1 Equipment and radiation protection

The equipment used should comply with the relevant Standards Association of Australia standards where appropriate and also comply with and be approved by the State Radiation Protection Authorities. The radiation protection in the fixed or mobile installations should be approved by the relevant State Radiation Protection Authority.

Appendix 3 should be consulted to give a guide for the purchase of *new* equipment.

2 Processing

Centres should be able to provide documentary evidence of their adherence to a quality assurance program. It is essential that optimal processing conditions are achieved and maintained, both to increase cancer detection rates and to minimise radiation dose.

Processing of mammography film must be carried out in film processors used only for single emulsion film and optimised in accordance with particular equipment and film-screen combinations. The processors should be cleaned and serviced regularly.

Wherever processing is undertaken, written protocols must exist for staff involved, which should include the detailed quality control steps to be followed and their frequency.

Protocols should also contain specific guidance on remedial procedures. Written records must be maintained by all screening units and assessment centres/services, documenting quality assurance checks, equipment failure or malfunctions and the remedial steps undertaken.

The discharge of chemical waste from fixed and mobile installations should meet appropriate standards designed to reduce environmental pollution.

Given the likelihood of ongoing technical advances in the field, overly prescriptive recommendations as regards processing are inappropriate.

All radiographers or technicians employed within the accredited Screening and Assessment Services should be provided with opportunities for ongoing education/training, to ensure their up-to-date knowledge and attention to quality assurance principles.

3 Mammogram evaluation

Mammograms should be of good quality, properly identified and with minimal artefact. They should be of appropriate density, resolution and contrast. Mammograms should show optimal positioning. In addition to the continuous assessment of film quality, mammograms should be formally evaluated on a 1 to 3 month basis by the designated radiologist and records kept of number and nature of defects detected.

It is desirable that each examination be clearly identified as to the machine used and the name of the radiographer. The results of the evaluation should be transmitted to the radiographic staff directly on an individual basis. Meetings should be held from time to time with the radiographers to discuss the results and rectify any problems. The frequency

of the formal assessments and staff meetings will vary depending on the number of radiographic defects, the experience of the staff and the length of time the particular program has been in operation.

4 Radiation dose measurement

The radiation dose on each mammographic unit should be calculated annually and records kept of the date, technique and dose measurement. The recommendation of the Australian Radiation Laboratory in the publication *Radiation Doses from Mammography in Australia*[6] should be a guide. A summary of the recommendation is as follows:

1 The International Commission of Radiological Protection recommendations (IC87) that 'the usual reference terms for radiation dose in the glandular tissue (excluding skin) in a uniformly compressed breast of 50% adipose, 50% glandular tissue composition. The reference breast thickness should be specified' be used as a standard within Australia.

2 The maximum mean glandular dose (MGD) from x-ray mammography in the glandular tissue (excluding skin) in a uniformly compressed breast of 50% adipose, 50% glandular tissue composition of 5 cm thickness for a single image of the breast, should not exceed 2.0 mGy when a grid is used and not exceed 1.0 mGy when a grid is not used.

3 Calculation of the MGD should be made using the method recommended by the NCRP (NC86) or by direct depth dose integration.

4 Regular quality assurance monitoring of x-ray equipment and processing, as recommended by the Australian Institute of Health (AI90b) should be undertaken by each centre conducting mammography.

5 The MGB for each mammographic unit should be measured annually by an independent body.

5 Breast ultrasound

A modern high resolution machine should be used with a hand held probe operating in the 5–10 megahertz range. A stand-off should be available for best resolution near the skin line, preferably attached to the transducer face.

Ultrasound examinations should be conducted under the supervision of a radiologist experienced in ultrasound of the breasts and preferably experienced in the use of ultrasound in other areas. The ultrasound machine should be regularly serviced.

An ultrasound phantom designed to check the system efficiency in detecting small lesions in a tissue equivalent material and to check the ability to distinguish small cysts from solid lesions should be designed and used to check ultrasound machines in all assessment centres/services.

2.3 DATA COLLECTION

2.3.1 *Principles of data collection*

The rationale, aims and objectives for the collection of data to monitor and evaluate the National Program have been clearly established and documented. This information should be available to, and understood by all staff participating in the Program.

The amount of data should be the minimum required to adequately assess the performance of the Program in general and individual services.

Assessment centres must be provided with the resources to collect and monitor their basic activity and have access to their performance data in a timely fashion. This feedback is essential to maintain staff interest and morale, as well as to improve individual program results.

Data which are collected should be accurate and should be collected to comparable standards by each clinic.

Access to individual client data should be restricted to the minimum number of persons, on a 'need-to-know' basis.

All data must be maintained with due respect to its personal nature. Staff should know and adhere to written protocols for maintaining clients rights to privacy and confidentiality of medical information.

Each data record should have a unique identifying number allocated to each client.

2.3.2 *Quality assurance*

Documented procedures are to be maintained for data collection including the designated movement of records within the clinic. This is to ensure records are not mislaid or sighted by unauthorised personnel.

Quality control procedures should be documented and undertaken at all levels in the screening and assessment pathway. These procedures should include regular audits of data quality and routine editing of relevant client/summary evaluation data. All staff must be instructed in these procedures and be able to demonstrate their knowledge and understanding of the procedures.

Standard maintenance procedures for hardware and software should be documented and adhered to.

There should be an identified person who takes overall responsibility for data integrity, assisted by clinical and administrative line managers.

2.3.3 Ethical and medico-legal considerations

All paper clinical records are to be signed by the health professional who is directly responsible for a particular episode in the screening or assessment pathway. This includes those taking and reading the mammograms, as well as those involved in clinical assessment.

Data items collected for each screening or assessment episode must be recorded accurately and legibly. Abbreviations should be avoided.

All records of each screening episode are to be securely maintained, using an accepted method of medical record filing that ensures easy access to a woman's record.

Screening and assessment units must obtain the woman's informed consent for all procedures. Her consent should also be obtained for the exchange of clinical data between clinicians involved in her management, and for the use of anonymous, aggregate data for program evaluation purposes.

Service protocols should provide guidance for staff in the event that the woman does not give her full consent at any stage of the screening/assessment pathway.

The consent form must contain a simple statement of the objectives of the screening program, as well as details of procedures to be performed. It should include an explanation, presented in lay terms, of the meaning of false positives and false negatives and their likelihood of occurrence. Every consent form should include:

- signed statement that the woman understands mammography does not pick up all cancers;
- agreement to/request for a mammogram (and fine needle aspiration and/or ultrasound if recalled);
- consent to provide information to the woman's doctor, or other doctors to whom she is referred;
- use of the information, providing identity is not disclosed, for monitoring and evaluation purposes;
- recording of identifying information on a confidential register primarily for the purposes of routine recall and follow-up.

It is intended to develop a form to be used as a model.

In those states where there are specific procedures or regulations governing privacy and confidentiality, screening and assessment units should provide written statements as to how these rights will be protected and all staff should demonstrate knowledge of the appropriate procedures.

2.4 TRAINING ACTIVITIES

Implementation of a National Program of Mammographic Screening is dependent on the availability of specially trained staff committed to providing a high quality efficient service. The need for specialised training of staff associated with the National Program has been recognised by the Intercollegiate Committee of the Royal Australasian College of Surgeons, the Royal College of Pathologists of Australasia, and the Royal Australasian College of Radiologists and these training guidelines draw on work already done by that Committee.

The creation of assessment centres with their associated screening units provides a focus for developing specialised training courses for all types of staff needed to expand the National Program. However, institutions providing basic training for radiographers should be urged to develop mammographic training facilities and provide training during the basic radiography course in mammographic positioning, equipment, radiographic techniques to minimise dosage, mammographic film processing and quality assurance. National co-ordination of course curricula is recommended via the Australian Institute of Radiography and the Royal Australasian College of Radiologists.

Facilitating the availability of appropriate and adequate training will be an integral part of the responsibility of the State Co-ordination Unit and such training will be part of a national network of recognised training centres. In some States the size of the program may not justify their own training course, however access to one should be assured.

It is likely that in States which develop a training program, an assessment centre/service (or possibly a consortium) will be charged with providing a specialised training course for all staff who join the screening program. The training course should cover not only professional aspects but also include an overview of the planning and development of assessment centres and their associated screening clinics.

Professional training should cover all aspects of screening and assessment of screen detected lesions. Although specific clinical/technical training should be provided for radiologists, radiographers, surgeons and pathologists who will be associated with the assessment centre/service and associated screening units, training should also be provided for management staff, data managers, counsellors and clerical staff. All trainees must be appropriately supervised.

It may be that some staff have received equivalent training elsewhere, however it is important also that they are familiar with local policies and practices.

Each State training program will be developed to suit the needs of that State, however it will be important that the expertise of staff from the training centre and the State Co-ordination Unit be utilised at the time new Screening and Assessment Services are being planned. After this initial stage all staff should have an appreciation of the policies and practice of the National Program.

Training courses will vary, but will include a period spent at an operational training centre. In general terms the course should include a planning and management component and professional group components. All staff of new Services should be trained, and wherever possible this should be in a multidisciplinary format.

Each State training centre will require:

- radiological expertise in screening maintained at a high level of screening activity which implies an annual rate of around 10,000 examinations;
- an extensive teaching file of mammograms;
- state of the art mammographic equipment, and facilities for localisation of impalpable lesions, and radiology of surgical biopsy specimens;
- a functional multi-disciplinary team;
- to appropriately liaise with any National Program which is developed.

The curriculum for an approved training program should include:

- the organisation of population screening programs including evaluation of process and outcome;
- technical aspects:
  - equipment
  - examination techniques
  - quality control routines
  - radiation dose monitoring;
- image interpretation in the screening context with particular attention to small carcinomas and exposure to a wide variety of normal and abnormal mammograms;
- the evaluation of screening detected abnormalities by radiological methods and in collaboration with clinical colleagues and the cyto and histo pathologist;
- the radiological localisation of non-palpable lesions;
- the radiology of surgical biopsy specimens;
- a working knowledge of modern surgical, radiotherapeutic and oncological procedures used in the management of breast cancer patients;
- an awareness of the possible psychological problems which may occur in dealing with women in a screening program.

2.4.1 Radiologists

Radiologists involved in breast screening programs who are responsible for screening mammography in a screening unit will have received an acceptable level of formal training and experience in mammography, and will have attended a course at a State or national level in screening mammography. A radiologist working at an accredited assessment

centre/service will in addition have received an acceptable level of formal training in the radiological assessment of women with abnormal screening mammograms.

All radiologists associated with the Mammographic Screening Program should attend the State training course.

2.4.2 Radiographers

Screening units should employ only radiographers with experience in mammography. All radiographers in accredited screening units and assessment centres/services, should have attended a course at State or national level in screening mammography.

2.4.3 Breast physicians/clinicians

The role of breast physicians/clinicians in assessment centres/services varies. Where breast screening services employ medical practitioners who are not qualified radiologists, surgeons or pathologists, they should have had formal training in breast cancer screening (including examination and counselling) and should be responsible to the Director of the assessment centre/service or the Program Manager.

The training of breast physicians/clinicians should involve an extended period of work under supervision in an assessment centre. In addition attendance at a formal training course is obligatory as well as attendance at a course run by the State training unit.

2.4.4 Surgeons

Surgeons involved in breast screening programs should be members of the Section of Breast Surgery of the Royal Australasian College of Surgeons and have appropriate training and expertise in:

- the clinical assessment of women with screen detected abnormalities;
- needle-localised biopsy of impalpable lesions;
- surgical management of benign and malignant breast lesions detected in the screening programs.

The surgeon should attend regular assessment sessions where women with detected abnormalities can be seen jointly with the radiologist and where future management can be planned.

All women requiring needle localised biopsy will be seen by a surgeon in conjunction with the radiologist.

The surgeon should attend regular conferences with pathologists and radiologists where the activities of the Screening and Assessment Services will be reviewed.

The surgeon will be responsible for recording surgical and related clinical details.

The surgeon is responsible for ensuring that surgical quality assurance guidelines are met.

The surgeon should have access to suitable operating hospital facilities for the surgical management of women with detected abnormalities.

The surgeon should promote participation in clinical trials.

Surgeons participating in breast screening programs should initiate and guide training programs for surgeons and surgical trainees wishing to become proficient in the techniques required for the management of screen detected abnormalities and participate in multidisciplinary training activities.

2.4.5 Pathologists

Pathologists involved in breast screening programs should be Fellows of the Royal College of Pathologists of Australasia or hold an equivalent academic qualification in Pathology.

The pathologist must be skilled in interpreting breast cytological and histological specimens.

The designated pathologist or a deputy should be a member of the assessment team and should be responsible for the reporting of review of *all biopsies and fine needle aspirations of lesions detected by screening*. Training of registrars and other pathologists associated with the centre is also the pathologist's responsibility.

The pathologist is responsible for ensuring that optimum handling of mammographically detected lesions occurs.

This includes:

- receipt of mammogram with biopsy;
- specimen mammography for:
  - confirmation of excision and clearance of the lesion (includes the availability of a radiologist for consultation);
  - guidance in the selection of tissue sections;
- analysis of the pathology and cytological data in a manner suitable for quality control, reports and publication.

The pathologist should participate in regular multidisciplinary meetings with the radiologists and surgeons of the Screening and Assessment Service and review all fine needle aspiration and biopsy diagnoses of screen detected cases by that unit. This may involve retrieving biopsy tissues and aspirates from various pathology practices.

The pathologist should attend an internationally recognised mammography screening unit or a recognised training centre in Australia to participate in a course run by that centre or spend sufficient time to acquire the special skills needed. Attendance is to be within the first twelve months of the commencement of appointment to the screening program.

Designated breast screening pathologists and their deputies in each State should meet locally on a regular basis, perhaps once every two or three months initially and then six monthly to discuss and clarify reporting nomenclature, diagnostic criteria and any specific problems that are encountered.

Free inter-unit referrals for problematic cases is strongly recommended.

Breast screening pathologists should meet nationally at least once a year to co-ordinate and correlate diagnostic criteria and performance statistics of each of the units. These meetings would also be an excellent forum for furthering education in aspects of fine needle aspiration, borderline cases and research possibilities.

2.4.6 Counsellors/educators

Counsellors/educators are an integral part of the staff of a Screening and Assessment Service. Most of these staff will have particular experience and training in counselling women with breast symptoms or with abnormal screening mammograms. Counselling may be undertaken by a range of health professionals.

All counsellors associated with Screening and Assessment Services should have attended a counselling course and a State training course.

2.4.7 Clinic/clerical Staff

All clinic/clerical staff attached to an assessment centre or screening unit should attend a State or national training program. Ongoing inservice training should be available to all staff within the service.

2.5 PROGRAM MANAGEMENT

2.5.1 Management structure

The management structure of the Screening and Assessment Service must be clearly documented in writing. The documentation must:

- identify one person who has responsibility for the management of all facets of the Service (hereafter referred to as the Director);
- document the various functions of the Service (e.g. recruitment, screening, assessment); the responsibilities of specific individuals and or committees in relation to those functions; and the relationships between them;
- clearly delineate the relationships and responsibilities of medical and non-medical staff;
- document the means by which any appointments (to staff, committees etc.) are to be made;

- document the representation of relevant client and professional groups on advisory or management groups as appropriate.

In Screening and Assessment Services, a radiologist, surgeon and pathologist should be designated who will each be responsible for those aspects of screening and assessment related to their particular discipline.

2.5.2 Management responsibilities

The Director of the Screening and Assessment Service shall:

- ensure that the operations and management of the Service are in accordance with the aims, objectives, and policies of the National Program;
- ensure that the short and long term plans of the Service are in accordance with the appropriate State or Territory Plan, and that the functions undertaken by the Service are as agreed with the relevant State Co-ordination Unit, including adherence to screening and assessment protocols developed by the State Co-ordination Unit;
- ensure that the aims, objectives and policies of the National Program are made freely available to clients, staff and other relevant health professionals;
- regularly review service provision in relation to policies and plans, and to make adjustments as necessary;
- ensure that the Service is conducted in such a way that barriers to participation by any eligible woman are minimised, and that active measures are taken where appropriate to ensure equitable access;
- be responsible for the provision of high quality services and client care within the Service and the implementation of a quality assurance program, including the co-ordination of and co-operation in any inspection undertaken by the State Co-ordination Unit;
- ensure that a multi-disciplinary team operates within the Service: integrating the various elements of the screening and assessment processes; meeting regularly; reviewing the performance of the component parts in relation to the performance measures adopted by the National Program; and taking steps as necessary to improve performance;
- ensure that a written record is made of meetings of advisory or management committees which form part of the management structure;
- ensure the efficient management of the financial resources of the Service and that it operates within the budget agreed with the State Co-ordination Unit;
- ensure that the Service operates within financial guidelines established from time to time by the National Program and/or the State or Territory Co-ordination Unit;

- ensure that adequate cost and financial data are provided to the State Co-ordination Unit as required as part of regular review of the cost effectiveness of the Service;
- ensure that data are collected as required by the National Program for the Early Detection of Breast Cancer. It should be provided in a timely fashion, as required by agreement with the State/Territory Co-ordination Unit, and also be available to be utilised by the Service to monitor its own performance;
- ensure that required medical and other client information is maintained in a discrete and confidential manner;
- ensure that appropriate liaison occurs between the Service and external community and community health and hospital personnel;
- ensure that appropriate staffing policies and procedures are in place and adhered to;
- ensure that adequate staff provision is made, and that orientation and in-service training programs are available for staff members, to maintain staff knowledge and skills and to improve performance.

Section 3

PERFORMANCE OBJECTIVES *and* ACCEPTABLE STANDARDS

3.1 INTRODUCTION

The ultimate goal of breast screening by mammography is a substantial reduction in breast cancer deaths in the target population. It is impossible to measure any mortality reductions in the early, implementation phases of an organised, population-based screening program. Therefore, it is essential that key intermediate performance objectives, that may act as indicators of eventual mortality reductions, be clearly identified and monitored from the outset of the National Program.

The definition of these performance measures and their attainment should be the key focus of every State Co-ordination Unit and its affiliated assessment and screening centres.

3.2 PERFORMANCE OBJECTIVES

This section provides explicit statements of the performance objectives and minimum acceptable standards for specific components of the National Program for Early Detection of Breast Cancer. These statements encompass recruitment, screening, assessment, biopsy, treatment outcomes, wait times for key steps in the pathway, and overall program goals.

All values quoted for acceptable standards in the table overleaf are the minimum acceptable values for the National Program and its individual components. These standards will be reviewed in the light of program experience.

The Standards have been devised from overseas experience and the Australian pilot projects. Relevant sources are:

- Forrest Report[7]
- Pritchard Report[8]
- Breast cancer screening in Australia: future directions[3]
- British Association of Surgical Oncology (BASO)[9]
- NHS/BSP/Vessey 1991[10]

PERFORMANCE COMPONENT	PERFORMANCE (QUALITY) OBJECTIVE	ACCEPTABLE STANDARD
1. Recruitment	1. To maximise the number of women participating in screening	≥ 50% of eligible women (40–69 years)
	2. To maximise participation by women from Aboriginal and non English speaking backgrounds	Attendance in proportion to their representation in the population
	3. To minimise anxiety and increase acceptance of service by women	Interval from booking to appointment ≤ 4 weeks
2. Screening	1. To minimise anxiety and x-ray exposure among screened women by limiting the proportion of technical repeat films and the numbers of women recalled for mammographic assessment	a) Technical repeats < 3% of total films used b) Assessment recalls < 10% of women screened at prevalent round c) Recalls at < 5% at subsequent rounds
	2. To maximise client acceptance while at the same time minimising anxiety among screened women by providing prompt, written notification of results	a) Notification to occur within ≤ 14 days b) > 80% to be notified within 10 working days
	3. To maximise client acceptance of the screening service as evidenced by high participation rates among those invited for routine rescreen	a) > 75% participation at round 2 b) > 50% at 3rd and subsequent rounds
3. Assessment	1. To minimise waiting time and women's anxiety between initial screen and the first assessment visit	Interval < 2 weeks for > 90% of recalls

PROGRAM COMPONENT	PERFORMANCE (QUALITY) OBJECTIVES	ACCEPTABLE STANDARD
3. Assessment (continued)	2. To minimise the proportion of women referred for open biopsy	< 2% of women screened
	3. To minimise unnecessary invasive procedures (i.e. surgical biopsies for histology on benign cases)	Positive predictive value of biopsy > 25% (at prevalent screen) i.e. Benign: malignant biopsy ratio of • ≤ 3:1 for prevalent round • ≤ 2:1 in incident rounds
	4. To minimise the number of visits needed for further investigations	a) < 5% of women recalled for assessment for a screen abnormality are invited for early review b) Minimum period for review should be 6 months
4. Biopsy	1. To minimise the operative identification of lesions producing mammographic abnormalities	> 95% of impalpable lesions should be correctly identified at the first localisation biopsy
	2. To minimise the interval from a decision to operate for diagnostic purposes and the first offered admission date	90% should be admitted for an operative biopsy within two weeks of their first attendance at any assessment centre
5. Treatment	1. To ensure appropriate audit of follow-up	An annual follow-up form should be completed by the treating surgeon and returned to the assessment centre with the agreed data items

PROGRAM COMPONENT	PERFORMANCE (QUALITY) OBJECTIVES)	ACCEPTABLE STANDARD
6. *Overall Program performance*	1. To minimise the cost per women screened, based on a consideration of all aspects of the program for community education and recruitment up to and including histological diagnosis	a) ≤ $120/screen* at the prevalent screening round b) ≤ $80/screen* by year 5 of Program operation * 1990 prices
	2. To maximise the number of cancers detected	a) > 50% per 10,000 women screened in the prevalent screening round, including ductal carcinoma in situ (DCIS), but excluding lobular carcinoma in situ (LCIS) b) > 20 per 10,000 at subsequent rounds
	3. To maximise the number of minimal invasive cancers detected	> 15 per 10,000 screened women found to have invasive cancers < 10mm diameter on pathology
	4. To detect a representative proportion of DCIS at the prevalent screening round	10–20% of cancers detected
	5. To minimise the number of interval cancers	Proportion of women who develop breast cancer (including DCIS, but excluding LCIS) in 12 months following screening < 6 per 10,000

Section 4

ACCREDITATION PROCESS

4.1 LEVELS *of* RESPONSIBILITY

Levels of responsibility are illustrated in the Diagram at Figure 4.1 These are spelt out more fully below. The process will be that State Co-ordination Units will ensure that application is made for accreditation, and that appropriate documentation and inspection occurs. The State Co-ordination Unit will then make recommendations to the National Accreditation Committee which will formally approve the accreditation.

The National Co-ordination Unit in conjunction with the National Accreditation Committee and the National Advisory Committee, has responsibility for setting national guidelines and overseeing their implementation. State Accreditation Guidelines may be developed which will be approved by the National Accreditation Committee.

National Accreditation Committee

This Committee will consist of representatives of the relevant professional groups and of State and National Co-ordination Units.

It will be responsible for the development, publication and review of the National Accreditation Guidelines and for the formal accreditation of each Screening and Assessment Service within the National Program on recommendation from the State Co-ordination Units, acting in concert with the State accreditation group.

It will report to the National Advisory Committee and the National Co-ordination Unit on the implementation of the Guidelines and make recommendations following review. The National Accreditation Committee will also approve any State and Territory Accreditation Guidelines which may be developed to ensure that they are consistent with the National Guidelines.

The National Accreditation Committee will maintain a register of suitably qualified and experienced professionals to be drawn upon by State Co-ordination Units when forming their Accreditation Inspection Teams.

The National Accreditation Committee will establish a direct relationship with the Intercollegiate Committee on Mammographic Screening, and will refer matters to that committee as appropriate for professional comment or advice.

National Co-ordination Unit

This Unit has been established by the Commonwealth to manage and co-ordinate the implementation of the National Program. It has a specific function to provide secretariat

support to the National Accreditation Committee and the National Advisory Committee in relation to accreditation issues.

State Co-ordination Unit

A State Co-ordination Unit (SCU) will be established in each State or Territory under the agreement signed between the Commonwealth and State and Territory governments. Each SCU will have similar functions which are defined by that agreement.

The SCU will have responsibility for ensuring that Screening and Assessment Services which are funded through the National Program in its State and Territory are accredited in line with these National Guidelines. The State Co-ordination Unit will also be responsible for the implementation of the National Guidelines within the State or Territory, and for the development of any State Accreditation Guidelines.

Each State Co-ordination Unit will establish an appropriate State Accreditation Group which will provide advice about accreditation within the State and Territory.

The State Co-ordination Unit will make recommendations to the National Accreditation Committee relating to the accreditation of each Screening and Assessment Service, and the National Committee will formally accredit the Service.

4.2 MECHANISMS *for* ACCREDITATION *and* REVIEW

The accreditation process will include the completion of an accreditation assessment form for the State Co-ordination Unit. The form will request information relating to:

- Screening and Assessment Service protocols;
- Quality Assurance Program for equipment, readers and takers, data collection and management, education and counselling services, booking/clerical staff;
- The qualifications of staff—only professionally qualified staff are to be used. Where College accreditation is applicable this should be the standard accepted.

As far as possible it is planned to develop nationally agreed forms and procedures for this process. This will be the responsibility of the National Co-ordination Unit in conjunction with the State Co-ordination Units.

The State Co-ordination Unit will appoint two independent persons, one a radiologist and preferably one from interstate, who will conduct inspections of Assessment and Screening Services, including equipment, following the provision of documentation as outlined above. The Service will be expected to achieve acceptable levels of performance based on data provided to the State Co-ordination Unit.

The National Accreditation Committee will establish criteria for the relative significance of various standards set in these National Guidelines, for use when an individual Screening and Assessment Service is being accredited.

After the above process has been undertaken, provisional accreditation for 12 months may be granted in the first instance to enable a particular Screening and Assessment Service time to implement the requirements of these Guidelines.

Within 12 months application must be made for full accreditation at which time the Service will be expected to comply with the Guidelines.

A fully accredited Screening and Assessment Service will be provided with appropriate certification by the National Accreditation Committee, and this certification, plus other related material will be displayed as appropriate in accredited Screening and Assessment Services.

Once full accreditation is granted to a Screening and Assessment Service, the accreditation will be reviewed at two yearly intervals.

The two yearly review will include a review of the performance outcomes of the Service as outlined in these National Guidelines, and will involve a reporting along similar, although less comprehensive, lines to that required in the first instance for accreditation.

The State Co-ordination Unit, either independently or at the request of the National Co-ordination Unit, may conduct additional reviews from time to time particularly if there is concern about maintenance of performance standards.

4.3 PROCEDURES *for* WITHDRAWAL *of* ACCREDITATION

Negotiation will take place between the State Co-ordination Unit and a Screening and Assessment Service which fails to meet the required standards, and opportunities will be provided for the Service to meet the standards within an agreed timeframe.

If the Service consistently fails to conform to the negotiated timetable for full compliance, the State Co-ordination Unit will notify the Service in writing of its intention to recommend that the National Accreditation Committee withdraw accreditation, and hence funding by a specified date. Sufficient notice should be provided, bearing in mind the impact on client services.

Such a recommendation should be considered by the National Accreditation Committee as expeditiously as possible.

A period of provisional accreditation, of not more than 12 months, may be an appropriate interim measure in an instance where the circumstances of an accredited Service have changed sufficiently to render it no longer accreditable at time of review.

4.4 REVIEW *of* ACCREDITATION GUIDELINES

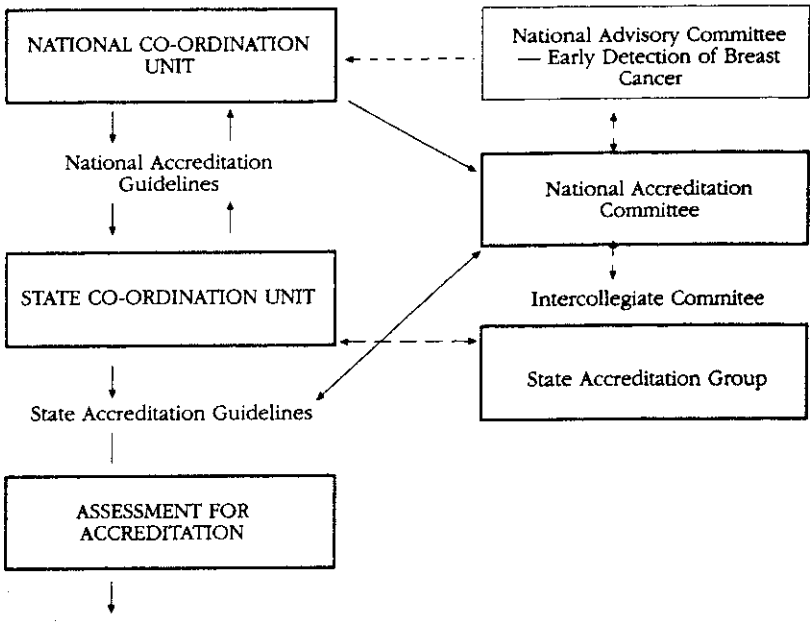
The National Accreditation Guidelines will be reviewed in the first instance in the third quarter of 1992, and thereafter each two years. They will be reviewed by the National Accreditation Committee which will make recommendations to the National Advisory Committee or the National Co-ordination Unit as appropriate.

At the same time State Co-ordination Units will be required to report on the implementation of any specific State Accreditation Guidelines.

State Co-ordination Units and/or their advisory groups on Accreditation will be able to make recommendations on the guidelines at any time to the National Accreditation Committee, and these will be considered, at least, in the next scheduled review.

Figure 4.1

ACCREDITATION *of* DEDICATED BREAST SCREENING *and* ASSESSMENT SERVICES



- Completion of Accreditation Assessment Form
  - — Provision of information to include
    - Screening and assessment service protocol
    - Quality assurance program outlined for
      - — equipment
      - — readers and takers
      - — data collection/management
      - — education/counselling services
      - — booking/clerical staff
- Achievement of acceptable levels of performance based on data provided to State Co-ordination Unit
- Independent inspection of services by two nominated persons
- Inspection and check of equipment by quality assurance program
- Provisional accreditation to new services for 12 months—then apply for full accreditation
- Thereafter two yearly review provided accreditation standards are maintained

- Breast screening and assessment services to ensure only professionally qualified staff are used—where College accreditation is applicable, this should be the accepted standard.

Section 5

IMPLEMENTATION

5.1 TIMEFRAME

An interim National Accreditation Committee was appointed following the November 1991 meeting of the National Advisory Committee which adopted the National Accreditation Guidelines.

The interim committee will oversee the early implementation of the Guidelines in those Screening and Assessment Services which are already provisionally accredited, or which will come into operation in the early stages of 1992.

The National Accreditation Committee will publish the Guidelines, and ensure that they are circulated as appropriate. It will also approve any State Accreditation Guidelines which are developed in addition to these Guidelines.

All Screening and Assessment Services currently operating will be required to submit to their State Co-ordination Unit for accreditation according to the National Guidelines by 30 June 1992. The National Accreditation Committee will devise a timetable, in consultation with the State Co-ordination Unit, for the orderly accreditation of existing services.

The Guidelines may also be used by planners of new Services within the National Program, as all Screening and Assessment Services funded by the National Program will be required to meet these standards.

Provision exists for provisional accreditation for up to 12 months. Thereafter re-accreditation will take place every two years.

The interim National Accreditation Committee will operate until 30 September 1992, or the nearest NAC meeting, when its functioning will be reviewed. Between 30 June and 30 September 1992 it will also review the National Guidelines and make appropriate recommendations to the National Advisory Committee.

5.2 BUDGET

The operating expenses of the National Accreditation Committee will be met from National Program Funds.

The Committee is expected to meet no more than three times each calendar year, and will meet in a location most suitable to the majority of members.

It is expected to operate within an annual budget determined by the National Advisory Committee.

Section 6

APPENDICES

APPENDIX 1—DEFINITIONS

Screening and Assessment Service	An integrated service consisting of an assessment centre and its associated screening units.
Assessment Centre	The centre within the Screening and Assessment Service where screen films may be read, and where women are recalled for diagnostic work-up following a screen-detected abnormality. It is anticipated that most assessment centres will have a number of associated screening units. Co-ordination of the Service, and functions such as training and performance review will take place from the assessment centre.
Dedicated	Services under the Program which are not provided concurrently with any other radiological or diagnostic service.
Screening Unit	This may be a fixed or mobile facility, the sole purpose of which is to provide the screening mammograms for presenting women. It may not function separately from an assessment centre/service.
False negative	Where women prove to have breast cancer but are mistakenly cleared by the screen.
False positive	Where women do not have breast cancer but have a screen that indicates they have breast cancer.

Definitions utilized in the minimum data set

Assessment	All follow-up investigative procedures arising from the woman's attendance for screening up to and including cytological or histological diagnosis.
Assessment unit identifier	Unique identification number for each assessment centre within the State and Territory.
Biopsy performed (in program)	'Program' is a centre or service accredited and funded as part of the national program.

Date of first attendance for assessment	First date of attendance for a given episode of assessment.
Date of commencement of primary treatment	First date of commencement of any of the primary treatment modalities used.
Date of open biopsy	Date of surgery for open biopsy.
Day procedure	Standard definition from the *Recommended minimum data set for institutional health care*[11].
Did the woman attend (for assessment)	Did the woman attend within three months of the screening mammogram.
Dominant lesion	If invasive, the largest size lesion; if invasive and of equal size then the one that has most Extensive Intra-duct Component (EIC); if the above does not help to discriminate, then lesion with most ductal carcinoma in-situ.
Episode	All attendances for screening and assessment relating to a particular round of screening. An episode is completed when i) a definitive diagnosis is made; or ii) the woman is returned to routine screening; or iii) the woman fails to attend for technical recall or assessment.
Family history	Mother or sister had breast cancer.
Grade	Use modified Bloom and Richardson system[12].
Initial screen	First screen in national program including pilot projects.
Interval cancer	Cancers detected after screening episode and with histologic confirmation not attributed to screening.
Length of Stay	Standard definition from *Recommended minimum data set for institutional health care*[11].
Localisation	Hook wire or carbon or dye to locate/identify impalpable lesion for surgical removal.
Lump	Palpable breast lump at time of presentation for screen irrespective of mode of detection.

Malignant	Includes ductal carcinoma in-situ (DCIS).	
Mode of presentation (of interval cancer)	*Clinical*	symptoms or signs were the first indication of the cancer.
	Mammogram	mammogram findings were the first indication of the cancer.
Nodes sampled	Nodes surgically removed for histological examination.	
Nodes examined	Nodes excised and examined histologically for presence of malignancy.	
Nodes positive	Number of nodes examined which show malignancy.	
Non-malignant	Includes normal and benign cases.	
Non-screen detected cancers	Cancers detected with histological confirmation not attributed to screening.	
Previous history of breast cancer	A previous diagnosis of breast cancer (to include ductal carcinoma in-situ).	
Previous mammogram in the Program	Previous mammogram in the National Program (including pilot projects).	
Previous mammogram outside the Program	A mammogram which a woman has had for any purpose (diagnostic or screening) excluding those already counted in Item 1.12 of the Program's minimum data set.	
Primary treatment	All treatment modalities initiated within six months of diagnosis. This does not include treatment for recurrence or metastases.	
Screening	Attendance by a woman for a mammogram to detect breast cancer.	
Screening unit identifier	Unique identifying number for each screening unit, within the State/Territory.	
Surgical unit identifier	Unique identification number for each surgical unit.	
Technical repeat	Repeats initiated by radiographer or radiologist due to inadequate films.	

Treating doctor identifier number	Unique identifier of principal treating surgeon.
Treatment declined	Woman chooses not to act on recommendation for treatment within three months of diagnosis.

APPENDIX 2—TECHNICAL ITEMS *to be* EVALUATED *in a* QUALITY ASSURANCE PROGRAM

ITEM	SPECIFICATION	FREQUENCY OF EVALUATION
Mammographic unit		
Focal spot	dual, 0.1 to 0.15mm and 0.3 to 0.4mm typically	acceptance, tube change annually
Leakage radiation	≤1 mGy/h at 1m from housing when maximum continuous rated technique factors used	acceptance, tube change
Half value layer	≤ 20uGy/h at 5cm from the cone on the chest wall margin	acceptance, tube change annually
Filter choice	0.03mm Mo	acceptance, tube change
kVp interlock	ensures Mo filter used at kVp≤35	acceptance, tube change annually
Light/X-ray field alignment	± 5mm of each other on all margins and not overlapping cassette holder on chest wall	acceptance, tube change annually
Compression device	should not be curved or mildly contoured	acceptance, annually
Output reproducibility	coefficient of variation ≤ 5%	acceptance, tube change annually
Output linearity	coefficient of linearity ≤ 0.1	acceptance, tube change annually
Timer accuracy	≤ 5%	acceptance, annually
Timer reproducibility	coefficient of variation ≤ 5%	acceptance, annually
kVp accuracy	≤ 2 kVp	acceptance, tube change annually
kVp reproducibility	≤ 1 kVp or coefficient of variation < 5%	acceptance, tube change annually

ITEM	SPECIFICATION	FREQUENCY OF EVALUATION
Automatic exposure control		
Reproducibility	coefficient of variation ≤ 5%	acceptance, tube change annually
Minimum response time	≤ 0.1 second	acceptance, annually
Backup timer	either operator set or < 2000mAs	acceptance, annually
Beam quality	OD = 1.4 ± 0.2	acceptance, annually
Routine quality control tests		
Assessment of image quality		
— step wedge radiograph		weekly
— imaging of breast phantom		weekly
Dose calculations		annually
Screens, films and cassettes		
— screen efficiency (≤ 10% variation)		every 3 to 6 months
— general screen conditions		every 3 to 6 months
Film processor		
— sensitometry		daily
— temperature and other operating conditions		daily
Viewing boxes		
— intra- and inter-box consistency of light output with time; image marking and ambient light control capability		weekly

Source: Australian Institute of Health. Screening mammography technology. Table 4: 14–15[5]. Health care Technology Series No 3> Canberra: AIH, 1990. (The AIH had, in turn, adapted their table from a position paper of the Australasian College of Physical Scientists and Engineers in Medicine.)

APPENDIX 3—SUGGESTED SPECIFICATIONS *for* MAMMOGRAPHY UNITS

This table is intended only as a guide for the purchase of new equipment. The suggested specifications should not be seen as mandatory requirements for equipment in any future screening program.

SPECIFICATIONS	SCREENING	ASSESSMENT
Target material	molydenum	molydenum
Norminal focal spot size	0.3 to 0.4	0.3 to 0.4 (regular) 0.1 to 0.15 (magnification)
Maximum ouput	≥ 100mA	≥ 100mA (regular focal spot)
Filtration	beryllium window molydenum filter aluminium filter with reversible interlock over 35 kVp	beryllium window molydenum filter aluminium filter with reversible interlock over 35 kVp
Automatic exposure control	essential	essential
Microprocessor control of automatic exposure	highly desirable	highly desirable
Magnification	not necessary	essential (1.5 to 2.2 times)
Motorised compression device with foot pedal (both directions) with quick release	essential	essential
Stiff support table (distorting less than 1mm under full compression)	essential	essential
Spot compression device	not necessary	essential
Stationary or moving grid	desirable	essential
Heat load capacity	important consideration (see text)	not critical

SPECIFICATIONS	SCREENING	ASSESSMENT
Film size	18 x 24cm essential, 24 x 30cm desirable	18 x 24cm essential, 24 x 30cm not critical
Dedicated single emulsion processor (cycle tailored to mammography film in use)	essential	essential

Source: Australian Institute of Health. Screening mammography technology. Health Care Technology Series No 3 Table 1.

Quality assurance test equipment

ITEM	DESCRIPTION AND REQUIREMENTS
Electrometer	must measure in integrate mode, should be a 3 1/2 digit device
Ion chamber	thin window chamber with a flat response down to 10 keV leakage chamber ideally capable of measuring down to 0.02 μGy
kVp meter	must be capable of measurement down to 24 kVp with Mo anode, and accuracy of 1 kVp
Timer	accurate down to 0.1 second
Star pattern	0.5 or 1 degree pattern
Filter	0.1mm, 0.3mm. Type 100 A1
Phantoms	i) perspex step wedge ii) breast phantom with inclusions mimicking clinical conditions
Sensitometer	sensitivity to blue and green. Should have 21 steps
Densitometer	should give readings in the range 0 to 3.0 optical density units and have its own light source

Source: Adapted from Australasian College of Physical Scientists and Engineers in Medicine. A quality assurance program for mass screening in mammography. 252–59: Table 5. Australasian Physical and Engineering Sciences in Medicine 1989; 12.

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