Preparing for Mammography Inspection

Each mammography provider will be inspected at least annually for the following:

- Equipment performance
- Quality Assurance (QA) records
- Quality Control (QC) records and tests
    - Technologist tests
    - Medical Physicist's annual survey report
    - Mammography equipment evaluations if any
- Personnel qualification records
    - Initial qualification documentation, including residency letter for physicians
    - Continuing education
    - Current State/Radiologic Health Branch (RHB) issued certificates for physicians and technologists
    - Current medical licenses for physicians
- Medical records
    - Mammography reports
    - Lay summaries.
- Medical audit and outcome analysis records
- Certificates displayed (American College of Radiology (ACR), Food and Drug Administration (FDA), State)
- Enhancing Quality Using the Inspection Program (EQUIP) review documentation

Inspection

- Mammography providers will generally be provided with 5 days' notice for inspection
- Quality Control / Quality Assurance technologist must be available on-site
- Lead interpreting physician must be available by phone
- Records shall be made available to the inspector during the inspection

Additional Resources
The FDA MQSA Policy Guidance Help System
ACR Mammography and Breast Imaging Resources

Mammography Post-Inspection Process

You will be provided a copy of the inspection findings within 2 weeks of your inspection. If you do not receive the findings, please contact the inspector directly. You will be allowed 30 days to provide adequate response to the findings. The response must be in writing, and you may need to include supporting documentation such as purchase orders, service reports, or polices or procedures that outline provider's attempt to prevent a repeat occurrence of a violation identified. A response via email is preferred. You will also need to respond directly to the FDA Mammography Quality and Standards Act (MQSA) program for Level 1 violations.