

RADIATION PROTECTION SECTION

2022 MQSA Mammography Inspection Checklist

(with important links)

Prior to Inspection:

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

State Inspection Items:

- ✓ All State Inspection Reports
- ✓ [State Regulations](#) (*printed or digital copy available*)
- ✓ For 3D units - Shielding plan and acknowledgement letter of that plan from the Radiation Protection Section
- ✓ FDA report of assembly (*installation form, often pink*)
- ✓ [Safety Survey](#) (*Post Installation*)
- ✓ [Radiation Protection Program](#) (*with annual RSO review*)
- ✓ Personnel monitoring records
- ✓ Dissolution policy
- ✓ Self-Referral policy
- ✓ Record retention/Image storage policy
- ✓ State Registration (*Notification of Registration or NOR*) -Ensure that ALL information is current. Update any changes in contact, ownership or unit information.
- ✓ [Notice to Employees](#) - current and posted conspicuously in an employee area
- ✓ 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*)

MOSA Inspection Items:

Quality Control:

- ✓ **EQUIP Initiative – 3 parts** - Learn facility responsibilities [HERE](#)
- ✓ 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*)
- ✓ ****IMPORTANT RWS INFORMATION** Know where your images are read.** For ALL on and off-site monitors used during the inspection year provide the following;
 - QC manuals
 - QC tests
 - Medical Physicist evaluations and credentials

Procedure Manual:

- ✓ Technique chart
- ✓ Responsibilities & personnel assignments by name for QC Tech/Medical Physicist/Lead Interpreting & Audit Reviewing Physician
- ✓ Service records (**including release notes for software upgrades**) & 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
- ✓ QC tests – Identify QC manuals in use for all imaging components

Medical Record Tracking:

- ✓ Five reports randomly selected by inspector
- ✓ Logs for tracking positive results

- ✓ Patient lay letter examples
- ✓ **2020** medical outcomes audit with annual review by audit reviewing physician
(*Individually & collectively for all interpreting radiologists at your facility performed by FDA number*)
- ✓ Screening facilities - demonstrate no positive exams occurred
- ✓ Documentation that all physicians have reviewed analysis (*recommendation*)

Credentials:

Medical Physicist (to include those involved in off-site monitor services):

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 **OR FDA APPROVAL LETTER**
- ✓ **Either** ABR, ABMP **OR** UNEXPIRED State Approval/License (*note: some state letters do not expire*)
- ✓ 8 CEU's of initial training in 2D and 3D (*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 (R) card & Training (*40 hours*)
- ✓ 25 Supervised Mammograms (*Techs qualified after 4/28/99, met with advanced registry (M) earned after 1/1/01*)
- ✓ 8 CEU's of initial training in 2D and 3D (*only if used at your facility, does not expire, 2D met with advanced registry (M) earned after 7/2017*)

Continuing Education/Experience:

- ✓ 15 CEU's in 3-year period
- ✓ Documentation of 200 Mammograms in a 24-month period

Interpreting Physician:

Initial Qualifications:

- ✓ Copy of ABR & Current MD License
- ✓ 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 2D and 3D (*only if used at your facility, does not expire*)

Continuing Education/Experience:

- ✓ 15 CEU's in 3-year period **Must be category 1**
- ✓ 960 Mammograms in 2-year period

Notes:

- Physicians completing residency beginning year 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: 15 breast specific CEU's in 3 years or 36 months Example: 960 Interpretations in 2 years or 24 months
Inspection date of 4/1/21 back to 3/31/18 Inspection Date of 4/1/21 back to 3/31/19

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

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