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

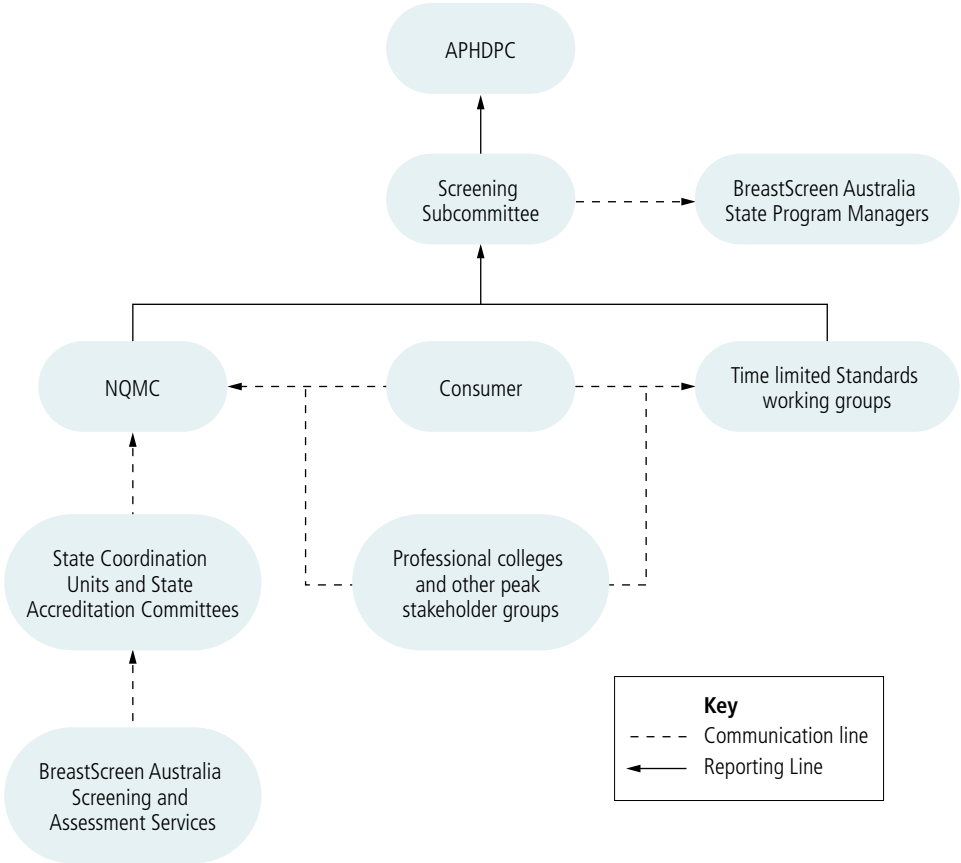
BreastScreen Australia is funded by the Commonwealth and state and territory governments with Commonwealth funding provided through broadband PHOFA's. The Australian Population Health Development Principal Committee (APHDPC), which reports to AHMAC, is responsible for oversight and evaluation of the 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.

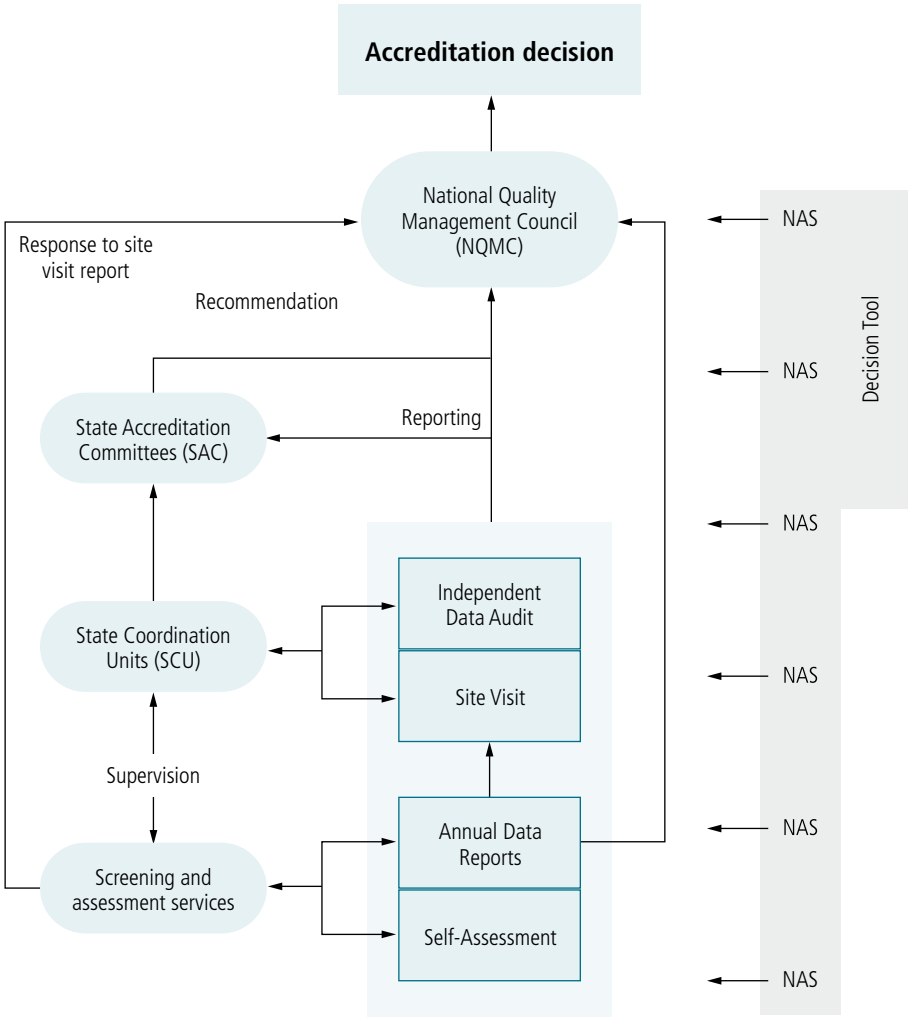
Accreditation Level	Achieved Standard	Required Performance
Four year accreditation with commendation	Service performs highly against all standards	Must meet all standards in all clusters
Four year accreditation	Service performs well against most standards, including all level 1 standards.	Overall Service 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

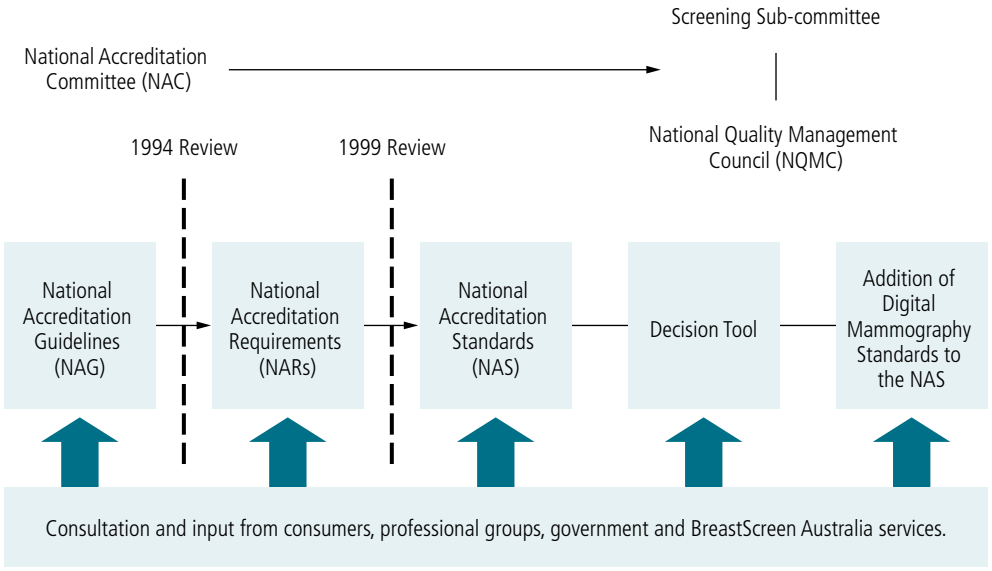


3.4.4 STANDARD DEVELOPMENT PROCESS

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.