Breast MRI Medical Outcome Audit

Program Methodology, Audit Architecture & Scope of Service

Prepared for: Anywhere Breast Imaging Practice | January 2025 – December 2025

Document Type: Client Reference | **Prepared by:** Mammologix Clinical Programs | **Benchmark Authority:** ACR BI-RADS® Atlas, 5th Ed.; BCSC

1. Purpose of This Communication

This document is provided by Mammologix to assist clients in understanding the scope, methodology, and clinical context of the Breast MRI Medical Outcome Audit (MRI MOA) reports produced through the Mammologix program, powered by I/O Trak. It explains what the audit measures, why its methodology is materially more complex than the standard mammography outcome audit, what the current Mammologix report includes, and what additional audit streams are available to clients who wish to pursue a more comprehensive quality assurance program.

Clients are strongly encouraged to read this document in conjunction with the interpretation notes and footnotes embedded in their MRI MOA reports. Those notes are not boilerplate — they provide the clinical and statistical context without which the performance metrics in the report cannot be responsibly interpreted.

2. Background: The Breast MRI Medical Outcome Audit

What it is, why it matters, and how it relates to the mammography audit

Breast MRI is the most sensitive imaging modality for breast cancer detection and is recommended by the American Cancer Society and the ACR as a supplemental screening tool for women at elevated lifetime risk. As with any diagnostic modality used in a clinical quality assurance context, interpreting radiologists and program administrators require a structured mechanism to evaluate performance, identify variation, and ensure that imaging outcomes meet established benchmarks.

The vehicle for that structured evaluation is the Medical Outcome Audit (MOA) — a systematic process of linking imaging assessments to pathologically confirmed cancer outcomes, calculating key performance indicators (KPIs), and comparing those results against published benchmarks. For mammography, this process is governed and mandated by federal law. For breast MRI, it is not.

> **The Regulatory Gap**
>
> The Mammography Quality Standards Act (MQSA) of 1992 mandates annual medical outcome auditing for every mammography facility in the United States. This mandate explicitly and exclusively applies to mammographic imaging. **The MQSA does not provide for the establishment of requirements related to breast MRI, and the MQSA regulations have not been amended to include MRI.** Federal Register, Final Rule (March 10, 2023). As a result, the vast majority of breast MRI practices in the United States operate without any structured, formal outcome audit — not because auditing is unnecessary, but because it is not federally required. ACR-accredited breast MRI facilities are expected to maintain a medical outcomes audit program as an accreditation standard, but this expectation is enforced through accreditation standing, not annual federal inspection.

The ACR BI-RADS® Atlas, 5th Edition (Sickles & D'Orsi, 2013) extended the audit framework to include breast MRI, establishing cross-modality KPI definitions and recommending outcome monitoring as a best practice. The Breast Cancer Surveillance Consortium (BCSC) has published the only large-scale community benchmark data for

screening breast MRI (Lee JM et al., Radiology, 2017; n=8,387 examinations). Together, these sources form the evidence base upon which the Mammologix MRI MOA is constructed.

3. Why Breast MRI Auditing Is More Complex Than Mammography Auditing

Five structural differences that define the methodology

The mammography audit, while comprehensive, operates against a relatively homogeneous context: a general-risk population receiving a standardized two-view examination, with a federally mandated outcome linkage system and decades of BCSC benchmark data drawn from millions of examinations. The breast MRI audit operates under materially different and more complex conditions across five key dimensions:

1

No Federal Mandate — Voluntary Quality Program

Because MQSA does not govern breast MRI, no standardized national inspection or reporting infrastructure exists. The Mammologix MRI MOA is a voluntary quality assurance initiative. This means that both the methodology and the interpretation of results require more explicit clinical judgment than is necessary for the mammography audit, where federal standards constrain the framework.

2

The Screening Population Is Fundamentally Different

Mammography screens the general population. Breast MRI screens a high-risk population — women with BRCA mutations, strong family history, prior chest irradiation, or personal history of breast cancer. This population has a substantially higher underlying cancer prevalence. As a result, MRI benchmark CDR (~20–30 cancers per 1,000 exams) is not comparable to mammography CDR (~5–6 per 1,000). Presenting MRI and mammography benchmarks on the same scale without this context is a material analytical error.

3

The Definition of a 'Positive' Exam Differs by Indication

For screening mammography, BI-RADS 0, 4, and 5 constitute a positive (abnormal) interpretation. For screening MRI, BI-RADS 0, 3, 4, and 5 are all positive — because BI-RADS 3 ('probably benign') triggers a short-interval follow-up before return to annual screening, which meets the definition of an abnormal result in the screening context. For diagnostic MRI, BI-RADS 3 is treated as negative (a routine follow-up recommendation). This classification difference directly affects AIR, PPV1, and denominator construction — and is a common source of error in practices attempting informal MRI auditing.

4

Three Distinct Clinical Indication Streams Must Be Audited Separately

Breast MRI is ordered for three distinct clinical indications — screening, diagnostic problem-solving, and preoperative extent-of-disease evaluation — each with different patient populations, cancer prevalence rates, benchmark reference ranges, and positive assessment definitions. Pooling these indications in a single audit produces metrics that are clinically uninterpretable. The peer-reviewed literature is unambiguous on this point: 'Practices should stratify breast MRI examinations by indication for quality assurance and auditing purposes' (Lee CI et al., Academic Radiology, 2014).

5

The Benchmark Evidence Base Is Comparatively Thin

Mammography benchmarks are derived from tens of millions of examinations accumulated over three decades of BCSC data collection under MQSA-mandated tracking. The breast MRI screening benchmark literature rests primarily on a single BCSC publication (Lee JM et al., 2017) covering 8,387 exams from 2005–2013, supplemented by a small number of single-institution studies. Diagnostic MRI and preoperative MRI benchmarks are even less well-established. This means that small practice volumes can produce extreme metric values that are artifacts of sample size — not evidence of interpretive performance — and that statistical interpretation caveats are not optional.

4. The Three-Stream Breast MRI Audit Architecture

What each stream measures, how it is constructed, and its current availability through Mammologix

The breast MRI MOA is organized around three audit streams, each corresponding to a distinct clinical indication for breast MRI. Each stream is calculated independently using its own examination population, positive assessment definition, and applicable benchmark reference. No cross-stream pooling is performed.

Stream 1 | Screening MRI

Indication: Examinations performed on asymptomatic women who are at elevated lifetime risk for breast cancer, including but not limited to: known BRCA1/2 mutation carriers; first-degree relatives of BRCA carriers (untested); women with a lifetime risk ≥20% by risk-assessment models; women with a history of prior chest wall irradiation between ages 10–30; and women with a personal history of breast cancer after completion of treatment.

Positive Assessment: BI-RADS 0, 3, 4, or 5. BI-RADS 3 is treated as positive in the screening context because it interrupts the annual screening cycle.

KPIs Calculated: Abnormal Interpretation Rate (AIR), Recall Rate, PPV1, Cancer Detection Rate (CDR), Sensitivity, Specificity.

Benchmark Source: BCSC (Lee JM et al., Radiology, 2017) for observed community performance; ACR BI-RADS® Atlas, 5th Edition for formal benchmark thresholds.

Currently Provided by Mammologix

Stream 2 | Diagnostic MRI

Indication: Examinations performed for problem-solving or clinical evaluation purposes, including: assessment of a clinical or imaging finding identified on prior mammography or ultrasound; symptom evaluation (palpable lump, nipple discharge, skin change); and short-interval follow-up of a prior BI-RADS 3 (probably benign) finding on a previous breast MRI.

Positive Assessment: BI-RADS 4 or 5 only. BI-RADS 3 is treated as negative (a routine management recommendation, not an abnormal interpretation) in the diagnostic context.

KPIs Calculated: AIR, CDR, PPV2, PPV3, Sensitivity, Specificity. Final BI-RADS assessment is recorded after inter-modality correlation where applicable.

Benchmark Source: Niell BL et al. (J Am Coll Radiol, 2014); Lee CI et al. (Academic Radiology, 2014; BCSC, n=11,654). Note: these are published reference values from community-practice studies, not formal ACR BI-RADS benchmarks equivalent to the screening MRI thresholds. They should be labeled as reference values and interpreted with appropriate caution.

Available Upon Request

Stream 3 | Preoperative / Extent-of-Disease MRI

Indication: Examinations performed in women with a newly diagnosed breast cancer to evaluate ipsilateral and contralateral extent of disease prior to surgical planning. This population is distinct from both screening and diagnostic MRI: cancer is known to be present in the ipsilateral breast at the time of imaging, making this stream structurally incomparable to the other two.

Positive Assessment: BI-RADS 4 or 5. For extent-of-disease auditing, the primary focus is on the accuracy of ipsilateral extent characterization and the detection of contralateral occult malignancy.

KPIs Calculated: CDR (contralateral), PPV2, Sensitivity, Specificity. Ipsilateral extent accuracy metrics are addressed separately per BI-RADS v2025 guidance.

Benchmark Source: ACR BI-RADS® v2025 Manual (published 2025); Cohen EO et al. (Radiology, 2025). This stream represents the newest addition to the formal breast MRI audit framework and benchmarks remain under active development.

Available Upon Request

5. What Your Current Mammologix Report Covers — and What It Does Not

An important scope statement

The Mammologix Breast MRI Medical Outcome Audit report provided to your facility represents the Stream 1 (Screening MRI) audit unless your program has specifically requested the activation of Stream 2 (Diagnostic MRI) or Stream 3 (Preoperative MRI) reporting.

Important Scope Limitation — Not All Breast MRI Examinations Are Captured

Because the three audit streams are indication-specific, the examinations included in your current MRI MOA report represent only those exams that meet the screening indication criteria. Diagnostic MRI and preoperative MRI examinations performed at your facility during the same audit period are **not included** in the screening stream report. This is not an omission — it is a methodological requirement. Including diagnostic or preoperative exams in the screening audit pool would systematically distort every calculated metric and render the benchmarks inapplicable.

Clients who wish to receive a comprehensive three-stream audit covering screening, diagnostic, and preoperative MRI should contact their Mammologix Client Support Manager. Additional data fields required to support the diagnostic and preoperative streams may need to be activated in your tracking workflow.

6. Mammologix at the Leading Edge of Breast MRI Outcome Auditing

A Program Ahead of the Regulatory Curve

There is no federal mandate, no national inspection standard, and no uniform reporting requirement for breast MRI outcome auditing. The field is governed by professional society guidance and a comparatively limited peer-reviewed benchmark literature. Breast MRI practices that have not pursued ACR accreditation face no federal audit requirement whatsoever, and even accredited facilities are not subject to the same MQSA-style annual inspection enforcement that governs mammography. Mammologix is operating in this space not because MQSA requires it — but because it is the right standard of care, and because our clients deserve the quality accountability infrastructure that the broader regulatory environment has not yet provided.

The Mammologix approach to breast MRI auditing is characterized by the following commitments:

- **BI-RADS Compliance:** All KPI definitions, positive assessment classifications, and outcome assignment windows conform strictly to the ACR BI-RADS® Atlas, 5th Edition framework.
- **Indication Stratification:** Screening and diagnostic examinations are calculated independently — the non-negotiable methodological requirement established by the peer-reviewed literature.
- **BCSC Benchmark Alignment:** Observed performance is compared against the most current published BCSC community benchmarks, with explicit citation of the source study for each reference value.
- **Transparent Interpretation Context:** Every report includes statistical interpretation notes that contextualize volume-sensitive metrics, flag small-denominator artifacts, and explain benchmark applicability — because without this context, the numbers can be actively misleading.
- **v2025 Readiness:** Mammologix is incorporating the ACR BI-RADS v2025 manual, which has been published and formalizes the preoperative MRI audit stream. Our methodology is being updated to align with the v2025 framework.

7. Summary: The Three-Stream Audit Architecture at a Glance

Audit Stream	Clinical Indication	Positive Assessment Definition	Key Performance Indicators	Benchmark Authority	Mammologix Status
Stream 1 Screening	High-risk, asymptomatic women (BRCA, FH, PHx, LCIS, etc.)	**BI-RADS 0, 3, 4, 5**	AIR, CDR, PPV1, Sensitivity, Specificity	BCSC / ACR BI-RADS 5th Ed. (Lee JM 2017)	**Currently Provided**
Stream 2 Diagnostic	Problem-solving, symptomatic evaluation, short-interval follow-up of BI-RADS 3 findings	**BI-RADS 4, 5 only**	AIR, CDR, PPV2, PPV3, Sensitivity, Specificity	Niell 2014; Lee CI et al. 2014 (BCSC, n=11,654)	**Available Upon Request**
Stream 3 Preoperative / Extent-of-Disease	Newly diagnosed breast cancer; extent-of-disease evaluation; preoperative staging	**BI-RADS 4, 5**	CDR, PPV2, Sensitivity, Specificity	BI-RADS v2025 (Cohen EO et al. Radiology 2025)	**Available Upon Request**

Note: *'Available Upon Request' streams require activation of additional data fields in your I/O Trak tracking workflow and may require a 12-month minimum data collection period before statistically meaningful results can be produced. Contact your Mammologix Client Support Manager to discuss readiness.*

8. Why Our Interpretation Notes Matter — A Direct Request to Our Clients

Every Mammologix Breast MRI MOA report contains a section of statistical interpretation notes and contextual footnotes. These notes are not legal disclaimers or filler text. They are substantive clinical guidance written to prevent the most common and consequential errors in reading breast MRI audit output.

We ask our clients — and particularly the medical directors, quality assurance committee members, and credentialing officers who review these reports — to read the interpretation notes before drawing conclusions from the KPI values. The reasons are specific:

- **Volume Sensitivity:** In small-volume MRI programs, a CDR of 0.0/1,000 does not mean no cancers were detected by the program — it means no cancers were detected in the screening-indicated pool during this reporting period. This is a statistical artifact of low denominator volume, not evidence of interpretive failure. The interpretation notes explain this explicitly.
- **Indication Mixing Risk:** If your facility's diagnostic or preoperative MRI volume is significantly larger than your screening volume, the 'All' combined metrics in your report may reflect the higher-cancer-prevalence diagnostic population more than the screening population. The interpretation notes flag this when relevant.
- **Benchmark Reference Source:** Every benchmark value in the report footnotes is cited to its peer-reviewed source. We encourage clients to request those references and review them. The Mammologix footnote citations are the evidentiary foundation for every performance threshold in the report.
- **Thin Literature for Diagnostic and Preoperative Streams:** Where the peer-reviewed benchmark literature is limited, we say so explicitly. Our reports will never present a benchmark with false precision. Where the evidence is thin, the interpretation guidance reflects that honestly.

Peer-Reviewed References & Regulatory Sources

[1] Sickles EA, D'Orsi CJ. ACR BI-RADS® Follow-up and Outcome Monitoring. In: ACR BI-RADS® Atlas, Breast Imaging Reporting and Data System, 5th Edition. American College of Radiology; Reston, VA; 2013:21–31. [Governing benchmark framework for all breast imaging modality audits, including MRI.]

[2] Lee JM, Ichikawa L, Valencia E, et al. Performance Benchmarks for Screening Breast MR Imaging in Community Practice. Radiology. 2017;285(1):44–52. doi:10.1148/radiol.2017162033 [Primary BCSC breast MRI benchmark study; n=8,387 screening MRI exams, 5,343 women, 2005–2013.]

[3] Niell BL, Gavenonis SC, Motazedi T, Chubiz JC, Halpern EP, Rafferty EA, Lee JM. Auditing a Breast MRI Practice: Performance Measures for Screening and Diagnostic Breast MRI. J Am Coll Radiol. 2014;11(9):883–889. doi:10.1016/j.jacr.2014.02.003 [Establishes mandatory separation of screening vs. diagnostic audit streams; n=2,444 exams.]

[4] Lee CI, Ichikawa L, Rochelle MC, et al. Breast MRI BI-RADS Assessments and Abnormal Interpretation Rates by Clinical Indication in US Community Practices. Acad Radiol. 2014;21(11):1370–1376. doi:10.1016/j.acra.2014.06.003 [BCSC four-indication framework; n=11,654 MRI exams. Establishes stratification requirement.]

[5] Lam DL, Lee JM. Breast Magnetic Resonance Imaging Audit: Pitfalls, Challenges, and Future Considerations. Radiol Clin North Am. 2021;59(1):57–65. doi:10.1016/j.rcl.2020.09.002 [Primary 'how-to' methodology paper for breast MRI audit in clinical practice.]

[6] Cohen EO, Tso HH, Shin K, et al. Feasibility of Auditing Preoperative Breast MRI for Extent-of-Disease Evaluation Using the BI-RADS v2025 Manual. Radiology. 2025;317(1):e243803. doi:10.1148/radiol.243803 [Establishes the third audit stream; v2025 preoperative framework.] Erratum in: Radiology. 2025;317(1):e259018. doi:10.1148/radiol.259018.

[7] Federal Register. Mammography Quality Standards Act — Final Rule. March 10, 2023; 88 FR 15126. [Confirms MQSA applies exclusively to mammography; MRI explicitly excluded from federal mandate.]

[8] Strigel RM, Rollenhagen J, Burnside ES, et al. Screening Breast MRI Outcomes in Routine Clinical Practice: Comparison to BI-RADS Benchmarks. Acad Radiol. 2017;24(4):411–417. doi:10.1016/j.acra.2016.10.014 [Community validation study; n=860 screening MRI exams; confirms applicability of BCSC benchmark framework in routine clinical practice settings.]

For questions regarding your breast MRI audit program, additional stream activation, or the methodology described in this document, please contact your Mammologix Client Support Manager or reach our Clinical Programs team at ***connect@mammologix.com*** | *(800) 739-6919.*