MQSA INSPECTION PROCEDURES 6.01 – (8/1/06)

1. INTRODUCTION 9
1.1 Further Details 10
1.1.1 Inspection Kit 10
1.1.2 Laptop Failure during an Inspection 10
1.1.3 Preventing Theft (ref. MQSA Document # 107) 10
1.1.4 Internet Access from the Laptop 11
1.1.5 Noting Change within a Facility 11

2. GENERAL GUIDANCE 13
2.1 Advance Notice for Inspections 13
2.1.1 Inspection Elements Common to Multiple Facilities 13
2.1.2 Routine Annual Facility Inspections - When should a facility be inspected? 13
2.1.3 Equipment Testing During an MQSA Inspection 14
2.2 Getting Started 15
2.2.1 Identification Cards 15
2.3 What to Do in Unusual Situations 15
2.3.A Operating without a Valid Certificate 15
2.3.B Conducting Mammography with an Unaccredited Machine 16
2.3.1 Expired Certificates Found During Inspections 16
2.3.2 Facilities that Changed Status, Moved, Ceased Operations, or Closed 17
2.4 When Certain Documents are Claimed but Unavailable for Review 22
2.4.1 Claimed Items Use During Inspections 22
2.5 Using the "Remarks" Sections 22
2.5.1 Remarks Section - What to Include 23
2.5.2 Additional Information for Level 1 and Level 2 Noncompliances 24
2.6 Facility Grouping for Inspection Fee Consolidation 24
2.6.1 Inspection Fees 24
2.6.2 Inspection Fee Consolidation 24
2.6.3 Billing Changes 25
2.7 Repeat Observations 25
2.8 Discussion of Inspection Observations with Facility Personnel (exit interview) 25
2.8.1 Inspection Citation Levels 26
2.8.2 Inspector Actions at the Facility after Completing the Inspection 27
2.8.3 Facility Personnel Responsibility Re Inspection Observations Follow-Up 27
2.8.4 Documentation and other Issues Related to Inspection Observations 28
2.8.5 Inspection Findings Disputed by Facilities 28
2.8.6 Inspection Errors Discovered by FDA or the State 29
2.8.7 Recording State vs. MQSA Requirements 30
2.8.8 Advice to a Facility Following a Serious Citation 30
2.8.9 Advice to Facilities Regarding Corrective Actions 31
2.8.10 Responding to FDA after Inspections (Letters with Inspection Report and Facility Comments) 31
2.8.11 Copying Records during Inspections and Using Remarks 32
2.8.12 Veteran Health Administration (VHA) Inspections 36
2.8.13 Corrected Before Inspection (CBI) Policy 36
2.8.14 Facilities Comments Concerning Their Inspections 37

3. PRELIMINARY INFORMATION and DATA RECORDING 38
3.1 General 38
3.2 Data Recording 38
3.2.1 Inspection Outline 38
3.2.2 Equipment Registration 41
3.2.3 Preliminary Facility and Inspection Information 42
3.2.4 Facility Contacts 44
3.2.5 X-ray System(s) Information 44
3.2.6 Updating Pre-filled Data (Important) 49
3.3 Further Details 50
3.3.1 Facility Inspection Download (FISS Screen. 2.0 on your laptop) 50
3.3.2 Individuals Accompanying on Inspections 50
3.3.3 Calibration Criteria for Densitometers and Sensitometers - Replacements 51
3.3.4 EIN and CFN (FEI) 52
3.3.5 Additional Sites 52
3.3.6 Post-Exposure Indication of Pre-selected Focal Spot and Target Material - Alternative Standard 52
3.3.7 Dedicated Buckys and Spot Compression Paddles 53
3.3.8 Unit Accreditation 53
3.3.9 Subsequent Use of X-Ray Units that Failed during the Inspection 54

4. SYSTEM PERFORMANCE TESTS 55
4.1 General 55
4.1.1 Equipment Measurements which Result in Borderline Values 55
4.1.2 Retention of MQSA Inspection Test Films 55
4.1.3 Unusual or Unexplainable Errors 56
4.1.4 Situations without Corresponding Questions in the Software 56
4.2 Phantom Image Quality Evaluation 57
4.2.1 Phantom Image Scoring - General Procedure 60
4.2.2 Phantom Scoring Video 61
4.2.3 Phantom Images Exposed in a Fully Automatic Mode - Assigning a kVp 61
4.3 The Sensitometric Technique for Evaluation of Processing (STEP) Test 62
4.3.1 The STEP Test – General Guidance 64
4.3.2 Step Reference Number for the Control Film 64
4.3.3 Control Film Used for the STEP Test 65
4.3.4 Update on Film Processor Testing 65
4.3.5 STEP (Test) Field Calibration Protocol 66
4.3.6 Processing Cycle and the STEP Test 67
4.4 The Darkroom Fog Test 68
4.4.1 Darkroom Fog - Daylight System Inspection Issues 70

5. QUALITY ASSURANCE (QA) PROGRAM 71
5.1 Background 71
5.2 Procedure 72
5.3 Further Details 72
5.3.1 General 72
5.3.2 Specific Personnel Responsibilities 73
5.3.3 Consumer Complaint Mechanism – Compliance Criteria 74

5.3.4 Procedures for Infection Control - Compliance Criteria 74
5.3.5 Dealing with Breast Implant Patients - Compliance Criteria 74
5.3.6 Consumer Complaint Mechanism – Handling Complaints about a Facility 74
5.3.7 Facility Complaints Regarding MQSA Inspectors - Resolution Process 75

6. QUALITY CONTROL (QC) RECORDS 77

6.0 General 77
6.0.1 QC Records Retention Requirement for Replaced Equipment 77
6.0.2 Documentation of the Required Screen-Film QC Tests 78
6.0.3 Darkroom Blacklight 79
6.0.4 Reviewing QA/QC Records for Retired Equipment 80
6.1 Processor Performance QC (Daily) 80
6.1.1 Charting of Quality Control (QC) Test Results 82
6.1.2 Performing the Daily Processor QC when the Sensitometer is not Available - Alternative Standard 82
6.1.3 Performing the Daily Processor QC when the Densitometer is not Available 82
6.1.4 Situations Warranting Re-establishment of Processor Operating Levels 82
6.1.5 Facility Actions while Establishing/Re-establishing Processor Operating Levels 83
6.1.6 Time Constraints on the 5-day Averaging Period for Establishing/Re-establishing Processor Operating Levels 83
6.1.7 Performing Daily QC on the Back-up Processor (General Purpose or Dedicated for Mammography) 83
6.1.8 Performing Daily QC on Mammography Processors that are also Used for Copying Mammograms and for Laser Films that are Used in Full Field Digital Mammography (FFDM) 84
6.1.9 Performing the Daily QC Tests on a Processor Used Only for Duplication of Mammograms 84
6.1.10 Performing the Daily Processor QC Tests on Days when Mammograms are Performed but not Processed 84
6.1.11 Performing Processor QC Using Phantom Image Measurements 84
6.1.12 Preset Scanning Densitometers 85
6.1.13 Automatic Densitometers and Saving Data 85
6.1.14 Sensitometer Calibration 85
6.2 Fixer Retention QC (Quarterly) 85
6.2.1 Fixer Retention QC Records 85
6.3 Phantom Image QC (Weekly) 86
6.3.1 Phantom Image QC Records - Operating Levels 87
6.3.2 Phantom Image QC Film 87
6.3.3 Reviewing Phantom Image QC Records 87
6.3.4 Test Conditions for the Weekly Phantom Image 87
6.3.5 Monitoring of the Weekly Phantom QC at a Facility with Multiple Processors and Multiple X-Ray Units 88
6.3.6 Facility Actions if and when the Optical Density (OD) for the Weekly Phantom Test Falls Outside Action Limits 89
6.3.7 Conducting the Weekly Phantom Image Test for Mammography Facilities Operating Intermittently - Alternative Standard 90
6.3.8 Facility Use of a Cracked Breast Phantom 90
6.3.9 Phantom Modifications 90
6.3.10 Using the Phantom Image QC Test as a Substitute for Sensitometry 91

6.3.11 Performance Verification Test for Mobile Mammography Units 91
6.4 Compression QC (Semi-annually) 92
6.4.1 Maintaining Compression 92
6.5 Repeat Analysis QC (Quarterly) 92
6.5.1 Repeat Analysis in a JCAHO Facility 93
6.6 Screen-Film Contact QC (Semi-annually) 94
6.6.1 Screen-Film Contact QC - Procedures Manual 94
6.6.2 S/F Contact - Test Conditions and Pass/Fail Criteria 94
6.7 Darkroom Fog QC (Semi-annually) 94
6.7.1 Darkroom Fog QC – Daylight System Issues 95
6.8 Digital Mammography QC 95
6.8.1 Evaluation Procedures for FFDM Systems (APPENDIX 2) 96
6.8.2 Facility's Use of Printers and Monitors not Specifically Approved as Part of its FFDM Unit 96

7. Annual PHYSICS SURVEY REPORT 98
7.1 Report Contents 98
7.2 Facility Response to Medical Physicist's Observations 99
7.3 Survey Report Screens 99
7.3.A Survey Report - Information Screen 99
7.3.B Survey Questions (Screens 3.10.1 & 3.10.2) 100
7.4 Further Details 104
7.4.1 Data Entry - Information Tab (Screen 3.10) 104
7.4.2 Survey Report Availability for FFDM Systems 105
7.4.3 Direct Supervision & Signature on the Survey or Mammography Equipment Evaluation (MEE) Report 105
7.4.4 Extension of the 14 Month Limit for the Medical Physicist Survey 105
7.4.5 Multiple Dates for the Medical Physicist Survey 106
7.4.6 If the Survey Shows Mistakes or Contradictions 106
7.4.7 Citation Levels Associated with Report Status and Date(s) 106
7.4.8 Using BR12 Rather than the RMI 156 Phantom for Dose Calculations 107
7.4.9 HVL Measurement 108
7.4.10 Focal Spot Condition (System Resolution) Test 108
7.4.11 AEC Performance – Clarification of Terms 108
7.4.12 AEC Performance – Meeting the Annual Survey Test Requirements 109
7.4.13 AEC Performance – Testing Units with Multiple Detectors 110
7.4.14 AEC Performance – Testing with Different Image Receptor Sizes 110
7.4.15 AEC Performance – Testing outside the 2-6 cm Range 111
7.4.16 Testing of AEC Modes not Used Clinically 111
7.4.17 AEC Reproducibility –Units with Multiple Detectors and AEC Modes 111
7.4.18 Collimation Test Scope 111
7.4.19 Artifact Test Scope 112
7.4.20 Artifact Test for Daylight Processing Systems 113
7.4.21 KVp Values Used during Testing 113
7.4.22 Screen Speed Uniformity – Cassettes with Different Speeds 114
7.4.23 Decompression Test – Alternative Standard 114
7.4.24 Scope of the Survey Tests 115
7.4.25 Use of Test Results 116
7.4.26 Facility Actions when the AEC Fails the Medical Physicist Testing 117

8. MAMMOGRAPHY EQUIPMENT EVALUATIONS (MEE) 119
8.1 General 119
8.1.A Newly Installed or Reassembled X-ray Unit 119
8.1.B Newly Installed or Reassembled Processor 119
8.2 Major Repairs 120
8.3 Data Entry 120
8.4 Further Details 121
8.4.1 General 121
8.4.2 AEC Performance Testing for the MEE – Scope and Action Limits 121
8.4.3 AEC Performance Testing during the MEE outside the 2-6 cm Range 122
8.4.4 Validity of the kVp(s) Used in MEE Testing 122
8.4.5 Motion of the Tube-Image Receptor Assembly 123
8.4.6 Manufacturer's Software Modification of the AEC – Alternative Standard 123
8.4.7 Conducting the Mammography Equipment Evaluation after a Software Upgrade under Medical Physicist Oversight – Alternative Standard 123

9. PERSONNEL QUALIFICATIONS 125
9.1 All Personnel Categories 125
9.1.1 Maintenance of Personnel Records 126
9.1.2 Letters from Approved Certifying Boards 126
9.1.3 Direct Supervision Issues 127
9.1.4 Past or Part Time Employees 127
9.1.5 Credits for Mammography Personnel Teaching a Course/Reading or Writing Articles 128
9.1.6 Criteria for Accepting Training/CME/CEU Certificates 128
9.1.7 Examples of New Mammographic Modalities 129
9.2 Interpreting Physician (Screen 3.11.1) 130
9.2.1 Qualification Requirements - Interpreting Physicians 133
9.2.2 Direct Supervision for Interpreting Physicians 135
9.2.3 Applicability of the Requirement for 8 Hours of Training in Each Mammographic Modality 135
9.2.4 Requirements for the Content of the FFDM Training 135
9.2.5 Training/Experience in Stereotactic Biopsy Systems with Digital Image Receptors Prior to 4/28/99 136
9.3 Radiologic Technologist (Screen 3.11.2) 136
9.3.1 Qualification Requirements - Radiologic Technologists 139
9.3.2 Direct Supervision for Radiologic Technologists 140
9.3.3 The ARRT (M) Certificate 140
9.3.4 Applicability of the Requirement for 8 Hours of Training in Each Mammographic Modality 141
9.3.5 Requirements for the Content of the FFDM Training 141
9.3.6 Training/Experience in Stereotactic Biopsy Systems with Digital Image Receptors Prior to 4/28/99 142
9.3.7 CME/CEU Credit for MQSA Teleconference (Live or Tape Viewing) 142
9.4 Medical Physicist (Screen 3.11.3) 143
9.4.1 Qualification Requirements - Medical Physicists 145
9.4.2 Direct Supervision for Medical Physicists 148
9.4.3 Meeting the Initial Survey Experience & Initial Training 148
9.4.4 Medical Physicist with a Physics Degree 148

9.4.5 Transcripts Instead of a Copy of Degree 149
9.4.6 General Medical Physics Continuing Education 149
9.4.7 Approval Letters by the State of Maryland 149
9.4.8 Approval Letters by the State of Pennsylvania 149
9.4.9 Approval/Licensing Letters by the State of Ohio - August 2006 Update 149
9.4.10 List of States with Approval/Licensing Procedure 149
9.4.11 Review of Physicist Qualifications at FDA Headquarters 150
9.4.12 Applicability of the Requirement for 8 Hours of Training in Each Mammographic Modality 151
9.4.13 Requirements for the Content of the FFDM Training 152
9.4.14 Training/Experience in Stereotactic Biopsy Systems with Digital Image Receptors Prior to 4/28/99 152

10. MEDICAL RECORDS 154
10.1 Patient Permanent Records 154
10.2 Mammography Reports 154
10.3 Further Details 157
10.3.1 Mammography Reports 157
10.3.2 Lay Summaries 157
10.3.3 Examples of Acceptable Assessment Categories 158
10.3.4 Modifications in the Assessment Categories Used in Medical Reports - Two Alternative Standards 160
10.3.5 Separate Assessment of Findings for Each Breast - Alternative Standard 161
10.3.6 Assessment Category for "Post Procedure Mammograms for Marker Placement" – Alternative Standard 161
10.3.7 Requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (45 CFR Parts 160 and 164)- Release of Information for MQSA Purposes 162

11. MEDICAL AUDIT and OUTCOME ANALYSIS 164
11.1 Overview 164
11.2 Data Entry 164
11.3 Further Details 165
11.3.1 Performing the Medical Audit 165
11.3.2 How to Meet FDA Requirements 165

GLOSSARY 166

APPENDICES 172
APPENDIX 1: Scheduling the Inspection and the Confirmation Notice 172
A1.1 Scheduling the MQSA Inspection 172
A1.2 MQSA Inspection Confirmation Notice (sample) 172
APPENDIX 2: Evaluating Full Field Digital Mammography (FFDM) Systems 173
A2.1 Objective 173
A2.2 Introduction - FFDM Units Approved by the FDA 173
A2.2.1 Procedures for Extending Facility Certification to FFDM Systems 174
A2.2.2 Information Needed When Requesting FFDM Certification Extension 175
A2.2.3 Facility Responsibilities Regarding FFDM Units with Extended Certification 175
A2.2.4 Location Constraints and Responsibilities Associated with FFDM Units other than those Accredited by ACR, STX, and SIA 175
A2.2.5 FFDM QC Manuals Used by the Facility - Inspector Actions Regarding Outdated

Manuals 176
A2.3 Evaluation Procedures - General 178
A2.4 Evaluation of GE FFDM Systems QC Records 182
A2.4.1 Approved Alternative Standard - Timing of Corrective Actions in GE FFDM Systems 183
A2.4.2 Radiologic Technologist QC Tests – GE FFDM Systems 185
A2.4.3 Medical Physicist QC Tests – GE FFDM Systems 187
A2.4.4 GE Guidance 189
A2.5 Evaluation of Fischer SenoScan System QC Records 189
A2.5.1 The Radiologic Technologist QC Tests – Fischer SenoScan 190
A2.5.2 The Medical Physicist Annual QC Tests – Fischer SenoScan 191
A2.5.3 Fischer Guidance 193
A2.6 Evaluation of Hologic Lorad Selenia FFDM System QC Records 193
A2.6.1 Alternative Standard. Correction Period When Components of the Selenia Full Field Digital Mammography System Fail Quality Control Tests 193
A2.6.2 The Radiologic Technologist QC Tests – Hologic Lorad Selenia 195
A2.6.3 The Medical Physicist QC Tests – Hologic Lorad Selenia 196
A2.6.4 Hologic Lorad Guidance 197
A2.7 Evaluation of Siemens Mammomat Novation^{DR} FFDM QC Records 197
A2.7.1 The Radiologic Technologist QC Tests – Siemens Mammomat Novation^{DR} 198
A2.7.2 The Medical Physicist QC Tests - Siemens Mammomat Novation^{DR} 198
A2.8 Evaluation of the Fuji Computed Radiography for Mammography (FCR*m*) FFDM QC Records 201
A2.9 Answering the QC Questions for FFDM Units 204
APPENDIX 3: MQSA Guide for Additional Mammography Review (AMR) 205
A3.1 Introduction 205
A3.2 Instructions to Inspectors (During and After the Inspection) 205
A3.3 Information for FISS* Remarks 206
A3.4 Additional Evaluations of Phantom Image 207
APPENDIX 4: Further Assistance 208
A4.1 Facility Hotline 208
A4.2 Computer Support 208
A4.3 Guidance Documents and Resources 208

Exhibits

Exhibit 1: Version 6.01 Inspection Program Outline 40

Exhibit 2: Sample AB Accreditation Sticker 49

Exhibit 3: Citation Levels for Unaccredited Units 53

Exhibit 4: QC Tests Other than Annual 79

Exhibit 5: Annual Survey Quality Control Tests 116

Exhibit 6: Medical Physicist Involvement in Equipment Repairs 117

Exhibit 7: Acceptable Documents for Interpreting Physicians 132

Exhibit 8: Acceptable Documents for Radiologic Technologists 138

Exhibit 9: Acceptable Documents for Medical Physicists 144

Exhibit 10: State Approval/Licensing List for Medical Physicists 149

Exhibit 11: (Table A2.1) – FFDM Systems Approved for Clinical Use 173

Exhibit 12: (Table A2.2) - List of FFDM QC Manuals – May 2006 176

Exhibit 13: (Table A-1). Technologist QC Tests – GE Senographe 2000D, 2000D Mobile, DS, Essential (Ess) , & Seno Advantage 186

Exhibit 14: (Table A-2). Med. Physicist's QC Tests - GE Senographe 2000D, 2000D Mobile, DS, Essential, & SenoAdvantage 188

Exhibit 15: (Table B-1). The Radiologic Technologist's QC Tests – Fischer SenoScan Unit ... 191

Exhibit 16: (Table B-2). The Medical Physicist's Annual QC Tests – Fischer SenoScan Unit.. 192

Exhibit 17: (Table C-1). The Radiologic Technologist's QC Tests – Lorad Selenia Unit 195

Exhibit 18: (Table C-2). The Medical Physicist's Annual QC Tests – Lorad Selenia Unit 196

Exhibit 19: (Table D-1). The Radiologic Technologist's QC Tests – Siemens Mammomat Novation^{DR} 198

Exhibit 20: (Table D-2). The Medical Physicist's QC Tests – Siemens Syngo MammoReport QC Manual for the soft copy review station 198

Exhibit 21: (Table D-3). The Medical Physicist's QC Tests – Siemens Mammomat Novation^{DR} System QC Manual # SPB7-250.623.50.03.24 200

Exhibit 22: (Table E-1). The Radiologic Technologist's QC Tests – Fuji FCR*m* System 201

Exhibit 23: (Table E-2). The Medical Physicist's Annual QC Tests – Fuji FCR*m* System 203

Figures

Figure 1: Phantom Image Quality Evaluation 58

Figure 2: Processing Evaluation Test – Identifying Emulsion Side 63

Figure 3: Darkroom Fog Test – Film Positioning in the Fog Folder 68

MQSA INSPECTION PROCEDURES

1. INTRODUCTION

This document describes the Food and Drug Administration (FDA) facility inspection procedures under the final regulations implementing the Mammography Quality Standards Act (MQSA) of 1992. The final regulations (21 CFR 900) were published on October 28, 1997, with an effective date of April 28, 1999, for most requirements. The MQSA was re-authorized by the U.S. Congress as the Mammography Quality Standards Reauthorization Act (MQSRA) in1998 and 2004. One important change in MQSRA of 1998 is clarification of the authority to inspect uncertified facilities, which is reflected in this document. Certified MQSA inspectors are to use these procedures in conjunction with the MQSA inspection software Version 6.00, and laptop computer.

This document differs from all the previous inspection procedures documents in two main aspects; 1) elimination of the collimation and dose estimate tests and, 2) incorporating the Full Field Digital Mammography (FFDM) guidance document, which was updated most recently on January 20, 2006, into the current document as an appendix (APPENDIX 2).

For questions about these procedures, contact the Division of Mammography Quality and Radiation Programs (DMQRP) by telephone (240-276-3332), fax (240-276-3272), or call the Facility Hotline at 800-838-7715, or fax them at 410-290-6351, or e-mail them at MQSAhotline@hcmsllc.com (see APPENDIX 4). Inspectors conducting an inspection on-site and needing immediate help should contact the Hotline directly. The Hotline operator will locate someone in DMQRP and transfer your call. This will assure your being able to reach someone in DMQRP and avoid delays caused by voice mail.

For questions regarding uploading/downloading the inspection software, your laptop computer, printer, or e-mail issues, contact MPRIS Computer Support via telephone at 240-276-3323 or e-mail at computersupport@cdrh.fda.gov. Please do not contact Computer Support with other than computer or e-mail specific issues.

This document consists of five main parts:

- **Overall Guidance** – Sections 2. & 3.
- **System Performance Tests –** Section 4.
- **Records Review**
  - Quality Assurance (QA) – Section 5. & Quality Control (QC) Records – Section 6. Medical Physicist's Survey Report – Section 7. & Mammography Equipment Evaluations (MEE) – Section 8.
  - Personnel Qualifications – Section 9.
  - Medical Records – Section 10.
  - Medical Audit & Outcome Analysis – Section 11.
- GLOSSARY

- APPENDICES

A complete mammography inspection kit is provided for each active MQSA inspector designated as primary. Backup inspectors are provided with partial kits (which do not include laptop computers). For additional information on this kit, a Laptop Failure during an inspection, Preventing Theft of your laptop and your kit, Internet Access from your laptop, and other general issues, see Further Details**,** Section 1.1 below.

1.1 Further Details

1.1.1 Inspection Kit

Listed below are components of the MQSA inspection kit that FDA provides to all MQSA primary inspectors. For back-up inspectors, FDA provides all the items listed below except 7.

1. Mammography Phantom
2. Timer
3. Sensitometer
4. Densitometer
5. Mammography control film
6. Magnifying glass
7. Laptop computer & Printer
8. Kit carrying case
9. Fog test folder
10. Ruler.

For questions regarding MQSA-issued inspection equipment (e.g., film requests, sensitometer or densitometer problems, phantom problems, need for other equipment such as magnifying glass, ruler, , timers, fog folders), contact Stephanie Belella via phone at 240-276-3332 or e-mail at stephanie.belella@fda.hhs.gov.

1.1.2 Laptop Failure during an Inspection

Computers, like any electronic product, can fail. If the computer fails during the inspection, the inspector should be prepared to record the data for the inspection on a paper copy of the inspection record and enter the inspection data at a later date when the computer is operating. In this case, the post-inspection report should be mailed to the facility. To the extent possible, however, the inspector should communicate with the facility at the end of the inspection any problems that could be identified without the use of the computer. The inspector should attempt to get a working computer to enter and upload the inspection data as soon as possible but no later than five working days following the inspection date. The inspector should contact MPRIS Computer Support via telephone or e-mail (240-276-3323 or computersupport@cdrh.fa.gov). This method would be preferable over canceling the inspection and having to come back at a later date.

1.1.3 Preventing Theft (ref. MQSA Document # 107)

Theft of portable items is on the increase all over the country, including cellular telephones and laptop computers. Often the machines are stripped and the parts are sold at local computer flea markets. The following are a few steps you can take to prevent your inspection equipment from being stolen.

- Always have your inspection equipment and FDA ID with you. Do not leave anything out in the open where it can be seen.
- Take your inspection equipment home with you. If that is not an option, lock it someplace where you are the only person with the key.
- If you have to leave the equipment in your car, leave it in the trunk.
- Be aware of your surroundings. Are there a lot of people wandering the halls of your building? If so, lock the inspection equipment up. Are you in an open office where everyone passing through can see your equipment? If so, lock it up.
- When conducting an inspection, don't leave your equipment in a place where it can be accessed by the general public.

If your inspection equipment is stolen

- Check if someone else may have borrowed it. Check the perimeter of the building, cabinets, etc.
- Send an e-mail to everyone in the building asking if they saw anyone hanging around or have seen the equipment. Maybe the person feels guilty about taking the equipment. Include the following escape clause in your message:

  "If the equipment is returned in the next 24 hours, no questions will be asked."
- File a police report after the inspection equipment has been missing for 24 hours. The police will ask for the serial numbers of the inspection equipment. It's important that you write your serial numbers down and keep them someplace separate from your inspection equipment.
- Send a copy of the police report to:

  FDA-DMQRP, c/o Computer Support, Rm. 240H, Mail Code HFZ-240, 1350 Piccard Drive, Rockville, MD 20850.

  Or fax the report to: (240) 276-3272, attention; Computer Support.

Occasionally you have to send your equipment in for repair. Periodically, we are unable to send back your original equipment. Therefore, check the equipment when you receive it and verify that the serial numbers have not changed. Print these instructions and file them with your serial numbers for easy reference.

If you have any questions, please send an e-mail message to the Facility Hotline.

1.1.4 Internet Access from the Laptop

There are no statutory prohibitions against configuring your laptop to access the Internet. However, there may be security issues and therefore FDA strongly recommends that you use the laptop to access only the MPRIS Website. Furthermore, all guidance issues and inspection policies regarding MQSA to date have been placed on your laptop for easy reference.

1.1.5 Noting Change within a Facility

During the course of scheduling and/or performing an inspection, you may become aware of a change within a facility (i.e., name, address, ownership, or no longer providing mammography services). Inspectors should direct facility staff to notify their Accreditation Body (AB) of this change. The AB is responsible for maintaining complete and accurate information for each facility they accredit, and

for then electronically transferring any change(s) to FDA or the Certifying State for its use in issuing certificates and performing inspections. Inspectors should record any changed information on the Address screen under 3.0 - Facility Inspections (click on Address Changes button).

2. GENERAL GUIDANCE

This section provides guidance to inspectors on scheduling inspections, getting started on inspections, handling unusual situations, using the "Remarks" sections, facility grouping, and how to conduct the exit interview with the facility personnel.

2.1 Advance Notice for Inspections

You are required to give each facility an advance notice. It should be at least five working days prior to the inspection. If you contact the facility by telephone, explain that you are calling to schedule the next annual MQSA inspection. Work with the facility personnel to schedule a mutually acceptable date. Request that personnel who are assigned to or who are familiar with the facility's mammography quality assurance program be available during the inspection. You should confirm your telephone call in writing via a confirmation notice.

If requested, give the facility an estimate of the time it takes to complete the inspection based on your experience. You may request some information in advance, such as the facility's Employer Identification Number (EIN) or a copy of the most recent medical physicist survey report. You may also remind a new facility about updating the continuing experience and continuing education records of their mammography professionals prior to the inspection. Also, when you perform inspections of facilities that share some common items, you can save time if you copy information regarding those common items on your laptop before each inspection.

You should fax the confirmation notice (see APPENDIX 1) to the facility. Retain a copy of your fax until after you have arrived at the facility, in case the facility questions the adequacy of your advance notice. If the facility does not have access to a fax machine, you should mail it. You should also provide a telephone number for the facility to contact you regarding any questions or concerns they might have about the inspection or the proposed date and time. For guidance regarding when to schedule routine annual facility inspections, which type of certified facilities you should inspect first in your State, and equipment testing issues, see further details below.

2.1.1 Inspection Elements Common to Multiple Facilities

This reminder concerns the entry of information into the laptop prior to an inspection. There may be situations when an inspector will perform inspections of facilities with different Facility ID Numbers but which share some common items which you will inspect. For example, the same interpreting physicians as a group of interpreting physicians may interpret mammograms at multiple facilities; and/or, the same medical physicist may provide a facility's annual survey to multiple facilities.

In these cases, it may prove more convenient for both the inspector and the facility, to enter the data into the laptop at your office prior to the actual inspection at the facility. It is important to remember that during the inspection you will still have to confirm the information you entered prior to the inspection, paying particular attention to time-sensitive items such as currency of licenses/certificates, continuing experience, and continuing medical education units. Whenever possible, pre-entering such common elements into the laptop could help shorten the on-site inspection time.

2.1.2 Routine Annual Facility Inspections - When should a facility be

inspected?

In most cases, a facility gets its 6 month provisional certificate and then goes on to get its full 3 year certificate. This facility should be inspected within 10-14 months of its initial provisional certification date and then every 10-14 months from its most recent inspection.

The timing of an inspection of a facility that has undergone provisional reinstatement or has lost its certification for some period of time depends on a number of factors and can best be illustrated using the following examples.

1. A facility gets its 6 month provisional certificate, fails to get fully accredited and is granted a provisional reinstatement within one month following the expiration date of its provisional certificate. This facility should be inspected within 10-14 months of its initial provisional certification date. If the facility has been without a certificate for more than a month, the timing of the inspection needs to be determined on a case by case basis and the inspector should contact the Facility Hotline at 1-800-838-7715 or MQSAhotline@hcmsllc.com.
2. A fully certified facility fails to become reaccredited and is granted provisional reinstatement within a month following the expiration date of its full certificate. This facility should be inspected within 10-14 months of its most recent inspection. If the facility has been without a certificate for more than a month, the timing of the inspection needs to be determined on a case by case basis and the inspector should contact the Facility Hotline.
3. A provisionally certified facility voluntarily returns its certificate because it stops doing mammography. Within a month, circumstances change and the facility asks for and is granted provisional reinstatement. This facility should be inspected within 10-14 months of its initial provisional certification date. If the facility has been without a certificate for more than a month, the timing of the inspection needs to be determined on a case by case basis and the inspector should contact the Facility Hotline.
4. A fully certified facility voluntarily returns its certificate because it stops doing mammography. Within a month, circumstances change and the facility asks for and is granted provisional reinstatement. This facility should be inspected within 10-14 months of its most recent inspection. If the facility has been without a certificate for more than a month, the timing of the inspection needs to be determined on a case by case basis and the inspector should contact the Facility Hotline.

Inspectors should note that the above deals only with routine annual inspections and that any facility may be inspected at any time for cause. The above also does not deal with the situation where a facility has ceased performing mammography but still retains an active certificate. These facilities should be inspected within 10-14 months of their most recent inspection (or in the case of a new facility within 10-14 months of its initial provisional certification date) even though they might not currently be performing mammography.

2.1.3 Equipment Testing During an MQSA Inspection

Before you test facility equipment during an MQSA inspection, make sure that the equipment is currently being used for mammography. If a facility has several x-ray systems and/or processors, make sure you confirm with facility personnel that all systems you plan to test are currently being used for mammography and are covered under current FDA regulations (x-ray systems routinely used for mammography, not units used exclusively for localization, biopsy, stereotactic, or investigational units). You should not test equipment that is out of service or awaiting final clearance to be used (final clearance would mean all assembly and testing has been completed). Before you review facility

equipment records, make sure that the equipment was used for mammography at some point since the last inspection.

2.2 Getting Started

When you arrive at the facility, introduce yourself and show your inspector identification card to the facility contact person. To accommodate the facility's schedule, discuss the inspection agenda and be flexible as to which part of the inspection to cover first. Advise facility personnel that you will review inspection observations with them and provide a report of these observations prior to your departure (at least a preliminary one if your State requires a prior review of the observations). For more information, see Section 2.2.1 below.

2.2.1 Identification Cards

MQSA inspectors are required to present his or her MQSA Inspector Identification Card to facility personnel at the beginning of an inspection. This card is issued to each inspector after he or she has completed all of the training required to conduct MQSA inspections, including the performance of at least 2 mentored inspections after passing Course III. Showing identification at the beginning of an inspection is a mandatory requirement under MQSA Section 354(g)(l)(B), which states:

"The Secretary, or State agency acting on behalf of the Secretary, may conduct inspections only on presenting identification to the owner, operator, or agent in charge of the facility to be inspected."

When you arrive at a facility to conduct an inspection, you must attempt to show your Identification Card to the most responsible official involved with mammography. Should that person be unavailable at the time of the inspection, you should present your Identification Card to the most responsible person available at the facility.

2.3 What to Do in Unusual Situations

Occasionally, you may encounter unusual conditions when you arrive at a facility. The following guidance should help you deal with such circumstances.

2.3.A Operating without a Valid Certificate

1. You should first determine if the facility has a current certificate. If facility personnel indicate that they do not have one, you should check (and document) whether or not they are/have been performing mammography without a valid certificate and, if so, for how long. Determine if there are extenuating circumstances for not having a current certificate (e.g., the facility has recently submitted an application for accreditation or re-accreditation to their accreditation body* (AB); there has been no response from the AB; there has been a recent change in the facility's name, etc.).

   * Currently, the FDA recognizes the following entities as accreditation bodies: The American College of Radiology (ACR), and the States of Arkansas (AR), Iowa (IA), and Texas (TX).

2. If you verify that the facility has been operating with an expired certificate (see Sec. 2.3.1 for details) or without a valid one, inform facility personnel that such performance is unlawful under MQSA (except for extenuating circumstances), proceed with your inspection and immediately call the Hotline at 800-838-7715 first, and if necessary, the FDA at 240-276-

3332 while at the facility. The FDA will review facility records and determine its current certification status and advise you on any additional information you may need to gather. Also, inform the appropriate FDA District or Regional personnel following completion of the inspection. Instruct facility personnel to immediately contact their AB and update their status.

For additional details regarding facilities that have changed Ownership status and related FDA Enforcement Actions, facilities that Moved or Ceased Operations, and Inspection decisions regarding those that Closed or are in the process of closing, see Sections 2.3.2.1 to 2.3.2.7).

2.3.B Conducting Mammography with an Unaccredited Machine

There are three cases where the units in use at the facility may not need to be accredited: 1) the unit is a "loaner" while repairs to the facility's unit are taking place (limited to 30 days without documentation showing extenuating circumstances), 2) the unit is installed in the facility for evaluation prior to purchase (limited to not more than 90 days), or 3) the unit is an investigational one installed and used under an Investigational Device Exemption (IDE) as described in the Safe Medical Devices Act of 1990. The requirements for accreditation of these units are dependent on the rules of the facility's accreditation body. Note* that under both 1) and 2) the unit still must have passed a mammography equipment evaluation (MEE) and each such unit will be tested by the MQSA inspector, regardless of its accreditation or ownership status.

* Note that some States may have more stringent rules and may require the facility to contact them as soon as possible and follow their guidelines prior to using any such units on patients.

You should ask to see documentation covering these circumstances during an inspection. Also, send an e-mail to the Facility Hotline about such loaner and demonstration units and inform the facility that the FDA will notify the AB that the facility is using an unaccredited unit.

New** units are also required to be accredited by the facility's AB and can be used on patients only **after** passing mammography equipment evaluations conducted by a medical physicist. The facility must immediately contact its AB and follow its guidelines for newly installed units, prior to using any such units on patients.

** In this context, the word "New" means that the unit is newly acquired by the facility, e.g., either new (never been used anywhere), or had been previously used elsewhere.

Investigational units installed and used under an Investigational Device Exemption (IDE) issued by FDA to the manufacturer are currently exempt from MQSA's final regulations (900.2(aa)(2)). Facilities using such units should have approval letters, investigational device labels, or other documentation indicating FDA's conditional approval of their use. Also, such units must not be used to perform conventional mammographic images. As a general rule, all units used on patients, whether accredited or not, must be inspected, except for units that are exempt from MQSA's final regulations.

2.3.1 Expired Certificates Found During Inspections

When the inspector finds a facility performing mammography and is in possession of only an expired certificate

Step 1: The inspector should determine whether the expired certificate on display is the only

certificate that the facility has; keeping in mind that the facility may have forgotten to replace the expired certificate with the current certificate when they received it in the mail.

Step 2: If facility personnel indicate that they have only the expired certificate, the inspector should confirm that they are/have been performing mammography and get as much information about what is going on with the facility as possible (e.g., has the facility submitted an application/reapplication to their accreditation body recently, have they received a response yet, has there been a change in the name of their facility recently, etc.?).

The inspector should tell facility personnel that taking mammograms when their certification is expired is unlawful.

Step 3: The inspector should call the Hotline at 800-838-7715 first, and if necessary, the FDA at 240-276-3332 while at the facility. The FDA will review the records regarding the certification status of this facility. Based on the information revealed during this review, FDA will advise the inspector regarding any additional instructions for conducting the inspection.

Step 4: The inspector should take possession of their expired certificate.

Step 5: As of October 1998, the MQSA was amended to allow FDA to inspect mammography facilities, regardless of whether they are certified at the time of the inspection or not. Therefore, you should proceed with your inspection and document any problems that are found.

Note: Inspectors in Certifying States should contact their State Certifying Agency to determine the policies that apply to them.

2.3.2 Facilities that Changed Status, Moved, Ceased Operations, or Closed

2.3.2.1 Facility Changing Ownership – New Owner Responsibility

Under MQSA, an owner/operator of a mammography facility is always responsible for the activities of that facility. If inspection observations for problems found during an MQSA inspection continue under the new management, these observations must be addressed by the new management, regardless of who owned the facility when the MQSA inspection was conducted. The fact that a change in ownership takes place does not relieve the current owner of his or her responsibilities under MQSA. Therefore, if the observations have not been addressed by the previous facility management, then the new management must address the issue(s). Facility personnel must take whatever corrective action is needed to bring the facility up to the standards required by MQSA and to assure that the problems will not continue.

2.3.2.2 Facility Changing Name but Keeping the Same Ownership, Personnel, and Equipment

For such a facility, the MQSA certificate is still valid. However, when a facility changes just its name, it must notify its accreditation body even though it still has the same owner, personnel, and equipment. The accreditation body will then inform FDA or the Certifying State of the facility's new name. FDA or the Certifying State will then issue a new MQSA certificate to the facility.

Until the new MQSA certificate is received, the facility must prominently display its original MQSA certificate. The expiration date of the new MQSA certificate will be the same as the original since the facility has not been reaccredited or recertified. After the new MQSA certificate

arrives, the original MQSA certificate should not be displayed. The facility should file or destroy the original MQSA certificate after it receives the new MQSA certificate.

2.3.2.3 FDA Enforcement Actions Following a Change in Ownership in a Facility that has Significant Violations

Agency decisions concerning enforcement actions against facilities that have changed ownership must be evaluated on a case-by-case basis. The issuance of Warning Letters, initiation of sanctions under MQSA, or other actions will depend on a variety of factors, including, but not limited to, the prior compliance profile of the facility.

If the violations occurred only under the direction of previous owners, then initiation of enforcement actions against a facility under the new management may not be appropriate. Issues such as contractual agreements surrounding the change in ownership and information about whether a "real" change in ownership has occurred (for example, a change in corporate holding name but same principals involved) may have to be evaluated and are beyond the scope of this policy.

2.3.2.4 Facilities that Moved

When a facility moves or relocates, its MQSA certificate is still valid. However, when a facility moves or relocates, it must notify its accreditation body. The facility is reminded that any mammography unit or processor that is disassembled and reassembled at the same or different location must have a mammography equipment evaluation (MEE). Any failures of a regulatory requirement found during the MEE must be corrected before that piece of equipment is used for patient examinations. The accreditation body will direct the facility regarding any additional information and/or testing that it may require. The accreditation body will then inform FDA or the Certifying State of the facility's new address. FDA will no longer issue replacement certificates for address changes. At the time of the next renewal, FDA-issued MQSA certificates will be issued with the facility name only. Facilities with State issued MQSA certificates should check with their State agencies for their policies regarding replacement of MQSA certificates.

2.3.2.5 Facilities that Ceased Operations

Before a facility permanently stops performing mammography, it should do the following:

1. Inform its accreditation body that it will no longer be performing mammography;
2. Notify its State radiation control program;
3. Arrange transfer of each patient's medical record (original mammography films and reports) to the mammography facility where the patient will be receiving future care, the patient's referring physician or health care provider, or the patient. This transfer will address the requirement that the facility maintain the patient's permanent medical record for a period of not less than 5 years, or not less that 10 years if no additional mammograms are performed at the facility, or longer if mandated by State or local law. The facility should make reasonable attempts to inform its former patients of how they can obtain their mammography records. Facilities should check with State or local agencies to determine if their requirements are more stringent. Note: Radiology practices and other medical facilities that still see patients but have permanently stopped performing mammography, may choose to keep the patients' medical records rather than transfer them to another facility (unless the patient requests such a transfer).

If option 3 is not viable, facilities could store the medical records in a hospital, if appropriate, or make arrangements to warehouse the records. The facility should assure that there is a mechanism to release the films to the appropriate entity when requested and that former patients are made aware of that mechanism. It should be noted that if no one else is willing to accept the records, the facility remains responsible for them. Under MQSA, facilities will not be held responsible for maintenance of examinations performed before October 1, 1994; however, State and local regulations may require otherwise.

Once the facility ceases operation, the MQSA certificate should no longer be displayed. The facility may file or destroy its MQSA certificate.

Due to the fact that some facilities have not followed the above recommendations, FDA has been receiving inquiries from patients complaining that their mammography facility has closed, that they were not informed, and that they cannot find out where or how to gain access to their mammography records. For this reason, FDA requests that the facility notify us of how it intends to fulfill its obligations with respect to medical records. Such information may be sent to:

FDA/CDRH/OCER/DMQRP
Attention: Closed Facility Notification of Records Retention
1350 Piccard Drive, HFZ-240
Rockville, MD 20850

Facilities certified by States (currently Iowa, Illinois, and South Carolina) may send the above information to:

Iowa:
Bureau of Radiological Health, Iowa Department of Public Health
Lucas State Office Bldg., 5th Floor
321 East 12th Street
Des Moines, IA 50319. Or call 515-281-3478

Illinois:
Illinois Emergency Management Agency, Division of Nuclear Safety
1035 Outer Park Drive
Springfield, IL 62704. Or call 217-785-9923

South Carolina:
South Carolina Department of Health and Environmental Control
Bureau of Radiological Health
2600 Bull St.
Columbia, SC 29201. Or call 803-545-4435

2.3.2.6 Inspection of Certified Facilities Currently Not Performing Mammography

A certified facility that is not currently performing mammography should be inspected. In keeping with the intent of the regulations, once a facility is certified, that facility must maintain its certified status by:

- having an annual physics survey (and mammography equipment evaluations, when applicable) performed,
- undergoing periodic audits and reviews by their accreditation body,
- permitting an annual MQSA inspection,
- paying an inspection fee, and
- correcting any deficiencies found during inspections.

Should a certified facility choose not to meet these requirements, it must relinquish its certified

status. This means the facility must notify its accreditation body and the FDA (Facility Hotline Number: 800-838-7715, MQSAhotline@hcmsllc.com, Address: FDA – MQSA, P.O. Box 6057, Columbia, MD 21045-6057) or the Certifying State as soon as possible. Once the facility's certified status has been relinquished, it cannot display the MQSA certificate and cannot lawfully perform mammography.

Should the facility decide to perform mammography services in the future, it must proceed through the accreditation process again.

2.3.2.7 When to Inspect a Closing/Closed Facility

Facility Certification Status

Occasionally, inspectors, State programs, and FDA field offices inform DMQRP about facilities that are listed as certified but that are no longer performing mammography. As you know, a facility's accreditation remains valid until it expires. Thus, the American College of Radiology (ACR) requires a facility that is in the process of closing to notify them so that the ACR can withdraw that facility's accreditation. In situations where such a facility did not contact the ACR about its new status, the ACR will continue to list it as accredited and subsequently certified.

The ACR has a standard operating procedure whereby they try to verify via a letter or telephone call the status of a facility when it learns of its change in status. Upon validating a facility's closure, the ACR updates its records to indicate accreditation withdrawal for the facility in question and notifies FDA of that facility's new status. The State accreditation bodies also have methods for verifying the status of a facility, although their approaches differ from the arrangement between the FDA and ACR because their inspection and accreditation programs communicate more directly.

If you learn of a facility that is closing or has closed, please contact the Facility Hotline at 800-838-7715 or MQSAhotline@hcmsllc.com**.** If you have any letters or other documents confirming the closure, please fax them to us. Upon receiving this information, DMQRP will work with the ACR and the State Accreditation Bodies to verify whether a facility is no longer performing mammography. DMQRP will then remove the facility's certification once their accreditation body has updated their database.

Facility Inspections

The Mammography Quality Standards Act (MQSA) authorizes FDA, or State or local agency acting on behalf of the FDA, to conduct inspections of mammography facilities (certified or uncertified).

All certified mammography facilities are required to undergo an annual inspection to determine compliance with the certification requirements and the established quality standards. In order to provide inspectors with some flexibility in scheduling "annual" inspections, FDA allows a window of 10 – 14 months from the anniversary date of the previous inspection (or from the date of the facility's certification for the initial inspection), within which the annual inspection must be scheduled (and inspected before the 14 months has expired). The focus of the discussion below is on how inspectors should schedule annual inspections of facilities that are temporarily or permanently closed or in the process of closing within this window.

WHEN TO CONDUCT AN ANNUAL MQSA INSPECTION

If, on the day that an inspector contacts a facility to schedule its Annual Inspection [for a date no less than 10 months after the previous inspection and no more than 14 months after the previous

inspections],

1. the facility has a valid certificate, and
2. the facility appears on FDA's certified facility list, and
3. the facility is providing mammography services (until a specified closing date which is more than 10 months from its previous inspection), then the inspection should be scheduled and conducted as usual prior to the specified closing date. If the inspector is unable to schedule the inspection before the facility's specified closing date, then the inspector should contact the FDA District Office and DMQRP so that a priority FDA inspection can be scheduled before the facility's specified closing date. If the facility has not notified its AB or FDA of its plans to close or cease performing mammography**,** the facility should be instructed to do so and to copy the inspector on that correspondence. If the facility has notified its AB or FDA of its plans to close or cease performing mammography**,** the inspector should request a copy of the correspondence.

If, on the day that an inspector contacts a facility to schedule its Annual Inspection [for a date no less than 10 months after the previous inspection and no more than 14 months after the previous inspections],

1. the facility has a valid certificate, and
2. the facility appears on FDA's certified facility list, and
3. the facility is *temporarily* not performing mammography services, then the inspection should be scheduled. However, the inspector can exercise discretion to delay the date of inspection to a point **no later than** the 14 month anniversary of the previous inspection if the facility is likely to be performing mammography again by that time. Otherwise, the inspection (which will consist of a "records review" since the x-ray unit and processor will not be in use) should be scheduled and conducted as planned.

If, on the day that an inspector contacts a facility to schedule its Annual Inspection [for a date no less than 10 months after the previous inspection and no more than 14 months after the previous inspections],

1. the facility has a valid certificate, and
2. the facility appears on FDA's certified facility list, **but**
3. the facility has *permanently* ceased performing mammography services, then the inspection should **not** be scheduled **unless** a compelling public health reason can be demonstrated to FDA. If the facility has not notified its AB or FDA of its closure (ceasing to perform mammography)**,** the facility should be instructed to do so and to copy the inspector on that correspondence. If the facility has notified its AB or FDA of its plans to close or cease performing mammography**,** the inspector should request a copy of the correspondence.

If, outside of the scheduling process described above, an inspector becomes aware of a facility that does not have a valid certificate or does not appear on FDA's certified facility list, but is performing mammography (or has performed mammography in the past while uncertified), the inspector should immediately contact the appropriate FDA District Office and DMQRP. The FDA District Office and DMQRP will coordinate the investigation and inspection of the uncertified facility (see FDA Compliance Program Guidance Manual, Compliance Program: 7385.014 - Mammography Facility Inspections).

If you have questions, please contact our Facility Hotline by electronic mail or by telephone.

2.4 When Certain Documents are Claimed but Unavailable for Review

When a facility is unable to furnish some of the required records at the time of the inspection, you should find out the reason why. Whenever possible, work with facility personnel and make sure that they would send you the missing documents as soon as possible, but before you upload the inspection results (within 5 days in most cases). In the meantime, you may defer answering the corresponding questions in the software until you have received and evaluated the missing documents. If the facility fails to provide you with the promised documents in the agreed upon time frame, you should answer the corresponding questions with "N," which would then result in actual citations. You should print and mail or fax the facility a final report (a revised report if you have left a preliminary report with the facility at the close of the inspection) showing the finalized inspection observations before uploading the inspection. You should also provide the facility with the appropriate "Inspection Handout" document (see Section 2.8).

For personnel documents, the facility is required to provide you with all personnel documents at the time of the inspection. If they are unable to do that without good cause, you should answer the corresponding question with an "N," which would result in a level 3 citation for not having such records on hand during the inspection. This citation is independent of how the individual questions regarding personnel qualifications are answered after completing the on-site inspection. This will be discussed further in Section 9. (PERSONNEL QUALIFICATIONS).

2.4.1 Claimed Items Use During Inspections

Since March 1, 2001, the Facility Inspection Support System (FISS) software has not allowed inspectors to use the Claimed "C" option. In the case where a facility is unable, at the time of the inspection, to supply proper documentation for personnel requirements or the medical physicist survey report, but claims that such documentation exists, the inspector should:

1. Leave the item blank. FISS will include this item in the missing data report.
2. The inspector should delay uploading the inspection for up to 5 business days. If the facility supplies the proper documentation, the inspection should be revised accordingly, uploaded to FDA as usual, and a printed post inspection report should be provided to the facility. If the facility does not supply the proper documentation within 5 business days, the inspection question(s) should be answered "NO". The inspection should then be uploaded to FDA as usual, and a revised post inspection report with the new non-compliance(s) should be provided to the facility.
3. With regard to personnel documents, the inspector should answer the question in Screen # 3.11.4 with a "NO." This answer should not be changed even if the facility provided the missing documents before uploading the inspection.

Note: In those cases where the facility's inability to provide the necessary documentation within the 5 day period is beyond the facility's control, the inspector should contact the facility hotline (1-800-838-7715 or MQSAhotline@hcmsllc.com) for further instructions.

2.5 Using the "Remarks" Sections

While the inspection software has been designed to capture a significant amount of detail concerning facility operations, there may be details that cannot be captured by using the answer options provided. To address this situation, inspectors can make use of the "Remarks" sections.

Examples of the type of information that may be recorded in these sections include, but are not limited to: clarification beyond a “yes” or “no” answer, failure to meet certain personnel requirements that can be expanded upon, requirements without matching inspection questions, equipment models that are not in the pull-down windows, and others.

The current software program has a “Remarks” screen that is accessible from any data-entry screen. You gain access to it by clicking on the “Notepad” icon in the upper right-hand side portion of all the data entry screens. The “Remarks” screen has two separate fields and you may copy or cut-and-paste information from one field into the other; 1) printable remarks, which will appear on the post-inspection report that the facility will receive, and 2) non-printable remarks, which will be part of the detail inspection record only. Each field has a limit of approximately 2000 characters for data entry.

While inspectors are encouraged to use the "Remarks" sections throughout the inspection screens, be aware that DMQRP staff and FDA field office personnel do not routinely access and review these sections. Therefore, do not use the "Remarks" screens as a mechanism for relaying messages to DMQRP or to FDA field offices. When you need to alert us about issues with a particular facility, you should send an e-mail message to the hotline, or call the FDA district or the hotline, or call us, as a last resort.

2.5.1 Remarks Section - What to Include

There are several reasons for using the Remarks feature in the inspection software.

Limitations of the Inspection Software

The inspection software used for conducting MQSA inspections has limitations. The numbers or YES/NO answers that are entered do not always tell a complete story regarding the inspection. In many cases, important details about facility conditions will be missed, unless the inspector uses the Remarks to record this useful information. For example, if an interpreting physician or radiologic technologist failed to meet a specific initial training requirement, the amount of training they actually obtained may be important when the facility responds to the observation. If an interpreting physician had one month of training in mammography and another had no training in mammography, the amount of training that is needed for these physicians to qualify is different. Also, the degree to which each failed to meet the requirement is different. In the area of quality control (QC) testing, the software only records the worst month for lack of processor QC data. If multiple months have data missing at the same level as this “worst” month, this information should be recorded in the Remarks.

Equipment – New or previously unknown models

While we try to keep the manufacturer and model tables in the inspection software up to date, inspectors may find new or unknown models of equipment. When an inspector finds that a manufacturer’s model of an x-ray unit or film processor is present at the facility, but is not on the list in the inspection software, he or she should make sure that the manufacturer name and model number are recorded in the Remarks.

Remarks do not replace e-mail

While the information recorded in the Remarks sections of the inspection is very useful, inspectors should not use the Remarks sections to send important messages to FDA. There are too many inspections and too many Remarks sections in each inspection for FDA to scan all inspections looking for messages to FDA. If an inspector needs to submit an important message to FDA, then he/she

should an e-mail message to the hotline, or call the FDA district or the hotline, or call us, as a last resort.

2.5.2 Additional Information for Level 1 and Level 2 Noncompliances

During an inspection, when serious noncompliances are found, it is important to record any information relating to these noncompliances in the REMARKS sections in the inspection software. Since no narrative report is produced as a result of the inspection, the only method to record information of this type is in the REMARKS sections. Normally, it will not be necessary to record additional information, such as when testing data leads to level 1 noncompliances. However, there may be additional supporting information that should be recorded when these other types of noncompliances are found, such as those relating to the medical audit, personnel, mammography reports, QC records, etc.

In the event that this additional information cannot be accommodated in the REMARKS sections, send an e-mail message to the Facility Hotline. This e-mail message should include the inspection ID number, the facility name, and a complete description of the issues. In the inspection software REMARKS section, you should state "ADDITIONAL INFO SENT BY E-MAIL."

2.6 Facility Grouping for Inspection Fee Consolidation

Some facilities, primarily mobile, may have several certificates (with the different ID numbers corresponding to different units). These facilities may be eligible for inspection fee consolidation. Sections 2.6.1 to 2.6.3 below contain additional information regarding inspection fees, the type of facility that is exempt from paying them, e.g., a Government Entity facility, criteria for facility grouping for inspection fee consolidation, conditions that mobile mammography facilities must meet for fee reduction, who should group eligible facilities for Inspection Fee Consolidation, and Billing Changes.

2.6.1 Inspection Fees

Clicking on the web address below, will take you to the web page in the Policy Guidance Help System (PGHS) where ample guidance regarding inspection fees is provided:

Link to PGHS

Governmental Entity Declaration Forms

Governmental Entity

Inspection Fee Consolidation

Mammography Inspection Fees

Mobile Mammography Facility Inspection Fee Reduction Fact Sheet

2.6.2 Inspection Fee Consolidation

Some certified facilities have contacted the MQSA facility hotline to request Group Billing for their annual inspections. As a reminder, grouping inspections for billing purposes must be performed by inspectors prior to uploading inspections.

Please use the FISS inspection software feature called "Grouping Inspections for Billing" for this purpose (Screen # 4.0 on your laptop). For assistance in how to enter data into this screen, please consult the "FISS 6.0 User's Guide" or any updated version of it on your laptops. As a reminder, the new software allows you to group only open inspections for this purpose.

2.6.3 Billing Changes

For changes in billing, please verify and modify the facility billing address and/or contact person at the time of the inspection (Screen # 3.3.4 in FISS). This step ensures that the inspection invoice is mailed to the proper contact, which may not be located at the facility. Please refer facility requests for other address changes to the accreditation body.

If you need technical support in grouping facilities or modifying the facility billing information on your laptop, please contact the Inspector Computer Support at 240-276-3323.

2.7 Repeat Observations

The inspection software will identify and list repeat observations at all three observation levels. An observation in the current inspection is termed a Repeat observation and denoted (REPEAT) if the facility was cited for the same observation during the previous inspection. Furthermore, the observation is considered a Repeat observation if it is of the same type of violation, whether or not it is part of the same entity (e.g., x-ray unit, processor, darkroom, interpreting physician, technologist, or physicist). For example, assume that x-ray unit #1 failed the Compression QC records review during the previous inspection (Level 3 observation). If either unit # 1 or unit # 2 fails the Compression QC records review during the current inspection, the new observation would be identified as a Repeat Level 3 observation. Likewise, if Technologist A did not meet the continuing education requirements of 15 CEU during the previous inspection (Level 2 observation) and if this requirement is not met during the current inspection by any technologist at the facility, the new observation would be identified as a "Repeat Level 2 observation."

Note: Some observations can be cited at one of two different levels (depending on the seriousness). Hence, if such an observation was cited at a given level (e.g., Level 2) during the previous inspection, and if the same observation type (as defined above) was cited during the current inspection at a higher level (e.g., Level 1), it will be recorded as a repeat violation at the higher level (e.g., Repeat Level 1).

2.8 Discussion of Inspection Observations with Facility Personnel (exit interview)

At the conclusion of the inspection, provide the facility with the printed report of the inspection observations, along with the "Important Information about Your MQSA Inspection" document (located in the document titled "Combined Inspection Information Sheet" on your laptop) reflecting the level(s) and type(s) of observation(s) found and checked off (Level 1/2/3, Repeat Level 1/2/3, or no observations). In general, you should discuss the following items with the appropriate facility contact(s):

- Inspection observations and their levels.
- The "Important Information about Your MQSA Inspection" document with the appropriate observation category checked off.
- Time frames for correspondence with the facility and the facility's written response.

- Differences (if any) between State and MQSA requirements (reporting time frames and reporting responsibilities).
- The importance of providing you with the pending documents (if any) within the agreed-upon time frame.
- Any inspection questions or comments facility personnel may have.

Whenever Level 1, Level 2, and/or Repeat observations are present, discuss them with the most responsible individual at the facility. This individual is the one who has the responsibility and authority to make major decisions regarding corrective actions and general mammography operations at the facility. If this individual is not available, discuss these observations with the highest official available. In the end, please record the name of this individual in the printable Remarks section. Additionally, record the name of the person whom you gave a copy of the Post Inspection Report, in Screen # 3.3.5 at the end of the inspection. For cases where you would send the Post Inspection Report to the facility at a later date following the inspection, please also record in this screen how the report was sent and the date it was sent. Also, record any additional information in the printable Remarks.

Explain the difference between the levels of observations and the appropriate time frame for responses at each level. In particular, make sure the facility understands its responsibility to provide any pending documents within the agreed upon time frame. For items that the facility has corrected during the course of the inspection, you should record this information in the appropriate printable Remarks section. However, these items should not be considered as "Corrected Before Inspection" items and therefore should be cited. Make sure to point out the appropriate State and FDA addresses in the documents, so that the facility knows where to send its responses.

Inspectors who are also conducting their State inspections, or who discover State violations during MQSA inspections, should make sure that these observations are identified as such. They should explain the difference between State and MQSA violations to facility personnel, and make sure that the staff understands the State violations and does not confuse them with MQSA violations. For further details on post inspection issues, see Sections 2.8.1 to 2.8.14 below.

For any questions you cannot answer on site, call your auditor or the Facility Hotline at 800-838-7715. For questions that do not require an immediate answer, e-mail the Facility Hotline (APPENDIX 4) for assistance. If the facility wants to make a specific comment on their inspection, direct them to call the Hotline at the above number or fax their comments at 410-290-6351.

Facilities may also refer to FDA's web site (http://www.fda.gov/cdrh/mammography) where we have placed several guidance documents, including the *"Policy Guidance Help System,"* "*Preparing for MQSA Inspections*" and, "*Mammography Facility Survey, Equipment Evaluation, and Medical Physicist Qualification Requirements Under MQSA."* Also, see additional guidance in Sections 2.8.1 - 2.8.14 below.

2.8.1 Inspection Citation Levels

When FDA designed the MQSA inspection program, we realized that some inspection observations would have a greater impact on the quality of mammography than others. For this reason, FDA adopted different levels of severity (or significance) for inspection observations.

There are three possible levels of observations resulting from an MQSA inspection. They range from Level 1 (representing the most serious noncompliances with MQSA standards) to Level 3 (representing minor deviations from MQSA standards).

A Level 1 observation indicates that the inspector found one or more deviations from MQSA standards that may seriously compromise the quality of mammography services offered by the facility.

A Level 2 observation indicates that the facility's performance is generally acceptable. However, the inspector did find one or more deviations from MQSA standards that may compromise the quality of mammography services offered by the facility.

A Level 3 observation indicates that the facility's performance is generally satisfactory. However, the inspection did show one or more minor deviations from MQSA standards.

If there are no observations, the inspection report will note "All Items in Compliance."

If any observations have not been corrected or have recurred since a facility's last MQSA inspection, they are identified as "repeat" observations.

2.8.2 Inspector Actions at the Facility after Completing the Inspection

Documents to Give the Facility. You should use only the current version of the Important Information about Your MQSA Inspection document, which you can find in the MQSA Documents folder on your laptop's Desktop. If you don't find this version there, try connecting again to MPRIS or contact the Facility Hotline. We have combined all previous versions into a single document. The previous seven versions were based on the highest level of inspection observation (Repeat Level 1, Level 1, Repeat Level 2, Level 2, Repeat Level 3, Level 3, and no adverse observations). With this new combined version, there is a check box at the beginning of four different sections that relates to the highest level of inspection observation. We have combined the observations as follows:

1. Repeat Level 1, Level 1, Repeat Level 2 – response within 15 working days
2. Level 2, Repeat Level 3 – response within 30 working days
3. Level 3 – no response needed, corrections checked during next inspection
4. No observations - no response needed.

Please check the appropriate box on the document before giving it to the facility with the inspection report.

1. **Recording Name of Person Receiving Report and Date.** We have added the name and title of the facility person given or mailed the inspection report, as well as the delivery method, and the date it was given or mailed. The FISS inspection software captures this information in Screen # 3.3.5 (Inspection Report Contact), which was added in 2005.

2.8.3 Facility Personnel Responsibility Re Inspection Observations Follow-Up

The most responsible individual connected with the violation(s) is the person at the facility who has the duty and power to make major decisions regarding corrective action and general operations. Major decisions can include the power to approve the purchase of expensive equipment (e.g. a new x-ray system), hire and fire personnel (e.g., interpreting physicians, radiologic technologists or medical physicists), and order as well as assure the implementation of significant quality assurance changes at the facility.

As an example, the chairman of a radiology department at a facility may report to a medical director or

an administrator. However, if the chairman of the department has the power to make the types of decisions mentioned above, the chairman is considered the most responsible individual connected with the violation. In this particular example, if serious noncompliances were found (listed in Attachment D of Compliance Program 7382.014, Mammography Facility Inspections, under Level 1), a Warning Letter would be addressed to the chairman of the department. Copies of the Warning Letter should always be sent to the addressee's superior (e.g. medical director) and to the highest known official in the organization (e.g. administrator or chief executive officer).

For MQSA inspections, the name and title recorded in the block for "responsible individual for compliance" would be the most responsible individual connected with the violation as described above. However, the inspection record must also include the name, title, and address of the highest official in the corporation, firm, facility, or organization; this information should be identified in the Remarks section of the Compliance Contact Data screen.

Highest Official for a Facility —There may be additional people who should get copies of the Warning Letters (i.e., the corporation president or hospital administrator might get a copy of the Warning Letter sent to the chief of radiology). In those facilities where the most responsible individual for mammography, as defined above, is different than the highest official in the corporation, organization or facility, please indicate the name, title, and mailing address of this individual(s) in the Remarks section of the Compliance Contact Data screen in the inspection software.

2.8.4 Documentation and other Issues Related to Inspection Observations

Whenever Level 1 observations are found during an inspection, supporting documentation (copies of facility documents) should be collected and forwarded to FDA or the Certifying State, when applicable. There are exceptions. Copying of documents would not normally be required when findings are generated from equipment testing during the inspection. Also, when an observation due to the failure by the facility to maintain certain records is found, there would probably be no records to copy. When no medical physicist survey has been conducted, there should be nothing to collect. However, in other areas, such as the quality control records or the personnel records, the noncompliance found may show up while inspecting these records. In these cases, the copies of these records should be collected as evidence to support the observation.

To identify the copies, mark them with the facility name, the date of the inspection, the inspection ID number, and inspector's name or initials.

2.8.5 Inspection Findings Disputed by Facilities

In some cases, the facility may disagree with the inspector's observations. The following guidance pertains to these situations.

Note that when a facility has been cited as the result of an MQSA inspection, regardless of whether it is a Level 1, Level 2 or Level 3 observation, the facility has the right to disagree with inspection observations.

Level 1 and Level 2 Observations

For Level 1 and Level 2 observations, the facility is requested to submit a written response to the observation(s). If the facility disputes an inspection observation(s), please follow these steps.

1. When a facility notifies the FDA district office in writing of a disagreement with the observations from an inspection, the FDA district should obtain any needed additional information from the facility about the disagreement and then contact the State and/or inspector to discuss the inspection

observations. After reviewing all the information, the FDA district will determine whether the inspection observation was justified.

2. If it is determined that the inspection observation was not justified:

   a) The inspector should download the inspection record, correct the inspection data, and upload the corrected inspection record within 10 days after being informed of the need for correction. A new MQSA Facility Inspection Report should be printed and submitted by FAX or mail to the FDA district office.

   b) The FDA district office should respond to the facility by letter (a phone call is optional) with regard to the disputed observation(s), indicating that FDA agrees with the facility, and that the inspection data has been modified to reflect the correction(s). The revised MQSA Facility Inspection Report should be included with the letter to the facility.

   Note: The facility should not be informed of any changes before the revised inspection data has been uploaded to MPRIS.

3. If the inspection observation was justified:

   a) If the matter pertains to a disagreement regarding policy, the FDA district office should contact DMQRP, via e-mail, regarding the dispute. Facts concerning the disputed observations should be included with this e-mail.

   b) If the matter pertains to a disagreement regarding facts or data for the inspection, the FDA district office should resolve the disagreement by contacting the facility and the State. The district office may contact DMQRP for additional guidance, when needed.

   d) If the inspection observation is correct, the district office should send a letter to the facility indicating that FDA supports the observations of the inspection and that the facility has a responsibility to correct the problems found. In those cases where contact has been made with DMQRP regarding the inspection, this should be stated in the letter to the facility. If a Warning Letter was sent and the disagreement arose from the letter, the response back to the facility should reiterate the intent of the FDA to take action should the facility fail to comply with MQSA.

Level 3 Observations

Level 3 observations are the least severe and do not require a response by the facility. However, many facilities will respond to these observations by letter to either the State or FDA. If the facility disputes a Level 3 observation, then the steps listed above should be followed.

2.8.6 Inspection Errors Discovered by FDA or the State

Inspection records containing errors need to be corrected, regardless of whether the observation(s) was disputed by the facility. In cases where errors are found by the FDA or the State, rather than the facility, the inspector should 1) correct the inspection record, 2) print the report, 3) upload the revised record to MPRIS, and 4) mail or FAX the report to the facility along with either a note or letter from the State explaining that a correction of the report was necessary. The State or the inspector may also call the facility about the correction, as long as the revised report is mailed before or after the call.

Note: Inspectors and facilities in Certifying States should contact their State Certifying Agency to determine the policies that apply to them.

2.8.7 Recording State vs. MQSA Requirements

FDA understands that it is both more efficient for inspectors and less disruptive for facilities when the State and MQSA inspections are performed back-to-back. However, it is important that inspectors take special care in communicating with facility personnel regarding which observations are State requirements versus MQSA requirements. This means that inspectors should clearly state when a citation is a State noncompliance and when a citation is an MQSA noncompliance.

Additionally, State noncompliances should not be listed on the MQSA Facility Inspection Report (including the printed Remarks sections), in the inspection cover letters, or any other documents created for the MQSA inspection program. All State noncompliances should be placed on the appropriate State forms, documents, or letters to the facility.

2.8.8 Advice to a Facility Following a Serious Citation

When a serious problem (such as a Level 1 observation) is identified at a facility, the inspector should tell facility personnel that, in the interest of public health, he/she recommends they discontinue using the equipment, personnel, or practice that resulted in this serious noncompliant observation. The inspector should also mention that there are sanctions which the facility could be subject to should the noncompliant observation continue.

Examples of sanctions include the imposition of a Directed Plan of Correction (specific orders by FDA identifying how a facility must correct their noncompliant observation(s)), civil money penalties (up to $10,000 per day per noncompliance), suspension or revocation of their MQSA facility certificate, or an injunction. The inspector may also indicate that continuing to use or to perform the cited item while the violative condition exists adds to the violations already found and that it would be in the best interest of the facility to correct the problems immediately.

Background:

DMQRP staffs have received questions from inspectors about what to tell a facility with serious findings and whether or not the inspector should tell the facility to stop using certain personnel or certain equipment. When these questions arose, the standard response had been that inspectors cannot, using their authority under MQSA, order a facility to stop any practice that is or appears to be in violation of MQSA. Examples of these practices include (but are not limited to) using the services of unqualified personnel, using equipment which produces sub-standard phantom images, or using film processors which are out-of-limits.

During routine inspections, FDA does not delegate to inspectors or investigators the authority to make specific directives to a facility about what they must do concerning a noncompliance(s). While some inspectors believe they have the responsibility to make sure that a facility has stopped a practice that is in violation of MQSA, it is in fact, the facility's responsibility to comply with MQSA, and it is the inspector's responsibility to document these noncompliant items during the inspection process.

Supplemental Information Regarding State Authority:

Some states delegate authority to their inspectors to order a facility to stop a violative practice or to stop performing mammography. The guidance described above is not designed to limit a state from exercising its authority with a facility that has been found to be in violation of state law or to prohibit state inspectors from exercising any authority delegated to them by state laws, regulations, or policies. However, when a state inspector takes such action at a mammography facility during an MQSA inspection, the inspector must make it clear to facility personnel that he/she is acting under and enforcing state laws and not representing MQSA.

2.8.9 Advice to Facilities Regarding Corrective Actions

While many inspectors have backgrounds in radiologic technology, equipment service and/or quality control, an inspector should not tell a facility what he or she believes is the source of the noncompliance or try to help the facility diagnose their problems. It is one thing to point out obvious light leaks in a darkroom that has a fog problem or stained or dirty view boxes. However, it is entirely different to suggest to a facility that it replace a motor in their processor, a filter in their mammography system, or to alter their clinical technique factors. Inspectors should be very careful not to give facilities suggestions or advice that could lead to costly repairs which may not fix the problem or which might, in fact, compromise image quality. Please leave it up to facility managers, service engineers, and/or the medical physicist to evaluate how to correct technical problems of this nature.

2.8.10 Responding to FDA after Inspections (Letters with Inspection Report and Facility Comments)

Facilities need to understand how to respond if they have received an adverse observation(s) during their inspection. Facilities need to respond in writing to any inspections with higher than a Level 3 observation. For repeated Level 1, Level 1, and repeated Level 2 observations, the facility should respond within 15 days after they receive their inspection results. For Level 2 and repeated Level 3 observations, the facility should respond within 30 days after they receive their inspection results. Non-repeated Level 3 observations do not need to be addressed in writing. However, these observations must be corrected and these corrections would normally be checked during the next annual inspection. Inspectors and facilities in Certifying States should contact their State Certifying Agency to determine the policies that apply to them. The inspector should make sure that facility personnel understand what they should do and/or what will happen after the inspection is over.

Corrective Action Communication:

For any facility inspection, the inspector should give facility personnel two separate documents:

1. A cover letter~~s~~ entitled "Important Information about Your MQSA Inspection" (with the appropriate section checked off by the inspector)
2. The post-inspection report (MQSA Facility Inspection Report).

These documents, along with verbal instructions, should be issued to the appropriate personnel at the facility. Inspectors are strongly encouraged to attempt to discuss the observations with the most responsible individual (official) available at the time of the inspection. The inspector should also explain how to submit the facility response to the appropriate FDA district (or regional) office (or State Certifying Agency where applicable), with the State radiation control office receiving a copy. The inspector might also mention that the facility response to the inspection observations should not be sent to the Division of Mammography Quality and Radiation Programs (DMQRP) address in Rockville, Maryland or the FDA address in Columbia, Maryland. That address should only be used if the facility intends to comment on the inspection process in general. Inspectors and facilities in Certifying States should contact their State Certifying Agency to determine the policies that apply to them.

Facility Comments/Questions:

Facilities should be instructed only to use the Facility Hotline number (1-800-838-7715) for general comments about the inspection process and general MQSA questions, not to ask questions about a specific inspection. If personnel at a facility have questions about a recent or upcoming inspection, they should contact the MQSA Inspector who conducted or will conduct the inspection, or the State radiation control office. If the inspector cannot answer the questions, the FDA district office, DMQRP

or State Certifying Agency should be contacted.

2.8.11 Copying Records during Inspections and Using Remarks

Our FDA field offices have asked us to remind our inspectors to routinely copy facility records relating to inspection observations and explain their observations in the appropriate "Remarks" section of the inspection software. By providing this information, we can compare facilities' responses to specific inspection observations and records you have provided. (Please see references to this topic in the Policy Guidance Help System under Documentation and Other Issues Related to Inspection Observations and, Additional Information for Level 1and Level 2 Noncompliances under the main topic "INSPECTION" and sub-topic "REPORT").

Please follow the guidance provided below for any inspection where a written response is required (i.e., highest observation is Level 1 or 2, as well as repeated Level 3):

Personnel Records – Personnel observations are very common. Often, facilities do not have the required documentation (for example, continuing medical education). If no records are available, obviously there is nothing to copy. However, for those inspections where you detect problems with a facility's records, please copy them and send them to the FDA field office after your inspection has been completed. In the "Remarks" section, you should record all relevant information regarding the inspection observations. For example, you may need to record the total number of hours or credits someone earns when they started working at the facility and if the facility had corrected their problem(s). Please also include any other information you feel would be helpful.

Quality Control (QC) Records – As with personnel records, you may find that a facility has not performed one or more tests when required. In this case, there may be nothing to copy. However, for most inspections, you will evaluate records documenting the problem. Therefore, please copy these records. For processor and phantom QC, make sure to copy all charts with missing or noncompliant data since the last inspection. Also, in situations where the software does not capture information you feel important, please use the "Remarks" section to document your observations (for example, problems with a facility's test equipment, or procedures).

Medical Physicist Survey Report – Ordinarily, you only need to make copies of specific pages with questionable tests. For survey reports with numerous problems, you may need to copy the entire report. For general questions in the software, such as "Action taken (if called for in Report)?" please record in the "Remarks" section how a facility failed to meet the regulations.

Medical Records – Please copy mammography reports or letters that indicate problems. However, **please ensure that patient-specific information (patient names, addresses, and telephone numbers) is removed from the copies before removing the copies from the facility or sending them to the FDA field office.** Additionally, there may be situations where you need to copy a facility's procedure for issuing reports and letters. Again, in the "Remarks" section, please explain the problems you observed with a facility's procedures, reports, or letters.

Quality Assurance Procedures – When you encounter problems with the medical audit, infection control, and consumer complaint procedures, please copy the records showing the problems. In the "Remarks" section, please explain why you cited the facility for these problems with their procedures.

There may be other situations not listed above where copying records or providing additional information in the "Remarks" section would be important. Whenever in doubt, please copy the records or record the information in the "Remarks" section.

The following table, which was sent to all inspectors as part of a memo dated 8/29/03, gives examples of documents to copy in support of a particular observation:

Inspection Observation	Examples of Records Supporting the Violation to Copy
Level 1 Observations	
X-ray system not accredited for over one year	Mammography film labels (mammographic image identification labels on the film. These should copy on the copier)*
	Copy of FDA form 2079 (Report of Assembly)
Uncertified facility	Mammography reports or Mammography film labels (mammographic image identification labels on the film. These should copy on the copier)*
	Mammography log book pages showing mammograms and dates*
Interpreting physician medical license	License, letter, or pocket card
Interpreting physician board certification or 2/3 months training	Attestations, letters, training certificates, transcripts, continuing medical education documents, or board certificates
Radiologic technologist State license or certification	State licenses, attestations, letters, training certificates, or board certificates
Medical physicist license or approval by a State or certification	State licenses, attestations, letters, training certificates, or board certificates
Medical physicist degree - masters degree or higher (bachelors degree or higher prior to 4/28/99)	Attestations, letters, training certificates, transcripts, or diplomas
Medical physicist - 10/20 hours in physics	Attestations, letters, training certificates, transcripts, or diplomas
No system to provide timely mammography reports	Mammography reporting procedures, log books*, or mammography reports*
No system to provide lay summaries	Patient letters, facility procedures, or log books*
No system to communicate serious or highly suggestive cases as soon as possible	Mammography reports, facility procedures, or log books*
Processor QC records missing	All processor QC charts for that processor since last inspection with missing days
	Copies of mammography reports, film labels with dates, or patient logs* (to show that mammography was done on missing days)
Mammograms processed when processor was out of limits	All processor QC charts for that processor since last inspection when processor was out of limits with no corrective action
	Copies of mammography reports, film labels with dates, or patient logs* (to show that mammography was done on missing days)
Phantom QC records missing	All phantom QC charts for that x-ray system since last inspection with missing weeks
	Copies of mammography reports, film labels with dates, or patient logs* (to show that mammography was done on missing days)

Physicist survey for x-ray system overdue for two years	Most recent survey report (or coversheet with date) for system
Level 2 Observations	
X-ray system not accredited	Mammography film labels (mammographic image identification labels on the film. These should copy on the copier)* (showing mammography unit identification)
Interpreting physician mammography education (40/60 hours)	Attestations, letters, training or continuing medical education certificates, or transcripts
Interpreting physician initial experience (240 mammograms in 6 months)	Attestations, letters, or facility tables of mammograms read
Interpreting physician continuing experience (960 mammograms in 24 months)	Letters, facility tables, or facility logs of mammograms read
Interpreting physician continuing medical education (15 Category I credits in 36 months)	Letters, training certificates, continuing medical education certificates, or attestations
Interpreting physician new modality training	Letters, attestations, training certificates, or continuing medical education certificates
Radiologic technologist mammography training	Attestations, letters, training certificates, continuing medical education certificates, or transcripts
Radiologic technologist continuing medical education (15 units in 36 months)	Letters, training certificates, continuing medical education certificates, or attestations
Radiologic technologist continuing experience (200 mammograms in 24 months)	Letters, facility tables, or facility logs of mammograms performed
Radiologic technologist new modality training	Letters, attestations, training certificates, continuing medical education certificates
Medical physicist 20/40 hours survey training	Attestations, letters, training certificates, continuing medical education certificates, or transcripts
Medical physicist initial experience (1 facility and 10/20 units)	Attestations, copy or coversheet of survey, letter from facility, or listing from company providing the physics survey services
Medical physicist continuing medical education (15 credits in 36 months)	Letters, training certificates, continuing medical education certificates, or attestations
Medical physicist continuing experience (2 facilities and 6 units in 24 months)	Survey report or coversheet of survey, letter from facility, or listing from company providing the physics survey services
Medical physicist new modality training	Letters, attestations, training certificates, continuing medical education certificates
Mammography reports unsigned by interpreting physician	Mammography reports*
Mammography reports without assessment category	Mammography reports*
Processor QC records missing	All processor QC charts for that processor since last inspection with missing days

	Copies of mammography reports, film labels with dates, or patient logs* (to show that mammography was done on missing days)
Mammograms processed when processor was out of limits	All processor QC charts for that processor since last inspection when processor was out of limits with no corrective action
	Copies of mammography reports, film labels with dates, or patient logs* (to show that mammography was done on missing days)
Phantom QC records missing	All phantom QC charts for that x-ray system since last inspection with missing weeks.
	Copies of mammography reports, film labels with dates, or patient logs* (to show that mammography was done on missing days)
Phantom QC testing not at clinical setting	Phantom QC chart, phantom QC procedure, or mammography film label (if settings on label) and a copy of the technique chart for the unit
Phantom QC background density < 1.20	Phantom QC charts
No corrective action for failed QC phantom	All phantom QC charts for that x-ray system since last inspection with phantom failures with no corrective action documented
	Copies of mammography reports, film labels with dates, or patient logs* (to show that mammography was done on missing days)
Medical physicist survey with missing tests, missing data, incorrect settings, or failure to take correct action	Survey report or specific pages from report showing problems or test failures
Full-Field Digital Mammography (FFDM) – Failure to follow manufacturers QC procedures for x-ray unit, monitor, laser printer, and/or other display device	Forms/charts from FFDM manufacturer's QC manual and a copy of the manufacturer's user specifications specific to the QC procedure not being followed
Performance verification test after each mobile unit move	Route schedule and patient log that shows location of unit on date in question; Phantom QC chart or other record to record phantom scores or mAs readouts
Overdue medical physicist survey (14 months)	Most recent or two most survey report(s) (or coversheet(s) with date) for system
Medical physicist not identified in survey report	Survey report or coversheet
Infection control procedure	Written procedure, forms, logs or charts and a copy of the unit manufacturer's recommendations
Medical Outcomes Audit – no examples/ attempts to get biopsy results	Printouts, forms, logs, charts, or contact records
Medical Outcomes Audit – positives not entered	Positive mammography reports, printouts, forms, logs, or charts
Medical Outcomes Audit – no review interpreting physician	Procedure, printouts, forms, logs, or charts
Consumer complaint procedure	Written procedure, forms, logs, charts, or copies of patient complaints

Repeat Level 3 Observations	
QA program is missing personnel responsibilities, QC test procedures, and/or current technique tables/charts	List of personnel responsibilities, facility procedures for QC, technique tables/charts
Fixer retention QC, repeat analysis QC, screen-film contact QC, compression device QC, and darkroom fog QC	QC charts or records since last inspection showing frequency of tests and problems with tests
Medical physicist survey with missing tests, missing data, incorrect settings, or failure to take correct action	Survey report or specific pages from report showing problems or test failures
No corrective action for survey test failures	Survey report or specific pages from report showing both test data, final calculated results, and failure indication/statement by medical physicist

*** Patient names and identification MUST be removed from all copies.**

If you have any questions, please contact the Facility Hotline. As a reminder, our web site address is: http://www.fda.gov/cdrh/mammography.

2.8.12 Veteran Health Administration (VHA) Inspections

For inspectors that conduct VHA Inspections, please give a copy of the post inspection report to the VHA facility representative at the end of the inspection. After you have uploaded the inspection to MPRIS, FDA will send the full inspection report to the VHA and they, in turn, will follow up with the facility on any inspection observation (s) found by the inspector.

If you have any questions, call the Facility Hotline.

2.8.13 Corrected Before Inspection (CBI) Policy

An inspector should not routinely cite a facility for Level 2 or Level 3 non-compliant observation(s) that occurred since the last inspection and were then corrected before the current inspection. These corrected problems could be in any part of the inspection. The most likely areas where this policy could be applied would be for quality control testing or personnel qualifications. Consideration needs to be given to those facilities that discover and correct their problem(s) before the problem(s) gets worse. Inspectors should use the printable Remarks Section to record the problematic observation(s) and verify that it had been CBI. During the exit interview at the end of the inspection, the inspector should remind facility personnel that the noncompliance should not be allowed to recur. The historical record entered into the Remarks Section(s) and the discussion during the exit interview is important, should the facility have serious problems later and FDA considers action against the facility in the future.

Since inspector observations and judgment are crucial in making a determination as to whether a facility has permanently corrected a problem, the following examples are provided as some guidance to help the inspector in making this determination.

When a noncompliance is found to have previously occurred, but is no longer present at the time of the inspection, the facility should be able to provide an explanation of what actions were taken to correct the problem. If facility personnel do not know why/how the problem was resolved or do not even know the problem existed, an inspector may assume that the noncompliance was not corrected by actions of the facility personnel. Furthermore, non-compliant item(s) that are corrected during the inspection ("on-the-spot" corrections) are not to be treated as though they were "corrected before inspection." So in both of the above scenarios the facility should be cited (i.e., the non-compliant item

not having been identified as a problem by facility personnel with actions taken to permanently correct it, and/or the correction of a non-compliant observation at the time of an inspection).
There is another example when inspectors should cite a facility. This is when there was a non-compliant observation cited during the prior year's inspection, the facility corrected the problem after that inspection, then the same noncompliance occurred again, and was again corrected by the facility. While this facility has corrected the problem(s), its corrective actions did not result in a permanent fix, and as such, the noncompliance is likely to occur again. In this type of situation, the facility should be cited.

Note: the above policy does not apply to Level 1 observations. Level 1 observations, even if corrected before the inspection, should still be cited.

2.8.14 Facilities Comments Concerning Their Inspections

The Division of Mammography Quality and Radiation Programs (DMQRP) is very interested in, and continually looking, for comments from facilities regarding their inspection and/or inspector (both good and "not-so-good"). We use such information to assess MQSA's progress and to learn which areas in our program require adjustments and improvements.

Since MQSA inspectors are in direct contact with facilities, we ask inspectors to be aware of our need for facilities' comments and we ask that you encourage each of your inspected facilities to contact us. Facilities may contact us either by using FDA's Hotline toll-free 1-800-838-7715 telephone number (callers may choose to remain anonymous) or, by sending written comments to us by FAX (240-276-3272) or mail at the address below.

We also encourage you to share with us any written comments that you receive. If facilities provide comments included in the facility response letters to inspection findings or send your office a separate letter, we would like you to share these comments with us.

If you have written comments from facilities that you would be willing to share with us, please fax them to 240-276-3272 or mail them to us at:

Center for Devices and Radiological Health
Division of Mammography Quality and Radiation Programs
1350 Piccard Drive – HFZ-240, Rockville, MD 20850.

3. PRELIMINARY INFORMATION AND DATA RECORDING

3.1 General

Although the tests and record reviews are listed in a certain order, you may choose a different one.

Ask for assistance from facility personnel for operation of the x-ray unit(s), cassette loading, film-processing, general assistance in the darkroom, retrieval of medical records, and other areas. An inspection kit is provided for each inspector. See "Further Details," Section 1.1, for the parts list.

Verify that all screen-film (S-F) phantom images taken during the inspection and for the weekly QC test use the facility's most commonly used clinical technique that corresponds to a craniocaudal (CC) examination of the Standard Breast, which is defined in the Glossary. Note however that, for Full Field Digital Mammography (FFDM) units, the phantom image procedures must follow the FFDM unit manufacturer's QC manual. See detailed guidance in Section 4.2.D.

If a facility is using more than one accredited x-ray system and associated processor and/or darkroom for mammography, test each one and review the appropriate QA/QC records for each. If a facility has more than one site under the same certificate (e.g., mobile facility), you need to review the records and conduct the applicable system performance tests for each site.

Whenever you review records that contain patient names, protect patient privacy. If it becomes necessary to photocopy records, conceal patient names to ensure confidentiality.

3.2 Data Recording

Record all data in the appropriate screens of your laptop computer as described below. Hard copies of all data entry computer screens can be accessed on your laptop by opening the latest version of the file: "FACILITY INSPECTION WORKSHEET" and making copies of each when necessary or as supplements to your laptop.

3.2.1 Inspection Outline

For a comprehensive review of the software program and how to navigate through the various screens, please consult the "Facility Inspection Support System (FISS) User's Guide Version 6.01" and "FISS Version 6.01 Release Notes," which are in the "MQSA Documents" folder on your laptop. These versions of the User's Guide and Release Notes describe several corrections and enhancements to the previous software and give guidance regarding the use of the FISS software and describe specific behind-the-scene changes in the program. The main focus of the guidance provided in this document is on answering the inspection questions using the FISS 6.01 software.

The inspection software program outline is shown in the table on the next page, Exhibit 1. When you open the FISS Version 6.01 file, you will find this outline on the left-hand side of your laptop screen as a list of screens and sub-screens corresponding to the various inspection categories.

While this document describes the inspection process in the order listed in the outline, you do not have to follow this order when conducting an actual inspection.

The focus of this document is to describe the steps you need to take to conduct an annual inspection. In the following table (titled Inspection Program Outline), Screen 1.0 covers inspector information, such as name and address (1.1) and equipment registration (1.2) and Screen 3.0 covers the inspection process itself. Most of the Screens 3.1 - 3.14 have multiple tabs, each of which can be selected for specific data entries corresponding to different inspection details. Some have only one data entry screen. Sub-screens 3.3, 3.9, and 3.14 are not for data entry, but are intended to provide you with a duplicate listing of the topics covered under each.

Facility Inspection Download (Screen 2.0), Grouping Inspections for Billing (Screen 4.0), and Facility Inspection Upload (Screen 5.0) are discussed in the FISS User's Guide (Version 6.01).

Once you have downloaded one or more facilities for new inspection(s) (using Screen 2.0 instructions), preliminary information on such facilities will be transferred from the Mammography Program Reporting and Information System (MPRIS) to your laptop. At a minimum, this information consists of facility type, name, address, phone and fax numbers, name(s) of facility contacts, and other accreditation information forwarded to the FDA from the AB's computer system. For facilities that have had prior inspections, additional information that is not likely to change since the most recent inspection will also be transmitted. Also, the most recent inspection for each of these facilities will be automatically downloaded to your laptop as a "view" (only) inspection.

Note that throughout the program, if a data entry field is gray (read-only), you cannot edit or update the information in it. If it is white, you can update it. If it is yellow, you must fill-in the required data (including updates) before you can upload the inspection into MPRIS.

For additional information, see "Further Details," Section 3.3.

Exhibit 1: Version 6.01 Inspection Program Outline

(Displayed on the left-hand side of your laptop screen)

FISS General Information

- **1.0 Inspector Information**
  - 1.1 Name and Address
  - 1.2 Equipment Registration (Densitometer, Sensitometer, X-ray Monitor (disabled), Mammography Probe (disabled), Phantom, Film)
- **2.0 Facility Inspection Download**
- **3.0 Facility Inspections (List, Facility, Address, Inspection)**
  - 3.1 Aliases
  - 3.2 Additional Sites (List – if applicable, Information)
  - 3.3 Contacts
    - 3.3.1 Facility Accreditation Contact
    - 3.3.2 Facility Inspection Contact
    - 3.3.3 Compliance Contact
    - 3.3.4 Billing Contact
    - 3.3.5 Inspection Report Contact
  - 3.4 Related Equipment (Densitometer, Sensitometer, X-ray Monitor (disabled), Mammography Probe (disabled), Phantom, Film)
  - 3.5 Units (List – if more than one, Information, Screen-Film, Evaluation)
  - 3.5.1 Collimation Assessment (disabled)
  - 3.5.2 Dose Estimate (Tech. Factors, Cassette Variability, Reproducibility, Beam Quality [HVL]) (disabled)
  - 3.5.3 Phantom Image Quality Evaluation (Image 1, Image 2)
  - 3.6 Processors (List – if more than one, Information, Evaluation, STEP Test)
  - 3.7 Darkrooms (List – if more than one, Information, Evaluation)
  - 3.8 Quality Assurance (Sites, Evaluation)
  - 3.9 Quality Control
    - 3.9.1 S-F Processor Performance QC (List – if more than one, Evaluation [Processor QC records, Fixer retention QC])
    - 3.9.2 Phantom Image QC (List – if more than one x-ray unit, Evaluation)
    - 3.9.3 Compression QC (List – if more than one x-ray unit, Evaluation)
    - 3.9.4 Repeat Analysis QC (Sites, Evaluation)
    - 3.9.5 Screen Film Contact QC (Sites, Evaluation)
    - 3.9.6 Darkroom Fog QC (List – if more than one, Evaluation)
    - 3.9.7 Digital Mammography QC (List – if more than one digital x-ray unit, Evaluation)
  - 3.10 Survey Report (List – if more than one x-ray unit, Information)
    - 3.10.1 Survey Report Part 1
    - 3.10.2 Survey Report Part 2
  - 3.11 Personnel (List – all personnel)
    - 3.11.1 Interpreting Physicians (List – if more than one, Evaluation)
    - 3.11.2 Technologists (List – if more than one, Evaluation)
    - 3.11.3 Medical Physicists (List – if more than one, Evaluation)
    - 3.11.4 Summary (Evaluation)
  - 3.12 Medical Records (Sites, Evaluation)
  - 3.13 Medical Audit and Outcome Analysis (Sites, Evaluation)
  - 3.14 Inspection Completion
    - 3.14.1 Missing Data Report
    - 3.14.2 Inspection Detail Report
    - 3.14.3 Post Inspection Report
    - 3.14.4 Remarks Report
- **4.0 Grouping Inspections for Billing**
- **5.0 Facility Inspection Upload**

3.2.2 Equipment Registration

Prior to each inspection, ensure that the data regarding calibration of your inspection equipment is accurate, and record it in Screen 1.2 (Equipment Registration) of your laptop program. When you select "Equipment Registration" in your laptop outline, you will gain access to multiple screens that correspond to each item in the inspection kit that needs periodic updating, e.g. you may need to update the following information:

- *Serial numbers for:*
  - *Sensitometer*
  - *Densitometer*
  - *Phantom (in the wax insert)*
- *Reference Step Number for the control film (will be automatically copied in the STEP test screen).*
- *Emulsion number for the control film*
- *Calibration Dates (for the sensitometer and densitometer)*
- *Calibration Report Number (if applicable).*

NOTE 3-1: Information regarding the manufacturer and model number for the equipment provided in the kit is pre-recorded as the default settings in the program. Also, the phantom information to be entered is about the FDA phantom provided in the inspection kit and not about the facility phantom that you will routinely use during the inspection. If you need to capture some unusual information about the facility's phantom, use the Remarks section.

NOTE 3-2: Once you have recorded the information in each of the screens under this section, you need not repeat it for your next inspection(s) until you receive a new control film or re-calibrate your equipment. In other words, this kit equipment will be identified as yours on your laptop. However, when you download a facility record for a new annual inspection using Inspector X's laptop, you will be prompted to re-enter the information for the kit equipment you are using in this inspection, even when you are using Inspector X's kit for it. In this case, you should verify that the equipment calibration information corresponding to this inspection is correctly updated. To verify, select Screen 3.4 (**Related Equipment**), select the equipment you want to check (the screens here are identical to those in Screen 1.2 except that the information type is read-only), and click on the "**Update Equipment**" button in the upper right-hand portion of this screen. Please note that this feature is not available when you download for edit or view.

If you are using approved and calibrated equipment other than what is provided in the inspection kit, then, in addition to the above data, you should also record:

- *Manufacturer's name*
- *Model number*

Additional information may be found under Section 3.3.3 (Calibration Criteria).

3.2.3 Preliminary Facility and Inspection Information

When you select and double-click on Screen 3.0 (Facility Inspections), a screen by the same title is displayed on the right-hand side of your laptop. Near the top of this screen the following tabs are displayed sequentially: List, Facility, Address, and Inspection. When you click on the "**List**" tab, a listing of the facilities that you had downloaded earlier from the MPRIS computer (see FISS Version 6.01 User's Guide) will appear on the screen. This listing gives the following information for each facility:

- Inspection ID
- Date of last inspection
- Date the inspection was uploaded
- Mode (whether you checked it out to **edit** or **view** a previous inspection, or to conduct a **new** inspection)
- Facility Name
- Type of Inspection (Annual, , Follow-up (Fee-Based), Compliance (Non-Fee-Based), Independent audit, Headquarters initiated)
- Facility ID, FEI (CFN in prior FISS versions), EIN, Street Address, City, State, & Zip Code.

To start a facility inspection, you need to click on (highlight) any tab on this list that corresponds to the selected facility you had earlier downloaded as "**new.**" Note that the name and inspection ID of the facility that you highlighted will be displayed in the top portion of the screen. This information will continue to be displayed on all subsequent inspection screens and will not change unless you select a different facility.

Next, verify the accuracy of information downloaded to your laptop regarding the facility. To do that, click on the Facility field and update (if necessary) the following information:

- ***Certificate***

  Displayed? (y/n)
  Expiration Date (mm/dd/yyyy) [pre-filled]
  *Operating with a valid certificate? (y/n)**

  * The answer to the last question would be defaulted to "n" if the expiration date is blank or is prior to inspection date and would be defaulted to "y" if the expiration date matches or follows the inspection date.

- ***Facility Identification*** *(typically pre-filled)*

  Name
  ID
  FEI (CFN)
  EIN

- ***Facility Category***

  Non Federal
  *Federal (*pop-up window with multiple options)

- ***Facility Type***

(pop-up window with multiple options)

Next, click on the Address tab. Note that the street address, city, state, and zip code are gray and you cannot update them directly. However, if you click on the "**Address Changes...**" button, a new screen entitled "**Enter Facility Address Changes,**" with white fields, will be displayed and should be used for this purpose. Note that the address changes you enter in this screen will not be automatically sent to the AB and therefore, you should inform the facility that it is their responsibility to advise their AB of any changes in their address. Let the facility know that only their AB can modify this information in the database.

Next, click on the Inspection tab and update the following information:

- **Inspector Name & ID #**
  Date (of inspection)
  Inspection Time (hours)
  – *On-Site*
  – *Other*
  Travel Time (hours)
- **Annual Inspection Type**
  Basic (the routine annual inspection)
  Joint Audit
  Mentored

If you checked "Joint Audit" or "Mentored," you also must add the name and ID number of the Accompanying Inspector. For definitions of the types of MQSA inspections, including those that are not mentioned above, e.g., "Follow-up (Fee-Based)," "Compliance (Non-Fee-Based)," "Independent Audit," and "Headquarters Initiated Action," see Inspection types in the Glossary section. For access and data entry regarding these types of inspections, refer to "Facility Inspection Download" in the FISS 6.01 User's Guide.

This screen also shows the regulation (interim or final) being deployed during the inspection and enforced by the software program (final for FISS 3.0 and all subsequent software versions). If the facility is referred to or is described by names other than the downloaded name, select Tab # 3.1 (**Aliases**) and record the appropriate information in the corresponding screen.

If the facility has more than one site operating under the same certificate (such as a mobile facility), select Tab # 3.2 (**Additional Sites**) and record the appropriate information in the corresponding screen. If the facility contracts with other certified facilities to provide additional mammography services on the premises of other facilities or at other fixed locations, you should enter those facilities and locations as additional sites for this facility and record the appropriate information in the corresponding site's screen for each.

Additional information may be found under Section 3.3.5.

3.2.4 Facility Contacts

These are the individuals you are likely to contact for scheduling the inspection and for compliance and billing issues. Screen 3.3 (Contacts) has no data-entry fields, but the four screens that follow it have data entry fields that may need to be updated:

- Facility Accreditation Contact (3.3.1) [pre-filled with AB data]
- Facility Inspection Contact (3.3.2)
- Compliance Contact (3.3.3) (the most responsible individual)
- Billing Contact (3.3.4)
- Inspection Report Contact (3.3.5)

Each of the screens above has two main tabs "**Responsible Person**" and "**Mailing Address**" listed sequentially near the top. Each tab has an associated data entry screen that can be accessed by selecting the tab in question. Information regarding the contact persons listed in the first three bullets above will be automatically displayed on the first page of the "Post Inspection Report."

The "**Facility Accreditation Contact**" screen has read-only fields that are pre-filled with AB data supplied to the FDA by the AB. Hence, to update any of its information you have to click on the **"Facility Changes.."** button in the upper right-hand portion of the screen. Record any additional facility contacts you may have and are likely to use in the "**Facility Inspection Contact**" screen. The "**Compliance Contact,**" the "**Billing Contact**" and the "**Inspection Report Contact**" screens may be changed directly, and they should be updated as needed.

3.2.5 X-ray System(s) Information

Prior to collecting any information in this section, select three routinely used (typically small) cassettes loaded with the facility's film. Allow at least 15 minutes to pass (after loading) before exposing them. Two cassettes will be used for the Phantom Image Quality test and one for the Darkroom Fog test, as described in Section 4.2 of this document.

When you double-click on Screen 3.5 **(Units)**, a screen with the same title and the following tabs will be displayed on your laptop: List**,** Information**,** Screen-Film**,** and Evaluation**.** The screen associated with the List tab gives a read-only listing and status of all the x-ray units in the facility as supplied to MPRIS by the AB (using MPRIS Web). When you select a unit from this list, its name will be displayed below the facility and inspection information and will appear on all subsequent inspection screens related to that x-ray unit, including the phantom test, the applicable QC records (for screen-film units), and the medical physicist's survey report.

To update a unit's status and other related information, select the desired unit from the list, click on the Information field, and update the questions/information in the following fields as needed:

- *(x-ray unit) Number (pre-filled with AB data)* [see **NOTE 3-6** and **NOTE 3-7** at the end of this section]
- *(x-ray unit) Room name or number…*
- *(x-ray unit) Serial Number…*
- *X-ray unit still in use* [status]*? (y/t/r/n)**
  * ("t": temporarily out of service; "r": evaluate records only)

- *x-ray Manufacturer (pre-filled with AB data)*
- *Model (pre-filled with AB data)*
- *AB Model (pre-filled with AB data)*
- *Manufacture Date (mm/dd/yyyy)* [if day of the month is not known, enter "01"]
- *Mobile [van, truck,..] (a checkmark in the box designates a mobile unit)***
  - *Image Receptor (IR) Type (F/D/CR)*** (pre-filled with AB data)*
  (F: Film Screen; D: Full-Field digital; CR: Computed Radiography)

** The checkmark will be pre-filled with AB data if the downloaded unit is mobile. For units that you add during the inspection, you have the option to fill it in, if applicable.

*** Up till recently, we have used the term Full Field Digital Mammography (FFDM) unit to describe an x-ray unit with a full field digital image receptor integrated into the unit design. With the recent approval of the Fuji computed radiography for mammography (FCR*m*) as another type of FFDM, a typical screen-film (SF) mammography unit can be converted to a CR unit by replacing its existing SF cassette by a CR mammography plate or cassette and a digital reader system. The digital image generated by a CR mammography unit as described above is also considered an FFDM image. Thus, beginning with the Version 6.01 FISS software, we have deleted xeromammography as an image receptor type but added Computed Radiography (CR) instead. As a result, when a new inspection is downloaded, the image receptor type will be one of three possible options: Film Screen (F), Full-Field Digital (D), or Computed Radiography (CR). X-ray units with image receptor types of either D or CR are considered FFDM units/systems. Such units are treated identically in FISS 6.01 and will be evaluated in the same manner during the inspection. Also, because CR systems use a standard mammographic x-ray unit, facilities may use this unit with both SF and CR receptors. Therefore a single mammographic x-ray unit may be downloaded to your laptop as two units, one SF and one CR. For inspection purposes, you are to treat these as two separate units and proceed with your inspection as if they were two different units.

If you are inspecting a facility with an FDA-approved FFDM unit that does not have an approved accreditation body, the FFDM unit(s) will be downloaded with the inspection and will be shown as accredited by FDA.

The table below **FFDM Systems Approved by FDA for Clinical Use** gives a list of the FFDM systems approved to date, the AB's that have been approved to accredit them, and the corresponding effective accreditation dates. AB names are defined in the Glossary section of this document.

FFDM Systems Approved by FDA for Clinical Use

Manufacturer & Model	FDA-Approval Date	Hard Copy	Soft Copy	AB Name	AB Effective Date
GE Senographe 2000D	1/28/2000	X	X (11/20/00)	ACR SIA STX	2/15/2003 10/1/2003 5/21/2004
Fischer SenoScan	9/25/2001	X	X	ACR STX	8/15/2003 5/21/2004
Lorad LDBI	3/15/2002	X			
Hologic/Lorad Selenia	10/2/2002	X	X	ACR SIA STX	9/15/2003 10/1/2003 5/21/2004
GE SenoAdvantage (display system only)	12/3/2003	X	X	No AB Needed	
GE Senographe DS (unit & acquisition system only)	2/19/2004	X	X	ACR STX SIA	9/15/2004 9/15/2004 1/17/2006
GE Senographe Essential (unit & acquisition system only)	4/11/2006	X	X	ACR	7/15/06
Siemens Mammomat Novation^{DR}	8/20/2004	X	X	ACR SIA STX	10/15/2005 2/1/2006 6/29/06
Fuji Computed Radiography for Mammography (FCR*m*)+	7/10/2006	X	X	None yet	

+ This system has just been approved for marketing by FDA's Office of Device Evaluation (ODE) (7/10/06). At the time this document is finalized, no AB's for it have been approved yet and facilities that acquire it have to apply to FDA's DMQRP for extending their certificate to include it before they can lawfully use it on patients.

Although you may still note for a short period of time following the above dates that some of these systems will be shown as accredited by FDA when downloaded, eventually, they will be shown as accredited by the appropriate AB once the transition period has passed.

When you select an FFDM unit (Screen #3.5 - List in the inspection software), none of the screens that are used only with the S-F image receptor or QC record reviews (Screens # 3.9.2 and # 3.9.3) should be accessible. Note that when you open the "Information" screen corresponding to the FFDM unit that you selected from the list, the *"Image receptor type"* field will be pre-filled with "Digital." To continue evaluating such units, you must first verify which display method(s) the facility uses by checking one or more of the following options (which become accessible only for digital units):

- *Display method: (Monitor/Laser film/Other)*

The inspection software currently includes only three questions regarding QC tests for FFDM systems. However, you must check at least one of the display options in order to be able to evaluate the FFDM QC records (discussed further in Section 6.8 Digital Mammography QC).

For Xeromammography (X) units, contact the Facility Hotline for further instructions. A survey of MQSA data showed that the most recent xeromammography unit underwent an MQSA inspection in August 1998 and was subsequently removed from service. Although the FISS software will keep Xeromammography as an image receptor option for historical purposes, we are no longer providing any inspection details regarding these units in this document.

For screen-film units, the *"Image receptor type"* field will be pre-filled with "Film Screen."

> **NOTE 3-3:** For facilities with multiple x-ray systems, whenever a unit is selected for evaluation from the list, its name will be displayed on the corresponding **"Information"** screen below the facility's name and inspection ID. The total number of x-ray units on the list is displayed on the bottom right-hand side of this screen.
>
> **NOTE 3-4:** Formats similar to the one described in **NOTE 3-3** are used in other areas of the program when the facility has multiple units of the same item. Items may include film processors, darkrooms, other sites, and/or multiple personnel (interpreting physicians, radiologic technologists, or medical physicists).
> **NOTE 3-5:** The question regarding unit status has 4 answer options: Yes (y), No (n), Evaluate Records Only (r) and, Temporarily out of Service (t). "Yes" (evaluate all) means the unit is functional on inspection day and should be evaluated for the phantom image test, the applicable QC records, and the physics survey. "No" means that the unit should not be evaluated for anything. It applies to a unit that has had no activity whatsoever since the previous inspection. Such units will be deleted from the records for the next inspection. "Evaluate Records Only" means the unit should be evaluated for the applicable QC records and survey report only. It applies to a unit that was in service for a period of time after the previous inspection but has since been permanently removed from service. "Temporarily out of Service" means the unit is being repaired or otherwise unavailable at inspection time. Such units should also be evaluated only for the applicable QC records and survey report.

To answer screen-film related information, open the Screen-Film tab and verify/update:

- *Film Manufacturer (pop-up list)*
- *Film Type (pop-up list)*
- *Screen Manufacturer (pop-up list)*
- *Screen Type (pop-up list)*

These fields may contain information from the previous inspection (if applicable) but are not grayed out. You can update them by selecting the applicable current information from the corresponding pop-up window.

To address compliance-related issues, click on the Evaluation screen and answer the following questions:

- *X-ray unit designed for mammography?* *(y/n)*
- ***Does x-ray system include the following?*** (default to "*y*") ***(y/n)***
  - *Image Receptors for 2 sizes* *(y/n)*
  - *Moving Grids for 2 sizes* *(y/n)*
  - *Compression Paddles for 2 sizes* *(y/n)*
  - *Post-Exposure Display in AEC mode* (for focal spot) *(y/n/NA)*

- *Post-Exposure Display in AEC mode* (for target material) *(y/n/NA)*

- *Is the unit accredited?* *(y/n/p/NA)*
  (pre-filled with AB data) ["*p*": pending, "NA": Not Applicable]
- *Is this a new unit?* *(y/n/NA)*
  (*new*: in clinical use at the facility for under one year)
- *Mammo equip. evaluation (by medical physicist) done?* *(y/n/NA)*
  (for new installation, reassembly, or major repairs)

[For a review of mammography equipment evaluations (MEE), see Section 8. of this document]

NOTE 3-6: X-ray units that are used on patients, except for investigational or research units and units that are currently excluded from the regulations, such as those used only for stereotactic procedures, must be tested regardless of their accreditation status (see Section 2.3, Situation 2 of this document for further information). Furthermore, all units at the facility that are used on patients (with the exception of demo units, loaners, those on a trial basis, & investigational units, for which the accreditation status should be "NA") must be accredited by the AB. If the facility has filed an application for accreditation with the AB, the pre-filled answer to the accreditation question above should be "y" or "p" (for pending). If, on the other hand, the pre-filled answer is "n", the program will cite a Level 1 (L1) or Level 2 (L2) non-compliance, depending on whether the unit has been in clinical use for at least one year (L1) or less than a year (L2).

NOTE 3-7: If an x-ray unit was downloaded as Unaccredited but the facility shows you documentation that its accreditation status was either approved or pending, answer the question "Is this a new unit?" with "NA", to avoid issuing the facility an inappropriate citation.

For questions related to digital/CR (FFDM) units, you only need to answer the following questions in the Evaluation tab of this screen:

- *Is the unit accredited?(y/n/p/NA)*
  (pre-filled with AB data) ["*p*": pending, "NA": Not Applicable]
- *Is this a new unit?* *(y/n/NA)*

  (*new*: in clinical use at the facility for under one year)

- *Mammo equip. evaluation (by medical physicist) done?* *(y/n/NA).*

  (for new installation, reassembly, or major repairs*)

* Note that software **upgrades** are considered to be "**major** repairs" requiring an onsite visit by the medical physicist (unless specifically exempted by an Approved Alternative Standard). Be sure to review the facility's service reports to identify modifications to the unit's software. Software **upgrades** may also be imbedded within a hardware change (e.g. updated software may be contained on a type of programmable chip located on one of the unit's printed circuit boards). The latter scenario may be difficult to identify, but potentially could be noted on service reports or manufacturer's instruction sheets covering system enhancements.

The rest of the data entry fields will be grayed out.

Record other information in the "Remarks" screen, as needed.

Additional information may be found in Sections 3.3.6 to 3.3.9.

3.2.6 Updating Pre-filled Data (Important)

Some x-ray unit information such as unit number, manufacturer & model, accreditation status, and image receptor type information, is pre-filled by the AB who transmits it to MPRIS through MPRIS Web. In general, to update such information, you should send an e-mail message to the Facility Hotline with the correct information. Subsequently, we will work with the AB to correct the CASS system data. In the meantime, there are some basic steps you can take during the inspection to minimize any uncertainty regarding unit information, particularly for facilities with multiple units, each of which has a different accreditation and use status.

For example, assume that a facility had two GE units (unit #1 in Room #1 and unit #2 in Room #2) that were used from early 1997 to April 2005, when they were removed from service. The facility replaced them with two Siemens units (unit #3 replacing unit #1 in Room #1 and unit # 4 replacing unit #2 in Room #2) and subsequently started using the replacement units on patients.

If you inspected this facility in July 2005, you would probably have four machines downloaded with the inspection information as follows: the two GE units designated as accredited (if their accreditation had not yet expired) and the two Siemens units, each showing an accreditation status of y, n, p, or N/A. Assuming that an MEE was conducted on each of the Siemens units by a medical physicist before the facility started using them on patients, you should proceed as follows:

1. Designate the use status of each of the GE units as "Evaluate Records Only" and each of the Siemens units as "Yes."
2. Assign Room # 1 to Siemens unit #3 and Room #2 to Siemens unit #4.
3. Look for ACR accreditation stickers* on each of the Siemens units. If the AB accredited the new units (accreditation status is "y") the facility should have such a sticker attached to each unit. The last two digits in the MAP number (located in the lower part the sticker) refer to the unit number assigned by the AB. A sample sticker is shown below in Exhibit 2.

   * Not all AB's issue stickers with accredited units, others such as TX issue state certificates instead.

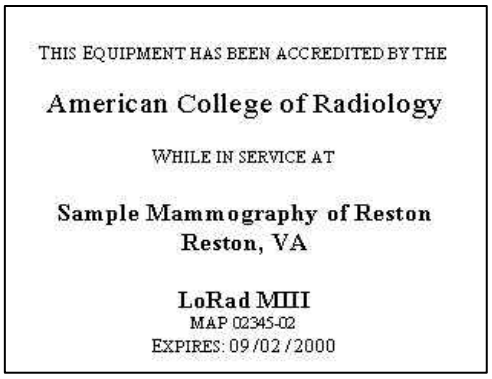

Exhibit 2: Sample AB Accreditation Sticker

4. If the facility received only a preliminary approval to use the units on patients while their application for accreditation is being reviewed, the accreditation status for the new units will most likely be downloaded as “p.” If the accreditation status is downloaded as “n” and the facility shows you otherwise, answer the question “Is this a new unit?” with “NA.” Note that when you answer this question with NA, the program will not issue an inspection observation for using an unaccredited unit clinically.
5. If other pre-filled information for the Siemens units (such as unit manufacturer and model) is in error, document your corrections in the printable Remarks section and send an e-mail to the Facility Hotline.
6. A final note regarding unit numbers. AB’s assign unit numbers. The ACR, for instance, does not (normally) re-use the unit numbers. Hence, if a facility is replacing units 1 and 2, the new ones will be numbered 3 and 4. Both FDA and ACR use this practice to keep track of the units. Therefore, regardless of what the facilities may call the units themselves, the only thing that matters for the inspection is what numbers the AB has given them. If the facility shows you what they term units 1 and 2, and your software shows units 1 and 2, and also units 3 and 4, keep in mind that the latter two are not "bad data" from the AB, but rather exactly how the system works. In essence, "Go with FISS data. It will be correct most of the time."

3.3 Further Details

3.3.1 Facility Inspection Download (FISS Screen. 2.0 on your laptop)

When you download a facility for an inspection, you have to designate the type of inspection as one of the following:

Annual or ‘A’ (default setting for most facilities),
Follow-up or ‘F’ (Fee-Based),
Compliance or ‘C’ (Non-Fee-Based)
Independent audit or ‘I’, or
Headquarters initiated or ‘H’.

Types ‘F’, ‘C’, or ‘H’ should be used only by FDA MQSA inspectors.

Type ‘I’ should be used only by MQSA auditors.

Once an inspection is designated as a Type ‘A’ during the downloading procedure, it will appear on your laptop Screen 3.0 Facility Inspections – Inspection, as such. In this screen, you need to further designate the type of annual inspection you will be conducting; you may choose “Basic” (for a routine annual inspection), “Joint Audit” (when you are accompanied by an MQSA auditor), or “Mentored” (when you are accompanied by another inspector acting as your mentor).

FDA MQSA auditors who are FDA-certified MQSA inspectors are required to accompany other inspectors on some annual inspections. However, only when a designated FDA MQSA auditor accompanies you on an inspection for the purpose of an audit should you enter the "Joint Audit" in the "Annual Inspection Type" field. Additionally, only under very unusual circumstances would an independent audit inspection be conducted and then only by a designated FDA MQSA auditor.

3.3.2 Individuals Accompanying on Inspections

When someone accompanies you on an MQSA inspection, please indicate the name of the person and

whom they represent (FDA, State of {name}, etc.) in the Remarks section of the inspection report which prints out for the facility (the 3.0 Facility Inspections - Inspection screen).

Example: Accompanied by Elvis Presley, State of MS.

There is an exception. When an MQSA auditor goes with a State or FDA inspector as part of an inspection audit, the auditor's number must be recorded in the Accompanying Inspector space provided for this purpose on the "3.0 Facility Inspections – Inspection" screen. Entry of the MQSA auditor information into this space will eliminate the need to use the printable Remarks section. Likewise, if you were accompanied by another inspector as your mentor, you must check the box "Mentored" and record the name of the mentor as the Accompanying Inspector.

3.3.3 Calibration Criteria for Densitometers and Sensitometers - Replacements

Calibration Criteria. Inspectors' sensitometers and densitometers must be calibrated periodically to ensure accuracy. FDA calibrates on the first Wednesday of each month. It is very important that your units arrive in a timely manner to be calibrated during the proper rotation for your State. Federal Express and United Parcel Service of America, Inc. (UPS) are recommended for shipping due to their tracking and reimbursement capabilities. To expedite the process, please send in your units so that we receive them **before** the first Wednesday of each month. If you have multiple units, you may separate shipments between your specified month and the following month. This will further decrease the possibility of being without a sensitometer and densitometer. The "turn around time" should be no more than 10 working days, provided we have received the units "on time." If units are received after the projected calibration date, they may not be calibrated until the next calibration on the first Wednesday of the following month. We will contact you to request disposition of the units.

The following is the rotational calibration schedule. Please note that although some of the states below do not have a contract with the FDA to do MQSA inspections, we have occasionally performed calibrations for them:

- February: CA, VT, IA
- March: CO, CT, DC, DE, FL, GA, HI, MA
- April: ID, IL, KS, LA, MO, KY
- May: MD, ME, MN, MI, NV
- June: NC, ND, NE, NH, NY, MS, MT, NYC, IN
- July: NJ, OH, OR, PR, SD, NM, OK, SC, DOE Contractors
- August: PA, TN, VA
- September: TX, WI, UT, WV
- October: AK, AR, AZ, RI, WY
- November: AL, WA, Coast Guard, Indian Health Service
- December: Air Force, Army, FCI, FEMA, NAMA, Other

Please send your units to:
Attn: Calibration: Tech Center
16071 Industrial Drive, Rm. 253
Gaithersburg, MD 20877

Additionally, an effort is being made to ensure that all FDA Computer equipment and Inspector equipment are being accounted for properly in our databases. Please help us with this ongoing

tracking by making a photocopy of the FDA Barcode # on the bottom of your laptop and printer and returning the copies to us with your units for calibration.

If you have any questions regarding your laptop and printer, please contact Computer Support at 240-276-3323.

Replacements for film, phantoms, densitometers, etc. Routine replacements are completed within 10 working days but emergency replacements are expedited. Plan accordingly.

3.3.4 EIN and CFN (FEI)

EIN (Employer Identification Number) for a facility is a number assigned by the IRS that CMS (formerly HCFA) uses to determine Medicare eligibility of a facility. It is a number that the AB maintains and the inspector can not edit. If you discover that a facility's EIN number is incorrect, please inform the facility that they should contact their AB directly to have it corrected. Do not send an e-mail to the Division asking us to fix it, since our correction would be overwritten the next time the AB sends us updated data for that facility.

Some facilities are asking for FDA's EIN for their income tax record keeping purposes. For those of you who are asked by facilities for the FDA's EIN, it is 53-0196965. If you need further information concerning FDA's EIN, you may call the Facility Hotline at 1-800-838-7715.

CFN/FEI is a file number that each FDA's District Office assigns to the facility. It is also a number that inspectors cannot edit and therefore, should not be concerned with. Since FISS 4.03, CFN has been completely phased out and replaced by FEI, which stands for "FDA Establishment Identifier."

3.3.5 Additional Sites

The Additional Sites tab (Screen 3.2) allows you to capture information on any mammography activity that a facility may have at its remote sites (if any). A typical application for this is a mobile facility with multiple sites operating under the same certificate. Examples of mammography activities at remote sites are interpretation of mammograms (which is even more convenient in digital mammography), keeping some or all mammography related records, performing on-site processing, having a laser printer, or any combination of these functions. To add a site, double-click on the 3.2 tab, select the "Record" option in the main menu, select the "+" key in the tool bar below the menu, and then fill out the corresponding new site "Information" screen. Note that for a facility with more than one site, the program will list the site you are entering data for in the top portion of each data entry screen.

> **NOTE 3-8**: With the increasing use of digital mammography, some interpreting physicians are reading soft copy mammograms that are transmitted to their homes electronically. In these cases, you should record the corresponding IP residence as a remote facility site and all the review work station monitors or laser printers used for mammography at that site will be subject to the required applicable QC tests.

3.3.6 Post-Exposure Indication of Pre-selected Focal Spot and Target Material - Alternative Standard

DMQRP approved an Alternative Standard that became effective on 4/19/99 for GE Senographe™ DMR machines.

As written, 21 CFR 900.12(b)(7) states that:

"(7) Focal spot selection. (i) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

(ii) When more than one target material is provided, the system shall indicate, prior to exposure, the pre-selected target material.

(iii) When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material and/or focal spot actually used during the exposure."

The approved alternative is:

"(7) Focal spot selection. (i) When more than one focal spot and/or more than one target material is provided, the system shall indicate, prior to exposure, the pre-selected focal spot and target material, and shall indicate, after the exposure, the focal spot and target material actually used during the exposure; **or**

(ii) When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall indicate, after the exposure, the target material and/or focal spot actually used during the exposure."

Under the approved alternative, an indication of the pre-exposure focal spot and target material would no longer be required when the pre-exposure target material and focal spot are set by a system algorithm based on exposure and the user has no control over that selection. In operating modes where the user has control of the pre-selected focal spot and/or target material, indication of the pre-selected values would still be required. In all cases, indication of the focal spot and/or target material actually used during the exposure would be required.

3.3.7 Dedicated Buckys and Spot Compression Paddles

A facility must have on hand at least one cassette-grid-compression paddle combination of each of the 18 x 24 cm and 24 x 30 cm sizes to equip each film-screen mammography x-ray unit in the facility. "Spot Compression" paddles are not required.

3.3.8 Unit Accreditation

The software will either generate a Level 1 citation, a Level 2 citation or no citation at all, based on the following table, Exhibit 3, ("Unit in-use?" set to "Yes"):

Exhibit 3: Citation Levels for Unaccredited Units

CITATION LEVELS FOR UNACCREDITED UNITS

Is the unit accredited?	Is this a new unit?	Resulting Noncompliance
Yes	Yes	No Citation
	No	
	NA	
Pending	Yes	No Citation
	No	
	NA	
No	Yes	Level 2 Citation
	No	Level 1 Citation
	NA	No Citation

You should use the NA answer option when the unit accreditation status in the inspection software is "N" but the facility provides evidence that the unit accreditation is either pending (P) or has been

granted (Y) but FISS does not reflect that.

FISS uses current AB unit accreditation data, which the AB updates three times a week. Since this information is frequently updated, it is more important than ever not to download new inspection records too far in advance of a scheduled inspection (we recommend that you do that within no more than 7 days). Otherwise the information may be out-of-date by inspection time.

3.3.9 Subsequent Use of X-Ray Units that Failed during the Inspection

If a mammographic unit is found to not meet one or more of the specific equipment requirements listed in 900.12(b) (3-10) during inspection, the unit need not be taken out of service immediately. However, the unit must be replaced, modified or repaired as soon as possible. The facility may continue to use the unit for a limited time, as long as it takes measures to ensure that the failure to comply with the requirement does not result in substandard patient care. The facility is reminded that regardless of what is stated above, the unit must remain in compliance with the requirements listed in 900.12(e) if it is to be used on patients and the facility remains subject to citation for having a mammographic unit that did not meet one or more of the requirements at the time of the inspection.

4. SYSTEM PERFORMANCE TESTS

4.1 General

These tests are designed to assess the performance of the x-ray units, processors, and darkrooms currently in use at the facility vis-à-vis the standards set in MQSA regulations. The tests and corresponding data entry sections are listed below:
4.2 Phantom Image Quality Evaluation (Screen 3.5.3) - for each x-ray unit
4.3 Processing Performance [the STEP test] (Screen 3.6) - for each processor
4.4 Darkroom Fog (Screen 3.7) - for each darkroom

> **NOTE 4-1:** If the results of any of the tests listed above fall abnormally short of expectations, make sure that you did not accidentally enter erroneous data or use the wrong techniques. If so, repeat the test before you finalize your data entry.

For additional guidance applicable to all tests, see Sections 4.1.1 to 4.1.4.

4.1.1 Equipment Measurements which Result in Borderline Values

For the equipment measurements portion of inspections, a range of numerical values is possible for the calculated results. While results above or below a certain value will clearly be noncompliant, other values will "just pass" the test with a "borderline value." While facility personnel may want to know how their facility performed on this part of the inspection, some inspectors may be tempted to point out that they "just passed" and ask them to "keep an eye on" certain areas that are borderline and close to the point of being noncompliant. While this may seem like innocent advice that could help a facility, many people are nervous during an inspection and will hang on every word the inspector says. Some may decide to schedule service calls to investigate the borderline test result, only to find that the service engineer cannot identify a problem. If you identify borderline test results during an inspection, please make sure you indicate clearly to the facility personnel that they passed the inspection with regard to that item and that the FDA is not requiring them to take action regarding the test result found.

Reminder for State Inspectors:

When performing an MQSA inspection along with a mammography inspection for your State, if your findings reveal a noncompliant item(s) with your State's requirements, please carefully distinguish between the State's requirements and MQSA's requirements [i.e., the State's noncompliant item(s) versus noncompliant MQSA item(s)] during the close-out interview with facility personnel. It is important that facilities understand whether noncompliance items are State requirements or MQSA requirements.

4.1.2 Retention of MQSA Inspection Test Films

Note: The following policy applies only to test films exposed during MQSA inspections. The retention of mammographic films and quality control test films by facilities is covered in separate policies.

Issue: During a routine MQSA inspection, films are produced while performing different tests, including phantom image evaluation, darkroom fog, and STEP. These films are evidence of a facility's performance during the inspection, as are copies of QC records and the data entered into the inspection software. For this reason, films should be retained as a record of the inspection observations by State

program offices, FDA District Offices, or Regional Offices. However, films present a bigger storage problem than paper records or data recorded in a computer. Copies of paper records are not always made during an inspection, except when problems are found, but films are always produced.

To address this problem, the following FDA policy will apply to the handling and retention of inspection films. Should the following guidance present a problem for a State, the State should contact their Regional Radiological Health Representative (RRHR) or their designated contact in the FDA District Office.

Policy: Inspection data are routinely obtained from test films taken during an MQSA inspection and are recorded electronically in the MPRIS inspection software. Radiographic images on film, as well as fog and STEP films produced during an inspection, should be identified with the facility name, facility ID number (or inspection ID number), and the inspection date. Additional relevant information (e.g., technique factors used to produce the phantom image film, equipment or room identification for multiple equipment facilities) should be recorded, as appropriate. The identification may be via paper sticker, handwritten, electronic imprint, or other permanent means.

Inspection films will be maintained for the following time:

a) Films documenting a Level 1 noncompliance should be maintained until the noncompliance is documented as being resolved by a subsequent inspection, plus 2 years.

   NOTE: For phantom image test films, both films (the first phantom image and the backup phantom image) should be maintained.

b) Films documenting Level 2 and Level 3 noncompliances should be maintained until all related noncompliances are documented as being resolved by a subsequent inspection, or 1 year; whichever is longer.

c) All other films (for inspections with no adverse observations) should be maintained for a minimum of 1 year so that they are available for an audit by an MQSA Auditor.

4.1.3 Unusual or Unexplainable Errors

We ask that you note patterns of noncompliance items appearing during your inspections. By pattern, we are referring to the same noncompliance items appearing in a large number of inspections conducted by the same inspector.

In some cases, these patterns could be the result of test equipment failures. In other cases, these noncompliance items could result from regional differences in how mammography facilities operate, an inspector utilizing an outdated policy, or another reason that may need investigating. These patterns could also be the result of random chance. If you come across a string of noncompliances during your inspections, it is important that you contact DMQRP or the Certifying State as soon as possible.

4.1.4 Situations without Corresponding Questions in the Software

The following policy pertains to situations where inspectors have found problems that should be brought to the attention of facility personnel, but do not have a specific question in the inspection software. Some examples are given below.

- Phantom image artifacts (other than fibers, specks, or masses)
- Dirty viewbox, or dirty conveyor for batch-viewing of mammograms
- Dirty darkroom or dirty screens.

None of these situations (and there may be others) have direct questions with simple answers in the software program, but yet each can pose a reporting dilemma for the inspector when he or she feels that the case in question affects mammographic quality to the point where the facility should be cited for it.

Whenever possible, the questions in the software program were designed to eliminate subjective answers and minimize the number of cases where a judgment call has to be made on the part of the inspector. While this is a straightforward process for most of the physical tests, some (like phantom image scoring and artifact subtraction) are still somewhat subjective. On the other hand, identifying artifacts due to processor roller marks, or the cleanliness of a viewbox or a darkroom, is not so easily and uniformly done.

Inspectors should use the following approach:

1. Phantom image artifacts. If the artifacts are objectionable to the point that they affect the visibility of any of the phantom objects appreciably, the score of the object in question should be adjusted appropriately, even though this artifact is not one of those normally counted in phantom scoring. Also, document your findings about this in the printable Remarks field for the 3.5.1 Phantom Image Quality Evaluation screen, and advise the facility about the problem. If the artifacts in question are objectionable enough but do not affect the visibility of any of the phantom objects, document your observations about this in the printable Remarks field and advise the facility about the problem.
2. Dirty viewbox, or dirty conveyor for batch-viewing of mammograms. Inspectors should document their observations about this in the printable Remarks field in the 3.9 Quality Control screen and advise the facility about the problem.
3. Dirty darkroom or dirty screens. Again, inspectors should document their observations about this in the printable Remarks field in the 3.9 Quality Control screen and advise the facility about the problem. In addition to that, if excessive dust and dirt is the problem, it is likely to affect the phantom image score.

4.2 Phantom Image Quality Evaluation

4.2.A Test Procedure – Screen-Film Units

Retrieve the three cassettes that you selected earlier (Section 3.2.5). Using the facility phantom, ask the technologist to take three phantom exposures with the technique factors the facility uses for the Standard Breast (for S-F units that use a computerized algorithm to select one of multiple AEC detectors, this could be the full auto mode or whatever the facility uses for the standard breast). If the technologist is not available to make the exposures and you have been trained to do that, do it yourself. If the facility phantom is not available (for whatever reason), use your phantom for these exposures and make a note of this in the printable Remarks screen. Ask the technologist to process two of the three, which you will evaluate as described below.

4.2.B Evaluation Procedure – Screen-Film (S-F) Units

Record all the data obtained in this section (for each x-ray system) in the **"Phantom Image Quality Evaluation"** screen (Screen 3.5.3 of your software program outline).

4.2.B.1 Measure and record the optical density at the center of phantom image # 1 (Figure 1).

4.2.B.2 View the phantom image using an appropriate mask on the view box used by the QC technologist and reduce the ambient lighting as much as possible.

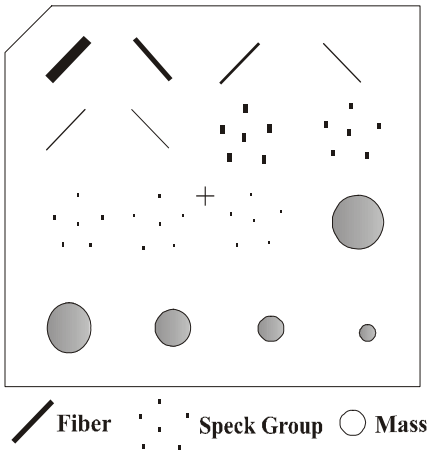

Figure 1: Phantom Image Quality Evaluation

Figure 1 Caption: Figure 1 is an illustration of the shape and location of each of the test objects in the FDA-approved mammography phantom.

NOTE 4-2: If clinical films at the facility are processed off-site, process and score the phantom where the facility normally processes its mammograms.

NOTE 4-3: The measured density should be within ± 0.20 of the background density operating level of the facility's routine weekly phantom images if they use (as they must) the same techniques for their routine phantom images as they do for the Standard Breast. This optical density must always be greater than or equal to 1.20 at the center of the phantom. If the optical density you measured differs from the facility's operating level by more than ± 0.20 or is less than 1.20, repeat the test using the same technique factors, cassette, image receptor, and processing conditions used by the facility for its weekly phantom image QC. Record the new optical density value and proceed with the rest of the test regardless of this value.

4.2.B.3 Record the number of objects and artifacts in each of the three object types as stated below. Details regarding how to score the phantom are described in Sections 4.2.1 and 4.2.2 (Phantom Image scoring and scoring video). Also, for additional information, see Sections 4.1.2 and 4.1.4.

- *Fibers (0 to 6 in integers or halves, e.g., 0, 0.5, 1, 1.5, ...5, 5.5, 6)*
- *Fiber artifacts (0,0.5, or 1)*
- *Speck groups (whole and partial) that you can see (an integer from 0 to 5)*
- *Specks in the last scored group (an integer from 2 to 6)*
- *Speck artifacts (any integer from 0 to 6)*

- *Masses (0 to 5 in integers or halves, e.g., 0, 0.5, 1, 1.5, …4, 4.5, 5*
- *Mass artifacts (0, 0.5, or 1)*

If the number of net objects visualized in all categories is equal to or above the minimum needed for a passing score, skip the next step and go to Section 4.3. Otherwise:

4.2.B.4 Record the background optical density and scores for the phantom image taken in the second cassette (Phantom Image # 2), in the appropriate fields by repeating the steps in Sections 4.2.B.1 to 4.2.B.3.

4.2.B.5 Identify each phantom image evaluated and label it with the name of the facility (and the machine if there is more than one unit), the date of the inspection, and the term "phantom image evaluation." Retain the image(s) with any other items and documents from this inspection.

4.2.B.6 If the phantom image fails at Level 1, consult APPENDIX 3, "MQSA Guide for Additional Mammography Review (AMR)," for further action.

For additional information, see Sections 4.2.1 to 4.2.3 below.

4.2.C Test Procedure – Digital/CR (FFDM) Units

Check the display method the facility uses for mammographic interpretation (e.g., softcopy or hardcopy) and indicate that by selecting the corresponding "Phantom image display method" in the "Evaluation" tab of Screen 3.5.3. Also note that for digital* systems, the background density field has been blocked. All other fields and missing data rules associated with Screen #3.5.3 are the same as for S-F units.

* Please note that, although a failing phantom image score in digital units will have the same citation level criteria as in S-F units, the actual implementation of any citation for a failing image score in digital units will not take place until most of the inspectors become familiar with this procedure. We will give you and the facilities a heads-up notice well in advance of such implantation.

4.2.D Evaluation Procedure – Digital/CR (FFDM) Units

For facilities using **softcopy** interpretation:

a. Have the technologist expose the facility's phantom using technique factors as recommended by the FFDM system manufacturer for the weekly phantom test and display the image for scoring on one of the monitors recommended by the FFDM unit manufacturer for the weekly phantom test (this could be the acquisition work station (AWS) or the review work station (RWS), depending on the FFDM unit), with the viewing conditions (window level and width) the facility uses to review and score its phantom images.
b. Score the image on the screen under these conditions ("a" above) and enter your answers under Image # 1 in the software screen.

c. If it passes, the phantom image quality evaluation is complete.
d. If it fails, repeat the procedure in "step a" above, score it and enter your answers under Image # 2.
e. If the second exposure passes, the phantom image quality evaluation is complete.
f. If this second image fails, print a hard copy of exposure #1 image, score it again and edit your answers under Image # 1; and if the hardcopy phantom image fails, print a hard copy of exposure #2 image, score it and edit your answers under Image # 2.
g. If the hard copy of Image #2 also fails, your answers will be used by the software to issue an inspection observation (when implemented by FDA). **Note:** When that occurs, you should keep both hard copies of the exposures for your records, as evidence.

For facilities using only **hardcopy** interpretation:

a. Have the technologist expose the facility's phantom and print the image using the techniques normally used by the facility for both the unit and the printer.

b. Score the hardcopy image and enter your answers under Image # 1.

c. If it passes, the phantom image quality evaluation is complete.

d. If it fails, have the technologist repeat the procedure in "step a" (above), print and score the second image, and enter your answers under Image # 2.

e. If it passes, the phantom image quality evaluation is complete.

f. If the second image also fails, your answers will be used by the software to issue an inspection observation (when implemented by FDA). **Note:** When that occurs, you should keep both hard copies of the exposures for your records, as evidence.

NOTE 4-4: For the Lorad Selenia and the Siemens Mammomat Novation^{DR}, the phantom test passing score is 5, 4, 4 (or 4.5, 4, 3.5 under certain conditiitions). While this is required for the facility QC procedures, for regulatory action, FDA uses the passing score established by the FDA-approved accreditation bodies, which is 4, 3, 3, as in S-F systems.

For additional details, see Screen # 3.5.3 in Appendix 2.

4.2.1 Phantom Image Scoring - General Procedure

Always count the number of visible objects from the largest object of a given type (fiber, speck group, or mass) downward, until a score of 0.0 or 0.5 is reached, then stop counting for that object type.

Fibers – Count each fiber as a point if the full length of the fiber is visible and the location and orientation of the fiber are correct. Count a fiber as 0.5 point if more than half, but not all the fiber is visible, and its location and orientation are correct. If a fiber-like artifact appears anywhere in the insert area of the image, but is not in an appropriate location or orientation, subtract the "artifactual" fiber only from the last "real" fiber scored if the artifactual fiber is equally or more apparent. Note that the most you can subtract for artifacts is the score of the last real fiber.

Speck groups – Use the large field of view 2.5X magnifying glass provided to assist in the visualization of specks. Count each speck group as one point. A full speck group is counted as one if four or more specks are visible in the group in the proper locations and as 0.5 if two or three specks in

the group are visible. If noise or speck-like artifacts are visible in the wrong locations in the phantom insert but are as apparent as the real specks you are counting, deduct them one for one from the individual specks you counted. Subtract artifactual specks only from "real" specks in the last group counted. Note that the most that you can subtract for artifacts is the score of the last real speck group.

Masses – Count each mass as one point if a density difference is visible in the correct location and the mass appears to be generally circular against the background. Count each mass as 0.5 point if a density difference is visible in the correct location, but the mass does not have a generally circular appearance (less than 0.75 of the circumference is visible). If there is a mass-like artifact appearing in the wrong location anywhere in the phantom insert, subtract the "artifactual" mass only from the last "real" mass scored if the artifactual mass is equally or more apparent. Note that the most you can subtract for artifacts is the score of the last real mass.

> **NOTE 4-5:** Scores for the artifactual fibers, specks, and masses described above should be entered in the computer program directly as an artifact count, which will be subtracted by the computer from the "raw" count of objects in each category. Note in particular, the way the computer counts specks (real or artifactual): 1 speck is counted as 0.0 or no group, 2-3 specks are counted as 0.5 or half a group, and 4 or more specks are counted as 1.0 or one group.
>
> **NOTE 4-6:** There are a total of 16 imaging objects (6 fibers, 5 speck groups and 5 masses) in the phantom. For the purposes of this test, the minimum number and type of objects that must be visible in order to get a passing score are: the 4 largest fibers, the 3 largest masses, and the 3 largest speck groups.

4.2.2 Phantom Scoring Video

In the latter part of 2000, FDA made available to MQSA inspectors, the final version of the videotape demonstrating the phantom scoring methodology. The procedure used in the tape for scoring the masses, which basically follows the 1999 ACR manual, is slightly different from earlier ACR manuals.

4.2.3 Phantom Images Exposed in a Fully Automatic Mode - Assigning a kVp

Many mammographic x-ray systems have more than one automatic mode of operation. The most common automatic mode requires that the technologist set a specific kVp value with the unit automatically determining the mAs for the exposure. This type of operation is commonly called the AEC, Auto-mAs, or Auto-timed mode. The technologist can vary the exposure in this mode by setting the kVp, adjusting the density control setting, or both. A more advanced mode is where the system automatically controls the kVp and the mAs (commonly called the Full-Auto mode). In this latter mode, the technologist can only adjust the exposure by use of the density control. The actual names for the different modes of operation will vary with the different make and model of the x-ray system.

For screen-film equipment testing involving the phantom, inspectors should use the same technique factors and mode of operation that the facility uses for its patients with the standard breast (compressed breast thickness of 4.2 cm, with breast tissue consisting of approximately 50% adipose (fat) tissue and 50% glandular tissue in composition). When a facility typically uses the Full-Auto mode for its clinical examinations, the inspector should make an exposure of the phantom using the Full-Auto mode and record the kVp selected by the x-ray system. In the event that the displayed kVp after the exposure with the phantom has a three-digit display (e.g., 25.7 kVp), but the manual mode only allows selection of two digits (e.g., 25 kVp), round up or down based on the final digit (example: for 25.1 to 25.4, use 25 kVp; for 25.5 to 25.9, use 26.0 kVp).

Note about facility phantom QC: If the facility typically uses the Full-Auto mode for its clinical examinations, it must use this same mode for its weekly phantom QC test.

4.3 The Sensitometric Technique for Evaluation of Processing (STEP) Test

The purpose of this test is to empirically evaluate film processing at the facility. It does not apply to laser printers (dry or wet) that are used for hardcopy interpretation in digital mammography.

4.3.A Test Setup

The STEP test should be conducted for each processor used for mammography (e.g., primary and or back-up) that is operable on inspection day. Record all the data for the test in the **"Processors – STEP Test"** screen of your laptop software program (Screen 3.6).

When you open the **"Processors"** screen, the following tabs will be displayed on your laptop: "**List, Information, Evaluation,** and **STEP Test."** The screen corresponding to the **"List"** tab will be the default screen if the facility has more than one processor and or laser printer.

The **"List"** screen will show all the processors used for mammography at the facility. For each processor it will display the following read-only information:

- Status (Evaluate All, Hold, Evaluate Records Only)
- Number (1, 2, etc.)
- Room name or number
- Site (if the facility has no additional sites, the name of the facility will be listed)
- Manufacturer (select code from pop-up window)
- Model (select code from pop-up widow)

To change the information in any of the fields in this screen, open the sub-screen corresponding to the **"Information"** tab and enter data. This sub-screen has two other fields that allow you to determine the processor type (Primary or Back up) and the processing method (Screen-Film or Digital), respectively.

Before proceeding with the STEP test, *record* the following information in the **"Developer"** section of the **"Information"** screen:

- *Developer Manufacturer (select from pop-up list)*
- *Developer Type (select from pop-up list)*
- *Processing Cycle (standard or extended)*

NOTE 4-7: The question regarding processor status has 3 answer options. "Evaluate All" means the processor is functional on inspection day and should be evaluated for the STEP test and the applicable QC records. "Hold" means that the processor should not be evaluated for anything. This applies to a processor that has had no activity whatsoever since the previous inspection but may be placed back in service sometime in the future. "Evaluate Records Only" means that the processor should be evaluated for the applicable QC records only. This designation applies to 1) a processor that was in service for a period of time after the previous inspection but has since been permanently removed

from service, 2) a processor temporarily out of service, or 3) one that is not in operation at inspection time but is otherwise used for mammography.

4.3.B Test Procedures

4.3.B.1 Set your calibrated sensitometer's selector switch to the "GREEN" position. Insert the FDA control film in the sensitometer slot with its **emulsion side DOWN** (see Figure 2 and the Glossary for emulsion side identification). Expose each of the 4 edges once in the facility's darkroom. Process the film using the same routine that the facility uses for processing their clinical films. **DO NOT USE THE FACILITY'S FILM, SENSITOMETER, OR DENSITOMETER FOR THIS TEST.**

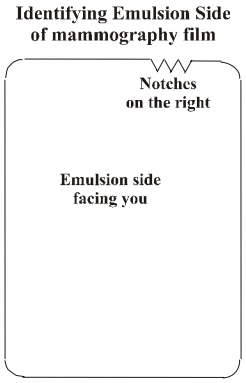

Figure 2: Processing Evaluation Test – Identifying Emulsion Side

Figure 2 Caption: Figure 2 shows how to identify the film emulsion side in the darkroom.

4.3.B.2 Verify the densitometer performance with its test strip.

Measure the background optical density (B+F) of the processed control film and *record it* in the lower part of the "**STEP Test**" screen.

Label this film with the name of the facility (and site if applicable), and the processor number (if more than one is being used), the date of the inspection, and the term "STEP Test." Retain this film as part of the inspection records.

4.3.B.3 Using measurement data from the 4 sensitometric strips on the processed film, *record* the following for each strip in the "STEP" test sub-screen:

- *The number of the step with optical density just below "1.00+B+F" (the speed density). (See Notes 4-10 and 4-11)*
- *The optical densities of the lower and the higher steps for each of the 4 strips.*

Disregard data from any strip if the density value for the same step on any of the 4 strips is different from the others by more than ±0.10. If you discarded more than two strips, repeat the test. The program will average the density values, and then calculate and display the processing speed.

Important Note. Always repeat the test if there is a noncompliance.

4.3.B.4 Click on the **Evaluation** tab and answer the following question*:

Processor/laser printer equip. evaluation (by medical physicist) done? (y/n/NA)

(When you attempt to answer the question, a hint at the bottom of the screen will read: After reassembly, major repair, or new installation), [see Section 8. regarding mammography equipment evaluations (MEE)].

* This MEE question applies to all film processors (primary and backup) or laser printers, depending on the processing method (Screen-Film or Digital) that you checked in the Information screen.

NOTE 4-8: If the calculated processing speed is abnormally low, ensure that you did not accidentally enter erroneous data or flash the film on the wrong side. If this happened, repeat the test before finalizing your data entry.

NOTE 4-9: The reference step number on the STEP test sub-screen is automatically copied from Screen 1.2 **(Equipment Registration – Film).** Update this number when it no longer corresponds to the control film you are using in this inspection (see Section 3.2.2).

NOTE 4-10: In general, the lower step number will be the same for all strips, but there may be rare conditions when it is not. By definition, the step number of the higher step is always greater by 1 than the lower step. Therefore the program will automatically record the higher step number once you record the lower one.

NOTE 4-11: For each strip, the densities of the lower and higher steps must always straddle the value you get for 1.00+B+F.

For additional information, see Sections 4.3.1 to 4.3.6 below.

4.3.1 The STEP Test – General Guidance

Prior to performing the STEP test on a processor, make sure that facility personnel have indicated that the processor is ready for processing mammograms. Processors that may not have reached operational temperature may have depleted developer chemistry, etc. may fail the STEP test and the facility will receive an inspection observation incorrectly. Prior to performing STEP tests on the processor, it is imperative to check with facility personnel to ensure that it is operational and in control.

Exception: if a facility has already performed their daily processor QC, has determined that the processor is within limits, and is processing mammograms, perform the STEP test regardless of the developer temperature or other conditions. In this exceptional situation, any data that shows they are underprocessing will demonstrate to facility personnel that they have a problem with their processor and their processor QC testing.

4.3.2 Step Reference Number for the Control Film

When performing the STEP test, it is critical that you identify the current Reference Step Number. You may check the current value displayed on your laptop screen # 3.6 – STEP Test and, if it is incorrect, you can reset it. To do this, simply go into the Equipment Registration Screen (#1.2 - Film) and, re-enter the correct value. Next, open Screen # 3.4 (Related Equipment - Film), the screen will

display the old Reference Step Number. Now click on the "Update Equipment" button, and the new Reference Step Number value will be updated in the STEP screen.

This procedure insures that the correct Reference Step Number will automatically be entered into the STEP Test screen from then on.

Note: When a new box of control film is issued, the Reference Step Number may change.

4.3.3 Control Film Used for the STEP Test

For routine clinical use the facility's clinical films should be processed according to the film manufacturer's specifications. For the STEP test, however, the control film does not have to be the same as that used clinically by the facility. The STEP test control film used by all inspectors is from the same emulsion batch, and is tested against the film manufacturers' processing specifications, i.e., it is tested in Kodak, Agfa, and other chemistries, in standard and extended cycle processing.

The STEP test control film is an accurate measure of the facility's processing. Inspectors should only use the control film provided by FDA. The facility's film should never be used to conduct the STEP test. The inspector needs to be certain to use only the control film provided by FDA.

4.3.4 Update on Film Processor Testing

Sometime in 2000, Kodak provided some industry technical representatives with "calibrated" sensitometers with which to verify processing performance. Unlike the STEP test, where a value of 100 corresponds to processing performance equivalent to the film manufacturer's recommendations, the "Aim Verification" program, as it is known, has only upper and lower limits. It does not have a "true central value." FDA feels that this "Aim Verification Program" is an extremely positive step, since the private sector, for the first time, will be empirically testing for film processing performance using instrumentation which is traceable to a "primary standard," the film manufacturer's recommendations.

Consequently, because of this renewed interest in processing by the technical community in the field, we want to remind you that when you conduct the STEP test, you need to remember the following points:

- The STEP test action limit of 80 represents a deviation from "standard" processing of 20%. This deviation assumes a calibration accuracy of 4% for the densitometer, which is traceable to the National Institute of Standards and Technology (NIST) national reference densitometer. The film emulsion variability is assumed to be 10% over the shelf life of the film and assumes that this film is stored and handled properly. The film and sensitometer together are calibrated to within 0.05 optical density, which corresponds to better than 2% agreement.
- FDA does expect some sensitometers, densitometers, and film to drift during the operational year, hence the annual calibration. Consequently, we expect MQSA inspectors to always maintain the high standards associated with this program and to question STEP test values when "other factors" do not necessarily support the STEP test results. Inspectors should periodically (monthly if possible) check their equipment with those of their colleagues to verify that their equipment performs the same.
- FDA does expect minor differences among film types and even among films of the same type. However, these differences have been incorporated within the 20% tolerance associated with the Level 2 non-compliance. The film will age and its performance will change over its

lifetime. Nevertheless, we have routinely tested the control film and found that aging effects are well within the 10% film performance criteria.

- FDA expects the inspectors to maintain their equipment properly. This maintenance includes ensuring that the sensitometer and the control film reach room temperature prior to performing the STEP test, especially during the winter months. During the summer months, the film should not be left in a hot car. Rather, it should be stored at room temperature, or even refrigerated for longer-term storage.
- Before conducting the STEP test at a facility, always allow the processor to get to its normal operating conditions. Testing the processor first may result in a low STEP test value simply because the processor has not warmed up yet. One suggestion would be to conduct the test at the end of the inspection. The inspector should be sensitive to the fact that if mammography films are not being processed during the day of the inspection, he or she needs to be assured that the processor is indeed in control.
- Always repeat the test if there is a noncompliance. In addition, for subsequent evaluation and discussion, the inspector may also want to obtain a mammography film from the batch used clinically at the facility that is exposed to the inspector's sensitometer. This additional information may be useful in subsequent discussions.
- FDA tests its control film against all of the other major mammography films under a variety of processing conditions. The criteria for selecting the control film are that it be representative of mammography films in clinical use, and that its performance is representative of most mammography films in use. There will always be subtle differences, as much as 5–10%, between films, and even calibrated sensitometers. This uncertainty has been incorporated into the 20% action range.

If you have any questions, please contact the Facility Hotline at 800/838-7715.

4.3.5 STEP (Test) Field Calibration Protocol

Inspectors' sensitometers and densitometers must be calibrated periodically (annually) to insure accuracy. As a further check on the consistency of field sensitometers between calibrations, we are asking each inspector to compare his/her sensitometer readings with other FDA-MQSA calibrated sensitometers on a monthly basis, whenever possible. Records of these sensitometer checks should be maintained by each inspector.

When there are two or more MQSA inspectors at a single location:

1. When you leave to go inspect a facility, bring along as many sensitometers as is reasonable for comparison.
2. Flash the sensitometers as follows:
   (a) In rapid succession
   (b) All with the same film (FDA-provided control film)
   (c) Process each film in rapid succession in the same processor
   (d) Read all the films with the same densitometer
3. If (and only if) the difference in the optical density readings at step-11 is equal to or larger than 0.1 between any two sensitometers, repeat the test. If the same results are obtained, please notify DMQRP.

(a) Notify DMQRP through MPRIS E-Mail.

(b) Please include in the E-Mail message the following information for each sensitometer tested:

1) Name of inspector
2) Inspector ID number
3) Sensitometer serial number (date of last calibration)
4) Optical Density at step-1, step-10, step-11, step-12, and step-13
5) Date of comparison testing and other sensitometers tested

Example:

Date: November 16, 2005

		Step Number				
Name/ID#	Serial #	1	10	11	12	13
John Doe (9534)	#14958	0.19	0.45	0.84	1.43	2.04
Bob Doe (7483)	#13494 0.19	0.45	0.85	1.46	2.07	
Jane Doe (8744)	#23404	0.19	0.56	0.95	1.56	2.18

NOTE 4-12: For this example, for step-11 the optical densities are 0.84, 0.85, and 0.95. Jane Doe's sensitometer (#23404) should be re-tested. If the density difference continues to be 0.10 or greater after the retest, contact DMQRP for further instructions before using sensitometer #23404 during an inspection.

NOTE 4-13: It is always important to periodically check the densitometer against the calibration strip that is provided with the inspector equipment.

When you are the only MQSA inspector in a particular region or State, without easy access to another inspector's FDA MQSA equipment:

1. Your auditor may check the performance of your sensitometer during your annual audit.
2. If you have reason to believe that your sensitometer is not performing correctly in the interim, please contact DMQRP through the Facility Hotline and we will assist you in verifying the performance of your unit.

Reminder: It is always important to periodically check the densitometer against the calibration strip that is provided with the inspector equipment.

4.3.6 Processing Cycle and the STEP Test

The proliferation of cycle times used in mammography has made the distinction between standard processing and extended processing confusing. This has resulted in uncertainty in recording the type of processing cycle for some systems used in the field.

Currently, the "**standard**" processing cycle which refers to a nominal cycle time of 90 seconds can have a range of 88s – 150s (which corresponds to 24s – ~35s development time), depending on the developer temperature. Likewise, the "**extended**" processing cycle can have a nominal cycle time in the range 170s – ~240s (43s – ~55s development time).

Furthermore, although the STEP test is an evaluation of the processing conditions regardless of the type of film used by the facility, the fact that some mammography films are designed to gain most of their speed increase at about 32s development time compared to their gain at a fully extended cycle (~55s development time) has created a tendency in such situations to refer to this as extended

processing and record it as such in conjunction with the STEP test, even though this falls within the standard cycle time range.

4.4 The Darkroom Fog Test

The purpose of this test is to evaluate darkroom fog levels (only at facilities using S-F systems).

4.4.A Test Set-up

Take the third cassette that was exposed earlier (Section **4.2.A**) into the darkroom. In the darkroom, place the cassette on the workbench under the same conditions that the technologist routinely uses for loading and unloading clinical films.

4.4.B Test Procedure

4.4.B.1 Remove the film from the cassette quickly and insert it into the fog test folder with its emulsion side up and with an orientation as shown in Figure 3. This placement ensures the phantom image is split by the folder edge along a line from the chest wall to the nipple. Ensure that the folder part covering the film remains flat against the film to prevent any ambient light from exposing the covered area.

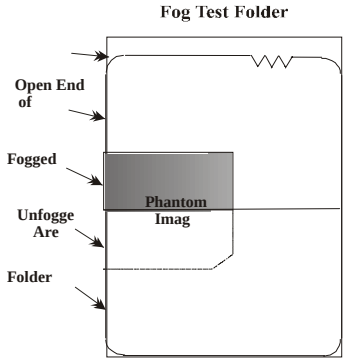

Figure 3: Darkroom Fog Test – Film Positioning in the Fog Folder

Figure 3 Caption: Figure 3 shows how to place the Fog Test film in the Fog Folder.

4.4.B.2 Expose the uncovered half of the film to normal darkroom conditions for two minutes. Make sure that you are not accidentally shielding the film from all potential fog sources (safe lights, indicator lights or other).

4.4.B.3 After 2 minutes, quickly remove the film from the fog test folder and process it normally.

Data for the darkroom fog test should be recorded in Screen 3.7 **(Darkrooms)** of your software program outline. Before recording data, select the appropriate darkroom. When selecting this screen, the **"Darkrooms"** multi-

tab screen will be displayed showing the following tabs: **"List," "Information,"** and **"Evaluation."** As with other multi-tab screens, the **"List"** sub-screen will be displayed as the default screen (if the facility has more than one darkroom). For each darkroom the list will show the following headings:

- Status (Evaluate All, Hold, Evaluate Records Only)
- Room name or number
- Site (if the facility uses darkroom(s) at additional sites).

If the information displayed on the list is incorrect, open the sub-screen corresponding to the "**Information**" tab and make the necessary changes.

4.4.B.4 Enter fog test data in the sub-screen corresponding to the "**Evaluation**" tab. If there is no visible border (corresponding to the folder edge) on the film, *record "no."* If a border is visible, *record "yes."* Measure the optical density on the covered and uncovered portions of the film at adjacent locations on either side of the boundary between the fogged and unfogged portions of the film.

Record the optical density values from the:

- *Unfogged portion of the image*
- *Fogged portion of the image.*

The program will give a "fail" indication if the fog level exceeds the action limit.

NOTE 4-14: The question regarding darkroom status has 3 answer options. "Evaluate All" means the darkroom is functional on inspection day and should be evaluated for the fog test and darkroom fog QC records. "Hold" means that the darkroom should <u>not</u> be evaluated for anything and applies to a darkroom that has had no activity whatsoever since the previous inspection but may be placed back in service sometime in the future. "Evaluate Records Only" means that the darkroom should be evaluated <u>only</u> for the darkroom fog QC records. It applies to a darkroom that was in service for a period of time after the previous inspection but has since been permanently removed from service, or to a darkroom which is not in operation at inspection time but is otherwise used for mammography.

NOTE 4-15: If the facility has more than one darkroom for mammography use, you should test each one for darkroom fog.

NOTE 4-16: If the facility does not have a darkroom (this may be the case if it uses a daylight system for automatic loading of films and processing) but is using another space as a make-shift darkroom for loading films into black bags or light-tight boxes, test each of these spaces for darkroom fog by using the following steps:

1. Select a loaded cassette out of the daylight system,
2. Take a phantom exposure with the x-ray unit,

3. Inside the darkroom or enclosure used for loading/unloading films, place the exposed image in the fog envelope for two minutes,
4. Place the film back in the cassette,
5. Place the cassette back in the daylight system's processor, and
6. Process the film and measure the fog level as described earlier.

For additional information, see Section 4.4.1 below.

4.4.1 Darkroom Fog - Daylight System Inspection Issues

There are two issues relating to daylight systems, namely: darkroom fog and the artifact evaluation test in the physicist survey. Darkroom Fog is addressed below. The other issue is addressed in the "Medical Physicist Artifact Test for Daylight Processing Systems," which may be found in the PGHS.

Darkroom Fog: First, if the facility has a darkroom which is used routinely for other diagnostic work but is used occasionally for mammography for loading the magazines in the daylight system, the argument has been raised that since the loading operation may effect only the first and last film in a box, there may be justification to raise the value of the action level for the darkroom fog test and not hold the facility accountable for the daily QC maintenance. Second, if the facility does not have a darkroom at all, how should the fog test be conducted, if at all.

Since excessive fog can adversely affect mammographic image quality, the place where daylight system magazines are loaded, whether it is a darkroom, a closet, or any other room used for this purpose, should be held to the same fog standard regardless of the number of images that may be affected. The following is the FDA policy on this issue:

- If the facility has a darkroom for magazine loading, this room should be checked for darkroom fog during the inspection. The facility should also have QC records for darkroom fog.
- If the facility does not have a darkroom but uses another enclosure for magazine loading, that enclosure should be tested during the inspection for fog levels under magazine loading conditions as if it were a "darkroom." However, the facility does not have to conduct QC testing for darkroom fog.

5. QUALITY ASSURANCE (QA) PROGRAM

The objective of the QA program is to assure that the facility develops and maintains policies and procedures to monitor and optimize the performance of facility personnel and equipment and improve the overall quality of their mammography. To accomplish this objective, review and evaluate the QA records as part of the inspection process.

5.1 Background

According to the final regulations, each facility must identify a lead interpreting physician who has the general responsibility for the quality assurance program. This responsibility includes ensuring that the quality assurance program meets all the requirements for the quality control (QC) tests (the annual tests done by the physicist and the other tests that are normally done by the QC technologist) and medical outcomes audit. The regulations specify that the lead interpreting physician, the quality control technologist, and the medical physicist must ensure that records concerning mammography technique and procedures, quality control, safety, protection, and employee qualifications, are properly maintained and updated.

The QC tests and tasks performed by the QC technologist and the medical physicist are designed to monitor the important technical parameters that affect mammographic image quality and patient dose. As emphasized in the regulations, they are components of an overall quality assurance (QA) program that the facility must have. The QA program includes, in addition to QC test records, several elements as described below (see "Further Details," Section 5.3, for additional information):

- Clearly assigned personnel responsibilities.
- Procedures for QC testing with action limits that meet the regulations.
- Mammographic technique tables or charts, including pertinent information regarding breast thickness and density, kVp-target-filter combinations for mammography, positioning, compression, exposure techniques, and appropriate image receptors.
- Radiation safety and protection.
- Records of corrective actions taken when QC tests fail, and records of verification tests conducted after corrective actions to assess the effectiveness of such actions.

For the purposes of MQSA inspections, the QA section includes a few questions pertaining to the QA program. Some items were not included because they are covered in other inspection questions. The requirement for infection control is listed in the regulations under the equipment part of the QA section, and the question on consumer complaints has been added for convenience even though it is not listed under the QA section in the regulations.

5.2 Procedure

Record in the **"Quality Assurance"** screen of your laptop software program (Screen 3.8) whether or not the following is true for the facility (and if applicable, for each additional site under the facility's certificate):

Do the QA records include the following? ***(y/n)***

- *QA Personnel Assigned (lead IP, QC technologist, med. physicist)?* *(y/n)*
- *Technique Tables/Charts?* *(y/n)*
- *Written S.O.P.'s for QC tests (with acceptable limits for each)?* *(y/n)*

NOTE 5-1: The above questions (and those in other sections in the program) are reformatted into what is termed in your software tutorial as a top-down question, e.g., a leading question followed by one or more sub-questions. A "y" answer to the lead question "Do the QA records include the following?" means that all the records listed below it are present and complete. An "n" answer to any or all of the detail questions will automatically result in an "n" answer to the lead question. Also, an "n" answer to the lead question will prompt you to indicate which item(s) should be answered by "n" (e.g., are non-compliant).

NOTE 5-2: An observation corresponding to a top-down question is termed a Repeat observation if the observation at the sub-question level below it is repeated during the subsequent inspection. Such a repeat observation will be identified in the post inspection report both at the level of the highest level lead question (where applicable) and at the level of the specific sub-question corresponding to the repeat observation. This approach is used for all top-down questions in the QC Records, Survey Report, Personnel and Medical Records.

- *S.O.P. for infection control [handling blood & other infectious materials]?* *(y/n)*
- *S.O.P. for handling consumer complaints?* *(y/n)*

NOTE 5-3: For a facility with one or more additional sites under the same or a different certificate(s) (e.g., mobile facilities), a list of these sites will be displayed once you open the **"Quality Assurance"** screen. Evaluate each site that keeps QA records. To do that, designate the status of that site as **"Evaluate"** (double-click next to the Site name) before you can get access to the data-entry fields in the **"Quality Assurance"** screen.

Record in the printable "Remarks" section any other deficiencies or specific problems that led you to answer "No" to any of the questions.

5.3 Further Details

5.3.1 General

MQSA regulations require each facility to designate a "lead interpreting physician" who is responsible for overall quality assurance and compliance with the quality standards at the facility. The QA program includes the following elements:

Clearly Assigned Personnel Responsibilities. These assignments mean: 1) identification of the lead interpreting physician, the QC technologist, the medical physicist, and the audit interpreting physician, and 2) if other individuals are assigned to perform all or part of the functions of the above

personnel, the responsibilities of the new individual(s) within the QA program in general, and the QC tests in particular, must be defined (see Specific Personnel Responsibilities below).

Procedures for QC Testing. These procedures 1) verify that all equipment functions in accordance with the quality standards set in the regulations, 2) monitor critical test parameters and/or conditions, and 3) describe corrective actions that must be taken within the time frames set in the regulations, including tests following such actions. Examples of such procedures are given in the 1999 ACR mammography QC manuals.

Mammographic Technique Tables or Charts. These items should include pertinent information on positioning, compression, appropriate image receptors, kVp-target-filter combinations, breast thickness and density, and exposure techniques. They should be posted by the control panel.

Procedures for Use and Maintenance of Equipment. These may be located in the equipment operation and service manuals.

Equipment Service Records (for both the x-ray equipment and processors).

Policies and Employee Responsibilities Concerning Personnel Radiation Monitoring and Protection for both the patient and the mammography equipment operator.

A Procedure for Infection Control. This procedure should show the steps the facility takes for cleaning and disinfecting mammography equipment after contact with blood and other potentially infectious materials.

The facility should take timely corrective actions when called for in the physicist report or when any of the equipment fails QC tests. These actions include calling for outside service when necessary. The facility should have a written report regarding each corrective action, whether the correction was done internally or by an outside service. The report should describe the problems found and their solutions. The facility should have retest data showing that corrective actions were successfully done where needed.

The facility may have a QA procedures manual. This "manual" may consist of several files containing the program elements mentioned above. In addition, it may contain:

- QA meeting records
- A page with signature and date blocks for the radiologist, medical physicist, and QC technologist, indicating approval of the manual
- A written procedure for consumer complaints (this is required but may not be part of the QA manual)
- Other QA-related records.

5.3.2 Specific Personnel Responsibilities

According to the regulations, responsibility for the quality assurance program and for each of its elements shall be assigned to individuals who are qualified for their assignments and who shall be allowed adequate time to perform these duties. You should look for the following documentation to determine that facilities meet the MQSA requirements for assigning responsibilities to quality assurance personnel:

The Names of Personnel With QC Responsibilities. You should look for the names of the lead-interpreting physician, medical physicist(s), quality control technologist(s), audit (reviewing) interpreting physician(s) and any other facility personnel with delegated quality assurance responsibilities.

A Statement of Their Respective Responsibilities. Because the regulations already specify the responsibilities of the lead-interpreting physician, medical physicist(s), quality control technologist(s), and audit interpreting physician(s), the facility does not have to restate the responsibilities of these individuals. However, if the facility delegates quality assurance responsibilities to someone other than the lead-interpreting physician, medical physicist(s), quality control technologist(s), or audit interpreting physician(s), a statement of responsibilities for that individual(s) has to be provided.

5.3.3 Consumer Complaint Mechanism – Compliance Criteria

To meet the requirements for dealing with consumer complaints, facilities must provide written documentation that describes their system for recording, maintaining, and resolving patients' complaints. The documentation must include the instructions that are, or would be, provided to patients describing how to proceed with referral of serious unresolved complaints to the accreditation body. The documentation must also include the procedures that are, or would be used by the facility to report serious unresolved complaints to their accreditation body.

If the facility has received serious complaints after 4/28/99, it must be able to produce records indicating that they are following their system and are maintaining the serious complaints for 3 years.

5.3.4 Procedures for Infection Control - Compliance Criteria

To meet the MQSA requirements for infection control, the facility must:

- Provide written documentation that describes the infection control procedures used by the facility. If reference material is cited in the facility's description of its procedures, the facility must have a copy of the referenced material. The procedures used by the facility must comply with applicable federal, state and local regulations as well as manufacturer's recommendations.
- Have documentation (e.g., Logs or charts) indicating that the infection control procedures were performed when the mammography equipment came into contact with blood or other potentially infectious materials. In those cases where there has not been an episode of contamination since the last inspection, the facility should make that clear to the inspector.

5.3.5 Dealing with Breast Implant Patients - Compliance Criteria

Facilities can meet the requirements for dealing with patients with breast implants by:

- Demonstrating to the MQSA inspector that the facility has asked its patients whether they have breast implants. This may be done by showing patient information forms that have this question answered. OR
- Having written procedures for inquiring, prior to the mammographic examination, whether the patient has breast implants.

5.3.6 Consumer Complaint Mechanism – Handling Complaints about a Facility

In the course of their activities, inspectors may become aware of complaints about a facility, usually either from patients themselves or staff at other facilities. In such circumstances, the inspector should not become a "middleman" in the dispute but rather should:

a. Advise the patient or other complaining party to bring their concerns to the attention of the

facility in question, so that they can be addressed according to the facility's complaint procedures.

b. Advise the complainant that if she/he believes the facility's response is not satisfactory, the complainant should refer the matter directly to the appropriate accreditation body for further investigation. All accreditation bodies have established procedures for dealing with these complaints. Some complainants may wish to remain "anonymous" by having the inspector pass along this information to the accreditation body. However, most of the accreditation bodies will not accept anonymous complaints. Even in cases where the accreditation body initially accepts an anonymous complaint, the body may still need to have direct contact with the complainant in order to get additional information before taking any action. Please assure complainants that all of the accreditation bodies have policies in place to protect the identity of complainants. Inspectors should not discuss with complainants possible actions the accreditation bodies may or may not take. The accreditation bodies will follow their established protocols for investigating the complaint and determining what actions, if any, are appropriate.

c. Advise the complainant that if she/he believes the accreditation body's actions are not satisfactory, the complainant may notify the appropriate certifying body for further investigation. The certifying body will then investigate the matter to see if additional actions are warranted.

5.3.7 Facility Complaints Regarding MQSA Inspectors - Resolution Process

Due to numerous comments/suggestions, the Division of Mammography Quality and Radiation Programs (DMQRP) has revised the complaint resolution process pertaining to MQSA inspectors to reflect all types of resolutions.

Receipt of Complaints. Comments concerning the inspector's proficiency or manner of performance may originate from:

1. Letters or telephone calls from facilities or other sources directly to DMQRP.
2. Reports from FDA's toll-free facility information telephone line.
3. Audit Reports.
4. Regional Radiological Health Representatives (RRHRs), MQSA Auditors, District offices, or State programs.

Process for Handling Complaints.

1. *DMQRP should:*
   A. Record the complaint.
   B. Assure confidentiality if the complainants release their identities to the Coordinator for the Inspector Quality Assurance Program
   C. Contact the RRHR.
   D. For state inspectors, contact the State Program Managers who are responsible for investigating and resolving inspector quality assurance issues as stated in the Statement of Work (SOW) contract for each state. For FDA inspectors, contact the FDA Supervisor.
   E. Discuss the alleged problem and provide the documentation and information that is received by DMQRP to the appropriate individuals.

F. Follow-up with written documentation to the State Program Manager or FDA Supervisor regarding the issue and DMQRP's complaint resolution processes.

G. If appropriate to the situation, notify the auditor of the concern about the inspector.

H. Send an acknowledgement letter to the complainant regarding the process that the State Program Manager/FDA Supervisor will follow to address the complaint.

2. *State Program Director/FDA Supervisor should:*

A. Investigate (includes consulting with inspector and facility) and provide DMQRP with written documentation of their observation regarding allegation.

B. Consult with the RRHR and DMQRP regarding the most appropriate resolution, particularly where FDA is involved in the solution.

C. Communicate directly with the inspector.

D. Notify the complainant, DMQRP, and the RRHR in writing about their investigation and the proposed resolution.

Types of Resolution

1. Special training (e.g., mentoring).
2. Suspension. During the investigation of serious or multiple complaints attributed to the inspector, the inspector may be suspended from conducting MQSA inspections. During suspension, DMQRP may deactivate the inspector's MPRIS account and request that the laptop computer and other equipment are turned over to the inspector's immediate supervisor. Return to active status should depend upon the satisfactory resolution of any problems.
3. De-certification. After a thorough review and audit of the inspector's work, and/or an investigation of any and all complaints, an inspector may be decertified if DMQRP determines that the inspector is not proficient in performing the duties of an MQSA inspector. Likewise, serious ethics violations, a breach of integrity or violations of the DMQRP Statement of Conduct can result in de-certification.
4. No action indicated. If a complaint was unfounded or the inspector followed FDA procedures and policies, no further action should be required. DMQRP closes the issue with a note for the record.

Record Keeping. DMQRP should:

1. Maintain a record of all complaints/action taken as part of the inspector's file.
2. Maintain confidentiality of all records (as required by the MQSA Privacy Act of 1995).
3. Provide yearly summary of complaints and resolutions to the DMQRP senior management, ORA, and the RRHRs.

NOTE 5-4- DMQRP also receives many positive comments concerning MQSA inspector's manner of performance and proficiency. DMQRP sends letters of acknowledgment to the sender and the inspector and their supervisor.

NOTE 5-5- FDA does not regard facility inquiries into inspector's observations during an inspection as a complaint against the inspector. Rather, DMQRP researches the inquiry with assistance from the inspector. FDA then notifies the facility of the outcome.

6. QUALITY CONTROL (QC) RECORDS

6.0 General

The purpose of reviewing QC records is to assure that the technologist's QC tests are routinely done at the frequencies required, that records of these tests are in order, and corrective actions are taken when test results exceed action limits.

Review the QC records for the past 12 months or since the last inspection, whichever is longer. For a new facility review the records back to the date of the original certification. The records that you will review for the main facility, and where applicable, any additional site(s) are:

- Processor QC records (daily QC and fixer retention) for all mammography processors at the facility/site.
- QC records for the phantom and compression device for each screen-film x-ray machine used for mammography.
- QC records for the darkroom fog test for each darkroom at the facility/site, and records for repeat analysis and screen-film contact.

While reviewing these records, look for trends and/or deviations from normally established operating levels.

The **"Quality Control"** section of your laptop software program (Screen 3.9) contains the following data entry sub-screens and corresponding QC tests:

3.9.1 S-F Processor QC (Processor Performance QC & Fixer Retention QC)
3.9.2 Phantom Image QC
3.9.3 Compression QC
3.9.4 Repeat Analysis QC
3.9.5 Screen Film Contact QC
3.9.6 Darkroom Fog QC
3.9.7 Digital Mammography QC

Record your observations regarding the QC records for each of these tests in the corresponding screen as described below:

For additional information or guidance pertaining to all QC records, see Sections 6.0.1 to 6.0.4 below.

6.0.1 QC Records Retention Requirement for Replaced Equipment

The requirement for equipment currently being used is that these records must be maintained until the next annual inspection that would verify compliance or until an individual test has been performed two additional times at the required frequency, whichever is longer. However, for film processors and/or mammographic x-ray systems that are no longer used clinically at the facility, the records need only be kept for that equipment until the next annual inspection.

6.0.2 Documentation of the Required Screen-Film QC Tests

Performance of the required QC tests must include clear and legible documentation. The documentation must include test results and the dates when the tests were performed. For each test result that falls outside the action limits, the documentation must also include the date and the corrective actions taken and their results. The data and results should be properly charted or tabulated. Facilities may consult any appropriate quality control manual for examples of charts and tables or establish their own format for documenting the test data and the results.

There are seven required tests for which the QC technologist is usually responsible:

Daily Tests: Processor QC

Weekly Tests: Phantom image evaluation

Quarterly Tests:
1. Repeat analysis
2. Analysis of fixer retention

Semi-annual Tests:
1. Darkroom fog
2. Screen-film contact
3. Compression

In addition to the above tests, the facility is required to establish and implement adequate protocols for maintaining cleanliness of:

1. Darkroom(s)
2. View Boxes
3. Screens

The QC technologist may incorporate all these tests and tasks into a QC checklist which he or she can initial and date to ensure that all these tests and tasks are performed on schedule.

NOTE 6-1

The Weekly Phantom Image Test must be performed each week. However, the test need not be performed on the same day each week. (For facilities that operate intermittently, see the alternative standard at the end of the Phantom Image QC section).

The Quarterly Tests must be performed 4 times a year. The 4 months that are chosen must be spaced 3 months apart (such as February, May, August, and November). However, for any of the 4 selected months, each test may be performed on any day (not necessarily the same day) in the month.

The Semi-annual Tests must be performed 2 times a year. The 2 months that are chosen must be spaced 6 months apart (such as January and July). However, for any of the 2 selected months, each test may be performed on any day (not necessarily the same day) in the month.

These non-annual QC tests, their frequencies, action levels, record retention times, and the timing requirements for corrective action for each are summarized in the table below, Exhibit 4.

Exhibit 4: QC Tests Other than Annual

QUALITY CONTROL TESTS OTHER THAN ANNUAL

Test & Frequency	Requirements for Acceptable Operation	Guidance for Acceptable Documentation Retention*	Timing of Required Corrective Action **
Processor QC- Daily	Established operating level for B+F, + up to 0.03 OD.	QC records for the last 12 months or since the last inspection, whichever is longer. QC test films for the last 30 days.	Before any further clinical films are processed.
"	Established operating level for MD, ± 0.15 OD.	"	"
"	Established operating level for DD, ± 0.15 OD.	"	"
Phantom QC-Weekly	Established operating level for OD at center of image 1.2 ± 0.20, but the minimum OD must be 1.2 at any time.	QC records for the last 12 months or since the last inspection, whichever is longer. Phantom images for the last 90 days.	Before any further examinations are performed using the x-ray machine.
"	Established operating level for contrast, ± 0.05 OD	"	"
"	Minimum score of 4 fibers, 3 speck groups, 3 masses.	"	"
Fixer retention in film-Quarterly	< 5 micrograms per square cm of residual fixer.	QC Records since the last inspection or for the past three tests, whichever is longer.	Within 30 days of the date of the test.
Repeat Analysis-Quarterly	Operating level for repeat or reject rate is < 2% change (up or down) from previous rate.	"	"
Darkroom Fog-Semi-annually	OD 0.05.	QC Records since last inspection or for the past three tests, whichever is longer. Fog QC films from the previous three tests.	Before any further clinical films are processed.
Screen-Film Contact-Semi-annually	All mammography cassettes used must be tested with a 40-mesh copper screen.	QC records since last inspection or for the past three tests, whichever is longer. S-F contact QC films from the previous three tests.	Before any further examinations are performed using the cassettes.
Compression Device Semi-annually	Min. Compression force of 111 newtons (25 pounds) & a max. force of initial power drive between 111 and 200 newtons (25 - 45 pounds).	QC records since last inspection or for the past three tests, whichever is longer.	Before examinations are performed using the compression device.

***** Guidance regarding the length of time for which the facility is required to keep QC records was given in the Policy Guidance Help System (PGHS) under Quality Assurance Records, 900.12(d)(2).
** Refer to 900.12(e)(8)(ii)(A) or (B) as applicable.

6.0.3 Darkroom Blacklight

It has been reported that inspectors have been telling facilities that they should replace some of their screens that they judged to be defective based on the use of the ultraviolet (UV) inspection light (also

known as a blacklight). Some of these screens have been returned by the facilities to the screen manufacturer for replacement. However, the screens are not defective, and the MQSA inspector is being blamed. Inspectors are reminded not to use the UV light to check intensifying screens.

The UV light is a great tool to have in the darkroom to check for dust and lint. The particular light supplied to some of you has both short and relatively long UV wavelengths, and because of the short wavelength component, it can detect screen stains or surface imperfections in addition to dust and dirt. Although the instrument has the capability of showing surface imperfections, not all screen surface imperfections imply that the screen is defective. The only screen surface imperfections that warrant screen replacement are the ones that show up as film-based image artifacts. MQSA inspectors who have the UV inspection light should use it ONLY for detection of dust and dirt in the darkroom.

6.0.4 Reviewing QA/QC Records for Retired Equipment

Frequently, inspectors encounter situations where facilities fail to produce QA/QC records for equipment (film processor and/or x-ray machine) which was in use for a period of time between the previous MQSA inspection and the current inspection, and has since been retired from use and replaced with new equipment. What to do in these situations is discussed below.

The following discussion applies to situations where the records for the current equipment (which replaced the retired equipment) are available. The inspector should review the previous inspection record for any evidence which may help clarify why the records were missing at the time of the inspection (i.e., past noncompliance citations which required significant and immediate repair, which may not have been done).

The inspector should also advise the facility of the time frame(s) that records must be kept and the importance of retaining records for all equipment which has been used since the previous inspection. This should all be documented in the Printable Remarks section.

Additionally, one of the following two actions should apply. When an inspector believes that the facility had completed the required QA/QC tasks/tests during the past year, but at the time of the inspection these records are not available for an understandable and acceptable reason, the inspector should not issue a noncompliance. An example of an acceptable reason for the records not being available would be if for a reason beyond the control of the facility, such as a fire or vandalism destroying the records.

When an inspector believes that the facility has purposefully caused the absence of the records, the inspector should issue a noncompliance to the facility and request a further investigation, which may include an audit of the facility records and/or a clinical image review. FDA will decide on any further actions on a case-by-case basis.

6.1 Processor Performance QC (Daily)

Evaluate the QC records for each processor used for mammography at the facility (and its other sites if applicable) since the last inspection, including back-up processors, processors that may be undergoing maintenance or repair on inspection day, and those that were used since the previous inspection but were removed from service prior to the current inspection.

The **"S-F Processor Performance QC"** screen (Screen 3.9.1) lists the processors* (primaries and back-ups) and their locations that you designated earlier (Screen 3.6) as "Evaluate All" and/or "Evaluate Records Only." At this point, select a processor from the list, evaluate its QC

records and enter the data in the lower part of the screen. Next, repeat the selection and evaluation process for all the processors on the list.

*Although the processor list in Screen 3.6 may include laser printers (if the facility provides digital mammography services), Screen 3.9.1 will not show any laser printers. It will only show the (S-F) processor(s) with a status other than "Hold."

For each processor, review the records since the last inspection and select a month that represents a worst case scenario regarding the daily QC tests. Record the following in the data entry fields:

- *Worst/Sampling Month/Year (mm/yyyy),* (such as 02/2001)
- *Number of days processed mammograms* (in the worst/sampling month)
- *Number of processing days without recorded data* (in the worst/sampling month)
- *Number of consecutive processing days missed* (since the last inspection)
- *Number of days operated out-of-limits [MD, DD: ±0.15, B+F: +0.03]*
- *Corrective Action (C/A) [before further exams were processed] documented? (y/n/NA)*

NOTE 6-2: You must enter a "Worst/sampling month/year" to gain access to the two data entry fields that follow it. If all months are the same, pick any one. "Without recorded data" means without either the mid-density (MD), or the density difference (DD), or the base plus fog (B+F).

NOTE 6-3: The "number of consecutive days missed" means that the facility did not record any one or all of the parameters listed in NOTE 6-2 above during two or more successive processing days in the review period (since the last inspection), including days that may fall across two different months. If there is more than one such occurrence in the year, record the worst one.

NOTE 6-4: "Operated out of limits" means that mammograms were processed when any of the processor parameters listed in NOTE 6-2 exceeded the action limits listed above.

NOTE 6-5: In cases where there are widespread problems with processor QC over the course of the year and/or problems with missing QC records and processing out of control, document all the problems, including pertinent dates when the problems were noted, in the Remarks section.

NOTE 6-6: Whenever any of the daily processor QC parameters exceed action limits, the facility must take corrective action (C/A) to bring the processor under control before processing any new mammograms in that processor. The regulations impose similar C/A time frames on QC tests for the phantom image, dose, compression, screen-film contact, and darkroom fog, which prohibit the clinical use of an item that fails a QC test until the failed item is fixed. For the remaining QC tests, the facility must take corrective action within 30 days. As reminders, the software program will provide you with helpful hints for each.

If you determine that an evaluation of the actual QC strips is necessary, examine strips from the most recent 30 days.

For additional information regarding processor QC, see Sections 6.0.1 to 6.0.4 and Sections 6.1.1 to 6.1.14.

6.1.1 Charting of Quality Control (QC) Test Results

While facilities are required to keep records for the required QC tests, facilities are not required to record the data on charts or graphs. However, we believe that charting/graphing of test data provides a valuable tool for the facility to monitor trends associated with the data and to take corrective action prior to equipment performance exceeding regulatory action limits. The use of charts/graphs will also serve to expedite the inspection process resulting in significant savings in facility time and resources.

6.1.2 Performing the Daily Processor QC when the Sensitometer is not Available - Alternative Standard

On October 18, 1999, FDA approved a request for an alternative to sensitometric testing of processor performance that can be used for a period of up to two weeks when the facility's sensitometer is unavailable. This alternative, previously permitted by policy under the interim regulations as described in the Summer 1995 issue of Mammography Matters, is based on evaluating a phantom image through measurements described in 21 CFR 900.12(e)(1) and (2).

When using the alternative test, processor performance is considered satisfactory if:

1. The optical density of the film at the center of an image of a standard FDA-accepted phantom is at least 1.20 when exposed under typical clinical conditions.
2. The optical density of the film at the center of the phantom image changes no more than +/- 0.20 from the established operating level.
3. The density difference between the background of the phantom and an added test object, used to assess image contrast, is measured and does not vary by more than +/- 0.05 from the established operating level.

   In addition:

4. To evaluate base + fog, an additional measurement of density must be made either of a shielded portion of the phantom image film or of an unexposed film. In accordance with 21 CFR 900.12(e)(1)(i), the base plus fog density must be within + 0.03 of the established operating level.

As with the original test, this alternative test must be conducted "each day clinical films are processed, but before processing of clinical films." All results must be recorded and charted. Again, as with the original test, if processor performance fails to meet any part of the alternative test, the problem must be corrected before processing is resumed.

6.1.3 Performing the Daily Processor QC when the Densitometer is not Available

The daily processor quality control is required prior to processing patient films. No alternative is currently available to verify processor performance without a densitometer. If the facility plans to use a loaner densitometer, reintroduces one into service after repair/calibration, or obtains a new densitometer, the facility should contact their medical physicist for instructions on how to proceed.

6.1.4 Situations Warranting Re-establishment of Processor Operating Levels

The most warranted and common situations for a facility to establish new processor operating levels are when processor QC testing is initiated for a new processor or when a significant change is made in the processing system. Some significant changes that may necessitate the establishment of new

operating levels include: change in film brand/type, change in chemical brand/type, change in replenishment rates, change in specific gravity auto-mixer settings, change of sensitometer or densitometer, or a change in processing conditions (standard vs. extended). Replacement of chemistry (same brand/type) as part of routine preventative maintenance should not necessitate establishment of new operating levels.

Facilities should not use the establishment of new operating levels to correct problems in the processing system, but should troubleshoot and solve the problem with appropriate corrective action. FDA recommends that the facility consult with their medical physicist prior to establishing new operating levels.

6.1.5 Facility Actions while Establishing/Re-establishing Processor Operating Levels

While establishing new operating levels (during which time the facility can continue to process mammograms), the facility must continue to perform the daily processor QC tests and should plot the data in the same manner it usually does. This may be done on the same graph as the previous data or on a different graph. In either event, this new data should be clearly identified as being derived during the establishment of the new operating levels, so that both the facility and the inspector are aware of the origins of this data. Because no operating level has yet been established, the facility is exempt from having to stay within any processor action limits during this five-day averaging period. FDA recommends that during the five-day averaging period, the facility daily perform and evaluate a phantom image as a means of monitoring image quality. Because phantom optical densities may also vary during this time period, the facility may limit its evaluation of the phantom image to the fiber/speck/mass scores. If the facility follows this recommendation and the scores fall below the minimum requirement, the facility must cease performing mammography until the problem has been corrected. 21C.F.R.90012(e)(8)(ii)(A).

6.1.6 Time Constraints on the 5-day Averaging Period for Establishing/Re-establishing Processor Operating Levels

The 5-day period is not a regulatory limit. Therefore, a facility may use a shorter or longer period if their situation calls for it. The number of days needed to establish the operating levels depends on the time it takes for the processor to reach chemical equilibrium or a “seasoned” status. In practice, this is usually achieved when the chemicals in the developer tank have been replaced or “turned over” 2-3 times.

For a given film, this time is a function of the developer tank size, the replenishment rate, and the number of films processed (patient volume). Also, different film emulsion types have different replenishment rates per sheet of film, thus requiring different periods for the same processor to reach a seasoned status.

Based on experience to date, we expect the majority of facilities to use up to a 5-day averaging period. However, if a facility uses a longer period, it should provide empirical data or recommendations from the film manufacturer explaining the reasons for the longer time period. Regardless of the length of time needed for establishing or re-establishing operating levels, the facility must document the MD, DD, and B+F values daily. Even though there are no regulatory action limits during this period, monitoring of processing conditions is still important as these values may identify problems with developer temperature, replenishment rates, and other variables.

6.1.7 Performing Daily QC on the Back-up Processor (General Purpose or

Dedicated for Mammography)

Facilities are not required to perform daily QC on these processors when they are not being used for mammography. However, intermittently used (so called back-up processors) used for mammography will be held to the same quality standards as the primary processor(s) used for mammography. It is the responsibility of the facility to assure that the processor is in control (monitored parameters are within the action limits) before processing any clinical images. One way to achieve this is to establish a baseline for any processor that might be used as a back-up for processing mammograms. Subsequently, on the day the back-up processor is needed, the daily processor QC tests should be performed prior to processing clinical images and if the test results fall outside the action limits, clinical images should not be processed until all problems have been fixed and the new test results show that the processor is in control.

6.1.8 Performing Daily QC on Mammography Processors that are also Used for Copying Mammograms and for Laser Films that are Used in Full Field Digital Mammography (FFDM)

Films that are used to copy mammograms (duplicating or copy films but not laser films) generally alter the performance of the processor by degrading the chemicals in the processor. This does not significantly affect processor performance if a small number of copies are made at a time. However, if a large number of copies are produced on a given day, FDA recommends that the daily processor QC tests be performed after the copies have been processed and prior to processing the clinical images. Daily QC on laser film processors must follow the procedures set by the manufacturer of the FFDM system.

6.1.9 Performing the Daily QC Tests on a Processor Used Only for Duplication of Mammograms

There are no MQSA requirements for processors that are used only for copying mammograms. However, if such a processor is also used to process original mammograms, then you must perform processor QC on it and assure that it is in control before you use it to process mammograms.

6.1.10 Performing the Daily Processor QC Tests on Days when Mammograms are Performed but not Processed

Facilities are required to perform these tests only on the days they process mammograms. However, FDA recommends that facilities that routinely process mammograms less than 5 days/week perform the daily processor QC tests on additional days. The additional tests can provide the facility more information to predict trends and thereby identify and correct problems earlier.

6.1.11 Performing Processor QC Using Phantom Image Measurements

The daily use of the optical density measurements (BD, contrast, and B+F) from a phantom image test in place of the normal processor QC tests is permitted ONLY when the facility's sensitometer is unavailable (for example, it has been sent in for repair) and for no longer than two weeks. During this use the facility must follow the procedures of the approved alternative requirement entitled **"**Performing the Daily Processor QC When the Sensitometer is not Available**."** The use of phantom image measurements of BD, contrast, and B+F as a substitute for processor QC tests is not permitted under any other conditions than those described in the alternative requirement.

6.1.12 Preset Scanning Densitometers

Some facilities have been sold scanning densitometers with steps for mid-density (MD) and density difference (DD) preset by the manufacturer, and the manufacturer's representative has not explained to the facility staff that they should reset the MD and DD to reflect the facility's actual conditions. While reviewing the QC records during an inspection, the fact that the facility is not using their own MD and DD aim values may not be obvious at first glance. Problems with facility's daily QC processor charting, however, will probably result and you should be aware that this may be the cause.

There is not a question in the inspection procedures regarding the particular MD and DD values which the facility is using. If, during an inspection, you determine that the MD and DD values were not set correctly and you assist the facility in correcting this, please note this information in the REMARKS section that prints out to the facility. By using this REMARKS section, the facility will be aware that this is a significant problem, which was discussed during the inspection, and needs to be remedied.

6.1.13 Automatic Densitometers and Saving Data

Inspectors are finding situations in which individuals that monitor processor performance with an automatic densitometer are on occasion forgetting to press the "save" button. As a result, when they print out their processor charts later, there are gaps in those charts.

This would be an inspection observation just as is the case when an individual doing the test manually forgets to record the data on the chart, unless the facility had recorded the density on another form or on the film. If the facility has no record that the test was done on that day, the facility has no evidence that the test was done and should be cited. The level of the observation would depend upon how often the facility did not save the required data.

6.1.14 Sensitometer Calibration

It is not a requirement that facilities have their sensitometers calibrated. However, it is recommended that they comply with the recommendations of the manufacturer or the facility's accreditation body.

6.2 Fixer Retention QC (Quarterly)

Check and record in the same screen (Screen 3.9.1), whether the following is true "y" or not "n" for all the processors you designated as "Evaluate All" or "Evaluate Records Only."

- ***Fixer retention QC adequate?*** ***(y/n)*** [default to *y*]
  - *Done at the required frequency?* *(y/n)*
  - *C/A [30 days] Documented?* *(y/n/NA)*

Record any other problems or observations in the "Remarks" section.

For additional information, see Sections 6.0.1 to 6.0.4 and Section 6.2.1.

6.2.1 Fixer Retention QC Records

Inspection reminder: FDA does not require facilities to retain the film(s) used for the fixer retention test(s). Since this test is based on a color comparison of the area where the fixer and the test chemical are applied to the film and since these areas change in color with time, the usefulness of these test films is limited to a relatively short period of time following the performance of the test.

For the fixer retention test, FDA requires the facility to keep records of the performance of the test (and any corrective action taken) since the last inspection or for the past three tests, whichever is longer.

6.3 Phantom Image QC (Weekly)

Evaluate the phantom image QC records for each x-ray unit used with S-F image receptors for mammography at the facility, including those that may be undergoing maintenance or repair on inspection day, and those that were used since the previous inspection but were removed from service prior to the current inspection.

The **"Phantom Image QC"** screen (Screen 3.9.2) lists all the S-F x-ray units that you had designated earlier (in Screen 3.5 of your laptop outline) as "Yes" (evaluate all), "Evaluate Records Only," or "Temporarily out of service." At this point, simply select one from the list, evaluate its phantom image QC records and enter the data in the appropriate fields. Next, repeat the selection and evaluation process for all units used with S-F image receptors on the list.

Review the QC records for the phantom images and verify that the test records reflect weekly or more frequent measurements of the background density (BD) at the center of the phantom, the density difference (DD) or contrast, and the number of test objects. Scan the records since the previous inspection, or for new facilities, from certification date, and record your answers to the following questions in the appropriate data-entry fields:

- ***Phantom QC records adequate?*** **(y/n)**
  - *Number of operating weeks missing in worst consecutive 12-week period* ---
  - *C/A [before further exams*] documented?* *(y/n/NA)*
  - ***Other phantom QC records/test conditions adequate?*** **(y/n)**
    - *Image taken at clinical (± 1 kVp) setting?* *(y/n)*
    - *Background Optical Density (BD) (@ center) ≥ 1.20* *(y/n)*

***** This means corrective action (for failing image score, background density, or contrast) before further exams were conducted using the x-ray unit or item that caused image failure.

For mobile units (van, truck):

- *Performance verification after each move?* *(y/n/NA)**

* For the overwhelming majority of units that are downloaded by FISS as stationary (e.g., not designated as mobile), NA (Not Applicable) will be the default answer to the above question. However, if a stationary unit has been moved to a different location since the previous inspection, NA may or may not be the appropriate answer depending on whether the facility conducted an MEE or a performance verification test for it after the move.

NOTE 6-7: The facility should keep phantom images for each of the weekly tests during the 90 days preceding the inspection and make them available if needed.

NOTE 6-8: Mobile mammography units have the same phantom image requirements as fixed units. In addition, the facility must document the test(s) it used to verify that the unit's performance continued to meet quality requirements after every move and prior to use on patients at the new location.

Record any other problems or observations in the "Remarks" section.

For additional information regarding the weekly phantom image QC, see the PGHS on your laptop, Sections 6.0.1 to 6.0.4, and Sections 6.3.1 to 6.3.10.

6.3.1 Phantom Image QC Records - Operating Levels

The operating level for the background optical density (OD) at the center of the phantom has a ± 0.20 control window subject to the requirement that the background optical density must always be ≥ 1.20. For example, if the facility chooses 1.32 as the operating level, the action limits would be 1.52 and 1.20, e.g., the lower limit would be 0.12 (not 0.20) below the operating level. Likewise, the operating level for the density difference between the background OD of the phantom and a test object must have control limits of ± 0.05. The facility must record the number of test objects of each type at each test and must follow the rules established by the accreditation body (e.g., must not decrease by more than 0.5 from the operating level).

6.3.2 Phantom Image QC Film

When performing the weekly phantom QC test, FDA recommends using films from the box currently being used to produce clinical images. If the facility uses dedicated boxes of QC films for the phantom tests, the chance of detecting problems with the clinically used film is sacrificed.

FDA realizes that, due to differences in emulsion batches, a phantom image test with films from a new box may show variance in optical density and density difference greater than the allowed limits (when measured against the operating level established with films from the previous box). In such a case, facilities are advised to first check the whole imaging chain including the processor performance (facilities may wish to contact their medical physicist for help with this process). If no problems are detected, the facility may assume the change is due to different film emulsion batches. They may then adjust their typical clinical technique factors to meet the phantom optical density requirements.

6.3.3 Reviewing Phantom Image QC Records

To determine the number of weeks missing (e.g., the facility did not conduct the phantom test), review the QC records for the past year (or since the previous inspection, whichever is longer), select the worst 12 consecutive working weeks, and record the number of missing weeks in those 12 working weeks – not in the entire year. As a reminder, a hint about this in the software program appears at the bottom of the screen when you click to answer the corresponding question. You may indicate the number of additional weeks missing outside this period in the printable Remarks if you want to emphasize this point. However, do not use entire year's data to cite the facility.

6.3.4 Test Conditions for the Weekly Phantom Image

Facilities must use the same technique factors for the weekly phantom image as those clinically used for the typical patient. For example, if the facility clinically uses the Full-Auto mode for its standard breast patients, the weekly phantom images must be obtained using that mode. FDA requires the weekly phantom image be produced using the same clinical conditions that are used for its patients with the standard breast (compressed breast thickness of 4.2 cm, with breast tissue consisting of approximately 50% adipose (fat) tissue and 50% glandular tissue in composition). Prior to performing mammography on patients, the phantom image must achieve at least the minimum phantom score established by the accreditation body and must be within the action limits established for the 3 optical density requirements.

A frequently asked question is whether the facility must monitor the kVp and/or mAs when performing the weekly phantom image test. The answer is No. The only requirements on the weekly

phantom image test are that the phantom image achieves at least the minimum phantom score established by the accreditation body and must be within the action limits established for the three optical density requirements. FDA is aware that many facilities are monitoring kVp and/or mAs as part of their weekly phantom QC testing. This is not required. If a facility uses the Full-Auto mode and monitors kVp and/or mAs, it will probably observe that, over time, the Full-Auto mode leads to small variations in the kVp selected by the unit for the phantom exposures. Even small variations in kVp may lead to significant variations in the mAs values obtained. While small variations in kVp are to be expected when using the Full-Auto mode, large variations in kVp (greater than 1 kVp of the value usually obtained) may indicate a problem and should be further evaluated. Facilities using the Full-Auto mode that wish to monitor kVp and/or mAs may want to establish baseline mAs values corresponding to the specific kVp values usually encountered during phantom testing. In this way, they can account for the mAs variability that may be caused by small changes in kVp.

Mobile facilities should be aware of the following if they are monitoring mAs as part of their post-move-pre-exam testing. Performing the post-move-pre-exam test in the Full-Auto mode may be problematic (due to the variability of kVp and mAs as previously mentioned). In these cases, the facility may:

1. Use the AEC mode (with fixed kVp) to perform the post-move-pre-exam test, even if they use the Full-Auto mode for their patients with the standard breast. Note: The weekly phantom QC test must be performed using the same clinical conditions that the facility uses for its patients with the standard breast. OR

2. Use the Full-Auto mode and establish baseline mAs values corresponding to the specific kVp values usually encountered during phantom testing. If the mAs value is within 10% of the baseline value for the post exposure kVp value, the unit has passed that portion of the post-move-pre examination test.

6.3.5 Monitoring of the Weekly Phantom QC at a Facility with Multiple Processors and Multiple X-Ray Units

Adequate monitoring for such a facility depends on whether the x-ray units and processors are used interchangeably, whether the processors are matched (established Processor Operating Levels for mid density and density difference for all processors are within 0.05 optical density), and whether each processor is operating within its own pre-established action limits.

If the processors are not matched and the facility is processing clinical films from its multiple x-ray units interchangeably through its processors, the facility must conduct the weekly phantom image test for each x-ray unit-processor combination. In this example, if a facility has 5 x-ray units and 2 processors, a total of 10 phantom images must be performed each week.

If the processors are matched and the facility is processing clinical films from its multiple x-ray units interchangeably through its processors, it is acceptable to produce a weekly phantom image from all x-ray units and process them through any processor, as long as each processor is tested with a phantom image at least once each week of use. (Note: in this scenario each processor must be operating within its own pre-established action limits). This will reduce the number of phantom images that must be performed. In this example, if a facility has 5 x-ray units and 2 processors, a total of 5 phantom images must be performed

each week. Note: At least 1 phantom image must be processed through each processor.

6.3.6 Facility Actions if and when the Optical Density (OD) for the Weekly Phantom Test Falls Outside Action Limits

If the OD at the center of the phantom image falls below the required minimum of 1.20 (and/or changes by more than +/- 0.20 from the established operating level), the facility should follow pathway A, B, or C; below, based on the situation at the facility:

A. If the film is of a different type (e.g., switch from Min-R 2000 to Min-R E) from the previous week's passing test, the facility should establish new phantom QC operating levels.

B. If the film emulsion batch is unchanged from the previous week's passing test:

   1. Ensure that the phantom is exposed using typical clinical conditions and that the position of the phantom and, where appropriate, the position of the AEC detector have not changed from that used for prior images.

   2. Reevaluate the daily processor performance and make sure the processor is properly optimized according to the film manufacturer's specifications.

   3. If the facility has been tracking mAs, check the function of the mammography unit by comparing the mammography unit's current mAs output with values obtained for previous phantom images. If the mAs has changed by more than 15%, and the facility has been using the same kVp, the same mammography unit density setting, and the processor is operating within its action limits, then the medical physicist should be called to check the entire imaging chain, including the mammography unit. If the mAs has not changed by more than 15%, then proceed with step 4.

      If the facility has not been tracking mAs, the facility should consult with its medical physicist for what to do next.

   4. If no problems are found in steps 2 and 3, adjust the density control setting to obtain an optical density of at least 1.20 at the center of the phantom image (or obtain an optical density within +/- 0.20 of the established operating level).

   5. Adjust the density control setting used clinically to be consistent with the changes made in step 4.

C. If the film is of the same type but of a different emulsion batch from the previous week's passing test, the facility should follow the steps as described in B, 1 through 5.

If the optical density again falls below 1.20 (and/or changes by more than +/- 0.20 from the established operating level) the next time the weekly phantom test is performed, the facility should follow the appropriate pathway (based on the film emulsion used) from the following three options:

- If film of a different type (e.g., switch from Min-R 2000 to Min-R E) is used, the facility should establish new phantom QC operating levels.
- If film of the same emulsion batch is used (assuming the same kVp and mammography unit density settings are used, and the processor is operating within its action limits), the facility should consult with its physicist and check the entire imaging chain before performing mammograms.

- If film of the same type (but not of the same emulsion batch) is used, the facility should repeat steps B 1 through B 5.

6.3.7 Conducting the Weekly Phantom Image Test for Mammography Facilities Operating Intermittently - Alternative Standard

This standard was approved on May 24, 1999 and was made retroactive to April 28, 1999. It applies to facilities that do not conduct mammography every week. Rather, they may conduct mammography only part of the time in a given month.

As published in the final MQSA regulations on October 28, 1997, the heading of 21 CFR 900.12(e)(2) states that:

(2) Weekly Quality Control Tests. Facilities with screen-film systems shall perform an image quality evaluation test, using a FDA-approved phantom, at least weekly.

The approved alternative standard is:

"(2) Weekly Quality Control Tests. Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, in each week that clinical mammography examinations are performed, prior to the performance of such examinations."

The alternative standard requires that if the number of weeks per month in which clinical mammography is performed increases or decreases, the frequency of the performance of the phantom image quality test must automatically undergo a corresponding increase or decrease. Because of this automatic adjustment to changing facility conditions, no time limit has been placed upon the period of approval.

6.3.8 Facility Use of a Cracked Breast Phantom

When a facility is using a cracked or broken breast phantom that interferes with the scoring of the phantom image (simulates masses, fibers or specks, and/or obscures one or more of the test objects) for their Phantom Image QC testing, the inspection question "C/A documented?", which is located in the 3.9.2 Phantom Image QC screen of the inspection software, should be answered "No" (since the use of such a phantom constitutes an uncorrected problem) and an explanation of the citation should be placed in the printable Remarks section for this screen. The facility should be advised to acquire a defect-free phantom.

6.3.9 Phantom Modifications

It has come to our attention that one or more inspectors may have directed (or suggested to) facilities to have their imaging phantoms modified by having the normal screw heads (which protrude above the top surface of the phantom) replaced by screws that are flush with the top surface.

Presumably this came about because DMQRP has modified (or asked States to modify) phantoms that were previously used in MQSA inspections in this manner. This note is simply a reminder of why these modifications were made and why it is inappropriate to require/recommend that facilities make similar modifications.

MQSA inspectors will encounter a wide variety of x-ray units and some of these units use the position of the compression paddle in the process of automatically selecting the exposure technique. When inspecting such units it is helpful to be able to bring the compression paddle down in contact with the top of the phantom. While this is not generally critical for QA purposes within a facility, it is critical for MQSA inspections of this subset of x-ray systems.

Facilities are required to make phantom images periodically to assure the relative consistency of their imaging system. In doing so it is critical that they expose the phantom reproducibly but it is not generally important that the compression paddle be in contact with the top of the phantom during exposure. In fact many facilities will make the phantom image with an acrylic disc on top of the phantom to assess contrast and this disc may protrude further above the top of the phantom than do the normal screws that secure the cover of the phantom.

Therefore, it is not necessary for facilities to modify their phantoms by using screw that are flush with the top surface and it is inappropriate to require or recommend that they do so. Such a requirement or recommendation would result in unnecessary expense for the facility or the phantom supplier.

6.3.10 Using the Phantom Image QC Test as a Substitute for Sensitometry

The daily use of the optical density measurements (BD, contrast, and B+F) from a phantom image test in place of the normal processor QC tests is permitted ONLY when the facility's sensitometer is unavailable (for example, it has been sent in for repair) and for no longer than two weeks. During this use, the facility must follow the procedures of the approved alternative requirement entitled "Conducting the Daily Processor QC Tests When the Sensitometer is not Available." The use of phantom image measurements of BD, contrast, and B+F as a substitute for processor QC tests is not permitted under any other conditions than those described in the alternative requirement

6.3.11 Performance Verification Test for Mobile Mammography Units

The QC test requirements for mobile units are basically the same as for fixed units, except for one additional requirement. Namely, each time the mobile unit is moved to a new examination location, the facility must verify satisfactory performance of the unit before it conducts any patient examinations. This requirement means that the facility must conduct a test (or tests) that establish the adequacy of the image quality produced by the machine after the move and prior to imaging any patients.

As an example of an acceptable test, a phantom image can be taken in the AEC mode (or the mode used clinically) after the move, but prior to patient examination. This image is then either processed and evaluated at the mobile unit site, if possible, or processed off-site and evaluated to verify performance prior to examining patients. A passing object score for this phantom image will be accepted as evidence that the unit is performing adequately after the move and before patient examination.

Another example, for use when processing is not immediately available, is to (1) for a given kVp, record the mAs resulting from a phantom exposure (in the AEC mode under typical clinical conditions or the mode used clinically); (2) compare that mAs to a standard mAs value previously established as ensuring output consistency; and (3) if the two readings are within +/- 10%, proceed with clinical examinations; otherwise take corrective actions to bring the two values within this limit before proceeding with clinical examinations. A crucial follow-up to this test by the facility is to process (using a processor in control) and score the objects in the phantom image taken in step (1) at the earliest time available and before batch processing any of the clinical images. If this phantom image score fails because of any processing problems, the problems should be corrected prior to processing any of the clinical images. If the phantom image score fails due to a non-processor problem, the mobile facility should still process all the films. Each clinical exam should be evaluated individually to determine whether any of the patients have to be recalled to have their images repeated. The entire imaging chain must be checked and adjusted or repaired prior to further clinical use.

If the facility takes a phantom image as part of its post-move/pre-examination testing, it needs to document the object score of the phantom image. The facility needs to keep the written records of post-move/pre-examination tests for the last 12 months or since the last inspection, whichever is longer, and the phantom images for the last 30 days.

Other tests designed by qualified personnel (the medical physicist should be consulted) could be acceptable but may have to be evaluated by the inspector on a case-by-case basis.

6.4 Compression QC (Semi-annually)

Check and record (Screen 3.9.3 on your laptop) for each x-ray unit with a S-F image receptor on the list that you had designated "Yes," "Evaluate Records Only," or "Temporarily out of service" earlier, whether the following is true "y" or not "n":

- ***Compression QC adequate?*** **(y/n)**
  - *Done at the required frequency?* *(y/n)*
  - *C/A [before further exams*] documented?* *(y/n/NA)*

  ***** Before further exams were conducted using the x-ray unit that failed the compression test.

Record any other problems or observations in the "Remarks" section.

For additional information, see Section 6.4.1.

6.4.1 Maintaining Compression

If the initial power drive is the sole means of providing compression for a mammographic unit, the unit must maintain a compression force of at least 25 pounds for the length of time it usually takes the radiologic technologist to complete an average exposure. If, during the semiannual compression QC test, the unit cannot maintain a force of at least 25 pounds for the specified timeframe, it fails the test and must be repaired, modified or replaced. If the unit passes this test, but still loses compression force during clinical examinations, the unit must be repaired, modified or replaced.

If the unit also has fine adjustment control (required on all units as of October 28, 2002), 21C.F.R.900.12(b)(8)(i)(B), the initial power drive must maintain a compression force of at least 25 pounds for the length of time it usually takes the radiologic technologist to engage the fine adjustment control. The fine adjustment control must then maintain a compression force of at least 25 pounds for the length of time it usually takes the radiologic technologist to complete an average exposure. If, during the semiannual compression QC test, the unit cannot maintain a force of at least 25 pounds for the specified timeframe, it fails the test and must be repaired, modified or replaced. If the unit passes this test, but still loses compression force during clinical examinations, the unit must be repaired, modified or replaced.

6.5 Repeat Analysis QC (Quarterly)

Check and record (Screen 3.9.4 on your laptop) for the main facility and for any additional site (if applicable) whether the following is true "y", or not "n":

- ***Repeat Analysis QC adequate?*** **(y/n)**
  - *Done at the required frequency?* *(y/n)*
  - *Evaluation* done?* *(y/n)*
  - *C/A [30 days] documented?* *(y/n/NA)*

(when a given repeat % changes by > ± 2%)

***** "Evaluation done" implies that the facility has a system for classifying and calculating the rate of repeat and reject films. Thus if the change in the overall repeat rate for either category exceeds ± 2%, the facility must evaluate the results to determine the cause of the change.

Record any other problems or observations in the "Remarks" section.

For additional information, see Sections 6.5.1 and 6.5.2 below

6.5.1 Repeat Analysis in a JCAHO Facility

Under 1995 Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) requirements, the repeat analysis (in a JCAHO hospital or facility) was to be performed on the basis of each individual technologist, rather than being based on the entire facility as is the MQSA standard. JCAHO has since modified its standards to allow the analysis to be performed on a facility basis. Whether the analysis is performed after the facility or the individual technologist has examined 250 mammogram patients is left up to the facility, but in all circumstances, the analysis must be performed at least quarterly in order to remain in compliance with MQSA.

6.5.2 Long Term Maintenance of Repeat Analysis Films

Because of the various types of films that may be included in a repeat/reject analysis and the various ways that facilities determine which films go into the analysis, the answer depends on the specifics of the situation. The following points cover the major possibilities.

1. Films that are included in the repeat/reject analysis but were considered by the interpreting physician (IP) to be necessary to interpret the study are considered part of the original mammogram and MUST be maintained for 5/10 years as required in the regulations and the law. 21 C.F.R. 900.12(c)(4)(i). For example, suppose a Rt. MLO film was sub-optimal but contained diagnostic information that was used by the IP to interpret the study. If the IP wanted that film included in the repeat/reject analysis, he or she could do so, but because this Rt. MLO was necessary for the interpretation, it would have to remain with the rest of the study and MUST be kept for 5/10 years. This would be the case even if they had done a second Rt. MLO.

2. If, however, the Rt. MLO was sub-optimal and was not considered to contain any additional diagnostic information over what the repeat Rt. MLO did, then the first Rt. MLO would not have to be considered necessary to interpret the study. In that case, the first Rt. MLO should be included in the repeat/reject analysis but would NOT have to be kept for 5/10 years. Once it was included in the repeat/reject analysis, the actual film could be discarded.

3. QC films that are included as part of the analysis (e.g., daily processor and weekly phantom), are still governed by applicable regulation and those films that were a necessary part of the QC test should be kept according to the guidance regarding these films (last 30 days for the daily processor QC and the last 12 weeks for the weekly phantom QC).

4. The written records of the repeat/reject analysis (not necessarily the actual films) MUST be kept as required by the regulations "until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements or until the test

has been performed two additional times at the required frequency, whichever is longer." 21 C.F.R. 900.12(d)(2).

6.6 Screen-Film Contact QC (Semi-annually)

Check and record (Screen 3.9.5 on your laptop) for the main facility and for any additional site (if applicable) whether the following is true "y" or not "n":

- ***Screen-Film Contact QC adequate?*** ***(y/n)***
  - *Done at the required frequency?* *(y/n)*
  - *All Mammography Cassettes in use tested?* *(y/n)*
  - *40-Mesh copper test tool used?* *(y/n)*
  - *C/A [before further exams*] documented?* *(y/n/NA)*

* Before further clinical use of the cassette that failed the screen-film contact test.

NOTE 6-9: The facility should keep test films for screen-film contact from the previous three tests and make them available if needed.

Record any other problems or observations in the "Remarks" section.

For additional information, see Sections 6.6.1 and 6.6.2 below.

6.6.1 Screen-Film Contact QC - Procedures Manual

The final regulations do not reference a specific manual giving facilities flexibility to use procedures that best enable them to meet the requirements. The facility may follow the film manufacturer's recommendation, their medical physicist's recommendation, or an appropriate manual in performing the screen-film contact test or any other QC test.

6.6.2 S/F Contact - Test Conditions and Pass/Fail Criteria

The final regulations do not specify an optical density, range, or pass-fail criteria because there has not been a consensus of expert opinion on these. If a facility follows the same criteria as in the interim regulations, namely a range of 0.70 to 0.80 for the density and fails a cassette for any poor contact area exceeding one centimeter, it would be acceptable. However, this does not preclude the facility from using other appropriate criteria.

6.7 Darkroom Fog QC (Semi-annually)

Evaluate the darkroom fog QC for all the mammography darkrooms at the main facility and at any additional site (if applicable) that you had designated earlier as "Evaluate all" or "Evaluate Records Only."

Review the records for the past year and record (Screen 3.9.6 on your laptop), whether the following is true "y" or not "n":

- ***Darkroom Fog QC Adequate?*** ***(y/n)***
  - *Done at the required frequency?* *(y/n)*
  - *Background Density > or = 1.20?* *(y/n/NA)*
  - *C/A [before further exams*] documented?* *(y/n/NA)*

* Before clinical use of the darkroom or any item that caused failure of the darkroom fog test.

NOTE 6-10: The facility should keep fog test films from the previous three tests and make them available if needed.

NOTE 6-11: For facilities that use a daylight system to process films and therefore may use make-shift darkrooms for magazine loading, determine if they performed the fog test on these rooms.

Record any other problems or observations in the "Remarks" section.

For additional information, see Section 6.7.1.

6.7.1 Darkroom Fog QC – Daylight System Issues

Darkroom Fog. First, if the facility has a darkroom which is used routinely for other diagnostic work but is used occasionally for mammography for loading the magazines in the daylight system, the argument has been raised that since the loading operation may affect only the first and last film in a box, there may be justification to raise the value of the action level for the darkroom fog test and not hold the facility accountable for the daily QC maintenance. Second, if the facility does not have a darkroom at all, how should the fog test be conducted? if at all.

Since excessive fog can adversely affect mammographic image quality, the place where daylight system magazines are loaded, whether it is a darkroom, a closet, or any other room used for this purpose, should be held to the same fog standard regardless of the number of images that may be affected. The following is the FDA policy on this issue:

- If the facility has a darkroom for magazine loading, this room should be checked for darkroom fog during the inspection. The facility must also have QC records for darkroom fog.
- If the facility does not have a darkroom but uses another enclosure for magazine loading, that enclosure should be tested during the inspection for fog levels under magazine loading conditions as if it were a "darkroom."

6.8 Digital Mammography QC

If the image receptor (IR) type (in the "**Units - Information**" screen) was downloaded as **"Full-Field Digital or Computed Radiography (CR),"** the software will block all other unit-related QC screens. Regardless of which display option (Monitor, Laser film, or Other) you checked in Screen # 3.5 (Units-Information) you must first answer the following question (Screen 3.9.7):

- *FFDM manufacturer QC followed (excluding monitor & printer QC)? (y/n)*

In order to answer the above question, you should review facility records to determine if they followed the QC procedures recommended in their full field digital mammography (FFDM) manual. Consult the more detailed guidance regarding this review starting in Section 6.8.1. In summary, these procedures are generally divided into two main sections: 1) Technologists tests (weekly, monthly, quarterly, and semi-annually), and 2) Medical Physicist tests (MEE and annual). Verify that:

- All the QC tests (technologist and physicist), except those QC tests and corrective actions relating to the display monitors and laser printers, were conducted according to the manufacturer recommendations (test procedures and frequencies).

- The facility took corrective actions for failed tests in the appropriate time frame, as specified in the manual, for each test.
- The facility used the RMI 156 phantom (The FFDM system manufacturer may have supplied some facilities with an RMI 156 phantom enclosed in a Styrofoam casing, which is also acceptable).

If the facility successfully completed all of the above, you should answer the question above with "y." Otherwise, you should answer the above question with "n."

Answer the next question if you checked 1) "**Monitor**" only, or 2) "**Monitor**" and "**Laser film**," or 3) "**Monitor**" and "**Other**" as the display mode option.

- *Monitor QC done per manufacturer's recommendation?* *(y/n)*

Answer the next question if you checked **"Laser film," "Other,"** or both for the display mode:

- *Printer QC done per manufacturer's recommendation?* *(y/n)*

For additional information, see Sections 6.8.1 to 6.8.3, and Appendix 2.

6.8.1 Evaluation Procedures for FFDM Systems (APPENDIX 2)

A comprehensive review of these procedures is provided in Appendix 2. You should read the material in this appendix before you inspect a facility with an FFDM system. Specifically, consult the tables that list the QC tests that must be conducted by the radiologic technologist and the medical physicist for each of the FFDM systems that have been approved for clinical use in mammography by the FDA. In addition, these procedures provide the necessary guidance regarding data entry for the survey report of an FFDM system.

6.8.2 Facility's Use of Printers and Monitors not Specifically Approved as Part of its FFDM Unit

FDA recommends that only printers and monitors specifically approved or cleared for FFDM use by FDA's Office of Device Evaluation be used. However, a facility may use other printers and monitors. Facilities need to ensure that all printers and monitors used by the facility with its FFDM unit comply with a quality assurance program that is substantially the same as that recommended by the FFDM manufacturer and pass the facility's accreditation body's phantom and clinical image review process. At the current time, no accreditation body reviews soft copy images so we recommend that the soft copy images be of such quality that if they were submitted they would pass the facility's accreditation body's phantom and clinical image review process.

Note: Each softcopy and hardcopy mammographic image used for final interpretation must indicate identifying information (view and laterality, technologist identification, patient name, etc.) (21 CFR 900.12(c)(5)).

6.8.3 Manufacture's Hook up to an FFDM Unit of Printers and Monitors that Were not Parts of the Original Pre-Market Approval (PMA) of that FFDM Unit

Manufacturers will need to check the exact wording of their PMA to see if this is allowed. However, the facility is not restricted by the PMA and may hook up and use printers and monitors other than those approved by FDA for use with the manufacturer's FFDM unit as long as they meet the requirements specified in 6.8.2.

7. ANNUAL PHYSICS SURVEY REPORT

The purpose of reviewing the annual physics survey report is to assure that all the physicist's QC tests and other tasks required in the annual survey of screen-film (S-F) units were done properly and the report contains a summary of test results and recommendations for corrective action(s) where needed.

Review the most recent medical physicist's survey report (unless reviewed in the previous inspection) and record your observations for the report in the appropriate data entry fields. Ask the facility for a copy of the previous survey and record its date in the appropriate field.

Note 7-1: Except where noted, the discussion and guidance in this section apply to S-F units. For survey reports of FFDM units, most of the data entry fields relating to the detailed survey questions will be inaccessible, except for some in Screen 3.10 – Information. Nevertheless, you need to review the reports for those units and evaluate them according to the procedures set in the corresponding FFDM unit's QC manual before you answer the first question in Screen 3.9.7.

7.1 Report Contents

The medical physicist's survey report must cover the following QC tests:

1. Collimation Assessment
2. Resolution Measurement
3. kVp Accuracy and Reproducibility
4. Beam Quality (HVL measurement)
5. AEC Performance Assessment
6. Uniformity of Screen Speed (including evaluation of screen artifacts)
7. Average Glandular Dose (including air kerma & AEC reproducibility)
8. Phantom Image Quality Evaluation
9. Artifact Evaluation (processor and x-ray system)
10. Radiation Output
11. Decompression (compression release)
12. QC Tests for New Modalities (if applicable)

For most of these tests, the final regulations do not specify the methods and procedures to be followed. Therefore, facilities and medical physicists may follow their own procedures as appropriate. However, we expect most facilities and medical physicists to follow the most recent (1999) ACR Mammography QC Manual. The regulations specify test criteria, action limits, and outcome results for the majority of the tests but only specify minimum requirements for others. In addition to these tests, the report must contain:

- An evaluation of the technologist's QC tests for the period between the previous survey and the one referenced in the report
- Test conditions, technique factors, measured or calculated results, and a pass/fail indication for each of the physicist's tests

- Documentation of any failed tests and/or problems identified along with recommendations for corrective actions for each.

The report must be dated and signed by the medical physicist who performed or supervised the conduct of the survey. If another person conducted all or part of the survey under the direct supervision of the medical physicist, that person and the part of the survey he/she conducted must also be identified in the report.

7.2 Facility Response to Medical Physicist's Observations

When reviewing the survey report, confirm that the physicist recognized when data or analysis showed that the equipment was not properly performing, and subsequently recommended appropriate corrective action(s). Regardless of who corrected the problems, the facility should have a written note or report indicating what was done. The facility should have retest data or documentation showing the dates of corrective actions and that any such action taken was successful (see Exhibit 5, the table titled "Annual Quality Control Tests" in Section 7.4.24.

If the physicist recommended taking actions regarding items that did not fail one or more required tests, and if the facility chose not to follow them, the facility must at least document that they evaluated the recommendation. In this case, you should answer the question "*Action Taken"* below with "NA" (Not Applicable) and enter any additional comments in the Remarks section.

7.3 Survey Report Screens

Record all survey-related entries in the **"Survey Report"** screens (Screens 3.10, 3.10.1, and 3.10.2 on your laptop). For each section of the report, record the specific information requested. Record in the "Remarks" section any other observations.

7.3.A Survey Report - Information Screen

Record the following in the **"Survey Report - Information"** screen for each S-F unit with a status designation of "Y," "Temporarily out of service," or "Evaluate Records Only."

- *Survey report available?* *(y/n/NA)*
- *Date of previous survey* *mm/dd/yyyy*
- *Date of current survey* *mm/dd/yyyy*
- *Dose Value (mrad) reported (by the Med. Phys.)* ----- If reported dose is > 300 mrad:
  - *C/A taken before resuming clinical use?* *(y/n)*
- *Survey conducted or supervised by*----- (select name from personnel list)
- *Action taken (if called for in Report)?* *(y/n/NA)*

Note: Record the following in the **"Survey Report - Information"** screen for each digital/CR **(FFDM) unit** with a status designation of "Y," "Temporarily out of service," or "Evaluate Records Only."

- *Survey report available?* *(y/n/NA)*
- *Date of previous survey* *mm/dd/yyyy*
- *Date of current survey* *mm/dd/yyyy*
- *Dose Value (mrad) reported (by the Med. Phys.)* ----- If reported dose is > 300 mrad:
  - *C/A taken before resuming clinical use?* *(y/n)*

Survey conducted or supervised by----- (select name from personnel list)

These are the only fields that will be accessible for data entry in the survey reports of FFDM units.

> **NOTE 7-2:** Regarding the first question, you should give the facility a little time (a few days) before you answer the first question with "n" and upload the inspection, if the survey was recently completed -less than 30 days before the inspection- but the report is not yet available. If this is the case and if the facility sends you the report shortly after you complete the on-site inspection, you may then review the report and upload the inspection. As a reminder, the regulations require the physicist to send the report to the facility in 30 days. Therefore, you should be thoughtful in answering this question.

> **NOTE 7-3:** For a unit with a status designation of "Evaluate Records Only," or "Temporarily out of service," if the survey was due before removal from service but the report was not available, answer the first question with "n" as explained in NOTE 7-2 above (if applicable). Otherwise answer the question with "NA." If the report was available but had been evaluated before, answer the question with "NA." If it was available but has never been evaluated, answer the question with "y" and continue to evaluate the report.

> **NOTE 7-4:** If parts of the survey are conducted on different dates, the survey date will be the date of the most recent item completed.

> **NOTE 7-5:** It is assumed that the person who conducted or directly supervised the conduct of the survey is the person whose name (or signature) is identified on the report. If that name appears on the facility personnel list from the previous inspection, enter it here. Otherwise, record the new name, add it to the personnel list, evaluate his/her qualifications, and record your observations in the appropriate screen (# 3.11.3). If no name or signature is identified in the report, select "unsigned." If you left it blank, it will be included in the missing data report.

Under the **"Overall Evaluation"** part of this screen, the program will determine the rules (interim or final) the survey report should be evaluated under, depending on the survey date you record (Interim - if survey date is < 4/28/99, Final – otherwise).

> **NOTE 7-6:** Depending on the date of the survey, a set of data entry screens will be accessible. Since the actual text change from the interim to the final in some of the screens is insignificant, the text in those screens that correspond to surveys conducted under the interim regulations was copied from that used for the final regulations.

See Sections 7.4.1 to 7.4.7 for further details and guidance regarding Screen 3.10 data entries.

7.3.B Survey Questions (Screens 3.10.1 & 3.10.2)

The answer (y/n) to the **"Overall Survey Complete"** question, which appears on each of the two

screens, is computed by the program. A "y" answer means that all of the medical physicist QC tests and/or checks (in Part 1 and Part 2 below) were done as called for in the survey, a pass/fail indication was given for each, the report contains recommendations for corrective actions regarding items that failed in the survey, the critical test conditions for each test were used, and numerical results (where applicable) were given by the physicist.

You should answer "n" to missing tests or inadequate conditions or actions. An "n" answer to each of the lead questions requires you to indicate which detail item(s) below it should be answered by an "n." Although one citation will be issued corresponding to the top lead question above, the compliance report will indicate the items or tests/reviews (or parts of) that are missing from the survey report.

The program computes the observation level associated with each "n" answer, based on your answers to Part 1 (Level 2) and Part 2 (Level 3) below. If both Level 2 and Level 3 items are found, only one observation at Level 2 will be cited.

- ***Part 1 Complete?*** (Screen 3.10.1) ***(y/n)***

  Resolution Measurement ***(y/n)***
  - *Done for all clinically used focal spots?* *(y/n)*
    (if clinically used, all targets, contact mode & at magnification closest to 1.5)
  - *Numerical results given?* *(y/n)*

  AEC Performance
  - ***Reproducibility*** *(mAs)* ***(y/n)***
  - *Numerical results given?* *(y/n)*
  - ***Performance Capability*** ***(y/n)***
    - *Done for 2, 4, and 6 cm at typical kVp(s)* *(y/n)*
      (for these thicknesses, in the contact mode only)
    - *Numerical results given?* *(y/n)*

  Dose (including entrance air kerma reproducibility) ***(y/n)***
  - *Exposure & HVL at same clinical kVp?* *(y/n/u*)*
    (all screen/film combinations, targets, & filters clinically used for the standard breast)
  - *RMI156 or equivalent phantom?* *(y/n/u)*
  - *Numerical results given?* *(y/n)*

  Phantom Image
  - *Done at the kVp normally used clinically?* *(y/n)*
  - *RMI156/equivalent phantom?* *(y/n/u*)*
  - *3 object scores given?* *(y/n)*

  Artifact Evaluation ***(y/n)***

  *(all clinically used processors, focal spots, cassette sizes, & target/filter combinations**)*

  QC Tests - New Modalities *(if applicable)* ***(y/n/NA)***

- ***Part 2 Complete?*** (Screen 3.10.2) ***(y/n)***

  Pass/fail list ***(y/n)***

  Recommendations for failed items ***(y/n/NA)***

  Physicist's Evaluation of Technologist's QC Tests ***(y/n)***
  - *Processor QC?* *[for each processor]* *(y/n)*
  - *Phantom image?* *[for each x-ray unit]* *(y/n)*
  - *Repeat analysis?* *(y/n)*
  - *Analysis of fixer retention?* *[for each processor]* *(y/n)*
  - *Darkroom fog?* *[for each darkroom]* *(y/n)*
  - *Screen-film contact?* *[for all cassettes]* *(y/n)*
  - *Compression?* *[for each x-ray unit]* *(y/n)*

  Collimation ***(y/n)***

  (all collimators, IR sizes, targets, & focal spots clinically used for full field imaging in the contact mode)
  - *x-ray Field - Light Field* *(y/n/NA)*
  - *x-ray Field - Image Receptor Alignment (y/n)*
  - *Compression Device Edge Alignment* *(y/n)*

  kVp Accuracy ***(y/n)***
  - *Done at these 3 clinical kVps?* *(y/n)*
    (lowest measurable, most often used, highest available)
  - *Numerical results given?* *(y/n)*

  kVp Reproducibility ***(y/n)***
  - *Done at the kVp most commonly used clinically?* *(y/n)*
  - *Numerical results given?* *(y/n)*

  Beam Quality (HVL) Measurement ***(y/n)***

  (all clinically used target/filter combinations)
  - *Done at the kVp most commonly used clinically?* *(y/n)*
  - *Numerical results given?* *(y/n)*

  Uniformity of Screen Speed ***(y/n)***

  (for all cassettes used – (cassettes) may be grouped by size & speed)
  - *Numerical results given?* *(y/n)*

  Radiation Output ***(y/n)***

  Decompression ***(y/n/NA)***

- *u is for unknown*
- *** The 2005 alternative standard provided an option whereby "all target-filter combinations" may be replaced with "all targets and filters. See Option 2, Section 7.4.19."*

NOTE 7-7: All tests must be conducted for all clinically used machines at the facility (except investigational & research units). Surveys or equipment evaluations of digital/CR (FFDM) units that have been approved by FDA and either accredited by an AB or given a certificate extension by DMQRP are included in the records review for digital/CR units and hence are excluded from this discussion**.** Consult Exhibit 5, Section 7.4.24 for a summary of all the QC test requirements, including scope, regulatory action levels, required documentation, and the timing for required corrective actions. The rest of these notes give additional comments. Please note, however, that the detail inspection questions for each test do not cover all the regulatory requirements.

NOTE 7-8: QC tests that are not unit-specific. If the facility has multiple units, answer all the survey questions for each unit. However, some of the questions do not relate to unit-specific tests (evaluation of the technologist QC tests, uniformity of screen speed, and some new mammographic modality tests). Therefore, repeat the answers entered for the first unit regarding these tests when you answer the same questions for the other units. The software associates each survey with one x-ray unit and expects all individual questions to be answered.

NOTE 7-9: The facility must take corrective action as recommended by the physicist for the required tests that failed during the survey. If the physicist recommended that the facility makes improvements or takes corrective actions regarding items that are not required in the regulations or items that did not fail, the facility is not required to follow them but it must show that it considered such recommendations.

NOTE 7-10: The Physicist's QC Tests

a. **Resolution Measurement.** Must be done for all clinically used targets and their appropriate focal spots at the most commonly used SID. Also, if the magnification mode is clinically used, the facility must measure system resolution at the magnification value closest to 1.5. The resolution measurement must be done for the clinically used screen-film combinations.

b. **AEC Performance.** Must be done only in the contact configuration for all clinically used AEC modes in the 2-6 cm range (conducting this part of the test in other configurations is required only for equipment evaluations). Outside this range, the test is not required, but is recommended. The AEC must hold the O.D. variations within ± 0.15 and manual technique factors allowing the AEC to pass this test will not be acceptable.

c. **Average Glandular Dose.** Must include measurement of the breast entrance air kerma (entrance skin exposure or ESE) and AEC reproducibility. The ESE and HVL measurements used in dose determination must be made at the same kVp. This kVp must be the clinical kVp (± 1) used for the "Standard Breast." ESE measurements must use the RMI 156 (or equivalent) phantom. If the dose reported by the physicist differs significantly from what you measured, discuss it with the facility and record your observation in the printable "Remarks" section.

d. **Phantom Image Quality Evaluation**. Must be done using the typical clinical kVp and the RMI 156 (or equivalent) phantom. The optical density (≥ 1.20 at the phantom center), the contrast, and the scores for fibers, specks, and masses, must be recorded.

e. **System Artifact Evaluation**. This evaluation includes both processor and x-ray system artifacts and must be done for all clinically used cassette sizes, focal spots, and target-filter combinations, or all targets and filters as specified in the June 2005 alternative standard**.**

f. **QC Tests for New Modalities** (if applicable). These are new tests required under the final regulations. The scope and action limits must be as set by the new modality manufacturer, except for the dose requirement, which has the same upper limit of 300 mrad (3 mGy).

g. **Uniformity of Screen Speed.** Must include all mammography cassettes used at the facility and must include an evaluation of screen artifacts.

h. **Beam Quality (HVL).** Must be done for all clinically used target-filter combinations.

i. **Collimation Test (s).** Must be done for all combinations of image receptor sizes, collimators, focal spots, and targets that are clinically used for full field imaging of the breast in the contact mode.

j. **Radiation Output.** Each mammography machine must produce a minimum of 7.0 mGy (800 milli Roentgen) air kerma/sec. (at 28 kVp w/Mo-Mo,) averaged over 3 sec., at any SID the system is designed to operate and when the center of the detector is located 4.5 cm above the patient support table. As guidance, one measurement at the maximum SID is acceptable.

k. **Decompression.** If the system is provided with automatic compression release after completing an exposure or after power interruption, the test must show that it has: 1) override capability to allow maintenance of compression, 2) a continuous display of the override status, and 3) a manual emergency compression release.

NOTE 7-11: Air kerma measuring instruments used by medical physicists must be calibrated at least once every 2 years (and after repairs) with an accuracy of ± 6 % (95% confidence level) in the mammography energy range by a laboratory traceable to a national standard. This requirement, however, is not part of the survey report review. If you encounter cases where the instrument used by the physicist was not properly calibrated, inform the facility, record your observations in the printable "Remarks" section, and inform the FDA.

For additional information and guidance in answering the questions in Screens 3.10.1 and 3.10.2, see Sections 7.4.8 to 7.4.26.

7.4 Further Details

7.4.1 Data Entry - Information Tab (Screen 3.10)

The program will generate a Level 1 observation only if you: 1) answer "n" to the question "Survey Report Available" (this will gray-out the data entry field regarding the date of survey and leave it blank by default), and 2) leave the date of the previous survey blank. This action implies that the survey was not conducted the previous 2 times. If the survey was recently conducted but the report is not yet available during the inspection, allow the facility a few days to make the report available for you to review. If you answered "Yes" to this question, you should also fill-in the "date of current survey," otherwise, it will be included in the missing data. The "date of previous survey" will be downloaded automatically from the previous inspection (if applicable). Hence, if the most recent survey was conducted more than 14 months prior to inspection date, the software will generate a Level 2 observation. If the time period between the current and the previous survey exceeds 14 months, the software will also generate a Level 2 observation.

If the only physicist's survey report performed within the last 14 months is the one already reviewed during the previous annual inspection, the inspector should include the following

comment in the printable remarks section of the report: "The latest available physicist's survey report was reviewed during the previous annual inspection. It is less than 14 months old and therefore does not constitute non-compliance."

The inspector should discuss with the facility the date by which they must have a new physicist's survey performed in order to remain in compliance.

7.4.2 Survey Report Availability for FFDM Systems

Information about a facility's FDA-approved digital/CR (FFDM) units will be downloaded with the inspection. As we mentioned in Section 6.8.1, Evaluation Procedures, when you select an FFDM unit, some of the screens pertaining to system performance and QC tests [# 3.5 - S-F tab , 3.9.2, and 3.9.3] will be blocked. However, Screen # 3.9.7 (Digital Mammography QC) will be accessible for you to answer the corresponding QC related questions. Please also note that most of the data entry fields in Screen # 3.10 - Information will also be accessible but Screens 3.10.1 and 3.10.2 will not.

7.4.3 Direct Supervision & Signature on the Survey or Mammography Equipment Evaluation (MEE) Report

The qualified physicist (if the supervision is done after 4/28/99, the supervising medical physicist must have qualified under the Master's or higher pathway) would have to be present during the survey or MEE and, at a minimum, provide direct supervision over his/her surrogate (supervisee). Direct supervision means that the qualified medical physicist (supervisor) is present to observe and correct, as needed, the performance of the supervisee. This requires that the supervisor be in the room during the performance of the individual equipment tests to assure that any mistakes made by the supervisee are corrected before the test is completed. The supervisor must review any calculations made from, and any conclusions drawn from the test results, before those results are provided to the facility.

Furthermore, the supervisor and supervisee must jointly review the QC program records. The supervisor does not have to be present when the supervisee initially reviews the QC program records. However, the supervisor must review, discuss, confirm, and if necessary, correct the findings made by the supervisee prior to either the initial or final survey report being issued.

The goal of direct supervision is to provide reasonable assurance that any mistakes made by the supervisee are corrected before the QC program review or tests are completed.

The supervisor must sign the survey report. The qualifications of the supervising medical physicist will be checked during the inspection. The names of all those being supervised must also be identified in the report.

7.4.4 Extension of the 14 Month Limit for the Medical Physicist Survey

When there is an extenuating circumstance(s), such as an impending move, which makes it impractical to have the annual physicist's survey performed within a 14-month time period, facilities should contact their State inspector, State Certifying Agency, or the FDA District Office (whichever conducts their annual inspections) and request permission to defer the current survey until after the move has been completed, or until the extenuating circumstance(s) is no longer applicable.

The facility must explain, in writing, the reason for the request and establish a reasonable schedule showing the date by which the deferred physics survey will be completed. The State inspector, State

Certifying Agency, or FDA, based on the facility's history and circumstances, may at their discretion, approve a delay for such cases. If needed, States may consult with the FDA on a case-by-case basis.

When the State inspector, State Certifying Agency, or the FDA district office approves a delay for the annual physicist survey and the MQSA inspection is conducted before the approved delay is over, then the inspector should enter an "N/A" ("N/A" denotes not applicable) as the answer to the question SURVEY REPORT AVAILABLE: and record the reason for this in the printable Remarks for the SURVEY REPORT section. The facility should be instructed to send a copy of the report to the inspector once the physicist survey is performed. The inspector will then need to evaluate the survey report, edit the inspection record (answer the physics survey questions), re-upload the inspection data to DMQRP, and send the facility a revised facility inspection report.

7.4.5 Multiple Dates for the Medical Physicist Survey

If the survey is conducted over a period of time, all dates of the individual parts should be indicated. The survey date that the inspector should enter in the laptop should be the date that corresponds to the date that the last required test is completed. The date of the survey corresponds to the date of the last test, not the date on the written report provided to the facility. If any individual part is more than 14 months old at the time of the inspection, the inspector should enter the date of that part as the date of the survey and the facility would get cited for having an overdue survey.

7.4.6 If the Survey Shows Mistakes or Contradictions

In general, MQSA inspectors should not make an in-depth analysis of the quality of the information reported by physicists in the survey reports. However, if there are obvious mistakes, errors, misrepresentations of the conditions in the facility, or other observations in the report that MQSA inspectors detect, they may resort to one of the following options:

- Discuss with the physicist, if available or possible;
- Tell the facility about it and record it in the printable remarks section;
- Inform DMQRP staff so that they may discuss with the physicist (& record in the printable remarks).

7.4.7 Citation Levels Associated with Report Status and Date(s)

There are many scenarios regarding the appropriate answers (for an annual inspection) in the survey report for new units, units that have been in clinical use for at least a year, units that have been removed from service, and units that are temporarily out of service. Those scenarios are summarized below:

Survey Report Availability Scenarios – Data entry options for Screen # 3.10

- **NO REPORT FOR AN OLD (in clinical use for at least a year) UNIT**

Previous Date:	Blank	L1 - Over 2 years
Previous Date:	< 14 Mo./ Inspect. Date	No citation
Previous Date:	> 14 Mo./ Inspect. Date	L2 - Not conducted 14 months

- **NO REPORT FOR A NEW (in clinical use for less than a year) UNIT** No citation
- **REPORT AVAILABLE FOR AN OLD UNIT**

Current Date	< 14 Mo./ Inspect. Date	No citation
Current Date	> 14 Mo./ Inspect. Date	L2 – Not conducted 14 months
Previous Date	Blank	No citation – treat as missing data not required for upload [use for a pre-approved delay, use Remarks to explain action]
Previous Date:	< 14 Mo./ Current Date	No citation
Previous Date:	> 14 Mo./ Current Date	L2 - Between previous and current over 14 months

- **REPORT AVAILABLE FOR A NEW UNIT**

Previous Date	Blank	No citation
Previous Date:	< 14 Mo./ Current Date	No citation

REPORT AVAILABLE FOR A UNIT with status of "Temporarily out of Service (T)"

Previous Date:	< 14 Mo./ Inspect. Date	No citation, no issue
Previous Date:	> 14 Mo./ Current Date	L2 - Between previous and current over 14 months
Previous Date	Blank	No citation – missing data not required for upload (Remarks)

- **REPORT AVAILABLE FOR A UNIT with status of "Evaluate Records Only (R)"**

Previous Date:	< 14 Mo./ Inspect. Date	No citation, no issue
Previous Date	Blank*	No citation – missing data not required for upload (Remarks)

* Apply to such units if the previous survey date is > 14 months from current survey date.

- **SURVEY REPORT AVAILABLE: N/A** No citation

Previous Date	Blank	Missing data not required for upload

Apply to:

units w/status of "T" or "R" if the survey was not due before they were removed

units w/status of "T" or "R" if the survey was done and the report was evaluated before removal

units w/status "R" if the previous survey date was > 14months from inspection date.

7.4.8 Using BR12 Rather than the RMI 156 Phantom for Dose Calculations

The dose tables used for the calculation of average glandular dose are based on a phantom that represents a patient with a compressed breast thickness of 4.2 cm and with breast tissue consisting of approximately 50% adipose (fat) tissue and 50% glandular tissue in composition. While BR12 is manufactured to represent this tissue composition, it is commercially available in whole or half centimeter thicknesses. If a medical physicist is using this material to determine the dose, the physicist must use a thickness equal to or larger than 4.2 cm to assure that the x-ray system passes this test.

7.4.9 HVL Measurement

We stated in our guidance that the physicist must conduct the HVL test for all clinically used target-filter combinations. The software questions regarding the HVL test, are:

Beam Quality (HVL) Measurement	y/n
- Done at the kVp most commonly used clinically	y/n
- Numerical results given?	y/n

The kVp most commonly used clinically usually applies to Mo/Mo, which is typically used for the standard breast. However, if a Mo/Rh combination is used clinically, it is typically used at a higher kVp than the one for Mo/Mo. Therefore, when the physicist measures the HVL for the Mo/Rh, the kVp most commonly used for this t/f combination may not be the same as the one he/she would use for the Mo/Mo, but rather higher.

If the physicist conducts the HVL test only for the Mo/Mo and does not conduct it for the Mo/Rh, you should answer "y" to the first sub-question above, but answer "n" to the question "Numerical results given?" This answer will result in an "n" answer to the top question and is justified by the fact that the software questions have to apply to both t/f combinations.

7.4.10 Focal Spot Condition (System Resolution) Test

This test need not be repeated for all possible combinations of image receptor sizes, target materials, and focal spots.

The test must be performed for those combinations of target materials, focal spots, and screen/film combinations used clinically, but image receptor size is not a factor in this measurement. However, the test must be conducted with all combinations of target materials and focal spots used clinically. Hence, if both focal spots for a given target material are used clinically, both spots must be tested.

The question of how and when to test the small focal spot is discussed below for each of the two modes of operation:

Contact mode – The resolution test must be conducted at the SID most used clinically. If both focal spots for a given target material are clinically used in this mode, each must be tested.

Magnification mode – Typically, the small focal spot is selected in this mode. The physicist should conduct the test at the magnification value closest to 1.5, following the guidance in the PGHS.

7.4.11 AEC Performance – Clarification of Terms

In its Diagnostic X-ray Performance Standard, FDA defines an automatic exposure control (AEC) as a device that automatically controls one or more technique factors in order to obtain a desired quantity of radiation at a pre-selected location. Such a device would automatically terminate the exposure when the selected quantity of radiation had been delivered. The AEC may control the selection of target material, focal spot, filter material, time, mA, mAs, kVp or a combination of any or all of these factors.

AEC mode refers to the type of AEC being used. Typically available AEC modes can range from fixed kVp and mA (where the kVp and mA are selected by the operator and the time is varied by the AEC), to fixed kVp (where the kVp is selected by the operator and the mAs is varied by the AEC), to various AEC modes in which all factors are varied by the AEC. Some of the more automated AEC modes are known by brand names such as BACE, OPDOSE, AUTO FILTER and AOP.

Mean Optical Density (MOD) means the average of the optical densities measured on the images produced with a given equipment configuration during the AEC performance test using 2, 4, and 6 centimeter thicknesses of a homogeneous material.

For AEC testing purposes, the only equipment configurations that need to be tested are the contact configuration, the magnification configuration (if used clinically), and the various image receptor sizes. Due to advances in AEC design, the example of a target-filter combination as an equipment configuration given in the regulations is no longer applicable. Therefore, we will not enforce testing a target-filter combination as a separate equipment configuration.

7.4.12 AEC Performance – Meeting the Annual Survey Test Requirements

Due to the proliferation of mammography units with multiple AEC modes, testing of AEC performance has become more complex in recent years. When units had only one AEC detector, a single AEC mode, and a single target-filter combination, testing was relatively straightforward. That is no longer the case for most units. The following guidance is designed to help medical physicists adequately test a unit's AEC performance without over-testing the unit.

During the annual physics survey, the physicist can limit testing of AEC performance to the contact configuration. To fulfill MQSA requirements, all AEC detectors (that can be individually selected by the operator) and all AEC modes used clinically over the 2 to 6 cm range in the contact configuration must be tested. While there are several ways to do the test, medical physicists who use the following guidance will have fulfilled this requirement. Note: Facilities that do not clinically use their AEC in the 2 to 6 cm range (only use manual techniques) must still test the AEC to ensure that at least one AEC mode for each available AEC detector meets the regulatory requirements.

In order to minimize sources of variability, the physicist should use a single cassette (or same cassette type), film from the same emulsion batch, and the same processing conditions throughout Steps 1 and 2 below.

Step 1: Determine the Mean Optical Density (MOD)

A. For an AEC detector used in the contact configuration, perform three exposures using 2, 4, and 6 cm thicknesses of a homogeneous material. The exposures are to be performed using an AEC mode clinically used at each of the thicknesses. For example, if a facility typically uses fixed kVp mode at 2 cm, fixed mA mode at 4 cm and OPDOSE mode at 6 cm, then the medical physicist should use these same modes at those thicknesses when conducting the AEC performance test. Note: Even if a facility clinically uses more than one AEC mode at a particular thickness, no more than one of the AEC modes should be tested at each thickness to establish the MOD. For example, if a facility clinically uses both the fixed kVp and the AOP CONTRAST modes at 2 cm, the medical physicist should use the more commonly used of these modes to determine the MOD.

B. Measure the optical density of the images obtained at 2, 4 and 6 cm (total of three images) and average them. This is your MOD.

Step 2: Determine if the AEC detector used in Step 1 is within the regulatory action limit of +/- 0.15 OD of the MOD

A. Check to see that all three of the optical densities obtained in Step 1B are within the action limit when compared to the MOD

B. If ALL three ODs are within the action limit AND no other AEC modes are clinically used in the 2 to 6 cm range, then this AEC detector has passed. The medical physicist then needs to repeat Steps 1 and 2 for each additional AEC detector clinically used in the 2 to 6 cm range (See Section 7.4.14 below for additional guidance on testing multiple AEC detectors).

C. If ALL three ODs are within the action limit AND the facility clinically uses an additional AEC mode(s) in the 2 to 6 cm range (other than the ones used to originally establish the MOD), the facility must test the additional AEC modes. The medical physicist needs to test EACH additional AEC mode(s) at any ONE clinically used thickness in the 2 to 6 cm range. If the OD(s) is within the action limit when compared to the MOD, then this AEC detector has passed. The medical physicist then needs to repeat Steps 1 and 2 for each additional AEC detector clinically used in the 2 to 6 cm range (See Section 7.4.14 below for additional guidance on testing multiple AEC detectors).

The medical physicist does not have to test the other clinically used equipment configurations during the annual physics survey, but will have to test these configurations whenever a mammography equipment evaluation involving the AEC is performed.

7.4.13 AEC Performance – Testing Units with Multiple Detectors

The general principle is that all AEC detectors must be tested. What is considered adequate testing will depend on the arrangement of the AEC detectors in the mammography unit.

1. Where a mammography unit has different AEC detectors in the different size cassette holders (buckys), each detector must be tested separately as described above in Section 7.4.12.

2. Where a mammography unit has more than one AEC detector in a single cassette holder (bucky), the physicist must test all the individually selectable AEC detectors and may test the detectors using either of the following methods:

a. All detectors as described above in Section 7.4.12, OR;

b. One detector as described above in Section 7.4.12 AND comparing the OD obtained at 4 cm from each of the other detectors to the MOD obtained from the first detector. When results across different detectors are compared, the medical physicist may use the action limit of +/- 0.30 OD even after October 28, 2002.

3. Where a mammography unit has multiple AEC detectors that are not individually selectable by the operator, the AEC can be tested as if it was a single detector. An example of such a system is one with three fixed detectors in which the system automatically chooses which detector will be active during the exposure. Similarly, a large field detector that automatically selects its active area needs to be tested only as a single detector. However, a system with three fixed detectors, each of which can be selected individually by the operator, needs to have all three detectors tested as described above. Please note that a detector that can be moved to different positions by the operator is still considered a single detector and needs to be tested at only one of those positions.

7.4.14 AEC Performance – Testing with Different Image Receptor Sizes

Different image receptor sizes are considered different configurations and have to be tested separately during the mammography equipment evaluation. With respect to AEC performance testing during the annual physics survey, the medical physicist can limit testing in the contact configuration to one image receptor size (usually the small size). However, FDA does recommend that in addition to this

required testing, the medical physicist also measure the optical density (MOD) obtained using the large image receptor and a 4 cm thick homogeneous material and compare it to the mean optical density obtained for the small image receptor. When results across different size image receptors (different equipment configurations) are compared, the physicist should use the action limit of +/- 0.30 OD.

7.4.15 AEC Performance – Testing outside the 2-6 cm Range

During the annual physics survey, the unit is not required to meet the AEC performance action limit outside the 2 to 6 cm range and the medical physicist is not required to test the AEC using thicknesses outside this range. However, we recommend that in addition to the required testing in the 2 to 6 cm range, the unit also be tested at all clinically used thicknesses outside this range and that the action limits specified in the regulations be applied to the extended test. If the unit cannot meet these action limits outside the 2 to 6 cm range, FDA recommends that a technique chart be developed showing appropriate technique factors (kVp, AEC mode, target/filter, and density control setting) for the different breast thicknesses and compositions so that optical densities (OD) within +/- 0.15 OD of the MOD under AEC testing conditions can be produced.

7.4.16 Testing of AEC Modes not Used Clinically

The intent of the regulation is to ensure that the AEC mode is operable in all equipment configurations used clinically by the facility. The term "operable," means the AEC must meet the performance requirements of 900.12(e)(5)(i) within the 2 to 6 cm range. One way is to have the AEC tested in all the configurations provided by the system. An alternative method is to ensure that the facility does not clinically use the AEC in those configurations not previously tested by the medical physicist. This can be accomplished by placing a label on the unit's control panel listing the configurations that cannot be used because they were not tested. These non-operational configurations must also be identified in the facility's quality assurance records.

7.4.17 AEC Reproducibility –Units with Multiple Detectors and AEC Modes

Because the AEC detectors are also being evaluated as part of the AEC performance test, only a single detector per bucky needs to be tested by the medical physicist. Units that have different AEC detectors in different buckys (e.g., different AEC detectors for the different size cassette holders) will need to have one detector in each bucky tested for reproducibility. Regarding units with multiple AEC modes, the medical physicist can limit AEC reproducibility testing to the AEC mode used most commonly for the standard breast.

7.4.18 Collimation Test Scope

When performing the annual survey, the medical physicist must conduct the x-ray field/light field/image receptor alignment test only for those combinations of beam-limiting devices, image receptor sizes, target materials and focal spots used by the facility to produce full-field clinical images in the contact mode. For example, most facilities perform full-field clinical images using the large focal spot(s) in the contact mode. In this case, the alignment test has to be done only in the contact mode using the large focal spot(s). If, in addition to the large focal spot, the facility also routinely uses the small focal spot(s) to produce full-field clinical images in the contact mode, then the x-ray field/light field/image receptor alignment test must also be performed using the small focal spot(s). Facilities that only use the small focal spot to perform magnification or coned/spot images do not have to perform the alignment test in these configurations.

7.4.19 Artifact Test Scope

The medical physicist must conduct the test for all x-ray units and processors clinically used at the facility, including processors at remote sites*.

* The FDA approved an alternative standard in December 2004, whereby the medical physicist may provide oversight for the facility regarding the evaluation of artifacts for processors at remote sites, in lieu of conducting the evaluation in person.

To evaluate x-ray system-related artifacts, the test must be conducted for all cassette sizes used clinically at the facility (typically 2) in order to test grid artifacts (typically 2 grids: one for each size cassette). If two cassette sizes are used with a given focal spot and target/filter combination and only one of the two cassette sizes needs to be tested to satisfy the requirements, the test must be conducted with the large cassette since it covers a larger part of the filter.

The medical physicist must repeat the test for all clinically used focal spots. However, if a given target material has two focal spots used clinically, the physicist must conduct the test for both, but only one of the two focal spots needs to be selected with a given filter material, since repeating the test with the other will not yield any additional information on filter artifacts.

Also, the medical physicist must repeat the test for all target/filter combinations used clinically. To meet this requirement, the physicist may choose either of the two options below:

1) Option 1 – repeat the test for all target/filter combinations used clinically, e.g., for all possible permutations of targets and filters used clinically, **or**
2) Option 2 – repeat the test for all targets and filters used clinically as specified in the Alternative Standard approved by FDA in June 2005.

As an example, assume that an x-ray unit has 3 targets (molybdenum (Mo), rhodium (Rh), and tungsten (W), and each target has both a small and a large focal spot), three filters (Mo, Rh, and aluminum (Al)), and the facility uses two cassette sizes (small and large). Assume also that they only use the following configurations clinically:

1. The Mo/Mo with the small cassette and the small Mo focal spot
2. The Mo/Mo with the small cassette and the large Mo focal spot
3. The Mo/Mo with the large cassette and the large Mo focal spot
4. The Mo/Rh with the small cassette and the large Mo focal spot
5. The Mo/Rh with the large cassette and the large Mo focal spot
6. The Rh/Rh with the small cassette and the small Rh focal spot
7. The Rh/Rh with the small cassette and the large Rh focal spot
8. The Rh/Rh with the large cassette and the large Rh focal spot
9. The W/Al with the small cassette and the small W focal spot
10. The W/Al with the small cassette and the large W focal spot
11. The W/Al with the large cassette and the large W focal spot

Under the clinical use conditions assumed, and using the general criteria described above, the physicist must conduct the artifact test for at least all targets and filters (using the alternative standard) used clinically, at least once for each focal spot and cassette size, and with the large cassette wherever applicable. Hence, the test needs to be conducted only for configurations 1, 3, 6, 8, 9, and 11 as summarized in the following Table:

Note: The configurations listed previously are used as an example. In practice, most facilities will use a subset of these in a given system.

Table - Artifact Test Requirements for Used Configurations

Configuration	Test? (Yes/Not Needed)	Target/Filter	Cassette (S/L) (Small/Large)	Focal Spot (S/L) (Small/Large)
1	Yes	Mo/Mo	S	S
2	Not Needed	Mo/Mo	S	L
3	Yes	Mo/Mo	L	L
4	Not Needed	Mo/Rh	S	L
5	Not Needed	Mo/Rh	L	L
6	Yes	Rh/Rh	S	S
7	Not Needed	Rh/Rh	S	L
8	Yes	Rh/Rh	L	L
9	Yes	W/Al	S	S
10	Not Needed	W/Al	S	L
11	Yes	W/Al	L	L

7.4.20 Artifact Test for Daylight Processing Systems

This guidance should assist medical physicists who survey facilities that have daylight system processors for mammography.

In a normal darkroom setting, this test involves feeding two films at two different orientations into the processor (one film along the long dimension and another film along the short dimension). In the daylight processor case, using a large cassette and the same enclosure that the facility uses for loading the magazines:

a) Load a small (18 x 24 cm) film in the cassette so that its long dimension is parallel to the long dimension of the cassette, follow the recommended normal artifact test procedure to expose the film, and place the cassette in the daylight system for processing.

b) After the film has been processed, load another small film transversely in the same large cassette so as to occupy only half the cassette. Expose the new film by following the rest of the steps in the recommended procedures for the artifact test, and place the cassette in the daylight system to process the new film.

Artifact analysis on the two films can then be done in the same manner as for manually loaded cassettes.

7.4.21 KVp Values Used during Testing

The term "kVp normally used clinically" should be considered as synonymous with the terms “clinical kVp” or “typical kVp.”

In cases where the kVp is selected by the operator, we have required the physicists to perform some tests at the kVp normally used clinically at the facility (except for surveys that are done before the facility has established that value, such as mammography equipment evaluations of new units). 21 C.F.R. 900.12(e)(5)(ii), (e)(9). The kVp used in the survey/mammography equipment evaluation tests of reproducibility (both for kVp and AEC performance), HVL, dose, and phantom image evaluation (i.e., for

all inspection questions where "the kVp used clinically," appears.) must not exceed +/- 1 kVp from the clinical kVp. For example, if the clinical kVp was 26, the test could be done at 25 kVp, 26 kVp, or 27 kVp. Likewise, fractional kVp values could be rounded off to the nearest integer without citing a noncompliance.

Note: There may be cases where the technique factors that the facility was using at the time of the survey/mammography equipment evaluation are different from the ones in use at the time of the inspection. In such cases, the technique factors in use at the time of the survey/mammography equipment evaluation should be applied.

For the kVp accuracy test and the kVp tracking portion of the AEC performance test, only the values used clinically at the facility need to be tested, up to a maximum of 3 values. If only 1 or 2 kVp's are used, only those kVp's need to be tested). If three or more kVp's are used, only three of those used need to be tested.

7.4.22 Screen Speed Uniformity – Cassettes with Different Speeds

The intent of this test is to provide the technologist performing the examination reasonable assurance that there will be consistency and reproducibility between the images produced using the same type cassette. However, a facility may use cassettes specifically designed to be of different speeds to deal with various clinical problems. In addition, cassettes of different sizes, even from the same manufacturer, may yield different screen speeds due to differences in design and the use of different types of screens. In those cases where a facility has clearly and permanently identified groups of cassettes of different speeds, has established mammographic technique charts to compensate for the different speed cassettes, and has made these charts available to all their radiologic technologists, the facility can group these cassettes for purposes of the screen speed uniformity test. As long as the difference between the maximum and minimum optical density of all cassettes within a group does not exceed 0.30, the requirement has been met. For any group of cassettes used to image the "standard breast", the facility must assure that the radiation dose does not exceed the requirement limit of 3.0 milliGray (mGy).

The test must include all mammography cassettes used at the facility and must include an evaluation of screen artifacts.

7.4.23 Decompression Test – Alternative Standard

<u>Continuous display of the override status for machines with decompression devices – approved alternative standard</u>

This alternative standard was approved on June 22, 1999 with a retroactive effective date of April 28, 1999 and no time limit. It allows facilities having machines equipped with automatic decompression devices that are never disabled, to permanently place a label on the panel indicating that the unit must always be operated in the automatic decompression mode, in lieu of a continuous display of the automatic decompression override status required in 21 CFR 900.12(e)(5)(xi)(B). The wording of this label must be:

"Unit always to be used in auto release mode. If auto release is overridden this status will not be displayed."

Regarding the amount of compression and for how long must it be maintained, note that the intent of this requirement is that systems in override status allow the continuation of compression so that it is not released in a manner likely to cause patient injury. The facility should evaluate system use in their clinical setting. The concerns for non-interventional procedures relate to the stability and

balance of the patient and the potential falling hazard resulting from unexpected release. Although interventional mammography is not covered under current regulations, these procedures add the concern of uncontrolled needle withdrawal and attendant tissue damage and we recommend that these units be tested against the same requirement.

Non-interventional units that were not designed to provide automatic release after the completion of an exposure or upon power interruption also are not covered under this requirement. However, we recommend that such units be tested to assure that they meet their design intent.

In each context, the degree of compression maintenance and the time for which it needs to be applied should be assessed with regard to the likely potential for patient injury. Any problems identified by the physicist should be evaluated together with other responsible facility personnel and should be based on the use of the system in their specific clinical setting.

7.4.24 Scope of the Survey Tests

The survey must cover all the units used clinically by the facility. For most mammography units, Mo-Mo is the target-filter combination that would be provided and used on the majority of patients.

Some of the newer x-ray units with multiple targets and filters and varying automatic modes (such as GE's DMR and Siemens Mammomat 3000) provide the user with additional capabilities and call for additional testing.
Assess only the tests that are “required” in the regulations. These tests, along with the applicability or scope for each, and the time limit for the corresponding corrective action, are listed in the summary table shown as Exhibit 5. If no additional targets or filters are listed for a given test, it is assumed that the test is to be done for the Mo-Mo combination only.

Exhibit 5: Annual Survey Quality Control Tests

ANNUAL QUALITY CONTROL TESTS

Test	Scope	Regulatory Action Taken if	Timing of required corrective action*
AEC Performance Capability	All x-ray units. Thickness tracking (2-6 cm, appropriate kVp's). kVp Tracking (clinic. range).	OD > the mean by more than ± 0.15 (over the 2-6 cm thickness range) Phant. image OD at center < 1.20.	Within 30 days after test failure.
kVp Accuracy & Reproducibility	All x-ray units.	kVp accuracy outside ± 5% of indicated /selected kVp. Reproducibility COV > 0.02.	"
System Resolution	All x-ray units, all clinically used target materials and focal spots Measurement must be done at the most used SID but if mag mode is used, also at SID w/mag value closest to 1.5 & for all clinically used screen-film combinations	11 cycles (line pairs)/mm with bars perpendicular to anode-cathode axis. 13 cycles (line pairs)/mm with bars parallel to anode-cathode axis.	"
HVL	All x-ray units. All clinically used target/filter combos.	< kVp/100 (mmAl).	"
Air Kerma & AEC Reproducibilities	All x-ray units.	Reproducibility COVs > 0.05.	"
Dose	All x-ray units. All targets/filter combos used for the Standard Breast.	Dose is > 3.0 mGy (0.3 rad) per exposure (for the Standard Breast).	Before performing further exams.
Phantom Image**	All x-ray units	< 4 fibers, 3 speck groups, 3 masses	"
X-ray field/light field **X-ray field/IR** **Compression device/IR**	All x-ray units. All combinations of collimators, image receptor sizes, targets & focal spots clinically used in full field imaging of the breast.	**X-ray/light field:** > 2% SID **X-ray field/IR:** Outside IR: > 2% SID (all sides.) Inside IR: full coverage at cw **comp. device/IR:** Outside IR:>1%SID Inside IR: Paddle visible on image	Within 30 days of the date of discovery.
Screen Speed Uniformity	All cassettes – sub-grouping allowed.	O.D. variation exceeds 0.30 from highest to lowest.	"
System Artifacts	All x-ray units and processors, all cassette sizes, all clinically used focal spots, target/filter combos, or targets & filters.	Determined by physicist.	"
Radiation Output	All x-ray units.	Output < 7 mGy/sec (800 mR/sec)	"
Decompression	All x-ray units (if auto decompression is provided).	Failure of override mechanism, manual release, or status indicator.	"
Applicable annual new modality tests	All x-ray units.	Depends on test.	Before clinical use.

* Refer to 900.12(e)(8)(ii)(A) or (B) as applicable.
** Not an annual test

7.4.25 Use of Test Results

How should a facility document the corrective actions that have been taken in response to quality control tests that fall outside the action limits and how should it document the effectiveness of those actions?

The individual who took such corrective actions should document them. The documentation can be in the form of a service report or any other document that lists the actions taken.

The documentation required on the effectiveness of the corrective actions depends upon their nature. For corrective actions involving major repairs, the facility's medical physicist must perform an equipment evaluation after completion of the corrective actions. The report of that evaluation

showing that the equipment now meets the requirements will serve as documentation that the corrective actions were effective.

For corrective actions that did not require a major repair, the facility must document that the failed tests were repeated following the corrective actions and that the test results are now within the action limits. In this case, the test may be performed by any person with adequate training, not just the medical physicist.

For any adjustment, change, or repair not listed in Exhibit 6, (which is copied from the PGHS), 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.

7.4.26 Facility Actions when the AEC Fails the Medical Physicist Testing

According to 900.12(e)(5)(i)(A), when the AEC performance is found to be outside the action limit during physicist testing, the medical physicist may create a temporary technique chart that includes the appropriate density settings (in addition to the other technique factors) to be used with the malfunctioning AEC. The facility can use this temporary chart for up to 30 days, or until the problem has been corrected and the equipment passes the AEC performance test, whichever comes first. If the AEC is completely non-functioning, the medical physicist may create a manual mode technique chart that includes all the appropriate manual technique factors. Use of the manual mode would be acceptable under the complete failure situation raised by the question. The facility can use manual techniques for up to 30 days while the non-functioning AEC is being repaired and can continue to use the unit on patients during this period.

Whether or not the physicist must retest the repaired AEC depends on the repair needed to fix the problem. If the repair is classified as "major" (see Exhibit 6), then the medical physicist must be onsite to perform the post repair testing. If the repair is not classified as "major" then the post repair testing may be done under the medical physicist's oversight. In either event, the appropriate testing must be performed and passed within the specified time frames.

Exhibit 6: Medical Physicist Involvement in Equipment Repairs

Item	Major Repair	Medical Physicist Involvement
Automatic Exposure Control		
AEC Replacement	Y	MP conducts evaluation in person
Thickness compensation internal* adjustment	N	MP oversight
AEC sensor replacement	Y	MP conducts evaluation in person
AEC circuit board replacement	Y	MP conducts evaluation in person
Density control – internal* adjustment	N	MP oversight
Bucky (New to Facility) Replacement		
AEC sensor also replaced	Y	MP conducts evaluation in person
AEC sensor not replaced	N	MP oversight
FFDM Detector also replaced	Y	MP conducts evaluation in person
FFDM Detector not replaced	N	MP oversight
Cassette replacement		
Same screen speed	N	MP involvement optional
Different screen speed	N	MP oversight
Slower screen speed with significant dose increase	Y	MP conducts evaluation in person
Collimator		
Replacement	Y	MP conducts evaluation in person

Reassembly with blade replacement	Y	MP conducts evaluation in person
Adjustment	N	MP oversight
Compression Device		
Pressure adjustment	N	MP involvement optional
thickness scale accuracy adjustment but only if it affects AEC performance	N	MP oversight
repair of auto decompression	N	MP involvement optional
Compression Paddle		
Paddle (new to facility) replacement	N	MP oversight
Deflection adjustment	N	MP oversight
Adjustment due to extension beyond allowable limit, or visibility on images	N	MP oversight
Darkroom		
Repair of light leaks	N	MP involvement optional
Safe light change	N	MP involvement optional
Film type change	N	MP oversight
Processor		
Chemistry type change	N	MP involvement optional
Fixer/Developer replacement	N	MP involvement optional
Installation	Y	MP conducts evaluation in person
Reassembly	Y	MP conducts evaluation in person
Replenishment rate adjustment	N	MP involvement optional
Roller replacement	N	MP involvement optional
X-ray Unit		
kVp, mA or time internal* adjustments	N	MP oversight
Filter Replacement	Y	MP conducts evaluation in person
High voltage generator replacement	Y	MP conducts evaluation in person
X-ray Tube Replacement	Y	MP conducts evaluation in person
Installation	Y	MP conducts evaluation in person
Reassembly	Y	MP conducts evaluation in person
Manufacturer's software modifications	Y	MP conducts evaluation in person
FFDM detector replacement or repair	Y	MP conducts evaluation in person
FFDM display (monitor)/printer replacement	Check FFDM manufacturer's QC manual	Follow FFDM manufacturer's QC manual

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

8. MAMMOGRAPHY EQUIPMENT EVALUATIONS (MEE)

The purpose of reviewing the Mammography Equipment Evaluations (MEE) report is to assure that the physicist conducted the appropriate QC tests and verifications required for mammography equipment evaluations of x-ray units and processors when needed, and that all items were in compliance before placing the equipment in clinical use.

Review MEE reports for any x-ray unit or a processor that was newly installed, disassembled and reassembled, or had major repairs since the last inspection. Record your answer in the appropriate "Evaluation" screen (# 3.5 - x-ray units, and # 3.6 – processors (& laser printers)) as described in Section 8.3.

8.1 General

According to the final regulations' Section 900.12(e)(10), new x-ray units and processors, those that have been disassembled and re-assembled, and those undergoing major repairs, must be evaluated by a medical physicist (or someone under their direct supervision) before clinical use.

As such, an MEE for a new unit is similar to an annual unit survey in that it includes all or most of the tests that are included in the annual survey (Section 900.12(e)(2, 5, 6)), except for evaluation of the facility's QA/QC program. In addition, it also includes evaluation of the x-ray unit and processor to ensure compliance with the applicable parts in Section 900.12(b) of the regulations as well. It may also include some of the non-annual tests listed in 900.12(e)(1-4, 6).

8.1.A Newly Installed or Reassembled X-ray Unit

The word "applicable" refers to:

1. Performing all the annual tests listed in section (e)(5) [except (e)(5)(viii), which need not be included if no new cassettes are added], the "other modality" tests listed in section (e)(6) (if applicable), the weekly phantom image test listed in section (e)(2), and the semi-annual compression test listed in section (e)(4)(iii)(B); and
2. Verifying that the new x-ray unit meets the equipment standards listed in Sections (b)(1-10). Furthermore, if the new unit is the first and/or the only one at the facility, then Sections (b)(11), (b)(12), (b)(14), and (b)(15), which relate to the screen-film combination and the lighting and viewing conditions used at the facility, must also be verified.

8.1.B Newly Installed or Reassembled Processor

The applicable MEE tests are:

1. Sensitometric testing as described in 900.12(e)(1)
2. Phantom testing as described in 900.12(e)(2)
3. Applicable portions of system artifact evaluation as described in 900.12(e)(5)(ix)
4. Dose determination as described in 900.12(e)(5)(vi) – if clinical techniques change such that the dose could reasonably exceed 300 mrad

5. Verification of the appropriate processing solutions as described in (900.12(b)(13)

We recommend that the fixer retention test described in 900.12(e)(3)(i) be performed and, in those cases where the integrity of the darkroom has been compromised, that the darkroom fog test described in 900.12(e)(4)(i) also be performed.

Each processor used clinically must have an MEE, even those at remote sites (if any).

8.2 Major Repairs

Mammography equipment evaluations are also required for **x-ray units and/or processors** whenever major components are changed or repaired. The medical physicist should decide which tests need to be performed following a particular repair, and should explain the rationale behind his or her decision.

Examples of major changes or repairs that would call for equipment evaluations are:

- Replacement of tube, filter, collimator, AEC, AEC circuit board, generator.
- Internal adjustments that affect the radiation output of the machine, and others.
- Total overhaul of the processor.

To get a more detailed list of items/tests that are defined as major repairs and or other tests that require the physicist to conduct in person, consult our Policy Guidance Help System (PGHS), which also provides guidance on many related topics. You can access the PGHS from the "Help" section on your laptop computer.

Note also that the 1999 ACR QC manual provides Equipment Evaluation forms for the physicists to use. These forms list all the MQSA requirements in a table format that is easy to review and evaluate.

8.3 Data Entry

We already described data entry in Sections 3.2.5 - Evaluation and 4.3.B.4 of this document. However, we will repeat it below for convenience.

For x-ray units, Screen 3.5 – Evaluation

- *Mammo equip. evaluation (by medical physicist) done? (y/n/NA)*,
  (for new installation, reassembly, or major repairs)
  This question applies to digital units also.

For processors, Screen 3.6 – Evaluation

- *Processor/laser printer equip. evaluation (by medical physicist) done? (y/n/NA)*
  (After reassembly, major repair, or new installation)

If the facility did not have any MEE during this period, answer the corresponding question with "NA" or "Not Applicable."

8.4 Further Details

8.4.1 General

Whenever a new unit or processor is installed, or a unit or processor is reassembled, or major components are changed or repaired, a mammography equipment evaluation (MEE) on it is required. The medical physicist should decide which tests need to be performed following a particular repair, and should explain the rationale behind his or her decision. Examples of major changes or repairs that would call for equipment evaluations are: replacement of an x-ray tube, collimator, AEC unit, AEC sensor, or x-ray filter. For the processor, a total overhaul would be an example of a major repair. Routine preventive maintenance, pump replacement, replacement of the developer or fixer racks, replacement of the control board or changes in chemistry brand are not examples of major changes or repairs and would not require evaluation by a medical physicist.

The mammography equipment evaluation is needed to verify that all functions that may have been affected by the change or repair have been successfully restored even if a full survey had recently been completed. A qualified medical physicist or an individual under the direct supervision of the medical physicist must perform the mammography equipment evaluation. The evaluation will be used to determine whether the new or changed equipment meets the requirements of applicable standards in 900.12(b) and (e). The facility must correct all the problems before the new or changed equipment is put into service for examinations or film processing. The facility must maintain (until the next inspection that verifies compliance) the report of the mammography equipment evaluation and all documentation showing that all problems identified in the mammography equipment evaluation were corrected before the equipment was used on patients. The report should document the date(s) on which the mammography equipment evaluation was performed and who performed the evaluation.

In cases where a surrogate or supervisee performs an MEE, the qualified physicist must be present during the equipment evaluation and, at a minimum, provide direct supervision over his/her surrogate (supervisee). Direct supervision means that the supervisor (who must have qualified under the Master's or higher pathway) is present to observe and correct, as needed, the performance of the supervisee. 21 C.F.R. 900.2(o)(2). This requires that the supervisor be in the room during the performance of the individual equipment tests to assure that any mistakes made by the supervisee are corrected before the test is completed. The supervisor must review any calculations made from, and any conclusions drawn from test results, before providing those results to the facility.

The supervisor must be identified in the report. The MQSA inspector will evaluate the qualifications of the supervising medical physicist during the inspection. The facility should also identify in the report the names of all those being supervised during the MEE.

8.4.2 AEC Performance Testing for the MEE – Scope and Action Limits

During a mammography equipment evaluation, the AEC must be operable in all equipment configurations (contact, magnification, and various image receptor sizes) used clinically by the facility. The term "operable," means the AEC must meet the performance requirements of 900.12(e)(5)(i) within the 2 to 6 cm range. Compliance with this requirement may be demonstrated by any of the following three methods:

1. Confirming AEC performance in the contact configuration. In the contact configuration, the AEC must maintain the film optical density (OD) over the 2 to 6 cm range within the action limit of +/- 0.15 OD of the MOD (See question 3 in the PGHS for additional guidance).

AND

Confirming AEC performance in all other clinically used configurations. This can be done by demonstrating that the AEC meets the density and reproducibility limits established by the manufacturer for those other configurations.

Note: Method #1 can be used only in those cases where the manufacturer has established AEC performance standards for the non-contact configurations provided.

2. Confirming AEC performance in the contact configuration. In the contact configuration, the AEC must maintain the film optical density over the 2 to 6 cm range within the action limit of +/- 0.15 OD of the MOD.

AND

Confirming AEC performance in all other clinically used configurations. This can be done by comparing the contact configuration MOD with measurements obtained using the 4 cm thick phantom in the other configurations used clinically at the facility. When results across different configurations are compared, the facility may use the action limit of +/- 0.30 OD even after October 28, 2002.

3. Confirming AEC performance by demonstrating that the AEC maintains the MOD within +/- 0.15 OD in all configurations used clinically by the facility. The action limit applies only within each specific configuration tested and does not apply to data collected across the different configurations.

8.4.3 AEC Performance Testing during the MEE outside the 2-6 cm Range

During the MEE (as defined in 900.12(e)(10)), the medical physicist must evaluate the AEC in all clinically used configurations (see 8.4.2). Section 900.12(e)(10) requires that the AEC meet the requirements of 900.12(b) and (e). Under 900.12(b)(10), the AEC is required to be "operable" under "configurations provided." The term "operable," means the AEC must meet the performance requirements of 900.12(e)(5)(i) within the 2 to 6 cm range. FDA also recommends that in addition to the required testing in the 2 to 6 cm range, the unit also be tested in all configurations at all clinically used thicknesses outside this range and that the action limits specified in the regulations be applied to the extended test. If the unit cannot meet these action limits outside the 2 to 6 cm range, FDA recommends that a technique chart be developed showing appropriate technique factors (kVp, AEC mode, target/filter, and density control setting) for the different breast thicknesses and compositions so that optical densities (OD) within +/- 0.15 OD of the MOD under AEC testing conditions can be produced.

8.4.4 Validity of the kVp(s) Used in MEE Testing

If the medical physicist survey report (which you review as part of an MQSA inspection) contains a mammography equipment evaluation for a new x-ray unit, be aware that, at the time of the mammography equipment evaluation, the physicist may not have known the exact kVp that the facility would be using for imaging the average breast. By the time of your inspection, the facility will probably have established this typical clinical value and it may differ from the value(s) the physicist used during the mammography equipment evaluation.

During MEE testing, if the physicist used a kVp that is different from what the facility is now using as the "average clinical kVp," DO NOT cite the facility for survey report inspection questions which

ask "Done at the kVp normally used clinically?" as long as the kVp(s) that was tested is within the usual range of kVp's used for mammography of an average breast.

8.4.5 Motion of the Tube-Image Receptor Assembly

The Policy Guidance Help System contains several questions and answers regarding this subject. Please refer to it for further details.

8.4.6 Manufacturer's Software Modification of the AEC – Alternative Standard

This alternative standard was approved on September 24, 2001. It has no time limit. The final regulation and its alternative standard are stated below:

21 CFR 900.12(e)(10) states:

(10) Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted whenever a unit or processor is installed, a unit or processor is dissembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in paragraphs (b) and (e) of this section. All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.

The alternative applies to the specific situations described below, in which manufacturer's software modifications have been made to specific units. In such cases, an onsite mammography equipment evaluation performed by the medical physicist is not required. Instead, all that is required is oversight by the medical physicist.

<u>The approved alternative standard states that for:</u>

1. the modification of the AEC component of Senographe™ 700T or 800T mammography systems described in the GE Medical System's Field Modification Instruction (FMI) 11451, "Seno 700/800T Optical Density Optimization", and
2. the optimization of the AEC component of the Senographe™ DMR mammography systems described in the GE Medical System's FMI 11450, "DMR V1/V2/+ Optical Density Optimization".

Verification testing to demonstrate that the affected equipment meets the applicable standards must be carried out after these actions are completed. However, the verification testing may be performed under Medical Physicist Oversight. Medical Physicist Oversight means that the medical physicist is consulted as to whether an on-site visit is required or if other personnel can verify that the standards are met, with direction by telephone or printed material from the medical physicist as needed.

8.4.7 Conducting the Mammography Equipment Evaluation after a Software Upgrade under Medical Physicist Oversight – Alternative Standard

This alternative standard was approved on May 31, 2002. It defines the conditions under which the mammography equipment evaluations performed after some computer software upgrades may be

performed either by a medical physicist on site or under the conditions of Medical Physicist Oversight. If these conditions are not met the mammography equipment evaluation after the upgrade must be performed by a medical physicist on site.

The original standard is contained within 21 CFR 900.12(e)(10).

> *(10) Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor is installed, a unit or processor is dissembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in paragraphs (b) and (e) of this section. All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist*

<u>The approved alternative and the conditions for its use are:</u>

Software changes or upgrades are considered by FDA to be major repairs, thus the facility must have a mammography equipment evaluation performed after installation of such a change or upgrade. The mammography equipment evaluation must be performed and all failures to meet the applicable standards must be corrected before the affected equipment is used for patient examinations. The tests to be included in the mammography equipment evaluation must be specified by the manufacturer. The specified tests must be adequate for determining whether all of the standards of 21 CFR 900.12(b) and (e) that are applicable to the upgrade are met. If the tests included in the mammography equipment evaluation are all tests that are performed by the quality control technologist as part of the quality assurance program required by the manufacturer, then the mammography equipment evaluation may be conducted either during an onsite visit by a medical physicist or under Medical Physicist Oversight. If any of the necessary tests after the software upgrade are required to be performed by the medical physicist, the mammography equipment evaluation must be performed in its entirety by the medical physicist on site.

Additional conditions for using this alternative requirement in association with a software upgrade are that:

1. The manufacturer must notify FDA of its intention to install the upgrade. The notification must include a brief description of the upgrade, the model(s) of the units that will be upgraded, and a copy of the information to be provided to each facility describing the upgrade and the facility's post installation responsibilities. The manufacturer must receive confirmation from FDA that the upgrade is covered by the alternative requirement before beginning installation.
2. By the completion of each individual upgrade, the manufacturer must inform the facility in writing of its post installation responsibilities under the alternative requirement, which are that the facility must:
   - Conduct a mammography equipment evaluation after installation of the upgrade, either during a medical physicist onsite visit or under Medical Physicist Oversight,
   - Include in its mammography equipment evaluation the tests specified by the manufacturer,
   - Perform the mammography equipment evaluation and correct all test failures before the affected equipment is used for patient examinations, and
   - Keep records of the test results and follow-up actions in accordance with 21 CFR 900.12(d)(2).

9. PERSONNEL QUALIFICATIONS

The purpose of reviewing personnel qualification records is to assure that all health professionals associated with mammography at the facility meet the minimum initial qualifications (licensing, certification, initial specific training and experience, etc.), the new mammography modality training (if applicable), and continuing experience and education requirements set by the regulations.

9.1 All Personnel Categories

Review personnel records for all interpreting physicians, radiologic technologists, and medical physicists involved in mammography activities at the facility and verify compliance with the regulations. Advise the facility in advance by way of the inspection notification letter that they should make all the necessary personnel documents available during the inspection. For specific details concerning what the regulations require, see Section 9.1.1.

Record all the required data in this section in the appropriate screen of your laptop software program. When you first open the "**Personnel**" screen (Screen 3.11 of your laptop outline), the following read-only list of all the personnel categories appears on your laptop:

- Status (Evaluate, Hold)
- Type (Interpreting Physician, Technologist, Medical Physicist)
- Last Name
- First Name
- Middle Initial
- Full Name

You can access the **"Information"** and **"Evaluation"** screens for each person on this list with a status designation as "Evaluate," by double-clicking on the name. This action opens the main screen that corresponds to the individual's category. From there you can get direct access to the individual's **"Information"** and **"Evaluation"** screens as described in Sections 9.2, 9.3, and 9.4 of this document. If an individual's Status is "Hold," it means that you should not evaluate the individual's records and you will not get access to the corresponding **"Evaluation"** screen. If you need to add a new name to the list, press the "+" key on the Tool bar and fill in the required information in the **"Information"** screen that will subsequently open-up. Likewise, if an individual on the list left the facility permanently sometime after the previous inspection, you may remove his/her name from the list by using the "-" key on the Tool bar. However, in general, you should use the "Hold" status for such persons until the next inspection. At that time, delete them if they have indeed left and are still listed as active by the program.

To change the contents of any field on the list, open the corresponding **"Information"** screen in the appropriate category. The first entry in the information screen contains the Status field, which allows you to determine whether or not an individual's records should be reviewed. According to DMQRP policies, if the person's records were reviewed during the previous inspection and if the person left the facility but may come back to work at the facility, you

should select "Hold." If this individual does not come back during the next inspection, remove his/her name from the records. Select "Evaluate" as the status for all persons who are currently providing services to the facility or for those that were hired after the previous inspection and left before the current one (including locum tenens or other temporary employees).

NOTE 9-1: Copies of original documents in all categories are acceptable.

NOTE 9-2: For most of the questions regarding personnel records, the answers are in the form of "y/n," where "y" indicates that the document that verifies compliance (or a copy of it), is present; "n" indicates that the document does not exist and can not be produced anywhere (which means the person lacks the evidence of qualification). Some answer options include "NA" to indicate "not applicable."

NOTE 9-3: The final regulations require personnel in all categories to have 8 hours of training in a new (additional) mammography modality before they may provide independent services in it (in this context, the word new means a modality other than the one the individual was previously trained in). Between 2000 and the date of this document, FDA approved seven Full Field Digital Mammography/CR (FFDM) systems. We expect the FDA to approve other FFDM systems in the future. As a result, we expect that, going forward, you will be evaluating an increasing number of documents for the 8 hours of training in digital mammography in each of the three personnel categories.

The final regulations allow citing a facility for failing to make personnel records available during the inspection. However, do not cite a facility (use the "NA" answer below) if they did not have the records because of reasons beyond their control. Hence, for all personnel categories:

- *Required personnel documents available? (y/n/NA)*

NOTE 9-4: The previous question is located in the "**Summary**" screen (Screen 3.11.4). If you answered "n" to this question and if the facility is expected to provide you with some or all of these documents at a later date, this Level 3 citation will stand regardless of how you would answer each personnel-related question after you have completed the on-site inspection.

For additional details, see Sections 9.1.1 to 9.1.7

9.1.1 Maintenance of Personnel Records

The regulations require facilities to maintain records that document the qualifications of all the mammography professionals (interpreting physicians, radiologic technologists, and medical physicists) who worked or are currently working at the facility.* Facilities must make these records available for MQSA inspectors to review and must not discard documentation of the person's qualifications until the person has permanently left the facility, the next annual inspection has been completed, and FDA has determined that the facility is in compliance with the MQSA personnel requirements. Acceptable documentation for all personnel requirements is summarized in separate tables at the end of each personnel section.

** MQSA regulations require that all personnel providing mammography services meet the quality standards related to their profession, even if they provide only temporary service.*

9.1.2 Letters from Approved Certifying Boards

One issue that we have included in our training program is that a letter (or a copy of a letter) from an approved certifying board, indicating that an individual has met the requirements for certification,

would be acceptable as proof that the individual has met the certification requirement. This would include certification from boards approved by FDA for the interpreting physician, radiologic technologist, and medical physicist. These letters should be considered as equivalent to a copy of the actual certificate.

Note: One of the types of letters from the ABR has the statement "A certificate will be sent to you when we have received verification from your Program Director that you have fulfilled all training requirements." This statement should not be grounds for rejecting the ABR letter as proof of ABR certification. Very few, if any, radiologists fail to complete their training requirements after passing the board examinations.

9.1.3 Direct Supervision Issues

While time spent being directly supervised can be counted by mammography personnel towards meeting their appropriate initial requirements, time spent directly supervising other personnel or being directly supervised cannot be counted towards the continuing education requirement for either the supervisor or the individual(s) being supervised.

While an individual's qualifications are still under evaluation, that individual may continue to provide mammography services to the facility in his or her area. Once it has been determined that an individual DOES NOT meet one or more of the personnel qualifications (e.g., a "No" answer has been entered in response to one or more of the qualification questions), that individual may lawfully provide mammography services to the facility only under the direct supervision of a fully qualified individual.

The direct supervision must continue until such time as the individual meets the qualifications, at which time he/she may resume working independently.

9.1.4 Past or Part Time Employees

All interpreting physicians, radiologic technologists, and medical physicists providing mammography services to the facility must meet the personnel qualification requirements for their respective specialty during the time they provide the service.

For inspection purposes, employees who were hired by the facility since the previous inspection (or all employees in the case of a new facility that has not yet had its first annual inspection) and are no longer at the facility at the time of the inspection, will have their qualifications verified only for the beginning date* of their employment by the facility. Records of past employees that were evaluated during the previous inspection but had left the facility since that date will not be routinely evaluated.

> ***NOTE 9-5:** For employees who left the facility and were rehired more than once since the previous inspection (or since the start of certification for new facilities), records of qualifications will be verified for each of the starting dates within the period described above or until a non-compliance with that qualification is discovered. Also, if a locum tenens individual works sporadically throughout the year, it may be necessary to verify his or her compliance regarding continuing experience and continuing education up to four times (once per quarter, if they worked in all four quarters).

Following are four examples:

1. If the previous inspection date is 2/10/05, the current inspection date is 2/18/06, and a locum tenens interpreting physician (Dr. T) provided services at the facility once for the period from 11/25/05 to 12/6/05, the applicable period for the record review for Dr. T would end on 11/25/05,

i.e. on the date Dr. T began providing the temporary service (and submitted a copy of his full qualifications to the facility). The qualification records for the period from 11/25/05 to 12/6/05 will not be checked at this inspection but they would be checked for the first day of employment at the next facility that would subsequently employ the services of Dr. T.

2. Assume that the facility hired Dr. T again for the periods of 12/23-31/05 and 1/28-31/06. In this case, the qualification records for Dr. T would be verified for 11/25/05, 12/23/05, and 1/28/06.
3. Assume that Dr. P had been a permanent employee at the facility from 11/1/04 until 2/14/06. Her qualifications would be verified for 2/10/05, which is the previous inspection date. None of her records after 2/10/05 would be reviewed during the present inspection.
4. If Dr. T was hired again by the facility for one week beginning on 2/17/06, his qualifications would be verified for 2/18/06 (the current inspection date), as they would be for permanent employees.

All facilities are obligated to ensure that all employees (permanent and temporary) providing mammography services at their facility meet MQSA qualification requirements. FDA expects temporary employees (and/or the agencies that provide temporary personnel services) to provide the facility with updated records of all their qualifications, including continuing education and continuing experience records (where applicable) in order for the facility to verify their qualifications before employment. FDA expects these individuals to make the appropriate arrangements with each facility regarding the maintenance of their qualification records during the periods they provide services to the facility.

9.1.5 Credits for Mammography Personnel Teaching a Course/Reading or Writing Articles

Mammography personnel may receive credit for presenting courses/lectures and/or reading/writing articles/papers for journals as long as the articles/papers and the courses/lectures pertain to the diagnosis or treatment of breast disease or other areas that will aid facility personnel in improving the quality of mammography. FDA has no way of determining the proper amount or type of credit to give for any individual article/paper or course/lecture. However, an organization authorized to award credit can assess and document the appropriate amount of CME/CEU awarded. Mammography personnel must get a letter or other documentation from the authorized organization stating how many and what type of CME's/CEU's are awarded and the date the credit was given. FDA would then accept the amount awarded toward the continuing education requirement.

9.1.6 Criteria for Accepting Training/CME/CEU Certificates

The wide variety of formatting and content of training/CME/CEU documentation has caused some confusion and presented a challenge to MQSA inspectors regarding what they should consider as acceptable documentation. Although the lack of standardization applies to all types of documentation, the discussion below will focus on documentation for training/CME/CEU certificates issued by training providers.

Regardless of the variety of formats used by training providers, each certificate must, at a minimum, contain the following 5 items of information in order to comply with the regulations. Some or all of the items listed below can be filled-in by the recipient of the training/CME/CEU, if done on a certificate provided by the training/CME/CEU provider.

- Identification of the training/CME/CEU provider
  - This usually will be the name of a teaching institution, educational or professional society,

private training organization, or medical facility.
- While identification of an individual representative of the training/CME/CEU provider is not required, if such identification is not present AND a clearly defined space for such identification is provided and is not filled in by hand or other means, the certificate will be considered incomplete and unacceptable.

- Name of the person receiving the training/CME/CEU
- Date(s) the training/CME/CEU was provided
  - If the training provided occurred over a long period, e.g., the dates indicated on the certificate extend over months or years, the number of credits within the 36 month counting period applicable to the current inspection must be identified on the certificate or in accompanying documents.
- Training/CME/CEU subjects(s)
  - Initial training must be in the subjects required by the regulations for the applicable personnel group (interpreting physician, radiologic technologist or medical physicist).
  - Continuing education must be in initial training subjects or other subjects related to the diagnosis or treatment of breast disease, or other areas that will aid facility personnel in improving the quality of mammography.
  - If the certificate is not specific as to subject matter, facility personnel may be able to use "Attestation For Continuing Education After October 1 1994" as described in the Policy Guidance Help System.
- Number of training/CME/CEU credits awarded
  - Interpreting physician credits must be identified as Category I (unless being used for initial new mammographic modality training).
  - If the certificate indicates the person may "claim up to "X" credits" <u>in acceptable training/CME/CEU subjects</u>, the inspector should assume "X" credits were awarded, unless the certificate indicates that fewer credits were actually earned.

9.1.7 Examples of New Mammographic Modalities

The term mammographic modality refers to a technology for radiography of the breast. Examples of long available mammographic modalities are screen-film mammography and xeromammography. An example of a relatively new mammographic modality is full field digital mammography (FFDM). Personnel whose training pertained solely to screen-film mammography would be required to obtain 8 hours of training in full field digital mammography, if they are to begin providing services or interpretations using this modality after April 28, 1999. However, if those personnel started using this modality before April 28, 1999, they are considered to have met the 8 hour requirement.

New modality training can be in many forms, including, but not limited to, residency training (for interpreting physicians), special training courses, continuing medical education, and training provided by the manufacturer.

9.2 Interpreting Physician (Screen 3.11.1)

For each interpreting physician at the facility, record the following in the **"Information"** screen, including the correct Universal Provider Identification Number (UPIN) (when available):

- ***Status*** *(Evaluate, Hold)*
- ***Lead interpreting physician? [ ] –*** *if you checked the box, it will print the name in the post inspection report & identify the interpreting physician as such*
- ***Name xxx*** *[FIRST, M. I., LAST] (capital letters, separate fields)*
- ***UPIN***

Answer the rest of the qualification-related questions in the "Evaluation" screens as follows:

- ***Rules qualifying under*** *(interim, final) [select one]*

  If you selected the interim rules:

Initial Qualifications under interim rules met?	***(y/n)*** *[prior to 4/28/99]*
– *Licensed?* [license must be current]	*(y/n)*
– *Certified or 2 months* (280 hours) *training?*	*(y/n)*
AND	
– *40 CME hours*	*(y/n)*
– *Initial experience adequate? (240 exams/6 mo.)*	*(y/n)*

  If you selected the final rules

Initial Qualifications met?	***(y/n)***
– *Licensed?* [license must be current]	*(y/n)*
– *Certified or 3 months* (420 hours) *training?*	*(y/n)*
AND	
– *60 CME hours?*	*(y/n)*
– *Initial experience adequate? (240 exams/6 mo.)*	*(y/n)*
Date completed initial requirements	*mm/dd/yyyy*
New modality training [8 hours] (if applicable)	*(y/n/NA)*

- ***Continuing Experience***

– *Continuing experience adequate? (960 exams/24 mo.)*	*(y/n/NA)*	If "n", then:
– *Number of exams in 24 months*	------	

- ***Continuing Education***

– *CME credits adequate? (15/36 m)*	*(y/n/NA)*	If "n", then:
– *Number of CME's in 36 months*	------	

Record in the "Remarks" section any other deficiencies.

NOTE 9-6: If documentation is not available, proper attestation will be acceptable for the 40 (or the 60) CME's and initial experience obtained prior to October 1, 1994.

NOTE 9-7: The date of completion of initial requirements is termed the starting date. It is the earliest date when all these requirements were met for the first time or October 1, 1994, for those who completed them prior to October 1, 1994. Once this date is determined for an individual, it must not be changed in the future for any reason.

NOTE 9-8: For physicians who use the 3-month (or 2-month) full-time training as an alternate to certification, the necessary 60 (or 40) hours could be part of that training.

NOTE 9-9: If the period from the starting date to inspection date is less than 24 months for an individual, you will not be able to access the software question regarding the continuing experience. Hence, such individuals can not be cited if they did not meet the continuing experience requirement. Those who fail to meet this requirement after 24 months from the starting date can be cited and must not read independently until they re-qualify. They may re-qualify by reading under direct supervision within a 6-month period, the lesser of 240 patient exams or the balance needed to bring their total to 960 exams in the previous 24 months. After they re-qualify, they will be exempt from an adverse observation regarding this requirement for 6 months from their re-qualification date. For interpreting physicians who did not meet this requirement but are reading under direct supervision, and those who re-qualified and are inspected during the exemption period, answer the continuing experience question with "NA." You should also indicate the person's re-qualifying status in the remarks section.

NOTE 9-10: Interpreting physicians may meet the continuing experience requirement by multi-reading (reading films already read by others) and or reading and interpreting films for more than one facility.

NOTE 9-11: If the period from the starting date to the inspection date is less than 36 months, the software question regarding the 15 CME credits will not be accessible and interpreting physicians who have not met the continuing education requirement will not be cited. Those who fail to meet this requirement are prohibited from reading mammograms independently until they re-qualify. They may re-qualify by acquiring the balance needed to bring their total CME credits to 15 in the previous 36 months. If they fail to meet this requirement but are reading under direct supervision, answer the continuing education question with "NA." You should also indicate the person's re-qualifying status in the remarks section.

NOTE 9-12: If an interpreting physician fails a qualification requirement at Level 1, consult APPENDIX 3 "Guide for Additional Mammography Review (AMR)" for further action.

The following table, Exhibit 7, summarizes the acceptable documentation for interpreting physicians. For additional details, see Sections 9.2.1 to 9.2.5.

Exhibit 7: Acceptable Documents for Interpreting Physicians

Requirement	Obtained Prior to 10/1/94	Obtained 10/1/94-4/28/99	Obtained after 4/28/99
State License	1. State license/ 2. Confirming letter from State licensing board 3. Pocket card/copy of license	1. State license/copy 2. Confirming letter from State licensing board 3. Pocket card/copy of license	1. State license/copy 2. Confirming letter from State licensing board 3. Pocket card/copy of license
Board Certification (ABR, AOBR, or RCPSC)	1. Original/copy of certificate 2. Confirming letter from certifying board 3. Confirming letter from ACR 4. Listing in ABMS directory	1. Original/copy of certificate 2. Confirming letter from certifying board 3. Confirming letter from ACR 4. Listing in ABMS directory	1. Original/copy of certificate 2. Confirming letter from certifying board 3. Confirming letter from ACR 4. Listing in ABMS directory
Formal Training (2 months-interim regs) (3 months-final regs)	1. Letters or other documents from US or Canadian residency programs 2. Documentation of formal mammography training courses 3. Category I CME certificates	1. Letters or other documents from US or Canadian residency programs 2. Documentation of formal mammography training courses 3. Category I CME certificates	1. Letters or other documents from US or Canadian residency programs 2. Documentation of formal mammography training courses 3. Category I CME certificates
Initial Medical Education (40 hours-interim regs) (60 hours/15 in last 3 years-final regs)	1. Attestation 2. Letter from residency program 3. CME certificates 4. Letter or other document confirming in-house or formal training	1. Letter from residency program 2. CME certificates 3. Letter or other document confirming in-house or formal training	1. Letter from residency program 2. Category 1 CME certificates 3. Letter or other document confirming in-house or formal training (category I)
Initial Experience (any 6 month period-interim regs) (last 6 months vs. 6 months in last 2 years of residency-final regs)	1. Attestation 2. Letter or other document from residency or training program or mammography facility	1. Letter or other document from residency or training program or mammography facility – done under direct supervision	1. Letter or other document from residency or training program or mammography facility – done under direct supervision
Initial Mammographic Modality Specific Training-8 hours-final regs	1. Attestation for training or experience with investigational units 2. Mammography modality specific CME certificates (category I or II) 3. CME certificates (category I or II) plus agenda, course outline, or syllabus 4. Confirming letters from CME granting organizations 5. Letters, certificates or other documents from manufacturers' or other formal training courses 6. Letter from facility where experience was obtained documenting experience in the new mammographic modality	1. Attestation for experience with investigational units 2. Mammography modality specific CME certificates (category I or II) 3. CME certificates (Category I or II) plus agenda, course outline, or syllabus 4. Confirming letters from CME granting organizations 5. Letters, certificates, or other documents from manufacturers' or other formal training courses 6. Letter from facility where experience was obtained documenting experience in the new mammographic modality	1. Attestation for experience with investigational units 2. Mammography modality specific CME certificates (category I or II) 3. CME certificates (category I or II) plus agenda, course outline, or syllabus 4. Confirming letters from CME granting organizations 5. Letters, certificates, or other documents from manufacturers' or other formal training courses
Continuing Experience (960/24 months)	N/A	1. Letter, table, facility logs, or other documentation from residency or training program or mammography facility	1. Letter, table, facility logs, or other documentation from residency or training program or mammography facility
Continuing Education (15 CME/36 months-interim regs) (15 category I CME/36 months-final regs)	N/A	1. CME certificates (category I or II) 2. Confirming letters from CME granting organizations 3. Letters, certificates, or other documents from manufacturers' training courses	1. CME certificates (category I) 2. Confirming letters from CME granting organizations
Continuing Mammographic Modality Specific Education-final regs	N/A	1. Mammography modality specific CME certificates (category I or II) 2. CME certificates (category I or II) plus agenda, course outline, or syllabus 3. Confirming letters from CME granting organizations 4. Letters, certificates, or other documents from manufacturers' or other formal training courses	1. Mammography Modality Specific CME certificates (category I) 2. CME certificates (category I) plus agenda, course outline, or syllabus 3. Confirming letters from CME granting organizations
Requalification-Experience–done under direct supervision	N/A	1. Letter, table, facility logs, or other documentation from residency or training program or mammography facility	1. Letter, table, facility logs, or other documentation from residency or training program or mammography facility
Requalification- Education	N/A	1. CME certificates (category I or II) 2. Confirming letters from CME granting organizations	1. CME certificates (category I) 2. Confirming letters from CME granting organizations

9.2.1 Qualification Requirements - Interpreting Physicians

Each physician responsible for interpreting mammograms at the facility must meet the following specific requirements in the final regulations [CFR 900.12(a)(1)] unless exempt because they previously qualified under the interim regulations prior to April 28, 1999:

1. State License – The facility's records must contain a license to practice medicine in a State for each interpreting physician. For documentation, FDA accepts any of the following; copy of the license, a pocket card, or a letter from the licensing board (bearing the board's letterhead) stating that the physician is licensed.

2. Certification OR Training.

   a. Certification. The facility's records must contain, for each interpreting physician, a certificate from an FDA-approved body (see note below). FDA also accepts a copy of the certificate, or a letter from the approved body (bearing the body's letterhead), or a letter from the ACR if the physician is certified by the ABR or the AOBR specifically stating that the physician is certified, or a listing of the physician in the directory of the American Board of Medical Specialties (ABMS).

      NOTE 9-13: The FDA-approved bodies are: the American Board of Radiology (ABR), the American Osteopathic Board of Radiology (AOBR), and the Royal College of Physicians & Surgeons of Canada (RCPSC). For all three, the certificate must be in radiology or diagnostic radiology.

   OR

   b. Three Months (420 hours) of Full-Time Training. For each interpreting physician, the facility's records must contain written documentation showing at least three months of full-time training in mammography. The documentation must indicate that the interpreting physician received training in mammographic interpretation, and in radiation physics, effects, and protection. It must also indicate the name of the institution or educational organization, the dates of training, the name of the course or training program, and the hours and/or credits received for the course or training.

3. 60 hours of Medical Education in Mammography – For each interpreting physician, the facility's records must contain written documentation showing at least 60 hours of category I medical education in mammography. At least 15 of these credits must have been acquired within the three years immediately prior to the date when the individual met the initial qualifications. The documentation must indicate the name of the institution or educational organization, the dates of training, the name of the course or training, and the hours and/or credits for the course or training. FDA accepts residency time specifically devoted to mammography, if documented in writing by an appropriate official of the training program.

   NOTE 9-14: For interpreting physicians who use the three-month full-time training as an alternate to certification, the necessary 60 hours could be part of that training. If documentation is not available, proper attestation will be acceptable for CME's earned prior to October 1, 1994, unless those CME's were earned as part of the three months full-time training, in which case attestation is not acceptable for training received at any date.

4. Initial Experience – Each interpreting physician must have read and interpreted, under the direct supervision of an interpreting physician, mammograms from the examinations of at least 240 patients in the six-month period prior to the date the individual met the initial qualifications, or in any six-month period during the last two years of a residency in diagnostic radiology, for those who became board-certified at the first allowable time as defined by the appropriate certifying board.

   FDA considers interpreting physicians who met the initial qualification requirements under the interim regulations (prior to April 28, 1999) as having met this requirement.

   For each interpreting physician who meets this requirement directly, the facility must have on file a signed statement or other documentation stating that this requirement has been met in the specified six months. The documentation should indicate the name of the facility and the date range in which this requirement was met. It should be signed by the residency program director or by the physician providing the direct supervision. Also, attestation will be acceptable for initial experience gained prior to October 1, 1994.

5. New Mammographic Modality Training – The interpreting physician must have at least 8 hours training in each new mammographic modality before using that mammographic modality.

   After April 28, 1999, before an interpreting physician may begin independently using a new mammographic modality for radiography of the breast, he or she must obtain 8 hours of training in that new mammographic modality. If the interpreting physician started using this mammographic modality before April 28, 1999, he/she is considered to have met the 8-hour training requirement. The interpreting physician can obtain the required training from many sources, including, but not limited to, residency training, special training courses, continuing education, and training provided by the manufacturer. New mammographic modality training can be in many forms, including, but not limited to, residency training, special training courses, continuing medical education, and training provided by the manufacturer. Also, it does not have to be category I continuing medical education.

6. Continuing Experience – The interpreting physician must continue to read and interpret mammograms from the examination of at least **960 patients over the 24-month period**:

   - preceding the inspection date, or
   - from the end of the calendar quarter preceding the inspection date, or
   - from any date in between the two.

   NOTE 9-15: In both 4 and 6, interpreting physicians may meet film reading requirements by combining readings from multiple facilities or by double or multi-reading films.

7. Continuing Education (15 CME Credits/36 months) – The interpreting physician must continue to participate in continuing medical education programs, either by teaching or completing a total of at least 15 continuing medical education (CME) credits in mammography over the 36-month period:

   - preceding the inspection date, or
   - from the end of the calendar quarter preceding the inspection date, or
   - from any date in between the two.

   The facility's records must contain, for each interpreting physician, written documentation showing that the individual has taught or completed at least 15 category I CME units in mammography. At least 6 of these must be in each mammographic modality used by the interpreting physician (Note: Inspectors will defer citing facilities for the mammography modality

specific continuing education requirement indefinitely). The documentation must indicate the name of the institution or educational organization, the dates of training, the name of the course or training, and the hours and/or credits for the course or training. The CME's must be related to the diagnosis or treatment of breast disease.

9.2.2 Direct Supervision for Interpreting Physicians

The supervising physician need not be present during initial reading and interpretation. Direct supervision for an interpreting physician means that during the joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, confirms, and if necessary, corrects the final interpretation of the physician being supervised before it is given to the patient. The physician being supervised should not provide final results to patients or referring physicians without prior confirmation from the supervising physician. Since each mammography report must be signed by a qualified interpreting physician, the facility must identify the supervising interpreting physician on the report as the interpreting physician of record.

Digital Mammography Issues. With the approval of primary soft copy interpretation using Full Field Digital Mammography (FFDM) systems, it now is possible to provide direct supervision of an interpreting physician exclusively through the use of an FDA approved tele-mammography system.

9.2.3 Applicability of the Requirement for 8 Hours of Training in Each Mammographic Modality

The interpreting physician at a facility using a Full Field Digital Mammography/CR (FFDM) unit must be a qualified interpreting physician who also meets the 8 hours training requirement for performing FFDM examinations.

Interpreting physicians who began performing FFDM examinations on investigational FFDM units (units that were used for investigational purposes before being approved by FDA for commercial distribution), are considered to have met the requirement for 8 hours of training with that mammographic modality. However, these interpreting physicians must either attest to or document that they were providing such services. Attestation should be done using an FDA attestation form (or equivalent) indicating where and when the FFDM examinations were performed. Interpreting physicians who document this training may use the same methods as those used to document other training (certificates, letters from the training provider, etc.). For more information, see "acceptable documents for interpreting physicians" in the PGHS.

9.2.4 Requirements for the Content of the FFDM Training

The 8 hours of initial training related to FFDM should include practical (hands-on) training in any aspects of the use of such systems in the interpreting physician's area of responsibility that are unique to the FFDM system (such as computer manipulation of images). The remainder of the 8 hours, if any, can be didactic or practical training related to any aspect of FFDM. The instruction must be provided by a qualified instructor. If this training is category I CME, such training can also be counted towards the interpreting physician's continuing education requirement.

FDA strongly recommends that interpreting physicians whose 8 hours of FFDM training did not include any training in soft copy interpretation, obtain such practical training under a qualified instructor before beginning to independently manipulate and interpret soft copy images. If category I CME, such training can also be counted towards the interpreting physician's continuing education

requirement.

For other changes that can occur in the field, such as introduction of a new quality control manual by the manufacturer or the introduction of a new model of a FFDM unit, the same general principle as described above with "soft copy" interpretation should be followed. If the new manual or model introduces new unique features to an FFDM system that fall into the interpreting physician's area of responsibility, practical training under a qualified instructor on those features should be included in the training of any interpreting physician who has not already met the 8 hour requirement. Interpreting physicians who have previously met this requirement should also receive training in the new unique features under a qualified instructor before beginning to use them independently. If category I CME, such training can also be counted towards the interpreting physician's continuing education requirement.

Qualifications of the Individual Providing the Training. The individual providing the training must be a qualified instructor. A qualified instructor is defined in 21 CFR 900.2(oo) as an individual whose training and experience adequately prepares him or her to carry out specified training assignments. FDA recognizes interpreting physicians who have previously met the 8 hour requirement for FFDM training as qualified to instruct other interpreting physicians in this area.

9.2.5 Training/Experience in Stereotactic Biopsy Systems with Digital Image Receptors Prior to 4/28/99

Interpreting Physicians who worked with stereotactic biopsy systems with digital image receptors prior to 4/28/99 are not considered to have met the 8 hours of training specific to FFDM. Because these stereotactic biopsy systems are currently excluded from MQSA regulation, experience with these systems cannot be used to meet the requirement of 8 hours of training specific to FFDM.

9.3 Radiologic Technologist (Screen 3.11.2)

For each technologist, record the following in the **"Information"** screen:

- S***tatus*** *(Evaluate, Hold)*
- ***Name yyy*** *[FIRST, M.I., LAST] (capital letters, separate fields)*

Answer the rest of the qualification-related questions in the "**Evaluation"** screens as follows:

- ***Rules qualifying under*** *(interim, final) [select one]*

  If you selected the interim rules:

  Initial qualifications under interim rules met? **(y/n)** *[prior to 4/28/99]*
  - *Licensed or certified* [must be current] *(y/n)*
  - *Training specific to mammography* *(y/n)*

  If you selected the final rules:

  Initial qualifications met? ***(y/n)***
  - *Licensed or certified?* *(y/n)*
  - *40 supervised hours* of training adequate?* *(y/n)*

  * This includes specific mammography subject training and 25 supervised exams.

Date completed initial requirements *mm/dd/yyyy*
New Modality Training [8 hours] (if applicable) *(y/n/NA)*

- ***Continuing Experience***
  Continuing Experience adequate? [200 exams/24mo.] *(y/n/NA)*

- ***Continuing Education***
  - *CEU credits adequate? [15/36 mo.]* *(y/n/NA)* If "n", then
  - *Number of CEU's in 36 months* ------

Record in the "Remarks" section any other deficiencies.

NOTE 9-16: If documentation is not available for training, proper attestation will be acceptable only for training received prior to October 1, 1994.

NOTE 9-17: The date of completion of initial requirements is termed the starting date. It is the earliest date when all these requirements were met for the first time or October 1, 1994, for those who completed them prior to October 1, 1994. Once this date is determined for an individual, it must not be changed in the future for any reason.

NOTE 9-18: If the period from the starting date to inspection date is less than 24 months for an individual, you will not be able to access the corresponding software question. Hence, such individuals can not be cited if they did not meet the continuing experience requirement. Those who fail to meet this requirement after 24 months from the starting date can be cited and must not conduct patient exams independently until they re-qualify. They may re-qualify by conducting 25 patient exams under direct supervision. Once they have re-qualified, they will be exempt from an adverse observation regarding this requirement for 6 months from their re-qualification date. For those who did not meet this requirement but are conducting mammograms under direct supervision, and those who re-qualified and are inspected during the exemption period, answer the continuing experience question with "NA." You should also indicate the person's re-qualifying status in the remarks section.

NOTE 9-19: Radiologic technologists may meet the initial or continuing experience requirement by working at multiple facilities, or by co-conducting exams on patients, either with another qualified technologist or under direct supervision. However, no more than two individuals may count the same exam towards meeting either of these requirements.

NOTE 9-20: If the period from the starting date to the inspection date is less than 36 months, the software question regarding the 15 CEU credits will not be accessible. In this case, radiologic technologists who have not met the continuing education requirement will not be cited. Those who fail to meet this requirement are prohibited from performing mammograms independently until they re-qualify. They may re-qualify by acquiring the balance needed to bring their total CEU credits to 15 in the previous 36 months. If they fail to meet this requirement but are conducting patient mammograms under direct supervision, answer the continuing education question with "NA." You should also indicate the person's re-qualifying status in the remarks section.

The following table, Exhibit 8, summarizes acceptable documentation for radiologic technologists. For additional details, see Sections 9.3.1 to 9.3.7

Exhibit 8: Acceptable Documents for Radiologic Technologists

Requirement	Obtained Prior to 10/1/94	Obtained 10/1/94-4/28/99	Obtained after 4/28/99
State Licensure	1. State license/copy 2. Confirming letter from State licensing board 3. Pocket card/copy of license	1. State license/copy 2. Confirming letter from State licensing board 3. Pocket card/copy of license	1. State license/copy 2. Confirming letter from State licensing board 3. Pocket card/copy of license
Board Certification (ARRT or ARCRT)	1. Original/copy of certificate 2. Confirming letter from certifying board 3. Pocket card/copy of certificate	1. Original/copy of certificate 2. Confirming letter from certifying board 3. Pocket card/copy of certificate	1. Original/copy of certificate 2. Confirming letter from certifying board 3. Pocket card/copy of certificate
Initial Training (~40 hours-interim regs) (40 hours with 25 supervised exams-final regs)	1. Attestation 2. Letter or other document from training program 3. CEU certificates 4. Letter or other document confirming in-house or formal training 5. ARRT(M) Mammography certificate 6. California Mammography certificate 7. Arizona Mammography certificate 8. Nevada Mammography certificate	1. Letter or other document from training program 2. CEU certificates 3. Letter or other document confirming in-house or formal training 4. Approved RT training courses 5. ARRT(M) Mammography certificate 6. California Mammography certificate 7. Arizona Mammography certificate 8. Nevada Mammography certificate	1. Letter or other document from training program 2. CEU certificates 3. Letter or other document confirming in-house or formal training 3. ARRT(M) Mammography certificate but only if issued after 1/1/01 4. Certain State issued Mammography certificate(s) - facilities need to check with their State inspectors
Initial Mammography Modality Specific Training (8 hours-final regs)	1. Attestation for training or experience with investigational units 2. Mammography modality specific CEU certificates 3. CEU certificates plus agenda, course outline, or syllabus 4. Confirming letters from CEU granting organizations 5. Letters, certificates, or other documents from manufacturers' or other formal training courses 6. Letter from facility where experience was obtained documenting experience in the new mammographic m	1. Attestation for experience with investigational units 2. Mammography modality specific CEU certificates 3. CEU certificates plus agenda, course outline, or syllabus 4. Confirming letters from CEU granting organizations 5. Letters, certificates, or other documents from manufacturers' or other formal training courses 6. Letter from facility where experience was obtained documenting experience in the new mammographic modality	1. Attestation for experience with investigational units 2. Mammography modality specific CEU certificates 3. CEU certificates plus agenda, course outline, or syllabus 4. Confirming letters from CEU granting organizations 5. Letters, certificates, or other documents from manufacturers' or other formal training courses
Continuing Experience (200/24 months-final regs)	N/A	N/A	1. Letter, table, facility logs, or other documentation from training program or mammography facility
Continuing Education (15 CEU/36 months)	N/A	1. CEU certificates 2. Confirming letters from CEU granting organizations 3. Formal training courses 4. Letters, certificates, or other documents from manufacturers' or other formal training courses	1. CEU certificates 2. Confirming letters from CEU granting organizations 3. Formal training courses 4. Letters, certificates, or other documents from manufacturers' or other formal training courses
Continuing Mammographic Modality Specific Education-final regs	N/A	1. Mammography modality specific CEU certificates 2. CEU certificates (plus agenda, course outline, or syllabus) 3. Confirming letters from CEU granting organizations 4. Letters, certificates, or other documents from manufacturers' or other formal training courses	1. Mammography Modality Specific CEU certificates 2. CEU certificates (plus agenda, course outline or syllabus) 3. Confirming letters from CEU granting organizations 4. Letters, certificates, or other documents from manufacturers' or other formal training courses
Requalification-Experience–final regs–done under direct supervision	N/A	N/A	1. Letter, table, facility logs, or other documentation from training program or mammography facility (done under direct supervision)
Requalification- Education	N/A	1. CEU certificates 2. Confirming letters from CEU granting organizations 3. Letter or other document confirming in-house or formal training 4. Letters, certificates, or other documents from manufacturers' or other formal training courses	1. CEU certificates 2. Confirming letters from CEU granting organizations 3. Letter or other document confirming in-house or formal training 4. Letters, certificates, or other documents from manufacturers' or other formal training courses

9.3.1 Qualification Requirements - Radiologic Technologists

Each technologist independently performing mammograms must meet the following specific requirements [see final regulations, October 28, 1997, §900.12(a)(2)] unless exempt because they previously qualified under the interim regulations prior to April 28, 1999:

1. License OR Certificate – The facility's records must contain, for each technologist, a license from a State or a general certificate from an FDA-approved body (see note below)*. A copy of the license or certificate, a pocket card, or a letter from the licensing board or certifying organization (bearing the board's or organization's letterhead) stating that the technologist is licensed or certified, is acceptable.

   *** NOTE 9-21:** Currently, the only FDA-approved body is the American Registry of Radiologic Technologists (ARRT). Technologists who were originally certified by the American Registry of Clinical Radiologic Technologists (ARCRT) and were later registered by the ARRT, when the ARCRT ceased to exist, also meet FDA certification requirements.

2. Training – Have 40 contact hours of documented supervised training specific to mammography, including:
   - breast anatomy & physiology, positioning & compression, quality assurance/quality control techniques, imaging of patients with breast implants
   - the performance of 25 supervised exams.

   For each technologist, the facility's records must contain written documentation from a medical or other institution showing the amount of training received. The documentation must indicate that credits were received for courses in mammography, including the name of the institution or educational organization, the dates of training, the name of the course or training, and the hours or credits for the course or training.

   NOTE 9-22: Under the interim regulations, FDA accepted several training courses and/or certificates as evidence of adequate training in mammography although some did not add up to 40 hours. Under the final regulations, FDA accepts each of these for the amount of credits allowed by the certifying body towards meeting requirement 2 above.

   NOTE 9-23: In general, the performance of 25 exams will be considered as equivalent to 12.5 hours of training. This means that the other training required under the 40 contact hours should add up to a minimum of 27.5 hours.

   NOTE 9-24: Radiologic technologists who were qualified under the interim regulations prior to April 28, 1999, are considered to have met the training requirement specified in 2 above.

3. New Mammographic Modality Training – The radiologic technologist must have at least 8 hours training in each new mammographic modality before using that mammographic modality.

   After April 28, 1999, before a radiologic technologist may begin independently using a new mammographic modality for radiography of the breast, he or she must obtain 8 hours of training in that new mammographic modality. Radiologic technologists who started using this mammographic modality before April 28, 1999, are considered to have met the 8-hour training requirement. The radiologic technologist can obtain the required training from many sources, including, but not limited to, special training courses, continuing education, and training provided by the manufacturer.

4. Continuing Experience – Effective the later of July 1, 2001, or two years after meeting the initial qualifications, the radiologic technologist must have performed **200 mammograms over the 24-month period**:

   - preceding the inspection date, or
   - from the end of the calendar quarter preceding the inspection date, or
   - from any date in between the two.

   For each technologist, the facility's records must contain written documentation showing the number of examinations and the period of time over which they were performed.

   NOTE 9-25: In 4 above, radiologic technologists may meet this requirement by working at multiple facilities. In this case, they must show documentation from each facility.

   AND

5. Continuing Education (15 CEU's /36 months) – The radiologic technologist must participate in continuing medical education programs, either by teaching or completing a total of at least 15 continuing education units in mammography over the 36-month period:

   - preceding the inspection date, or
   - from the end of the calendar quarter preceding the inspection date, or
   - from any date in between the two.

   For each radiologic technologist, the facility's records must contain written documentation showing that the individual has taught or completed at least 15 CEU units in mammography. At least 6 of these credits must be in each mammographic modality used by the radiologic technologist (Note: Inspectors will defer citing facilities for the mammography modality specific continuing education requirement indefinitely). The documentation must indicate the name of the institution or educational organization, the dates of training, the name of the course or training, and the hours and/or credits for the course or training. The CEU's must be in mammography or related to the diagnosis or treatment of breast disease.

9.3.2 Direct Supervision for Radiologic Technologists

For the performance of a mammography examination, direct supervision means that the supervisor is present to observe and correct, as needed, the performance of the trainee. This oversight requires that the supervisor be in the examination room itself during the conduct of the examination. The goal of direct supervision is to provide reasonable assurance that any mistakes made by the trainee are corrected before harm is done to patients.

9.3.3 The ARRT (M) Certificate

While we have added the 2001 ARRT (M) certificate as acceptable documentation for meeting radiologic technologist initial training requirements in this document, a similar statement will NOT appear in the version that will appear on the public website. Our reason for not including this version on the website is that while the 2001 ARRT (M) certificate adequately documents meeting the training, it does not state the person's actual MQSA starting date (date when the person first met all applicable MQSA requirements). We believe that having the facility use this certificate to routinely document technologist qualifications could lead to unnecessary confusion about a person's starting date during inspections, possibly leading to inappropriate citations.

Facilities can use the 2001 ARRT (M) certificate as acceptable documentation that the technologist meets the training requirement. For technologists who had already met the training requirement by a different option before obtaining this certificate (as may be evidenced by their starting date already appearing in the downloaded inspection), their starting date should remain as before and must not be changed.

For new technologists who are using this certificate to qualify under MQSA for the first time, you will still need to determine their starting date. FDA is giving the facility the option of using either the certificate issuance date or the date when the person first met all applicable MQSA requirements as the person's starting date. While the first option reduces the paperwork that the facility has to maintain, it cannot be used if the person has independently performed mammographic examinations prior to the certificate date. If the radiologic technologist has performed such examinations, additional documentation will be necessary to demonstrate that all MQSA requirements had been met prior to the performance of these examinations.

9.3.4 Applicability of the Requirement for 8 Hours of Training in Each Mammographic Modality

The radiologic technologist at a facility using a Full Field Digital Mammography/CR (FFDM) unit must be a qualified radiologic technologist who also meets the 8 hours training requirement for performing FFDM examinations.

Radiologic technologists who began performing FFDM examinations on investigational FFDM units (units that were used for investigational purposes before being approved by FDA for commercial distribution), are considered to have met the requirement for 8 hours of training with that mammographic modality. However, these radiologic technologists must either attest to or document that they were providing such services. Attestation should be done using an FDA attestation form (or equivalent) indicating where and when the FFDM examinations were performed. Interpreting physicians who document this training may use the same methods as those used to document other training (certificates, letters from the training provider, etc.). For more information, see "acceptable documents for interpreting physicians" in the PGHS.

9.3.5 Requirements for the Content of the FFDM Training

The 8 hours of initial training related to FFDM should include practical (hands-on) training in any aspects of the use of such systems in the radiologic technologist's area of responsibility that are unique to the FFDM system (such as the procedure for performing a FFDM examination or FFDM QC testing to be performed by the radiologic technologist). The remainder of the 8 hours, if any, can be didactic or practical training related to any aspect of FFDM. The instruction must be provided by a qualified instructor. Such training can also be counted towards the radiologic technologist's continuing education requirement.

FDA strongly recommends that radiologic technologists whose 8 hours of FFDM training did not include any training in QC tests related to soft copy interpretation, obtain such practical training under a qualified instructor before beginning to independently perform such tests. Such training can also be counted towards the radiologic technologist's continuing education requirement.

For other changes that can occur in the field, such as introduction of a new quality control manual by the manufacturer or the introduction of a new model of a FFDM unit, the same general principle as described above should be followed. If the new manual or model introduces new unique features to an FFDM system that fall into the radiologic technologist's area of responsibility, practical training

under a qualified instructor on those features should be included in the training of any radiologic technologist who has not already met the 8 hour requirement. Radiologic technologists who have previously met this requirement should also receive training in the new unique features under a qualified instructor before beginning to use them independently. Such training can also be counted towards the radiologic technologist's continuing education requirement.

Qualifications of the Individual Providing the Training. The individual providing the training must be a qualified instructor. A qualified instructor is defined in 21 CFR 900.2(oo) as an individual whose training and experience adequately prepares him or her to carry out specified training assignments. FDA recognizes radiologic technologists who have previously met the 8 hour requirement for FFDM training as qualified to instruct other radiologic technologists in this area.

9.3.6 Training/Experience in Stereotactic Biopsy Systems with Digital Image Receptors Prior to 4/28/99

Radiologic Technologists who worked with stereotactic biopsy systems with digital image receptors prior to 4/28/99 are not considered to have met the 8 hours of training specific to FFDM. Because these stereotactic biopsy systems are currently excluded from MQSA regulation, experience with these systems cannot be used to meet the requirement of 8 hours of training specific to FFDM.

9.3.7 CME/CEU Credit for MQSA Teleconference (Live or Tape Viewing)

For personnel who were present at the live MQSA Teleconference on the Final Regulations that was televised on February 18, 1999, the 3 CME/CEU credits that were initially awarded for the teleconference did expire in 2002, unless the individual is claiming this credit toward the initial training.

For personnel in facilities that review the tape of the MQSA Teleconference, DMQRP will accept 3 CME/CEU credits for viewing if the videotapes are part of the instruction within a seminar, without written testing. Under such a scenario, an instructor must be present for a question and answer session following the videotape. However, should an individual view the videotape outside a seminar setting for continuing education, the ASRT requires successful completion of a written test before CEU's are awarded.

Because ASRT is not the organization issuing credit for this teleconference but FDA is applying ASRT-like rules, the inspector should apply this policy to all personnel viewing the videotape of the MQSA Teleconference. The inspector should accept 3 CME/CEU credits for personnel if they view the tape in a formal in-house training setting with a discussion or question and answer period at the end of the tape. Because there is no written test for this teleconference, the tape must be viewed in a setting as described above. The inspector would therefore look for a letter (or other appropriate documentation) from the facility (or viewing site) stating that the personnel reviewed the teleconference video in a formal setting, and was present for the entire viewing and discussion or question and answer period. When applying this policy to interpreting physicians, the viewing of the videotape must take place prior to 4/28/99 because after that date only category I CME is acceptable toward meeting the interpreting physician continuing education requirement.

9.4 Medical Physicist (Screen 3.11.3)

For each medical physicist, record the following in the **"Information"** screen:

- ***Status*** (Evaluate, Hold)
- ***Name yyy*** [FIRST, M.I., LAST] *(capital letters, separate fields)*

Answer the rest of the qualification-related questions in the "**Evaluation"** screens as follows:

- ***Degree qualifying under*** *(Masters or higher, Bachelors, None) [select one]*

  If you selected "Masters (or higher)":

Initial Qualifications met?	***(y/n)***
– *Certified or state licensed/approved?*	*(y/n)*
– *Masters degree in a physical science? [w/20 semester hrs in physics]*	*(y/n)*
– *20 contact hours of training in surveys?*	*(y/n)*
– *Experience in conducting surveys (1 facility & 10 units)*	*(y/n)*

  If you selected "Bachelors":

Alternative initial qualifications met before 4/28/99?	***(y/n)***
– Certified or state licensed/approved	*(y/n)*
– Bachelors degree in a physical science [w/10 semester hrs in physics]	*(y/n)*
– *40 contact hours of training in surveys [after Bachelors]*	*(y/n)*
– *Experience in conducting surveys [after Bachelors] (1 fac. & 20 units)*	*(y/n)*
– *Date completed initial requirements*	*mm/dd/yyyy*
– *New Modality Training [8 hours] (if applicable)*	*(y/n /NA)*

  If you selected "None", the program will answer "n" to all the questions above and the date field will not be accessible.

- ***Continuing Experience***
  - *Continuing Experience adequate? [2 facilities & 6 units/24m]* *(y/n/NA)*

- ***Continuing Education***

– *CME Credits adequate? (15/36m)*	*(y/n/NA)*	*If "n," then:*
– *Number of CME's in 36 months*	------	

Record any other deficiencies in the "Remarks" section.

NOTE 9-26: If documentation is not available for training and experience, proper attestation will be acceptable only for training and experience acquired prior to October 1, 1994.

NOTE 9-27: The date of completion of initial requirements is termed the starting date. It is the earliest date when all these requirements were met for the first time or October 1, 1994, for those who completed them prior to October 1, 1994. Once this date is determined for an individual, it must not be changed in the future for any reason.

NOTE 9-28: If the period from the starting date to inspection date is less than 24 months, you will not be able to access the software question regarding the continuing

experience. Hence, such individuals can not be cited if they did not meet the continuing experience requirement. Those who fail to meet this requirement after 24 months from the starting date can be cited and must not conduct mammography surveys or equipment evaluations independently until they re-qualify. They may re-qualify by conducting the balance of surveys needed to meet the continuing experience requirement (2 facilities & 6 units in the previous 24months). If they fail to meet this requirement but are conducting surveys or equipment evaluations under direct supervision, answer the continuing experience question with "NA." You should also indicate the person's re-qualifying status in the remarks section.

NOTE 9-29: If the period from the starting date to the inspection date is less than 36 months, the software question regarding the 15 CME credits will not be accessible and medical physicists who have not met the continuing education requirement will not be cited. Those who fail to meet this requirement are prohibited from conducting mammography facility surveys and equipment evaluations independently until they re-qualify. They may re-qualify by acquiring the balance needed to bring their total CME credits to 15 in the previous 36 months. If they fail to meet this requirement but are conducting surveys or equipment evaluations under direct supervision, answer the continuing education question with "NA." You should also indicate the person's re-qualifying status in the remarks section.

The following table, Exhibit 9, summarizes the acceptable documentation for medical physicists. For additional details, see Sections 9.4.1 to 9.4.14.

Exhibit 9: Acceptable Documents for Medical Physicists

Requirement	Obtained Prior to 10/1/94	Obtained 10/1/94-4/28/99	Obtained after 4/28/99
State Licensure or Approval	1. Original/copy of State license or approval 2. Confirming letter from State licensing board	1. Original/copy of State license or approval 2. Confirming letter from State licensing board	1. Original/copy of State license or approval 2. Confirming letter from State licensing board
Board Certification (ABR or ABMP)	1. Original/copy of certificate 2. Confirming letter from certifying board 3. Pocket card/copy of certificate 4. Confirming letter from ACR	1. Original/copy of certificate 2. Confirming letter from certifying board 3. Pocket card/copy of certificate 4. Confirming letter from ACR	1. Original/copy of certificate 2. Confirming letter from certifying board 3. Pocket card/copy of certificate 4. Confirming letter from ACR
Degree in a physical science-final regs (Master's pathway) (Bachelor's pathway - alternative)	1. Original/copy of diploma 2. Confirming letter from college or university 3. FDA Approval Letter	1. Original/copy of diploma 2. Confirming letter from college or university 3. FDA Approval Letter	1. Original/copy of diploma 2. Confirming letter from college or university 3. FDA Approval Letter
Initial physics education-final regs (20 semester hours) (10 semester hours - alternative)	1. College or university transcripts 2. Confirming letter from college or university 3. Master or Bachelor degree specifically in physics 4. FDA Approval Letter	1. College or university transcripts 2. Confirming letter from college or university 3. Master or Bachelor degree specifically in physics 4. FDA Approval Letter	1. College or university transcripts 2. Confirming letter from college or university 3. Master or Bachelor degree specifically in physics 4. FDA Approval Letter
Survey Training-final regs (20 contact hours) (40 contact hours - alternative)	1. Attestation 2. Letter or other document from training program 3. CME/CEU certificates 4. Letter or other document confirming in-house or formal training 5. Training gained performing surveys 6. FDA Approval Letter	1. Letter or other document from training program 2. CME/CEU certificates 3. Letter or other document confirming in-house or formal training 4. Training gained performing surveys 5. FDA Approval Letter	1. Letter or other document from training program 2. CME/CEU certificates 3. Letter or other document confirming in-house or formal training 4. Training gained performing supervised surveys 5. FDA Approval Letter
Initial Experience-final regs (1 facility-10 units) (1 facility-20 units - alternative)	1. Attestation 2. Copy or coversheet of survey 3. Letter from facility or listing from company providing the physics survey services documenting performance of survey done	1. Copy or coversheet of survey 2. Letter from facility or listing from company providing the physics survey services documenting performance of survey done 3. FDA Approval Letter	1. Copy or coversheet of survey done under direct supervision 2. Letter from facility or listing from company providing the physics survey services documenting performance of survey done under

	4. FDA Approval Letter		direct supervision 3. FDA Approval Letter
Initial Mammography Modality Specific training (8 hours-final regs)	1. Attestation for training or experience with investigational units 2. Mammography modality specific CME/CEU certificates 3. CME/CEU certificates plus agenda, course outline, or syllabus 4. Confirming letters from CME/CEU granting organizations 5. Letters, certificates, or other documents from manufacturers' or other formal training courses 6. Letter from facility where experience was obtained documenting experience in the new mammographic modality	1. Attestation for experience with investigational units 2. Mammography modality specific CME/CEU certificates 3. CME/CEU certificates plus agenda, course outline, or syllabus 4. Confirming letters from CME/CEU granting organizations 5. Letters, certificates, or other documents from manufacturers' or other formal training courses 6. Letter from facility where experience was obtained documenting experience in the new mammographic modality	1. Attestation for experience with investigational units 2. Mammography modality specific CME/CEU certificates 3. CME/CEU certificates plus agenda, course outline, or syllabus 4. Confirming letters from CME/CEU granting organizations 5. Letters, certificates, or other documents from manufacturers' or other formal training courses
Continuing Experience (2 facilities-6 units/24 months-final regs)	N/A	N/A	1. Copy or coversheet of survey 2. Letter from facility or listing from company providing the physics survey services documenting performance of survey done
Continuing Education (15 CME/36 months)	N/A	1. CME/CEU certificates 2. Confirming letters from CME/CEU granting organizations 3. Letters, certificates, or other documents from manufacturers' or other formal training courses	1. CME/CEU certificates 2. Confirming letters from CME/CEU granting organizations 3. Letters, certificates, or other documents from manufacturers' or other formal training courses
Continuing Mammographic Modality Specific Education-final regs	N/A	1. Mammography modality specific CME/CEU certificates 2. CME/CEU certificates (plus agenda, course outline, or syllabus) 3. Confirming letters from CME/CEU granting organizations 4. Letters, certificates, or other documents from manufacturers' or other formal training courses	1. Mammography Modality Specific CME/CEU certificates 2. CME/CEU certificates (plus agenda, course outline, or syllabus) 3. Confirming letters from CME/CEU granting organizations 4. Letters, certificates, or other documents from manufacturers' or other formal training courses
Requalification - Experience–final regs–done under direct supervision	N/A	N/A	1. Copy or coversheet of survey done under direct supervision 2. Letter from facility or listing from company providing the physics survey services documenting performance of survey done under direct supervision
Requalification - Education	N/A	1. CME/CEU certificates 2. Confirming letters from CME/CEU granting organizations 3. Letters, certificates, or other documents from manufacturers' or other formal training courses	1. CME/CEU certificates 2. Confirming letters from CME/CEU granting organizations 3. Letters, certificates, or other documents from manufacturers' or other formal training courses

9.4.1 Qualification Requirements - Medical Physicists

Each medical physicist providing services to a mammography facility must meet the following specific requirements [see final regulations, October 28, 1997, §900.12(a)(3)]:

Initial Qualifications

1. State License, State Approval, or Board Certification.

The facility's records must contain, for each medical physicist, documentation indicating approval or licensing by a State or certification from an FDA-approved body.*

FDA accepts a copy of the approval, license or certificate, a pocket card, or a letter from the state or FDA- approved body (bearing the body's letterhead) stating that the physicist is licensed or certified.

***NOTE 9-30:** the FDA-approved bodies are the American Board of Radiology (either in diagnostic radiological physics or radiological physics) or the American Board of Medical Physics (in diagnostic imaging physics).

2. Qualifying Degree – A Masters or higher degree in a physical science, with a minimum of 20 semester hours (30 quarter hours) in physics.

   All qualifying degrees must be from the physical sciences. In this context, physical science degree means a degree in one of the specialties or sub-specialties of physics, chemistry, radiation science (including medical physics and health physics), or engineering.

   Acceptable documentation for this requirement must indicate that the physicist has the appropriate degree, including the name of the institution or educational organization, the date of degree, and the subject area in which the degree was awarded. FDA accepts a copy of the degree or a letter from the institution that awarded the degree.

3. Specialized Training – Have **20 contact hours** of documented **specialized training** in conducting surveys

   Physicists may use various types of training to meet the requirement for specialized training in conducting surveys, including continuing medical education units (CME), formal academic training, or other types of training programs. To satisfy the specialized survey training requirements, CME's must be specifically related to technical or QA topics pertinent to mammography facility surveys. Therefore, not all CME's that are acceptable as continuing education units will satisfy the requirement for specialized training. Additionally, physicists who qualified before April 28, 1999, and obtained their survey training prior to this date may count the survey training for both CME's and the "specialized training in conducting surveys" requirement. However, physicists who qualify after April 28, 1999, may only use the survey training to meet their initial requirements and not as CME's. Physicists originally qualified prior to October 27, 1997, under the education, training, and experience route in the interim regulations, would meet the final regulations if they conducted at least one facility survey and a total of 10 units.

4. Initial Experience – Have the experience in conducting surveys of at least one mammography facility and a total of at least 10 mammography units.

   NOTE 9-31: Surveys conducted after April 28, 1999, to meet this requirement must be conducted under direct supervision of a fully qualified medical physicist who meets the initial requirements listed in 1–4, as well as the continuing requirements.

   FDA recognizes that some physicists may be unable to visit multiple facilities to meet the experience requirements. FDA, therefore, allows the survey of the same facility and the same mammography units to count towards the total requirements for initial, continuing, and re-qualification training and experience. However, there are restrictions on the frequency under which we will allow such re-surveying. For the unit survey requirements in each of these categories, physicists can count no more than one survey of any single unit in any 60-day period towards the total. For both the continuing experience and re-qualification requirements, the physicist can count no more than one survey of a specific facility in any ten-month period.

   Acceptable documentation to establish experience may be a written statement by the company that provides medical survey services, the physicist's supervisor, or the management of the facility surveyed, indicating where and when the physicist performed the required number of surveys, or an official listing from a company that provides medical physicist survey services.

Alternative Initial Qualifications

1. Have qualified as a medical physicist and maintained active status under the interim regulations (Certified, State licensed or State approved);

AND prior to April 28, 1999, have:

2. Qualifying Degree – A bachelor's degree or higher in a physical science (with 10 semester hours or equivalent in physics). **AND**

3. Specialized Training – Have **40 contact hours** of documented **specialized training** in conducting surveys. **AND**

4. Initial Experience – Have the experience in conducting surveys of at least one mammography facility and a total of at least 20 mammography units.

   NOTE 9-32: If documentation is not available for requirements 3 or 4 above (under initial or alternative initial requirements), proper attestation will be acceptable only for training or experience gained prior to October 1, 1994.

   NOTE 9-33: Persons meeting the initial qualifications through the alternative requirements cannot supervise others in conducting mammography surveys for the purpose of meeting the initial or continuing experience requirements.

5. New Mammographic Modality Training – The medical physicist must have **at least 8 hours** training in each new mammographic modality before conducting surveys on that mammographic modality.

   After April 28, 1999, before a medical physicist may begin independently surveying a new mammographic modality for radiography of the breast, he or she must obtain 8 hours of training in that new mammographic modality. Medical physicists who started conducting surveys on this mammographic modality before April 28, 1999, are considered to have met the 8-hour training requirement. The medical physicist can obtain the required training from many sources, including, but not limited to, special training courses, continuing education, and training provided by the manufacturer.

6. Continuing Experience – Effective the later of July 1, 2001, or two years after meeting the initial qualifications, the medical physicist must have **surveyed 2 facilities and 6 units over the 24-month period:**

   - preceding the inspection date, or
   - from the end of the calendar quarter preceding the inspection date, or
   - from any date in between the two.

   Guidance regarding how to meet this requirement is similar to that given above for the initial experience**.**

7. Continuing Education (15 CME Credits/36 months) – The medical physicist must participate in continuing medical education programs, either by teaching or completing a total of at least 15 continuing medical education (CME) credits in mammography over the 36-month period:

   - preceding the inspection date, or
   - from the end of the calendar quarter preceding the inspection date, or
   - from any date in between the two.

   For meeting the continuing education requirement for physicists, FDA accepts CEU credits or units either related to the diagnosis and/or treatment of breast disease or to areas that will aid medical physicists in improving the quality of the survey. At least 1 of these credits must be in each mammographic modality used by the medical physicist (Note: Inspectors will defer citing

facilities for the mammography modality specific continuing education requirement indefinitely). The documentation must indicate the name of the institution or educational organization, the dates of training, the name of the course or training, and the hours and/or credits for the course or training.

9.4.2 Direct Supervision for Medical Physicists

For the physics survey and/or mammography equipment evaluations, direct supervision means that the supervisor (if the supervision is done after 4/28/99, the supervising medical physicist must have qualified under the Master's or higher pathway) is present to observe and correct, as needed, the performance of the supervisee. This requires that the supervisor be in the room during the performance of the individual equipment tests to assure that any mistakes made by the supervisee are corrected before the test is completed. The supervisor must review any calculations made from, and any conclusions drawn from the test results, before those results are provided to the facility.

Furthermore, when conducting a physics survey, the supervisor and supervisee must jointly review the QC program records. The supervisor does not have to be present when the supervisee initially reviews the QC program records. However, the supervisor must review, discuss, confirm, and if necessary, correct the observations made by the supervisee prior to issuing either the initial or final survey report.

The goal of direct supervision is to provide reasonable assurance that any mistakes made by the supervisee are corrected before the QC program review or tests are completed.

9.4.3 Meeting the Initial Survey Experience & Initial Training

Time spent in the actual performance of surveys can be used to meet the survey contact hours requirement. As guidance, however, no more than four hours for each facility survey and two hours for each unit survey should be counted toward the required total hours of training. In order to count toward the survey training contact hours requirement, surveys performed after April 28, 1999 must be under the direction of a qualified instructor. If these surveys are also being used to meet the initial experience requirement, they must be done under the direct supervision of a medical physicist who meets all the requirements of 21 CFR 900.12(a)(3)(i) and (iii). This means that in the typical Master's degree situation, surveying one facility and a total of ten units meets both the initial contact hours of specialized training and the initial experience requirements. In the Bachelor's degree situation, surveying one facility and a total of 20 units meets both the initial contact hours of specialized training and the initial experience requirements. Please note that time spent in the actual performance of surveys applies only to the initial training and does not apply towards meeting the 15 CME continuing education requirement.

9.4.4 Medical Physicist with a Physics Degree

As a reminder, if the physicist has a Bachelors degree in physics, it can be assumed that he or she has at least 10 semester hours credit in physics. Similarly, if the physicist has a masters or doctorate in physics, it can be assumed that he or she has at least 20 semester hours credit in physics. If the physicist's diploma clearly shows that the degree is in physics, no further documentation of the semester hours is needed. Unfortunately, the diplomas of many colleges and universities merely indicate the degree and not the field. In that case, the physicist will still have to provide a transcript or other document from his college(s) showing either that the degree is in physics or that he or she has the required number of hours.

9.4.5 Transcripts Instead of a Copy of Degree

If the transcripts of a physical science degree also name the appropriate degree, inspectors should consider the transcripts as sufficient documentation of the degree itself and can waive reviewing an actual copy of the degree.

9.4.6 General Medical Physics Continuing Education

Medical physicists may count all continuing education credits related to the diagnosis or treatment of breast disease or other areas that will aid facility personnel in improving the quality of mammography toward meeting the continuing education requirement. Diagnostic medical physics continuing education not directly related to mammography or general continuing education in mammography unrelated to medical physics would also be acceptable.

9.4.7 Approval Letters by the State of Maryland

Based on recent discussions with the State of Maryland (MD), DMQRP will accept MD approval letters issued to medical physicists qualifying them for providing mammography services under MQSA, if dated July 23, 1999 and beyond. The criteria MD uses in their approval process are based on the initial qualification requirements for medical physicists under the final regulations. Namely, the physicist must meet the degree, experience, and training requirements as specified in MQSA's final regulations (900.12(a)(3)), in order to gain approval by MD. Approval letters from MD will be valid for three years from the date of each letter.

9.4.8 Approval Letters by the State of Pennsylvania

For physicists who are using the State of Pennsylvania new approval letter to meet the initial requirements, such letters should be accepted only if they reference the final regulations. Such letters are typically dated after May 27, 1999. Note that if a previously approved physicist receives a new approval, this does not change the date originally established for when he or she met the initial requirements.

9.4.9 Approval Letters by the State of Ohio - August 2006 Update

Based on discussions (2001) with the State of Ohio (OH), DMQRP respected OH's request not to accept OH approval letters issued to medical physicists qualifying them for providing mammography services under MQSA. However, OH recently informed us that they would like to resume providing medical physicists with such letters. A medical physicist obtaining an approval letter to do mammography surveys in OH under MQSA is termed by OH as a "certified" radiation expert (CRE) in mammography. You should accept any OH approval letter issued as of August 2006, as documentation that the individual has met the requirement of being approved by a State, under MQSA.

9.4.10 List of States with Approval/Licensing Procedure

The following table, Exhibit 10, shows which states have acceptable procedures for approval/licensing of medical physicists under MQSA.

Exhibit 10: State Approval/Licensing List for Medical Physicists

State	Approval	Licensing	Renewal Frequency	State	Approval	Licensing	Renewal Frequency

AK	~~N~~ Y		Annual fee basis	MT	N		
AL	Y			NC	N		
AR	Y			ND	N		
AZ	Y			NE	N		
CA	Y			NH	N		
CO	~~N~~ Y		2 Years	NJ	Y		
CT	~~Y~~ N			NM	N		
DE	N			NV	N		
DC	N			NY	N		
FL	Y	~~Y~~ N		OH	~~Y~~ ~~N~~ Y		
GA	N			OK	Y		
HI	N			OR	N		
IA	Y			PA	Y		
ID	~~Y~~ N			PR	Y		
IL	Y			RI	Y		
IN	Y		For cause only	SC	Y		
KN	N			SD	N		
KY	Y			TN	N		
LA	Y			TX	Y	Y	Annually
MA	Y			UT	Y		
MD	~~N~~ Y		3 Years	VA	Y		3 Years
ME	Y			VT	N		
MI	Y		3 Years	WA	Y		
MN	N			WI	N		
MO	Y			WV	Y		3 Years
MS	Y			WY	N		

9.4.11 Review of Physicist Qualifications at FDA Headquarters

Upon request, FDA's Division of Mammography Quality and Radiation Programs (DMQRP) will review a medical physicist's credentials to determine whether or not the physicist meets the initial requirements under the MQSA regulations. After the review, DMQRP will send the physicist a letter identifying the initial requirements that he or she meets. The physicist can then provide this letter to the mammography facilities he or she serves. The information identified in this letter will be accepted by the MQSA inspector as adequate evidence that the cited initial requirements are met. You will also need to supply all facilities where you provide mammography services a copy of your Board certification or a current State approval or State license. Please be aware that if your State approval or State license expires after a certain period, you must provide your facilities with a new copy of the documentation after each renewal. Consequently, the physicist will not need to provide facilities with copies of the more detailed credentials that he or she sent to us for evaluation.

This service can be particularly valuable for medical physicists who serve many facilities because it reduces the amount of paperwork that they have to provide to each of their facilities. Physicists who are uncertain about whether or not they meet the initial requirements may use this service for getting their questions related to the initial requirements answered.

We stress, however, that the decision to utilize this service is entirely yours. If you choose not to use this service, our inspectors will continue to evaluate your detailed credentials during their annual inspections of the mammography facilities you serve. Should you be interested in using this service, the following "Questions and Answers" contain additional details on the submission of your credentials that will be necessary for review.

1. Must all medical physicists send documentation of their credentials to FDA headquarters for review by the mammography program?

No, only those wishing to obtain FDA's medical physicist approval letter. While we are willing to provide this review as a service, whether you use the service is up to you. If you wish, you may continue to have all of your credentials reviewed during the annual inspection of the mammography facilities you serve.

2. What would be the advantage of sending my credentials to the FDA headquarters for review?

We see two possible benefits for you. First, if you are in doubt about whether you meet any of the initial requirements, this is an opportunity to get an answer from FDA. Second, after the review, a letter signed by the Director of FDA's Division of Mammography Quality and Radiation Programs, will identify the initial requirements that you have met. This letter can be given to the facilities you serve in place of the documents related to those initial requirements that you presently provide to them for evaluation and credentialing purposes. This will reduce the volume of material that has to be given to the facility.
Note: You will still need to supply all facilities where you provide mammography services a copy of your Board certification or a current State approval or State license. Please be aware that if your State approval or State license expires after a certain period, you must provide your facilities with a new copy of the documentation after each renewal.

3. Will this review cover all of my MQSA personnel requirements?

No, it will be limited to the initial requirements. Your compliance with the continuing requirements will continue to be reviewed during the facility's annual MQSA inspection. Any re-qualification for these requirements also will be monitored by the inspectors and the FDA district offices. If you have a State approval or license that has to be renewed regularly, that credential will be reviewed during inspections and not at FDA headquarters.

4. What if this assessment of whether or not I meet the initial requirements disagrees with an earlier inspection finding?

In general, we do not plan on revisiting past inspection decisions. The letter you receive from us is intended for use during future inspections and will be accepted by MQSA inspectors.

Medical physicists interested in this service should mail their credentials to the following address:

DHHS/PHS/FDA/CDRH, Office of Communication, Education, and Radiation Programs,
Division of Mammography Quality and Radiation Programs,

HFZ-240, 1350 Piccard Drive, Rockville, MD 20850

Or you may fax the information to us at: 1-240-276-3272

In either case, mark them:
ATTN: Medical Physicist Credentials

9.4.12 Applicability of the Requirement for 8 Hours of Training in Each Mammographic Modality

Medical physicists who conduct surveys or mammography equipment evaluations of Full Field Digital Mammography/CR (FFDM) systems must meet the requirement for 8 hours of training in conducting such surveys or equipment evaluations.

Medical physicists who began performing FFDM examinations on investigational FFDM units (units that were used for research purposes before being approved by FDA for commercial distribution), are considered to have met the requirement for 8 hours of training with that mammographic modality. However, these medical physicists must either attest to or document that they were providing such services. Attestation should be done using an FDA attestation form (or equivalent) indicating where and when the FFDM examinations were performed. Interpreting physicians who document this training may use the same methods as those used to document other training (certificates, letters from the training provider, etc.). For more information, see "acceptable documents for interpreting physicians" in the PGHS.

9.4.13 Requirements for the Content of the FFDM Training

The 8 hours of initial training related to FFDM should include practical (hands-on) training in any aspects of the use of such systems in the medical physicist's area of responsibility that are unique to the FFDM system (such as FFDM QC testing to be performed by the medical physicist). The remainder of the 8 hours, if any, can be didactic or practical training related to any aspect of FFDM. The instruction must be provided by a qualified instructor. Such training can also be counted towards the medical physicist's continuing education requirement. Training received in digital image receptors used for stereotactic biopsy can count toward the 8 hours of training specific to FFDM if the training is essentially the same as that being given for FFDM. For example, if the medical physicist received training in the performance of a QC test for stereotactic digital image receptors, and the FFDM QC test is essentially the same as the stereotactic QC test, that training could count toward the 8 hours of training specific to FFDM.

FDA strongly recommends that medical physicists whose 8 hours of FFDM training did not include any training in QC tests related to soft copy interpretation, obtain such practical training under a qualified instructor before beginning to independently perform such tests.

For other changes that can occur in the field, such as introduction of a new quality control manual by the manufacturer or the introduction of a new model of a FFDM unit, the same general principle as described above should be followed. If the new manual or model introduces new unique features to an FFDM system that fall into the medical physicist's area of responsibility, practical training under a qualified instructor on those features should be included in the training of any medical physicist who has not already met the 8 hour requirement. Medical physicists who have previously met this requirement should also receive training in the new unique features under a qualified instructor before beginning to evaluate them independently. Such training can also be counted towards the medical physicist's continuing education requirement.

Qualifications of the Individual Providing the Training. The individual providing the training must be a qualified instructor. A qualified instructor is defined in 21 CFR 900.2(oo) as an individual whose training and experience adequately prepares him or her to carry out specified training assignments. FDA recognizes medical physicists who have previously met the 8 hour requirement for FFDM training as qualified to instruct other medical physicists in this area.

9.4.14 Training/Experience in Stereotactic Biopsy Systems with Digital Image Receptors Prior to 4/28/99

Medical Physicists who worked with stereotactic biopsy systems with digital image receptors prior to 4/28/99 are not considered to have met the 8 hours of training specific to FFDM. Because these stereotactic biopsy systems are currently excluded from MQSA regulation, experience with these

systems cannot be used to meet the requirement of 8 hours of training specific to FFDM.

10. MEDICAL RECORDS

The purpose of reviewing medical records is to assure that patient permanent medical records are kept and maintained for at least the minimum period specified in the regulations, and that test results are routinely communicated to patients and referring health care providers.

10.1 Patient Permanent Records

These records include mammograms and mammography reports and any follow-up reports. The facility must maintain patient records for at least 5 years, or at least 10 years if no other patient mammograms are available, and for a longer period if required by state law, or until requested by the patient to transfer the records to another institution, physician, or to themselves.

10.2 Mammography Reports

Under the final regulations, the facility is required to send a lay summary to **all** the patients to whom they provide mammography services, whether they were referred by a health care provider or not. The "lay summary" must be written in lay language that is easily understood by persons unfamiliar with medical terminology.

Also, the regulations require the facility to send a written report of the examination in a timely manner (within 30 days) to the referring health care provider or directly to the patient who does not have a referring health care provider. If the results of the examination are "suspicious or highly suggestive of malignancy," the facility is required to make reasonable attempts to ensure that the results are communicated to the patient as soon as possible (ASAP). Therefore, check on the type of services the facility provides, and follow the guidance given below before you answer these questions. This guidance was given in the all-inspector e-mail message dated 12/10/1999 and is reproduced below for you convenience:

During a routine inspection, the facility can satisfy the "provision of lay summaries and mammography reports" requirement through <u>either</u> options #1 (demonstrating compliance through actual reports) or #2 (written procedures), <u>or a combination of options #1 and #2.</u>

Option 1. Demonstrate that:

- The facility is notifying patients and health care providers of positive examinations as soon as possible (as guidance, within 5 and 3 business days respectively). In the case of verbal communication, this may be done by documenting such communication in the mammography report or in patient logs. In the case of written communication, see the next two bulleted items.

- The facility is providing written mammography reports. This may be done by having copies of the mammography report available within 30 days of the examination (positive mammography reports <u>should</u> be available within 3 business days).

- The facility is providing written lay summaries. This may be done by having copies of the lay summary available within 30 days of the examination (positive lay summaries should be available within 5 business days). If the facility does not keep copies of the patients' lay summaries, it may document such communication in the mammography report, or in patient logs, or by stating in the facility's Quality Assurance (QA) manual that the lay summary is provided within the appropriate time frames. **OR**

Option 2. Provide written documentation describing the procedure for:

- Providing (sending or giving) the written lay summary to patients within 30 days of the examination.
- Providing the mammography report to the health care provider (or the patient, if self referred) within 30 days of the examination.
- Communicating the results of positive (suspicious or highly suggestive of malignancy) examinations to patients and health care providers as soon as possible (as guidance, within 5 and 3 business days respectively). This communication may be verbal or written. If verbal, it must be followed by a written lay summary and mammography report provided within 30 days of the examination.

If the facility is using Option 1, you may use the procedure outlined below to determine if a facility meets the MQSA requirements for providing lay summaries and mammography reports to their patients and health care providers:

a. You should check a total of 5 randomly selected mammographic examinations performed at least 30 days prior to the inspection (these may be the same examinations whose reports are checked for signatures and assessments later in this section). Alternatively, if the facility keeps send-out logs, you may review those logs instead of the actual reports. If all five examinations have mammography reports or log entries dated (date the report was generated) within 30 days of the examination date, you should answer "YES" to the question "System to provide medical reports within 30 days?" If two or more of the five examinations have a mammography report or log entry dated more than 30 days from the examination date, then you should answer "NO" to the question "System to provide medical reports within 30 days?" If only one of the five examinations has a mammography report or log entry dated more than 30 days from the examination date, you should review another 5 randomly selected reports or log entries from examinations performed at least 30 days prior to the inspection. If two or more of the ten examinations have mammography reports or log entries dated more than 30 days from the examination date, then you should answer "NO" to the question "System to provide medical reports within 30 days?"

b. If the facility keeps dated copies of their individual patient lay summaries (or logs), you can use the same procedure as described in "a" to answer the question "System to provide lay summaries within 30 days.

c. When evaluating "positive" examination reports and lay summaries special attention is required, because the number of "positive" reports generally represents only a small portion of the total number of reports. You are less likely to see "positive" reports in your random samples. In many cases, the facility will be using written documentation, as described in

option 2 above, to address this requirement. Alternatively, the facility can demonstrate that they are fulfilling this requirement by selecting five mammographic examinations performed at least 30 days prior to the inspection ("positive" examinations may be identified by a review of the mammography medical outcomes audit). If the facility keeps send-out logs, you may review those logs instead of the actual reports. If all five examinations have mammography reports dated "as soon as possible" from the performance of the examination (as guidance, three business days), you should answer "YES" to the question "System to communicate serious cases ASAP?" If two or more of the five examinations have a mammography report dated more than 3 business days from the examination date, then apply instructions in "e." If only one of the five examinations has a mammography report dated more than 3 business days from the examination date and does not meet the extenuating circumstances in "e," you should review another 5 reports. If two or more of the ten examinations have mammography reports dated more than 3 business days from the examination date, then apply the instructions in "e."

d. If the facility can supply you with dated copies of "positive" patient lay summaries (or log entries), then follow the instructions in "c" but substitute five business days.

e. **Note:** If the "positive" lay summaries and mammography reports (or log entries) are not dated within five and three business days respectively of the examination, you should not automatically answer "NO" to the question above. Rather, you should evaluate the facility's system to determine whether there are reasonable extenuating circumstances (e.g. waiting for comparison films) that make this "as soon as possible" for the facility. Remember, the time period of 3-5 business days mentioned in the guidance, is just that, GUIDANCE, it is not regulation. If the "system" routinely takes longer than 3-5 days, the inspector must use his/her judgment as to whether the facility's "system" for communicating results ASAP is reasonable for its conditions. In some cases (for example, where they are waiting for old exams), it can be quite appropriate for the facility to take 15-20 days or even longer (but in no case more than 30 days) to provide the report.

Please be aware that the facility may have other methods of showing that they provide their reports within the specified time frames. Any method that shows that they provide their reports within the specified time frames should generate a "YES" answer to the appropriate question.

Site List

If applicable, select the site to be evaluated to gain access to the Medical Records Screen 3.12.

- ***Evaluation***

1. ***System (to communicate results) adequate?*** ***(y/n)***
   a. *System to provide medical reports within 30 days?* *(y/n)*
      (to referring health care providers or self-referred patients)
   b. *System to provide lay summaries within 30 days?* *(y/n)*
      (to all patients)
   c. *System to communicate serious cases ASAP?* *(y/n)*
      (Serious: suspicious or highly suggestive cases)

Ensure that the facility selects 5 random medical records (reports and films) that were completed after April 28, 1999 and check if the signature and assessment categories (any one of the six

listed in the box below) are present for each (acceptable signature forms are defined in Further Details (Section 10.3). Record your observations by filling in the numbers in the data-entry fields (Screen 3.12) as shown below:

2. Random written reports

- *Number of random written reports reviewed* ----
- *Number with assessment categories* ----
- *Number with qualified interpreting physician identification* ----

The assessment categories are: "negative," "benign," "probably benign," "suspicious," "highly suggestive of malignancy," and "incomplete: need additional imaging evaluation."

For additional information regarding assessment categories, refer to the guidance under "Help" on your laptop.

Record in the "Remarks" section any other deficiencies in medical records.

10.3 Further Details

10.3.1 Mammography Reports

Facilities need not record mammography reports on a special form. They could use ordinary letter format, general x-ray report format, or other. Reports must be in writing. Documentation of a phone call or a verbal communication is not acceptable unless supplemented by a written communication.

Each report must identify the name of the interpreting physician who has seen the mammogram and rendered the interpretation. The name may be hand written in ink, typed or stamped, autopenned, or electronic (as in a computer-based approval system). The minimum identification is a last name and a first initial.

When Checking for Assessment Categories – you should check five randomly selected reports to see if they have final assessments listed. You do not have to check to see if the facility is using all six of the different assessment categories. There is no requirement that a facility uses all six categories, only that each report has one of the six categories. Keep in mind that a facility can legitimately decide not to use one or more of the categories. For example, a screening type facility may never assign a "Suspicious" or "Highly Suggestive of Malignancy" assessment category to any of its screening exams.

10.3.2 Lay Summaries

The regulations require facilities to "send lay summaries to all patients as soon as possible, but no later than 30 days from the date of the mammography examination. If the assessment is "Suspicious" or "Highly suggestive of malignancy," the facility must make reasonable attempts to communicate the results as soon as possible" (ASAP).

When the results are incomplete and additional imaging is needed – Even if the facility verbally transmits the results to the patient, the facility must provide, within 30 days of the examination, a written lay summary indicating that additional imaging is required. If the results of the follow-up examination are available within 30 days of the initial examination, the facility has the option of combining the results into one lay summary (rather than providing two lay summaries). If one combined lay summary is provided, it must state specifically that it refers to both the initial and the follow-up examinations.

If the results of the follow-up examination are not available within 30 days of the initial examination, the facility must provide two lay summaries, one for the initial examination and one for the follow-up. Each must be provided within 30 days of the examination it covers.

Computer generated lay summaries are acceptable under the final regulations. The facility may develop appropriate procedures for providing these lay summaries to their patients. Where electronic means (e.g., E-mail) will successfully provide the lay summaries to the patients, they may be used. However, where electronic means can't achieve this goal, hard copy (paper) lay summaries must be provided.

10.3.3 Examples of Acceptable Assessment Categories

Since the start of inspections under the final regulations, FDA has become aware of a specific type of problem with many facilities' use of final overall assessment categories in their mammography reports. The problem concerns the wording that facilities may be using to identify the assessment categories. Many facilities are continuing to use wording for the assessment categories that had been previously widely accepted in the mammographic community, but which may not exactly coincide with what appears in the final regulations. This has led to confusion as to what constitutes an acceptable final overall assessment category. It is imperative that FDA's position on this matter be clarified in order to avoid inappropriate citations of large numbers of facilities.

The goal of the final regulation assessment category classification system is to bring some consistency to the reporting of mammographic results. It should be kept in mind that FDA's classification system is based on previously developed systems (especially ACR's BIRADS) that were in use prior to the development of the final regulations. While these other systems use the same six assessment categories as in the final regulations, their wording of the categories has changed over time and may be slightly different from what appears in the final regulations. Many facilities and mammography reporting computer software companies continue to use the wording of these earlier systems and have not adopted the exact words from the final regulations. This matter was discussed at the July 12, 1999 NMQAAC meeting where there was unanimous consensus that FDA should exercise reasonable flexibility when it encounters facilities that are using the six assessment category system but may be using the wording of one of these earlier systems to identify the individual category.

In order to provide inspectors with appropriate guidance in this area, we have developed a list of commonly used "equivalents" that inspectors may run across. While these "equivalent" assessments may use slightly different wording than that found in the final regulations they do not change the meaning of the assessment category. FDA is currently working with the major parties involved to try and bring more consistency to this issue, but until this can be accomplished and until further notice, facilities using these "equivalents" to identify the six final overall assessment categories should not be cited. Inspectors should not take this to mean that facilities are not required to meet the basic requirement. Facilities that are not using the final overall assessment category classification system at all or are using wording that is unclear or that changes the meaning of the assessment category should still be cited.

The following examples should be considered equivalent to the wording listed in the final regulations and are acceptable final overall assessments.

- Negative

  Negative Mammogram

- Benign

  Benign Finding
  Benign Findings
  Benign Abnormality
  Benign Abnormalities
  Benign Mammogram

- Probably Benign

  Probably Benign Finding
  Probably Benign Findings
  Probably Benign Abnormality
  Probably Benign Abnormalities
  Probably Benign- Short Interval Follow-up Suggested
  Probably Benign Finding - Short Interval Follow-up Suggested
  Probably Benign Mammogram

- Suspicious

  Suspicious Finding
  Suspicious Findings
  Suspicious Abnormality
  Suspicious Abnormalities
  Suspicious for Malignancy
  Suspicious of Malignancy
  Suspicious Abnormality - Biopsy Should Be Considered
  Suspicious Finding - Biopsy Should Be Considered
  Suspicious Mammogram

- Highly Suggestive of Malignancy

  Highly Suggestive for Malignancy
  Highly Suggestive of Malignancy - Appropriate Action Should Be Taken

- Incomplete: Need Additional Imaging Evaluation

  Incomplete: Needs Additional Imaging Evaluation
  Incomplete: Additional Imaging Evaluation Needed
  Incomplete: Need Additional Imaging Evaluation- Comparison with Prior Studies
  Need Additional Imaging Evaluation (the term "Incomplete" can be inferred in this example as this is the only Incomplete assessment category)
  Incomplete Mammogram: Need Additional Imaging Evaluation.
  Incomplete: Need prior mammograms for comparison
  Incomplete: Need additional imaging evaluation and/or prior mammograms for comparison

- Known Biopsy Proven Malignancy

  Known Biopsy Proven Cancer, Known Malignancy, Known Cancer

- Post Procedure Mammograms for Marker Placement

10.3.4 Modifications in the Assessment Categories Used in Medical Reports - Two Alternative Standards

The following two alternative standards were approved and became effective on August 29, 2003. One of these adds a new assessment category for use in the reports of the mammography examinations and also adds clarifying language to the existing assessment categories. The second adds a reference to the possible need to obtain prior mammograms in order to make a final assessment. The alternatives were approved for an indefinite period.

The original standards are 21 CFR 900.12(c)(1)(iv) and (v), which state:

21 CFR 900.12(c)(1): *Medical records and mammography reports…..*

(iv) Overall final assessment of findings, classified in one of the following categories:
(A) "Negative:" Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained)";
(B) "Benign:" Also a negative assessment;
(C) "Probably Benign:" Finding(s) has a high probability of being benign;
(D) "Suspicious:" Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;
(E) "Highly suggestive of malignancy:" Finding(s) has a high probability of being malignant:
(v) In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and

The approved alternatives are:

21 CFR 900.12(c)(1): *Medical records and mammography reports…..*

(iv) Overall final assessment of findings, classified in one of the following categories:
(A) "Negative:" Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained)";
(B) "Benign Finding(s):" Also a negative assessment;
(C) "Probably Benign Finding(s):" Initial short-interval follow-up suggested. Finding(s) has a high probability of being benign;
(D) "Suspicious Abnormality:" Biopsy should be considered. Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;
(E) "Highly suggestive of malignancy:" Appropriate action should be taken. Finding(s) has a high probability of being malignant:
(F) "Known Biopsy Proven Malignancy:" Appropriate action should be taken.
(v) In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: Need additional imaging evaluation and/or prior mammograms for comparison" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and

As was the case with the original standards, only the words in quotation marks are required to be included in the medical report when giving the assessment category or indicating that no final category can be assigned at the present time. The remaining language is intended to provide explanations of the categories in order to promote their consistent use. It is not required to be included in the medical report, although the interpreting physician may do so if he or she wishes.

10.3.5 Separate Assessment of Findings for Each Breast - Alternative Standard

FDA approved this alternative standard July 3, 2003 for an indefinite period. It allows the interpreting physician to provide a separate assessment of findings for each breast in the medical report, without the need to also provide an overall assessment of findings. Therefore, the interpreting physician can choose between providing separate assessments under this alternative or providing an overall assessment for the examination under the original standard.

The original standard is 21 CFR 900.12(c)(1)(iv), which states:

21 CFR 900.12(c)(1): *Medical records and mammography reports*

(iv) Overall final assessment of findings, classified in one of the following categories:

The approved alternative is:

21 CFR 900.12(c)(1): *Medical records and mammography reports*

(iv) A separate assessment findings for each breast, classified in one of the following categories:

When this alternative is used, the following conditions apply.

- A single medical report covering the assessment of both breasts will be sent to the referring physician (or to the patient if there is no referring physician;
- A single lay report will be sent to the patient, containing information based on the overall assessment for both breasts; and

Even though separate assessments are made for each breast, the interpretation will count as only one examination towards meeting the MQSA experience requirements and will be billed as a single examination.

10.3.6 Assessment Category for "Post Procedure Mammograms for Marker Placement" – Alternative Standard

This alternative standard was approved on September 17, 2003. This approved assessment category can only be used for a post procedure mammogram to confirm the deployment and position of a breast tissue marker. The lay summary, which must be provided to the patient, must be specific to the procedure. If the facility makes this post procedure examination part of the interventional study instead of a separately charged examination, then it does not fall under MQSA and the approved alternative standard does not apply. The alternative was approved for an indefinite period

The original standard is 21 CFR 900.12(c)(1)(iv), which states:

21 CFR 900.12(c)(1): *Medical records and mammography reports*

(iv) Overall final assessment of findings, classified in one of the following categories:
(A) "Negative:" Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained)";
(B) "Benign:" Also a negative assessment;
(C) "Probably Benign:" Finding(s) has a high probability of being benign;
(D) "Suspicious:" Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;
(E) "Highly suggestive of malignancy:" Finding(s) has a high probability of being malignant:

(v) In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and

The granted alternative is:

21 CFR 900.12(c)(1): *Medical records and mammography reports*

(iv) Overall final assessment of findings, classified in one of the following categories:

(A) "Negative:" Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained)";
(B) "Benign:" Also a negative assessment;
(C) "Probably Benign:" Finding(s) has a high probability of being benign;
(D) "Suspicious:" Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;
(E) "Highly suggestive of malignancy:" Finding(s) has a high probability of being malignant:
(F) "Post Procedure Mammograms for Marker Placement"

(v) In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and…

10.3.7 Requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (45 CFR Parts 160 and 164)- Release of Information for MQSA Purposes

Implementation of the Health Insurance Portability and Accountability Act (HIPAA) has raised a number of issues with respect to mammography facilities that operate under the Mammography Quality Standards Act (MQSA). Three issues are arising with increasing frequency. The first concerns the protection of patient information during MQSA inspections. The second deals with whether other medical entities (e.g., referring physicians, pathology departments, surgeons) can release patient biopsy information to mammography facilities for purposes of the MQSA medical outcomes audit without obtaining patient authorization. The third deal with transfer of medical records from one medical entity to another for treatment, payment, or healthcare operation purposes. The HIPAA regulations address these matters as follows:

Regarding the first issue, sections 164.512(b) and (d) of the HIPAA regulations allow a mammography facility to release patient information to an MQSA inspector without patient authorization because MQSA inspectors are performing health oversight activities required by law.

As to the second issue, section 164.512(b) of the HIPAA regulations allows a covered entity (e.g., referring physician, pathology department, surgeon) to release patient biopsy information to a mammography facility for purposes of the MQSA medical outcomes audit without patient authorization because the disclosure: (1) is to "a person subject to FDA jurisdiction;" (2) concerns an FDA-regulated product or activity for which the mammography facility has responsibility; and (3) relates to the quality, safety or effectiveness of the product or activity.

Regarding the third issue, section 164.506 of the HIPAA privacy regulations permits release of information for treatment, payment, or healthcare operation purposes without a specific patient authorization. Consequently the regulation allows a mammography facility to transfer medical records to another covered entity in most situations without a specific patient authorization. The Office of Civil Rights has also stated that, "a covered health care provider may share protected health

information with another health care provider for treatment purposes without a business associate contract."

11. MEDICAL AUDIT AND OUTCOME ANALYSIS

The purpose of reviewing these records is to assure that clinical outcomes are followed-up.

11.1 Overview

The facility should have a system or a procedure for reviewing and tracking outcomes of positive mammograms and correlating them with biopsy results. The facility must use this system annually both individually for each interpreting physician and for the facility as a whole.

Determine if the facility has a medical audit system, i.e., if it tracks or attempts to track results of positive mammograms.

Ask the facility to explain how they track positive mammograms to get results of biopsies. Ask to see a sample of a biopsy result from a positive mammogram.

11.2 Data Entry

Record all the required data in this section in the **"Medical Audit and Outcome Analysis"** screen (Screen 3.13 of your laptop software program).

- **Site List**

If applicable, select the site to be evaluated, to gain access to the Medical Audit and Outcome Analysis screen.

- **Evaluation**
  - *ALL positive mammograms entered in system?* *(y/n/NA)*
  - *Biopsy results present (or attempt to get)* *(y/n/NA)*
  - *Is there a designated audit (reviewing) interpreting physician?* *(y/n/NA)*

The next 3 questions will not result in citations until a facility has been certified for at least two years. After that, a Level 2 citation will result if answering any of these questions with "n". Since it takes a newly established facility at least two years before you can answer any of these questions appropriately, answer each question with "x" (Not Applicable) when inspecting such a facility, in order to avoid issuing an inappropriate citation.

  - *Analysis done annually?* *(y/n/NA)*
  - *Done separately for each individual?* *(y/n/NA)*
  - *Done for the facility as a whole?* *(y/n/NA)*

Record in the "Remarks" section any other deficiencies in medical audit and outcome analysis.

11.3 Further Details

11.3.1 Performing the Medical Audit

The regulations require each facility to establish and maintain a mammography medical outcomes audit program to follow up positive mammographic assessments and to correlate pathology results with the interpreting physician's observations. This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms. In addition, any cases of breast cancer among women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate follow-up on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of malignancy.

11.3.2 How to Meet FDA Requirements

Facilities that have had positive examinations, can meet the requirements of the medical outcomes audit program by demonstrating to the MQSA inspector that the facility has obtained, or attempted to obtain, pathology results for their positive cases (and cases of breast cancer among patients imaged at the facility that subsequently became known to the facility) and has performed appropriate analyses annually. The audit (reviewing) interpreting physician(s) must be identified.

For facilities that have not had positive examinations, the medical outcomes audit program requirements can be met by providing written documentation describing how the facility's medical audit system would follow-up on positive cases (and any cases of breast cancer among patients imaged at the facility that subsequently became known to the facility), would correlate pathology results with the interpreting physician's observations and would perform appropriate analyses annually. The audit (reviewing) interpreting physician(s) must be identified. An example of such a facility is a screening facility that classifies all problematic mammograms as "Incomplete, Need additional imaging evaluation" and sends those patients to a diagnostic center for further evaluation. Because the screening facility never classifies a patient as positive, the facility does not have to track any patients and does not have to include them in their audit.

GLOSSARY

Accreditation Body (AB). An entity that has been approved by FDA under Sec. 900.3(d) to accredit mammography facilities. As of 3/31/06, the FDA-approved AB's are: The American College of Radiology (ACR), the State of Arkansas (SAR), the State of IA (SIA), and the State of Texas (STX)

Air kerma. The amount of kerma (see separate definition) in a given mass of air. It is measured in units of Gray (Gy). For x-rays with energies below 300 keV, 1Gy =100 rad and is equivalent to 114 Roentgens (R) of exposure.

ACR. American College of Radiology

Artifact. Any unwanted or complicating structure visible in the image, or any aspect of an image not part of the object being imaged.

Automatic exposure control (AEC) systems. Automatic exposure control systems, often referred to as phototimers, are designed to automatically determine and provide the exposure needed to produce an adequate density image by sampling the x-ray intensity after passage through the patient and image receptor.

Average glandular dose. Calculated from values of entrance exposure in air, the x-ray beam quality (half-value layer), kVp, and compressed breast thickness, average glandular dose is the energy deposited per unit mass of glandular tissue (by far the most radiosensitive tissue in the breast) averaged over all the glandular tissue in the breast. See also: dose. The average, or mean, glandular dose is the value, which can be used to estimate the risk associated with an x-ray exposure.

Base density. The optical density due to the supporting base of the film alone. The base density of a film is the optical density that would result if an unexposed film were processed through the fixer, wash, and dryer, without first passing through the developer.

Base-plus-fog-density. The optical density of a film due to its base density plus any action of the developer on the unexposed silver halide crystals. The base-plus-flog-density can be measured by processing an unexposed film through the entire processing cycle and measuring the resultant optical density.

Cassette. A light-tight case, usually made of thin, low x-ray absorption plastic, for holding x-ray film. One or two intensifying screens for the conversion of x-rays to visible light photons are mounted inside the cassette so that they are in intimate contact with the film.

Compression device. A plastic paddle used to help hold the breast stationary and eliminate blurring due to motion, to decrease the thickness of breast tissue, minimizing the amount of radiation used and the amount of scattered radiation reaching the film, and to help separate structures within the breast. Ideally, the compression device is made of rigid, thin plastic and has a flat bottom surface that is parallel to the plane of the image receptor and a chest wall edge that is perpendicular to the plane of the image receptor to assist in moving breast tissue away from the chest wall and into the field of view.

Computed Radiography (CR). A radiographic technology whereby, x-rays expose a photostimulable phosphor plate, which captures the latent radiographic image. The phosphor plate is subsequently placed into a device that generates a digital image. When this (CR) plate is used in the bucky of a screen-film

cassette in a mammography unit, a full field digital mammogram is obtained. An x-ray unit equipped with a CR plate approved for mammography is considered a full field digital mammography (FFDM) unit.

Control chart. A graphical means of displaying data in which the variable of interest is plotted on the vertical axis as a function of time (date) on the horizontal axis. The control chart also allows for easy and rapid review of the data to determine whether the process is "in control."

Control limit. The upper and lower control limits are those values which when exceeded indicate that the process is "out of control" and require that some action be taken immediately. It is prudent to immediately repeat the measurement to verify that the system is "out of control" before taking corrective action. If the repeated measurement is "out of control," then corrective action is required immediately.

Corrective action plan (CAP). A set of procedures designed to correct deficiencies observed.

Craniocaudal (CC) view. One of the two routine views for mammography. The image receptor is placed caudal to (below) the breast and the vertical x-ray beam is directed from cranial to caudal (downward) through the breast.

Dedicated mammography equipment. X-ray systems designed specifically for breast imaging, providing optimum imaging geometry, a device for breast compression and that can consistently produce mammographic images of optimum quality.

Densitometer. An instrument which measures the degree of blackening or optical density of film.

Detents. Mechanical settings that limit or prevent the movement or rotation of an X-ray tube, cassette assembly, or image receptor system or allow exposure for specified tube orientation.

Developer. A chemical solution that changes the film latent image to a visible image composed of black metallic silver.

Developer replenishment. The process whereby fresh developer replenisher is added in small amounts to the solution in the developer tank of the processor. The purpose is to maintain the proper chemical activity and level of solution in the developer tank.

Direct supervision. Means that:

1) During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient's records, or
2) During the performance of a mammography examination or survey of the facility's equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination or conducting the survey.

Dose. The amount of energy deposited in tissue per unit mass due to X-ray exposure. The S.I. unit of absorbed dose is the Gray (Gy). One Gray equals 100 rads; 1 milliGray (mGy) equals 0.1 rad (1 mrad).

Emulsion side identification. In single-sided mammography films, the emulsion is coated on one side of the base only. To identify the emulsion side, note that when looking at the film in the portrait orientation (the long dimension is vertical), the film notches are in the upper right hand corner (along the shorter dimension) when the emulsion side is facing the observer (see Figure 5, Section 4.3.B.1).

Exposure. The amount of x-irradiation, quantified by measuring the amount of ionization in air caused by the radiation.

Facility ID. The 6-digit FDA number displayed on the front of the certificate, just below the accreditation body name and above the certificate expiration date. This is not to be confused with Certificate Number, which is also displayed on the front of the certificate in the extreme lower right corner.

Fixer. A chemical solution which removes the undeveloped silver halide crystals from film. The fixer also helps film drying by hardening the gelatin containing the black metallic silver.

Fixer retention. The incomplete removal of fixer from the film by the water in the wash tank of the processor. Retained fixer causes eventual brown discoloration of the radiograph (often within a year).

Focal spot size. The focal spot is the area of the target or anode that is bombarded by electrons from the cathode of the x-ray tube to produce x-rays. The smaller the focal spot, the better the limiting spatial resolution of the x-ray system, especially in magnification mammography.

Fog. The unwanted density added to a radiograph due to action of the developer on the unexposed silver halide crystals or by light, radiation, or heat exposure during storage, handling, and processing.

Grids. A set of thin, closely spaced lead strips, inter-spaced by fiber or aluminum for mammographic applications. The grid is placed between the breast and the screen-film image receptor to reduce scattered radiation reaching the image receptor. Scattered radiation reduces image contrast in mammography and limits the detection of low-contrast structures such as fibers and masses.

Half-value layer (HVL). The thickness of a specified substance which, when introduced into the path of a given beam of radiation, reduces the exposure rate by one-half. HVL is a measure of beam quality and is usually specified in millimeters of aluminum for diagnostic units. The higher the HVL, the more penetrating the x-ray beam.

Image contrast. The optical density difference between adjacent areas of a radiograph resulting from a difference in the x-ray attenuation.

Image quality. The overall clarity and detail of a radiographic image. Limiting spatial resolution (or resolving power), image sharpness, image contrast and noise are common measures of image quality.

Image sharpness. The overall impression or perception of detail and clarity in a radiographic image.

Inspection types (A, F, C, I, J, M, HIA). Several types of inspections are defined below. Inspections may fall under one or more of the following types:

- **Annual 'A' inspection -** Refers to the routine but mandatory facility inspection conducted by a federally certified MQSA inspector. This includes the "Basic" or routine inspection (done in the overwhelming majority of cases), the "Joint Audit" inspection, and the "Mentored" inspection, both of which are defined below.
- **Follow-up 'F' (Fee-Based) inspection -** Usually conducted by FDA MQSA inspectors to assess corrective actions the facility has taken since the previous annual inspection. It incurs a fee. State inspectors should not conduct these inspections unless requested to do so by the FDA District Office or FDA's Regional Radiological Health Representative (RRHR).
- **Compliance 'C' (Non Fee-Based) inspection -** Usually conducted by FDA MQSA inspectors to assess corrective actions the facility has taken after being sent a Warning Letter (which may be

the case if the results of a follow-up inspection were unsatisfactory). It does not incur a fee. State inspectors should not conduct these inspections unless requested to do so by the FDA District Office or FDA's Regional Radiological Health Representative (RRHR).

- **Independent audit 'I' inspection** - Conducted by FDA MQSA auditors sometime after an annual or a biennial inspection has been completed, to assure that State or FDA-conducted inspections are done properly.
- **Joint audit 'J' inspection** - Conducted together by a certified MQSA inspector and an FDA MQSA auditor to assess the performance of the certified inspector during a routine annual or biennial inspection. When this type of inspection is used, ID numbers for the inspector and the auditor are recorded.
- **Mentored 'M' inspection** - Conducted together by an MQSA inspector who is being mentored (either a new graduate, one that had been through an audit and judged to require mentoring, or a re-qualifying inspector) and a certified inspector acting as the mentor. When this type of annual or biennial inspection is used, ID numbers for the mentor and the one being mentored should be recorded.
- **Headquarters initiated action 'HIA' inspection** - Usually conducted by FDA MQSA inspectors after a request from DMQRP/CDRH to follow up on a specific problem, complaint, or for some other reason. State inspectors should not conduct these inspections unless requested to do so by the FDA District Office or the RRHR.

Kerma. The sum of the initial energies of all the charged particles liberated by uncharged ionizing particles in a material of given mass.

Kilovoltage, peak (kVp). The maximum potential difference setting between the anode and the cathode in an x-ray tube. This setting is also the maximum energy of x-rays emitted by the x-ray tube in kilo-electron volts (keV).

Mammogram. A radiographic image of the breast (an image produced through mammography).

Mammographic modality. A technology for radiography of the breast, such as screen-film, full field digital mammography (FFDM), and Xeromammography.

Mammography Equipment Evaluation (MEE). An onsite assessment of mammography unit or image processor performance by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable standards in Sec. 900.12(b) and (e).

Mean glandular dose. See average glandular dose.

Milliampere (mA) setting. The electron current passing from the cathode to the anode in an x-ray tube. For a fixed kVp, the tube output of x-rays per unit time from is linearly proportional to the mA setting.

Milliampere-seconds (mAs). The product of electron current (mA) and the exposure time (seconds). For a fixed kVp, the total X-ray output is linearly proportional to mAs.

Operating level. The central value about which day-to-day measurements are expected to fluctuate. An example would be the empirically determined mid-density on a sensitometric film.

Phantom (breast). A test object which simulates both the average composition of the breast, and the various structures within it. An ideal breast phantom would allow objective rather than subjective analysis and would be sensitive to small changes in mammographic image quality.

- The RMI 156 phantom was adopted by the ACR Mammography Accreditation Program and has been frequently referred to as the "ACR" phantom. The "CDRH" phantom uses the RMI image quality insert and is technically equivalent to it.
- Another phantom that has been referred to in the 1994 ACR QC manual as equivalent to the RMI 156 is the Nuclear Associates Model 18-220 phantom.

Processor. An automated device that transports film at a constant speed by a system of rollers through developing, fixing, washing, and drying cycles.

Processor artifact. Any unwanted or artificial density appearing on a radiograph due to the processor.

Quality assurance (QA). A management tool that includes policies and procedures designed to optimize the performance of facility personnel and equipment.

Quality control (QC). The routine performance and interpretation of tests of equipment function and the corrective actions taken in response to detected deficiencies.

Quality control technologist. The technologist assigned the task of quality control testing and maintaining records of radiographic imaging systems.

Repeat analysis. A systemic approach to determining the causes for repeated radiographs.

Replenishment rate. The amount of chemicals added per sheet of film in order to maintain the proper chemical activity of developer and fixer solutions.

Safelight. A lighting fixture with appropriate filters that produces light which will not fog radiographic film exposed to it for a specified period of time. The filter removes most of the light to which the radiographic film is sensitive. Most safelights will fog film if the amount of light or exposure time is increased, i.e., there is no such thing as a "safe" light.

SAR. State of Arkansas

Screen (intensifying). Microscopic phosphor crystals coated on a plastic support which emit visible light when exposed to x-irradiation, thereby creating a latent image on x-ray film.

Screen-film combination. A particular intensifying screen used with a particular type of film. Care must be taken to match the number of screens (one or two) to the number of emulsions coating the film and to match the light output spectrum of the screen to the light sensitivity of the film.

Screen-film contact. The close proximity of the intensifying screen to the emulsion of the film, essential in order to achieve a sharp image on the film.

Screen-film mammography. Mammography performed with high-detail intensifying screen(s) in intimate contact with the film.

Sensitometer. A device used to reproducibly expose film to a number of known levels of light.

Sensitometric strip. A sheet of film exposed by a sensitometer. Such strips are used to determine the range of densities, from minimum to maximum, resulting from a reproducible exposure.

Sensitometry. A quantitative measurement of the response of film to radiation (including light) exposure and photographic processing.

SAR. State of Arkansas

SIA. State of Iowa

SIL. State of Illinois

SSC. State of South Carolina

STX. State of Texas

Standard Breast. A 4.2 cm* compressed breast consisting of 50% adipose and 50% glandular tissue.

* A phantom, which has the same transmission properties as this standard breast, is the RMI 156 phantom. This phantom is typically referred to as the "ACR" phantom since it is this phantom that was adopted by the ACR Mammography Accreditation Program.

Viewbox. A device providing a relatively uniform surface luminance for viewing mammographic films. Mammographic viewboxes should have a luminance level of at least 3,000 nit (candela per sq. meter).

Xeromammography (XM). The technology whereby xeroradiography principles and techniques are used for breast imaging.

Xeroradiography (XR). A technology whereby an x-ray beam is used to form an electrostatic latent image on a photoconductive surface. This latent image is then made visible by a dry processing technique.

APPENDICES

APPENDIX 1: Scheduling the Inspection and the Confirmation Notice

A1.1 Scheduling the MQSA Inspection

After the inspection has been scheduled with the facility, the following confirmation notice should be sent to the facility, completely filled out. The confirmation notice should be faxed to the facility as a first option and mailed if the facility does not have fax capabilities. This notice should always provide a telephone number to allow the facility to contact you regarding any questions they might have about the inspection or problems with the proposed date and time.

To minimize time spent at the facility during the inspections, inspectors may make arrangements with facilities to review documents submitted to the inspector's office prior to the inspection. If this arrangement has been made, the inspector should mention this in the confirmation notice as a reminder.

A1.2 MQSA Inspection Confirmation Notice (sample)

This notice confirms our telephone conversation of {insert date here} regarding the scheduled inspection. If you have questions, contact the inspector at the telephone number below.

Date and time of inspection:
Name and address of facility:
Facility person contacted:
Facility telephone number:
Inspector name:
Inspector office address:
Inspector telephone number:
Inspector fax: number:

The MQSA inspection will cover the following areas:

- Equipment performance (including image quality)
- Technologist and physicist quality control/quality assurance (QC/QA) tests and tasks
- Medical audit and outcome analysis records
- Medical records (mammography reports and films)
- Personnel qualification records

The average on-site inspection time is approximately six hours. Testing for each mammography x-ray unit, darkroom and film processor combination takes approximately 30 minutes.

The remainder of the inspector's time will be spent reviewing facility records. We recommend that you schedule a block of time for the testing of each x-ray unit and film processor combination to help minimize any inconvenience to patient care from the inspection process. For the remainder of the inspection time, staff may conduct their usual duties but should be available to the inspector during the records review portion, should he or she have questions or need assistance.

APPENDIX 2: Evaluating Full Field Digital Mammography (FFDM) Systems

A2.1 Objective

To provide guidance to MQSA inspectors, regarding the evaluation of system performance and review of the QC procedures for Full Field Digital Mammography (FFDM) systems that have been approved for clinical use by the FDA. The material in this Appendix supersedes the guidance document dated 1/20/06 and all others preceding it, regarding the same subject. This appendix gives a comprehensive summary of the QC test procedures for each of the FFDM systems that FDA has approved to date. You should review it prior to inspecting facilities with digital units and use it as a quick guide for the specific tests applicable to each system

A2.2 Introduction - FFDM Units Approved by the FDA

To date, FDA's Office of Device Evaluation (ODE) has approved the FFDM systems listed in Table A2.1 below. The same table also identifies, where applicable, the accreditation body (AB) and effective date for each system:

Exhibit 11: (Table A2.1) – FFDM Systems Approved for Clinical Use

Manufacturer & Model	FDA-Approval Date	Hard Copy	Soft Copy	AB Name	AB Effective Date
GE Senographe 2000D	1/28/2000	X	X (11/20/00)	ACR SIA STX	2/15/2003 10/1/2003 5/21/2004
Fischer SenoScan	9/25/2001	X	X	ACR STX	8/15/2003 5/21/2004
Lorad LDBI*	3/15/2002	X			
Hologic/Lorad Selenia**	10/2/2002	X	X	ACR SIA STX	9/15/2003 10/1/2003 5/21/2004
GE SenoAdvantage*** (display system only)	12/3/2003	X	X	No AB Needed	
GE Senographe DS (unit & acquisition system only)	2/19/2004	X	X	ACR STX SIA	9/15/2004 9/15/2004 1/17/2006
GE Senographe Essential (unit & acquisition system only)	4/11/2006	X	X	ACR	7/15/2006
Siemens Mammomat Novation^{DR}	8/20/2004	X	X	ACR SIA STX	10/15/2005 2/1/2006 6/29/2006
Fuji Computed Radiography for Mammography (FCR*m*)+	7/10/2006	X	X	None yet	

+ The Fuji system was approved for marketing by FDA's Office of Device Evaluation (ODE) on7/10/06. At the time this document is finalized, no AB's for it have been approved yet and facilities that acquire it have to apply to FDA's DMQRP for extending their certificate to include it before they can lawfully use it on patients.

***NOTE A2.1:** Although Lorad obtained FDA approval for the LDBI system before the Selenia system, only one LDBI was clinically used and only at one facility. This unit was later taken out of service in September 2003. Since no other LDBI units have been in clinical use to date, and none in the future according to the manufacturer, we will delete any reference to this model in the remainder of this appendix.

****NOTE A2.2:** The QC manual refers to this system as the Lorad Selenia FFDM System, even though Lorad has been acquired by Hologic. You may see the terms Hologic and Lorad used interchangeably in the field.

******NOTE A2.3:** ODE approved GE's SenoAdvantage through the 510K process. Being a display system only, the SenoAdvantage does not need to be accredited by an AB before being used clinically. This system was initially introduced as an upgrade for the display system originally used with the Senographe 2000D unit. However, after obtaining FDA approval for the Senographe DS, GE began marketing the SenoAdvantage as a stand-alone display system for use with either the Senographe DS or as a replacement for the display system used with the Senographe 2000D.

To date, the x-ray units listed in Table A2.1 are the only FFDM units that are approved by FDA for marketing. Once FDA-approved, these units were subject to MQSA inspections and to the requirements of the final regulations as are screen-film mammography units used for screening and noninvasive diagnostic mammography. The broad guidance described in this appendix is only applicable to these units. When FDA approves other systems/manufacturers or imaging modes for FFDM use, we will update this guidance accordingly.

Certified facilities that have installed FDA-approved FFDM units for which an AB is listed in Table A2.1 must apply to and get approval by the appropriate AB to accredit these units before using them clinically.

If you have any questions about ACR-accredited units, please contact ACR at 1-800-227-6440 or via their website at http://www.acr.org.

If you have any questions about the SIA-accredited units, please contact the State of Iowa at 1-515-281-3478.

If you have any questions about the STX-accredited units, please contact the State of Texas at 1-512-834-6688, ext. 2246.

To date, the State of Arkansas, which is an FDA-approved AB for S-F systems, has not yet been approved to accredit any of the FDA-approved FFDM systems.

A2.2.1 Procedures for Extending Facility Certification to FFDM Systems

Certified facilities that have installed FDA-approved full field digital/CR (FFDM) units for which no AB is listed in Table A2. 1 may start using them on patients only after they have been informed in writing by FDA's Division of Mammography Quality and Radiation Programs (DMQRP) that they have met all the necessary requirements under MQSA. In the absence of AB performance standards for such units, the MQSA requirements are evaluated through a procedure developed by DMQRP, which is outlined below. Until FDA approves AB standards for these units, it will continue to use this procedure for allowing certified facilities under MQSA to use them on patients.

Applicants with FFDM units without an AB must continue to apply to and be approved by FDA for extension of their certificate (whether S-F or digital) to include the use of the new FFDM units, in order to legally operate those digital units. The FDA will send these facilities:

- **A letter to the facility.** This letter addresses steps the facility must take to add the FFDM system to its present MQSA certification.
- **Certification requirements related to personnel and quality control.** This is information a facility must submit for FDA approval before the facility may use, and continue to use, the FFDM system for clinical examinations.

To begin this procedure, a facility must submit an application directly to DMQRP. If the application is approved, DMQRP will send a letter to the facility allowing it to use the specified FFDM unit (s) on patients. This procedure extends the facility's certification to include the specified FFDM units. Throughout the clinical use of these units, facilities must follow all the QC procedures recommended by the FFDM unit manufacturer.

NOTE A2.4: If you encounter any FFDM units other than those approved by FDA being used on patients at this time, they should be investigational units not subject to inspection. If you find any of the above units being used on patients without a DMQRP certificate extension letter or evidence of accreditation once FDA approves an accreditation body, even if you are told it is only being used for research, please inform DMQRP via e-mail to the Facility Hotline.

A2.2.2 Information Needed When Requesting FFDM Certification Extension

The Facility needs to provide a list of all personnel who began working in (i.e., interpreting, performing, and surveying) the FFDM mammographic modality prior to April 28, 1999 (if any) as well as a list of personnel who began working in the FFDM mammographic modality after April 28, 1999. In addition, it needs to provide a satisfactory FFDM mammography equipment evaluation (MEE) (including an evaluation of the Soft/Hard Copy Display system, if applicable) performed by a qualified medical physicist within 6 months prior to the date of the application.

The facility will also need to follow the manufacturer's guidelines for quality assurance and quality control tests as described by the manufacturer's QC manual. No later than 9 months after it begins clinical examinations using the FFDM unit, the facility must submit to the FDA the results of the tests performed during the first 6 months after beginning clinical FFDM examinations.

A2.2.3 Facility Responsibilities Regarding FFDM Units with Extended Certification

Once the facility receives FDA's Letter of Acceptance, it may lawfully begin using the FFDM unit for clinical examinations. However, the facility must meet the following conditions while using the FFDM unit:

1. Maintain accreditation status for at least one mammography unit to which the FFDM unit is linked. During the annual onsite MQSA inspection, all units at the certified facility, including the FFDM unit, will be evaluated.
2. Upon completion of the first semi-annual quality control tests, the facility must provide FDA with the results of the weekly, monthly, quarterly, and semi-annual quality control tests outlined in the manufacturer's quality control manual. The report must include the results of the required QC tests for the Soft Copy Display system (if applicable).
3. Send test results to FDA no later than nine months after starting clinical examinations using the FFDM unit.
4. Have the FFDM unit surveyed annually by an MQSA qualified medical physicist.

A2.2.4 Location Constraints and Responsibilities Associated with FFDM Units

other than those Accredited by ACR, STX, and SIA

The FFDM unit must be located within the same inspection jurisdiction as the certified facility. In most cases, this means that the FFDM unit must be located in the same State as the certified facility (an exception to this rule could be a Federal or Indian Health Service facility). If the FFDM unit is being used at a different location than the certified facility, the lead interpreting physician must oversee the quality assurance programs for both the certified facility and off-site FFDM units.

A2.2.5 FFDM QC Manuals Used by the Facility - Inspector Actions Regarding Outdated Manuals

Since early 2000 and up to the date of this document, FDA has approved five manufacturers and seven full field digital mammography (FFDM) systems. Each of these systems has a QC manual describing a number of QC tests and tasks the facility has to conduct periodically in order to maintain high quality mammography standards and remain compliant with MQSA requirements. By regulation, facilities must follow these manuals (in terms of the frequency of the QC tests as well as the QC test procedures) when performing their routine QC tests, mammography equipment evaluations (MEE), and annual physics surveys. Because of continuing innovations in digital mammography and software programs, FFDM system manufacturers typically issue updates or revisions of their QC manuals to keep them current. Once a facility acquires an FFDM system, it usually receives its QC manual and, where applicable, any subsequent updates or revisions. Exhibit 12 (Table **A2.2**) provides an updated list (as of January 2006) of these manuals:

Exhibit 12: (Table A2.2) - List of FFDM QC Manuals – May 2006

Manufacturer	FFDM System	QAP/QC Manual Name/Description	Manual Number & Rev. Number	Approx. Date Issued
GE Medical Systems	Senographe 2000D (Pre-Onyx software upgrade)	Senographe 2000D QAP Manual. First GE FFDM QC manual. Applies only to a few early units.	2277390-100 **Rev. 0**	7/2000
“	Senogr. 2000D (Post-Onyx software upgrade) – M3	Senographe 2000D QAP Manual	2277390-100 **Rev. 2**	7/2001
”	Senogr. 2000D (Post-Onyx software upgrade) – M4	Senographe 2000D QAP Manual	2277390-100 **Rev. 3**	10/2001
“	Senogr. 2000D	Addendum to the above QAP Manual	2354312-100 **Rev 0**	10/2002
“	“	Senographe 2000D QAP Manual QC Tests for MQSA Facilities	2371472-100 **Rev. 0**	3/2003
“	Mobile Seno. 2000D (Post-Onyx software upgr.)	Mobile Senographe 2000D - QAP supplement	2309129-100 Rev. B	1/2001
“	Mobile Senographe 2000D	Mobile Senogr. 2000D QAP QC Tests for MQSA Facilities	2371698-100 **Rev. 0**	3/2003
“	Senographe 2000D/DS Display System	Seno Advantage – CE QC Manual	2391082-100 **Rev. 1**	10/2003
“	Senographe DS (unit & acquisition system)	Senographe DS Acquisition System Quality Control Tests QC Manual	2404641-100 **Rev. 0C-13feb04**	2/2004
“	“	“	2404641-100 **Rev. 2**	6/2004
“	“	“	5133453-100 **Rev. 1**	7/2005
“	“	“	5133453-2-100- **Rev. 1**	2/2006
“	Senographe 2000D, mobile Senographe 2000D	Senographe 2000D QAP Addendum: Sub-system MTF Measurement	**QAP Addendum** 5124952-100 – Rev.1	9/2004

“	“	“	**QAP Addendum** 5124952-100 – Rev.2	7/2005
“	Senographe Essential (unit & acquisition system)	Senographe Essential Acquisition System QC Manual	5141465-2-100 – Rev. 1	5/2006
Fischer	SenoScan	Operator manual - SenoScan FFDM 94001G-3	**Issue 1, Rev. 000**	7/2001
“	SenoScan	SenoScan FFDM 94001G-3	P-55933-OM Issue 1, **Rev. 2-4**	6/2003-1/2004
“	SenoScan 4.0 & higher	SenoScan FFDM 94001G-3	P-55943-OM **Issue 1, Rev. 5**	1/2004
“	“	“	P-55943-OM Issue 1, Rev. **10**	10/2004
Hologic/Lorad	Selenia	Lorad Selenia FFDM System QC Manual	MAN-00042**, Rev. 001**	6/2002
“	Selenia	Lorad Selenia FFDM Sys. QC Manual	9-500-0285**, Rev. 003**	4/2003
“	Selenia Mobile	Lorad Selenia Mobile FFDM Sys. QC Manual	9-500-0285 **Rev. 004**	2/2004
“	Selenia	Lorad Selenia QC Manual	MAN –00093**, Rev. 004**	6/2005
“	Selenia	Lorad Selenia QC Manual	MAN –00093, **Rev. 005**	1/2006
“	MAMMOMAT Novation^{DR}	Siemens Quality Control Manual MAMMOMAT Novation^{DR}	P030010/A13/C2/V	8/2004
”	MAMMOMAT Novation^{DR}	Siemens Quality Control Manual MAMMOMAT Novation^{DR}	SPB7-250.623.50.03.24	10/2005
”	Softcopy Workstation	Siemens Q.C. Manual MammoReport^{Plus}		3/2004
”	Softcopy Workstation	Siemens Q.C. Syngo MammoReport	SPB7-420.621.20.03.02	10/2005
Fuji	Fuji FCR*m*	FCR*m* Quality Control Manual, First Edition: July 2006	07.2006 897N0602	7/2006

Inspector Actions re Outdated Manuals

1. In general, we expect the facility to use the latest version of the QC manual issued to it by the manufacturer. If the manufacturer has sent the facility more than one version since the previous inspection, the facility would likely use the first version for a period of time and the updated version (s) afterwards. As a general principle, you should base your evaluation on the QC manual in the facility’s possession during a given time period to determine if the facility met MQSA requirements in that time period.
2. If the facility had used an earlier version of the QC manual for a period of time after it acquired an updated version, you should cite it for not following the manufacturer’s QC recommendations. However, if the updated version became available but the facility had not yet acquired it, you should not cite the facility. Instead, you should discuss the matter with facility personnel, advise them to obtain and use the latest version if they do not have it, and explain to them why they should always use the updated version. You should also document your discussion in the printable remarks section. If you find during the next inspection that the facility has continued to use an outdated manual, you should then cite it.
3. If the medical physicist used an updated version of the QC manual that he/she had but the facility did not have at the time of the annual survey or the MEE, there is no issue. If the medical physicist conducted an annual survey or an MEE using an earlier version of the QC manual at a time an updated version was available at the facility, you should cite the facility.

However, if the updated version was not yet in the facility's possession at that time, you should not cite the facility. Instead, you should advise the facility about acquiring and using an updated version (follow the procedure described in item 2 above) and that, if it does not do so, it will be cited during the next annual inspection. DMQRP will be issuing guidance to physicists and facilities regarding this issue in the near future.

NOTE A2.5: In the above discussion, an updated QC manual means an updated version that applies to the specific FFDM system/unit model used at the facility.

A2.3 Evaluation Procedures - General

When downloading a new inspection for a facility with an FDA-approved full field digital/CR (FFDM) unit(s), the FFDM unit(s) will be included in the download and will be designated as accredited by the appropriate AB or by FDA for any new FDA-approved units (if any) that do not yet have an AB. The unit(s) will be displayed on the list with a unit number from the "90" series. The first approved FFDM at a facility is usually indicated as number "99" with subsequent digital units indicated as "98," "97" and so on. Once FDA approves one or more AB for FFDM unit models currently without one, the appropriate AB rather than FDA, will be identified in the download of those units.

The balance of this section applies to all FDA-approved FFDM units, regardless of how they became accredited. When you select the FFDM unit(s) from the "List" tab (Screen 3.5 in the inspection software) and open the Screen-Film tab, a pop-up window will remind you that some of the system performance tests (Screens 3.5.1 and 3.5.2) do not apply. Also, even though some of the Quality Control tabs under Screen 3.9 may be accessible, the only screen you need to enter data regarding FFDM QC records is Screen 3.9.7 (Digital Mammography QC).

Screen 3.5 - Evaluation

Answer the question, "Mammo equip. evaluation (by medical physicist) done ?" for each of the FFDM units in use at the facility. The scope of the MEE tests depends on the FFDM system in question. For additional details, consult the appropriate FFDM system QC manual.

Screen 3.5.3 – Phantom Image Quality Evaluation

For FFDM units, you need to first determine the way the facility uses for interpretation of mammograms (softcopy or hardcopy) and use that information to select the corresponding "Phantom image display method." Also, for FFDM units the background density field has been blocked. All other fields and missing data rules associated with Screen #3.5.3 are the same as for S-F units. No citations will be issued for phantom scoring failures until some future date. Use the following procedures:

<u>For facilities using **softcopy** interpretation:</u>

a. Have the technologist expose the facility's phantom using technique factors as recommended by the FFDM system manufacturer for the weekly phantom test and display the image for scoring on <u>one</u> of the monitors recommended by the FFDM unit manufacturer for the weekly phantom test (this could be the acquisition work station (AWS) or the review work station (RWS), depending on the FFDM unit), with the viewing conditions (window level and width) the facility uses to review and score its phantom images.

b. Score the image on the screen under these conditions ("a" above) and enter your answers under Image # 1 in the software screen.
c. If it passes, the phantom image quality evaluation is complete.
d. If it fails, repeat the procedure in "step a" above, score it and enter your answers under Image # 2.
e. If the second exposure passes, the phantom image quality evaluation is complete.
f. If this second image fails, print a hard copy of exposure #1 image, score it again and edit your answers under Image # 1; and if the hardcopy phantom image fails, print a hard copy of exposure #2 image, score it and edit your answers under Image # 2.
g. If the hard copy of Image #2 also fails, your answers will be used by the software to issue an inspection observation (when implemented by FDA). **Note:** When that occurs, you should keep both hard copies of the exposures for your records, as evidence.

*** NOTE A2.6:** The technologist must use the same technique factors for exposure as those used for the weekly phantom image QC. These technique factors will vary with the FFDM unit since the facility must follow the procedures stated in the FFDM system QC manual. Some manufacturers (like GE and Lorad) also instruct the facility to conduct and pass the flat field test before conducting the phantom image test. Although the FFDM system QC manual may instruct the facility to specify which monitor or monitors (acquisition workstation (AWS) or review workstation (RWS)) to score the image on, use the same scoring procedure recommended on one monitor only, if available and if it does not interfere with the facility's practice. Otherwise, use the AWS monitor.

- For facilities using only **hardcopy** interpretation:

a. Have the technologist expose the facility's phantom and print the image using the techniques normally used by the facility for both the unit and the printer.

b. Score the hardcopy image and enter your answers under Image # 1.

c. If it passes, the phantom image quality evaluation is complete.

d. If it fails, have the technologist repeat the procedure in "step a" (above), print and score the second image, and enter your answers under Image # 2.

e. If it passes, the phantom image quality evaluation is complete.

f. If the second image also fails, your answers will be used by the software to issue an inspection observation (when implemented by FDA). **Note:** When that occurs, you should keep both hard copies of the exposures for your records, as evidence.

Note A2.7: For the Lorad Selenia and the Siemens Mammomat Novation^{DR}, the phantom test passing score is 5, 4, 4*. While this is required for the facility QC procedures, for regulatory action, FDA uses the passing score established by the FDA-approved accreditation bodies, which is 4, 3, 3, as in S-F systems.

***** Under certain conditions, Lorad allows 4.5, 4, 3.5 as a passing score. Check the applicable QC manual for details.

Screen 3.6

With FFDM units, interpreting physicians may provide a diagnosis from an image of the mammogram viewed on a monitor or printed on a laser printer. However, when requested, facilities must be able to provide a hardcopy printout of a mammogram to the patient, to the referring health care provider, or to the accreditation body. For all FFDM systems approved to date, the QC manuals instruct the facility to perform a Mammography Equipment Evaluation (MEE) on the laser printer. You need to fill the required information in the two tabs in this screen:

Information Tab

The data entry field labeled "Processing Method," has two answer options: Screen-Film and Digital. You should first check "Digital" for FFDM systems, and then select the applicable manufacturer and model codes for each laser printer in use at the facility.

Evaluation Tab

If applicable, answer the question "Processor/laser printer equip. evaluation (by med. phys.) done?" regarding an MEE for each laser printer you selected from the list. Any laser printer inspection observation associated with your "No" answer will be a Level 2 noncompliance.

Screen 3.10 – Survey Report – Information

For full field digital/CR (FFDM) units, the question "Survey report available" has three answer options (just as in S-F units); Yes, No, and NA (not Applicable). You should answer "Yes" if the report is available. This answer will allow access only to the following questions/data entry fields:

- *Date of the previous survey (mm/dd/yyyy)*
- *Date of the current survey (mm/dd/yyyy)*
- *Dose value (mrad) reported (xxx.x).* If the dose value recorded is >300 mrad, then*:*
- *C/A taken before resuming clinical use? (Yes/No)*
- *Survey conducted/supervised by* _____

All the remaining questions in this and the other two survey screens will be blocked. By filling in the entries above, inspection observations for not conducting the survey within 14 months from the previous survey or from inspection date (Level 2), or for not conducting the survey in two successive years (Level 1), or if the person conducting the survey is not identified (Level 2), will be in effect immediately, as is the case for S-F units.

You should use the NA answer to the question "Survey report available" only to avoid issuing inappropriate inspection observations for surveys of both FFDM and S-F systems. When this question is answered "N/A," all the survey report questions and data entries in Screen # 3.10-Information are blocked except for the date fields corresponding to the previous and current surveys, and the two dose-related questions. Also, all the questions in Screens # 3.10.1 and # 3.10.2 will be blocked.

When you answer "No" to the question "Survey report available," all the data entry fields in the survey report (except date of the previous survey) will be blocked. This applies to both S-F and FFDM units.

We have deliberately blocked most of the survey questions for FFDM units until a standard set of tests and questions applicable to all FFDM systems is developed and incorporated in the software. Even though a survey or a mammography equipment evaluations (MEE) report for the FFDM unit should be available for evaluation, you will not be able to record the individual test details of your evaluation as you would for the survey of a screen-film unit. You will, however, be able to document your overall evaluation of the FFDM unit's medical physicist's survey or MEE when you answer two of the QC questions regarding FFDM units (Q1 and Q3 in Screen 3.9.7 below). Meanwhile, we would like to point out that:

For FFDM units at the facility, DMQRP or the appropriate AB would have already evaluated all the initial MEE-required physicist tests. For FFDM units currently without an AB, if the inspection is conducted more than 6 months after approval, FDA would have reviewed the first 6 months of QC data as part of the process of evaluating the facility's application for approval of the FFDM unit for clinical use.

Before you answer the specific QC questions regarding FDA-approved FFDM units in the "Digital Mammography QC" section (Screen 3.9.7), you will be reviewing all the required physicist tests listed in the unit's QA manual provided by the manufacturer. This listing will help you answer the specific QC questions regarding FFDM units.

After you have selected an FFDM unit from the list, click on the "Information" tab (in Screen 3.5) to open the "information" screen corresponding to this unit. Note that the box corresponding to *"Image receptor type:"* will be pre-filled with *"Digital."*

Next, verify which display method(s) the facility uses by checking one or more options in the following field (which becomes accessible only for digital units):

Display method: *(Monitor/Laser film/Other)*

You must check at least one of the display options in order to be able to evaluate the FFDM QC records, but you may select multiple options. The inspection software program currently includes three general questions (in Screen 3.9.7) regarding QC test records for FFDM systems.

The first question (Q1 below) becomes accessible regardless of which display option you checked in Screen 3.5 - Information:

Q1- *FFDM Manufacturer QC followed? (excluding monitor & printer QC)* *(y/n)*

If you checked *"Monitor"* <u>only</u> or *"Monitor"* and at least one other option as the display mode, you need to answer the next question (Q2 below):

Q2- *Monitor QC done per manufacturer's recommendation?* *(y/n)*

If you checked "*Laser film*" <u>only</u> or "*Laser film*" and at least one other option as the display mode, then you need to answer the third question (Q3) below:

Q3- *Printer QC done per manufacturer's recommendation?* *(y/n)*

Each of these three questions covers a large amount of information and the selection of the correct answer for each can be complex. The remainder of the document will focus on how to determine whether you should answer each of these questions with a "yes" or a "no," e.g., to determine whether or not the facility followed the applicable manufacturer- recommended QC procedures.

> **NOTE A2.8:** When the first digital mammography unit was approved in early 2000, it was initially approved only for hard copy interpretation. Facilities that bought that unit had to use hard copy interpretation as the only option at the time. However, after soft copy interpretation received FDA approval in the latter part of 2000, all facilities with FDA-approved digital units could use both soft and hard copy interpretation. Furthermore, since each facility with a digital unit must at least have access to a laser printer, we expect MQSA inspectors to check both "Monitor" and "Laser film" as the display methods for most of the digital/CR (FFDM) units currently in use.

Since there are no uniform standards for FFDM system QC tests at this time, we will inspect facilities with FFDM systems against quality standards established in the final regulations using the manufacturer-provided procedures for <u>all</u> the FFDM system QC tests. Also, facilities will continue to use the same accreditation phantom as the one used in screen-film systems. GE, however, prohibits the use of a contrast disk with an FDA-approved phantom.

As previously stated, the only FDA-approved FFDM systems in use at this time are the GE Senographe 2000D (and 2000D – Mobile), the GE Senographe DS, the GE Senographe Essential, the Fischer SenoScan, the Hologic/Lorad Selenia, the Siemens Mammomat Novation^{DR}, the Fuji FCR*m*, and the GE SenoAdvantage display system. Since the required tests and action limits are not all the same in these systems, we will outline these tests and action limits separately for each system.

A2.4 Evaluation of GE FFDM Systems QC Records

The Senographe 2000D was the first FDA-approved FFDM system. GE initially provided the Senographe 2000D QAP manual to facilities that purchased these units (7/2000). The manual was revised in 7/2001, 10/2001, and 3/2003. GE also provided a manual for its mobile Senographe 2000D in 1/2001 and later revised it in 3/2003. In 9/04, GE developed a new filmless test termed "Sub-system MTF Measurement" to use as an alternate sub-system resolution test for the Senographe 2000D and the mobile 2000D and provided a manual for it as an addendum to the 2000D unit manual. This manual was revised in 7/2005.

In October 2003, GE introduced a new display system (termed the Seno Advantage) as an upgrade on the display system used with the 2000D. Also, early in 2004, they introduced a new FFDM (acquisition-only) system, termed the Senographe DS Acquisition System, which is designed to work with the Seno Advantage display system. Hence the combination of the two provides a full FFDM system that is marketed as an upgrade to the Senographe 2000D FFDM system.

In April 2006, GE obtained FDA approval for a new FFDM unit (the Senographe Essential) designed to image large patients. Like the Senographe DS, the Essential unit has only an image acquisition system and is designed to work with an image display system such as the Seno Advantage.

The QC manuals associated with all these systems and sub-systems are listed in Table 2. The applicable QC tests required by the technologist and the medical physicist for all GE systems and sub-systems are summarized in Tables A-1 and A-2 below.

All the GE FFDM QC manuals contain the QC tests/checks the technologist and physicist are required to perform, along with their frequencies, procedures, data recording forms, and applicable guidance. They are all organized into three main sections:

1. QC Tests (& procedures) for the Radiologic Technologist
2. QC Tests (& procedures) for the Medical Physicist
3. Guidance (to the technologist & the physicist)

The Senographe 2000D - Quality Assurance Procedures (QAP) Manual

Guidance and QC tests for the Senographe 2000D (and the mobile version) listed in Tables A-1 and A-2 of this document are based on QC Manual # 2371472-100, Rev.0 (dated 3/03), its addendum regarding the filmless measurement of subsystem resolution # 5124952-100, Rev. 2 (dated 7/2005), and the mobile unit QC Manual # 2371698-100, Rev. 0 (dated 3/2003).

Both of these manual instruct the facility to use the same accreditation phantom as for screen-film systems (except that a contrast disk must not be used) and incorporates references to the printer manufacturer's QC manual, the 1999 ACR QC manual, and MQSA regulations.

The Seno Advantage (Display System) – CE QC Manual

Guidance and QC tests for the Seno Advantage display system listed in Tables A-1 and A-2 of this document are based on QC Manual # 2391082-100, Revision 1 (dated 10/2003). As mentioned earlier, you may find this system at facilities that are using the 2000D (as an upgrade to the older version of the initial display system supplied with the 2000D, or with facilities that have recently acquired the Senographe DS acquisition system).

The GE Senographe DS (Acquisition System) - Quality Assurance Manual

Guidance and QC tests for the Senographe DS acquisition system listed in Tables A-1 and A-2 of this document are based on QC Manual # 2404641-100, Rev. 2 (dated 6/2004). The QC tests described in this manual apply only to the digital image acquisition and pre-processing sub-system. QC tests applicable to the display systems intended for clinical image review are not included in this manual. Instead, they are included in a separate manual. We will refer to this manual as the GE Senographe DS QC Manual in the remainder of this document.

The GE Senographe Essential (Acquisition System) - Quality Assurance Manual

Guidance and QC tests for the Senographe Essential acquisition system listed in Tables A-1 and A-2 of this document are based on QC Manual # 5141465-2-100, Rev.1 (dated 5/2006). The QC tests described in this manual apply only to the digital image acquisition and pre-processing sub-system. QC tests applicable to the display systems intended for clinical image review are not included in this manual.

Like the GE QAP manual for the Senographe 2000D unit, it instructs the facility to use the same accreditation phantom as for screen-film systems (except that a contrast disk must not be used) and incorporates references to the printer manufacturer's QC manual, the 1999 ACR QC manual, and MQSA regulations.

A2.4.1 Approved Alternative Standard - Timing of Corrective Actions in GE FFDM Systems

When FDA's DMQRP extended a film-screen facility's certificate to cover the GE Senographe 2000D unit as an FFDM unit in 2000, the GE QAP manual stated that if any of the required tests fail, the facility must identify the problem and take corrective action before further exams are performed, which was in accordance with MQSA requirements regarding QC test failures in new mammographic modalities. It was also recognized then that some of the required QC tests for the 2000D unit were the same or similar to those of screen-film units. Since MQSA requirements for screen-film units allowed the continuing use of equipment for 30 days while corrective action was taking place for some of the QC tests, it was viewed that the requirements for the 2000D unit were more restrictive that those for screen-film units. GE applied to the FDA and obtained approval on June 27, 2002 for an alternative standard to correct this problem. This alternative standard allowed facilities to use the 30 day period for corrective actions following the failure of specified quality control tests by the Senographe 2000D FFDM system.

GE applied to the FDA and obtained approval for an amendment to this alternative standard on August 25, 2003 and FDA placed no time limit upon the period of approval. The amended standard replaces the specific reference to the GE Senographe™ 2000D FFDM system with a generic reference to an "FDA-approved GE" FFDM system. Like the original standard, it allows a 30 day period for corrective actions following the failure of specified quality control tests by an FDA-approved GE FFDM system. However, it divides into two groups the tests whose failure requires corrective action before the failing component is used again during patient examinations. This

division makes it clear that when the test failure is related to the acquisition of images only, the review of already acquired images can continue and when the test failure is related to the image review components only, images can continue to be acquired. In approving the amendment, FDA stated that if GE introduces new FFDM systems having QC tests other than what is included in the original or amended standard, the amended alternative standard would not be applicable to these systems.

The approved amendment, which supersedes the original alternative standard, is:

21 CFR 900.12(e)(8): *Use of test results.*

For the image acquisition system

(i) If the test results for the image acquisition system of the FDA-approved GE full-field digital mammography (FFDM) equipment fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:

(A) Before any further mammographic images are acquired using the image acquisition system that failed any of the following tests:

(1) Monitor cleaning for the acquisition work station (AWS)
(2) Flat Field Test
(3) CNR Test
(4) Phantom Image Quality Test for the AWS
(5) MTF Measurement
(6) AOP Mode and SNR Check
(7) Visual Check List
(8) Compression Force Test
(9) Average Glandular Dose
(10) Post-move, Pre-examination Tests for a mobile FDA-approved GE FFDM
(11) Filmless measurement of Sub-system Resolution (this test was added to the list in 7/2005 for the Senographe 2000D and in 2/2006 for the Senographe DS)

(B) Before any further films of mammographic images are printed or processed using the component of the FDA-approved GE FFDM equipment that failed any of the following tests:

(1) Phantom Image Quality Test for the Printer
(2) Viewbox and Viewing Conditions Test
(3) Printer QC

(C) Within 30 days of the test date for the following tests:

(1) Repeat Analysis
(2) Collimation Assessment
(3) Evaluation of Focal Spot Performance
(4) Exposure and mAs Reproducibility
(5) Artifact Evaluation; Flat Field Uniformity
(6) kVp Accuracy and Reproducibility
(7) Beam Quality Assessment (Half-Value Layer Measurement)
(8) Radiation Output

(9) Mammographic Unit Assembly Evaluation

For the image display system

(ii) If the test results for the image display system of the FDA-approved GE full-field digital mammography (FFDM) equipment fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:

(A) Before any further mammographic images are reviewed or any films are printed or processed using the component of the image display system that failed any of the following tests:

(1) Monitor cleaning for the review workstation (RWS)
(2) Viewing Conditions for the RWS (Radiologic Technologist's test)
(3) Viewing Conditions Check and Setting (Medical Physicist's test for the RWS)
(4) Phantom Image Quality Test for the RWS
(5) Phantom Image Quality Test for the Printer
(6) Viewbox and Viewing Conditions Test
(7) Monitor Calibration Check (Radiologic Technologist's test for the RWS)
(8) Image Quality—SMPTE Pattern (Medical Physicist's test for the RWS)
(9) Printer QC

(B) Within 30 days of the test date for the following tests:

(1) Monitor Calibration (Medical Physicist's test for the RWS)
(2) Analysis of the RWS Screen Uniformity.

Thus, according to this alternative standard, if test results for the FDA-approved GE FFDM system such as the Senographe 2000D, the Senographe DS (acquisition system), or the Seno Advantage (display system) fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:

(A) Before any further mammographic images are acquired using the FDA-approved GE FFDM system that failed any of the following tests [designated as group A in Tables A-1 and A-2]

(B) Before any further mammographic images are reviewed or interpreted or any films are printed or processed using the component of the FDA-approved GE FFDM system that failed any of the following tests [designated as group B in Tables A-1 and A-2]

(C) Within 30 days of the test date for the following tests [designated as group B in Tables A-1 and A-2].

NOTE A2.9: Tables A-1 and A-2 below apply to some or all of the GE FFDM systems approved to date, as indicated in the "Applicability" column.

A2.4.2 Radiologic Technologist QC Tests – GE FFDM Systems

This section contains the technologist QC tests/checks, procedures, frequencies, and data recording charts (forms.) These tests/checks, their frequencies, areas of applicability, and data charts are listed in Exhibit 13 (Table A-1).

Exhibit 13: (Table A-1). Technologist QC Tests – GE Senographe 2000D, 2000D Mobile, DS, Essential (Ess) , & Seno Advantage

Test/Item	Frequency	Corr. Action Timing	Applicability	Corrective Action Taken If:	GE Data Chart #
Monitor Cleaning (AWS)	Daily or (*)	A	2000D, 2000D Mobile, DS, Ess	Test failure. See (1)	1
Monitor Cleaning (RWS)	Daily or (*)	B	2000D, 2000D Mobile, Seno Adv	Test failure. See (1)	1
Viewing Conditions Check (RWS)	Daily or (*)	B	2000D, 2000D Mobile, Seno Adv	Test failure. See p: 10 of the Seno Adv. manual.	1
Viewbox and Viewing Conditions Test	Weekly	B	2000D, 2000D Mobile, Seno Adv DS, Ess	Test failure. See (2)	1
Flat Field Test	Weekly, or post move & pre- clinical use (mobile)	A	2000D, 2000D Mobile , DS, Ess	Test failure.	1 (tests done), 2 (results)
**Phant. Image Quality (IQ) on acquisition work station (AWS) & Printer Test.	"	A	2000D, 2000D Mobile, DS, Ess	Phantom score: < 4 fibers, or 3 speck groups, or 3 masses.	1 (tests done), 2 (results)
Contrast to Noise Ratio (CNR) Test	Weekly	A	2000D, 2000D Mobile	CNR changes > 0.2.	2 (results)
**Phantom IQ Tests on RWS & Printer if applicable	Weekly	B	2000D, 2000D Mobile	"	1 (tests done), 2 (results)
MTF and CNR Measurement	Weekly	A	DS, Ess	MTF 2 lp/mm ≤ 58% MTF 4 lp/mm ≤ 25%. CNR changes > 0.2.	2 (results)
MTF Measurement	Monthly	A	2000D, 2000D Mobile	MTF 2 lp/mm ≤ 58% MTF 4 lp/mm ≤ 25%.	3
AOP Mode and Signal to Noise Ratio (SNR) Check	Monthly	A	2000D, 2000D Mobile, DS, Ess	AOP Exposure parameters are outside range. SNR < 50.	3
Visual Checklist	Monthly	A	2000D, 2000D Mobile, DS, Ess	Each item must pass or get a check mark.	4, 5(Essential)
Monitor Calibration Check (SMPTE pattern on RWS)	Monthly	B	2000D, 2000D Mobile, Seno Adv	Test Failure. Sec. 1-10	8- x-ray units 2- Seno Adv
Repeat Analysis Check	Quarterly	C	2000D, 2000D Mobile, DS, Ess	Total repeat/reject rate changes > 2%. See (3)	6, 7 (data & analysis)
Compression Force Test	Semiannually	A	2000D, 2000D Mobile, DS, Ess	Max. force for initial power drive outside 25 - 45 lbs. range.	5
Printer QC	Per Printer Mfr.'s Rec.	B	2000D, 2000D Mobile, Seno Adv, DS, Ess	Typically, daily (wet) & weekly (dry printer)	N/A
Record of Checks – with sign-off by QC tech. & physicist	All applicable	N/A	2000D, 2000D Mobile, DS, Ess	Must be signed off by QC tech. & physicist.	5, (chart 1 Essential, Tech. only)

(*) when clinical image acquisitions/reviews are planned.

(**) the facility may obtain phantom images using 26 kVp & 125 mAs (GE recommendation) or with technique factors that are most commonly used for the standard breast.

A: Corrective action must be taken before acquiring clinical images.

B: Corrective action must be taken before reviewing, printing, or interpreting clinical images.

C: Corrective action must be taken within 30 days of the test date.

(1) No dust, fingerprints, or other marks on the screen. Otherwise, the facility must take corrective action before further clinical images are acquired, if the affected monitor is on the AWS, or reviewed if the affected monitor is on the RWS.

(2) Free of marks. Uniform lighting. Masking capability. Clean, service, or replace if necessary. See the 1999 ACR manual for details.

(3) If the test fails, the facility must identify the problem(s), take documented corrective action(s), and assess its effectiveness.

A2.4.3 Medical Physicist QC Tests – GE FFDM Systems

The medical physicist (annual) QC tests are divided into three categories. Most of the tests have procedures that are unique to the GE Senographe 2000D, the Senographe DS, and or the Seno Advantage system, and some of those are also included in the technologist section. The last five are the same as in screen-film systems and use the ACR test procedures. The tests, procedures and area of applicability are listed in Exhibit 14 (Table A-2).

Exhibit 14: (Table A-2). Med. Physicist's QC Tests - GE Senographe 2000D, 2000D Mobile, DS, Essential, & SenoAdvantage

Test/Item	Comments/Procedures	Corr. Action Timing	Applicability	Corrective Action Taken If:	GE Data Chart # (physicist)
Flat Field Test	Also done by Radiologic Technologist	A	2000D, 2000D Mobile, DS, Ess	See Table A-1	1, 2 (Tech Charts)
Phantom IQ Tests on AWS, Contrast to Noise Ratio (CNR) Test	"	A	2000D, 2000D Mobile, DS, Ess	"	1, 2 (Tech Charts)
Phantom IQ Tests on RWS and Printer	"	B	2000D, 2000D Mobile	"	1, 2 (Tech Charts)
MTF Measurement	"	A	2000D, 2000D Mobile, DS, Ess	"	3 (Tech Charts)
AOP Mode and Signal to Noise Ratio (SNR) Check	"	A	2000D, 2000D Mobile, DS, Ess	"	3 (Tech Charts)
Filmless measurement of Sub-system Resolution	Replaces MTF & Focal Spot tests – Med. Phys.	A	2000D, 2000D Mobile, DS	Test failure per table in the QC manual	7/2005 Add'm
Site & System Summary	Information Sheet	N/A	All	N/A	0-units, 3-Seno Adv
Collimation Assessment	Job Card VF-P01	C	2000D, 2000D Mobile, DS, Ess	X-ray/light: >2% SID X-ray/IR: > 2% SID, < full cover, c.w. side IR/paddle: > 1% SID	1
Evaluation of Focal Spot Performance	Job Card VF-P02	C	2000D, 2000D Mobile, DS, Ess	Same as MQSA req. for screen-film	2
Breast Entr. Exp. Repro.	Job Card VF-P03	C	2000D, 2000D Mobile, DS, Ess	No limit specified	3
Average Glandular Dose	"	A	2000D, 2000D Mobile, DS, Ess	> 3 mGy	3
Reproducibility (mAs)	"	C	2000D, 2000D Mobile, DS, Ess	mAs/exp. COV > .05	3
Artifact Evaluation	Job Card VF-P04	C	2000D, 2000D Mobile, DS, Ess	image visualization	4
Flat Field Uniformity	"	C	2000D, 2000D Mobile, DS, Ess	"	4
Viewing Conditions Check and Setting (RWS)	Job Card VF-P05	B	2000D, 2000D Mobile, Se. Ad	ambient light > 20 lux [10/03 & later]	5– units 4– Se. Ad.
Monitor Calibration (Check, RWS)	Job Card VF-P06	C	2000D, 2000D Mobile, Se. Ad	Test Fail.- Sec. 2-7, units. Sec.3, Se. Ad.	6- units 5- Se. Ad.
Image Quality - SMPTE Pattern (RWS)	Job Card VF-P07	B	2000D, 2000D Mobile, Se. Ad	Test Fail. - Sec. 2-8, units. Sec. 4, Se. Ad.	7- units 6- Se. Ad.
Analysis of RWS Screen	Job Card VF-P08	C	2000D, 2000D	Test Fail. - Sec. 2-9,	8- units

Uniformity	(only MEE/when needed)		Mobile, Se. Ad	units. Sec. 5, Se. Ad.	7- Se. Ad.
KVp Accuracy and Reproducibility	ACR Procedures & Charts	C	2000D, 2000D Mobile, DS, Ess	Accuracy > ±5% Repro. COV >.02	ACR or similar
Beam Quality (HVL) Measurement	"	C	2000D, 2000D Mobile, DS, Ess	KVp/100 mmAl	"
Radiation Output	"	C	2000D, 2000D Mobile, DS, Ess	< 7 mGy	"
Mammographic Unit Assembly Evaluation	"	C	2000D, 2000D Mobile, DS, Ess	See ACR manual	"
Decompression	" (part of previous test)	C	2000D, 2000D Mobile, DS, Ess	Per MQSA regulations	"

NOTE A2.10: All these tests are required for the annual survey. Some may be required for the MEE. Also, consult the appropriate manual for the summary of the applicable Equipment Evaluation (MEE) tests.

A: Corrective action must be taken before acquiring clinical images.

B: Corrective action must be taken before reviewing or interpreting clinical images.

C: Corrective action must be taken within 30 days of the test date.

A2.4.4 GE Guidance

This section contains GE guidance regarding procedures and additional clarifications for all the quality control tests to be performed by the technologist and the medical physicist on the GE Senographe 2000D, Senographe DS, or Seno Advantage, as applicable.

A2.5 Evaluation of Fischer SenoScan System QC Records

Fischer initially provided an FDA-approved quality assurance manual to facilities with Fischer SenoScan units. The manual is entitled: SenoScan Full Field Digital Mammography System 94001G-3, Issue 1, Rev. 4. This manual was updated for SenoScan 4.0 and higher several times. The latest update is # P-5593-OM Issue 1, Rev. 10 (dated 10/2004). Tables B-1 and B-2 below are referenced to this version. We will refer to it as the Fischer SenoScan QC manual in the remainder of this document. The manual instructs the facility to use the same accreditation phantom as for screen-film systems and incorporates references to the printer manufacturer's QC manual, the ACR 1999 QC manual, and MQSA regulations. It contains the QC tests/checks the technologist and physicist are required to perform, along with their frequencies, procedures, data recording forms, and applicable guidance. The manual is organized into seven main sections and three appendices but the focus of this guidance is contained in Section 6 (Quality Control). This section contains the QC tests and procedures to be followed by the radiologic technologist (6-2) and the medical physicist (6-3) as described below:

NOTE A2.11: For all the QC tests listed in Tables B-1 and B-2, the Fischer SenoScan QC manual (which can be more restrictive than MQSA) states that if a test fails, the facility must identify the problem and take corrective action before further exams are performed.

A2.5.1 The Radiologic Technologist QC Tests – Fischer SenoScan

Section 6-2 of the Fischer SenoScan manual provides description and guidance regarding the nine technologist QC tests/checks. These tests/checks, their frequencies, and areas of applicability are listed in Exhibit 15 (Table **B-1**).

Exhibit 15: (Table B-1). The Radiologic Technologist's QC Tests – Fischer SenoScan Unit

Test/Item	Frequency	Applicability	Corrective Action Taken If:	Test Form - Chart #
Image Display Check for the Barco MGD521 CRT Monitors	Daily	SenoScan Systems using CRT displays for the RWS	Test failure. See (1)	A-3
Image Display Check for Planar c5i Flat Panel Monitors	Daily	SenoScan Systems using flat panel displays for the RWS	Test failure. See (1)	A-3B
Laser Imager (Printer) Quality (if applicable)	Daily	SenoScan Systems with hard copy interpretation	Per laser imager manufacturer	A-2
Phantom Image Acquisition	Weekly	Detector Performance, X-ray Unit	Δ Background Mean > ±100 ADU and Background RMS StDev > 50 ADU from baseline values. Δ ADU Level Diff. > -100/+300	A-1
Phantom Image Quality	Weekly	All imaging chain components (including the RWS monitor)	Phantom score: < 4 fibers, or 3 speck groups, or 3 masses with no unexplained artifacts.	A-4
Detector Calibration and Flat Field	Weekly	Detector Performance, X-ray unit	Images are flat w/no unexplained artifacts or variation in ADU level. See Manual's Sec. 6-2-2-3-2	A-5
System Resolution (detector alignment/ Scan Speed Uniformity)	Monthly	All imaging chain components	< 5 trans. @ 10% modul. in 7 lp/mm, both directions – standard mode < 5 trans.@ 5% modul. in 11.1 lp/mm, both dir. –high resol. mode. Sec.6-2-3-1	A-8
System Operation	Monthly	All imaging chain components	If any item on the system operation checklist fails	A-9
Reject/Repeat Analysis	Quarterly	All repeat & reject films in the quarter	Same as MQSA requirements.	A-6, A-7
Compression force	Semi-annually	X-ray unit	Same as MQSA requirements.	A-10

NOTE A2.12: All data recording charts are in Appendix A of the SenoScan QC manual

(1) Minimum Illuminance ≤ 1 ft-L. Maximum Illuminance ≥ 70 ft-L. SMPTE pattern: 0-5% and 95-100% equally visualized, all line pairs resolved with no smearing or blurring.

A2.5.2 The Medical Physicist Annual QC Tests – Fischer SenoScan

Section 6-3 of the Fischer SenoScan manual describes the 14 annual medical physicist tests for the SenoScan unit. These tests and their action limits are listed in Exhibit 16 (Table **B-2**).

Exhibit 16: (Table B-2). The Medical Physicist's Annual QC Tests – Fischer SenoScan Unit

Test/Item	Comments/Procedures	Applicability	Corrective Action Taken If:	Test Forms – Chart #
X-ray Field, Light Field, and Chest Wall Missed Tissue Checks	Sec. 6-3-1 (6-3-1-1 to 6-3-1-7)	X-ray Unit	X-ray field size: >2% SID. X-ray field inside ch. wall edge of image receptor. X-ray/light field > 2% SID. Missed tissue > 8.5 mm	A-11
Compression Paddle Alignment	Sec. 6-3-2		IR/paddle: > 1% SID or paddle edge visible	A-11
kVp Accuracy Test	Sec. 6-3-3	X-ray Unit	5% of selected kVp COV > 0.02 (each kVp)	"
Linearity, Reproducibility & Accuracy of X-ray output	Sec. 6-3-4	X-ray Unit	Linearity > 0.08 Reproducibility > 0.035	"
Beam Quality (HVL) & Output	Sec. 6-3-5	X-ray Unit	KVp/100 mmAl	"
Dosimetry – Average Glandular Dose	Sec. 6-3-6	X-ray Unit	> 3 mGy	"
Phantom Image Acquisition	Sec. 6-3-7 Same as Tech's weekly	Detector Perf, X-ray Unit	Test failure (1)	"
(Phantom) Image Quality	Sec. 6-3-8 Same as Tech's weekly	All im. chain (incl. RWS monitor)	Phantom score: <4 fibers, or 3 speck groups, or 3 masses with no unexplained artifacts.	"
System Resolution and Scan Speed Uniformity	Sec. 6-3-9 Same as Tech's monthly	All im. chain components	Test failure (2)	"
Flat Field	Sec. 6-3-10	AWS/RWS Monitors	Mean Deviation between ROI in each corner & center > ± 20%.	"
Geometric Distortion & Resolution Uniformity	Sec. 6-3-11	RWS Monitor	Obvious distortions or blurring in the image.	"
Automatic Decompression	Sec. 6-3-12	X-ray Unit	Failure of compression control override or manual release	"
System Artifacts	Sec. 6-3-13	"	No visible artifacts w/ window width ≥ 800	"
Daily Image Display Monitors Check (review daily test log)	Sec. 6-3-14	RWS Monitor	Daily monitor checks not maintained as required.	"
Image Viewing Room Illuminance	Sec. 6-3-15	RWS Monitor & ambient	> 20 lux at screen of either high resolution monitor	"

(1) Test fails if any of the following is not met: Δ Background Mean < ± 100. StDev of Background RMS < 50 ADU from QC baseline values. Δ ADU level difference < ± 300 ADU limit.

(2) Test fails if any of the following is not met: at least 5 transitions (5 peaks & 4 valleys) @ 10% modulation for the 7 lp/mm pattern, both directions –standard mode.

at least 5 transitions (5 peaks & 4 valleys) @ 5% modulation for the 11.1 lp/mm pattern, both directions – high resolution mode. See Sec.6-2-3-1.

A2.5.3 Fischer Guidance

The Fischer SenoScan manual is organized into seven main sections and three appendices but the focus of their guidance is contained in Section 6 (Quality Control). This section contains procedures and additional clarifications for all the quality control tests.

A2.6 Evaluation of Hologic Lorad Selenia FFDM System QC Records

Hologic, Inc. has provided an FDA-approved quality assurance manual to facilities with FDA-approved FFDM Selenia units. The manual is entitled: Lorad Selenia FFDM System Quality Control Manual, MAN-00042, Rev. 001, issued in 6/2002. It has been updated several times since then, as shown in Table 2 above. The most recent update is # MAN - 00093, Rev. 004 (dated 6/2005). Tables C-1 and C-2 below are referenced to the 2005 version. We will refer to it as the Lorad Selenia QC Manual in the remainder of this document. The manual instructs the facility to use the same screen-film accreditation phantom and incorporates references to the printer manufacturer's QC manual, the ACR 1999 QC manual, and MQSA regulations. It contains the QC tests/checks the technologist and physicist are required to perform, along with their frequencies, procedures, data recording forms, and applicable guidance. The Lorad Selenia QC manual is organized into five main sections and two appendices as described below:

1. Introduction (describes MQSA requirements and the alternative standard for the Selenia system) and gives a list of all the required QC tests
2. Quality Control Activities for the Medical Physicist (required QC tests & procedures)
3. Quality Control Activities for the Radiologic Technologist (required QC tests & procedures)
4. Quality Control Guidance for the Medical Physicist
5. Quality Control Guidance for the Radiologic Technologist
6. Appendix A- QC Forms for the Medical Physicist
7. Appendix B- QC Forms for the Radiologic Technologist

A2.6.1 Alternative Standard. Correction Period When Components of the Selenia Full Field Digital Mammography System Fail Quality Control Tests

FDA approved this alternative requirement on August 21, 2003 and it became effective on that date. It allows a 30 day period for corrective actions following the failure of specified quality control tests by the Selenia Full Field Digital Mammography System. The specified tests are equivalent to quality control tests for screen-film systems for which a 30 day correction period is already allowed. The alternative standard also divides into two groups the quality control tests whose failure requires corrective action before the failing component is used again during patient examinations. This division makes it clear that when the test failure is related to the acquisition of images only, image acquisition must cease until the problem is corrected but image interpretation can continue. Similarly if the test failure is related to the interpretation of images, image acquisition can continue but image interpretation with the failed component must cease until the problem is corrected. The alternative was approved for an indefinite period.

The original standard is 21 CFR 900.12(e)(8)(ii), which states:

21 CFR 900.12(e)(8): *Use of test results*

(ii) If the test results fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:

(A) Before any further examinations are performed or any films are processed using the component of the mammography system that failed any of the tests, described in paragraphs (e)(1), (e)(2), (e)(4)(i), (e)(4)(iii), (e)(5)(vi), (e)(6), or (e)(7) of this section;

The approved alternative is:

21 CFR 900.12(e)(8): Use of test results.

(ii) If the test results for the Selenia FFDM System fall outside the action limits, the source of the problem shall be identified and corrective actions shall be taken:

(A) If any of the following quality control tests that evaluate the performance of the image acquisition components of the Selenia FFDM system produces results that fall outside the action limits as specified by the manufacturer, the source of the problem shall be identified and corrective action shall be taken before any further examinations are performed:

(1) Evaluation of System Resolution
(2) Breast Entrance Exposure and Average Glandular Dose
(3) Phantom Image Quality Evaluation (Medical Physicist)
(4) Phantom Image (Radiologic Technologist)
(5) Signal-to-Noise and Contrast-to-Noise Measurements
(6) Detector Flat-Field Uniformity (Calibration)
(7) Compression
(8) Post-Move and Pre-Examination Tests for Mobile Selenia™ FFDM systems

(B) If any of the following quality control tests that evaluate the performance of *a diagnostic device used for mammographic image interpretation* (i.e. laser printer, physician's review station) produces results that fall outside the action limits as specified by the manufacturer, the source of the problem shall be identified and corrective action shall be taken before that device can be used for mammographic image interpretation. Clinical imaging can be continued and alternative approved diagnostic devices shall be used for mammographic image interpretation:

(1) Phantom Image Quality Evaluation (Medical Physicist)
(2) Phantom Image (Radiologic Technologist)
(3) Softcopy (Diagnostic Review) Workstation QC
(4) Laser Printer Quality Control
(5) Dark Room Cleanliness
(6) Processor Quality Control
(7) Viewboxes and Viewing Conditions
(8) Darkroom Fog

(C) If any of the following quality control tests that evaluate the performance of components *other than the digital image receptor or the diagnostic devices used for mammographic image interpretation* produces results that fall outside the action limits as specified by the manufacturer, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date. Clinical imaging and mammographic image interpretation can be continued during this period:

(1) Mammographic Unit Assembly Evaluation
(2) Collimation Assessment
(3) Artifact Evaluation
(4) kVp Accuracy and Reproducibility
(5) Beam Quality Assessment – HVL Measurement
(6) Automatic Exposure Control (AEC) Function Performance
(7) Automatic Exposure Control (AEC) Reproducibility
(8) Radiation Output Rate
(9) Viewbox Luminance and Room Illuminance
(10) Compression Thickness Indicator
(11) Visual Checklist
(12) Analysis of Fixer Retention in Film
(13) Repeat Analysis

A2.6.2 The Radiologic Technologist QC Tests – Hologic Lorad Selenia

This section of the manual provides description and guidance regarding the 15 technologist QC tests/checks. These tests/checks, their frequencies and areas of applicability are listed in Exhibit 17 (Table **C-1**).

Exhibit 17: (Table C-1). The Radiologic Technologist's QC Tests – Lorad Selenia Unit
(Tests are in Section 3 & forms are in Appendix B of the Selenia QC manual)

Test/Item	Frequency	Corr. Action Timing	Applicability	Corrective Action Taken If:
1. Darkroom Cleanliness	Daily	B	"wet" processors	Same as screen-film (S-F). Dust artifacts on film.
2. Processor Quality Control	Daily	B	"wet" processors that are not docked to laser printer	Same as for S-F. B+F > 0.03, MD & DD outside ± 0.15 of aim values
3. Laser Printer QC	Daily – wet pr. Weekly - dry	B	Printer	LD, MD, DD outside ± 0.15 of aim values
4. Viewboxes & Viewing Conditions	Weekly	B	View boxes & room layout	Same as the 1999 ACR manual
5. Diagnostic Review Workstation QC	Weekly	B	RWS Monitors & room layout	Test failure. See Tech. Test 5.0 in the Selenia QC Manual
6. Artifact Evaluation (incl. printer artifacts)	Weekly	C	All imaging chain components.	Image visualization (1)
7. SNR and CNR Measurements	Weekly	A	X-ray unit.	Test failure (2)
8. Phantom Image	Weekly	A B	All imaging chain components.	< 5 fibers, 4 speck groups, 4 masses. For hard copy images: Bkgd. OD < 1.4 ± 0.20, cont.< 0.40 ± 0.05. (3)
9. Detector Flat Field Calibration	Bi-Weekly	A	X-ray unit, AWS monitors	Test failure. See (4)
10. Compression Thickness Indicator	Bi-Weekly	C	X-ray unit	Indicated thickness outside ± 0.5 cm of the actual thickness.
11. Visual Checklist	Monthly	C	"	Same as the 1999 ACR manual
12. Analysis of Fixer Retention in Film	Quarterly	C	"wet" processors	Same as the 1999 ACR manual. Residual fixer > 0.05 g/sq. m
13. Repeat Analysis	Quarterly	C	Facility practice	No action taken when rate of repeat-reject changes by > 2% of the total films analyzed.

14. Darkroom Fog	Semi-annually	B	"wet" processors (other than daylight systems)	Same as S-F. Fog O.D. over 0.05
15. Compression	Semi-annually	A	X-ray unit.	Same as S-F. Comp. outside 25-45 lb. range

(1) See Tech. Test 6.0 in the Selenia QC manual for more details.
(2) If any of the SNR values are ≤ 40, repeat the test. If the test fails again, the problem must be corrected by a Lorad authorized service engineer before proceeding with further QC tests or patient imaging. The CNR shall remain within ± 15% of the CNR determined by the medical physicist as part of the MEE for the Selena unit. See Tech Test 7.0 in the QC manual.
(3) See Tech. Test 8.0 in the Selenia QC manual for more details.
(4) Test is done automatically by the software. See Tech. Test 9.0 in the QC manual for more details.

A2.6.3 The Medical Physicist QC Tests – Hologic Lorad Selenia

This section of the manual provides description and guidance regarding the 14 annual QC tests conducted by the medical physicist. Two tests are also included in the technologist section. Several tests are similar to their counterparts in screen-film systems and use the 1999 ACR test procedures. The tests, procedures and area of applicability are listed in Exhibit 18 (Table C-2).

Exhibit 18: (Table C-2). The Medical Physicist's Annual QC Tests – Lorad Selenia Unit
(Tests are in Section 2 & forms are in Appendix A of the Selenia QC manual)

Test/Item	Comments/Procedures	Corr. Action Timing	Applicability	Corrective Action Taken If:
1. Mammographic Unit Assembly Evaluation (Incl. Decompression)	Same as '99 ACR manual	C	X-ray Unit	Test failure as set in MQSA regulations
2. Collimation Assessment	Same as '99 ACR manual	C	X-ray Unit	X-ray/light: >2% SID X-ray/IR: >2% SID on c.w. side IR/paddle: >1% SID
3. Artifact Evaluation (incl. printer artifacts)	", (same as Tech's)	C	All imaging chain	image visualization. See Med. Phys. Test 3 for more details
4. kVp Accuracy and Reproducibility	Same as '99 ACR manual	C	X-ray Unit	Accuracy > ±5% Repro. COV >.02
5. Beam Quality Assessment— HVL	"	C	X-ray Unit	Same as 1999 ACR manual. More restrictive than MQSA
6. Evaluation of System Resolution	Set-up similar to S-F units. Results interpreted on monitor	A	All imaging chain	< 7 lp/mm when bars are at 45 degrees to anode/cathode axis
7. Automatic Exposure Control (AEC) Function Performance	New Test for the Selenia. Implemented in 2005.	C	X-ray Unit	Test failure. See Med. Phys. Test 7 for detail
8. Breast Entrance Exposure, AEC Reproducibility, and Average Glandular Dose	Test set-up & procedure similar to S-F units.	AEC: C Dose: A	X-ray Unit	mAs/exposure reproducibility COV >.05. Dose > 3 mGy
9. Radiation Output Rate	"	C	"	< 7 mGy/s @ max SID

10. Phantom Image Quality (IQ) Evaluation (same as the technologist's)	Test set-up & procedure similar to S-F units.	A B	All imaging chain	< 5 fibers, 4 speck groups, 4 masses. For hard copy images: Bkgd. OD < 1.4 ± 0.20, cont.< 40 ± 0.05
11. SNR and CNR Measurements	Uses the accreditation phantom	A	X-ray unit.	Test failure (2)
12. Viewbox Luminance and Room Illuminance	Same as '99 ACR procedures for S-F units	C	Viewboxes & room layout	Ambient level - required > 50 lux Ambient level – recom. > 20 lux
13. Diagnostic Review Workstation QC	Same as Tech's test	B	RWS Monitors & room layout	Test failure. See Med. Phys. Test 13 for detail
14. Detector Ghosting (optional)	Optional test	A	All imaging chain	Test failure. See Med. Phys. Test 14 for detail

(1) MQSA requirements apply to the Lorad Selenia system when the test is performed with a mammography S-F cassette
(2) If any of the SNR values are ≤ 40, repeat the test. If the test fails again, the problem must be corrected by a Lorad authorized service engineer before proceeding with further QC tests or patient imaging. The CNR shall remain within ± 15% of the CNR determined by the medical physicist as part of the MEE for the Selena unit. See Sec. 2-11.6 in the Selenia QC manual for more detail.

A2.6.4 Hologic Lorad Guidance

This section contains Lorad guidance regarding procedures and additional clarifications for all the quality control tests and the responsibilities of the interpreting physician, the radiologic technologist, and the medical physicist regarding the Lorad Selenia system.

A2.7 Evaluation of Siemens Mammomat Novation^{DR} FFDM QC Records

Siemens has provided FDA-approved quality assurance manuals to facilities with Mammomat Novation^{DR} FFDM systems in 2004. They provided two separate manuals; one for the x-ray unit and the other for the soft copy workstation and both manuals were updated in 10/2005. The updated x-ray unit manual is coded # SPB7-250.623.50.03.24 and is entitled: Siemens Quality Control Manual - Mammomat Novation^{DR}. We will refer to it as the Siemens Novation^{DR} QC manual in the remainder of this document. The updated soft copy workstation manual is coded # SPB7-420.621.20.03.02 and is entitled: Quality Control Manual Syngo MammoReport. The QC tests for the radiologic technologist (Table D-1) and the medical physicist (Tables D-2 and D-3) below are based on the 2005 updates. Like the other FFDM system manuals approved to date, the x-ray unit manual instructs the facility to use the same accreditation phantom as for screen-film systems and incorporates references to the printer manufacturer's QC manual, the ACR 1999 QC manual, and MQSA regulations. It contains the QC tests/checks the technologist and physicist are required to perform, along with their frequencies, procedures, data recording forms, and applicable guidance. Since the Novation^{DR} image receptor is the same as the Lorad Selenia receptor, many of the QC tests are identical but some are different or new. The manual is organized as follows:

1. Five sections that contain QC test procedures for the:
    - Medical physicist (MEE tests, and annual survey tests)
    - Radiologic technologist (daily, weekly, and when needed), and

2. Two appendices; the first one contains the test forms for the required tests to be conducted by the physicist and the technologist, and the second one contains the test forms for the optional tests.

NOTE A2.13: For all the QC tests listed in Tables D-1, D-2, and D-3, the Siemens Mammomat Novation^{DR} system QC manuals (which can be more restrictive than MQSA) state that if a test fails, the facility must identify the problem and take corrective action before further exams are performed.

A2.7.1 The Radiologic Technologist QC Tests – Siemens Mammomat Novation^{DR}

These QC tests/checks, their frequencies, and areas of applicability are listed in Exhibit 19 (Table D-1).

Exhibit 19: (Table D-1). The Radiologic Technologist's QC Tests – Siemens Mammomat Novation^{DR}

QC manual # SPB7-250.623.50.03.24, and the **Syngo MammoReport QC Manual #** 420.621.20.03.02**,** for the soft copy review station.

Test #	Test/Item	Frequency	Applicable Manual	Corrective Action Taken If:	Page #
	Monitor Cleaning	Daily	Syngo MammoReport	Test failure	5
1	Reflection	Daily	"	"	9
2	Overall Evaluation	Daily	"	"	10
4.8	Phantom Image QC	Daily	Mammomat Novation^{DR}	< 5 fibers, 4 speck groups, 4 masses. Bkgd.	44
4.17	Printer Check	Daily	"	See Appendix 1	124
4.1	Detector Calibration	Weekly	"	Test failure	21
*	CNR Measurement	Weekly	" (test added in 1/2006) – will be in mobile unit manuals and subsequent stationary unit manuals	Test failure	
4.2	Artifact Detection	Weekly	"	Image visualization	26
*	Repeat Analysis	Quarterly	Test will be added in future manuals	Test failure	
*	Compression	Semi-Annually	Test will be added in future manuals	Test failure	
5.1	Pixel Correction (optional)	As needed	"	Test failure	70
5.5	Image Quality Test-Syngo MammoReport (optional)	As needed	"	Test failure. See (5.5)/ SyngoMammoReport	81

*** NOTE A2.14:** Implementation of these tests by the facilities is pending the distribution by Siemens of updated QC manuals or addendums to the facilities using their systems. Inspectors should refrain from citing facilities regarding this test until notified by the FDA.

A2.7.2 The Medical Physicist QC Tests - Siemens Mammomat Novation^{DR}

These QC tests/checks, their frequencies, and areas of applicability are listed in Exhibit 20 (Table **D-2**) (for the review work station) and Exhibit 21 (Table **D-3**) (for the x-ray unit).

Exhibit 20: (Table D-2). The Medical Physicist's QC Tests – Siemens Syngo MammoReport QC Manual for the soft copy review station

Test #	Test/Item	Frequency / Comments	Applicability	Corrective Action Taken If:	Page #
	Monitor Placement	MEE, annual	Soft copy review station, left & right monitors	Test failure	7
1	Reflection	MEE, annual, Tech test also	“	Visibility of reflected high cont. objects	9
2	Overall Evaluation	MEE, annual, Tech test also	“	Test failure	10
3	Geometrical Distortion	MEE, annual	“	Sp. dev. < 2% in any direction & across quadrants	12
4	Luminance Response	“	“	$L_{min} > 0.5$ cd/m^2 $L_{max} < 250$ cd/m^2 LR= L_{max} / $L_{min} < 350$	14
5	Luminance uniformity	“	“	Max. luminance Dev. ≥ 30%	16
5	Resolution	“	“	line-pair patterns discernible at all locations at Nyquist freq.	17
7	Noise	”	“	Failure to visualize all but the smallest targets for primary class	18

Exhibit 21: (Table D-3). The Medical Physicist's QC Tests – Siemens Mammomat Novation^{DR} System QC Manual # SPB7-250.623.50.03.24

Section	Test/Item	Frequency / Comments	Applicability	Corrective Action Taken If:
4.1	Detector Calibration	MEE, Annual	Image Receptor	Test failure
4.2	Artifact Detection	"	All imaging chain	Image visualization
4.3	Acquisition Workstation Monitor Check	MEE, Annual	AWS workstation	Test failure
4.4	Mechanical Inspection (Mammo. Unit Assem. Eval. (Decompression)	"	X-ray Unit	Test failure as set in MQSA regulations
4.5	Collimator Assessment	"	X-ray Unit	X-ray/light: >2% SID X-ray/IR: >2% SID on c.w. side
4.6	Compression Plate Position	"	X-ray Unit	IR/paddle: >1% SID
4.7	Spatial Resolution	"	All imaging chain	< 7 lp/mm when bars are at 45 degrees to anode/cathode axis
4.8	Phantom Image Quality	"	"	< 5 fibers, < 4 speck groups, < 4 masses
4.9	Detector Uniformity	"	Image Receptor	Test failure
4.10	Radiation Output	"	X-ray Unit	< 800 mR/second (for 3 seconds)
4.11	kVp Accuracy and Reproducibility	MEE, Annual	X-ray Unit	Accuracy > ±5% Repro. COV >.02
4.12	Beam Quality - HVL	"	X-ray Unit	KVp/100 mmAl
4.13	Mean Glandular Dose	"	"	> 3 mGy
4.14	AEC Stability, Reproducibility & SNR	"	"	Test failure
4.15	SNR and CNR Measurements	MEE, Annual	"	SNR < 40, Dev. From mean: CNR & SNR > +- 15%
4.16	AEC Thickness Tracking	"	"	Dev. From mean > +- 0.15%
4.17	Printer Check		Printer	See Appendix 1, page 124
	Optional Tests and Troubleshooting			
5.1	Pixel Correction	As needed	Image Receptor	Test failure
5.2	Chest Wall and Missed Tissue	MEE, Annual	X-ray Unit	"
5.3	Radiation Safety	"	"	"
5.4	Ghost Image Evaluation	"	Image Receptor	"
5.5	Image Quality test-Syngo MammoReport	As needed	RWS monitors	Test failure. See (5.5)/ SyngoMammoReport
5.6	Monitor Contrast and Brightness*	"	"	*Test failure. Test performed by Siemens customer service engineer

A2.8 Evaluation of the Fuji Computed Radiography for Mammography (FCR*m*) FFDM QC Records

Fujifilm Medical Systems (Fuji) received approval of the Fuji computed radiography for mammography (FCR*m*) as another type of FFDM on July 10, 2006. As stated earlier in this document, a typical screen-film (SF) mammography unit can be converted to a CR unit by replacing its existing SF cassette by a CR mammography plate or cassette and a digital reader system. The digital image generated by a CR mammography unit as described above is considered an FFDM image. Such units are identified in FISS 6.01 by an image receptor type "Computed Radiography" or (CR) and will be evaluated in the same manner as all the previously approved FFDM units during the inspection.

We expect Fuji to provide all facilities using the FCR*m* system with an updated QC manual. Meanwhile, the QC tests listed in Table E-1 and Table E-2 below are based on a draft QC manual (FCR*m* Quality Control Manual, First Edition: July 2006, # 07.2006 897N0602) that Fuji shared with us for the purpose of updating these procedures and may be initially provided to their facilities until the final version is ready for distribution. Also, Fuji recently applied (and received FDA approval on 8/2/2006) for Alternative Standard #15, whereby corrective action for failing some of the FCRm QC tests may be performed within 30 days instead of prior to using the failing component. The results of this alternative standard are reflected in Tables E-1 and E-2 below in the column labeled "Corr. Action Timing." Thus, the QC tests are split into three groups referred to as A, B, and C in this column, whereby corrective action must be completed:

Group **A:** Prior to acquiring new mammograms, but reading mammograms may continue
Group **B**: Prior to reading new mammograms, but acquiring new mammograms may continue
Group **C**: In 30 days.

Exhibit 22: (Table E-1). The Radiologic Technologist's QC Tests – Fuji FCR*m* System
(Tests are listed in Sections B , C, D, and E of the FCR*m* QC manual)

Test/Item	Frequency*	Corr. Action Timing	Applicability	Corrective Action Taken If:
1. CNR Weekly Check	Weekly		All imaging chain	Outside ± 20% of baseline value
2. Phantom Image	Weekly		All imaging chain	< 4 fibers, 3 speck groups, 3 masses.
3. Printer QC	Weekly/Daily (dry/wet)**	B	Printer	MD, DD outside ± 0.15 of aim values. B+F outside 0.03 of aim value
4. Monitor QC	Weekly	B	All monitors	Test failure
5. Visual Checklist	Monthly	B	X-ray unit.	Item missing or not checked
6. Repeat Analysis	Quarterly	C	Facility practice	No action taken when rate of repeat-reject changes by > 2% of the total films analyzed.

7. Compression	Semi-Annual	A	X-ray unit.	Same as S-F. Max. Auto. Comp. outside 25-45 lb. range

* In addition to the stated frequencies, tests must be repeated during an MEE (if applicable) and when problems are encountered

** Or as recommended by the printer manufacturer QC manual

Exhibit 23: (Table E-2). The Medical Physicist's Annual QC Tests – Fuji FCR*m* System
(Tests are in Section F of the FCR*m* QC manual)

Test/Item	Frequency	Corr. Action Timing	Applicability	Corrective Action Taken If:
1. S Value Confirmation	Annual*	C	FCR*m* Reader	Corrected S value outside 120 ± 20%
2. System Resolution	"	A	All imaging chain	Resolution outside 8 ± 2 lp/mm
3. CR Reader Scanner Performance	"	A	FCR*m* Reader	T test image not smooth or sharp
4. Imaging Plate (IP) Fog	"	A	Imaging plate (IP)	Fogged image or + density artifacts
5. Mammographic Unit Assembly Evaluation (includes decompression)	"	C	X-ray unit	Test failure
6. Collimation Assessment	"	C	X-ray unit	X-ray/light: >2% SID X-ray/IR: >2% SID on any side. X-ray field does not cover all IR on c.w. side. IR/paddle: >1% SID. cw edge of paddle visible on image
7. Automatic Exposure Control (AEC) System Performance Assessment	"	C	All imaging chain	mAs change/density step outside 5-15 % COV reproducibility > 0.05 CNR levels for 2 & 6 cm are outside ± 10% of 4 cm level
8. Printer QC	"	B	All printers	Test failure
9. Monitor QC	"	B	All monitors	Test failure
10. System Artifact Evaluation	"	C	All imaging chain	Test failure
11. Image Quality Evaluation	"	A, B	All imaging chain	< 4 fibers, 3 speck groups, 3 masses.
12. Dynamic Range	"	A	CR reader & imaging plate	Test failure
13. Primary Erasure (Additive & Multiplicative Lag Effects)	"	A	CR reader & imaging plate	Intolerable artifacts on image
14. Inter-Plate Consistency	"	C	Imaging plate	Δ mAs outside ± 10% of Ave. Δ SNR outside ± 15% of Ave.
15. kVp Accuracy & Reproducibility	"	C	X-ray unit	Accuracy outside ± 5% of indicated value Reproducibility COV > 0.02
16. Dose	"	A	X-ray unit	Dose > 3 mGy (0.3 rad)
17. Beam Quality Assessment & Half-Value Layer Measurement	"	C	X-ray unit	HVL (mmAl) < kVp/100
18. Radiation Output	"	C	X-ray unit	Minimum air kerma/s < 7 mGy (800mR)
19. Viewing & Viewing Conditions	"	B	Room layout	Room Illum. > 20 lux**

* In addition to annual testing, tests must be repeated during an MEE (if applicable) and when problems are encountered

** Or the limit set by the monitor manufacturer (if less than 20 lux)

A2.9 Answering the QC Questions for FFDM Units

In order to answer the questions in Screen 3.9.7, you should review the facility records (such as the data charts listed in the latest version of the appropriate manufacturer's QA/QC manual, which would be one of the four discussed above) and determine if the facility:

a) conducted all the QC tests listed in the manual provided by the manufacturer of the unit in question, and

b) took (and documented) timely corrective action(s) for the tests that failed.

If the facility followed all the procedures in the subject manual (e.g., if items (a) and (b) above were completed), the answer to the first question in Screen 3.9.7 should be "yes." Since each of the subject manuals includes specific procedures regarding the monitor and the printer, you should answer each of the two subsequent questions in this screen also with a "yes."

If the answer to the first question is "no," you should answer each of the two subsequent questions with a "yes" or a "no,"* depending on the tests and corrective actions corresponding to the monitor and printer, respectively (as applicable).

You should also be aware that there are FFDM models other than those currently approved by FDA and discussed above. These non-approved FFDM models may be used on patients only if they are part of a clinical investigation or research. These investigational units are not subject to inspection because they are specifically excluded from MQSA. If you find any FDA approved FFDM unit being used on patients at a facility without a DMQRP approval letter or evidence of accreditation by an accreditation body, even if you are told it is only being used for research, please inform DMQRP via e-mail to the Facility Hotline at **MQSAhotline@hcmsllc.com**.

APPENDIX 3: MQSA Guide for Additional Mammography Review (AMR)

A3.1 Introduction

We are issuing this guide to assist FDA field offices and MQSA inspectors in following up on inspections or investigations where an AMR may be warranted. Under 21 C.F.R. Part 900.12(j), it states:

(1) If FDA believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by FDA, for review by the accreditation body or other entity designated by FDA. This additional mammography review will help the agency to determine whether the facility is in compliance with this section and, if not, whether there is a need to notify affected patients, their physicians, or the public that the reliability, clarity, and accuracy of interpretation of mammograms have been compromised.

(2) If FDA determines that any activity related to the provision of mammography at a facility may present a serious risk to human health such that patient notification is necessary, the facility shall notify patients or their designees, their physicians, or the public of action that may be taken to minimize the effects of the risk. Such notification shall occur within a timeframe and in a manner specified by FDA.

On February 25, 2000, we issued a document entitled *Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #2*. On page 45 of this document, we included guidance specific to inspections where Level 1 observations were present for phantom image failure or qualifications of interpreting physicians. This document can no longer be downloaded as a separate document from the Web. All of the guidance from Document #2 is now included in a comprehensive Policy Guidance Help System, which is located at http://www.fda.gov/CDRH/MAMMOGRAPHY/robohelp/START.HTM . We have provided this help system to all MQSA inspectors on the laptop computers that they use for inspections. You should review the guidance on AMR from this Help System prior to implementing the procedures outlined in this inspection guide.

A3.2 Instructions to Inspectors (During and After the Inspection)

These instructions include steps that will help ensure that FDA has been informed about the extent of the problems and the time frame(s) over which they were present. The time frame(s) is important, since we will use it to set the boundaries of the AMR. For the phantom image test, the additional follow up that you should conduct and other information you should collect during the inspection will help us determine whether an AMR will be done.

For both the phantom image test and the qualifications of the interpreting physician, FDA should verify that the inspection observations are valid before considering an AMR. The section below entitled **Additional Evaluations of Phantom Image** provides instructions on methods that you may use to verify that the inspector's Level 1 phantom image test result is valid.

If both phantom images mentioned above fail at Level 1, determine the extent of imaging problems. Evaluate the facility's weekly phantom images to see if an ongoing problem can be determined. Evaluate the most recent 12 weekly phantom images. Facilities are only required to keep the phantom images for

the last 12 weeks, but some facilities may have phantom images dating back to the last inspection. If any of these images also shows a Level 1 phantom score, continue scoring images back to the last inspection (or as far back as they kept images) until the scores no longer show a Level 1 observation. To speed up the review, only score one phantom image per month, if Level 1 observations continue to show up in these images. In addition, record the phantom image score from the most recent medical physicist survey report (if the medical physicist has recorded the numerical scores; if not, record whether he or she passed or failed the facility for the x-ray unit survey). Record the facility's phantom image scores and the medical physicist's scores in the Remarks section for Phantom Image Quality Evaluation.

Advise the facility that the scores are preliminary and that further evaluation may be required. In the event that the facility agrees with your preliminary scores, advise the facility to immediately determine the cause and correct the problem before additional mammograms are produced using the equipment that caused the failure.

You or your supervisor should contact your FDA district office (or regional office, where appropriate) about this situation as soon as possible.

A3.3 Information for FISS* Remarks

Phantom Failure: Scores of facility QC phantom films for x-ray unit with Level 1 phantom - Remarks information to record under screen #3.5.3 [Phantom Image Quality Evaluation]:

Date of phantom film _____
Net Fibers Score _____
Net Speck Score _____
Net Mass Score _____

Date of phantom film _____
Net Fibers Score _____
Net Speck Score _____
Net Mass Score _____

Date of phantom film _____
Net Fibers Score _____
Net Speck Score _____
Net Mass Score _____

Repeat these as often as needed

Score of medical physicist phantom film - Remarks information to record under screen #3.10.1 [Survey Report Part 1]:

Date of phantom test _____
Net Fibers Score _____
Net Speck Score _____
Net Mass Score _____
Pass/fail (no numerical score)? _____

Interpreting Physician**:** Dates when interpreting physician with Level 1 observation was reading and interpreting mammograms at facility - Remarks information to record under 3.11.1 Interpreting Physicians

Starting date at facility (if physician started since last inspection) _____

Ending date at facility (if no longer reading at facility) _____
Number (or estimate) of mammograms read in the past 24 months preceding the inspection date (from continuing experience documentation) _____

* Field Inspection Support System (this is the laptop computer software used during MQSA inspections).

A3.4 Additional Evaluations of Phantom Image

Every Level 1 phantom score from an inspection must be followed up with at least one additional confirmatory evaluation, as part of an established phantom-image quality assurance process. This process may consist of one of the following:

- **State Program Office review process**: The State conducting the inspection may develop a process where a designated inspector or group of inspectors are responsible for providing confirmatory scores for the Level 1 phantom images. The important factor is that the inspector conducting the confirmatory review must have adequate training in phantom image evaluation and also routinely review and score phantom images (either through conducting MQSA inspections or through regular evaluations of inspection phantom films). The Regional Radiological Health Representative (RRHR) and/or MQSA auditor should evaluate the State's process before accepting that State's review for phantom image scoring.
- **MQSA auditor review process**: In the event that the State prefers not to establish a process as outlined above or if the inspection is conducted by an FDA MQSA inspector, the auditor can provide confirmatory scoring for the Level 1 phantom images.
- **Division of Mammography Quality and Radiation Programs (DMQRP) review process**: In the event that the State cannot establish a process as outlined above and there is no MQSA auditor to cover the State, the films may be shipped to DMQRP for confirmatory scoring.

In all cases where the Level 1 phantom images must be mailed to another location for scoring, use overnight shipping to expedite the scoring. Shipping costs for the films may be included for inspections under cost-reimbursement contracts, where applicable.

APPENDIX 4: Further Assistance

A4.1 Facility Hotline

DMQRP established the Facility Hotline to assist you in the performance of your duties as a certified MQSA inspector.

- For assistance while performing an inspection or for other emergency situations:

  Call: 800-838-7715 or F**ax: 410-290-6351**

- For assistance in non-emergency situations: **E-mail** the Hotline: **MQSAhotline@hcmsllc.com**.

Calling individual division staff defeats the purpose of the Facility Hotline. By using the Facility Hotline, we in the division will be able to respond more efficiently to your needs and to track the types of calls, thereby enabling us to make improvements in training and inspector quality assurance or performance. The Hotline is staffed between 8:30 AM and 4:30 PM East Coast time, Monday through Friday.

A4.2 Computer Support

For help with problems regarding your laptop, call computer support at: **240-276-3323**.

A4.3 Guidance Documents and Resources

Guidance regarding inspections under the final regulations is usually published on FDA's web site and will also be integrated into the "Policy Guidance Help System (PGHS)" on your laptop after it becomes final. For all additional information regarding FDA mammography publications, guidance policies and other useful information, visit DMQRP's web site at the following address:

http://www.fda.gov/cdrh/mammography

Our **web site** contains several items, including:

- Approved Alternative Standards (of the MQSA)
- MQSA and *Federal Register* Notices
- Mammography Quality Standards Reauthorization Act (MQSRA) of 1998 and 2004
- *Mammography Matters* Newsletter (up to the fall 2000). With that issue, the newsletter was suspended and replaced with Web updates of mammography issues afterwards.
- Guidance for Industry and Compliance - updated
- Policy Guidance Help System (PGHS) (and subsequent modifications)
- Other Selected Items:
  - Listing of FDA Certified Mammography Facilities (updated weekly)
  - Mammography Facility Performance
  - Preparing for MQSA Inspections (11/01)
  - "Mammography Facility Survey, Equipment Evaluations, and Medical Physicist Qualification Requirements Under MQSA,"
  - MQSA Final Regulations - Motion of Tube-Image Receptor Assembly (3/99)
  - Quality Assurance Documentation (12/99)
  - AHRQ's (Agency for Healthcare, Research, and Education, formerly AHCPR) Sample Letters for Communicating Mammography Results to Women