

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

1. Is your quality assurance/control (QC) 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: _____

<u>TECHNOLOGIST QC TESTS</u>	<u>MINIMUM FREQUENCY</u>	<u>MEDICAL PHYSICIST EQUIPMENT EVALUATION AND ANNUAL QC</u>
1. DICOM Printer Quality Control	Weekly	1. Mammographic Unit Assembly Evaluation
2. Viewboxes and Viewing Conditions	Weekly	2. Collimation Assessment
3. Artifact Evaluation	Weekly	3. Artifact Evaluation
4. Signal-To-Noise and Contrast-To-Noise Measurements	Weekly	4. kVp Accuracy and Reproducibility
5. Phantom Image	Weekly	5. Beam Quality Assessment—HVL Measurement
6. Detector Flat-Field Calibration	Weekly	6. Evaluation of System Resolution
7. Compression Thickness Indicator	Bi-weekly	7. Automatic Exposure Control (AEC) Function Performance (<i>if applicable</i>)
8. Visual Checklist	Monthly	8. Breast Entrance Exposure, AEC Reproducibility (<i>if applicable</i>) and Average Glandular Dose
9. Reject Analysis	Quarterly	9. Radiation Output Rate
10. Compression	Semi-annually	10. Phantom Image Quality Evaluation
11. Review Workstation QC-Overall	See FDA Guidance	11. Signal-To-Noise Ratio and Contrast-To-Noise Ratio Measurement
		12. Viewbox Luminance and Room Illuminance
		13. 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 systems (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)