



Inspection Checklist for DIGITAL Facilities 2014

State Inspection Items:

- ✓ All State/FDA Inspection Reports
- ✓ FDA report of assembly (*Pink installation form*)
- ✓ State Regulations (*Yellow Book*)
- ✓ Safety Survey (*Post Installation*)
- ✓ Radiation safety 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
- ✓ Technique chart posted
- ✓ Protective aprons available
- ✓ **NEW BREAST DENSITY LAW**
 - Demonstrate method for tracking “extremely” and “heterogeneously” dense breast patterns and including required verbiage in patient lay letter
 - method to direct patients to information regarding breast density (*recommendation*)

Quality Control Manual:

- ✓ We recommend that your QC records include films produced for QC testing
- ✓ Verify that your printer, 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 printers and monitors in use

Procedure Manual:

- ✓ Technique chart
- ✓ Troubleshooting guides
- ✓ 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 meeting minutes
- ✓ QC tests – **written standard operating procedures used for QC tests or written documentation of the QC manual used**

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

<http://www.ncradiation.net>

Medical Record Tracking:

- ✓ Five sets of reports randomly selected by inspector
- ✓ Logs for tracking positive results
- ✓ Patient lay letter examples
- ✓ Analysis of **2012** 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**
- ✓ **8 CEU's Breast Tomosynthesis only if used at your facility**

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**
- ✓ **8 CEU's Breast Tomosynthesis only if used at your facility**

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)**
- ✓ **8 CEU's Breast Tomosynthesis only if used at your facility**

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 4/1/13 back to 3/31/10*

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

Good luck!

Please complete and email to your inspector PRIOR TO inspection date

Select your inspector:

Facility Information

FDA#: _____ Facility Name: _____
 Address: _____
 Department phone#: _____ fax#: _____ Email: _____
 Contact person: _____ Title: _____

General Questions

- Have you verified proof of initial 8 hrs digital and/or tomo training for all personnel (technologists, radiologists and physicists)?
- Average number of exams performed per day _____
- Do you perform post procedure mammograms?
- If yes, is there an additional imaging charge?
or is it covered under the procedure charge?
- Have you signed up for the Radiation Protection Mammography and XRAY Listserv?

Image Receptor Questions

- Baseline CNR: Rm _____ Rm _____ Rm _____ Rm _____
- Who establishes new baseline CNR when warranted?
- If newly installed, was compression performed before initial unit use?
- Version of image receptor QC manual _____
Revision number _____
- List phantom technical factors Manual AEC Mas _____ kVp _____
- Do they differ from clinical settings?
- Service Engineer _____ Phone: _____
- List the dates and description of digital unit repairs/maintenance/moves since last inspection.

Date	brief description

- Did you check with your physicist to see if MEE was required?
- Name and date of most recent software upgrade _____

Review Workstations

Number of on-site workstations? _____ Number of off-site review workstations? _____
 List any installations/repairs/moves since last inspection? _____

