

# DEMONSTRATION PROGRAM SELECTION CRITERIA – NMQAAC DRAFT

January 31, 2000

## STATE CRITERIA

### Inclusion

- Legal ability to modify state laws/regulations/policy, which require yearly inspections of mammography facilities (units and records), in order to comply with the inspection frequency designated by FDA
- Agreement to participate in the demonstration program
- Agreement to inspect participating facilities at the frequency designated by FDA
- Agreement to modification in the State contract based on the number of facilities to be inspected
- Agreement to notify FDA of any potential serious public health risks, of which they become aware, at any of the participating facilities

### Exclusion

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## FACILITY CRITERIA

### Inclusion

- Selected to formally participate in the demonstration program
- Full certification maintained throughout the demonstration program
- Anticipates providing mammography services throughout the entire demonstration program
- Received two annual inspections under the final regulations

### Exclusion

- Level 1 or 2 citation(s) during inspections conducted under the final regulations
- Level 3 citation(s) received during the second year of inspections under the final regulations
- Level 1 citation during the last two years of inspections under the interim regulations
- Regulatory action taken or under consideration (i.e., compliance action) by FDA