BC CANCER BREAST SCREENING
Provincial Health Services Authority

Policy Title:	Equipment Test Failure Protocol		
Section:	Quality Management	**Reference No.**	SG 110
Effective:	May 2002	**Revision:**	September 2009, February 2018

1. SCOPE

Breast Screening Program Chief Technologists
Breast Screening Program Chief Radiologists
Breast Screening Quality Assurance Support Group
Professional Practice Leader – Breast Screening Technologists
Radiology Managers

BACKGROUND:

This policy is based upon the Mammography Quality Standards Act's (MQSA) regulation of the United States Food and Drug Administration and Health Canada Safety Code 36 (section C:1.3–3.6). It specifies the timing and extent of medical physicist and facility involvement in response to equipment test failures.

The policy was developed by the Breast Screening Quality Assurance ("QA") Support Group.

2. POLICY

When a mammography facility fails any of the BC Cancer Breast Screening program/CAR digital quality control tests, adjustment, change or repair of the equipment and/or environment may be required.

After corrective action has been completed, the failed test(s) must be repeated. This will provide evidence that the unit is now performing within the Imaging Quality Standards.

Some tests **must** be repeated by the medical physicist (see Table - Medical Physicist Involvement in Equipment Adjustments, Changes, or Repairs at the end of this policy).

Note: If it is absolutely not feasible for the medical physicist to attend promptly, the test may be performed by a qualified service representative or IT personnel under the verbal instruction of the medical physicist.

Some tests may be repeated by the technologist, (after consultation with the medical physicist). In the body of the physics assessment report, the medical physicist will indicate which verification tests may be performed by the technologist, service representative or IT personnel, and which tests require the presence of a medical physicist.

Category I Tests	
QC Checklists	
Monitor cleanliness	
SDNR	
Artefact	
Image Quality evaluation test	
RMI Phantom	
Mechanical Inspection	
Acquisition Monitor evaluation - AAPM test pattern	
Compression Force	
Display Monitor - Review Workstation	
Laser Printer sensitometry & Artefacts tests	
Printed image quality test	

Category I Failures:

Verification test(s) or repeated test(s) ***must*** be passed prior to using the item associated with the failed test. The medical physicist must be consulted to arrange for verification testing either by him/her or an appropriate designate.

Category II Failures:

The facility has a maximum of **30 days** from the date of the initial test failure to correct the problem and pass the verification test. Facilities should have verification test(s) performed immediately after the adjustment change or repair has been performed. This will allow the necessary time to schedule any additional corrective action, should the equipment continue to fail the verification test. Verification testing must be performed by a qualified person (e.g. technologist, service specialist, or IT personnel with appropriate training/experience).

The program recommends that the medical physicist be consulted during this process.

Note: If the verification test is not passed within the 30-day time period, contact your physicist to determine the best action plan.

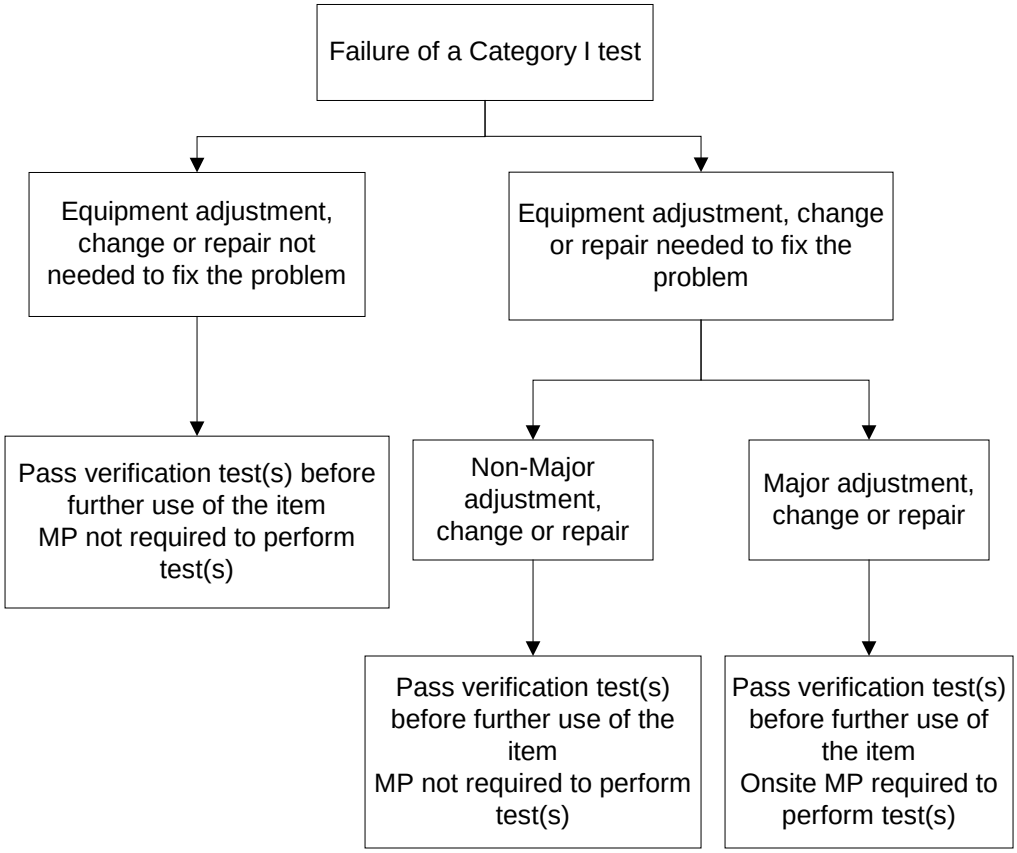
The decision not to use an item clinically (that leads to operational shut down of the facility), must be made in consultation with the Chief Screener, Professional Practice Leader, Medical Physicist and Screening Operations Director. This decision must be communicated to the facility administrator in writing by the medical physicist. Written communication will be reviewed by the Breast Screening Quality Management ("QM") Committee and an action plan recommended.

Statement Regarding Consequence of Non-Compliance
The BC Cancer Breast Screening program anticipates prompt, voluntary compliance regarding this policy. Not following the Breast Screening QM Committee's recommendations for an operational shutdown may result in the program suspending its affiliation to provide screening services.

Decision Trees

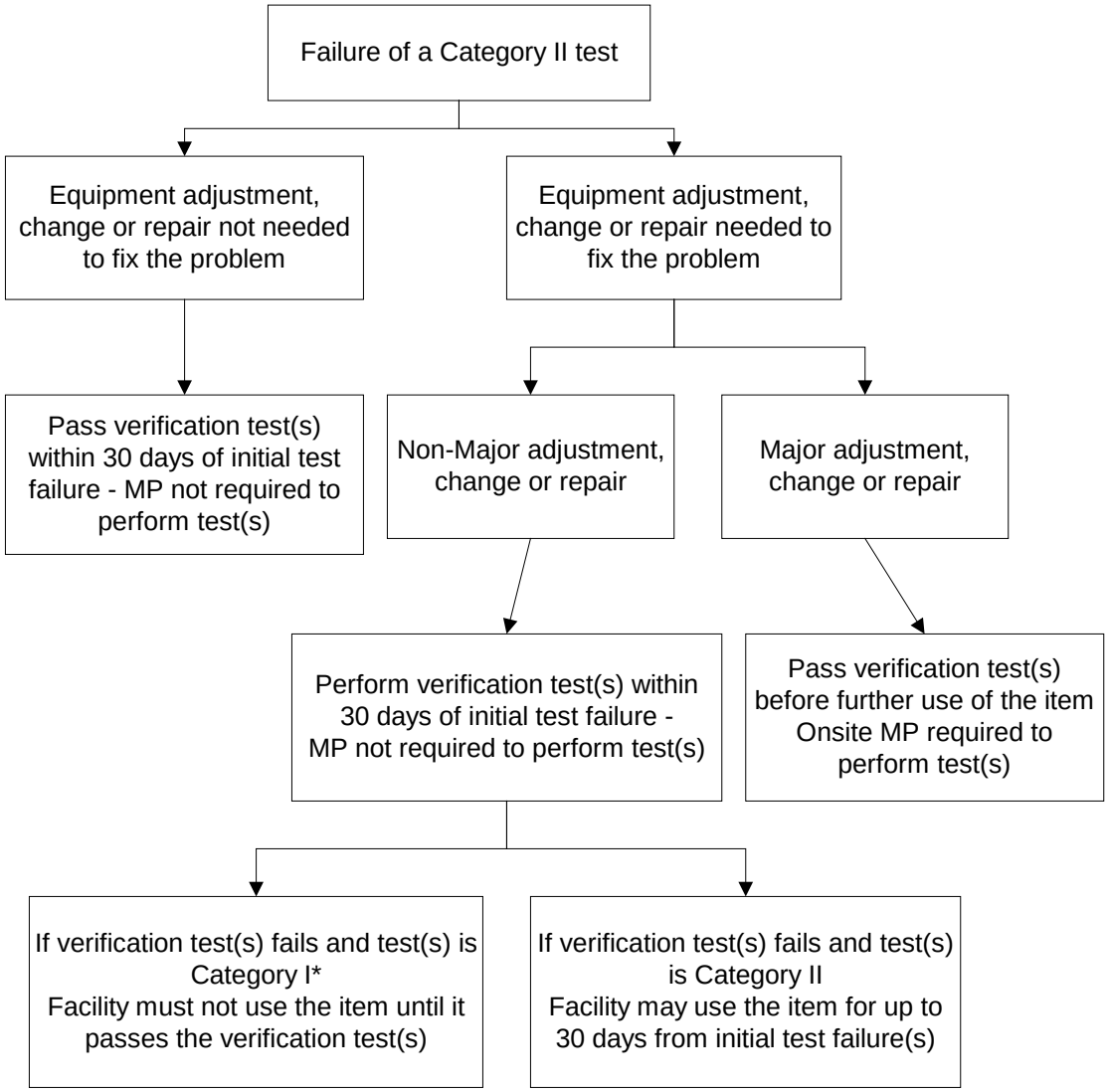
As required by WorkSafe BC Regulation Part 7 - Ionizing Radiation, equipment producing ionizing radiation must be installed, operated and maintained in accordance with Health Canada Safety Code 36. To comply with this regulation, the following Decision Trees have been established to help in determining the timing and extent of medical physicist and facility involvement in response to test failures, equipment adjustments/changes/repairs and equipment evaluations.

DECISION TREE #1 - Failure of a Category I test

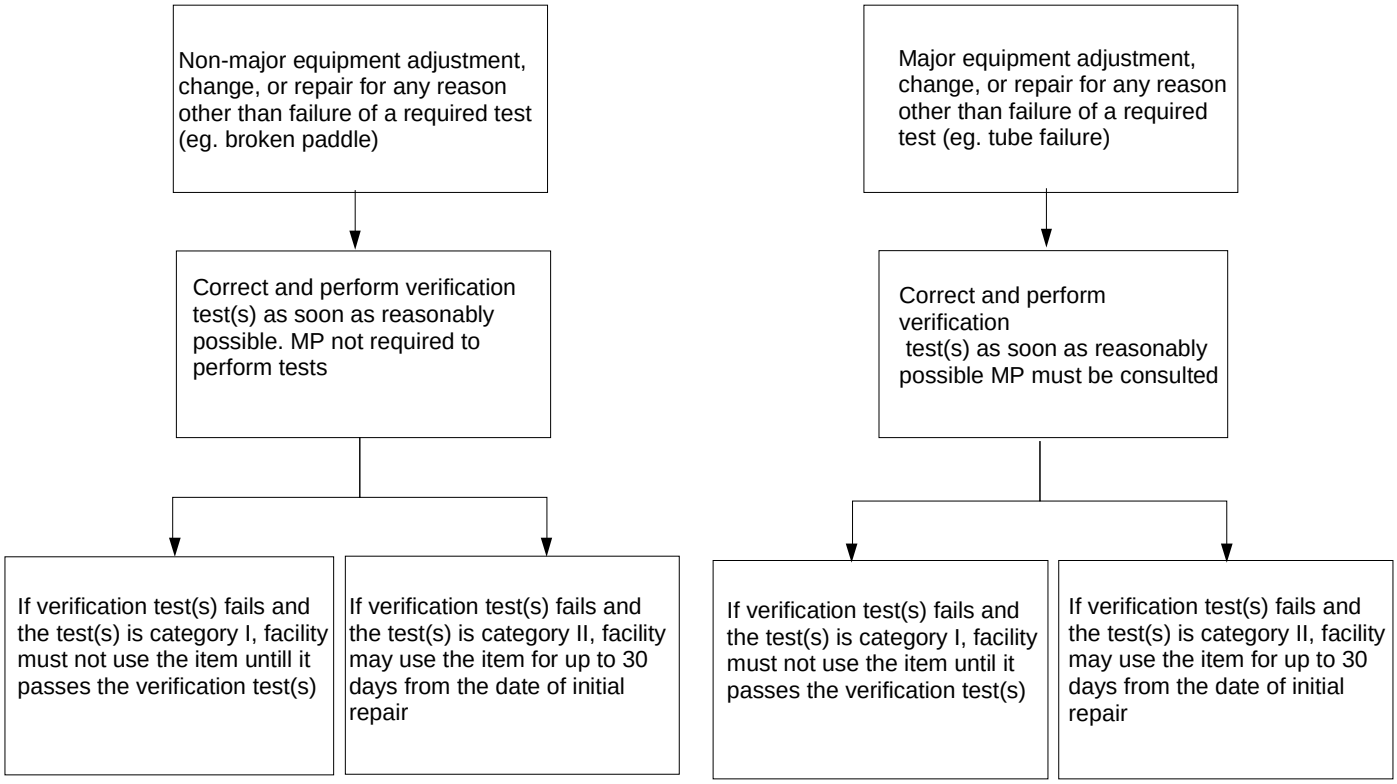


MP – Medical Physicist

DECISION TREE #2 – Failure of a Category II test(s)



DECISION TREE #3 – Equipment adjustment, change, or repair for any reason other than failure of a required test.



CATEGORY TESTS (FFDM Acquisition system(s))

Category I Tests

1. Daily Quality Control Tests

Monitor Cleanliness and Daily Checklist

The monitor must be free of dust, fingerprints and other marks that may interfere with image interpretation.

2. Weekly Quality Control Tests

SDNR Test

- The phantom exposure mAs should be within ± 10% of the baseline mAs value.
- The measured signal value should be within ± 10% of the average baseline signal value.
- The calculated SDNR value should be within ± 10% of the average baseline SDNR value.

Artefacts Test

- There should be no conspicuous linear structures, artefacts mimicking mass objects, blotches, or regions of altered noise appearance.
- There should be no observable grid lines or table top structure
- There should be no significant “bright” or “dark” pixels evident.

Viewbox Cleanliness

- Viewboxes should be free from dirt, grease pencil marks, marker, etc.
- Viewboxes should appear uniformly bright and of the same hue.

3. Monthly Quality Control Tests

Image quality evaluation test, using the RMI phantom

The phantom image shall achieve at least the minimum score established by the CAR and MQSA (four (4) fibres, three (3) speck groups and three (3) masses). Note that any artefacts that mimic a fibre, speck group or mass must be subtracted from the gross score to obtain a final score.

Mechanical Inspection

- Items that are hazardous, inoperative, out of alignment or operate improperly should be repaired before any patients are imaged.
- Each of the items in the Monthly Checklist should pass or receive a check mark.

- Items missing from the room should be replaced immediately.
- Room temperature should be in the manufacturer's recommended range.

Acquisition Display Monitor Evaluation of AAPM test pattern

- There should be no noticeable artefacts in the image.
- All 16 luminance patches should be distinct from each other in shade.
- The smaller, 5% contrast squares should be visible in both the dark (0-5%) and light (95-100%) squares.
- You should be able to see at least "QUALITY CONT" in each of the three regions on the primary display devices.

4. Quarterly

NONE

5. Semi-annual Quality Control Tests

Compression Force – Consistency of Pressure

The compression device must be able to maintain a constant pressure throughout the duration of the examination.

6. Annual Quality Control Tests (Physics)

The physicist will perform a complete assessment on the mammography facility on a yearly basis. The testing includes the x-ray mammography machine, Quality Control procedures, acquisition and review workstation, image archive and storage. The physicist will use his/her professional judgment to assess the severity and clinical impact of the failure of any test performed during the annual assessment. Category I failures must be immediately communicated to the facility. Category II failures can be communicated in the "Breast Screening Physicist Report on Site Visit" documentation. This documentation should be completed within two (2) weeks of the assessment.

Category II Tests

All other tests specified in the Breast Screening Quality Management Manual that are not listed under Category I tests are considered Category II tests. However, the medical physicist may reserve the right to use his/her professional judgment to assess the severity and clinical impact of the failure of any test.

Equipment Adjustment, Changes or Repairs

For any adjustment, change or repair not listed in the Medical Physicist Involvement Table, or if the facility is unsure as to the full extent of the adjustment, change or repair, the facility should consult their medical physicist to determine the proper extent of his or her involvement in evaluating the item.

CATEGORY TESTS (Image Review, Storage and Archive System)

Category I Tests

1. Daily Quality Control Tests

Monitor Cleanliness and Daily Checklist

The monitor must be free of dust, fingerprints and other marks that may interfere with image interpretation.
The lighting conditions and room configuration must match what is described on the medical physicist's worksheet.

2. Weekly Quality Control Tests

Display Monitor QC – Review Workstation

Evaluation of the AAPM test pattern

- There should be no noticeable artefacts in the image.
- All 16 luminance patches should be distinct from each other in shade.
- The smaller, 5% contrast squares should be visible in both the dark (0-5%) and light (95-100%) squares.
- You should be able to see at least "QUALITY CONT" in each of the three regions on the primary display devices.
- The line pair limiting resolution pattern in the centre and the four (4) corners of the pattern should be distinct and defined.

The images on all primary display monitors should appear to be visually identical. The background should be black.

Evaluation of clinical image

- The images on all primary display monitors should appear to be visually identical. The background should be black.
- Contrast on the two (2) 5MP monitors should match
- Dense breast tissue on the two (2) 5 MP monitors should match

3. Monthly

Laser Printer Sensitometry

- If the Dmax falls below the control limit of -0.15 of its respective operating level or is less than 3.50, the source of the problem must be determined and corrected before digital mammograms are printed.

- If the DD or MD exceeds the control limit of ±0.15 from its operating level, the source of the problem must be determined and corrected before digital mammograms are printed.
- If the B+F exceed the control limit of +0.03 from its operating level, the source of the problem must be determined and corrected before digital mammograms are printed.

Laser Printer Artefacts Test

- The resulting film should be of uniform optical density.
- There should be no streaks, lines, speaks, blotches or other objectionable artefacts on the films, which in the opinion of a Radiologist could interfere with the interpretation of a mammogram.

4. Quarterly

Printed Image Quality Test

- All 16 luminance patches should be distinct from each other in shade.
- The line pair limiting resolution pattern in the centre and the four (4) corners of the pattern should be distinct and defined.
- The 0-5% contrast squares and 95-100% contrast squares should be distinguishable.
- The lines shall appear straight and even without distortion.
- There shall be no distracting artefacts.
- The 5 cm lines will measure between 4.7 and 5.3 cm long on the printed image.

5. Semi-annual Quality Control Tests

None

6. Annual Quality Control Tests (Physics)

The physicist will perform a complete assessment on the mammography facility on a yearly basis. The testing includes the x-ray mammography machine, Quality Control procedures, acquisition and review workstation, image archive and storage. The physicist will use his/her professional judgment to assess the severity and clinical impact of the failure of any test performed during the annual assessment. Category I failures must be immediately communicated to the facility. Category II failures can be communicated in the “Breast Screening Physicist Report on Site Visit” documentation. This documentation should be completed within two (2) weeks of the assessment.

Category II Tests

All other tests specified in the Breast Screening Quality Control Manual that are not listed under Category I tests are considered Category II tests. However, the medical physicist may reserve the right to use his/her professional judgment to assess the severity and clinical impact of the failure of any test.

Equipment Adjustment, Changes or Repairs

For any adjustment, change or repair not listed in the Medical Physicist Involvement Table, or if the facility is unsure as to the full extent of the adjustment, change or repair, the facility should consult their medical physicist to determine the proper extent of his or her involvement in evaluating the item.

Internal adjustments refer to equipment adjustments that typically cannot be made by the operator

3. RELATED POLICIES

Breast Screening Technologist Manual

4. RESPONSIBLE PARTY

Screening Operations Director
Professional Practice Leader – Breast Screening Technologists
Breast Screening Quality Assurance Support Group

Table - Medical Physicist (MP) Involvement in Equipment Adjustments, Changes, or Repairs:

DIGITAL

Item	Major Repair	Medical Physicist Involvement
X-ray Unit		
Installation	Y	MP conducts evaluation in person
Move/Reassembly	Y	MP conducts evaluation in person
High Voltage Generator Replacement	Y	MP conducts evaluation in person
X-ray Tube		
X-ray tube Replacement	Y	MP conducts evaluation in person
Filter Replacement	Y	MP conducts evaluation in person
Detector		
Replacement	Y	MP conducts evaluation in person
Compression Device		
Pressure adjustment	N	MP involvement optional
thickness scale accuracy adjustment but only if it affects AEC performance	N	MP oversees
repair of auto decompression	N	MP involvement optional
Compression Paddle		
Paddle (new to facility) replacement	N	MP oversees
Deflection adjustment	N	MP oversees
Adjustment due to extension beyond allowable limit, or visibility on images	N	MP oversees
Automatic Exposure Control		
AEC/Detector calibration	N	MP oversees
Acquisition Workstation		
Software Upgrade	N	MP oversees
Monitor Calibration	N	MP oversees
Monitor Replacement	Y	MP conducts evaluation in person
Review Workstation		
Installation	Y	MP conducts evaluation in person
Software Upgrade	N	MP oversees
Monitor Calibration	N	MP oversees
Monitor Replacement	Y	MP conducts evaluation in person
Laser Printer		
Installation	Y	MP conducts evaluation in person
OD Calibration	N	MP oversees
Image Archive		
Software Upgrade	N	MP oversees
CAD		
Software Upgrade	N	MP oversees