

RADIATION PROTECTION SECTION

2024 MQSA Mammography Inspection Checklist

(with important links)

Prior to Inspection: Consider setting aside ample space for non-disruptive records review by the inspector
MQSA Inspection Items

Facility Contacts

Contacts are verified during EACH annual inspection. Verify name, title, phone, fax and email PRIOR TO inspection day for the following contacts;

- Inspection Contact – receives the inspection confirmation
- Most Responsible – with authority to hire, terminate, purchase equipment and maintain compliance
- Billing Contact – email MUST be valid and current as billing is now electronic

Medical Records

Five reports randomly selected by inspector

Patient lay letter examples

Medical Audit and Outcome Analysis

2022 medical outcomes audit with annual review by audit reviewing physician

- Analyze data individually & collectively for all interpreting radiologists at your facility
- Analysis must be performed by FDA number within networks
- Documentation that all physicians have reviewed analysis (*recommendation*)
- *Screening facilities demonstrate no positive exams occurred in 2022.*

Quality Assurance

- Personnel duties assigned by name
 - QC Mammographer
 - Medical Physicist – name the MP(s), **NOT** the company name
 - Lead Interpreting Physician
 - Audit Reviewing Physician
- Consumer Complaint Policy – records of complaints if applicable
- Dissolution Policy
- Record retention/Image storage policy
- EQUIP
 - Learn facility responsibilities [HERE](#)
 - LIP QA/QC oversight is verified during each annual inspection **one** of three ways;
 - verbal confirmation with LIP in person or by phone
 - signed policy dated within the inspection year
 - signed attestation – MUST use FDA format

Quality Control

- Verify that your monitor and unit QC manuals are current versions. Identify within written procedures QC manuals in use for all imaging components
- Provide release notes for software upgrades
- Must provide QC testing records back to last inspection (*plus one additional test cycle prior to confirm test frequency*)
- **** RWS ** You MUST 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 since last inspection
 - Medical Physicist Credentials
- Physicist report(s) & correlating service records since previous inspection

Personnel Credentials**Medical Physicist - include those involved in off-site monitor services**

Medical Physicist Qualification Worksheet	
<i>This worksheet may be used by facilities to help ensure that their personnel meet all applicable requirements prior to providing mammography services</i>	
Initial Qualifications	
Need one of the following: <input type="checkbox"/> ABR or ABMP certification <input type="checkbox"/> State licensed to perform x-ray services- unexpired <input type="checkbox"/> State approved to perform x-ray services- unexpired	
Need all of the following: <input type="checkbox"/> Masters degree or higher with no less than 20 semester hours in physics, in: Physics Chemistry Engineering Radiation Science (including Health Physics or Medical Physics) <input type="checkbox"/> 20 contact hours of training in surveys <input type="checkbox"/> Surveys of one facility and 10 mammography units (under direct supervision after 4/28/99) Retrieve survey summary pages to support letters of training <i>FDA approval letter may be presented in lieu of initial training</i>	
START DATE _____ (The later of 10/1/94 or date the last initial qualification was completed)	
<input type="checkbox"/> 8 hours initial training in additional mammographic modality used <input type="checkbox"/> 2D (if applicable, does not expire) <input type="checkbox"/> 3D (if applicable, does not expire)	
Continuing Qualifications	
All of the following: <input type="checkbox"/> Surveys of two facilities and 6 units in the 24 months prior to the current date (applicable 24 months after start date) <input type="checkbox"/> 15 CMEs in the 36 months prior to the current date (applicable 36 months after start date)	

Radiologic Technologist Worksheet	
<i>This worksheet may be used by facilities to help ensure that their personnel meet all applicable requirements prior to providing mammography services</i>	
Initial Qualifications Met Before 4/28/99 (INTERIM)	Initial Qualifications Met After 4/28/99 (FINAL)
Need one of the following: <input type="checkbox"/> General radiography license (any State) <input type="checkbox"/> General certification (ARRT or ARCRT)	Need one of the following: <input type="checkbox"/> General radiography license (any State) <input type="checkbox"/> General certification (ARRT)
Need one of the following: <input type="checkbox"/> 40 hours of mammography training <input type="checkbox"/> ARRT (M) <input type="checkbox"/> CA Mammography Certification <input type="checkbox"/> AZ Mammography Certification <input type="checkbox"/> NV Mammography Certification <input type="checkbox"/> Completion of prior FDA accepted course or training <i>(attestation allowed if training completed prior to 10/1/94)</i>	Need one of the following: <input type="checkbox"/> 40 hours of mammography training including the following subjects: <input type="checkbox"/> Breast Anatomy <input type="checkbox"/> Physiology <input type="checkbox"/> Positioning/Compression <input type="checkbox"/> QA/QC <input type="checkbox"/> Breast Implants
	<input type="checkbox"/> 25 supervised patient exams (generally up to 12.5 hours can be counted toward the 40 hours, but must be documented)
START DATE _____ (The later of 10/1/94 or date the last initial qualification was completed)	
<input type="checkbox"/> 8 hours initial training in additional mammographic modality used <input type="checkbox"/> 2D (if applicable, does not expire) <input type="checkbox"/> 3D (if applicable, does not expire)	
Continuing Qualifications	
All of the following: <input type="checkbox"/> 200 patient exams in the 24 months prior to the current date (applicable 24 months after start date) <input type="checkbox"/> 15 breast specific CMEs in the 36 months prior to the current date (applicable 36 months after start date)	

Interpreting Physician Worksheet	
<i>This worksheet may be used by facilities to help ensure that their personnel meet all applicable requirements prior to providing mammography services</i>	
Initial Qualifications Met Before 4/28/99 (INTERIM)	Initial Qualifications Met After 4/28/99 (FINAL)
Need: <u>Valid NC license</u>	Need: <u>Valid NC license</u>
Need one of the following: ___ ABR, AOBR, or RCPSC ___ Two months of training (stated in <u>Letter of Residency</u> in the absence of initial ABR)	Need one of the following: ___ ABR, AOBR, or RCPSC ___ Three months of training (stated in <u>Letter of Residency</u> in the absence of initial ABR)
Need: ___ 40 hours CMEs <i>attestation allowed if CMEs obtained prior to 10/1/94</i>	Need: ___ 60 hours CMEs
Need: ___ 240 patient exams in any 6month period <i>attestation allowed if the exams were completed prior to 10/1/94</i>	Need one of the following: ___ 240 patient exams in a 6 month period in the last two years of residency If certified AFTER 6/2014 ___ 240 patient exams in any 6 month period in the last two years of residency If certified at the first allowable time prior to 6/2014 ___ 240 patient exams in the LAST 6 months of residency If NOT certified at the first allowable time prior to 6/2014
START DATE _____ (The later of 10/1/94 or date the last initial qualification was completed)	
___ 8 hours initial training in additional mammographic modality used ___ 2D (if applicable, does not expire) ___ 3D (if applicable, does not expire)	
Continuing Qualifications	
Need All of the following: ___ 960 patient exams in the previous 24 months (applicable 24 months after start date) ___ 15 AMA PRA Category I CMEs in the previous 36 months (applicable 36 months after start date)	

State Inspection Items

- Report of Sale/Installation Report (*FDA 2579 Form, often pink*) [.0115]
- **Current** Notice of Registration [.0209]; [.0603(a)(2)(A)]; [.1001(a)(5)]; [.1601(c)]
- Copy of Shielding Design (*Also called plan review. Required for 3D units and stereo tables but not 2D and BMD units*) [.0603(a)(2)(A)]; [.0603(b)]
- Copy of Letter of Acknowledgement (*for units requiring a shielding plan*) [.0603(a)(2)(A)]
- Copy of Radiation Area Survey (*Post Install*) [.0603(a)(2)(B)]; [.0603(c)]
- Written Safety Procedures [.0603(a)(1)(D)]; [.0603(a)(1)(H)(i) & (ii)]
- Current copy radiation protection program with annual review [.1601(a)(7)]; [.1601(a)(49)]
- Records of maintenance or modification, which affect the useful beam (*service records*) [.0603(a)(2)(C)]
- Personnel monitoring and exposure records [.1601(a)(24)]; [.1601(a)(53)]
- Technique Chart [.0603(a)(1)(C)]
- Notice to Employees (*current and posted conspicuously in an employee area*) [.1001(a)(5)]
- Radiation Caution Signs [.1601(a)(34)]; [.1601(a)(35)]
- **Current** copy of N.C. Regulations for Protection Against Radiation (*Eff. 2/1/15*) [.1001(a)(5)]

Copies of the regulations may be in electronic form or printed. Applicable sections of the regulations for Medical X-ray: 10A NCAC 15 [.0100]; [.0200]; [.0600]; [.1000]; [.1100] and [.1600]

[Consolidated PDF of Regulations](#)
[N.C. Regulations Online](#)

- 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*)
- Self-Referral policy
- Protective aprons available

Visit the North Carolina Mammography website for help and important information!
<https://radiation.ncdhhs.gov/mammo/index.htm>