


Inspection Checklist for SCREEN/FILM Facilities 2016

(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 (*Pink installation form*)
 - ✓ Plan review
 - ✓ [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 (*most current version dated 9/2015*)
 - ✓ 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:

- ✓ We recommend that your QC records include films produced for QC testing
- ✓ Retain all records and supporting films for tests for at least 1 year
- ✓ Keep sensitometer strips and corrective action documentation
- ✓ Must provide QC records back to last inspection (plus one additional test cycle prior to confirm test frequency)

Procedure Manual:

- ✓ Technique chart
- ✓ Responsibilities & personnel assignments for QC Tech/Physicist/Lead Interpreting & Audit Reviewing Radiologist
- ✓ Service records & operator manual for mammo unit and processor
- ✓ Physicist report & correlating service records/previous physicist report
- ✓ Consumer complaint policy – records of complaints if applicable
- ✓ Infection control policy – Unit and solution manufacturer recommendations, documentation of hi-level events. Documentation of routine cleaning is not required
- ✓ Quality assurance meeting minutes
- ✓ QC tests – written standard operating procedures used for QC tests or written documentation of the QC manual used

Medical Record Tracking:

- ✓ Five sets of reports randomly selected by inspector
- ✓ Logs for tracking positive results
- ✓ Patient lay letter examples
- ✓ Analysis of 2014 medical outcomes with annual review documented by reviewing interpreting radiologist audit (individually & collectively for all interpreting radiologists at your facility)
- ✓ 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

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)

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)

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

Example: For the 3-year period on CEU's:

Example: 960 Interpretations in 24-month period

Inspection date of 4/1/15 back to 3/31/12

Inspection Date of 4/1/15 back to 3/31/13

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

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