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FDA developed the speech (also available on the mammography website), "The Final Regulations with Inspection Guidance," for use by FDA and State mammography experts, as well as non-government educators and professional health organizations. Using this comprehensive speech, which may be tailored to the needs of each audience, a presenter can be confident that the information is consistent with FDA's MQSA program. In addition to the speech, the complete speaker's kit contains slides, overhead transparencies, and a diskette with text in Word, WordPerfect, and Powerpoint. To borrow a kit, send your request by fax message to SciComm, (301) 986-8015, or e-mail dmqrp@scicomm.com.

Final Mammography Quality Standards Act (MQSA) Regulations

Effective April 28, 1999

Objectives

- Revisions to the final rule
- Development of guidance for the final rule
- Preparation for an MQSA inspection under the final rule
- New regulated areas covered in the final rule
- Where you can get additional information

MQSA Final Regulations

- Proposed Regulations Published 4/3/96
- Final Regulations Published 10/28/97
- Implementation Date 4/28/99

Amendments to the Final Regulations Published in the *Federal Register*

- Start date for the continuing experience requirement for radiological technologists and medical physicists changed to April 28, 1999 [10/22/98]
- Collimation requirement modified [4/14/99]
- MQSRA communicating-results-to-patients requirement and other wording incorporated into final rule – Proposed and Direct Final Rule [6/17/99]

MQSA Reauthorization

- MQSA originally authorized for 5 years
- Reauthorization signed into law 10/9/98
- Extends the Act until 2002
- Lay summaries to ALL patients
- Release of original mammograms — temporary and permanent

Inspection Demonstration Project

- Conduct less-than-annual inspections of facilities that are “substantially free of incidents of noncompliance”
- Program may not be implemented before April 1, 2001
- Watch FDA’s mammography website for further information

Good Guidance Practices 1997

- Guidance represents one, but not necessarily the only, way to comply with an MQSA requirement
- Must have public input to new guidance prior to implementation
- Proposed guidance
  - Published on FDA's mammography website
  - Notice of availability published in the *Federal Register*
- Final guidance incorporated into the MQSA Policy Guidance Help System on FDA's website

http://www.fda.gov/cdrh/mammography

The Inspection Process

- Inspector will normally give facilities 5 days advance notice
- Inspections of facilities with a single x-ray unit/film processor take approximately 5 hours
  - One hour for inspection of the unit
  - Balance of time reviewing procedures and records
- Inspector will meet with facility representatives at the beginning and end of the inspection

Specific Inspection Items

- Certificate displayed in each patient waiting area
- Personnel records for all medical personnel providing services since the last MQSA inspection
- Equipment tests on owned, leased, and loaned equipment including that being evaluated for purchase

cont.

Specific Inspection Items (cont.)

- QA and QC program review
- Two most recent Medical Physicist's Survey Reports
- Medical physicist evaluation of equipment that is new to the facility or has undergone major repair
- Review of selected patient medical records

cont.

Specific Inspection Items (cont.)

- Review of procedure for communicating examination results to patients and referring physicians
- Review of mammography medical audit and outcomes analysis program
- Review of other operating procedures

Personnel Standards: General Notes

- Interpreting physicians and radiological technologists, who qualified under the interim regulations, are exempt from the additional initial requirements of the final regulations
- Medical physicists, who qualified under the interim regulations, have to meet additional initial requirements
- Prior to independent use, all personnel must have training in each mammographic modality used

Personnel Standards: General Notes (cont.)

- To evaluate the meeting of continuing education and experience requirements the inspector will count back the appropriate number of months from:
- The date of the inspection, OR
  - The end of the full calendar quarter immediately preceding the inspection, OR
  - Any date between the inspection date and the end of the previous full calendar quarter

Interpreting Physicians
Initial Qualifications

- State license
- Diagnostic radiology certification OR
  3 months of formal training
- 60 hours of category I CME in mammography
- 240+ mammograms interpreted under direct supervision
  - In the 6 months immediately prior to independent interpretation OR
  - If board certified at first allowable time, within the last 2 years of residency

Interpreting Physicians Continuing Requirements

- Continuing experience
  - Interpret at least 960 examinations / 24 months
- Continuing education
  - At least 15 category I CME credits / 36 months
  - At least 6 of the 15 CME units must be in each mammographic modality used
- 8 hours of training in each mammographic modality before independent use

Interpreting Physicians Reestablishing Qualifications

- Continuing experience
  - Interpret or multi-read under direct supervision
    - EITHER 240 examinations
    - OR enough examinations to bring total to 960 / 24 months
  - Interpretations performed in immediate 6 months prior to resuming independent reading
- Continuing education
  - Bring total continuing education credits up to 15 CME units / 36 months

Radiologic Technologists
Initial Qualifications

- State license OR
  Certified by FDA-approved body
- 40 hours of documented mammography training
- Performing at least 25 examinations under direct supervision
- 8 hours of training in each mammographic modality to be used

Radiologic Technologists Continuing Requirements

- Continuing experience
  - At least 200 examinations / 24 months
- Continuing education
  - At least 15 CEUs / 36 months
  - At least 6 of the 15 CEUs must be in each mammographic modality used
- 8 hours of training in each mammographic modality used before independent use

Radiologic Technologists
Reestablishing Qualifications

- Continuing experience
  - Complete 25 examinations under direct supervision
- Continuing education
  - Bring total continuing education credits up to 15 CEUs / 36 months

Medical Physicists
Initial Requirements

- Licensed or approved by a State OR
  Certified by FDA-approved body
- Master's or higher degree in a physical science
- 20 semester hours of physics
- 20 hours of documented mammography survey training
- One facility and 10 units surveyed
- 8 hours of training in each modality surveyed before surveying independently

Medical Physicists
Alternative Initial Requirements*

- Licensed or approved by a State OR Certified by FDA-approved body
- Maintained active status

(cont.)

*For physicists who were qualified under the interim regulations

Medical Physicists Alternative Initial Requirements* (cont.)

- Prior April 28, 1999, have:
  - Bachelor's degree in physical science with at least 10 semester hours of physics
  - 40 hours of documented mammography survey training after earning the bachelor's degree
  - One facility and 20 units surveyed after earning the bachelor's degree

*For physicists who were qualified under the interim regulations

Medical Physicists Continuing Requirements

- Continuing experience
  - Survey at least 2 facilities and 6 units / 24 months
- Continuing education
  - At least 15 CEUs / 36 months
- 8 hours of training in any modality before surveying independently

Medical Physicists Reestablishing Qualifications

- Direct Supervision
- Continuing experience
  - Bring total number of supervised surveys up to 2 facilities and 6 units / 24 months
- Continuing education
  - Bring total continuing education credits up to 15 CEUs / 36 months

Reporting and Recordkeeping Standards Overall Assessment of Findings

- Report identifies interpreting physician
- Assessment categories
  - “Negative”
  - “Benign”
  - “Probably benign”
  - “Suspicious”
  - “Highly suggestive of malignancy”
  - “Incomplete: Need additional imaging evaluation”

Reporting and Recordkeeping Standards Communication of Results

- Report sent to referring health care provider (or patient with no health care provider) within 30 days
- “Suspicious” or “Highly suggestive of malignancy” results communicated to health care provider and patient as soon as possible (ideally, within 3-5 days)
- Summary report written in lay language sent to all patients within 30 days
- Self-referred patients receive both the lay language letter and the mammography report

Reporting and Recordkeeping Standards Mammographic Image Information

- Name of patient and patient identifier
- Date of examination
- View and laterality
- Facility name and location
- Technologist identification
- Mammography unit identification

Medical Records and Reports

- Medical reports and films kept by facilities for:
  - 5 years, OR
  - 10 years if no additional mammography performed on patient at that facility, OR
  - Longer if required by state or local law
- Original films transferred (temporary or permanent) upon request of patient or patient's representative
  - Fee charged may not exceed documented cost incurred by the facility

cont.

Medical Records and Reports (cont.)

Inspectors will ask to see:

- Randomly selected records
- Sample reports sent to referring health care provider
- Template of lay summary of mammography report sent to patients
- System for communicating findings
- Randomly selected reports
  - Interpreting physician identified
  - Assessment categories

Equipment Standards Overview

- Primarily new requirements
- Equipment must be “designed for mammography”
- Based on:
  - Recommendations of ACR focus groups on equipment
  - Comments from manufacturers and other interested parties
- Fewer items than initially proposed

Equipment Standards
Effective October 28, 2002

- Application of compression
  - Operable from both sides of patient
  - Initial power-driven compression with hands-free controls
  - Fine adjustment compression controls
- Maximum compression force for initial power drive must be between 111 newtons (25 pounds) and 200 newtons (45 pounds)

cont.

Equipment Standards
Effective October 28, 2002 (cont.)

- Automatic exposure control performance limits on variations tightened
  - Maintain film optical density within ±0.15 of mean optical density
- Focal spot condition only evaluated by determining system resolution
- Radiation output goes from 513 mR/sec to 800 mR/sec

Equipment Standards
Specific Requirements

- Motion of tube-image receptor assembly
  - Capable of being fixed in any position
  - No unintended motion during power interruption
- Image receptor sizes for each screen-film unit
  - 18 x 24 cm and 24 x 30 cm cassettes
  - 18 x 24 cm and 24 x 30 cm moving grid mechanisms

cont.

Equipment Standards
Specific Requirements (cont.)

- Light fields
  - Provide average illumination of 160 lux at 100 cm
- Magnification capacity
  - Systems designed for magnification provide at least one magnification in the range of 1.4 to 2.0

cont.

Equipment Standards
Specific Requirements (cont.)

- Breast compression devices
  - Compression paddles
    - For each image receptor size
    - Flat and parallel to the breast support table, OR
    - If paddle not designed to be flat and parallel, meet manufacturer's design and maintenance requirements

cont.

Equipment Standards
Specific Requirements (cont.)

- Breast compression devices (cont.)
  - By October 28, 2002:
    - Hands-free initial power driven compression
    - Operable from both sides of patient
    - Fine adjustments controls

Equipment Standards
Specific Requirements (cont.)

- Technique factor selection and display
  - Manual selection of mAs available
  - Technique factors indicated before exposure
- Automatic exposure control
  - AEC operable in all clinically used modes
  - Flexible positioning of detector
  - Selected optical density may be varied from normal (zero) setting

cont.

Equipment Standards
Specific Requirements (cont.)

- Display of selected focal spot and/or target material
- X-ray film designed for mammography
- Intensifying screens matched to film
- Film processing solutions meet film requirements
- High-intensity lighting (hot-lights) available
- Film masking devices available

Inspection Equipment Tests

- Unit is designed for mammography
- Unit has required image receptors, moving grids, and compression paddles
- Unit has functioning post-exposure display of x-ray focal spot and target material
- Collimation assessment
- Exposure reproducibility

cont.

Inspection Equipment Tests (cont.)

- Beam quality and half-value layer (HVL) measurement
- Dose calculation for a cranio-caudal view
- Processor evaluation
- Darkroom fog
- Phantom image quality evaluation

Quality Assurance Standards

General Administrative Requirements

Equipment Quality Assurance

Medical Outcomes Audit

General Administrative Requirements

- Responsible staff :
  - Lead interpreting physician
  - Interpreting physicians
  - Medical physicist
  - Quality control technologist
- Responsible for meeting quality assurance recordkeeping requirements

Equipment Quality Assurance
Screen-Film Units

- Specifications for:
  - Tests to be performed
  - Frequency
  - Action limits
- Facility generally free to choose test procedures that meet its needs
- For non-screen-film equipment, follow manufacturer's quality assurance instructions

Equipment Quality Assurance
Tests Other Than Annual

- Daily tests
  - Film processor
- Quarterly tests
  - Fixer retention
  - Repeat analysis
- Weekly tests
  - Phantom image
- Semiannual tests
  - Darkroom fog
  - Screen-film contact
  - Compression device performance

Equipment Quality Assurance
Annual Tests

- Automatic exposure control
- Kilovoltage peak accuracy
- Focal spot condition
- Beam quality and half-value layer
- Breast entrance air kerma and AEC reproducibility
- Dosimetry

cont.

Equipment Quality Assurance
Annual Tests (cont.)

- X-ray field / light field / image receptor / compression paddle alignment
- Uniformity of screen speed
- System artifacts
- Radiation output
- Decompression

Equipment Quality Assurance
Mobile Units

- Performance testing of mobile units for image quality accuracy
- At each location and before imaging patients
- Examples of acceptable tests
  - Phantom testing
  - Acceptable limits for variation in mAs
  - Other tests

Equipment Quality Assurance
Test Results

- Use of test results
  - Compare results to action limits
- For results “out of limits”
  - Identify source of problem
  - Take corrective action and document

Equipment Quality Assurance
Corrective Action Time Frames

- Before use of failed component for:
  - Processor
  - Phantom
  - Fog
  - Screen-film contact
  - Compression
  - Dose
  - Other modality receptors
  - Mobile unit
- Within 30 days for all other tests

Equipment Quality Assurance
Medical Physicist Survey

- All annual QC tests for screen-film and other modalities
- Review of facility's equipment test records and corrective actions
- Survey report
  - Includes summary and recommendations for corrective action
  - Dated and signed by qualified medical physicist who performed or supervised the survey
  - Sent to facility within 30 days (earlier for major problems)

Equipment Quality Assurance Mammography Equipment Evaluations

- Conducted or supervised by medical physicist
  - On newly installed equipment prior to use on patients
  - After disassembly and reassembly of equipment
  - After major component change or repair
- Problems detected must be corrected before equipment is put into service
- Facility must maintain documentation for system

Infection Control

- Facility must establish procedures for cleaning and disinfecting mammography equipment
- Procedures must comply with existing federal, state, and local laws
- Procedures must comply with manufacturer's recommendation for cleaning and disinfection

Inspection of QA and QC Programs

- Inspector will confirm that facility has:
  - Established a QA program
  - Designated qualified personnel
- The inspector will check records for:
  - Daily processor quality control tests
  - Weekly phantom image tests
  - Quarterly analysis of fixer retention in films tests
  - Quarterly repeat analysis tests
  - Semiannual darkroom fog tests

cont.

Inspection of QA and QC Programs (cont.)

- The inspector will check records for (cont.):
  - Semiannual screen-film contact tests
  - Semiannual compression tests
  - Personnel responsibilities and procedures for QA/QC testing
  - Other QA-related written policies, procedures, and records
  - Mammography technique charts

Inspection of QA and QC Programs (cont.)

The QC records should show that tests were:

- Conducted at regulated frequencies
- Conducted according to the appropriate manual or manuals
- Followed up by any corrective actions shown to be necessary
- Corrective actions must be documented

Mammography Medical Outcomes Audit

- Effective tool for maintaining or improving the quality of interpretations
- Conducted annually
- Follow-up system required to track all positive mammograms
- Facility assigns at least one physician to ensure that:
  - Data is collected and analyzed once every 12 months
  - Follow-up actions are documented, if any taken

Medical Audit and Outcome Analysis Records

- Track all positive mammograms
- Correlate findings with surgical biopsy results obtained
- Include cancers of which the facility becomes aware
- Inspector will:
  - Examine tracking system
  - Ask how biopsy results obtained
  - Ask to see examples of reports obtained by the facility
  - Confirm that analysis is performed annually

Breast Implant Imaging

- To ensure adequate examinations of the estimated 2 million women with breast implants
- Primary requirements
  - Inquire about implants before the exam is performed
  - Maximize visualization of breast tissue
- Radiologic technologists qualifying after April 28, 1999, must have breast imaging training

Consumer Complaints

- Facility must develop written system for collecting and resolving complaints
- Complaints that cannot be resolved at facility are referred to the accreditation body
- Complaints not resolved by accreditation body are referred to FDA
- Serious complaints are reports of events that could adversely affect clinical outcomes
- Facility must maintain records of serious complaints for at least 3 years

Additional Mammography Review and Patient Notification

- FDA believes mammography quality compromised
- Facility provides clinical images for additional review to accreditation body or an entity designated by FDA
- Based on review, FDA determines whether to notify affected patients and referring health care providers

MQSA Internet Site
http://www.fda.gov/cdrh/mammography

- MQSA Policy Guidance Help System
- Documents such as:
  - Current and back issues of *Mammography Matters*
  - *Federal Register* notices
  - *Preparing for MQSA Inspections*
  - *Mammography Facility Survey and Medical Physicist Qualification Requirements under MQSA*
- Other useful information

...for more Information on MQSA

- MQSA Facility Hotline:
  - Phone: 1-800-838-7715
  - Fax: 1-410-290-6351
- Requests for published information:
  - Fax: 1-301-986-8015
  - Mail: MQSA
    c/o SciComm, Inc.
    PO Box 30224
    Bethesda, MD 20824-9998