

## **FDA Approves Alternative Standard to the Medical Outcomes Audit Requirement under MQSA**

The Food and Drug Administration (FDA) has approved an alternative standard to the Medical Outcomes Audit requirement on October 26, 2009. Previously, separate facilities were not allowed to combine their medical audit results for the same interpreting physician even if all facilities were under the same ownership or lead interpreting physician. The new alternative standard allows multiple mammography facilities to combine their medical outcomes audits if they meet certain criteria.

The approved alternative states:

- 21 CFR 900.12(f): Each facility shall establish and maintain a mammography medical outcomes audit program to follow-up positive mammographic assessments and to correlate pathology results with the interpreting physician's findings. This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.
- 21 CFR 900.12(f)(1): General requirements. Each facility shall establish a system to collect and review outcome data for all mammograms performed, including follow-up on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate follow-up on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy. **In situations where multiple stationary mammography facilities are under the same ownership, they may be treated collectively as a single "facility" for the purposes of meeting these requirements, if all of the following conditions are met.**

- (i) All of the included facilities provide services to the same patient population.**
- (ii) The same entity or group administers the operation of all of the included facilities.**
- (iii) The same lead interpreting physician has the responsibility for assuring that all of the included facilities meet the requirements of 21 CFR 900.12(d) through (f).**
- (iv) The audit interpreting physicians(s), interpreting physician(s), medical physicist(s), QC technologist(s) and radiologic technologist(s) are the same for all of the included facilities.**
- (v) All of the facilities are inspected at the same time under the Inspection Fee Consolidation program.**
- (vi) Patient exams are scheduled centrally for all of the included facilities.**
- (vii) All mammography reports and lay summaries are entered into the same radiology information system.**

No time limit has been placed on the period of approval for this alternative requirement and all facilities that meet the above conditions may use the alternative.

A full description of alternative requirement #16 is available on the [FDA's Approved Alternative Requirements](#) page on their website.