QUALITY ASSURANCE PROGRAM IN MAMMOGRAPHY
MINISTRY OF HEALTH

Introduction

The Ministry of Health launched the Quality Assurance Program. (QAP) in 1985 as a strategy to evaluate the quality of services provided in a planned and systematic manner. It started off with the Patient Care Program in 1986 and was then followed by the Health and Pharmacy Programs in 1990. In 1992, the Dental and Engineering Programs were launched. The QAP was initially implemented in the 14 general hospitals and 2 large district hospitals using 12 indicators in 1986. This was further expanded to cover all hospitals in the following year, with an additional 9 indicators being introduced in the general hospitals and large district hospitals. Subsequently there has been increasing attention paid to quality assurance initiated at the hospital level.

QAP in mammography is vital because mammography is technically one of the most demanding radiological investigation and consistently high quality mammograms are essential. Poor quality mammogram will lead to mistaken diagnosis and increased number of inappropriate biopsies.

QAP in mammography is a combined effort by all staff to ensure that every aspects of their work is directed towards the achievement of high quality performance. It can be expressed as the maintenance of standards and continual pursuit of excellence.

QAP has two components: Quality Management and Quality Control. Quality Management is the overall management function that determines and implements a policy for quality. Quality Control is the technical part that deals with techniques and activities required to maintain the quality of the performance.
Objectives

The objective of the program is to ensure that the patient, family and the community obtain optimum achievable benefits from the services of the Ministry of Heath within the available resources.

The specific objectives are to:

i. achieve consistently high quality mammogram
ii. to limit radiation dose to patients
iii. to minimize the number of women undergoing repeat examination
iv. to minimize the number of women for further views
v. to minimize the number of unnecessary invasive procedures.

These are achieved by the establishment of a mechanism to monitor the quality in a planned manner, to systematically investigate the causes of shortfalls and subsequently instituting appropriate corrective measures so as to improve quality.

Organizational Structure

a. Departmental Level

While the head of department is overall in charge of QAP for the department, the radiologist in charge of mammography service will be responsible for QAP in mammography. Within the unit, radiographic quality assurance and quality control is the responsibility of all radiographers and is monitored by the senior radiographer in charge of mammography unit. The radiologist and radiographer in charge of mammography unit will be members of the Department Quality Assurance Committee.
The radiologists’ responsibilities:

i. Radiologists performing mammography must assume the primary responsibility for the quality of mammography and for the implementation of an effective quality assurance program at their site.

ii. Review the test results and trends periodically and provide direction when problems are detected.

iii. To select a radiographer to be the quality control radiographer, performing the prescribed quality control tests.

iv. To arrange staffing and scheduling so that adequate time is available to carry out the quality control tests, to record and interpret the results.

v. To provide frequent and consistent feedback to the radiographer about clinical film quality and quality assurance procedures.

vi. To review the radiographers’ results at least every 3 months or more frequently, to review ‘concession company’ results annually or more frequently when needed.

vii. To oversee or designate a qualified individual to oversee the radiation protection program for employees, patients and others in the surrounding areas.

viii. To ensure that records concerning employees’ qualifications, mammography techniques and procedures, quality assurance, safety and protection are properly maintained and updated in the procedures manual.

ix. To assist the head of department to approve the planned preventive (PPM) schedule and to monitor that PPM has been performed according to schedule.

x. To monitor ‘uptime’ of equipment according to Master Agreed Procedures (MAP)

xi. To furnish a report in the monthly management meeting about QAP activities in the unit.
xii. To submit a report on QAP to the head of department. The report must include QC activities, Reject Analysis, and Training requirement.
Radiographers’ responsibilities:

i. To assist the radiologist in QAP.

ii. In charge of Quality Control activities, Film reject analysis, documentation and record of test results.

iii. To provide feedback on quality control activities, film reject analysis and test results.

iv. To perform the prescribed tests with the indicated minimum frequencies.

<table>
<thead>
<tr>
<th>Minimum Frequency</th>
<th>Test</th>
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<tbody>
<tr>
<td>Daily</td>
<td>Darkroom Cleanliness</td>
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<tr>
<td></td>
<td>Sensitometry</td>
</tr>
<tr>
<td>Weekly</td>
<td>Screen Cleanliness</td>
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<tr>
<td></td>
<td>Viewbox and Viewing Condition</td>
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<tr>
<td>Monthly</td>
<td>Phantom Image Analysis</td>
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<td></td>
<td>Visual Checklist</td>
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<tr>
<td>Quarterly</td>
<td>Film Reject Analysis</td>
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<tr>
<td></td>
<td>Fixer Retention Test</td>
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<tr>
<td>Semi-Annually</td>
<td>Darkroom Fog</td>
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<tr>
<td></td>
<td>Film-Screen Contact</td>
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<tr>
<td></td>
<td>Compression Device</td>
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</tbody>
</table>
b. **State Level**

The head of Diagnostic Imaging Department of the state general hospitals is the co-ordinator at the state level and is responsible for coordinating quality assurance activities for the various hospitals in the state. He will also be responsible to ensure that QAP is carried out in all hospitals with mammography facility in the state. He/she needs to submit a report to ‘Jawatankuasa Induk QAP Radiologi & Keselamatan Sinaran’ for the period of January to June and July to December. The report should include:

a. Film reject analysis

b. Quality Control Tests record

c. Training requirement

d. Recommendation (if any)

c. **National Level**

The QAP for mammography will be monitored by the ‘Jawatankuasa Induk QAP Radiologi dan Keselamatan Sinaran, Kementerian Kesihatan Malaysia’ which will be chaired by the Director of Engineering Service / Head of Department, Department of Diagnostic Imaging, Hospital Kuala Lumpur. This committee reports to the Steering Committee for QAP, Ministry of Health.
Methods of Quality Assurance

1. Quality Control

   a. QC tests that must be performed by the medical physicists:
      
      i. Mammography unit assembly evaluation
      ii. Collimation assembly test
      iii. Focal spot size measurement
      iv. kVp accuracy and reproducibility
      v. Beam quality assessment
      vi. AEC system performance
      vii. Uniformity of screen speed
      viii. Breast entrance exposure and average glandular dose
      ix. Image quality evaluation

   b. QC tests that must be performed by the radiographers.
      
      i. Darkroom cleanliness
      ii. Sensitometry
      iii. Screen cleanliness
      iv. Phantom image analysis
      V. Darkroom fog
      vi. Screen-film contact
      vii. Compression
      viii. Film reject analysis
      ix. The fixer retention test
      x. Viewbox and viewing conditions
      xi. Visual checklists
2. **Film reject analysis**

a. **Objective**
   
   To determine the number and cause of rejected mammogram. Analysis will help identify ways to improve quality of mammogram and reduce costs as well as reduce patients' exposure.

b. **Frequency**
   
   Quarterly

c. **Procedure**
   
   i. Dispose all existing reject film in the department.
   
   ii. Take inventory of film used.
   
   iii. Collect all rejected mammogram.
   
   iv. Sort and count the rejected films according to categories listed in the data sheet.
   
   v. Determine the percentage of film rejected i.e.

   \[
   \text{Total rejected mammograms} \times \frac{100\%}{\text{Total films used}}
   \]

   vi. Record the result in the data sheet.

d. The overall reject rate ideally should be 2% but less than 3% is probably acceptable.

**Definition:**

*Rejected mammograms:*
Mammograms films which has been exposed to X-radiation during mammography that has no diagnostic value and has to be discarded.

Exclusion:
   
   a. any films discarded due to testing purposes.
   
   b. any films used for quality control tests that are discarded.

*Films used:*
Mammography films used for mammography.
3. **Quality Audit**

A comprehensive quality assurance program for not only evaluations of equipment imaging and image processing but also evaluation of the accuracy of image interpretation and competency of invasive/interventional procedures. Medical audits are useful to virtually everyone involved in the operation of a mammography practice. Successful audit result builds morale among the mammography staff. Should an audit uncover an area of deficiency, this indicates the existence of a problem and also may provide clue to identifying the source of the difficulty, from which corrective measures may be deduced. Once corrective action has been taken, repeat audit limited to the area of deficiency can be used to demonstrate improvement. All mammography facility should perform medical audit yearly. Each facility must have:

- a tracking system to collect outcome data
- a tracking system for all positive mammography report
- biopsy results for all positive cases

Data

- **True Positive (TP) / False Positive (FP)**
  - determine ultimate clinical outcome of all positive cases
- **True Negative (TN) / False Negative (FN)**
- The cause of all known FN interpretations should be recorded by retrospective review of images - why lesion not detected?
  - poor quality image (over exposure/under exposure etc.)
  - improper patient positioning
  - inaccurate interpretation
  - dense breast
- **Histological diagnosis of all specimens**
- For all cases - TNM classifications should be noted.
Results:

a. Sensitivity = \frac{TP}{TP + FN}

b. Specificity = \frac{TN}{FP + TN}

c. Positive Predictive Value (PPV) = \frac{TP}{TP + FP}

d. Biopsy yield of malignancy – number of cancers number of biopsies.

e. Calculation to characterize the nature of the cancers detected at mammography.

% of non-palpable cancers and stage 0 and stage I cancers - expressed in term of total number of mammography examinations or total number of abnormal interpretation.

How to interpret audit results?

a. Compare with other published data.

b. Second and subsequent audit results to be compared with the first/earlier audit results.
4. Training

a. Basic training

i. To achieve the level of expertise required to produce consistently high quality mammogram.

ii. It is compulsory for radiographers before practising mammography.

iii. It will be held in Kuala Lumpur, Pulau Pinang and Johor Bharu.

iv. It will be organized by ‘Jawatankuasa Induk QAP Radiologi dan Keselamatan Sinaran’ Ministry of Health. The total duration of the training, will be ONE month. It may be done in periods of 2 weeks at interval of one month.

v. Content of the training:
   - Theory (total of 6 hours):
     - Basic mammography equipment.
     - Mammography techniques and patients positioning.
     - Mammography standard guidelines.
     - Quality control
   - Practical:
     - Mammography techniques and patient positioning
     - Quality Control Tests.

b. Refresher Course:

i. To maintain and develop radiographers’ knowledge

ii. Radiographers who have attended the basic training must attend at least two refresher course in 5 years.

iii. It will be organized by ‘Jawatankuasa Induk QAP Radiologi dan Keselamatan Sinaran’ Ministry of Health.

iv. Total duration of the training will be 2 - 3 days.

v. Content of training:
   - Mammography equipment
   - Mammography techniques and patients positioning
   - Breast disorders
   - Interpretation of mammograms
   - QAP in Mammography
Conclusion

The Quality Assurance Program in mammography which is an extension of the already on going quality assurance program in the imaging department will ensure consistently high quality mammogram leading to accurate diagnosis at low cost and um radiation to patients. This will contribute towards the Ministry of Health’s objective, vision and mission of providing affordable and quality healthcare for all Malaysians.
QC TESTS
PERFORMED BY
MEDICAL PHYSICISTS
QC TEST 1: MAMMOGRAPHIC UNIT ASSEMBLY EVALUATION

OBJECTIVE: To ensure that all braking devices, angulation indicators and mechanical support devices for the x-ray tube and cassette holder assembly are functioning properly.

TEST PROCEDURE:
1. Check all the free-standing mammography unit is mechanically stable under normal operating conditions.
2. Ensure that there are no obstructions which could prevent the full range of available motions and that all moving parts move smoothly without undue function.
3. Ensure that mechanical motion is prevented when the lock is set by testing each of them independently.
4. Check that the image receptor holder assembly is free from wobble or vibration during normal operation.
5. Check that the image receptor slides smoothly into the proper position in the image receptor holder assembly and that the image receptor is held in place securely by the image receptor compartment for any orientation of the image receptor holder assembly.
6. Check that the compressed breast thickness scale (analog or digital) is accurate to within $\pm 1\%$ and reproducible to within $\pm 1$ mm.
7. In normal operation, check that the patient and operator are not exposed to sharp or rough edges or other hazards including electrical hazards.

RESULTS: Enter results in Mammo QC Form 1

PERFORMANCE STANDARD: Anything that is found to be hazardous, non functional or functioning improperly should be repaired by appropriate service personnel.
QC TEST 2: COLLIMATION ASSESSMENT TEST

OBJECTIVE: To assure that the collimator does not allow significant radiation beyond the edges of the image receptor.

TEST EQUIPMENT:
i) Five coins, for with same size (e.g. 1 sen) and one of a large size (e.g. 10 sen)
   ii) Two loaded mammographic cassettes
   iii) 2 cm thickness of perspex large enough to cover the surface of the cassette

TEST PROCEDURE:
1. Place one loaded cassette in the normal manner in the image receptor holder.
2. Load the film with emulsion side of the film away from the intensifying screen in the second cassette. (The reversal of the unexposed film is necessary to reduce the density of the film to a level that permits accurate measurements of the edges of the coins).
3. Place the second cassette on top of the image receptor. Ensure that the cassette extends about 1 cm beyond the image receptor holder on the chest wall side.
4. Select the collimator size which is to be evaluated.
5. Remove the compression paddle. (The compression paddle should be removed before placement of the coins to assure a sharp demarcation at the edge of the light field.
6. Turn on the collimator light and place the four identical smaller coins inside the light field with one edge of each coin just touching the edge of the light field. The coin on the chest wall side should be shifted to the right of centre about 5 cm so it does not overlay the phototimer detector panel.
7. Replace the compression paddle and position it approximately 6 cm from the breast support. Place a sheet of perspex on top of the paddle, so that all radiation reaching the cassette is attenuated.
8. Tape the larger coin the underside of the compression paddle, at right angles to the chest wall edge and shifted to the left (so it does not overlay the phototimer detector) to mark the chest
9. Make an exposure using automatic exposure control.
10. Repeat steps through 9 for all available collimator sizes.
QC TEST 3: FOCAL SPOT SIZE MEASUREMENT

OBJECTIVE: To determine that the focal spot dimensions measured both parallel and perpendicular to the anode-cathode axis is within acceptable limits and in compliance with manufacture-provided and standard specifications.

TEST i) 0.50° star pattern with suitable test stand

EQUIPMENT: ii) Loaded mammographic screen-film cassette

iii) Measuring tape/ruler

TEST 1. Remove the compression device.

PROCEDURE: 2. Position the focal spot test stand on top of the image receptor holder..

3. Place the star pattern on top of the stand close to the focal spot to get maximum obtainable magnification.

4. Place the test stand alignment device on the test stand and align it using the collimator light. This may result in part of the test stand extending beyond the image receptor holder.

5. Remove the alignment device and position the star pattern on top of the focal spot test stand.

6. Place the loaded mammographic cassette in the image receptor holder.

7. Choose a nominal focal spot size and kVp. setting normally used for mammographic imaging (26-30kVp) and the highest mA station possible for that particular focal spot size. Record the exposure factors on the data form.

8. Choose an exposure time to obtain a film optical density between 0.80 and 1.20.


10. Record the actual diameter of the star pattern, Ds.

11. Measure and record the outer diameter of the image of the star pattern, Di.

12. Steps 4-12 should be repeated for any additional focal spot sizes that are present.
RESULTS: Record data in QC Mammo Form 3

DATA ANALYSIS:

1. Calculate the magnification, \( m \) using the following formula:

\[
m = \frac{D_i}{D_s}
\]

Where \( D_i \) is the diameter of the image of the star pattern and \( D_s \) is the diameter of the star pattern.

2. Following the anode-cathode axis direction on the image, reading from the outside edge of the star inward, mark the first blur pattern on the anode side. Measure the distance from the blur to the center of the star. Record twice this distance as \( D_{\text{blur, parallel}} \).

3. Calculate the focal spot size in the direction perpendicular to the anode-cathode axis from the above measurements:

\[
f_{\text{perp}} = \frac{\theta \ degrees}{180\ degrees (m-I)} \times D_{\text{blur, parallel}}
\]

Where \( \theta \) is the star pattern degree (e.g. 0.50\ degrees for a 0.5\ degrees star pattern).

4. Reading from the outside edge of the star inward, in a direction perpendicular to the anode-cathode axis on the image, mark the first blur pattern on opposite sides of the center. Measure the distance from blur to blur through the centre of the centre of the star. Record this distance as \( D_{\text{blur, perp}} \).

5. Calculate the focal spot size in the direction parallel to the anode-cathode axis from the formula:

\[
f_{\text{parallel}} = \frac{\theta \ degrees}{180\ degrees (m-I)} \times D_{\text{blur, parallel}}
\]
Measurement of focal spot size is of importance in commissioning tests and as a baseline for determining gradual deterioration of the tube.

Focal spots of nominal sizes less than 0.6 mm, which should include all mammography unit focal spots, may have actual sizes greater than the nominal focal spot sizes. Measured sizes can be up to the following dimensions and still meet the NEMA standard:

<table>
<thead>
<tr>
<th>Nominal Focal Spot size (mm)</th>
<th>Maximum measured dimensions Width (mm)</th>
<th>Length (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.10</td>
<td>0.15</td>
<td>0.15</td>
</tr>
<tr>
<td>0.15</td>
<td>0.23</td>
<td>0.23</td>
</tr>
<tr>
<td>0.20</td>
<td>0.30</td>
<td>0.30</td>
</tr>
<tr>
<td>0.30</td>
<td>0.45</td>
<td>0.65</td>
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<tr>
<td>0.40</td>
<td>0.60</td>
<td>0.85</td>
</tr>
<tr>
<td>0.60</td>
<td>0.90</td>
<td>1.30</td>
</tr>
</tbody>
</table>

- Width is the dimension perpendicular to the anode-cathode axis, length is parallel.
QC TEST 4: kVp ACCURACY & REPRODUCIBILITY

OBJECTIVE: To determine the accuracy and the reproducibility of the kVp

TEST EQUIPMENT: i) Mammographic kVp meter or any meter capable of measuring kVp to an accuracy of + 1.0 kVp with a precision of 0.5kVp

PROCEDURE:
1. In manual timing mode, select the kVp at which the system is normally used clinically and record on Mammo. QC form 4. Also record nominal focal spot size, exposure time and mA or mAs setting.
2. Set up the test device following the manufacturer’s instructions.
3. Make four exposures in the same manual mode setting and record the measured kVp values.
4. Repeat the procedure at other clinically important kVp's as appropriate.

RESULTS: Record data in Mammo QC Form 4.

DATA ANALYSIS:
1. Determination of kVp accuracy
   Average the four kVp readings for each kVp setting tested and compare the average value to the present nominal kVp value.

2. Determination of kVp reproducibility
   Compute the standard deviation of the kVp values for each kVp setting and then calculate the coefficient of variation (standard deviation divided by the average value).
PERFORMANCE CRITERIA: If the average measured value differs by more than ± 5% (± 1.5kVp at 30 kVp) from the nominal kVp setting, the unit should be checked by appropriate service personnel.

If the coefficient of variation exceeds 0.02 for any kVp setting, the unit should be checked by appropriate service personnel.
QC TEST 5: BEAM QUALITY ASSESSMENT
(HALF-VALUE LAYER MEASUREMENT)

OBJECTIVE: To assure that the half value layer of the x-ray is adequate to minimise patient breast dose, while not so excessive that contrast is lost in the resultant image.

TEST EQUIPMENT:

i) Aluminium HVL attenuator set RMI 15A
ii) Farmer dosemeter with 35 c.c. ionization chamber or full-function meter model RMI 242

TEST PROCEDURE:

1. Place the breast compression paddle as close as possible to the x-ray tube.
2. Place the ionization chamber approximately 5 cm above the image receptor holder assembly centered left to right and 4 cm in from the chest wall edge of the image receptor. The ionization chamber should be fully within the x-ray field.
3. Select the kVp at which the system is normally used clinically and record it.
4. Set the unit to sufficient mAs (around 40-50) to provide an exposure of approximately 500 mR.
5. Make an exposure without any aluminium between x-ray tube and ionization chamber. Make sure that the ionization chamber is fully exposed. Record the ionization chamber reading.
6. Add 0.2 mm of aluminium between the x-ray tube and the ionization chamber, placing it on top of the compression paddle. Use the light field (if available) to verify that the x-ray path to the ionization chamber is fully blocked by the aluminium sheet. Make an exposure and record the ionization chamber reading.
7. Repeat step 6 with additional 0.1 mm sheets of aluminium between the x-ray and the ionization chamber, recording the ionization chamber reading each time until the reading is less than one-half the original exposure reading.
8. Remove all aluminium sheets from the top of the compression paddle, make a final exposure and record the chamber reading. If the result of the final exposure differs by more than 2% from the exposure in step 6, repeat the measurement sequence.

9. Repeat steps 4 - 9 for other kVp setting ranging from the lowest to the highest used clinically.

10. Plot the ionization chamber readings versus the thickness of the aluminium attenuators on a semi-log graph paper.

**RESULTS:**
Record data in Mammo QC Form 5.

**DATA**
For mammographic kVp range (below 50kVp), the HVL must be equal to, or greater than, the value.

\[
HVL \geq \frac{kVp}{100} \quad (\text{in units of mm Al})
\]

(e.g., HVL > 0.28 mm of Al at 28 kVp). If the value is below this limit at any kVp setting, service personnel should be contacted to check whether appropriate filtration is in place.

If HVL for screen-film units is excessive, both subject contrast and image contrast will be reduced. For screen-film units, it is recommended that the HVL be near (within 0.1 mm of Al) the minimum acceptable HVL.

\[
HVL \geq \frac{kVp + 0.1}{100} \quad (\text{mm of Al})
\]

(e.g., HVL < 0.38 mm of Al at 28 kVp). If the HVL is found to be excessive, the unit should be checked by service personnel to assure that the x-ray has an appropriate window the mirror and filtration are correctly installed.
QC TEST 6: AUTOMATIC EXPOSURE CONTROL (AEC)
SYSTEM PERFORMANCE ASSESSMENT

OBJECTIVE: To access the performance of the AEC system of the mammography unit with regard to

a) To short term reproducibility
b) Performance capability (kilovoltage and thickness compensation) and
c) Density control selector function.

TEST EQUIPMENT:

i) A perspex phantom consisting of at least three 2 cm - thick slabs to provide thickness of 2 cm, 4 cm and 6 cm of linear dimensions and large enough to cover the cassettes being used.
ii) Routine mammographic screen - film combination cassette used with the mammographic imaging system being evaluated.
iii) Lead numbers
iv) Densitometer

TEST PROCEDURE:

a) Reproducibility

1. Set the mammographic imaging system for operation in the AEC mode with "Normal" density control setting. Select the AEC sensor closest to the patient’s chest wall.
2. Select the imaging mode (e.g., contact, grid) and cassette size (e.g., 18cm by 24cm) most commonly used for mammographic examinations. Record these.
3. Select the kilovoltage, focal spot, and tube current (mA) routinely used for the selected imaging mode. Record these factors on Mammo QC Form 6.
4. Select a single mammographic cassette of the size selected in step 2 and keep aside a box of film for use in this test.
5. Load the cassette with film from this box.
6. Place the loaded cassette in the cassette holder assembly. Position a lead number in the upper right quadrant on top of the cassette holder assembly to ensure identification of the specific image.

7. Place a 4 cm thickness of the perspex phantom on the cassette holder assembly. Position the compression device in contact with the perspex phantom. Ensure that the perspex completely covers the active AEC sensor.

8. Make an AEC exposure and record the actual mAs on Mammo QC Form 6.


10. This procedure (steps 5-9) should be repeated four times to produce a series of four images using the same cassette. This test should be completed in as short a period of time as possible.

11. The image optical density at the centre of the phantom image should be measured and recorded on the data form.

12. From the measured mAs and image optical density, calculate the mean values and standard deviations for each. The coefficients of variation (standard deviation divided by the mean) for both mAs and optical density should be determined. The maximum acceptable coefficient of variation for both mAs and optical density is 0.05. The unit should be checked by the service personnel if this value is exceeded.

b) Performance Capability

This refers to the ability of an AEC system to maintain a constant image optical density over a wide range of imaging techniques and variables. The following tests are designed to assess the performance capability of the AEC system.

1. Follow steps 1 through 9 of the AEC reproducibility method except:
   - For step 3 choose the lowest kVp used clinically
rather than used routinely
- For step 7 use a 2 cm thickness perspex rather than the 4 cm

2. Repeat the procedure above (Steps 1-9 under Reproducibility) using perspex thickness of 4 cm and 6 cm.

3. At all other kvp’s which are normally used clinically repeat steps 1 and 2 above.

4. For the other imaging modes (e.g., contact, non-grid, magnification, etc.) which are used clinically, repeat steps 1 through 3 above.

5. Measure the image optical density at the centre of the perspex image on the processed film and record on the data form.

c) Density Control Function

1. Follow the AEC reproducibility procedure from steps 1 through 9.

2. Repeat step 1 for each other available setting of the AEC system’s density control selector.

3. Measure the optical density at the centre of the perspex image on the processed film and record on the data form.

4. Calculate the relative mAs (ratio of mAs to that at the "Normal" setting) and relative image optical density (difference between the optical density and the optical density at the "Normal" setting).

RESULTS:

1. Record the test results, technique factors used in each section of the test instantly during the procedure.

2. Identify properly the test films so that the final density readings can be accurately recorded on the Mammo QC Form 6.
a) **Reproducibility**

For the reproducibility test data, calculate and record the mean values and associated standard deviations of the mAs and image optical density obtained.

b) **Reproducibility**

The performance capability data should be reviewed with respect to mAs and image optical density. The following trends should be noted:

- At a given kVp level, the mAs should increase with increasing perspex thickness.
- At a given perspex thickness, the mAs should decrease with increasing kVp.

c) **Density Control Function**

In general as the density setting is increased or decreased with respect to the normal setting, the mAs and image optical density should increase or decrease respectively.

**PERFORMANCE CRITERIA:**

A properly functioning AEC system may be expected to give a coefficient of variation (standard deviation divided by the mean) of LESS THAN 0.05 for both mAs and optical density.

The image optical density should ideally remain constant within + 0.10 as kVp and phantom thickness are varied; however, variations of up to + 0.10 or greater may be observed in older equipment.

For a normally functioning system, each density control step change should result in a 12 - 15% change in mAs or approximately 1 0.15 change in optical density.
QC TEST 7: UNIFORMITY OF SCREEN SPEED

OBJECTIVE: To check the uniformity of the radiographic speed of cassettes used for mammography.

TEST EQUIPMENT:
i) Mammographic cassettes
ii) A single box of mammography film
iii) A 4.0cm thick cassettes sized perspex phantom
iv) A densitometer

TEST PROCEDURE:
1. Identify all cassettes to be evaluated by a numbering system.
2. Load one of the cassettes with film and record on Mammo QC form 7 the details of the cassette being evaluated and the emulsion number of the film used with film and record on Mammo QC Form 7 the details of the cassette being evaluated and the emulsion number of the film used.
3. Select AEC mode and kVp most commonly used for mammography.
4. Place the phantom of the cassette holder assembly and ensure that the compression device is in contact with the phantom.
5. Determine the density control setting to get an image optical density in the range of 1.1 to 1.5 in the centre of the phantom image. Record the reading on the data form.
6. Load all of the cassettes to be tested with film from the same Box.
7. Expose each cassette under the conditions determined in step 5 sequentially. Lead numbers can be used to identify the images but ensure that they are not placed in the vicinity of the AEC detectors. The phantom should remain in the same position during all exposures. Record the actual mAs for each exposure on the data form.
8. When half of the cassettes have been exposed, process the film from the first (control) cassette, reload the cassette and expose the control cassette. Expose the remaining cassettes. After all the cassettes have been exposed,
process the control cassette to give control film no. 2. 
Reload and expose the control cassette.

9. Process all the exposed films in the film processor routinely 
used for mammographic imaging including the third control 
film.

10. Measure the optical density at the centre of the phantom 
and record on the data form.

11. If more than one size or type of cassette is used for 
mammographic imaging repeat steps 1 through 10 for 
each.

**DATA**

**ANALYSIS:**

Calculate the standard deviation of the control film optical 
densities. If the standard deviation exceeds 0.05, the 
variability of the X-ray exposures or film processing is 
excessive and the screen speed uniformity tests cannot be 
carried out adequately under these conditions. If the standard 
deviation of the control films does not exceed 0.05, then 
measure the maximum and minimum optical densities from all 
cassettes. The difference between the maximum and 
minimum values should not exceed 0.30. Corrective action 
should be taken for any cassette screen combination that is 
not within this range.

**CORRECTIVE**

**ACTION:**

Check the misidentification of a cassette with the type of 
screen it contains. If screens of the same speed are contained 
within cassettes of different manufacturers, it is possible that 
variations in attenuation of the cassette may cause significant 
differences in film density. If no identifiable cause for image 
density variation can be determined, the cassette-screen 
combination that results in optical densities outside the 0.30 
range should be replaced.
QC TEST 8: BREAST ENTRANCE EXPOSURE AND AVERAGE GLANDULAR DOSE

OBJECTIVE: To measure the normal entrance exposure for an average patient (approximately 4.5 cm compressed breast thickness 50% adipose, 50% glandular composition) and to calculate the associated average glandular dose.

TEST EQUIPMENT:

i) Ionization chamber and electrometer calibrated at mammographic x-ray beam energies.

ii) RMI-156 mammographic breast phantom

iii) Mammographic cassette loaded with mammography film (film is not to be processed or reviewed)

PROCEDURE:

1. Verify that the AEC is functioning properly.

   NB: The proper functioning of the AEC should be verified as this test procedure is normally carried out in AEC mode.

2. Prepare the mammographic imaging system in the imaging mode and position a loaded mammographic cassette in the image receptor.

3. Adjust the system to the SID most commonly used for mammographic imaging. Record the SID on the data form.

4. Select the density control setting that is normally used clinically for an average patient on the AEC.

5. Place the mammographic phantom on the cassette holder assembly at the position which would normally be occupied by the patient's breast, with one edge coincident with the chest wall edge of the cassette holder assembly. Ensure that the phantom completely covers the active area of the AEC sensor.

6. Place the ionization chamber in the x-ray field beside the phantom, centered 4cm in from the chest wall edge of the cassette holder and with the centre of the chamber level with the top surface of the phantom. Ensure that the entire chamber is exposed and that its radiographic shadow does not overlap the active area of the AEC sensor.
7. Secure the chamber in position and maintain position for all measurements as this is critical for comparison purposes.
8. Lower the compression device in the x-ray beam, just in contact with the phantom and chamber.
9. Select the kVp at which the system is normally used clinically in the AEC mode and record the kVp.
10. Make an exposure and record it. Repeat until a total of four exposures have been recorded. There is no need to change the cassette or film between exposures.
11. Repeat at other kVp's used clinically ensuring that the HVL values have been measured at these additional kVp's.
12. Replace the exposed film in the cassette before the cassette is returned to clinical use.

RESULTS: Record data in Mammo QC Form 8

DATA

ANALYSIS: Compute the average of the exposures at each set of exposure conditions and record the values. Calculate the average glandular dose as follows:-

1. Determine whether target is molybdenum (with molybdenum filtration) or tungsten (with aluminium filtration) and find the appropriate column in the table provided (table 1) for the target and filtration combination used clinically.
2. With the HVL already determined during the beam quality assessment for the kVp selected in this test, obtain the exposure to average glandular dose conversion factor for a 4.5 cm compressed thickness form table 1.
3. Multiply this factor by the average entrance exposure value computed earlier. The product obtained represents the mean dose received by the glandular tissue for that specific energy, breast composition and compressed thickness and is an approximation of the actual patient dose.
NB: These conversion factors only apply to a 4.5cm compressed breast thickness.
The average glandular dose to a 4.5 cm compressed breast should not exceed 3 mGy (0.3 rads) per view for screen-film image receptors. If the values exceed these levels, action should be taken to evaluate and eliminate the cause of excessive dose.
QC TEST 9: IMAGE QUALITY EVALUATION

OBJECTIVE: To assess mammographic image quality and to detect changes in image quality from time to time.

TEST EQUIPMENT:

i) RM-156 mammography phantom

ii) Acrylic disc, about 4nim thick by 1 cm in diameter. This is to be placed on top of the phantom, in the image area (in the bottom right hand corner but not over any object)

iii) Mammography cassette and film

iv) Film mask

v) Magnifying lens

vi) Densitometer

TEST PROCEDURE:

1. Load cassette with film.

2. Place cassette in cassette holder of mammography machine.

3. Place phantom on the cassette holder, with the chest wall edge of the phantom aligned with the chest wall side of the image receptor.

4. Lower the compression paddle until it is just in contact with the top of the phantom.

5. Make sure that the phototimer detector is located beneath the centre of the phantom. The same location is maintained for subsequent image quality evaluation checks.

6. Select the kVp and density control settings used clinically for a breast of thickness and density corresponding to the phantom.

7. Make an exposure using AEC mode, recording all technique factors on the data form.

8. Process the film in the mammography processor.

9. Measure the central background optical density on the film. Record this reading as the background optical density on the data form. Use the same location each time.

10. Measure the optical density of the film over the disc and just outside the disc to the left or right (perpendicular to the
anode- cathode axis). Record the difference as the density difference on the data form.

11. With the use of the film mask, film viewer, magnifying glass and dim or no room light, determine the number of test objects of each type that is visible in the phantom image.

12. Examine the image carefully for artifacts.

RESULTS: Enter the score in step 11 in Mammo QC Form 9.

PERFORMANCE CRITERIA:

1. The optical density of the film in the centre of the phantom image should be about 1.25, in the range from 1.10 to 1.50, for films exposed at 28kVp. It should not change by more than +0.20.

2. The density difference as obtained from procedure step 10 above should be about 0.40 ± 0.05 for film exposed at 28kVp. It should not change by more than 0.05.

3. The mAs or exposure time should not change by more than ±15% from one phantom image to another.

4. The minimum score for the RMI-156 mammography phantom is 21. For a good imaging system, it should be able to image.
   i. the 0.75mm nylon fibre
   ii. the 0.32mm simulated micro-calcification
   iii. the 0.75mm tumor-like mass

5. This test measures all components of the imaging chain from x-ray tube to processor except positioning, motion error and image interpretation.
QC TESTS PERFORMED BY RADIOGRAPHERS
QC TEST A: DARKROOM CLEANLINESS

OBJECTIVE: To minimise artefacts on film images by maintaining cleanliness in the darkroom. Artefacts due to bits of dirt and dust are troublesome with single emulsion imaging system in mammography. They may mimic micro-calcifications and lead to misdiagnosis.

TEST a. Wet mop and pail

EQUIPMENT: b. Lint-free towel
c. Liquid hand soap

PROCEDURES: 1. Turn the processor water and power on so that the developer temperature can stabilize during this procedure.
   2. Damp mop the darkroom floor. Use a clean, damp towel to wipe off the processor feed tray, counter tops and other surfaces in the darkroom.
   3. Keep hands clean to minimise fingerprints and handling artefacts.
   4. Wipe or vacuum overhead air ventilator and safelight weekly before cleaning the feed tray and counter tops.

RESULT: Record result in Mammo QC Sheet A

TEST FREQUENCY: Daily
QC TEST B: SENSITOMETRY

OBJECTIVE: To assure on a day-to-day, basis that all film processors are operating at the same level and producing consistent high quality mammogram. Sensitometry, information will enable the Imaging Department to consistently maintain the upper limits of informational content in their radiographs within the department and achieve total system control of quality between other imaging department.

TEST EQUIPMENT:

a. Sensitometer
b. Densitometer
c. Digital Thermometer (Mercury or other liquid thermometer should never be used since the content may contaminate the processor if the thermometer is broken).
d. Films - A box of mammography film normally used in the department should be set aside for exclusive sensitometry use.
e. Processors to be monitored.

TEST PROCEDURES:

a. Follow the processor start-up procedures everyday
b. Allow sufficient time for processor to stabilize (about 30 minutes).
c. Check and record the developer temperature.
d. Run several clean-up sheets and check them for roller marks and scratches.
e. Producing the sensitometric strips:
   i. Switch on the sensitometer.
   ii. Select exposing colour. Optimum sensitometric control occurs when the proper colour light exposes the film. E.g. when using mammography films, expose in GREEN position.
   iii. Select ‘SINGLE’ exposure.
   iv. Insert the film (emulsion side facing, down) into the sensitometer with the back edge against the stop and the film centred in the unit. (NOTE: The procedure is done under proper safelight condition in the darkroom).
v. Press the 'EXPOSE' button down and hold until the buzzer sounded.

vi. Release the 'EXPOSE' button and remove the film immediately.

vii. Process the film in the processor to be monitored.

viii. After processing, record the date, time and processor identification on the film.

DATA ANALYSIS: The sensitometer exposes film with a known quantity of light through 21 steps light modulators. The maximum light is emitted from step number 21. The following three points should be monitored to give pertinent processing data:

a. **Base + Fog (Step no. 1)**

   The least exposed portion of the film is at step no. 1. It is the base support density plus any silver emulsion density developed in the area where negligible exposure occurs.

b. **Speed Index (Step no. 11)**

   The step on the exposed film with a density nearest to 1.0. This step is a direct indicator of film speed. Variations in processor conditions are monitored on this step.

c. **Contrast Index**

   'This is the straight line portion of the D Log E Curve. Select the step closest to but not larger than 2.20 OD. Subtract from this step the step closest to but not lower than 0.45 OD, Contrast index is used to monitor processor variations in conjunction with speed index.

   (NOTE: Monitor subsequent films on the same steps selected for base + fog, speed index and contrast index.)
Plot / record the following data on the 'Processor Monitoring Chart' (Fig.1).
i. Developer temperature
ii. Base + fog density
iii. Speed Index
iv. Contrast Index
v. Date
vi. Processor Identification

Acceptance Limit:

Acceptance limit on the speed and contrast index should be±0.1 in density (±10%) while the limit on Base+ fog should be ±0.05 but should not be more than 0.25 in overall base fog density.

Daily Plotting of Data on Processing Monitoring Chart:
Plot the result on the monitoring chart each time a control film is developed daily. Figure 2 shows a sample of daily processor monitoring chart.

RESULT: Record result in Processor Control Chart

TEST Daily
FREQUENCY:
QC TEST C: SCREEN CLEANLINESS

OBJECTIVE: To ensure that mammography cassettes and screens are free of dust and dirt particles which may degrade image quality or mimic micro-calcification.

TEST EQUIPMENT:

a. Intensifying-screen cleaner
b. Lint-free gauze pad or equivalent lint-free cloth.

test PROCEDURES:

a. Prepare the cassette and screen to be cleaned.
b. Open the cassette to be cleaned on the darkroom counter.
c. Dampen a small, clean non-abrasive lint-free cloth with liquid screen cleaner.
d. Gently clean the screen. Avoid pressure and excessive rubbing which could damage screen surface.
e. Dry the screen with a second lint-free cloth.
f. Wipe any dust particle from the inside surface of the back cover of the cassette using slightly dampen cloth.
g. Visually inspect screen from scratches or other artifacts not removed by cleaning. Cassette with defective screen must not be used.
h. Inspect cassette for cracks and check the latches work properly.
i. Stand the cassette vertically to air dry before loading the cassette for use.

RESULT: Record result in Mammo QC Sheet A

TEST FREQUENCY: Frequency of cleaning is determined by the environment and usage but should be carried out at least weekly. Wet cleaning (using cleaning liquid) should be done less frequently e.g monthly or as required.
QC TEST D: PHANTOM IMAGE ANALYSIS

OBJECTIVE: To ensure that the imaging system and processor are performing optimally. A breast phantom is used which radiographically simulates a breast with a variety of conditions typically detected through mammography (e.g. masses, microcalcifications etc.) This test includes a check on film density, image quality, contrast uniformity.

TEST EQUIPMENT:

a. RMI 156 Mammography Phantom.
b. Densitometer capable of spot readings.
c. Mammography cassette and film. Always use the same cassette for all phantoms image tests.
d. Phantom Image Worksheet.
e. Mammography Phantom Image Control Chart.
f. Magnifying glass. Use the same magnifying glass used for clinical mammogram.
g. Viewboxes.

TEST PROCEDURES:

a. Load the film in the cassette.
b. Place the cassette in the cassette tray.
c. Place the phantom on top of the cassette tray (where the breast is normally placed when the examination is performed). Position the phantom so that the edge of the phantom is aligned with the chest wall side of the image receptor.
d. Position the acrylic disc on top of the phantom so that the notch is at 12 o'clock for consistency.
e. Lower the compression device into contact with the phantom.
f. In system with automatic exposure control (AEC), verify the location of the photo-timer sensor. (It should be in the same location used for previous test and completely covered by the phantom. In manual system, select the appropriate focal spot, kVp, exposure time and mA.
g. Make an exposure using the technique used most
frequently for clinical mammogram. Record exposure information in the Phantom Image Worksheet.

h. Plot the exposure time or the mAs value (if known) on the Mammography Phantom Image Control Chart.

i. Process the film processor normally used for using processing clinical mammography using film.

j. Measure the optical density in 'disc B' and the background directly adjacent to 'disc A'.

k. Calculate the density difference('disc A' minus'disc B') on the control chart.

l. Using the phantom image worksheet as a reference tool, count the number of simulated masses, fibres and specks visible in the image and plot the value on the control chart. Examine the image for non-uniform areas, grid lines or artefacts and the presence of any artifacts (dirt, dust or processing). Compare the film to the original and previous films.

m. Mark any artefacts or grid lines.

n. Investigate the source of any artefacts or grid lines.

o. Date and initial the image.
QC TEST E: DARKROOM FOG

OBJECTIVE: To assure that darkroom safelights and other light sources inside and outside the darkroom do not fog mammography films. Fog on mammography films reduces contrast and results in variations in film density from one sheet of film to another.

TEST EQUIPMENT:

a. Sensitometer
b. Densitometer
c. Fresh unopened box of mammography film
d. Masking card made from thin cardboard so that light is unable to pass through it.
e. Watch or timer

TEST PROCEDURES: This procedure assumes that you have already checked the darkroom for light leak and assure that all safelights, bulb wattage and the safelight distance met manufacturer’s specification and do not appear faded or cracked.

a. Turn off darkroom lights as well as safelights and wait for your eyes to adjust.
b. Look for obvious light leaks around doors, cassette hatch, the processor and ceiling. Be careful in moving around a darkroom without safelight illumination.
c. In total darkness open box of film.
d. Remove a single sheet and expose two sensitometric strips; one along both long edges.
e. Place the film, emulsion side up on the counter top and cover half the film with the mask.
f. With the film and mask laying on the counter top, turn on all safelights for two minutes.
g. Process the film using usual processing procedure.
h. Measure the density of the unfogged (unexposed) portion of the step (the portion covered with the card) having the density closest to 1.40.
i. Measure in the same manner, the density of the
fogged (exposed) portion of the steps.

j. Compare the two readings. If the second reading as the first, conditions in the darkroom will not fog the type of films being used for the test. If the second reading is greater, calculate the increased fog level by subtracting the first reading from the second.

DATA ANALYSIS: The fog should not be greater than 0.02. If the fog is greater than 0.02 then the source of fog must be determined and immediate corrective action taken. It is essential that this test be carried out with different type of films used in the darkroom.

RESULT: Record the result in Mammo QC Sheet B

TEST FREQUENCY: The test should be carried out when a darkroom is initially put into use or remodelled, when safelight lamps or housings are changed or at least semi-annually.
QC TEST F: SCREEN-FILM CONTACT

OBJECTIVE: To evaluate how close the contact is between the emulsion of an x-ray film and the intensifying surface. Screen-film contact has significant influence on image sharpness. Good contact throughout a cassette is crucial because of screen-film mammography’s high resolution requirements (16-20 lp per mm as opposed to 4-8 lp per mm for conventional system).

TEST a. Film-screen contact test tool (40 mesh)
EQUIPMENT: b. Acrylic sheet (sufficient to provide 4 cm thickness)
c. Mammography film
d. Densitometer
e. Cassette with screen to be tested.

TEST PROCEDURES: a. Place the cassette to be tested on top of the cassette holder.
b. Place the test tool on top of the cassette.
c. Place the acrylic sheet on top of the compression device and move the compression device as close as possible to the x-ray tube.
d. Select a manual technique (at 28 kVp) which will produce a film density between 0.7 and 0.8 when measured over the mesh near the chest wall side of the film.
e. Expose and process the film.
f. View the film at a distance of at least 1 meter. Look for areas of poor contact, i.e. darken areas in the mesh image.

RESULT: Record result in Mammo QC Sheet B

TEST FREQUENCY: a. Initially and for all new cassettes.
b. Semi-annually.
c. Where reduced image sharpness is suspected.

PRECAUTIONS: Poor film-screen contact usually result from specs of dirt, dust
or other foreign objects on the screen. In addition the following factors may contribut to poor contact:

a. Entrapped air. It may be necessary to wait for at least 15 minutes after loading the cassette before making exposure.
b. Damaged cassette frame.

c. Damaged and dented intensifying screen.
d. Damage latches on the cassette.
QC TEST G: COMPRESSION

OBJECTIVE: To assure that the mammography system provide adequate compression and it does not allow too much compression to be applied. Compression reduces thickness of breast tissue (thus thickness is more uniform, resulting, in more uniform film density), thereby reducing scattered radiation and increasing contrast while reducing radiation exposure to the breast.

TEST EQUIPMENT: a. Weighing scale (must be flat). The scale must be analogue type. Digital scale samples the data and may not respond properly as additional pressure applied slowly to the scale.
b. Several towels or form pad.

TEST PROCEDURES: a. Place a towel on the cassette holder (to protect it) then place the scale on the towel with the read-out positioned for easy reading.
b. Locate the centre of the scale directly under the compression device. Place several towels or foam pad on top of the scale (to protect the compression device).
c. Using the power drive, activate the compression device and allow it to operate until it stops automatically.
d. Read and record the compression.
e. Release the compression device.
f. Using the manual drive, move the compression device downwards until it stops.
g. Read and record the compression.
h. Release the compression device.

RESULT: Record result in Mammo QC Sheet B

TEST FREQUENCY: a. Initially
b. Semi-annually
c. When reduced compression is suspected.
DATA ANALYSIS: Adequate compression of the breast should range from 25-40 pound for both the manual and power drive

PRECAUTIONS: It may be possible to damage the compression device and associated components if the safety mechanism is not properly adjusted. In the power drive mode the compression should not exceed 45 pounds.
QC TEST H: FILM REJECT ANALYSIS

OBJECTIVE: To determine the number and cause of rejected mammogram. Analysis will help identify ways to improve efficiency and reduce costs as well as reduce patients' exposure.

TEST a. All rejected mammograms.

EQUIPMENT: b. Mean to count the total number of film used.

TEST a. Take inventory of films used.

PROCEDURES: b. Collect all rejected films and continue collection for the length time of needed to radiograph about 250 patients.
c. Sort and count the rejected films according to categories listed in the Mammo QC Sheet C.
d. Determine the percentage of film rejected i.e. Total film rejected divided by Total film used multiply by 100.

RESULT: Record result in Mammo QC Sheet C

DATA ANALYSIS: The overall reject rate ideally should be 2% but less than 5% is probably acceptable. The percentage from each category ought to be similar. One that is significantly higher than the others indicates an area for improvement.

TEST FREQUENCY: At least quarterly. (In order for this test to be meaning a patient volume of at least 250 patients is recommended).

DEFINATION: a. Rejected Film: All films that has been exposed during mammography examination which has no or insufficient diagnostic value that are rejected.

b. Film used: Films that are used to record images during mammography examination.
QC TEST I: VIEWBOX AND VIEWING CONDITION

OBJECTIVE: To assure that the viewbox and viewing conditions are optimized and maintained at optimum level. The accuracy of the diagnosis and the efficiency of the radiologists are influenced by the condition under which the mammograms are viewed.

TEST

a. Window cleaner.

EQUIPMENT:
b. Soft towel.

test

TEST

a. Clean viewbox surfaces using window cleaner and soft towel.
b. Assure that all masks have been removed.
c. Visually inspect the viewbox for uniformity of luminance.
d. Assure that all viewboxes, masking equipment (if any) is functioning properly and easily.
e. Visually check the room illumination levels and assure that sources of bright light are not present in the room.

RESULT:

Record result in Mammo QC Sheet A

DATA

a. Mammograms or phantom images should be viewed under identical conditions e.g. using the same viewbox, with the same lighting conditions and using the same magnifier as is used for viewing clinical mammograms.

b. Contrast is extremely important in the mammographic image and is degraded by extraneous light. It is essential to mask the area around the mammograms to exclude extraneous light.

TEST

Weekly

FREQUENCY:
QC TEST J:  THE FIXER RETENTION TEST

OBJECTIVE: To determine the quantity of a residual fixer (hypo) in processed films as an indicator of keeping quality.

Residual 'hypo' indicates insufficient washing. If an excessive fixer is retained by the film the image may degrade over time. It would then be worthless for comparison with subsequent mammography studies.

TEST EQUIPMENT: Hypo estimator (e.g. Kodak Hypo Estimator and Kodak Hypo Test Estimator.)

TEST PROCEDURES:

b. Place the processed film on top of a white sheet of paper in such a way that the emulsion side is facing towards you.
c. Working under normal lighting conditions place one drop of the residual hypo test solution on the film.
d. Blot off the solution after 2 minutes.
e. Immediately place the estimator over the film. Position the test spot between the coloured section of the estimator.
f. Determine which section of the estimator most closely matches test spot.

RESULT: Record result in Mammo QC Sheet B

DATA ANALYSIS/ EVALUATION:

a. Patch 3 (recommended) represents approximately 5 microgram of l/h retained fixer per square centimeter of film.

At this level mammography images are suitable for long term keeping (100 years).

b. Patch 2 represents about 2 microgram per square centimeter indicating the film has archival (forever) keeping quality.

NOTE: The comparison should be made immediately after the excess test solution has been removed. Direct sunlight will cause the spot to darken rapidly and a prolonged delay between the blotting of the solution and comparison will
allow the spot to darken.

TEST

FREQUENCY:

Quarterly
QC TEST K: VISUAL CHECKLIST

OBJECTIVE: To ensure that the system indicates lights, displays and mechanical locks are working properly and that the mechanical rigidity and stability of the equipment is optimum.

TEST EQUIPMENT:

a. Equipment to be inspected.

TEST PROCEDURES:

a. Review all the items on the visual checklist sheet and indicate the status.
b. Date and initial the checklist where indicated.

DATA ANALYSIS: Each of the items listed should pass or receive a check mark, otherwise it should be replaced or corrected immediately.

RESULT: Record result in Visual Checklist Sheet

TEST FREQUENCY: Monthly and after any services on the system.
APPENDIX 1: VIEWBOX LUMINANCE & ILLUMINANCE

OBJECTIVE: To ensure optimal view box luminance to obtain diagnostic interpretation of the mammographic images.

TEST TOOL: Lux meter

STANDARD
CRITERIA:

Viewbox luminance: 3000 - 3500 nit
Ambient illumination level: 50 Lux or less

Luminance:
The amount of light either scattered or emitted by a surface, measured in nit.

Illuminance:
The amount of light falling on a surface, measured in Lux.
APPENDIX 2: STEREOTACTIC OPERATION AND ACCURACY

The stereotactic device allows the radiologist to locate in three directions (X, Y and Z) of a radiographic image with suspected lesion previously detected on mammogram.

OBJECTIVE: To check the operational functions and accuracy of the stereotactic assembly.

TEST TOOL: Stereotactic phantom
Needle and needle holder

Note Please refer to the equipment manual to assemble the device.

Test 1 - First Exposure
1. Place the phantom so that the holes face the opening in the paddle.
2. Compress the phantom and make exposure.
Note: Tilting movements are inhibited once the compression paddle leaves the park position.

Test 1 - Second Exposure
1. Place 18x24 film cassette in the film holder Push to the right hand side.
2. Tilt the tube 15 degrees on the right hand side by pressing lever of the tube arm support and by pushing the arm gently. When lock is engaged release the lever
3. Select radiation parameters.
4. Make an exposure.
5. The tube and the film cassette must be positioned on the same side.
6. Then push the film cassette to the left hand side of the film holder.
7. Tilt the tube to the left hand side.
8. Make another exposure.
9. Remove film cassette and develop film.
CRITERIA:  The film comprises two exposures, left and right.  The projection of the copper disks contained in the phantom should appear in the projection of the compression paddle aperture.

Test 2  To check accuracy using phantom and needle.

Note: please refer to the equipment manual.