AbstractID: 5906 Title: ACR Mammography Accreditation Program"s Early Digital Mammography Results

The Mammography Quality Standards Act (MQSA) of 1992 requires that all mammography facilities in the United States (including those using full field digital mammography [FFDM] equipment) be accredited by an approved body, certified by the U.S. Department of Health and Human Services (HHS), and receive an on-site inspection by a state agency acting on behalf of the HHS (or by HHS inspectors). The FDA approved the first premarket approval application for a FFDM unit in January 2000. Immediately accrediting these units presented a dilemma for the American College of Radiology (ACR) since, historically, programs are only developed for mature, widely-available technologies, so that reasonable standards may be developed based on expert experience. Consequently, the ACR could not have an accreditation program available for this new technology at the time FDA approved it to be sold in the US. To provide time for accreditation development, the FDA provided a process to exempt FFDM units from the MQSA accreditation requirement if an accreditation program was not yet available for the specific FFDM model. The FDA approved the ACR to accredit the General Electric Senographe 2000D, the Fischer SenoScan and the Lorad Selenia FFDM units in 2003; the General Electric Senographe DS in 2004 and the Siemens Mammomat Novation in 2005. Although some of the accreditation instructions and submissions are different for digital accreditation, each unit is still required to pass clinical image quality, phantom image quality and dose. Data since 2003 shows that the deficiency rate for FFDM units making their first attempt at accreditation is lower than with screen-film applicants (approximately 7% vs. 11%). Accreditation results from over 1200 units at 900 facilities will be presented.