TechNation
Webinar ▶ Wednesday

John DiPasquale presents:

Mammography & MQSA - An Overview

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TechNation
Webinar ▶ Wednesday

Wednesday, November 16th, 2016, 2:00pm ET

PRESENTER: John DiPasquale

John DiPasquale, Technical Trainer for Technical Prospects, obtained his associate degree in Instructor Technologies and Biomedical Equipment from Community College of the Air Force; his bachelor's degree in Business Administration and Electronics Technology from WaylandBaptist University; and his master's in Education from Boston University. He is a Certified Biomedical Equipment Technician (CBET), and has over 25 years of experience in the HTM industry.

WEBINAR AGENDA: The primary purpose of this presentation is to acquaint the field engineer with the MQSA law that surrounds the mammography modality that is part of the imaging world. Those attending will receive an overview with a short history associated with it, learn about the requirements under MQSA including the equipment, what are the specific personnel responsibilities, some associated key terminology and lastly how does the law apply to the current digital equipment that is very common place today.

This presentation is only designed to familiarize and give an overview for someone with the MQSA regulations

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Our presenters will end today's webinar with a Q&A session. If you have a question, please submit it early by emailing webinar@mdpublishing.com.

All questions will be addressed at the end of today's presentation or the presenter will follow up with you offline.

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Mammography & MQSA – An Overview

John DiPasquale

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A little about me…

- **Got my start in electronics while in the USAF**
  - Aircraft electrician – 4 yrs.
  - BMET – 18 yrs.
    - **Technician, Manager, Instructor and Regional Manager**
- **After military service**
  - 8 years in various imaging and biomedical capacities including asset management for both in-house and 3rd party contract positions
  - Left industry to teach HS Mathematics in the Connecticut Vocational Technical HS System
  - Came back to industry in 2006
    - 1st OEM experience with Hologic
    - Technical trainer on both analog / digital imaging systems and support systems for their mammography lines
  - Moved to Wisconsin in early 2013 and began career with TP in December of that year.
- **Education & Credentials**
  - Masters degree in Education
  - Bachelors degree in Electronics Engineering and Business Administration
  - AAS in Instructor and Biomedical Equipment Technologies
  - ICC CBET since 1994
  - USAF Master Instructor

The hard question:

What is MQSA???

A possible answer…

- It is the United States supplemental law for establishing requirements for the mammography modality. In addition to 20 CFR, Part 1020, Sub chapter J (which provides governing oversight for radiation emitting products), it establishes the additional specific guidance for accrediting bodies, mammography facilities, equipment (both analog & digital), personnel, radiation dosage, patient notification & record keeping, and quality control for this modality.
  - *Additional note* – while this law only applies to the United States, personnel should understand that our law closely reflects those of the international community where mammography is also performed and while there may be differences consult your country's regulations for the specifics that apply to you.

Disclaimer…

- This presentation is only designed to familiarize and give an overview for someone with the MQSA regulations and not replace the actual document authored by the FDA.
- One can find the actual document at this internet address:
  - http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/
    - Or Google "MQSA" and the top item will lead you to the above link

What we will cover today…

Overview
MQSA Requirements
Personnel Responsibilities
Terminology
Digital Equipment

TECHNICAL PROSPECTS

Overview

Key Terms
Preface
Introduction
Background

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TECHNICAL PROSPECTS

Key Terms

- ACR – American College of Radiology
- FDA – Food and Drug Administration
- HHS – Health and Human Services
- CME – Continuing Medical Education
- ABR – American Board of Radiologists
- ABMP – American Board of Medical Physicists
- CFR – Code of Federal Regulations
- ARRT – American Registry of Radiologic Technologists
- ARCT – American Registry of Certified Technologists

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Preface

- These are the questions we are going to try to answer today – keep them in mind as we go through the material.
- What is the MQSA?
- When does MQSA apply?
- Where does it apply?
- Why does it apply?
- Who is MQSA?
- How does it apply?

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Introduction – 1

WHO is MQSA???

- It's the Federal Government of the United States.
- Its public law
  - Enforced by the charter & policies of the Food & Drug Administration (FDA).
  - Policed by Health & Human Services (HHS)

WHAT is MQSA???

- MQSA is the **M**ammography **Q**uality **S**tandards **A**ct passed into public law in October 1992.
- By definition, MQSA is an FDA program that certifies mammography centers meet quality standards for personnel, equipment, radiation dosage, patient notification & record-keeping.

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Background – 1

- Breast cancer is the leading form of cancer amongst women.
- In comparison, during the 10 years of the Viet Nam war 57,000 soldiers died, whereas during this same period 330,000 women died from breast cancer.
- There have been various pioneers in the field of mammography dating as far back as 1913 when a German surgeon, Dr. Salomon, conducted studies and reported the correlation of clinical and radiographic findings of breast tumors, particularly the characteristics of invasive carcinoma.

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TECHNICAL PROSPECTS

Background – 2

- In the 50 years following Dr. Saloman's studies, support of breast cancer studies had varied as a direct onset of wars and the depression.
- Mammography finally got its recognition in the 1960's when Dr. Robert Egan developed a direct film mammography technique whose key factors were:
  - A generator capable of producing 20-32 kVp
  - 1800 mAs
  - A cylinder type or "D" cone was used as a collimator
  - The film was a fine grain, slow speed film requiring an 8-minute hand processing cycle
  - Three views for complete coverage with a 97% diagnostic accuracy

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TECHNICAL PROSPECTS

Background – 3

- Since these early studies there have been significant advancements in both the equipment & film processing technologies.
- Smaller doses of radiation are now possible due to in part to advancements in the:
  - Different types of anode materials being used
  - Different filters being utilized
  - Smaller focal spots
  - Use of compression devices
  - Dedicated processors, film, film speeds & film-screen combinations
- As an example of these improvements, the change to the entrance skin dose:
  - It **WAS** 8.3 R (pre- 1970)
  - It's **NOW** .4 - .6R (post –1984)

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TECHNICAL PROSPECTS

Background – 4

- The most significant factor was the signing of public law 102-539, in October 1992, as it established the Mammography Quality Standards Act.
  - This law defined the federal regulatory requirements for mammography.
- From 1992 - 1994, MQSA approval could be granted at the state level only after the state's mammography program was approved by the federal government.
- On October 1, 1994 all facilities required certification by the Secretary of Health and Human Services.
- This law was re-certified in 1999 & 2004, and remains in effect today.
- MQSA - Public law 102-539
  - The passing of this public law empowered the HHS by providing strength, creditability and oversight of mammography programs, while forbidding any person, business or practice from engaging in a mammography program without certification.

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TECHNICAL PROSPECTS

Introduction – 2

WHEN does MQSA apply???

- Under the MQSA and after October 1, 1994 all mammography facilities-whether in a hospital, doctor's office, mobile van, military base, or any other public or private enterprise—must be accredited and federally certified as meeting quality standards.
- All will be subject to federal inspection and certification.
- After initial certification, facilities must pass annual inspections by approved federal or state inspectors.

WHERE does MQSA apply???

- Since October 1, 1994, and the passing of the public law, all mammography programs in the continental United States, inclusive of its territories and commonwealths (Puerto Rico, Guam, U.S. Virgin Islands) are now required to operate under the MQSA.
  - Veterans Administration hospitals are exempt from the law.
    - However, the House Committee on Veterans Affairs has stated it will take steps to ensure that mammography in veterans facilities is subject to the same quality standards required by the MQSA.

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TECHNICAL PROSPECTS

Introduction – 3

WHY does MQSA apply???

- In the most simple of terms, the purpose of MQSA is to improve the quality and delivery of mammography to the patient.

HOW does MQSA apply???

- That's next and will be discussed in detail when we cover the MQSA requirements.

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TECHNICAL PROSPECTS

MQSA Requirements

Accrediting Body
Facility
Personnel
Equipment
Radiation Dosage
Patient Notification
Record Keeping
Quality Control

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TECHNICAL PROSPECTS

Accrediting Body – 1

- An accrediting body is an FDA approved representative/group that notifies FDA or the Certifying State after it has determined the initial facility accreditation application is acceptable, or when a facility has been accredited.
- FDA or Certifying State issues the appropriate certificate which must be prominently displayed where all can see
  - 3 year
    - Must re-certify before this expires
  - 6 month provisional
  - Must be approved, certified & have its certificate before it can legally perform mammography exams.
- Who are the accrediting bodies??
  - American College of Radiology (ACR)
  - Arkansas Department of Health & Human Services
  - Iowa Department of Public Health
  - Texas Department of State Health Services
- State accrediting bodies can only approve within their state or the facility can use the ACR.
  - State laws may require additional requirements for them to be certified
    - These are independent of MQSA
    - And facilities in these states must satisfy both the state and federal (MQSA) requirements to be certified.

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TECHNICAL PROSPECTS

Accrediting Body – 2

Requirements

- Facility standards review
- Clinical Image Review
- Physics Survey Review
- On-site visits
- Complaint reporting process
- Reporting and Recordkeeping
- Maintaining reasonable fees

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TECHNICAL PROSPECTS

Facility

- Legislation has called for all mammography facilities (screening and diagnostic) to be:
  - Accredited
  - Certified
  - Inspected
- Must demonstrate a system of checks & balances
- The following *annual* updates ***MUST*** be provided (self reporting):
  - Personnel changes
  - Equipment changes
  - Quality Control logs
  - Medical Physicist Report

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TECHNICAL PROSPECTS

Personnel – 1

Who is affected??

- Interpreting Physician (IP) / Radiologist
- Medical Physicist
- Radiologic Technologist

Must comply with…

- Initial qualifications
- Continuing education
- Continuing experience
- Re-establishing qualifications

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TECHNICAL PROSPECTS

Personnel – 2

Interpreting Physician / Radiologist

- Initial Qualifications
  - Licensed, Board Certified or at least 3 months training in interpretation; radiation physics, effects & protection
  - 60 hours - Category 1 CME in Mammography
    - 15 hours w/in 3 years prior to meeting initial requirements
  - Read a minimum of 240 exams with supervision w/in six month prior to meeting the initial requirement
  - Received 8 hours of training in new modality before use
- Exemptions – Initial Qualifications
  - Considered to have initial qualifications
  - Must meet continuing education and experience requirement
- Continuing Education and Experience
  - 15 hours of Category 1 CME every 3 years
    - 6 hours in each modality
  - 960 mammograms read over 24 month period.

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TECHNICAL PROSPECTS

Personnel – 3

Medical Physicist

- Initial Qualifications
  - Certified by ABR or ABMP in an appropriate specialty OR, licensed OR approved by a State
  - Masters Degree or higher in a physical science
  - 20 semester hours of physics
  - 20 contact hours of training in conducting surveys of mammography facilities
  - Survey at least 10 systems/1 facility (under supervision) after 4/28/99
  - 8 hours of training in a new modality before surveying
- *ALTERNATIVE* Initial Qualifications
  - By April 28, 1999 qualified under Interim rules
  - Bachelor's Degree or higher in a physical science
  - 10 semester hours of physics
  - 40 contact hours of training in conducting surveys of mammography facilities
  - Survey at least 20 systems/1 facility
  - 8 hours of training in a new modality before surveying

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TECHNICAL PROSPECTS

Personnel – 4

Radiological Technologist

- Initial Qualifications
  - Certified by ARRT or ARCT, OR State licensed in general Radiology
  - 40 hours training (breast anatomy, physiology, positioning, and compression, QA/QC Techniques, imaging of patients w/ implants
  - 25 mammography examinations under direct supervision
  - 8 hours of training in new modality before use
- Initial Qualifications *EXEMPTION*
  - If qualified under Interim Rules
    - Considered to have met the initial qualifications
    - Must meet continuing experience and education requirements

PARTS TRAINING SUPPORT

TECHNICAL PROSPECTS

Equipment – 1

- The equipment must be specifically designed for mammography & dedicated to this use only.
- It must also be certified according to the Code of Federal Regulations (CFR) section 1020.3 and 1020.31 as of the date of manufacture.

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TECHNICAL PROSPECTS

Equipment – 2

Motion of tube – image receptor assembly

- This unit must not have any unintended motion once fixed in a position and shall not fail in the event of a power failure.

Image receptor sizes

- Must be capable of providing operation with image receptors of 18 x 24 centimeters (cm) and 24 x 30 cm at a minimum.
- Systems using screen – film image receptors shall be equipped with moving grids matched to all the image receptor sizes provided.
- Systems using magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.

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TECHNICAL PROSPECTS

Equipment – 3

Light Field

- The light beam passing through the x-ray beam limiting device shall be of 160 lux (15 foot candles) at 100cm or the maximum source to image distance (SID), whichever is less.

Magnification

- Systems used to perform non-interventional problem solving procedures shall have this capability available for use by the operator.
- They must have at least one magnification value in the range of 1.4 to 2.0.

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TECHNICAL PROSPECTS

Equipment – 4

Focal spot selection

- When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.
- When more than one target material is provided, the system shall indicate prior to exposure, the pre-selected target material.
- 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.

Technique factor selection & display

- Manual selection of mAs (milli-amperes times time in seconds) or at least one of its components shall be available, mA or time.
- The technique factors, kVp, mA, time, or mAs shall be indicated before exposure begins except when automatic exposure control (AEC) is used, in which case the settings prior to the exposure shall be indicated.
- Following AEC mode use, the system shall indicate the actual values used for kVp, mA, time or mAs.

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TECHNICAL PROSPECTS

Equipment – 5

Compression

- All mammography systems shall incorporate a compression device.
  - Effective October 28, 2002 all systems shall have an initial power driven compression activated by hands free controls from both sides of the patient and fine adjustment compression controls operable from both sides of the patient.
- Compression Paddle Requirements:
  - Systems shall be equipped with different size compression paddles to match the different size image receptors provided. Special purpose compression paddles that are provided do not have to meet this requirement.
  - 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 when compression is applied.
  - 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.
  - The chest wall of the paddle shall be straight and parallel to the edge of image receptor.
  - The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.

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TECHNICAL PROSPECTS

Equipment – 6

Automatic Exposure Control (AEC)

- Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, IE grid, non-grid; magnification, non-magnification; and various target-filter combinations.
- The unit needs to have multiple and selectable detectors which must be clearly indicated on the surface of the compression paddle and also which one is being used for the exposure.
- The operator must be able to vary the selected optical density from the normal setting.

Mammography in Mobile Settings

- A physician need not be present for the screening to take place
- Films will be batch processed and referred for reading
- Strict adherence to documented protocols must be met
- Phantom shots must be successfully accomplished after each relocation of a mobile unit

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TECHNICAL PROSPECTS

Equipment – 7

X-ray film

- The facility must use film specifically designated as appropriate for use in mammography.
- All films must be kept and accounted for.
  - Mammograms, good and bad
  - Maintenance films
- Film records must be kept for a minimum of 5 years

Intensifying screens

- The facility must use screens that are specifically designated as appropriate for mammography.
- The film used must match the spectral output of the screens as specified by the manufacturer.

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TECHNICAL PROSPECTS

Equipment – 8

Film Processing

- The chemicals used must meet or exceed the minimum requirements for processing as specified by the film's manufacturer.

Viewing Films

- Lighting
  - Special lights for film illumination must be provided for the interpreting physicians, which is brighter than the standard illumination provided by the view-box.
  - "Hot Lights"
- Film masking devices
  - The facility must ensure that masking devices are provided for the interpreting physicians that can limit the area equal to or smaller than the exposed area of the film.

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TECHNICAL PROSPECTS

Radiation Dosage

Radiation Output

- Conditions for measuring:
  - Use standard mammography mode
  - Any source to image distance (SID)
  - Measured at 4.5cm above the breast support surface
  - Compression paddle in place between source and detector
- The minimum *average* output over a 3 sec period is:
  - **Prior** to October 28, 2002 : 513mR/sec @ 28 kVp
  - **After** October 28, 2002 : 800mR/sec @ 28 kVp
  - Average is used in the event of a "pulsed" exposure.

Radiation Dose

- Glandular dose is to be certified annually by the physicist.
- Conditions:
  - Using 4.2 cm thick, 50–50 compressed breast equivalent phantom material (BR-12. Perspex, or Acrylic), consisting of 50% glandular, and 50% adipose tissue @ 28 kVp.
- Previous requirement: (Per exposure, prior to October 28, 2002)
  - (per exposure) the glandular dose will be ≤513mR/sec when operating at 28 kVp.
- New requirements (per exposure, After Oct 28, 2002)
  - 300mR/sec @ 26 kVp FDA standard nationwide
  - 200mR/sec @ 26 kVp in Michigan, Oregon and some international communities

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Patient Notification

- If the FDA believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by FDA, for review by the accreditation body or other entity designated by FDA.
- This additional mammography review will help the agency to determine whether the facility is in compliance with this section and, if not, whether there is a need to notify affected patients, their physicians or the public that the reliability, clarity and accuracy of interpretation of mammograms has been compromised.
- If the FDA determines that the quality of mammography performed by a facility, whether or not certified under Sec. 900.11, was so inconsistent with the quality standards established in this section as to present a significant risk to individual or public health, the FDA may require such facility to notify patients who received mammograms at such facility and their referring physicians of the deficiencies presenting such risk, the potential harm resulting, appropriate remedial measures and such other relevant information as FDA may require.
- Such notification will occur within a timeframe and in a manner specified by FDA.

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TECHNICAL PROSPECTS

Record Keeping – 1

- *Medical records and mammography reports*
  - (1) Each facility shall prepare a written report of the results of each mammography examination performed under its certificate. The mammography report shall include the following information:
    - (i) The name of the patient and an additional patient identifier;
    - (ii) Date of examination;
    - (iii) The name of the interpreting physician who interpreted the mammogram;
    - (iv) Overall final assessment of findings, classified in one of the following categories:
      - (A) "Negative:" Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained);
      - (B) "Benign:" Also a negative assessment;
      - (C) "Probably Benign:" Finding(s) has a high probability of being benign;
      - (D) "Suspicious:" Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;
      - (E) "Highly suggestive of malignancy:" Finding(s) has a high probability of being malignant;
    - (v) In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and
    - (vi) Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.

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TECHNICAL PROSPECTS

Record Keeping – 2

- (2) *Communication of mammography results to the patients*.
  - Each facility shall send each patient a summary of the mammography report written in lay terms within 30 days of the mammographic examination. If assessments are "Suspicious" or "Highly suggestive of malignancy," the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.
    - (i) Patients who do not name a health care provider to receive the mammography report shall be sent the report described in paragraph (c)(1) of this section within 30 days, in addition to the written notification of results in lay terms.
    - (ii) Each facility that accepts patients who do not have a health care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.

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TECHNICAL PROSPECTS

Record Keeping – 3

- (3) *Communication of mammography results to health care providers*.
  - When the patient has a referring health care provider or the patient has named a health care provider, the facility shall:
    - (i) Provide a written report of the mammography examination to that health care provider as soon as possible, but no later than 30 days from the date of the mammography examination; and
    - (ii) If the assessment is "Suspicious" or "Highly suggestive of malignancy," make reasonable attempts to communicate with the health care provider as soon as possible, or if the health care provider is unavailable, to a responsible designee of the health care provider.

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TECHNICAL PROSPECTS

Record Keeping – 4

- (4) *Recordkeeping*. Each facility that performs mammograms:
  - (i) Shall (with some exception) maintain mammography films and reports in a permanent medical record of the patient for a period of not less than 5 years, or not less than 10 years if no additional mammograms of the patient are performed at the facility, or a longer period if mandated by State or local law; and
  - (ii) Shall upon request by, or on behalf of, the patient, permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly;
  - (iii) Any fee charged to the patients for providing the services shall not exceed the documented costs associated with this service.

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Record Keeping – 5

- (5) *Mammographic image identification*. Each mammographic image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:
  - (i) Name of patient and an additional patient identifier.
  - (ii) Date of examination.
  - (iii) View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body and approved by FDA in accordance with Sec. 900.3(b) or Sec. 900.4(a)(8) shall be used to identify view and laterality.
  - (iv) Facility name and location. At a minimum, the location shall include the city, State, and zip code of the facility.
  - (v) Technologist identification.
  - (vi) Cassette/screen identification.
  - (vii) Mammography unit identification, if there is more than one unit in the facility.

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Record Keeping – 6

- *Consumer complaint mechanism*. Each facility shall:
  - (1) Establish a written and documented system for collecting and resolving consumer complaints;
  - (2) Maintain a record of each serious complaint received by the facility for at least 3 years from the date the complaint was received;
  - (3) Provide the consumer with adequate directions for filing serious complaints with the facility's accreditation body if the facility is unable to resolve a serious complaint to the consumer's satisfaction;
  - (4) Report unresolved serious complaints to the accreditation body in a manner and timeframe specified by the accreditation body.

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TECHNICAL PROSPECTS

Quality Control – 1

Quality Assurance – Records

- Personnel Responsible
  - Lead Interpreting Physician (LIP)
  - QC technologist
  - Medical physicist
- Types of records
  - Mammography technique & procedures
  - Quality Control
    - Monitoring data
    - Detected problems
    - Corrective actions & its effectiveness
  - Safety
  - Protection
  - Personnel qualifications
- Time Frame
  - All records until next annual visit & FDA determines compliance

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TECHNICAL PROSPECTS

Quality Control – 2

Quality Assurance – Equipment (1)

- Daily Checks
  - Accomplished BEFORE any clinical procedures are performed
- Film Processors
  - Operating levels tailored for that facility
    - Base + Fog Density (+0.03)
    - Mid – density (± 0.15)
    - Density difference (± 0.15)
- Weekly Checks
  - Requires an FDA approved phantom
- Tests
  - Phantom OD image ≥ 1.2 OD at image's center
  - Density obtained must be within ± 0.20 of the operating level
  - Phantom image achieves minimum score for fiber, masses & specks
  - Background density difference shall not vary more than ± 0.05 from the operating level

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Quality Control – 3

Quality Assurance – Equipment (2)

- Quarterly Checks
  - Fixer retention on film
  - Repeat analysis
    - Maximum allowable is 2%
    - Why it happened
    - Corrective measures implemented
    - Effectiveness of the above
- Semi-annual Checks
  - Darkroom Fog
    - ≤ 0.05 maximum after a 2 exposure to the normal darkroom conditions
  - Screen Film Contact
    - Requires a 40 mesh copper screen
    - All cassettes used in the facility must be tested
  - Compression Device Performance
    - Minimum force attainable of 111 newtons (25 pounds)
    - Initial power compression drive shall be between 111 newtons (25 pounds) and 200 newtons (45 pounds).

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TECHNICAL PROSPECTS

Quality Control – 4

Quality Assurance – Equipment (3)

- Annual Checks
  - Automatic exposure control (AEC) performance
  - Kilovoltage peak (kVp) accuracy & reproducibility
  - Focal spot condition
    - System resolution
    - Dimensions
  - Beam quality & half-value layer (HVL)
  - Breast entrance air kerma (absorbed dose) & AEC reproducibility
  - Dosimetry
- Annual Checks (continued)
  - X-ray field / light field / image receptor / compression paddle alignment
  - Uniformity of screen speed
  - System artifacts
  - Radiation output
    - MUST be measured 4.5 cm above the breast plate – sensor position of the device being used for measuring
    - 800 mR/sec (7.0 mGy air kerma/sec) @ 28kVp
  - Decompression

PARTS TRAINING SUPPORT

TECHNICAL PROSPECTS

Quality Control – 5

Quality Assurance – Equipment (4)

- Other Modalities
  - Applies to systems other than film-screen
  - Should be substantially the same
  - May not exceed the maximum allowable dose established for film-screen systems
- Mobile Units
  - Must be tested at each location BEFORE doing clinical exams
  - Testing method should establish the adequacy of the image quality produced.

PARTS TRAINING SUPPORT

TECHNICAL PROSPECTS

Quality Control – 6

Quality Assurance – Equipment (5)

- Test Results Usage
  - Compare to previous results or manufacturers standards for compliance and deviation
  - If previously discussed test are outside the allowable limits
    - System is shutdown and no further exams can be done until the problem is identified and corrected
      - May require physicist involvement and recertification
    - Other deficiencies must be corrected within 30 days
- Surveys
  - Required annually by Medical Physicists
    - Performance testing
    - Weekly phantom image quality testing
  - Medical physicist determines adequacy of all testing, corrective actions & its results.
  - Written report prepared, signed & delivered to facility within 30 days
    - Contains a summary of findings
    - Recommendations for necessary improvements

PARTS TRAINING SUPPORT

TECHNICAL PROSPECTS

Quality Control – 7

Quality Assurance – Equipment (6)

- **Mammography Equipment Evaluations**
  - Requires that they be certified by a medical physicist or their representative prior to use if a new installation, used equipment installation or if a system is re-located within a facility.
  - Equipment may ***NOT*** be used for clinical exams until passed
- **Facility Cleanliness**
  - The facility shall establish and implement adequate protocols for maintaining darkroom, screen, and view box cleanliness.
  - The facility shall document that all cleaning procedures are performed at the frequencies specified in the protocols.
- **Calibration of air kerma measuring instruments**
  - Medical physicists instruments MUST be calibrated once every two years and if repaired.
  - Calibration must be traceable back to a national standard and have a ± 6% accuracy in the mammography range.

PARTS TRAINING SUPPORT

TECHNICAL PROSPECTS

Quality Control – 8

Infection Control

- Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials.
- The documenting of facility compliance shall include:
  - Comply with federal, state & local regulations, and
  - Comply with manufacturer's recommendations for cleaning & disinfecting the equipment, or
  - Comply with generally accepted guidance until made available.

QA Medical Outcomes Audit

- Have a program for reviewing all positive mammograms & to correlate pathology results with the physician findings.
- Designed to ensure reliability, clarity & accuracy of the diagnosis.
- Audit frequency
  - 12 months
  - Program & Interpreting Physician
- General Guidelines
  - Review all mammograms performed w/ follow-ups on positive mammograms & the correlating pathology results
  - If a patient who is examined by the facility subsequently is diagnosed with breast cancer shall have all data reviewed prior to diagnosis of malignancy.

PARTS TRAINING SUPPORT

TECHNICAL PROSPECTS

Personnel Responsibilities

Interpreting Physician / Radiologist

Medical Physicist

Radiologic Technologist

PARTS TRAINING SUPPORT

TECHNICAL PROSPECTS

Personnel Responsibilities – 1

Common to All

- They ***MUST*** be state certified to work in mammography
  - Service Engineer does NOT have to be
- They ***MUST*** be part of an active continuing education program in order to maintain their certification

PARTS TRAINING SUPPORT

TECHNICAL PROSPECTS

Personnel Responsibilities – 2

Interpreting Physician / Radiologist

- Ensure the technologists have adequate training, and continuing education in mammography
- Provide an orientation program for technologists based upon a carefully established procedures manual.
- Ensure that an effective quality control (QC) program exists for all mammography performed at the site. The radiologist should provide motivation, oversight, and direction to the QC program.
- Select a primary, and alternate QC person for each of the QC tests to be done.
- Ensure that appropriate test equipment and materials are available to perform the technologist's QC test.
- Arrange staffing and scheduling so that adequate time is available, to carry out the QC tests and to record and interpret the results.
- Provide feedback to the technologists regarding clinical film quality and QC procedures.
- Select the medical physicist who will oversee the equipment related QC program and perform the physicists test.

PARTS TRAINING SUPPORT

TECHNICAL PROSPECTS

Personnel Responsibilities – 3

Interpreting Physician / Radiologist (2)

- Conduct periodic review of the technologist's tests every 3 months and annually for the physicist.
- Appoint a contact to oversee the radiation protection program for employees, patients and other individuals
- Quality Assurance (QA) Procedures Manual
  - Must remain current and updated
  - Must contain the following information:
    - Records concerning employee qualifications
    - Mammography technique and procedures to include all pertinent information for technicians as well as the glandular dose
    - Infection control procedures
    - QC Processes and Guidelines
    - Safety Procedures
- All mammography physicians
  - Follow facility's protocol when asked to interpret images of poor quality
  - Participate in the facility's medical outcomes audit program
  - Provide documentation of their current qualifications to each mammography facility where they practice

PARTS TRAINING SUPPORT

TECHNICAL PROSPECTS

Personnel Responsibilities – 4

Medical Physicist

- Performance testing is broken down into 3 major areas:
  - Image quality
  - Patient dose evaluations
  - Operator safety concerns
- An annual performance test ***MUST*** be accomplished and documented.

PARTS TRAINING SUPPORT

TECHNICAL PROSPECTS

Personnel Responsibilities – 5

Medical Physicist (2)

- Testing Areas are:
  - Mammography unit assembly evaluation
  - Collimation assessment
  - System resolution evaluation
  - Automatic Exposure Control (AEC) system performance evaluation.
  - Uniformity of screen speed
  - Artifact evaluation
- Testing Areas (cont.)
  - Image quality evaluation
  - Reliability and accuracy of kVp
  - Beam quality assessment (half value layer (HVL) measurement)
  - Breast entrance exposure, AEC reproducibility, average glandular dose, and radiation output rate
  - Measurement of view-box and room luminance.

PARTS TRAINING SUPPORT

TECHNICAL PROSPECTS

Personnel Responsibilities – 6

Medical Physicist (3)

- With the exception of image quality and average glandular dose, which must be corrected ***immediately****, all other corrections to the physicists findings must be corrected within 30 days of the test date.
  - * Immediately: If the issue cannot be resolved, the system will be shut-down until the issue is resolved to the satisfaction of the Medical Physicist.
- Whenever a major component of the system is changed or if unit is reassembled after dismantling, he must be notified and perform the appropriate testing to ensure the image quality has been maintained.
- Generally speaking these are the certified components of the system, IE collimator assembly, x-ray tube, AEC detectors, etc.

PARTS TRAINING SUPPORT

TECHNICAL PROSPECTS

Personnel Responsibilities – 7

Radiological Technologist

- Primary concern is patient care and image quality.
  - The above includes the following:
    - Proper patient positioning
    - Compression
    - Image production
    - Film handling and processing
    - Infection control in the event of blood or other substances getting on the equipment
- Varying levels of QC tasks to be accomplished
  - Daily
    - Darkroom cleanliness & Processor quality control
  - Weekly
    - Screen cleanliness, View-box and viewing conditions
    - Phantom images
  - Monthly
    - Visual checklist
  - Quarterly
    - Repeat analysis
    - Analysis of fixer retention in the film
  - Semi-annually
    - Darkroom fog, Screen-film contact
    - Compression

PARTS TRAINING SUPPORT

TECHNICAL PROSPECTS

Terminology Used

Clinical

Medical Physicist

Equipment

PARTS TRAINING SUPPORT

TECHNICAL PROSPECTS

Terminology – 1

Clinical – Mammography Positioning & Views

- Right = (Patient view)
- Left = (Patient view)
- Medial = Middle
- Lateral = Outside
- Cranial = Head
- Caudal = Tail (foot)
- Posterior = Rear
- Superior = top
- Inferior = bottom
- Prone = face down
- Supine = face up
- Oblique = at an angle
- Anterior = front
- Axillary = upper angle (of pectoral muscle/armpit)

PARTS TRAINING SUPPORT

TECHNICAL PROSPECTS

Terminology – 2

Clinical – Mammography Positioning & Views (2)

- Primary Mammogram Positions
  - Medio-Lateral Oblique (MLO)
  - Cranial-Caudo (CC) – vertical shot
    - These are the two primary views applied for screening of patients, 2 exposures for each breast, for a total of 4 exposures
- Common Tissue Types
  - Glandular (Muscular/dense tissue)
  - Adipose (Fatty tissue)
  - Fibrous (Connective tissue with high concentrations of collagen and protein)

PARTS TRAINING SUPPORT

TECHNICAL PROSPECTS

Terminology – 3

Clinical – Mammography Positioning & Views (3)

- Mammography Projection and Special Views
  - Miscellaneous labeling used on images
    - M = Magnification
    - X = Exaggerated
    - CV = Cleavage
    - R = Rolled
    - ID = Implant displaced
    - AT = Axillary Tail
    - TAN = Tangential (on the edge)
    - FB = From Below (C-arm is > +/- 90 degrees)

PARTS TRAINING SUPPORT

TECHNICAL PROSPECTS

Terminology – 4

Medical Physicist

- Material and Dose Measurements
  - B.E.M. = Breast Equivalent Material
  - Kerma = Alternate term for absorbed dose
  - AGD = Average Glandular Dose
    - Calculated from values of entrance exposure in air, the X-ray beam quality (half-value layer), and compressed breast thickness, is the energy deposited per unit mass of glandular tissue averaged over all the glandular tissue in the breast.
  - EGD = Entrance/Effective Dose
    - dose absorbed at the surface of the skin where the x-ray beam enters.
  - MGD = Mean Glandular Dose
    - is deduced from measurement of the air kerma at the entrance surface of a 4 cm phantom by applying a series of conversion factors
- Dose Values and Conversions
  - R = Rad (basic unit of absorbed dose, 1 unit)
  - mR = milliRad (1000th of a Rad, or .001R)
  - Gy = Gray (equal to 100 Rad)
  - mGy = MilliGray (1000th of a Gray, or .001Gy)
  - 1 mGy = 100 mR (conversion)

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TECHNICAL PROSPECTS

Terminology – 5

Medical Physicist – Test Tools

- Invasive / Non-Invasive
  - Methods of testing
  - Invasive is the term used to describe a test result that is acquired directly from the source. e.g connecting a divider to the generator to test kV.
  - Non-invasive is the term used to describe a test result that is acquired by an indirect measurement. e.g calculated measurement of kV from the x-ray source.
- Phantom / B.E.M.
  - Test tool that simulates at specific (breast) tissue equivalence used for establishing an anticipated result when conducting dose, or resolution testing.
    - Common Phantoms Include: ACR 156, Line Pair Resolution, CIRS
    - BEM types include: Homogenous Acrylic, BR-12, Perspex, BEM 50/50, 70/30, or 30/70 (the values noted in BEM represents the % of Glandular & Adipose tissue equivalence), with the most common being 50/50.

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TECHNICAL PROSPECTS

Terminology – 6

Equipment

- kV = Kilovolt (1000 volts = 1kV)
- kVp = Kilovolt Peak (used as an alternate to kV, Ripple dependent, the difference from kV is benign)
- mA = milliampere (1000th of an Ampere, 1mA = .001A)
- mAs = milliamp/second (1000th of an ampere per second of time)
- HVL = Half value layer (Thickness of Aluminum to reduce the X-Ray output at surface by factor of 2X).
- Lux = Measurement of light Illuminence (for collimator lamp output)
- SID = Source to Image Distance (x-ray tube focal spot to image receptor)
- Grid = Anti scatter device (cellular, linear, reciprocating, fixed, focused, single/multi pass)
- AEC = Automatic Exposure Control (Mode of operation for controlling film density)
- O.D. = Optical Density (density measurement of film emulsion)
- I.R. = Image Receptor (this is the film, though the breast tray (a.k.a breast receptor is often referred to as the Image receptor)

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TECHNICAL PROSPECTS

Terminology – 7

Equipment (2)

- X-ray Beam Filtration (Various)
  - "Mo" = Molybedum/Moly (X-ray Tube Filter, & X-ray Tube Anode material)
  - "W" = Tungsten (X-ray Tube Anode material)
  - "Rh" = Rhodium (X-ray Tube Filter material)
  - "Ag" = Silver (X-ray Tube Filter material)
  - "Cu" = Copper (X-ray Tube Filter material)
  - "Al" = Aluminum (X-ray Tube Filter material)

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TECHNICAL PROSPECTS

Digital Equipment

Alternate Rule

Mammography System QC Manual by the OEM

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TECHNICAL PROSPECTS

Alternate Rule

- MQSA regulation predominantly applies to screen-film, wet processing mammography
- FDA approves all alternate rules compliance prior to use as a standard
  - For mammography equipment this is the accompanying QC manual for the digital system.
- Digital equipment ***MUST*** meet the requirements of the above, yet allow for the significant difference between analog & digital mammography modalities
  - Example: Reproducibility testing
    - Analog world
      - 10 exposures
      - OD obtained after processing
    - Digital world
      - 3-5 exposures
      - Dose produced in generating the image

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TECHNICAL PROSPECTS

Mammography System QC Manual

- FDA requires its approval of the QC manual used for digital systems
  - The instructions therein become the regulatory requirement.
- OEM digital mammography equipment will come with an approved QC manual which ***MUST*** be followed and complied with.
  - If a difference exists between the general law and the specific requirements specified in the OEMs QC manual, the OEMs QC manual will take precedence.
- **NEW** alternate rule #24, effective as of ***3/7/2016*** – facility option
  - ACR Digital Mammography Quality Control Manual for FFD mammography systems may be used on systems WITHOUT advanced imaging capabilities (IE 3D tomo-synthesis & contrast enhancement)
    - Advanced imaging capabilities is being worked on but must be approved prior to use – expect this announcement within the year(?).
  - Also requires a new Digital Mammography QC Phantom
    - Covers more of the image receptor platform
    - At present ONLY Gammex & CIRS are approved to produce this new phantom.
  - Additional information on this can found at:
    - http://www.acraccreditation.org/Modalities/Mammography

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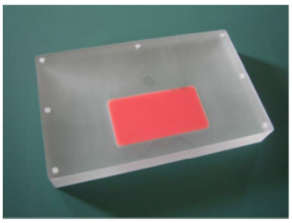
TECHNICAL PROSPECTS

New ACR Digital Mammography (DM) Phantom



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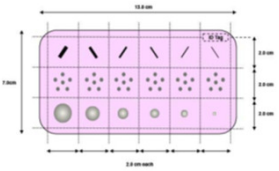
TECHNICAL PROSPECTS

New ACR DM Phantom Scoring



Test Object	Full Point	Half Point
Fibers (6)	• Full length visible (≥ 8 mm) • Correct location • Correct orientation • 1 break allowed – must be ≤ fiber width	• At least half length visible (≥ 5mm & ≤ 8mm) • Correct location • Correct orientation • 1 break allowed – must be ≤ fiber width
Speck Groups (6)	• 4 – 6 specks visible • Correct locations	• 2 – 3 specks visible • Correct locations
Masses (6)	• Density difference visible • Border is continuous & generally circular (≥ ¾ border visible) • Correct location	• Density difference visible • Border is continuous & generally circular (≥ ½ & ≤ ¾ border visible) • Correct location

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TECHNICAL PROSPECTS

Hot off the presses… "New Requirement"

EQUIP: Enhancing Quality Using the Inspection Program

- Introduced 10/27/2016
- Effective 1/1/2017
- 1 year grace period where no citations will be issued beginning with effective date but will be noted on the inspection report.
  - If not corrected during the initial year, Level 2 violations will be issued during annual review.
- Adds 3 new questions & deletes 2 others but will be still be looked at for compliance in different means
- New questions to help meet Practice Quality Improvement (PQI) of the American Board of Radiology (ABR) for certified Interpreting Physicians (IPs) who are subject to PQI requirements.
- Newly added questions
  - Do the facility procedures ensure that clinical images continue to comply with AB standards &include regular reviews of sample images from each technologist & interpreting physician
  - It will access for corrective procedures when clinical images are of poor quality, including a feedback mechanism for the technologist & other personnel.
  - Assess the procedures for LIP oversight of QA/QC records – including the frequency of performance of all required tests - & the determination whether corrective action were taken when needed

PARTS TRAINING SUPPORT

TECHNICAL PROSPECTS

What we covered today…

Overview
MQSA Requirements
Personnel Responsibilities
Terminology
Digital Equipment

PARTS TRAINING SUPPORT

TECHNICAL PROSPECTS

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