

National Mammography Quality Assurance Advisory Committee (NMQAAC)

24- Hour Summary

On November 4, 2011, the National Mammography Quality Assurance Advisory Committee (NMQAAC) provided advice and recommendations on the following issues: (1) proposed changes to the Mammography Quality Standard Act (MQSA) policies and inspection procedures; (2) accreditation body review of soft copy mammography images; and (3) reporting breast density on mammography reports and patient lay summaries. The committee also received updates on the MQSA program and the status of the American College of Radiology's (ACR) Full Field Digital Mammography (FFDM) universal quality control manual. Mr. Michael Divine, MS, FDA Consumer Safety Officer, provided the committee with updates on MQSA inspection results, facility statistics, changes to inspection procedures, use of certification extension for digital breast tomosynthesis, and newly cleared FFDM units. Dr. Charles Finder, FDA Medical Officer, followed Mr. Divine's presentation by reporting on alternative standards approved since the last meeting and proposed changes to MQSA policies and inspection procedures. The committee was in general agreement on FDA's proposed changes to the inspection procedures. Dr. Eric Berns from the ACR presented an update on their Full Field Digital Mammography Universal Quality Control Manual. Dr. Finder then opened the discussion of accreditation body review of soft copy mammography images. The committee acknowledged the difficulties in switching over to soft copy review and had several suggestions for FDA and the accreditation bodies for implementing the change.

During the Open Public Hearing the committee heard from 13 speakers; the session included presentations from clinicians and lay participants. Representatives from the American Cancer Society; Susan G. Komen for the Cure; Breast Cancer Choices; Are You Dense, Inc; and other patient advocacy groups presented and were in attendance. These presentations included a range of views, mostly discussing the need for patients to be informed of their mammographic breast density and the difficulties in detecting cancer in patients with dense breast tissue.

The committee members were in general agreement on requiring reporting breast tissue density in reports and lay summaries but several members did express concerns about what constitutes a dense breast and what recommendations might be made in advising physicians and patients on what to do with the information. The committee did not reach a consensus in the professional community on the magnitude of the risk that having dense breasts confers on patients or the best way to further evaluate these patients through the use of alternative imaging modalities. The committee members also stressed that a negative mammogram does not mean that a woman is cancer free.

**Contact: Shanika Craig, MHA, MBA Designated Federal Officer,
(301) 796- 6639 Shanika.Craig@fda.hhs.gov**

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