Mammography: Acceptance Testing & QC Programs

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Disclosures

- No financial disclosures to report

Overview

- Today
- Tomorrow

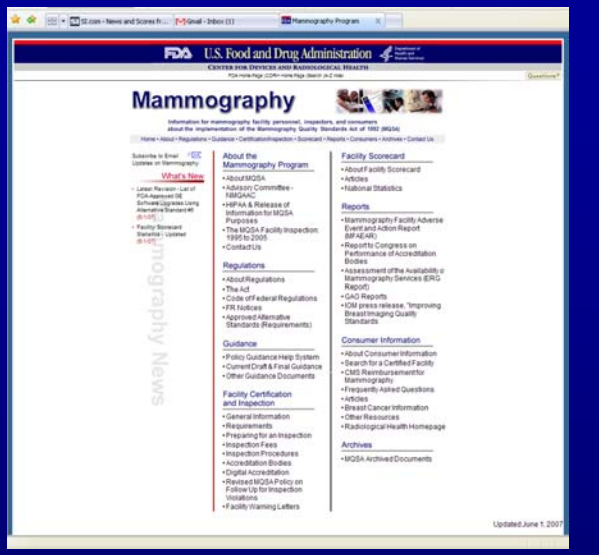
Overview

- Today
  - Total Certified Facilities: 8,626 (7,313 w/FFDM)
  - Total Units: 12,367 (10,639 FFDM Units)
  - Total Annual Mammography Procedures:

    39,505,387

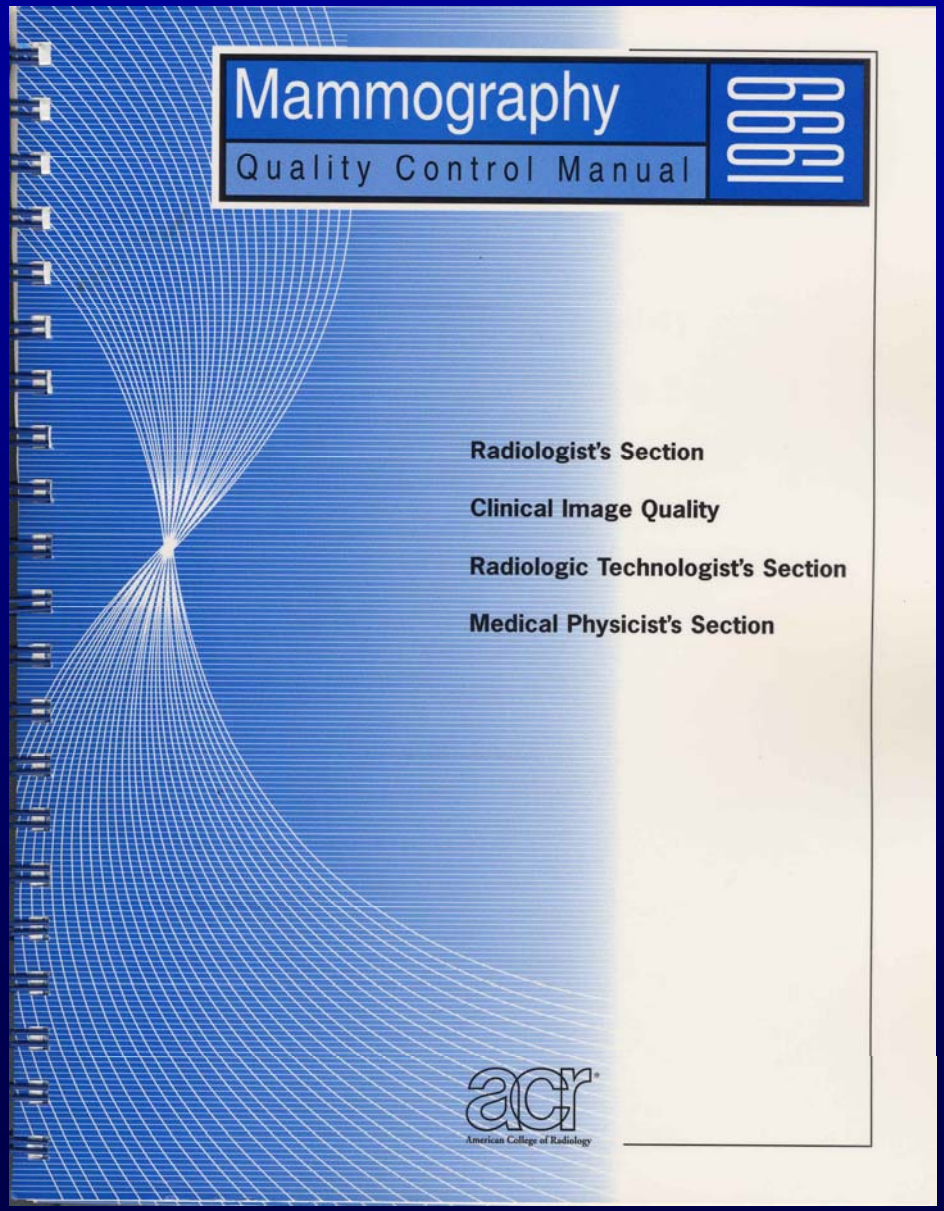
Introduction

- MQSA
  - Mammography Quality Standards Act
- ACR
  - American College of Radiology



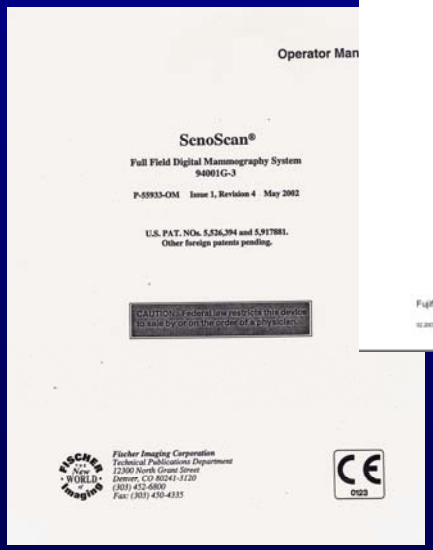
Introduction

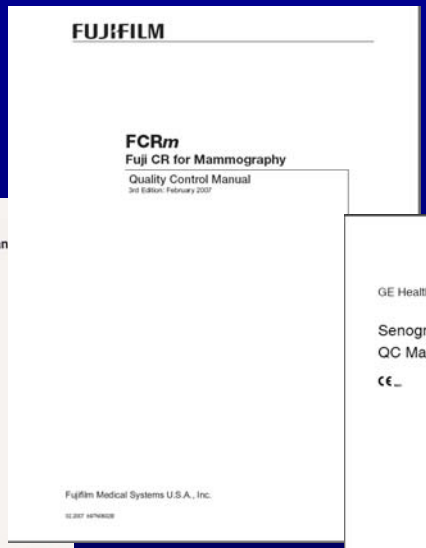
- Screen Film

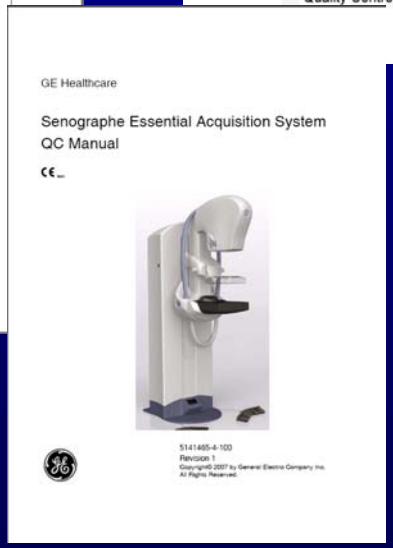


Introduction

- FFDM







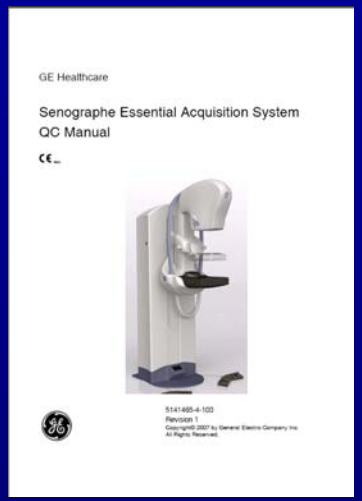
- In FFDM, the manufacturer designs and mandates their own QC program
- In FFDM, you must the manufacturers' QC program

Introduction

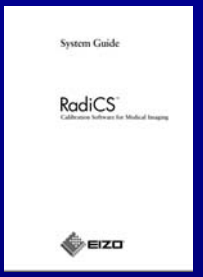
- RWS

Introduction

VS.



Workstations
Monitors
Printers



Introduction

- Current State….

Name	Date Modified	Size	Kind
Agfa 2008 Drystar Axys Ref Manual.pdf	9/27/10 5:59 PM	7.4 MB	Adobe PDF document
AGFA CR Mammo QC User Manual - 2011.pdf	2/21/12 9:21 AM	5.7 MB	Adobe PDF document
Agfa Quality Manual - IMPAX MA3000 Version 2 7.pdf	1/25/06 5:13 AM	442 KB	Adobe PDF document
Barco - Medical Pro Agent User Guide.pdf	10/18/11 10:57 AM	1.7 MB	Adobe PDF document
Barco & MediCal Pro - QC Manual 5-2007.pdf	4/24/07 6:01 PM	2.5 MB	Adobe PDF document
Barco QA Mammo.pdf	10/13/11 1:19 PM	823 KB	Adobe PDF document
Barco Recommended QA Mammo.pdf	6/24/10 11:39 AM	676 KB	Adobe PDF document
Carestream Mammo QC Manual - Rev3.pdf	12/12/08 4:21 AM	487 KB	Adobe PDF document
CareStream Mammo QC Manual v2.0.pdf	11/22/10 4:48 PM	3.2 MB	Adobe PDF document
Carestream_QC_Manual__2010_Ver_1.pdf	1/14/11 6:52 PM	1.4 MB	Adobe PDF document
Cedara Eizo QC1 - System Guide - 6-2006.pdf	1/25/06 5:00 PM	1.2 MB	Adobe PDF document
Cedara Eizo QC2 - Operation Guide - 6-2006.pdf	1/25/06 5:00 PM	582 KB	Adobe PDF document
Cedara QC Guideline - Eizo Brian Cote 3-2008.ppt	3/7/08 7:49 AM	2.8 MB	Microsoft PowerPoint 97-20
Cedara QC List - 6-2006.pdf	1/25/06 5:00 PM	70 KB	Adobe PDF document
Eizo - How to use RadiCS-V23.pdf	4/25/07 8:45 AM	4.3 MB	Adobe PDF document
Fischer QC Manual - Rev 2.pdf	2/15/06 4:26 AM	3 MB	Adobe PDF document
Fischer QC Manual - Rev 4.pdf	11/27/04 2:18 PM	680 KB	Adobe PDF document
Fuji Drypix 5000 and 7000 QC Mammo.pdf	4/18/08 9:22 AM	803 KB	Adobe PDF document
Fuji - QC DP 4000.pdf	9/19/08 2:57 PM	676 KB	Adobe PDF document
Fuji Aspire HD_QCman_8...61_US_FINAL_110711.pdf	11/8/11 9:34 PM	2.7 MB	Adobe PDF document
Fuji Drypix 5000 7000 QC Mammo.pdf	9/19/08 5:31 PM	803 KB	Adobe PDF document
Fuji FCRm QC Forms.pdf	2/14/07 1:12 PM	274 KB	Adobe PDF document
Fuji FCRm QC Manual - Rev 3.pdf	3/22/07 1:16 PM	836 KB	Adobe PDF document
Fuji QC DryPix 4000.pdf	4/18/08 9:21 AM	676 KB	Adobe PDF document
GE 2000D QC Manual - Rev 0.pdf	3/27/08 9:54 AM	1.3 MB	Adobe PDF document
GE Centricity 2.1 QC Manual.pdf	2/20/06 12:33 PM	430 KB	Adobe PDF document
GE DS 2009 Rev 1.pdf	5/11/11 2:57 PM	2.5 MB	Adobe PDF document
GE DS QC Manual - Rev 1.0.pdf	3/27/08 9:55 AM	2 MB	Adobe PDF document
GE Essential QC 5305863-5-S-1EN_r1.pdf	11/4/09 5:01 AM	2.7 MB	Adobe PDF document
GE Essential QC Manual - Rev 1.0.pdf	3/27/08 9:55 AM	1.9 MB	Adobe PDF document
GE Essential QC Manual - Rev 1.1 - 2008.pdf	1/23/09 6:44 AM	1.3 MB	Adobe PDF document
GE Essential QC Manual - Rev 1.1.pdf	9/3/08 7:47 AM	2.1 MB	Adobe PDF document
GE Seno Advantage QC Manual - Rev 1.0.pdf	3/27/08 9:57 AM	311 KB	Adobe PDF document
GE Tomo DBT QC Plan 20-Sep-10.doc	3/22/11 8:38 AM	4.1 MB	Microsoft Word 97 - 2004 d
GIOTTO IMAGE 3D-3DL QC Manual v1.4 Jan 2012.pdf	2/21/12 9:25 AM	2.1 MB	Adobe PDF document
Hologic Customer Release Notes AW - 3-2010.pdf	3/29/10 6:40 AM	504 KB	Adobe PDF document
Hologic Dimensions 2D_3...ual Rev 2 - Feb 2011.pdf	4/12/11 8:40 AM	10.8 MB	Adobe PDF document
Kodak - 5850 - QC Manual - Carestream.pdf	9/14/10 11:02 AM	266 KB	Adobe PDF document
Kodak - 8900MQC.pdf	10/13/05 12:51 PM	86 KB	Adobe PDF document
Kodak 6800 QC Forms.pdf	10/24/07 2:33 AM	37 KB	Adobe PDF document
Kodak 8900 - QC Manual.pdf	9/14/10 11:03 AM	5.1 MB	Adobe PDF document
Kodak Dry View 6800 QC manual.pdf	11/12/07 6:24 PM	250 KB	Adobe PDF document
Kodax 8900 - Ver 3.pdf	3/21/07 6:57 AM	6.5 MB	Adobe PDF document
Konica Drypro 793 - Rev1_0.pdf	1/25/06 3:39 AM	918 KB	Adobe PDF document
Konica Minolta Xpress Digital QC Manual.pdf	2/21/12 9:24 AM	2.9 MB	Adobe PDF document
Lorad QC - TOMO - Rev 7 - 12-2008.pdf	8/13/09 9:12 AM	4.5 MB	Adobe PDF document
Lorad QC - TOMO - Rev 8 - 2-2010.pdf	2/22/10 3:40 PM	3.8 MB	Adobe PDF document
Lorad QC - TOMO - Rev 9 - 8-2010.pdf	8/23/10 1:27 PM	4.1 MB	Adobe PDF document
Lorad QC - TOMO - Rev 10 - 2-2011.pdf	2/18/11 9:10 AM	11.1 MB	Adobe PDF document
Lorad QC Manual - Rev 1 - June 2009 - Mo and W.pdf	8/6/09 9:55 AM	6.4 MB	Adobe PDF document
Lorad QC Manual - Rev 7.pdf	10/24/07 2:09 PM	7.6 MB	Adobe PDF document
Lorad QC Manual - Rev 8.pdf	2/27/08 5:57 AM	7.6 MB	Adobe PDF document
Lorad QC Manual Tunsten - Rev 3.pdf	2/8/08 5:51 AM	8 MB	Adobe PDF document
Lorad Selenia Dimensions 2D_3D 2011 Rev 3.pdf	2/23/12 7:59 PM	11.1 MB	Adobe PDF document
Nuance and Excel QC Manual 20008109_3.pdf	11/8/11 9:33 PM	6.2 MB	Adobe PDF document
Philips - Addendum QC ...ost DR V1 2010-03-29.pdf	5/26/11 12:01 PM	279 KB	Adobe PDF document
Philips - Microdose L30 QC Manual Sofware 8.3.pdf	2/21/12 9:22 AM	4.1 MB	Adobe PDF document
Philips - QC MammoDiagnost DR v1.pdf	5/26/11 12:00 PM	2 MB	Adobe PDF document
Planar Dome C51 and Dome E5 Rev B.pdf	11/21/06 3:00 AM	463 KB	Adobe PDF document
Planmed Nuance and Excel QC Manual.pdf	10/18/11 11:48 AM	6.2 MB	Adobe PDF document
Sectra 2011 Ver 8.3.pdf	7/13/11 7:24 PM	4.2 MB	Adobe PDF document
Sectra QC Manual - 7-2011 Version G.pdf	7/23/11 1:03 PM	2.2 MB	Adobe PDF document
Sectra QC Manual - Ver 8.3 - 4-2011.pdf	4/28/11 10:48 PM	4.2 MB	Adobe PDF document
Sectra QC Manual - Ver 11.1.pdf	2/19/08 6:51 PM	1.2 MB	Adobe PDF document

Introduction

- As of 6/8/12

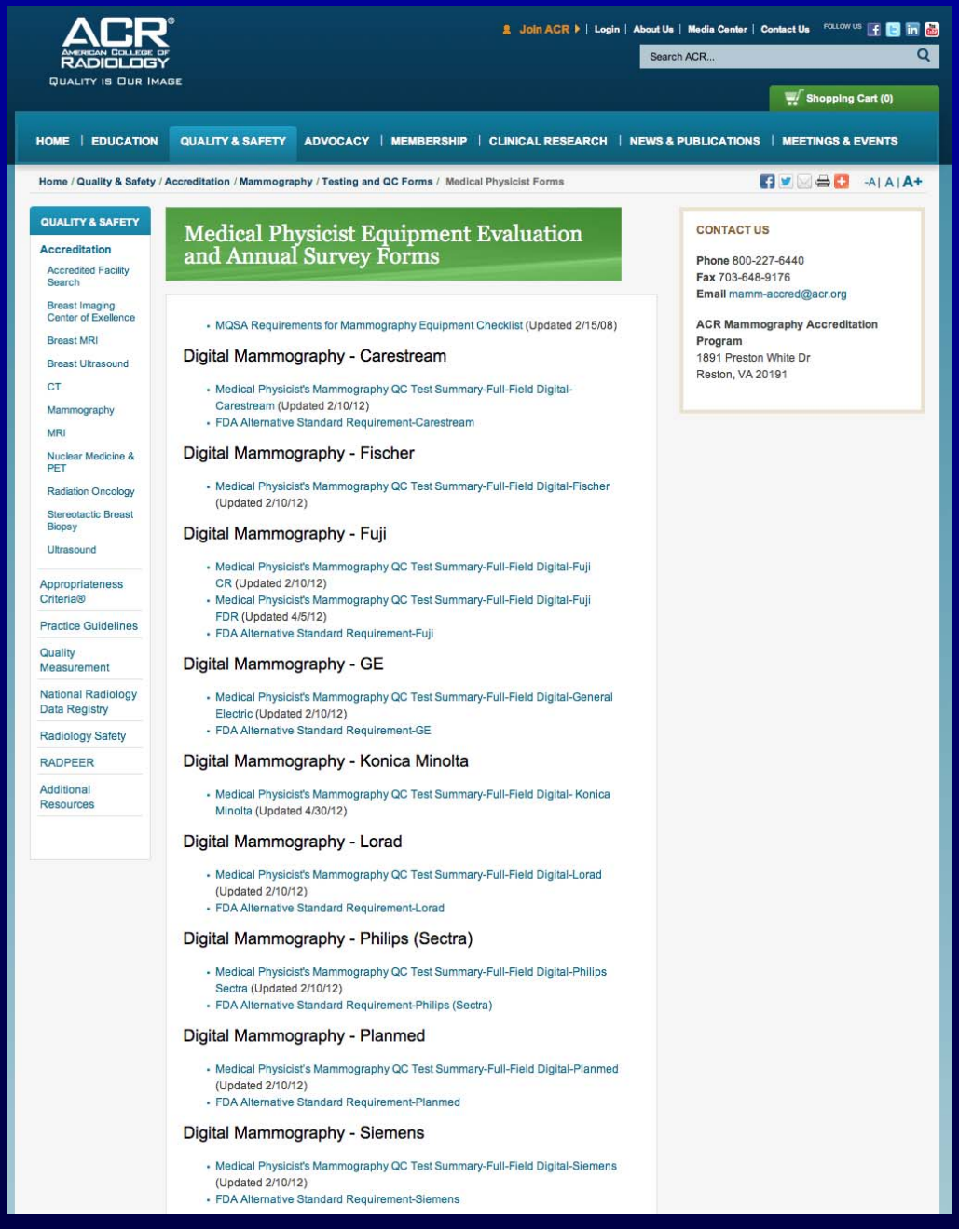
Facilities calling about the following systems must call the FDA for the FDA Certificate Extension program at 800-838-7715:

- Giotto 3D-3DL
- Agfa CR

Full Field Digital Mammography (FFDM) or Digital Breast Tomosynthesis (DBT) Unit	Accreditation Body Approval Date Effective Date			
	ACR	SAR	SIA	STX
GE Senographe 2000D	12/18/02 02/15/03	08/15/06 08/15/06	08/28/03 10/01/03	05/21/04 05/21/04
Fischer Imaging SenoScan	07/24/03 08/15/03			05/21/04 05/21/04
Lorad/Hologic Selenia (Molybdenum target)	09/02/03 09/15/03	08/15/06 08/15/06	08/28/03 10/01/03	05/21/04 05/21/04
GE Senographe DS	08/12/04 09/15/04	08/15/06 08/15/06	01/12/06 01/17/06	08/12/04 09/15/04
Siemens Mammomat Novation DR	10/07/05 10/15/05	08/26/08 08/26/08	01/26/06 02/01/06	06/29/06 06/29/06
GE Senographe Essential	06/29/06 07/15/06	08/15/06 08/15/06	08/24/06 08/24/06	09/05/06 09/05/06
Fuji Computed Radiography for Mammography	11/13/06 11/15/06	10/12/06 10/12/06	11/13/06 11/13/06	11/13/06 11/13/06
Hologic Selenia (Tungsten target)	02/01/08 02/01/08	02/01/08 02/01/08	02/01/08 02/01/08	02/01/08 02/01/08
Siemens Mammomat Novation S	02/11/09 02/11/09	02/11/09 02/11/09	02/11/09 02/11/09	02/11/09 02/11/09
Hologic Selenia S	02/11/09 02/11/09	02/11/09 02/11/09	02/11/09 02/11/09	02/11/09 02/11/09
Hologic Selenia Dimensions 2D	02/11/09 02/11/09	02/11/09 02/11/09	02/11/09 02/11/09	02/11/09 02/11/09
Carestream Directview Computed Radiography (CR) Mammography	02/08/11 02/16/11	01/07/11 01/07/11	01/07/11 01/07/11	02/08/11 02/08/11
Siemens Mammomat Inspiration	02/11/11 02/11/11	02/11/11 02/11/11	02/11/11 02/11/11	02/11/11 02/11/11
Hologic Selenia Encore	06/15/11 06/15/11	06/15/11 06/15/11	06/15/11 06/15/11	06/15/11 06/15/11
Philips (Sectra) MicroDose L30	10/20/11 10/21/11	07/18/11 07/18/11		08/03/11 08/03/11
Siemens Mammomat Inspiration Pure	08/23/11 08/23/11	08/23/11 08/23/11	08/23/11 08/23/11	08/23/11 08/23/11
GE Senographe Care	10/07/11 10/07/11	10/07/11 10/07/11	10/07/11 10/07/11	10/07/11 10/07/11
Planmed Nuance	12/13/11 12/27/11	12/20/11 12/20/11		01/20/12 01/20/12
Planmed Nuance Excel	12/13/11 12/27/11	12/20/11 12/20/11		01/20/12 01/20/12
Fuji Aspire Computed Radiography for Mammography	01/20/12 01/20/12	01/20/12 01/20/12	01/20/12 01/20/12	01/20/12 01/20/12
Giotto Image 3D/3DL				03/09/12 03/09/12
Fuji Aspire HD	03/28/12 04/10/12		05/25/12 05/25/12	03/28/12 04/10/12
Konica Minolta Xpress Digital Mammography CR System	04/19/12 04/27/12			04/19/12 04/27/12
Agfa CR Mammography System				06/08/12 06/08/12

Introduction

- ACR Accreditation Program

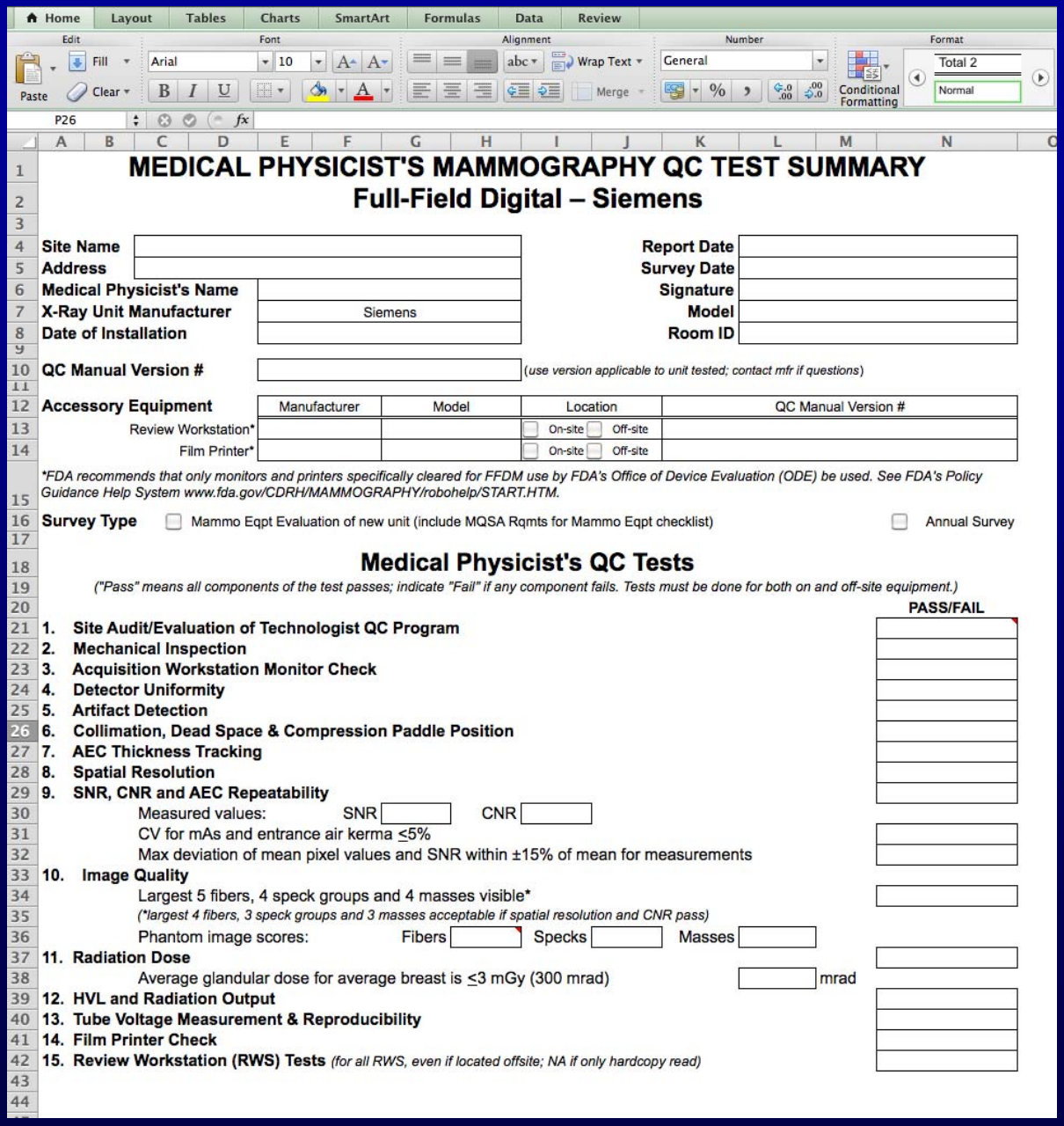


Introduction

- ACR

  Accreditation

  Program



Home | Layout | Tables | Charts | SmartArt | Formulas | Data | Review

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Paste | Fill | Clear | Arial | 10 | Wrap Text | General | Merge | Conditional Formatting | Total 2 | Normal

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MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY
Full-Field Digital – Siemens

Site Name		**Report Date**	
Address		**Survey Date**	
Medical Physicist's Name		**Signature**	
X-Ray Unit Manufacturer	Siemens	**Model**	
Date of Installation		**Room ID**	

QC Manual Version # _____ *(use version applicable to unit tested; contact mfr if questions)*

Accessory Equipment	Manufacturer	Model	Location	QC Manual Version #
Review Workstation*			☐ On-site ☐ Off-site	
Film Printer*			☐ On-site ☐ Off-site	

**FDA recommends that only monitors and printers specifically cleared for FFDM use by FDA's Office of Device Evaluation (ODE) be used. See FDA's Policy Guidance Help System www.fda.gov/CDRH/MAMMOGRAPHY/robohelp/START.HTM.*

Survey Type ☐ Mammo Eqpt Evaluation of new unit (include MQSA Rqmts for Mammo Eqpt checklist) ☐ Annual Survey

Medical Physicist's QC Tests

("Pass" means all components of the test passes; indicate "Fail" if any component fails. Tests must be done for both on and off-site equipment.)

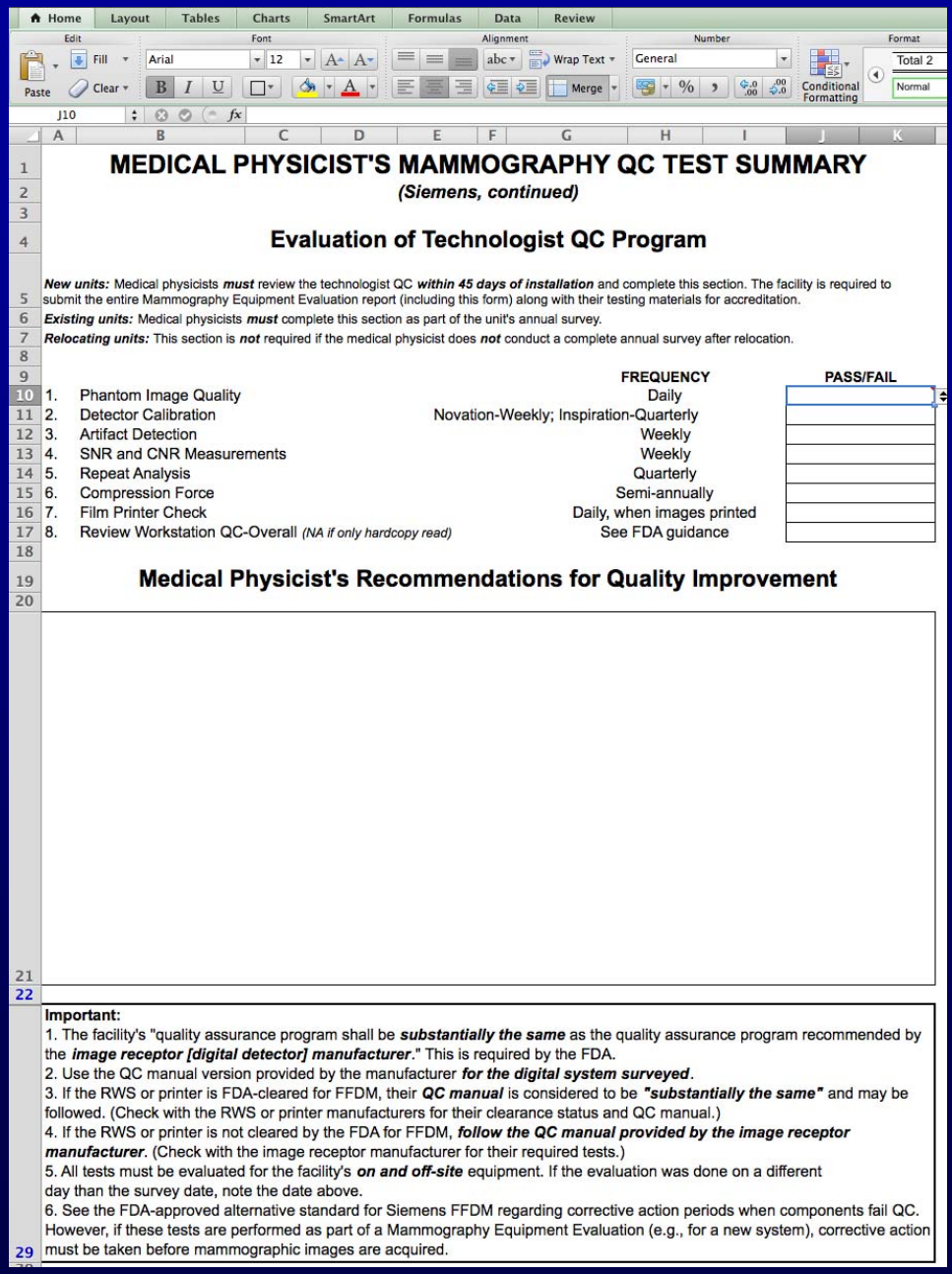
	PASS/FAIL
1. Site Audit/Evaluation of Technologist QC Program	
2. Mechanical Inspection	
3. Acquisition Workstation Monitor Check	
4. Detector Uniformity	
5. Artifact Detection	
6. Collimation, Dead Space & Compression Paddle Position	
7. AEC Thickness Tracking	
8. Spatial Resolution	
9. SNR, CNR and AEC Repeatability	
Measured values: SNR _____ CNR _____	
CV for mAs and entrance air kerma ≤5%	
Max deviation of mean pixel values and SNR within ±15% of mean for measurements	
10. Image Quality	
Largest 5 fibers, 4 speck groups and 4 masses visible*	
*(*largest 4 fibers, 3 speck groups and 3 masses acceptable if spatial resolution and CNR pass)*	
Phantom image scores: Fibers _____ Specks _____ Masses _____	
11. Radiation Dose	
Average glandular dose for average breast is ≤3 mGy (300 mrad) _____ mrad	
12. HVL and Radiation Output	
13. Tube Voltage Measurement & Reproducibility	
14. Film Printer Check	
15. Review Workstation (RWS) Tests *(for all RWS, even if located offsite; NA if only hardcopy read)*	

Introduction

- ACR

  Accreditation

  Program



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MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY

(Siemens, continued)

Evaluation of Technologist QC Program

New units: Medical physicists ***must*** review the technologist QC ***within 45 days of installation*** and complete this section. The facility is required to submit the entire Mammography Equipment Evaluation report (including this form) along with their testing materials for accreditation.

Existing units: Medical physicists ***must*** complete this section as part of the unit's annual survey.

Relocating units: This section is ***not*** required if the medical physicist does ***not*** conduct a complete annual survey after relocation.

		FREQUENCY	PASS/FAIL
1.	Phantom Image Quality	Daily	
2.	Detector Calibration	Novation-Weekly; Inspiration-Quarterly	
3.	Artifact Detection	Weekly	
4.	SNR and CNR Measurements	Weekly	
5.	Repeat Analysis	Quarterly	
6.	Compression Force	Semi-annually	
7.	Film Printer Check	Daily, when images printed	
8.	Review Workstation QC-Overall *(NA if only hardcopy read)*	See FDA guidance	

Medical Physicist's Recommendations for Quality Improvement

Important:

1. The facility's "quality assurance program shall be ***substantially the same*** as the quality assurance program recommended by the ***image receptor [digital detector] manufacturer***." This is required by the FDA.
2. Use the QC manual version provided by the manufacturer ***for the digital system surveyed***.
3. If the RWS or printer is FDA-cleared for FFDM, their ***QC manual*** is considered to be ***"substantially the same"*** and may be followed. (Check with the RWS or printer manufacturers for their clearance status and QC manual.)
4. If the RWS or printer is not cleared by the FDA for FFDM, ***follow the QC manual provided by the image receptor manufacturer***. (Check with the image receptor manufacturer for their required tests.)
5. All tests must be evaluated for the facility's ***on and off-site*** equipment. If the evaluation was done on a different day than the survey date, note the date above.
6. See the FDA-approved alternative standard for Siemens FFDM regarding corrective action periods when components fail QC. However, if these tests are performed as part of a Mammography Equipment Evaluation (e.g., for a new system), corrective action must be taken before mammographic images are acquired.

Introduction

MEDICAL PHYSICIST'S CHECKLIST
MQSA REQUIREMENTS FOR MAMMOGRAPHY EQUIPMENT

Model:
Year Mfr:
Room ID:
Survey Date:

FDA Rule Section	Requirement	Applies to	Meets FDA Requirements? *(if NA, please explain)*
3(i)	The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.	S-F & FFDM	Yes No NA
3(ii)	This mechanism shall not fail in the event of power interruption.	S-F & FFDM	Yes No NA
4(i)	Systems using screen-film image receptors shall provide, at a minimum, for operation with image receptors of 18 x 24 cm and 24 x 30 cm.	S-F	Yes No NA
4(ii)	Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.	S-F	Yes No NA
4(iii)	Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.	S-F & FFDM	Yes No NA
5(i)	All systems shall have beam limiting devices that allow the useful beam to extend to or beyond the chest wall edge of the image receptor.	S-F & FFDM	Yes No NA
5(ii)	For any mammography system with a light beam that passes through the X-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 ft-candles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.	S-F & FFDM (except Fischer)	Yes No NA
6(i)	Systems used to perform noninterventional problem-solving procedures shall have radiographic magnification capability available for use by the operator.	S-F & FFDM	Yes No NA
6(ii)	Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.	S-F & FFDM	Yes No NA
7(i)	When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.	S-F & FFDM	Yes No NA
7(ii)	When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.	S-F & FFDM	Yes No NA
7(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.	S-F & FFDM	Yes No NA
8(i)(A)	Each system shall provide an initial power-driven compression activated by hands-free controls operable from both sides of the patient.	S-F & FFDM	Yes No NA
8(i)(B)	Each system shall provide fine adjustment compression controls operable from both sides of the patient.	S-F & FFDM	Yes No NA
8(ii)(A)	Systems shall be equipped with different sized compression paddles that match the sizes of all full-field image receptors provided for the system.	S-F & FFDM	Yes No NA
8(ii)(B)	The compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.	S-F & FFDM (except Fischer)	Yes No NA
8(ii)(C)	Equipment intended by the manufacturer's design to not be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.	S-F & FFDM	Yes No NA
8(ii)(D)	The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.	S-F & FFDM	Yes No NA
8(ii)(E)	The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.	S-F & FFDM	Yes No NA
9(i)	Manual selection of mAs or at least one of its component parts (mA and/or time) shall be available.	S-F & FFDM	Yes No NA
9(ii)	The technique factors (kVp and either mA and seconds or mAs) to be used during an exposure shall be indicated before the exposure begins, except when AEC is used, in which case the technique factors that are set prior to the exposure shall be indicated.	S-F & FFDM	Yes No NA
9(iii)	Following AEC mode use, the system shall indicate the actual kVp and mAs (or mA and time) used during the exposure.	S-F & FFDM	Yes No NA
10(i)	Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, non-grid; magnification, nonmagnification; and various target-filter combinations.	S-F	Yes No NA
10(ii)	The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue. The size and the available positions of the detector shall be clearly indicated at the X-ray input surface of the breast compression paddle. The selected position of the detector shall be clearly indicated.	S-F	Yes No NA
10(iii)	The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.	S-F	Yes No NA
11	The facility shall use X-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography.	S-F	Yes No NA
12	The facility shall use intensifying screens for mammography that have been designated by the screen manufacturer as appropriate for mammography and shall use film that is matched to the screen's spectral output as specified by the manufacturer.	S-F	Yes No NA
13	For processing mammography films, the facility shall use chemical solutions that are capable of developing the films used by the facility in a manner equivalent to the minimum requirements specified by the film manufacturer.	S-F	Yes No NA
14	The facility shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the view box, available to the interpreting physicians.	S-F & FFDM (for hardcopy comparison)	Yes No NA
15	Facilities shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.	S-F & FFDM (for hardcopy comparison)	Yes No NA

Introduction

- Golden Rules
  - Must use manufacturer's QC procedures
    - Mandate action limits
  - Manufacturers' QC may refer to Monitor & Printer Manufacturers' QC
  - Multimodality Workstations may have own separate QC
  - Printers may have their own QC
  - Most failures result in stopping clinical imaging until failure can be corrected

Introduction

- Golden Rules – Clinical Tips
  - Always get latest version of ACR Summary Forms
  - Verify you're using correct Mfr QC Manual
  - Record the correct Mfr QC Manual on your report
  - Read the Mfr QC Manual - make sure you perform all tests
    - Always seem to be updates or changed manuals

Future

- ACR Subcommittee on Quality Assurance
  - Clinical Representatives
  - MITA Representatives
  - ACR Staff

ACR Subcommittee on Quality Assurance

- ACR Clinical Representatives
  - Eric Berns, PhD – University of Colorado - **Chair**
  - Chris Adent-Delaney, RT - Northwestern Memorial Hospital
  - Jay Baker, MD – Duke University Medical Center
  - Lawrence Bassett, MD – UCLA Medical Center
    - Chair, Joint Committee on Breast Imaging for Appropriateness Criteria and Guidelines
  - Shelli Dixon, RT – The Women's Imaging Center of Denver
  - R. Edward Hendrick, PhD – University of Colorado Hospital
  - Debra Monticciolo, MD – Texas A&M Health Sciences Center
    - Chair of ACR Accreditation Program Chairs
    - Chair of ACR Mammography Accreditation
  - Douglas Pfeiffer, MS – Boulder Community Hospital
  - Margarita Zuley, MD – University of Pittsburgh Medical Center

Subcommittee on Quality Assurance

- MITA Representatives
  - Gail Rodriguez, PhD - MITA
  - John Sandrik, PhD (Ret.) – GE Medical Systems
  - Robert Uzenoff - FUJIFILM Medical Systems
  - Stephen Vastagh – (Ret.) - MITA
  - Moustafa Zerhouni – Computerized Imaging References Systems

- ACR Staff
  - Marion Boston, RT – Assistant Director, ACR Breast Imaging Accreditation
  - Priscilla Butler, MS – Senior Director, ACR Breast Imaging Accreditation Programs

ACR FFDM QC Manual Project

- Subcommittee Charge:
  - Design ACR Accreditation Phantom for FFDM
  - Write QC Manual for ACR FFDM Mammography Accreditation Program

ACR FFDM QC Manual Project

- Subcommittee Goals:
  - Standardize all QC tests for all digital manufacturers
  - Standardize test frequencies
  - Standardize performance criteria

ACR FFDM QC Manual Project

- Subcommittee Goals:
  - QC Tests:
    - Tests come from a variety of sources (MQSA, ACR SFM Manual, ACRIN DMIST Results, Manufacturer's QC programs, MITA, European Guidelines, AAPM TG18, subcommittee clinical experience, etc.)
    - Clinically relevant
    - User friendly
  - Hope manufacturers will adopt this manual
  - This manual will become basis of new regulations

ACR FFDM QC Manual Project

- Subcommittee Goals:
  - Realize critical component of the ACR MAP
    - Account for all past, present, and future FFDM systems
    - Reasonable and appropriate for mass implementation
    - Eliminate unnecessary complicated procedures & analysis
    - Maximize user experience
      - Especially for Techs, Rads, & Facilities
  - Philosophy
    - Measurements be made with external equipment
      - Dosimeters, photometers, etc.
    - Minimal software requirements
      - CNR & SNR

ACR Digital QC Draft Manual

- Structure of Manual:
  - Radiologist's Section
  - Clinical Image Quality Section
  - Radiologic Technologist's Section
  - Medical Physicist's Section
  - Educational, Guidance, and Troubleshooting Section
  - Glossary
  - References
  - Index

What Will Be New?

- Radiologist Section
  - Image ID regulations
  - Hanging protocols (left vs. right)
  - Monitor and viewing conditions guidance
  - Section on diagnostic tools for analyzing poor images
  - How to score the ACR FFDM Phantom
  - Guides for understanding their role and responsibility for overseeing the QC program

What Will Be New?

- Tech Section
  - Enhanced positioning and image quality section
  - New Test: Monitor QC for the Radiologist
  - New Test: Facility QC Review
  - New Format: Corrective Action Log
  - New Documentation: Facility Equipment Inventory
  - Improved QC Forms
  - Instructions for Mobile Units
  - Eliminate calculations (TBD)

What Will Be New?

- Medical Physicist Section
  - Theme: provide better documentation and communication
    - Single MP Summary Form
      - For Facility, ACR, State and MQSA Inspectors
      - Include an Action Item Summary
    - MP form for Tech for Operating Levels (if app.) and QC instructions
    - Procedures for evaluating and documenting Tech QC
    - MP letter to the Radiologist
    - MP to use same Corrective Action Log form as Techs

What Will Be New?

- Medical Physicist Section
  - Provide QC forms in both PDF and Excel Worksheets
  - Will include guidance on how to test
    - Multiple units (FFDM's, AW's, RW's, Printers, etc)
    - Multiple facilities

What Will Be New?

- Facility
  - Guidance on how to handle multiple units at multiple locations.
  - Guidance on who/what/when tests need to be performed when “major” and “minor” repairs are performed on unit.
  - Facility QC Review (Tech Test) – Quarterly

ACR Digital QC Draft Manual

Technologist QC Tests			
Test Number	Name (# of Test Elements)	Minimum Frequency	Required Corrective Action
1	ACR Phantom Image Quality (5)	Weekly	Before Clinical Use
2	Acquisition Workstation (AW) Monitor QC (3)	Weekly	Before Clinical Use
3	Radiologist Workstation (RW) Monitor QC (5)	Weekly	Before Clinical Use
4	Laser Printer QC (5)	Weekly	Before Clinical Use
5	Viewbox Cleanliness (1)	Weekly	Before Clinical Use
6	Visual Checklist (1)	Monthly	Before Clinical Use
7	Repeat Analysis (1)	Quarterly	Within 30 Days
8	Monitor QC for the Radiologist (1)	Quarterly	Before Clinical Use
9	Facility QC Review (1)	Quarterly	Not Applicable
10	Compression Force (1)	Semiannual	Before Clinical Use
11	Manufacturer Detector Calibration (If Applicable)	Per Mfr Recommendation	Before Clinical Use
Supplemental Forms			
	Corrective Action Log		
	Facility Equipment Inventory Form		

ACR Digital QC Draft Manual

Medical Physicists QC Tests

Test Number	Name (# of Test Elements)	Minimum Frequency	Required Corrective Action
1	ACR Phantom Image Quality (6)	Annual	Before Clinical Use
2	Ghost Image Evaluation (1)	Annual	Before Clinical Use
3	Spatial Resolution (1)	Annual	Before Clinical Use
4	Automatic Exposure Control System Performance (2)	Annual	Before Clinical Use
5	Collimation Assessment (3)	Annual	Within 30 Days
6	kVp Accuracy and Reproducibility (1)	MEE Only	Before Clinical Use
7	Beam Quality (Half-Value Layer) Assessment (1)	Annual	Within 30 Days
8	Average Glandular Dose (2)	Annual	Before Clinical Use
9	Unit Checklist (1)	Annual	Before Clinical Use
10	Evaluation of Site's Technologist QC Program (1)	Annual	Within 30 Days
11	MQSA Equipment Requirements (1)	MEE Only	Before Clinical Use
12	Computed Radiography (If Applicable) (3)	Annual	Before Clinical Use
13	Acquisition Workstation (AW) Monitor QC (6)	Annual	Before Clinical Use
14	Radiologist Workstation (RW) Monitor QC (11)	Annual	Before Clinical Use
15	Laser Printer QC (7)	Annual	Before Clinical Use
16	Viewbox Luminance and Room Illuminance (2)	Annual	Before Clinical Use
17	Evaluation of Off-Site Technologist QC Program (If Applicable)	Annual	Before Clinical Use

ACR Digital QC Draft Manual

Medical Physicists QC Tests	
Test Number	**Name**
	Supplemental Forms
1	Medical Physicist Summary Report
2	Technologist Operating Level Information and QC Instruction Form
3	Medical Physicist Summary Letter for the Radiologist
4	Mammography Corrective Action Log
5	Technologist Pre-Inspection Interview Form
6	Technique Chart

ACR Digital QC Draft Manual

Tech & MP	
Test Number	**Name**
Educational and Example Forms	
1	Complete set of forms with example data, scores, and calculations
2	ACR Phantom Scoring Guide
3	SNR & CNR Calculation Guide
4	Monitor Test Pattern Evaluation Guide
5	Printed Film Evaluation Guide
6	FFDM Artifact Guide

The ACR FFDM Phantom Prototype

Design Summary

- Phantom Prototype Design Principles
  - Base on existing ACR Accreditation Phantom
  - Similar imaging and scoring to current SFM phantom
  - Build on experience of QC techs and physicists at 8000+ US facilities who already know how to use and score the existing phantom
  - Can be used on both SFM & FFDM
  - Total attenuation matched to current SFM phantom
    - Similar thickness
    - Similar total dose
  - Permits testing of 3.0 mGy dose limit

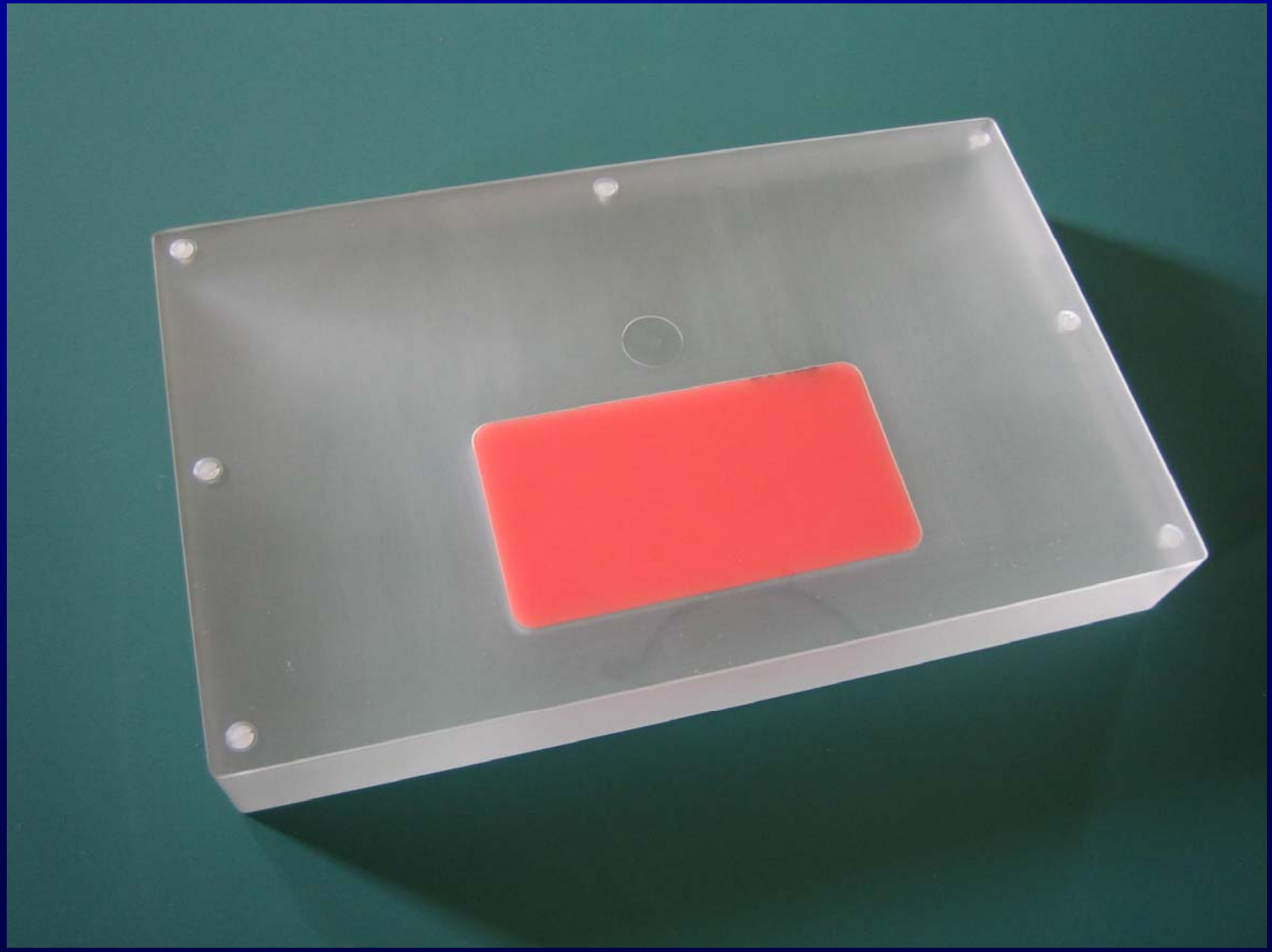
Design Summary

- Phantom Prototype Design Principles
  - Cover all (or most) of detector on all digital systems
  - Single exposure results in all relevant information
  - All evaluation (including artifacts) can be done at one WW, WL
  - Provide detailed specifications to manufacturer's
- Manufacturing will be open to all qualifying vendors
  - Must receive approval from ACR (ACR will test sample phantom)

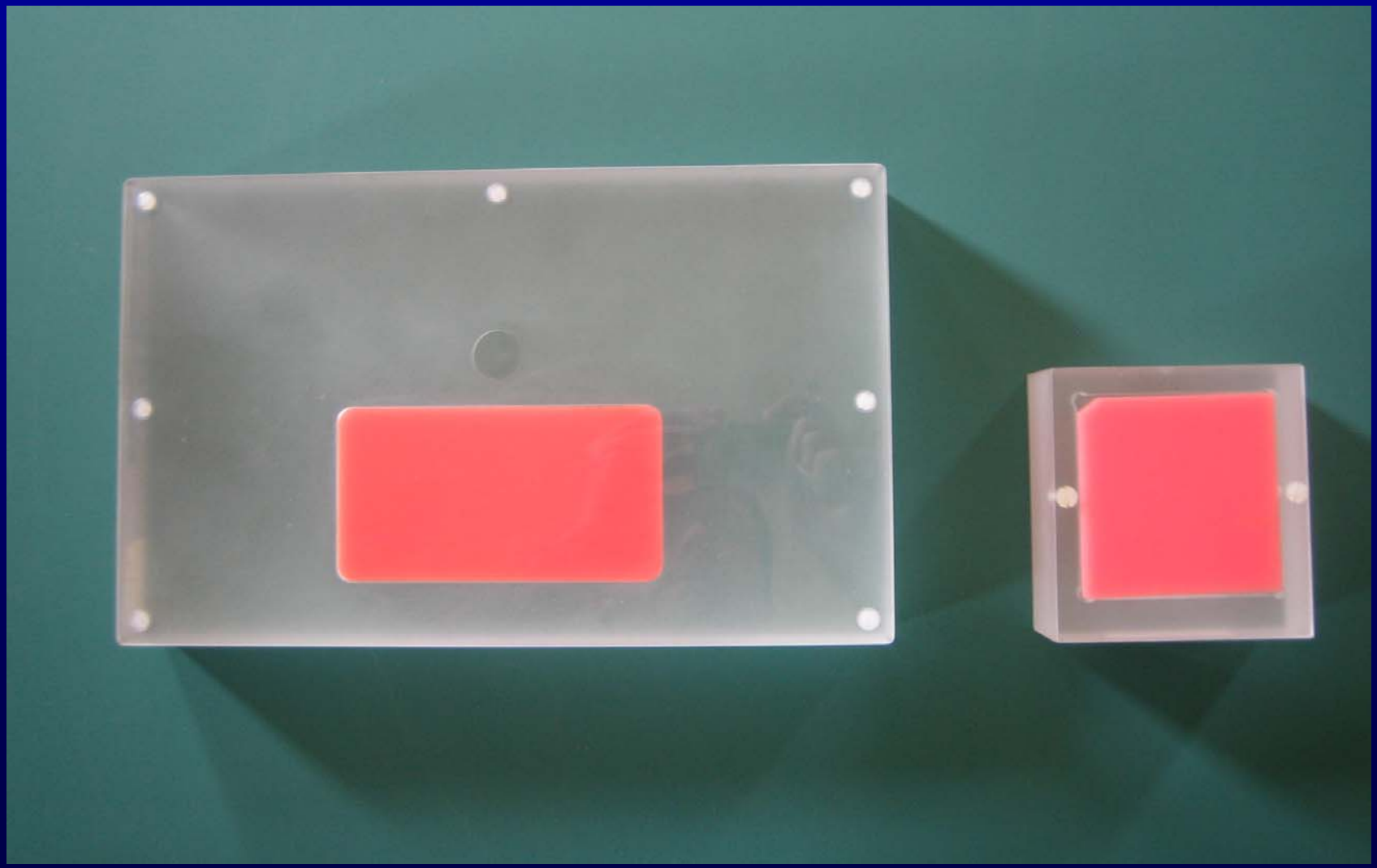
Proposed Scoring Changes

- Differences from screen-film phantom
  - Eliminate subtraction for artifacts
  - Add “Fail” for artifacts
  - Improve specific rules for scoring
  - Change pass/fail criteria from
    - 4,3,3
    - To: 2,3,2
    - **But, objects are the same (effective) size as SFM Phantom

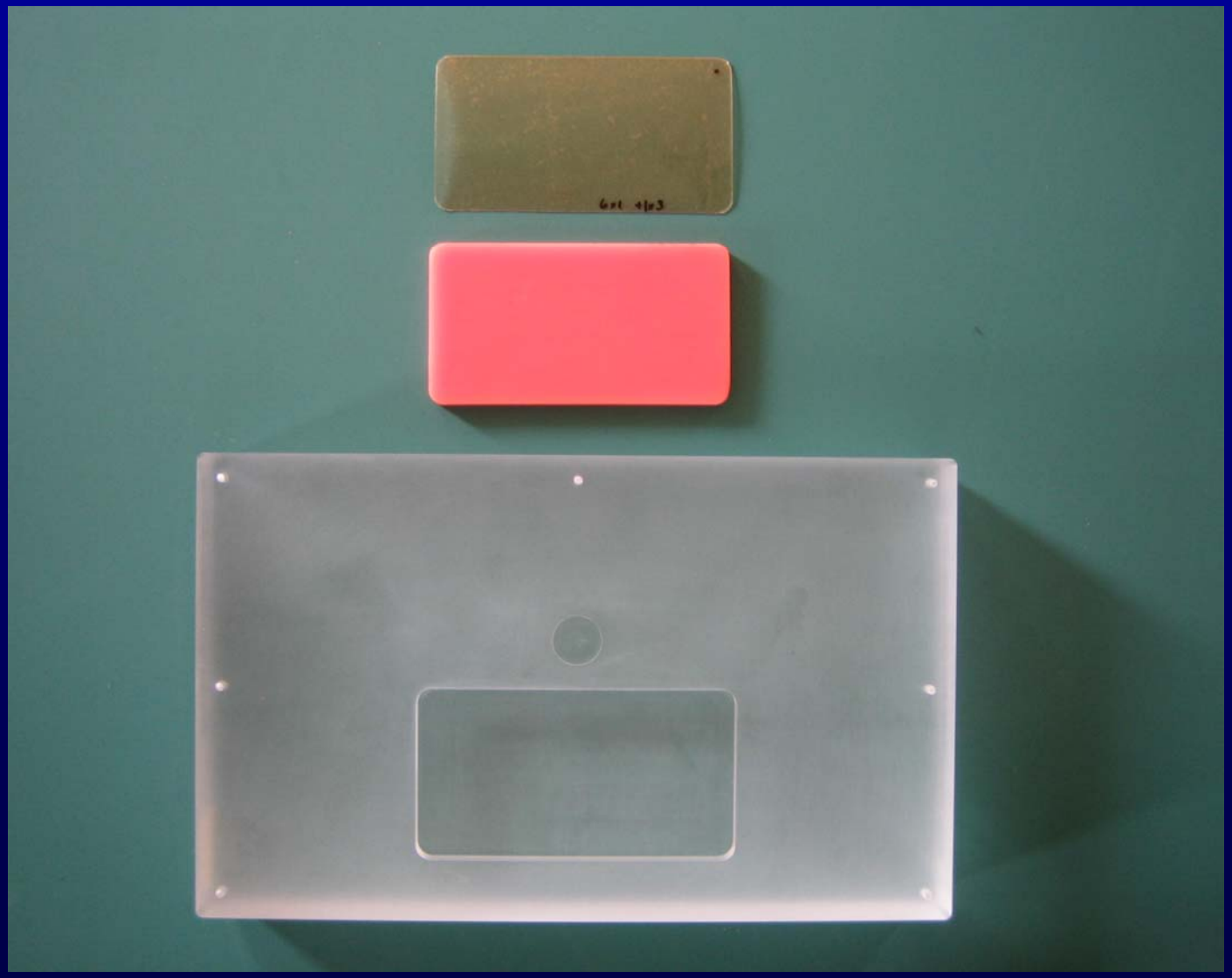
The ACR FFDM Phantom Prototype



The ACR FFDM Phantom Prototype vs. SFM ACR Phantom



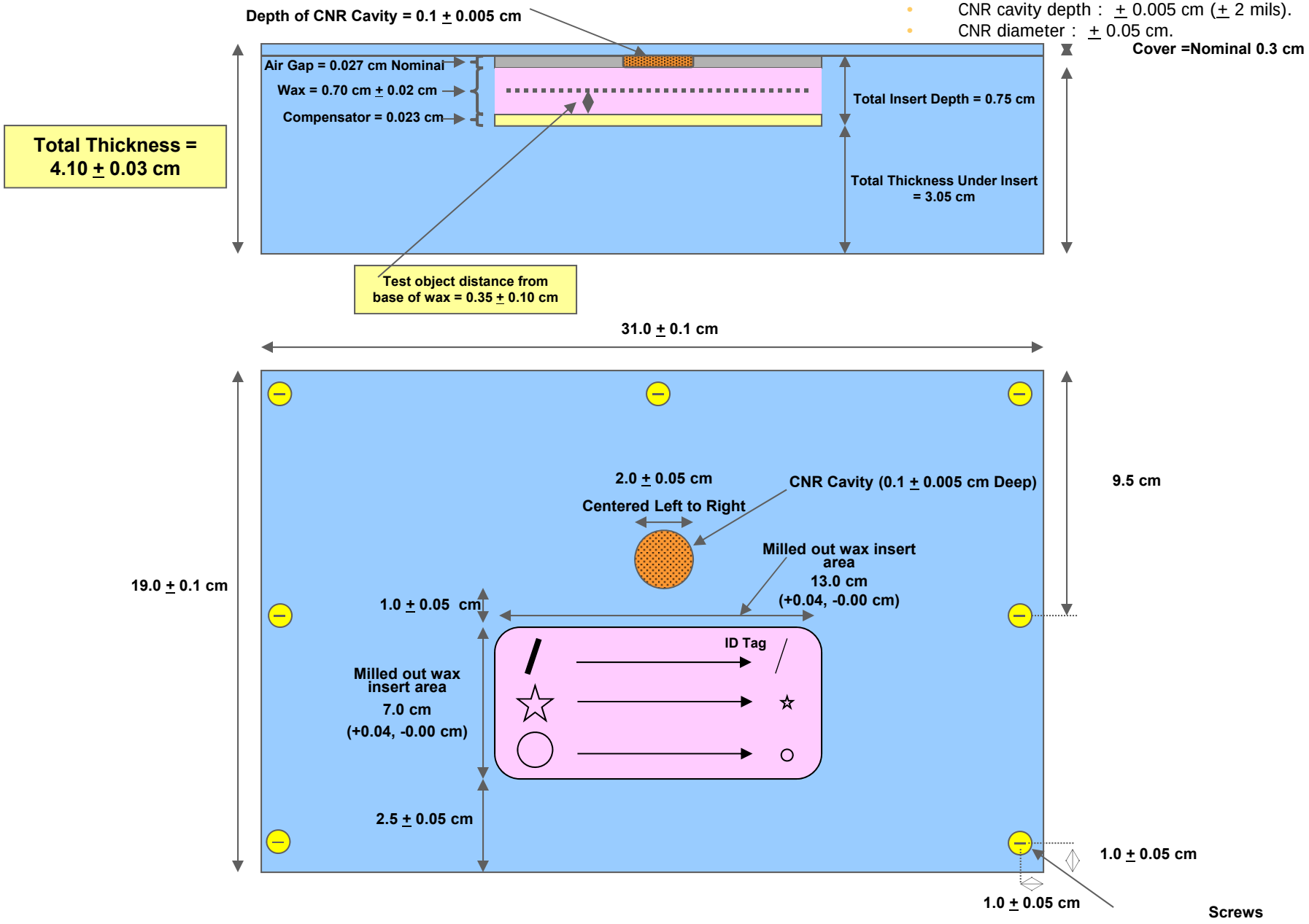
The ACR FFDM Phantom Prototype



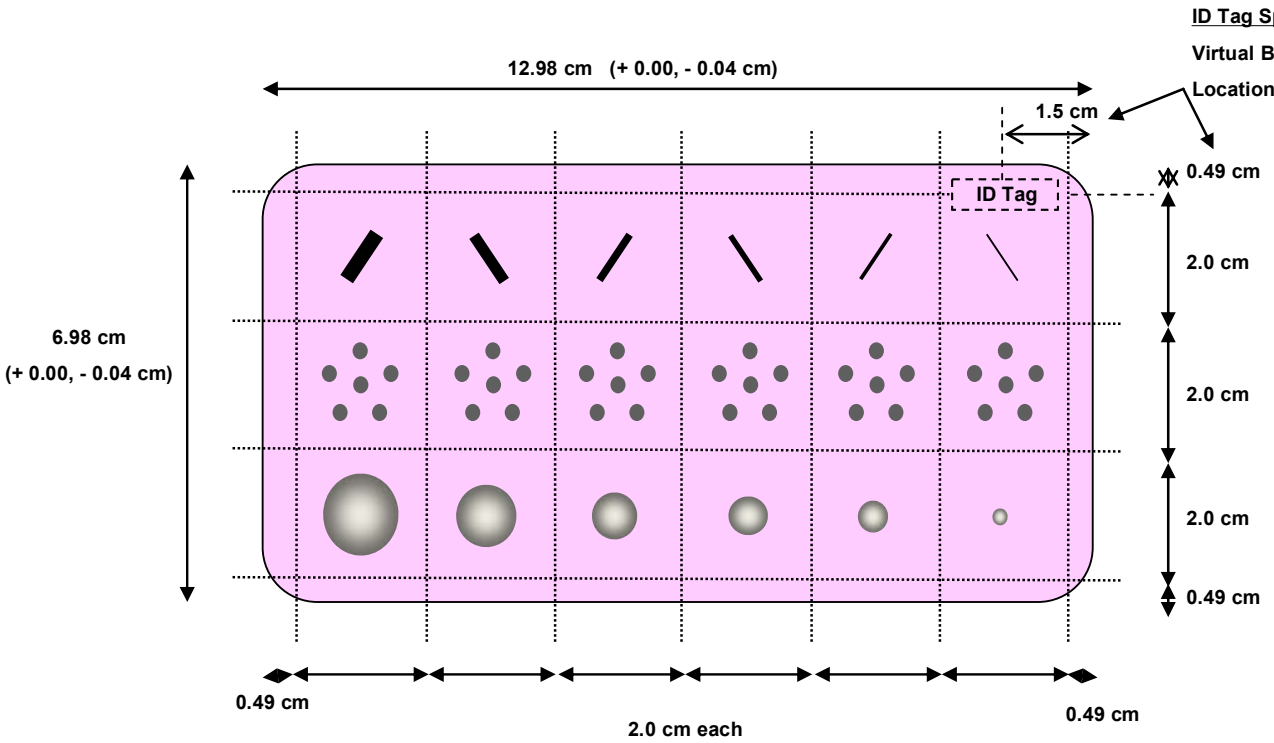
ACR Phantom Prototype

Tolerances (Insert Well & CNR Cavity)

- Wax insert well depth : ± 0.005 cm (± 2 mils).
- Wax insert well width and length : + 0.04 / -0.00 cm.
- CNR cavity depth : ± 0.005 cm (± 2 mils).
- CNR diameter : ± 0.05 cm.



Wax Insert Specifications with Virtual "Placement Grid"



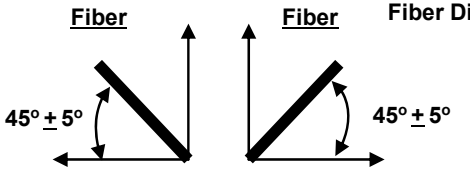
Notes:

Test objects to be centered on their respective "placement grid" locations.

0.49 cm perimeter around test object "placement grid".

0.635 cm (1/4 inch) radius on corners of wax insert.

Fiber Placement specs



Fiber specifications

Fiber Length = 1.0 cm ± 0.1 cm

Fiber Diameter = See Table

Speck Placement & Specs

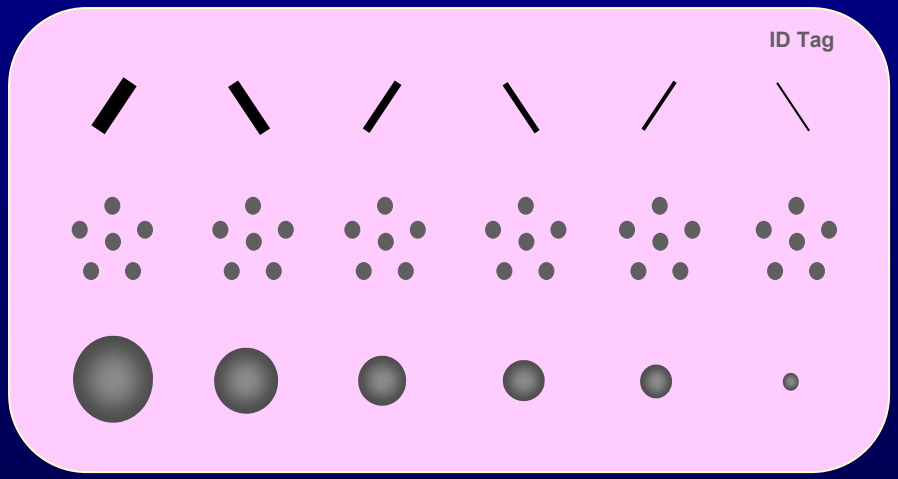
1. Specks to be placed at points on star and middle of star
2. Speck Size (spherical) = See Table
3. Center speck placement to be within ± 0.1 cm of center of virtual grid
4. Distance from center speck to center of speck on perimeter = 0.5 cm ± 0.1 cm

Mass Placement & Specs

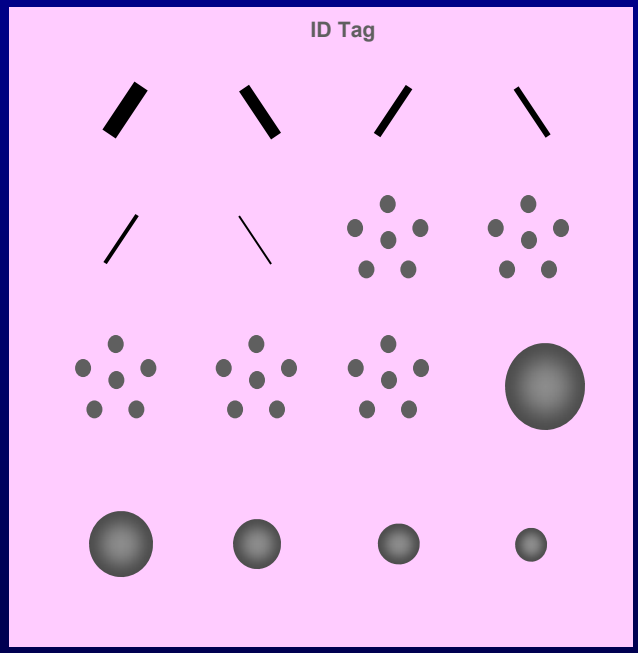
1. Mass pre-cut sphere diameter = 5/8 inch
2. Mass placement to be within ± 0.1 cm of center of virtual grid

Wax Insert Comparison

FFDM



SFM



Summary of Test Object "Visual Equivalency"

Test Object	Fibers (mm)		Specks (mm)		Masses (mm)	
	ACR 156	FFDM	ACR 156	FFDM	ACR 156	FFDM
	1.56					
	1.12		0.54		2.00	
	0.89	0.89	0.40		1.00	1.00
	0.75	0.75	0.32	0.33	0.75	0.75
		0.61		0.28	0.50	0.50
	0.54	0.54	0.24	0.23		0.38
	0.40	0.40		0.20	0.25	0.25
		0.30	0.16	0.17		0.20
				0.14		

Pass/Fail Criteria

Test Object	Fibers (mm)		Specks (mm)		Masses (mm)	
	ACR 156	FFDM	ACR 156	FFDM	ACR 156	FFDM
	1.56					
↑	1.12		0.54		2.00	
Fail	0.89	0.89	0.40		1.00	1.00
Pass	0.75 (4) ↔	0.75 (2)	0.32 (3)	0.33	0.75 (3) ↔	0.75 (2)
↓		0.61		0.28	0.50	0.50
	0.54	0.54	0.24	0.23 (3)		0.38
	0.40	0.40		0.20	0.25	0.25
		0.30	0.16	0.17		0.20
				0.14		

Wax Insert Test Object Specifications

Test Object	Fiber Diameter	Speck Diameter (Glass Spheres)	Mass Thickness
	mm	mm	mm
1	0.89 ± 0.05	0.33 ± 0.0100	1.00 ± 0.05
2	0.75 ± 0.03	0.28 ± 0.0083	0.75 ± 0.05
3	0.61 ± 0.03	0.23 ± 0.0069	0.50 ± 0.05
4	0.54 ± 0.03	0.20 ± 0.0059	0.38 ± 0.04
5	0.40 ± 0.03	0.17 ± 0.0084	0.25 ± 0.03
6	0.30 ± 0.03	0.14 ± 0.0070	0.20 ± 0.02

The ACR FFDM Phantom Prototype

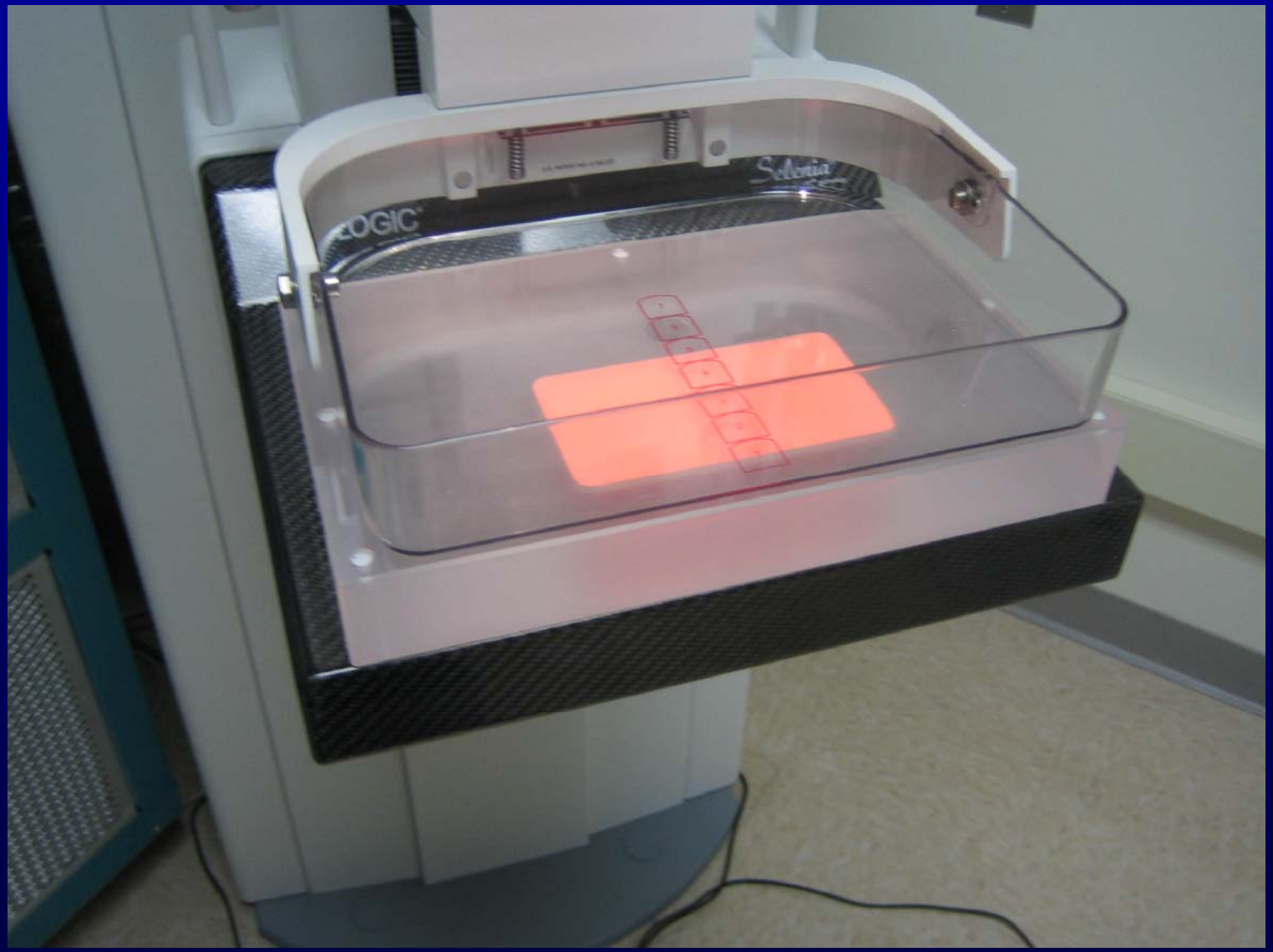


Image of Entire Phantom

*Note: Gray dot in lower left corner of wax insert is an artifact due to a bubble in wax insert.

Expanded view of Wax Insert

Wax Insert

Expanded view of Wax Insert

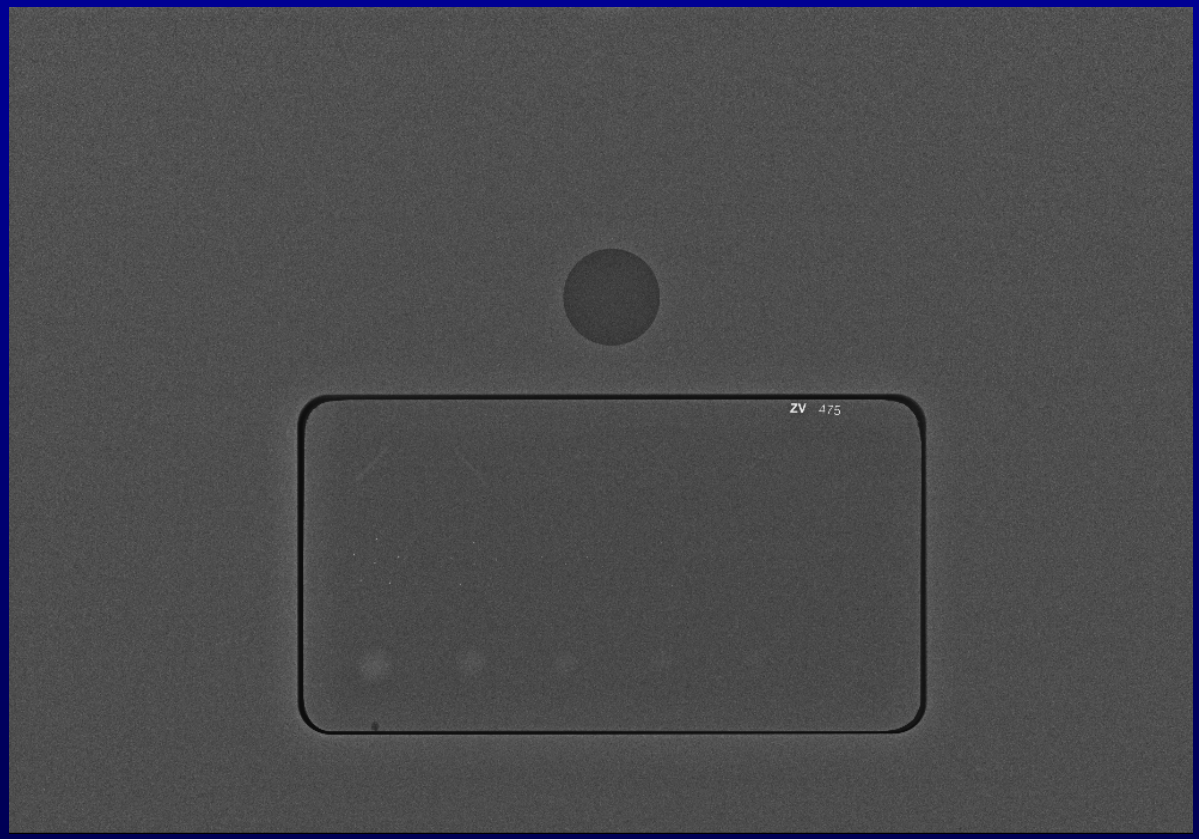
Pass Criteria: ***2 Fibers, 3 Specks, 2 Masses***

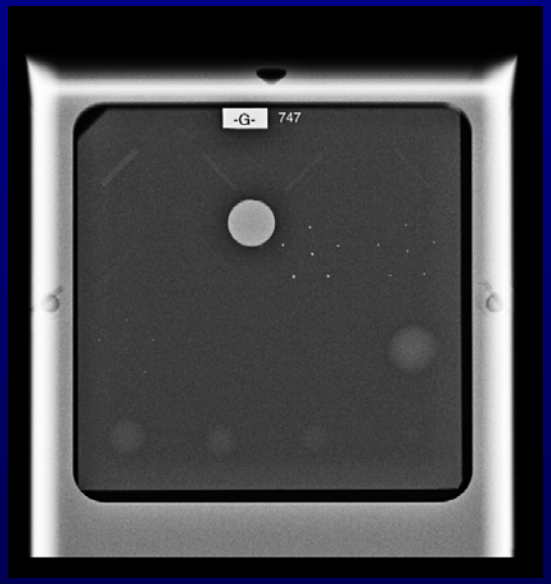
Equivalent to SFM Phantom: ***4 Fibers, 3 Specks, 3 Masses***

Image of Entire Phantom Prototype

CNR

Effects of Thickness Equalization

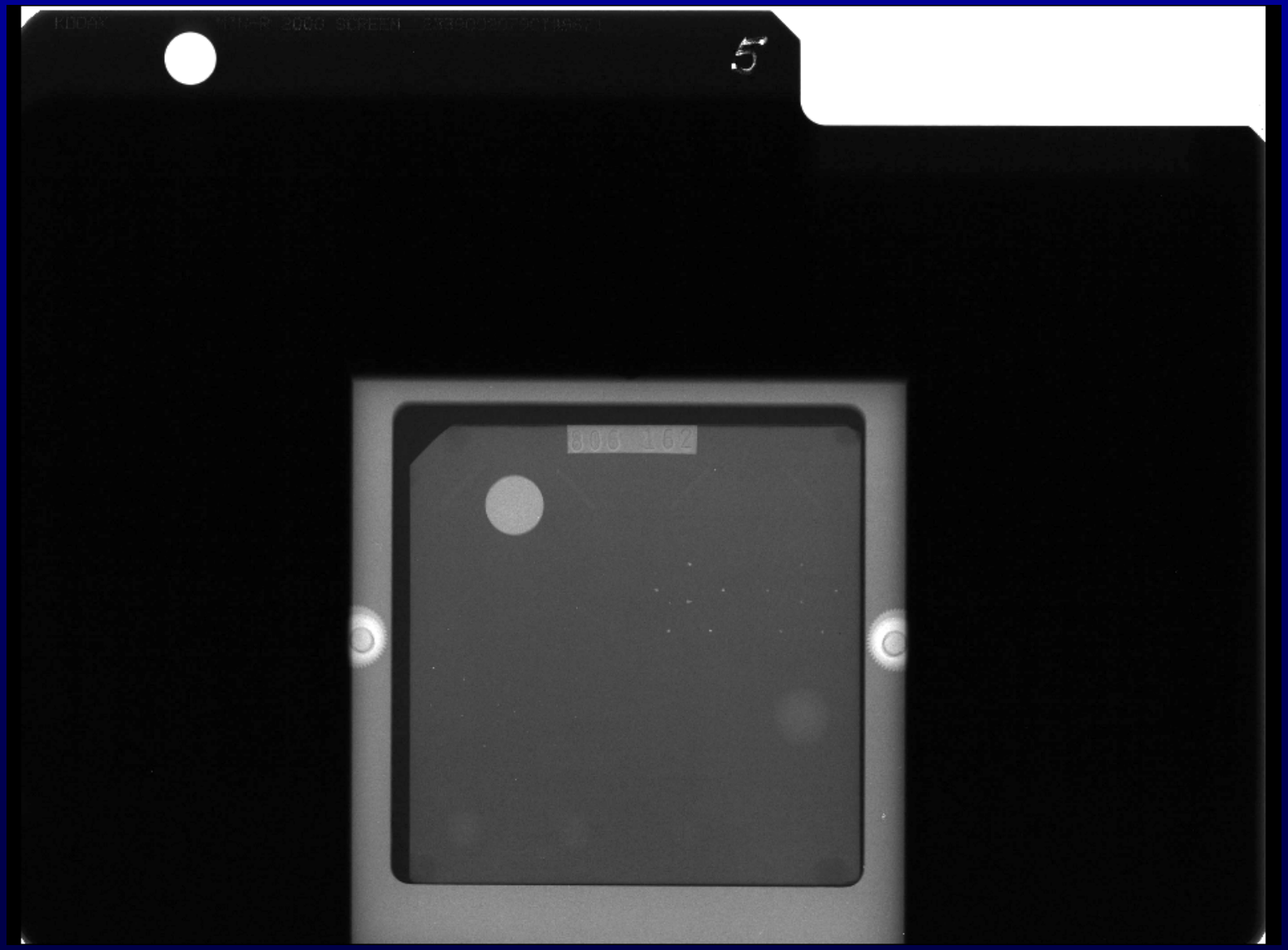




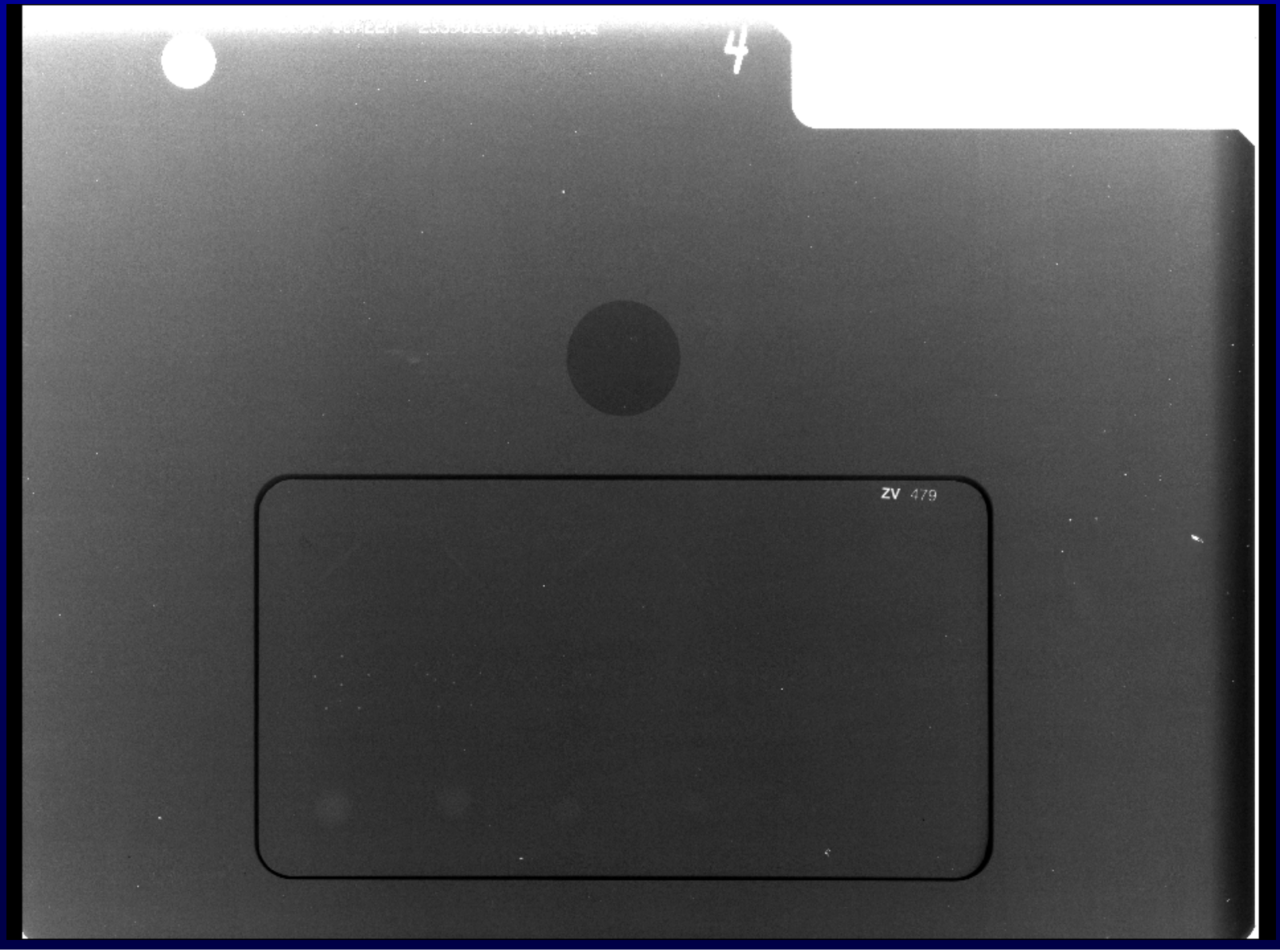
- New FFDM phantom equalizes attenuation inside and outside wax insert.
- This permits evaluation of artifacts over entire phantom area with same WW and WL used to score test objects.

CR 24x30

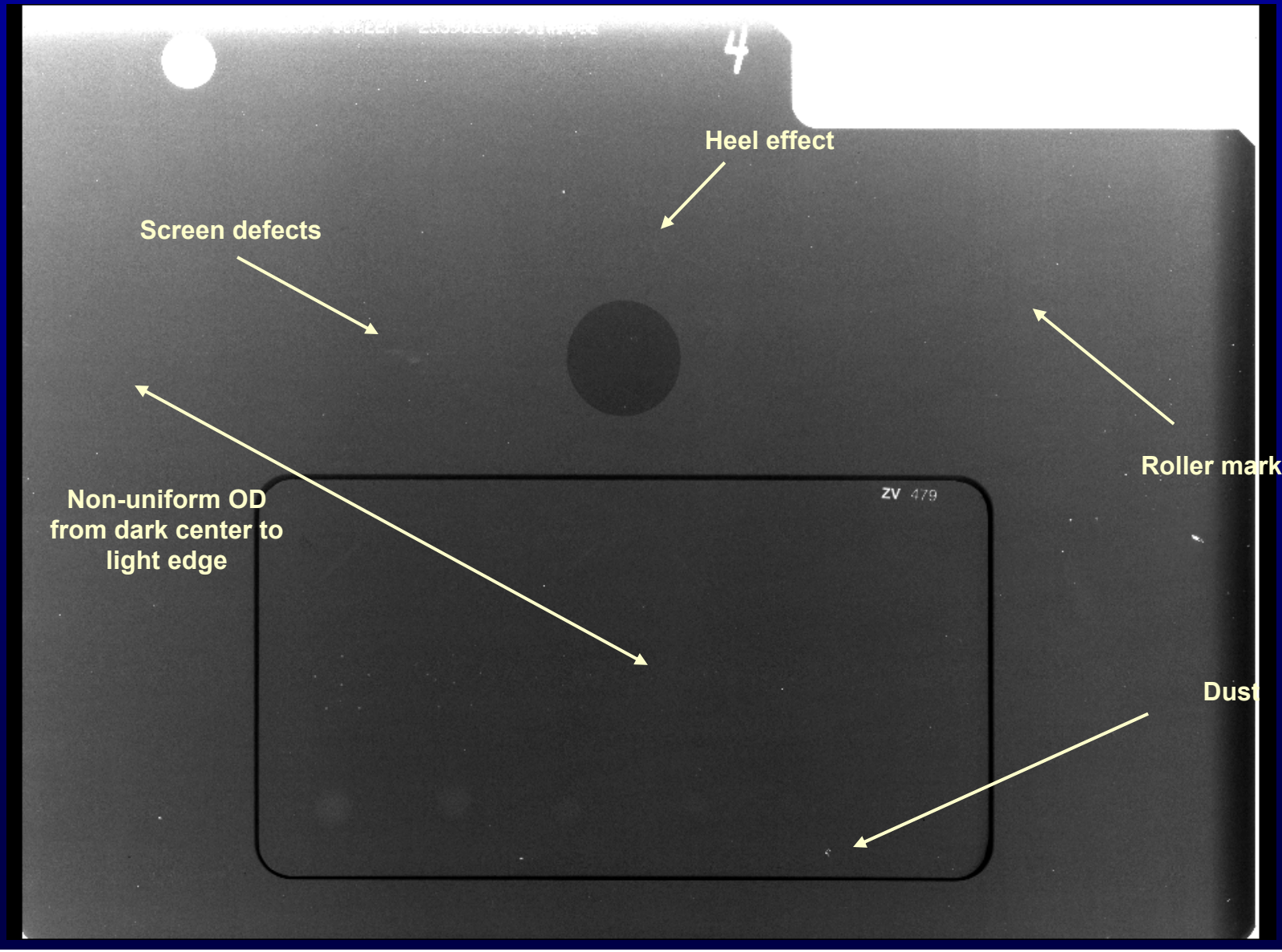
Screen-Film 18x24



Screen-Film 18x24



Screen-Film 18x24



Manual Technique Signal Comparison

	Lorad – Mo	
Mode	Manual	
Phantom	FFDM Prototype	SFM
Target/Filter	Mo/Mo	Mo/Mo
kVp	29	29
mAs	65	65
Signal Wax	542.0	546.5
St. Dev. Wax	9.7	9.7

AEC Technique Comparison

	Lorad – Mo		Lorad - W		Fuji CR 18 x 24 cm		Fischer	
Mode	Auto-Filter		Auto-Filter		AA		Auto-Technique	
Phantom	FFDM	SFM	FFDM	SFM	FFDM	SFM	FFDM	SFM
Compression Thickness (cm)	5.2	5.2	5.2	5.2	4.0	4.0	5.74	4.05
Target/Filter	Mo/Mo	Mo/Mo	W/Rh	W/Rh	Mo/Mo	Mo/Mo	W/Al	W/Al
kVp	29	29	28	28	27	27	31	27
mAs	66.4	65.4	92.5	97.6	90	89	177 mA	158 mA
Machine Reported Dose (mGy)	1.64	1.61	1.03	1.08	**	**	0.954	1.211

Design Summary

- Measurements using the FFDM Phantom
  - Phantom used in
    - 3 of 11 Tech tests
    - 12 of 24 Tech sub-tests
    - 7 of 17 Physicists tests
    - 19 of 48 Physicist sub-tests

50% Tech Tests

41% Physics Tests

ACR Digital QC Draft Manual

- Benefits of Prototype Phantom Design
  - Provides view of entire detector – artifact evaluation
  - W/L optimized for test objects optimizes for artifact eval
  - Finer gradations of test objects
  - Test objects go to smaller sizes
  - AGD measurement & limit same as SFM – Meets MQSA
  - Provides single image/exposure for evaluation(s)
  - Minimal training (~ 25,000 Techs currently trained)
  - Provides basis for monitor and laser printer QC
  - ACR Physics Reviewers
    - Can see scores and artifacts on single submitted film (or image)
    - Do not need different WW/WL settings

Tech Tests

9. Facility QC Review

Frequency: Tech Quarterly

Facility: _____ **Date of QC Mtg:** _____

	Reviewed
1. Review and update "Facility Equipment Form"	☐
2. Review Medical Physics Surveys and Results	☐

	Room 1	Room 2	Room 3	Room 4	Room 5
Room ID					
Date of last Medical Physicist (MP) survey					
Written survey results communicated to Radiologist by MP?					
"Summary Report" \reviewed by Radiologist?					
All MP corrective action completed?					
ACR Phantom Dose (mGy)					
Fibers					
Specks					
Masses					

3. Review Tech QC

	Test	*Frequency*	*Summary Comments from Last Quarter*	
1	**ACR Phantom Image Quality**	Weekly		☐

Scores of most recent phantom image:	Room 1	Room 2	Room 3	Room 4	Room 5
Room ID					
Fibers					
Specks					
Masses					
Artifacts? (Yes/No)					

2	**AW Monitor QC**	Weekly		☐
3	**RW Monitor QC**	Weekly		☐
4	**Laser Printer QC**	Weekly		☐
5	**Viewbox Cleanliness Check**	Weekly		☐
6	**Visual Checklist**	Monthly		☐
7	**Repeat Analysis**	Quarterly	% Repeats ____	☐
8	**Monitor QC for the Radiologist**	Quarterly		☐
9	**Facility QC Review**	Quarterly		☐
10	**Compression Force**	Semiannual		☐
11	**Manufacturer Detector Calibration (If App.)**			☐

4. Review and verify completion of all "Corrective Action".		☐
5. Technique Chart review for each room (see MP report for recommended chart) - (Annually).		☐
6. Offsite RW(s) & Laser Printer(s) QC Reviewed.		☐
7. Recent past and future service or service upgrades reviewed and discussed (if app).		☐
8. Recent past and future State and/or MQSA inspections reviewed and discussed (if app).		☐
9. ACR Accreditation issues discussed (if app.)		☐

Lead Interpreting Radiologist | Facility Manager (If App) | Lead QC Tech

Tech Tests

9. Facility QC Review - Cont'd

Frequency: Tech Quarterly

Facility: _____ **Date of QC Mtg:** _____

QC Meeting Notes

6. Significant or notable findings during QC meeting

Follow-up Confirmed (If App.)

7. Items for quality improvement from QC Meeting

8. Other QC Notes:

Action Limit:	Supervising radiologist and facility manager must review QC quarterly. Technologist should update the Facility Summary Form at least annually. Technologist and Lead Intepreting Radiologist should review technique charts at least annually for each FFDM system. **Timeframe:** NA

Corrective Action Log

Facility Name _____ **MAP ID# (00000-00)** _____

Room or Equipment ID _____ **Date** _____

QC Test Name and # (if app.): _____

Description: _____

Relevant Personnel Notified:

(Rad, MP, Tech, Manager, Service Engineer)

Personnel Name:	Date/Time of Call/Notification:
_____	_____
_____	_____
_____	_____

Describe Actions Taken: _____

Confirmation of Resolution:	**Yes**	**To Be Monitored**	**NA**
Event resolved?	☐	☐	☐
Documentation from Service Engineer Obtained?:	☐	☐	☐

Tech Signature _____

Date _____

Tech Tests

Facility Equipment Inventory Form

Facility _____

Address _____

Address _____

Address _____

QC Technologist: _____

Lead Interpreting Radiologist _____

Medical Physicist: _____

Facility Manager _____

Date Last Updated: _____

List facility and equipment data for entire breast imaging network.

Facility Location	Example: Main Breast Center					
MAP ID	12345					
Location Designation	Room 3					
Device (See Key Below)	FFDM					
Manufacturer	GE					
Model	2000D					
Serial Number	1234-56-7890					
Customer Service ID	111-222-333					
Service Telephone #	800-123-4567					
Date of Manufacture	December-09					
MP Survey Date	9/17/2011					
MP Survey Date	9/23/2012					
MP Survey Date	9/5/2013					
MP Survey Date	9/13/2014					
MP Survey Date	etc…					
MP Survey Date						
MP Survey Date						
MP Survey Date						
MP Survey Date						
MP Survey Date						
MP Survey Date						

Device Key

FFDM = Full Field Digital Unit
SFM = Screen-Film Unit
CR = Computed Radiography Unit
LP = Laser Printer
FP = Film Processor for Screen-Film Unit
AW = Acquisition Workstation
RW = Radiologist Workstation.

MP Tests

1. ACR Phantom Image Quality

Facility Name	Anywhere Breast Center	**Room ID, Mfr & Model**	**Room 1, Hologic Selenia**
ACR Phantom Serial Number:	123	**MAP ID-Unit#** *(00000-00)*	10/18/1933
SID (cm):		**Survey Date**	March 4, 2011

Procedure

Required Eqpt: ACR FFDM Phantom, foam pad(s) if used clinically

- Largest image receptor size and clinical paddle (reg. or flex)
- Clinical technique for typical screening patient
- Apply 5 daN or 12 lbs comp. force
- Use typical # of foam pads (0, 1, or 2) (top, bottom, both)
- Score and analyze on AW
- Adjust W/L to optimize test objects, do not subtract for artifacts
- Must zoom and pan across entire image to evaluate artifacts
- SNR & CNR data must be obtained from raw image
- Image Config 2 & 3 using kVp & mAs closest to phantom techniques (both contact & mag modes)
- Measure distance across wax insert parralle to AC axis (perpendicular to chest wall edge).

Phantom Setup

Paddle Size (IR Size):	
Paddle Type (Reg or Flex):	
Exposure Mode:	
Compression Force:	12 lbs or 5 daN
AEC Cell Position (If Avail):	Center of wax
Target/Filter (If App.):	
kVp (If App.):	
Density Setting (If App.):	
Foam Pad(s): 0, 1, or 2 (If App.)?	
Foam Pad (top, bottom, both) (If App.)?	

For Radiologist Review: ACR Phantom Patient Name:

For Radiologist Review: ACR Phantom Patient ID:

For Radiologist Review: ACR Phantom Date:

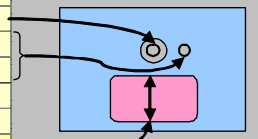
Image Sent to Which PACS?:

Image Sent to Which RW?:

Image Sent to Which Printer?:

		Contact Mode			Mag Mode		
		Clinical - ACR Phantom	Manual - Target/Filter Config 2	Manual - Target/Filter Config 3	**Clinical** - Target/Filter Config 1	Manual - Target/Filter Config 2	Manual - Target/Filter Config 3
Resulting Techniques from Image Acquisition	Target/Filter						
	kVp						
	mAs						
	Machine Indicated AGD (mGy)						
	Compression Thickness (mm)						
Artifacts	Artifacts? (P or F)						
Phantom Scores & Artifacts	Fiber Score						
	Speck Group Score						
	Mass Score						
	Overall Phantom (P or F)						
Exposure Time	mA						
	Exposure Time (s)						
	Exposure Time < 2.0 sec. (P or F)						
SNR & CNR	DC Offset (if applicable)						
	Signal in Cavity						
	Signal in Background						
	Std. Dev. in Background						
	SNR						
	CNR						
	SNR & CNR (P or F)						
Distance	Parallel to Anode-Cathode Axis (mm)						
	Distance Measurement (P or F)						
Overall Phantom Pass/Fail (P or F)							

	Full Point	1/2 point
Fiber	10 ± 2 mm	5 to 8 mm
Specks	4 to 6 specks	2 or 3 specks
Masses	75-100% of circle	50-75% of circle



SNR = (Signal Bkgd - DC Offset if app.) / Std Dev Bkgd

CNR = (Signal Cavity - Signal Bkgd) / Std Dev Bkgd

Action Limits

- Fiber score must be ≥ 2.0
- Speck Group score must be ≥ 3.0
- Mass score must be ≥ 2.0
- The ACR Phantom image must be free of clinically significant artifacts.
- Exposure duration time must be ≤ 2.0 seconds for the clinical technique in contact and mag mode.
- SNR must be ≥ 40
- CNR TBD
- Distance of wax insert = 70.0 mm ± 7.0 mm
- **Timeframe:** Before clinical use on any of the above parts.

D = Kgcs

D = Mean Glandular Dose

K = Entrance surface air kerma

g = glandularity of 50%

c = corrects for difference in composition (age dependent)

s = X-ray spectrum correction (Target/Filter)

Note: g and c depend on thickness, glandularity, and HVL.

Primary Ref: D.R. Dance, et al. Additional for the Estimation of Mean Glandualar Breast Dose Using the UK Mammography Dosimetry Protocol. Physics in Medicine and Biology 45, 3225-3240, 2000.

8. Average Glandular Dose

Facility Name _____ Room ID, Mfr & Model: Room 1, Hologic Selenia

MAP ID-Unit# *(00000-00)* _____

Survey Date _____

Procedure

Required Eqpt: Dosimeter

Foam Pad(s): 0, 1, or 2? _____

Use techniqeus from ACR Phantom image page & AEC page.
Measure mR/mAs or total exposure for dose calculations.
If applicable, position foam pads similar to clinical use (0, 1, or 2) (top, bottom, both).

ACR FFDM Phantom S/N _____ SID (cm) _____

Dosimeter Mfr/Model _____ Source-detector distance (cm) _____

Dosimeter correction factor _____ source-bucky distance (cm) _____

Calibration Date _____

		ACR Phantom	2 cm	4 cm	6 cm
Manual Technique Factors	Actual Phantom Thickness (cm)	4.1	2.0	4.0	6.0
	AEC Mode				
	Target/Filter				
	kVp				
	mAs				
	Measured HVL (mm Al)				
AGD Exposure Data	Exposure #1 (R)				
	Exposure #2 (R)				
	Exposure #3 (R)				
	Mean values	#DIV/0!			
	Standard deviation	#DIV/0!			
	Coefficient of Variation	#DIV/0!			
	Coef of Var. Compliance	#DIV/0!			
AGD Calculation — D = Kgcs Method	**K**				
	g				
	c	#DIV/0!			
	s	#DIV/0!			
	Computed AGD (mGy)				
	Compliance	**Pass**			
	Indicated Machine AGD (mGy)				
	Unit Reported Dose Within ± 25% of MP Measured Dose				
	Previous Year's Computed AGD (mGy) (If Available)				

Action Limits

Unit Reported AGD should be within ± 25% of measured AGD.
MQSA: The AGD delivered during a single cranio-caudal view of the ACR Phantom shall not exceed 3.0 mGy.
Timeframe: Before clinical use.

MP Tests

14. Radiologist Workstation (RW) Monitor QC

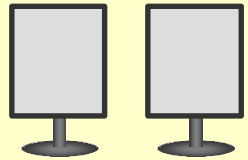
Facility Name _____ **Workstation ID** RW #1

Medical Physicist *(If app)* _____ **MAP ID#** *(00000)* _____

Signature *(If app)* _____ **Survey Date** _____

Procedure	**Required Eqpt:** ACR Phantom Image, Photometer Monitor screen eval: adjust window level to bright white for visual evaluation. Defective pixel check: adjust window level to bright white and all black for visual evaluation. ACR Phantom: use phantom acquired from any FFDM within facility network, preferably one MP has acquired. Clinical Image Check: bring up same clinical image on both monitors for visual evaluation.

Part 1 Visual Inspection

		Left Monitor	Right Monitor
	Monitor Manufacturer		
	Monitor Model		
	Monitor Serial Number		
	Monitor Date of Manufacture		
Monitor Screen Evaluation	Screen free of scratches, defects, etc.?		
	Screen free of fingerprints, dust, and marks?		
	Defects indicated on figures at right		
Defective Pixel Check	Monitor all black: No defective pixels		
	Monitor all white: No defective pixels		
TG18-QC Test Pattern Evaluation	Test pattern artifact free		
	Test pattern centered appropriately		
	Grayscale continuity adequate		
	0%-5% contrast visible		
	95%-100% contrast visible		
	Alphanumerics sharp		
	3 "Quality Control" patches visible		
	Line-pair images (center & corners)		
	Grayscale ramps smooth		
ACR Phantom	Artifact free*		
	Fiber score		
	Speck group score		
	Mass score		
	Distance measurement across wax insert (mm)		
	Distance 70 mm ± 7mm?		
Clinical Image Check (Monitor Comparison)	Does the image background match?		
	Does the color match?		
	Does the contrast look the same?		
	Overall Pass/Fail (P or F)		

Action Limits	Any identified defective pixels that could be clinically significant should be repaired. TG18-QC test pattern must pass all visual tests. Fiber score must be ≥ 2.0 Speck Group score must be ≥ 3.0 Mass score must be ≥ 2.0 *The ACR Phantom image must be free of clinically significant artifacts. Clinical image check must pass all tests. **Timeframe:** Before clinical use.

MP Tests

14. RW Monitor QC - Cont'd - Page 2 of 3

Facility Name _____ Workstation ID RW #1

Medical Physicist (If app) _____ MAP ID# *(00000)* _____

Signature (If app) _____ Survey Date _____

Procedure	**Required Eqpt:** Photometer Ambient light: Place meter on center of monitor surface facing away from monitor. Luminance Check: Utilize appropriate TG18 patterns or other patterns that give measure Lmax & Lmin. Luminance Uniformity: Utilize appropriate TG18 pattern or other pattern that give uniform image. MP to decide if Mfr tests apply to FFDM monitor QC.

Part 2 Quantitative Evaluation

		Left Monitor	Right Monitor
	Monitor Manufacturer		
	Monitor Model		
	Monitor Serial Number		
	Monitor Date of Manufacture		
Ambient Light Conditions	Illuminance at monitor surface (Lux)		
	(meter facing away from monitor)		
	Is ambient light conditions adequate for FFDM?		
Luminance Check	Luminance Minimum (cd/m2)		
	Lmin appropriate for FFDM?		
	Luminance Maximum (cd/m2)		
	Lmax appropriate for FFDM?		
	Luminance Ratio (Lmax/Lmin)	#DIV/0!	#DIV/0!
	Luminance Ratio adequate?		
	Left-Right monitor ratio (Min luminance)	#DIV/0!	
	Left-Right monitor ratio (Max luminance)	#DIV/0!	
	Left-Right monitor ratio's adequate?		
Luminance Uniformity	Center		
	Upper Left		
	Upper Right		
	Lower Left		
	Lower Right		
	Uniformity error		
	Uniformity pass?		
Manufacturer Recommended QC Tests (if Applicable)			
	Overall Pass/Fail (P or F)		

Action Limits	Ambient light conditions should be appropriate for interpreting digital mammograms (<10 lux). Total darkness is not recommended. Lmax and Lmin are Mfr recommendations. Typically Lmax ≥ 450 cd/m2 & Lmin < 1.0 cd/m2. Luminance ratio should be > 250. Ratio's for Right and Left monitors for Lmin and Lmax should be within 10% of each other. Luminance uniformity should be < 30% for CRT display and < 10% for LCD display. Mfr's tests must pass per manufacturer recommendations if applicable. **Timeframe:** Before clinical use.

MP Tests

14. RW Monitor QC - Cont'd - Page 3 of 3

Facility Name _____ **Workstation ID** RW #1

Medical Physicist *(If app)* _____ **MAP ID#** *(00000)* _____

Signature *(If app)* _____ **Survey Date** _____

Procedure

Required Eqpt: Photometer

Utilize appropriate TG18 patterns or SMPTE pattern that gives relevant luminance values for calculation of GSDF.
Note that different patterns may require different numbers of measured luminance steps.

Note: This test intended to be performed with MP's external photometer.

Part 3
DICOM GSDF

	Left Monitor	Right Monitor
Monitor Manufacturer		
Monitor Model		
Monitor Serial Number		
Monitor Date of Manufacture		

DICOM Grayscale Standard Display Function

	Luminance (cd/m2)	Luminance (cd/m2)
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		
Maximum deviation compared to DICOM (%)		
Overall Pass/Fail (P or F)		

Action Limits

Contrast response should not deviate from the DICOM GSDF contrast values by more than ± 10%.

Timeframe: Before clinical use.

MP Tests

17. Evaluation of Off-Site Technologist QC Program

Facility Name _____ Room ID, Mfr & Model _____

Medical Physicist (If app) _____ MAP ID-Unit# *(00000-00)* _____

Signature (If app) _____ Survey Date _____

Procedure	Required Eqpt:

List of Inventory for Off-site Facility

Device Description	Device Designation	Location or Rm ID	Manufacturer	Model

		Frequency	Pass/Fail/ NA	Missing Data	Incorrect Scoring or Calculations	Missing Corrective Action Documentation	Other
1	RW Monitor QC	Weekly		☐	☐	☐	☐
2	Laser Printer QC	Weekly		☐	☐	☐	☐
		Operating Levels correct and current?			☐ Yes	☐ No	
3	Viewbox Cleanliness Check	Monthly		☐	☐	☐	☐
4	"Corrective Action Log" documentation adequate?				☐ Yes	☐ No	

"Other" Description: _____

Action Limits	It is recommended that all QC Tests pass review by the MP and corrective action is documented correctly. **Timeframe:** 30 Days.

MP Tests

Medical Physicist's FFDM QC Test Summary

Facility Name	ABC Breast Center	*Room ID*	Room 1
Address	Dept of Radiology	*Survey Date*	February 16, 2011
Address	123 Smith Street	*Report Date*	February 16, 2011
Address	New York, NY 01234	*Medical Physicist*	MP Name Here, PhD
MAP ID Unit# (00000-00)	12345-01	*Signature*	Signature
X-Ray Unit Manufacturer	Lorad	*Telephone*	123-456-7890
X-Ray Unit Model	Selenia		
X-Ray Unit Control Serial #	12345	CR Unit Mfr	Fuji
X-ray Unit Date of Manufacture	December 20, 1995	CR Unit Model	MA5000
Date of Installation	January 20, 2009	CR Unit Serial #	1234567899

Unit Description: ☐ DR ☐ CR ☐ Tomosynthesis

Unit Type: ☐ Diagnostic & Screening Only ☐ Diagnostic Only ☐ Screening Only

Survey Type: ☐ Acceptance Testing - Mammography Equipment Evaluation (MEE) ☐ Routine Annual Survey

☐ Partial Testing Due To Service - Description: New Detector

Medical Physicist's QC Tests

("Pass" means all components of the test passes, indicate "Fail" if any components fails)

Medical Physicists Tests	Pass/Fail/NA	See Action Items
1. ACR Phantom Image Quality	Pass	☐
2. Ghost Image	Pass	☐
3. Spatial Resolution	Pass	☐
4. AEC System Performance	Pass	☐
5. Collimation	Pass	☐
6. kVp Accuracy & Repro. (MEE Only)	Pass	☐
7. Beam Quality (HVL)	Pass	☐
8. Average Glandular Dose	Pass	☐
9. Unit Checklist	Pass	☐
10. Evaluation Tech QC Program	Pass	☐
11. MQSA Requirements (MEE Only)	Pass	☐
12. Computed Radiography (if App)	Pass	☐
13. AW Monitor QC	Pass	☐

Tech QC Evaluation	Pass/Fail/NA	See Action Items
1. ACR Phantom Image Quality	Pass	☐
2. AW QC	Pass	☐
3. RW QC	Pass	☐
4. Laser Printer QC	Pass	☐
5. Viewbox Cleanliness	Pass	☐
6. Visual Checklist	Pass	☐
7. Repeat Analysis	Pass	☐
8. Monitor QC for the Radiologist	Pass	☐
9. Facility QC Review	Pass	☐
10. Compression Force	Pass	☐
11. Mfr Detector Calibration (If App.)	Pass	☐

	Pass/Fail/NA	All Surveyed	Subset Surveyed*	None Surveyed	All surveyed within last 12 months	See Action Items Below	See Included Reports	See Other Reports
14. RW Monitor QC	Pass	☐	☐	☐	☐	☐	☐	☐
15. Laser Printer QC	Pass	☐	☐	☐	☐	☐	☐	☐
16. Viewbox Lum. & Rm Illuminance	Pass	☐	☐	☐	☐	☐	☐	☐
17. Off-Site Tech QC Program (If App)	Pass	☐	☐	☐	☐	☐	☐	☐

Phantom Summary		Action Limit
Fiber Score:	2.0	≥ 2.0
Speck Score	3.0	≥ 3.0
Mass Score:	2.0	≥ 2.0
SNR	45.2	≥ 40.0
CNR	3.45	**
ACR AGD (mGy)	1.75	≤ 3.0
2 cm AGD (mGy)	1.75	**
4 cm AGD (mGy)	1.75	**
6 cm AGD (mGy)	1.75	**

Medical Physicist's FFDM QC Test Summary

Facility Name	**ABC Breast Center**	***Room ID***	**Room 1**
Address	Dept of Radiology	***Survey Date***	February 16, 2011
Address	123 Smith Street	***Report Date***	February 16, 2011
Address	New York, NY 01234	***Medical Physicist***	MP Name Here, PhD
MAP ID Unit# (00000-00)	12345-01	***Signature***	Signature
X-Ray Unit Manufacturer	Lorad	***Telephone***	123-456-7890
X-Ray Unit Model	Selenia		
X-Ray Unit Control Serial #	12345	**CR Unit Mfr**	Fuji
X-ray Unit Date of Manufacture	December 20, 1995	**CR Unit Model**	MA5000
Date of Installation	January 20, 2009	**CR Unit Serial #**	1234567899

Unit Description: ☐ **DR** ☐ **CR** ☐ **Tomosynthesis**

Unit Type: ☐ Diagnostic & Screening Only ☐ Diagnostic Only ☐ Screening Only

Survey Type: ☐ Acceptance Testing - Mammography Equipment Evaluation (MEE) ☐ Routine Annual Survey

☐ Partial Testing Due To Service - Description: New Detector

Medical Physicist's QC Tests

("Pass" means all components of the test passes, indicate "Fail" if any components fails)

Medical Physicists Tests	Pass/Fail/NA	See Action Items
1. ACR Phantom Image Quality	Pass	☐
2. Ghost Image	Pass	☐
3. Spatial Resolution	Pass	☐
4. AEC System Performance	Pass	☐
5. Collimation	Pass	☐
6. kVp Accuracy & Repro. (MEE Only)	Pass	☐
7. Beam Quality (HVL)	Pass	☐
8. Average Glandular Dose	Pass	☐
9. Unit Checklist	Pass	☐
10. Evaluation Tech QC Program	Pass	☐
11. MQSA Requirements (MEE Only)	Pass	☐
12. Computed Radiography (if App)	Pass	☐
13. AW Monitor QC	Pass	☐

Tech QC Evaluation	Pass/Fail/NA	See Action Items
1. ACR Phantom Image Quality	Pass	☐
2. AW QC	Pass	☐
3. RW QC	Pass	☐
4. Laser Printer QC	Pass	☐
5. Viewbox Cleanliness	Pass	☐
6. Visual Checklist	Pass	☐
7. Repeat Analysis	Pass	☐
8. Monitor QC for the Radiologist	Pass	☐
9. Facility QC Review	Pass	☐
10. Compression Force	Pass	☐
11. Mfr Detector Calibration (If App.)	Pass	☐

		All Surveyed	Subset Surveyed*	None Surveyed	All surveyed within last 12 months	See Action Items Below	See Included Reports	See Other Reports
14. RW Monitor QC	Pass	☐	☐	☐	☐	☐	☐	☐
15. Laser Printer QC	Pass	☐	☐	☐	☐	☐	☐	☐
16. Viewbox Lum. & Rm Illuminance	Pass	☐	☐	☐	☐	☐	☐	☐
17. Off-Site Tech QC Program (If App)	Pass	☐	☐	☐	☐	☐	☐	☐

Phantom Summary		Action Limit
Fiber Score:	2.0	≥ 2.0
Speck Score	3.0	≥ 3.0
Mass Score:	2.0	≥ 2.0
SNR	45.2	≥ 40.0
CNR	3.45	**
ACR AGD (mGy)	1.75	≤ 3.0
2 cm AGD (mGy)	1.75	**
4 cm AGD (mGy)	1.75	**
6 cm AGD (mGy)	1.75	**

Medical Physicist's FFDM QC Test Summary

Medical Physicist's QC Tests - Cont'd

Facility Name	**ABC Breast Center**	***Room ID***	**Room 1**
MAP ID Unit# (00000-00)	12345-01	***Survey Date***	December 25, 2010
		Medical Physicist	MP Name Here, PhD
		Signature	Signature

Action Item Summary*

**Note: This is only a summary page, the Corrective Action Log Form may contain further details.*

Required or Recommended	Time Frame	Description	Utilize Corrective Action Log Form	Date Completed	Initials
Required	Immediately	1. Artifacts seen on detector, perform recalibration	X		
Required	Immediately	2. CNR outside limits, give copy of Corrective Action Log form to service engineer.	X		
Required	30 Days	3. Collimation is out of compliance, give copy of Corrective Action Log Form to a qualified service engineer.	X		
Recommended	30 Days	4. Post and follow the new Technique Chart on Page X.			
NA	NA	5. QC Tech doing outstanding job with performing and documenting QC. Keep up the good work.			

MP Tests

Medical Physicist's FFDM QC Test Summary

Technologist Operating Level Information and QC Instruction Form

Facility Name	**Anywhere Breast Center**	***Room ID***	**Room 1**
MAP ID Unit# (00000-00)	12345	***Survey Date***	March 4, 2011
Medical Physicist	MP Name, PhD	***Telephone***	303-111-2222

Survey Type

- ☐ Acceptance Testing - Mammography Equipment Evaluation (MEE)
- ☐ Routine Annual Survey
- ☐ Partial Testing Due To Service

Instructions

1. Place entire report in QC notebook.
2. Update the "Baseline Values" reported below into your QC records for the applicable tests.
3. Read the "Action Items" on the Medical Physicist's Report, address necessary corrective action, and document on the Corrective Action Log Form.
4. Read the instructions below for monitor and/or detector calibration QC and implement in QC records (if app).
5. Please call your Medical Physicist if **any** of the following occur:
   - **a:** Equipment failures - software or hardware.
   - **b:** Equipment moves, replacements, upgrades, service work, or software changes.
6. See below for instructions on obtaining "raw" images for QC analysis (If applicable).
7. See included forms and/or films to help you perform QC (if app).
9. Post the new technique chart (if provided).

Operating Levels

New Value[1]	No Change[2]	Value	
☐	☐	Auto-Filter	Imaging mode to be used for ACR Phantom QC.
☐	☐	10 x 12 (Large)	Paddle size to be used for ACR Phantom QC.
☐	☐	1	# of foam pads used for majority of Pt. imaging & QC (0, 1, or 2).
☐	☐	1.76	Operating Level (OL) for indicated AGD (mGy) for Phantom.
☐	☐	10 x 12	Film size to be printed for Laser Printer QC (should match paddle size).
☐	☐	File Room Wkstn	Device for printing films for Laser Printer QC.
☐	☐	1.88	OL for "Background OD" for Laser Printer QC.
☐	☐	0.78	OL for "Contrast OD" for Laser Printer QC.
☐	☐	Auto-Filter	Recommended clinical imaging mode (See Technique Chart).

[1]Update your QC forms with new baseline value. [2]Baseline value does not change.

Phantom Image Quality Comparison

	Physicist Scores	Tech Scores
Fibers	2.0	2.0
Specks	3.0	3.0
Masses	2.0	2.0

Comments:

Additional QC Instructions for Monitors and/or Detector[1]

Additional or Updated QC Instructions

Yes	No	
☐	☐	**Acquisition Workstation Monitor**
☐	☐	**Radiologist Workstation Monitors**
☐	☐	**Detector Calibration**

[1]See attached page(s) for detailed instructions.

MP Tests

Medical Physicist's FFDM QC Test Summary

Technologist Operating Level Information and QC Instruction Form - Cont'd

Facility Name	Anywhere Breast Center	*Room ID*	Room 1
MAP ID Unit# (00000-00)	12345	*Survey Date*	March 4, 2011
Medical Physicist	MP Name, PhD	*Telephone*	303-111-2222

Required Monitor QC Tests per Medical Physicist (If Applicable):

Acquisition Workstation Monitor

Mfr QC Test Name	Frequency	Instructions	Action Limits
Automatic Cal	Weekly	1. Start by…..	Must pass

Radiologist Workstation Monitors

Mfr QC Test Name	Frequency	Instructions	Action Limits
Automatic Cal	Weekly	1. Start by…..	Must pass

Detector Calibration

Mfr QC Test Name	Frequency	Instructions	Action Limits
Detector Calibration	Weekly	1. Start by…..	Must pass

MP Tests

Medical Physicist's FFDM QC Test Summary for the Radiologist

March 4, 2011

Anywhere Breast Center
1234 Smith Road
Suite 900
New York, NY, 12345

Re: Medical Physicist Survey:	Room & Unit Mfr/Model	Survey Date
	Room 1, Hologic Selenia	03/04/2011

Dear Lead Interpreting Radiologist,

On April 12, 2010 Room #1 (Hologic Selenia) at Anywhere Breast Center underwent an annual Medical Physics survey. Below is the relevant summary information as a result of this survey. Please note that your facility must follow-up on the Action Items below and obtain relevant documentation from the service engineer. Please evaluate the ACR Phantom image acquired during the Medical Physicist testing (Image ID information listed below) and see my comments. If you have any questions please don't hesitate to call.

- **Image Quality**

Patient Name: Phantom Image Room 1
Patient ID: 1234
Date: 04/22/2010

ACR Phantom Scores

	Your Unit Room 1	Passing Criteria	Pass /Fail
Fibers	2.0	≥ 2.0	**Pass**
Speck Groups	3.0	≥ 3.0	**Pass**
Masses	2.0	≥ 2.0	**Pass**
Artifacts	None	No Clinically Significant Artifacts	**Pass**

Comments on Phantom Image: ACR image has artifacts galore and detector should be replaced.

- **Radiation Dose**

Phantom Radiation Dose Values

	Your Unit		Pass /Fail
ACR Phantom Dose (mGy)	1.52	≤ 3.0	**Pass**
2 cm breast dose (mGy)	0.52	NA	
4 cm breast dose (mGy)	1.46	NA	
6 cm breast dose (mGy)	2.85	NA	

Note: Above doses are estimates measured for phantoms, not patients. Specific patient doses can be calculated by the Medical Physicist.

Comments on Radiation Dose: Doses are in acceptable ranges.

MP Tests

ACR FFDM Medical Physicist Summary for the Radiologist - Cont'd

- **Required Action Items**

Time Frame	Description
Immediately	1. Artifacts are seen on the detector. Service should recalibrate.

- **Recommended Action Items**

Time Frame	Description
30 Days	1. An updated techniqe chart was generated and it is recommended that it is posted and followed.

- **Comments on Monitors, Monitor QC, & Viewing Conditions**

Time Frame	Description
NA	Add general statement from ACR on lighting conditions.

- **Comments on Tech QC**

Time Frame	Description
NA	1. Tech QC is being performed above and beyond expectations.
NA	2. QC records are in excellent order.

If you have any questions, please do not hesitate to call.

Sincerely,

Signature _____ Phone _____

MP Name Email _____

MP Tests

16. Technique Chart

Facility Name Anywhere Breast Center

Room ID, Mfr & Model Room 1, Hologic Selenia

MAP ID-Unit# *(00000-00)* 12345

Survey Date March 4, 2011

Screening/Diagnostic Mammography

Compressed Breast Thickness	Fatty		50% Fatty - 50% Dense		Dense	
	Mode	Density	Mode	Density	Mode	Density
<3 cm						
3 to 5 cm						
5 to 7 cm						
> 7 cm						

Manual Techniques

Compressed Breast Thickness	Fatty		50% Fatty - 50% Dense		Dense	
	Mode	Density	Mode	Density	Mode	Density
<3 cm						
3 to 5 cm						
5 to 7 cm						
> 7 cm						

Implant Displaced Views

Compressed Breast Thickness	Fatty		50% Fatty - 50% Dense		Dense	
	Mode	Density	Mode	Density	Mode	Density
<3 cm						
3 to 5 cm						
5 to 7 cm						
> 7 cm						

Magnification Views

Compressed Breast Thickness	Fatty		50% Fatty - 50% Dense		Dense	
	Mode	Density	Mode	Density	Mode	Density
<3 cm						
3 to 5 cm						
5 to 7 cm						
> 7 cm						

Specimen Radiography

Compressed Breast Thickness	Small		Mediuim		Large	
	Mode	Density	Mode	Density	Mode	Density
<3 cm						
3 to 5 cm						
5 to 7 cm						
> 7 cm						

Signature

MP Name

Summary

- QC Tests
  - We did take into consideration the following:
    - MQSA, ACR SFM Manual, ACRIN DMIST results, Manufacturer's QC programs (FFDM, CR, Monitor, Printer), MITA, European Guidelines, AAPM TG18, and others...
  - Subcommittee and others clinical experience

Challenges

- Accounting for, and incorporating, all the different FFDM technologies
- Handling offsite equipment
- Predicting and accounting for future FFDM systems
- Ensuring all necessary tests are included, meaningful, and relevant

What's Next

3 Steps

- When ready, draft will be sent to manufacturers, FDA, and select reviewers for preliminary feedback
- Subcommittee to review comments and edit manual
- Final draft to be sent to FDA from ACR to apply for alternative standard under current regulations
  - Alternative standard will allow facilities to use this instead of the manufacturer's manuals
  - Potential for ACR QC Manual to be basis for new MQSA Regulations

Preemptive Questions

- Cost of phantom?
  - Don't know. Reason to believe it will be affordable.
- Implementation and roll-out?
  - ACR to develop a plan to include some sort of training.
- When?
  - Draft review is underway.

End of Presentation

Questions?

Learning Objectives

- Describe current QC procedures for FFDM
- Describe the upcoming ACR FFDM QC Manual
- Describe the Prototype ACR Phantom
- Introduce the documentation procedures for the upcoming ACR FFDM QC Manual