MQSA Regulations and ACR Mammography Accreditation Update

The ACR Mammography Accreditation Program has been in existence since 1987. The Mammography Quality Standards Act was signed by the President in 1993 and required that any facility performing x-ray imaging of the breast (for screening and/or diagnostic purposes) be accredited and certified by 1994. The FDA published interim regulations in 1994 and final regulations in 1997. As of January 1, 2011, 19,000 mammography units at 8000 facilities are accredited and certified. Although the vast majority of facilities are conscientiously meeting the MQSA requirements, some poor quality facilities have required investigation by both the ACR and the FDA and some, fines and criminal penalties. In spite of these anomalies, mammography has significantly improved in the United States, mainly due to these accreditation standards and regulations. Full-field digital mammography (FFDM) is introducing new challenges to maintaining this hard-won quality improvement. In 2010, the FDA revised its clearance criteria for new FFDM units to allow for applications under the 510k process (rather than the more strict PMA process). This is resulting in a larger volume and variety of new FFDM units reaching the market in a shorter timeframe. The ACR is developing a universal FFDM quality control manual for FFDM to make the QC process across the different vendors more uniform. The purpose of this presentation is to provide updates on the ACR Mammography Accreditation Program and the FDA regulations.

Goals:

1. Learn about MQSA history.
2. Understand the impact of FFDM on mammography in the US.