APPENDIX 8

NATIONAL ACCREDITATION GUIDELINES

NATIONAL PROGRAM *for the* EARLY DETECTION
of BREAST CANCER

NATIONAL ACCREDITATION GUIDELINES

Developed by a Working Party of the National Advisory Committee
for the Early Detection of Breast Cancer

NOVEMBER 1991

NATIONAL ACCREDITATION GUIDELINES

These Guidelines were developed by a working party of the National Advisory Committee for the Early Detection of Breast Cancer.

The National Advisory Committee is comprised of representatives of the following organisations and interests:

Aboriginal and Torres Strait Islander Commission
ACT Board of Health
Australian Cancer Society
Australian Institute of Radiography
Australian Medical Association Ltd.
Commonwealth Department of Health, Housing and Community Services
Consumers' representative
Department of Health, Tasmania
Health Department Victoria
Health Department of Western Australia
New South Wales Health Department
Northern Territory Department of Health and Community Services
Public Health representative
Queensland Department of Health
Royal Australasian College of Surgeons
South Australian Health Commission
The Royal Australian College of General Practitioners
The Royal College of Pathologists of Australasia
The Royal Australasian College of Radiologists

The hard work and expertise contributed by the individuals on the working party to the development of these Guidelines is greatly appreciated.

The Guidelines were ratified by the National Advisory Committee for the Early Detection of Breast Cancer on 22 November 1991.

The Guidelines were developed to set accreditation standards within existing policy, as was the brief of the working party. Policy is set by State and Commonwealth Ministers. In ratifying the Guidelines, the National Advisory Committee noted reservations by some groups about current policy:

- The reading of screening mammograms by non-radiologist readers (Royal Australasian College of Radiologists, Intercollegiate Committee on Mammographic Screening);

- The inclusion of women 40–49 years in the Program (Royal Australasian College of Radiologists, Australian Medical Association);
- The inclusion of breast physicians (Australian Medical Association);
- The inclusion of open surgical biopsy in the Program (Intercollegiate Committee).

For further information on the Guidelines, please contact the National Co-ordination Unit, National Program for the Early Detection of Breast Cancer, Department of Health, Housing and Community Services, on (06) 289 7323.

Additional copies of the Guidelines can be obtained from each State Co-ordination Unit.

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Section 1

OVERVIEW *of the* NATIONAL PROGRAM

1.1 INTRODUCTION

Breast cancer is the most common cancer threatening the lives of Australian women. Over 5000 Australian women develop breast cancer each year, and each woman has a one in 16 chance of developing breast cancer during her life.

Each year more than 2000 Australian women die from breast cancer. Despite technical advances in the treatment of breast cancer, survival rates have remained unchanged in the last 50 years.

There is now widespread agreement among public health authorities that well controlled mammographic screening can substantially reduce deaths from breast cancer among women aged 50–69. Mammography is the only effective means for detecting non-palpable cancers, which are at a stage when they are more likely to be amenable to effective treatment.

The evidence that breast cancer screening by mammography is efficacious comes from a number of studies, including four randomised controlled trials and three studies of case-control design.

In the United States, 29 tightly monitored demonstration projects have shown that screening mammography is practical and effective under normal 'field' conditions.[1,2]

Based on the results of the overseas trials, individual women participating regularly in mammographic screening of high quality can expect their risk of death from breast cancer to be reduced by more than half while they participate in such a program.

Currently, the evidence suggests that breast cancer deaths could be reduced by around one third among those offered screening, which includes those women who choose not to participate in screening.

The report of the Australian Health Ministers' Advisory Council (AHMAC) Screening Evaluation Steering Committee, *Breast Cancer Screening in Australia: future directions*[3] suggests that, with a fully operational screening program and a 70% participation rate amongst eligible women, the reduction in mortality from breast cancer amongst all Australian women would be around 17% (p. 26).

1.2 PROGRAM HISTORY *and* ORGANISATION

Between 1987 and 1990, 11 breast cancer screening projects in five Australian States participated as pilots in a three year evaluation which advised the Australian Health

Ministers' Advisory Council on the various policy aspects of developing national strategies for extensive screening programs.

Based on this evaluation the Commonwealth Government announced that it would contribute $64m in the first three years towards the development of a national breast cancer screening program. The National Program for the Early Detection of Breast Cancer (the National Program) is to be implemented over five years from the time of agreement by the States and Territories to participate.

Subsequently five States have signed participation agreements with the Commonwealth, and the others have conducted feasibility studies (as at October 1991).

The National Program will be funded through cost shared arrangements between the Commonwealth Government and the Governments of the States and Territories. In the start-up phase, the Commonwealth is providing $14m in unmatched funds to enable States and Territories to either establish a program or expand their services in line with the National Program policies and objectives.

Funding will be provided to State and Territory Governments through agreements between the Commonwealth and State and Territory Governments, and is expected to be administered through the State Co-ordination Units.

The National Program will be a clearly identifiable, integrated, systematic and co-ordinated program. A network of accredited and dedicated Screening and Assessment Services will be established within each participating State and Territory to provide screening to all women over 40 years of age. Women aged 50–69 will be actively recruited.

Each Screening and Assessment Service will operate as an integrated system consisting of an assessment centre/service, and associated screening unit(s). The Service will be responsible as a whole to the State Co-ordination Unit. Screening units may be fixed or mobile, and will not operate independently but in close association with a designated assessment centre/service.

The State Co-ordination Unit (SCU) in each State and Territory will have primary responsibility for implementation of the National Program within the State or Territory. This responsibility includes recommendations about the location, type and number of screening units and assessment centres/services, recruitment, training co-ordination, accreditation monitoring, financial management and data management.

The National Co-ordination Unit will provide a central co-ordination and management function for the National Program and the National Advisory Committee for the Early Detection of Breast Cancer. It will be responsible for national data collection, compilation and analysis, and National Program evaluation and monitoring.

1.3 ACCREDITATION *within the* NATIONAL PROGRAM

For a population based mammographic screening program to achieve its full potential, it must be of high quality and achieve high participation rates. Furthermore, women with screen detected abnormalities must receive appropriate follow-up assessment as well as have access to high standard treatment facilities where required.

The development of successful overseas programs has been based on a recognition that, for benefits to be maximised and any adverse effects minimised, screening mammography must be implemented with stronger control and guidance than is customary in health service development. The possible adverse effects of screening which must be minimised may include anxiety, radiation exposure, over diagnosis and under diagnosis and unnecessary intervention (including open biopsy).

The report of the AHMAC Breast Cancer Screening Evaluation Steering Committee[3] emphasised the need for a highly integrated, systematic and co-ordinated program, including standardised accreditation processes, specialised training, quantitative performance criteria, ongoing monitoring and evaluation, and national and state level co-ordination mechanisms[3].

The Accreditation process, and these National Guidelines, will together be a critical component in the achievement of sufficiently high standards throughout the national network of Screening and Assessment Services to enable the achievement of the desired outcomes.

It is the integrated Screening and Assessment Service which will be accredited under these Guidelines. The Service, or parts of it, may be located in the public or private sectors, but all elements will need to meet accreditation guidelines in order for the Service to qualify for funding under the National Program.

The Screening and Assessment Service must be a discretely identifiable Service, with a clear management and service delivery structure and processes dedicated to the purpose of mammographic screening.

The services under the National Program should not be provided concurrently with any other radiological or diagnostic services.

The continued funding of such Screening and Assessment Services will depend upon their compliance with these National Accreditation Guidelines which have been developed and approved by the National Advisory Committee for the National Program for the Early Detection of Breast Cancer. That Committee consists of professional, program management, government, consumer and public health representatives.

Their implementation will be overseen and regularly reviewed by a National Accreditation Committee. This Committee will include relevant professional and program management representation. It will have direct reference to an Intercollegiate Committee on Breast

Cancer Screening for advice on professional matters. It will also maintain a register of accreditation experts upon which States and Territories may draw to assist the process of accreditation.

Responsibility for ensuring the accreditation of Screening and Assessment Services lies within the State or Territory Co-ordination Unit. Each State will have in place an appropriate accreditation advisory group for this purpose (see Section 4).

These National Accreditation Guidelines apply to the accreditation of Screening and Assessment Services as described above. They do not apply to the accreditation of professional personnel. The latter process is seen to be the prerogative of the relevant Professional Colleges and Institutes. The Guidelines require that staff employed by the Services funded by the National Program be appropriately qualified, and that where recognised professional guidelines exist they should be the standards (see Section 2.2).

Screening and Assessment Services may be provisionally accredited for 12 months after which re-accreditation will be required each two years.

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All health services can be conceptualised to consist of three elements—structure, process and outcome, and these are integral to the processes of quality assurance and evaluation.

Structure encompasses the resources of the Screening and Assessment Service which may be primarily expressed as financial or human. It also includes less tangible features of the management and administration such as quality assurance programs, clear program objectives and policies, programs of training and continuing education, procedures for ensuring client satisfaction, and staff appraisal and performance mechanisms.

Process refers to the activities of the Screening and Assessment Service and includes recruitment strategies, screening and assessment processes, and monitoring and evaluation activities.

Outcome relates to the results of activities undertaken through the Program. The ultimate aim of this National Program is reduction in mortality from breast cancer.

A population of women over 50 years of age offered breast screening can expect an approximate 30% reduction in deaths from breast cancer. Because this mortality reduction follows a delay of about five years from the commencement of screening, it is important to adopt interim performance measures for this key program outcome.

The basis of the anticipated reduction in mortality is the earlier detection of cancers (particularly small cancers) followed by their successful treatment. Therefore, the proportion of cancers detected, and more so the proportion of invasive cancers less than 10mm, have been adopted as two suitable intermediate indicators of the ultimate outcome (see Section 3).

While a reduction in breast cancer mortality is the ultimate goal of the National Program, this goal should not be pursued to the total exclusion of other important process or outcome objectives such as participation by women in health decision making, and recognition of women's rights and needs as health care consumers.

If the National Program is not to fall into disrepute with women, then there must be recognition of individual women's needs in service delivery. This philosophy has served as a guiding principle in the development of these National Accreditation Guidelines.

The three elements—structure, process and outcome—which underlie the aims and objectives of the Program, also define the scope of these Accreditation Guidelines, and form the basis of the various standards established herein.

It is important that the National Program, and each of the Screening and Assessment Services which comprise it, recognise that it is crucial to determine standards for these three elements and then to measure achievement of those standards, so that progress towards the end results can be effectively monitored.

Considerable evaluative work has already been done on the effectiveness of mammographic screening and these results have been used extensively in the development of the policies and management structures of the National Program, and in the development of the various standards established in these Guidelines. This includes the pilot projects conducted in Australia in the late 1980s as well as data from the various overseas trials.

The Guidelines have also drawn heavily on standards established by the Professional Colleges and Institutes, the Australian Institute of Health, the National Health and Medical Research Council and overseas programs.

The quality of a health service is a function of five different types of outcome:

Effectiveness	the degree to which the service reaches the objectives.
Efficiency	the maximisation of benefits for the minimum cost in resources of reaching the objectives.
Equity	the degree to which resources are used for the benefit of the whole population.
Appropriateness	the balance of risks and benefits.
Client satisfaction	the degree of satisfaction experienced by the clients.

These five types of outcome are implicit in the aims and objectives of the National Program and in these National Accreditation Guidelines.

Also integral to the Guidelines is the notion that quality of structure, process and outcomes will be continually monitored, evaluated, reviewed and improved. It is National Program policy that multi-disciplinary teams will be established in each accredited

Screening and Assessment Service for this purpose, in conjunction with appropriate processes of review and change.

Whilst monitoring and evaluation is critically important in relation to the clinical activities, it is also vital that the Program be equally rigorous in its monitoring and evaluation of recruitment, resource management, data collection and training activities. The establishment and maintenance of high quality standards in all its component parts and all its objectives will be imperative if the National Program is to achieve an acceptable balance between cost and public health benefit.

Criteria for establishing quality and for measuring performance need to be selected for validity, reliability and feasibility and be reviewed on an ongoing basis.

These National Accreditation Guidelines set minimum standards for the accreditation of Screening and Assessment Services as part of the National Program for the Early Detection of Breast Cancer. They are intended to ensure the achievement of the Program aims and objectives, which follow.

1.4 *The* AIMS *and* OBJECTIVES *of the* NATIONAL PROGRAM

The aims and objectives of the National Program have been derived from the report of the Breast Cancer Screening Evaluation Steering Committee[3], particularly from its recommendations. They have been developed by the National Co-ordination Unit in consultation with the Program's National Advisory Committee and its Working Parties. They will be reviewed from time to time.

Aims of the National Program

- To ensure that the Program is implemented in such a way that significant reductions can be achieved in morbidity and mortality attributable to breast cancer.
- To maximise the early detection of breast cancer in the target population.
- To ensure that screening for breast cancer in Australia is provided in dedicated, accredited Screening and Assessment Services as part of the National Program for the Early Detection of Breast Cancer.
- To ensure equitable access of eligible women to the Program.
- To ensure that services are acceptable and appropriate to the needs of the eligible population.
- To achieve high standards of program management, service delivery, monitoring and evaluation, and accountability.

Objectives of the National Program

- After five years, a 70% participation rate in the National Program by women in the target group (50–69 years) and access to the Program for women aged 40–49 years and 70–79 years.
- All women in the Program rescreened at not more than two yearly intervals.
- To achieve agreed performance outcomes to minimise recall rates, retake films, invasive procedures, 'false negatives', and 'false positives', and maximise the number of cancers detected, in particular the number of small cancers detected.
- Referral to appropriate treatment services and the collection of information about the outcome of treatment.
- Funding by the National Program through State Co-ordination Units of only Screening and Assessment Services accredited according to agreed National Accreditation Guidelines, and the monitoring and review of those guidelines by appropriate National and State Accreditation Committees.
- Recognition of the real costs to the women clients of participation in the Program, and the minimisation of those costs, including the provision of services at minimal or no charge, and free to eligible women who would not attend if there were a charge.
- Information about mammographic screening and the implementation and outcomes of the National Program available in easily comprehensible and appropriate forms in a variety of forums and to women and health care providers in particular.
- Patterns of participation in the Program which are representative of the socio-economic, ethnic and cultural profile of the target population.
- Services provided in accessible, non-threatening and comfortable environments by staff with appropriate expertise, experience and training.
- Appropriate service in that counselling, education and information is provided as an integral part of the Program, sensitive procedures for notification of recall are in place, and the time between initial screen and assessment is minimised.
- High levels of participation in the development and management of the Program by members of significant professional and client groups.
- The collection and analysis of data sufficient to monitor the implementation of the Program, to evaluate its effectiveness and efficiency, and to provide the basis for future policy and program development decisions.

1.5 PROGRAM POLICIES

The report of the Breast Cancer Screening Evaluation Steering Committee[3] has also formed the basis for the development of the policies of the National Program for the Early Detection of Breast Cancer[4].

Screening and Assessment Services accredited under the National Program for the Early Detection of Breast Cancer will be expected to operate according to, and to make freely available, the policies and information statements of the National Program.

Major policy features of the National Program

- The National Program for Early Detection of Breast Cancer selects women on the basis of age alone. In line with the recommendations of the Evaluation Report[3], the Program will be made available and publicised for women aged 40 years and above, but recruitment strategies will be targeted at women aged 50–69 years[5].
- There is international consensus that mammographic screening is effective for women aged 50 years and above, while there is not yet consensus in relation to women aged 40–49 years. Under the Program women in this latter group will have access to organised, high quality screening.
- The age range for screening will be monitored and reviewed as new data becomes available.
- Screening will be made available as widely as possible to all eligible women with the intention of rescreening them every two years.

  The screening interval will be reviewed as new data become available.
- Screening will be made available at minimal or no cost to the woman, and free of charge to eligible women who would not attend if there was a charge.
- Comprehensive and easily understood information, emotional support and counselling will be provided as appropriate. Women will be advised on the effectiveness and risks of mammography and on the maintenance of a regime of breast care e.g. breast self examination to reinforce the message that a negative mammographic screen does not preclude the diagnosis of breast cancer prior to the next screen.
- Screening services will be provided in a manner which is acceptable to women in the target group and in accessible, non-threatening and comfortable environments.
- General Practitioners should be kept informed of the results of screening and any further work-up required, unless a woman directs otherwise. Although a doctor's referral is not a prerequisite for attendance, a letter from the woman's doctor is welcomed.
- Screening will employ film-screen mammography alone as the principal screening method for reducing breast cancer mortality.

- All women will be screened with two view mammography. At a subsequent rescreening one view may be used if previous mammograms have indicated that two views are not required.
- All mammograms will be taken by a radiographer appropriately trained in screening mammography.
- All mammographic films will be read and reported independently by two or more readers, at least one of whom shall be a radiologist. Both readers must be specially trained in screening mammography and both meet the same performance criteria. Reports will be combined into a single recommendation.
- The results of screening will be provided promptly and directly to the woman who is the subject of the screening in a way which is sensitive to her possible anxiety.
- Women will be actively involved in decisions about their management, particularly in relation to further assessment and treatment, and written information will be provided.
- Screening and assessment will be carried out at accredited centres/services.
- The Program will take a woman from screening up to and including histological or cytological diagnosis of breast cancer.
- Women with histologically or cytologically confirmed breast cancer will be given the option of referral to a treatment clinic specialising in the treatment of screen detected breast cancer or returning to their General Practitioner for referral to a specialist breast surgeon.

1.6 CONCLUSION

In summary, both the objectives of the National Program and these Accreditation Guidelines require a comprehensive and integrated approach to the screening process. Without this, the Program will fail to achieve its public health goal as well as its potential to benefit individual women.

Further, without a commitment to effective teamwork and a screening 'culture' by all staff involved in the screening and assessment pathway (including administrative and clinical personnel), the Program will inevitably fail to fulfil its promise.

The remaining sections of this document cover the following matters, in sufficient detail it is hoped, to permit an evaluation of the extent to which a Screening and Assessment Service is meeting, or is likely to meet Program objectives.

Section 2 contains guidelines for various Program components, including education and recruitment, screening and assessment, data collection and management, training for staff, and program administration/management.

This section is intended to provide an outline of what aspects of an individual program will be evaluated, on what broad criteria, and some guidance on how various aspects of the Screening and Assessment Service should be delivered to the target group.

Section 3 gives performance objectives and standards. This section provides brief statements of the key performance objectives for each major program component, as well as quantifiable/objective standards for their measurement.

The Accreditation Process is spelled out in Section 4, including levels of responsibility within and between States, procedures for withdrawal of accreditation and so on.

Implementation, including relevant timeframes and a budget for the accreditation process is found in Section 5 and finally, the appendices cover specific aspects of all the above in greater detail.

So as to ensure greater uniformity in interpretation of these guidelines, a series of definitions has been agreed (see Appendix 1). These will facilitate not only uniformity of interpretation but also greater uniformity of implementation of the National Program.

Section 2

ACCREDITATION GUIDELINES *for* COMPONENTS *of the* PROGRAM

2.1 RECRUITMENT

The National Program for the Early Detection of Breast Cancer is a population screening program for women which is dependent upon obtaining high participation rates for its success and effectiveness. The aim of the program is to screen 70% of women aged between 50–69 years at two year intervals and to make breast screening available for women aged 40–49 years and 70 years and over. It is essential that these women return for subsequent screening.

Non-individualised and individualised strategies should be developed, monitored and evaluated centrally to ensure their effectiveness and efficiency. Equitable participation in the program should be achieved with eligible women having access to screening services irrespective of their social, economic, cultural or geographical circumstances.

2.1.1 Community education

The National Program should have co-ordinated community education strategies that operate within the following guidelines:

- The aim of community education should be to raise the awareness of the community in general and eligible women in particular about the objectives and policies of the National Program for Early Detection of Breast Cancer.
- Educational/promotional strategies should be developed from an understanding of the information needs of the target population.
- These strategies should recognise that women are not a homogeneous group—socio-economic status, culture, language, educational status and marital status should be considered.
- Educational/promotional programs should be developed in consultation with women from the target population to ensure their appropriateness and potential to be effective.
- Strategies used to recruit women for breast screening should be efficient with costs per woman recruited monitored closely.
- Educational resources should be produced at the State Co-ordination Unit level, based on qualitative and quantitative research that recognises the complexity of the relationship between knowledge, attitudes, beliefs and behaviour, so that a uniform message can be conveyed to women.

- Educational resources should provide accurate, honest and sensitive information to women so that they can make an informed decision whether or not to participate in the program.
- Educational resources should also be provided in a culturally sensitive way and in languages other than English.
- The priorities for education are to:
    - inform women that the goal of the National Program is to reduce morbidity and mortality amongst eligible women;
    - explain the eligible age group for screening including information about why it is not offered to women outside the eligible age group;
    - acknowledge women's anxiety about breast cancer;
    - highlight the benefits of early detection of breast cancer, including better treatment options;
    - reduce women's fear of breast cancer and its treatment;
    - explain the limitations of mammography screening in detecting breast cancer;
    - inform women of their risk of developing breast cancer;
    - inform women that there might be some discomfort with mammography;
    - inform women that up to 10% may be called back for further assessment in the first round, but that recall does not imply cancer;
    - encourage women who notice changes between screens to seek prompt medical advice;
    - provide women with practical information about the services i.e. how to book, what to wear etc.;
    - produce written material in plain language and present it in a manner that is appropriate to the eligible women—easy to read and appealing.
- All educational/promotional activities should seek the active participation of women in their development, design and implementation and be undertaken in the wider context of women's health.

2.1.2 *Professional education*

As the major providers of primary health care to women in the target population, general practitioners must themselves be a key focus of professional education strategies. However, professional education strategies should include the roles that are, or might be, played by other health workers in the community, particularly those with a community health/ women's health interest.

Thus, the National Program should have co-ordinated professional education strategies that function within the following guidelines:

- The strategies are developed from an understanding of the information needs of various health professional groups, these needs being identified from qualitative and quantitative research.
- Education activities and resources should be developed in consultation and close co-operation with relevant health professionals and their organisations.
- Education activities and resources should be developed and co-ordinated at National or State level, so as to avoid duplication of effort and to ensure consistency with respect to information and screening recommendations/guidelines.
- Educational materials should provide an up-to-date, accurate and honest appraisal of the research literature on screening mammography, with particular reference to its role, its relevance to different age groups, and relationship to other screening modalities (e.g. breast self examination), so as to assist health professionals in educating and/or advising women on whether or not to participate in the Program.
- Educational resources should provide guidance to health professionals on where to find additional information on key issues if required.
- Strategies and education materials should clearly support the role of the woman's general practitioner in the key areas of client education, recruitment and counselling. Educational strategies should recognise that in the event that an abnormality is confirmed at assessment, many women will turn to their general practitioner for advice and support.

Priorities for professional education are to:

- explain the rationale for limiting the screening program to women in the eligible group, and specifically targeting women 50–69 years;
- highlight the benefits and disadvantages of screening mammography;
- explain the rationale for a controlled, staged implementation process in the National Program, and for a funding mechanism other than Medicare fee-for-service.

2.1.3 Participation rates

The breast screening services will need to be implemented within a geographically defined population of eligible women to enable participation rates to be calculated.

In conjunction with appropriately timed recruitment strategies the following should be features of the breast screening service that will ensure high levels of participation:

- friendly and efficient bookings system;
- minimum waiting time for appointments;
- confirmation of booking and provision of clear instruction about the location of the service, parking, public transport etc.;
- after hours services, i.e. evenings and/or Saturday mornings.

To ensure high rates of participation, adequate resources should be allocated for the recruitment of women, which should be centrally co-ordinated.

2.1.4 Rescreen compliance

High levels of compliance to attend for rescreen must be an important feature of effective breast screening and assessment services.

Women's attendance for rescreen should be enhanced through inclusion of the following features:

- ensuring that the initial visit is as pleasant as possible for the woman. This would include both friendly, considerate and sensitive care from the staff and pleasant surroundings;
- informing women that they will receive a letter inviting them to attend for rescreening in the recommended period. This should be included in the woman's notification of her results. A booklet that includes a section for the woman to record her mammography history may also be useful;
- reminder letters to each woman preferably with an appointment date.

2.1.5 Equitable participation

There should be an understanding of the features of the eligible population in the defined area for the breast Screening and Assessment Service so that the recruitment strategies can be appropriately developed and implemented in the first instance.

Participation should be sampled regularly to assess the levels of participation on the basis of age, socio-economic status, language spoken at home, Aboriginality and marital status. Relevant qualitative and quantitative research should be undertaken to identify barriers to participation among eligible women, in conjunction and consultation with relevant women's groups.

Steps should be taken to redress any under representation of any sector of eligible women.

2.2 SERVICES *and* FACILITIES *for* SCREENING *and* ASSESSMENT

2.2.1 Introduction

The service to the client and the facilities provided to screen women for breast cancer will to a large extent determine the level of participation of women in the program, and will minimise any negative effects of the program, in particular unnecessary anxiety to the woman and her family and unnecessary biopsy.

Screening services are the first stage in the screening pathway and as such must be of a high quality as outlined in Section 2.2.2.

Assessment is an integral component of the screening pathway and should provide dedicated multi-disciplinary and simultaneous assessment in the following modalities; imaging (includes mammographic and/or ultrasound), clinical, cytological (sampling and interpretation) and communication and counselling skills needed to inform women of the outcome. Either one of the two screen readers should be part of the assessment team.

2.2.2 Screening

The services provided under the National Program should not be provided concurrently with any other radiological or diagnostic services. Such facilities could be developed within the public or private sector.

Individual screening units, which may be fixed or mobile, shall not operate independently of a dedicated assessment centre/service (see Section 2.2.3).

Written policies and management protocols should exist for each screening unit and the staff working in it. These should clearly identify:

- staff responsibilities and lines of authority;
- client consent procedures;
- procedures for handling complaints;
- procedures for early recall (if applicable);
- procedures for routine recall;
- procedures for discharge from the Program (e.g. in event of death, client too young, etc.);
- roles of the various components within the recruitment/screening/assessment pathway, and staff accountabilities within and between these components;
- information for clients;
- counselling procedures where appropriate.

Screen taking

Screening units within a State should possess *as far as possible* common protocols and data forms for management of the screening process which are in turn compatible with Commonwealth funding criteria and screening policies. A specified person should be designated to maintain these protocols in an up-to-date format at all participating assessment centres/services and to distribute these to affiliated screening units.

All staff should receive training in the procedures to be followed, including regular updates.

In accordance with national funding criteria, all mammograms must be performed by appropriately trained and qualified radiographers.

Staff working in screening units and assessment centre/services should be trained to provide concise, accurate information to women attending the screening unit, and to relate to women at all times in a reassuring and confident manner.

At the prevalent screening round, the two standard views (cranio-caudal and medio-lateral-oblique) must be taken of each breast.

Written protocols should exist, and be adhered to, for the following situations:

- women presenting with breast prostheses;
- choice of film format to be used for women with very large breasts; and
- minimum number of views to be performed at second and subsequent screening rounds.

To minimise anxiety and radiation exposures to individual women, radiographers and other technical staff (dark room attendant) must be able to maintain adequate technical standards, thus keeping client returns for technical repeats to a minimum.

Radiographic and technical staff should be able to demonstrate knowledge of and adherence to appropriate quality control procedures. (see Section 2.2.10 for quality assurance standards).

Screening units should have a minimum throughput of 5000 women per annum. These films to be read by the minimum number of readers.

Reading

All screening films must be read independently by two readers at least one of whom must be a radiologist, with the reports being combined into a single recommendation. Both readers must be specially trained in screening mammography.

The standard report of the initial screen should clearly indicate an outcome in a non-narrative form, approved by the State Co-ordination Unit.

Screening units must have explicit protocols for the procedures to be followed in the event of discordant calls between the film readers. This may involve use of a third reader or in other centres discussion between the two readers to reach consensus.

Film readers must have appropriate training and demonstrated experience and expertise in reading screening mammograms. Individually, screening film readers should each read a minimum of 2000 screening mammograms per annum and be able to meet the overall program performance standards, detailed in Section 3.2 of this document: 2.1(b), 2.1(c), 6.2(a), 6.2(b), 6.3.

2.2.3 *Assessment*

Assessment centres/services shall be responsible for all work-up and diagnostic procedures provided as part of the Program up to and including cytological or histological diagnosis of breast cancer.

Assessment centres/services should have access to comprehensive facilities for evaluating women with an abnormal screening mammogram and for evaluating women who report breast symptoms at the screening visit.

The assessment centre/service should have the capability for complete mammographic work-up (including cone compression and magnification views), ultrasound examination, clinical evaluation, needle biopsy (including ultrasound-guided and sterotactically-guided needle biopsies), and aspiration cytology.

Specific counselling services should also be available for the women involved, both prior to and during the assessment process as required.

Privacy should be provided for women at the assessment centre/service for counselling purposes.

The assessment centre/service should have access to and close liaison with facilities for open biopsy that can perform radiographic localisation of impalpable lesions and specimen radiography, as well as special histopathological techniques for evaluation of these lesions. Assessment centres/services must also have close liaison with facilities providing all forms of management, treatment and counselling for women with diagnosed breast cancer.

Centres/services should show evidence of educational and liaison activities conducted with general practitioners to support them in their role as the primary care provider, and as a major contributor in the recruitment, education and counselling processes associated with the screening/assessment pathway.

Where appropriate, assessment centres/services should also liaise with other relevant health professionals in their regions.

Written management protocols and policies should exist for each assessment centre/service and for the staff working within it. These should clearly identify:

- staff responsibilities and lines of authority within the service;
- client information;
- client consent procedures;
- procedures for early review;
- procedures for routine recall;
- procedures for discharge from the Program;
- the roles of various components within the recruitment/screening/assessment pathway, and staff accountabilities within and between these components.

Follow-up protocols

Assessment centres/services should have documented procedures to ensure that appropriate follow-up is undertaken for women with screen-detected abnormalities. This is critical to the eventual success of the National Program.

Common protocols for the management of screen detected abnormalities should be developed as far as possible at the State Co-ordination Unit in consultation with Radiologists, Surgeons, Pathologists and Directors.

Staff should be aware of the reason for attendance at assessment centres/services to permit appropriate client management and throughput arrangements.

Diagnostic procedures

Assessment centres/services and affiliated diagnostic services should have written protocols for the management of recall clients, that include criteria for case selection for specific diagnostic procedures and procedures to be followed at each step of the diagnostic pathway.

Assessment and biopsy centres/services should have an appropriately constituted group to develop these clinical protocols and to keep them under regular review.

Centres/services performing open biopsy should have co-located facilities for specimen radiography, as well as access to nearby facilities for performing special histopathological techniques for impalpable breast lesions.

All assessment/biopsy centres/services should have developed close links with facilities that provide a full range of treatment and counselling for women with diagnosed breast cancer.

Recommendations concerning pathology standards shall be made in consultation with the National Pathology Accreditation Advisory Council, the National Association of Testing Authorities and the Royal College of Pathologists of Australasia.

Review processes and quality assurance

Each assessment unit must have established, formal mechanisms for review of clinic policies and individual client outcomes. These should include written procedures for regular audit of film quality, equipment functioning, and clinical outcome measures.

2.2.4 *Staffing*

The assessment centre/service and its affiliated screening units should have an integrated administrative/management structure which ensures a close liaison between professional staff in the screening units and affiliated assessment centres/services, preferably with some staff overlap.

Assessment centres require multi-disciplinary, professional input, provided by teams that must include a radiologist, breast surgeon, and cytologist/pathologist as required.

Radiographers involved in screening units should spend some part of each year in an assessment centre/service. At least one of the radiologists involved in reading original screening films should also be involved in the assessment centre. The radiologists, surgeons and pathologists involved in the assessment centre should also be involved in open biopsy procedures performed as part of the Program.

These associations are necessary to maintain high standards for the screening process, by facilitating mechanisms for review and quality control and the development of diagnostic and therapeutic expertise.

The diagnosis and management of women with a screen detected abnormality requires a multi-disciplinary team approach with ongoing consultation and review of procedures and outcomes.

Medical personnel should have accreditation status or appropriate qualifications as defined by their respective Colleges.

Medical personnel should participate in at least monthly meetings to monitor performance and review the experience of the Service.

Radiographers are to be fully trained in screening mammography through training courses that have been accredited by the Australian Institute of Radiography.

Those personnel acting in a counselling role are to be specifically trained in breast cancer screening, in particular dealing with anxiety, and discussing with women the outcomes of screening.

Clinical and support staff all should have participated in specific in-service training in breast cancer screening that included developing skills to deal sensitively with anxious women.

2.2.5 Provision of information

Women attending breast screening and assessment services should be provided with comprehensive and easily understood information about screening.

Each woman attending for screening should sign a consent form that clearly outlines the screening process including the possibility of recall for follow-up assessment. The woman should also be informed in writing that screening does not prevent breast cancer, nor does it detect all breast cancers.

Information provided by the woman and data collected by the Service should be held in the strictest confidence. Service procedures must ensure the confidentiality of individual client information. All women must be informed that data will be collected about each screening episode for the purpose of monitoring and evaluating the screening service.

Women should be advised of the benefit to them of information about their screening being included in their family practitioner's record.

2.2.6 Physical environment

Services should be provided in pleasant surroundings that are comfortable and non-threatening.

It is desirable that the setting of the service is separate from medical services, either in the community or a separate setting within a hospital environment.

Waiting areas provided for women once they have gowned in preparation for their examination should allow women to feel comfortable while maintaining their privacy.

Wheelchair access should be provided where possible at screening and assessment services. Whenever possible, clinics should be located at ground level to enable easy access for women in older age groups.

2.2.7 Education and counselling for Screening and Assessment Services

Within a Screening and Assessment Service, education and counselling are integrally linked. Counselling will often be given in the context of provision of further information to the woman, and it is important that counselling is not seen as an isolated element of the program—all information should be provided in a sensitive manner.

Educational guidelines

The education of women at a screening unit or assessment centre is an essential component of a successful screening program. A large number of women who attend for screening will be informed about screening mammography and about the Program, but this cannot be assumed.

Therefore, while the major emphasis of an educational program within a screening and assessment service is to inform women about the procedure they are about to undergo and encourage and motivate women to attend for regular mammography screening, there will still be a need to educate women about mammography and the benefits and limitations of screening. This is also an opportune time for women to voice any of their queries about screening or breast cancer.

A combination of individualised and non-individualised approaches can be used to educate women within screening and assessment services.

General information about the Program and about breast screening can be provided on a non-individualised basis using similar material to that used for community education e.g. booklets, pamphlets, posters as well as continuous play breast self-examination videos, breast models, etc.

These resources should be made available in the waiting room or given to women to take home, and should be available in languages other than English.

The purpose of this material should be to:

- educate women about the benefits and limitations of mammography screening and the benefits of early detection;
- encourage and motivate women to attend for mammography screening on a regular basis and advise them of the recommended screening interval;
- educate women about the importance of regular clinical examination and encourage them to seek advice if changes occur between regular visits;
- provide information that will enable women to overcome barriers associated with breast screening;
- encourage women to ask questions and to voice any concerns they may have about breast cancer and screening;
- inform women who document that they have breast symptoms (lump or nipple discharge) at the time of screening that they will be recalled for assessment.

Information should also be provided to women on an individual basis.

The woman should be provided with information about breast self examination.

Accurate information on risk should be available where appropriate to those women who have a strong family or personal history of breast cancer or benign breast disease.

The woman should be advised of how and when the results of screening will be received.

If a woman is recalled or further work-up is required, the woman should be advised exactly what is involved and the reason for it.

Counselling guidelines

An integral component of a dedicated breast screening and assessment service is the provision of professional counselling. It is important that all women who attend for screening or assessment have access to counselling to reduce the level of anxiety and to assist those who are diagnosed with breast cancer to better cope with their diagnosis.

All counselling should be provided by counsellors who have received some level of appropriate training and who are able to determine the level of counselling required by each woman.

Counselling should be accessible to all women and their supporters who attend screening units or assessment centres.

Emotional support should be provided at all stages of the screening pathway, but particularly during assessment or if there is a diagnosis of breast cancer.

Women with a diagnosis of breast cancer should be given comprehensive and easily understood information on treatment options and encouraged to be actively involved in decisions about these options.

Women should be encouraged to voice their feelings or concerns about breast cancer and their treatment options.

If language is a difficulty all care should be taken, where appropriate, to utilise the services of qualified interpreters.

2.2.8 *Notification procedures*

So as to minimise anxiety, women should be notified in writing and at the earliest opportunity of the outcome of their screens. The results of screening should be provided in a way which is sensitive to the woman's possible anxiety. All letters sent to women should be subject to review.

The woman who attends for assessment should be informed of the outcome by a member of the assessment team who has skills in communication and counselling.

The woman's general practitioner should be kept informed of the screening and/or assessment outcome, unless otherwise directed by the woman.

Women who are recommended for open biopsy following assessment, and who have not nominated a general practitioner, should be encouraged to do so before proceeding with referral.

2.2.9 *Involvement of women in decisions*

All women attending for breast screening and assessment should be actively involved in decisions about, and discussion of, all procedures undertaken.

Women recommended to have open biopsy/cancer treatment should be encouraged to discuss this fully before proceeding. This may involve more than one session and could include follow-up counselling undertaken by a trained breast cancer counsellor. The information provided must be both comprehensive and easily understood by the women to enable them to make an informed decision.

2.2.10 *Quality assurance standards*

The Screening and Assessment Service should have a documented quality assurance program, the supervision of which will be the responsibility of the designated radiologist. The position paper *A Quality Assurance Program for Mass Screening in Mammography*[4] and the publication *Screening Mammography Technology*[5] give useful information. Appendix 2 is an extract from these publications, and should be used as a guide in the administration of the Program.