

POLICY & PROCEDURE

Policy 1.20 — Lay Letter (Patient Results): Timeliness & Content

FACILITY NAME	[FACILITY LEGAL NAME — as registered with FDA]
POLICY NUMBER	1.20
POLICY TITLE	Lay Letter (Patient Results): Timeliness & Content
DEPARTMENT	Breast Imaging / Mammography Services
PRIMARY REGULATION	21 CFR §900.12(c)(1) & §900.12(c)(1)(ii) — Patient Notification; Dense Breast Notification
EFFECTIVE DATE	[INSERT EFFECTIVE DATE]
VERSION	2.0
SUPERSEDES	Version 1.0 or N/A — Initial Issue
REVIEWED BY	[Medical Director Full Name, MD/DO] [Date]
APPROVED BY	[MQSA Responsible Individual Name, Title] [Date]
NEXT REVIEW DATE	[Effective Date + 2 Years]
RELATED POLICIES	1.02 1.14 1.16 1.17 1.19 1.21 1.22 1.25 1.26 1.27 3.01 5.01
KEYWORDS	MQSA, Lay Letter, Patient Notification, Mammologix, Timeliness, BI-RADS, Dense Breast Notification, 21 CFR §900.12(c), Abnormal Result, Referring Provider, 30-Day, 7-Day
APPLIES TO	All client facilities that contract with Mammologix for lay letter generation and patient result communication services. Also applies to all facility staff and contracted services involved in mammography report delivery, patient result communication, and lay letter generation — including interpreting physicians, lead technologists, lay letter coordinators, administrative staff, and the Mammologix platform.

Quick Reference Summary

Review this table before performing any lay letter or patient notification action under this policy.

REQUIREMENT	STANDARD / THRESHOLD	RESPONSIBLE ROLE	IF NOT MET
Lay letter — all results	Within 30 calendar days of examination date	Lay Letter Coordinator	MQSA violation; CAPA required; corrective notification issued
Lay letter — abnormal results (BI-RADS 0, 4, 5)	Written notification to patient AND referring provider within 7 calendar days of final signed report	Medical Director / Interpreting Physician / Lay Letter Coordinator	Immediate Medical Director escalation; CAPA record initiated

REQUIREMENT	STANDARD / THRESHOLD	RESPONSIBLE ROLE	IF NOT MET
Lay letter content — required elements	Patient name, exam date, facility name, interpreting physician, overall assessment in lay language, BI-RADS category, breast density / dense breast notification, recommendations, facility contact info	Lay Letter Coordinator / Interpreting Physician	Letter corrected and reissued; corrective action documented
Dense breast notification	Required in all applicable reports per 21 CFR §900.12(c)(1)(ii) effective September 10, 2024; state overlay applies — see Appendix B	Medical Director / Lay Letter Coordinator	Non-compliant letter reissued; CAPA initiated
Referring provider notification — abnormal	Written notification within 7 calendar days of final signed report for BI-RADS 0, 4, 5	Lay Letter Coordinator	Escalate to Medical Director; document in event log
Lay letter record retention	Minimum 5 years from examination date (state law may require longer — see Appendix B)	Lay Letter Coordinator / Records Manager	FDA inspection finding; reconstruct records; CAPA initiated
Returned / undeliverable letter	Document event; re-attempt delivery within 7 business days; notify referring provider if patient unreachable after 14 days	Lay Letter Coordinator	Escalate to Medical Director; document resolution in event log

⊘ ABSOLUTE RULE — NO EXCEPTIONS

No lay letter may be issued for a result that has not been confirmed by a final signed mammography report from a currently authorized, MQSA-qualified interpreting physician. No verbal-only results are acceptable as the basis for patient notification. Any lay letter issued without a final signed report is a regulatory violation.

Revision History

VERSION	DATE	REVISED BY	SUMMARY OF CHANGES
N			

1. Policy Statement

This facility shall ensure that all patients who undergo mammography examination receive a written lay letter summarizing their results in plain, easily understandable language, within the timeframes mandated by the Mammography Quality Standards Act (MQSA) and FDA regulations at 21 CFR §900.12(c)(1) and §900.12(c)(1)(ii). Lay letters shall be accurate, complete, and compliant with all federal and applicable state requirements for content, timeliness, and delivery documentation.

No lay letter shall be issued on the basis of a preliminary, verbal, or unsigned report. All lay letters must be based on a final signed mammography report issued by a currently authorized MQSA-qualified interpreting physician per Policy 1.02.

Any requirement imposed by applicable state law, the facility's accreditation body (e.g., ACR, NAPBC), or this facility's own standards that is more stringent than the MQSA federal minimum shall also apply and shall govern

where it exceeds that minimum. Facilities must identify and apply their state-specific overlay using Appendix B — State Law Reference Matrix before this policy's effective date.

2. Purpose

The purpose of this policy is to:

- Establish a standardized, auditable process for generating and delivering lay letters within MQSA-mandated timeframes.
- Define the required content elements for every lay letter issued by this facility.
- Establish the facility's urgent notification workflow for abnormal and suspicious results (BI-RADS 0, 4, 5).
- Define the procedure for handling undeliverable or returned lay letters.
- Ensure dense breast notification is included in every applicable lay letter per 21 CFR §900.12(c)(1)(ii) (effective September 10, 2024) and applicable state law.
- Protect patient safety by ensuring timely access to mammography results and clear direction for follow-up.
- Comply with 21 CFR §900.12(c) and all applicable state law requirements.

3. Scope

This policy applies to all mammography examinations performed at this facility, including screening and diagnostic mammography. It governs the actions of:

- Interpreting physicians who issue final signed reports.
- Lead technologists and lay letter coordinators responsible for generating and transmitting lay letters.
- Administrative and clerical staff involved in lay letter printing, mailing, or electronic delivery.
- Any third-party vendor engaged to generate or distribute lay letters on behalf of this facility — who remains subject to all requirements in this policy and must maintain records producible for FDA inspection.
- The Medical Director, who is responsible for clinical oversight of patient notification content and urgent result escalation.

4. Responsibility

Medical Director

Provides clinical oversight of lay letter content standards. Reviews and approves the lay letter template(s) used at this facility. Receives escalation notifications for abnormal and urgent results. Bears overall accountability for ensuring the patient notification program complies with MQSA requirements. The Medical Director may not delegate template approval or urgent result escalation response.

MQSA Responsible Individual (RI)

Designated per 21 CFR §900.12(d)(1) and named in Policy 1.25. Ensures this policy is implemented and enforced. Verifies that lay letter logs and delivery records are complete and current for FDA inspection. Escalates any timeliness failure to the Medical Director immediately.

Lay Letter Coordinator / Lead Technologist

Responsible for the day-to-day operation of the lay letter program. Monitors final signed report receipt, initiates lay letter generation, tracks delivery dates, manages returned mail, and maintains all documentation required under this policy. Reports timeliness failures and abnormal result notifications to the Medical Director and RI.

Interpreting Physician

Responsible for issuing final signed mammography reports that contain all required content elements per Policy 1.19. Must flag urgent results (BI-RADS 4 or 5) to the Lay Letter Coordinator immediately upon signing. Must not delay report signing in a manner that causes lay letter timeliness failures.

Third-Party Lay Letter Vendor (If Applicable)

Any vendor contracted to generate or deliver lay letters on behalf of this facility must: (a) operate under a written agreement referencing this policy and the facility's MQSA obligations; (b) maintain records of lay letter generation, content, and delivery that are producible to FDA inspectors upon request; (c) notify this facility of any delivery failures within 24 hours; and (d) comply with HIPAA requirements for handling patient health information per Policy 5.01.

5. Definitions

Lay Letter: A written patient notification summarizing the results of a mammography examination in plain, easily understandable language — not technical or clinical report language. Required by 21 CFR §900.12(c)(1).

Final Signed Report: A completed mammography interpretation report signed by a currently authorized, MQSA-qualified interpreting physician. The lay letter may not be issued until the final signed report is on file.

BI-RADS Assessment Category: The standardized Breast Imaging Reporting and Data System classification (ACR BI-RADS) assigned to each mammography examination: 0 (Incomplete), 1 (Negative), 2 (Benign), 3 (Probably Benign), 4 (Suspicious), 5 (Highly Suggestive of Malignancy), 6 (Known Biopsy-Proven Malignancy).

Dense Breast Notification: Required statutory or regulatory language included in the lay letter when breast density is identified. Mandated federally by 21 CFR §900.12(c)(1)(ii) effective September 10, 2024, and by numerous state statutes. See Appendix B for state-specific requirements.

Abnormal Result: For purposes of this policy, any mammography result assigned BI-RADS category 0 (incomplete — needs additional imaging), 4 (suspicious), or 5 (highly suggestive of malignancy). These results trigger the 7-day urgent notification requirement.

Lay Letter Coordinator: The staff member (or designee) responsible for managing the lay letter generation, delivery, and documentation process at this facility. May be the Lead Technologist or another designated individual approved by the Medical Director.

Delivery Confirmation: Documentation that a lay letter was transmitted to the patient, including: mail date, certified mail tracking number (if applicable), electronic delivery timestamp, or patient portal access log.

Returned Mail: A lay letter returned to the facility by postal service or electronic delivery system as undeliverable. Triggers the returned mail procedure in Section 10D.

More-Stringent Requirement: Any state law, state regulation, or accreditation standard imposing a requirement exceeding the MQSA federal minimum. The more-stringent requirement governs and must be documented. See Appendix B.

6. Regulatory & Accreditation References

- 21 CFR §900.12(c)(1) — Medical Records and Reports: Mammography Results [PRIMARY FEDERAL STANDARD — Lay Letter Timeliness and Content]
- 21 CFR §900.12(c)(1)(ii) — Dense Breast Notification (effective September 10, 2024) [FEDERAL BASELINE — ALL STATES]
- 21 CFR §900.12(c)(2) — Patient Records: Retention and Release
- 21 CFR §900.12(d)(1) — Responsible Individual Designation
- Mammography Quality Standards Act of 1992, as amended (42 U.S.C. §263b)
- ACR BI-RADS Atlas, 5th Edition — Breast Density Classification and Assessment Categories
- ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography
- FDA MQSA Program:
<https://www.fda.gov/radiation-emitting-products/mqsa-insights/mammography-quality-standards-act-and-program>
- HIPAA Privacy Rule, 45 CFR Part 164 — cross-reference Policy 5.01
- State-specific statutes and administrative codes — see Appendix B, State Law Reference Matrix.

7. Timeliness Standards

7A. Standard Results — 30-Day Requirement

Per 21 CFR §900.12(c)(1), this facility shall issue a lay letter to every patient who undergoes a mammography examination within 30 calendar days of the examination date. The 30-day clock begins on the date of the mammography examination — not the date the report is signed. This facility shall maintain internal workflows that ensure the final signed report is available in time to meet the 30-day notification deadline.

CRITICAL — TIMELINESS CLOCK

The 30-day clock runs from the mammography examination date, not the report signing date. Interpreting physician delays in signing do not extend the facility's obligation to the patient. The Lay Letter Coordinator must flag any unsigned report that risks a timeliness failure to the Medical Director no later than Day 20 from the examination date.

7B. Abnormal / Urgent Results — 7-Day Requirement

Results categorized as BI-RADS 0 (incomplete), BI-RADS 4 (suspicious), or BI-RADS 5 (highly suggestive of malignancy) shall be communicated to the patient AND to the referring or ordering provider within 7 calendar days of the final signed report date. This communication must be in writing — lay letter, certified letter, or documented electronic notification. Verbal communication may be made as an immediate first step but does not satisfy the written notification requirement and must be followed by written documentation.

ABSOLUTE RULE — NO EXCEPTIONS

For BI-RADS 4 or 5 results: The interpreting physician must notify the Lay Letter Coordinator immediately upon signing the report. The 7-day written notification clock begins at the time of the final signed report. Any failure to meet this 7-day standard must be reported to the Medical Director and documented as a corrective action event per Policy 1.26.

7C. Timeliness Monitoring

The Lay Letter Coordinator shall maintain a timeliness log documenting, for each mammography examination: examination date, report signed date, lay letter generation date, delivery date, and any exceptions or delays. This log shall be reviewed monthly by the Medical Director or designee. Any pattern of timeliness failures shall be addressed through the CAPA process per Policy 1.26. The timeliness log constitutes primary evidence of MQSA timeliness compliance at FDA inspection.

8. Lay Letter Content Requirements

Per 21 CFR §900.12(c)(1), every lay letter issued by this facility must contain the following elements at minimum. The lay letter template must be approved by the Medical Director and reviewed at each annual policy review cycle.

8A. Required Content Elements — All Results

- Patient full name and date of mammography examination.
- Name and address of the facility where the examination was performed.
- Name of the interpreting physician who signed the final report.
- Overall assessment result expressed in plain, easily understandable language — not BI-RADS code alone. The lay letter must translate the BI-RADS assessment into language the patient can understand without medical training.
- BI-RADS assessment category — number and category name (e.g., 'BI-RADS 1 — Negative').
- Breast density description in lay language, and — where required by 21 CFR §900.12(c)(1)(ii) or applicable state law — the dense breast notification language per Section 8C.
- Recommendations for follow-up, if any, stated in clear, actionable language.
- Facility contact information — phone number and mailing address — for patient follow-up questions.
- Referring or ordering provider name (where available from the final signed report).

8B. Required Content Elements — Abnormal Results (BI-RADS 0, 4, 5)

In addition to all elements in Section 8A, lay letters for abnormal or urgent results must also include:

- A clear, plain-language statement that additional follow-up is needed and why — without creating undue alarm.
- Specific recommended next step in actionable language (e.g., 'Your provider has been notified and will contact you to schedule additional imaging' or 'Please contact your doctor or call us at [phone] within [X] days.').
- A statement that the referring provider has been notified, or the date provider notification is expected.

8C. Dense Breast Notification

Effective September 10, 2024, 21 CFR §900.12(c)(1)(ii) requires that all mammography lay letters inform patients about breast density and, where applicable, recommend discussion of supplemental screening with the patient's provider. This applies in all 50 states as a federal baseline. State laws imposing more stringent or specific language requirements take precedence and are identified in Appendix B. The Medical Director must approve the dense breast notification language used in the facility's lay letter template before policy activation and at each annual review.

⚠ **IMPORTANT — DENSE BREAST NOTIFICATION TEMPLATE**

The facility's lay letter template must include the FDA-required density notification language and any applicable state-required language as a standing template section. The Medical Director must review and approve this language at initial policy activation and at each annual review. Do not use generic placeholder language — use only the approved template verified against 21 CFR §900.12(c)(1)(ii) and current applicable state law.

9. Referring Provider Notification

Per established MQSA practice and patient safety standards, this facility shall notify the referring or ordering provider of all mammography results — not only abnormal results — as part of standard report transmission. For abnormal and urgent results (BI-RADS 0, 4, 5), written notification to the referring provider must be completed within 7 calendar days of the final signed report, concurrent with the patient lay letter. The notification to the referring provider may be the clinical mammography report (not the lay letter), transmitted via the facility's standard report delivery mechanism. Documentation of provider notification must be retained in the patient file.

10. Procedures

10A. Standard Lay Letter — Generation and Delivery

Step 1

Role: Lay Letter Coordinator

Action: Upon receipt of a final signed mammography report, confirm the examination date and calculate the timeliness deadline: examination date + 30 calendar days. Log the examination in the timeliness tracking log with examination date, report receipt date, and deadline date. If the report has not been signed by Day 20 from the examination date, immediately flag to the Medical Director in writing.

Output: *Timeliness log entry created. 30-day deadline recorded. Any Day-20 unsigned-report flag escalated to Medical Director in writing.*

Step 2

Role: Lay Letter Coordinator

Action: Generate the lay letter using the current Medical Director–approved template. Confirm all required content elements from Section 8A are present: patient name, exam date, facility name, interpreting physician name, overall assessment in lay language, BI-RADS category, breast density description and dense breast notification language, recommendations, and facility contact information.

Output: *Draft lay letter generated from approved template. All Section 8A elements confirmed present. Draft retained in patient file pending delivery.*

Step 3

Role: Lay Letter Coordinator

Action: Deliver the lay letter to the patient via the facility's standard delivery method (first-class mail, certified mail, patient portal, or other Medical Director–approved method). Document in the patient file: delivery method, date of delivery or mailing, and tracking number or electronic confirmation if applicable.

Output: *Lay letter delivered within 30-day deadline. Delivery method, date, and confirmation number (if applicable) recorded in timeliness log and patient file.*

10B. Abnormal / Urgent Result Notification (BI-RADS 0, 4, 5)

Step 4

Role: Interpreting Physician

Action: Upon signing a report with a BI-RADS 0, 4, or 5 result, immediately notify the Lay Letter Coordinator verbally or via the facility's designated urgent result notification channel — do not wait for the standard report workflow. Document the date and time of this notification in the report or event log.

Output: *Lay Letter Coordinator notified of urgent result. Date and time of notification documented by interpreting physician.*

Step 5

Role: Lay Letter Coordinator

Action: Generate the abnormal result lay letter within 7 calendar days of the final signed report date using the approved abnormal result template per Section 8B. Simultaneously prepare written notification for the referring provider. This is a separate, accelerated workflow — do not wait for the standard 30-day cycle.

Output: *Abnormal lay letter and referring provider notification both generated. Both ready for delivery within the 7-day window.*

Step 6

Role: Lay Letter Coordinator

Action: Deliver the abnormal lay letter to the patient and transmit written notification to the referring provider — both within 7 calendar days of the final signed report date. Document delivery method, date, and confirmation for both. Notify the Medical Director in writing that notification has been completed.

Output: *Patient lay letter and referring provider notification both delivered within 7-day window. Delivery documented in timeliness log and patient file. Medical Director notified of completion.*

10C. Timeliness Escalation — Day 20 Flag

Step 7

Role: Lay Letter Coordinator

Action: If a final signed report has not been received by Day 20 from the examination date, escalate to the Medical Director in writing: patient name (or study ID), examination date, current day count, and reason for delay if known. The Medical Director shall take action to obtain the signed report or arrange coverage to prevent a timeliness failure.

Output: *Written Day-20 escalation notice sent to Medical Director. Date and time of escalation documented in timeliness log. Medical Director response documented.*

10D. Returned / Undeliverable Lay Letter

Step 8

Role: Lay Letter Coordinator

Action: Upon receipt of a returned or undeliverable lay letter, document in the event log: patient name, examination date, original delivery method, date of return, and reason for non-delivery (if indicated by postal or electronic service). Attempt re-delivery via an alternate method — phone contact to obtain updated address, patient portal enrollment, or certified mail to alternate address — within 7 business days.

Output: *Returned letter event log entry created with full documentation. Re-delivery attempt initiated within 7 business days.*

Step 9

Role: Lay Letter Coordinator

Action: If re-delivery is unsuccessful after 7 business days, notify the referring provider in writing that the patient's lay letter has not been successfully delivered and provide the reason. Document: date of provider notification and method. Escalate to the Medical Director for further action. Continue to document all outreach attempts in the event log.

Output: *Referring provider notified of undeliverable letter in writing. Medical Director escalation documented. Event log updated with all outreach attempts and outcomes.*

10E. Third-Party Vendor Management

Step 10

Role: Lay Letter Coordinator / Medical Director

Action: If a third-party vendor is used for lay letter generation or delivery: (a) confirm that a written service agreement is on file referencing this policy and MQSA compliance obligations; (b) confirm the vendor's audit logs for the prior month are accessible and no delivery failures are outstanding; (c) report any vendor-reported failures to the Medical Director within 24 hours of notification. Review vendor performance against timeliness standards at each monthly log review.

Output: *Vendor service agreement confirmed on file. Monthly audit log access confirmed. Outstanding failures escalated to Medical Director within 24 hours. Vendor performance documented in monthly timeliness review.*

11. Documentation & Record Retention

The following records shall be maintained and retained for a minimum of 5 years from the date of examination, or longer if required by applicable state law (see Appendix B — State Law Reference Matrix):

- Copy of each lay letter issued — with examination date, patient name, BI-RADS category, and issue date.
- Delivery confirmation for each lay letter — mail date, tracking number, electronic delivery timestamp, or patient portal access log.
- Timeliness tracking log — examination date, report signed date, lay letter generation date, delivery date, any exceptions or escalations.
- Returned mail event log — documentation of each undeliverable letter, re-delivery attempts, and resolution.
- Abnormal result urgent notification log — patient, BI-RADS result, date of notification, delivery method, referring provider notification date.
- Medical Director–approved lay letter template(s) — current approved version and prior versions with approval dates.
- Third-party vendor service agreement(s) and vendor audit logs — if applicable.

Complete, current lay letter records maintained in accordance with this policy constitute the facility's primary evidence of MQSA patient notification compliance and shall be made available to FDA inspectors, state agency inspectors, and accreditation body reviewers upon request without advance preparation.

⚠ IMPORTANT — STATE-SPECIFIC RETENTION PERIODS

Federal minimum: 5 years from examination date. California: 7 years (Cal. Health & Safety Code §123111). Florida: 7 years (Fla. Stat. §456.057). Texas: 7 years (25 TAC §165.1). New York: 6 years, or 3 years after patient reaches age 18, whichever is longer (10 NYCRR §405.10). All other states: verify and enter applicable

requirement: [State: ____ Retention: ____ years Citation: ____]. The most stringent requirement governs.

12. Corrective Action & Non-Compliance

If a lay letter timeliness failure, content deficiency, or patient notification error is identified, the following actions are mandatory:

- Immediately notify the Medical Director and MQSA RI in writing within 2 business days of discovery.
- Issue a corrected or late lay letter to the patient as soon as possible — document the reason for the delay and the corrective notification date in the patient file.
- Notify the referring provider of the notification failure if the result was abnormal or urgent.
- Initiate a CAPA record per Policy 1.26 — Corrective and Preventive Action, documenting root cause, corrective actions, and preventive measures.
- Assess whether the non-compliance event constitutes a significant adverse finding requiring FDA notification. Document the assessment outcome regardless of result.
- Review the timeliness tracking log to identify whether additional patients may be affected by the same root cause — conduct a look-back assessment if indicated.

13. Inspection Readiness

This facility maintains all lay letter and patient notification records in a format producible for FDA inspectors and state surveyors upon request. The Lay Letter Coordinator shall:

- Maintain the timeliness tracking log current — updated within 2 business days of each lay letter delivery.
- Keep the current Medical Director–approved lay letter template on file with the approval date visible.
- Ensure all lay letter records are organized, complete, and accessible within 30 minutes of an inspection request.
- Conduct an internal completeness review of lay letter records at least quarterly using the Appendix A checklist as the audit instrument.
- Confirm that the Appendix B state law overlay has been reviewed and applied at each annual review cycle.
- Reference Policy 3.03 — Internal Audit & Mock Inspection protocol before scheduled accreditation surveys.

14. Mammologix Vendor Integration

This facility contracts with Mammologix for lay letter generation and patient result communication services. The following provisions govern the Mammologix integration and supplement — but do not replace — the facility's MQSA obligations under Sections 1 through 13 of this policy. The facility remains the MQSA-responsible entity for all patient notification requirements; Mammologix serves as the designated service vendor operating under the facility's direction and oversight.

14A. Facility and Mammologix Responsibilities

- Client facilities are responsible for transmitting final signed mammography reports to Mammologix using an approved secure transmission method (see Section 14C).
- Mammologix is responsible for generating and distributing lay letters in compliance with MQSA timeliness and content standards as defined in this policy.
- Mammologix monitors processing timelines to ensure compliance with client service-level agreements (SLAs) and MQSA standards, and notifies the facility of any timeliness risks or delivery failures within 24 hours.

14B. Data Fields Transmitted to Mammologix

The following data fields are required for Mammologix lay letter generation. Required fields must be populated in every report transmission. Optional fields are included where the facility elects to track additional data.

- Patient name -- split into first and last name fields; middle name is optional.
- Patient sex.
- Patient date of birth (DOB).
- Patient MRN(s).
- Patient mailing address -- split into separate fields for street address, city, state, and ZIP code.
- Phone number and email address -- optional; include if the facility wishes Mammologix to retain this information for reporting purposes.
- Date the breast exam was performed.
- Facility where the breast exam was performed.
- Breast exam technologist(s) -- required only if Mammologix is tracking technologist volumes for this facility.
- Breast exam referring doctor name.
- Breast exam interpreting physician name -- preferably a separate data field; acceptable as part of the report body if a separate field is unavailable.
- Report of test results, which must contain:
 - The reason for the procedure (e.g., screening or diagnostic).
 - The procedure performed.
 - The BI-RADS assessment category.
 - Breast density description and BI-RADS density category.
 - Recommendations for follow-up.
 - Date the breast exam was interpreted -- optional; include if the facility is tracking turnaround times.
 - Lifetime risk score -- optional; include if the facility performs lifetime risk calculations.
 - Reading station identifier -- optional; include if the facility tracks reading stations.

14C. Approved Report Transmission Methods

Final signed mammography reports shall be transmitted to Mammologix using one of the following approved secure methods, as mutually agreed between this facility and Mammologix:

- HL7 TCP server via IPsec VPN.
- SFTP server -- Mammologix hosted.
- SFTP server -- client hosted.
- Manual upload by authorized facility user into the secure Mammologix web application.
- Other secure client-hosted file access methods as mutually agreed in writing.

All transmission methods utilize secure, encrypted communication channels consistent with HIPAA requirements and industry security standards. Cross-reference Policy 5.01 -- Privacy and Confidentiality (HIPAA).

14D. Mammologix Audit Logs and Inspection Support

Mammologix maintains audit logs documenting report receipt, lay letter generation, and delivery confirmation for each patient record processed. These logs are available to client facilities upon request and shall be produced for FDA or state MQSA inspection upon the facility's request without advance preparation. The Lay Letter Coordinator shall confirm audit log accessibility at each monthly timeliness review.

14E. Clarification Workflow

If the Mammologix team determines that information in a transmitted report is unclear or insufficient to generate a compliant lay letter, a clarification request will be sent to the facility. The facility shall respond to clarification requests within 2 business days to avoid timeliness failures. The date of the clarification request and the date of facility response shall both be documented in the timeliness log and treated as part of the lay letter generation record.

14F. Lay Letter Delivery Options

The facility may choose one of the following delivery options for completed lay letters generated by Mammologix:

- Download, print, and mail the letter directly -- the facility assumes responsibility for delivery confirmation and documentation.
- Utilize Mammologix mailing service -- Mammologix assumes responsibility for physical mailing and provides delivery confirmation records to the facility. The facility retains these records per Section 11.

Regardless of the delivery option selected, the facility remains the MQSA-responsible entity for ensuring patient notification occurs within required timeframes. The delivery option in use must be documented in the facility's lay letter program records and reviewed at each annual policy review.

Appendix A — Lay Letter Compliance Checklist

Complete this checklist for each monthly lay letter audit cycle. Both the Lay Letter Coordinator and Medical Director must sign upon completion.

☐ DOCUMENTATION ITEM	DATE VERIFIED	VERIFIED BY	NOTES / FILE LOCATION
ALL STAFF — Required for Every Lay Letter Cycle			
☐ Lay letter issuing system or vendor confirmed operational			
☐ Final signed mammography report received before lay letter generation			
☐ Lay letter generated within 30 calendar days of examination date — date logged in timeliness log			
☐ All Section 8A required content elements confirmed present in lay letter			
☐ BI-RADS assessment category present and translated to lay language			
☐ Dense breast notification language included per 21 CFR §900.12(c)(1)(ii) and applicable state law			
☐ Lay letter delivered to patient — delivery method and date documented			
☐ Delivery confirmation retained in patient file			
ABNORMAL / URGENT RESULTS (BI-RADS 0, 4, 5) — Additional Requirements			
☐ Interpreting physician notified Lay Letter Coordinator immediately upon signing urgent report			
☐ Patient notification completed within 7 calendar days of final signed report — date documented			
☐ Referring provider written notification completed within 7 calendar days — date documented			
☐ Medical Director notified of urgent result — notification date documented			
☐ Abnormal result event log entry created			
RETURNED / UNDELIVERABLE LETTERS			
☐ Undeliverable letter documented in event log — reason recorded			
☐ Re-delivery attempt via alternate method within 7 business days — documented			
☐ Referring provider notified if patient unreachable after 14 days — documented			
RECORD RETENTION			

DOCUMENTATION ITEM	DATE VERIFIED	VERIFIED BY	NOTES / FILE LOCATION
☐ Lay letter copies retained per Section 11 (minimum 5 years or applicable state law)			
☐ Delivery confirmation or tracking log retained with lay letter file			
☐ Dense breast notification delivery documented per applicable state requirement			
☐ Medical Director–approved lay letter template on file with approval date			
Lay Letter Coordinator	Signature: _____ Date: _____		
Medical Director	Signature: _____ Date: _____		

Appendix B — State Law Reference Matrix

i HOW TO USE THIS MATRIX

(1) Find your state in the table. (2) Review each applicable row. (3) Incorporate the identified requirement into the lay letter template and relevant sections of this policy. (4) Document your review: 'State law overlay confirmed for [State] — [Date] — Verified by [Name/Title].' **FEDERAL BASELINE:** The federal dense breast notification requirement at 21 CFR §900.12(c)(1)(ii), effective September 10, 2024, applies in all 50 states.

STATE	AREA AFFECTED	CITATION	REQUIREMENT EXCEEDING MQSA MINIMUM
California	Dense Breast Notification	Cal. Health & Safety Code §109275	Written notice required for all patients with dense breast tissue in specific statutory language. Lay letter template must incorporate California-specific notification language.
California	Record Retention	Cal. Health & Safety Code §123111	Lay letters and mammography records must be retained for minimum 7 years from date of service, or 1 year after patient reaches age 18 — whichever is longer.
Texas	Dense Breast Notification	Tex. Health & Safety Code §161.831	Dense breast notification required in lay letters using specific statutory language. Template must include Texas-mandated patient notification language verbatim.
Texas	Record Retention	25 TAC §165.1	Mammography records including lay letters must be retained for minimum 7 years from date of last treatment for adult patients.
Florida	Dense Breast Notification	Fla. Stat. §381.933	Dense breast notification required in lay letters using Florida-specific statutory language.
Florida	Record Retention	Fla. Stat. §456.057	Mammography records including lay letters must be retained for minimum 7 years for adult patients.
New York	Patient Report Delivery Timeline	NY Public Health Law §2797	Mammography lay notification must be delivered to patient within 30 days. Specific statutory language required in the letter.
New York	Dense Breast Notification	NY Public Health Law §2797-a	Dense breast notification required with New York-specific statutory language in lay letter.
New York	Record Retention	10 NYCRR §405.10	Records must be retained for 6 years from date of service, or 3 years after patient reaches age 18, whichever is longer.
Illinois	Dense Breast Notification	210 ILCS 145	Dense breast notification required with Illinois-specific language per the Illinois Mammography Quality Assurance Act.
New Jersey	Dense Breast Notification + Supplemental Screening	N.J.S.A. 26:2-173 et seq.	Dense breast notification AND information about supplemental screening options required in lay letter.
All States	Dense Breast Notification — Federal Baseline	21 CFR §900.12(c)(1)(ii)	Federal dense breast notification requirement effective September 10, 2024 applies in all 50 states. Lay letters must include breast density language and, where applicable, recommend patient discuss supplemental screening with provider. State laws more stringent than federal standard continue to govern.

State Law Overlay Confirmed for: _____ Date Confirmed: _____
Confirmed By: _____

Policy Acknowledgment & Approval

By signing below, the authorized individuals confirm this policy has been reviewed, is accurate and complete for this facility's jurisdiction, incorporates all applicable state law overlays from Appendix B, and is effective as of the date indicated.

Medical Director

Name: _____

Signature: _____

Date: _____

MQSA Responsible Individual / Facility Administrator

Name: _____

Signature: _____

Date: _____