


Inspection Checklist for DIGITAL Facilities 2017

(with important links)

Prior to Inspection:

Consider setting aside ample space for non-disruptive records review by the inspector

State Inspection Items:

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- ✓ All State/FDA Inspection Reports
 - ✓ [State Regulations](#) (*printed or digital copy available*)
 - ✓ FDA report of assembly (*installation form, often pink*)
 - ✓ [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 (*both 3/2015 and 9/2015 print dates are current versions*)
 - ✓ 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:

- ✓ ****NEW** EQUIP Initiative!** Learn facility responsibilities [HERE](#). Citations begin 1/2018.
- ✓ 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 manuals, QC tests and physicist testing records for ALL on and off-site monitors used during the inspection year. 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
- ✓ Quality assurance meeting minutes (*may be used to meet portions of EQUIP initiative*)
- ✓ QC tests – Identify QC manuals in use

Medical Record Tracking:

- ✓ Five reports randomly selected by inspector (*consider methods to produce examples of rarely occurring assessment categories*)
- ✓ Logs for tracking positive results

- ✓ Patient lay letter examples
- ✓ **2015** medical outcomes audit with annual review by audit reviewing physician
(*Individually & collectively for all interpreting radiologists at your facility performed by FDA number. A global, multi-site analysis would not meet the intent of the regulation*)
- ✓ 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

<i>Example: For the 3-year period on CEU's:</i>	<i>Example: 960 Interpretations in 24-month period</i>
<i>Inspection date of 4/1/17 back to 3/31/14</i>	<i>Inspection Date of 4/1/17 back to 3/31/15</i>

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

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