The FDA's New MQSA Facility Portal: What Every Certified Mammography Facility Must Do Before October 22, 2026

A Mammologix / MammoComply Regulatory Advisory for Client Facilities

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Executive Summary

Effective **October 22, 2026**, the U.S. Food and Drug Administration (FDA) will stop mailing Mammography Quality Standards Act (MQSA) certificates and certification-related letters and will deliver those documents instead through a new online system, the MQSA Facility Portal[1]. Beginning **September 14, 2026**, and continuing through the October 22 implementation date, facilities may receive dual delivery, meaning a mailed U.S. Postal Service copy and a portal notification email for the same certificate or letter[1]. The change does not apply to facilities certified by an FDA-approved State Certifying Agency (SAC); currently Illinois, Iowa, South Carolina, and Texas[1,2]. The legal duty to prominently display a printed MQSA certificate on-site continues without change[1,3]. This advisory summarizes the verified FDA guidance, identifies exactly what certified facilities must do, and describes how Mammologix, acting as a vendor-agnostic MammoComply fulfillment partner, supports client facilities through this transition.

Background: How MQSA Certification and Display Requirements Work

Congress enacted the Mammography Quality Standards Act (MQSA) on October 27, 1992, to help ensure that women nationwide have access to quality mammography for the early detection of breast cancer[4]. Under the statute, mammography facilities other than those operated by the Department of Veterans Affairs must be accredited by an FDA-approved accreditation body, meet federal quality standards, and be certified by FDA or an approved SAC before performing mammography[2,4]. A full accreditation and certification cycle yields a certificate valid for three years; a provisional certificate may be issued for up to six months to allow a new or reinstating facility to collect the clinical images needed to complete accreditation, with one 90-day extension available in qualifying circumstances through the facility's accreditation body[2,5].

Accreditation and certification are related but distinct steps. Accreditation is the review conducted by an accreditation body of a facility's equipment, personnel, clinical image quality, and practices against federal standards; certification is the resulting approval, issued by FDA or a SAC, to provide mammography services[2]. Facilities maintain that certification through periodic clinical image review, an annual medical physicist survey, ongoing adherence to quality standards, and at least annual inspection by a certified MQSA inspector[2,4,6].

The statute independently requires that a facility's certificate, or provisional certificate, be displayed prominently on-site[3]. FDA's certificate delivery notice reaffirms that obligation under 42 U.S.C. § 263b(b)(1)(A)(iii) and (b)(1)(B)(iii), and its implementing regulation at 21 CFR § 900.11, and states plainly that

portal access alone does not satisfy the display duty[1,3,5]. A facility that receives a portal notice involving a certificate update remains responsible for downloading, printing, and posting that certificate[1]. This distinction matters operationally: annual MQSA inspections review equipment performance, QA/QC records, technologist testing, the physicist's annual survey, personnel qualifications, and medical outcome audit records, and CMS treats current MQSA certification as a condition of Medicare and Medicaid payment eligibility for screening and diagnostic mammography[6]. An expired or missing displayed certificate is therefore both a lawful-operation risk and a payment-readiness risk, independent of how the certificate arrived.

What Is Changing on October 22, 2026

FDA will no longer mail MQSA certificates or certification-related letters after October 22, 2026[1]. Going forward, it is the facility's responsibility to log in and download FDA-issued certificates and letters from the MQSA Facility Portal[1]. Notification emails will come from the Division of Mammography Standards at *fdsa_mqsa_certs@fda.hhs.gov*, a send-only address that does not accept replies[1].

FDA's notice lists the specific certificate and letter types that will trigger a portal notification[1]:

- 3-year certificates issued upon full accreditation and certification, with additional copies printable through the portal for units sharing an MQSA Facility ID, and Spanish-language certificates available alongside English
- Replacement or duplicate certificates, retrievable from the original electronic file for as long as that certificate remains active
- Provisional six-month certificates for new or reinstating facilities
- One-time 90-day extensions, which still must be applied for through the facility's accreditation body
- Interim Notices (45-Day), issued to fully accredited, certified facilities that may need more time to gain their next full accreditation and certification
- Facility name-change certificates, which still depend on the accreditation body notifying FDA of the change
- Accreditation body (AB) switch notices
- Pending-expiration letters, issued 10 calendar days before certification expires
- No-longer-certified letters, denied accreditation or reaccreditation letters, and letters documenting three unsuccessful accreditation attempts under 21 CFR 900.4(a)(6)(ii)

The download workflow FDA describes generally involves logging into the portal with the facility's Facility ID and email address, completing identity verification through a one-time passcode sent to that email, and downloading the current certificate or letter; each notification email includes step-by-step instructions specific to that event[1].

The Dual-Delivery Transition Window

FDA describes a transition period running from **September 14, 2026** through full portal implementation on **October 22, 2026**. During that window, a facility may receive both a mailed certificate or letter and a portal notification email for the same document[1]. FDA states this overlap is expected and temporary[1].

That overlap carries a practical risk worth naming plainly: staff may assume a mailed paper copy is authoritative and disregard the email, or treat the portal notice as optional while waiting on mail that may arrive late, or not arrive at all once mailing stops. The more reliable practice, a Mammologix operational recommendation rather than an FDA instruction, is to treat every portal notification as an action item in its own right: log in, download, print, and update the displayed certificate, whether or not a mailed copy also arrives. After October 22, 2026, facilities certified directly by FDA should plan on portal-only delivery, with no USPS backup path[1].

Who Receives the Notifications

Portal notification emails go to three facility contacts collected or verified during the annual inspection: the Accreditation Contact, the Most Responsible Individual, and the Inspection Contact[1]. Those individuals are responsible for logging in and retrieving the documents[1]. FDA recommends confirming that the names and email addresses on file are current, and directs facilities to the CDRH MPRIS Helpdesk (cdrhmqrp@cdrh.fda.gov) for updates or verification[1]. FDA also recommends adding fdsa_mqsa_certs@fda.hhs.gov to approved contact lists to reduce the likelihood that certification communications land in a spam folder[1].

If any of the three designated roles point to a shared inbox, a departed employee's address, or an account outside an organization's IT allow-list, a portal notice can go unseen even though FDA delivered it successfully. Verifying contact accuracy before September 14, 2026, is accordingly one of the highest-value near-term actions a facility can take.

Facilities Certified Through a State Certifying Agency

The portal transition described above applies to facilities certified directly by FDA. It does not apply to facilities certified by an FDA-approved State Certifying Agency (SAC); currently Illinois, Iowa, South Carolina, and Texas[1,2]. Under the States as Certifiers program, those states issue, renew, deny, suspend, and revoke mammography certificates and conduct their own annual inspections within the scope FDA has delegated to them[2]. Issuance of certificates by FDA-approved SACs is not changing as part of this notice[1,2].

Multi-state organizations should segment their internal guidance accordingly: FDA-certified locations prepare for dual delivery and then portal-only retrieval, while SAC-certified locations in IL, IA, SC, and TX continue under existing state processes unless and until their state agency announces otherwise[1,2]. A corporate policy that assumes every site now uses the FDA portal would misstate the rule for SAC-certified locations.

What Your Facility Should Do Now

The following checklist reflects FDA's stated process and existing certification and display requirements. It is operational guidance, not legal advice; facilities with questions about a specific certification status should contact their accreditation body or the CDRH MPRIS Helpdesk directly.

1. **Confirm certifying authority.** Identify whether each of your locations is FDA-certified or SAC-certified (IL, IA, SC, TX). Only the FDA-certified path changes starting September 14, 2026; SAC issuance in those four states continues unchanged[1,2].

2. **Validate the three FDA inspection contacts.** Confirm current names and working email addresses for the Accreditation Contact, Most Responsible Individual, and Inspection Contact; correct any gaps through the CDRH MPRIS Helpdesk[1].

3. **Harden email delivery.** Add fdsa_mqsa_certs@fda.hhs.gov to your approved contact list, which FDA states reduces the likelihood of certification emails being filtered as spam; separately, confirm staff understand the address does not accept replies; and check spam or quarantine folders as a general precaution during the September 14 through October 22, 2026 window[1].

4. **Pre-stage portal access.** Make sure the designated contacts know the facility's Facility ID, can receive a one-time passcode by email, and understand who is responsible for downloading versus printing and posting the certificate on each site[1].

5. **Refresh the download, print, and display procedure.** On any portal notice involving a certificate update, download, print, and prominently display the current certificate[1,3]; Spanish-language and same-Facility-ID additional prints are available through the portal where applicable[1]. Retiring the superseded copy once the new certificate is posted is a Mammologix operational recommendation, not an explicit FDA requirement; we offer it based on supporting nearly 200 client facilities through prior FDA process changes.

6. **Manage the dual-delivery period deliberately.** If both a mailed copy and a portal email arrive for the same event, treat the portal file as authoritative for display purposes, a Mammologix operational recommendation rather than an explicit FDA instruction, and do not wait on USPS. After October 22, 2026, do not expect a mailed certificate at all[1].

7. **Connect certificate events to accreditation timelines.** Name changes still route through your accreditation body first, and 90-day extensions are still requested through your accreditation body[1,2]. Building a reaccreditation project timeline around interim or pending-expiration letters, rather than treating them as a printing task, is a Mammologix operational recommendation, not an FDA instruction.

8. **Keep the displayed certificate current as inspection and CMS eligibility evidence.** Certification maintenance, including the physicist survey, annual inspection, applicable fees, and correction of deficiencies, continues unchanged by this delivery update[6].

Why This Matters for Accreditation and Inspection Readiness

The portal changes how certificates and related letters arrive; it does not relax accreditation, quality-standard, or inspection obligations[1,2,4,6]. Because certificate types map to known lifecycle events, including full 3-year certification, provisional status, extensions, interim notices, accreditation body switches, denials, and loss of certification, a delayed portal retrieval can compress an already tight timeline. A pending-expiration letter, for example, is issued only 10 calendar days before expiration[1].

A facility's obligations continue regardless of delivery channel: maintain accreditation, complete the annual medical physicist survey, undergo annual inspection, pay applicable fees, and correct any deficiencies identified[6]. A prominently displayed, unexpired printed certificate remains the visible proof of lawful operation for patients and inspectors alike[1,3]. For organizations operating multiple sites, the dual-delivery window functions as a practical stress test of contact accuracy, spam filtering, portal login handling, and print-and-display discipline before the USPS backup disappears.

Uncertainties and What Remains Settled

Three items are genuinely uncertain for any individual facility reading this advisory, and this document cannot resolve them on your behalf:

- Whether a specific location is FDA-certified or SAC-certified is not always obvious from day-to-day operations, and one carve-out is worth naming directly: FDA has not delegated certification authority to any state for federal facilities, so a federal facility physically located in Illinois, Iowa, South Carolina, or Texas is FDA-certified, not SAC-certified, despite sitting in a SAC state[2]. Confirm certification path against your facility's own record rather than assuming it from geography alone.
- Whether the email address FDA holds for each of the three inspection contacts will actually deliver the one-time passcode needed for portal login is unknown until it is tested; a stale or mistyped address surfaces only at the moment someone tries to log in. Across the client facilities we support, this is consistently where a portal-based delivery change goes wrong first.
- Whether the three contacts on file are still employed at the facility, and still monitoring that inbox, is a question every multi-site operator should answer individually rather than assume carried forward from a prior inspection cycle.

One related question is settled rather than uncertain and is worth separating out. A facility name change still requires the accreditation body to notify FDA before an updated certificate is issued[1,2]; that sequencing is fixed and should be treated as a routing step, not an open question.

The Mammologix Role: MammoComply as a Vendor-Agnostic Fulfillment Partner

Mammologix, through its MammoComply pillar, supports client facilities in treating this transition as an operational hygiene and evidence-handling task rather than a system replacement project. The posture is deliberately vendor-agnostic: Mammologix enhances the accreditation tracking, inspection preparation,

contact registries, and document-control practices a facility already has in place, and does not displace clinical systems of record such as an EMR or RIS.

In practical terms, that support includes inventorying which client locations are FDA-certified versus SAC-certified; auditing the three FDA inspection contacts against active, monitored mailboxes; assisting with allow-list requests for fdsa_mqsa_certs@fda.hhs.gov; helping define a clear download, print, and display chain of custody; reconciling dual-delivery artifacts during the September 14 through October 22, 2026 window; and linking portal-issued letters to a facility's existing accreditation project timeline[1,2]. This work sits alongside, not inside, a facility's clinical software, and it is offered as part of Mammologix's fulfillment-partner role rather than as a substitute for the facility's own compliance ownership.

Conclusion: Near-Term Actions Before Monday, September 14, 2026

Before the dual-delivery window opens on Monday, September 14, 2026, FDA-certified facilities should verify their three inspection contacts and the helpdesk update path, allow-list the FDA certs mailbox, assign clear ownership of portal login and one-time-passcode handling, and refresh the download, print, and display procedure so that a portal notice converts smoothly into a prominently displayed printed certificate without waiting on the mail[1,3]. Multi-state operators should separately confirm that any Illinois, Iowa, South Carolina, or Texas locations remain on their unchanged state issuance process[1,2].

Through October 22, 2026, expect the possibility of duplicate delivery. Treating the portal email as the authoritative version for retrieval, even when a mailed copy also arrives, is a Mammologix operational recommendation rather than an FDA instruction, and it is the practice we advise. After that date, plan on portal-only delivery from FDA, with the legal duty to print and prominently display the certificate on-site unchanged[1,3]. The operational standard remains straightforward: accurate contacts, deliverable email, timely portal retrieval, and an unexpired printed certificate on the wall, sustained through the same accreditation and annual inspection cycle that this delivery-channel change does not alter[1,2,4,6]. Mammologix remains available to client facilities as a fulfillment partner throughout this transition and welcomes questions about how these steps apply to a specific location or multi-site organization.

About the Author

Richard Lippert is the founder and president of Mammologix, a breast imaging operations and quality company headquartered in Altamonte Springs, Florida. He has more than three decades in breast imaging operations and was clinically trained in radiologic technology and mammography before founding the company in 1995.

Mammologix works with imaging programs on mammography medical outcome auditing, MQSA compliance, clinical performance analytics, and patient follow-up across the United States with independent and enterprise breast imaging practices.

Commercial Disclosure

Mammologix provides breast imaging tracking, medical outcome auditing, MQSA compliance, and patient navigation services to imaging facilities. The operational recommendations in this article describe capabilities that fall within those service categories.

This is educational content produced by a commercially interested organization. It is intended to inform clinical and operational leaders, not to substitute for facility-specific clinical, legal, regulatory, or accreditation guidance, and not to direct the management of any individual patient.

Note to Patients

If you are a patient reading this article, please understand that Mammologix supports the operational side of breast imaging facilities. We are not your care team, we cannot access or interpret your results, and we cannot answer questions about your individual care. Please direct those questions to the facility that performed your imaging or to your own physician.

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This advisory reflects direct review of the FDA pages cited above as they read on the publication date and does not substitute for guidance from your facility's accreditation body, State Certifying Agency, or legal counsel. It is operational guidance, not legal advice; facilities should direct facility-specific certification questions to their accreditation body or the CDRH MPRIS Helpdesk. This document is time-bound to the transition window it describes (September 14 through October 22, 2026); it should be re-verified against the live FDA source pages before that date and either updated or retired once the transition is complete.