RADT-2660: MQSA AND ACR REGULATORY STANDARDS

Cuyahoga Community College

Viewing: RADT-2660 : MQSA and ACR Regulatory Standards

Board of Trustees:
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Academic Term:
Fall 2023

Subject Code
RADT - Radiography

Course Number:
2660

Title:
MQSA and ACR Regulatory Standards

Catalog Description:
An overview of the mammography departmental structure and essential personnel. Review of specific guidelines set forth by the regulatory agencies and accrediting bodies that closely monitor a facility's quality assurance and quality control program, which provide the foundation for quality patient services offered by a facility. Discussion of how these regulations affect the daily operations of a facility or services it provides.

Credit Hour(s):
1

Lecture Hour(s):
1

Requisites

Prerequisite and Corequisite
RADT-2610 Fundamentals of Mammography; and RADT-2620 Anatomy and Pathology of the Breast; and RADT-2630 Positioning Techniques for Breast Imaging, and RADT-2640 Physics of Mammography; and concurrent enrollment in RADT-2930 Mammography Applications.and concurrent enrollment in RADT-2930 Mammography Applications.

Outcomes

Course Outcome(s):
Define the current and historical national guidelines and standards set forth by the Mammography Quality Assurance Advisory committee, the Food and Drug Administration (FDA).

Essential Learning Outcome Mapping:
Not Applicable: No Essential Learning Outcomes mapped. This course does not require application-level assignments that demonstrate mastery in any of the Essential Learning Outcomes.

Objective(s):
a. Describe the historical relevance for regulatory compliance for mammography facilities.
b. Discuss the current regulatory compliance factors for facilities that deliver mammography services.
c. Describe legal terms related to mammography regulations.
d. Discuss the accreditation process according to the Food and Drug Administration (FDA).
e. Describe the process for a mammography inspection according to the Mammography Quality Standards Act (MQSA).

Course Outcome(s):
Identify essential personnel and their requirements and responsibilities in a mammography facility.

Essential Learning Outcome Mapping:

Not Applicable: No Essential Learning Outcomes mapped. This course does not require application-level assignments that demonstrate mastery in any of the Essential Learning Outcomes.

Objective(s):

a. Discuss the role of the physician, mammographer, quality control technologist, and medical physicist within the quality management program.

Course Outcome(s):

Describe the purpose and scope of a quality assurance program for mammography services.

Essential Learning Outcome Mapping:

Not Applicable: No Essential Learning Outcomes mapped. This course does not require application-level assignments that demonstrate mastery in any of the Essential Learning Outcomes.

Objective(s):

a. Recognize the purpose of the quality assurance program for a mammography facility.
b. Discuss the quality control component of a quality assurance program.
c. Identify initial qualification and continuing qualification standards for quality assurance programs.
d. Recognize image quality standards needed for mammography imaging.

Methods of Evaluation:

a. Participation and discussion
b. Written assignments
c. Case studies
d. Exams
e. Quizzes
f. Other methods deemed appropriate by department

Course Content Outline:

a. Types of Mammmography Departments
    i. Hospitals
    ii. Outpatient departments
    iii. Clinics
    iv. Private radiology practices
    v. Mobile units
    vi. Government-owned facilities
    vii. Other
b. Essential Personnel Requirements and Responsibilities
    i. Interpreting physicians
        1. Initial qualifications
            a. Medical licensing
            b. Certification/initial training
        2. Clinical experience
            a. Interpretation of mammograms according to MQSA guidelines
        3. Continuing education
            a. Regulations
            b. Requirements
        4. Continuing clinical experience
        5. Re-establishing qualifications
        6. Lead interpreting physician
            a. Responsibilities
            b. Duties
    ii. Mammographers

1. Initial qualifications
    a. Licensing
    b. Certification
2. Clinical experience
3. Continuing education
    a. Regulations
    b. Requirements
4. Continuing clinical experience
5. Re-establishing qualifications
6. Quality control (QC) technologist
    a. Responsibilities
    b. Duties

iii. Medical physicist
1. Initial qualifications
    a. License or approval by state
2. Clinical experience
3. Certification
4. Continuing education
    a. Regulations
    b. Requirements
5. Continuing clinical experience
6. Re-establishing qualifications

iv. Retention of personnel records

c. National Guidelines and Standards
i. FDA
1. Approved accrediting and certification agencies for mammography
    a. Private, nonprofit organizations (e.g. ACR)
    b. States that have approved accrediting bodies
    c. States that are approved certifying agencies
2. Responsibilities of accrediting or certification agencies
    a. Facility standards
        i. Physician standards
        ii. Mammographer standards
        iii. Medical physicist standards
        iv. X-ray equipment standards
        v. QA and QC programs
        vi. Phantom image quality testing
        vii. Radiation dose limits
        viii. Information update provisions
        ix. Medical records
            1. Image retention
            2. Digital image retention
            3. Physician notification
                a. Timeline
                b. Assessment categories
        x. Patient notification requirements
            1. Lay report
            2. Timeline
        xi. Clinical image review
            1. MQSA Enhancing Quality Using the Inspection Program (EQUIP)

ii. MQSA requirements for compliance
1. Accreditation and certification of mammography facilities
2. Annual mammography facility physics survey, consultation and evaluation performed by a certified or state-licensed medical physicist
3. Annual inspection of mammography facilities, performed by federally certified or state-certified inspectors
4. Qualification standards for interpreting physicians, mammographers, medical physicists and mammography facility inspectors
5. Specified boards or organization eligible to certify the training and experience of mammography personnel
6. Quality standards for mammography equipment and practices, including QA and QC programs

7. Standards governing consumer complaints, record-keeping for patient files and requirements concerning mammography reporting and patient notification by physicians
8. Review of outcome data, including disposition of all positive mammograms and correlation of pathology results
9. Procedures addressing (EQUIP) criteria

d. Additional Quality Assurance Procedures
   i. Initial qualification and continuing qualification standards
      1. Physicians
         a. Lead interpreting physician
      2. Mammographers
         a. QC technologist
      3. Medical physicist
   ii. MQSA inspection by federally-certified or state-certified inspectors
      1. On-site testing of equipment
      2. Analysis of QA program
         a. State inspection
e. Image Quality Standards
   i. Proper identification
      1. Patient name and additional identifier
      2. Date of examination
      3. View and laterality
      4. Facility name and location
      5. Technologist identification
      6. Mammography unit identification
   ii. Proper placement of markers
f. Guidelines for Accreditation
   i. Annual mammography facility survey, consultation and evaluation performed by a certified or state-licensed medical physicist
   ii. Annual inspection of mammography facilities, performed by federally certified or state-certified inspectors
   iii. Qualification standards for interpreting physicians, mammographers and medical physicists
   iv. Specified boards or organizations eligible to certify the training and experience of mammography personnel
   v. Quality standards for mammography equipment and practices, including QA and QC programs and clinical image review
   vi. Standards governing consumer complaints, record-keeping for patient files and requirements concerning mammography reporting and patient notification by physicians

Resources

American College of Radiology. ACR Mammography Manual. Reston, VA.

American Registry of Radiologic Technologists (ARRT). (current edition) Content Specifications for Mammography. St. Paul, MN. https://www.arrt.org/docs/default-source/discipline-documents/mammography/mammography-content-specifications.pdf?sfvrsn=8a6303fc_8

American Society of Radiologic Technologists. (Current) American Society of Radiologic Technologists Mammography Curriculum. Albuquerque, NM. https://www.asrt.org/docs/default-source/educators/curriculum/mammography/2018-adopted-mammography-curriculum.pdf

Cardenosa, Gilda. (2017) *Breast Imaging Companion*, Philadelphia: Wolters-Kluwer.

FDA: U.S. Food and Drug Administration. *Policy Guidance Help System*, https://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem/default.htm

Lille, Shelly L. Marshall, Wendy. (2019) *Mammography Imaging-A Practical Guide*, Philidelphia: Wolters-Kluwer.

Peart, Olive. (2022) *Lange Q and A: Mammography Examination*, New York: McGraw-Hill.

Peart, Olive. (2022) *Mammography and Imaging Prep: Program Review and Exam Prep*, New York: McGraw-Hill.

Philpotts, Liane. Hooley, Regina. (2017) *Breast Tomosynthesis*, Philidelphia: Elsevier.

Resources Other

U. S. Department of Health and Human Services. *Quality Determinants of Mammography Clinical Practice Guidelines*

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