**Prior to Inspection:**
Consider setting aside ample space for non-disruptive records review by the inspector

**State Inspection Items:**
- All State/FDA Inspection Reports
- **State Regulations** *(printed or digital copy available)*
- FDA report of assembly *(Pink installation form)*
- Plan review and Letter of acknowledgement FOR TOMO ONLY
- **Safety Survey** *(Post Installation)*
- **Radiation Protection Program** *(with annual signatures)*
- Personnel monitoring records
- Dissolution policy
- Self Referral policy
- Record retention/Image storage policy
- State Registration *(Notification of Registration)* - Verify that ALL information in the copy you retain in your records is current. Update any changes in contact, ownership or unit information.
- Notice to Employees posted *(most current version dated 9/2015)*
- Technique chart posted
- Protective aprons available
- **BREAST DENSITY LAW**
  - Demonstrate compliance by required verbiage in patient lay letter for “extremely” and “heterogeneously” breast densities
  - method to direct patients to information regarding breast density *(recommendation)*

**Quality Control:**
- We recommend that your QC records include films produced for QC testing
- Verify that your monitor and unit QC manuals are current versions
- Must provide QC records back to last inspection (plus one additional test cycle prior to confirm test frequency)
- QC and physicist testing records for off-site monitors in use
- QC procedures for both on and off-site RWS. Testing records in monitor software should match QC forms

**Procedure Manual:**
- Technique chart
- Responsibilities & personnel assignments for QC Tech/Physicist/Lead Interpreting & Audit Reviewing Radiologist
- Service records & operator manual for mammo unit(s) & monitor(s) *(including ALL off-site RWS)*
- Physicist report & correlating service records/previous physicist report
- Consumer complaint policy – records of complaints if applicable
- Infection control policy – Unit and solution manufacturer recommendations, documentation of hi-level events. **Documentation of routine cleaning is not required**
- Quality assurance meeting minutes
- QC tests – Identify QC manuals in use
Medical Record Tracking:
- Five reports randomly selected by inspector
- Logs for tracking positive results
- Patient lay letter examples
- 2014 medical outcomes audit with annual review by audit reviewing physician
  (Individually & collectively for all interpreting radiologists at your facility)
- Documentation that all physicians have reviewed analysis (recommendation)

Credentials:

Physicist:
Initial qualifications:
- Copy of degree, 20 semester hrs in Physics, 20 contact hrs in mammography surveys and
documentation of surveying 1 facility and 10 units MAY BE REPLACED BY FDA
APPROVAL LETTER
- Copy of ABR, ABMP, State Approval/State License (in addition to FDA letter)
  Any expiration dates present must not be expired. NC does not have state approval
- 8 CEU’s of initial training in Digital and DBT (only if used at your facility, does not
  expire)

Continuing Education/Experience:
- 15 CEU’s in 3 year period (No Attestation)
- Maintain records of surveys (2 facilities & 6 units per 24 month period)

Radiologic Technologist:
Initial Qualifications:
- Copy of ARRT card & Training (40 hours)
- 25 Supervised Mammograms (Techs qualified after 4/28/99)
- 8 CEU’s of initial training in Digital and DBT (only if used at your facility, does not
  expire)

Continuing Education/Experience:
- 15 CEU’s in 3 year period (No Attestation)
- Documentation of 200 Mammograms in 24 month period

Radiologist:
Initial Qualifications:
- Copy of ABR & Current MD License (No attestation)
- 60 CME and 3 months training (If initially qualified after 4/28/99)
- 40 CME and 2 months training (If initially qualified before 4/28/99)
- 240 Supervised Readings in 6 month period (No attestation if occurred after 10/1/94)
- 8 CEU’s of initial training in Digital and DBT (only if used at your facility, does not expire)

Continuing Education/Experience:
- 15 CEU’s in 3 year period Must be category 1 (No Attestation)
- 960 Mammograms in 2 year period (No Attestation)

Notes:
- Physicians completing residency beginning 6/2014 will have a newly formatted Letter of Residency
- NC MD License renewed on the Physicians birthday
- Continuing experience and education time frames are the 2 and 3 year period from inspection date back
  
  Example: For the 3-year period on CEU's:  
  Inspection date of 4/1/15 back to 3/31/12
  
  Example: 960 Interpretations in 24-month period  
  Inspection Date of 4/1/15 back to 3/31/13

Check out the North Carolina Mammography website for help and important information!

http://www.ncradiation.net/mammo/index.htm

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