

MAMMOLOGIX


SAMPLE

Interpreting Physician Initial Qualifications

Standard Operating Policy & Procedure

Breast Imaging / Mammography Services

Policy 1.01



I. Administrative Document Information

Facility Name	SAMPLE
Policy Number	1.01
Policy Title	Interpreting Physician Initial Qualifications
Department	Breast Imaging / Mammography Services
Primary Regulation	21 CFR §900.12(a)(1) — Interpreting Physician Qualifications
Effective Date	[INSERT EFFECTIVE DATE]
Version	1.0
Supersedes	Version 2.0
Reviewed By	[Medical Director / Lead Interpreting Physician Full Name, MD/DO] [Date]
Approved By	[Facility Administrator / MQSA Compliance Lead / Responsible Individual Name, Title] [Date]
Next Review Date	[Effective Date + 2 Years]
Related Policies	1.02 1.19 1.23 1.25 1.26 1.27 3.02 3.04
Keywords	MQSA, Initial Qualifications, Interpreting Physician, Board Certification, CME, Supervised Interpretation, 21 CFR §900.12(a)(1), FDA, Credentialing
Applies To	All physicians who will independently interpret mammograms for this facility, including full-time, part-time, locum tenens, teleradiology, contracted, covering, and returning physicians.

II. Quick Reference Summary

Review this table before performing any credentialing action under this policy. It summarizes the federal MQSA requirements and the facility's internal authorization controls.

Requirement	Standard / Threshold	Req. Type	Responsible Role	If Not Met
Medical license	Licensed to practice medicine in a State. Facility must verify state-specific requirements.	Federal + state overlay	Credentialing Coordinator	No independent interpretation permitted.
Certification or formal training	Certified in appropriate specialty by FDA-recognized body, OR at least 3 months of documented formal mammography-related training.	Federal	Credentialing Coordinator	No independent interpretation permitted.
Mammography education	At least 60 Category I hours in mammography. At least 15 hours acquired within 3 years before qualification.	Federal	Credentialing Coordinator	No independent interpretation permitted.
Initial mammographic experience	At least 240 mammographic exams interpreted or multi-read under direct supervision within 6 months before qualification, unless residency exemption applies.	Federal	Credentialing Coordinator	No independent interpretation unless exemption documented.
Residency exemption	240 exams under direct supervision in any 6-month period in last 2 years of diagnostic radiology residency + board certified at first allowable time.	Federal exemption	Credentialing Coordinator + Approval Official	If not documented, initial 240-exam experience required.
Modality training	At least 8 hours of training in any modality not previously trained before independent interpretation.	Federal	Credentialing Coordinator	Physician may not independently interpret that modality.
Facility authorization	Written facility authorization required before physician added to active independent interpreting roster.	Facility control	Medical Director / Approval Official	No independent interpretation permitted.
Personnel records	Maintain records of training and experience. Departed personnel retained at least 24 months after departure.	Federal	Credentialing Coordinator	Inspection finding risk; corrective action required.
Facility retention	This facility retains records for [INSERT FACILITY STANDARD — e.g., 3 years after departure].	Facility control	Credentialing Coordinator	Corrective action under facility policy.
LOA / return	File review required before reactivation. Continuing qualification confirmed under Policy 1.02.	Facility + federal	Credentialing Coordinator + Approval Official	No independent interpretation until status confirmed.

III. Facility Access Control Standards

No physician may independently interpret mammograms for this facility until:

- The facility has documentation showing that the physician meets applicable MQSA initial qualification requirements.
- Any applicable state-law, accreditation, credentialing, or contractual requirements have been reviewed.
- The facility's designated approval official has issued written authorization.
- The physician has been added to the active independent interpreting roster.

■ *This authorization rule is a facility-level control designed to prevent unverified or undocumented independent interpretation. It supports MQSA compliance but is not a separate federal authorization form requirement.*

● **IV. Revision History**

Version	Date	Revised By	Summary of Changes
1.0	[INSERT DATE]	[INSERT NAME]	Initial issue.

1. Policy Statement

This facility shall ensure that every physician who independently interprets mammograms for the facility meets the applicable initial qualification requirements under the Mammography Quality Standards Act and FDA regulations at 21 CFR §900.12(a)(1).

Before independent interpretation begins, the facility shall verify and maintain documentation showing that the physician meets all applicable MQSA initial qualification elements: medical licensure, certification or formal training, mammography education, initial mammographic experience unless exempt, and mammographic modality training when applicable.

This facility shall also require written facility authorization before any physician is added to the active independent interpreting roster. Written authorization is an internal facility control intended to confirm that MQSA qualification documentation has been reviewed and that the physician is approved to interpret mammograms independently for this facility.

Any state law, accreditation requirement, medical staff requirement, payer requirement, contract requirement, or facility credentialing standard that is more stringent than the MQSA federal baseline shall be identified, documented, and applied as applicable.

2. Purpose

The purpose of this policy is to:

- Establish a standardized and auditable process for verifying and documenting interpreting physician initial qualifications.
- Correctly apply the MQSA qualification framework under 21 CFR §900.12(a)(1).
- Prevent independent mammography interpretation before qualification records are complete and facility authorization is issued.
- Define documentation requirements for licensure, certification or formal training, mammography education, initial experience, modality training, and exemptions.
- Apply the same qualification-review process to full-time, part-time, locum tenens, teleradiology, contracted, covering, and returning physicians.
- Create a clear handoff from initial qualification tracking under this policy to continuing qualification tracking under Policy 1.02.
- Support patient safety, inspection readiness, and defensible facility governance.

3. Scope

This policy applies to all physicians who will independently interpret mammograms for this facility, including:

- Full-time and part-time radiologists employed by the facility.
- Contracted interpreting physicians.
- Locum tenens physicians.
- Teleradiology physicians.
- Covering physicians.
- Physicians returning after an inactive period, contract gap, leave of absence, or change in interpretation status.
- Physicians who are qualified or credentialed at another facility but will interpret mammograms for this facility.

4. Responsibility

Medical Director / Lead Interpreting Physician / Facility Approval Official

The facility shall designate the individual responsible for final review and written authorization under this policy. This role may be filled by the Medical Director, Lead Interpreting Physician, credentialing committee chair, or another qualified approval official consistent with facility governance.

Responsibilities include:

- Reviewing completed interpreting physician qualification files.
- Determining whether documentation supports facility authorization.
- Issuing written facility authorization before the physician begins independent interpretation.
- Reviewing deficiencies or unresolved credentialing concerns.
- Reviewing reactivation after leave of absence or inactive status.
- Confirming handoff to Policy 1.02 continuing qualification tracking.

MQSA Compliance Lead / Responsible Individual

"Mammologix Responsible Individual," "MQSA Responsible Individual," or similar title may be used by the facility as an internal governance role. This role is responsible for ensuring that the policy is implemented and that credentialing records are maintained and inspection ready.

Responsibilities include:

- Ensuring this policy is implemented consistently.
- Escalating any qualification or authorization gap.
- Confirming that active physician rosters are current.
- Coordinating inspection-readiness activity with the Credentialing Coordinator.
- Confirming that state law and accreditation overlays are reviewed when applicable.

Credentialing Coordinator

Responsibilities include:

- Opening and maintaining interpreting physician credentialing files.
- Collecting qualification documentation.
- Performing primary source verification when feasible.
- Completing Appendix A.
- Tracking deficiencies and resolutions.
- Presenting completed files to the designated approval official.
- Maintaining active and inactive physician rosters.
- Initiating Policy 1.02 continuing qualification tracking after authorization.
- Managing leave-of-absence and reactivation documentation.

Interpreting Physician

Responsibilities include:

- Providing complete and accurate qualification documentation.
- Notifying the facility of licensure, certification, CME, modality training, or experience changes that may affect qualification.
- Refraining from independent mammography interpretation until written facility authorization is issued.

- Completing any required supervised interpretation, training, or requalification activity before independent interpretation.
- Complying with continuing qualification requirements under Policy 1.02.

5. Definitions

Interpreting Physician

A licensed physician who independently reads and interprets mammographic images and issues a final mammography interpretation report.

Initial Qualifications

The qualification requirements that must be met before a physician begins independent mammography interpretation under 21 CFR §900.12(a)(1), unless a regulatory exemption applies.

Certification or Formal Training Element

The MQSA requirement that the physician must either: (1) be certified in an appropriate specialty area by a body determined by FDA to have procedures and requirements adequate to ensure competency to interpret radiological procedures, including mammography; or (2) have at least 3 months of documented formal training in mammography interpretation and related topics, including radiation physics, mammography-specific radiation physics, radiation effects, and radiation protection. This element does not replace the separate mammography education and initial experience requirements.

FDA-Recognized or FDA-Accepted Certifying Body

A certifying body determined by FDA to have adequate procedures and requirements to ensure physician competency in radiological procedures, including mammography. The facility shall rely on current FDA, accreditation body, and legal/compliance guidance when determining whether a certifying body is acceptable.

Formal Mammography Training

Documented training of at least 3 months in the interpretation of mammograms and topics related to mammography. The training must include radiation physics, mammography-specific radiation physics, radiation effects, and radiation protection. The mammographic interpretation component must be under the direct supervision of a physician who meets MQSA interpreting physician requirements.

Category I Medical Education in Mammography

Documented Category I medical education in mammography. The required 60 hours must include instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, physiology, technical aspects of mammography, and quality assurance and quality control in mammography. At least 15 of the Category I hours must have been acquired within the 3 years immediately before the physician qualifies as an interpreting physician.

Initial Mammographic Experience

Interpretation or multi-reading of at least 240 mammographic examinations within the 6-month period immediately before the physician qualifies as an interpreting physician. The interpretation or multi-reading must be under direct supervision of an interpreting physician unless the residency exemption applies.

Residency Exemption

The regulatory exemption from the initial 240-exam experience requirement for physicians who interpreted or multi-read at least 240 mammographic examinations under direct supervision during any 6-month period in the last 2 years of diagnostic radiology residency and who become appropriately board certified at the first allowable time, as defined by an eligible certifying body.

Mammographic Modality Training

Training required before an interpreting physician independently interprets mammograms produced by a mammographic modality in which the physician has not previously been trained. The physician must have at least 8 hours of training in the new modality before independent interpretation of that modality.

Primary Source Verification

Confirmation of a credential directly with the issuing or authoritative source, such as a state medical board, certifying board, CME provider, residency program, prior facility, or official credentialing authority. Primary source verification is a facility control and Mammologix-recommended best practice for reliable documentation.

Written Facility Authorization

A signed and dated approval issued by the facility's designated approval official confirming that the physician's qualification file has been reviewed and that the physician is authorized under facility policy to independently interpret mammograms for this facility.

Leave of Absence

Any planned or unplanned absence from mammography interpretation duties for this facility lasting 30 or more consecutive calendar days, or any shorter period that may affect continuing qualification, scheduling, credentialing, or interpretation privileges.

State-Law or Accreditation Overlay

Any state law, accreditation requirement, licensing rule, medical staff standard, contract requirement, or facility-specific requirement that adds to or exceeds the MQSA federal baseline.

6. Regulatory & Accreditation References

1. 21 CFR §900.12(a)(1) — Interpreting physician qualifications.
2. 21 CFR §900.12(a)(1)(ii) — Continuing experience, continuing education, and modality training.
3. 21 CFR §900.12(a)(1)(iii) — Exemptions.
4. 21 CFR §900.12(a)(1)(iv) — Reestablishing qualifications.
5. 21 CFR §900.12(a)(4) — Retention of personnel records.
6. 21 CFR §900.12(d) — Quality assurance responsibilities.
7. Mammography Quality Standards Act of 1992, as amended.
8. FDA MQSA inspection guidance.
9. Applicable accreditation body requirements.
10. Applicable state medical licensure, radiation control, facility licensure, and medical staff requirements.

7. Initial Qualification Requirements

FDA regulations at 21 CFR §900.12(a)(1) do not create a complete standalone "board-certified pathway" that eliminates the education and experience requirements. Instead, the physician must satisfy each applicable initial qualification element before independent interpretation begins.

7A. Requirement 1 — Medical License

Before independent interpretation, the physician must be licensed to practice medicine in a State.

Facility documentation shall include:

- Copy or record of current medical license.
- Primary source verification from the applicable state medical board or licensing authority.
- License number.
- Expiration date.
- Status.
- Any restrictions, limitations, disciplinary conditions, or pending issues identified during verification.

■ *Facility control: This facility requires the license to be current, valid, unrestricted, and acceptable under applicable state law, facility credentialing standards, medical staff rules, contracts, and payer requirements.*

7B. Requirement 2 — Certification or Formal Training

The physician must satisfy one of the following:

Option 1 — Certification

The physician is certified in an appropriate specialty area by a body determined by FDA to have adequate procedures and requirements to ensure competency to interpret radiological procedures, including mammography.

Documentation shall include:

- Certification documentation.
- Primary source verification, when available.
- Certifying body.
- Certification type.
- Certification status.
- Verification date.
- Evidence that the certifying body is acceptable under current FDA, accreditation body, or qualified regulatory guidance.

Option 2 — Formal Mammography Training

The physician has at least 3 months of documented formal training in mammography interpretation and related topics.

Documentation shall include:

- Training program name.
- Training dates.
- Curriculum or attestation documenting required topics.
- Documentation that training included radiation physics, mammography-specific radiation physics, radiation effects, and radiation protection.
- Documentation that the mammographic interpretation component occurred under direct supervision of a physician meeting MQSA interpreting physician requirements.

- Signed attestation from the training program, supervising physician, residency/fellowship program, or other authoritative source.

■ **Important clarification: Formal mammography training is an alternative to the certification element only. It does not replace the separate 60-hour mammography education requirement or the initial 240-exam experience requirement unless a specific regulatory exemption applies.**

7C. Requirement 3 — Mammography Education

Before independent interpretation, the physician must have at least 60 hours of documented Category I medical education in mammography.

The 60 hours must include:

- Instruction in interpretation of mammograms.
- Education in basic breast anatomy.
- Breast pathology.
- Breast physiology.
- Technical aspects of mammography.
- Mammography quality assurance.
- Mammography quality control.

At least 15 of the Category I hours must have been acquired within the 3 years immediately before the physician qualifies as an interpreting physician.

Residency hours specifically devoted to mammography may count as equivalent to Category I CME if documented in writing by the appropriate representative of the training institution.

Documentation shall include:

- CME transcript, certificate, residency program documentation, or other acceptable education record.
- Date of each education activity.
- Category I status.
- Topic or course description.
- Total qualifying hours.
- Identification of at least 15 Category I hours acquired within the 3 years immediately before qualification.

■ **Important clarification: MQSA does not state that the 15 recent Category I hours must specifically be mammographic image interpretation hours. The requirement is that at least 15 of the Category I hours were acquired within the 3 years immediately before qualification.**

7D. Requirement 4 — Initial Mammographic Experience

Before independent interpretation, the physician must have interpreted or multi-read at least 240 mammographic examinations within the 6-month period immediately before the date the physician qualifies as an interpreting physician, unless the residency exemption applies.

This interpretation or multi-reading must occur under direct supervision of an interpreting physician.

Documentation shall include:

- Exam volume report, supervised interpretation log, residency program attestation, or other authoritative record.
- Date range of the 6-month period.
- Total number of mammographic examinations interpreted or multi-read.
- Supervising interpreting physician name and qualification status.
- Attestation that interpretations or multi-reads were performed under direct supervision.
- Source of the exam-volume documentation.

■ **Important clarification:** *The 240-exam initial experience requirement is not replaced by the 3-month formal training option. The 3-month formal training option addresses the certification/formal-training element. The 240-exam requirement is a separate requirement unless the residency exemption applies.*

7E. Residency Exemption from Initial 240-Exam Requirement

The physician may be exempt from the initial 240-exam requirement if both of the following are documented:

- The physician interpreted or multi-read at least 240 mammographic examinations under direct supervision during any 6-month period in the last 2 years of diagnostic radiology residency.
- The physician became appropriately board certified at the first allowable time, as defined by an eligible certifying body.

Documentation shall include:

- Residency program attestation.
- Date range of the qualifying 6-month period.
- Number of mammographic examinations interpreted or multi-read.
- Confirmation of direct supervision.
- Board certification documentation.
- Evidence that board certification occurred at the first allowable time.

7F. Mammographic Modality Training

Before independently interpreting mammograms from any modality in which the physician has not previously been trained, the physician must have at least 8 hours of training in that modality.

Documentation shall include:

- Modality name.
- Training date.
- Training provider.
- Number of hours.
- Course certificate, vendor training record, CME documentation, or other acceptable record.
- Approval to interpret that modality.

■ *Examples may include digital mammography, digital breast tomosynthesis, or other mammographic modalities used by the facility.*

8. Locum Tenens and Teleradiology Physicians

Locum tenens and teleradiology physicians interpreting mammograms for this facility are subject to the same MQSA qualification requirements as other interpreting physicians.

Before independent interpretation, the facility shall obtain or confirm documentation of:

- Medical licensure.
- Certification or formal training.
- 60 hours of Category I mammography education.
- Initial 240-exam experience or applicable residency exemption.
- Mammographic modality training.
- Continuing qualification status if the physician has previously qualified.
- Facility-specific written authorization.
- Contractual access to records when the physician is supplied by a group, agency, or teleradiology vendor.

For teleradiology arrangements, contracts should require the group or vendor to:

- Confirm that each interpreting physician meets MQSA requirements before reading for this facility.
- Maintain qualification documentation.
- Produce records promptly upon facility, accreditation body, FDA, or state inspection request.
- Notify the facility of any change affecting a physician's qualification status.
- Support corrective action if a documentation or qualification deficiency is identified.

■ *These contract provisions are facility controls and should be reviewed by counsel.*

9. Leave of Absence — Absence and Return Procedures

This section governs the facility's process for managing physician absence, inactive status, and return to independent interpretation.

9A. Notification and Documentation

The interpreting physician should notify the Credentialing Coordinator of any planned absence expected to last 30 or more consecutive calendar days. For unplanned absences, notification should occur as soon as practicable.

The Credentialing Coordinator shall document:

- Absence start date.
- Expected return date, if known.
- Actual return date.
- Reason category, if appropriate and non-confidential.
- Whether the absence may affect continuing experience, continuing education, modality training, licensure, or facility authorization.

■ *Specific medical diagnosis or protected health information is not required for the credentialing file.*

9B. Return to Practice — Standard Review

Before a physician returning from leave, inactive status, or contract gap resumes independent interpretation, the Credentialing Coordinator shall confirm:

- Medical license remains current and acceptable.
- Certification or formal training documentation remains on file.
- Continuing qualification requirements under Policy 1.02 are met or reestablished.
- Mammographic modality training remains appropriate for the modalities to be interpreted.
- No state-law, accreditation, contract, medical staff, or credentialing issue prevents reactivation.

The designated approval official shall issue written reactivation authorization before the physician resumes independent interpretation.

9C. Return to Practice — Continuing Qualification Deficiency

If the physician has failed to maintain continuing experience or continuing education requirements, the physician must reestablish qualifications before resuming independent interpretation.

Under MQSA, an interpreting physician who fails to meet continuing experience must reestablish qualifications by interpreting or multi-reading supervised mammographic examinations as specified in 21 CFR §900.12(a)(1)(iv). An interpreting physician who fails to meet continuing education must obtain enough additional Category I CME in mammography to meet the required total before resuming independent interpretation.

10. Supervised Interpretation Standards

A physician may not independently interpret mammograms while initial credentialing, reactivation, or requalification review is pending.

If the facility permits supervised interpretation during the review period:

- Each interpretation must be reviewed under the supervision of a currently qualified interpreting physician.
- The supervising physician must be responsible for the final interpretation if the supervised physician is not yet authorized for independent interpretation.
- Reports may not be finalized independently by the unauthorized physician.
- Supervised activity must be documented.
- The arrangement must comply with applicable MQSA, accreditation, state-law, medical staff, and facility requirements.

■ **Important clarification: Interim supervised interpretation used as an administrative safeguard is not automatically sufficient to satisfy MQSA formal training, initial experience, or requalification requirements. The facility must document which regulatory requirement, if any, the supervised activity is intended to satisfy.**

■ *The designated approval official should complete review of a complete credentialing file within 10 business days. This timeframe is a facility performance standard, not a federal MQSA deadline.*

11. Procedural Steps

11A. Initiation — New Physician Credentialing

Step	Role	Action	Output
1	Credentialing Coordinator	Upon notification that a physician may interpret mammograms for this facility, open a credentialing file and initiate Appendix A.	File opened; checklist initiated.
2	Credentialing Coordinator	Determine whether the physician will satisfy the certification element through board certification or formal mammography training.	Certification/formal-training route identified.
3	Credentialing Coordinator	Provide physician with documentation request list.	Documentation request sent.

11B. Medical License Verification

Step	Role	Action	Output
4	Credentialing Coordinator	Collect license documentation and perform primary source verification with applicable state medical board or licensing authority.	License verification record filed.
5	Credentialing Coordinator	Identify any state-specific licensure requirements applicable to facility location, patient location, teleradiology, or professional practice.	State-law overlay noted in Appendix C.

11C. Certification or Formal Training Verification

Step	Role	Action	Output
6A	Credentialing Coordinator	If physician relies on certification, collect certification documentation and verify status with the certifying body when feasible.	Certification verification filed.
6B	Credentialing Coordinator	Confirm certifying body acceptability using current FDA, accreditation body, or regulatory guidance.	Acceptability documented.
7A	Credentialing Coordinator	If physician relies on formal training, collect documentation of at least 3 months of formal mammography-related training.	Formal training documentation filed.
7B	Credentialing Coordinator	Confirm training covered required topics and supervised mammographic interpretation.	Training element confirmed.

11D. Mammography Education Verification			
Step	Role	Action	Output
8	Credentialing Coordinator	Collect CME transcript, residency documentation, certificates, or equivalent education records.	Education records filed.
9	Credentialing Coordinator	Confirm at least 60 Category I hours in mammography.	Total hours documented.
10	Credentialing Coordinator	Confirm at least 15 Category I hours acquired within the 3 years immediately before qualification.	Recent 15-hour requirement documented.
11	Credentialing Coordinator	Confirm content includes mammogram interpretation and required mammography topics.	Education content review documented.

11E. Initial Experience or Exemption Verification			
Step	Role	Action	Output
12	Credentialing Coordinator	Obtain documentation of 240 mammographic examinations interpreted or multi-read within the 6 months immediately before qualification under direct supervision.	Initial experience documentation filed.
13	Credentialing Coordinator	If physician claims residency exemption, obtain residency program documentation and board certification timing documentation.	Exemption documentation filed.
14	Credentialing Coordinator	Confirm whether the exemption is complete. If not complete, require documentation of initial 240-exam experience.	Initial experience or exemption confirmed.

11F. Modality Training Verification			
Step	Role	Action	Output
15	Credentialing Coordinator	Identify mammographic modalities the physician will interpret for this facility.	Modality list created.
16	Credentialing Coordinator	Confirm at least 8 hours of training for any modality in which the physician has not previously been trained.	Modality training documentation filed.
17	Credentialing Coordinator	Restrict physician from interpreting any modality for which training is not documented.	Modality restriction noted if needed.

11G. Facility Authorization			
Step	Role	Action	Output
18	Credentialing Coordinator	Complete Appendix A and submit file to designated approval official.	Complete file submitted.

11G. Facility Authorization			
Step	Role	Action	Output
19	Medical Director / Lead Interpreting Physician / Approval Official	Review file for completeness and compliance.	Authorization or deficiency notice issued.
20	Approval Official	If complete, issue signed and dated written facility authorization.	Authorization letter filed.
21	Credentialing Coordinator	Add physician to active independent interpreting roster.	Roster updated.
22	Credentialing Coordinator	Open Policy 1.02 continuing qualification tracking record.	Continuing tracking initiated.

11H. Deficiency Management			
Step	Role	Action	Output
23	Approval Official	If file is incomplete, return written deficiency list to Credentialing Coordinator.	Deficiency notice filed.
24	Credentialing Coordinator	Notify physician and obtain missing documentation.	Deficiency resolution tracked.
25	Credentialing Coordinator	Resubmit complete file for review.	File resubmitted.
26	Approval Official	Issue authorization only after deficiencies are resolved.	Authorization issued or denied.

11I. Leave of Absence / Reactivation			
Step	Role	Action	Output
27	Credentialing Coordinator	Document absence or inactive status.	LOA/inactive record opened.
28	Credentialing Coordinator	Assess impact on continuing qualification under Policy 1.02.	Continuing status assessment filed.
29	Approval Official	Review reactivation file.	Reactivation decision documented.
30	Credentialing Coordinator	Update active roster only after written reactivation authorization.	Roster updated.

12. Documentation & Record Retention

The facility shall maintain records of training and experience relevant to MQSA qualification for interpreting physicians who work or have worked at the facility.

Credentialing files shall include, as applicable:

- Completed Appendix A checklist.
- Current medical license documentation and verification.

- Certification documentation and verification, if applicable.
- Formal mammography training documentation, if applicable.
- Category I mammography education documentation.
- Documentation of at least 60 Category I hours in mammography.
- Documentation of at least 15 Category I hours acquired within the 3 years immediately before qualification.
- Initial 240-exam supervised interpretation or multi-reading documentation, unless exempt.
- Residency exemption documentation, if applicable.
- Mammographic modality training documentation.
- Written facility authorization.
- Deficiency notices and resolutions.
- Locum tenens or teleradiology documentation, if applicable.
- Leave-of-absence, inactive status, and reactivation documentation, if applicable.
- Signed physician acknowledgment of this policy and Policy 1.02.
- State-law, accreditation, or facility-specific overlay documentation.

Federal MQSA Personnel Record Retention

MQSA requires facilities to maintain records of personnel training and experience relevant to qualification and to make those records available for MQSA inspectors. Records for personnel no longer employed by the facility must be maintained for no less than 24 months after departure and must be available for inspection during that period.

Facility Retention Standard

This facility shall retain interpreting physician qualification files for:

[INSERT FACILITY RETENTION STANDARD — e.g., at least 3 years after last date of affiliation, or longer if required by state law, accreditation standards, contract, litigation hold, medical staff bylaws, or facility policy.]

■ **Important clarification:** *State medical-record retention laws generally apply to patient medical records. They should not be automatically applied to personnel credentialing files unless counsel or a qualified compliance professional confirms that they apply.*

13. Corrective Action & Non-Compliance

If it is discovered that a physician independently interpreted mammograms for this facility without complete qualification documentation or written facility authorization, the following actions are required:

- Immediately suspend independent interpretation assignments for that physician pending review.
- Notify the designated approval official, Credentialing Coordinator, and MQSA Compliance Lead.
- Determine whether the issue is a facility policy violation, an MQSA qualification deficiency, a documentation deficiency, or a combination of these.
- Determine whether any mammograms interpreted during the affected period require review by a currently qualified and authorized interpreting physician.
- Initiate a CAPA record under Policy 1.26.
- Document root cause, affected dates, affected physicians, affected examinations if applicable, corrective action, and preventive action.
- Assess whether FDA, accreditation body, state agency, medical staff, payer, patient, or referring provider notification is required.
- Do not reinstate independent interpretation privileges until qualification status is confirmed and written facility authorization or reauthorization is issued.

■ *The CAPA record should be completed within [INSERT FACILITY TIMEFRAME — e.g., 15 business days] unless an extension is approved and documented.*

● 14. Inspection Readiness

The facility shall maintain interpreting physician qualification records in an organized format that can be produced promptly for MQSA inspectors, state inspectors, and accreditation body reviewers.

The Credentialing Coordinator shall:

- Maintain an active roster of all physicians authorized to independently interpret mammograms for this facility.
- Identify each physician's authorization date.
- Identify modalities the physician is authorized to interpret.
- Maintain inactive, departed, and locum/teleradiology physician files according to retention requirements.
- Conduct an internal completeness review at least annually.
- Confirm that Policy 1.02 continuing qualification tracking is active for each authorized physician.
- Confirm that any state-law or accreditation overlay has been reviewed.

■ *This facility may adopt an internal benchmark requiring credentialing records to be accessible within 30 minutes of request. This is an internal inspection-readiness goal, not a separate federal MQSA deadline.*

APPENDIX A

Initial Qualification Credentialing Checklist

Complete for every physician before independent interpretation begins. Complete again for reactivation when required.

Physician Name	NPI
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Credentialing Type

<input type="checkbox"/> New physician	<input type="checkbox"/> Locum tenens
<input type="checkbox"/> Teleradiology	<input type="checkbox"/> Contracted physician
<input type="checkbox"/> Returning physician	<input type="checkbox"/> Leave-of-absence reactivation
<input type="checkbox"/> Requalification review	

A1. All Physicians — Required

Item	Date Verified	Verified By	Notes / File Location
Physician full name, NPI, and contact information on file			
Current medical license documentation on file			
Medical license primary source verified			
State-law licensure overlay reviewed			
Certification or formal training route identified			
60 Category I mammography education hours documented			
At least 15 Category I hours acquired within prior 3 years documented			
Initial 240-exam supervised interpretation/multi-reading documentation on file, unless exempt			
Residency exemption documentation on file, if applicable			
Mammographic modality training documented for all modalities physician will interpret			
Written facility authorization issued before independent interpretation			
Physician signed acknowledgment of Policy 1.01 and Policy 1.02			
Policy 1.02 continuing qualification tracking opened			

A2. Certification Route			
Item	Date Verified	Verified By	Notes / File Location
Certification documentation on file			
Certifying body identified			
Certification type documented			
Certification status verified where feasible			
Certifying body acceptability confirmed under current FDA/accreditation guidance			
Certification current and in good standing			

A3. Formal Mammography Training Route			
Item	Date Verified	Verified By	Notes / File Location
At least 3 months formal mammography training documented			
Training in mammogram interpretation documented			
Radiation physics training documented			
Mammography-specific radiation physics training documented			
Radiation effects training documented			
Radiation protection training documented			
Mammographic interpretation component performed under direct supervision			
Supervising interpreting physician qualification confirmed			

A4. Mammography Education			
Item	Date Verified	Verified By	Notes / File Location
Total Category I mammography hours ≥ 60			
At least 15 Category I hours acquired within 3 years immediately before qualification			
Instruction in mammogram interpretation included			
Breast anatomy education included			
Breast pathology education included			

A4. Mammography Education			
Item	Date Verified	Verified By	Notes / File Location
Breast physiology education included			
Technical aspects of mammography included			
Mammography QA/QC education included			
Residency mammography hours documented by training institution, if used			

A5. Initial Mammographic Experience			
Item	Date Verified	Verified By	Notes / File Location
240 mammographic examinations interpreted or multi-read			
Date range is within 6 months immediately before qualification			
Interpretation or multi-reading occurred under direct supervision			
Supervising interpreting physician identified			
Supervising interpreting physician qualification confirmed			
Exam volume source documented			

A6. Residency Exemption, If Claimed			
Item	Date Verified	Verified By	Notes / File Location
240 exams interpreted or multi-read under direct supervision during residency			
Exams occurred during any 6-month period in last 2 years of diagnostic radiology residency			
Residency program attestation on file			
Physician became appropriately board certified at first allowable time			
Exemption approved by designated approval official			

A7. Locum Tenens / Teleradiology Additional Items			
Item	Date Verified	Verified By	Notes / File Location
Facility-specific authorization issued before first independent interpretation			
External credentialing packet or attestation received			
Contract requires production of qualification records upon request			
Continuing qualification status confirmed if physician is already qualified			
State licensure and telemedicine requirements reviewed			

A8. Leave of Absence / Reactivation			
Item	Date Verified	Verified By	Notes / File Location
Absence or inactive dates documented			
Medical license remains current			
Continuing experience under Policy 1.02 confirmed or reestablished			
Continuing education under Policy 1.02 confirmed or reestablished			
Modality training remains current for assigned modalities			
Written reactivation authorization issued before independent interpretation			

Signatures

Role	Signature	Date
Credentialing Coordinator		
Medical Director / Lead Interpreting Physician / Approval Official		

APPENDIX B

Supervised Interpretation and Training Documentation Log

Use when documenting formal mammography training, initial 240-exam experience, requalification, or other supervised interpretation activity.

Physician Being Supervised		Facility	
Supervision Start Date		Target End Date	
Supervising Physician		MQSA Qualification Confirmed	<input type="checkbox"/> Yes <input type="checkbox"/> No

Purpose of Supervision

<input type="checkbox"/> Formal 3-month mammography training	<input type="checkbox"/> Initial 240-exam experience
<input type="checkbox"/> Requalification — continuing experience	<input type="checkbox"/> Interim supervised interpretation pending facility authorization
<input type="checkbox"/> Other: _____	

Date	Accession # / Case ID	Study Description	Purpose Category	Supervising Physician	Supervisor Signature

Total Exams Supervised		Period Completed	<input type="checkbox"/> Yes <input type="checkbox"/> No
Completion Date			

Supervising Physician Attestation

I attest that the supervised interpretation or training documented above was performed under my direct supervision and that I meet MQSA interpreting physician qualification requirements.

Supervising Physician Signature		Date	
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APPENDIX C

State Law, Accreditation, and Facility Requirement Matrix

Identify requirements in addition to MQSA. Do not insert state-law summaries unless verified by counsel or a qualified compliance professional.

Jurisdiction / Source	Area Affected	Citation / Source	Requirement	Applies to Section	Verified By	Date Verified
Federal MQSA	Interpreting physician qualifications	21 CFR §900.12(a)(1)	Initial qualification requirements	Sections 7–12		
Federal MQSA	Personnel records	21 CFR §900.12(a)(4)	Maintain qualification records; departed personnel records retained at least 24 months	Section 12		
State	Medical licensure	[INSERT]	[INSERT]	Sections 7A, 8		
State	Teleradiology / telemedicine	[INSERT]	[INSERT]	Section 8		
Accreditation body	Personnel documentation	[INSERT]	[INSERT]	Sections 11–14		
Medical staff / credentialing	Privileging	[INSERT]	[INSERT]	Sections 4, 11		
Contract / payer	Credentialing documentation	[INSERT]	[INSERT]	Sections 8, 12		

State Law / Overlay Confirmed For		Date Confirmed	
Confirmed By			

POLICY ACKNOWLEDGMENT & APPROVAL

Authorization Signatures

By signing below, authorized individuals confirm this policy has been reviewed and facility-specific overlays identified.

By signing below, the authorized individuals confirm that this policy has been reviewed, that facility-specific overlays have been identified where applicable, and that the policy is effective as of the date indicated.

Medical Director / Lead Interpreting Physician / Approval Official

Name	
Signature	
Date	

MQSA Compliance Lead / Facility Administrator

Name	
Signature	
Date	

State Law / Accreditation Overlay Confirmation

Confirmed For	
Date Confirmed	
Confirmed By	

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