Enhancements to MQSA Inspector Training

Preet Sudhaker
Chief, Program Management Branch
Division of Mammography Quality Standards
Office of In Vitro Diagnostics and Radiological Health
Solicitation Process

- CDRH/Division of Mammography Quality Standards (DMQS) solicits candidates for MQSA inspector training in consultation with FDA’s Regional Radiological Health Representatives (RRHRs) and Office of Regulatory Affairs’ (ORA) Office of Partnerships.
- Solicitation typically takes place six months prior to Course I.
Nominations

• The RRHRs along with the ORA/ Office of Partnerships serve as FDA’s liaisons to the State Program Directors and FDA supervisors in soliciting nominees for inspector training.

• They review and make recommendations to DMQS

• DMQS makes final decisions

• No cost to states
Inspector Ratio

- General ratio is one inspector for every 50 facilities in a state
- DMQS evaluates any requests for additional inspectors on a case by case basis
- Encourage states to be proactive in planning for retirements and departures of inspectors
MQSA Training - 3 Part Program

Course I: Basic Radiographic Imaging and Radiologic Physics (Online)

Course II: Mammography Quality Assurance & Survey Procedures (Online) & (3) Field Inspection Observations prior to Course II

Course III: MQSA Inspection Procedures (In-Residence) & at least (3) Mentored Inspections before students are deemed fully certified
MQSA Course I

• Introduction to Radiologic Health Physics -
Course I Objectives (online):

  • Course I contains two courses, (1) Mosby’s Radiography Online: Radiographic Imaging and (2) Mosby’s Radiography Online: Radiologic Physics

  • Provides students with the fundamental concepts of radiation physics as a foundation for inspections
Why Switch to Online Resources for Course II?

- State travel restrictions
- State workloads
- Strain on students’ personal schedules
- Center wide initiative to utilize more online resources
- Access to recording studio
MQSA Course II

• MQSA Fundamentals Course II Objectives (online):
  • Gain an understanding of the basics of breast cancer and the mammography exam
  • Gain knowledge about mammography equipment and quality assurance procedures specific to mammography
  • Have a foundation for the MQSA Inspection Procedures
Enhancements to Course II

• Transitioned residence Course II to primarily being offered online
• Evaluated what topics are still best served in lecture format
• Enhanced observational inspections to increase their benefit
MQSA Course III

- MQSA Inspection Procedures Course III

Objectives *(in-residence)*:
- Learn the specific protocol to be used by MQSA inspectors, both technical and procedural components
- Acquire the skills necessary to perform MQSA inspections accurately, reliably, confidently, and courteously
- Learn to enter inspection data collected at facilities into laptop computers and upload it to headquarters for tracking, analysis and compliance
Enhancements to Course III

• More focus on “real world” scenarios
• Use of role playing
• Highlighting communication throughout the inspection process
MQSA Training – Pass/Fail Criteria

• Course I: 70%

• Course II: 75% and then (3) observational inspections (ASRT: 15 MEU’s)

• Course III: Successful role playing evals & 70% on the written exam with at least (3) directed mentored inspections (ASRT: 35.5 MEU’s)
MQSA Training – Continuing Experience Requirement

• Perform an average of 24 MQSA inspections every 24 months

• If inspectors leave the program and want to return, we have mechanisms to bring them back into the program
Course II available as Mammography Education Units (MEU)

- Reduced State travel funding
- Available to be taken every three years to satisfy MEU requirements
MQSA Training- Continuing Education Requirement for Inspectors

• 15 Mammography Continuing Education Units (MEUs) (15 contact hours) every 36 months

• DMQS supports inspectors by providing educational funds via state contracts
Factors in Student Success

• Adequate time given for online courses
• Assigning the best mentor for each student for observational and mentored inspections
• Interest in the program / workload
• Utilization of resources
Clarifying Questions

Preet Sudhaker

Preetham.sudhaker@fda.hhs.gov