

ABSTRACT

Mammography Facility Survey Requirements Under the Final Rule

The 1992 Mammography Quality Standards Act (MQSA) requires each facility to have, as part of the accreditation process, an on-site annual survey to assure that the facility meets the standards. The survey must be conducted by a medical physicist and consists of two parts: 1) survey of the mammography equipment, and 2) oversight of the facility's quality assurance practices. In 1993, FDA published interim regulations in which the American College of Radiology's (ACR) Mammography Quality Control Manuals were adopted by reference and have been used since MQSA went into effect on 10/1/94. Medical physicists have been expected to conduct the quality control tests on mammography equipment using test criteria that are substantially the same as the ACR's.

FDA published the final regulations on 10/28/97 and will implement them on 4/28/99. The emphasis in the new regulations is more on outcome and performance and less on procedure. The physicist may use procedures that are different from the ACR's as long as the basic test conditions outlined in the regulations are followed. Furthermore, in addition to the 10 QC tests that are conducted by the medical physicist under the interim regulations, a few tests have been added in the final regulations, some of which are part of the survey.

The paper will describe the new medical physicist qualification requirements and the changes (in focus and content) in the annual survey requirements as a result of the final regulations.