



**PRIVILEGED and CONFIDENTIAL • PEER REVIEW**

Code of Virginia 8.01-581.17

**SECTION K • EQUIPMENT • SCREEN-FILM • IMAGE RECEPTOR**

1. Type of Film Primarily Used: *check one*

- |  |   |  |
|--|---|--|
| <input type="checkbox"/> <sup>21</sup> Agfa Mamoray HT         | <input type="checkbox"/> <sup>27</sup> Fuji AD-M        | <input type="checkbox"/> <sup>12</sup> Konica CM-H |
| <input type="checkbox"/> <sup>23</sup> Agfa Mamoray HDR-C      | <input type="checkbox"/> <sup>32</sup> Kodak Min-R EV   |  |
| <input type="checkbox"/> <sup>30</sup> Agfa Mamoray HDR-C Plus | <input type="checkbox"/> <sup>20</sup> Kodak Min-R L    |  |
| <input type="checkbox"/> <sup>25</sup> Sterling Microvision Ci | <input type="checkbox"/> <sup>13</sup> Kodak Min-R M    | <input type="checkbox"/> <sup>99</sup> Other       |
| <input type="checkbox"/> <sup>26</sup> Fuji UM-MA HC           | <input type="checkbox"/> <sup>28</sup> Kodak Min-R 2000 | <i>specify</i> _____                               |

2. Type of Screen Primarily Used: *check one*

- |  |   |   |
|--|---|---|
| <input type="checkbox"/> <sup>10</sup> Agfa Mamoray Detail S | <input type="checkbox"/> <sup>23</sup> Fuji UM Fine       | <input type="checkbox"/> <sup>33</sup> Konica                           |
| <input type="checkbox"/> <sup>20</sup> Agfa Mamoray Detail R | <input type="checkbox"/> <sup>24</sup> Fuji UM Medium     | <input type="checkbox"/> <sup>27</sup> Sterling Microvision Detail      |
| <input type="checkbox"/> <sup>29</sup> Agfa Mamoray HD       | <input type="checkbox"/> <sup>1</sup> Kodak Min-R         | <input type="checkbox"/> <sup>28</sup> Sterling Microvision Fast Detail |
| <input type="checkbox"/> <sup>30</sup> Agfa Mamoray HD-S     | <input type="checkbox"/> <sup>31</sup> Kodak Min-R EV 150 | <input type="checkbox"/> <sup>14</sup> 3M Trimax 2 (single)             |
| <input type="checkbox"/> <sup>11</sup> DuPont QuantaVision   | <input type="checkbox"/> <sup>32</sup> Kodak Min-R EV 190 |   |
| <input type="checkbox"/> <sup>21</sup> Fuji AD Fine          | <input type="checkbox"/> <sup>25</sup> Kodak Min-R 2000   | <input type="checkbox"/> <sup>99</sup> Other                            |
| <input type="checkbox"/> <sup>22</sup> Fuji AD Medium        | <input type="checkbox"/> <sup>26</sup> Kodak Min-R 2190   | <i>specify</i> _____  |

3. Is more than one screen-film combination used?       <sup>1</sup> No       <sup>2</sup> Yes, *specify* \_\_\_\_\_
- \_\_\_\_\_

Complete and label a separate form for *each processor that is used for mammography at this facility and staple a copy of its QC chart to this page. (Photocopy this form as necessary.)*

*Place a "Processor Data Sheet" label here.  
(If films are processed from more than one mammography unit in this processor, place the "Processor Data Sheet" labels from the other units on the back of this form.)*

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**SECTION L • EQUIPMENT • SCREEN-FILM • PROCESSOR**

1. How many processors are used for mammography at this facility? *enter a number* \_\_\_\_\_
2. Processor manufacturer: *check one*

<input type="checkbox"/> 1 3M	<input type="checkbox"/> 4 Alpha Tek	<input type="checkbox"/> 7 Ecomat	<input type="checkbox"/> 10 Kodak	<input type="checkbox"/> 13 Philips
<input type="checkbox"/> 2 AFP	<input type="checkbox"/> 5 Curix	<input type="checkbox"/> 8 Fuji	<input type="checkbox"/> 11 Konica	<input type="checkbox"/> 14 Picker <input type="checkbox"/> 99 Other
<input type="checkbox"/> 3 Agfa	<input type="checkbox"/> 6 DuPont	<input type="checkbox"/> 9 Hope	<input type="checkbox"/> 12 Pako	<input type="checkbox"/> 15 Vari-X <i>specify</i> _____
3. Processor model: \_\_\_\_\_
4. Chemistry manufacturer: *check one*

<input type="checkbox"/> 1 Agfa	<input type="checkbox"/> 3 Clayton	<input type="checkbox"/> 5 H.R. Simon	<input type="checkbox"/> 7 Picker	<input type="checkbox"/> 99 Other, <i>specify</i> _____
<input type="checkbox"/> 2 Autex	<input type="checkbox"/> 4 DuPont/Sterling	<input type="checkbox"/> 6 Kodak	<input type="checkbox"/> 8 White Mountain	
5. Chemistry source: *check one*     Manufacturer     Non-manufacturer distributor     Other, *specify* \_\_\_\_\_
6. Chemistry preparation: *check one*

<input type="checkbox"/> 1 Pre-mixed	<input type="checkbox"/> 2 Concentrate; mixed onsite by personnel	<input type="checkbox"/> 3 Concentrate; mixed onsite w/automixer	<input type="checkbox"/> 99 Other
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7. Is this processor used exclusively for mammography?     1 No     2 Yes
8. Total processor cycle time: *enter a number* \_\_\_\_\_ seconds
9. Developer temperature: *enter a number* \_\_\_\_\_ ° Fahrenheit

**PROCESSOR QC**

10. Film manufacturer used for processor QC: \_\_\_\_\_
11. Film type: \_\_\_\_\_

*You must submit at least one month of processor quality control data (consisting of at least 20 days of data points) for each processor used for mammography. IMPORTANT: The clinical and phantom images must be taken within the same 30-day time frame and must be within the time period shown on the processor QC chart. Attached is a sample form for processor quality control data. You may either transfer your data to this form or send us a good photocopy of your quality control chart. Be sure that your processor QC chart includes the following:*

1. Facility name
2. MAP ID#
3. Processor manufacturer and model
4. Density difference
5. Mid-density
6. Base-plus-fog
7. Remarks on corrective action as necessary

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**SECTION M • QUALITY CONTROL • SCREEN-FILM**

1. Do you have a QC program in place that complies with the requirements described in the FDA's Quality Mammography Standards; Final Rules that went into effect April 28, 1999?

 <sup>1</sup> No <sup>2</sup> Yes

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 processor QC chart *and* QC checklists):

1. Processor 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 product 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)