ACR® AMERICAN COLLEGE OF RADIOLOGY
QUALITY IS OUR IMAGE

Quality and Safety in Mammography

Priscilla Butler, MS, FAAPM, FACR, FSBI
Retired
American College of Radiology

1

I have no conflicts…I'm retired!

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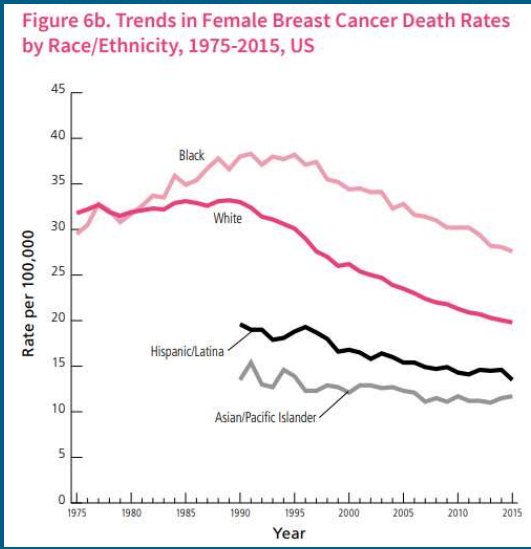
2

Breast Cancer

- 2nd most common CA in US women (skin CA is higher)
  - 1 in 8 women will develop breast CA
- 2nd leading cause of CA death in women (only lung cancer kills more)
  - 1 in 38 women will die from breast CA
- But ACS reports death rates have gone down…Why?
  - Higher quality mammography
  - Earlier detection and better treatment
- Role of physics in getting there



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Breast Cancer Impacts Patients, Family and Friends

Libby was a survivor and a fighter for quality mammography

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History of Mammography – 1930s

- 1st successful use of x-rays to diagnosis breast cancer (Dr. Warren, University of Rochester)
  - Screen-film with grid, 60 kVp and 2.5 sec
  - Quality was unreliable
  - Rarely used

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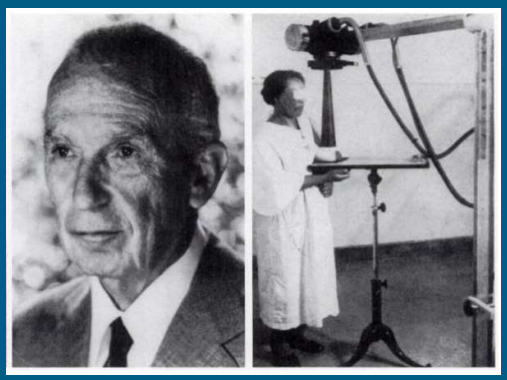
History of Mammography – 1950s

- Dr. Gerson-Cohen (Philadelphia)
  - Direct exposure film
  - Compensation filters
- Dr. Leborgne (Uruguay)
  - Microcalcifications
  - Light compression



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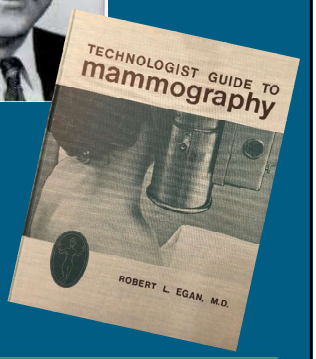
History of Mammography – 1960s

- Robert Egan, MD (Emory University)
  - Low kV
  - High mA
  - Industrial film
  - Easily reproducible
  - Widespread mammography
- He "wrote the book"
- US Public Health Service
  - Sponsored conference at MD Anderson
  - Usefulness and reproducibly of mammography



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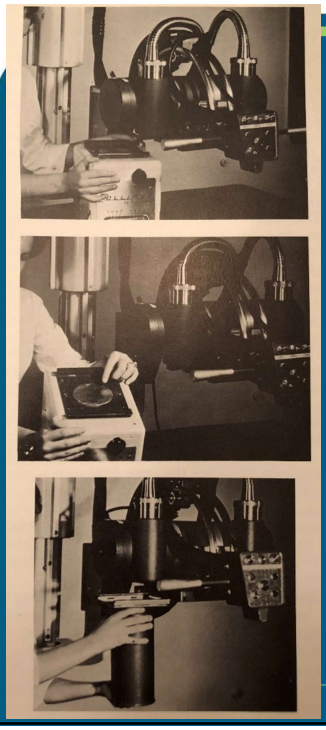

Egan Technique – 1960s to early 1970s

- Conventional x-ray unit
- Film processing by hand

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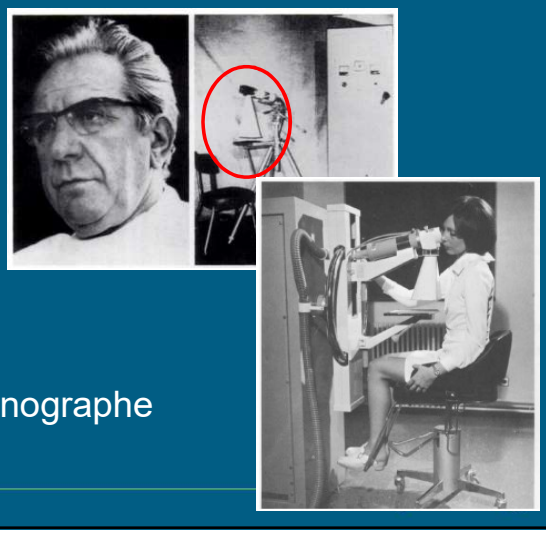
History of Mammography – 1960s

- 1967 – Dr. Gros (physicist at U of Strasbourg) invented x-ray tube designed for mammography
  - Low voltage
  - Mo target instead of W
  - Compression cone
    - Reduce breast thickness
    - Spread out structures
    - Yes, it was invented by a man
- 1967 – 1st dedicated unit - CGR Senographe



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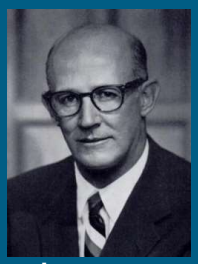
History of Mammography – 1960s



- Dr. Wendell Scott (Washington U)
  - Chairman of the ACR's 1st mammography committee
- Supported by USPHS and aid of Dr. Egan, developed training aids and teaching centers throughout the US for radiologists and techs
- Asked Xerox to design a machine which could easily be operated, which remained clean and dry, and which could produce superb images

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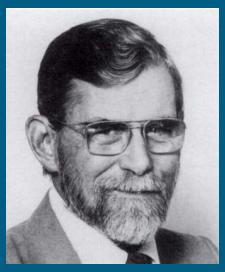
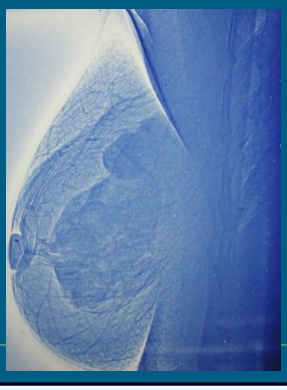
History of Mammography – 1970s



- Xeromammography (1971)
  - Championed by John Wolfe, MD
  - A photoelectric method of recording an x-ray image on a coated metal plate and dry chemical developers



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History of Mammography – 1970s

- Screen-film mammography (1972)
  - Single emulsion film with high resolution intensifying screen
  - Vacuum cassette (DuPont)

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History of Mammography – 1970s

- US Breast Cancer Detection Demonstration Project (BCDDPs)
  - Conducted between 1973 and 1980
  - Sponsored by the ACS and the NCI
  - 29 screening centers with 60 x-ray machines
  - 5 annual breast examinations to 283,222 women
- 6 Centers for Radiological Physics to support
  - Coordinated by AAPM
  - Radiation dose
  - Equipment/image receptor performance

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History of Mammography – 1970s

- Radiation dose at BCDDPs (1975)
  - "Lo-dose" film, "non-screen" film and Xerox used
  - Median surface exposure – 2.8 Roentgen (R)
  - One center used "non-screen film" resulting in high exposures…8 R…practice ceased
  - 6 R reported for a Xerox site…practice modified
- Concern about screening large #s of women with potentially high radiation doses

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History of Mammography – 1970s

- Pennsylvania State inspector
  - Hank Bicehouse
  - 70 eastern PA facilities
  - Entrance exposures to breast ranged from 0.25 R to 47 R!!!!

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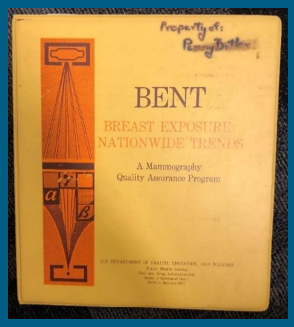
FDA's Bureau of Rad Health – 1975

- Breast Exposures: Nationwide Trends (BENT)
  - Administered by FDA (with support from NCI)
  - Conducted by state radiation control agencies
  - Cooperation of state radiological societies
- Objectives
  - Determine ranges of patient exposures
  - Determine causes of unnecessarily high and low exposures
  - Reduce unnecessary exposures through practice improvements



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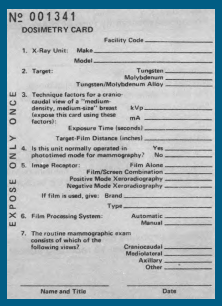
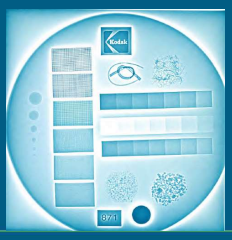
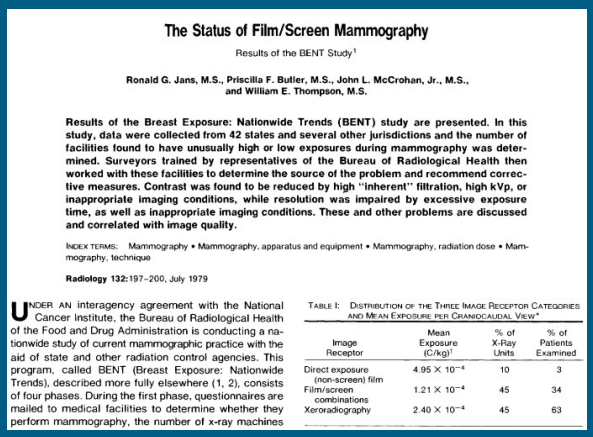
FDA's BENT – 1970s





- States mailed dosimetry card to all mammography facilities in state



The Status of Film/Screen Mammography

Results of the BENT Study[1]

Ronald G. Jans, M.S., Priscilla F. Butler, M.S., John L. McCrohan, Jr., M.S., and William E. Thompson, M.S.

Results of the Breast Exposure: Nationwide Trends (BENT) study are presented. In this study, data were collected from 42 states and several other jurisdictions and the number of facilities found to have unusually high or low exposures during mammography was determined. Surveyors trained by representatives of the Bureau of Radiological Health then worked with these facilities to determine the source of the problem and recommend corrective measures. Contrast was found to be reduced by high "inherent" filtration, high kVp, or inappropriate imaging conditions, while resolution was impaired by excessive exposure time, as well as inappropriate imaging conditions. These and other problems are discussed and correlated with image quality.

INDEX TERMS: Mammography • Mammography, apparatus and equipment • Mammography, radiation dose • Mammography, technique

Radiology 132:197–200, July 1979

UNDER AN interagency agreement with the National Cancer Institute, the Bureau of Radiological Health of the Food and Drug Administration is conducting a nationwide study of current mammographic practice with the aid of state and other radiation control agencies. This program, called BENT (Breast Exposure: Nationwide Trends), described more fully elsewhere (1, 2), consists of four phases. During the first phase, questionnaires are mailed to medical facilities to determine whether they perform mammography, the number of x-ray machines

TABLE I: DISTRIBUTION OF THE THREE IMAGE RECEPTOR CATEGORIES AND MEAN EXPOSURE PER CRANIOCAUDAL VIEW*

Image Receptor	Mean Exposure (C/kg)[1]	% of X-Ray Units	% of Patients Examined
Direct exposure (non-screen) film	4.95×10^{-4}	10	3
Film/screen combinations	1.21×10^{-4}	45	34
Xeroradiography	2.40×10^{-4}	45	63

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ACR Mammography Accreditation Program - 1987

- Developed by the radiologists and physicists of the ACR's Breast Task Force
  - Seed money provided by ACS
  - Voluntary
  - Purpose was to address documented concerns for inadequate and varying mammography quality

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American Cancer Society®

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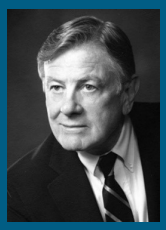
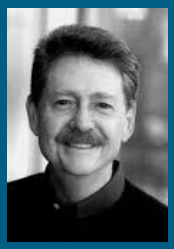
ACR Mammography Accreditation Program - 1987

- Chairs
  - Gerald Dodd, MD – Breast Task Force
  - Robert McClelland, MD – Committee on Mammography Accreditation
  - Dr. Hendrick – Subcommittee on Mammography Physics
- ACR staff
  - Marie Zinninger
  - Pam Wilcox





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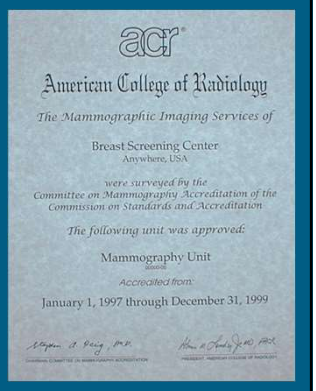
ACR Mammography Accreditation Program - 1987

- First site applied for accreditation in Aug 1987


acr
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The Mammographic Imaging Services of
Breast Screening Center
Anywhere, USA
were surveyed by the
Committee on Mammography Accreditation of the
Commission on Standards and Accreditation
The following unit was approved:
Mammography Unit
Accredited from:
January 1, 1997 through December 31, 1999

- By 1991, 4717 sites with 5745 mammography units applied (over half of all in the US)

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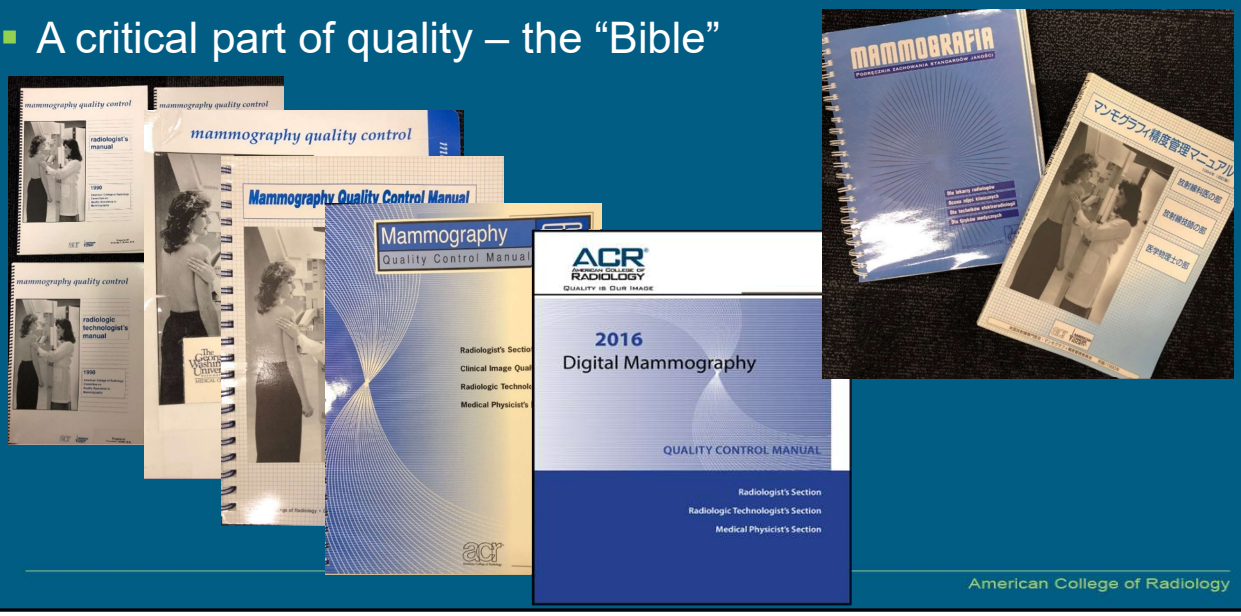
ACR Quality Control Manuals

- A critical part of quality – the "Bible"



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ACR Cooperative Agreement w/CDC

- 1990 - Bob Smith, PhD developed concept for the National Breast and Cervical Cancer Detection Program - passed by Congress
- Created the opportunity for a new grant for Mammography Quality Improvement Activities
- Co-chaired by Larry Bassett, MD and Ed Hendrick, PhD



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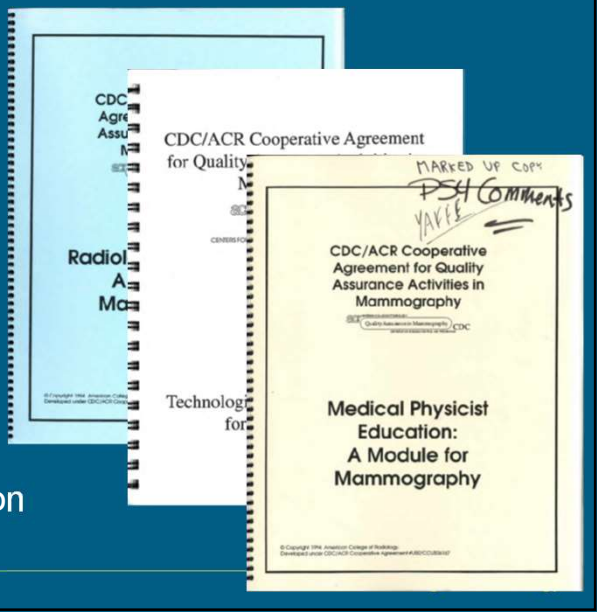
Cooperative Agreement – 1990 to 1994

- CDC provided $4M over 4 years
- Committees
  - Radiologist Education
  - Radiologic Technologist Education
  - Medical Physicist Education
  - State Inspectors Education
  - Mammography Skills Assessment
  - Clinical & Phantom Image Correlation



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CMS Regulation – 1992

- Congress passed Medicare coverage of screening mammography
  - Facilities seeking coverage had to register with Health Care Financing Administration (HCFA) and meet quality standards similar to ACR's Mammography Accreditation Program
  - Federal inspections of Medicare-registered screening facilities began in 1992
- Some people still believe that regulation and accreditation only apply to screening

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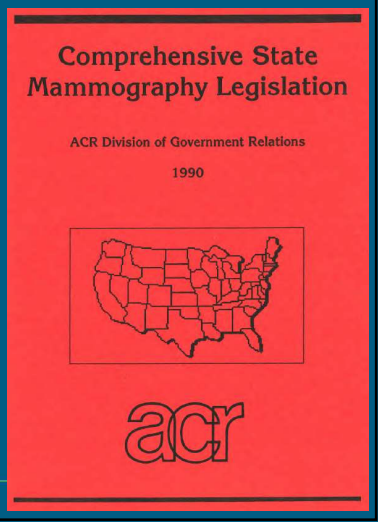
Patchwork of State Regulations

- Only 9 states had Quality Assurance provisions in regulations
  - They were all different
  - Michigan was the most rigorous
- There was no quality requirement for all women at all mammography facilities in US



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Mammography Quality Standards Act – early 1990s

- MQSA - originally introduced in 1990 by Brock Adams of WA
  - Didn't pass
- Reintroduced by John Dingell of MI
  - Shepherded by Barbara Mikulski of MD 1992
  - Passed with implementation date of 1994
  - Signed by George HW Bush August 22, 1992
- Assigned to the FDA
- Required establishment of National Mammography Quality Assurance Advisory Committee (NMQAAC)

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NMQAAC - 1994

- 13–19 members…radiologists, radiologic technologists, medical physicists, referring physicians, nurses, state radiation control reps and breast CA consumer health organization reps
- Advise FDA on
  - Developing regs for mammography facilities and sanctions
  - Developing regs for accrediting bodies
  - Developing procedures for monitoring compliance
  - Establishing a consumer complaint mechanism
  - Determining if shortage of facilities in rural and health professional shortage areas exists
  - Determining if sufficient # of medical physicists exist

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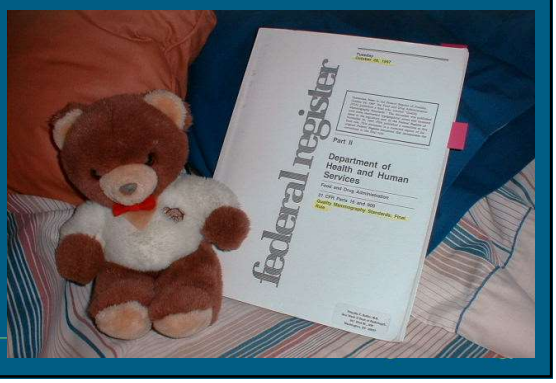
FDA MQSA Regulations

- Interim rules – 1994
- Final rules – 1997
  - Most rules effective April 28, 1999
  - Some rules effective October 28, 2002



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Regulation - MQSA

- In order to legally perform mammography in the US, facilities must
  - Meet all quality rules
  - Be accredited every 3 years
  - Be inspected every year
  - Have an MQSA certificate
- Certification
  - FDA
  - States (Iowa, Illinois, South Carolina, Texas)


U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration

CERTIFIED MAMMOGRAPHY FACILITY

This certifies that

Wonderful Mammography, Inc.
1 Penny Lane
Your Town, USA

has complied with the requirements of the Mammography Quality Standards Act of 1992 and is hereby authorized to perform mammography examinations, pursuant to 42 U.S.C. 263b.

Accreditation Body: *American College of Radiology*

Facility ID Number: *173112*

Expiration Date: *May 29, 2004*

B A Schwetz DVM, PhD (for)

COMMISSIONER OF FOOD & DRUGS
FOOD AND DRUG ADMINISTRATION

John L. McCrohan

DIRECTOR
DIVISION OF MAMMOGRAPHY QUALITY AND RADIATION PROGRAMS
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Patients may report comments/complaints to:

Mammography Accreditation Program
American College of Radiology
1891 Preston White Drive
Reston, Virginia 20191-4397

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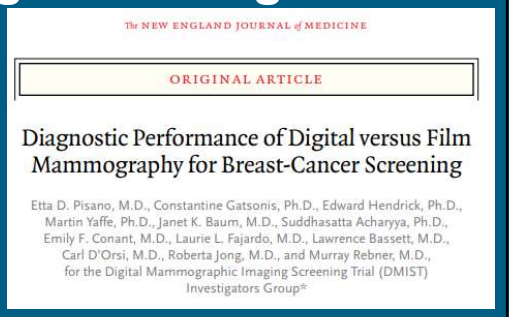
Digital Mammographic Imaging Screening Trial (DMIST)

- 2005 NEJM paper
  - Over 42K women at 33 facilities
  - Digital mammography more accurate for women over 50 and those with dense breast
- Physics acceptance and QC integral to trial


The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Diagnostic Performance of Digital versus Film Mammography for Breast-Cancer Screening

Etta D. Pisano, M.D., Constantine Gatsonis, Ph.D., Edward Hendrick, Ph.D., Martin Yaffe, Ph.D., Janet K. Baum, M.D., Suddhasatta Acharyya, Ph.D., Emily F. Conant, M.D., Laurie L. Fajardo, M.D., Lawrence Bassett, M.D., Carl D'Orsi, M.D., Roberta Jong, M.D., and Murray Rebner, M.D., for the Digital Mammographic Imaging Screening Trial (DMIST) Investigators Group*


MEDICAL PHYSICS
The International Journal of Medical Physics Research and Practice

Radiation imaging physics

Quality control for digital mammography in the ACRIN DMIST trial: Part I

Aili K. Bloomquist, Martin J. Yaffe, Etta D. Pisano, R. Edward Hendrick, Gordon E. Mawdsley, Stewart Bright, Sam Z. Shen, Mahadevappa Mahesh, Edward L. Nickoloff ... See all authors

Quality control for digital mammography: Part II recommendations from the ACRIN DMIST trial

Martin J. Yaffe, Aili K. Bloomquist, Gordon E. Mawdsley, Etta D. Pisano, R. Edward Hendrick, Laurie L. Fajardo, John M. Boone, Kalpana Kanal, Mahadevappa Mahesh ... See all authors

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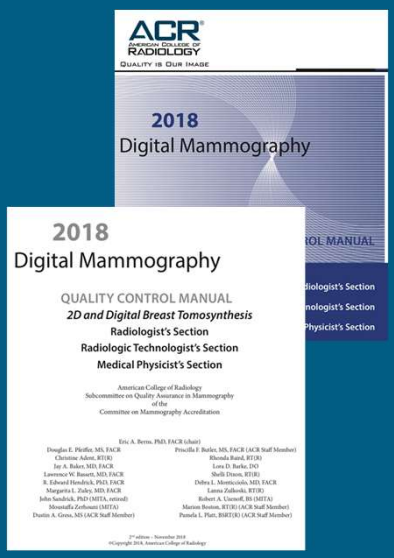
ACR Digital Mammography QC Manual

- 2016: FDA approved ACR DM QC Manual as alternative standard
- 2018: FDA approved supplemental DBT material to be integrated into ACR DM QC Manual
- November 2018: New manual published and made available at no charge to all ACR accredited facilities and ACR medical physicist members
- Adoption is a choice



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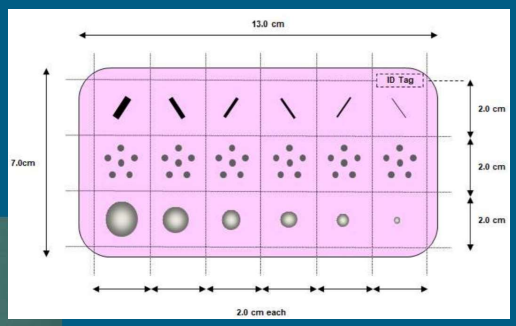
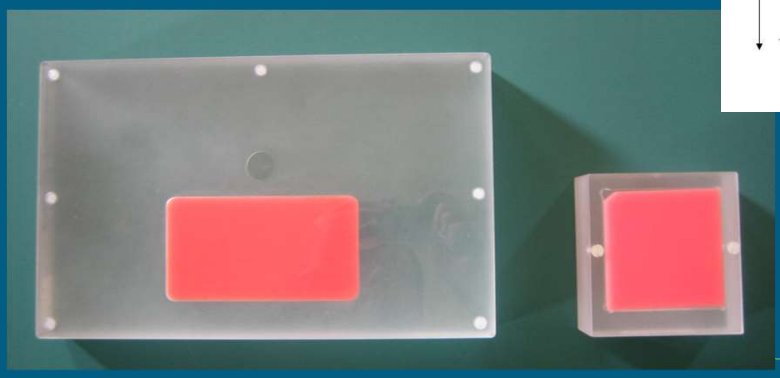
Phantom for Digital and DBT

- New ACR phantom <u>must</u> be used with new ACR Digital QC manual
  - Old, small phantom may <u>not</u> be used





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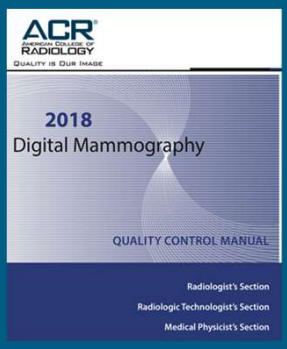
New Manual Provides Standardization Across Manufacturers and Models

- Its good
- QC program structured for modern facilities
  - Multiple units… multiple RWS… multiple facilities
- What's standardized?
  - Tests themselves
  - Test frequencies
  - Performance criteria
  - Clinical relevance
  - Operator-friendliness



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Standardization Benefits

- Improved efficiency
  - Fewer QC tests than mfr
  - Less total time spent on QC tests
  - More efficient artifact detection
  - 2D and DBT both included, streamlined
- Overall benefits
  - Expect cleaner MQSA inspections
  - Reduces errors
  - No more chasing down mfr manual versions
  - Current and future revisions will always be available
  - Current and future Excel forms will always be free
- Team approach for mammography professionals

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9. Facility QC Review

Quarterly

Image Mode (2D, 2D w/Add-on DBT, DBT)

Facility _____ Date of QC Mtg _____

Reviewed

1. 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					
MP DM QC Test Summary reviewed by radiologist?					
All MP corrective actions completed?					
ACR DM Phantom Average Glandular Dose (mGy)					
Fiber Score					
Speck Score					
Mass Score					

2. Review Tech QC

Test	Frequency	Summary Comments from Last Quarter
1. ACR DM Phantom Image Quality	Weekly	
2. CR Cassette Erasure (if app)	Weekly	
3. Compression Thickness Indicator	Monthly	
4. Visual Checklist	Monthly	
5. AW Monitor QC	Monthly	
6. RW Monitor QC	Monthly	
7. Film Printer QC	Monthly	
8. Viewbox Cleanliness (if app)	Monthly	
9. Facility QC Review	Quarterly	
10. Compression Force	Semiannual	
11. Manufacturer Calibrations (if app)		
Optional - Repeat Analysis	As Needed	% Repeats

Scores of most recent phantom image:	Room 1	Room 2	Room 3	Room 4	Room 5
Date					
Fiber score					
Speck group score					
Mass score					

3. Review and verify completion of all "Corrective Action"
4. Technique Chart review for each room (see MP report for recommendations) - (Annually)
5. Infection Control procedures followed
6. Offsite RW(s) & Film Printer(s) QC reviewed
7. Past and future service or service upgrades discussed (if app)
8. Past and future State and/or MQSA inspections discussed (if app)
9. Past and future ACR Accreditation issues discussed (if app)

9. Facility QC Review (cont)

Quarterly

Facility _____ Date of QC Mtg _____

10. Notable findings during QC meeting — Follow-up Confirmed (If App.)

11. Items for quality improvement from QC Meeting

12. Other QC Notes

Overall Pass/Fail

Lead Interpreting Radiologist *signature* | Facility Manager (If App) *signature* | QC Technologist *signature*

Action Limit:		
	Required:	Lead interpreting radiologist and facility manager must review QC quarterly. The test passes if meeting held.
	Recommended:	Technologist and lead interpreting radiologist should review technique charts at least annually for each DM system.
	Timeframe:	Not applicable.

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Medical Physicist QC Letter for the Radiologist

January 25, 2019

Lead Rad, MD
Breast Center USA
1234 Smith Road

Los Angeles, CA. 10001

Re: Medical Physicist Survey of Room 1 Manf AA Unit BB on January 25, 2019

Dear Lead Interpreting Radiologist,

The above mammography unit at your facility recently 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 Digital Mammography 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): Phantom 1
Patient ID (Phantom): 123
Date: 1/25/19

ACR Digital Mammography Phantom Scores

	Room 1			
	2D	DBT	Passing Criteria	Pass /Fail
Fiber score	5.0	5.0	≥ 2.0	Pass
Speck group score	4.0	4.0	≥ 3.0	Pass
Mass score	4.0	4.0	≥ 2.0	Pass
Artifacts	None	None	No Clinically Significant Artifacts	Pass

Comments on phantom image:

- **Radiation Dose**

ACR Digital Mammography Phantom Radiation Dose Values

	Room 1			
	2D	DBT	Passing Criteria	Pass /Fail
ACR Phantom Dose (mGy)	1.35	1.49	≤ 3.0	

Note: The above dose is an estimate determined with a phantom representing the FDA-defined 4.2 cm thick, 50% glandular/50% adipose standard breast. Doses will vary with patient size and density. Specific patient doses can be estimated by your medical physicist.

Comments on radiation dose:

Medical Physicist QC Summary Letter for the Radiologist (cont)

- ***Required Action Items***

Time Frame	Description

- ***Recommended Action Items***

Time Frame	Description

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

Time Frame	Description

- ***Comments on Tech QC***

Time Frame	Description

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

Sincerely,

MP Name

Phone 111-222-3333
Email mp.email@email.com

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Resources

- Up-to-date FAQs
- Phantom scoring key (good for teaching!)
- Excel forms for QC tests (tech and med phys!)
- Webinars by Eric (tech and med phys!)
- Approved phantom vendors

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Search this site

MODALITIES | ACCREDITED FACILITY SEARCH | HOW TO | RESOURCES

DIGITAL MAMMOGRAPHY QC MANUAL RESOURCES

Digital Mammography Quality Control Test Forms

- Radiologic Technologist Forms (Excel) — **Updated 11/19/18**
- Medical Physicist Forms (Excel) — **Updated 11/19/18**

ACR Digital Mammography QC Manual Webinars

Webinars for 2019 — register now!

- ACR Digital Mammography QC Manual Webinar for Technologists
  Friday, January 18, 2-3pm EST
  View the webinar »
  View presentation slides for Technologists »
- ACR Digital Mammography QC Manual Webinar for Medical Physicists
  Friday, January 25, 12-1pm EST
  View the webinar »
  View presentation slides for Medical Physicists »

Approved ACR Digital Mammography Phantoms – approved for 2D and DBT

- CIRS
- Gammex
- Pro-Project
- RaySafe
- Supertech

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Mammography Quality Standards Act: FDA's 2019 Proposed Rule

- First changes since 1997 Final Rule
- Published March 2019
- Comments were due 6/26/2019

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 900

[Docket No. FDA–2013–N–0134]

RIN 0910–AH04

Mammography Quality Standards Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

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2019 Proposed Rule

- Possible major changes
  - Breast CT excluded from MQSA
  - Accrediting bodies cannot accept applications from facility with 3 failures for at least 1 year
  - Facilities must provide copies of their personnel records to current or former personnel
  - Digital accessory components (eg, monitors) must have been cleared/approved by FDA for mammography
  - Unit converted from one modality to another (eg, film-screen to digital) is a "new unit" and needs equipment evaluation

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2019 Proposed Rule

- Possible major changes (continued)
  - Interpretation must be done on modality originally produced (eg, not copies or digitized from analog)
  - Several new final assessment categories for reports
  - Lay summaries for "Suspicious" or "Highly suggestive of malignancy" communication
    - Referrer - 7 days from interpretation; 14 days from exam date
    - Patient - 7 days from interpretation; 21 days from exam date
  - Breast density notification to patients –language specified
  - If MQSA certificate revoked, owners/operators may not own or operate again for 2 years

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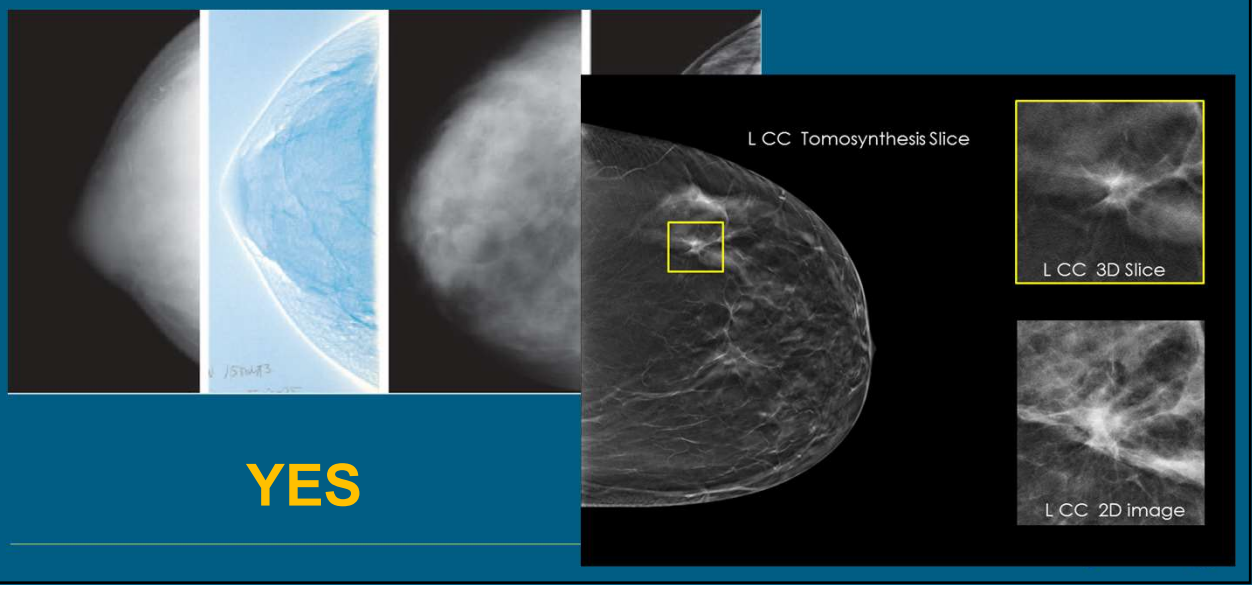
In Summary, Has Mammography Quality Improved?



YES

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Thank You

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- Dustin Gress, MS, DABR, DABSNM
  - ACR Senior Advisor for Medical Physics
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