

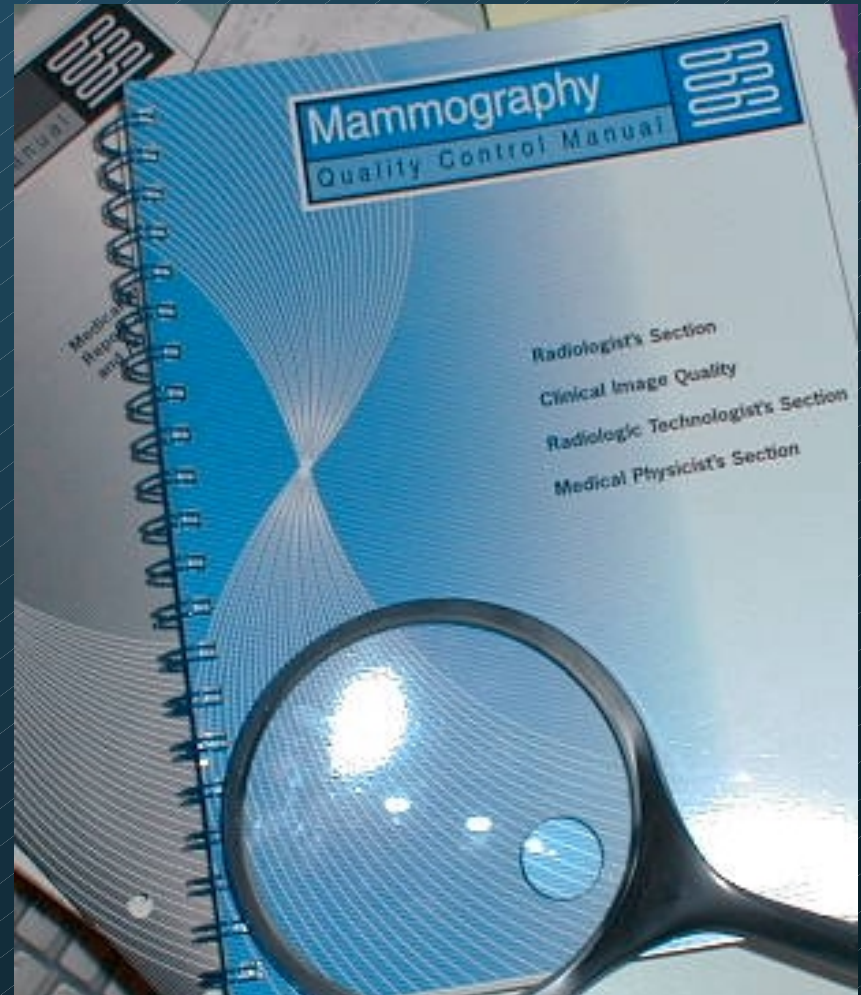
**American College of
Radiology
Mammography
Accreditation Program**

Objectives

- **Overview of the ACR Mammography Accreditation Program**
- **Interrelationship between mammography accreditation, FDA certification and annual inspections**
- **How to successfully apply for accreditation**
- **What to do if you do not succeed**
- **Analysis of accreditation deficiencies**

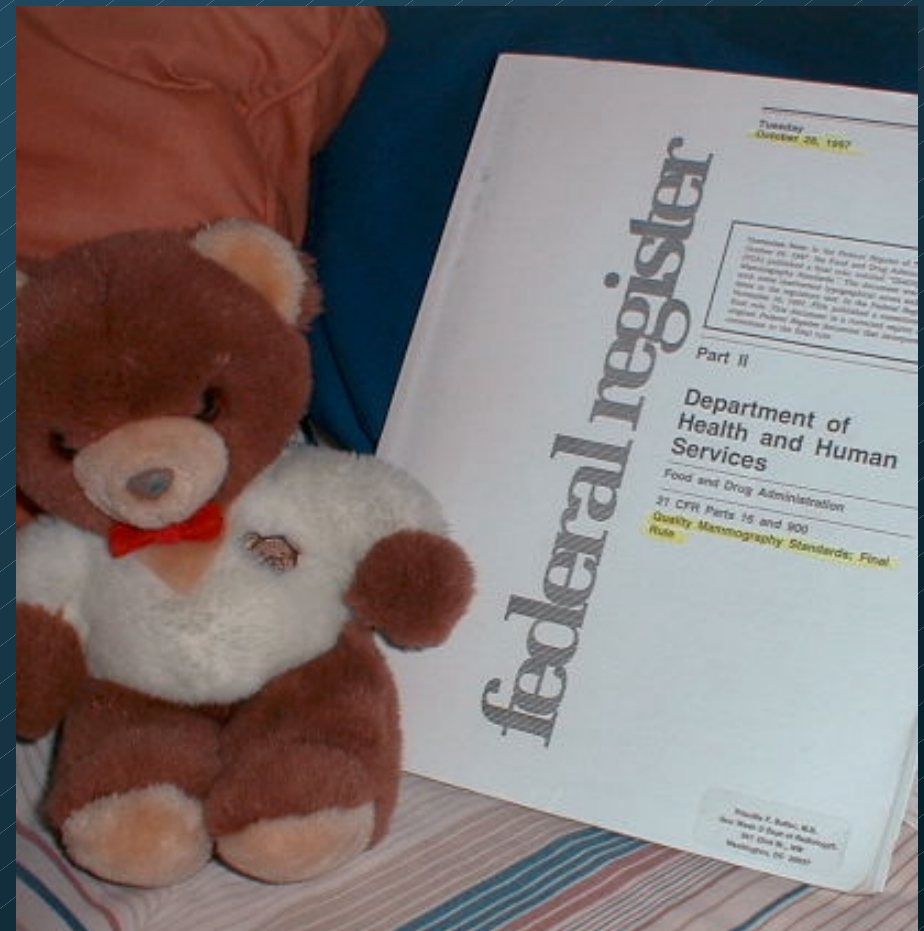
ACR Mammography Accreditation Program

- Began in 1987
- QC Manual first published in 1990
- Judy M. Destouet, M.D. chairs Committee on Mammography Accreditation
- Currently accredit over 12,000 units at 9000 facilities



Facility Requirements Under MQSA

- All mammography facilities must be
 - Accredited
 - Certified
 - Inspected
- Complementary, not duplicative



Accrediting Bodies Responsibilities Under MQSA

- **Facility standards review**
- **Clinical image review**
- **Physics survey review**
- **Random clinical image review**
- **On-site visits**
- **Mechanism to deal with complaints**
- **Reporting and record keeping**
- **Maintain reasonable fees**

ACR has Updated all Application Materials and Final Reports

- **Forms**

- Revised to be consistent with Final Rules (*FDA regulates accrediting bodies, too*)
- New personnel sections no longer ask for CV's, training certificates
- Streamlined: redundant and unnecessary questions eliminated

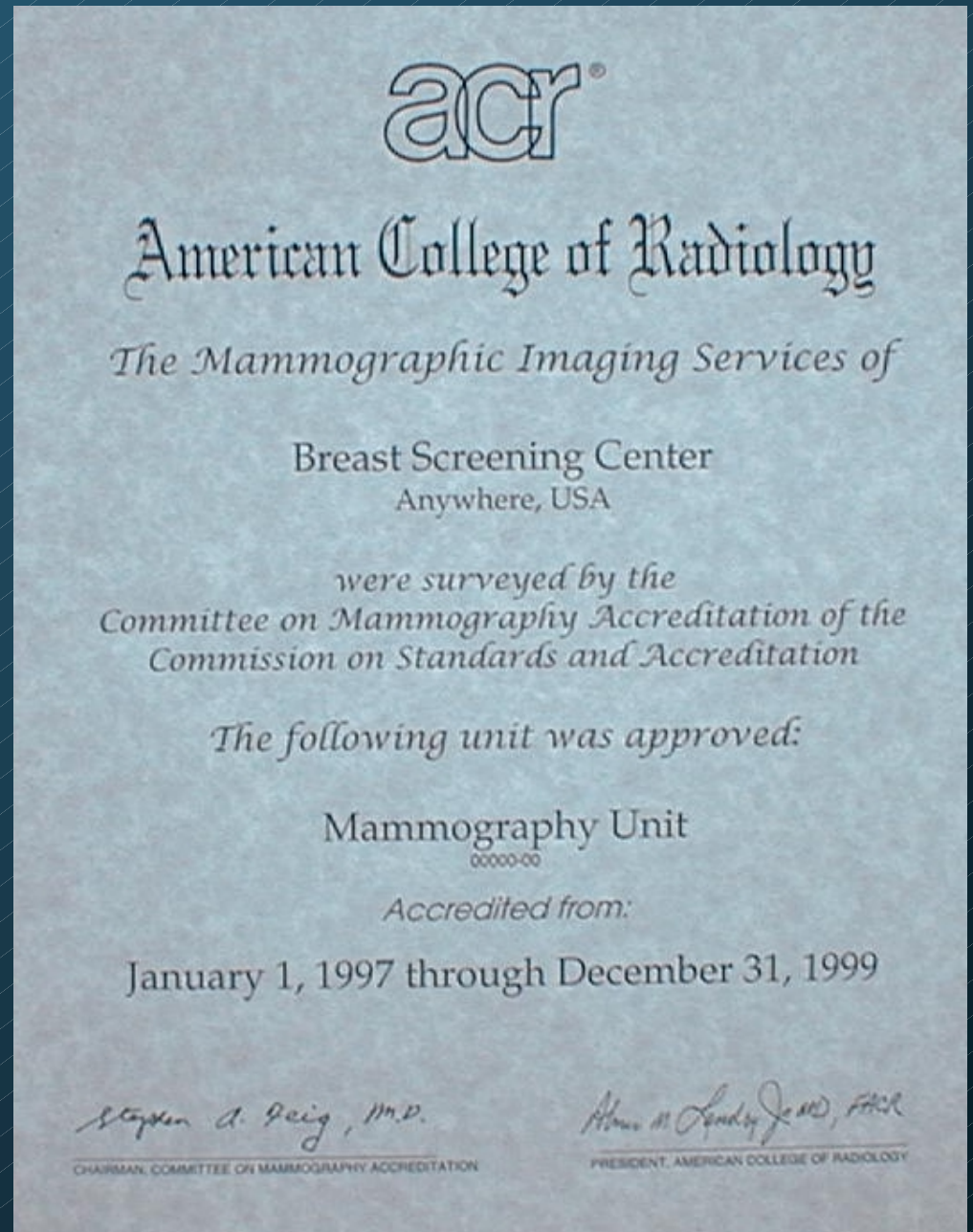
- **Reports**

- Take advantage of capabilities of ACR's new accreditation software
- Clear instructions for proceeding after deficiencies

What Must a Facility Do to Pass Accreditation?

Know When Your MQSA and Accreditation Certificates Expire

- Against the law to perform mammo without a current MQSA certificate
- Medicare will not reimburse under expired certificate
- Look for ACR expiration dates on certificate and unit label



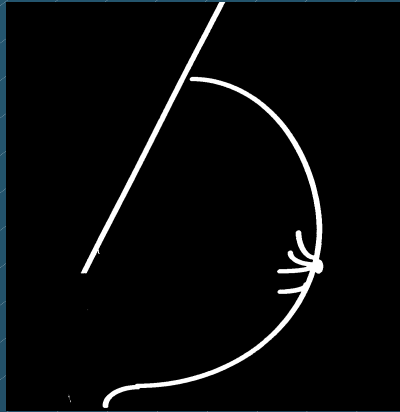
Meet All Application Deadlines

- **Renewal notices sent out 8 months prior to accreditation expiration**
 - **ACR must receive the complete entry application within 6 months prior to expiration**
- **You have 45 calendar days to return completed testing to ACR**
 - **This guarantees completion of the review process before accreditation expiration**

Follow Instructions Submitting Clinical Images

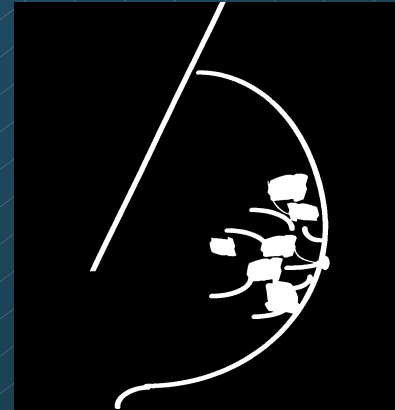
- Images should be “negative”
 - BI-RADS assessment category 1
 - “nothing to comment on...breasts are symmetrical...no masses, architectural disturbances or suspicious calcifications”
 - BI-RADS assessment category 2 (“benign”) will be accepted with prior approval from ACR
- Examples of your facility’s best work
- Within 30 days of the phantom image and within the time period on the QC chart
- Supervising radiologist should review & approve the images

Submit Appropriate Density Images

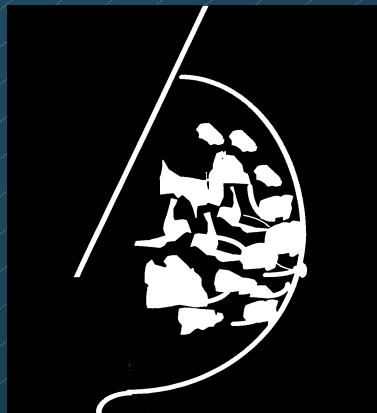


Fatty

BI-RADS Composition Cat 1
Composed Almost Entirely of Fat



BI-RADS Composition Cat 2
Scattered Fibroglandular Densities



Dense

BI-RADS Composition Cat 3
Heterogeneously Dense



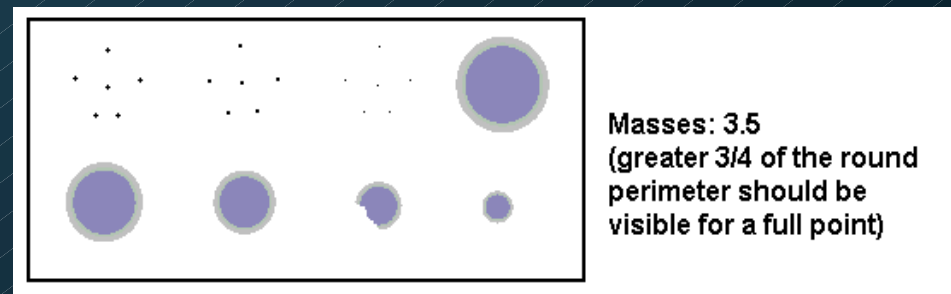
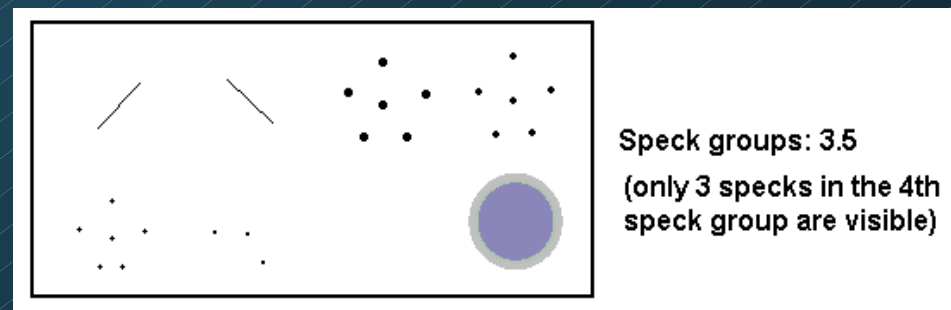
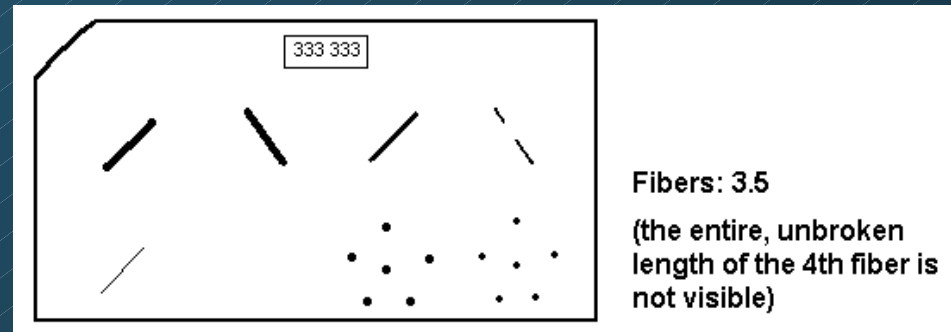
BI-RADS Composition Cat 4
Extremely Dense

Clinical Image Quality Evaluated in Eight Categories

- Positioning*
- Compression*
- Exposure level
- Contrast
- Sharpness
- Noise
- Artifacts
- Exam identification
- Review evaluation criteria in “*Clinical Image Evaluation*” section of 1999 QC Manual before submitting images
- (**Primary reasons for accreditation failure*)

Follow Instructions Submitting Phantom Images & Dosimeter

- Make a test exposure without the dosimeter
- Dosimeter or disk should not cover fibers, specks or masses
- Criteria used by ACR Phantom Image Reviewers is in 1999 ACR QC Manual

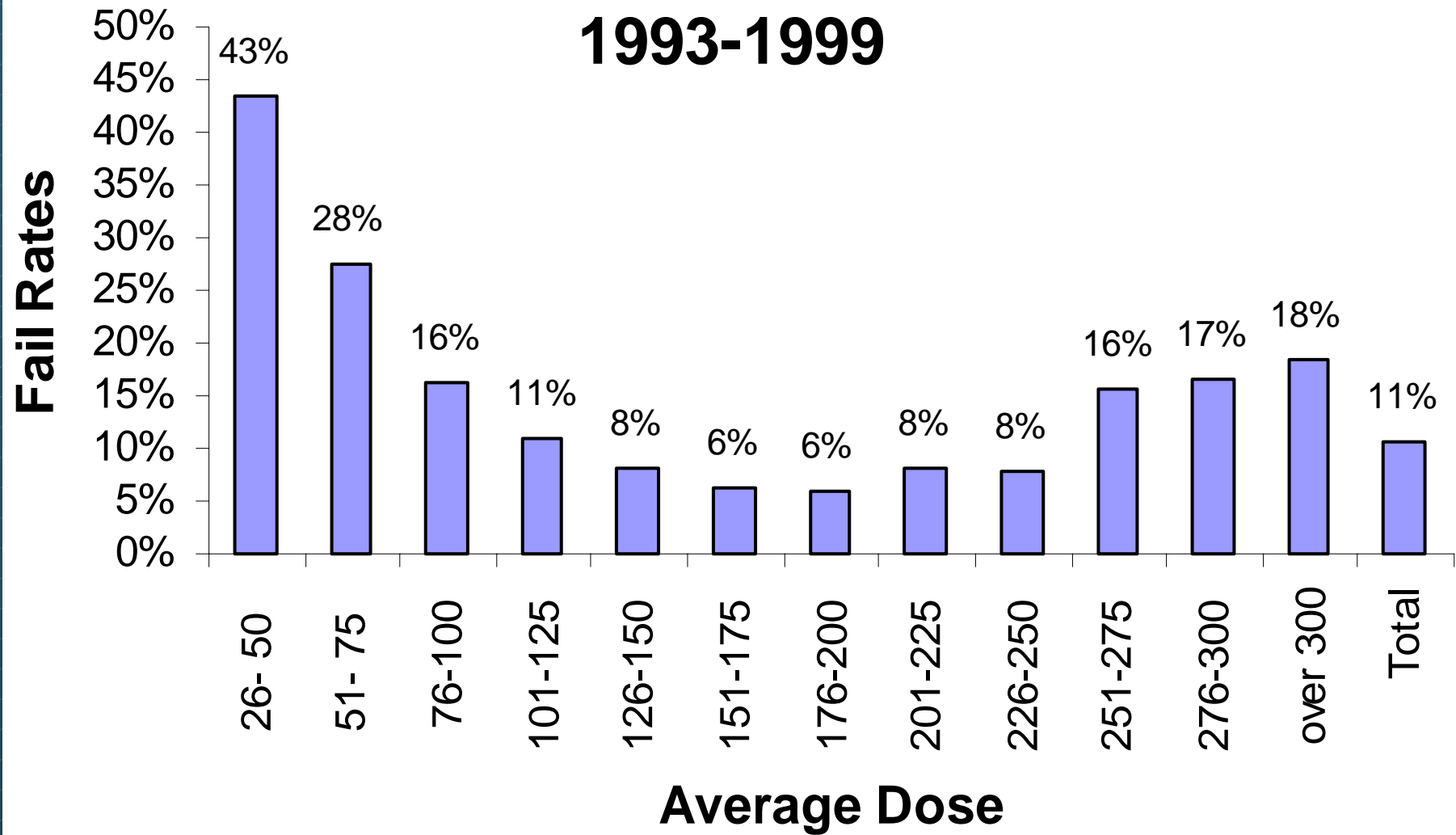


Phantom Results Have Improved

% of films not meeting ACR criteria

- Approx 11% did not meet criteria between 1993 and 1999
- 1993 – approx 16%
- 1994 – approx 16%
- 1995 – approx 16%
- 1996 – approx 7%
- 1997 – approx 6%
- 1998 – approx 6%
- 1999 – approx 7%

Overall Phantom Fail Rates 1993-1999



Other Things to Keep in Mind

Notify ACR When Installing a “New” Mammography Unit

- Before use
 - Physicist must conduct *Equipment Evaluation*
 - Call ACR for instructions to accredit the unit
- If more than 1 year left on accreditation
 - Full testing (clinical-phantom-dose-processor)
 - Reduced fee
 - If approved, same exp dates as other unit(s)
- If less than 1 year left on accreditation
 - Early renewal of entire facility (all units)
 - Usual fee
 - If approved, exp date for all units is old +3 yrs

Equipment Evaluation

- Must be done by qualified medical physicist
- This evaluation is an “acceptance test;” evaluates different features in addition to those tested as part of the medical physicist’s annual QC survey
- Must be done (& all problems fixed) before equipment used on patients
- Must be submitted to ACR during initial application of new (or used) mammo unit

FDA Final Rules

- **Equipment Standards: section 900.12(b)**
 - X-ray units (e.g., flat and parallel compression)
 - Film and intensifying screens
 - Film processing
 - Film viewing
- **Quality Assurance - Equipment: section 900.12(e)**
 - Facilities must conduct these tests at proscribed intervals and equipment must meet performance standards
 - Different from equipment standards

ACR Has a Form to Help You Supplement Your Annual QC Survey Report for the Equipment Evaluation

- **Section VI (MQSA Requirements for Mammography Equipment) in physicist's chapter of QC Manual**
- **Also downloadable from the ACR website**
- **Simple Yes/No/NA checklist format**



Mammography Accreditation Program

- [Program Overview](#)
- [Program Basic Requirements](#)
- [Mammography Direct Reporting Letters](#)
- [The FDA's MQSA Requirement Information](#)
- [Frequently Asked Questions](#)
- [ACR 1999 Mammography Quality Control Manual](#)
 - [Medical Physicist's Summary Report and Data Recording & Analysis Forms](#)
 - [Radiological Technologist's Quality Control Checklists, Control Charts and Data Forms](#)
 - [Quality Control Section of Mammography Frequently Asked Questions](#)



Stereotactic Breast Biopsy Accreditation Program

When Must a Facility Have an Equipment Evaluation Done?

- After installation of new (or used) x-ray unit or processor
- After x-ray unit or processor disassembled and reassembled at the same or new location
- After x-ray tube replacement
- After collimator replacement
- After filter replacement
- After AEC unit or sensor replacement

FDA Policy Guidance Help System

Revised May 2001

The screenshot shows a web browser window titled "MDSA Final Regulations". The browser's address bar and menu bar are visible. The main content area is titled "Equipment Evaluations" and contains a search interface on the left and a list of search results on the right. The search interface includes a search box with the text "equipment evaluation", a list of matching words, and a list of topics to display. The search results on the right include a citation, a discussion, and five numbered questions with their respective answers.

Equipment Evaluations

[Questions](#) [Decision Tree](#) [Table](#) [Key Words/Related Topics](#)

Citation:

900.12(e)(10): *Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor is installed, a unit or processor is disassembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in paragraphs (b) and (e) of this section. All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.*

Discussion:

Question 1: When are "additional mammography equipment evaluations" required and who must conduct the evaluations?

Question 2: When performing a physics survey or equipment evaluation on a unit with multiple target/filter combinations, what tests or measurements must be performed for each combination?

Question 3: Must a currently certified facility or a facility undergoing certification for the first time have the "final" written report of the equipment evaluation before clinically using a newly added or modified unit?

Question 4: Can a medical physicist sign-off on an equipment evaluation done by a surrogate if the medical physicist was not present during the evaluation?

Question 5: What are the minimum tests and/or reviews that the medical physicist must perform for a facility survey, survey of a mammography unit, equipment evaluation of a unit or processor that has been installed or disassembled and reassembled, and an equipment

You Have 2 Attempts at Accreditation Before Failing

- A “first deficiency” is NOT a Failure (ACR does not notify FDA)
 - Do NOT have to discontinue mammo
 - Take corrective action on your own
- Repeat deficient test (if >2 months on MQSA certificate)
- Reinstate (if \leq 2 months on MQSA certificate)
- Appeal
- Withdraw

A 2nd Deficiency is a Fail

- **ACR notifies FDA after a 2nd deficiency**
 - **FDA sends cease mammo letter**
- **Facility may Reinstate by reapplying and retesting in all areas after**
 - **Submitting corrective action plan to ACR**
 - **ACR reviews and approves completion**
- **ACR sends facility testing materials**
- **ACR notifies FDA of Reinstatement**
- **FDA sends interim notice and 6-mo provisional certificate (if necessary)**

A 3rd Deficiency is a 2nd Failure

Closer Oversight Necessary

- **ACR notifies FDA after a 3rd deficiency**
 - **FDA sends cease mammo letter**
- **Facility must have Scheduled On-Site Survey (SOSS) in order to Reinstate**
 - **Submit corrective action plan to ACR**
 - **ACR reviews and approves completion**
- **SOSS – radiologist, medical physicist, ACR staff technologist**
- **After SOSS, if no other corrective action needed, facility may reinstate**

Accreditation Approval Rates 2000

- **After *Initial* or *Renewal* application**
 - 69% approved
 - 31% had a deficiency
- **After *Reinstating***
 - 90% approved
 - 10% had a deficiency resulting in failure
- **Majority of deficiencies are due to poor clinical image quality**

**“Alex, I’ll take “RADIOLOGY,”
please, for \$200.”**

**“OK, John. The American
College of Radiology wants
increased Medicare
reimbursement for this breast
imaging procedure.”**

“What is mammography?”

Knowledge Challenge on the Web
CME: Earn 2 hours Category 1 [Click here for details!](#)

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WHAT'S NEW:

- 06/13/01
Updateline: ACR's Mammography Access Campaign Hits TV's Jeopardy > MORE
- 06/07/01
Updateline: Health Funds Will Be Tight, Budget Official Tells ACR Board > MORE
- 06/06/01
Bush Nominates Rehnquist as HHS Inspector General > MORE
- 05/31/01
Updateline: ACR Board to Look at Mammography Reimbursement, Other Issues at Spring Meeting