

SECTION M: QUALITY CONTROL • FULL-FIELD DIGITAL • FISCHER

1. Is your quality/control assurance program substantially the same as the quality assurance program recommended by the image receptor manufacturer? (At a minimum, the program should evaluate the applicable components below.)

¹ No ² Yes Comments: _____

TECHNOLOGIST QC TESTS

1. Laser Imager Quality Test (*if applicable*)
2. Phantom Image Acquisition Test
3. Phantom Image Quality Test
4. Detector Calibration and Flat Field Test
5. System Resolution (Detector Alignment/Scan Speed Uniformity)
6. System Operation
7. Reject/Repeat Analysis
8. Compression Force Test
9. Review Workstation QC-Overall*

MINIMUM FREQUENCY

- Daily
- Weekly
- Weekly
- Weekly
- Monthly
- Monthly
- Quarterly
- Semiannually
- See FDA guidance

MEDICAL PHYSICIST EQUIPMENT EVALUATION AND ANNUAL QC

1. X-Ray Field Size Alignment and Chest Wall Missed Tissue Checks
2. Compression Paddle Alignment
3. kVp Accuracy Test
4. Linearity, Reproducibility and Accuracy
5. Half-Value Layer and Output
6. Dosimetry – Average Glandular Dose and Output
7. Phantom Image Acquisition Test
8. Image Quality
9. System Resolution/Scan Speed Uniformity
10. Flat Field Test
11. Geometric Distortion and Resolution Uniformity
12. Automatic Decompression Control
13. System Artifacts
14. Image Viewing Room Illuminance Test
15. Review Workstation Tests*

* FDA *recommends* that only monitors and printers specifically cleared for FFDM use by FDA's Office of Device Evaluation (ODE) be used. However, a facility may legally use others. FDA MQSA regulations require that all FFDM system (including monitors and printers) comply with a QC program that is **substantially the same** as that recommended by the *image receptor* manufacturer. If the monitor or printer has been approved by the FDA's ODE for FFDM, the FDA considers its QC manual to be "substantially the same" and you may follow it for QC. (Check with the monitor or printer manufacturer for their system's FDA clearance status and their QC manual.) If the monitor or printer has not been approved by the FDA's ODE for FFDM, you **must** follow the QC manual provided by the *image receptor* manufacturer. (In this case, check with the image receptor manufacturer for their required tests.)

Submit the following QC records for **equipment used both on and off-site** (either by transferring your data to the attached sample chart and checklists or sending a good photocopy of your laser printer QC chart **and** QC checklists):

1. Laser film printer quality control chart (as described in SECTION L)
2. **One month** of the "Daily and Weekly Tests" checklist (if a new unit, all available)
3. **Previous 12 months** of the "Monthly, Quarterly, and Semi-Annual Tests" checklist (if a new unit, all available)

In addition, submit:

1. The **entire, most recent medical physicist's survey report** for each unit. All reports must include 1) the completed Medical Physicist's Mammography QC Test Summary form (enclosed) signed by your medical physicist, 2) the completed "Evaluation of Site's Technologist QC Program" page (even for new units), and 3) all data pages. The survey must have been performed **no earlier than 14 months** before the date on this full application.
2. Documentation of **corrective action taken for failures** of MQSA regulations that were noted on the medical physicist's report.

Please staple all QC charts, checklists, the medical physicist's report and documentation of corrective action (if necessary) to this page.

There is no requirement that mammography facilities currently accredited by the ACR, or those applying for accreditation in the future, purchase any ACR products in order to obtain or maintain their ACR accreditation.

I certify that the information submitted on the foregoing application and addenda are true and correct, to the best of my knowledge, and that this facility complies with the facility requirements described in the FDA's Quality Mammography Standards; Final Rules that went into effect April 28, 1999. In addition, I have personally reviewed the enclosed clinical and phantom hardcopy images. The clinical images are examples of this facility's best work and have been interpreted as negative (i.e., BI-RADS® Assessment Category 1).

Executed on: _____ Date _____ Signature of Supervising Radiologist (Lead Interpreting Physician) _____