Inspection Checklist for Mammography Facilities

2013

**State Inspection Items:**
- FDA report of assembly *(Pink installation form)*
- State Registration *(Notification of Registration)*
- State Regulations *(Yellow Book)*
- Safety Survey *(Post Installation)*
- Radiation safety program *(with annual signatures)*
- MSDS for Chemistry
- All State/FDA Inspection Reports

**Quality Control Manual:**
- Retain all records and supporting films for tests for at least 1 year
- Keep sensitometry strips and corrective action documentation
- Must retain QC items, films, tests back to last inspection
  (exception-must retain semi-annual QC records and film for 3 test cycles)

**Procedure Manual:**
- Technique chart
- Personnel monitoring records
- Troubleshooting guides
- Dissolution policy
- Self-referral policy
- Responsibilities & personnel assignments for QC Tech/Physicist/Lead Interpreting & Reviewing Radiologist
- Service records & operator manual for mammo unit & processor
- Physicist report & correlating service records/previous physicist report
- Consumer complaint policy
- Infection control policy - documentation that equipment was disinfected after contamination (not just routine cleaning) must be verified
- Quality assurance minutes
- QC tests – written standard operating procedures used for QC tests or written documentation of the QC manual used
- Film storage policy
- 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.

**Medical Record Tracking:**
- Five sets of reports randomly selected by inspector
- Logs for tracking positive results
- Patient lay letter examples
- Analysis of 2011 medical outcomes audit
  (individually & collectively for all interpreting radiologists at your facility)
- Annual review documented by reviewing interpreting radiologist
- Documentation verifying that all physicians have reviewed analysis *(sign-off sheet)*
Physicist:

Initial qualifications:

- Copy of ABR, ABMP, State Approval/State License (in addition to FDA letter)
- (If there is a date on the documentation, it must not be expired information)
- (NC does not have state approval)
- Copy of degree, 20 semester hrs in Physics, 20 contact hrs in mammography surveys
- Documentation of surveying 1 facility and 10 units
- 8 CEU’s of initial training in a new modality (ex. Digital, Breast Tomosynthesis)

Continuing Education/Experience:

- 15 CEU’s in 3 year period (No Attestation)
- Maintain records of survey’s (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 a new modality (ex. Digital, Breast Tomosynthesis)

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 (If initially qualified after 4/28/99)
- 40 CME (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 a new modality (ex. Digital, Breast Tomosynthesis)

Continuing Education/Experience:

- 15 CEU’s in 3 year period (No Attestation)
- 960 Mammograms in 2 year period (No Attestation)

Notes:

- NC MD License are renewed on the Physicians birthday
- Continuing experience and education time frames are the 2 and 3 year period from the inspection date backwards.

Example: For the 3-year period on CEU’s: Inspection date of 4/1/13 back to 3/31/10

Example: 960 Interpretations in 24-month period Inspection Date of 4/1/13 back to 3/31/11

Check out the North Carolina Mammography website for lots of important information!

http://www.ncradiation.net

Good luck!
Please contact your service engineer and verify this information prior to inspection
Make a copy for your inspector

Facility Information
- FDA #: __________________ Facility Name: _______________________________________________________
- Address: ___________________________________________________________________________________
- Department phone#: __________________ Department fax#: __________________ E-mail: ________________
- Contact person: __________________ Title: _______________________________________________________

Please have these STATE inspection items for the inspector to review during the inspection

FDA Report of Assembly (pink sheet) ______ Radiation Protection Program ______
Post Installation Area Radiation Survey ______ Annual Review of Radiation Safety Program ______
Notice of Registration ______ Protective aprons ______
Notice to Employees ______ Technique Chart ______
State Regulations ______ Self-Referral Policy ______
Film Badge Records ______ Dissolution Policy ______

Darkroom and Processor Information
Name or location of darkroom: ________________________________________________________________
Counters cleaned daily: yes _____ no _____ Film stored in darkroom: yes _____ no _____
Chemicals stored in darkroom: yes _____ no _____ Overhead storage in darkroom: yes _____ no _____
Air vents in darkroom: yes _____ no _____

Name or location of processor: ________________________________________________________________
- Processor dedicated to mammography: yes _____ no _____
- Manufacturer __________________ Model Name __________________
- Daylight Processor: yes _____ no _____
- Developer Temp: Mfg. recommended temp. ______ Temp day of inspection ______
- Do you check temp daily and record the results? yes _____ no _____
- Estimate of average # of films processed a day: ______
- Replenishment rates: standard _____ (or) flooded _____
- Replenishments rates: developer _____ fixer _____
- Processor replenishment based on: area ______ 18x24 cm feed (lw) ______
  18x24 cm feed (cw) ______ or 14x17 in feed (non-dedicated) ______
- Replenishment rates posted near processor: yes _____ no _____
- Developer Manufacturer __________________ Type_________________
- Fixer Manufacturer __________________ Type_________________
- Chemistry is mixed by: auto-mixer _____ hand mix _____ or pre-mix _____
- Sensitometric strip is processed: lengthwise _____ crosswise _____ other (explain) _____
- Sensitometric strip is processed: emulsion up _____ emulsion down _____
- Sensitometric strip is processed with least exposed edge first: yes _____ no _____
- Clinical films (18x24) are run: single _____ double (side by side) _____ other (explain) _____
- Clinical films are run: emulsion up _____ down _____
- Check types of film processed in this processor: mammo _____ double _____ U/S Laser _____ other/Laser _____ copy _____
- How many brands of films processed in processor: one _____ or more than one _____
**Chemistry**

- Starter used: yes _____ no _____
- Total amount of starter added: _____ (oz or cc/ml) or amount per gallon _____ (oz or cc/ml)
- Starter is added in: the processor _____ or developer replenishment tank _____
- Do you use seasoned developer: yes _____ no _____

**QC Contacts**

- QC Technologist: __________________________ Phone #: __________________ Fax #: __________________
- Mammography Unit Service Company __________________________
- After major repairs, does the service personnel verify parameters before leaving? yes _____ no _____
- Equipment Service Person’s Name __________________________ Phone #: __________________
- Processor Service Company __________________________
- After cleaning the processor, does the service personnel verify parameters before leaving? yes ___ no ___
- Engineer’s Name __________________________ Phone #: __________________

**Service Cleaning Frequency**

- Crossover rollers cleaned daily: yes _____ no _____
- Squeegee rollers cleaned daily: yes _____ no _____
- Master rollers cleaned monthly: yes _____ no _____
- Developer filter changed monthly: yes _____ no _____

**QC Equipment**

- Date the fixer retention solution was opened: _______________
- Last calibration dates for: sensitometer ______________ densitometer ______________
- Expiration date for densitometer strip: _______________
- How do you perform sensitometry when your sensitometer has been sent off for calibration?
  (Example) Daily phantom, loaner equipment, or back-up sensitometer _______________

**Screen and Film Combo**

- Film Manufacturer ______________ Type ______________
- Screen Manufacture ______________ Type ______________

**Unit Information**

- List the number of units relating to mammography that your facility has:
  FDA Certified _____ Stereo Attachment to FDA Certified Unit: yes _____ no _____
  Stereotactic Table _____
  Biopsy/Needle Loc. _____
  Specimen Cabinet _____

**Room (Optical or Background Density on Phantom QC Chart)**

Room 1 _____ Room 2 _____ Room 3 _____ Room 4 _____

Revised 12/28/12