MAP ID No. _____

PRIVILEGED and CONFIDENTIAL • PEER REVIEW
Code of Virginia 8.01-581.17

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

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: _____

TECHNOLOGIST QC TESTS	MINIMUM FREQUENCY	MEDICAL PHYSICIST EQUIPMENT EVALUATION AND ANNUAL QC
1. CNR Weekly Check	Weekly	1. S Value Confirmation
2. Phantom Image	Weekly	2. System Resolution
3. Visual Checklist	Monthly	3. CR Reader Scanner Performance
4. Repeat Analysis	Quarterly	4. Mammography Unit Assembly Evaluation
5. Compression	Semi-annually	5. Collimation Assessment
6. Imaging Plate (IP) Fog	Semi-annually	6. Automatic Exposure Control (AEC) System Performance Assessment
7. Printer QC	See Fuji QC Manual	7. System Artifact Evaluation
8. Review Workstation QC-Overall	See Fuji QC Manual	8. Phantom Image Quality Evaluation
		9. Dynamic Range
		10. Primary Erasure
		11. Inter-Plate Consistency
		12. kVp Accuracy and Reproducibility
		13. Dose
		14. Beam Quality Assessment and Half-Value Layer Measurement
		15. Radiation Output
		16. Viewing and Viewing Conditions
		17. Review Workstation Tests
		18. Printer 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. Fuji specifies that the printer and monitor manufacturers' QC program must be followed; if no manufacturer-provided QC is available, the Fuji manual includes testing information.

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)

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