZMC vocational register in anatomic or general Pathology.</td>
<td></td>
</tr>
<tr>
<td>Enrolment in the RCPA's Continuing Professional Development Programme [CPDP]</td>
<td></td>
</tr>
<tr>
<td>Enrolment in the RCPA Australasian Breast External Quality Assurance Scheme (ABEQAS).</td>
<td></td>
</tr>
</tbody>
</table>

Pathology experience with breast screening

- 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, e.g. involvement in MDT meetings
- Assessment – FNAC alone, core biopsy alone or combined FNAC and core biopsy count/volumes

Training and Experience

Courses attended, e.g. FRCP multidisciplinary meetings attended, and when

Additional meetings/courses attended relevant to breast pathology

BreastScreen Aotearoa

Please outline your current/planned involvement e.g. working with lead provider/subcontracted, working in one centre or more

General

Please make any other comments relating to breast pathology that are not summarised elsewhere Include Publications/Presentations
## SURGEONS ACCREDITATION TO WORK IN THE BSA PROGRAMME

<table>
<thead>
<tr>
<th>Lead Provider</th>
<th>Code Identifier</th>
</tr>
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<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

### Pre-Employment Criteria [Statutory Requirements]

<table>
<thead>
<tr>
<th>NZMC Registration</th>
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<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vocationally registered in General Surgery with NZMC</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Annual Practising Certificate</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Evidence of hospital credentialing</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>References/Performance Appraisal</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

### Qualifications (Applicant to complete)

- Basic surgery qualifications, e.g. FRACS.
- Where and when?
  - Post FRACS diploma
  - When and where?

### Surgical experience with breast screening

- Where worked
- Amount of time spent there
- Whether involved in screening or diagnostic
- Role in screening unit, e.g. MDT meetings and assessment
- Estimations of time spent dealing with breast surgery, e.g. weekly/monthly

## PATHOLOGIST ACCREDITATION TO WORK IN THE BSA PROGRAMME

<table>
<thead>
<tr>
<th>Panel Evaluation</th>
<th></th>
</tr>
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<tbody>
<tr>
<td>Lead Provider Name/Code</td>
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<tr>
<td>Pre-Employment Requirements</td>
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<td>• NZ Registration</td>
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<tr>
<td>• APC</td>
<td></td>
</tr>
<tr>
<td>• References</td>
<td></td>
</tr>
<tr>
<td>Qualifications</td>
<td></td>
</tr>
<tr>
<td>• NZ</td>
<td></td>
</tr>
<tr>
<td>• Overseas</td>
<td></td>
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<tr>
<td>• Vocational Enrolment</td>
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<td>• CPDP Enrolment</td>
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<tr>
<td>• ABEQAS Enrolment</td>
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<tr>
<td>Pathology Experience</td>
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<td>• Sufficient</td>
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<tr>
<td>• Insufficient</td>
<td></td>
</tr>
<tr>
<td>Training and Courses Attended</td>
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<td>• Borderline</td>
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<td>• Insufficient</td>
<td></td>
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<tr>
<td>Overall Grading</td>
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<td>• Sufficient</td>
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<td>• Borderline</td>
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<tr>
<td>• Insufficient</td>
<td></td>
</tr>
<tr>
<td>Recommendation</td>
<td></td>
</tr>
<tr>
<td>• Suitably Qualified</td>
<td></td>
</tr>
<tr>
<td>• Requiring a specific set of defined training activities</td>
<td></td>
</tr>
<tr>
<td>• Not eligible to practice as a principle</td>
<td></td>
</tr>
</tbody>
</table>

### For example – A specific set of activities

- May continue working in the programme
- Recommend working under supervision while completing courses
- Recommend exposure to a major multidisciplinary course within 12 months
### Surgeon Accreditation to Work in the BSA Programme

#### Panel Evaluation

<table>
<thead>
<tr>
<th>Pre-Employment Requirements</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>NZ Qualifications</td>
<td></td>
</tr>
<tr>
<td>Overseas Qualifications</td>
<td></td>
</tr>
<tr>
<td>Requires NZ Registration</td>
<td></td>
</tr>
<tr>
<td>APC</td>
<td></td>
</tr>
</tbody>
</table>

| 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 practice as a principle          |          |

| For example:                                      |          |
| May continue working in the programme             |          |
| Recommend working under supervision while completing courses |          |
| Exposure to a major multidisciplinary course within 12 months |          |

#### Lead Provider/Code Identifier

| Participation in a re-certification programme in general surgery |          |
| Courses attended, e.g. FRACS multidisciplinary meetings attended, and when |          |
| Additional meetings/courses attended relevant to breast surgery |          |
| CME requirements for re-certification – RACS Breast Section Audit |          |
| Participation in local and national breast screen audit with peer review |          |

<table>
<thead>
<tr>
<th>BreastScreen Aotearoa</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Please outline your current/planned involvement e.g. working with lead provider/subcontracted, working in one centre or more</td>
<td></td>
</tr>
</tbody>
</table>

| General               |          |
| Please make any other comments relating to breast surgery that are not summarised elsewhere include publications/presentations |          |
APPENDICES

71. APPENDIX W: FNAC QUALITY ASSURANCE

CYTOLOGY AND CORE BIOPSY PERFORMANCE

Suggested thresholds for cytology and core biopsy performance are shown in Tables W:I and W:II respectively. These figures will obviously depend on sampling techniques and the experience and care of the aspirator and will vary widely between units.

HOW TO INTERPRET THE RESULTS

The performance measures are interrelated, and strategy to improve one aspect of performance will affect others. Thus, an attempt to reduce the inadequate rate will often increase the number of suspicious results, attempts to improve the sensitivity are likely to increase the false positive rate, attempts to improve the specificity will increase the false negative rate, and so on. Also, attempts to reduce the benign biopsy rate by not biopsying the majority of lesions called benign on cytology will reduce the specificity where this is based on benign histology results rather than on all aspirated cases.

The most common problem encountered in the NHSBSP surveys appears to be low sensitivities combined with high false negative rates and high inadequate rates from lesions that subsequently turn out to be cancer. This combination of statistics suggests a problem with the accurate localisation of lesions for aspiration. A significant proportion of these lesions will have been palpable or thought to be palpable as an area of thickening. aspiration of these areas without radiological guidance may account for some of the problems. It is of interest to note that, in centres where cytology has not been as useful in non-operative diagnosis, there has been a swing towards the use of core biopsy, as is commonly reported in publications from the United States. Audit of core biopsy in the NHSBSP shows similar variability in practice. Some units are using the two techniques to complement each other and are achieving higher non-operative diagnosis rates in difficult cases. This can be especially useful in lobular and tubular carcinomas where cytology is less able to give an unequivocal diagnosis.

| Table W:I SUGGESTED THRESHOLDS FOR CYTOLOGY PERFORMANCE (WHERE THERAPY IS PARTIALLY BASED ON FNAC) |
| Minimum (%) | Preferred (%) | Current median (%) |
| Absolute sensitivity (AS) | >60 | >70 | 57.1 |
| Complete sensitivity (CS) | >80 | >90 | 81.5 |
| Specificity (full) (SPEC) (including non-biopsied cases) (as calculated above) | >55 | >65 | 58.4 |
| Positive predictive value (+PV) | >98 | >99 | 99.6 |
| False negative rate (F–) | <6 | <4 | 6.3 |
| False positive rate (F+) | <1 | <0.5 | 0.2 |
| Inadequate rate from cancers | <10 | <5 | 9.8 |
| Inadequate rate from lesions | <20 | <15 | 15.8 |

| Table W:II SUGGESTED THRESHOLDS FOR CORE BIOPSY PERFORMANCE |
| Minimum (%) | Preferred (%) | Current median (%) |
| Absolute sensitivity (AS) | >70 | >80 | 76.4 |
| Complete sensitivity (CS) | >80 | >90 | 84.5 |
| Specificity (full) (SPEC) (including non-biopsied cases) (as calculated above) | >75 | >85 | 81.2 |
| Positive predictive value (+PV) | >99 | >99.5 | 100 |
| False negative rate (F–) | <0.5 | <0.1 | 0 |
| Miss rate (B1 + B2) from cancer | <15 | <10% | 15.1 |
| Suspicious rate | <10 | <5 | 4.8 |

### 72. APPENDIX X: SCHEDULE OF UNI- AND MULTIDISCIPLINARY GROUP MEETINGS

**TABLE X:1 MEETING SCHEDULE**

<table>
<thead>
<tr>
<th>Meeting</th>
<th>Location</th>
<th>Standard</th>
<th>Required Attendees</th>
<th>Weekly</th>
<th>Fort-nightly</th>
<th>Monthly</th>
<th>Quarterly</th>
<th>Six Monthly</th>
<th>Annual</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Liaison meetings/phone or written contact</strong></td>
<td>Lead Provider site GP/PCP sites</td>
<td>14.1</td>
<td>Lead Provider GP liaison GP/PCPs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td><strong>Lead and Independent service provider coordination</strong></td>
<td>Lead Provider site ISP’s</td>
<td>14.3</td>
<td>Lead Provider Manager, Health Promoters, ISP’s</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Joint Planning Sessions</strong></td>
<td>Lead Provider site ISP’s</td>
<td>14.3</td>
<td>Lead Provider Manager Health Promoters, ISP’s</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td><strong>Management Multidisciplinary Team</strong></td>
<td>Lead Provider site</td>
<td>15.1</td>
<td>Lead Provider Manager Clinical Director, Data Manager, Lead MRT, Lead Clinicians, Health Promoter, Quality Coordinator</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td><strong>Management Multidisciplinary Team</strong></td>
<td>Subcontracted sites</td>
<td>15.1</td>
<td>Subcontracted Provider MRTs, Clinicians and Manager</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td><strong>Review films for technical quality</strong></td>
<td>Lead Provider site</td>
<td>23.11</td>
<td>MRTs, Designated Radiologist/ Clinical Director</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Clinical Multidisciplinary Team</strong></td>
<td>Lead Provider Assessment sites</td>
<td>26.1</td>
<td>Clinical MDT**</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Clinical Multidisciplinary Team</strong></td>
<td>Subcontracted Assessment sites</td>
<td>34.1</td>
<td>Clinical Director Clinical MDT**</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Meeting** | **Location** | **Standard** | **Required Attendees** | **Weekly** | **Fort-nightly** | **Monthly** | **Quarterly** | **Six Monthly** | **Annual** |
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Regional radiologists Meeting</strong></td>
<td>Lead Provider Region</td>
<td>34.1</td>
<td>Lead Radiologist Regional BSA radiologists</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td><strong>Regional MQA Committee: Review of all sites QA results</strong></td>
<td>Lead Provider Region</td>
<td>34.1</td>
<td>Lead Radiologist Lead MRT Medical Physicist***</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td><strong>Regional Pathology Meeting</strong></td>
<td>Lead Provider Region</td>
<td>35.1</td>
<td>Lead Pathologist Regional BSA pathologists</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td><strong>Regional Surgical Meeting</strong></td>
<td>Lead Provider Region</td>
<td>36.1</td>
<td>Lead Surgeon Regional BSA surgeons</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td><strong>Site visits (could coincide with Clinical MDT at assessment sites)</strong></td>
<td>Lead Provider Region</td>
<td>33.1</td>
<td>Clinical Director</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td><strong>Site visits</strong></td>
<td>Lead Provider Region</td>
<td>37.2</td>
<td>Lead MRT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td><strong>Site visits (could coincide with Management MDT)</strong></td>
<td>Lead Provider Region</td>
<td>38.1</td>
<td>Lead Provider Manager</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td><strong>MQA Committee QA Programme Review</strong></td>
<td>Screening or Assessment sites</td>
<td>34.2</td>
<td>Medical Physicist/ Designated Radiologist</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td><strong>UniDisciplinary Meetings</strong></td>
<td>National</td>
<td>All Professional Groups</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

* May be an extension of the Clinical Multidisciplinary Team Meeting.

** Attendance requirements are outlined in Section 4: Professional Requirements.

*** The Medical Physicist must be involved, either with a presence at the meeting, by phone or at the planning stage.
APPENDICES

73. APPENDIX Y: FUNNEL PLOTS

FUNNEL PLOTS

The proportion of cancers detected in a screening programme is dependent on the background incidence of breast cancer, the proportion of women screened in the programme, the screening interval (for second or subsequent screening) and the sensitivity of the screening process.

The following targets and 95% credible intervals have been calculated from the background incidence of breast cancer in NZ women aged 50-64 in the absence of screening, and take into account the expected increased in cancers over the next (3-5) years. (Paul et al)

PURPOSE

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% credible 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% credible 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.

Eg. For incident (subsequent screen) cancers detected in a 6 month period of 27 from 8700 screened women:

Rate 27/8700 x 10,000 = 31.0

Use the funnel plot for incident (subsequent 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.

TABLE XII: MEETING GROUPS

<table>
<thead>
<tr>
<th>Clinical MDT</th>
<th>Management MDT+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead Provider Manager</td>
<td>Lead Clinicians</td>
</tr>
<tr>
<td>Clinical Directors</td>
<td>Data Manager</td>
</tr>
<tr>
<td>Pathologists (reading and assessing)</td>
<td>Lead Clinician</td>
</tr>
<tr>
<td>Breastcare nurses</td>
<td>Radiologists</td>
</tr>
<tr>
<td>Pathologists (reporting both FNAC and core biopsy)</td>
<td>MRTs</td>
</tr>
<tr>
<td>Surgeons</td>
<td>Breastcare nurses</td>
</tr>
<tr>
<td>Other professionals as appropriate</td>
<td>Data Managers</td>
</tr>
<tr>
<td>Treatment Data Collectors</td>
<td>Medical Physics</td>
</tr>
<tr>
<td>Medical Promoters</td>
<td>Others working in the Programme as appropriate</td>
</tr>
</tbody>
</table>

* These may be annual 2-day meetings (e.g., Physicists) or be convened more frequently for some groups (e.g., HP Managers and Clinical Directors) and may be either face to face or as a teleconference.

** All mandated team members shall attend at least 60 percent of management MDT meetings. Team members must nominate a delegate to attend on their behalf if they are unable to attend.

Other professionals as appropriate include surgeons, Clinical Co-ordinator, breastcare nurses, pathologists, Health Promotion representative, and any other professionals working in the Programme as appropriate.
**Small Invasive Cancers** detected on first (prevalent) screen (<=10mm)

**Small Invasive Cancers** detected on subsequent (incident) screen (<=10mm)

![Graph showing cases detected per 10,000 screens vs. number of screens for small invasive cancers.](image)

- **Target Rate**
- **95% Bounds for credible interval**

**Cases detected per 10,000 screens**

- 0
- 5
- 10
- 15
- 20
- 25
- 30
- 35
- 40
- 45
- 50
- 55
- 60
- 65
- 70
- 75
- 80
- 85
- 90
- 95
- 100
- 105
- 110
- 115
- 120
- 125
- 130
- 135
- 140
- 145
- 150
- 155
- 160
- 165

**Number of Screens**

- 0
- 500
- 1000
- 1500
- 2000
- 2500
- 3000
- 3500
- 4000
- 4500
- 5000
- 5500
- 6000
- 6500
- 7000
- 7500
- 8000
- 8500
- 9000
- 9500
- 10000
- 10500
- 11000
- 11500
- 12000
- 12500
- 13000
- 13500
- 14000
- 14500
- 15000
- 15500
- 16000
- 16500
74. APPENDIX Z: QUALITY INDICATORS, EVALUATION PROCESS AND EVALUATION TARGETS

<table>
<thead>
<tr>
<th>Quality Indicator</th>
<th>Evaluation Process</th>
<th>Evaluation Target</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Standard 1. Well Women-Centred Services</strong>&lt;br&gt;The entire screening pathway and all other activities provided within BreastScreen Aotearoa have a key focus on women and their needs (as they relate to breast screening) to ensure each woman has confidence in the Programme.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>1.1 WELL WOMEN-CENTRED SERVICES</strong>&lt;br&gt;BreastScreen Aotearoa Providers have a commitment to work collaboratively with women; women’s groups or community organisations or with women and their representatives to ensure the Programme is well women-centred and reflects the particular issues relevant to the screening of asymptomatic women.</td>
<td>1. Satisfaction surveys.&lt;br&gt;2. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.</td>
<td>1. 95% of women surveyed report that the overall service they received is women centred and meets their needs.&lt;br&gt;2. All other criteria are met.</td>
</tr>
<tr>
<td><strong>1.2 WELL WOMEN-CENTRED SERVICES – BREASTSCREEN AOTEAROA PRIORITY GROUPS</strong>&lt;br&gt;BreastScreen Aotearoa Providers have a commitment to maximise coverage and participation of the women from the BreastScreen Aotearoa Priority Groups from invitation to screening and re-screening through to possible assessment and/or treatment.</td>
<td>The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.</td>
<td>All criteria are met.</td>
</tr>
</tbody>
</table>
### Cultural Appropriateness

1. **Cultural Appropriateness – Treaty of Waitangi**
   - Staff practice reflects knowledge of the principles and Articles of the Treaty of Waitangi and applicability to the services provided.
   - Satisfaction surveys
   - Specific feedback from Māori women
   - Formal cultural evaluation of the service, for example, an external cultural audit
   - Partnership with Iwi and Māori to establish appropriate monitoring and evaluation processes.
   - The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

   - 95% of Māori women surveyed report that their cultural needs were addressed in a manner that was culturally appropriate.
   - All other criteria are met.

2. **Cultural Appropriateness – Te Whare Tapa Wha**
   - Staff recognise the philosophy of Te Whare Tapa Wha in their practice.
   - Satisfaction surveys
   - Specific feedback from Māori women
   - Formal cultural evaluation of the service, for example, an external cultural audit
   - Partnership with Iwi and Māori to establish appropriate monitoring and evaluation processes.
   - The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

   - 95% of Māori women surveyed report that their cultural needs were addressed in a manner that was culturally appropriate.
   - All other criteria are met.

3. **Cultural Appropriateness – Individual Cultural Needs**
   - The individual cultural needs of each woman and her family during each stage of the Programme are recognised and relevant cultural advice and/or guidance is sought to ensure both the practice and maintenance of cultural appropriateness.
   - Satisfaction surveys
   - Formal cultural evaluation of the service, for example, an external cultural audit
   - The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

   - 95% of women surveyed report that their cultural needs were addressed in a manner that was culturally appropriate.
   - All other criteria are met.

4. **Cultural Appropriateness – Pacific Women**
   - The individual cultural needs of each Pacific woman and her family during each stage of the Programme are recognised and relevant cultural advice and/or guidance is sought to ensure both the practice and maintenance of cultural appropriateness.
   - Satisfaction surveys
   - Formal cultural evaluation of the service, for example, an external cultural audit
   - The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

   - 95% of Pacific women surveyed report that their cultural needs were addressed in a manner that was culturally appropriate.
   - All other criteria are met.
### Standard 4. Access to the Programme

There is acceptable access to BreastScreen Aotearoa services for all eligible women.

<table>
<thead>
<tr>
<th>Quality Indicator</th>
<th>Evaluation Process</th>
<th>Evaluation Target</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>4.1 ACCESS TO THE PROGRAMME</strong></td>
<td>Each woman in the eligible age group has access to BreastScreen Aotearoa services.</td>
<td>1. Information is collected through the National Minimum Data Set for monitoring and evaluation purposes (Refer: Current DMM). 2. Review of the provision of access to the Programme and related information, prior to a decision being made to change the configuration, Mobile routes or location of fixed sites. 3. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.</td>
</tr>
</tbody>
</table>

### Standard 5. Consent

Each woman is able to make informed choices about having a screening mammogram and further assessment, if necessary, based on full and accurate information, and informed consent practices comply with the requirements of The Code of Health and Disability Services Consumers’ Rights.

<table>
<thead>
<tr>
<th>Quality Indicator</th>
<th>Evaluation Process</th>
<th>Evaluation Target</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5.1 CONSENT</strong></td>
<td>Each woman is appropriately informed through the use of effective information and communication, enabling her to make an informed choice and provide informed consent where it is required.</td>
<td>1. Satisfaction surveys. 2. Monthly auditing of clinical records for women screened in the previous month at each screening unit. 3. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.</td>
</tr>
</tbody>
</table>
### Standard 6. Support/Advocacy
Each woman’s right to have support persons and/or advocates present is recognised and upheld.

<table>
<thead>
<tr>
<th>Quality Indicator</th>
<th>Evaluation Process</th>
<th>Evaluation Target</th>
</tr>
</thead>
</table>
| **6.1 RIGHTS**    | Providers respect the woman’s right to a support person or advocate being present. | 1. Satisfaction surveys.  
2. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.  
3. 95% of women surveyed, who chose to have a support person or advocate with them, report that they were encouraged to bring a support person, and that they were made to feel welcome.  
4. All other criteria are met. |

### Standard 7. Personal Privacy
The personal privacy and practices at all BreastScreen Aotearoa facilities provide personal privacy for all women participating in the Programme.

<table>
<thead>
<tr>
<th>Quality Indicator</th>
<th>Evaluation Process</th>
<th>Evaluation Target</th>
</tr>
</thead>
</table>
| **7.1 PRIVACY INDICATOR** | The personal privacy of each woman receiving services is respected at all times. | 1. Satisfaction surveys.  
2. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.  
3. 95% of women surveyed report that their privacy was respected.  
4. All other criteria are met. |

### Standard 8. Complaint Management
The right of each woman to complain, if dissatisfied with the service, is upheld by BreastScreen Aotearoa staff.

<table>
<thead>
<tr>
<th>Quality Indicator</th>
<th>Evaluation Process</th>
<th>Evaluation Target</th>
</tr>
</thead>
</table>
| **8.1 COMPLAINT MANAGEMENT** | A clearly documented and accessible process for the identification, management and resolution of complaints. | 1. Satisfaction surveys.  
2. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.  
3. 95% of women participating in the Programme surveyed have received detailed information of the complaint process.  
4. 100% of complaints are managed in accordance with the service's specified policy and timeframes.  
5. All other criteria are met. |

### Standard 9. Information Privacy
Individual clinical records are unique to each woman, protected from unauthorised access and treated confidentially.

<table>
<thead>
<tr>
<th>Quality Indicator</th>
<th>Evaluation Process</th>
<th>Evaluation Target</th>
</tr>
</thead>
</table>
| **9.1 INFORMATION PRIVACY** | All staff ensure that the confidentiality and privacy of information is ensured and maintained. | The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.  
All criteria are met. |

### Standard 10. Clinical Record
Each woman’s clinical record provides an accurate record of services received and is readily accessible to the relevant clinicians.

<table>
<thead>
<tr>
<th>Quality Indicator</th>
<th>Evaluation Process</th>
<th>Evaluation Target</th>
</tr>
</thead>
</table>
| **10.1 CLINICAL RECORD KEEPING** | Each woman’s clinical records (including films, slides and reports) are accurate, accessible, authorised and complete. | 1. Monthly auditing of clinical records for women screened during the previous month at each screening and assessment site. (The may occur in conjunction with the Data Quality Plan requirements).  
2. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.  
3. 100% of records audited are complete and accurate.  
4. All other criteria are met. |
| **10.2 CLINICAL RECORD MANAGEMENT** | Each woman’s clinical records (including films, slides and reports) are appropriately referenced, kept secure, tracked and readily accessible. | 1. Monthly auditing of clinical records for women screened during the previous month at each screening and assessment site. (The may occur in conjunction with the Data Quality Plan requirements).  
2. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.  
3. 100% of hard copy clinical records audited are referenced, secured, tracked and readily accessible.  
4. All other criteria are met. |
### Standard 12. Quality Management Systems

The BreastScreen Aotearoa Provider has an established, quality and risk management system that reflects continuous quality improvement principles.

<table>
<thead>
<tr>
<th>Quality Indicator</th>
<th>Evaluation Process</th>
<th>Evaluation Target</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>12.1 DATA MANAGEMENT – ELECTRONIC CLINICAL INFORMATION SYSTEM</strong> The clinical information system complies with legislative requirements, Government policy on health information, and new policy principles where appropriate.</td>
<td>The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.</td>
<td>All criteria are met.</td>
</tr>
<tr>
<td><strong>12.2 DATA MANAGEMENT – DATA COLLECTION AND MONITORING</strong> Sufficient data are collected to enable BreastScreen Aotearoa Providers to operate at the highest standard and to undertake/participate in evaluation at both a regional and national level.</td>
<td>The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.</td>
<td>All criteria are met.</td>
</tr>
<tr>
<td><strong>12.3 DATA MANAGEMENT – DATA INTEGRITY</strong> The BreastScreen Aotearoa Provider will ensure that captured data is accurate and complete before use.</td>
<td>1. Monthly auditing of clinical records for women screened during the previous month at each screening and assessment site. (This may occur in conjunction with the Data Quality Plan requirements). 2. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.</td>
<td>1. 100% of records audited were entered correctly into the system. 2. All criteria are met.</td>
</tr>
<tr>
<td><strong>12.4 DATA MANAGEMENT – RELEASE OF DATA</strong> The BreastScreen Aotearoa Provider will ensure that women’s personal information and data about women is used in a way that is consistent with BSA overall purpose and goals, protects the interests and privacy of women involved in the Programme, whilst complying with health information and privacy legislation.</td>
<td>The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.</td>
<td>All criteria are met.</td>
</tr>
</tbody>
</table>

### Standard 13. Adverse/Sentinel Events Reporting

There is a robust process for adverse/sentinel event management, which is linked to the Continuous Quality Improvement (CQI) process to ensure the safety of women, staff and others is protected.

<table>
<thead>
<tr>
<th>Quality Indicator</th>
<th>Evaluation Process</th>
<th>Evaluation Target</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>13.1 ADVERSE/SENTINEL EVENTS REPORTING</strong> The Provider systematically records all adverse/sentinel, unplanned or untoward events.</td>
<td>The internal audit process confirms that the adverse/sentinel events reporting system is available and complied with.</td>
<td>All criteria are met.</td>
</tr>
</tbody>
</table>
**Standard 15. Programme Management and Official Requirements**
The BreastScreen Aotearoa programme is effectively and efficiently managed by each Provider and ensures a high level of public confidence.

<table>
<thead>
<tr>
<th>Quality Indicator</th>
<th>Evaluation Process</th>
<th>Evaluation Target</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>15.1 PROGRAMME MANAGEMENT</strong></td>
<td>The day-to-day operation of the service is managed in an efficient and effective manner which ensures the provision of timely, appropriate and safe services to all women.</td>
<td>All criteria are met.</td>
</tr>
<tr>
<td><strong>15.2 LEGISLATIVE REQUIREMENTS</strong></td>
<td>The day-to-day operation of the Programme complies with the principles and detail of relevant legislation.</td>
<td>All criteria are met.</td>
</tr>
<tr>
<td><strong>15.3 STANDARDS</strong></td>
<td>The BreastScreen Aotearoa Provider utilises relevant Standards as guidelines for evidence informed practice.</td>
<td>All criteria are met.</td>
</tr>
</tbody>
</table>

**Standard 16. Human Resource Management**
Processes and systems ensure that human resource management complies with good employment practice and legislation.

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<tr>
<th>Quality Indicator</th>
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<th>Evaluation Target</th>
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<tbody>
<tr>
<td><strong>16.1 HUMAN RESOURCE MANAGEMENT</strong></td>
<td>Human resource management processes are conducted in accordance with good employment practice and meet the legislative requirements.</td>
<td>All criteria are met.</td>
</tr>
</tbody>
</table>
Standard 20. Health Promotion
Health promotion activities are planned and delivered within recognised public health population-based promotional frameworks. This will ensure maximum participation based on evidence-informed strategies to increase awareness and informed choice.

### 20.1 HEALTH PROMOTION – OBJECTIVES
Health promotion plans and strategies support the overall objectives of BreastScreen Aotearoa in the reduction of illness, disability and death from breast cancer and meet the key health promotion objectives.

**Evaluation Process:**
- 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:**
- All criteria are met.

### 20.2 HEALTH PROMOTION MANAGEMENT
Effective health promotion management ensures the implementation of appropriate health promotion principles and practices through the development and support of those involved in health promotion.

**Evaluation Process:**
- 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:**
- All criteria are met.

### 20.3 HEALTH PROMOTION MANAGEMENT – GENERAL REQUIREMENTS
Health promotion strategies are aligned with the Public Health Services Handbook and the National Health Promotion Strategy for BreastScreen Aotearoa.

**Evaluation Process:**
- 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:**
- All criteria are met.

### 20.4 INVITATION – ELIGIBILITY OF WOMEN
Only eligible women are invited to participate in BreastScreen Aotearoa.

**Evaluation Process:**
- 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:**
- All criteria are met.
21.1 ENTERING THE PROGRAMME – APPOINTMENT MAKING

All eligible women will receive an appropriate invitation to attend an appointment with BreastScreen Aotearoa. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

All criteria are met.

21.2 ENTERING THE PROGRAMME – SPECIAL NEEDS

Information relating to special needs is obtained prior to the finalising of an appointment for a woman. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

All criteria are met.

21.3 ENTERING THE PROGRAMME – SIGNIFICANT SYMPTOMS PRIOR TO ATTENDANCE

Women who indicate current symptoms, that have not previously been investigated, prior to attendance at screening, shall be advised to see their GP/PCP for a consultation. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

All criteria are met.

---

22.1 FIRST IMPRESSIONS – FIRST POINT OF ENTRY

Telephone and reception staff demonstrate effective communication and listening skills, and respond in a professional manner. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

1. Satisfaction surveys.
2. 95% of women surveyed find the reception and booking staff professional, caring and helpful.
3. All other criteria are met.
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<tr>
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<th>Evaluation Process</th>
<th>Evaluation Target</th>
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<tbody>
<tr>
<td><strong>Standard 23. Screening</strong></td>
<td>The screening service is well women-centred and produces timely, reliable and high quality results.</td>
<td></td>
</tr>
</tbody>
</table>

### 23.1 SCREENING – WAITING TIMES
The screening unit processes ensure that women are not kept waiting unnecessarily.

1. Satisfaction surveys.
2. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.
3. 95% of women surveyed report that they did not wait unnecessarily.
4. All other criteria are met.

### 23.2 SCREENING – BREAST HISTORY
Each woman shall have a specified breast history recorded, and this information will be made available to the reading radiologist.

1. Monthly auditing of clinical records for women screened during the previous month at each screening unit. (This may be undertaken in conjunction with the Data Management Manual requirements).
2. 100% of women who comply shall have the specified breast history recorded so that it is readily available to the reading radiologist.
3. All other criteria are met.

### 23.3 SCREENING – EXPLANATION OF PROCEDURE
Each woman receives a full explanation of the procedure before commencement of her screen.

1. Satisfaction surveys.
2. 95% of women surveyed report finding the mammogram process acceptable, which encourages her return for subsequent re-screening.

### 23.4 SCREENING – MRT COMMUNICATION SKILLS AND RAPPORT
Each woman finds the mammogram process reassuring, caring and helpful.

1. Satisfaction surveys.
2. 95% of women surveyed report finding the MRT reassuring, caring and helpful.

### 23.5 SIGNS AND SYMPTOMS AT SCREENING
Women who present to a screening appointment with signs and symptoms shall have their mammogram performed, but will be appropriately referred for symptom management of screening outcome.

1. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.
2. All criteria are met.

### 23.6 SCREENING – ROUTINE VIEWS PERFORMED
All screening examinations shall be comprehensive and complete with unnecessary exposure to radiation kept to a minimum.

1. The MRT monthly peer review process will review films for completeness. (Refer: Section 4, Professional Requirements: Medical Radiation Technologist and Appendix N: Mammographic Image Quality (MIQ) Classification.)
2. Monthly auditing of clinical records for women screened during the previous month at each screening unit. (This may occur in conjunction with the Data Management Manual requirements).
3. Information is collected through the National Minimum Data Set for monitoring and evaluation purposes (Refer: Current DMM).
4. 100% of all screening examinations are comprehensive and complete according to MIQ Classification. (Refer: Appendix N: Mammographic Image Quality (MIQ) Classification.)
5. >80% of women screened have four films or less.
6. All other criteria are met.

### 23.7 SCREENING – SPECIAL IMAGING PROTOCOLS
Specific imaging protocols are used within screening units for women who have large breasts, breast implants, had a mastectomy, breast conservation surgery or are at high risk.

1. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.
2. All criteria are met.

### 23.8 SCREENING – FILM IDENTIFICATION LABELLING
Each mammographic image shall have the following information on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures.

1. Monthly auditing of clinical records for women screened during the previous month at each screening unit.
2. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.
3. 100% of films are correctly labelled.
4. All other criteria are met.
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<tr>
<th>Quality Indicator</th>
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<tbody>
<tr>
<td><strong>23.9 SCREENING – FILM PROCESSING</strong></td>
<td>Film quality is not compromised as a result of delays in film processing.</td>
<td>All criteria are met.</td>
</tr>
<tr>
<td><strong>23.10 SCREENING – MAMMOGRAPHIC FILM</strong></td>
<td>Mean film optical density is maintained between 1.6 – 1.8 in order to optimise the detection of small cancers and minimise radiation dose.</td>
<td></td>
</tr>
<tr>
<td><strong>23.11 SCREENING – HIGH QUALITY RADIOPHASIC TECHNIQUE</strong></td>
<td>All screen detectable breast cancers are shown on the mammogram which should include as much breast tissue on the plate as possible.</td>
<td></td>
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<tr>
<td><strong>23.12 SCREENING – MAMMOGRAPHIC QUALITY ASSURANCE (MQA)</strong></td>
<td>A Mammographic Quality Assurance (MQA) programme shall be complied with to ensure high quality mammographic imaging.</td>
<td></td>
</tr>
<tr>
<td><strong>23.13 SCREENING – READING THE SCREENING MAMMOGRAM</strong></td>
<td>The reading of the screening mammogram shall occur in such a manner as to maximise detection of any mammographic abnormality that could be cancer.</td>
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</table>

**Radiologist Specific Targets**

Individual radiologists’ reading statistics shall 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
### Quality Indicator Evaluation Process Evaluation Target

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<tr>
<th>Quality Indicator</th>
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<tbody>
<tr>
<td>Programme Evaluation Targets</td>
<td>In addition to the above evaluation of the Programme will include:</td>
<td></td>
</tr>
<tr>
<td>4. Cancer detection rate (including DCIS) per 10,000 women screened:</td>
<td>Initial (Prevalent) Screening Examination ( \geq 3 \times ) the background incidence ( = 69.0 )</td>
<td></td>
</tr>
<tr>
<td>5. Small invasive screen-detected cancers ( (\leq 10 \text{ mm}) ) per 10,000 women screened:</td>
<td>Initial (Prevalent) Screening Examination ( \geq 25% ) (of invasive cancers) ( = 17.3 )</td>
<td></td>
</tr>
<tr>
<td>6. Small invasive screen-detected cancers ( (&lt;15 \text{ mm}) ) per 10,000 women screened:</td>
<td>Initial (Prevalent) Screening Examination ( &gt; 50% ) (of invasive cancers) ( = 34.5 )</td>
<td></td>
</tr>
<tr>
<td>7. Node-negative invasive screen-detected cancers: Initial (Prevalent) Screening Examination ( &gt; 70% ) (of invasive cancers)</td>
<td>Subsequent (Incident) Screening Examination ( &gt; 75% ) (of invasive cancers) ( = 17.3 )</td>
<td></td>
</tr>
<tr>
<td>8. Ductal carcinoma in situ (DCIS) (of all cancers detected by the programme) ( &gt; 10% - 25% )</td>
<td></td>
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<tr>
<td>9. Interval cancers (including DCIS):</td>
<td>Per 10,000 women screened within one calendar year of previous screen ( &lt; 6.9 )</td>
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</table>

#### 23.14 SCREENING – FILM ACCESSIBILITY

BreastScreen Aotearoa retains ownership of all original mammogram films taken within the Programme.

The internal audit process ensures the criteria are complied with and identified shortfalls are addressed through the Continuous Quality Improvement (CQI) process.

All criteria are met.

### Standard 24. Outcome of Screening

Women are followed up appropriately to ensure they either return to routine re-screening or are recalled to assessment.

#### 24.1 OUTCOME OF SCREENING – NOTIFICATION OF RESULTS OR RECALL

Each woman receives timely and accurate notification of her results.

1. Regular reports, which identify women who are outside the target parameters, shall be generated and reviewed by the Clinical Director and Lead Provider Manager or a designated individual.
2. Information is collected through the National Minimum Data Set for monitoring and evaluation purposes. (Refer: Current DMM)
3. The internal audit process ensures the criteria are complied with and identified shortfalls are addressed through the Continuous Quality Improvement (CQI) process.

1. Films must be read promptly enough so that \( > 90 - 95\% \) of women can be notified within 10 working days of the screening mammogram.
2. All other criteria are met.
## 24.2 Outcome of Screening – Routine Re-screening

Each woman eligible for routine re-screening is invited back to the programme in an appropriate timeframe.

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<tr>
<th>Quality Indicator</th>
<th>Evaluation Process</th>
<th>Evaluation Target</th>
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</table>
| 24.2 Outcome of Screening – Routine Re-screening | 1. Regular reports shall be generated and reviewed by the Lead Provider Manager to ensure scheduling enables women to be screened within the targets and timeframes.  
2. Information is collected through the National Minimum Data Set for monitoring and evaluation purposes (Refer: Current DMM).  
3. The internal audit process ensures the criteria are complied with and identified shortfalls are addressed through the Continuous Quality Improvement (CQI) process. | 1. > 75% of women who return for a screen are re-screened between 20 and 24 months from their previous screen.  
2. > 85% of women screened in a Programme round are subsequently (if eligible) re-screened in the next Programme round.  
3. All other criteria are met. |

## 24.3 Outcome of Screening – Recall to Assessment

All women with mammographic abnormalities that may be malignant are recalled to assessment.

<table>
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<tr>
<th>Quality Indicator</th>
<th>Evaluation Process</th>
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</table>
| 24.3 Outcome of Screening – Recall to Assessment | 1. Reports that identify women who are to be recalled for assessment shall be generated regularly and are reviewed by the Lead Provider Manager, Clinical Director or a designated individual and retained for future audit activities.  
2. Information is collected through the National Minimum Data Set for monitoring and evaluation purposes (Refer: Current DMM).  
3. The internal audit process ensures the criteria are complied with and identified shortfalls are addressed through the Continuous Quality Improvement (CQI) process. | 1. 90% of women are offered an assessment appointment within 15 working days of their final screening mammogram.  
2. All other criteria are met. |

## 24.4 Outcome of Screening – Failure or Refusal to Attend Assessment

The BreastScreen Aotearoa Provider ensures timely and appropriate follow-up when a woman fails or refuses to attend for assessment.

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<tr>
<th>Quality Indicator</th>
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<th>Evaluation Target</th>
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</thead>
<tbody>
<tr>
<td>24.4 Outcome of Screening – Failure or Refusal to Attend Assessment</td>
<td>1. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.</td>
<td>All criteria are met.</td>
</tr>
</tbody>
</table>
### Standard 26. Multidisciplinary Management

Each stage of the programme is co-ordinated in a manner that promotes a multidisciplinary team approach where appropriate.

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<thead>
<tr>
<th>Quality Indicator</th>
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<tbody>
<tr>
<td><strong>26.1 MULTI-DISCIPLINARY TEAM – CLINICAL</strong></td>
<td>A close, co-operative working relationship between all staff involved in the Programme ensures an effective multidisciplinary approach to care.</td>
<td>All criteria are met.</td>
</tr>
</tbody>
</table>

1. A register of minutes for all these meetings is held, including attendees.
2. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

### Standard 27. Level 1 Assessment

Women with abnormal screening mammograms who do not have a screen detected lesion requiring biopsy diagnosis are returned to routine re-screening.

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<tr>
<th>Quality Indicator</th>
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</thead>
<tbody>
<tr>
<td><strong>27.1 LEVEL 1 ASSESSMENT – IMAGING THE BREAST AT ASSESSMENT</strong></td>
<td>The radiologist must be able to prove a lesion is benign or confirm a malignancy while keeping invasive procedures for benign abnormalities to a minimum. The aim therefore is to increase specificity without compromising sensitivity.</td>
<td>All criteria are met.</td>
</tr>
</tbody>
</table>

1. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.

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<tr>
<th>Quality Indicator</th>
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<th>Evaluation Target</th>
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<tbody>
<tr>
<td><strong>27.2 LEVEL 1 ASSESSMENT – GRADING OF LESIONS</strong></td>
<td>At the completion of Level 1 Assessment a radiological category will be assigned to all lesions assessed.</td>
<td>All criteria are met.</td>
</tr>
</tbody>
</table>

1. 100% of radiological specialised diagnostic techniques are performed by staff competent in the procedure and are reviewed by another radiologist.
2. All other criteria are met.

### Standard 28. Level 2 Assessment – Non-Operative Diagnosis

The non-operative diagnosis of screen detected abnormalities is maximised by obtaining accurate needle biopsy specimens of palpable and impalpable lesions.

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<tr>
<th>Quality Indicator</th>
<th>Evaluation Process</th>
<th>Evaluation Target</th>
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</thead>
<tbody>
<tr>
<td><strong>28.1 LEVEL 2 ASSESSMENT – MINIMISING DELAY TO NEEDLE BIOPSY</strong></td>
<td>The delay between the decision to perform a needle biopsy and it being undertaken should be minimised.</td>
<td>All criteria are met.</td>
</tr>
</tbody>
</table>

1. Regular reports which identify women who are to be recalled for needle biopsies are reviewed by the Lead Provider Manager or a designated individual.
2. Information is collected through the National Minimum Data Set for monitoring and evaluation purposes. (Refer: Current DMM)

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<th>Quality Indicator</th>
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<tbody>
<tr>
<td><strong>28.2 LEVEL 2 ASSESSMENT – WORK UP, INFORMATION AND CONSENT</strong></td>
<td>Women shall be given both appropriate information work-up prior to invasive breast procedures (Level 2 and Level 3 assessment) being performed.</td>
<td>All criteria are met.</td>
</tr>
</tbody>
</table>

1. 100% of records audited show women provided written consent before a Level 2 assessment was carried out.
2. All other criteria are met.
**APPENDICES**

### 28.3 LEVEL 2 ASSESSMENT – NEEDLE BIOPSY TISSUE SAMPLING OF SCREEN DETECTED LESIONS – (FNAC), CORE BIOPSY, INCLUDING VACUUM-ASSISTED BIOPSY SPECIMENS

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<tr>
<th>Quality Indicator</th>
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<th>Evaluation Target</th>
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</table>
| **Needle biopsies** are used to maximise preoperative diagnosis of cancer and non-operative diagnosis of benign abnormalities requiring further work-up.** | 1. The Clinical Director shall ensure that the sensitivity and specificity according to the operator, biopsy technique, mode and reporting pathologist is measured and monitored.  
2. Information is collected through the National Minimum Data Set for monitoring and evaluation purposes. (Refer: Current DMM)  
3. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process. | 1. Screen detected cancers are diagnosed pre-operatively:  
   - > 70% minimum, > 90% desired.  
2. Image guided FNAC procedures with an inadequate/insufficient result should be:  
   - < 25% minimum, < 15% desired.  
3. Other suggested thresholds for cytology and core biopsy performance (Refer: Appendix W: FNAC Quality Assurance)  
4. All other criteria are met. |

### 28.4 LEVEL 2 ASSESSMENT – LABELLING OF SPECIMENS

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<thead>
<tr>
<th>Quality Indicator</th>
<th>Evaluation Process</th>
<th>Evaluation Target</th>
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<tbody>
<tr>
<td>A written protocol for the labelling of pathology specimens exists.</td>
<td>The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.</td>
<td>All criteria are met.</td>
</tr>
</tbody>
</table>

### 28.5 LEVEL 2 ASSESSMENT – PATHOLOGIC EXAMINATION OF CORE NEEDLE BIOPSY SPECIMEN (CNBS)

<table>
<thead>
<tr>
<th>Quality Indicator</th>
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| Successful pathologic readings of specimens.                                     | The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process. | 1. > 80% of core biopsy results are reported to the assessment centre within 3 working days of a core or vacuum assisted biopsy being performed.  
2. All other criteria are met. |

### 28.6 LEVEL 2 ASSESSMENT – PATHOLOGIC EXAMINATION OF FINE NEEDLE ASPIRATION CYTOLOGY (FNAC) SPECIMENS

<table>
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<tr>
<th>Quality Indicator</th>
<th>Evaluation Process</th>
<th>Evaluation Target</th>
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</table>
| All Fine Needle Aspiration Cytology (FNAC) specimens shall be appropriately reported. | The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process. | 1. 100% of written reports containing FNAC results are received by the screening assessment unit within 2 working days.  
2. All other criteria are met. |

### 28.7 LEVEL 2 ASSESSMENT – LABORATORY FACILITIES AND PROCESSES FOR REPORTING ON SCREEN DETECTED MATERIAL

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<tr>
<th>Quality Indicator</th>
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<tr>
<td>Pathologists and laboratories participating in the programme must demonstrate that there are adequate facilities and processes for reporting on screen-detected material.</td>
<td>The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.</td>
<td>All criteria are met.</td>
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</table>

### Standard 29, Level 3 Assessment – Surgical Biopsy

Open surgical biopsy should be carried out in a timely and accurate manner that minimises morbidity for women.

### 29.1 LEVEL 3 ASSESSMENT – SURGICAL BIOPSY GENERAL PRINCIPLES

The aim of the open surgical biopsy is to successfully identify and remove mammographically detected lesion(s) for pathological assessment with the minimum of morbidity for the woman.

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<th>Evaluation Process</th>
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</table>
| 1. Information is collected through the National Minimum Data Set for monitoring and evaluation purposes. (Refer: Current DMM)  
2. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process. | 1. Open biopsies performed for benign disease per 1,000 women screened  
   - Prevalent s 3.5, Incidence s 1.6  
2. 90% of women requiring open surgical biopsy should have their operation performed within 15 working days of being notified for the need for this operation  
3. All other criteria are met. |

### 29.2 LEVEL 3 ASSESSMENT – PRE-OPERATIVE LOCALISATION OF IMPALPABLE LESIONS

Lesions are successfully localised preoperatively.

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<th>Evaluation Process</th>
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</table>
| The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process. | 1. > 95% of impalpable lesions should be successfully localised preoperatively.  
2. > 90% of markers should be within 10mm of the lesion.  
3. All other criteria are met. |

### 29.3 LEVEL 3 ASSESSMENT – ORIENTATION OF SPECIMEN

To enable the radiologist and the pathologist to orientate the specimen in order to assist any potential wider local excision, where appropriate marking is essential.

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<th>Evaluation Process</th>
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<tbody>
<tr>
<td>The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.</td>
<td>All criteria are met.</td>
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</table>
## Standard 30. Outcome of Assessment

### 30.1 OUTCOME OF ASSESSMENT – NOTIFICATION OF RESULTS

Each woman is notified of her assessment results, and if required, is referred to treatment in a manner that is unbiased and cognizant of her informed decision.

<table>
<thead>
<tr>
<th>Quality Indicator</th>
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<tbody>
<tr>
<td>1. Time taken from final diagnostic needle biopsy to reporting results to the woman – 90% of women receive results within 5 working days of final diagnostic needle biopsy.</td>
<td>1. Regular reports, which identify women who have not been notified of their results, are reviewed by the Lead Provider Manager or a designated person and the reason for the delay is documented. 2. Information is collected through the National Minimum Data Set for monitoring and evaluation purposes (Refer: Current DMM). 3. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.</td>
<td>1. In 90% of cases a written histology report is received by the screening unit within 5 working days of the pathology laboratory receiving the specimen. 2. All other criteria are met.</td>
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</table>

### 30.2 OUTCOME OF ASSESSMENT – REFERRAL TO TREATMENT

Comprehensive information relevant to her situation, provided within a supportive environment, allows the woman to make an informed decision regarding her treatment options and the process of a woman’s referral to treatment.

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<tr>
<th>Quality Indicator</th>
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<tbody>
<tr>
<td>1. 95% of women surveyed report that they are satisfied with the information that was provided in choosing a treatment provider. 2. 90% of women should normally receive their first surgical treatment within 20 working days of receiving their final diagnostic results. 3. Data entry of treatment outcomes (in particular histopathology details) is completed for 90% of women within nine months of their last screening exam.</td>
<td>1. Satisfaction surveys. 2. Information is collected through the National Minimum Data Set for monitoring and evaluation purposes (Refer: Current DMM). 3. The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process.</td>
<td>1. &gt; 90% of biopsy results proved to be benign, should weigh &lt; 30 grams. 2. All other criteria are met.</td>
</tr>
</tbody>
</table>
### Standard 31. No Further Active Recall
Women have a clear understanding of the reasons for no longer being eligible for the programme, the process of no further active recall to BreastScreen Aotearoa or choosing not to participate in BreastScreen Aotearoa.

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| **31.1 NO FURTHER ACTIVE RECALL**
Each woman is informed that she will no longer be actively recalled for routine re-screening when the eligibility criteria are no longer met, or she chooses to leave BreastScreen Aotearoa. | The internal audit process ensures that the criteria are complied with, and identified issues are addressed through the Continuous Quality Improvement (CQI) process. | All criteria are met. |