



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