Mammography Accreditation and MQSA Certification Readiness Consulting

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What to have ready

- Your choice of FDA-approved accreditation body: ACR, or the State of Arkansas body if your facility is in Arkansas (FDA [https://www.fda.gov/radiation-emitting-products/mammography-quality-standards-act-mqsa-and-mqsa-program/facility-accreditation-and-certification]).
- If you use ACR, a separate mammography application, since ACR handles mammography apart from its other modality programs (ACR [https://accreditationsupport.acr.org/support/solutions/articles/11000045691-the-accreditation-process-revised-8-4-2026-]).
- For a new facility, a plan for the provisional certificate period, which is "valid for up to six months" (FDA [https://www.fda.gov/radiation-emitting-products/mammography-quality-standards-act-mqsa-and-mqsa-program/facility-accreditation-and-certification]) and is when you obtain the clinical images for accreditation (21 CFR 900.11(b)(2)(i) [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-I/part-900/subpart-B/section-900.11]).
- Records that show you meet "the quality standards in § 900.12," which FDA certification requires (21 CFR 900.11(a) [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-I/part-900/subpart-B/section-900.11]).
- A medical physicist arrangement. "Each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility" (21 CFR 900.12(d) [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-I/part-900/subpart-B/section-900.12]).
- A lay summary process and tracking log. Each facility must give "each patient a summary of the mammography report written in lay terms within 30 calendar days of the mammographic examination," including "an assessment of breast density" (21 CFR 900.12(c)(2) [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-I/part-900/subpart-B/section-900.12]).
- A faster track for urgent results: if the assessment is "Suspicious" or "Highly Suggestive of Malignancy," the lay summary is due "within 7 calendar days of the final interpretation of the mammograms" (21 CFR 900.12(c)(2) [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-I/part-900/subpart-B/section-900.12]).
- A medical outcomes audit program "to followup positive mammographic assessments and to correlate pathology results with the interpreting physician's findings" (21 CFR 900.12(f) [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-I/part-900/subpart-B/section-900.12]).
- An inspection file ready at least once a year for the certified MQSA inspector (FDA [https://www.fda.gov/radiation-emitting-products/mammography-quality-standards-act-mqsa-and-mqsa-program/facility-accreditation-and-certification]).
- A renewal calendar keyed to the three-year certificate (FDA [https://www.fda.gov/radiation-emitting-products/mammography-quality-standards-act-mqsa-and-mqsa-program/facility-accreditation-and-certification]).