**Date Issued:** May 21, 2021

The U.S. Food and Drug Administration (FDA) is alerting patients who had mammograms at Advanced Women Imaging, located in Guttenberg, NJ, on or after March 11, 2020, about possible problems with the quality of their mammograms.

# Recommendations for Patients

- If you have had a more recent mammogram at a different Mammography Quality Standards Act (MQSA)-certified facility on or after March 11, 2020, follow the recommendations from that facility.
- If you have not had a mammogram at a different Mammography Quality Standards Act (MQSA)-certified facility on or after March 11, 2020, follow these guidelines:
    - Consider asking for your mammogram and copies of your medical reports from Advanced Women Imaging, and have your mammogram reviewed at another MQSA-certified facility to decide if a repeat mammogram or more medical follow-up is needed. As a patient, you or your representatives have the right to ask for your mammograms and copies of your medical reports.
    - A database of Mammography Quality Standards Act (MQSA)-certified facilities can be found online, or you can call the National Cancer Institute's information telephone number at 1-800-422-6237 to find a MQSA-certified facility in your area.

# Device Description

A mammogram is a safe, low-dose, X-ray picture of the breast. It is currently the most effective primary screening method for detecting breast cancer in its earliest, most treatable stages.

# Summary of Problem or Scope

The FDA became aware of problems associated with the quality of mammograms performed at:

Advanced Women Imaging
560A 60th Street
Guttenberg, NJ 07093

The facility's annual MQSA inspection indicated that required quality control tests were not performed from March 11, 2020, through August 25, 2020. As a result, the FDA notified the facility that it was required to undergo an Additional Mammography Review (AMR) to determine if the overall quality of mammography performed at the facility was compromised due to the failure of the facility to operate in compliance with the MQSA, and whether there was a need to notify affected patients.

The American College of Radiology (ACR), at the request of the FDA, contacted the facility to request the clinical images and documentation needed to conduct the AMR of mammograms performed at Advanced Women Imaging. The facility did not comply with the ACR's request. On September 12, 2020, the facility's accreditation expired, and on September 15, 2020, the FDA notified the facility that it was no longer certified and must cease performing mammography.

Under the MQSA, the FDA requires that all mammography facilities meet certain baseline quality standards and be certified to legally operate in the United States. This facility did not meet the standards for mammography quality under the MQSA. This facility may not legally perform mammography at this time, as it does not have an active MQSA certificate.

## FDA Activities

The FDA will continue to monitor this issue and keep the public informed as new information becomes available. At this time, the FDA recommends that patents contact Advanced Women Imaging to gain access to their medical records.

## Contact Information

If you have questions about this communication, please contact the Mammography Quality Standards Act Hotline by phone: 1-800-838-7715, email: MQSAhotline@versatechinc.com or fax: 1-443-285-0689.