FDA Medical Outcomes
Audit Regulations:

(f) Quality assurance-mammography medical outcomes audit. Each facility shall establish and maintain a mammography medical outcomes audit program to followup 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.

(1) General requirements. Each facility shall establish a system to collect and review outcome data for all mammograms performed, including followup 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 followup on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy.

(2) Frequency of audit analysis. The facility’s first audit analysis shall be initiated no later than 12 months after the date the facility becomes certified, or 12 months after April 28, 1999, whichever date is the latest. This audit analysis shall be completed within an additional 12 months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses will be conducted at least once every 12 months.

(3) Reviewing interpreting physician. Each facility shall designate at least one interpreting physician to review the medical outcomes audit data at least once every 12 months. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results, notifying other interpreting physicians of their results and the facility aggregate results. If followup actions are taken, the reviewing interpreting physician shall also be responsible for documenting the nature of the followup.

Data from "Clinical Practice Guidelines Number 13, Quality Determinants of Mammography", U.S. Dept of Health & Human Services Pages 74-86, October 1994, Table 10: Analysis of medical audit data; Desirable goals:

- PPV₁ based on abnormal screening examination: 0.5-10%
- PPV₂ when biopsy recommended (surgical, FNA, or core): 25-40%
- Tumors found-Stage 0 or 1: >50%
- Tumors found-Minimal cancer (<1 cm or in situ ductal Ca): >30%
- Node positivity: <25%
- Cancers found per 1,000 cases: 2-10
- Prevalent cancers found per 1,000 first-time examination: 6-10
- Incident cancers found per 1,000 follow-up examination: 2-4
- Recall Rate: 10%
- Sensitivity (if measurable): >85%
- Specificity (if measurable): >90%