

Inspection Checklist for Mammography Facilities

2011



Miscellaneous Items:

- ✓ FDA report of assembly (*Pink installation form*)
- ✓ State Registration (*Notice of Registration*)
- ✓ State Regulations (*Yellow Book*)
- ✓ Plan Review (*Prior to installation*)
- ✓ Letter of Acknowledgement for Plan Review (*From State*)
- ✓ Safety Survey (*Post Installation*)
- ✓ Radiation safety program (*with annual signatures*)
- ✓ MSDS for Chemistry
- ✓ All Previous Annual FDA and State 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
- ✓ Film badge records
- ✓ Trouble shooting 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
- ✓ Notice of Registration-Verify that ALL information in the copy you retain in your records is current. If contact, ownership or unit information is not current you are in violation of 15A NCAC 11 .0209.

Medical Record Tracking:

- ✓ Five sets of reports randomly selected by inspector
- ✓ Logs for tracking positive results
- ✓ Lay reports for all patients
- ✓ Analysis of **2009** 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**)

Credentials:

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)

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)

Continuing Education/Experience:

- ✓ 15 CEU's in 3 year period (No Attestation)
- ✓ Documentation of 200 Mammograms in 24 month period

Radiologist:

Initial Qualifications:

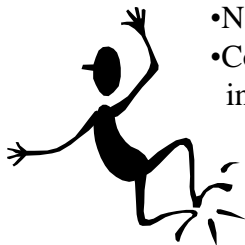
- ✓ Copy of ABR & Current MD License (No attestation)
- ✓ 60 CME (If initially qualified after 4/28/99)
- ✓ 40 CME (If initially qualified before 4/28/99)
- ✓ 240 Supervised Readings in 6 month period (No attestation if occurred after 10/1/94)
- ✓ 8 CEU's of initial training in a new modality (ex. Digital)

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 4/1/04 back to 3/31/01*

*Example: 960 Interpretations in 24-month period
Inspection Date of 4/1/04 back to 3/31/02*

Good luck!

<http://www.ncradiation.net>

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

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 _____