

FDA / CRDH / MQSA REQUIREMENTS

The Food & Drug Administration has established the following requirements:

- Identification of a **lead interpreting physician** and **reviewing interpreting physician** (biopsy follow-up). The **lead** and **reviewing interpreting physician** should be **clearly identified** in the **QC/QA manual**.
- Identification of a **quality control (QC) technologist**. The **quality control technologist** should be **clearly identified** in the **QC/QA manual**.
- Verification that all mammography reports contain all data required, including **overall final assessment** ("**negative**", "**benign**", "**probably benign**", "**suspicious**", "**highly suggestive of malignancy**", or "**incomplete: need additional imaging evaluation**").
- Ensuring that **lay-term reports** are sent to **all** patients within **30 days** (within **one week** if "**suspicious**" results).
- Implementation of a written **infection control policy**. Have **available** in **QC/QA manual**. Use the policy in the technologist's section of the 1999 ACR QC Manual on pages 221-222.
- Implementation of a **consumer complaint mechanism**. Have **available** in **QC/QA manual**. Use the MPC policy for Consumer Complaint (see **FORMS** section).
- Inquiring of all patients if they have **implants** before conducting the exam. A **written** standard operating **procedure** inquiring whether the patient has **breast implants** will be sufficient to meet requirements. Have **available** in **QC/QA manual**.
- Ensuring that **hot-lighting** and **film masking devices** are available to the radiologist.
- Ensuring that compression paddles have **visible ion chamber position indicators**.
- If your mammography **unit** or **processor** is **replaced**, or **disassembled** and **reassembled**, or if **major components** are **replaced**, you may need **additional** testing. See **MPC Medical Physicist Inspection Before Use** section