

BreastScreen

AUSTRALIA

A joint Australian, State and Territory Government Program

BREASTSCREEN AUSTRALIA
DECISION TOOL

**To assist with accreditation
decision-making against the
National Accreditation Standards**

Endorsed by the National Advisory Committee
to BreastScreen Australia,
27 February 2003

Updated under the auspices of the
National Quality Management Committee,
November 2004

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PURPOSE OF THE DECISION TOOL

The decision tool was developed primarily to assist the NQMC in making accreditation decisions, and to improve the transparency of the accreditation process by allowing stakeholders to see the basis of those decisions.

It can also be used to assist program managers and SCUs and/or SACs to prioritise and deal with issues of performance against the NAS, and to develop strategies for continuous quality improvement.

A working group of the NQMC developed the decision tool, in close consultation with program managers, basing it upon a risk management model.

The decision tool:

- clusters standards in relation to key performance areas for BreastScreen Australia;
- allocates standards to one of three risk levels, categorised in relation to key performance outcomes;
- describes a tiered accreditation system;
- clearly links accreditation decisions to performance against the standards; and
- outlines a strategy for managing gaps in performance, setting out roles and responsibilities.

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COMPONENTS OF THE DECISION TOOL

2.1 CLUSTERS

The BreastScreen Australia National Accreditation Standards (NAS) are grouped together in ten clusters. These clusters are based on ten key outcome areas, all equally important for achieving the aims and objectives of BreastScreen Australia.

The clusters are outlined below.

- Assessment
- Cancer detection
- Continuity, counselling and support
- Data management
- Equitable access
- Information given
- Management
- Participation
- Timeliness
- Unnecessary recall

2.2 RISK LEVELS FOR EACH STANDARD

Each standard is allocated a risk rating as a way to consider the impact of not meeting that standard on the key outcome areas of the program. The risk rating for each standard is provided in Attachment 1. The seven risk categories of severe, high, major, significant, moderate, low and very low are grouped into levels as follows.

- Level 1** Severe and high risk
- Level 2** Major and significant risk
- Level 3** Moderate, low and very low risk.

Table 1 on page 6 summarises the number of standards per risk level in each cluster.

Attachment 2 gives a more detailed summary of each cluster and the standards within that categorised by risk level.

Table 1: Summary of the number of standards per risk level per cluster

Cluster	Ranking of standards		
	Level 1 (severe/ high)	Level 2 (major/ significant)	Level 3 (moderate/low/ very low)
<i>Assessment</i>	4	13	5
<i>Cancer detection</i>	7	15	5
<i>Continuity, counselling and support</i>	-	8	5
<i>Data management</i>	-	11	4
<i>Equitable access</i>	-	5	-
<i>Information given</i>	-	8	2
<i>Management</i>	2	46	5
<i>Participation</i>	-	6	4
<i>Timeliness</i>	1	8	1
<i>Unnecessary recall</i>	-	7	1
TOTALS	14	127	32

2.3 TIERED ACCREDITATION

The accreditation scheme is tiered, with levels of accreditation outlined below.

There are four levels of accreditation an existing Service can attain, with various time periods applying, and non-accreditation is also possible. A new Service comes into the Program at the provisional level of accreditation.

Table 2: Accreditation levels

Accreditation level	Achieved standard
Four year accreditation with commendation	Service performs highly against all standards.
Four year accreditation	Service performs well against most standards, including all level 1 standards.
Two year accreditation	Service meets all level 1 standards but not a significant proportion of level 2 and 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.
Provisional accreditation	Two years provisional accreditation for new services.
Non-accreditation	Service does not meet requirements for accreditation for 2 year accreditation with high priority recommendations, or accreditation has lapsed.

The NQMC may vary from the requirements set out in Table 2 provided there is sufficient justification. In such cases, the NQMC's reasons will be fully documented by the NQMC secretariat and communicated in writing to the relevant SAC.

The Accreditation Handbook details the implications for services of each level of accreditation, and of non-accreditation.

2.4 REQUIRED PERFORMANCE LEVELS

In making accreditation decisions, the NQMC considers the balance of the performance of services across all ten clusters of standards. The requirements set out in Table 3 guide the NQMC's decision-making.

Table 3: Required levels of performance for each tier of accreditation

Accreditation level	Required performance level against National Accreditation Standards
Four year accreditation with commendation	Must meet all standards in all clusters.
Four year accreditation	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	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	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	Entry level for new services.
Non-accreditation	Where service does not meet at least the requirements for 2 years with high priority recommendations (including where accreditation has lapsed).

In assessing performance against quantitative indicators, the NQMC considers outcomes within 95% confidence intervals. This is particularly critical in the case of services screening small numbers of women, where performance may vary from the standard as a result of chance. To assist services to determine whether their performance truly differs from the standards or differs as a result of chance, funnel plots have been developed and included in the NAS document.

2.5 GUIDELINES FOR MANAGING GAPS IN PERFORMANCE

Using a risk management approach requires not only a categorisation of risk of an event occurring, but also the development and implementation of a strategy for managing the risks. The management of service performance resides with the BreastScreen Australia State and Territory program managers.

The role of the NQMC is to make decisions on the accreditation status of services and to monitor performance of services against the NAS in the period between accreditation reviews. This ongoing monitoring is important for the NQMC to gain a national perspective on the overall performance of BreastScreen Australia, to review the adequacy of the standards themselves, and to provide advice to any national advisory body on activities to support quality improvement in BreastScreen Australia.

Table 4 sets out management guidelines for each risk level and outlines the roles and responsibility of the stakeholders involved in BreastScreen Australia for dealing with gaps in performance.

Table 4: BreastScreen Australia NAS risk management policy

Risk categorisation	BreastScreen Australia management category	BreastScreen Australia NAS risk management policy
Severe or High risk	Level 1	<ul style="list-style-type: none"> • Service to provide reasons for not meeting the standard to State/Territory managers (SCU/SAC). • State/Territory managers/SCU/SAC to assist the Service to develop a detailed management plan to address the failure. This plan should be managed /monitored by the State/Territory managers (SCU/SAC). • The SAC (with a copy to relevant Program Manager) to notify the NQMC of Service's failure to meet the standard, including the reasons for not meeting the standard and planned improvement strategies. • NQMC may advise the SAC (with copy to relevant Program Manager) of alternative strategies to assist the State/Territory managers/SCU/SAC to improve the Service's performance against the standard. • Service to provide data to demonstrate monitoring of requirements of standard.
Major or Significant risk	Level 2	<ul style="list-style-type: none"> • Service to provide reasons for not meeting the standard to State/Territory managers/SCU/SAC. • State/Territory managers/SCU/SAC to assist Service to develop a detailed management plan to address the failure. This plan should be monitored by the State/Territory managers (SCU/SAC). • Service to provide data to demonstrate monitoring of requirements of standard.
Moderate or Low or very low risk	Level 3	<ul style="list-style-type: none"> • Service to provide reasons for not meeting the standard to State/Territory managers/SCU/SAC. • Service to provide data to demonstrate monitoring of requirements of standard. • State/Territory managers/SCU/SAC to monitor Service's management of performance against the standard.

ATTACHMENT 1

BREASTSCREEN AUSTRALIA—COLLATED CLUSTER RISK CATEGORISATIONS

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
1.1 The Service maximises the proportion of women aged 50-69 years who are screened every two years	1.1.1 ≥70% of women aged 50–69 years participate in screening in the most recent 24-month period	Participation	Almost certain	Low	Major	Level 2
	1.1.2 The Service monitors the proportion of women aged 40–49 years and 70 years and over screened.	Participation	Unlikely	Low	Low	Level 3
1.2 The Service maximises the proportion of women aged 50-69 years who are rescreened every two years.	1.2.1 ≥75% of women aged 50–69 years who attend for their first screen within the Program are rescreened within 27 months.	Participation	Moderate	Very High	Major	Level 2
	1.2.2 Of women aged 50–69 years participating in their second and subsequent rescreens within the Program, ≥90% are rescreened within 27 months of their previous screening episode.	Participation	Moderate	Very High	Major	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
1.3 The Service demonstrates a systematic approach to maximising participation in screening, and implements strategies: a) to disseminate accurate and consistent community information; b) to inform general practitioners and other relevant health professionals about breast cancer screening; c) to recruit women from special needs groups.	1.3.1 The Service implements a recruitment plan which: • documents strategies for encouraging participation in screening and rescreening in the defined catchment; • analyses participation data and identifies areas or groups where additional strategies are required; • is developed in consultation with relevant consumer, general practitioner and other health professional groups; • is reviewed annually in consultation with the State Coordination Unit and relevant local stakeholder groups.	Participation	Unlikely	Very High	Significant	Level 2
	1.3.2 The Service disseminates information resources which are: • developed by the State Coordination Unit; or • approved by the State Coordination Unit and consistent with state and national policies and with the resource Facts about Breast Cancer and Screening.	Information given	Unlikely	Medium	Moderate	Level 3

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
	1.3.3	Participation	Unlikely	Medium	Moderate	Level 3
	1.3.4	Participation	Unlikely	Medium	Moderate	Level 3
	1.3.5	Participation	Unlikely	Very High	Significant	Level 2
1.4	1.4.1	Participation	Unlikely	Very high	Significant	Level 2
	1.4.2	Participation	Unlikely	Low	Low	Level 3

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
1.5 Annual screening is offered only to women at substantially increased risk of developing breast cancer.	1.5.1 The Service offers annual screening for ≤10% of women aged 50–69 years.	Unnecessary recall	Moderate	Medium	Significant	Level 2
	1.5.2 The Service monitors the proportion of women aged 40–49 years and 70 years and over who are offered annual screening.	Unnecessary recall	Unlikely	Low	Low	Level 3
2.1 The Service maximises the detection of invasive breast cancer.	2.1.1 ≥50 per 10,000 women aged 50–69 years who attend for their first screen are diagnosed with invasive breast cancer (see Appendix C).	Cancer Detection	Moderate	Extreme	High	Level 1
	2.1.2 ≥35 per 10,000 women aged 50–69 years who attend for their second or subsequent screen are diagnosed with invasive breast cancer (see Appendix C).	Cancer Detection	Moderate	Extreme	High	Level 1
2.2 The Service maximises the detection of small invasive breast cancer.	2.1.3 The Service monitors the rates of invasive breast cancer among women aged 40–49 years and 70 years and over.	Cancer Detection	Unlikely	Very High	Significant	Level 2
	2.2.1 ≥25 per 10,000 women aged 50–69 years who attend for screening are diagnosed with small (≤15mm) invasive breast cancer (see Appendix C).	Cancer Detection	Moderate	Extreme	High	Level 1
2.2.2 The Service monitors the rates of small (≤15mm) invasive breast cancer among women aged 40–49 years and 70 years and over.	Cancer Detection	Unlikely	Very High	Significant	Level 2	

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
2.3 The Service maximises the detection of DCIS.	2.3.1 ≥12 per 10,000 women aged 50–69 years who attend for their first screen are diagnosed with DCIS (see Appendix C).	Cancer Detection	Unlikely	Extreme	Major	Level 2
	2.3.2 ≥7 per 10,000 women aged 50–69 years who attend for their second or subsequent screen are diagnosed with DCIS (see Appendix C).	Cancer Detection	Unlikely	Extreme	Major	Level 2
	2.3.3 The Service monitors the rates of DCIS among women aged 40–49 years and 70 years and over.	Cancer Detection	Unlikely	Very high	Significant	Level 2
2.4 The Service minimises the number of invasive interval cancers and ensures that all invasive interval cancers are reviewed and investigated.	2.4.1 The Service implements a protocol for: <ul style="list-style-type: none"> identifying all invasive interval cancers through cancer registry data; reviewing and investigating all invasive interval cancers within the Service on an annual basis; identifying and implementing changes to improve practice where necessary, particularly when the invasive interval cancer rate is greater than the standard. 	Cancer Detection	Moderate	Extreme	High	Level 1

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
	2.4.2 The Service will collect data about invasive interval breast cancers. (a) <7.5 per 10,000 women aged 50–69 years who attend for screening are diagnosed with an invasive interval breast cancer between 0 and less than 12 months following a negative screening episode. (b) The number per 10,000 women aged 50–69 years who attend for screening and who are diagnosed with an invasive interval breast cancer in the period between 12 and less than 24 months following a negative screening episode.	Cancer Detection	Moderate	Extreme	High	Level 1
	2.4.3 The Service monitors the number of women aged 40–49 years and 70 years and over diagnosed with an invasive interval breast cancer.	Cancer Detection	Unlikely	Extreme	Major	Level 2
2.5 The Service ensures that all interval cases of DCIS are reviewed and investigated.	2.5.1 The Service implements a protocol for: <ul style="list-style-type: none"> identifying all interval cases of DCIS through cancer registry data; reviewing and investigating all interval cases of DCIS within the Service on an annual basis; and identifying and implementing changes to improve practice where necessary. 	Cancer Detection	Moderate	Extreme	High	Level 1

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
2.6 The Service minimises recalls for assessment.	2.6.1 <10% of women who attend for their first screen are recalled for assessment.	Unnecessary Recall	Moderate	Very High	Major	Level 2
	2.6.2 <5% of women who attend for their second or subsequent screen are recalled for assessment.	Unnecessary recall	Moderate	Very High	Major	Level 2
	2.6.3 The Service monitors the rates of recall among women aged 40–49 years and 70 years and over.	Unnecessary recall	Unlikely	Very High	Significant	Level 2
2.7 The Service maximises the pre-operative diagnosis of invasive cancer and DCIS.	2.7.1 ≥75% of invasive cancers or DCIS are diagnosed without the need for diagnostic open biopsy.	Assessment	Unlikely	Very High	Significant	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
2.8 The Service minimises the proportion of benign open biopsies for diagnostic purposes.	2.8.1 $\leq 0.35\%$ of women who attend for their first screen are found not to have invasive cancer or DCIS after a diagnostic open biopsy.	Assessment	Moderate	Extreme	High	Level 1
	2.8.2 $\leq 0.16\%$ of women who attend for their second or subsequent screen are found not to have invasive cancer or DCIS after a diagnostic open biopsy.	Assessment	Moderate	Extreme	High	Level 1
	2.8.3 $\leq 4.0\%$ of women assessed after their first screen are found not to have invasive cancer or DCIS after a diagnostic open biopsy.	Assessment	Moderate	Extreme	High	Level 1
	2.8.4 $< 3.2\%$ of women assessed after their second or subsequent screen are found not to have invasive cancer or DCIS after a diagnostic open biopsy.	Assessment	Moderate	Extreme	High	Level 1

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
2.9 The Service ensures high quality of breast imaging systems.	2.9.1 X-ray systems, premises and users meet radiation protection regulations.	Management	Unlikely	Extreme	Major	Level 2
	2.9.2 Breast imaging quality control test equipment meets the minimum standards specified in Appendix L.	Management	Unlikely	Extreme	Major	Level 2
	2.9.3 Quality control procedures that meet the standards specified in Appendices K and H are implemented.	Management	Unlikely	Extreme	Major	Level 2
	2.9.4 Breast imaging systems, including ancillary items, meet: <ul style="list-style-type: none"> • manufacturer's specifications; • performance standards as specified in Appendices H and I. 	Management	Unlikely	Extreme	Major	Level 2
	2.9.5 Acceptance and annual testing of mammography systems is performed by, or under the close supervision of, suitably qualified and experienced persons as specified in Appendix J.	Management	Unlikely	Extreme	Major	Level 2
	2.9.6 Preventative maintenance and repair of imaging equipment meets manufacturer's recommendations or other appropriate standards.	Management	Unlikely	Extreme	Major	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
2.10 The Service ensures high quality imaging.	2.10.1 Mammography is performed by diagnostic radiographers who are appropriately trained and supervised, as specified in Appendix J.	Management	Unlikely	Extreme	Major	Level 2
	2.10.2 The Service ensures: <ul style="list-style-type: none"> that mammographic screening examinations consist of the two standard views (that is, cranio-caudal and medio-lateral oblique); documentation of reasons for any deviation from the standard two views; implementation of a protocol for adequate examination of women with internal breast prostheses. 	Cancer Detection	Rare	Very High	Moderate	Level 3
	2.10.3 The overall repeat rate for the Service is <3% of all screening films.	Cancer Detection	Rare	Very High	Moderate	Level 3

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
	2.10.4	The Service demonstrates annually that each radiographer achieves 50% or greater P or G ratings in a PGMI evaluation of 50 randomly selected film sets as outlined in Appendix M.	Cancer Detection Rare	Very High	Moderate	Level 3
	2.10.5	The Service has a designated radiographer who is appropriately qualified and who is responsible for all aspects of quality assurance in radiography as outlined in Appendix N.	Management Unlikely	Extreme	Major	Level 2
	2.10.6	The designated radiographer implements a process for providing ongoing assessment and feedback to radiographers in all units (see Appendix K) about the quality of screening films using criteria such as those used in the PGMI evaluation system outlined in Appendix M.	Management Moderate	Very High	Major	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
2.11 The Service ensures the adequate identification of imaging films.	2.11.1 Film identification complies with relevant radiation licensing regulations. Each film or hardcopy image is clearly marked with the date and sufficient information to identify the client and enable correct interpretation. All identifying information is on the film and is transferred to each copied film.	Management	Rare	Extreme	Significant	Level 2
	2.11.2 The Service demonstrates the identification of the radiographer and X-ray machine used for each screening mammogram.	Management	Rare	Extreme	Significant	Level 2
2.12 The Service ensures high quality screen reading.	2.12.1 Two readers read all screening films independently, in a 'blind' relationship.	Cancer Detection	Rare	Extreme	Significant	Level 2
	2.12.2 The Service demonstrates that at least one reader of screening films is a radiologist.	Cancer Detection	Rare	Very High	Moderate	Level 3
	2.12.3 All film readers read at least 2,000 mammographic screening cases within the Program per year.	Cancer Detection	Moderate	Very High	Major	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
	2.12.4 The Service provides audit and feedback which advises each reader of: <ul style="list-style-type: none"> (a) their individual rate of detection of small invasive cancers in all screens and their invasive cancer detection rate in initial and subsequent screens (see Appendix P); and, (b) timely feedback about: <ul style="list-style-type: none"> • any interval invasive cancers not detected in films read by the reader; and • any invasive cancers not detected as an abnormality by an individual reader at screen reading. 	Cancer Detection	Unlikely	Very High	Significant	Level 2
	2.12.5 The Service implements a review process, and where necessary, implements strategies to address the individual reader's performance.	Cancer Detection	Moderate	Very High	Major	Level 2
	2.12.6 The Service ensures that a designated radiologist who is appropriately qualified is responsible for all issues of quality assurance and undertakes the roles and responsibilities related to radiology as outlined in Appendix O.	Management	Unlikely	Extreme	Major	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
2.13 The Service ensures high quality reporting of breast images at screening.	2.13.1 The reports of the independent screen readers are combined into a single recommendation for every woman, which indicates whether or not further assessment for the presence of cancer is required.	Cancer Detection	Rare	Extreme	Significant	Level 2
	2.13.2 The recommendation is provided in a non-narrative form approved by the State Coordination Unit.	Cancer Detection	Rare	Medium	Low	Level 3
	2.13.3 Where there is discordance between the two independent screen readers on whether further assessment for the presence of cancer is required, the Service implements a protocol to achieve a single recommendation, through either: <ul style="list-style-type: none"> • a third reader where that reader is a radiologist with a high level of expertise in screen reading; or • consensus reads by the two readers. 	Cancer Detection	Rare	Extreme	Significant	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
2.14 The Service implements a protocol for the management of women who report breast symptoms consistent with the National Policy Framework for the Management of Women with Symptoms.	2.14.1 The Service implements a protocol for the management of women who report symptoms in accordance with the National Policy Framework for the Management of Women with Symptoms by BreastScreen Australia Services.	Cancer Detection	Unlikely	Very High	Significant	Level 2
2.15 The Service implements a comprehensive approach to the assessment of breast abnormalities.	2.15.1 The Service implements protocols for the evaluation of all women recalled to assessment which incorporates: <ul style="list-style-type: none"> • clinical examination; • mammography/ultrasound; and • FNA cytology/core biopsy as required. 	Assessment	Unlikely	Extreme	Major	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
2.16 The Service ensures that all members of the multi-disciplinary team involved in the assessment of women are appropriately trained and qualified, and have access to all relevant diagnostic equipment.	2.16.1 The Service demonstrates that all members of the multidisciplinary team involved in the assessment of women recalled from screening have the relevant training and qualifications as outlined in Appendix J.	Management	Unlikely	Extreme	Major	Level 2
	2.16.2 The Service ensures that the multidisciplinary team involved in the assessment of women recalled from screening has expertise in: <ul style="list-style-type: none"> • breast examination; • mammographic film reading and work-up; • ultrasound performance and interpretation; • biopsy (FNA and core); • pathology technique and interpretation; and • supportive care. 	Management	Unlikely	Extreme	Major	Level 2
	2.16.3 The Service will have available the diagnostic equipment to perform: <ul style="list-style-type: none"> • complete mammographic work-up; • breast ultrasound examinations; • FNA cytology (including ultrasound and stereotactic guided biopsy); and • core biopsy (including ultrasound and stereotactic guided biopsy). 	Management	Unlikely	Extreme	Major	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
	2.16.4	Assessment	Unlikely	Extreme	Major	Level 2
	2.16.4	Assessment	Unlikely	Extreme	Major	Level 2
2.17	2.17.1	Assessment	Moderate	Very High	Major	Level 2
The Service demonstrates a multi-disciplinary approach at assessment.	The Service implements a protocol which ensures that the radiologist and the surgeon and other designated examining clinician from the multidisciplinary team, are in attendance together at assessment to correlate and evaluate the clinical and imaging findings and to decide on further investigations or management. Where the medical officer is the initial examining clinician, the medical officer discusses and evaluates all patient findings with the surgeon and radiologist.	Assessment	Moderate	Very High	Major	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
2.18 The Service demonstrates the effective use of FNA cytology and core biopsy in assessment.	2.18.1 <25% of all lesions aspirated through FNA are classified with the result inadequate/insufficient.	Assessment	Moderate	Medium	Significant	Level 2
	2.18.2 The proportion of core biopsy procedures with a false negative or inadequate result. Note: RCPA has recommended that no benchmark be set for this standard but data collected against it for a period of time. The standard, with associated data, will be reviewed at a later time and a benchmark established.	Assessment	Moderate	Medium	Significant	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
2.19 The Service demonstrates high quality pathology.	2.19.1 The Service ensures that a designated pathologist is appropriately qualified and responsible for all issues of quality assurance related to pathology, as specified in Appendix Q.	Management	Unlikely	Extreme	Major	Level 2
	2.19.2 The designated pathologist and any deputy/ies participate in the Royal College of Pathologists of Australasia Quality Assurance Program Breast Pathology Module.	Management	Moderate	Very High	Major	Level 2
	2.19.3 The Service uses pathology laboratories which maintain Royal College of Pathologists of Australasia National Association of Testing Authorities accreditation.	Management	Unlikely	Extreme	Major	Level 2
	2.19.4 The designated pathologist and deputy/ies implement the recommendations for quality assurance and uniform reporting of breast FNA cytology and core biopsy in Breast fine needle aspiration cytology and core biopsy—a guide for practice ^{81A} as amended from time to time as outlined in Appendix R and S.	Assessment	Unlikely	Extreme	Major	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
	2.195	Assessment	Unlikely	Medium	Moderate	Level 3
	<p><6% of malignant lesions assessed by FNA have a false negative result.</p>					
	2.196	Assessment	Unlikely	Medium	Moderate	Level 3
	<p>(a) <1% of malignant lesions assessed by FNA have a false positive result.</p> <p>(b) The proportion of non-malignant lesions assessed FNA with a false positive result</p>					
	2.197	Assessment	Unlikely	Extreme	Major	Level 2
	<p><0.5% of lesions sampled through core biopsy procedures have a false positive result.</p>					
	2.198	Assessment	Unlikely	Extreme	Major	Level 2
	<p>The absolute sensitivity of a diagnosis of breast cancer based on FNA cytology is >60%.</p>					
	2.199	Assessment	Rare	Very high	Moderate	Level 3
	<p>The complete sensitivity of FNA biopsy in the assessment of breast lesions is >80%.</p>					
	2.19.10	Assessment	Unlikely	Very high	Significant	Level 2
	<p>The absolute sensitivity of core biopsy in the assessment of breast lesions is >70%.</p>					

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
	2.19.11 The complete sensitivity of core biopsy in the assessment of breast lesions is >80%.	Assessment	Unlikely	Very high	Significant	Level 2
	2.19.12 The positive predictive value of a malignant FNA diagnosis is >98%.	Assessment	Rare	Very high	Significant	Level 3
	2.19.13 The positive predictive value of a malignant core biopsy diagnosis is >99%.	Assessment	Rare	Very high	Moderate	Level 3
	2.19.14 The designated pathologist and deputy/ies implement the recommendations for reporting DCIS and invasive breast cancer in the Recommendations for the pathology reporting of breast cancer as amended from time to time as outlined in Appendix S.	Assessment	Unlikely	Extreme	Major	Level 2
2.20 The Service minimises the number of visits and time required to achieve an outcome of assessment.	2.20.1 ≥95% of women require no more than two assessment visits to receive a definitive outcome.	Unnecessary Recall	Unlikely	Very High	Significant	Level 2
	2.20.2 ≥95% of women complete all assessment within a two week period.	Timeliness	Unlikely	Extreme	Major	Level 2
	2.20.3 ≥95% of women not requiring FNA cytology or core biopsy at assessment receive a definitive outcome at their first assessment visit.	Unnecessary Recall	Unlikely	Very High	Significant	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
2.21 The Service maximises the operative identification of lesions requiring open biopsy.	2.21.1 The Service refers women for open biopsy to facilities which are fully equipped to provide: <ul style="list-style-type: none"> • image-guided localisation (mammographic or ultrasound); • specimen radiography; and • specialist histopathological techniques. 	Management	Unlikely	Extreme	Major	Level 2
	2.21.2 All women with impalpable lesions undergoing open biopsy have specimen radiography performed.	Assessment	Moderate	Very High	Major	Level 2
	2.21.3 ≥95% of all impalpable lesions are correctly identified at first open biopsy.	Assessment	Unlikely	Extreme	Major	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
2.22 The Service minimises the proportion of women on early review.	<p>2.22.1 <0.2% of women who attend for screening are recommended for early review for further assessment.</p> <p>Early review is the recall for further assessment within 12 months of the screening date and following an equivocal assessment visit (where a decision cannot be made).</p> <p>Early review within six months of the screening date is considered to be part of the screening episode and cancers found as a result of the review are considered to be screen-detected. Early review carried out at six months or more from the date of screening, occurs after the screening visit is complete and cancers found are considered to be interval cancers.</p>	Unnecessary Recall	Moderate	Very High	Major	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
2.23 The Service ensures that women diagnosed with breast cancer are appropriately referred for treatment.	2.23.1 The Service implements a protocol for the referral of all women with a diagnosis of breast cancer to the person of their choice, either their nominated general practitioner or to a surgeon or treatment clinic with known expertise in the treatment of breast cancer.	Continuity, Counselling and Support	Unlikely	Extreme	Major	Level 2
	2.23.2 The Service ensures that all referrals to treating clinicians for women diagnosed with breast cancer include: <ul style="list-style-type: none"> • results of tests and a diagnosis; • copies of imaging films; • copies of pathology reports; and • a request for appropriate follow-up information. 	Continuity, Counselling and Support	Moderate	Very High	Major	Level 2
	2.23.3 The Service ensures that all women with a diagnosis of breast cancer are advised in writing of their status in relation to the Program in future years.	Information given	Unlikely	Medium	Moderate	Level 3

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
2.24 The Service ensures the collection of treatment information about women with breast cancer.	2.24.1 The Service implements a protocol for: <ul style="list-style-type: none"> the collection of information from treating clinicians, which satisfies BreastScreen Australia Data Dictionary requirements, about the surgical histopathology and primary treatment of all women diagnosed with breast cancer; and following up those clinicians who do not respond to the initial request for information. 	Data Management	Moderate	Very High	Major	Level 2
	2.24.2 All surgical histopathology and primary treatment information is requested by the Service.	Data Management	Rare	Very High	Moderate	Level 3
	2.24.3 ≥95% of responses to requests for surgical histopathology is received by the Service.	Data Management	Unlikely	Very High	Significant	Level 2
	2.24.4 ≥80% of responses to requests for primary treatment information is received by the Service.	Data Management	Unlikely	Medium	Moderate	Level 3

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
2.25 The Service implements strategies for multi-disciplinary case review, follow-up of individual cases and professional education.	2.25.1 The Service ensures that all cases which underwent FNA cytology or core biopsy are reviewed by a radiologist and at least one other clinician before giving the results to the woman. Where results of radiology and pathology are inconclusive or inconsistent, the cases must be reviewed minimally by a radiologist together with a pathologist.	Cancer Detection	Unlikely	Very High	Significant	Level 2
	2.25.2 The Service implements a protocol for reviewing and correlating the clinical, radiological, cytological and histopathological findings for all lesions detected as a result of screening which required surgery.	Cancer Detection	Moderate	Extreme	High	Level 1
	2.25.3 Where there is discordance between these results the Service implements a protocol for the follow-up of these women which may include: <ul style="list-style-type: none"> • notification of the surgeon; • notification of the general practitioner; • notification of the woman for review and assessment at the Service, or any combination of these. 	Cancer Detection	Unlikely	Extreme	Major	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
2.25 The Service implements strategies for multi-disciplinary case review, follow-up of individual cases and professional education (Continued).	2.25.4 Each member of the multi-disciplinary assessment team attends at least five professional educational meetings per year either within or outside the Service.	Management	Moderate	Medium	Significant	Level 2
3.1 The Service monitors and responds to women's views about the appropriateness and acceptability of screening and assessment.	3.1.1 The Service actively seeks feedback from women about the acceptability and appropriateness of screening and assessment. For example, but not limited to: <ul style="list-style-type: none"> • information; • waiting time; • physical environment; • staff; and • pain and discomfort. A process for reviewing, evaluating and incorporating feedback is documented and implemented.	Information given	Moderate	Medium	Significant	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
3.2 The Service ensures that all women are provided with information to make informed decisions about their participation in screening and assessment.	3.2.1	Information given	Unlikely	Very High	Significant	Level 2
	Written information, which has been approved by the State Coordination Unit and is consistent with state and national policies is available to all women attending for screening, and includes: <ul style="list-style-type: none"> • purpose of screening; • likelihood of recall; • possibilities of false positive and false negative results; • uncertainties and risks; • rescreening. 					
	3.2.2	Information given	Unlikely	Extreme	Major	Level 2
	Written information, which has been approved by the State Coordination Unit and is consistent with state and national policies is available to all women attending assessment. It includes: <ul style="list-style-type: none"> • the investigations which may be required; • the benefits, limitations and risks of the investigations; • the possible outcomes of assessment. 					

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
3-3 All women provide written consent prior to screening and assessment procedures.	3.3.1 Women are offered the opportunity to ask questions in private before giving consent for any procedure. Health care providers are available to answer any clinical questions.	Information given	Unlikely	Extreme	Major	Level 2
	3.3.2 The consent forms provide a record that information has been given and understood to the woman's satisfaction. The forms clearly indicate that the woman may decline or request discontinuance of a procedure at any time.	Information given	Unlikely	Extreme	Major	Level 2
	3.3.3 Written consent is obtained from all women before: <ul style="list-style-type: none"> the screening mammogram; investigations at the assessment visit. 	Information given	Rare	Extreme	Significant	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
3-4 The woman's consent is obtained before identified information or data are transferred for clinical or monitoring purposes.	3-4.1 Written consent is obtained from the woman before: <ul style="list-style-type: none"> her general practitioner, or other doctor to whom she is referred, is notified of her results; the Service requests information about procedures and treatment from doctors to whom she is referred; data, including identifying details, are transferred for clinical and monitoring purposes or released in any form; she is sent an invitation letter for rescreening. 	Information given	Unlikely	Extreme	Major	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
3-5 The Service meets the needs of women from indigenous and culturally and linguistically diverse backgrounds by recognising linguistic, cultural and socio-economic diversity.	3-5.1 The Service has protocols for service delivery to women from (a) indigenous and (b) culturally and linguistically diverse backgrounds, which have been developed in collaboration with relevant organisations that reflect the socio-demographics of the Service.	Equitable Access	Moderate	Very High	Major	Level 2
	3-5.2 Information in the common community languages represented in the Service catchment are available for women attending for screening and assessment.	Equitable Access	Unlikely	Very High	Significant	Level 2
	3-5.3 The Service ensures that: <ul style="list-style-type: none"> women are asked when they book if an interpreter is required; a gender appropriate interpreter is available for women attending for screening and assessment whenever possible; a telephone interpreter service is used if an interpreter cannot attend in person. 	Equitable Access	Moderate	Very High	Major	Level 2
	3-5.4 All staff attend at least one cultural awareness training course.	Equitable Access	Likely	Medium	Major	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
3.6 The Service meets the needs of women with disabilities.	<p>3.6.1 The Service has a protocol to ensure the appropriate management of women with disabilities, which:</p> <ul style="list-style-type: none"> • has been developed in consultation with relevant organisations; • requires that appropriate information and support is available to women with an intellectual disability and/or a low level of literacy; • requires that appropriate consent is obtained; • requires that additional staff and longer appointment times be made available if necessary; • requires that, with the woman's consent, her nominated general practitioner is informed if a woman seeks advice about participating in or attends for screening or assessment and the service is unable to be provided as a result of the woman's disability. 	Equitable Access	Moderate	Very High	Major	Level 2
	3.6.2 The Service complies with AS1428 for at least one screening unit and one assessment unit.	Management	Unlikely	Very High	Significant	Level 2
	3.6.3 New units and units undergoing refurbishment comply with AS1428, wherever possible.	Management	Unlikely	Very High	Significant	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
3-7 The Service ensures that women progress through the screening and assessment pathway in a timely manner.	3-7.1 ≥90% of women attend for a screening appointment within 28 calendar days of their booking date (fixed sites only).	Timeliness	Moderate	Medium	Significant	Level 2
	3-7.2 (a) ≥90% of women requiring assessment attend an assessment visit within 28 calendar days of their screening visit. (b) All women will be provided with information on waiting times. (c) Programs will collect data on: <ul style="list-style-type: none"> • date of screening; • date of screening result notification; • date of offered assessment appointment; • date of attendance at assessment; and be able to calculate the time taken for all women to attend assessment.	Timeliness	Likely	Very High	High	Level 1
	3-7.3 ≥70% of open biopsies are performed within 14 calendar days of the recommendation for the procedure.	Timeliness	Moderate	Very High	Major	Level 2
	3-7.4 Where ≥70% of open biopsies are not performed within 14 calendar days of the recommendation, the Service implements a plan to reduce waiting times.	Timeliness	Unlikely	Very High	Significant	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
3.8 The Service ensures that the results of screening and assessment are provided to women in a timely and appropriate manner.	3.8.1 ≥90% of women have a letter sent notifying them of the results of screening in writing, within 14 calendar days of the date of screening.	Timeliness	Unlikely	Medium	Moderate	Level 3
	3.8.2 All women are notified of the results of their screening in writing, within 28 calendar days of the date of screening.	Timeliness	Unlikely	Very High	Significant	Level 2
	3.8.3 ≥70% of women are verbally given the results of: a) FNA biopsy within seven calendar days of the assessment procedure; b) core biopsy within seven calendar days of the assessment procedure.	Timeliness	Unlikely	Extreme	Major	Level 2
	3.8.4 All women receive the results of FNA biopsy and core biopsy in writing within 14 calendar days of the assessment procedure.	Timeliness	Rare	Extreme	Significant	Level 2
	3.8.5 All histological and cytological results are given by a clinical member of the assessment team.	Information given	Unlikely	Extreme	Major	Level 2
	3.8.6 All women are notified of the results of their assessment in writing within 14 calendar days of the date of completion of assessment.	Timeliness	Moderate	Very High	Major	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
3.9 Women are informed of a diagnosis of breast cancer in an appropriate manner and provided with information about their treatment options.	<p>3.9.1 All women diagnosed with breast cancer are told their results by a clinician in accord with the recommendations in Appendix U and with a member of staff responsible for providing counselling present, unless the woman specifically asks them not to be.</p> <p>3.9.2 All women diagnosed with breast cancer are:</p> <ul style="list-style-type: none"> provided with the consumer guide based on NHMRC clinical practice guidelines; encouraged to discuss options with their clinician. 	Continuity, Counselling and Support	Unlikely	Extreme	Major	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
3.10 Appropriate counselling is offered to women and their support person/s	3.10.1 All women who attend for screening and their support persons have access to counselling.	Continuity, Counselling and Support	Unlikely	Medium	Moderate	Level 3
	3.10.2 All women who attend for assessment or to received pathology results and their support persons have access to counselling on site.	Continuity, Counselling and Support	Rare	Extreme	Significant	Level 2
	3.10.3 Counselling for women and their support persons is provided in uninterrupted privacy and is appropriate for a screening program.	Continuity, Counselling and Support	Unlikely	Extreme	Major	Level 2
	3.10.4 All counselling is provided by staff who have specialist knowledge of breast screening and assessment and relevant counselling skills and training (see Appendix J).	Management	Moderate	Very High	Major	Level 2
	3.10.5 All staff who provide counselling have access to professional support provided by an appropriate counsellor.	Continuity, Counselling & Support	Likely	Medium	Major	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
3.11 The Service assists general practitioners and other health care providers to support women through all stages of the screening and assessment pathway.	3.11.1 All women screened are asked to nominate a general practitioner to whom their results will be forwarded	Continuity, Counselling and Support	Rare	Medium	Low	Level 3
	3.11.2 All women recalled for assessment are asked to confirm or nominate a general practitioner to whom their results will be forwarded.	Continuity, Counselling and Support	Rare	Very High	Moderate	Level 3
	3.11.3 The Service has a protocol to ensure that the nominated general practitioner is notified of all results in writing on the same day as the woman.	Continuity, Counselling and Support	Rare	Very High	Moderate	Level 3
	3.11.4 The Service has a protocol to ensure that all reasonable efforts are made to notify a woman's nominated general practitioner on the day of any diagnosis of cancer or recommendation for open biopsy.	Continuity, Counselling and Support	Rare	Very High	Moderate	Level 3
	3.11.5 The Service allows women to nominate a health care provider, in addition to their general practitioner, to receive their results if they request to do so.	Continuity, Counselling and Support	Unlikely	Very High	Significant	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
4-1 The Service ensures that requirements for accountability of service management are met.	4.1.1	Where the Service and State Coordination Unit are separate, there is a written contract detailing their responsibilities and the need for the Service to comply with the national standards.	Management Rare	Extreme	Significant	Level 2
	4.1.2	The Service implements a protocol for managing finances to maximise efficiency and accountability, including a delegation schedule.	Management Unlikely	Very High	Significant	Level 2
	4.1.3	The Service demonstrates a minimum annual throughput for each independent screening unit of: <ul style="list-style-type: none"> • 4,000 women for urban units; and • 3,000 women for rural/remote units. 	Management Moderate	Low	Moderate	Level 3

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
4.2 The Service encourages participation of key stakeholders in its structure, processes and activities.	4.2.1 The Service implements a strategy to encourage participation of key stakeholders in its structure, processes and activities, which details: <ul style="list-style-type: none"> ways to encourage participation of key stakeholders; representation of key stakeholders on committees or reference groups. 	Management	Moderate	Medium	Significant	Level 2
	4.2.2 The Service has a management or advisory structure which has representation from all key stakeholder groups.	Management	Unlikely	Medium	Moderate	Level 3
	4.2.3 The Service encourages consumer participation by: <ul style="list-style-type: none"> having appropriate representation with a minimum of at least two consumer representatives on any policy or advisory committee; offering access to training and development opportunities to consumers; having a designated member of staff to support consumers. 	Management	Moderate	Medium	Significant	Level 2
	4.2.4 A consumer rights module is included in the education and training of staff at the Service.	Management	Moderate	Medium	Significant	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
4-3 All staff employed by the Service have appropriate expertise, experience and training.	4-3.1 All new and existing staff meet the relevant expertise, experience and training standards outlined in Appendix J.	Management	Unlikely	Very High	Significant	Level 2
	4-3.2 All professional staff undertake continuing education and meet the continuing medical requirements of the professional bodies which represent their discipline.	Management	Unlikely	Very High	Significant	Level 2
4-3.3	The Service implements a plan for training.	Management	Unlikely	Medium	Moderate	Level 3
4-3.4	All staff receive appropriate orientation and training within three months of commencement of employment at the Service.	Management	Moderate	Medium	Significant	Level 2
4-3.5	In-service training, of at least six hours, is provided to all staff annually.	Management	Unlikely	Medium	Moderate	Level 3
4-3.6	All staff undergo annual performance appraisal, where they have the opportunity to identify any training needs that have not been met and agree to a plan for addressing these needs.	Management	Moderate	Medium	Significant	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
4.4	<p>The Service ensures that all staff of screening units are an integrated part of the assessment unit.</p> <p>4.4.1 The Service has systems in place to ensure that screening unit staff work closely with the assessment unit to ensure an integrated service, including:</p> <ul style="list-style-type: none"> at least one of the film readers will be part of an assessment team in the Program there will be liaison between staff in the screening units and assessment centre. 	Management	Moderate	Medium	Significant	Level 2
	4.4.2 The Service implements a protocol which delineates staff roles and responsibilities between the various components of screening and assessment.	Management	Moderate	Medium	Significant	Level 2
4.5	<p>The Service implements an effective quality improvement program.</p> <p>4.5.1 The Service implements a detailed quality improvement plan which includes case review, review of missed and interval cancers, educational meetings, review of comment from consumers and other key stakeholder, unidisciplinary and multidisciplinary activities; review of policies and procedures and review of program data. The plan will:</p> <ul style="list-style-type: none"> include all staff; include strategies for improving care in areas of need or focus; and be reviewed annually. 	Management	Moderate	Very High	Major	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
4.6 The Service ensures that all screening and assessment units use common policies, protocols and procedures.	4.6.1	The Service has an up-to-date Policy and Procedures Manual which: <ul style="list-style-type: none"> is consistent with State/Territory and national policies; contains common protocols as outlined in Appendix V; is maintained and updated by a designated member of staff. 	Management	Unlikely	Extreme	Major Level 2
	4.6.2	The Service ensures that all of the policies and procedures outlined in the Policy and Procedures Manual are implemented, monitors compliance and where necessary develops strategies for improving compliance.	Management	Moderate	Extreme	High Level 1
	4.6.3	All staff are trained to ensure an understanding of the policies, protocols and procedures of the Service.	Management	Moderate	Very High	Major Level 2
4.7 The Service ensures that relevant infection control and occupational health and safety standards are met.	4.7.1	The Service implements protocols to meet relevant State/Territory and national infection control standards.	Management	Unlikely	Extreme	Major Level 2
	4.7.2	The Service implements protocols to meet relevant State/Territory and national occupational health and safety standards.	Management	Unlikely	Extreme	Major Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
4.8 The Service ensures that all screening and assessment units operate in a dedicated space, at a dedicated time and with dedicated staff and facilities.	4.8.1 The Service ensures that all screening and assessment units operate in: <ul style="list-style-type: none"> a dedicated space, which is clearly identifiable as a BreastScreen Australia Service; at a dedicated time, so that screening and assessment of screen-detected abnormalities is exclusively performed at a given time; with dedicated staff and facilities. 	Management	Unlikely	Very High	Significant	Level 2
4.9 The Service provides integrated facilities.	4.9.1 All screening units within the Service are linked to a specific assessment centre.	Management	Rare	Extreme	Significant	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
4.10 The Service introduces new technologies in a planned and appropriate manner.	4.10.1 New technologies in use at the Service are introduced only if there is evidence of safety and effectiveness.	Management	Unlikely	Very High	Significant	Level 2
	4.10.2 For new technologies being introduced at the Service: <ul style="list-style-type: none"> • a protocol for introduction exists; • relevant staff receive appropriate training in the use of such technologies prior to commencing their use; • quality assurance protocols are in place; • where relevant, introduction is in accord with State/Territory and national policies; • where relevant, evaluation of the technology is undertaken. 	Management	Likely	Very High	High	Level 1

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
4.11 The Service ensures that confidentiality and security of client information is maintained.	4.11.1 The Service implements protocols to ensure that information collected about a woman is treated in a confidential manner, consistent with State/Territory and national requirements.	Data Management	Unlikely	Extreme	Major	Level 2
	4.11.2 All staff sign a confidentiality form outlining their responsibilities and obligations upon commencement of employment at the Service and each year thereafter.	Management	Moderate	Very High	Major	Level 2
4.11.3 For any research projects using screening and/or assessment data, the Service has evidence of Institutional Ethics Committee approval where appropriate and that they have advised the State Coordination Unit/State Accreditation Committee. Where data are to be published, the State Coordination Unit/State Accreditation Committee is advised and an independent final review is undertaken.		Management	Unlikely	Extreme	Major	Level 2
4.11.4 All client records are securely stored, using an accepted method of medical-record filing, and access is restricted to appropriate persons only.		Data Management	Unlikely	Extreme	Major	Level 2
4.11.5 The Service implements a protocol, consistent with relevant State/Territory protocols for a woman to have access to her own records, including copies of films.		Management	Unlikely	Very High	Significant	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
4-1.2 The Service ensures that sufficient and high quality data are collected.	4.1.2.1 The Service collects all data detailed in the BreastScreen Australia Data Dictionary and as agreed from time to time between the States/Territories and the Australian Government.	Data Management	Unlikely	Very High	Significant	Level 2
	4.1.2.2 The Service cooperates with the State Coordination Unit to ensure that State/Territory and national reporting requirements are met.	Data Management	Rare	Very High	Moderate	Level 3
	4.1.2.3 The Service implements a protocol for data collection and any movement of client records which includes staff responsibilities, the transfer of records between units and the file tracking system used.	Data Management	Unlikely	Very High	Significant	Level 2
	4.1.2.4 The definitions and methods used by the Service in the calculation of screening indices conform to the definitions and methods specified in the national standards and BreastScreen Australia Data Dictionary.	Data Management	Rare	Very High	Moderate	Level 3
	4.1.2.5 Each client has one unique identifier within each State/Territory program.	Data Management	Rare	Extreme	Significant	Level 2
	4.1.2.6 All paper clinical records held by all units in the Service are dated and identifiable to the relevant health professional for that part of the screening and/or assessment pathway.	Data Management	Unlikely	Very High	Significant	Level 2

Performance Objective	Standard	Cluster	Likelihood of not meeting standard	Consequence of not meeting standard	Risk Category	Risk Level
	4.1.2.7 The Service undertakes ongoing quality control procedures for data throughout the screening and assessment process, including: <ul style="list-style-type: none"> • review of the completeness and legibility of paper clinical records; • review of the consistency between paper and computer records; and • verification of the accuracy of the output. 	Data Management	Unlikely	Very High	Significant	Level 2
	4.1.2.8 All relevant staff are instructed in procedures to ensure quality of data at all levels of the screening and assessment pathway.	Data Management	Unlikely	Very High	Significant	Level 2
	4.1.2.9 The Service has a designated person responsible for data management, security and integrity.	Data Management	Rare	Extreme	Significant	Level 2
	4.1.2.10 The Service has standard procedures for the maintenance of computer hardware and software.	Management	Unlikely	Medium	Moderate	Level 3

ATTACHMENT 2

CLUSTERS AND RISK CATEGORY GROUPING

Cluster	Risk Category Grouping		
	Level 1	Level 2	Level 3
Assessment	2.8.1	2.7.1	2.19.5
	2.8.2	2.15.1	2.19.6
	2.8.3	2.17.1	2.19.9
	2.8.4	2.18.1	2.19.12
		2.18.2	2.19.13
		2.19.4	
		2.19.7	
		2.19.8	
		2.19.10	
		2.19.11	
		2.19.14	
		2.21.2	
		2.21.3	
	Cancer Detection	2.1.1	2.1.3
2.1.2		2.2.2	2.10.3
2.2.1		2.3.1	2.10.4
2.4.1		2.3.2	2.12.2
2.4.2		2.3.3	2.13.2
2.5.1		2.4.3	
2.25.2		2.12.1	
		2.12.3	
		2.12.4	
		2.12.5	
		2.13.1	
		2.13.3	
		2.14.1	
		2.25.1	
	2.25.3		
Continuity, Counselling and Support		2.23.1	3.10.1
		2.23.2	3.11.1
		3.9.1	3.11.2
		3.9.2	3.11.3
		3.10.2	3.11.4
		3.10.3	
		3.10.5	
		3.11.5	

Cluster	Risk Category Grouping		
	Level 1	Level 2	Level 3
Data Management		2.24.1 2.24.3 4.11.1 4.11.4 4.12.1 4.12.3 4.12.5 4.12.6 4.12.7 4.12.8 4.12.9	2.24.2 2.24.4 4.12.2 4.12.4
Equitable Access		3.5.1 3.5.2 3.5.3 3.5.4 3.6.1	
Information Given		3.1.1 3.2.1 3.2.2 3.3.1 3.3.2 3.3.3 3.4.1 3.8.5	1.3.2 2.23.3
Management	4.6.2 4.10.2	2.9.1 2.9.2 2.9.3 2.9.4 2.9.5 2.9.6 2.10.1 2.10.5 2.10.6 2.11.1 2.11.2 2.12.6 2.16.1 2.16.2 2.16.3 2.16.4 2.19.1 2.19.2	4.1.3 4.2.2 4.3.3 4.3.5 4.12.10

Cluster	Risk Category Grouping		
	Level 1	Level 2	Level 3
Management continued		2.19.3 2.21.1 2.25.4 3.6.2 3.6.3 3.10.4 4.1.1 4.1.2 4.2.1 4.2.3 4.2.4 4.3.1 4.3.2 4.3.4 4.3.6 4.4.1 4.4.2 4.5.1 4.6.1 4.6.3 4.7.1 4.7.2 4.8.1 4.9.1 4.10.1 4.11.2 4.11.3 4.11.5	
Participation		1.1.1 1.2.1 1.2.2 1.3.1 1.3.5 1.4.1	1.1.2 1.3.3 1.3.4 1.4.2
Timeliness	3.7.2	2.20.2 3.7.1 3.7.3 3.7.4 3.8.2 3.8.3 3.8.4 3.8.6	3.8.1

Cluster	Risk Category Grouping		
	Level 1	Level 2	Level 3
Unnecessary Recall		1.5.1 2.6.1 2.6.2 2.6.3 2.20.1 2.20.3 2.22.1	1.5.2