IOM Interventional Mammography Recommendations

Remove exemption for stereotactic breast biopsy procedures and develop regulations

Section 900.2 (aa):

Mammography means radiography of the breast, but, for the purposes of this part, does not include:

(1) Radiography of the breast performed during invasive interventions for localization **<or biopsy>** procedures; or

(2) Radiography of the breast performed with an investigational mammography device as part of a scientific study conducted in accordance with FDA's investigational device exemption regulations in part 812 of this chapter

IOM Interventional Mammography Recommendations

Rationale:

- Stereotactic breast biopsy uses mammographic x-ray imaging
- FDA indicated intent to regulate interventional (preamble to proposed final MQSA regulations dated April 3, 1996)
- Profession now has more experience with stereotactic procedures

IOM Interventional Mammography Recommendations

"In 1997, the ACR and the American College of Surgery (ACoS) developed a joint set of qualifications for physicians performing stereotactic breast biopsy procedures, which included requirements for CME training and continuing experience. These standards became the basis for the ACR's and the ACoS's voluntary stereotactic biopsy accreditation programs (American College of Surgeons and American College of Radiology, 1998; ACR, 2004). However, in testimony to the Senate Committee on Health, Education, Labor, and Pensions on the reauthorization of MQSA, the American Cancer Society noted that of the 4,000 to 5,000 interventional mammography machines in use, fewer than 500 are accredited through the ACR program (American Cancer Society, 2003). Only 11 are accredited by the ACoS program. In similar testimonies, speakers on behalf of the Susan G. Komen Breast Cancer Foundation (Rowden, 2003) and the Society of Breast Imaging (Dershaw, 2003) advocated removing the exemption on interventional mammographic procedures from MQSA."

IOM Interventional Mammography Recommendations

"The Committee urges FDA to promptly remove the exemption of all interventional mammography from MQSA regulations. Specifically, all stereotactic breast biopsy procedures and equipment should be accredited by the appropriate accreditation body. Equipment used for other interventional procedures (e.g., needle localization) should also be regulated by FDA. (While there are accreditation programs for stereotactic biopsy, no programs exist for the other interventional procedures; the Committee believes mandatory accreditation of interventional equipment, not the interventional procedures themselves, is sufficient.) In addition, FDA inspectors should be trained to perform onsite inspections of stereotactic breast biopsy procedures and interventional equipment, as a paper review and review of films obtained by the site would be insufficient for ensuring quality."