

Inspection Checklist for DIGITAL 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*)
- ✓ All Previous Annual FDA and State Inspection Reports

Quality Control Manual:

- ✓ Retain all records and supporting films for tests for at least 1 year
- ✓ DOCUMENT, DOCUMENT, DOCUMENT Some Digital QC testing leaves no films to produce as proof when a test is missed.
- ✓ Must retain QC items, films, tests back to last inspection
(**exception-must retain semi-annual QC records 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, printer & monitor
- ✓ 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**
- ✓ Image 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 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 Digital**

Continuing Education/Experience:

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

Radiologist:

Initial Qualifications:

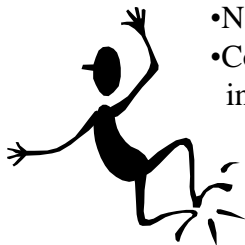
- ✓ Copy of ABR & Current MD License (No attestation)
- ✓ 60 CME (If initially qualified after 4/28/99)
- ✓ 40 CME (If initially qualified before 4/28/99)
- ✓ 240 Supervised Readings in 6 month period (No attestation if occurred after 10/1/94)
- ✓ **8 CEU's of initial training in Digital (does not have to be category 1)**

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:

- 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!

**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

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

General Questions

- Have you verified proof of initial 8 hrs digital training for all personnel (technologists, radiologists and physicists? yes _____ no _____
- Do you ever utilize lossy image compression? yes _____ no _____
- If so under what circumstances? _____
- Do you have offsite image storage backup? yes _____ no _____
- Average number of exams performed per day _____

Image Receptor Questions

- Baseline CNR: _____
- If newly installed, was compression performed before initial unit use? Yes _____ No _____
- Version of image receptor QC manual _____
revision number _____
- List phantom technical factors Manual _____ AEC _____ Mas _____ .KvP _____
- Do they differ from clinical settings? Yes _____ No _____
- List the dates and description of digital unit repairs/maintenance since last inspection.

Date

brief description

_____	_____
_____	_____
_____	_____
_____	_____

- Did you check with your physicist to see if MEE was required? Yes _____ No _____
- Name and date of most recent software upgrade _____

Laser Printer Questions

•Printer(s) manufacturer _____ model _____ In-house _____ Off-site _____
_____ In-house _____ Off-site _____
_____ In-house _____ Off-site _____

•Wet laser _____ or dry _____

•If wet, has fixer retention been performed? Yes _____ No _____ N/A _____

•List any additional modalities that use this printer(s) _____

•Version of printer QC manual _____
revision number _____

•List the dates and description of laser printer repairs/maintenance since last inspection:

Date brief description

•Did you check with your physicist to see if MEE was required? Yes _____ No _____

•Last densitometer calibration date _____

•Which QC manual do you follow for sensitometric test frequency recommendations?:
image receptor _____ or laser printer _____

•How often are clinical films printed? daily _____ weekly _____

•FOR OFFSITE PRINTERS ONLY: Describe your process for maintaining QC for off-site printers at your site. Include a description of your notification process for QC failures.

Review Workstations

How many review workstations do you have? _____

Are there any off-site review workstations? Yes _____ No _____

If yes, where is it located? _____

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 #: _____

• Printer Service Company _____

• After servicing the printer, does the service personnel verify parameters before leaving? yes _____ no _____

• Engineer's Name _____ Phone # : _____

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 _____