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BreastScreen Australia Evaluation

Review of the BreastScreen Australia Accreditation System

June 2009

BreastScreen Australia Evaluation – Review of the BreastScreen Australia Accreditation System
June 2009

Prepared by KPMG for the Australian Government Department of Health and Ageing

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ABBREVIATIONS

AGQC	Accreditation Guidelines and Quality Committee
AHMAC	Australian Health Ministers' Advisory Council
AHMAC BCSEC	Australian Health Ministers' Advisory Council Breast Cancer Screening Evaluation Committee
AIHW	Australian Institute of Health and Welfare
APLAC	Asia-Pacific Laboratory Accreditation Cooperation
ASAC	Australian Screening Advisory Committee
CBCDB	Canadian Breast Cancer Data Base
CBCI	Canadian Breast Cancer Initiative
CBCSD	Canadian Breast Cancer Screening Database
CBCSI	Canadian Breast Cancer Screening Initiative
CCC	Comprehensive Care Centres (Netherlands)
CCS	Canadian Cancer Society
DCIS	ductal carcinoma in situ
DoHA	Department of Health and Ageing
EAC	BreastScreen Australia Evaluation Advisory Committee
EU	European Union
EUREF	European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services
EUSOMA	European Society of Mastology
GP	General Practitioner
GRS	Global endoscopy rating scale
IARC	International Agency for Research against Cancer
ILAC	International Laboratory Accreditation Cooperation
ISQua	The International Society for Quality in Health Care
JAG	Joint Advisory Group on Gastrointestinal Endoscopy
NAC	National Accreditation Committee
NAR	National Accreditation Requirements
NAS	BreastScreen Australia National Accreditation Standards
NATA	National Association of Testing Authorities
NBCSP	Norwegian Breast Cancer Screening Program
NBHW	National Board of Health and Welfare, Sweden
NCIC	National Cancer Institute of Canada
NHS	United Kingdom National Health Service
NHSBSP	National Health Service Breast Screening Program (England)
NQMC	National Quality Management Committee for BreastScreen Australia

NSU	National Screening Unit, New Zealand
PHAC	Public Health Agency of Canada
PPV	positive predictive value
QA	Quality assurance
QARC	Quality Assurance Reference Centre (England)
RANZCR	Royal Australian and New Zealand College of Radiologists
SAC	State Accreditation Committees
SALAR	Swedish Association of Local Authorities and Regions
SAS	Screening and Assessment Services
SCU	State Coordination Units
SHAs	Strategic Health Authorities (England)
SPRI	Sjukvaerdens och Socialvaerdens Plaenerings och Rationaliserings Institut (trans Health Care and Social Planning and Rationalization Institute), Sweden
The Network	Europe Against Cancer Breast Screening Network

GLOSSARY

The primary source of the definition of terms is the Australian Commission for Safety and Quality in Health Care, although other sources were also used. While there are some definitional differences within the literature, it was deemed that the Commission was the appropriate reference point.

Term	Definition
Assessment	An examination of something and calculation of its value based on various factors.
Accreditation body	An organisation that is recognised to have the authority to assess health services against agreed standards.
Accreditation	The process of being granted recognition for meeting designated standards for structure, process and outcome. The two conditions for accreditation are an explicit definition of quality (i.e. standards) and an independent review process aimed at identifying the level of congruence between practices and quality standards.
Benchmark	A criterion against which something is measured.
Evaluation	A systematic assessment of value and formation of a judgment about something based on an understanding of the situation.
Feedback	Comments, opinions and reactions intended to provide useful information for future improvement and development.
Health care	Services provided to individuals or communities to promote, maintain, monitor, or restore health. Health care is not limited to medical care and includes self-care.
Health care outcome	The health status of an individual, a group of people or a population which is wholly or partially attributable to an action, agent or circumstance.
Outcome	The status of an individual, a group of people or a population which is wholly or partially attributable to an action, agent or circumstance.
Peer assessment	A process whereby the performance of an organisation, individuals or groups are evaluated by members of a similar organisation or the same profession or discipline and status as those delivering the services.
Quality	The extent to which a service or product produces a desired outcome or outcomes.
Quality improvement	Improvement in the ability of a service to achieve its objectives and desired outcomes for consumers
Quality assurance	Providing a measure of certainty that a service is able to achieve its objectives and desired consumer outcomes
Risk	The chance of something happening that will have a negative impact that is measured in terms of consequences and likelihood.

Risk management	In health care, designing and implementing a program of activities to identify and avoid or minimise risks to patients, employees, visitors and the institution; to minimise financial losses (including legal liability) that might arise consequentially; and to transfer financial risk to others through payment of premiums (insurance).
System improvement	The result or outcome of the culture, processes and structures that are directed towards the prevention of system failure and the improvement in safety and quality.
Stakeholder	Those people and organisations who may affect, be affected by, or perceive themselves to be affected by, a decision or activity.
Standard	Agreed attributes and processes designed to ensure that a product, service or method will perform consistently at a designated level.
Safety	Freedom from a circumstance or agent that can lead to harm, damage or loss.

1. EXECUTIVE SUMMARY

Key findings

The BreastScreen Australia Accreditation System:

- has evolved and strengthened since its inception and has widespread support among stakeholders, providing assurance to government agencies on the high quality of breast cancer screening services provided by the BreastScreen Australia Program to women within the target population
- provides a critical role in supporting a national programmatic approach through the NAS and the NQMC that is not evident elsewhere in the program
- is underpinned by the NAS that provides valuable direction to services on providing a high quality service; however, issues relating to currency, format, volume and lack of clarity regarding processes for review of the NAS weaken the accreditation system in general and the decision making process in particular
- creates a burden that threatens the viability of the program in two ways: firstly, the burden on services to comply with accreditation processes detracts from the core business of breast cancer screening and other quality improvement activities and, secondly, the sustainability of multidisciplinary involvement in accreditation activities, particularly in the current environment of escalating workforce shortages.

This final report presents the findings of a project undertaken by KPMG to review the BreastScreen Australia accreditation system. The project aimed to:

- identify national and international best practices for accrediting healthcare services and determine core criteria for a robust accreditation system
- benchmark the current system for accrediting BreastScreen Australia services against national and international best practices and the determined criteria
- identify the strengths and weaknesses of the current accreditation program
- identify suitable options, consistent with current Australian accreditation reforms, for ensuring the safety and ongoing quality improvement of the screening and assessment services provided by the Program
- assess whether the current accreditation system meets its aims, through independent review, to strengthen and sustain the quality of service provision, proving it worthy of public confidence.

There are a number of challenges in identifying best practice in accreditation of health services in general and in cancer screening and breast cancer screening in particular. Challenges include:

- there is little empirical evidence regarding the impact of accreditation
- accreditation is just one of a number of quality improvement strategies making it difficult to separate out the relative impact on safety and quality of care of each component
- accreditation programs have a number of purposes, the primary ones being accountability for the quality of care and quality improvement. The relative emphasis will determine the most appropriate accreditation model.

The BreastScreen Australia accreditation system has a number of strengths including:

- strong stakeholder engagement and support
- credibility as a means of providing assurance of the quality of service provision
- a process that challenges clinicians within the multidisciplinary team to review and critique performance
- the perceived value to services of the site visit process
- the close alignment of the NAS to program objectives
- the inclusion of measures and targets to drive services to achieve these objectives

The NQMC provides leadership for the BreastScreen Australia Program and accreditation system, and together with the NAS, provides a critical unifying factor at a national level. In addition BreastScreen Australia documentation and the NAS clearly outline the accreditation process and accreditation requirements.

The accreditation program also has a number of weaknesses. These include:

- the lack of a process to accommodate ongoing revision of the NAS
- the use of existing Australian data to set realistic targets that take into account the statistical challenges of measuring these targets
- the burden of the accreditation process, including the totality of the focus of effort on the accreditation system which limits the capacity of the BreastScreen Australia to support other mechanisms for improving safety and quality
- limited willingness and lack of technical capability to share assessment data
- the potential for conflict of interest in the assessment and accreditation decision due to a lack of separation between governance of accreditation, operational management of the program, assessment and standards setting (this is an acknowledged challenge where expertise resides within a smallish pool of individuals most of whom are involved in service provision in some form).

Three options are presented for consideration although there are a number of secondary options that may be adopted in isolation or in various combinations:

Option1 – Maintain the current model and structure of the accreditation system however the risks in relation to sustainability and lost opportunity to improve the safety and quality of services should be recognised.

Option 2 – Maintain the existing model and structure but with modifications to the NAS, the quality improvement program and accreditation assessment processes. These modifications include a national database with sharing of performance data with services and the public, development of other strategies to support safety and quality improvement such as sentinel incident reporting and analysis, forums to share learning, collaborate on research and provide professional development opportunities for all BreastScreen Australia personnel.

Benefits of modifying the existing model are:

- current strengths of the accreditation system will be retained with less risk to stakeholder engagement and ownership
- modifications will be able to be more quickly and easily implemented than if functions are to be re-established within a different organisation
- improving the consistency and objectivity of the decision making process will increase services confidence in the accreditation system
- disruption to the accreditation system and program staff activities will be minimised.

The major risk of adopting this approach is a continued concern among some stakeholder groups regarding the independence and objectivity of accreditation decision making.

Option 3 – Separate the assessment, service delivery and policy development arms of the accreditation program. This may be achieved through outsourcing or separation of management of the accreditation process while maintaining multidisciplinary service team input into assessment of services against the NAS.

The benefit of this approach is an increase in the objectivity of the assessment and accreditation decision-making, thereby increasing accountability to the public. There are two major risks in outsourcing management of the accreditation process; firstly this may lead to decreased ownership of the accreditation process by BreastScreen Australia personnel. Secondly, it will expose the real costs of running the accreditation program, which in its current form, is significantly greater than that recognised due to the "voluntary" nature of much of the accreditation activity. If this option is adopted mechanisms should be in place to ensure that there are links and robust communication processes between the accreditation and policy making/standard setting entities so that the policy development in accreditation is informed by what is found in the site visits.

2. BACKGROUND

The Department of Health and Ageing (DoHA) engaged KPMG to undertake a review of the BreastScreen Australia accreditation system as part of its comprehensive evaluation of the BreastScreen Australia Program.

2.1 EVALUATION OF BREASTSCREEN AUSTRALIA

In June 1990, in response to growing evidence showing the potential of well organised mammographic screening to substantially reduce deaths from breast cancer, the Health Ministers in all States and Territories of Australia joined the Commonwealth in agreeing to jointly fund a national mammography screening program (BreastScreen Australia, 2008). The National Program for the Early Detection of Breast Cancer, now known as BreastScreen Australia, was subsequently established in 1991.

In October 2005, the Australian Health Ministers' Advisory Council (AHMAC) agreed to a comprehensive evaluation of BreastScreen Australia to be overseen by a committee of Australian and international experts. It was deemed to be an appropriate time for an evaluation with the BreastScreen Australia program being fully operational for more than 10 years. Several cohorts of women had by then participated in screening at two-yearly intervals, allowing the program's health outcomes to be measured effectively. The aim of the BreastScreen Australia evaluation is to measure the impact of the program as well as determine future directions (BreastScreen Australia, 2007).

In June 2006, AHMAC endorsed the objectives and terms of reference for the evaluation, as well as the structure of the evaluation advisory committee. Subsequently, the BreastScreen Australia Evaluation Advisory Committee (EAC) was formed, consisting of Australian and international experts, along with consumer and jurisdictional representatives.

A review of the BreastScreen Australia accreditation system is one component of this overall evaluation and is consistent with the evaluation's objective to identify opportunities for improvement to the program.

2.2 CONTEXT OF THIS REPORT

This final report provides the detailed findings of the review of the BreastScreen Australia Accreditation system and provides information, insights and recommendations to inform the final BreastScreen Australia evaluation report. This first draft final report was submitted to DoHA and the EAC project sponsors for review on 3 November 2008[1]. A second draft final report incorporating feedback from the Project Management Team will be provided to the EAC for their December meeting and a final draft provided to the EAC out-of-session for comment before being endorsed and finalised. The final report will be completed by 19 January 2009.

1 The role of the EAC project sponsors is to provide input on specific issues such as the evaluation approach, key informants, emerging trends in accreditation for consideration, sources of technical information and specific strategies to maximise stakeholder engagement

The report was prepared based on the findings of:

- a review of BreastScreen Australia documentation related to the accreditation system
- a review of international literature on quality assurance and accreditation for breast cancer screening programs
- a review of national and international literature on best practice models for accreditation in health care
- a review and analysis of strategic directions in healthcare accreditation within Australia
- consultation interviews with representatives from government, professions, BreastScreen Australia State Program Managers, SACs and NQMC members
- four focus groups with BreastScreen Australia service staff and clinicians
- international informants from the UK, Canada, Sweden, New Zealand and the European Union.
- development of the core criteria for a best practice accreditation system based on findings from the desktop and literature reviews and key informant interviews
- an assessment of current practice against core best practice criteria in relation to accreditation and quality improvement within BreastScreen Australia.

For a complete list of consultation interviews, focus group attendees and international informants see Appendix A.

The findings of this review should be considered within the context of the outcomes of other parts of the comprehensive evaluation of BreastScreen Australia and particularly the findings of the Governance and Management Project, and the Participation and Performance Trends Project.

2.3 PROJECT OBJECTIVES

The aim of this project is to undertake a review of the BreastScreen Australia accreditation system. The project will address the question: Is the current quality assurance mechanisms ensuring a high standard of quality within BreastScreen Australia? The objectives of the project are to:

- identify national and international best practices for accrediting healthcare services and determine core criteria for a robust accreditation system
- benchmark the current system for accrediting BreastScreen Australia services against national and international best practices and the determined criteria
- identify the strengths and weaknesses of the current accreditation system
- identify suitable options, consistent with current Australian accreditation reforms, for ensuring the safety and ongoing quality improvement of the screening and assessment services provided by the Program
- assess whether the current accreditation system meets its aims, through independent review, to strengthen and sustain the quality of service provision, proving it worthy of public confidence.

2.4 PROJECT METHODOLOGY

The project methodology included five stages.

As agreed upon with DoHA and EAC project sponsors in the Project Plan, KPMG adopted a five stage methodology as follows:

1. project initiation
2. research
3. development of core criteria
4. assessment of current practice
5. development of recommendations and final report.

A detailed description of the methodology is provided within relevant sections of the document.

2.5 STRUCTURE OF THIS REPORT

This report is structured to provide an overview of elements of accreditation and quality assurance practices in breast cancer screening services and within the wider health sector. It also assesses the BreastScreen Australia accreditation system against best practice criteria and discusses options for change. The report sections are outlined below:

- **Section 2** – A background to the report and an overview of the project approach
- **Section 3** – An overview of the current BreastScreen Australia accreditation system, including information on developments over the previous ten years that have fostered the current environment
- **Section 4** – An overview of the literature review including methodology and limitations; current international cancer screening accreditation systems; other health care accreditation systems; and current initiatives and new directions in accreditation methods
- **Section 5** – Synthesis of the findings of the literature review and identification of characteristics of a better practice model for accreditation
- **Section 6** – Assessment of current practice in BreastScreen Australia accreditation against better practice core criteria
- **Section 7** – A summary of key findings and options for change in BreastScreen Australia accreditation

Appendices – Details of consultations undertaken as part of the assessment of the current state. Summary of the major findings of the review of literature on other breast cancer screening accreditation systems, other health care accreditation systems and strategic directions and initiatives.

3. BREASTSCREEN AUSTRALIA AND THE ACCREDITATION SYSTEM

3.1 THE ROLE OF ACCREDITATION

The benefits of any health service are dependent on high-quality service provision. This can be achieved by applying the underlying basic principles of training, specialisation, volume levels, multidisciplinary team working, use of set targets and performance indicators and audit (Perry, Broeders, de Wolf, Toernberg, Holland & von Larsa, 2008).

The purpose of accreditation is *"to ensure all health service providers in the national health care system provide the highest possible levels of safety and quality to consumers"* (Australian Commission on Safety and Quality, 2008). Recently, health care providers and funders have sought to widen its role from the traditional assurance mechanism to that of supporting implementation of a continuous quality improvement and governance framework within organisations.

Accreditation is just one of many possible assurance mechanisms and quality improvement strategies and one on which there is limited empirical evidence on its efficacy or the efficacy of other approaches in improving quality of health outcomes.

3.2 QUALITY AND BREAST CANCER SCREENING

Throughout the 1960s and 1970s there was an accumulation of evidence showing the benefit of screening mammography in reducing morbidity and mortality due to breast cancer (Zorbas, 2003). A large body of knowledge regarding cancer screening programs across Europe has been compiled by screening networks. The potential benefits of screening programs can only be achieved if quality is optimal at every point in the screening process (European Commission, 2008). Quality-assured, systematic examination of predominantly asymptomatic individuals of average risk and of appropriate age using evidence-based breast cancer screening tests and followed by appropriate treatment has the potential to prevent many deaths due to breast cancer, and significantly reduce the burden of disease at a population level (European Commission, 2008).

As with any intervention, it is important to consider the possible risks to participants. For screening mammography, potential benefits need to be considered in relation to the following risks:

- the creation of unnecessary anxiety and morbidity
- false reassurance in false negative cases
- inappropriate and over-invasive treatment in false positive cases
- inappropriate economic cost
- the concomitant risks of using ionising radiation (Perry et al, 2008).

Harm associated with the above further emphasises the necessity for quality control, with program standards and accreditation forming a strong foundation to maximise potential benefits of the breast cancer screening program, simultaneously minimising potential harm.

3.3 ADMINISTRATION AND SERVICE COORDINATION

Currently BreastScreen Australia offers over 500 service locations nationwide which can cover vast regional areas to defined locales in major cities, with screening units being fixed, relocatable or mobile. The State and Territory Governments have primary responsibility for organisation and implementation of services at the jurisdictional level, whereas the Commonwealth Government provides overall coordination of policy formulation, national data collection, quality control, and monitoring and evaluation. Within States and Territories there are two levels of organisation delivering the operational component of the screening service:

- State Coordination Units (SCU)
- Screening and Assessment Services

The SCUs undertake the planning and overall co-ordination of the Program in each State and Territory and play a large role in the recruitment of women through health promotion activities. SCUs are also central in assisting services to meet accreditation requirements and organising accreditation activities. There is a major difference in how the SCU and the Screening and Assessment Services interact between the large States that have multiple Services (NSW, Queensland and Victoria) compared to the small States or Territories where there is only one service of which the SCU is an integral part of that service (WA, SA, Victoria, Tasmania and NT). In small states and territories the SCU is integrated into the Screening and Assessment Services with SCU staff often carrying out dual roles at service and State level.

The Screening and Assessment Services provide all services from the initial mammogram to any follow-up diagnostic procedures required. The basic structure of Services is similar across Australia with each having an assessment centre and one or a number of screening units. Screening and Assessment Services can be co-located. The initial mammogram is performed in a screening unit. If a woman requires further investigation she is recalled to the assessment centre where the abnormality is assessed by a multidisciplinary team.

3.4 ACCREDITATION

3.4.1 GOVERNANCE, POLICY AND PROGRAM CONTEXT

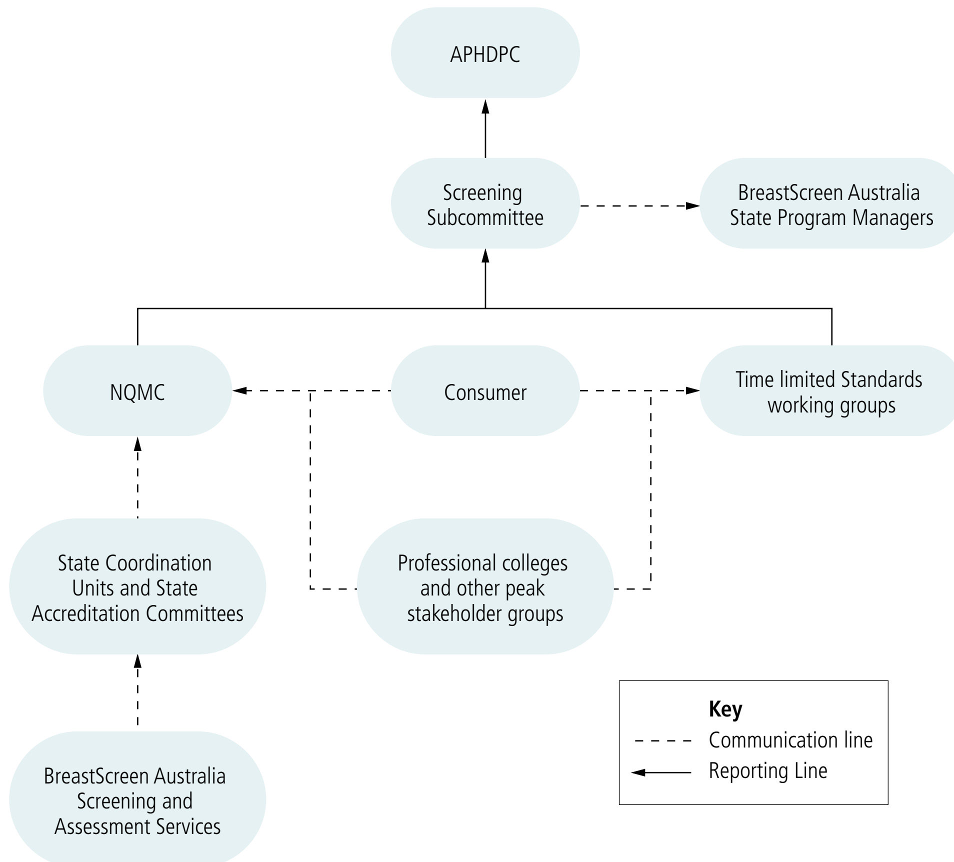
BreastScreen Australia is funded by the Commonwealth and state and territory governments with Commonwealth funding provided through broadband PHOFA's. The Australian Population Health Development Principal Committee (APHDPC), which reports to AHMAC, is responsible for oversight and evaluation of the program. Reporting to the APHDPC, the Australian Screening Subcommittee, is responsible for coordinating policy for BreastScreen Australia and has oversight of the National Quality Management Committee (NQMC) and the BreastScreen Australia

accreditation system. The NQMC has a dual role. It is the accreditation decision making body and has responsibility for the development and revision of the BreastScreen Australia National Accreditation Standards (NAS).

At the outset, quality assurance was identified as an integral component of the Program to achieve the intended goals. Necessary components of quality assurance include standardised accreditation processes, specialised training of assessment teams, quantitative performance criteria, ongoing monitoring and evaluation, and national and state-level coordination mechanisms. The NQMC exists as an overarching body to consider all of these components. The NQMC comprises of representatives from stakeholder groups and meets four times per year. Representation on the NQMC is listed in Appendix B.

The NAS and other BreastScreen Australia documentation provide the policy framework for the accreditation system. The governance structure, communication lines and stakeholder representation on key committees and working groups allow the incorporation of feedback from individual States and Territories, the Commonwealth Government and relevant professional and consumer bodies (Figure 1).

Figure 1: Governance and communication lines for BreastScreen Australia.



3.4.2 REGULATORY FRAMEWORK

When the Australian Health Ministers' Advisory Council (AHMAC) agreed in 1990 to establish a national mammographic screening program, it stipulated that only accredited services should perform mammography screening and assessment in an effort to ensure high quality of the program. This is in keeping with evidence demonstrating quality assurance being a necessary component of screening mammography services to achieve reduced mortality and morbidity attributable to breast cancer (Klabunde, Sancho-Garnier, Taplin et al, 2002). There is an additional ethical responsibility to do no harm to the to the target population of well women.

Accreditation is central to the Program's quality management and all BreastScreen Australia services are required to be accredited against the BreastScreen Australia National Accreditation Standards (NAS). While Commonwealth funding to States and Territories is not affected by accreditation status, non-accredited services are not allowed to practice under the BreastScreen Australia name. There is also a strong political imperative to maintain accreditation.

3.4.3 ACCREDITATION MODEL

The accreditation model for BreastScreen Australia is that of assessment of service performance against standards (the NAS). The NAS are described in detail in Section 3.4.5 however a detailed evaluation of the NAS is out of scope of this review.

The major steps undertaken by services in applying for full accreditation are provided in detail in the National Accreditation Handbook but may be summarised as follows:

- Completion of application for accreditation and self assessment against the NAS by the service
- Site visit by data auditor, comprehensive data audit and submission of data auditor report
- Site visit by multidisciplinary team, verbal feedback to service and submission of written report to the SCU, SAC and services
- Service preparation of written response to data auditor and multidisciplinary site visit reports and submission to SCU/SAC
- SAC consideration of reports and service performance and formulation of recommendation and forwarding of all reports and recommendations to the NQMC
- NQMC considers evidence and makes a decision on accreditation, notifies service and SAC of decision and rationale

Responsibilities for self assessment, data collection and provision lie with the individual services, and the State Accreditation Committees (SAC) provide accreditation recommendations to NQMC based on this data together with site visit reports.

The BreastScreen Australia NQMC accredits each service according to a five tier system (Table 1).

Table 1: Accreditation Levels and Required Levels of Performance.

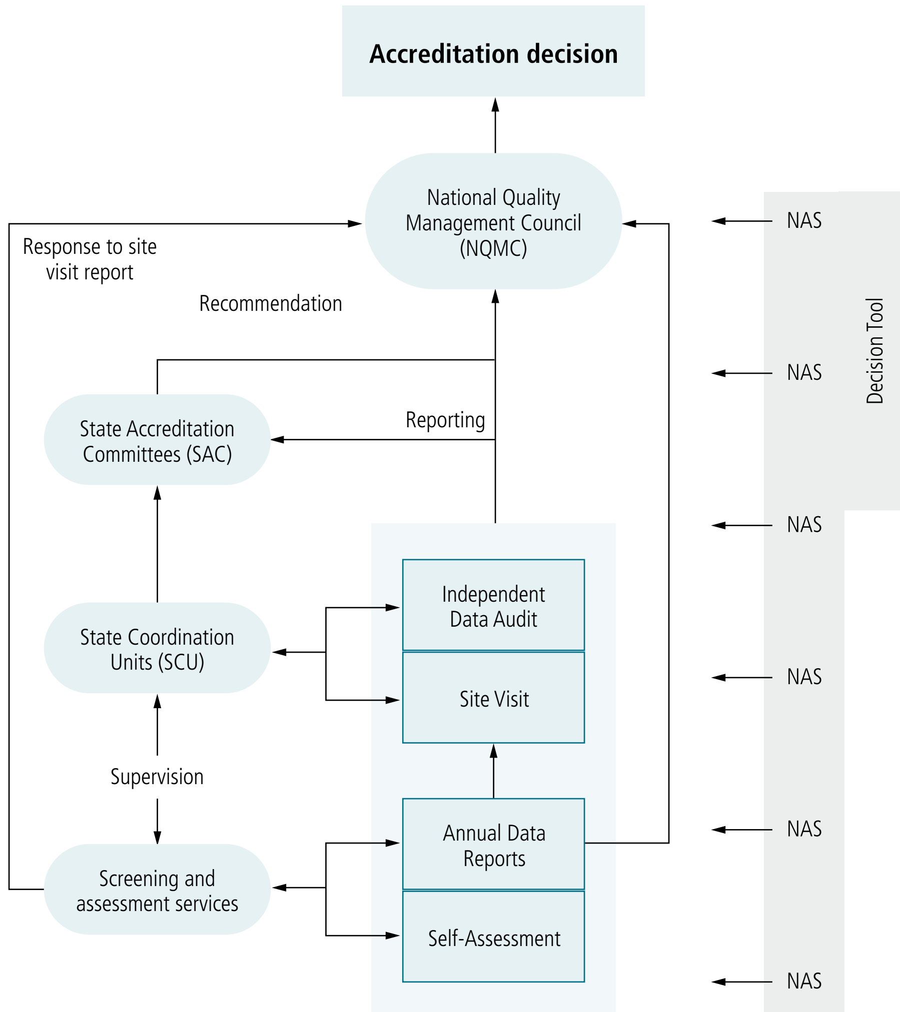
Accreditation Level	Achieved Standard	Required Performance
Four year accreditation with commendation	Service performs highly against all standards	Must meet all standards in all clusters
Four year accreditation	Service performs well against most standards, including all level 1 standards.	Overall Service must meet at least 89% of the NAS; and 100% of all level 1 standards; 90% of all level 2 standards; and 80% of all level 3 standards
Two year accreditation	Service meets all level 1 standards but not a significant proportion of level 2 and 3 standards	Overall Service must meet at least 80% of the NAS; and 100% of all level 1 standards; 80% of all level 2 standards; and 70% of all level 3 standards
Two year accreditation with high priority recommendations	Service meets the requirements for a two year accreditation term other than meeting a number of level 1 standards	Overall Service must meet at least 79% of the NAS; and 90% of all level 1 standards; 80% of all level 2 standards; and 70% of all level 3 standards
Provisional accreditation	Two years provisional accreditation for new services	Entry level for new Services.
Non-accreditation	Service does not meet requirements for accreditation for 2 year accreditation with high priority recommendations, or accreditation has lapsed.	Where Service does not meet at least the requirements for accreditation for 2 year accreditation with high priority recommendations, or where accreditation has lapsed.

Sourced BreastScreen Australia (2005)

Although the NQMC makes the final decisions on accreditation of breast screening services, State Coordination Units (SCU) are central in ensuring services adhere to the NAS and organise accreditation activities. The diagram below outlines the accreditation process and responsibilities within the organisational structure (Figure 2).

The accreditation process consists of numerous layers of supervision and reporting avenues, but the importance of transparency of the process to all parties involved is acknowledged in the National Accreditation Handbook (BreastScreen Australia, 2005).

Figure 2: BreastScreen Australia Accreditation Process

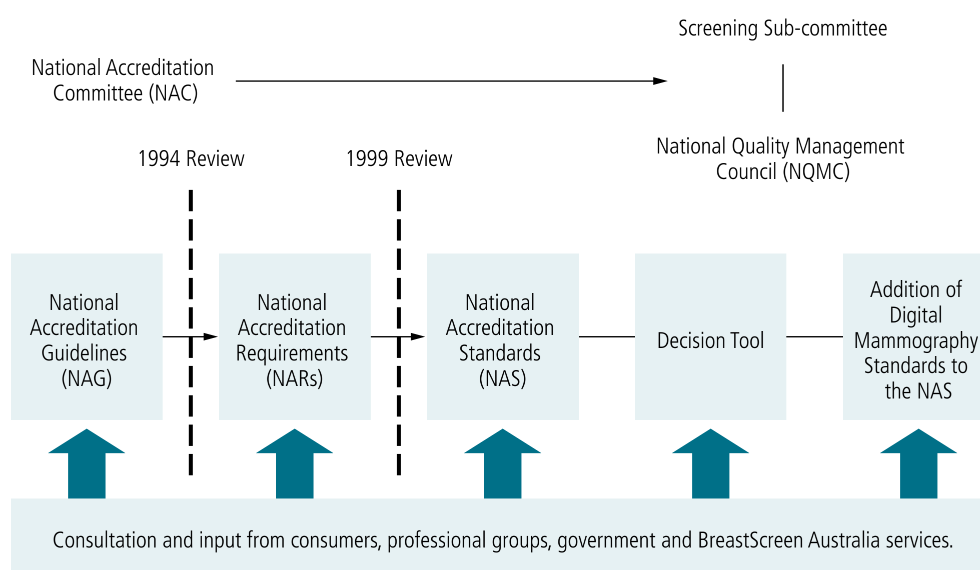


3.4.4 STANDARD DEVELOPMENT PROCESS

The first National Accreditation Requirements (NARs) were developed and put in place at the commencement of the national implementation of screening mammography, and have subsequently undergone review and revision twice, once in 1994 and once in 1999 (BreastScreen Australia, 2004). The review process involved consultation with the State and Territory BreastScreen Australia Services, consumers and representatives of the disciplines, professions and occupational groups involved in the Program. The second review was undertaken with the support of the National Breast Cancer Centre (now the National Breast and Ovarian Cancer Centre) and in 1999 saw the National Accreditation Standards (NAS) being endorsed with amendments in July 2001, and formally implemented in July 2002. In addition, a process has recently been completed to develop digital mammography accreditation standards. The revised standards have been incorporated into an updated NAS document which was endorsed by the NQMC in April 2008 and by AHMAC in October (Figure 3).

In February 2003 the NAC endorsed a tool to assist in the accreditation decision-making process. The Decision Tool was updated in November 2004 by the NQMC and complements the NAS by grouping standards and enabling them to be used in a risk management framework. The NAS and Decision Tool are integral to the accreditation process, and the NQMC provides a supervising body responsible for final accreditation decisions.

Figure 3: Evolution of the NAS.



Currently, revision of the NAS occurs as required under the auspices of the Screening Sub-committee through time limited Standards Working Groups that have representation from key stakeholder groups. The NQMC identifies the need for review of the NAS or development of a new standard and makes a submission to the Screening Subcommittee to initiate the process.

3.4.5 THE NATIONAL ACCREDITATION STANDARDS AND DECISION TOOL

There are a total of 177 NAS against which the performance of individual screening services is measured. The NAS can be categorised as data and non-data standards, reflecting the quantitative and qualitative elements of performance measurement. Furthermore, in order to assist in the assessment of services for accreditation, the Decision Tool groups standards together in the following clusters:

- assessment
- information given
- cancer detection
- management
- continuity, counselling and support
- participation
- data management

- timeliness
- equitable access
- unnecessary recall (BreastScreen Australia, 2005).

The above ten clusters represent the key outcome areas for achieving the aims and objectives of BreastScreen Australia. Although some standards may be capable of fitting into more than one cluster, in the interests of simplicity each is allocated only to the most relevant cluster.

One important consideration is the level at which the standards are set. The introduction to the NAS states that one of several components of the accreditation system are *'minimum standards for the provision of screening and assessment within BreastScreen Australia'*. Elsewhere in the NAS document standards are described as *'achievable by most services. However, the NAS are challenging as they have been developed to ensure a high quality program, not merely to be met by all services.'* (BreastScreen Australia 2004).

The Decision Tool employs a risk management approach to decision-making. Risk management is a structured, objective approach that enables the use of a tiered accreditation system as utilised by BreastScreen Australia. Furthermore, risk management is considered to accord with best practice (Standards Australia and Standards New Zealand, 2001). By applying a matrix that considers the potential consequences of not meeting a NAS and the likelihood of those consequences occurring, a risk rating is determined (Table 2). The Decision Tool groups each NAS according to three levels of risk:

- **level 1** – severe and high risk
- **level 2** – major and significant risk
- **level 3** – moderate, low and very low risk.

Table 2: Matrix used to determine the level of risk allocated to each standard.

	Consequences				
	Extreme	**Very High**	**Medium**	**Low**	**Negligible**
Almost Certain	Severe	Severe	High	Major	Significant
Likely	Severe	High	Major	Significant	Moderate
Moderate	High	Major	Significant	Moderate	Low
Unlikely	Major	Significant	Moderate	Low	Very low
Rare	Significant	Moderate	Low	Very low	Very low

Source: BreastScreen Australia (2005).

The decision tool risk rating identifies those areas of practice that represent a higher risk to the safety of the target population and the quality of care. It also provides a mechanism to allow services to prioritise their quality improvement activities however there is a clear commitment to all of the NAS as important to the delivery of a high quality service. The number of standards per risk level of each cluster of standards is shown in the following table (Table 3).

Table 3: Summary of the number of standards per risk level per cluster.

Cluster	Level 1 (severe/high)	Level 2 (major/significant)	Level 3 (moderate/low/ very low)
Assessment	4	13	5
Cancer Detection	7	15	5
Continuity, Counselling and Support	-	8	5
Data Management	-	11	4
Equitable Access	-	5	-
Information Given	-	8	2
Management	2	46	5
Participation	-	6	4
Timeliness	1	8	1
Unnecessary Recall	-	7	1
TOTALS	14	127	32

Source: BreastScreen Australia (200)5.

3.4.6 UNDERPINNING PRINCIPLES

Quality management and improvement are ongoing processes, and have evolved along with the BreastScreen Australia program since its inception. Accreditation is a component of quality assurance and enables consumer confidence that the service being utilised is of high quality.

Once accredited, BreastScreen Australia services agree to abide by the standards of the Program, and to self-regulate by taking responsibility for service improvement during the period for which accreditation has been awarded.

It is the intention of supervising bodies to continually review the accreditation process to ensure its effectiveness is sustained and increased over time, allowing objectivity and transparency to be developed to best practice standards. The core principles that have guided the development of the accreditation system are outlined in Table 4.

Table 4: Core principles of quality improvement, core standards and targets

Core Principle	Rationale
Quality improvement, core standards and targets	The accreditation process is designed to foster a continuous quality improvement approach within BreastScreen Australia As all of the performance objectives reflect key components of provision of a high quality program, it is not possible to identify core criteria. It should be the intention of services to meet all NAS, although extenuating circumstances are taken into account when certain NAS are considered irrelevant
Achievable by most services	The NAS are designed to be achievable by most services. However, the NAS are challenging as they have been developed to ensure a high quality program, not merely to be met by all services
Recognition of factors affecting individual Services	It is anticipated that certain factors will contribute to individual Services not being able to meet all NAS. In relation to unmet NAS, the individual Service is expected to demonstrate a quality improvement program designed to move towards meeting the NAS over time

Core Principle	Rationale
Evidence based	NAS are evidence-based wherever possible. In some cases evidence from overseas has been used, but many NAS are now based on what appears to be achievable in the Australian context. The NAS have been made consistent with other nationally agreed guides where appropriate
Clear rationale	It is the intention of the NQMC to clearly identify the relationship between the aims and objectives of the Program and each of the performance objectives. Text included in the NAS provides rationale for including each performance objective in relation to achieving program goals
Concrete and measurable	Having concrete and measurable NAS is an effort to avoid confusion about accreditation decisions
Context of decision making process within NQMC	The NQMC recognises that the NAS are viewed in the context of the approach it takes to decision making. To simplify and make transparent the decision making process, the Decision Tool was developed in 2003. Additionally, strategies have been put in place to ensure that membership of the NQMC is regularly reviewed

Information source: National Accreditation Standards BreastScreen Australia (2004)

3.4.7 CONSUMER INPUT

BreastScreen Australia outlines a commitment to consumer input in an effort to achieve the best possible outcomes for women. Individual needs of women require recognition, and the best way to achieve this is through consumer participation in decision making. Although consumers are not directly contacted throughout the accreditation process, they are central to numerous measures and outcomes of the existing 177 NAS. Processes adopted by BreastScreen Australia to ensure consumer input include encouraging consumers to provide feedback about individual services and the Program in general through either e-mail or a national telephone line. Previous reviews of the NAS have involved input from numerous stakeholders including consumers.

Consumer representation also occurs through consumer representation on the NQMC, representation on the State and Territory SACs and occasionally as consumer representatives on site visit teams.

3.4.8 PROGRAM PERFORMANCE

The success of the BreastScreen Australia Program is reflected in published reports on BreastScreen Australia screening activity and outcomes. A reporting interval of two years is used because it corresponds with the recommended interval between screens for asymptomatic women in the target age-group. The positive findings of biannual reports are supported by reviews of BreastScreen Australia in independent publications (Giles and Amos, 2003).

The collection of data is a high priority in the Program as it enables monitoring of the Program's efficiency and performance. A National Standardised Data Set exists to guide each State and Territory as to the relevant performance measures, and it is a requirement of States and Territories to collect this data. Each State and Territory maintains their own database and submits a subset of

data to the AIHW. In NSW each service maintains its own database. A bi-annual report is released by the AIHW which focuses on the performance indicators a selection of which are listed below. The most recent report relates to the two year period of 2004 and 2005 (AIHW, 2008):

- Participation – 56.2 per cent of women in the target population of 50 to 69 year olds; 35.8 per cent of Indigenous women; 43.1 per cent of women whose primary language spoken at home is not English.
- Detection of all size and small invasive breast cancers – 2,823 invasive breast cancers were detected in the target population in 2005.
- Interval cancer rate – an interval breast cancer is an invasive cancer that is detected subsequent to a screening mammogram but prior to the next scheduled mammogram two years later. During the period 2001 to 2003, the age-standardised rate for interval cancers in women aged 50 to 69 after attending their first screening was 9.2 per 10,000 women-years over the 24 months following a negative screening episode.
- Program sensitivity (screen detected cancers) – this is a calculation of the percentage of all breast cancers detected within the BreastScreen Australia Program out of all invasive breast cancers (interval cancers plus screen-detected cancers) diagnosed in women participating in the program in the 2 year screening interval.. Sensitivity has been improving with 79.2 per cent detected by initial breast screening during the period 2001 to 2003, compared with 74.8 per cent during the period 1998 to 2000.
- Detection of ductal carcinoma in situ (DCIS) – DCIS is considered a precursor to invasive breast cancer with malignant cells confined to the breast ducts and not invasive. For the age group 50 to 69 years, the detection rate increased significantly in 2005 to 11.5 cases per 10,000 women, from 9.1 cases per 10,000 in 1996.
- Recall to assessment – this is a measurement of the number of women who are recalled, usually because of signs on mammogram suspicious for breast cancer. As would be expected women attending for a first screening have a significantly higher recall rate of 9.8 per cent compared to 4.0 per cent for women attending subsequent screenings
- Rescreening – is a measure of the proportion of women who return for screening in the program within the recommended screening interval.
  - 60.5 per cent of all women aged 50-69 years had an initial screen with BreastScreen Australia in 2003
  - Of those who had an initial screen 69.5 per cent attended for a second screen
  - Of those who had a second screen, 80.1 per cent attended for subsequent screens (AIHW 2008)

There are challenges in attempting to determine the impact of the accreditation system on program performance. Many activities contribute to quality of service provision and it is not possible to single out the effect that may be attributed to each of these activities. Despite these challenges it is widely recognised that quality assurance is a necessary component to ensure achievement of program goals (AHMAC BCSEC, 1990) and accreditation is identified as an integral component of quality assurance.

4. ACCREDITATION MODELS AND INITIATIVES

This section provides an overview and analysis of the findings of the review of literature and consultations regarding other accreditation models in breast cancer screening and health care more generally. This section includes an overview of the implications for BreastScreen Australia of current initiatives and drivers for future changes in healthcare accreditation. Detailed findings of the literature review may be found within the appendixes to this report:

- International models of quality assurance for breast cancer screening (Appendix C)
- Other accreditation systems in health (Appendix D)
- Accreditation – current initiatives and future directions (Appendix E).

4.1 OVERVIEW OF THE LITERATURE REVIEW

The purpose of the review of other quality assurance and accreditation models is to understand developments in breast and other cancer screening services internationally to inform our understanding of best practice quality assurance and accreditation models.

The following guidelines were applied to source appropriate information for the literature review:

- existing literature reviews of accreditation systems and particularly documents produced as part of the Australian Commission on Safety and Quality in Healthcare's review of accreditation systems and the proposed model for health care accreditation;
- searches on databases with on-line access through the World Wide Web, such as MedLine (PubMed);
- other sources of relevant information including websites of major health and social care departments and international health information agencies; and
- an assurance that information reviewed is up-to-date, with consideration primarily of current practices in the United Kingdom, Sweden, Canada, New Zealand, Netherlands and the European Union.

4.2 SEARCH STRATEGY

This review has examined accreditation and monitoring practices in developed nations with similar breast cancer incidence rates and screening services, as follows:

- European Union
- United Kingdom
- Netherlands
- Sweden
- Norway
- Canada
- New Zealand

The areas of investigation included the following:

- accreditation models and their regulatory framework
- elements of the different models including standards development processes and core criteria of the accreditation system/s
- policy and program context that the accreditation program/s sits within
- assessment of the impact of accreditation programs, in particular on client outcomes
- incorporation of the consumer perspective into accreditation models
- results of accreditation system evaluation and reviews and subsequent recommendations and changes implemented
- underpinning principles of accreditation programs
- accreditation decision making and the appeals process
- governance models
- standards development process
- communication of accreditation system information to services and information provision to new services
- applying for accreditation, the preparation and any self assessment process including information to quantify the burden of the system at different levels of the organisation
- external review process (site visits and data audits)
- training and education including site visitor training.

Where websites were written in a language other than English, they have been translated using *Windows Live Translator* with a 'sensibility test' of the translations being conducted by the authors of this report.

4.3 LIMITATIONS AND ASSUMPTIONS

The literature review has been developed using publicly available information. In some cases, this information was supplemented and verified through discussions with relevant representatives (reported in the body of the text as 'personal communication'). These are listed in Appendix A (Consultations). Information was verified through personal communication for the following countries:

- England
- European Union
- Canada
- Sweden
- New Zealand.

There are few studies that explore the effectiveness of accreditation in improving safety and quality. There are significant technical difficulties in constructing a robust evaluation methodology due to the complexity of factors that affects the quality of care provided by a service.

"It is difficult to evaluate or determine the benefits that accreditation can bring to an organisation because the 'end points or products' of accreditation are hard to define. They vary according to the expectations of users and observers, the starting point of the organisation and the rigour of the accreditation process." (Australian Commission for Safety and Quality in Health Care 2006)

The following assumptions are made regarding the effects of accreditation and quality assurance:

- Accreditation and quality assurance processes increase the quality of the screening program
- High quality programs have high rates of detection of small invasive breast cancers and ductal carcinoma in situ
- High quality programs have lower rates of interval cancers (cancers that may have been missed during screening)
- High quality programs have high rates of participation and re-screening
- Where direct evidence is not available on the impact of accreditation and quality assurance per se, the above shall be used as indicators of the efficacy of quality assurance mechanisms.

This report also acknowledges limitations due to the 'considerable variation' in the data definitions and validation procedures as well as the quality of reporting of clinical indicators. This impacts on the specificity and sensitivity of indicators as comparators and therefore their use in drawing conclusive findings (Lynge, Olsen, Fracheboud & Patnick 2003). Therefore no direct benchmarking of key performance indicators for cancer detection and participation was undertaken.

4.4 INTERNATIONAL MODELS OF QUALITY ASSURANCE FOR BREAST CANCER SCREENING

The universal acknowledgement of the critical importance of the delivery of high quality screening services to maximise benefit and minimise harm has led all breast cancer screening programs to invest in quality improvement. Investment in quality assurance is more variable ranging from the decentralised locally managed quality models as seen in Canada and Sweden to more highly regulated and monitored programs in England and New Zealand.

All countries studied have defined quality standards and a number of key performance measures relating to cancer detection and participation. Reporting, monitoring and assessment mechanisms vary considerably in their complexity and the requirements of screening services to participate. Canada is the only country of those studied that does not have at least some element of a mandatory compliance model although strong peer pressure effectively produces similar results. Most countries utilised self assessment of service performance against standards, periodic reporting of key performance measures and site visits by an external multidisciplinary team to validate self assessment findings.

4.4.1 THE FOLLOWING THEMES AND OBSERVATIONS WERE SYNTHESISED FROM THE REVIEW OF INTERNATIONAL BREAST SCREENING MODELS:

- There is considerable variation in the different international models of quality assurance for breast screening programs. A number of factors appear to determine the model including historical models of governance of service quality, the nature of the service, funding levers, political drivers, and the type of service.
- There are a number of challenges in interpreting the relative value of the different models of quality assurance in place within breast cancer and bowel cancer screening programs in the countries studied. In some countries, particularly in Europe there has been considerable change in recent years as harmonisation of systems and standards occur. Much of the written information that is available is out of date or significant changes are planned in the near future. Limited detailed information is available on the actual quality assurance processes. In addition many countries have regional management of quality assurance activities and can have different approaches although standards setting remain centralised.
- There is a move towards harmonisation of standards and quality assurance processes among the European Union member states. This state of flux in the accreditation and certification processes limits the applicability of accreditation models to a review of the BreastScreen Australia accreditation system.
- The principle that quality assurance activities are an essential and integral part of health service delivery is firmly established through policy directives and there is evidence that this is strengthened where it is supported through regulatory levers including legislation and funding drivers
- There is increasing recognition of the disparity in standards and quality of service between screening and diagnostic services. This has led towards merging of screening and diagnostic standards in some countries and anecdotal evidence of a significant improvement in the quality of care provided to women on their journey through the screening, diagnostic and treatment cycle.
- Differences in measurement and reporting of key performance indicators make it difficult to make a true comparison between the quality of services. It would also be inappropriate to draw conclusions regarding the comparative benefits of one quality assurance model over another based on the relative performance due to the effects on quality of other variables such as workforce, program funding and regulatory mechanisms.

4.5 OTHER HEALTH CARE ACCREDITATION PROGRAMS

There is an increasing push among both developed and developing countries for accreditation of health related services, primarily to provide funders and consumers with information regarding the safety and quality of care provided by these services. Within Australia, there are a number of independent, not for profit organisations that undertake assessment of service compliance against set standards. As part of the review of literature the following accreditation programs were researched. Detailed findings are presented in Appendix D):

- ACHS Evaluation and Quality Improvement Program (EQuIP)
- National Association of Testing Authorities (NATA) accreditation against RANZCR medical imaging standards
- International Society of Quality in Health Care (ISQua) accreditation programs
- Bowel Cancer Screening Program – England

Both ACHS and NATA are independent, not-for-profit organisations that run multiple accreditation programs and have strong industry and government support. Both undergo external evaluation of their programs and are recognised international leaders within their scope of practice.

The ISQua accreditation programs have particular relevance to this review in that they focus on the health care sector and have developed standards for accreditation programs, development of health care standards and site visitor training. These provide a combination of expert opinion and evidence based standards that may be used as a reference for development of the core criteria for best practice in accreditation.

The bowel cancer screening model demonstrates the importance of partnership with professional colleges and the potential for flow on improvements to diagnostic and treatment services from quality improvement activities initiated within screening services.

4.6 CURRENT INITIATIVES AND DIRECTIONS IN ACCREDITATION

In response to increasing dissatisfaction with the impact and burden of existing quality assurance systems and findings of the Patterson Report, the Australian Commission for Safety and Quality in Health Care (the Commission) identified the need to:

- review existing health standards and identify opportunities to streamline or reduce duplication
- identify a best practice model of accreditation
- improve the rigour and robustness of accreditation surveys
- develop mechanisms to ensure there is an appropriate response where unacceptable threat to patient safety or quality of care is identified through the accreditation process (Patterson 2005).

The Commission identified several issues around the performance of accreditation programs including effectiveness in identifying poor performance, transparency, governance and resource requirements. The Commission also identified a number issues around standards including the proliferation of standards, access to standards, the process of developing standards, differences in terminology between sets of standards, variance of structure, style, and purpose, and the appropriateness of their use in assessment.

The Commission conducted a review of current accreditation arrangements within Australia and international directions in improving accreditation systems within health and subsequently developed an alternative model for safety and quality accreditation of health care organisations which responds to the issues identified.

4.6.1 FUTURE DIRECTIONS

In describing the way forward the Commission has outlined 11 reform strategies, all of which have some relevance in considering options for improving the BreastScreen Australia accreditation system. The Commission proposed an integrated package of reforms to be applied nationally, the primary focus being to avoid overlap and duplication within standards and accreditation processes and include:

- developing a register of accrediting bodies
- standardising accreditation language and definitions
- training and competency testing of surveyors
- better use of data for evaluation of health service performance
- system-wide accreditation against safety and quality standards
- introduction of unannounced surveys
- introduction of tracer methodology in external accreditation reviews
- registration of sets of health care standards
- harmonisation of health service standards
- detailed mapping of standards
- identification of core safety and quality areas.

4.6.2 IMPLICATIONS FOR BREASTSCREEN AUSTRALIA ACCREDITATION PROGRAM

While the Commission reforms are in the early stages of development and are unlikely to be implemented for some time, changes to BreastScreen Australia should align with the principles and objectives of the proposed reforms. Specifically, options for change to the BreastScreen Accreditation system should consider such issues as training and competency testing of surveyors, and decreasing burden through harmonisation of health standards, use of unannounced surveys, and identification of core safety and quality areas. The characteristics of the alternative model for healthcare accreditation should also be taken into account in considering options for the BreastScreen Australia accreditation system. These characteristics have been used to inform the development of core criteria outlined in Section 5.6 of this report.

The introduction of the Private Insurance (Accreditation) Rules 2008 marks an increasing concern from government regarding the consistency and integrity of accreditation programs. These rules require hospitals or health care organisations to be accredited or certified by an appropriate accrediting body (or engaged in the process to be accredited). The rules specify that an appropriate accrediting body is one that is accredited by:

- The International Society for Quality in Health Care Inc (ISQua) or
- The Joint Accreditation System of Australia and New Zealand (JAS-ANZ) or
- An entity that has been accredited by ISQua or JAS-ANZ.

Up until the introduction of these rules accreditation and certification of accrediting agencies was voluntary although most of the larger agencies such as ACHS and NATA have ISQua or JAS-ANZ accreditation. While currently not required to undergo accreditation, it may become an expectation that the BreastScreen Australia accreditation system undergoes accreditation in the future to bring it into line with other accreditation systems within Australia.

4.7 MODEL ELEMENTS OF INTEREST

There are a number of characteristics within international models and other healthcare accreditation models that provide interesting elements for consideration in developing options for the BreastScreen Australia accreditation system. These characteristics are outlined briefly below.

Articulated strategic framework for quality improvement

This approach ensures that there is a balance of funded quality improvement and assurance activities including research and development, supported collaboration and networking of breast cancer screening professionals, quality improvement, risk management, standards setting and compliance activities. Risk management activities include centralised reporting of sentinel incidents, credentialling and privileging. This approach is well developed in New Zealand.

Central management and sharing performance data

There is a move towards standardisation and centralisation of performance data including sharing performance data between services to assist a service to identify exemplar sites, and to access and share ideas for improving services. Most programs identified this as an objective of the program either currently or in the future.

External management of audit program

External management of the audit program in place occurs in quite different forms in New Zealand and the European Union. This approach provides the ability to separate service provision, standards setting and funding bodies from the quality assurance process (Appendix Section C). It also removes the management of the logistics of the accreditation/assurance process from government. Providing the external organisation is an accreditation agency it also has the potential to maximise the efficiency and effectiveness of the operational processes as this is being performed by an organisation whose core business is accreditation.

A number of weaknesses however have been reported in relation to the use of external auditors. These include:

- the external auditors are not specialist in breast cancer screening leading to a perception among providers that auditors did not understand the service
- difficulty in maintaining corporate knowledge within the external organisation due to staff changes
- issues with the alignment of the philosophy of the audit. External auditors are reported to have a more subjective approach with individual interpretation and discretionary decision making taking a greater focus in determining the outcomes of the audit.

Continual standards review and update

The establishment of standing specialist and/or multidisciplinary representative groups creates a resource that may be used to develop or review standards. These groups are resourced and supported to undertake this function and allows standards to respond to changes in evidence, technology and clinical practice.

Timing of accreditation cycle

Most accreditation systems have a standard cycle period for all services. This generally ranges from three to five years. Where services have underperformed or where performance presents a significant risk to safety and quality, services are required to report progress on improvement strategies to address accreditation recommendations with review periods from six weeks to one year.

Staged assessment against standards

Some accreditation systems stage the assessment of standards so that not all standards are assessed during every accreditation review. For example compliance with higher priority standards may be assessed at every cycle while lower priority standards may be assessed every second cycle. Priority is determined by consideration of risk to the quality of care or safety of people within the organisation if evaluation of that standard is not undertaken.

Unannounced survey visits

One strategy that is having increased uptake by other accreditation programs is the unannounced survey. Benefits include:

- decreased burden on health services to "prepare" for an accreditation visit,
- obtaining a more realistic view of the service as the site visitors see the service during business as usual
- potential to more accurately assess the degree to which continuous quality improvement is embedded into the practice.

Weaknesses of unannounced site visits include:

- site visitors may not have the opportunity to see the full spectrum of activities undertaken by the services
- Increased burden on site visitors as they are required to sift through material to find the information they need or wait to access information, films or notes.

5. BEST PRACTICE IN HEALTH ACCREDITATION PROGRAMS

Many of the elements of the accreditation systems examined thus far are similar. There is little evidence that clearly substantiates the benefits of one model over another.

A number of sources in the literature explore the characteristics of best practices in quality assurance mechanisms, accreditation and standard setting however many of the conclusions drawn are based on professional experience and expert opinion rather than robust research. To further inform the development of the core assessment criteria for review of the Breast Screen Australia accreditation system we have consulted and synthesised information from the following sources:

- Australian Commission on Safety and Quality in Health Care
- International Society for Quality in Health Care
- Other reports, reviews, accreditation programs and standards setting processes referred to in this report.

5.1 PRINCIPLES

There are a wide range of approaches to assessing the safety and quality of healthcare provision. These include clinical or management systems audit, peer review, ad hoc external reviews, self assessment against standards and formal accreditation programs. There is broad consensus on the principles that should underpin external assessment processes. These principles include:

- Consumer/patient focus and involvement
- Openness and transparency of standards, the assessment process and findings
- Measurement of outcomes for consumers/patient
- Assessment by peers who have been trained and evaluated in assessing against the standards
- The program is based on quality improvement principles and includes evaluation and continuous improvement of the assessment process
- The burden of assessment should be appropriate to the level of risk to patient safety and the quality of care

5.2 STANDARDS

5.2.1 CHARACTERISTICS OF STANDARDS

When reviewing accreditation programs it is critical to consider the different approaches and issues related to the development of standards.

Standards may be anywhere along a continuum ranging from high level with little detail to a precise prescription of the detailed requirements of the organisation. High level standards that are less prescriptive, while more flexible in application across different contexts, have the disadvantages of:

- being open to interpretation
- demanding considerable professional judgement
- requiring assessors to be well trained in identifying evidence of their implementation.

Detailed standards have the advantage of providing services with a framework as well as a checklist to guide their application and are less open to incorrect interpretation (Scrivens 2004).

There are clear requirements for robust standards for service delivery. These require standards to:

- have synergy and integrate with other standards operating within the service environment
- be based on sound research and expert technical knowledge
- incorporate a continuous quality improvement model and consideration of relevant legislative requirements
- include of a mix of disease specific clinical outcomes and organisational design elements
- include measurable indicators of patient outcomes and service performance
- use language that reflect outputs and outcomes (what the organisation is trying to achieve) rather than inputs
- focus on the consumer/patient perspective and their journey through the service
- accommodate a mix of the level of development of systems and processes, clearly defining minimum standards and optimum achievable standards that incorporate developmental or stretch standards to encourage the pursuit of perfection.

5.2.2 STANDARDS DEVELOPMENT AND UPDATE

In relation to the process for setting and updating standards, the following should be in place:

- an open, transparent standard development process, available for public scrutiny and supporting public participation
- balanced representation from stakeholder groups including relevant technical expertise
- a fair, consensus decision making approach in agreeing standards
- a systematic consideration of the costs and benefits of developing or updating a standard

- a cycle for review and update of standards to support the evolution of the system including the flexibility to quickly review and amend standards when issues are identified
- standards are subject to consultation, risk assessment, impact analysis, piloting and validation prior to broad implementation (Productivity Commission 2006, Scrivens 2004, Australian Commission on Safety and Quality in Health Care 2008b)

5.2.3 MEASURING PERFORMANCE AGAINST STANDARDS

Standards need to be developed in a way that enables a consistent and transparent rating or measurement of achievement against each criterion. There are a number of factors which support this including:

- objective measures of performance and clear communication of benchmarks to services
- defined methodology for measuring achievement of standards and provision of guidelines to assessors on rating performance for each standard and criterion
- evaluation of inter-rater reliability for all new standards and ongoing periodic assessment
- ongoing evaluation of the satisfaction of assessed organisations and the assessors with the measurement system
- evaluation findings are used to make improvements in the system for measuring performance against the standards (ISQua 2007).

The literature describes two principal uses of performance measures and benchmark standards. Firstly as a mechanism for external accountability and verification in assurance systems and secondly, as a formative mechanism for internal quality improvement (Freeman 2002).

There is some criticism of the use of indicators as a basis for praise and sanction and their use in public reporting of quality and safety, however there is universal acceptance of the formative use of indicators in comparing performance with peers and identifying opportunities for improvement. Using performance indicators to drive innovation is key to their effective use, supporting discussion and interpretation by clinicians and managers with the aim of continuously improving the quality of clinical care (Independent Pricing and Regulatory Tribunal 2003).

5.3 ACCREDITATION PROCESS

5.3.1 ASSESSMENT

Assessment processes should be appropriate to the level of risk associated with the activities undertaken and the complexity of the service. A range of assessment mechanisms may be used however there is general consensus that the following components are essential:

- Services undertake self assessment to:
  - provide a check of an organisations' readiness for an accreditation survey
  - act as a trigger for improvement activity
  - increase ownership of the assessment process, findings and recommendations

- Services undergoing accreditation are subject to periodic external assessment, including short notice or unannounced site visits to assess the operation of the organisation under "business as usual" conditions
- External assessment includes peer review to ensure credibility of assessment and support cross-organisational learning and information sharing (ISO, Australian Commission for Safety and Quality in Health Care 2008b, Scrivens 2004)

5.3.2 SURVEYOR PERFORMANCE

The role of the surveyor or assessor is central to current accreditation programs which rely on their judgement to review organisation performance against the accreditation standards. In essence, the surveyor verifies the organisations' claim that of compliance with the accreditation standards. Surveyors usually provide both formal and informal feedback to the organisation in a manner that is constructive and stimulates improvement.

There is little empirical research into characteristics of an accreditation system that supports high levels of inter-rater and intra-rater reliability although this is an issue of widespread concern for both accreditation agencies and organisations that are being accredited (Greenfield D et al 2007a).However, there is broad consensus on the need for appropriate recruitment and selection processes. All new surveyors should undertake training in assessment techniques and ensure that they have a thorough understanding of the relevant standards. Mechanisms to support ongoing review and improvement of assessor performance should also be in place.

5.3.3 ORGANISATIONAL CONTEXT OF ACCREDITATION

Accreditation assessment should be centred around one organisation. The heterogeneity of structures and processes across multiple organisations leaves the assessment of networked organisations as one entity, open to inconsistency and weakens its ability to accurately measure compliance. Where accreditation occurs across a network of organisations with different governance there can be a lack of ownership regarding the process, findings and improvement strategies. (Scrivens 2004).

All organisations providing high risk health services and those undertaking activities covered by the standards should be part of the accreditation system including both public and private providers (Australian Commission for Safety and Quality in Health Care 2008b, ISQua 2004).

5.3.4 DATA COLLECTION AND REPORTING

Accreditation processes should support the collection of meaningful information on safety and quality of services and allow analysis and reporting on emergent risks, exemplar practice and system changes to deliver service improvement. Data sets should be harmonised and where there is overlap of data reporting requirements these should be integrated to avoid unnecessary burden of collection on services.

Public reporting of the accreditation status of organisations is strongly supported. In addition there is a strong push by those driving reform in health care safety and quality for public reporting of service performance against standards. There is a view that greater openness and transparency of assessment results will support benchmarking opportunities, foster improved public understanding of the healthcare risks and engage consumers in the quality agenda.

5.4 GOVERNANCE OF THE ACCREDITATION PROCESS

Where a substantial focus of accreditation is a mechanism to ensure accountability for the standard of care, it is important that the accrediting organisation is separate to the standards setting body. The accreditation agency should be governed by an independent group that includes professional, community, consumer and government representation. The group should be formulated in a way that prevents undue influence from any stakeholder group and supports objective decision making and reporting (ISQua 2006).

Generally activities such as monitoring, assessment and analysis of whole of system health care are retained by a central agency. This increases consistency, objectivity and maximises the opportunity to achieve economies of scale. There remains a mix of independent accreditation agencies and government initiated systems although there is a body of opinion that participation in accreditation is more likely to be compulsory for government systems. As a major funder of services, government is more likely to be able to apply regulatory levers to drive participation in accreditation and response to findings (Scrivens 2004). Either way, to function effectively, accreditation organisations or systems require government acknowledgment and in-principle support.

Accrediting organisations should have a board of governance (or similar governance body) that is representative of stakeholders. The board of governance should have appropriate organisational structures and processes in place including strategic and operational plans, terms of reference and standard operating procedures (ISQua 2006).

Independence of the standards development and accreditation decision-making is seen as a critical characteristic of an accreditation system to ensure transparency and avoid conflict of interest. It is also seen as a key to avoiding anti-competitive actions such as setting unrealistic, overly prescriptive technical requirements or allowing an environment where there may be a conflict of interest influencing accreditation decisions (Productivity Commission 2006). The Commission has identified the need for an independent national entity that has responsibility for development or adoption of standards. The establishment of such an entity will address the issue of separation of standards setting and accrediting bodies (Australian Commission for Safety and Quality in Health Care 2008b).

5.5 REGULATORY FRAMEWORKS

Governments are required to ensure that the services that they are providing and/or funding are functioning efficiently, effectively and achieving their stated objectives. This is achieved through regulatory mechanisms and through quality improvement. Regulatory mechanisms in the larger health arena while complex and multifaceted, are broadly applicable to the BreastScreen Australia context. The system of checks and balances that comprise the regulatory framework include a number of mechanisms that may be sorted into four phases (Mello et al 2005):

- Identification of a safety or quality of care problem
- Research and innovation to identify or develop interventions that address the identified problem
- Establishment of standards that may be in the form of recommendations, accreditation or certification standards, government policy or legislative requirements
- Enforcement of standards through rewards or penalties that may include funding mechanisms, sanctions or legal penalties.

An effective accreditation or external review system requires a balance of incentives and sanctions to give leverage to recommendations and drive improvement in quality (Shaw 2001).

There is increasing pressure by government, media and consumers to move away from the traditional self regulation approach in health to a more interventionist approach. The emerging model which appears to have most support at present describes a responsive regulatory approach. The model acknowledges the importance of a range of mechanisms from professional self regulation through to external command and control. The model acknowledges that existing internal and quasi-regulatory mechanisms such as accreditation are effective in most situations but allows for escalation to requirements that are mandated through legislation or integrated into funding mechanisms (Australian Commission for Safety and Quality in Health Care 2008b).

Recent research into different models in health care regulation has described a triple-loop learning approach to ensure that safety, quality and improvement are supported through each organisational level. The triple loop includes:

- individual healthcare professional monitoring their own effectiveness at improving outcomes for clients/patients
- deteriorating performance or other early warning flag triggering a response by management to revise management systems, culture and practice
- government revising regulatory goals and strategies in response to significant system wide issues (Braithwaite 2005).

5.6 CORE CRITERIA FOR BEST PRACTICE ACCREDITATION PROGRAM

Information from the research stage regarding best practice in accreditation has been synthesised into a number of core criteria that reflect elements and characteristics of better practice accreditation models. There are significant limitations and gaps in the evaluation of the accreditation programs with few studies that demonstrate an impact on consumer outcomes. In developing these core criteria the following issues are considered:

- the framework for the BreastScreen Australia accreditation system
- aims and objectives of the BreastScreen Australia accreditation system
- characteristics of better practice accreditation systems outlined earlier

Key documents and reports that were considered in developing the core criteria are:

- BreastScreen Australia Accreditation system documentation including the *National Accreditation Handbook* (BreastScreen Australia 2005), *National Accreditation Standards* (BreastScreen Australia 2008) and the Decision Tool (BreastScreen Australia 2004)
- *Standard Setting and Laboratory Accreditation* – Australian Productivity Commission Research Report November 2006
- *An Alternative Model for Safety and Quality Accreditation* – Australian Commission on Safety and Quality in Health Care February 2008
- *International Principles for Healthcare Standards* – The International Society for Quality in Health Care (ISQua 2007)
- *International Accreditation Standards for Healthcare External Evaluation Organisations* – The International Society for Quality in Health Care (ISQua 2007a)
- *Toolkit for Accreditation Programs* - The International Society for Quality in Health Care December (ISQua 2004)
- Other articles accessed as part of the review of the literature for this project.

The criteria have been divided into two groups and are listed in Section 6.6. The first group comprises those that have relevance to the whole of system or the accrediting organisation (Table 5). The second group comprises those that relate to particular accreditation system elements or activities (Table 6).

Table 5: Core criteria – accreditation system and accrediting organisation

Key					
✓	Present	P	Partial	×	Absent
?	Inconclusive	#	Information not available	+	Not applicable

Dimension	Elements	BSA
Consumer focus	Consumer participation in accreditation activities	P
	Consumer participation in standards development and/or review	✓
Stakeholder engagement	Stakeholders support the accreditation program	✓
	Stakeholder participation in accreditation activities	✓
	Stakeholder representation on accreditation decision making body	✓
	Ongoing communication with participating organisations	✓
Governance	The accrediting organisation demonstrates independence from the health services it assesses and has no conflict in relation to the services provided	×
	Clear relationships with professional, government and funding bodies	✓
	Memorandum of understanding or other formal agreement between accrediting organisation and key stakeholder organisations	×
	Accrediting organisation has a governance board/body	✓
	The governance body of the accrediting organisation is representative of stakeholders	✓
	The governance body is supported by government but independent of it	P
	The governance body has strategic and operational plans	×
	The governance body has a constitution, terms of reference and standard operating procedures	P
Open and transparent	Standards are feely available to all stakeholders	✓
	Accreditation outcomes are reported to the public	P
	Information from complaints system and feedback is used to inform improvement of the accreditation program	×
	Accreditation processes support a culture of transparency	P
	There is a process for appealing an accreditation decision	✓
	Appeals system is fair and accessible	?
	Communication of mission, values and aims of accreditation program	✓
	Cost or burden of appeal does not prevent initiating appeal	?
	Accrediting organisation has strategic and operational plans	×
	Defined roles, responsibilities and accountabilities for the accreditation program	✓
Based on quality improvement principles	Accreditation program has ongoing external evaluation or accreditation through an accreditation agency	×
	Evaluation steps and feedback loops in accreditation activities	×
	The accreditation program has a quality improvement framework	✓
	The accreditation program generates internal organisational commitment to improvement	✓
	Accreditation stimulates internally initiated improvement projects	?
	Services undergo self assessment of performance	✓
	Facilitates ongoing monitoring of service performance	✓

Table 5: Core criteria – accreditation system and accrediting organisation (continued)

Dimension	Elements	BSA
Focus on systems improvement	National indicator data is analysed to detect trends and identify system risks and opportunities for improvement	✗
	Risks and opportunities identified through accreditation process and analysis of indicator data is communicated to services	?
	Services are able to benchmark their performance against other like services	P
	Supports culture of personal and corporate responsibility for safety & quality of care	✓
Objective assessment	Accreditation program supports objective assessment of safety and quality	#
	Scope of accreditation program is defined	✓
	Services are provided with information that clearly sets out requirements for achieving accreditation	✓
	Standards are clearly defined and include comparative measures of quality and performance	P?
Supports accountability to public	All high risk services participate in accreditation process	✓
	Applies to all organisations providing like services	✗
	Public review and feedback on draft standards	✗
	There is a separation of standards setting (development and review) from the assessment of services performance against the standards	✗
	External assessment of compliance with standards in participating organisations is independent and free from conflict of interest.	✗
	Funding of the accreditation organisation is independent of assessment and award functions There is no conflict of interest that may prevent sanctions for non-compliance	✗
	Separate independent functions of assessment, award and service management	✗
	In assessing public services government does not dominate accreditation process	✓
	Stakeholder commitment that accreditation process will be free from undue influence by any party	?
	There is a balance between improvement and regulation	✓
Compliance is mandatory	Policy incentives for participation	✓
	Accreditation status is linked to increased funding, preferred provider status, professional development activities	✓
	Sanctions are applied where there is persistent non-compliance with standards	✓
Cost effective	Balance of costs and benefits considered in establishing the need for standards and the accreditation program	✗
	Collection of data to support accreditation is part of ongoing operational management of the service	✓
	The accreditation program is able to demonstrate a net benefit to the community as a whole	?
	The cost of accreditation to participating organisations has been determined	✗
	Indicative costs available to participating organisations in accreditation documentation	✗
	Accreditation costs are funded and identified in organisational budgets	✗
	Accreditation effort is proportional to the risk presented	P
	There is no duplication or overlap with other accreditation/certification activities	✗

Table 6: Core criteria — accreditation elements

Accreditation Activities	Criteria	BSA
Standards development and review	Balanced and rigorous assessment for need for standards that includes economic and service impact	?
	Balanced representation of all relevant stakeholder groups on development groups and consensus decision making	✓
	Participation by public is maximised, including publication of works programs and drafts for comment	P
	Ongoing evaluation of the performance of Standards	×
	There is a standards revision plan that includes objectives, resources and timeframes	×
	Consideration is given to links and overlap with other standards	✓
	New and revised standards are tested prior to general implementation	✓
Standards	Scope and purpose of the standards is clear	✓
	Consumer outcomes, safety and quality focussed	✓
	Based on current available evidence, internationally recognised guidelines or recommendations	✓
	The Standards have a clear framework that enhances their ease of use	✓
	Standards use plain English and define terms	✓
	Standards are risk rated	✓
	Standards are measurable, quantifiable and reproducible	✓
	Measures are timely and able to be replicated	✓
	Standards are freely available to all stakeholder and the public	✓
	Standards are externally evaluated	×
Assessment	Guidelines are available to assist in interpreting and applying standards	✓
	There is periodic external assessment of the organisations performance against the standards	×
	Assessment criteria are transparent to services, assessors and consumers	✓
	There is a measurement system for measuring compliance/achievement of standards	✓
	Appropriate tools and guidelines are available to support transparency, validity, completeness and accuracy of the assessment	P
	Assesses business as usual	?
	Site visits arranged to minimise burden of inspection on organisations using strategies such as short notice visits	×
Accreditation decision	There is consistency between decisions regarding accreditation status which is exhibited by services with similar levels of safety and quality are awarded with similar accreditation status	#
	Accreditation decision is based on assessment against standards	✓
	Clearly defined decision criteria. Reasons for accreditation decision available to service	✓
	Consideration of effect of accreditation status on quality improvement activities	#
Accreditation reporting	External assessment findings and ratings against each standard are provided in a written report to participating organisations	✓
	Accreditation reports undergo review and feedback prior to finalisation	✓
	Accreditation reports support improvement	✓

Table 6: Core criteria — accreditation elements (continued)

Accreditation Activities	Criteria	BSA
Assessors - site visitors and data auditors	Planning is undertaken to ensure ongoing availability of assessors	×
	Assessors are recruited via an open rigorous and transparent process	×
	Selection criteria are available and used	×
	Responsibilities and expectations of assessors are clearly defined	✓
	Assessors include peers with appropriate professional qualifications, experience and professional development	✓
	Assessors receive orientation and training	P
	Continuing education and training in the application of revised or new standards is provided	×
	Assessment team are selected external to the service being assessed and with regard to conflicts of interest, and specific needs of the organisation. Services have the right to refuse nominated assessment team members (number of refusals allowed is limited)	✓
	Feedback and evaluation of site visitor performance	×
	Employers release site visitors to undertake visits	✓
	Site visitors are motivated to improve quality of services	✓
Appeals process	The appeals process is non-adversarial and occurs independent of initial decision making group	?
	Is accessible to services with cost and burden not prohibitive	?
	Appeals process is clear and easy to follow and is communicated to participating organisations,	✓
	Number of standards	177
	Number of performance indicators	?

*The ACSQHC has identified a small number of key risk areas for the development of Australian Health Standards (AHS). It is likely there will be approximately 10-12 standards which all health care organisations will be required to comply with (Personal communication – Banks 2008)

6. ASSESSMENT OF CURRENT PRACTICE

6.1 ASSESSMENT APPROACH

The assessment of current practice has been informed by the following:

- desktop review of BreastScreen Australia documentation
- observation of a meeting of the NQMC
- interviews with stakeholders
- focus groups with BreastScreen Australia Services (participants listed in Appendix A)
- benchmarking against the core criteria

6.2 ASSESSMENT AGAINST BEST PRACTICE MODEL DIMENSIONS

The performance of BreastScreen Australia against each dimension of the best practice model is described. Where relevant, options for change have been identified and these are briefly outlined and the advantages and disadvantages of each option discussed.

6.2.1 CONSUMER FOCUS

The BreastScreen Australia Program has a strong consumer focus which is integrated into many aspects of the governance and operation of the Program as well as the accreditation process. A consumer centred model that empowers consumer participation in screening and assessment processes is operationalised through:

- Representation on the NQMC
- Representation on NAS development or review working party
- Training of consumer site visitors
- Participation of consumers in some site visit teams
- Consultation of peak consumer bodies by State/Territory Programs on aspects related to the quality and operational management of services

The accreditation system has made real effort to meaningfully involve consumers in the process and appears to be working effectively at many levels. However service managers and those service providers who are site visitors report continuing challenges in meaningfully involving consumers in these activities. While some services reported having consumer groups who are actively involved in improving the quality of service delivery, this did not appear to be universal.

Options

Involve target group and wider consumer consultation in NAS review process to test underlying assumptions on community and consumer expectations and preferences.

Support initiatives to explore opportunities and methods to more effectively involve consumers and their experience into quality improvement initiatives.

Enhance consumer participation at a broader level through greater openness and reporting of assessment results and incidents to foster greater public understanding of cancer screening and its risks as well as engaging consumers in the quality agenda.

6.2.2 STAKEHOLDER ENGAGEMENT

Almost all stakeholders consulted demonstrated strong engagement in accreditation. However, while most were supportive of the concept and the basic model in place, many identified a number of opportunities for improvement.

Stakeholder engagement and participation in accreditation activities was evident at all organisational levels and across all professional groups including professional colleges, funders and Program representatives.

6.2.3 GOVERNANCE

The NQMC has a key role in governance and oversight of the accreditation system and the development of policy relating to the safety and quality of BreastScreen Australia services. Oversight of the NQMC is provided by the Screening Sub-committee which consists of jurisdictional members. While the NQMC has government support from both DoHA and the jurisdictions, it does not appear to be influenced by government agendas.

Currently the NQMC includes six BreastScreen Australia Program representatives, four college representatives, and one representative each of consumers, DoHA, an external adviser (epidemiologist) and the secretariat (See Appendix B for list of stakeholder groups represented). The NQMC Chair is presently held by one of the State Program managers acting in an interim capacity, and has been acting in that capacity for over three years. The NQMC has terms of reference and while there are no formal written operating procedures, there are clearly understood and standardised meeting protocols and procedures that are consistently followed.

Currently all four college representatives and the NQMC Chair have operational roles within the Program. The large proportion of Program personnel (11 of 15) creates an environment that questions the NQMC's ability to demonstrate independence in assessing services' accreditation status.

Currently, the NQMC does not have any clearly defined strategic or operational plans The NQMC has outlined a number of imperatives in communications to the Screening Sub-Committee that outline a program of work for the near future.

The NQMC has strong support from stakeholders and is seen as critical to the viability of BreastScreen Australia as a national program. The current NQMC interim Chair has strong support from NQMC members and from key personnel within the jurisdictions.

> **Options**
>
> The NQMC undertake an exercise to formulate strategic and operational plans for management of the safety and quality of BreastScreen Australia services, the accreditation system and policy development.
>
> Appoint a permanent independent Chair of the NQMC and define a process for regular review of the appointment.
>
> Review representation on the NQMC and consider balance and alignment with functions and objectives.

6.2.4 OPENNESS AND TRANSPARENCY

Openness and transparency are embraced in principle and are apparent in many aspects of the accreditation system:

- The NAS and the Decision Tool that explains the decision making process are freely available on the internet.
- During the latest revision of the NAS a draft was made available on the website and comments invited from stakeholders and the public.
- The accreditation status of services is reported to the public, and reports are regularly updated and available on the internet.
- Roles and responsibilities and accountabilities for accreditation are clearly laid out in the Accreditation Handbook and the NAS.

Openness and transparency are less apparent in the following:

- All reports including regular data reports are managed as confidential documents.
- The only outputs of the NQMC accreditation decision making process is the accreditation status and a letter outlining the basis for the decision and any special conditions or action required by the service.
- There is no sharing of performance data at a national level except for the AIHW reports (reporting data that is at least three years old and reported on a national or jurisdictional basis).
- States maintain ownership of their data and currently Queensland appears to be the only State that shares performance data between services.

Consultations identified considerable differences in stakeholder perceptions of the openness and transparency of the decision making process. Generally members of the NQMC were satisfied that this was open and transparent although acknowledged that jurisdictions and services may not have this view.

> **Option**
>
> Move towards sharing all indicator data and relevant system learnings.

6.2.5 BASED ON QUALITY IMPROVEMENT PRINCIPLES

The BreastScreen Australia accreditation system is underpinned by a quality improvement framework. There was strong agreement that for services to be accredited they must first have a quality improvement framework in place and this is supported in documentation providing guidance to services seeking accreditation. Self assessment against the NAS and annual review of data reports support ongoing monitoring and quality improvement. Most stakeholders agree that accreditation generates internal organisational commitment to improvement however this is eroded by the following factors:

- the burden of reporting and associated accreditation activities prevent services from undertaking other quality improvement initiatives
- the perception that some standards are unachievable within the current context is de-motivating for services
- the only BreastScreen Australia Program staff that had access to formal opportunities for collaboration were those on the NQMC or site visitors
- the cyclical nature of the accreditation process means that the process does not support a continuous approach to quality improvement.

Currently the formal program quality improvement activities occur entirely within the accreditation framework. There are no opportunities at national level for collaborative learning, research and development, cross service/jurisdictional quality improvement projects. There are no centralised risk identification and reporting mechanisms. Informal examples of collaboration were cited such as the Queensland Surgery Quality Group, a Radiologists Quality Group, research and development in SA, Victoria and WA, and at Program Manager level through quarterly meetings.

There is no ongoing evaluation of the performance of the accreditation system or formal feedback and performance assessment. This current evaluation of BreastScreen Australia is the first time that the performance of the accreditation system and its various components has been reviewed.

Options

Consider implementation of regular learning, development, research and collaboration meetings to allow greater cross fertilisation of ideas, spread opportunities for learning, improvement and innovation.

Develop feedback mechanisms to allow ongoing review of the performance of the accreditation system and its elements.

6.2.6 FOCUS ON SYSTEMS IMPROVEMENT

The BreastScreen accreditation system is focussed on individual services performance and as with other accreditation systems, there is little emphasis on system wide issues and trends. While there is public reporting of a small number of performance measures there are a number of other barriers to systems improvements including:

- long lag time between collection and reporting performance data
- little formal analysis of underlying reasons for strong performance
- Inadequate centralised data systems restricting ability to analyse longitudinal, comparative data and identify system trends
- limited opportunities to collaborate and share lessons learned
- no formalised central incident reporting and analysis. In NSW and Queensland incident reporting and analysis occurs as part of mainstream health services however there is no opportunity for central reporting and analysis of sentinel incidents relating to breast cancer screening on a national level.

While there is ad hoc sharing through site visit teams, there are differing opinions from both service staff and site visitors about the value and systems learnings from site visits.

Option

Move towards sharing performance data between services.

6.2.7 OBJECTIVE ASSESSMENT

As the primary assessment decision making body, the NQMC is under heavy scrutiny regarding its independence and freedom from conflict of interest. A number of stakeholders made reference to the difference between small and large States and Territories, the bias that the accreditation system has towards small States and the lack of understanding of the NQMC regarding the issues faced by large states. To investigate the substance of these claims in detail is beyond the remit of this project as it would require an in-depth investigation of each NAS and its potential for bias in this way. However the following observations of the current accreditation structure, process and the underlying characteristics demonstrate the potential to allow bias to impact accreditation status decisions.

- The NAS are not set at a consistent level. Some are set at aspirational targets, some are minimum standards while others are somewhere in between. The Decision Tool while sound in theory, is designed to operate within a system where the NAS are all set at a consistent level and this lack of consistency diminishes the ability of the Decision Tool to function as it is designed. The variation in the levels at which the NAS are set means that a significant amount of interpretation of assessment results is required to come up with a logical outcome. In their current form, using a literal interpretation of the NAS and Decision Tool would lead to a large proportion of services either failing or only achieving two year accreditation.
- Statistical considerations for the cancer detection NAS targets which arise as a result of small detection numbers in large populations mean that a small variation in cancers detected (one cancer less) can mean failure to meet the standard. The assessment of services with small screening volumes (or small volumes within certain categories such as first screens in a well screened population) and application of statistical significance was a point of much controversy and tension. The following strategies may be used to overcome statistical issues:
  - the NAS aggregation index allows small services to "meet with exception", standards where performance falls below the target but within acceptable statistical limits.
  - funnel plots to identify wide confidence intervals
  - increasing the timeframe (and thus the sample size) over which the measurement is taken

While these strategies attempt to address the issue of random fluctuations in small services, they do not address all services' concerns.

- The NQMC has a critical role as the accreditation decision making body and its makeup is representative of stakeholder groups. The following combination of factors generates a perception of conflict of interest and a lack of independence by the NQMC.
  - As described in Section 6.2.3, of the 15 members of the NQMC, 11 are employed by the Program in some operational capacity.
  - Of those 11 BreastScreen Australia employees, four are from "large" States and seven are from the single service states and territories.
  - There is a perception that services not represented on NQMC are at a disadvantage as they do not have a voice during accreditation deliberations. A number of NQMC members voiced this opinion although some thought that the use of the Decision Tool and the decision making process made this influence immaterial.
  - There is little input from outside BreastScreen Australia into accreditation status decisions.
- SCU selection of site visitors creates the perception that some states or territories are able to "pick and choose" those that will be more favourably disposed towards their service. This is particularly seen as an advantage for small states and territories over large states as they only review one service and are more likely to only require a site visit every four years. (Currently 12 of 26 (46 percent) "large" State services have four year accreditation while four of five (80 percent) of "small" State services have four year accreditation). While difficult to substantiate the reality of this perceived bias, it does create tensions within the program and raises questions regarding the objectivity of the assessment.

Options

Establish a level for the NAS, based on existing Australian data that is achievable and provides clear guidance on levels of achievement. For quantitative standards this may take the form of three identified levels – bottom 10 percent, 50 percent and top 20 percent performance of BreastScreen Australia services.

Explore the use of interval targets rather than point targets to address issues regarding random variation and small population volumes.

Remove the selection of site visitors from the functions of the SCU. This may be managed centrally through an adequately resourced NQMC secretariat or through an external service provider.

6.2.8 SUPPORTS ACCOUNTABILITY TO THE PUBLIC

There was strong consensus among all stakeholders that BreastScreen Australia in general provided high quality, safe care that was responsive to consumers. The Screening Sub-committee Chair supported the supposition that achievement of BreastScreen Australia accreditation provided assurance to government and the public that breast cancer screening services were safe and delivered high quality care.

Structural and functional characteristics of the BreastScreen Australia accreditation system that support accountability to the public include separation of funding from assessment and award of accreditation. Government interests do not appear to dominate the accreditation process, demonstrated by the use of accreditation as a lever for services to access resources. There is a balance between improvement and regulation demonstrated by consideration of improvement strategies services in place, as well as a willingness to deny accreditation to services that have failed to demonstrate a satisfactory level of achievement against the NAS. The stronger focus on regulation reflects the nature of accreditation, which is primarily a compliance and accountability mechanism.

While there is strong commitment from the NQMC and site visitors that the accreditation process be free from undue influence by any party there are underlying structural and process issues that prevent this. There was consensus that the data audits and assessment of service performance against the NAS during site visits were fair and unbiased. There was some concern regarding the accreditation decision making. Of concern is the lack of separation between assessment, award of accreditation status and the management of services.

Options

Realign membership of the NQMC to change the balance of internal BreastScreen Australia Program personnel and external members. Review financial support for NQMC participants to ensure this does not preclude participation from a broad base of potential members. Establish a recruitment process that increases the reach to a wider pool of potential representatives. Recruit an external NQMC Chair.

Outsource management of the assessment and accrediting process. This will achieve separation of the various functions and allow the NQMC to focus on strategy and policy development. There are two major risks in outsourcing management of the accreditation process. First, this may lead to decreased ownership of the accreditation process by BreastScreen Australia personnel. Second, it will expose the real costs of running the accreditation program, which in its current form, is significantly greater than that recognised due to the "voluntary" nature of much of the accreditation activity.

6.2.9 COMPLIANCE IS MANDATORY

Within BreastScreen Australia services there were differing levels of understanding regarding the imperatives in place relating to accreditation. Most understood that for a service to continue functioning under the BreastScreen Australia banner the service must be accredited. A couple of service staff thought that funding was reliant on achievement of accreditation and this may be a lever which is used at state or territory level but does not effect the Public Health Outcome Funding Agreements (PHOFA). There is however, significant political and peer pressure on services to achieve accreditation.

All stakeholders expressed the strong belief that BreastScreen Australia breast cancer screening was superior to breast cancer screening services (or other screening type services including initial diagnostic mammography) provided within the private sector because they were not bound by a similar quality standard. The reported high levels of screening that occurs in the private sector (those not contracted to BreastScreen Australia) where services do not recognise or comply with the NAS, has potential to diminish the overall value and quality of breast cancer screening for Australian women.

6.2.10 COST EFFECTIVE

When the BreastScreen Australia Program and the initial standards and accreditation system were established there was no formal economic cost benefit. The evidence regarding quality and screening was considered adequate rationale for its establishment.

The real cost of the accreditation system is not realised at present. Most program managers, service managers and clinicians report that many accreditation activities are undertaken in an individuals' own time or at personal cost to the individual. This is a particular issue for medical clinician site visitors with radiologists and pathologists funding, either personally or through budget allocated to service provision, the cost of obtaining locums to cover site visitor commitments. Surgeons are also significantly impacted through loss of operating or consultation time limiting their ability to generate income. All services consulted stated that accreditation placed a significant burden on the service.

Service and Program Managers agree that a core set of the quantitative NAS provide performance data that is an essential tool for efficient operational management of the service.

> **Options**
>
> Reduce the overall number of NAS so that external assessment is only on those relating to the key objectives of the program and reflective of the quality of the service. This will reduce burden on the services, site visitors and others involved in the assessment processes such as the SACs and NQMC.
>
> Explore alternative options to maximise the value of surgeon, radiologist and pathologist time in site visits through focussing input into assessment of those standards most relevant.

6.3 ASSESSMENT AGAINST BEST PRACTICE ACCREDITATION ELEMENTS

6.3.1 STANDARDS DEVELOPMENT AND REVIEW

At present the NAS are updated on an ad hoc basis. There is no formal ongoing evaluation of the NAS however the NQMC during its review of accreditation reports has become aware of issues with performance of individual NAS. In addition state program managers and others involved in preparing services for accreditation informally report issues with individual NAS.

The ability to undertake continual or even timely review of individual NAS is hampered by the lack of availability of national performance data and ongoing capacity to undertake the task. The NQMC meeting agendas are almost completely consumed with accreditation reviews and review of annual data reports, leaving little time to formulate changes to the NAS. To date, special purpose working parties are convened each time the NAS are reviewed. This is a lengthy process required to achieve consensus on changes with the last review taking over two years from commencement to endorsement. Draft standards were placed on the BreastScreen Australia website and stakeholder and public comment invited. Currently the NQMC has identified six NAS requiring urgent review.

> **Option**
>
> Establish an ongoing mechanism for review and update of the NAS by either enhanced resourcing and establishment of a standing committee to undertake this role or through redesign of the NQMC work program to allow incorporation into its standing items.

6.3.2 STANDARDS

The scope and purpose of the NAS are clearly set out within the documentation. The risk framework and the inclusion of quantitative standards are seen as significant strengths although the quantitative standards could be improved by calibrating against current Australian data. Stakeholders view the NAS document as difficult to use, requiring a significant amount of "flicking back and forward" within the document.

There was overwhelming agreement that there are too many NAS. Most thought that the NAS should focus on the key objectives of breast cancer screening – "finding as many cancers as possible (in the target population) as early as possible" without causing unnecessary harm and that other general management standards should be available as guidelines but not assessed during site visits. A needs analysis of the accreditation system and for each NAS including economic and service impact was not undertaken at the time it was established. However, the integration of the NAS into a risk management framework provides an assessment of service impact of each NAS.

As discussed in Section 6.2.7, the variable levels of the NAS make interpretation and use of the Decision Tool problematic, requiring subjective interpretation of performance. Assessment of some standards that act as part of a cluster were thought to be redundant if a high level standard was achieved.

Option

Develop consensus agreement among stakeholders on a consistent performance level at which the NAS should be set. Undertake an extensive revision of the NAS:

- Review quantitative standards based on current Australian data (see Section 6.2.7)
- Only include those NAS that relate to the key objectives of the service
- Explore the possibility of focussing on fewer high level standards and only assess lower level elements where there is failure to achieve a high level standard
- Change the more generic management standards into guidelines for services and remove from the list of NAS.

6.3.3 ASSESSMENT

The accreditation model includes a periodic assessment of the organisation's performance against the standards. There are a number of strategies in place to ensure consistent assessment of services against the NAS including:

- site visitor training in assessment methods and criteria
- the site visitor training manual which sets out methods for verifying the NAS and other site visit activities such as reporting
- a clear measurement system, the quantitative NAS, and guidance on assessment of the qualitative NAS

Services describe a long preparation period prior to site visits. Activities are scheduled during the site visit to ensure key clinical staff are available and representative activities are observed by the site visit team. Reporting templates assist service and site visit teams to provide information in a standard format and facilitate reporting. The current forms were felt to be an improvement from previous systems however services find them overly complex and burdensome to complete.

Option

Streamline reporting requirements and templates.

Consider introducing unannounced survey visits.

6.3.4 ACCREDITATION DECISION

The accreditation decision is based primarily on the assessment of the service's performance against the standards as determined by the site visit team and the data audit. Results are then interpreted using the Decision Tool although other issues are taken into consideration in formulating the accreditation decision including:

- evidence of strategies to address performance issues
- trends in performance i.e. improvement or deterioration
- recommendations from the SAC.

A service's accreditation status is a source of professional pride for those services gaining four year status. It provides some granularity to the conferring of accreditation status to have the potential to differentiate high performing services. However the difference in burden to services of a two year with high priority recommendations versus a four year status is significant. Most stakeholders acknowledged that the burden of reporting, responding to findings and preparation for accreditation prevented those services with two year and high priority recommendations from implementing changes and improvements

Currently while a service is awarded a particular status during their full accreditation assessment, this may be revised by the NQMC on the basis of the annual data reports. One questions why services are conferred with different accreditation status if that can be changed subsequently, for example a four year accredited service may have its status changed to a two year or two year with high priority recommendations.

There was acknowledgement of the difficulty in maintaining consistency of decision making. This is primarily due to:

- the variable level of the NAS eroding the ability to use the Decision Tool as it was intended
- inability to access data on previous decisions
- variable interpretation of the significance of trends in performance and
- \improvement strategies.

Stakeholders not on the NQMC expressed concern that the reasoning behind accreditation status decisions often was not evident. Underlying reasons are explored in further detail in Section 6.2.7.

Options

Review the timing of accreditation status categories and reporting requirements for services responding to high priority recommendations.

Review the rationale and benefit of revisions to accreditation status.

6.3.5 ACCREDITATION REPORTING

Site visit reports are compiled during the site visit and in some cases finalised after the completion of the site visits. All members of the site visit team review and sign off the report.

There is general agreement that the quality of the accreditation reports is reasonable and that they provide useful material to services for planning improvement actions. Many perceived that the quality and consistency of reporting has improved since implementation of the site visitor training. Services generally thought that the reporting templates are unwieldy and time consuming to use. Services find that responding to findings of data audit and site visitor reports is burdensome and often repetitive, bureaucratic and without value.

6.3.6 ASSESSORS

Recruitment of site visitors occurs on an ad hoc basis by SCUs. All state program managers cited challenges in securing site visitors particularly radiologists and surgeons. There is no formal open recruitment program and selection criteria for site visitors does not currently exist.

The recent site visitor training was well received and stakeholders agreed it was an effective training and orientation although currently it is not funded on a recurring basis and there are no other mechanisms for ongoing education and training.

Currently there is no formal assessment of the performance of site visit teams and any feedback from services is handled through formal letters between the SCU and in some instances the NQMC.

Options

Institute an open process for recruiting site visitors, using explicit selection criteria, and evaluate performance of new site visitors.

Implement ongoing training and development including updates on adjustments to the NAS and learning from feedback on the performance of site visit teams.

6.3.7 APPEALS PROCESS

The appeals process is clearly defined in the Accreditation Handbook. During consultations services were asked if they considered making an appeal however those who had considered making an appeal did not continue either because of the perceived increase in burden of the appeals process or the belief that an appeal would not change the outcome. The reimbursement of costs to eligible members of the appeal committee is the responsibility of the relevant SCU and these costs may include site visits and meeting costs.

The appeals process set out in the Accreditation Handbook has not been adequately tested as yet. Only one recent appeal was identified and the decision to appeal was made in consultation with the NQMC. The appeal was undertaken to allow the SCU time to restructure the service and make changes to key personnel required to achieve a sustainable improvement in quality without having to close the service down completely.

6.4 STRENGTHS

The BreastScreen Australia accreditation system has a number of strengths that include:

- overwhelming stakeholder commitment and ownership of the accreditation system
- strong consensus that accreditation and the NAS are central to the broader BreastScreen Australia Program
- improvements made in recent years to the NAS, the decision tool and site visitor training
- a genuine drive to make accreditation about quality improvement at all organisational levels
- a process that challenges clinicians within the multidisciplinary team to review and critique performance
- site visits and annual data reports to assess and monitor service performance.

While acknowledging issues with the detail of accreditation decision making, stakeholders are confident that the accreditation system has credibility as a means of providing assurance of the quality of service provision. The NQMC provides leadership for the wider BreastScreen Australia Program and together with the NAS and accreditation system provides a critical unifying factor

that underpins and brings together the program at a national level. In addition BreastScreen Australia program documentation and the NAS clearly outline the accreditation process and accreditation requirements and is a critical driver for services to achieve program objectives.

The accreditation system supports the consumer centred approach at the NQMC and State and Territory program levels. In some services there are examples of strong consumer input and engagement.

6.5 WEAKNESSES

Weaknesses of the BreastScreen Australia accreditation system may de divided into those relating to the NAS and those related to assessment, burden and sustainability of the system.

There is strong consensus that there are too many NAS and that some could be removed and used as operational guidelines. The current variable performance levels at which the NAS are set creates significant difficulty in applying the decision tool objectively. The lack of a process to accommodate ongoing revision of the NAS, limited use of existing Australian data to set realistic targets that take into account the statistical challenges and statistical issues with smaller sample sizes weakens their use as a fair and objective measure.

Other weaknesses include:

- no central database, and with the exception of one state, performance results are not shared between services
- a culture of confidentiality surrounding data reporting and lack of reporting and analysis of sentinel incidents, does not support systems learning
- insistence that the program remains isolated from mainstream services which creates:
  - a siloed approach rather than supporting continuity of care for those women requiring further diagnostic and treatment services
  - a small isolated group of services, a small pool of expertise from which to draw on which in turn has the danger of isolation in group thinking and an insular service workforce for decision making processes. The service is then not open to responding to feedback and learning from their experiences.

These factors all contribute to perceptions of a lack of independence, potential for conflicts of interest and lack of transparency and are significant risks to the credibility of the accreditation program.

Sustainability is a real issue for a number of reasons:

- the burden of accreditation was detracting from service provision because of decreases in real funding and increases in the target population requiring services to do more with less.
- services are having difficulty recruiting to clinical positions
- SCUs are struggling to secure site visitors, particularly radiologists and surgeons
- unrecognised costs are currently absorbed by individuals committing their own time to accreditation activities.

7. SUMMARY AND OPTIONS

7.1 THEMES AND OBSERVATIONS

There are a number of themes, issues and observations that are emerging from the review of the literature and further informed by consultation activities.

- There are separate issues relating to standards development and to accreditation programs although the success of the system is reliant on the quality of the standards against which organisations are accredited.
- Healthcare accreditation programs are operating within a rapidly changing environment. A number of factors such as workforce shortages, increasing demand and a corresponding push for increased efficiency are driving rapid reforms within the sector.
- Current initiatives within the safety and quality arena will impact Australian health care accreditation in the future and should be closely considered in formulating any proposed changes to the current BreastScreen Australia accreditation system. Planned changes will lead towards fewer accreditation programs, fewer standards and standards focussed on program objectives, safety and quality.
- There is a body of expert opinion that provides adequate direction on a best practice accreditation model although there is limited empirical evidence to support the effectiveness of accreditation in achieving its aims. Despite the lack of evidence there is strong consensus around the characteristics of most of the individual elements of an accreditation program.

The following issues and themes are emerging in relation to the operation of the BreastScreen Australia accreditation system.

- There have been significant improvements to BreastScreen Australia accreditation since its inception in 1991 and it is now a data driven, outcomes-focussed program underpinned by a comprehensive set of standards that are based on BreastScreen Australia service performance data.
- The BreastScreen Australia Program has a strong client focus and a high degree of ownership and commitment from program and service managers and clinicians, many of whom have a long term involvement in the provision of breast cancer screening services and the BreastScreen Australia Program.
- There are a number of challenges related to the relationship between the Commonwealth and the respective jurisdictions in the areas of governance, operational management and funding that impact on the operation of the accreditation system.
- There is a tension between the need for independence of the accrediting body and the need for expert peer input into the accreditation process through site visits and evaluation of service performance against the NAS. This is a particular challenge in achieving an appropriate balance between quality improvement and compliance with standards.

- While some issues relate to the accreditation process as a whole, there are others that impact differently between the "large states" (Queensland, NSW, Victoria) and "small" or single service states (ACT, SA, WA, NT, Tasmania). For example the burden of scheduling accreditation site visits and other accreditation activities or low screening volumes effecting confidence internals for performance results.
- The relevance of many of the national accreditation standards in day to day operations means that the accreditation process is meaningful to services and is therefore seen to be more relevant than other accreditation programs.
- The current system which involves more than a 'tick and flick' approach is beneficial in allowing some leeway in decisions regarding the granting of accreditation status however this in turn makes accreditation decisions more subjective and less transparent to those outside the NQMC.
- While operational management and structure of the BreastScreen Australia Program is outside the remit of this project, the move towards integration of screening, diagnostic and treatment functions within accreditation standards and assurance mechanisms has led to an overall improvement in the quality of breast cancer care. This is also consistent with the broader health care drive to model services around the patient journey, to achieve a seamless experience for consumers rather than a series of discrete interactions within separate silos of care.

7.2 OPTIONS FOR CHANGE

Three main options for change are presented below. However within each of options two and three, a number of changes may be considered to each of the different accreditation elements. These are set out in Section 7.2.4

7.2.1 OPTION 1 – CONTINUATION OF THE STATUS QUO

Maintain the current model and structure of the accreditation system however there are significant risks in relation to the ability of BreastScreen Australia to sustain the status quo and lost opportunity to improve the safety and quality of services.

7.2.2 OPTION 2 – MODIFICATION OF THE EXISTING MODEL

Maintain the existing model and structure but with modifications to the NAS, the quality improvement program and accreditation assessment processes. These modifications include a national database with sharing of performance data with services and the public, development of strategies to support safety and quality improvement such as failure of cancer diagnosis analyses, forums to share learning, collaboration on research and providing professional development opportunities for all BreastScreen Australia personnel.

Benefits of modifying the existing model are that the current strengths of the accreditation system will be retained with less risk to stakeholder engagement and ownership. Modifications will be able to be more quickly and easily implemented than if functions were established within a different organisation. Options targeted at improving the consistency and objectivity of the decision making process will increase services confidence in the accreditation system. Modification of the existing model will minimise the disruption to the accreditation system and program staff activities.

If existing processes were streamlined and the burden reduced there should be efficiency gains that would be realised such as the potential reallocation of capacity to service delivery or other quality improvement strategies. However, if the accreditation was outsourced the real cost of the accreditation process would be born by the Program and any efficiencies may be absorbed by the additional structural, contractual and administration costs.

The major risk of adopting this approach is a continued concern among some stakeholder groups regarding the independence and objectivity of accreditation decision making. There is also concern regarding the lack of separation between standards setting and decision making however this is less significant an issue in the context of BreastScreen Australia because commercial interests do not come into play.

7.2.3 OPTION 3 – CHANGE TO THE EXISTING MODEL

Separate the assessment, service delivery and policy development arms of the accreditation program. This may be achieved through outsourcing or separation of management of the accreditation process while maintaining multidisciplinary service team input into assessment of services against the NAS.

Benefits of this approach is an increase in the objectivity of the assessment and accreditation decision making thereby increasing accountability to the public. There are two major risks in outsourcing management of the accreditation process. Firstly, this may lead to decreased ownership of the accreditation process by BreastScreen Australia personnel. Secondly, it will expose the real costs of running the accreditation program, which in its current form, is significantly greater than that recognised due to the "voluntary" nature of much of the accreditation activity. If this option is adopted mechanisms should be in place to ensure that there are links and robust communication processes between the accreditation and policy making/ standard setting entities so that the policy development in accreditation is informed by what is found in the site visits

In addition, significant changes to the BreastScreen Australia accreditation system may be required as a consequence of the current reform agenda being driven through the Commission. Two such major changes to the program may risk destabilisation of the quality assurance and improvement systems putting at risk the capacity of BreastScreen Australia services to meet program objectives.

7.2.4 OPTIONS FOR CHANGES TO ACCREDITATION SYSTEM ELEMENTS

The detailed options for change to accreditation system elements are divided into three sections

- Options that apply to modification of the existing model only with no fundamental change to governance and management of the accreditation process
- Options that only apply to changing the existing governance and management model
- Options that apply to both of the above

The following specifically relate to Option 2, modifying the existing accreditation model.

- Realign the membership of the NQMC to change the balance of internal BreastScreen Australia Program personnel and external members.
- Remove the selection of site visitors from the functions of the SCU. This may be managed centrally through an adequately resourced NQMC secretariat or through an external service provider.
- Review financial support for NQMC participants to ensure this does not preclude participation from a broad base of potential members. Establish a recruitment process that increases the reach to a wider pool of potential representatives.

The following specifically relate to Option 3, implementing a new accreditation model.

- Outsource management of the assessment and accrediting process. This will achieve separation of the various functions and allow the NQMC to focus on strategy and policy development.

The following apply to both Option 2 and Option 3.

Governance

- Appoint a permanent independent Chair of the NQMC and a define process for regular review of appointment.
- Review representation on the NQMC and consider balance and alignment with functions and objectives.
- Support initiatives to explore opportunities and methods to more effectively involve consumers and their experience into quality improvement initiatives.
- Enhance consumer participation at a broader level though greater openness and reporting of assessment results and incidents to foster greater public understanding of breast cancer screening and its risks as well as engaging consumers in the quality agenda.

Standards

- Involve the target group and wider consumer consultation in NAS review process to test and update underlying assumptions on community and consumer expectations and preferences.
- Establish a level for the NAS, based on existing Australian data that is achievable and provides clear guidance on levels of achievement. For quantitative standards this may take the form of three identified levels – bottom 10 percent, 50 percent and top 20 percent performance of BreastScreen Australia services.

- Reduce the overall number of NAS so that only those relating to the key objectives of the program are assessed. This will reduce burden on the services, site visitors and others involved in the assessment processes such as the SACs and NQMC.
- Develop consensus agreement among stakeholders on a consistent performance level at which the NAS should be set. Undertake an extensive revision of the NAS:
  - Review quantitative standards and base on current Australian data
  - Only include those NAS that relate to key objectives of the service
  - Explore the possibility of focussing on the high level standards and only assess lower level elements where there is failure to achieve a high level standard
  - Transition some of the more generic management standards into guidelines for services and remove from the list of NAS to be assessed during site visits
- Establish an ongoing mechanism for review and update of the NAS by enhanced resourcing and establishment of a standing committee to undertake this role.

Performance improvement

- The NQMC undertake an exercise to formulate strategic and operational plans for management of the safety and quality of BreastScreen Australia services, the accreditation system and policy development.
- Develop feedback mechanisms to allow ongoing review of the performance of the accreditation system and its elements.
- Review the timing of accreditation status categories and reporting requirements for services responding to high priority recommendations
- Review the rationale and benefit of revisions to accreditation status.
- Streamline reporting requirements and templates.
- Move towards sharing performance data between services. Identify and investigate breast cancer screening safety and quality issues centrally to identify systems issues and share lessons learned between services.
- Consider implementation of annual learning, development, research and collaboration meetings to allow greater cross fertilisation of ideas, spread opportunities for learning, improvement and innovation.
- Institute an open process for recruiting site visitors, using explicit selection criteria, and evaluate performance of new site visitors.
- Implement ongoing training and development for site visitors including updates on adjustments to the NAS and learning from feedback on the performance of site visit teams.
- Consider introducing unannounced survey visits.
- Explore alternative options to maximise the value of surgeon, radiologist and pathologist time in site visits through focussing input into assessment of those standards most relevant.

APPENDIX A: CONSULTATION

Table 9: One on one interviews

	Name	Position/Agency
1	Ms Lou Williamson	Chair – NQMC (Program Manager SA) Digital Mammography Accreditation Standards Working Group
2	Prof David Roder	NQMC - Epidemiologist
3	Dr Liz Wylie	NQMC – Australian College of Radiologists (Program Manager BreastScreen WA) Digital Mammography Accreditation Standards Working Group
4	Ms Pam Brackman	NQMC – Australian Institute of Radiography (State Radiographer BreastScreen Queensland) Digital Mammography Accreditation Standards Working Group
5	Mr Alan Keith	NQMC - Australian Government Digital Mammography Accreditation Standards Working Group
6	Ms Roberta Higginson	NQMC - Consumer
7	Mr John Buckingham	NQMC - College of Surgeons Digital Mammography Accreditation Standards Working Group
8	Mr Warwick May	NQMC – Accreditation managers (Accreditation manager BreastScreen coordination unit NSW)
9	Ms Gail Raw	NQMC – Program Manager small states/territories (State Program Manager BreastScreen Tasmania)
10	Ms Jan Tresham	NQMC – Data managers (Coordinator data management and support service BreastScreen WA)
11	Dr Gelareh Farshid	NQMC – Royal College of Pathologists of Australasia (Clinical Director BreastScreen South Australia)
12	Ms Lyn Sartori	NQMC – Program Managers Large States/Territories (Director Cancer Screen NSW)
13	Ms Fleur Webster	NQMC – Secretariat
14	Dr Darren Lockie	Digital Mammography Accreditation Standards Working Group (Chief Radiologist Gippsland BreastScreen)
15	Mr Mark Costello	Deputy Director Cancer Screening NSW Digital Mammography Accreditation Standards Working Group
16	Dr Madeleine Wall	Digital Mammography Accreditation Standards Working Group Clinical leader BreastScreen Aotearoa
17	Dr Bronwyn Harvey	DoHA Medical Adviser – Targeted Prevention Programs
18	Dr Helen Zorbas	Director, National Breast and Ovarian Cancer Centre (NBOCC)
19	Dr Denis Smith	Chair - NSW State Accreditation & Quality Improvement Committee
20	A/Prof Margaret Banks	Australian Commission for Safety and Quality in Health Care
21	Dr Larry Von Karsa	Screening Quality Control Group, European Cancer Network Coordination Office
22	Dr Simon Towler	Chair of the Screening Subcommittee, Australian Population Health Development Principal Committee and WA Premier's Physical Activity Taskforce

Table 9: One on one interview (continued)

	Name	Position/Agency
23	Ms Andriana Koukari	Assistant Secretary, Department of Health and Ageing
24	Dr Mary Rickard	Radiologist
25	Dr Allison Rose	Radiologist
26	Dr Roz Glazebrook	State Program Manager Queensland
27	Ms Vicki Pridmore	State Program Manager Victoria
28	Ms Chris Tyzak	State Program Manager NT
29	Ms Helen Sutherland	State Program Manager ACT
30	Prof John Boyages	Director Western Sydney BreastScreen Program

Personal communication with international program personel

- Dr Larry Von Karsa – European Cancer Screening Network Coordination Office
- Mr Jay Onsyko – Canada Public Health Agency of Canada
- Dr Madeleine Wall and Catherine Hillstone – BreastScreen Aotearoa, New Zealand
- Dr Sven Törnberg – Sweden
- Prof Julietta Patnick – UK
- Dr Jaques Fracheboud - Netherlands

BreastScreen Australia Service – Focus groups

- Mackay service – Helen Archibald (Medical Director, Mackay BreastScreen), Alyssa Hatherly (Medical Officer, Mackay BreastScreen), Katy Edwards (Manager, Mackay BreastScreen), Roxanne Watling (Service manager, Darling Downs – West Moreton Health Service District)
- ACT Service – Jane Haynes (Senior Radiologist), Cathy Meredith (Quality and improvement manager), Helen Porrit (Nurse counsellor), Anne Porrege (Medical practitioner), Helen Phil Crawford (Data manager), Helen Sutherland (Program Manager ACT and South-Eastern NSW Service)
- Hunter-New England Service – Michael Symonds (Director), Shane McDonald (Acting operations manager), Allan Knight (Business manager), Jennifer Woodhead (Senior data manager)
- North Western Victoria BreastScreen – Victoria Cuevas (Service Manager), Susy Alessandri (Data manager), Allison Rose (Clinical Director)
- Western Sydney BreastScreen Program (impromptu meeting) John Boyages (Medical Director), Judy Bursle (Chief radiographer), Barry Finch (Service manager), Owen Ung (Surgeon).

APPENDIX B: NQMC REPRESENTATION

- Chair
- Epidemiologists
- Royal Australian and New Zealand College of Radiologists
- Australian Institute of Radiography
- Australian Government
- Consumer
- Royal Australasian College of Surgeons
- Nurse/Counsellors
- Accreditation Managers
- Program Managers (Small States/ Territories)
- Data Managers
- Marketing and Recruitment Officers
- Royal College of Pathologists of Australasia
- Program Managers (Large States/ Territories)
- Secretariat

APPENDIX C: REVIEW OF INTERNATIONAL MODELS OF QUALITY ASSURANCE FOR BREAST SCREENING

C.1 EUROPEAN UNION

C.1.1 OVERVIEW OF THE BREAST CANCER SCREENING PROGRAMS

Breast screening programs utilizing mammography are being run in all but one of the 27 European Union (EU) Member States, mainly through population-based programs (von Karsa et al, 2008). The primary aim of these programs is to 'reduce mortality from breast cancer through early detection' (Perry et al, 2008).

The Council of the EU made recommendations in 2003 that breast screening as a public policy initiative should target healthy, asymptomatic women aged 50-69, providing mammography every two years (Perry et al, 2008). The programs are voluntary and recommended recruitment procedures involve sending invitations to participate with sufficient information to enable women to make an informed choice about their participation in the program.

In the EU, it is recommended that symptomatic and asymptomatic women attend separate clinics and there are separate certification governance bodies for screening and diagnostic centres (described in more detail below). There are four types of breast screening centres:

- Diagnostic Mammography Unit
- Breast Assessment Centre
- Loco-regional Screening Program
- European Reference Centre for Screening (Perry et al, 2008).

C.1.2 BACKGROUND AND POLICY CONTEXT

Accredited Breast Screening in Europe occurs in the context of the European Action Against Cancer. This action was initiated by the heads of the Member States of the EU more than twenty years ago and included establishment of a Committee of Cancer Experts. [2]

In mid 2003, the European Parliament called for a program which could lead to a 25 percent reduction in breast cancer mortality rates in the EU and only a 5 percent disparity between survival rates between member states. At the end of 2003, the Health Ministers of the European Union unanimously adopted the Council Recommendation of 2 December 2003 on cancer screening, reinforcing a decision to focus on screening for breast, cervical and bowel cancer. It also called for the implementation of the European guidelines on quality assurance in mammography and that

2 Each of the twelve Member States appointed an expert in oncology or public health, as did Sweden who was not yet a member of the EU but invited as an observer. For more details refer EUREF Certification Protocol.

Adequate human and financial resources should be available in order to assure the appropriate organisation and quality control in all the Member States'.[3] In 2006, the European Parliament re-emphasised its intention, including efforts within the expanded EU.

Initially, a Pilot Project Network in EU Member States established by the Europe Against Cancer (funded by the European Commission) brought together Member States to 'examine and develop the methodologies of breast cancer screening in different health environments, share knowledge and experience' (Perry et al, 2008). After a few years, the focus (and funding) shifted to quality, as described in the next section.

C.1.3 QUALITY ASSURANCE, ACCREDITATION MODELS AND REGULATORY FRAMEWORK

The European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis (the European Guidelines) state that breast cancer screening in the EU is conducted under the following principles:

> *'Implementation of population-based breast screening programs, prioritisation of quality assurance activities such as training and audit, together with the setting up of specialist breast units for management of breast lesions detected inside or outside screening programs are regarded as essential…' (Perry et al, 2008).*

Furthermore, the European Guidelines identify that:

Seven common elements are outlined in the European Guidelines to support the delivery of high quality breast screening services. Three of these elements are of particular interest namely:

- all units must work to agreed protocols within a local QA manual that is based on accepted clinical standards and published values
- accreditation is required for all screening (and symptomatic) units
- staff should hold professional qualifications and undergo professional development and training
- screening centres are to be staffed by a multidisciplinary team, including radiologist, radiographer, pathologist, surgeon, nurse counsellor and medical oncologist/radiotherapist
- clinical findings and variation should be discussed in multidisciplinary meetings
- quality assurance programs are mandatory in order to qualify for funding
- a lead professional has the power to suspend elements the service if required to maintain the service standards and outcomes (European Commission, 2006).

The European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services developed a European program for voluntary certification of high quality mammography services (EUREF, 2001). The stated impetus for the development of the program is the belief that 'it is important to help consumers, health care professionals, government authorities and other interested parties to identify high quality mammography services appropriate to women's needs' (EUREF, 2001).

3 For more details and the full recommendation please refer http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003H0878:EN:HTML

At this point in time, accreditation remains voluntary however, EUREF refers to the importance of 'purchasing power' and the supportive role certification may have in directing GPs, women's groups or health insurance agencies towards accredited services.

Services are assessed against the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis (European Guidelines). Certificates are available for the four types of screening centres previously outlined, which range from single units to substantially sized centres. The process for certification includes self-assessment and a site visit by a EUREF certification team. Certificates are only provided on the achievement of set standards (shown in the following section) and can be withdrawn if these standards are not maintained. Certificates are time-limited and EUREF recommend re-certification every five years (EUREF, 2001).

It should be noted that a recent report on the implementation of Council Recommendations regarding cancer screening similarly recommends the 'development and piloting of an EU-wide accreditation/certification scheme… to continually improve performance and would help consumers recognise which services achieve the EU standards' (von Karsa, 2008).

C.1.4 STANDARDS DEVELOPMENT PROCESSES

The European Guidelines built on previous European Commission Guidelines as well as other guidelines, including the United Kingdom National Guidelines and specific physico-technical/professional standards (i.e. the European Guidelines for Quality Assurance in Mammography Screening, American Mammography Quality Standards Act and the European Council directive on radiation protection). There has been a significant shift within Europe over recent years from support for stand alone breast cancer screening towards integration of screening, diagnostic and management services. The integration of diagnostic and treatment related standards with the screening standards has been a significant driver of improved quality of service for symptomatic patients and cancer care (Personal communication - von Karsa 2008).

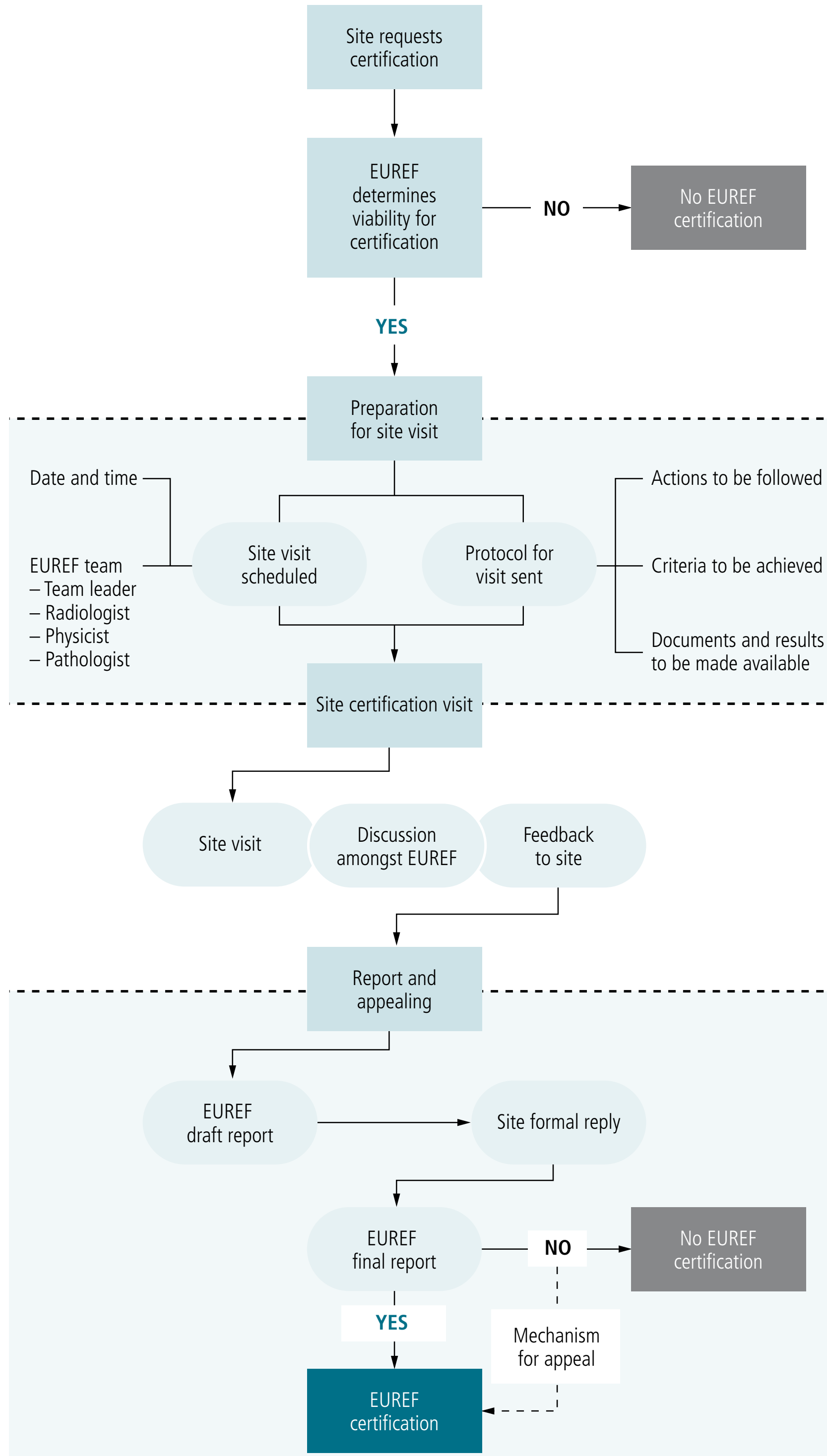
The European Guidelines were developed by more than 200 authors including client and patient advocates from 18 member states (Perry et al, 2008) and were endorsed by the European Breast Cancer Network.

C.1.5 THE ACCREDITATION PROCESS

As previously described, EUREF has separated certification for diagnostic service (targeting predominantly symptomatic women) and screening program (targeting predominantly asymptomatic women) services in recognition of the differing facilities and skills that may be required. EUREF is therefore issuing separate certificates for each - 'EUREF SCREENING' and 'EUREF DIAGNOSTIC'.

There are a number of steps involved in seeking certification in the European Union. These commence with the site requesting certification, include a site visit (including informal feedback during the visit), an initial formal written report by the visiting team, a formal reply by the site and a final report and (where appropriate) provision of certification (Figure 4). The guidelines also refer to a 'mechanism for the right of appeal in cases of dispute' although details regarding this process are not available. Figure 4 provides an outline of the EUREF accreditation process.

Figure 4: Process for EUREF accreditation



Information sourced from EUREF, 2001

C.2 ENGLAND (BREAST CANCER SCREENING)

For the purpose of delivery of cancer screening services the UK now operates as four separate jurisdictions, England, Scotland, Wales and Ireland.

In 1999, England established a National Cancer Director role within the Department of Health, which was followed by a National Cancer Plan in 2000. In 2007, the Plan was revised, resulting in the Cancer Reform Strategy (NHS, 2007). There are nationally coordinated screening programs for breast, bowel and cervical cancer overseen by NHS Cancer Screening Programs (NHS, 2008).

C.2.1 OVERVIEW OF THE NATIONAL HEALTH SERVICE BREAST SCREENING PROGRAM

England has the longest running population level breast cancer screening program, in existence for the past two decades. The National Health Service Breast Screening program (NHSBSP) provides population level screening for women aged 50-70 (the NHS website reports that this will be extended to 47–73; NHS, 2008) with a recommended standard screening interval of three years. In 2005, the program was using two view mammography and screening 1.3 million women aged 50–70 years every three years. This represents approximately 75 percent of those women invited to attend for screening (NHSBSP, 2006).

C.2.2 POLICY AND PROGRAM CONTEXT

Breast screening occurs in England under the broader Cancer Reform Strategy. The breast screening program commenced in 1987

The objectives of the NHSBSP are to:

- identify and invite eligible women for mammographic screening
- carry out high quality mammography on those women attending for screening
- provide services that are acceptable to those who receive them
- follow up all women who are referred for further investigations
- minimise the adverse effects of screening – anxiety, radiation dose and unnecessary investigations
- diagnose cancers accurately
- make effective and efficient use of resources for the benefit of the whole population
- encourage the provision of effective and acceptable treatment that has minimal psychological or functional side effects
- evaluate the program regularly and provide feedback to the population served and those working in the program
- enable those working in the program to develop their skills and potential and find fulfilment in their work
- support audit and research (NHSBSP, 2002).

As with bowel and cervical cancer screening programs, breast screening operates at a regional level. Each screening program has an administrative office which sends out invitations to women eligible for screening in their area. This information is derived from details of women registered with NHS GPs locally (known as an 'Exeter Register') (NHS, 2008).

There are approximately 80 breast screening units within England located at hospitals, other fixed sites (i.e. within shopping centres) or through mobile services (NHS, 2008a). Two views of the breast are taken for each woman (from above and diagonally into the armpit), reported to substantially increase detection of small cancers (NHS, 2008a).

NHS guidelines stipulate that screening programs are required to provide a minimum of 9000 screening attendances per year for routinely invited women aged 50-70 years. This requirement is based on findings that programs screening less than 9000 women annually perform less well than medium to large programs (by detecting fewer cancers, referring more women for assessments and having a lower positive predictive value for assessment) (NHSBSP, 2002).

C.2.3 QUALITY ASSURANCE MODEL, ACCREDITATION PROCESS AND REGULATORY FRAMEWORK

There are currently a number of tiers of governance associated with the program:

- National coordinator – there has been a national coordinator of the NHSBSP since 1990 who oversees the program, including quality assurance (NHSBSP, 2006).
- Within each region of England's NHS Breast Screening Program, there is a quality assurance reference centre (QARC) with a quality assurance director for breast screening and a quality assurance team staffed by a professional coordinator from disciplines relevant to breast screening - radiology, radiography, pathology, surgery, breast care nursing, administration and medical physics (NHS, 2008).

QARCs are the public face of NHS Breast Screening as they are the first point of contact for information about breast screening within that region. Their role is to 'collect and collate data about the performance and outcomes of the breast screening program, organise quality assurance visits, and provide support for the regional director of quality assurance and the professional coordinators' (NHS, 2008).

The professional coordinators are the link between staff within the Breast Screening Programs and the quality requirements for the services. The role of the coordinators includes meeting regularly with their colleagues to 'review the performance and outcomes of the breast screening program, to share good practice and to encourage continued improvement in the program' (NHS, 2008).

External Quality Assurance (QA) site visits occur at least once every three years and statistical data is monitored annually (NHSBSP, 2002). QA visit teams must include professional coordinators from all the relevant disciplines (radiology, radiography, pathology, surgery, breast care nursing, administration and medical physics) and may include members who are internal or external to the service region. Where the service is split across sites all sites should be visited every three years.

Prior to the site visit the service is required to prepare a data report including a number of outcome and process indicators. Information exists on the national cancer screening website for existing services and new services in relation to quality assurance (NHS, 2008).

The National Director of Cancer Screening reviews service performance data and site visit reports from the regional coordinators. Where there is concern about service performance the National Director is able to initiate action that includes suspending operation of a service (personal communication - J. Patnick, 2008).

The quality assurance model for the Breast Screen Program was conducted through a purchaser/provider arrangement from 1994 to 1997 with quality assurance being provided external to the trust and program structure. However this resulted in quality problems not being identified and a lack of accountability mechanisms that prevented action being taken when problems were identified in one of the programs. Public pressure after two deaths due to false negative screens led to changes to quality assurance including establishment of accountability of screening programs to the trust in which they operate. In addition a direct line of accountability between the national coordinator to the Deputy Chief Medical Officer was introduced (NHSBSP, 2006).

C.2.4 STANDARDS AND CORE CRITERIA

Standards are developed in conjunction with relevant professional bodies. The development of standards, targets, guidelines and other quality assurance matters occurs within national coordinating committees – overarching bodies involving regional quality assurance directors, professional coordinators and other professional organisations such as relevant Royal Colleges. This can include guidance on 'good practice and (the) set(ting of) standards and targets for staff working in the breast screening program and for the technical performance of equipment. National standards and targets for the performance and outcomes of the program are also published'. The national coordinating committees publish this guidance in a series of NHSBSP publications available through the NHS Cancer Screening Program website. Topics include program management, quality assurance visits, program administration and screening office practices (NHS, 2008).

One of these coordinating committees is a national QA Directors group that publishes quality assurance guidelines. As an example, Table 7 has been reproduced from the most recent version available and refers to core activity and outcome data for breast screening programs (NHS, 2008).

Table 7: Core activities and outcome measures for NHS Breast Screening Program.

Criteria	Calculation
To maximise the number of eligible women who attend for screening	The percent of eligible women who attend for screening
To maximise the number of cancers detected	a) The rate of invasive cancers detected in eligible women b) The rate of cancers detected which are in-situ carcinoma c) Standardised detection ratio (SDR)
To maximise the number of small invasive cancers detected	The rate of invasive less than 15mm in diameter detected in eligible women invited and screened
To minimise the number of women screened who are referred for further tests	a) The percentage of women who are referred for assessment b) The percentage of women screened who are placed on short-term recall
To ensure that the majority of cancers, both palpable and impalpable, receive a non-operative tissue diagnosis of cancer	The percentage of women who have a non-operative diagnosis of cancer by cytology or needle histology after a maximum of two visits
To minimise the number of unnecessary operative procedures	The rate of benign biopsies

C.2.5 IMPACT OF ACCREDITATION ON PROGRAM PERFORMANCE

Whilst an earlier report concluded that the benefits of screening in reducing breast cancer mortality had been less than anticipated (Sasieni, 2003), NHS figures show that the program in the UK has screened more than 19 million women, detected around 117,000 cancers. This means that for every 500 women screened one life is saved (NHS, 2008).

C.3 NETHERLANDS

The Netherlands was one of the first countries to conduct population-based screening. Its program has been growing since 1989, with national coverage achieved by 1997 (Verbeek and Broeders, 2003). The program is administered regionally and much has been written about the effectiveness and clinical outcomes of the programs (Verbeek and Broeders, 2003).

C.3.1 OVERVIEW OF THE BREAST SCREENING PROGRAM

Population level breast cancer screening occurs across the Netherlands at a regional level. There are nine organisations that oversee screening and operate in different geographic areas. Women between the ages of 50 and 75 are invited to be screened every two years (iKCnet, 2008).

The Netherlands is divided into nine regions with between one to five reading assessment centres per region. The reading of mammograms takes place in 27 reading centres. All mammograms are independently (but not blinded) double read. In case of discordant interpretation, both radiologists must find consensus (or sometimes arbitration by a third reader). The Screening centres can be fixed or mobile however a large proportion are mobile (60 of 66) (Personal communication – J Fracheboud).

C.3.2 POLICY

All women aged from 50 up to and including 75 receive an invitation to receive free and voluntary screening for breast cancer biennially. The aim of the screening is to reduce mortality associated with breast cancer (Bevolkingsonderzoekborstkanker, 2008).

C.3.3 QUALITY ASSURANCE MODEL, ACCREDITATION PROCESS AND REGULATORY FRAMEWORK

In the Netherlands, regulation of cancer screening and treatment operates at a number of levels, both within and outside Government. Quality assurance occurs through regional private centres called Comprehensive Care Centres (CCC), that describe themselves as: '*centres of knowledge and quality control that maintain an extensive network and fulfil a coordinating function within the field of oncology*' with services '*directed towards improving the professional, organisational and relational quality of care…*' (iKCnet, 2008). These centres have a quality oversighting role of breast cancer diagnosis and treatment (though not screening), with all hospitals, radiological centres and pathology laboratories having affiliations to one of the CCCs. Government funding is provided to 'develop guidelines' and 'cover the costs of consultants and cancer registration' (iKCnet, 2008).

The website for the breast cancer screening program also describes a complaints and appeals process for women dissatisfied with the service. This process operates at a regional level, whereby women can address their complaints to the regional screening office, an internal complaints officer at the organisational level, or an independent complaints committee. In all cases, the complaint will be considered by the internal officer in the first instance to identify possibilities for internal improvement. This person is responsible for responding to both the complainant and the organisation (Bevolkingsonderzoekborstkanker, 2008).

All nine regions are accredited/certified according to a quality management system ("HKZ-certificatieschema", 2006). In addition a site visit is undertaken to assess technical, medical and radiological quality at the level of the reading units carried out by the National Expert and Training Centre in Nijmegen. The assessment and site visit process is focussed on reviewing a certain number of mammograms with regard to the positioning of the breast. They also review a defined number of screening mammograms of interval and large subsequent screen-detected cancers and compare them with the diagnostic mammogram. These site visits do not consider organisational issues (organisational review was phased out in around 2004). (Personal communication – J Fracheboud)

C.3.4 STANDARD DEVELOPMENT PROCESS AND CORE CRITERIA

The key body for quality assurance and accreditation in the Netherlands appears to be an independent, non-Government body established in the 1970s by the Dutch Association of Medical Specialists and by the Dutch Association of Chief Medical Officers. The CBO Dutch Institute for Health Care Improvement develops audit and visitation programs, clinical guidelines and runs educational and training programs (CBO Dutch Institute for Health Care Improvement, 2008).

In approximately 2001, guidelines were developed by a working group with representatives from the CBO Dutch Institute for Health Care, the Association of Comprehensive Cancer Centres and the National Breast Group of the Netherlands on 'Breast Cancer: Screening and Diagnosis' and were 'based on the best available evidence' (Rutgers and Tuut, 2001).

The guidelines included the following:

- *indications for screening within the population screening program*
- *screening outside the population screening program*
- *the diagnostic procedures of symptomatic and asymptomatic lesions in the breast*
- *organisation of the diagnostic work-up of patients with breast symptoms.*

Key recommendations include:

- *individual screening is recommended to certain groups of women who do not participate in the population screening program, based on their risk profiles*
- *available evidence does not support the extension of the population screening program to women 40-49 years of age*
- *For quality-controlled implementation of this guideline, uniform prospective registration of patients, diagnosis and treatment related data is an important condition (Rutgers & Tuut, 2001).*

C.3.5 IMPACT OF ACCREDITATION ON PROGRAM PERFORMANCE

In 2000, an interim assessment of the program identified the importance of quality assurance as one of four key lessons from the first ten years of the program, stating 'systematic improvement of the program's performance can only be based on feedback from a detailed quality and outcome monitoring system' (van der Maas, 2000).

In 2006, a review of the program found a significant decline in breast cancer mortality for women aged 55-74. In 2006, breast cancer mortality in this age group was reduced by 25.5%, (Fracheboud et al, 2006).

C.4 SWEDEN

C.4.1 OVERVIEW OF THE BREAST SCREENING PROGRAM

Health care in Sweden is decentralised and breast screening is provided at a regional (county) level. There are 21 county and regional councils with substantial decision-making powers under the supervision of the national government which, in essence, drive a decentralised system of health care. Despite national recommendations, there are differences in the way screening has been implemented, especially in relation to eligible age groups and screening intervals across counties.

Two key relevant non-Government bodies provide input into health care and are cited in relation to breast screening. The two key bodies are described below.

- Cancerfonden – the Swedish Cancer Society is a sizeable independent non-profit organisation involved in developing information about cancer.
- Sjukvaerdens och Socialvaerdens Plaenerings och Rationaliserings Institut (SPRI, Health Care and Social Planning and Rationalization Institute) was established in the early 1970s and is funded by Government and peak bodies in Sweden to 'gather facts in order to plan and rationalise government actions' (Watson & Ovseiko, 2005).

Government appears to work closely with these bodies. The process for decision making about screening intervals appears to have commenced with the independent Swedish Cancer Society conducting meta-analyses of trial data. Government National Board of Health and Welfare (NBHW) and non-Government (SPRI) conducted four evaluations of the available evidence from 1986 – 1989, leading to NBHW recommendations that screening mammography should be offered to women aged 40 to 74, with an interval of 18 months for women aged 40 to 54 and 24 months for those older than 54 years (Jonsson, 2001).

C.4.2 POLICY

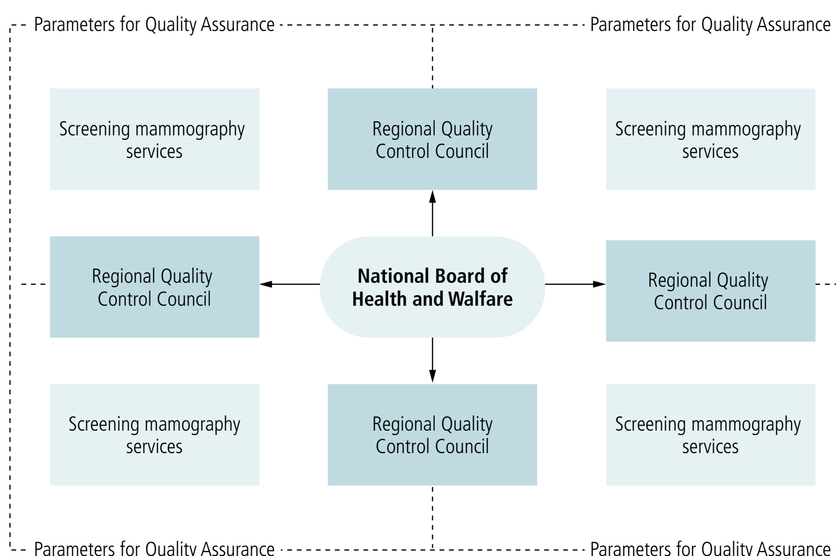
In 1993, the NBHW – the Government department responsible for monitoring and supervision of the sector - issued a general advisory report for quality assurance in health care. This was followed by a Parliamentary amendment to the 1982 National Health Act stating that quality assurance should be an integrated part of all health services. Standards are set by the NBHW and were last updated in 2007.

In relation to breast screening, national guidelines published by the National Board of Health and Welfare provide general advice. The European Guidelines for Quality Assurance in Screening Mammography are also used in supervision and there is a requirement that screening services meet the EU criteria (Klabunde et al, 2002).

C.4.3 QUALITY ASSURANCE MODEL, ACCREDITATION PROCESS AND REGULATORY FRAMEWORK

Quality assurance is monitored at the national level by the NBHW with additional local quality assurance mechanisms (Hendrick et al, 2002). Quality control councils have been established in each region based on the recommendation of the NBHW for quality assurance (Figure 5). These councils have representatives from all involved specialties. Responsibilities include education and training in relevant areas and quality of x-ray equipment and radiation protection (i.e. NBHW, 1998).

Figure 5: Decentralised Screening Mammography Service Delivery in Sweden.



On a regional level some regions have an accreditation style system whereby they require services to state their compliance status against the National QA standards at the time of contract renewal. If services don't meet standards then there are financial penalties.

The NBHW recognises national monitoring of quality assurance as an area for potential improvement, as there are challenges comparing services in different regions relating to differences in years of service provision and the age range of women who are invited to receive mammography (SALAR, 2008). While the NBHW has established "National Quality Registers" with the task of collecting regional data to populated a central national data to allow comparison of performance across the country this has not yet become operational (Personal communication – Sven Törnberg Director, Cancer Screening, Karolinska University Hospital).

C.4.4 STANDARD DEVELOPMENT PROCESS AND CORE CRITERIA

Quality assurance in Sweden is governed by a framework that has at its centre the domains of quality, responsiveness, accessibility, medical effectiveness, and problems in quality including safety and gender equity.

Within this, quality indicators are selected based on their:

- *relevance (volume, cost, variation)*
- *validity (evidence base, confounding)*
- *measurability (practicability)*
- *possibility of influencing (sensitivity, specificity)*
- *interpretability (gold standard, what's the right rate)*
- *comprehensiveness (Jonsson et al, 2004).*

In Sweden, recommendations about breast cancer screening appear to be made based on evidence from a number of sources and involving multiple bodies. As previously outlined, Sweden has conducted significant trials into mammography and this information, together with input from two non-Government organisations, has led to some decisions about breast screening. NBHW use 75 quality and performance general health care indicators. Performance indicators are grouped as follows:

- *medical results*
- *patient experiences*
- *availability of care*
- *costs* (SALAR, 2008).

C.4.5 IMPACT ON PROGRAM PERFORMANCE

Sweden has experienced an improvement in five-year breast cancer survival rate from 65 per cent in the mid 1960s to 84 per cent in the mid-1990s. According to the NBHW, the most significant contributor to this improved five-year survival has been screening mammography (SALAR, 2008).

The impact of quality assurance on program performance is difficult to ascertain for the following reasons:

- the decentralised approach to health care in Sweden, with screening mammography services being implemented at different times and targeting varying age groups in different regions
- inaccessibility of data regarding regional screening mammography service performance
- inaccessibility of data regarding five-year breast cancer survival since the mid-1990s, when active promotion of quality assurance by the NBHW was initiated
- the fact that regional quality control councils are responsible for monitoring service provision. The NBHW has identified scope for improvement of nation-wide monitoring, as deficiencies have potentially contributed to varying practices between regions.

C.5 CANADA

C.5.1 OVERVIEW OF THE CANADIAN BREAST SCREENING PROGRAM

Canada's organised breast screening approach commenced twenty years ago, when a group of key experts from Government, professional bodies and voluntary organisations recommended the establishment of early detection programs for cancer where women aged 50 to 69 years are invited for screening every two years (The Workshop Group, 1989 cited in PHAC, 2007).

The Canadian Breast Cancer Initiative (CBCI) was launched in 1993 and has a responsibility to 'support research, care and treatment, professional education, programs for early detection and access to information to women' (PHAC, 2008). The Canadian Breast Cancer Screening Initiative (CBCSI) was among the priorities of the CBCI. In 2004, the Public Health Agency of Canada (PHAC) was established and has since assumed responsibility for overseeing the CBCI.

The CBSCI's goal is to support and coordinate breast cancer screening programs in Canada. As a part of the wider CBCI, the CBCSI is composed of representatives from provincial and territorial screening programs, representatives from the provincial governments, various stakeholders, and support staff from the Public Health Agency of Canada. The formation of working groups has been a particular feature of the CBCSI and include the Canadian Breast Cancer Data Base (CBCDB), the Quality Determinants working group, and the Indicators Working Group. The CBCSI and its working groups have proved invaluable initiatives in supporting, guiding and evaluating screening mammography services in the context of multiple provincial-based programs.

Breast screening services, as with other health care services in Canada, function at a regional (provincial/territory) level. There are programs in all but one region with some variability in their implementation (for instance, year of commencement (1988-2003) and age of women eligible outside of the 50 to 69 age group (>40-70+) (PHAC, 2007). Breast cancer screening consists of two view mammography and physical examination by a trained examiner. Assessment is undertaken in diagnostic centres and requires referral from the screening service. This separation is reflected in the diagnostic interval performance with 49.4 percent of cases requiring tissue diagnosis being completed within seven weeks (Wadden 2005).

In 1993, a National Forum on Breast Cancer identified the following as central to organised screening and continues to underpin the program objectives and standards:

- a population-based outcome goal
- information about the target population
- special emphasis on hard-to-reach groups (including rural communities)
- meticulous quality assurance, including equipment and interpretation
- outcome data and analysis
- information systems and linkages
- a women-centred focus
- excellent coordination with high-quality diagnosis and follow up (PHAC, 1995).

C.5.2 QUALITY ASSURANCE MODEL, ACCREDITATION PROCESS AND REGULATORY FRAMEWORK

The importance of coordinated quality assurance (particularly given the regional implementation of the program) was first formally discussed in 1990, two years after the establishment of the first breast screening program. At '*Interchange 90 – A Canadian Forum to Collaborate on Breast Cancer Screening Program Development*', Health Canada, representatives from each province and territory, the community-based Canadian Cancer Society (CCS, and their research arm, the National Cancer Institute of Canada, NCIC) agreed on the need for a national surveillance database and quality assurance programs. The CBCSI was subsequently developed, a group constituted by representatives from Health Canada, Statistics Canada, interested provinces/territories, the Canadian Cancer Society and the National Cancer Institute of Canada (PHAC, 1995). CBCSI was later expanded to incorporate other relevant experts and associations such as the Canadian Association of Radiologists, Canadian Association of Medical Radiation Technologists, Canadian Breast Cancer Network, Canadian Breast Cancer Foundation and Canadian Cancer Society (Bryant, 1999).

A national surveillance system, the Canadian Breast Cancer Screening Database (CBCSD), developed under the auspices of the CBCSI, was also established in 1993 (PHAC, 2007). This database, populated with information collected at the provincial level from program inception, is updated every two years and holds information for all but one of the Canadian provinces (PHAC, 2007).

The need to measure quality led to a Working Group on the Quality Determinants of Organised Breast Cancer Screening Programs being established in 1995 and in 2001 the working group described a mandate to:

- identify the key indicators and activities of quality assurance for screening mammography programs and translate these into written policies or statements for the National Committee of the CBCSI
- promote the adoption of quality assurance in screening mammography programs
- link with international activities with respect to quality assurance in screening mammography.

Consistent with this mandate, Quality Determinants of Organized Breast Cancer Screening Programs was published in 2003, and now forms the basis for evaluating the performance and quality of organised breast cancer screening programs. Individual service programs have used this document to design and refine their quality assurance and quality control practices. Programs are expected to adhere to a series of standardised performance indicators and targets that have been developed by the CBCDB, and these program measures are used to evaluate the performance and quality of organised breast cancer screening programs. The European Guidelines for Quality Assurance in Screening Mammography have informed the development of these program measures (Health Canada, 2003).

Assessment of performance

Participation in the quality assurance program is voluntary, with each of the 13 Territories or Provinces being responsible for this however the PHAC plays a facilitating and coordinating role in convening working parties and quality meetings. There is no external assessment of performance such as site visits except for the accreditation of imaging equipment which is undertaken by the Canadian Association of Radiologists. Individual radiologists are provided with a quarterly score card that provides assessment of sensitivity and specificity. Service managers and clinicians meet regularly to discuss and collaborate on quality and performance improvement and research (Personal communication – Jay Onsyko PHAC).

Evaluation indicators were developed by the Quality Determinants Working Group with 14 performance measures and targets chosen (PHAC, 2007). The performance measures for Canada are provided in the guidelines with explanatory notes (including definition, context, calculations, details, targets, current status, evidence source and modification history).

C.5.3 IMPACT ON PROGRAM PERFORMANCE

Canadian screening mammography programs have achieved the following performance levels:

- participation rates of approximately 50 per cent by well-established programs such as those in British Columbia and Saskatchewan
- recall rate of 12.1 per cent after the initial screen and 6.5 per cent after subsequent screens
- interval cancer detection rate of 5.4 per 10,000 person years (within 0 to 12 months of screening).

The CBCI recognises scope for improvement of the above performance measures, and anticipates that continued commitment to quality assurance will aid in achieving target outcomes over time.

C.6 NEW ZEALAND

C.6.1 OVERVIEW OF THE NEW ZEALAND BREAST SCREENING PROGRAM

In New Zealand, BreastScreen Aotearoa provides free breast screening to eligible women in the community, at public hospitals and through mobile screening units on a biannual basis. The service was established in 1999 and the age of eligibility was expanded from the initial 50 to 64 years to 45 to 69 years in 2004.

Screening is administered through eight regional organisations within BreastScreen Aotearoa, each with a responsibility for '*ensuring that eligible women in it's region are given the chance to enrol in the program…provide services of a high standard and refer women who are found to have cancer to treatment services*' (BreastScreen Aotearoa, 2007)

As with other countries, this program sits within the broader National Screening Unit at the Ministry for Health. The National Screening Unit reports on agreed measures quarterly (BreastScreen Aotearoa, 2008).

C.6.2 QUALITY ASSURANCE MODEL, ACCREDITATION PROCESS AND REGULATORY FRAMEWORK

New Zealand developed a quality framework for managing quality within screening programs, a key policy underpinning the breast, cervical and bowel cancers screening programs administered through the National Screening Unit. Principles and key quality requirements were developed (based on work undertaken in England by the Nuffield Institute on Quality Management for Screening (Balmer, Bowens, Bruce, Farrarr, Jenkins and Williams, 2000)), tested and refined within the National Screening Unit in the document, 'A Framework for Improving Quality in Screening Programs' (The NZ Quality Framework) (BreastScreen Aotearoa, 2005).

There are three main elements of the New Zealand Quality assurance and improvement strategy:

- policy and standards development
- advisory groups to 'formalise ongoing professional and consumer input'
- audit and evaluation of programs (BreastScreen Aotearoa, 2005).

Advisory groups

There is a peak advisory group, the BreastScreen Aotearoa Advisory Group, that oversights service evaluation and standards development and review. This is a multidisciplinary group and includes representatives from ten uni-disciplinary groups. The uni-disciplinary groups each represent key stakeholder groups within BreastScreen such as radiologist Clinical Directors, service managers, radiographers, pathologists etc. The groups meet between two and four times per year. Their role is to consider proposed changes to standards, review credentials of all new staff, determine position requirements, report and discuss sentinel events and other issues related to the program as they arise.

Audit and evaluation of programs

Management of the audit program has been contracted to an external organisation, International Accreditation New Zealand. This includes selection of site visitors (from clinicians active within BreastScreen Aotearoa or relevant aligned services), formulating the audit report and review of the audit tools. Rationale for the decision to contract out management of the audit function is that:the process is extremely resource intensive and requires experience in audit and accreditation. BreastScreen Aotearoa is able to access relevant experience and expertise through International Accreditation New Zealand.

The audit and evaluation of programs occurs through three mechanisms. Firstly there is a three year cycle of audit through all of the eight BreastScreen Aotearoa providers. The providers have access to the audit tool and workbook which prescribes external auditor activities and there is an expectation they will undertake regular internal audits (self assessment) using the audit tool. An external data and process audit is undertaken to verify data collection and reporting processes. A site visit is undertaken by an external multidisciplinary team, led by a member of International Accreditation New Zealand.

Secondly, monitoring of six monthly quantitative and qualitative reports occurs by the BreastScreen Aotearoa Advisory Group

Thirdly, the National Screening Unit may request an issues based audit of a service if particularly safety and quality issues are identified either though the six monthly data or through reported incidents.

The quality assurance and improvement program has a number of elements:

- Standard setting and monitoring
- Performance management
- Training and certification
- Coordination and opportunities for shared learning
- Effective information systems
- Appropriate resources
- Research and development
- Information for individuals and communities

Breast Screen Aotearoa describes roles and responsibilities for quality at the level of the national body and an organisation, team or individual working in a screening program (BreastScreen Aotearoa, 2005) across eight ‘requirement’ areas.

C.6.3 STANDARDS AND THEIR DEVELOPMENT

More recently, the New Zealand Ministry of Health published the ‘National Policy and Quality Standards for BreastScreen Aotearoa’ (NZ Standards). The NZ Standards reference both the European Guidelines for Quality Assurance in Mammography Screening and the BreastScreen Australia National Accreditation Standards and apply to all providers of Breast Screening services in New Zealand (BreastScreen Aotearoa 2008). The domains in which quality is determined are equity and access, safety, efficiency and effectiveness. (BreastScreen Aotearoa, 2005).

The NZ Standards are subject to continual review through the ten uni-disciplinary advisory groups. The National Screening Unit refers options for changes to the NZ Standards to these groups for comment. Comments are considered by the multidisciplinary BreastScreen New Zealand Advisory Group and the Consumer reference group prior to adoption of the changes. There are 42 quantitative targets and 92 standards.

C.6.4 CONSUMER INVOLVEMENT

According to the National Screening Unit website, the cancer screening programs are underpinned by a 'well-woman' focus and development is 'influenced by the role that individuals and women's health organisations play in advocacy, education and in the identification and communication of women's health issues related to screening' (BreastScreen Aotearoa, 2007). The consumer and cultural focus of the program is reflected through many aspect and the Standards require that all providers receive cultural competence training.

Further, the National Screening Unit website reports consumer involvement in the following:

- Standards development and review
- as a member of the audit team
- Advisory groups to 'formalise ongoing professional and consumer input (BreastScreen Aotearoa, 2005).

The National Screening Unit subcontract a cultural and consumer group, Kahui Tautoko to lead this aspect of the program. They organise consumer input into Standards review and as a member of the audit team, audit the cultural competence capabilities of services.

APPENDIX D: OTHER ACCREDITATION PROGRAMS IN HEALTH

D.1 AUSTRALIAN COUNCIL FOR HEALTHCARE STANDARDS

The Australian Council for Healthcare Standards (ACHS) is an independent, not-for-profit organisation and is one of the largest health care assessment and accreditation providers in Australia. The ACHS Council is made up of over thirty representatives of peak industry bodies, government and professional colleges.

In consultation with industry, ACHS develops performance measures and delivers quality improvement programs. The core accreditation program offered by ACHS is the Evaluation and Quality Improvement Program (EQuIP), guiding health care organisations through a four year cycle of Self-Assessment, Organisation-Wide Survey and Periodic Review to meet ACHS standards. EQuiP is a voluntary program however some jurisdictions mandate some level of quality assurance through participation in an accreditation program as part of funding agreements.

D.1.1 GOVERNANCE

The ACHS, is governed by a board of directors elected by the ACHS Council. The Board is responsible to the ACHS Council for the direction of ACHS activities, and provides an annual report on performance of the organisation. The Board reviews the organisations missions, goals, strategic directions and policy framework. The Chief Executive Officer and Executive are responsible for day to day management. Validation of survey results is undertaken by the ACHS Council or members of an assessment panel trained in the interpretation of the standards.

D.1.2 EQUIP STANDARDS DEVELOPMENT

The ACHS undertakes a comprehensive EQuIP standards review and consultation process every four years to ensure the standards continue to reflect best practice and current evidence and that they are achievable. ACHS accreditation standards have been reviewed 17 times since the inception of the program. A methodology is used that includes consultation with professional groups and consumers to develop and update standards.

The standards review process takes approximately two years. The key stages of a review include:

- a literature review of current best practice
- a review and comparison with other countries' standards
- establishment and or collaboration with reference groups, expert advisory groups and relevant working groups
- focus groups with stakeholders and experts within the field to examine specific aspects of the standards

- wide-ranging consultation with key stakeholders in both the public and private sectors
- a review of draft standards by a range of stakeholders across industry and revision of the text
- pilot testing of the standards in a range of sites and onsite assessment by a survey team
- final drafting by the Standards Committee
- final consideration and adoption by the ACHS Board.

Detailed feedback on the draft standards was obtained from most of the professional of colleges, health departments, and peak industry bodies, including consumer representation.

D.1.3 ASSESSMENT

The Evaluation and Quality Improvement Program (EQuIP) is a four phase cycle generally carried out over four years. The EQuIP accreditation cycle is described below.

- **Phase 1 –** Self Assessment: Organisations undertake self- assessment against criteria set out in the EQuIP standards. Organisations that are new to the program self-assess against all criteria. Existing program members undertake a self assessment against all mandatory criteria, one of the function criteria areas (clinical function or support and corporate function) and review progress on previous recommendations.
- **Phase 2 –** Organisation-wide survey: Self assessment against all criteria is undertaken in preparation for the survey and provided to the on site survey team. The survey team assess performance against every standard and criterion plus review progress against Periodic Review (Phase 4) recommendations.
- **Phase 3 –** Self Assessment: Organisations undertake a self- assessment against all mandatory criteria, one of the function criteria areas (clinical function or support and corporate function) not assessed in Phase 1 and review progress on Phase 2 recommendations.
- **Phase 4 –** Periodic review: Self assessment against mandatory criteria in preparation for survey. Survey team assesses performance against mandatory criteria and review progress against Organisation-wide survey (Phase 2) recommendations.

Following Phase 2, the Organisation-wide survey or Phase 4, the periodic review, the survey team provides an accreditation report to the organisation which includes an objective account of their findings. This report provides general feedback on organisational performance including acknowledgement of quality improvements and recommendations for improvement. This is provided to the organisation in written format and during a summation conference at the conclusion of the on-site survey (ACHS 2006).

The ACHS standards are essentially qualitative so there are not discrete quantitative measures that organisations may use to demonstrate compliance with standards however they are for the most part objective. However, to meet the standards of the ACHS accreditation program an organisation

is required to collect and evaluate relevant clinical indicators. The ACHS offers a clinical indicator program however this is voluntary and organisations may chose to use their own set of clinical indicators.

Following lengthy analysis and evaluation, the ACHS Council (or an assessment panel) determines a recommendation for the organisations accreditation status. The following Accreditation awards structure is used:

- **Full accreditation** (four years) to those organisations that demonstrate a Moderate Achievement grading against all mandatory criteria, address all previous recommendations, receive no high priority recommendations and have no significant risks
- **Conditional accreditation** (1 year) to those organisations with a Some Achievement rating in six or more non-mandatory criteria, high risk in any non-mandatory criteria, moderate risk recommendations from a previous survey not addressed and high priority recommendations in any two criteria that are not able to be resolved in less than 60 days.
- **Non-accreditation** to those organisations with Some Achievement rating in one or more mandatory criteria that are not able to be resolved in less than 60 days, high risk recommendations from a previous survey not addressed and high priority recommendations in any two criteria that are not able to be resolved in less than 60 days.

D.1.4 APPEALS AGAINST THE ACCREDITATION DECISION

Decisions by the ACHS Council regarding accreditation status may be appealed. Appeals must be made in writing and are considered by the ACHS Board without involvement of the ACHS Council. There is a nominal cost to the assessed organisation for lodging an appeal.

D.1.5 CONSUMER INVOLVEMENT

ACHS includes consumer representation on the standards development working groups and committees. They also include consumers in survey teams on mental health surveys and on general surveys.

D.1.6 SURVEYOR RECRUITMENT AND TRAINING

Surveyors are recruited and selected based on their experience and qualifications and include health service managers and clinicians. To ensure an adequate supply of surveyors ACHS has an ongoing recruitment program which is an open process, inviting applications through newspaper and internet advertising. They undergo a three day training program prior to participating in a survey and are subject to ongoing feedback and evaluation on their performance.

A recent study by the UNSW Centre for Clinical Governance and ACHS (not yet published), identified that EQuiP accreditation is associated positively with a good organisational climate, effective culture, sound leadership and comparatively better performance on clinical indicators (Personal communication – Pawsey 2008)

D.2 NATIONAL ASSOCIATION OF TESTING AUTHORITIES

The National Association of Testing Authorities (NATA) is an Australian private company that provides accreditation for laboratories and similar testing facilities, and is also a peak authority for the accreditation of inspection bodies (NATA 2008). A Memorandum of Understanding (MoU) exists between the NATA and the Commonwealth Government and recognises NATA as the sole national body to ensure competent laboratory practice (NATA, 2004). A core component to the recognition of NATA accredited facilities is NATA's presence at both a regional and international level:

- Asia-Pacific Laboratory Accreditation Cooperation (APLAC) – as one of the founding members, NATA cooperates with a number of laboratory accreditation bodies in Asia and the Pacific Rim
- NATA is regularly evaluated by its mutual recognition partners in Europe, North America and the Asia-Pacific region according to its competence as a provider of accreditation, and this ensures that NATA practices are consistent with current evidence (NATA, 2004).

In addition to the credibility afforded by involvement with regional and international bodies such as APLAC and International Laboratory Accreditation Cooperation (ILAC), NATA is able to actively promote its accredited facilities both nationally and internationally (NATA, 2004).

D.2.1 MEDICAL IMAGING ACCREDITATION

NATA's medical imaging accreditation program is one of more than ten in a variety of fields. The medical imaging program was launched in 2004 and is jointly administered with the Royal Australian and New Zealand College of Radiologists (RANZCR, 2008).

In 1997 RANZCR began developing a program to enhance and continually improve the quality of practices offering medical imaging services (NATA, 2008a). In 1999 an MoU was signed between RANZCR and NATA to provide assistance with the administration of the accreditation program. NATA's standing at both a domestic and international level has afforded credibility to the RANZCR / NATA medical imaging accreditation program (Chang, 2002).

The RANZCR / NATA program provides accreditation to medical imaging sites who demonstrate "good practice" in accordance with the international standard ISO / IEC 17025 and the RANZCR Accreditation Standards for Diagnostic and Interventional Radiology (NATA, 2008a). Demonstration of compliance with the program standards is through a peer review process including on-site review, which is described subsequently in more detail.

D.2.2 REGULATORY FRAMEWORK

Since July 1 2008, diagnostic imaging services must be carried out at an accredited practice or from a practice with 'deemed accreditation' to be eligible for Medicare benefits. Whilst still 'voluntary' (practices can continue to perform diagnostic imaging services without being accredited) the linking of accreditation status to Medicare benefits provides a strong financial lever to enforce compliance to standards and participation in the RANZCR / NATA accreditation program.

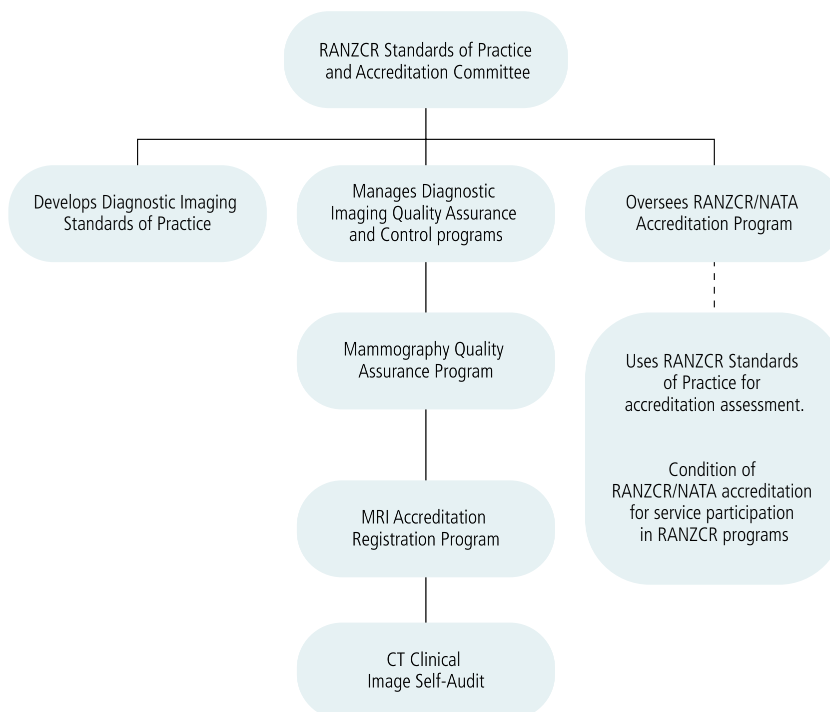
D.2.3 STANDARD DEVELOPMENT

At the outset of program development in 1997 RANZCR appointed an Accreditation Guidelines and Quality Committee (AGQC), consisting of RANZCR Fellows, as a supervising body. With the assistance of RANZCR members and the secretariat the AGQC developed the set of professional, technical and administrative standards referred to collectively as the Accreditation Standards for Diagnostic and Interventional Radiology (RANZCR, 2006). These standards are the foundation upon which the RANZCR / NATA program affords accreditation and are underpinned by continual evolution with the emergence of new technologies and professional developments.

Development of accreditation standards is one of three main functions of the RANZCR Standards of Practice and Accreditation Committee (Figure 6). Involvement through a MoU with NATA for the accreditation of diagnostic imaging services exists for the following reasons:

- NATA facilitates administration of the accreditation program
- facilities satisfying the requirements for accreditation are afforded the domestic and international recognition associated with NATA as a brand.

Figure 6 – Functions of RANZCR Standards of Practice and Accreditation Committee.



Since their inception, the standards have used the international ISO / IEC 17025 as a "framework" standard against which practices are accredited (NATA, 2004). As ISO / IEC 17025 is a generic document and is applicable to all types of testing and procedural services, interpretation with respect to the discipline(s) offered and the techniques/procedures involved, in this case imaging, is required (NATA, 2004). However, with development of the most recent version of the Standards for Diagnostic and Interventional Radiology (version 9), there has been a conscious effort by the RANZCR Practice Standards and Accreditation Committee to make them more user-friendly and reflective of how diagnostic and interventional radiology are practiced in Australia and New Zealand (RANZCR, 2008).

The RANZCR Standards of Practice and Accreditation Committee's intention has been for the standards to be a more intuitive record of the standard at which diagnostic and interventional radiology needs to be practiced in order that safe and quality services are provided to patients (RANZCR, 2008). Additionally, there has been restructuring to allow practices to work more easily through the standards in order to determine how they are performing against the standards. A range of diagnostic imaging stakeholders were consulted throughout the standards development process, in an effort to achieve the goals of greater relevance and usability.

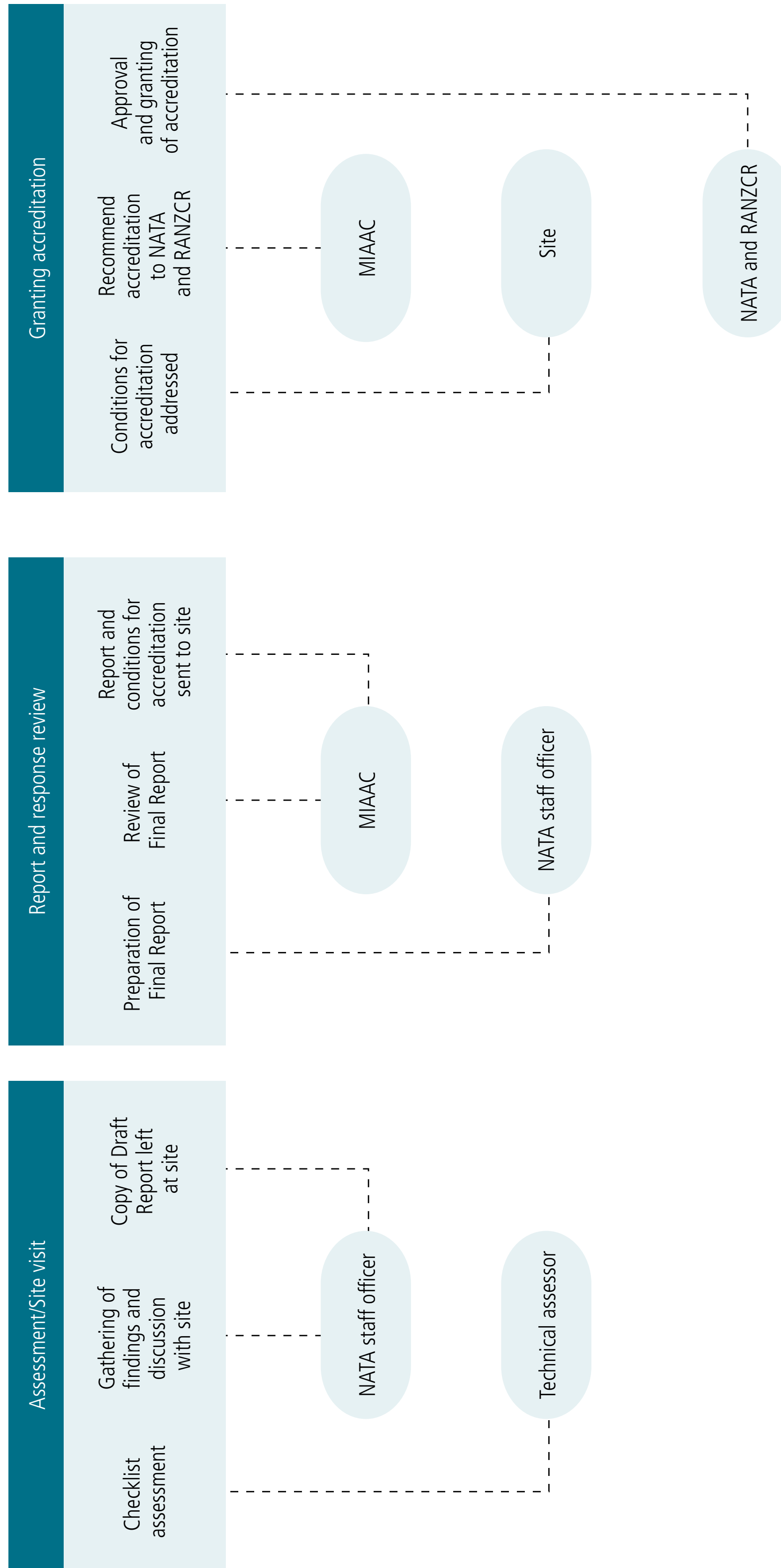
D.2.4 ACCREDITATION PROCESS

As previously mentioned, the RANZCR / NATA program provides accreditation to sites who demonstrate "good practice" in accordance with the international standard ISO / IEC 17025 and the RANZCR Accreditation Standards for Diagnostic and Interventional Radiology. ISO / IEC 17025 provides the accreditation process with a generic framework, and the latest version of RANZCR Accreditation Standards affords greater specificity to imaging services. Demonstration of compliance, and thus achievement of accreditation, is achieved through a peer review process which includes on-site review by one NATA accreditor and one peer radiologist. Detail of the assessment, reporting and decision making steps are outlined in Figure 7.

The cornerstone of RANZCR / NATA accreditation is peer assessment, and support from the radiological profession has been identified as crucial in order to maintain the success of the program (NATA, 2004a). The role of the peer (technical assessor) is to evaluate a facility's technical competence. Currency of RANZCR / NATA assessment is ensured by selecting technical assessors on the basis of technical knowledge, expertise, and familiarity with relevant professional issues.

NATA survey teams are comprised of a NATA staff officer, two peer surveyors including a Radiologist / medical specialist and a radiographer /technologist/ sonographer. The NATA staff officer is a paid surveyor that has extensive experience and knowledge of the accreditation and survey process and the standards.

Figure 7 – RANZCR / NATA Accreditation Process.



D.2.5 ASSESSOR/SURVEYOR RECRUITMENT AND TRAINING

Assessors are invited to participate on a voluntary basis against the following specific criteria:

- appropriate qualification(s)
- professional experience of at least five years
- participation in continuing professional development (NATA, 2004a).

In addition to the above criteria, technical assessors are required to participate in a NATA Assessor Development Program (ADP), as well as display a willingness to participate in three to four site assessments each year (NATA, 2004a).

The number of assessors required for a site visit depends on the range of services offered (i.e. the modalities and subspecialties provided). In addition to technical assessors, each assessment team is lead by a NATA staff officer (NATA, 2004a).

Prior to assessment, sites are forwarded a proposed list of assessors to allow the right of refusal of any assessor where there may be a genuine conflict of interest. During the site visit, assessors are provided with a checklist to serve as both a prompt and to facilitate them recording their findings. Findings are discussed with the site's staff at the end of the visit, and a copy of the draft report is left with the site.

D.2.6 REPORT AND RESPONSE REVIEW

Following the assessment, the NATA staff officer prepares the final written report. Initial review of this report is by NATA, and it is then forwarded with the assessors' checklists to members of the Medical Imaging Accreditation Advisory Committee (MIAAC) for final review (Table 8).

Table 8: Medical Imaging Accreditation Advisory Committee (NATA, 2004a).

Role(s)	Oversees RANZCR / NATA accreditation program – provides professional/technical guidance together with strategic planning and administrative support for the management of the program.
Representatives	Chaired by a RANZCR Fellow. Representatives from Australian Diagnostic Imaging Association (ADIA); Australian Institute of Radiography (AIR); Australian and New Zealand Association of Physicians in Nuclear Medicine (ANZAPNM); and Australasian Society for Ultrasound in Medicine (ASUM). NATA provides the secretariat. The Committee meets every 12 to 18 months.

Following MIAAC approval of the report the final version is forward to the site identifying any conditions for accreditation. Failure to address the conditions by a MIAAC-specified date precludes the service from accreditation.

Following review and approval of the site's response to any conditions for accreditation, the Chair of MIAAC makes a recommendation for accreditation to both RANZCR and NATA. On approval of the recommendation by RANZCR and NATA, the site is formally notified and issued with a certificate of accreditation. The reassessment cycle occurs every three years, and throughout that time sites are expected to adhere to the accreditation standards.

D.2.7 SUMMARY

Numerous conclusions of relevance can be drawn from NATA's approach to accreditation, particularly in relation to the NATA / RANZCR accreditation program of diagnostic and interventional radiology facilities. The success of the program is built upon the following foundations:

- An international presence through involvement with bodies such as ILAC and APLAC, allowing for continual peer-review and maintenance of standards consistent with current best practice
- At a domestic level, relationship with professional bodies possessing the relevant, specific skill-set(s) which in turn enhances the quality of service provided by NATA
- Engagement and involvement of peer reviewers.

D.3 ENGLAND (BOWEL CANCER SCREENING)

In undertaking this review of the literature, it was recommended that the NHS Bowel Cancer Screening Program (NHSBCSP) be included.

D.3.1 OVERVIEW OF THE BOWEL CANCER SCREENING PROGRAM

The implementation of a population based bowel cancer screening program is currently underway in England. The stated intention is for all eligible men and women between the ages of 60-69 to be invited to participate in the program by the end of 2009 and from 2010, extend the age of eligible individuals to 75 years (NHSPHRU, 2008). Individuals are sent a kit in the mail so they can conduct a test at home and send it by return post to the laboratory at their nearest program hub. In the event of an abnormal test result, individuals are invited to attend a screening centre (NHSPHRU, 2008).

As with the breast cancer screening program, bowel cancer screening is organised at a regional level with oversight at the national office.

The national office commissions and initially provides funding to one of five geographically based 'program hubs' – with the same geographic allocations as the NHS program, Connecting for Health, regional clusters. Each hub will ultimately have up to twenty screening centres (servicing populations between 500,000 and 2 million people) attached to it. Strategic Health Authorities (SHAs) are responsible for coordinating the selection of centres to ensure the population they are responsible for will have access to screening facilities at the conclusion of the 2009 rollout.

The program therefore occurs at a number of levels:

- **National office –** oversee the rollout of the program (including commissioning hubs, services and a national IT service system to support and evaluate the program), develop quality assurance measures and monitor the effectiveness of these measures and work with key stakeholders.
- **Strategic Health Authorities –** oversee the selection of screening centres and make a final recommendation to the national office. Their role also includes commissioning new services and monitoring performance of standards against the national standards.

- **Primary Care Trusts –** it is understood that once the Program is established, Primary Care Trusts will be required to commission additional screening centres as needed through their local delivery plan.
- **Program hubs –** conduct the invitation (and recall) process for the screening process, including the provision of a telephone helpline for screening as well as providing operational support to the screening centres (i.e. despatch and process test kits, send test result letters, notify GPs and organise initial appointment at an appropriate clinic for individuals returning an abnormal test result).
- **Screening centres –** promote the program locally, provide information and support for people completing the test at home, conduct clinical assessment for individuals who have returned an abnormal test result and collect data relating to service performance.

D.3.2 QUALITY ASSURANCE MODEL, ACCREDITATION PROCESS AND REGULATORY FRAMEWORK

Screening can only commence in areas that have an accredited screening centre and approval from the national office (NHSPHRU, 2008). In addition to quality assurance from within the NHS, an external specialist centre is involved in the development, support and implementation of accrediting staff and sites.

The national NHS Cancer Screening office provides a list of sites to be visited to the Joint Advisory Group on Gastro Intestinal Endoscopy (JAG) office (the body responsible for accreditation (see below)), which then arranges the site visits. Sites are required to complete a self-assessment including providing relevant documentation prior to a site visit (JAG, 2008)

Self-assessment and site visits are supported by information provided to both the site being accredited and the assessors at an online portal (http://www.jagvisits.org.uk), including documents on 'Guidelines for Audit', 'Passing your JAG visit' and detailed directions on how to use the tools provided (JAG, 2008).

D.3.3 STANDARD DEVELOPMENT PROCESS AND CORE CRITERIA

This program is still maturing and as of February 2008, process quality standards were still in development. The standards in use at that time were reported to be based on the measures used in the screening trials and 'elsewhere in the literature'. According to the NHS publication, Guidance for Public Health and Commissioners, 'regular reviews of performance against these standards and revision of these standards will be a feature of the operation of the bowel cancer screening program in the longer term' (NHSPHU, 2008).

As with the breast cancer screening program outlined above, national professional coordinators are being established and it is expected that a Quality Assurance Director will be appointed for each Strategic Health Authority.

There is also a specialist body responsible for conducting site visits for accreditation. The Joint Advisory Group on Gastro Intestinal Endoscopy (JAG), sponsored and funded by the Royal Colleges of Physicians, Surgeons, Radiologists and General Practitioners, was set up over a decade ago

to 'define the standards for the training of all endoscopists no matter what their professional background'. It is now also mandated to oversee the quality of endoscopists and endoscopy units involved in the bowel screening program (JAG, 2008).

The current core criteria for bowel cancer screening centres are three-fold and relate to timeliness, staffing and quality:

- Units wishing to be screening centres must be able to demonstrate that they have 'sufficiently high scores' on an existing measure (the endoscopy global rating scale, GRS), with a focus on timeliness.
- The screening centre must have a minimum of two colonoscopists who have successfully completed the process for accreditation for screening colonoscopists (JAG, 2008).
- The units must also be given full or conditional accreditation after a visit by the Joint Advisory Group (JAG) on Gastrointestinal Endoscopy (NHSPHU, 2008).

D.3.4 IMPACT ON PROGRAM PERFORMANCE

As the program is still undergoing initial roll-out, the impact of accreditation on program performance is not yet available.

However, it is widely acknowledged that accreditation of colonoscopy (and other gastroenterological procedures) has increased the quality and safety of the clinical care provided, utilizing key performance measures such as adenoma detection rates and withdrawal time to improve cancer detection rates (West, Poullis and Leichester, 2008; Rex 2006).

D.4 ISQua – ACCREDITING THE ACCREDITORS

The International Society for Quality in Health Care, is a non-profit, independent organisation. ISQua provides services to guide health professionals, providers, researchers, agencies, policy makers and consumers, to achieve excellence in healthcare delivery and improve the quality and safety of care. ISQua has three major programs. These programs assess, survey and accredit:

- health care standards
- accrediting organisations and external review agencies
- surveyor/assessor training programs.

ISQua accreditation is external recognition and an award that is offered to national or regional accrediting and certifying bodies and involves a four year accreditation cycle. The program offers assessment tools, guidance on the accreditation program and self assessment, independent peer assessment of standards and survey performance. Organisations are provided with a full report and recommendations for improvement.

The standards assessment program offers external evaluation of standards to provide assurance to standards setting bodies, government, funders and other stakeholders that standards are in line with international best practice. In 2004 ISQua accredited over thirty sets of standards covering a range of healthcare settings.

There are six International Principles for Healthcare Standards that have been developed by ISQue which are based on current evidence, reflect an emphasis on patient safety and are valid, relevant and can be interpreted consistently. These principles are reproduced below (ISQua 2007)

- *Quality improvement: Standards are designed to encourage healthcare organisations to improve quality and performance within their own organisations and the wider healthcare system*
- *Patient/Service User Focus: Standards are designed with a focus on patients/service users and reflect the patient/service user continuum of care or service*
- *Organisational Planning and Performance: Standards assess the capacity and efficiency of healthcare organisations*
- *Safety: Standards include measures to protect and improve the safety of patients/service users, staff and visitors to the organisation*
- *Standards Development: Standards are planned, formulated and evaluated through a defined and rigorous process*
- *Standards Measurement: Standards enable consistent and transparent rating and measurement of achievement*

The process for assessment of standards through ISQua includes a preview of the standards, a self assessment by the standard setting organisation using an assessment tool and guidance documents provided on application and an independent assessment by an ISQua standards assessment team. Criteria within each of the principles are assessed on a three point scale (met, partially met or not met).

Standards may be ISQua accredited for up to four years with requirement to maintain ongoing monitoring and improvement in performance of the standards within the interim period. This is substantiated through submission of progress reports and an action plan.

D.5 SKILLS FOR HEALTH PROGRAM

Within England, efforts are currently underway to increase the capacity of the health and healthcare workforce through their 'Skills for Health' program. One of the main aims for Skills for Health is to 'develop and manage national workforce competences', which will be supported through the Quality Assurance framework model (EQuIP Enhancing Quality in Partnership), currently under development (Skills for Health, 2008a)

As part of the Skills for Health strategy, there is a statement of shared principles in the quality assurance of healthcare education (Skills for Health, 2008b). These principles were developed through discussions in 2006 held at the Partners Forum for Quality Assurance of Healthcare Education (Skills for Health, 2008b). A selection of key principles relevant to this review are outlined below:

- Public safety, through accountability of commissioners and providers and public confidence in the quality and appropriateness of provision
- Public choice, through publication of information
- Proportional and risk based approaches which offer value for money whilst also assuring agreed standards are maintained
- Quality enhancement, through the identification and dissemination of good/notable practice and action plans designed to remedy any shortcomings where identified
- Minimisation of burden and duplication through the identification and sharing of existing evidence, where this is available
- The engagement of learners and service users in quality assurance judgements and processes, thereby informing future education commissioning and quality enhancements, and leading to demonstrable change
- Recognising and valuing the different roles, contributions and responsibilities of individual stakeholders involved in quality assuring health care education
- Organisational and individual reflection upon and evaluation of the quality of provision (Skills for Health, 2008).

APPENDIX E: ACCREDITATION – CURRENT INITIATIVES AND FUTURE DIRECTIONS

E.1 AUSTRALIAN COMMISSION FOR SAFETY AND QUALITY IN HEALTH CARE

Since its inception in 2001 the Australian Council for Safety and Quality in Health Care (the Council) has been exploring issues and developing strategies to improve the safety and quality of health care. Central to this was an investigation of health standards and accreditation. Following a recommendation from the Australian Health Minister's Advisory Council in 2006, in its new arrangement as the Australian Commission for Safety and Quality in Health Care (the Commission) a review of current accreditation arrangements within Australia and international directions was conducted in order to develop an alternative model for safety and quality accreditation.
The recommendation responded to the earlier work by the Council and the findings of the Patterson Report identifying the need to:

- review existing health standards and identify opportunities to streamline or reduce duplication
- identify a best practice model of accreditation
- improve the rigour and robustness of accreditation surveys
- develop mechanisms to ensure there is an appropriate response where unacceptable threat to patient safety or quality of care is identified through the accreditation process.

The Commission identified several issues around the performance of accreditation programs including effectiveness in identifying poor performance, transparency, governance and resource requirements. The Commission also identified a number issues around standards including the proliferation of standards, access to standards, the process of developing standards, differences in terminology between sets of standards, variance of structure, style, and purpose, and the appropriateness of their use in assessment.

E.1.1 DEVELOPMENT OF AN ALTERNATIVE MODEL FOR HEALTHCARE ACCREDITATION

Following research and extensive consultation the Commission developed a proposed alternative model for accreditation of health services in Australia. There are three aspects of this work that have significance for BreastScreen Australia. Firstly, implementation of the alternative model will have implications for the future structure and operation of the BreastScreen Australia accreditation system. Secondly, the model proposes the development of a core set of Australian Health Standards (AHS) which all organisations providing health care will be required to comply with. These AHS focus on areas of practice that present the greatest risk to patient safety and the quality of care. Thirdly, the alternative model identifies a number of best practice elements for health service accreditation programs that may be used for benchmarking within the BreastScreen Australia accreditation model. These are explored further in Section 5 of this report.

Other elements of the alternative model that should be noted are:

- development of a national data collection in priority safety and quality areas and reporting of performance outcomes and improvements allow service comparison and track the effectiveness of the AHS
- the principle of mutual recognition of accreditation processes to reduce duplication and minimise the burden of accreditation for health services
- national coordination of the reform of the safety and quality accreditation program, using a model of collaborative governance.

E.1.2 FUTURE DIRECTIONS

At the Health Ministers meeting of 18 April 2008 the Commission's Alternative Model was endorsed in-principle, and there was agreement to progress to a first phase of implementation involving:

- Development of a preliminary set of Australian Health Standards
- Determination of the processes and costs, including exploring funding options, to implement the alternate accreditation model.

The preliminary set of AHSs are likely to include standards relating to clinical handover, medication safety, open disclosure, patient identification. Healthcare organisations and standards setting bodies will be required to use the AHSs or if they have existing standards within these domains they can apply to the Commission to have the standard recognised. The Commission will approve the standard if the standard is assessed as being at the same or at a higher level than the AHS (Personal communication – Banks 2008).

E.2 ACCREDITATION AS A REGULATORY MECHANISM WITHIN AUSTRALIA

In June 2008 the Private Insurance (Accreditation) Rules 2008 were introduced as part of the Private Health Insurance Act 2007. These rules require hospitals or health care organisations to be registered to operate within the relevant State or Territory and that the organisation must be accredited or certified by an appropriate accrediting body (or engaged in the process to be accredited). The rules specify that an appropriate accrediting body is one that is accredited by:

- The International Society for Quality in Health Care Inc (ISQua) or
- The Joint Accreditation System of Australia and New Zealand (JAS-ANZ) or
- An entity that has been accredited by ISQua or JAS-ANZ.

In some jurisdictions, participation in hospital accreditation programs remains voluntary, in others accreditation is mandated through policy and/or funding agreements. In 2007 all hospitals in Victoria, Western Australia, ACT and Northern Territory were accredited. General Practice accreditation remains voluntary however there are financial incentives through enhanced Medicare scheduled benefits for accredited practices.

E.3 EUROPEAN UNION

There have been a number of initiatives within the European Community (EC) around accreditation. The current state of quality activities within breast screening in the European Community are outlined previously in Section 5.1. However there is much activity underway to further establish and harmonise standards and quality assurance processes across Europe that are being coordinated centrally, endorsed by the European Parliament and subsidised by the European Commission.

Europe is currently looking to establish a widespread accreditation system which allows screening services in member states to become accredited against the European Guidelines for Breast Screening or Bowel Screening. There is strong direction from the EC towards harmonisation of the range of services offered and the standards achieved by services. An EC directive has established a framework for accreditation whereby each member state may establish one accreditation body although they may elect to use accreditation bodies from other member states. There is central licensing of the accrediting bodies. A multilateral agreement is in place whereby accrediting bodies are peer reviewed against the accreditation framework to ensure consistency in assessment and accreditation decisions. This model aims to stimulate competition between accrediting bodies to drive efficiency at the same time achieving consistency of services (Personal communication – von Karsa 2008).

E.4 USE OF ALTERNATE METHODS OF ASSESSMENT

There has been increasing interest in exploring different methods for exploring the safety and quality of care from the patient perspective.

E.4.1 TRACER METHODOLOGY

One model currently in use for assessing and accrediting an organisation by Joint Commission on Accreditation of Healthcare Organisations (JCAHO), the major accrediting organisation of health services within the USA, is the Tracer methodology. The method "traces" the patient journey from point of entry to post discharge and at all points in between.

Tracer evaluations begin with the surveyors selecting an active patient or recently discharged patient and using that individuals medical notes as a 'road map' to move through the organisation to "assess and evaluate the facility's compliance with selected standards and systems of providing care and services". Surveyors interview staff in areas that provide the service for that patient/client, assessing the safety and quality of the care provided. The team follows the patient's treatment path and assesses compliance with Standards and the use of pathways and protocols as well as risks and responses to identified risk. Clinicians also find the process meaningful because it looks at the service from the perspective of the patient (Johnson et al, 2004). While it has been concluded that Tracer methodology is useful in evaluating quality of care it has not been systematically evaluated within an accreditation context (Greenfield D et al, 2007b).

E.4.2 UNANNOUNCED SURVEYS

Since 2006 the JCAHO have undertaken unannounced surveys to healthcare organisations undergoing accreditation. The rationale for unannounced surveys is that it will shift the focus of the organisation from:

- the next accreditation survey to the next patient
- operation systems to clinical patient care processes
- ramping up performance prior to an accreditation survey to embedding safety and quality changes into business as usual.

Unannounced surveys also serve to decrease the burden of preparation for accreditation survey by accrediting organisations. There is a perception that an unannounced survey will provide a more accurate picture of day-to-day performance of the organisation and that it will therefore be a more credible process to the public and funders of services. Accreditation is therefore more likely to be supported as a fundamental part of the organisations continuous quality improvement rather than compliance with standards at a point in time.

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